THEORY- AND EVIDENCE-BASED HEALTH PROMOTION PROGRAM PLANNING; INTERVENTION MAPPING

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PERSPECTIVE
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Intervention Mapping: Theory- and Evidence-Based Health Promotion Program Planning: Perspective and Examples

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Evidence-informed health intervention planning that incorporates theoretical and empirical evidence and engages key stakeholders and community members or patients in the planning process results in interventions that are more effective. Nevertheless, exactly how and when to use evidence, theory, and community-based participation during planning represents a challenge. In this Perspective, we describe Intervention Mapping (IM), a framework for theory- and evidence-based health promotion program planning that addresses this challenge by providing a systematic and stepwise approach to planning interventions. IM has been used to develop health promotion interventions and implementation strategies in community and clinical settings globally, with over 1000 published articles employing the framework. In this Perspective, we also highlight recent and innovative applications of IM described in the articles of the Frontiers in Public Health Special Topic on IM. We conclude by discussing new directions in the application of IM including novel methods for identifying determinants of behavior and environmental conditions, the application of IM for planning implementation strategies, and IM for adaptation of evidence-based programs in new settings.

Keywords: health promotion planning, health promotion theory, intervention mapping, implementation, planning frameworks

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INTRODUCTION

The development of effective health promotion interventions often requires reviews of the relevant literature, application of theories, collection of new data, and involvement of experts, community members, and stakeholders in the planning process. Applying information from these varied sources to inform intervention development presents a challenge for even well-trained health promotion practitioners. The purpose of this perspective paper is to provide an overview of Intervention Mapping, a framework for theory- and evidence-based health promotion program planning, and to highlight examples of applications of IM, as described in the articles of the *Frontiers in Public Health Special Topic on Intervention Mapping* publication (1).

IM is a planning framework that provides a systematic process and detailed protocol for effective, step-by-step decision-making for intervention development, implementation, and evaluation. It is grounded in community based participatory research methods to ensure that the intervention matches priority population needs and intervention contexts. IM takes an ecological approach to understand health problems and to intervene at multiple levels (e.g., individual, interpersonal, organization, and community) and as such guides the development of multi-level interventions.

IM provides guidelines and tools to ensure health promotion program is based on empirical evidence and sound theories. IM is also used for the planning and development of implementation strategies for program adoption, implementation, and maintenance (2). Following the IM process results in guidance and documentation of decisions at each step, charting a map from the initial steps of recognizing a need or problem through evaluation and dissemination. Compared to other protocols in health promotion planning, such as PRECEDE-PROCEED (3), Behavior Centered Design (4), and COMBI (5), IM helps planners to apply theories by linking social-cognitive determinants of behavior to methods for behavior and environmental change and by linking methods for behavior change to practical applications that operationalize these methods.

INTERVENTION MAPPING STEPS

The IM intervention development process has six steps: (1) Establish a detailed understanding of the health problem, the population at risk, the behavioral and environmental causes, and the determinants of these behavioral and environmental conditions; and, assess available resources; (2) Describe the behavioral and environmental outcomes, create objectives for changes in the determinants of behavior and environmental causes, and specify the targets of the intervention program; (3) Identify theory- and evidence-based behavior change methods that influence the determinants and translate these to practical applications that fit the intervention context; (4) Combine the intervention components into a coherent program that uses delivery channels that fit the context; (5) Develop implementation strategies to facilitate adoption, implementation, and maintenance of the program; and (6) Plan both process and outcome evaluation to assess program implementation, and efficacy or effectiveness (2).

IM thus defines and describes an iterative path from problem identification to problem solving or mitigation (2). Each of the six steps comprises several tasks, and completion of these tasks creates a foundation for the next step. Completion of all six steps results in a blueprint for designing, implementing, and evaluating the intervention.

An IM approach is characterized by three perspectives, applied during the program planning process: participatory planning, eclectic use of theory, and an ecological and systems approach for understanding health problems and intervening to address them (3). Participatory perspectives emphasize equity in decision-making and community and stakeholder engagement in all phases of planning (6, 7). From this perspective, all aspects of decision-making should involve the priority population and program implementers to ensure that the program adequately addresses community needs (6, 7). IM provides guidance at each step for how to do this. Additionally, IM guides the use of theories to understand the behavioral and environmental causes of health problems, identify their determinants, and select change methods to address them. Theories are abstractions of reality and may provide only partial explanations for understanding the causes of health problems (8, 9). In program planning, it is unlikely that one theory can sufficiently explain influences on health and provide guidance to address the causes. Thus, multiple theories are often used. IM provides a framework for incorporating multiple theories during intervention planning (10). Finally, an ecological and systems perspective recognizes that social and physical environmental conditions may have an even stronger impact on behaviors than do factors related to individuals (11).

Below, we describe IM steps and tasks and highlight key papers on IM that provide examples of how IM has been applied. Finally, we present new directions and applications for IM in the field of health promotion and beyond.

Figure 1 shows the six steps of the IM process and their related tasks, while **Figure 2** shows the environmental conditions that influence individual behavior.

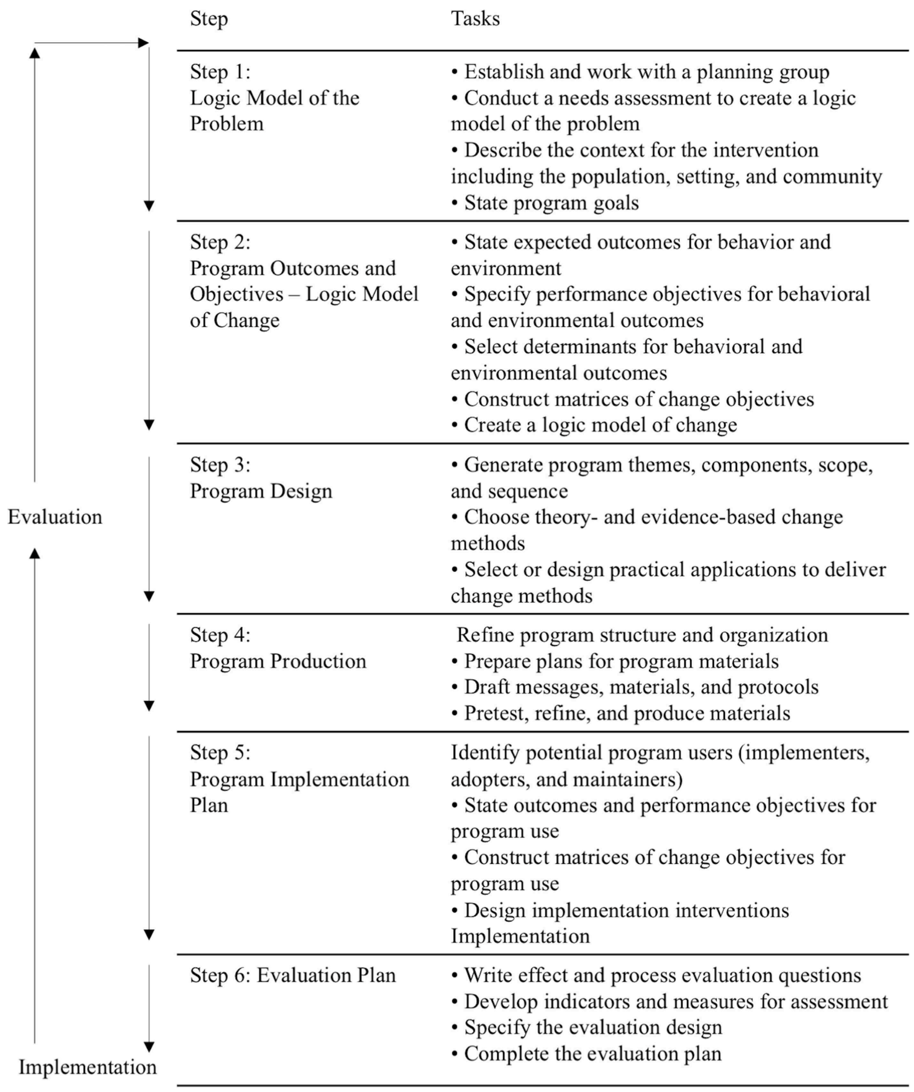
Step 1. Logic Model of the Problem

Step 1, which is based on the PRECEDE model (3), is a careful description of the problem that will enable intervention planning. The program-planning group conducts an analysis of health and quality of life, behaviors, and environmental conditions that contribute to the health problem directly or to the risk behaviors. The group also identifies factors (determinants) that influence the risk behaviors and problematic environmental conditions contributing to the health problem. This step helps planners distinguish between behaviors, environmental conditions, and their determinants, helping them better articulate and document needed changes and desired outcomes in Step 2.

Step 2. Logic Model of Change

In Step 2, the planning group articulates the desired health promoting behaviors and environmental conditions. The group then specifies performance objectives (or sub-behaviors) for the at-risk group and for those responsible for making changes in the environment. The planning group sets performance objectives breaking down each behavior and environmental condition into subcomponents by answering certain questions: "What does the person need to do to accomplish the behavior?" and "What does the environmental agent need to do to create the environmental change?" They then identify determinants of health-promoting behaviors and environmental conditions by asking: "Why would someone do this behavior?" and "Why would someone make this environmental change?"

To make decisions about salient determinants that should be targeted with the intervention, IM guides planners through four core processes (2): (1) involving representatives from the target population, stakeholders, and implementers in brainstorming in the planning group; (2) searching through empirical literature for determinants of behavior or environmental conditions; (3) identifying and applying pertinent theories on determinants that influence these; and (4) conducting qualitative and quantitative research to explore unanswered questions. Using the information generated, the planning group sets priorities and selects a final list



Step	Tasks
Step 1: Logic Model of the Problem	• Establish and work with a planning group • Conduct a needs assessment to create a logic model of the problem • Describe the context for the intervention including the population, setting, and community • State program goals
Step 2: Program Outcomes and Objectives – Logic Model of Change	• State expected outcomes for behavior and environment • Specify performance objectives for behavioral and environmental outcomes • Select determinants for behavioral and environmental outcomes • Construct matrices of change objectives • Create a logic model of change
Step 3: Program Design	• Generate program themes, components, scope, and sequence • Choose theory- and evidence-based change methods • Select or design practical applications to deliver change methods
Step 4: Program Production	Refine program structure and organization • Prepare plans for program materials • Draft messages, materials, and protocols • Pretest, refine, and produce materials
Step 5: Program Implementation Plan	Identify potential program users (implementers, adopters, and maintainers) • State outcomes and performance objectives for program use • Construct matrices of change objectives for program use • Design implementation interventions Implementation
Step 6: Evaluation Plan	• Write effect and process evaluation questions • Develop indicators and measures for assessment • Specify the evaluation design • Complete the evaluation plan

FIGURE 1 | Intervention mapping steps and tasks [Bartholomew-Eldredge et al. (2), chapter 1].

of determinants to target (2, 12). The group then creates a matrix of change objectives through combining performance objectives and determinants. These same core processes are use in each step of the IM process.

IM provides guidance on how to use theory to inform the development process. Planning groups can identify appropriate theories by (1) searching the literature on the health topic, (2) matching ideas from the brainstorming process to theoretical constructs, and (3) applying frequently used theories (9). The theories can guide the identification of determinants and, subsequently, the selection of methods (in Step 3) to influence these determinants. For example, while answering, "Why would someone engage in this behavior?" the planning group might brainstorm, "The person has confidence that he or she could do it," which points to the theoretical construct of "self-efficacy" in social cognitive theory (13). This labeling of answers to the "why" question, using theory-based psychosocial constructs, leads to the selection of appropriate change methods (e.g., modeling) in Step 3.

Step 3. Program Design

In Step 3, the planning group discusses initial ideas for the program and selects theory- and evidence-based behavior change methods based on the determinants that they need to change (2). A number of systematic reviews and meta-analyses of health promotion programs show that reasonable use of theory-based methods increases intervention effectiveness in changing behavior (14–19). In this step, program objectives are arranged or grouped by determinants. Theoretical methods that may help achieve the program objectives are identified, and then translated into practical applications or strategies. A theory-based change method is a technique for changing a behavioral determinant of an individual or environmental agent, while a practical application is a specific strategy that delivers the method

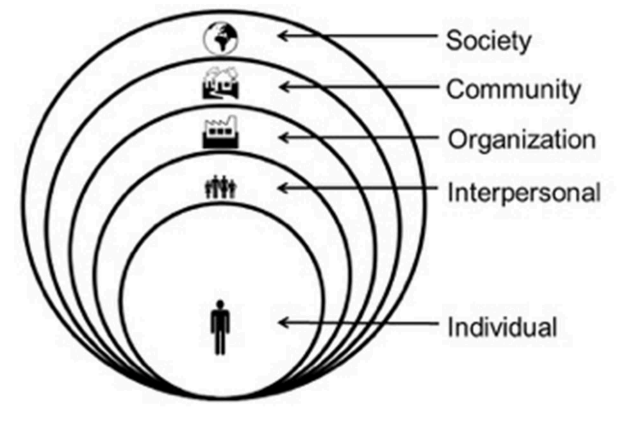


FIGURE 2 | Multilevel factors influencing health.

in a way that fits the needs of the priority group and the program setting. Some methods can be used for several determinants, while others work only for a specific determinant (2).

There has been growing interest in systematic descriptions of health promotion interventions, their theoretical methods, and the determinants these methods are expected to change. Abraham and Michie (20), for example, created the Behavior Change Technique (BCT) taxonomy, used to identify intervention content (21, 22). Peters et al. (18) nevertheless, note that BCT taxonomies fail to describe the specific conditions or requirements that make these methods effective (23). IM, however, describes the parameters of methods that are essential for both identifying successful methods in the literature and for developing intervention components (21). For instance, modeling is effective only if reinforced and when observers pay attention, have adequate self-efficacy and skills, identify with the model, and observe a coping model instead of a mastery model (13). Each theoretical method has its own conditions for effectiveness; for example, goal setting is effective only when the selected goal is challenging but attainable (24). Fear arousal requires high self-efficacy expectations about behavior (18), which can be difficult due of the complex nature of most behavior change settings. Khan et al. (25) described processes (and their measures) that can be used by communities and local governments in planning and monitoring environmental and policy-level interventions for obesity prevention. Mesters et al. (26) notes, however, that it is often difficult to determine which components of the programs contribute to the effectiveness of the health promotion program. Moreover, inadequate reporting of theory and evidence-informed behavior change methods and their applications further limits the ability to advance the science of what works and makes program adaptation challenging. IM responds to the call for better understanding and reporting of intervention (27, 28).

Step 4. Program Production

In Step 4, the various applications selected in Step 3 are organized and produced (2). The program planning group decides the overall structure, themes, channels, and vehicles of the program. They design and produce materials that are culturally relevant and appealing, work with other stakeholders, and pilot-test the pertinent program elements. The program planning group is responsible for correctly translating theoretical methods into practical applications, using the methods' parameters. To this end, the program planning group and production professionals (writers, video producers, graphic artists) must work together to ensure that the final program products are appealing and accessible as well as reflect the key methods, practical applications, and messages developed during the planning process. Step 4 includes pretesting and ensures the implementation of effective program materials and program fit with the particular context and population. Typically, during pretesting, comprehension, attractiveness, acceptance, believability, motivation, and preliminary indications of effectiveness are assessed, and recommendations for improvement are provided. Pretesting should be conducted after concept and message design and materials development but before materials are finalized (29, 30). It can be executed using experimental research designs (31), focus groups, in-depth interviews, and intercept surveys, among other methods.

Step 5. Program Implementation Plan

Effective health education and promotion programs can lose their impact if they are not used before desired health impacts are achieved (32–34). IM provides a systematic process for the development of implementation strategies either for initial use of the program or for scale-up and spread of evidence-based programs already developed and tested. The use of IM to develop implementation strategies provides for the clear articulation of the mechanisms contained in these strategies, a gap in the implementation science literature (35–37). Step 5 guides the development of implementation approaches, also known as strategies or interventions. This step guides the planning group through thinking about adoption, implementation, and maintenance as well as who has to do what at each of these stages and why. Understanding the factors that influence implementation is critical for the selection of methods to address these factors.

Program implementers are the people who are responsible for the delivery of the program and can include organizational leaders responsible for program adoption and maintenance as well as those responsible for actual delivery of program materials and activities to participants. For example, nurses will present programs to patients, and teachers will deliver health education programs to students. Others in the organization or setting, even though they are not program implementers, may be responsible for making decisions about whether or not the program is adopted and for identifying individuals who will deliver the program. For example, school principals may not deliver health education curriculum; however, their support for program adoption and maintenance is critical.

IM Step 5 can be used not only to plan implementation the first time a program is developed and used but also can be used to develop plans for scale up and spread of existing evidence-based interventions. Program planning groups can address program implementers' personal determinants, like knowledge and outcome expectations for the program and self-efficacy for enacting program activities at the individual level with methods, such as persuasive communication, tailoring, and modeling. However, implementation almost always involves organizational change, which means program planning groups also have to apply methods at environmental levels. Organizational theory and implementation science frameworks can be used to understand the determinants and contextual factors that influence implementation and to guide the selection of methods that will support program implementation (38, 39).

Step 6. Evaluation Plan

Effect and process evaluation will verify if the objectives chosen in Steps 2 and 5, respectively, have been reached, and need to be carefully planned. Previous IM steps help inform the evaluation plan since behaviors, environments, their sub-components, and determinants are clearly spelled out (2). Fernandez et al. (57) describe the use of Intervention Mapping for planning implementation strategies, a process we call *Implementation Mapping*.

INTERVENTION MAPPING IN THE REAL WORLD

Special-topic authors provide examples of the application of IM across settings and topics (1). There are several examples of the use of IM for the development of eHealth interventions. Shegog and Begley (40), using IM, involved both a diverse planning group and a patient provider advisory group to develop a decision support tool (DST) to increase self-management among epilepsy patients and their care providers. The tool is used to increase awareness and efficacy of self-management behaviors among epilepsy patients and their healthcare providers and to improve communication during clinic visits. The Shegog and Begley (40) paper includes a table that illustrates the identification of methods, organized by determinants, and how these were operationalized, using practical applications of the DST. The authors demonstrate how the online decision-support system in this case can include multiple methods and practical applications to address users' determinants of self-management.

Pot et al. (41) present the application of IM in the development of a web-based, tailored intervention that promotes HPV vaccination acceptance. In their study, mothers were the target group and were systematically involved in the development process. The mothers were ambivalent about HPV vaccination, and the intervention focuses on informed decision-making. The needs, behavioral outcomes, and targeted determinants are carefully described and include examples, and the full matrices of change objectives are found in the supplementary materials. The web intervention combined freedom of choice with tunneling and virtual assistants who delivered the tailored feedback. The intervention was pilot-tested, and the implementation plan focuses on the web-based intervention owners.

Rodriguez et al. (42) and Serra et al. (43) describe the application of IM in planning interactive multimedia applications for low-income Hispanics (Mexican Americans and Puerto Ricans). Rodriguez et al. used IM in the development of an intervention for parents to increase HPV vaccination in adolescent girls. The authors also used IM steps to adapt the intervention and create a module for parents of boys. The authors select and operationalize methods targeting parents' decision-making, with implicit recognition of parameters. They also describe using IM Step 5 for the development of implementation strategies (delivery by lay health workers).

Serra et al. (43) applied IM to plan an intervention to increase colorectal cancer screening (CRCS) in Puerto Rico. The authors developed a needs and asset assessment that included a review of factors that influence CRCS among Hispanics, taking into account the preferences of the target group, and collected data. They describe objectives at the level of behavior (performance objectives) and determinants (change objectives). They identified two overarching methods: entertainment education and behavioral journalism. The intervention materials included an interactive tablet-based application, print materials, an action plan, with a follow-up phone call to determine and address remaining barriers. As in the Shegog and Begley (40) and Rodriguez et al. (42) examples, IM helped to identify determinants, and the interactive tailoring features of the intervention provided specific messages for users that depended on their beliefs, knowledge, and identified barriers. Targeting health care providers directly was not possible, but a patient activation element (patient-mediated prompts) was added to the intervention to increase provider recommendations and referrals for CRCS.

Fassier et al. (44) describe the use of IM in the development of an intervention to help breast cancer survivors in France successfully return to work after treatment. The authors emphasize the importance of taking an ecological perspective to planning and note that IM can help identify and document interpersonal, organizational, community, and societal influences. They also describe the development of the planning group, which included a broad array of stakeholders who helped to identify priorities, and environmental conditions that influenced the return to work. The paper provides an example of the use of IM in the early stages of program development to understand a problem at multiple levels, develop a logic model of change, and guide assessment.

ten Hoor et al. (45) used IM to develop an intervention to prevent obesity among Dutch adolescents. Using the socioecological approach that underlies the IM process, they identified important contributors to physical activity in the adolescent's social context, as based in social determination and social comparison theories. They also extended the theory of expanded, extended, and enhanced opportunities (TEO) for physical activity to include "enriched" opportunities, such as the incorporation of weight training into the school-based physical activity program. The paper is an example of how IM can assist in incorporating elements of different theoretical perspectives to inform program development.

Vissenberg et al. (46) used IM to develop a social network-based intervention for diabetes self-management targeted to Dutch, Surinamese, Moroccan, and Turkish families who live in the Netherlands. The authors note that underlying the challenges to self-management behavior among these populations are cultural factors and socioeconomic status. In line with IM, they recommend a greater engagement of the priority populations and other stakeholders in the planning process. The article provides an example of a logic model as derived from the IM process.

Mesters et al. (26) used IM to analyze an effective intervention to promote breastfeeding of infants at risk for asthma. The authors noted that the literature suggests certain demographic, biological, and social determinants at three time periods: prenatal, postnatal initiation, and postnatal continuation. IM was used to describe performance and to develop change objectives. Environmental factors included the mother's partner. Mesters et al. provide examples of how the process of writing performance objectives forced program planners to describe in detail the actions necessary to accomplish behaviors, which ultimately led to important content and effective strategies that may have otherwise been omitted, e.g., the inclusion of the mother's partner. An evaluation of the program showed that it resulted in positive behavioral changes, which the authors attributed to a careful analysis of the determinants and preparation for the unexpected negative attitudes of others (26).

NEW DIRECTIONS

Although IM provides guidance to identify needs and develop interventions, additional research and approaches are needed to more accurately address the questions posed by each of the steps including the identification of determinants and the selection of methods. Crutzen et al. (12) describe an approach for selecting determinants to target in interventions. They suggest visualization of confidence intervals and correlations. The authors clearly explain the importance of identifying determinants. They also note that currently used approaches for identifying determinants are insufficient. They propose a confidence interval-based estimation of relevance (CIBER) approach for selecting determinants to target in an intervention. In CIBER, the data are visualized as diamond plots. They presented an MDMA (ecstasy) study, in which four determinants are discussed, as an example of the use of CIBER. The statistical tool is available at no cost.

Additional research is needed to build the evidence base for the effectiveness of certain methods to address determinants. Peters et al. (18) highlight the limitations of existing taxonomies of methods derived from the meta-analyses of interventions, which include misapplied methods without consideration of parameters, confounding factors such as co-occurring methods, and the interaction of methods and context. In response, they propose an "iterative protocol for evidence base accumulation," whereby researchers conduct meta-analyses of applied health behavior change interventions, taking into consideration the parameters of those methods. This research would then lead to basic experimental studies that test methods under various conditions. Meta-analyses of these experiments would then provide information about which methods are effective and under which conditions.

IM addresses the growing body of evidence on the influence of the environmental context on health and health behavior [e.g., (47)] by providing a robust framework for planning health interventions that considers various facets of the environment. Springer et al. (48) explore how health planners and practitioners can further incorporate the environmental context of health intervention design through the concept of *health promotion interweaving*. Building from theoretical perspectives rooted in social-ecological models, improvement science, and systems thinking, this paper advances an indigenous health intervention development approach that takes into account the environmental context, to designing interventions. While IM is specifically structured for the community and stakeholder involvement, an important contribution of this paper is its description of theory- and practice-based *interweaving* concepts (49, 50) in relation to specific environments, such as *Health in All Policies* (policy environment), *environmental print* (information environment), *appropriable organization* (social/organizational environment), and *shared use agreements* (built environment). Springer and colleagues' exploration of health promotion interweaving as a health planning approach promotes greater intentionality for designing health promotion strategies, practices, programs, and policies (47, 49, 50).

Using IM to plan implementation strategies has recently gained attention (37, 51) partly due to the challenges of applying implementation science theories and framework to inform the planning process. Highfield et al. (52) describe the use of IM to develop an implementation intervention to increase adoption, implementation, and maintenance of an existing evidence-based program to improve mammography adherence in community healthcare clinics. The goal was to scale-up the Peace of Mind Program, which had been previously adapted, using IM (53), for African American Women served by community clinics. The authors describe the steps in their process and provide examples of how implementation science theories and frameworks can inform the IM process.

Based on the recognition that evidence-based sexual health education programs are underutilized by school districts, Peskin et al. (54) used IM to create an online tool to help school districts to adopt, implement, and maintain evidence-based sexual health education programs. The authors had previously developed the Choosing and Maintaining Effective Programs for Sex Education in Schools (CHAMPS) model. They provide an example of the use IM for planning implementation interventions. This paper also provides an example of how IM can be useful in adapting evidence-based interventions so that they can be delivered through different platforms.

The use of IM as a tool in implementation science for the development of implementation strategies is growing (55–57). Using IM increases the ability to map strategies to specific barriers and facilitators of implementation, with a particular focus on the mechanisms and methods that will bring about the needed changes. Thus, the application of IM in the development of implementation strategies can address a knowledge and practice gap in implementation science.

CONCLUSION

IM helps health promoters to develop well-thought-out theory- and evidence-based programs through the identification of key changeable determinants of risk behaviors, the choice of appropriate intervention methods and applications, and the development of implementation strategies to ensure use and dissemination. Although the IM process is described through its sequential steps, IM is intended to be iterative, and, indeed, most of the studies presented above describe the IM planning process this way. Throughout the process, planners gain new knowledge about the population, determinants, environment, and/or effective and appropriate methods that sometimes requires cycling through earlier steps to expand or refine the program.

The IM protocol assists program-planning groups to optimize the chances of program effectiveness, and IM has been utilized widely across multiple health domains, populations, and settings all over the world. The use of IM can make health education and health promotion programs stronger, more effective, and more widely disseminated to improve the impact of public health programs.

AUTHOR CONTRIBUTIONS

MF, RR, CM, and GK contributed to the manuscript conceptualization, discussion of new directions and the conclusions. GK and MF contributed to the description of studies in the special topics issue.

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METHODS
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Using Confidence Interval-Based Estimation of Relevance to Select Social-Cognitive Determinants for Behavior Change Interventions

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When developing an intervention aimed at behavior change, one of the crucial steps in the development process is to select the most relevant social-cognitive determinants. These determinants can be seen as the buttons one needs to push to establish behavior change. Insight into these determinants is needed to select behavior change methods (i.e., general behavior change techniques that are applied in an intervention) in the development process. Therefore, a study on determinants is often conducted as formative research in the intervention development process. Ideally, all relevant determinants identified in such a study are addressed by an intervention. However, when developing a behavior change intervention, there are limits in terms of, for example, resources available for intervention development and the amount of content that participants of an intervention can be exposed to. Hence, it is important to select those determinants that are most relevant to the target behavior as these determinants should be addressed in an intervention. The aim of the current paper is to introduce a novel approach to select the most relevant social-cognitive determinants and use them in intervention development. This approach is based on visualization of confidence intervals for the means and correlation coefficients for all determinants simultaneously. This visualization facilitates comparison, which is necessary when making selections. By means of a case study on the determinants of using a high dose of 3,4-methylenedioxymethamphetamine (commonly known as ecstasy), we illustrate this approach. We provide a freely available tool to facilitate the analyses needed in this approach.

Keywords: determinants, beliefs, behavior change, methods, intervention development, Confidence Interval-Based Estimation of Relevance

INTRODUCTION

When developing an intervention aimed at behavior change, one of the crucial steps in the development process is to select the most relevant determinants (1). In lay terms, these determinants are the closest approximation to "the buttons one needs to push" to establish behavior change. Insight into these determinants is needed to select behavior change methods (i.e., general behavior change techniques that are applied in an intervention) in the development process. The aim of the current paper is to introduce a novel approach to select the most relevant determinants and use them in intervention development.

There are three main types of variables that have an influence on behavior: environmental, genetic, and psychological variables. When developing an intervention aimed at behavior change, the focus is mostly on psychological variables. First, because these variables are most likely to be changeable by an intervention (2). Second, because overt behavior results from neural activation patterns (3). Hence, all overt behavior is necessarily caused by psychological variables in all conceivable cases except physical coercion. In other words: all environmental (e.g., social or physical) and genetic influences on behavior eventually operate through (and manifest as) psychological variables (4),[1] of which, in the context of behavior change, social-cognitive determinants have received the most attention.

Theories aiming to explain behavior, such as the Reasoned Action Approach [RAA (5)], the Health Belief Model [HBM (6)], and the Extended Parallel Process Model [EPPM (7)], postulate specific social-cognitive determinants and their relationships to each other and behavior. Each of these theories applies to specific (antecedents of) behaviors: for example, the RAA explains reasoned action, the HBM health behavior, and the EPPM the processing of threatening communication. This property of theories (i.e., dealing with bounded aspects of reality) is not a shortcoming, but in line with the definition of theories as reductions of reality, which is also emphasized by Occam's razor (8). This means that to obtain the most exhaustive understanding of which psychological variables determine a behavior, it will often be necessary to combine several theories of behavior explanation (9).

Identifying Determinants at Different Levels of Psychological Aggregation

In intervention planning, this combination of theories informs the so-called logic model of change (1). Such a logic model contains, for a specific behavior in a specific target population, what is known about the psychological variables and environmental conditions that predict the behavior. For each relevant environmental condition, environmental agents who control the condition are identified, and an intervention may then be developed for each of them (10). Because targeting those environmental conditions occurs through targeting the determinants of the relevant agents, the process of selecting relevant determinants for environmental agents is comparable to selecting relevant determinants for the target population (1). It is important to note that these determinants have a given level of psychological aggregation. For example, in the RAA, behavior is the highest level of psychological aggregation (level 1), followed by intention (level 2), attitude (level 3), experiential attitude (level 4) and behavioral beliefs (level 5) (5, 9). In other words, determinants of behavior can be organized on the aggregation level hierarchy in terms of specificity versus generality, and various sub-determinants can often be distinguished for any determinant. For example, behavioral beliefs are sub-determinants of attitude. In this paper, we use "sub-determinants" to refer to determinants at a lower level of psychological aggregation.

The overarching determinants at higher levels of generality (e.g., attitude and self-efficacy) are those needed to select appropriate behavior change methods. Behavior change methods have different components and are not equally effective for all determinants. For example, while stimulating enactive mastery experiences can be used to improve self-efficacy, it is less suitable to foster attitude change. We refer to Kok et al. (11) for an overview of behavior change methods linked to specific determinants.

Sub-determinants formulated at a high level of specificity (e.g., beliefs in the case of RAA) are crucial when studying determinants, because those very specific aspects are what is used in operationalizations and intervention messages. As operationalizations are stimuli that people process (and respond to, for example, items in a questionnaire), they need to have sufficient specificity to relate to real-world phenomena (e.g., a questionnaire item in ordinary language). Similarly, as intervention messages will necessarily address more or less tangible aspects of reality, these, too, are based on sufficiently specific sub-determinants. For example, even though the RAA postulates that intention is the most proximal determinant of behavior, intervention messages mostly concern beliefs underlying, for example, attitude (e.g., "being physical active is enjoyable") or perceived norm (e.g., "X% of people your age adhere to recommended levels of physical activity").

Thus, before developing a behavior change intervention, it is important to establish the determinants and underlying sub-determinants that predict the target behavior. This is an essential part of the needs assessment, which ultimately results in the logic model of change, in Intervention Mapping (1) as well as other frameworks (12). Therefore, a determinant study is often conducted as formative research in the intervention development process. When conducting such a study, it is important to include all possible sub-determinants that might be relevant for the target behavior of the intervention. Using the core processes (i.e., the processes involved in understanding a problem or answering a question with empirical data and theory) is critical to identify sub-determinants at all levels of aggregation (11). The first step in using the core processes is to conduct a brainstorm about possible sub-determinants for the specific behavior and the specific target group. The second step is to gather evidence from previous empirical studies. It is important to stress that different (but complementary) types of studies can be used. For example, while a meta-analysis can provide evidence for the strength of the association between higher level determinants (e.g., self-efficacy) and the target behavior, an interview study can provide more in-depth insight into lower level determinants (e.g., specific situations in which target population members exhibit low levels of self-efficacy). The third step is to use insights from psychological theories (7). The fourth step is to collect new empirical data that are specific to the target population, context, and behavior at hand. In this step, different types of studies can be conducted as well. For example, Peters (13) provides a practical guide regarding synthesizing previous literature and qualitative exploration of (sub-)determinants.

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[1] Please note that this does not imply that changes in the environment cannot have an impact on behaviour, only that this impact operates through psychological variables (either consciously or unconsciously).

Subsequently, one needs to establish which of the potential (sub-)determinants are the most relevant given the target behavior, population, and context. This is important because practical considerations prohibit targeting all (sub-)determinants. For example, there are limits in terms of resources available for intervention development and the amount of content that participants of an intervention can be exposed to. To optimize intervention effectiveness, the selection of which (sub-)determinants will be targeted by an intervention should be guided by (sub-)determinant relevance. This paper focuses on establishing relevance based on data that are collected by means of surveys.

Approaches to Establishing Relevance

Establishing relevance of determinants is a crucial step in the planning of behavior change interventions; however, as yet, no guidelines exist for establishing relevance of determinants. Due to a lack of clear guidelines, a variety of methods is used. For example, dichotomizing (a determinant of) behavior and then comparing means of (sub-)determinants; computing correlation coefficients for the association between (sub-)determinants and (a determinant of) behavior; or conducting regression analyses where (a determinant of) behavior is regressed on relevant (sub-) determinants [for some examples pertinent to the current subject matter, see, e.g., Ref. (14–18)]. These approaches combine two types of analyses: (1) assessing the univariate distribution of each (sub-)determinant and (2) assessing associations to behavior and/or determinants of behavior.

Assessing the associations of (sub-)determinants with behavior and/or determinants is important: those sub-determinants that are not associated to behavior and/or more proximal determinants will often be the least likely candidates to intervene upon. The univariate distributions are important because bimodal distributions may be indicative of subgroups, and strongly skewed distributions have implications for how a (sub-)determinant should be targeted. For example, if a sub-determinant is positively associated with behavior but left-skewed, most population members already have the desired value, so an intervention developer will want to reinforce it. Conversely, right-skewed positively associated sub-determinants imply a need for change, as most population members do not have the desired value yet. This latter category of sub-determinants would be more viable intervention targets, should a choice have to be made: there is more room for improvement.

Although these conventionally employed analyses have sensible aims, the analyses employed to achieve those aims are problematic. Regression analyses, for example, are useful to obtain a measure of the total explained variance in an outcome (e.g., R^2) based on the sub-determinants included in a model. However, the regression coefficients provide little information as to determinant relevance because they are conditional upon the other predictors in the specific model (13, 19–21). These problems are resolved when looking at bivariate associations, but the common practice of dichotomizing behavior or a proximal determinant such as intention leads to information loss and underestimation of variation (22–24). Furthermore, Cohen's *d* point estimates of differences between groups (e.g., intenders and non-intenders) can vary substantially from sample to sample (25), rendering them unfit for determinant selection on the basis of one sample. Although to a lesser extent, the same is true for estimates of means and correlation coefficients (26). Instead resorting to basing conclusions on *p*-values from null hypothesis significance tests is also widely discouraged (27–31). Using a frequentist approach, the most widely accepted method would be to base these decisions on the *confidence intervals* for the means and correlation coefficients.

However, such an approach is problematic because it requires intervention developers to parse a large amount of information simultaneously. For each (sub-)determinant, the univariate distribution and mean, as well the lower and upper confidence interval bounds would have to be inspected, as well as the correlation coefficients with behavior and perhaps a proximal determinant of behavior such as intention, again together with the lower and upper confidence interval bounds. Even with only 10 (sub-)determinants, and even if associations with a proximal determinant are not considered, this would mean researchers would have to simultaneously evaluate 60 estimates. The main challenge, therefore, is to find a method of assessing this large amount of information simultaneously. This is the challenge we aim to undertake with the presently proposed Confidence Interval-Based Estimation of Relevance (CIBER) approach.

Confidence Interval-Based Estimation of Relevance

The presently proposed CIBER approach is based on data visualization. Visualizing the relevant data has three advantages. First, visualization enables mapping the data onto spatial dimensions, facilitating comparison, which is necessary when making selections. Second, visualization foregoes the seeming accuracy and objectivity afforded by numbers (32). Given the relative width of most sampling distributions and the subsequent variation that occurs in estimates over samples (25, 26), caution in basing decisions on the exact computed numbers seems prudent. Third, visualization enables assessing confidence intervals for means in the context of the raw data.

In the visual representations used in the CIBER approach, confidence intervals are represented using the diamond shapes commonly used for the aggregated effect size in meta-analyses (32). Unlike error bars with whiskers, diamonds do not draw attention to the confidence interval bounds. They are an efficient method of representing both the mean and the confidence interval in one shape, allowing both stroke and fill colors, which makes it possible to use the fill color to further facilitate interpretation, and the stroke color to identify, for example, which determinant a shape represents. Another advantage is that it is not easy to see the exact values of the three estimates represented by the diamond (the mean and lower an upper confidence bounds). Although this might not seem like an advantage at first glance, this lack of clarity is consistent with the estimates' imprecision [i.e., their variation from sample to sample (32)]. These diamond plots are then used to visualize the raw data, the point estimate and confidence interval for the mean, and the point estimate and confidence interval for the correlation with behavior and/or one or several determinants of behavior. Each (sub-)determinant, the question used to assess it, as well as the anchors can be shown.

In other words, the CIBER approach acknowledges that several metrics need to be combined (correlation coefficients, means, and confidence intervals of both) and interpreted in order for data to become valuable information. In the next section, we will illustrate this approach by means of a case study on the determinants of using a high dose of 3,4-methylenedioxymethamphetamine (MDMA, commonly known as ecstasy).

CASE STUDY

In the Netherlands, MDMA content of ecstasy pills has gradually increased (33, 34), and the likely association of dose to risk (35) warrants intervention efforts to discourage using a high dose of MDMA. In our illustrations, we will use data collected in a determinant study designed to inform such intervention efforts. This study is conducted as part of the Party Panel initiative (for more information, see http://partypanel.eu/info). The full determinant study will be described elsewhere,[2] but the most relevant information for the current paper is provided here. The materials and analysis script for this study have been made available at the Open Science Framework repository at https://osf.io/qf3sq. The data are under embargo until July 1, 2017, but will then be added to that repository. These efforts are taken to acknowledge a recent call for full disclosure to maximize scrutiny, foster accurate replication, and facilitate future data syntheses (e.g., meta-analyses) (36, 37).

Recruitment, Procedure, Participants, and Ethical Approval

Participants were recruited through social media posts by Dutch nightlife prevention campaign Celebrate Safe and partner organizations and one funded Facebook post. Participation was voluntary, and no incentive was offered.

Participants visited http://partypanel.nl where they could open the survey. The survey was developed in LimeSurvey (38) and hosted on a secure TIER3+ server in the Netherlands. After providing online informed consent, participants completed the questions in the survey. These questions were mainly based on RAA (5). In addition, a number of target population members, specifically peers from the Amsterdam-based peer education project Unity, completed an online questionnaire with open-ended questions prompting for potential reasons for performing (or not performing) certain target behaviors (e.g., using a high dose of MDMA). This questionnaire was designed to approximate a belief elicitation procedure (5). The resulting beliefs were integrated in the questionnaire for this study (see Operationalizations).

The data presently analyzed were provided by 227 participants (all MDMA users, because only they could answer questions about their MDMA use). Of these, 203 reached the section where demographics were assessed, where 60% indicated they were male, 39% female, and 1% did not answer or indicated not identifying as male or female. The mean age was 25 years (SD = 7.0).

Ethical approval was provided by the ethical committee of the Dutch Open University (the form and the approval letter are available at https://osf.io/qf3sq).

Operationalizations

All operationalizations (i.e., questions in the survey) were originally in Dutch. These original questions are available at https://osf.io/qf3sq and translations will be provided here. Please note that the term "ecstasy" is used in the translation of the questions to English and the remainder of this paper, as this more closely resembles the original questions in Dutch. In this case study, behavioral beliefs are associated with both attitude and intention. All questions regarding behavioral beliefs, attitude, and intention used 7-point response scales with varying anchors per question. Intention to use a high dose of ecstasy was measured with three questions assessing what in English could be described as participants' intention, motivation, and expectation. The direct measure of attitude was a semantic differential where participants indicated what they thought about using highly dosed ecstasy pills if they used ecstasy, on the dimensions bad versus good, unpleasant versus pleasant, stupid versus smart, unhealthy versus healthy, and boring versus exciting. The behavioral beliefs, specifically the expectancies, were measured with a series of 21 items, each expressing a potential belief about using a high dose of ecstasy. The items and anchors can be seen in **Figure 1**.

Output

Figure 1 provides the output following the proposed analytical approach. The items that were used to assess the behavioral beliefs (i.e., the sub-determinants in this case study) are shown to the left of the left hand panel. The anchors of the items are on the side of the left hand panel. The diamonds in the left hand panel show the item means with 99.99% confidence intervals. The fill color of the diamonds is indicative of the item means—the redder the diamonds are, the lower the item means; the greener the diamonds are, the higher the items means (blue denotes means in the middle of the scale). The dots surrounding the diamonds show the item scores of all participants with jitter added to prevent overplotting. The diamonds on the right hand panel show the association strengths (i.e., correlation coefficients with 95% confidence intervals) between individual items and determinants at different levels of psychological aggregation (attitude and intention in this example). The fill color of the diamonds is indicative of the association strengths and their direction—the redder the diamonds are, the stronger and more negative the associations are; the greener the diamonds are, the stronger and more positive the associations are; the grayer the diamonds are, the weaker the associations are. The stroke color of the diamonds (i.e., the "line color") can be used to differentiate associations between behavioral beliefs with different determinants (attitude and intention in this case study). In this example, the diamonds with a red stroke show the association with attitude, and the diamonds with a blue stroke show the association with intention. The confidence intervals of the explained variance (R^2) of attitude and intention based on all behavioral beliefs are depicted at the top of the figure. The items concerning behavioral beliefs can also be ranked based on association strengths with a specific

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[2] Peters G-JY, Noijen J. *Harder, Better, Faster, Stronger: Informing Behavior Change Interventions to Discourage Using High Doses of Ecstasy* (forthcoming).

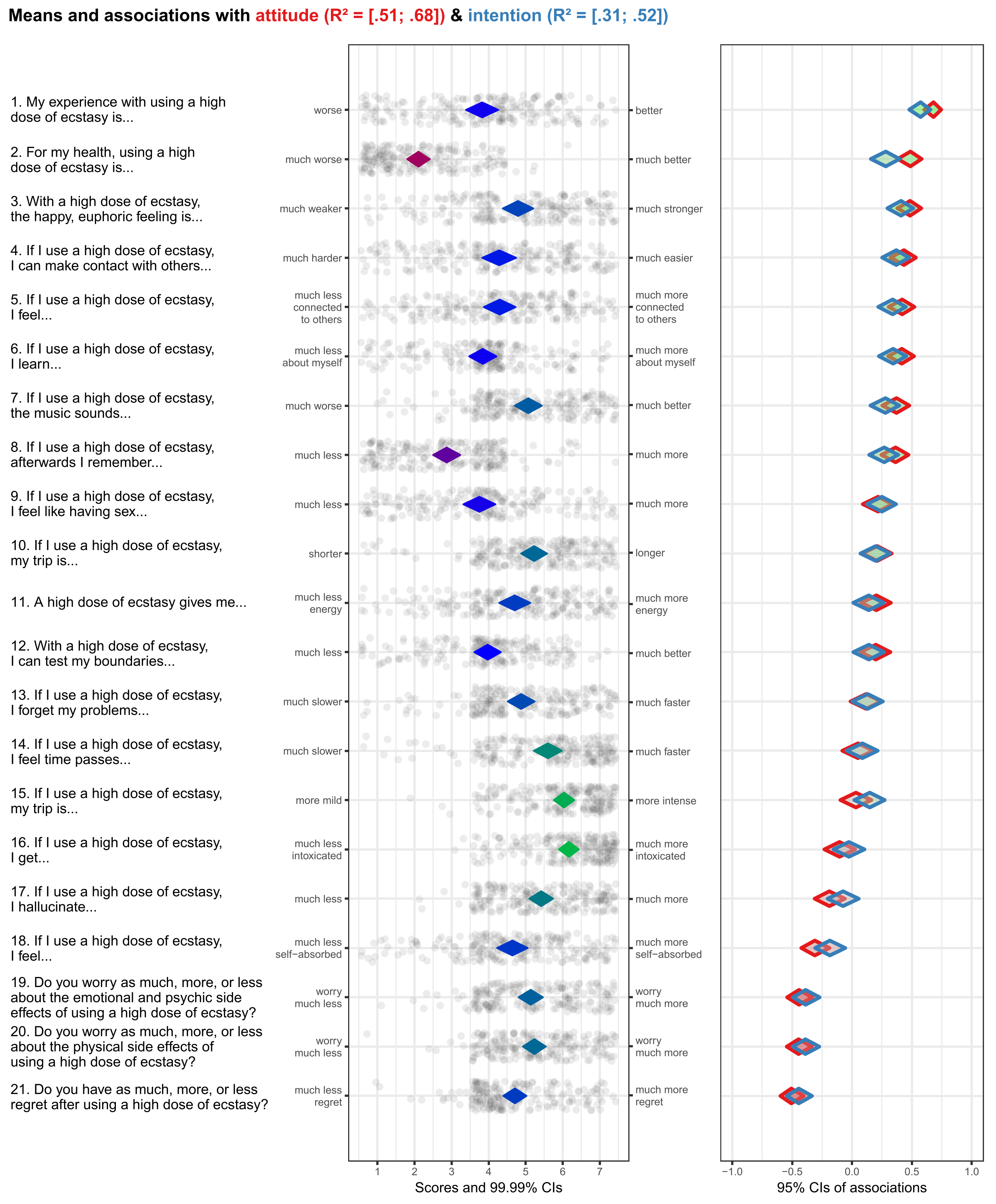

FIGURE 1 | Output of case study regarding sub-determinants of attitude and intention to use a high dose of ecstasy. (Diamond fill color in left hand panel is indicative of items means: the redder the diamonds are, the lower the item means; the greener the diamonds are, the higher the item means. Diamond stroke color in right hand panel is used to differentiate between determinants. Diamond fill color in right hand panel is indicative of association strengths and their direction: the redder the diamonds are, the stronger and more negative the associations are; the greener the diamonds are, the stronger and more positive the associations are.).

determinant. In this example, the items are ranked based on their association with attitude. It would be overly simplified to use this ranking to select the most relevant sub-determinants (in this case behavioral beliefs). Instead, correlation coefficients, means, and confidence intervals of both need to be combined to select behavioral beliefs to be targeted in an intervention.

Sub-Determinant Selection and Implications for Intervention Content

The procedure to select relevant sub-determinants and what this implies for intervention content is illustrated by using the visualizations regarding four items depicted in **Figure 1**. We selected four items that exhibit different univariate and bivariate patterns.

First, the item “For my health, using a high dose of ecstasy is… [much worse/much better; item 2 in **Figure 1**].” This belief has a strong positive association with attitude and intention. However, the relevance is relatively low, because the scores on the middle panel indicate that participants are already convinced that using a high dose of ecstasy is much worse for their health. If this belief is targeted in an intervention, then this would mean that the belief needs to be confirmed, unless it is possible to tailor the intervention message to only target the small subgroup of participants who are not convinced of the dose/risk relationship.

Second, the item “If I use a high dose of ecstasy, my trip is more… [mild/intense; item 15].” Although the scores on the middle panel indicate that participants are convinced that this makes their trip more intense, the relevance is relatively low, because this belief is not associated with attitude and very weakly with intention.

Third, the item “My experience with using a high dose of ecstasy is… [worse/better; item 1].” This belief has a strong positive association with attitude and intention, and the scores are on the middle of the scale. This combination makes it a highly relevant belief. In terms of intervening, this would imply that the belief that a high dose of ecstasy leads to a better experience needs to be negated. Other data from this study showed that common consequences of high doses of ecstasy, such as remembering less, hallucinating more, and being less sociable, were rated as very undesirable. This suggests that there may be enough leverage for a persuasive message that emphasizes the disadvantages of using a high dose.

Fourth, the item “Do you have as much, more, or less regret after using a high dose of ecstasy? [much less regret/much more regret; item 21].” This belief has a strong negative association with attitude and intention, and the scores are roughly normally distributed around the middle of the scale. This combination makes it a highly relevant belief. In terms of intervention, this would mean that feelings of regret need to be reinforced.

These four examples demonstrate the added value of combining several metrics (correlation coefficients, means, and confidence intervals of both) by means of visualizations. The next section is a practical guide on a freely available tool that can be used to obtain the visualizations needed to apply CIBER.

A Practical Guide to Obtain Visualizations

We implemented this tool as a function in the open source package “userfriendlyscience” (39) for the open source statistical package R (40), which is often used in conjunction with the graphical user interface provided by the open source software RStudio (41). To use the function, the following commands can be used in an R analysis script or entered in the R console:

```
install.packages('userfriendlyscience');
require('userfriendlyscience');
```

The first of these commands downloads the package and installs it. This command only needs to be run once: the package will remain installed. The second command loads the package in the current session: this command has to be repeated in every session where the user wishes to use this package. After loading the package, the following command can be used to request the plot to apply CIBER:

```
CIBER(data = getData(),
      determinants = c('variable1',
                       'variable2'
      targets = c('behavior', 'intention'));
```

In this simplest case, the first argument specifies the dataset to use. In this example, the function “getData” is used to load a dataset from, for example, an SPSS datafile. The second and third arguments are used to specify the variable names of the sub-determinants (which will appear in the rows of the plot) and the variable names of behavior and potentially other determinants. The associations of the sub-determinants with these latter variables will be shown in the panel to the right. Of course, more than two sub-determinants and targets can be specified by adding more variable names, delimited by commas and each enclosed in single (or double) quotes. Note that R is case sensitive, so the variable names have to match those in the datafile exactly.

The function has many optional arguments, the most relevant ones of which will briefly be listed here (use “?CIBER” to consult the function’s manual page). “subQuestions,” “leftAnchors,” and “rightAnchors” can be used to specify the items and anchors that were used to measure the sub-determinants. Setting “decreasing” to TRUE or FALSE orders the sub-determinants based on their means in descending or ascending order, respectively. If a target variable name is specified in the argument “orderBy,” then the sub-determinants are ordered by their association to that target variable instead. We refer to https://osf.io/qf3sq for the specific arguments used to create **Figure 1** and the Supplementary Material for a general description of the arguments to be specified when using CIBER. All these optional arguments can be used to tailor the plots to the specific needs of a study aimed at selecting relevant sub-determinants.

DISCUSSION

The current paper demonstrates how to select the most relevant sub-determinants and how this can have an impact on choices made during intervention development (as demonstrated by the case study). We have described an analytical approach, denoted as CIBER, to look at associations between sub-determinants and (multiple) outcomes (e.g., behavior, but also determinants at lower levels of psychological aggregation). To facilitate the implementation of CIBER in future research, we have made an easy-to-use tool freely available, and we have described how to use it in practice. This tool provides the output needed to select relevant sub-determinants.

However, the utility of the output depends on the quality of the operationalizations (e.g., questions in the survey). Two aspects are crucial in ensuring high-quality operationalizations: (1) identifying all possible sub-determinants that need to be operationalized (e.g., included in the survey) and (2) making sure that they are adequately operationalized. With regard to the first aspect, we refer to the core processes (described in Section "Identifying Determinants at Different Levels of Psychological Aggregation") that are critical to identify sub-determinants at all levels of aggregation (11). When identifying possible sub-determinants, it is warranted to be theoretically promiscuous and to remain critical toward all individual theories (9). After all, the aim is not to test a specific theory, but to identify all relevant aspects of the target population's psychology where it concerns the behavior at hand (i.e., all possible sub-determinants). Hence, limiting oneself to only operationalize determinants in any one theory would be unwise. With regard to the second aspect, it is good to be aware that data about a determinant are only as good as its operationalization, and therefore, any theory should include instructions for operationalization of each determinant (42). For example, Witte et al. (43) provide a Risk Behavior Diagnosis Scale that contains skeleton items to be completed with the target behavior and health threat at hand, such as "[Recommended response] is effective in pre- venting [health threat]." Both aspects are essential to ensure utility of the output when applying CIBER.

Moreover, decisions regarding selection of sub-determinants cannot be solely based on the output of data analysis (regardless of which analytical approach is taken). The output should be seen as complementary to the expertise of a behavior change expert (e.g., health psychologist or health promoter). This expertise is needed to choose appropriate behavior change methods if a certain sub-determinant is selected and to translate these methods into practical applications (11). For example, providing stereotype-inconsistent information (i.e., positive examples from the stigmatized group) is a behavior change method aimed at reducing stigma. This method is only effective when there are many different examples, and these examples are not too discrepant from the original stereotype (11, 44). If providing stereotype-inconsistent information is operationalized in such a way that only few different examples are used, people might think that just one exception is presented. If the examples are too discrepant, people might deem the information to be irrelevant regarding their views on the stigmatized group. Expertise regarding parameters for use is crucial to adequately translate behavior change methods into practical applications.

Behavior change expertise is also needed to make judgments regarding changeability. Besides relevance, changeability is the other part of the equation when selecting sub-determinants during intervention development (1). For example, it is often assumed that knowledge about a certain behavior is relatively easy to change in comparison with self-efficacy toward that same behavior. Whenever possible, judgments regarding changeability should be based on evidence from the research literature (45). However, when data regarding changeability are scarce, such judgments have to rely on a theoretical or conceptual basis.

Finally, using CIBER might result in a large number of relevant (and changeable) sub-determinants. In practice, however, the available resources (e.g., time and money) are often limited. This can have an impact on the quantity and quality of intervention content that can be developed, but also delivered. The latter is especially relevant in case there are additional costs per participant (e.g., delivering an intervention in a face-to-face setting with a health professional). However, also when the additional costs per participants are low (e.g., when using an Internet-delivered intervention), then there are still limits in terms of the amount of intervention content that participants can be exposed to. Although intervention content can be delivered in multiple sessions over a longer period of time, this might lead to increased levels of dropout (46), which also limits exposure to intervention content. So, besides output of the proposed analytical approach and behavior change expertise, also practical constraints affect the ultimate selection of sub-determinants that are targeted in an intervention.

The proposed analytical approach can be applied at all levels of psychological aggregation. For example, as explained in Section "Identifying Determinants at Different Levels of Psychological Aggregation," there are five levels of psychological aggregation in the RAA: behavior (level 1), intention (level 2), attitude (level 3), experiential attitude (level 4), and behavioral beliefs (level 5) (5, 9). Investigating associations between, for example, beliefs and intention/behavior might result in valuable insights, but also, for example, investigating associations between beliefs and attitude, or attitude and intention/behavior. The associations to look at depend on the exact question to be answered. For example, if one wants to know what the most relevant determinants are, then one needs to look at the associations between attitude, perceived norm, and perceived behavior control (level 3), and intention (level 2) or behavior (level 1). However, if one wants to know which beliefs to target in an intervention, then associations between beliefs (level 5), and intention (level 2) or behavior (level 1) are recommended. In the latter example, determinants such as attitude or perceived behavior control (level 3) are still important, because behavior change methods are linked to determinants at this level (11). For example, some methods are more appropriate to change attitude (e.g., arguments), while other are more appropriate to change perceived behavior control (e.g., guided practice). The exact content when applying these methods in an intervention, however, depends on the behavioral beliefs and control beliefs underlying, respectively, attitude and perceived behavioral control. Associations between beliefs (level 5) and determinants (level 3) shed more light on the latter. Independent of the levels of psychological aggregation one is interested in, CIBER can be applied to select the most relevant sub-determinants.

It needs to be stressed that conclusions regarding relevance of sub-determinants (e.g., when discussing the results of the case study presented in this paper) do not imply causality between sub-determinants and (multiple) outcomes. This is independent of the analytical approach, but is due to the cross-sectional nature of the data used in the study at hand. This is in line with the current literature that is dominated by cross-sectional determinant studies (47), although there are also experimental studies available [e.g., Ref. (48)]. Furthermore, we also do not want to imply that the associations between sub-determinants and outcomes are necessarily unidirectional in a theoretical sense. In fact, many theories assume a reciprocal relationship. For example, Bandura denotes this as reciprocal determinism in his Social Cognitive Theory (49). Weiner's attributional model, as another example, indicates that unexpected or negative behavioral outcomes lead a person to search for causal ascriptions (e.g., specific beliefs) that can explain the outcomes (50). Longitudinal and experimental data are needed to test such assumptions.

In sum, CIBER is a useful approach to select the most relevant social-cognitive determinants, which can be applied across behavioral domains. Currently, however, CIBER is based on linear correlations between variables. That means that it cannot be applied yet to, for example, dichotomous variables. The underlying idea of the proposed analytical approach (i.e., using data visualization to combine several metrics regarding univariate distributions and associations), however, can also be applied to dichotomous variables. Therefore, we intend to continue to develop CIBER, to enable this in the future. Moreover, we are also aware of other developments, such as the use of network models that allow for modeling complex systems of observable items underlying psychological variables in general (51). These network models can also be applied to social-cognitive determinants, such as attitude (52). Within such network models, centrality measures (e.g., degree centrality and closeness centrality) might give complementary insights in the relevance of sub-determinants in relation to each other (53). The aim of this paper, however, was to demonstrate CIBER, not to compare it with other methods. Future research might focus on such comparisons and shed light on, for example, whether network models have added value on top of the proposed analytical approach. Using CIBER, however, is already a step forward from commonly used methods (e.g., regression analyses). To use CIBER, one needs to learn the rudiments of the statistical package R. However, the function is developed in such a way that substantive researchers can actually take this step and apply CIBER in future research and, therewith, optimize the development process of future behavior change interventions.

ETHICS STATEMENT

The protocol for collecting the data that are used in the case study was approved by the ethical committee of the Dutch Open University (the form and the approval letter are available at https://osf.io/qf3sq). All participants gave online informed consent.

AUTHOR CONTRIBUTIONS

Study conception and design; drafting of manuscript: RC, G-JP, and JN; acquisition of data: G-JP and JN; analysis of data: G-JP; interpretation of data: RC and G-JP. All the authors agree on the final version of the manuscript.

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SUPPLEMENTARY MATERIAL

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METHODS
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Using Intervention Mapping for Program Design and Production of *iCHAMPSS*: An Online Decision Support System to Increase Adoption, Implementation, and Maintenance of Evidence-Based Sexual Health Programs

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In Texas and across the United States, unintended pregnancy, HIV, and sexually transmitted infections (STIs) among adolescents remain serious public health issues. Sexual risk-taking behaviors, including early sexual initiation, contribute to these public health problems. Over 35 sexual health evidence-based programs (EBPs) have been shown to reduce sexual risk behaviors and/or prevent teen pregnancies or STIs. Because more than half of these EBPs are designed for schools, they could reach and impact a considerable number of adolescents if implemented in these settings. Most schools across the U.S. and in Texas, however, do not implement these programs. U.S. school districts face many barriers to the successful dissemination (i.e., adoption, implementation, and maintenance) of sexual health EBPs, including lack of knowledge about EBPs and where to find them, perceived lack of support from school administrators and parents, lack of guidance regarding the adoption process, competing priorities, and lack of specialized training on sexual health. Therefore, this paper describes how we used intervention mapping (Steps 3 and 4, in particular), a systematic design framework that uses theory, empirical evidence, and input from the community to develop *CH*oosing *A*nd *M*aintaining Effective *P*rograms for *S*ex Education in *S*chools (*iCHAMPSS*), an online decision support system to help school districts adopt, implement, and maintain sexual health EBPs. Guided by this systematic intervention design approach, *iCHAMPSS* has the potential to increase dissemination of sexual health EBPs in school settings.

Keywords: dissemination, evidence-based, intervention mapping, sexual health, adolescents

INTRODUCTION

In Texas and across the United States, unintended pregnancy, HIV, and sexually transmitted infections (STIs) among adolescents remain serious public health issues. In the U.S., the 2015 teen birth rate (among 15- to 19-year-old females) was 22.3 births per 1,000 (1). Furthermore, national estimates indicate that half of all new STIs occur among young people between the ages of 15 and 24 (2). Texas has one of the highest teen birth rates in the nation at 34.6 per 1,000 (3) and currently ranks sixth in the nation for the estimated number of HIV diagnoses among adults and adolescents (4). Sexual risk-taking behaviors, including early sexual initiation (5), are factors that contribute to these high rates of teen births and HIV/STIs (6–12).

National agencies, including the U.S. Department of Health and Human Services' Office of Adolescent Health (13) and National Campaign to Prevent Teen and Unplanned Pregnancy (14), have developed online repositories (or lists) of evidence-based HIV, STI, and teen pregnancy prevention programs [hereafter referred to as sexual health evidence-based programs (EBPs)]. These programs are designated as *evidence-based* because they have been rigorously evaluated (usually in an experimental or quasi-experimental design) and shown to reduce sexual risk behaviors (e.g., sexual initiation, contraceptive use, frequency of sexual activity, and number of sexual partners) and/or prevent teen pregnancies or STIs (13). Examples of sexual health EBP categories from these online repositories include abstinence education, comprehensive sexual health education (where abstinence is stressed but information on contraception is also included), and positive youth development programs. Over 35 sexual health EBPs are designed for multiple settings (e.g., school, after school, clinic, and home), but more than half are school based (13).

The broad dissemination of sexual health EBPs in school settings could reach a considerable number of adolescents and help adolescents delay sexual initiation and reduce other sexual behaviors that increase their risk for unintended pregnancy, HIV, and STIs (15, 16). *Dissemination* is often used to describe the adoption, implementation, and maintenance process for the delivery of a new innovation. A sexual health EBP is an "innovation" because it may be "perceived as new by an individual or unit of adoption" (17). *Adoption* refers to the decision to use a particular innovation (17, 18). *Implementation* refers to the process of program use, often measured in terms of general use, completeness (how much of the program is taught), and fidelity (adherence to core program elements) (19, 20). *Maintenance*, or institutionalization, refers to the process whereby a program is integrated fully into the practices and activities of an organization (21, 22).

Most school districts across the U.S. and in Texas do not adopt and implement sexual health EBPs (15, 23, 24). In Texas, there are many individual- and school district-level barriers that impede dissemination of these programs (and non-EBPs), including lack of knowledge about EBPs and where to find them, perceived lack of support from school administrators and parents, lack of guidance regarding the adoption process, competing priorities, lack of specialized training on sexual health, misinterpretation of state sexual education policies, and removal of health education as a graduation requirement (24–26). Many of these barriers are present nationally as well (27–29).

Many dissemination models for EBPs have been developed for various health topics, and some have been applied for sexual health (30–40). These models have some limitations, however, and have not been particularly successful in helping school districts disseminate sexual health EBPs. First, existing models provide guidance for adopting and implementing EBPs in *community* settings rather than *school* settings. Consequently, these models may be less helpful to school districts that are often characterized by complex organizational structures and decision-making processes (41–43). This complexity can make it challenging, in particular, for program administrators, teachers, and other stakeholders to use EBPs in schools. Examples of such tasks include getting district-level approval to adopt and implement the program, competing against other district priorities (e.g., standardized testing), and coordinating implementation across several campuses that have a diverse set of resources. Second, most models (e.g., ADAPT-ITT, McKleroy et al.'s framework) (35, 36) stress *adaptation* of EBPs to fit the target population's needs and culture, which may not be practical for school districts, versus *replication* of EBPs. Program adaptation requires knowledge of how to balance intervention fit with program fidelity (44), as well as sufficient time and resources to pilot test the adaptation (35, 36, 44), which many school districts often lack. In addition, because of the sensitive nature of the topic, an adaptation to a sexual health EBP that is improperly conducted could potentially negatively impact students. Subsequently, a program that is not properly adapted may not produce the same results as the original EBP (44). Thus, a more practical option for school districts may be to replicate an EBP with fidelity. Third, previous models (e.g., RE-AIM, Getting to Outcomes) (30, 38) provide theoretical guidance on *what* needs to be accomplished to adopt, implement, and maintain EBPs (or change some general behavior, as in the transtheoretical model) (39), but they do not give step-by-step direction on *how* to complete these tasks, particularly in school settings. This type of practical guidance is critical for the successful dissemination of sexual health EBPs in complex school settings.

To overcome limitations of these previous dissemination models, we used intervention mapping (IM), a six-step systematic process that uses theory, empirical evidence, and community input (44) to develop the *CH*oosing *A*nd *M*aintaining Effective *P*rograms for *S*ex Education in *S*chools (*CHAMPSS*) Model. Specifically, we used IM Step 1 (*conduct logic model of the problem, including needs assessment*) and Step 2 (*develop matrices of change objectives for each behavioral outcome*) to develop the model. The development of the model using these IM steps has been described in detail elsewhere (25). Briefly, we developed three matrices for three behavioral outcomes—adopt, implement, and maintain—which ultimately informed the development of the *CHAMPSS* Model described below and in **Figures 1** and **2**. As an example, a partial IM matrix for the adopt behavioral outcome is provided in **Table 1**.

The *CHAMPSS* Model comprises three phases: "adoption," "implementation," and "maintenance" and seven steps: "prioritize," "assess," "select," "approve," "prepare," "implement," and "maintain." A core element is "Getting Others on Board" (i.e., connecting with other supporters of EBPs and adolescent sexual health), which extends across all seven steps (**Figure 1**). Akin to some previous models (e.g., RE-AIM, Getting to Outcomes) (30, 38), the *CHAMPSS* Model is circular because school district stakeholders may enter the model at any step, depending on their readiness. Furthermore, school district stakeholders may complete one step but then realize that they need to go back to a previous step. A unique feature of the model, though, is the corresponding list of prescribed critical tasks that must be accomplished to complete a step (**Figure 2**). As an example, the performance objectives (PO) (sub-steps required to complete each behavioral outcome) (44) in **Table 1** informed the development of the prioritize, assess, select, and approve steps and associated critical tasks within the *CHAMPSS* Model adoption phase in **Figure 2**.

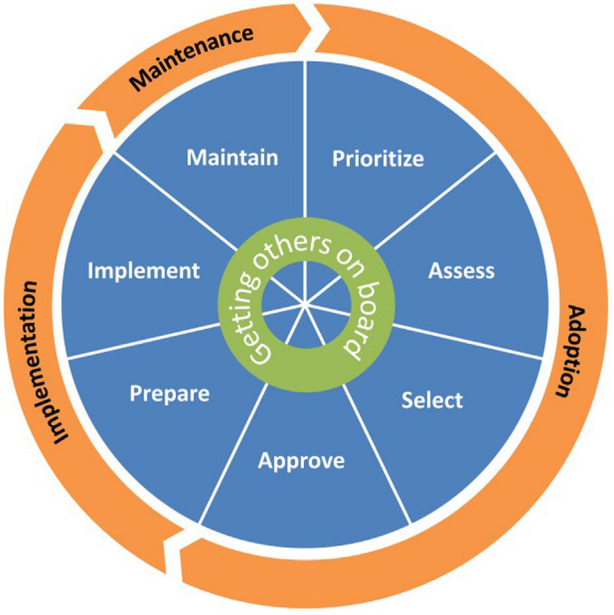


FIGURE 1 | The *CH*oosing *A*nd *M*aintaining Effective *P*rograms for *S*ex Education in *S*chools Model.

Key stakeholders, who have the authority and ability to adopt, implement, and maintain sexual health EBPs in the school setting, are included throughout the CHAMPSS Model (25). Key adopter stakeholders may include members of the school district's Board of Trustees (who vote to approve adoption of a sexual health EBP in the school district) and School Health Advisory Committee (SHAC, a school district subcommittee which includes parents—required by law in Texas—and makes health-related program recommendations to the school board) (45). Key implementers may include individuals at the school district level (e.g., a district curriculum coordinator) and at the local school level (e.g., principals, school curriculum coordinators, and teachers). Individuals responsible for maintaining implementation of a sexual health EBP may include district and school curriculum coordinators. In addition, any other person who is interested in and committed to supporting the dissemination of a sexual health EBP (a "sexual health advocate") can be an adopter, implementer, or maintainer.

The CHAMPSS Model overcomes limitations of previous dissemination models because it specifically targets school district stakeholders; stresses replication with fidelity; and

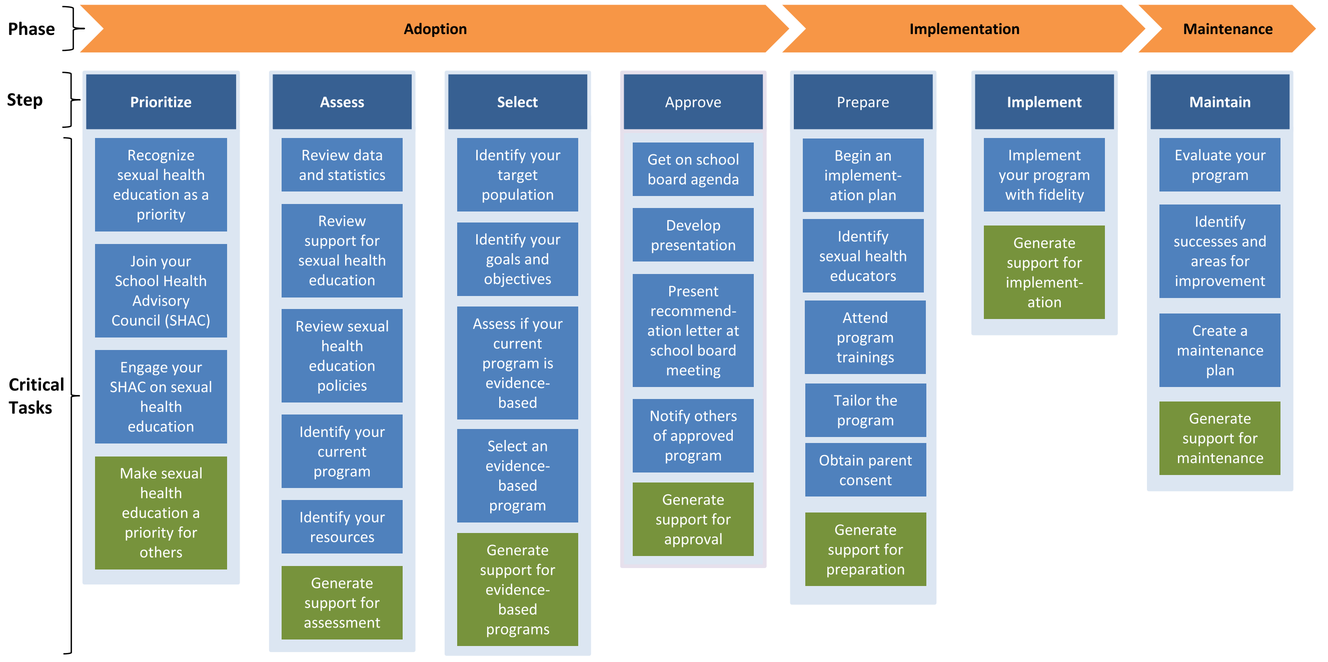


FIGURE 2 | Steps and critical tasks for each phase in the *CH*oosing *A*nd *M*aintaining Effective *P*rograms for *S*ex Education in *S*chools Model.

TABLE 1 | Partial intervention mapping Step 2 matrix of change objectives for adopt behavioral outcome[a]: school district board members will adopt (i.e., vote to approve) a sexual health evidence-based program (EBP).

	Determinants[c,d]				
Performance objectives (PO)[b]	**Awareness/knowledge (A/K)**	**Attitudes (A)**	**Skills and self-efficacy (SSE)**	**Outcome expectations (OE)**	**Perceived norms (PN)**
PO.1. Sexual health advocate will attend a School Health Advisory Committee (SHAC) meeting when discussions of adolescent sexual health education are taking place	A/K.1.a. Identify chair of SHAC to obtain SHAC meeting schedule	A.1.a Describe effort to attend SHAC meetings and to collaborate with the SHAC as essential to adopting an EBP		OE.1.a. State that attending SHAC meetings when sexual health education is discussed will lead to increased knowledge of current sexual health education practices and opportunity to advocate for EBPs in his/her district. OE.1.b. State that attending SHAC meetings when sexual health education is discussed will lead to increased support for EBPs in his/her district	PN.1.a. Recognize that other sexual health advocates attend SHAC meetings in decision making of sexual health curricula
PO.4. Sexual health advocate will engage his/her SHAC on sexual health education by including sexual health education on a SHAC meeting agenda	A/K.4.a. Describe the steps needed to include an item on a SHAC meeting agenda	A.4.a. Feel positive about including sexual health education on the SHAC meeting agenda	SSE.4.a. Feel confident in ability to include sexual health education on the SHAC meeting agenda	OE.4.a. Believe that including sexual health education on the SHAC meeting agenda will result in greater SHAC engagement on sexual health education	PN.4.a. Believe other sexual health advocates engage their SHACs on sexual health education by including sexual health education on a SHAC agenda
PO.5. SHAC will review current data and statistics on teen pregnancy and HIV/sexually transmitted infection (STI) in its district/school	A/K.5.a. List resources where current data and statistics can be obtained, and do so A/K.5.b. Summarize sexual behavior, HIV, STI, and pregnancy statistics among students	A.5.a. Describe review time as necessary and important A.5.b. Believe sexual health education is a priority for his/her school district	SSE.5.a. Demonstrate ability to find statistics related to sexual health in his/her city/district SSE.5.b. Correctly interpret statistics related to sexual health SSE.5.c. Feel confident in interpreting sexual behavior, HIV, STI, and pregnancy statistics	OE.5.a. Expect that evaluating student statistics of HIV, STI, and pregnancy will result in a better understanding of the needs and priorities regarding sexual health education in the district	PN.5.a. Recognize that other districts and their own students, families, teachers, and principals see teen pregnancy, HIV, and STIs as a problem that needs to be addressed PN.5.b. Perceives that other districts are reviewing most current data to identify the need for effective sexual health education
PO7. SHAC will identify the goals, target population, and desired outcomes regarding middle and high school (adolescent) sexual health education	A/K.3.a. List the health learning objectives (TEKS) for middle and high school students by grade level A/K.3.b. Describe desired students (age, ethnicity, and gender) to participate in a curriculum A/K.3.c. List desired goals (e.g., reduce teen pregnancy/HIV/STIs, decrease dropout rates, increase academic performance)	A.7.a. Describe identifying goals and target population as necessary and important to student health	SSE.3.a. Demonstrate ability to create effective goals for sexual health education SSE.3.b. Feel confident in identifying goals, target population, and outcomes for sexual health education in his/her district	OE.3.a. Expect that identifying goals and target population will help lead to a reduction in adolescent and teen HIV/STI/pregnancy, decrease dropout rates, and increase academic performance among students OE.3.b. Describe how identifying goals, target population, and desired outcomes will help identify the most appropriate EBP that will fit the needs of the district	PN.7.a. Recognize that school board, superintendents, principals, teachers, and parents share these goals and desired outcomes

(*Continued*)

TABLE 1 | Continued

	Determinants[c,d]				
Performance objectives (PO)[b]	**Awareness/knowledge (A/K)**	**Attitudes (A)**	**Skills and self-efficacy (SSE)**	**Outcome expectations (OE)**	**Perceived norms (PN)**
PO.8. SHAC will review current state/district/school policy regarding adolescent sexual health education	A/K.8.a. Obtain and describe state policy on middle school sexual health education A/K.8.b. Obtain and describe district policy on middle school sexual health education A/K.8.c. Obtain and describe individual school policies on middle school sexual health education	A.8.a. Feels positive about reviewing state/district/school policy regarding sexual health education	SSE.8.a. Summarize the state/district/school policy for sexual health education and implications for implementing an EBP SSE.8.b. Feel confident in interpreting state/district/school policy regarding sexual health education	OE.8.a. Describe how reviewing state/district/school policies will result in adopting an EBP that is in accordance with district policy	PN.8.a. recognizes that other district ally and sexual health advocates are reviewing current policy and making sure it reflects what is necessary given current statistics
PO.11. SHAC will determine if the district is currently implementing a pregnancy/HIV/STI curriculum(s) and if so, will review and assess whether the curriculum(s) is evidence-based and meets the identified goals and objectives	A/K.11.a. Describe what an EBP is (has program evaluations that are experimental in nature, participants are randomly assigned to treatment and control groups, focus on changes in the behavior of program participants, etc.) A/K.11.b. List advantages of EBPs and why they are important to implement	A.11.a. Feel positive about EBPs	SSE.11.a. Demonstrate ability to identify EBPs when presented with a non-EBP SSE.11.b. Feel confident in identifying EBPs	OE.11.a. State that EBPS will lead to desired behavioral change among students	PN.11.a. Believe that other districts are changing to EBPs, which are important for student behavior change
PO.12. SHAC will review and evaluate evidence-based pregnancy and HIV/STI prevention program(s) available to the school district that meet the goals, target population, and desired outcomes PO.12.a. SHAC will find EBPs	A/K.12a.a. Describe where to find EBPs	A.12a.a. Feel positive about finding EBPs	SSE.12a.a. List EBPs SSE.12a.b. Feel confident in finding EBPs		
PO.13. SHAC will elicit support of potential EBPs with other district sexual health advocates, principals, parents, and community members, discussing feasibility and resources required	A/K.13.a. List strategies for obtaining support for EBP adoption A/K.13.b. List barriers that may derail support A/K.13.c. List possible strategies for overcoming adoption barriers	A.13.a. Feel positive about eliciting support and overcoming barriers	SSE.13.a. Demonstrate ability to use strategies for increasing support of EBPs SSE.13.b. Feel confident in eliciting community support for EBPs	OE.13.a. State that endorsement of EBPs by key stakeholders will lead to increased probability of adoption of EBPs by district/school leaders	PN.13.a. Recognize that other SHACs have overcome these obstacles and successfully elicited support for such programs
PO.14. SHAC members will create and present a position statement/paper with recommendations for sexual health education in their district, including recommending school board approval of curriculum(s)	A/K.14.a. List components of an effective statement/position paper A/K.14.b. List recommended EBP(s) for school board approval A/K.14.c. List effective strategies for presenting the recommended EBP(s) to the school board (e.g., formal presentation at a board meeting)	A.14.a. Feel positive about recommending an EBP program to school board	SSE.14.a. Demonstrate ability to write components of a position statement SSE.14.b. Demonstrate ability to develop a presentation for school board SSE.14.c. Feels confident in recommending EBP to School board through position statement and presentation	OE.14.a. Describe how creating a position statement may lead to increased support for selected EBP by school board OE.14.b. Describe how giving a presentation to the school board regarding recommended EBP(s) will lead to an opportunity to advocate for the selected EBP(s)	PN.14.a. Believe other SHACs create position statements with recommendations to school board for EBPs

(Continued)

TABLE 1 | Continued

Performance objectives (PO)[b]	Determinants[c,d]				
	Awareness/knowledge (A/K)	Attitudes (A)	Skills and self-efficacy (SSE)	Outcome expectations (OE)	Perceived norms (PN)
PO.16. School board members will adopt (an) evidence-based pregnancy and HIV/STI prevention program(s)	A/K.16.a. Describe process for school board approval A/K.16.b. List recommended EBPs approved	A.16.a. Feels positive about adopting an EBP			PN.16.a. Notes that other districts are adopting EBPs, which are important for student behavior change

[a] This matrix informed the development of the CHAMPSS Model adoption phase in ***Figure 1****.*

[b] POs are the sub-steps required to complete the behavioral outcome; informed the development of the prioritize (PO 1, 4), assess (PO 5, 7, 8), select (PO 7, 11, 12, 13), and approve (PO 4, 16) steps and associated critical tasks within the CHAMPSS Model adoption phase in ***Figure 2****.*

[c] Determinants are identified from theory and empirical evidence for the behavioral outcome and POs.

[d] Change objectives are written where rows and columns intersect and ask the question "What needs to change in determinant 'X' for an individual to do PO 'Y' (44)." There may be more than one change objective per cell (designated as a, b, etc.).

provides detailed, step-by-step instructions that include realistic tasks for school district stakeholders to accomplish in each step of the model (25). Although the CHAMPSS Model provides a useful guiding framework for school district stakeholders, we envisioned the development of an online decision support system that further operationalizes the steps of the model. This online decision support system would specifically guide users through the prescribed critical tasks within the CHAMPSS Model, provide resources and skills specific to each task, provide technical assistance to help overcome barriers, and foster linkages with users in other school districts. Thus, the purpose of this "Methods" paper is to describe how we used IM Steps 3, *Program Design*, and 4, *Program Production*, to develop this online decision support system, ultimately named *iCHAMPSS* (so named because it was the *interactive* version of the CHAMPSS Model).

METHODS

The *iCHAMPSS* development group was an academic-community-health department collaboration that was formed during the development of the *CHAMPSS* Model (25). Group members comprised study investigators (epidemiologists, behavioral scientists, psychologists); masters-level staff trained in public health; county health department representatives; and the "*CHAMPSS* Group," a group of school-based community stakeholders who themselves adopted the name of the model. Briefly, the CHAMPSS Group comprised individuals from a subgroup of the Harris County School Health Leadership Group that was convened by the Harris County Public Health department. This subgroup included 22 members and was formed to specifically help school districts in Harris County adopt and implement sexual health EBPs. Members of the CHAMPSS Group represented 15 area school districts and included parents, nurses, science curriculum coordinators, and SHAC representatives. The CHAMPSS Group met together bimonthly; study investigators and/or staff often presented at their meetings to provide skills related to using and implementing sexual health EBPs (e.g., developing program objectives, finding data on adolescent sexual health, and assessing parental support for EBPs) as well as to garner buy-in and input for *iCHAMPSS* intervention development. By working with the CHAMPSS Group, we hoped to ensure the development of a user-friendly and useful online decision support system for school districts.

To develop *iCHAMPSS*, the development group completed Steps 3 (*Program Design*) and 4 (*Program Production*) of IM (44). In Step 3, we used theory and empirical evidence to (a) identify intervention delivery vehicles and program themes; (b) identify theoretical methods and practical applications for each group of change objectives, organized by determinants, for each behavioral outcome; and (c) draft a program scope and sequence. According to Bartholomew and colleagues, "a theory- and evidence-based change method is a general technique for influencing the determinants of behaviors…." Practical applications include the intervention strategies used to operationalize those methods. It was also important to specify the "parameters" or situations under which a method is used appropriately. In Step 4, we used our methods and applications from Step 3 to (a) refine the *iCHAMPSS* program structure and organization; (b) prepare plans for program materials; (c) draft messages, materials, and protocols; and (d) pretest, refine, and produce materials. This study was approved by the University of Texas Health Science Center at Houston Institutional Review Board.

RESULTS

Step 3: Program Design

Program Delivery Vehicle and Theme

As part of the initial design process for *iCHAMPSS*, we first identified the delivery vehicle by which we would operationalize the CHAMPSS Model. Early on, during IM Steps 1 and 2, we had decided that we would use the Internet to create an online decision support system to accomplish this task. The Internet is widely used to transmit information, and members of the CHAMPSS Group agreed that a website would be the most efficient way to provide access to the *iCHAMPSS* tools and resources. Furthermore, the Internet has been widely used to disseminate information about sexual health EBPs (13, 14), although this information predominantly focuses on describing EBPs, providing program materials, and linking users to training resources. In addition, other online decision support systems have been designed to help health care providers make decisions regarding their patients' symptoms and treatment plans within the clinical arena (46, 47). Recently, for example, an online decision support system was developed in Canada to promote the use of research evidence to inform decisions regarding public health (48). We also identified a program theme for the online decision support system, which was to be a sexual health advocate, or champion, for the dissemination of sexual health EBPs by school districts. Finally, we created an *iCHAMPSS* logo, which incorporated the round CHAMPSS Model, and the byline of the *iCHAMPSS* website (which appears on every web page) is "*CH*oosing *A*nd *M*aintaining Effective *P*rograms for *S*ex Education in *S*chools."

Methods and Practical Applications

To begin the process of developing specific activities for *iCHAMPSS*, we identified methods, parameters, and practical applications. We used several behavioral science theories, including theories of information processing (44, 49), social cognitive theory (44, 50, 51), and diffusion of innovations (17) to identify specific methods for each group of change objectives, organized by determinants, for each behavioral outcome. **Table 2** provides examples of methods, parameters, and practical applications for each critical task from the CHAMPSS Model adoption phase-select step (informed by the adopt behavioral outcome matrix provided in **Table 1**). For example, in task 1 (identify the target population), theories of information processing (44, 49) informed our use of elaboration as a theoretical method to influence change objectives associated with increasing awareness and knowledge related to describing the target population (age, ethnicity, and gender) for the EBP curriculum (change objectives A/K.7.b). In addition, modeling from social cognitive theory (44, 50, 51) was used to help promote more favorable attitudes and outcome expectations (OE) related to identifying the target population (change objectives A.7.a, OE.7.a, OE.7.b).

Next, we brainstormed practical applications that would correspond to each theoretical method. For elaboration (theoretical method), we included a video/animated tutorial by an expert on selecting EBPs that covered identifying the target population for desired outcomes (practical application). Experts were members of the *iCHAMPSS* development group who were personal, motivating, understandable, and relevant to each school district, which were parameters for elaboration. To change attitudes and OE using modeling (theoretical method), we recommended a video-based testimonial of SHAC members and other school personnel discussing how and why they selected the target population for their school district (practical application). Models were similar to potential *iCHAMPSS* users (and, thus, relatable), explained the specific steps they used to overcome challenges, and expressed receiving reinforcement for their decisions (44), which were all parameters for modeling. **Table 2** (first five columns) provides additional examples of the methods, parameters, and practical applications for the five critical tasks from the CHAMPSS Model adoption phase-select step (**Figure 2**), organized by determinants and change objectives from **Table 1**.

We also solicited input on other practical applications from the CHAMPSS Group. CHAMPSS Group members, in particular, requested a discussion forum to learn about what other school districts were doing. This suggestion corresponds to the method of interpersonal networking, which has been shown to facilitate adoption of effective programs by later users (17, 52, 53). CHAMPSS Group members also requested customizable templates that they could use, such as needs assessment and program evaluation forms, as well as tips sheets on engaging administrators, school board members, and others in getting district support for sexual health EBPs. These practical applications correspond to the method of facilitation from social cognitive theory (44, 50). The "Stage Your District" tool was another practical application suggested by the CHAMPSS Group. The original concept for this tool came from our partner at Harris County Public Health who had developed a simple four-question worksheet that would allow districts to determine in which stage of the CHAMPSS Model they were, indicating their level of readiness to adopt, implement, or maintain sexual health EBPs. At the beginning of every CHAMPSS Group meeting, members would stage themselves informally in the CHAMPSS Model, which they found useful for staying on track and monitoring progress. The "Stage Your District" practical application corresponds to the method of tailoring from the transtheoretical model (39, 44).

After examining the list of practical applications for all CHAMPSS Model critical tasks, organized by determinants and change objectives from each matrix, we identified some commonalities in the types of applications being proposed. These common practical applications included step overviews, success stories (videos/testimonials), facts and tips, helpful Internet links to outside resources, and templates. Next, we organized the list of practical applications by specific topical areas (e.g., sexual health priority, needs assessment, state law, and SHACs) to narrow the list and determine if there was any overlap among applications. These practical applications became known as the five types of "tools" available in *iCHAMPSS*. **Table 2** (sixth column) provides

TABLE 2 | Partial intervention mapping Steps 3 and 4: identifying methods, parameters, practical applications, tool types, and example messages for each critical task from the CHAMPSS Model adoption phase-select step.

CHAMPSS Model critical tasks[a]	Determinants and change objectives[b]	Methods[c]	Parameters[c]	*iCHAMPSS* practical application[c]	*iCHAMPSS* tool type	Example messages in *iCHAMPSS*
1. Identify your target population	Awareness/ knowledge (A/K.3.b)	Elaboration	Messages must be personal, understandable, and highly relevant for users, individuals must be motivated to receive messages	– Video/animated tutorial by an expert on selecting EBPs that covers identifying target population for desired outcomes – Recommendation letter to school board which includes identified target population	Step overview Templates	"*Step overview*": "…what population do you want to serve? Select a program that was tested among a similar population to that in your district. It will be more likely to have a similar impact on *your* students. Determine if there's a certain school or a particular grade level in which teen pregnancy is most prevalent"
	Attitudes and outcome expectations (OE) (A.7.a, OE.3.a, OE.3.b)	Persuasive communication	Messages must be relevant, not too dissimilar from user, often repetitive	– Video testimonials of School Health Advisory Committee (SHAC) members and other school personnel discussing how/why they selected the target population for their district	Success stories	"*Success stories*": "… our initial goal was to have a program from sixth through ninth grade… we figured if we can get them in seventh and eighth grade, we can kind of nip some of the risky behaviors in the bud before they have that transition over the summer as eighth graders going to ninth grade and then starting their freshman year in high school"
		Modeling	Model must be relatable, describe specific steps or skills, and receive reinforcement			
2. Identify your goals and objectives	Awareness/ knowledge (A/K.3.a, A/K.3.c)	Elaboration	Messages must be personal, understandable, and highly relevant for users, individuals must be motivated to receive messages	– Video/animated tutorial by an expert on selecting EBPs that covers setting goals – Recommendation letter to school board which includes identified goals	Step overview Templates	*Helpful links:* Centers for Disease Control and Prevention—Communities of Practice—SMART Objectives Template
	Skills and self-efficacy (SSE) (SSE.3.a, SSe.3.b)	Goal-setting	Being committed to achieving goals	– Internet links to interactive exercises on identifying and creating goals and objectives	Helpful links	Download this "SMART Objectives Template" from the Centers of Disease Control to quickly develop your own SMART (specific, measurable, achievable, realistic, time-bound) objectives (http://www.cdc.gov/phcommunities/resourcekit/evaluate/smart_objectives.html)
	Attitudes OE Perceived norms (PN) (A.7.a, OE.3.a, OE.3.b, PN.7.a)	Persuasive communication	Messages must be relevant, not too dissimilar from user, often repetitive	– Video testimonials of school personnel discussing the goals and objectives their district identified	Success Stories	
		Modeling	Model must be relatable, describe specific steps or skills, and receive reinforcement			
3. Assess if your current program is evidence based	Awareness/ knowledge (A/K.11.a, A/K.11.b)	Elaboration	Messages must be personal, understandable, and highly relevant for users, individuals must be motivated to receive messages	– Video/animated tutorial by an expert on selecting EBPs that covers how to assess whether a district's current program is evidence based – Internet links to national lists of sexual health EBPs	Step overview Helpful links	"*Step overview*": "Are any sexual health education programs currently used in your district on the list? A program may be *labeled* as evidence-based or a vendor may have *told* you the program has evidence but if it's not on the list it's probably *not* evidence based"

(*Continued*)

TABLE 2 | Continued

CHAMPSS Model critical tasks[a]	**Determinants and change objectives**[b]	**Methods**[c]	**Parameters**[c]	***iCHAMPSS* practical application**[c]	***iCHAMPSS* tool type**	**Example messages in *iCHAMPSS***
4. Select an evidence-based program (EBP)	Awareness/knowledge (A/K.12a.a) SSE (SSE.11.a, SSE.11.b, SSE.12a.a, SSE.12a.b) Attitudes OE PN (A.11.a, OE.11.a, PN.11.a, A.12a.a)	Elaboration Technical assistance Persuasive communication Modeling	Messages must be personal, understandable, and highly relevant for users, individuals must be motivated to receive messages Must fit the user's needs Messages must be relevant, not too dissimilar from user, often repetitive Model must be relatable, describe specific steps or skills, and receive reinforcement	– Video/animated tutorial by an expert on selecting EBPs that covers where to find EBPs – Fact sheet on characteristics of EBPs – Fact sheet on how to interact with non-EBP vendors (being a smart shopper) – Internet links to national lists of EBPs that provide guidance on how to select the best EBP for one's setting – Video testimonials of SHAC members and other district why EBPs are beneficial and important	Step overview Facts and tips Facts and tips Helpful Links Success stories	From *"Smart Program Shopping" facts and tips* *Select a sexual health education program if it…* – Is listed on a respected registry for EBPs (e.g., Office of Adolescent Health, National Campaign to Prevent Teen and Unplanned Pregnancy) – Was tested among a population with similar demographics to those of your district or school (e.g., gender, race/ethnicity, grade) – Was effective in changing the behaviors you want to target (e.g., delay sexual initiation, increase condom or contraceptive use) – Meets your district or school's goals and objectives – Reflects values consistent with those in your district or school
5. Generate support for EBPs	Attitudes OE PN (A.13.a, OE.13.a, PN.13.a) SSE (SSE.13.a, SSE.13.b)	Persuasive communication Modeling Shifting perspective Technical assistance	Messages must be relevant, not too dissimilar from user, often repetitive Model must be relatable, describe specific steps or skills, and receive reinforcement Model must be able to take the perspective of the learner Must fit the user's needs	– Video testimonials of SHAC members and other district parents/personnel describing how they get support for EBPs – Skills and tips on communicating effectively with others – Practice worksheet for analyzing key audiences for messaging on EBPs	Success stories Facts and tips Templates	"*Success Stories*": "…And what I've learned is that if you address these issues that are potentially controversial in a very straightforward manner you have information readily available for people who have questions. You're able to rebut any myths that come up quickly. And to have an external resource that can help you as well in answering those questions—an expert, someone who can also give data about the reality for kids who don't get this information and just being pretty frank and up front and not stopping your march forward just because you're afraid that something negative is going to occur"

[a] *From **Figure 2**.*

[b] *Determinants and changes objectives from the adopt behavioral outcome matrix in **Table 1**.*

[c] *A theory-and evidence-based method "is a general technique for influencing the determinants of behaviors…"; parameters refer to the situations under which a method is used appropriately; practical applications include the intervention strategies used to operationalize those methods (44).*

an example of how the tool types were matched to practical applications.

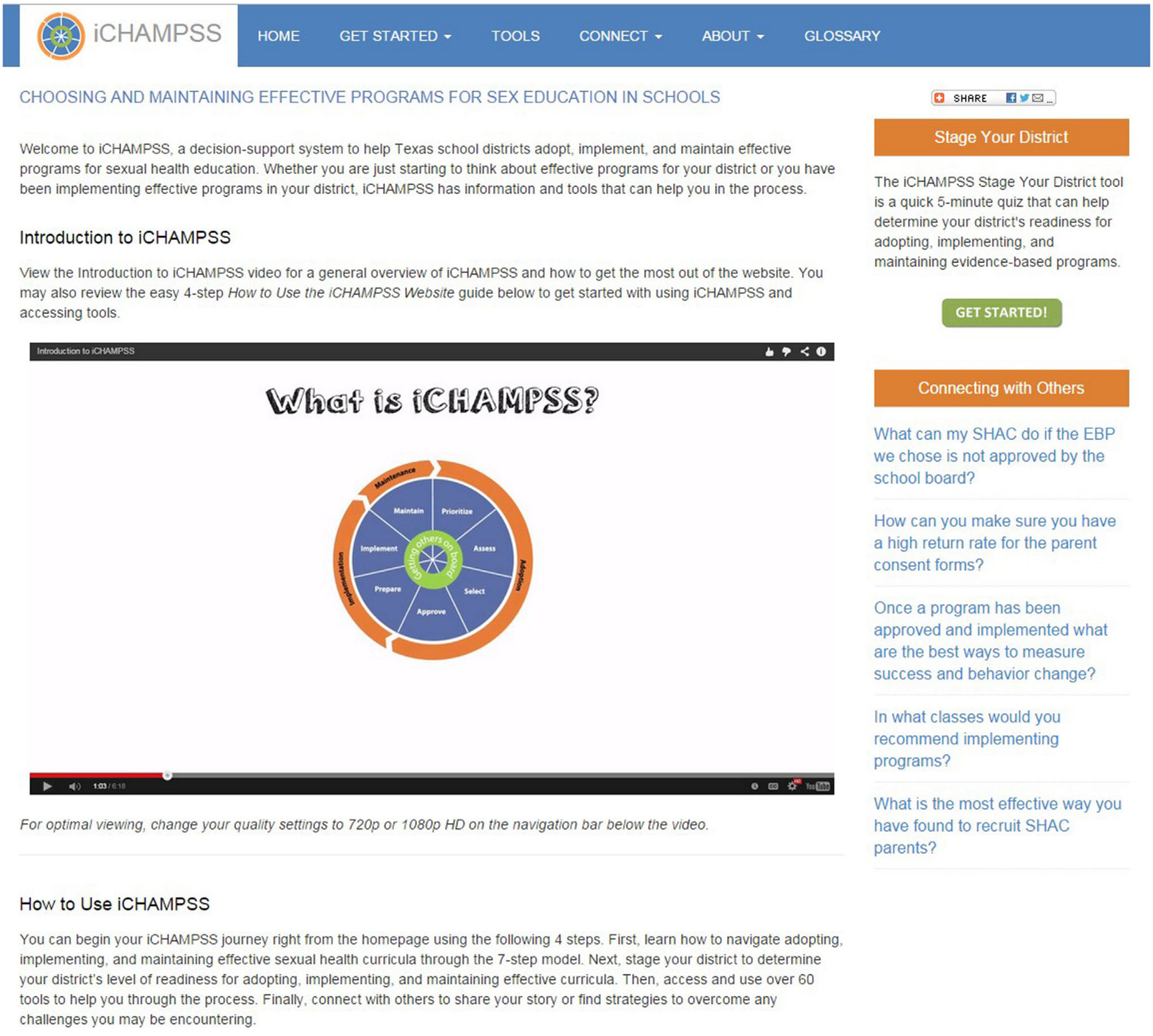
Scope and Sequence

We described the scope and sequence of *iCHAMPSS* as self-directed and self-paced. However, we recommended that users (e.g., school district stakeholders) first complete the staging tool, "Stage Your District," which would direct them to specific tools based on their level of readiness to adopt, implement, or maintain sexual health EBPs. Message tailoring is recognized as a crucial element in the creation of effective interactive health promotion programs (54). *iCHAMPSS* was also designed to allow users from any step of the CHAMPSS Model the flexibility to use whichever *iCHAMPSS* tools they deem most appropriate at any given time.

Step 4: Program Production

Refining Program Structure and Organization

The goal of *iCHAMPSS* was to provide decision support to aid sexual health advocates in adopting, implementing, and maintaining a sexual health EBP in their district/school. To that end, *iCHAMPSS* included *four features*. The first feature, the CHAMPSS Model description, was designed to familiarize users to the CHAMPSS Model. In addition to introducing users to this conceptual framework, there is a video-based tutorial that guides users through the *iCHAMPSS* process to learn how all the *iCHAMPSS* tools and CHAMPSS Model steps fit together (see **Figure 3**). The second feature comprises the staging tool described in IM Step 3. Also described in IM Step 3, the third feature, the tools library, disseminates useful information and forms through the five iCHAMPSS "tool types" (step



CHOOSING AND MAINTAINING EFFECTIVE PROGRAMS FOR SEX EDUCATION IN SCHOOLS

Welcome to iCHAMPSS, a decision-support system to help Texas school districts adopt, implement, and maintain effective programs for sexual health education. Whether you are just starting to think about effective programs for your district or you have been implementing effective programs in your district, iCHAMPSS has information and tools that can help you in the process.

Introduction to iCHAMPSS

View the Introduction to iCHAMPSS video for a general overview of iCHAMPSS and how to get the most out of the website. You may also review the easy 4-step *How to Use the iCHAMPSS Website* guide below to get started with using iCHAMPSS and accessing tools.

For optimal viewing, change your quality settings to 720p or 1080p HD on the navigation bar below the video.

How to Use iCHAMPSS

You can begin your iCHAMPSS journey right from the homepage using the following 4 steps. First, learn how to navigate adopting, implementing, and maintaining effective sexual health curricula through the 7-step model. Next, stage your district to determine your district's level of readiness for adopting, implementing, and maintaining effective curricula. Then, access and use over 60 tools to help you through the process. Finally, connect with others to share your story or find strategies to overcome any challenges you may be encountering.

Stage Your District

The iCHAMPSS Stage Your District tool is a quick 5-minute quiz that can help determine your district's readiness for adopting, implementing, and maintaining evidence-based programs.

Connecting with Others

What can my SHAC do if the EBP we chose is not approved by the school board?

How can you make sure you have a high return rate for the parent consent forms?

Once a program has been approved and implemented what are the best ways to measure success and behavior change?

In what classes would you recommend implementing programs?

What is the most effective way you have found to recruit SHAC parents?

FIGURE 3 | Screenshot of the iCHAMPSS introductory video tutorial.

overviews, success stories, fact and tips, helpful Internet links, and templates). Users do not need to understand the CHAMPSS Model to find and use the tools. Finally, the fourth feature (also described in IM Step 3) comprises a linkage system, or online discussion board, to help users communicate with other users across school districts and receive technical assistance from experts in the field.

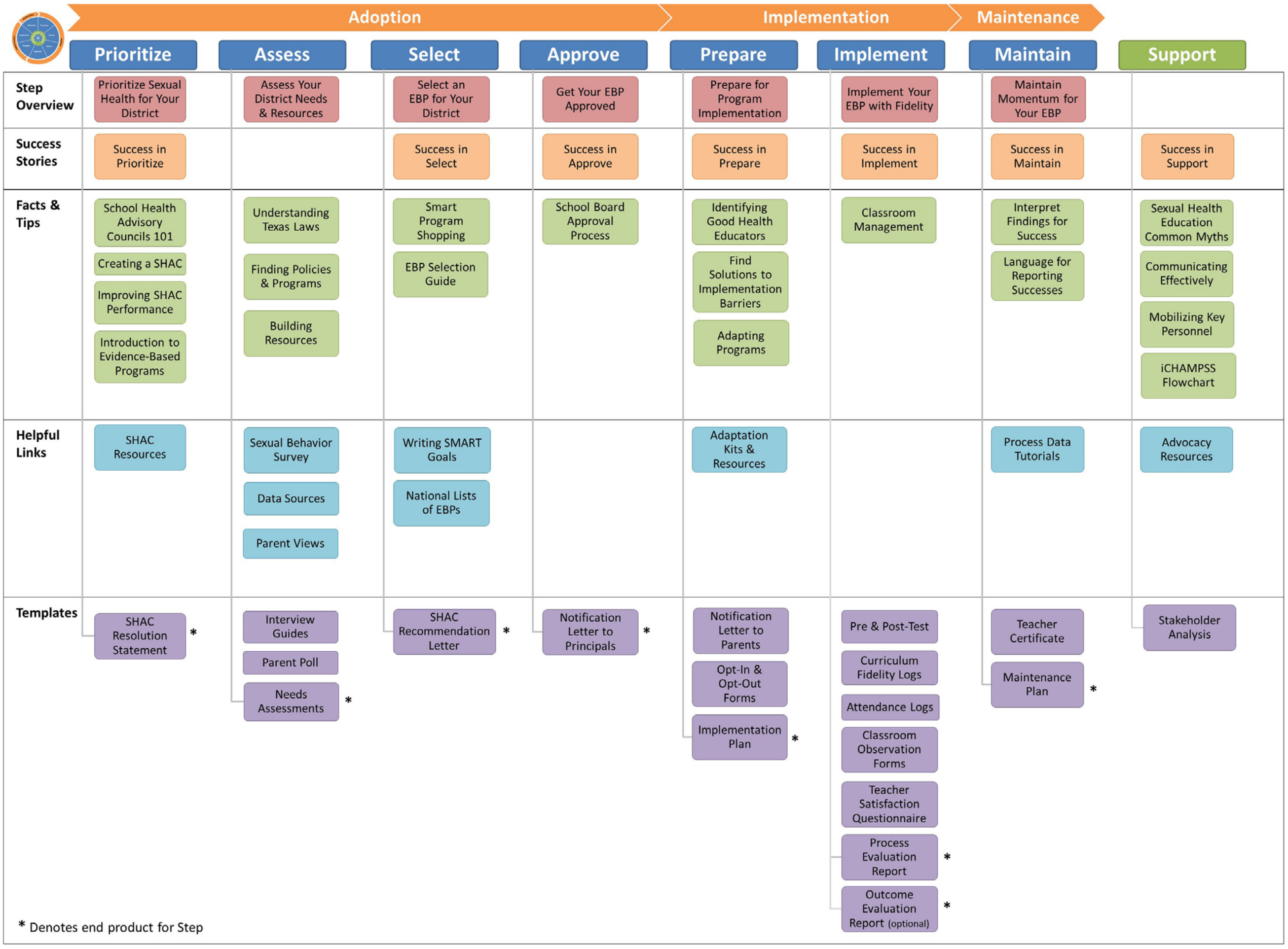
Preparing Plans for Program Materials

As part of IM Step 4, we developed design documents for *iCHAMPSS's* features, website, and tools. Design documents are detailed planning documents that instruct the program designers on how to produce the program materials (44). For *iCHAMPSS's* features and website, we developed a 35-page design document outlining their specifications. In this design document, we specified several critical features of *iCHAMPSS* (available online at http://www.iCHAMPSS.org), including how it would be accessible to school district stakeholders, data collection features (only basic site usage data to be collected but user sign-in is necessary for the discussion board), hosting and maintenance capabilities, development constraints (e.g., server specificities and compatibility with all Internet browsers), and user interface frame (i.e., header, dashboard, content space, and footer). We also specified what users would see on the *iCHAMPSS* homepage: the name and an introduction to the system, photographs indicating that the focus of the site is on the health of adolescents, social networking share buttons, and direct links with short descriptions to the CHAMPSS process, the tools library, and the connect with others forum. Embedded within the CHAMPSS process page is an image of the circular, seven-step CHAMPSS Model, which expands to give a description of each phase or step when the user clicks on that part of the model.

For the five tool types, we also developed design documents that specified the purpose/main objectives of the tools, target audience/likely users, instructions for use, format (e.g., PDF file and video), and detailed description of tool content. For each tool type, the goal was to develop a variety of tools mapped to each CHAMPSS step and associated critical tasks.

Drafting Messages, Materials, and Protocols

We procured the services of an IT developer, computer graphic designer, video production, and post-production specialists to

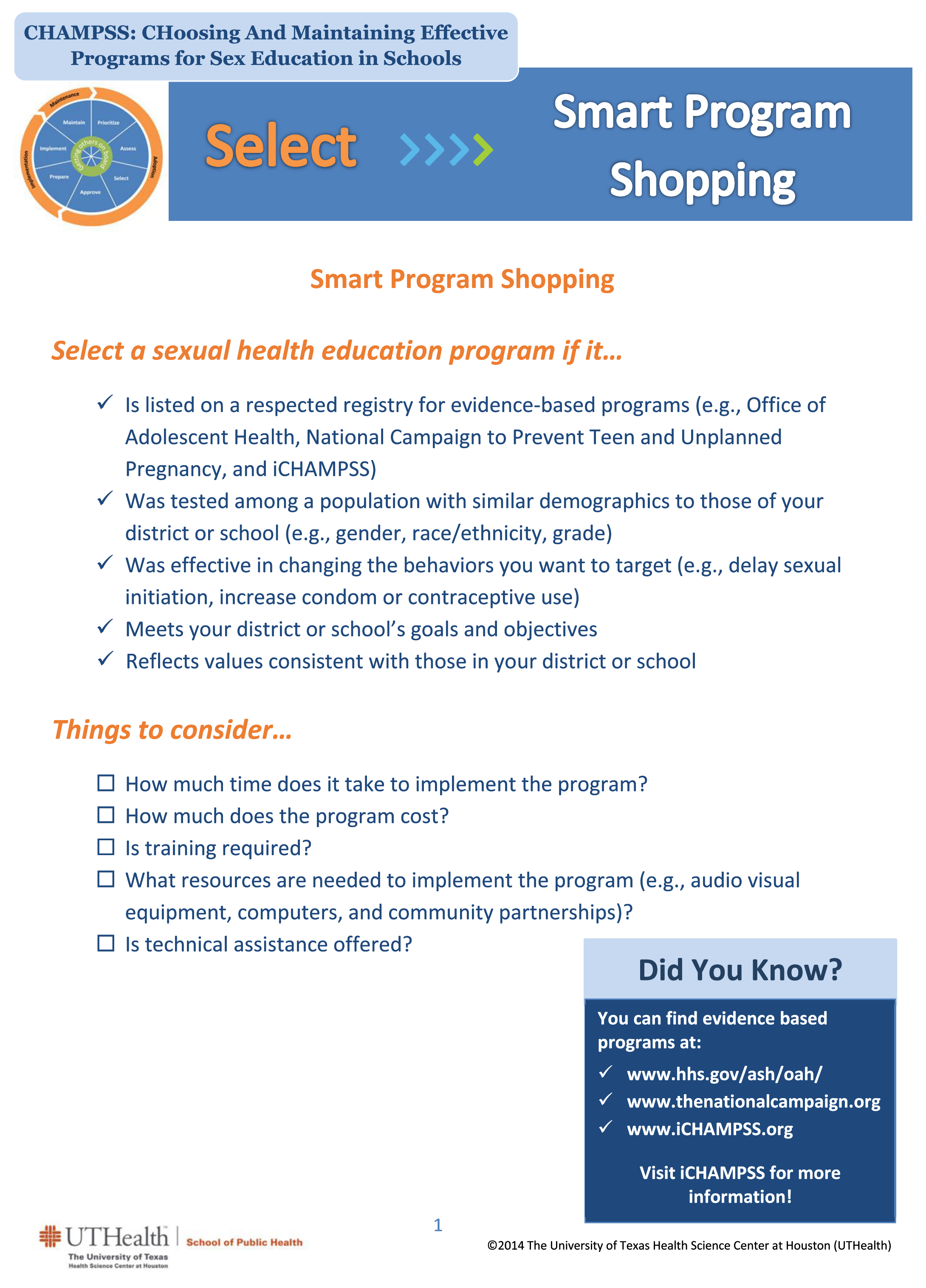


	Adoption				Implementation		Maintenance	
	Prioritize	Assess	Select	Approve	Prepare	Implement	Maintain	Support
Step Overview	Prioritize Sexual Health for Your District	Assess Your District Needs & Resources	Select an EBP for Your District	Get Your EBP Approved	Prepare for Program Implementation	Implement Your EBP with Fidelity	Maintain Momentum for Your EBP	
Success Stories	Success in Prioritize		Success in Select	Success in Approve	Success in Prepare	Success in Implement	Success in Maintain	Success in Support
Facts & Tips	School Health Advisory Councils 101 Creating a SHAC Improving SHAC Performance Introduction to Evidence-Based Programs	Understanding Texas Laws Finding Policies & Programs Building Resources	Smart Program Shopping EBP Selection Guide	School Board Approval Process	Identifying Good Health Educators Find Solutions to Implementation Barriers Adapting Programs	Classroom Management	Interpret Findings for Success Language for Reporting Successes	Sexual Health Education Common Myths Communicating Effectively Mobilizing Key Personnel iCHAMPSS Flowchart
Helpful Links	SHAC Resources	Sexual Behavior Survey Data Sources Parent Views	Writing SMART Goals National Lists of EBPs		Adaptation Kits & Resources		Process Data Tutorials	Advocacy Resources
Templates	SHAC Resolution Statement *	Interview Guides Parent Poll Needs Assessments *	SHAC Recommendation Letter *	Notification Letter to Principals *	Notification Letter to Parents Opt-In & Opt-Out Forms Implementation Plan *	Pre & Post-Test Curriculum Fidelity Logs Attendance Logs Classroom Observation Forms Teacher Satisfaction Questionnaire Process Evaluation Report * Outcome Evaluation Report (optional) *	Teacher Certificate Maintenance Plan *	Stakeholder Analysis

* Denotes end product for Step

FIGURE 4 | iCHAMPSS tools library.

design and produce *iCHAMPSS's* website, features, and tools. However, we produced the content for the tools in-house, including the "Stage Your District" tool. We wrote the messages within each tool with the goals of accomplishing each critical task outlined in the CHAMPSS Model; these critical tasks were previously identified through the PO in each of the intervention matrices. One or two project team members initially developed each tool's content, but we regularly included discussion of the



CHAMPSS: CHoosing And Maintaining Effective Programs for Sex Education in Schools

Smart Program Shopping

Smart Program Shopping

Select a sexual health education program if it…

- ✓ Is listed on a respected registry for evidence-based programs (e.g., Office of Adolescent Health, National Campaign to Prevent Teen and Unplanned Pregnancy, and iCHAMPSS)
- ✓ Was tested among a population with similar demographics to those of your district or school (e.g., gender, race/ethnicity, grade)
- ✓ Was effective in changing the behaviors you want to target (e.g., delay sexual initiation, increase condom or contraceptive use)
- ✓ Meets your district or school's goals and objectives
- ✓ Reflects values consistent with those in your district or school

Things to consider…

- ☐ How much time does it take to implement the program?
- ☐ How much does the program cost?
- ☐ Is training required?
- ☐ What resources are needed to implement the program (e.g., audio visual equipment, computers, and community partnerships)?
- ☐ Is technical assistance offered?

Did You Know?

You can find evidence based programs at:

- ✓ **www.hhs.gov/ash/oah/**
- ✓ **www.thenationalcampaign.org**
- ✓ **www.iCHAMPSS.org**

Visit iCHAMPSS for more information!

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FIGURE 5 | Screenshot of iCHAMPSS facts and tips tool type.

TABLE 3 | *iCHAMPSS* "Stage Your District" tool and tool types[a]: delivery vehicles, purpose, description, and development.

Category	Delivery vehicle	Purpose	Description	Key development tasks
"Stage Your District"	Internet	To provide users with tailored feedback related to the step of the CHAMPSS Model their school district was currently in	21 questions mapped to the seven CHAMPSS Model steps User receives staging report that indicates where he/she should begin in *iCHAMPSS*	Develop staging algorithm (CHAMPSS Model matrices used to identify critical tasks from the model for successful completion of each step) Program staging algorithm Test tool to ensure algorithm and recommendations were logical based on the responses
Step overview	Video of expert lecturing with light whiteboard animation style	To provide users with an overview of each step and guide them through the basic knowledge and critical tasks required to complete each step of the CHAMPSS Model	7 step overviews—one for each step of the CHAMPSS Model Each approximately 5 min or less	Write script Identify visual text and graphics Film experts Edit video clips Create animation
Success stories	Video of evidence-based program end user	To provide users with video-based testimonials (role modeling stories and experiences) from school district stakeholders regarding challenges they faced or strategies used when going through a particular CHAMPSS step with their district	38 total from 17 school district stakeholders Each approximately 7 min or less Designed in an interview-style format in school-like settings Sample interview questions displayed at the beginning of each topic segment	Develop interview questions for stakeholders Identify interviewees from diverse school districts representing multiple district roles Film interviews and transcribe video Edit video content Finalize videos
Facts and tips	Print documents	To provide users with documents summarizing factual information or strategies critical to accomplishing the critical tasks in a particular CHAMPSS Model step	20 1–3 page, easy-to-read downloadable PDFs that could be printed	Write content Format document
Helpful links	Hyperlinks to external website	To provide users with relevant external website links relevant to accomplishing the critical tasks in a particular CHAMPSS Model steps	51 Internet links that provide helpful resources Included a thumbnail image of each website, a brief summary of resources on website, hyperlinks to website	Identify relevant websites
Templates	Print documents	To provide users with customizable documents that can be downloaded to aid in completion of CHAMPSS Model steps	19 Microsoft Word templates that varied in content and length; customizable so that they could be tailored to fit each district's needs, data, and policies For each model step, one served as the "end product"	Write content Format document

[a] *Specific iCHAMPSS tools for each tool type are listed in **Figure 4**.*

tools to assess progress and address development questions and concerns in weekly meetings. **Table 2** (seventh column) provides an example of how methods, parameters, and practical applications were operationalized to produce example messages that were incorporated into each of the tool types. During the development of messages, we also specified one of the templates as the "end product" for each CHAMPSS step that signified that step's completion. We produced 62 tools, which are listed in a "tools library" on the *iCHAMPSS* website (**Figure 4**). See **Figure 5** for screen capture of a selected facts and tips tool. Because we were producing a variety of tools with different delivery vehicles, the purpose and development approach varied for each tool (see **Table 3** for a summary).

Pretesting, Refining, and Producing Materials

Members of the CHAMPSS Group reviewed *iCHAMPSS* after it was initially completed. Overall, the majority felt the website was professional, informative, and visually pleasing. However, some felt that the image on the homepage was too scientific and that the homepage lacked sufficient information to draw visitors to the website. Their suggestions included the following: (a) placing a prominent description of *iCHAMPSS* on the homepage; (b) reorganizing the placement of some of the dashboard buttons, and (c) including upcoming national and local trainings and events. Members of the CHAMPSS Group also reviewed the "Stage Your District" tool and suggested changing the color scheme and enabling a print option. Some felt that the

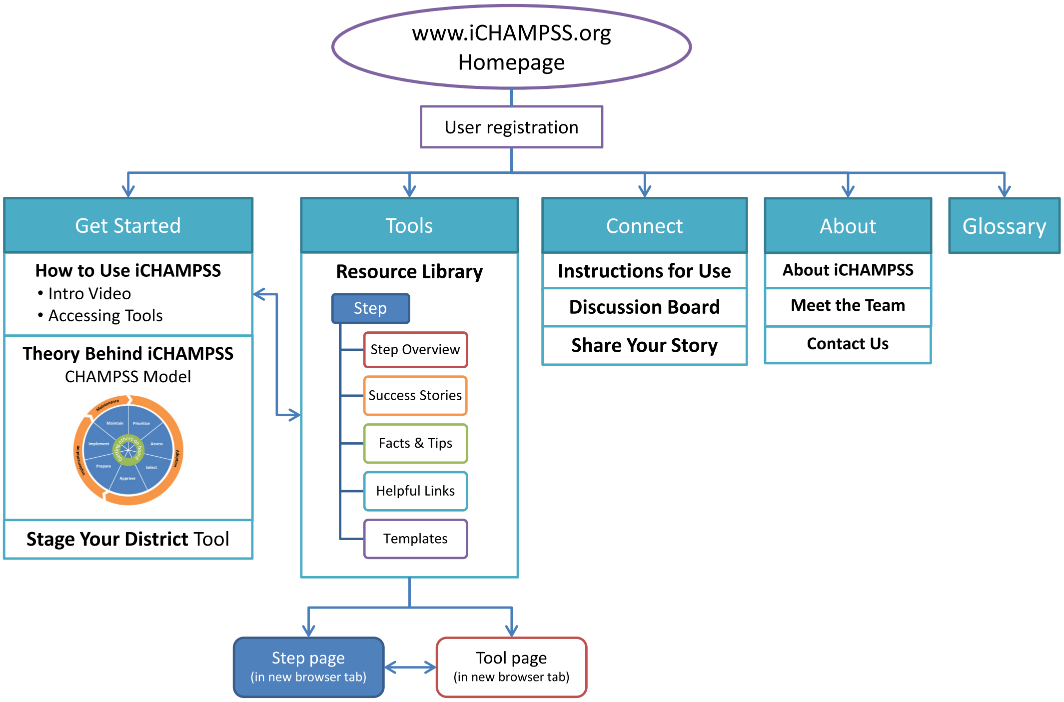

FIGURE 6 | Final mock-up of iCHAMPSS online decision support system.

staging tool was unclear. Lastly, project team members reviewed *iCHAMPSS* and tested it in different Internet browsers and on mobile phones to ensure that it would function on different platforms.

Based on these reviews, we made several changes to the website to clarify its purpose and specify where a user should begin. First, we revised the website name. Originally, CHAMPSS stood for "*CH*oosing *A*nd *M*aintaining *P*rograms for *S*ex Education in *S*chools." However, it was important to add the word "Effective" before the word "Programs" because this was a distinguishing feature of the website. We added this new tagline to every page of the website, so that the purpose of the website was clear. Second, we modified the dashboard to clearly direct users to a "Get Started" button. The "Get Started" button included three drop-down menus: "How to use *iCHAMPSS*," "Theory behind *iCHAMPSS*," and "Stage Your District." Third, we added a direct link to the "Stage Your District" tool on the homepage and modified its color scheme to be more clear and visually appealing. We also included a brief description of this staging activity so that users would understand its purpose. Stylistic modifications were also made to the entire website, including changing coloring to be consistent throughout the website and fixing spacing issues. A final mock-up of the *iCHAMPSS* online decision support system is provided in **Figure 6**.

Members of the CHAMPSS Group also provided feedback during the development process of various tools, mainly the end product templates and facts and tips. Most CHAMPSS Group members reported that the tools were useful, feasible, and likely to be used by their districts. After the *iCHAMPSS* tools were developed, three project team members successively reviewed each tool to assess its content, readability, and ability to meet intended objectives. The original tool developer(s) then finalized the tool content based on the feedback from all reviewers and submitted the tool for one final review and approval by the project team.

To further assess the usability, acceptability, and potential impact of *iCHAMPPS*, we also conducted a pilot study with 16 participants who were given access to *iCHAMPSS* for 3 weeks (55). During this time period, participants could download and use any of the tools on the website. They were asked to complete a web-based pretest and immediate posttest using Qualtrics survey software. Participants included professional staff from school districts and community organizations throughout Texas, and parents of school-aged children. To recruit participants, we distributed (*via* e-mail) a flyer describing the study to our community partners, which include the state health department, school districts, community organizations, the Texas School Health Advisory Committee, and The Texas Campaign to Prevent Teen Pregnancy. A description of the study was also placed within the "Friday Beat," the state health department's weekly newsletter. Participants received a $50 gift card for completing both surveys. In summary, 16 participants reported that *iCHAMPSS* was motivational, easy to use, trustworthy, and helpful. They also reported that their self-efficacy for obtaining approval to implement an evidence-based sexual health education program from the School District Board significantly increased as a result of using *iCHAMPSS*. Elaborate results of this pilot test are published elsewhere (55).

CONCLUSION

Steps 3 and 4 of the IM process provided a systematic framework that was critical for translating the CHAMPSS Model (developed using IM Steps 1 and 2) into the *iCHAMPSS* online decision support system to help school district stakeholders adopt, implement, and maintain sexual health EBPs. Specifically, these steps provided a detailed process for ensuring that appropriate theoretical methods were identified and practical applications were developed to best meet the change objectives in the CHAMPSS Model matrices. The use of parameters, in particular, was most helpful in ensuring that the applications we chose best operationalized our chosen theoretical methods (44).

Some lessons can be learned from our experience developing *iCHAMPSS*. First, while we worked closely with the CHAMPSS Group to ensure the development of a system that was compatible with school district needs, time constraints prevented us from obtaining their feedback on every aspect of *iCHAMPSS*. For example, they never reviewed the final iteration of the discussion board, which was particularly disappointing because this feature was specifically requested by them. In addition, we received less feedback from the CHAMPSS Group on the implementation and maintenance plans because most group members did not have experience with these tasks (most CHAMPSS Group members were in the earlier stages of the CHAMPSS Model). It will be critical to obtain additional input on these tools from *future* iCHAMPSS users. Second, we learned important lessons about developing technology-based applications: (a) we did not anticipate the lengthy amount of time that would be needed to identify an appropriate IT developer and (b) it is important to adequately vet the IT developer to ensure that he/she has the requisite qualifications and communication skills. Regarding the former, the IT developer "search" process took approximately 9 months, which significantly delayed production of *iCHAMPSS*. For the latter, we had to hire a new IT developer mid-way through the development process because the original developer was not adequately meeting the needs of the project (e.g., the original "tools library" had to be rebuilt because the original programmed version did not allow us to add, delete, or format existing tools).

Future studies should focus on a rigorous evaluation of *iCHAMPSS* (IM Steps 5 and 6) to assess its impact on adoption, implementation, and maintenance of sexual health EBPs in school settings. This study should also assess the impact of *iCHAMPSS* on school district personnel's psychosocial factors related to adoption, implementation, and maintenance, such as knowledge, attitudes, self-efficacy, and perceived support for sexual health EBPs. If effective in improving these outcomes, *iCHAMPSS* could serve as a model implementation science practice for sexual health EBPs nationally. Furthermore, *iCHAMPSS* could be adapted to increase dissemination of school-based EBPs that address other adolescent health issues, such as substance use and violence prevention.

ETHICS STATEMENT

This study was carried out in accordance with the recommendations of "University of Texas Health Science Center at Houston Institutional Review Board" with passive informed consent from all subjects when required, in accordance with the Declaration of Helsinki. This publication only described our intervention development process. Verbal permission from the community advisory board partners for their input was obtained during the development process. The papers by Hernandez et al. (25, 55) did require passive informed consent which was required and stated in those manuscripts.

AUTHOR CONTRIBUTIONS

All authors (MP, BH, EG, PC, DL, ER, KR-H, YR, KJ-B, SE, and RS) made substantial contributions to the conception and design of the work; or the acquisition, analysis, or interpretation of the data; drafted the work or critically revised it for important intellectual content; provided final approval of the manuscript; and agreed to be accountable to all aspects of the work.

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Health by Design: Interweaving Health Promotion into Environments and Settings

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The important influence of the environmental context on health and health behavior—which includes place, settings, and the multiple environments within place and settings—has directed health promotion planners from a focus solely on changing individuals, toward a focus on harnessing and changing context for individual and community health promotion. Health promotion planning frameworks such as Intervention Mapping provide helpful guidance in addressing various facets of the environmental context in health intervention design, including the environmental factors that influence a given health condition or behavior, environmental agents that can influence a population's health, and environmental change methods. In further exploring how to harness the environmental context for health promotion, we examine in this paper the concept of *interweaving of health promotion into context*, defined as weaving or blending together health promotion strategies, practices, programs, and policies to fit within, complement, and build from existing settings and environments. Health promotion interweaving stems from current perspectives in health intervention planning, improvement science and complex systems thinking by guiding practitioners from a conceptualization of context as a backdrop to intervention, to one that recognizes context as integral to the intervention design and to the potential to directly influence health outcomes. In exploring the general approach of health promotion interweaving, we examine selected theoretical and practice-based *interweaving* concepts in relation to four key environments (*the policy environment*, *the information environment*, *the social/cultural/organizational environment*, and *the physical environment*), followed by evidence-based and practice-based examples of health promotion interweaving from the literature. Interweaving of health promotion into context is a common practice for health planners in designing health promotion interventions, yet one which merits further intentionality as a specific health promotion planning design approach.

Keywords: context, health and place, environments, settings, health promotion, health planning

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INTRODUCTION

A growing body of evidence highlights the influence of the context that surrounds us on our health and health-related behaviors, including where we live, study, work, pray, and play (1). Low-income populations who live in certain geographic areas of the United States (US), for example, have been found to live longer compared to populations of the same low-income status living in other parts of the country, with differences due not only to individual-level health behaviors and outcomes, such as physical activity (PA), smoking, and obesity, but also area-level characteristics, such as composition of educated population, immigrant population, and government expenditures (2). While selection bias is an important consideration for studies on place and health, the Moving to Opportunity study found that low-income families who were randomly assigned to live in economically better off census tracts experienced better health and social outcomes compared to families who remained in economically disadvantaged neighborhoods, such as lower rates of extreme obesity and diabetes (3) and increased college attendance and lower single parenthood for children moving at a younger age (4).

Beyond place of residence, specific organizational settings such as schools have also been found to influence health and health behavior. In examining PA engagement in the US, for example, some research finds that white adolescents are more physically active compared to other racial/ethnic groups (5, 6). However, when examining PA in relation to the schools that adolescents attend, white adolescent girls have been found to have the same levels, and white adolescent boys lower levels, of PA when compared to African-American and Hispanic adolescents attending the same economically disadvantaged schools (7). Childhood obesity also appears to pattern by the school the child attends. While white adolescents in the US tend to have lower levels of obesity compared to African-American and Hispanic adolescents (8, 9), our research with Texas public middle school students found similar levels of obesity among these three ethnic groups when attending the same high economically disadvantaged schools (10). Adjusting for the school a child attends has also been found to eliminate racial/ethnic disparities for a range of other health-related outcomes in research on fifth grade children from three large metropolitan areas in the US, including witnessing of violence, health status, and quality of life, as well as PA and obesity (11). These findings contribute to a growing body of evidence on the role of place [e.g., Ref. (12–15)] and settings [e.g., Ref. (16–19)] in shaping health and health behavior.

The important influence of the environmental context on health, which includes place, settings and the multiple environments within place and settings (e.g., policy, information, social/cultural/organizational, and physical environments) (20), has directed health promotion practitioners and researchers from a focus solely on changing individuals, as emphasized in earlier conceptualizations of the concept of health promotion (21), toward a focus on harnessing and changing context for the promotion of individual and community health. *Intervention Mapping (IM)* (22) is one of several health promotion planning frameworks [e.g., Ref. (23–25)] that explicitly guides planners in addressing environmental factors for health intervention planning. In addition to providing a robust model for health promotion planning that has been widely applied across a range of health issues, settings, and populations (22), IM directs health planners to identifying various facets of the environment that can be incorporated into health intervention design, including *environmental factors* that influence the health problem or risk behavior; *environmental agents* who can directly influence health and behavior and the environmental conditions that impact health and behavior; and *environmental change methods for influencing* different health determinants at different ecological levels, such as *organizational diagnosis and feedback, participatory problem solving,* and *advocacy*—methods aimed at changing organizational and societal level outcomes (22, 26).

In further exploring how to harness the environmental context for health promotion, we examine in this paper the concept of *interweaving* of health promotion into context, which focuses on designing health promotion interventions in concert with people's settings and environments. *Health promotion interweaving* builds from current perspectives in health intervention planning (22, 26), improvement science, and complex systems thinking (27–31) by guiding practitioners from a conceptualization of context as a backdrop to intervention, to one that recognizes context as integral to the intervention design and to the potential to directly influence health outcomes. In exploring the general approach of health promotion interweaving, we examine selected theoretical and practice-based *interweaving* concepts in relation to four key environments (*the policy environment*, *the information environment*, *the social/cultural/organizational environment*, and *the physical environment*), and then illustrate health promotion interweaving with evidence-based and practice-based examples.

INTERWEAVING: DESIGNING INTERVENTIONS IN CONCERT WITH SETTINGS AND ENVIRONMENTS

Interweaving, defined as weaving or blending together (Webster Dictionary, 2017), is a common practice for health promotion planners in designing health promotion interventions in relation to people's environmental context, yet one which we argue merits further intentionality as a specific health planning design approach and method. *Interweaving of health promotion into context* has also been described as *coupling* and *embedding* of health intervention with context (27–29) and generally refers to an intentional process of designing health promotion interventions, which may include health promotion strategies, practices, programs, and policies, to fit within, complement, and build from existing settings and environments. While concepts such as coupling and embedding hold specific relevance for harnessing context for health promotion (27–29), the concept of *interweaving* seeks to more directly communicate the idea of *blending together* the intervention with the properties of a given place or setting in order to create a unique and emergent health promoting context.

Health promotion interweaving into context embraces and aims to advance an *indigenous* health intervention development perspective in which interventions are developed from the "bottom up" in direct partnership with communities, building from site-specific knowledge, practices, and values (28, 32). This perspective differs from the dominant pipeline approach to knowledge generation in which health interventions are first designed by researchers under optimal conditions as part of an efficacy trial, and then tested under "real world" conditions as part of an effectiveness trial, where "real world" may be viewed as a potential for dilution of intervention effects, and "optimally designed" interventions often experience low diffusion (28, 32). In contrast to health intervention planning approaches that first begin with developing a program and then explore how the program fits within a given context, health promotion interweaving begins with identifying and understanding "real world" context, including the settings and multiple environments that surround people, which then become both the opportunity and platform for designing interventions. We posit that *health promotion interweaving* holds potential to not only enhance the population-specific relevance and sustainability of a given intervention, but also to increase impact on health outcomes by broadening the "environmental canvas" upon which to plan and build health interventions.

In guiding health promotion planners to more intentionally design health promotion interventions in relation to people's environmental context, we recently published a basic environmental asset assessment conceptual framework (33) inspired in part by the IM needs assessment phase (22) and informed by ecological models of behavior (20, 34) and implementation science and systems thinking (27). Under this basic framework, health promotion practitioners are encouraged to first identify settings where to reach populations (e.g., school, worksite, church, community) and then explore assets of various environments (policy, information, social/cultural/organizational, and physical environments) within those settings that can be incorporated into health intervention design (33).

A settings and environments approach has been a central feature of other established health intervention planning processes and models (20, 34–37) and may provide additional benefits for health promotion planning. While ecological models are often defined in terms of levels (e.g., interpersonal, organizational, community, and societal levels) (38), conceptualizing the ecological space in terms of environments and behavioral settings (20, 33–37) offers further direction for health promotion planners as a given setting encompasses multiple environments and assets that can be activated for intervention design. For example, within a school setting, existing assets and environments that might be catalyzed for a given health promotion intervention include a parent/teacher organization within the school social/organizational environment, as well as the student morning announcements within the school information environment.

In building from this environmental asset assessment framework, we present in **Table 1** selected theoretical and practice-based concepts that both support and provide further direction

TABLE 1 | Exploring selected theoretical and practice-based concepts in support of health promotion interweaving into context as organized by key environments.

Concept	Definition	Practice or theory perspective
Interweaving (coupling, embedding)	The process of designing and inserting health promotion intervention into existing context, including settings and environments	*Complex Systems and Improvement Science* (27–31)
Policy environment		
Health-in-all policies	Incorporating health considerations into decision-making across sectors and policy areas with the aim of improving people's health (39)	*Community and Municipal Planning*, NACCHO (40)
Information environment		
Environmental print	The print of everyday life, including the symbols, signs, numbers, and colors found in the school, neighborhood, and Internet (41). A concept from the field of childhood literacy that holds promise for enhancing everyday contexts for health communication	*Child Literacy*, Neumann (41)
Behavioral journalism	Incorporating authentic role model stories of behavior change into mass and local media based on priority population [(22) p. 393]	*Health Communication*, McAlister et al. (42), Reininger et al. (43)
Cues to action	Providing positive reinforcement for a health behavior or health action *via* visual cues (e.g., messages, symbols) and strategic placement of stimulus [(22) p. 381]	*Health Belief Model*, Janz and Becker (44)
Social/cultural/organizational environment		
Appropriable organization	Harnessing social organization that is created for one purpose to provide a valuable resource for other, different purposes (45)	*Social Capital Theory*, Coleman (45)
Mobilizing social networks and social support	"Encouraging social networks to provide informational, emotional, appraisal, and instrumental support." [(26) p. 16]	*Theories of Social Networks and Social Support*, Holt-Lunstad and Uchino (46), Valente (47)
Structural redesign	Changing organizational elements such as mission, communication, reward systems, and job descriptions to support health promotion [(22) p. 395]	*Organizational Development Theory*, Cummings and Worley (48)
Common agenda	Creating a shared vision for change that includes a common understanding of the problem and joint approach to solving the problem through agreed-upon actions (49)	*Collective Impact*, Flood et al. (50)
Physical environment and settings		
Facilitation	"Creating an environment that makes the action easier or reduces barriers to action." [(26) p. 6]	*Social Cognitive Theory*, Bandura (51)
Shared use	Establishing a formal or informal agreement between two or more separate entities, such as a school and a city or county, that describes the terms and conditions for shared use of public property or facilities (52)	*Community and Municipal Planning*, ChangeLab Solutions (52)

for *health promotion interweaving into context* as a health intervention design approach in relation to the *policy, information, social/cultural/organizational,* and *physical environments*. These theoretical and practice-based concepts were chosen to illustrate how health interventions can directly build from, connect with, and "interweave" health promotion into different environments located within settings and geographic place that hold potential to influence health and health behavior. In the following section, we describe these theoretical and practice-based *interweaving concepts* with examples from the health promotion literature and practice field.

POLICY ENVIRONMENT

In harnessing the policy environment for health promotion, the *Health-in-All Policies* (HiAP) approach embodies the concept of health promotion interweaving. HiAP aims to improve population and individual-level health outcomes by incorporating health considerations into decision-making and policy areas across sectors of a community or society (39). In addition to exploring how a given policy or planning proposal may adversely impact health (53), HiAP explicitly promotes the incorporation of health promoting policies and actions in community planning through collaboration with non-traditional health partners, such as transportation, housing, land development, and employment-sectors that directly affect social determinants of health (39, 54). While HiAP is often considered at the community or societal levels—with a recent review indicating that HiAP is growing within municipal governments (55), HiAP represents a promising approach for harnessing the policy environment at different ecological levels, including the organizational and interpersonal levels such as worksites, schools, and even households. Examples of health promotion interweaving into the policy environment include the following:

- *Physical activity and city planning*: *Imagine Austin* is an example of a comprehensive long-term plan emerging in cities and counties across the US that incorporates quality of life and health considerations into city planning beyond just a focus on land use (56). With guidance from this plan, Austin residents voted in 2016 to approve a multi-million dollar bond package that includes funding for sidewalks, safe routes to school, bikeways, and urban trails (56).
- *Lactation support and the workplace*: State legislation in Texas under the Mother-Friendly Worksite Program from 1995 and more recent legislation under the Right to Express Breastmilk in the Workplace from 2015 directly interweaves health promotion into the worksite by providing recognition for and requiring that worksites in Texas support women to express milk at the workplace *via* a designated room or space as well as break time for lactation (57).
- *Teen driving and parent-imposed limits*: Simons-Morton et al.'s (58) findings on the reduction of risky driving among teenagers *via* the promotion of parent–teen driving agreements is an example of interweaving of health-related policies into the household setting that hold benefit for adolescent health promotion.

INFORMATION ENVIRONMENT

The information environment exists in most behavioral settings (20) and can take on many forms, including written, symbolic, verbal, and non-verbal messaging (33). Promoting health *via* the information environment has been a key practice of health promotion practitioners, with examples that include inserting nutrition information in restaurant menus (59), installing seatbelt warning lights in the cars we drive (60), and delivering public service announcements *via* the television to promote parent–child communication about alcohol use (61). The concept of *environmental print,* which refers to the symbols, signs, numbers, and colors of everyday life that enhance children's literacy (41, 62), holds relevance for harnessing the information environment by guiding health promotion practitioners to interweave health messaging across everyday-life contexts of individuals. Examples of theoretical change methods cited in IM (22) that can contribute to the creation of an environmental print for health include *cues to action* (44), in which cues are embedded into a given behavioral setting, such as stickers within bathrooms to promote handwashing with soap (63) and point-of-choice prompts that encourage stair climbing (64), and *behavioral journalism*, in which health-related role model stories are interwoven into newspapers, magazine articles, and other media (42, 43). Examples of interweaving of health promotion into everyday information environments include:

- *Healthy eating and PA promotion on the Texas–Mexico border:* In promoting fruit and vegetable (FV) consumption and PA among a US–Mexico border population living in one of the poorest counties in the US, role model stories and personal testimonies were delivered *via* 30-s radio segments on Spanish-language stations during morning drive times, 4–5 min weekly TV health segments shown during a Spanish-language morning show, and a Spanish-language newsletter and website (65). Participants exposed to both radio and TV messages consumed more portions of FV, and participants exposed to radio and Community Health Worker discussions were more likely to meet PA recommendations (65).
- *Substance use prevention in secondary school students*: In harnessing the school and community information environments for adolescent substance use prevention, Slater and colleagues (66) inserted print messages into posters, book covers, tray liners, T-shirts, water bottles, rulers, and lanyards within US school settings as well as verbal messaging such as public service announcements delivered *via* community organizations. At two-year follow-up, youth in the eight media-enhanced intervention communities reported lower marijuana and alcohol use compared to a classroom curriculum comparison condition (66).

SOCIAL/CULTURAL/ORGANIZATIONAL ENVIRONMENT

With foundation in ecological models of health behavior (20, 34), we broadly define this environment in terms of the social and cultural organization that exist within a given setting, as well as the social, cultural, or organizational factors that relate to health and health behavior (33). Three theoretical concepts for interweaving health promotion into this environment are *appropriable organization* from Social Capital Theory (45); *mobilizing social networks* and *social support*—theoretical methods identified in IM (26) and based in theories of the same names (46, 47); and *structural redesign*, also cited in IM (22) and stemming from theories of organizational development (48) [see also *normative restructuring* (29)]. These concepts embrace an interweaving approach *via* appropriating, mobilizing, and restructuring existing social organization (e.g., a school committee or worksite) or elements of an organization (e.g., organizational norms, mission, roles) that were created for one purpose to be activated for health promotion purposes. As interweaving into existing organization holds important ethical implications, the creation of a *common agenda*—a concept from the field of Collective Impact in which two or more parties create an agreed-upon approach for action (49)—merits emphasis. Examples of interweaving health promotion into the social/cultural/organizational environment include:

- *Contraceptive use and drug shops in Uganda*: In response to the low accessibility of contraceptives in rural and peri-urban areas of Uganda, the STRIDES for Family Health project successfully incorporated family planning products and services into private drug shops, which are similar to pharmacies but not required to employ trained pharmacists (67). Drug shop operators in four districts were trained to counsel clients, of whom over half were of low socioeconomic status, and safely administer contraceptive injections, resulting in high levels of client satisfaction and delivering equivalent proportions of contraceptive protection compared to clinics and community health workers (67).
- *HIV risk reduction and peers*: Activating peer networks and peer-led education have been found to be an effective strategy in promoting HIV risk reduction behaviors [e.g., Ref. (68–70)] and HIV screening (71) among diverse at-risk populations. This large and growing body of research underscores both the power and potential of mobilizing existing social networks within the social environment for health promotion.
- *Physical activity promotion and the school setting*: Marathon Kids (MK), an international non-profit organization, interweaves PA into existing school schedules and organization by encouraging teachers to incorporate opportunities for children to run during recess and other times of the day, tracking miles run as part of classroom learning on topics such as math, and inserting MK awards into existing end-of-year school award ceremonies to provide positive PA reinforcement, among other school organizational enhancements (72). Children attending economically disadvantaged schools that participated in MK reported increased PA participation and other related outcomes such as increased athletic identity self-concept (72).

PHYSICAL ENVIRONMENT

The physical environment, defined broadly as features of the built and natural environments (73), has received increased attention in the past several years for its effects on health (74), including physical health (75–79), mental health (80–83), and social health (84, 85). While the growing body of evidence on the built and natural environment and health is beyond the scope of this paper [see Ref. (74, 79, 83, 86)], this literature underscores the importance of how we design, shape, organize, and connect with the physical environment in enhancing population health. Two basic *interweaving* concepts that provide direction for harnessing the physical environment for health promotion are *facilitation* and *shared use*. With applicability across the environments presented above, facilitation is a broad and robust theoretical method (22) with roots in Social Cognitive Theory (51) that refers to creating an environment that makes a given health action easier. A shared use agreement, a specific example of how facilitation can be operationalized for the physical environment, is an important practice-based concept in which an agreement is made between two or more parties to allow use of a given physical space for health-related activity (52). Examples of interweaving health promotion into existing physical environments include:

- *Pop-up parks, PA, and social capital:* Pop-up parks, like Ciclovias/Recreovias (open-street events) (87, 88) or dual-use facilities (e.g., parks located in-school grounds that are open to the community after school hours) (89) challenge the notion that urban spaces are naturally permanent. Pop-up parks are by definition small and temporary, and are located in areas typically reserved for cars (parking lots, streets) (90). A recent study in Los Altos, CA, USA, found that a small, urban pop-up park attracted a large number of multigenerational users (91). High levels of PA in the pop-up park were observed among youth. Among users, the presence of the pop-up park was associated with less screen time, and with more time spent at a park, outdoors, and in the downtown central business district of Los Altos (91). Pop-up parks represent a promising strategy for communities with limited space for public recreation facilities, both to promote PA, as well as to improve social capital and quality of life through the revitalization of urban settings.
- *Train stations and blood pressure screening:* In 2016, the St. Louis County Department of Public Health and a non-profit arm of the Bi-State Development Agency received federal funding to provide preventative health-care services such as blood pressure screening for commuters at a train station in north St. Louis County, Missouri, USA (92). This innovative project demonstrates the potential of interweaving health promotion into existing physical public spaces such as train stations that have wide population reach.

APPLYING HEALTH PROMOTION INTERWEAVING TO HEALTH PROMOTION PLANNING

A *health promotion interweaving into context* approach, as illustrated with the above examples, holds important implications as a specific design strategy for health promotion planning frameworks such as IM. Step 1 of IM, which includes conducting a health needs assessment (22), presents an ideal opportunity for incorporating health promotion interweaving by directing planners to identify not only the factors contributing to the health problem, but also the environmental assets that can be incorporated into the design of the health intervention. Examples of environmental assets that may be identified during the needs assessment phase include a code of conduct for employees in the *policy environment (interweaving concept: HiAP)*, existing communication channels such as a parent bulletin board in the school *information environment (environmental print)*, established forms of social organization such as a neighborhood civic council in the *social/cultural/organizational environment (appropriable organization),* and existing physical spaces for intervention activities in the *physical environment (shared use)*. A health promotion interweaving approach can also inform other health promotion planning steps as described in IM, including the identification of *environmental outcomes* of a given intervention (Step 2 of IM) (e.g., a HiAP approach that includes a policy on prohibiting e-cigarette use delivered *via* student handbooks), the provision of *a platform* or *practical application for delivery of key theoretical methods* (Step 3) (e.g., role modeling stories on sleep health delivered *via* the company newsletter), guidance with the overall *design of a given health intervention* (Step 4) (e.g., the four environments described above inform the creation of program components), and identification of existing human resources *who can implement* a given aspect of the intervention (Step 5) (e.g., cafeteria workers encourage students to take a fruit or vegetable in the cafeteria line). Finally, the health promotion interweaving concepts presented in **Table 1** aim to advance an approach of "designing from within" a given setting or system, in order that a given health intervention "sticks" and does not wash out over time, an ongoing challenge of health interventions (27).

DISCUSSION

Health promotion planning frameworks such as IM (22) provide helpful guidance in developing health interventions focused not only on changing individuals, but also the environmental context with which the individual interacts on a daily basis. In this paper, we aimed to complement such planning frameworks by examining how health promotion planners can intentionally design health promotion interventions that build from a priority population's context *via* the concept of *health promotion interweaving*. A specific contribution of this paper is the exploration of theoretical and practice-based interweaving-related concepts that provide guidance for designing health interventions in relation to environments and settings. Given the potential to directly harness contexts that can shape health and health behavior while broadening the environmental canvas for developing health promotion strategies, health promotion interweaving-related approaches merit greater emphasis and study within the field of health promotion intervention planning.

In recent years, a growing number of organizations and initiatives have embraced similar *health-by-design* approaches in which interventions are explicitly developed in relation to the environmental context, including the *Health, Behavioral Design, and Built Environment Project* of the National Collaborative on Childhood Obesity Research (93), OLE! Texas- a state-wide initiative aimed at enhancing childcare outdoor environments (94), the Michael & Susan Dell Foundation funded *Go Austin-Vamos Austin* place-based initiatives[1], and the Robert Wood Johnson Foundation's built environment initiatives (95), among others. While the selected examples provided in this paper aim to both illustrate and provide foundation for the practice of interweaving of health promotion into context, we recognize that more applied research and practice is needed to fully understand and harness the power of interweaving. In looking forward, a growing body of research on concepts from complex systems science and social-ecological theory offer promising direction for exploring further how health promotion is interwoven across a given setting and how different environments may interact with each other over time to produce (or inhibit) health and health behavior change. These concepts include: *extensiveness and intensiveness* of an intervention within a given setting (27)—which may include assessing how a given intervention is interwoven across environments of a given setting, *interactions of influence* across environments and levels that may enhance or inhibit behavior change (34), *emergent properties* within a setting that result from a given modification or intervention (28, 29)—with implications that include understanding how health interventions that are interwoven into environments produce changes—possibly positive or negative—across a given setting or system, *timing and sequencing* of intervention modifications within settings (28, 29, 93)—recognizing that the impact of health promotion interweaving on health or health outcomes may not follow a linear sequence, and *agency* for intervention (28, 29, 93), among others [see Ref. (28, 29) for recent reviews].

As the concept of health promotion interweaving is context specific by nature, new approaches may be needed for exploring how to best evaluate such interventions. The complex systems literature holds relevance for exploring how a health promotion interweaving approach may best be evaluated (28, 29, 31). Two relevant concepts for evaluation of health promotion interweaving approaches from this literature are the need for a *new conceptualization of fidelity of program implementation* (27), and the need for a shift from a linear planning and evaluation framework to one that *acknowledges the complexity of context* and the *importance of process* (28, 29, 31). Fidelity under a traditional program evaluation would focus on keeping constant the delivery of the intervention across different study sites, yet this conceptualization of fidelity contradicts the nature of health promotion interweaving, which embraces the uniqueness of different settings as an opportunity for identifying setting-specific intervention approaches *via* harnessing its multiple environments (policy, information, social/organizational, and physical). In recognition of the diversity of sites and systems, Hawe et al. recommend a refined conceptualization of fidelity—one that conceives the intervention as a dynamic event within a system where the "function" of a given intervention (e.g., delivering 30 min of PA *via* a defined process for identifying strategies) is more important than the form (e.g., strategies for delivering PA are tailored to a given school), which may vary by site (27). Related to this new conceptualization of fidelity is the need to identify evaluation approaches that move from a linear process, often based on an oversimplified linear logic model in which the planner is expected to have all the answers upon intervening in a given system (28), to one which embraces

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[1] *Go Austin-Vamos Austin!* Available from: http://www.goaustinvamosaustin.org/

complexity of context and emphasizes a process of co-learning with people from a given context to identify environmental modifications and make adaptations to these approaches over time (28, 29). Given that public health actions and effects often do not follow a linear time period and may require long periods of time (28, 29, 93), Rutter and colleagues emphasize the importance of tracking proximal, intermediate, and distal processes and outcomes, as well as the importance of modifying approaches in responses to changes in systems (31). The growing field of participatory learning and action (96, 97)—which includes visual and group-based inquiry methods for exploring the process of a given intervention (98, 99)—holds specific relevance for engaging populations in co-learning around implementation and evaluation of health promoting interweaving approaches.

While we were purposeful in this paper in exploring interweaving as a practical health promotion planning approach for health promotion practitioners—building from Einstein's famous dictum that "everything should be made as simple as possible, but not simpler," we also recognize the need for field-based research to inform best approaches for interweaving and understand further its impact on health promotion. Kok and colleagues (26), the authors of IM, have provided important advances to the field of health promotion planning in recent years by examining the parameters, or conditions, under which a given environmental change method may be effective. While health promotion interweaving can inform the approach for designing interventions in relation to environments, and the different environments cited in this paper may help provide the "canvas" upon which to design interventions, there is a need to understand the parameters that make health promotion interweaving an effective health promotion planning approach that ultimately results in positive individual-level and community-level health changes. As an example, and as mentioned above, "appropriating" organization may hold important ethical implications, and as such, a possible parameter for health promotion interweaving is that it is most effective when people from a given setting are involved in making decisions regarding health promotion changes to their organization. Furthermore, we provided only a selected sample of interweaving-related concepts in this paper to illustrate the overall interweaving design approach; the growing menu of theoretical methods identified *via* approaches such as IM (22, 26) offers further direction for exploring best approaches for interweaving.

We also recognize other inherent limitations of our basic overview of interweaving in this paper, including the challenge of classifying specific environments, given the overlap of different types of environments such as a "policy environment" and a "social/organizational environment," as well as our limited conceptualization of the environment in terms of the four key environments examined. As we previously recognized (33), there are undoubtedly other important environments that should be explored that have relevance for shaping health and health behavior. One such environment is the *economic environment*, which Swinburn and colleagues define in their ANGELO obesogenic environmental planning framework in terms of costs related to food and PA (35). While economic forces often appear outside the control of health promotion practitioners, Swinburn and colleagues (35) offer examples of how the economic environment may be harnessed for health promotion *via* monetary incentives in terms of taxes, pricing policies, and subsidies; financial support for health promotion programs; healthy food purchasing policies; and budget allocations for a given health intervention such as the creation of a bike path. Economic subsidies, in particular, represent a potential interweaving concept by directly shaping the economic environment of a given setting or organization to be more supportive of a given health behavior or outcome. In central Texas, for example, the non-profit organization Sustainable Food Center (SFC) established a "double dollar" program for their farmers' markets in which economically disadvantaged residents can double the amount of government subsidies (e.g., SNAP, WIC, and FMNP) to increase their purchasing power of healthy foods at SFC markets (100). Beyond directly intervening in the economic environment, the interweaving concepts and other environments explored in this paper also hold relevance for enhancing health for economically disadvantaged populations, as illustrated by several of the examples cited in this paper that included low-income populations. While further exploration of each of these environments, as well as additional environments such as the economic environment, are warranted, the basic settings and environments framework that we present here provides an initial foundation to build upon in exploring health promotion interweaving.

Health promotion interweaving presents a basic yet promising approach for designing health promotion interventions that moves beyond a perspective of context as the delivery setting of an already-designed intervention, to one that embraces context as integral to the design of health interventions. We look forward to continuing to co-learn with health promotion practitioners and researchers about best practices for interweaving health promotion into context.

ETHICAL CONSIDERATIONS

This paper is based on a review of existing literature and does not report any individual data.

AUTHOR CONTRIBUTIONS

AS and AE jointly conceived of this paper. AS drafted the paper with major section contributions and editing of the manuscript from AE and DS. JO and MA provided key contributions with review of the literature and editing of the paper.

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Clinic-Based Mobile Health Decision Support to Enhance Adult Epilepsy Self-Management: An Intervention Mapping Approach

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Introduction: Epilepsy is a neurological disorder involving recurrent seizures. It affects approximately 5 million people in the U.S. To optimize their quality of life people with epilepsy are encouraged to engage in self-management (S-M) behaviors. These include managing their treatment (e.g., adhering to anti-seizure medication and clinical visit schedules), managing their seizures (e.g., responding to seizure episodes), managing their safety (e.g., monitoring and avoiding environmental seizure triggers), and managing their co-morbid conditions (e.g., anxiety, depression). The clinic-based Management Information Decision Support Epilepsy Tool (MINDSET) is a decision-support system founded on theory and empirical evidence. It is designed to increase awareness by adult patients (≥18 years) and their health-care provider regarding the patient's epilepsy S-M behaviors, facilitate communication during the clinic visit to prioritize S-M goals and strategies commensurate with the patient's needs, and increase the patient's self-efficacy to achieve those goals.

Methods: The purpose of this paper is to describe the application of intervention mapping (IM) to develop, implement, and formatively evaluate the clinic-based MINDSET prototype and in developing implementation and evaluation plans. Deliverables comprised a logic model of the problem (IM Step 1); matrices of program objectives (IM Step 2); a program planning document comprising scope, sequence, theory-based methods, and practical strategies (IM Step 3); a functional MINDSET program prototype (IM Step 4); plans for implementation (IM Step 5); and evaluation (IM Step 6). IM provided a logical and systematic approach to developing and evaluating clinic-based decision support toward epilepsy S-M.

Keywords: epilepsy, self-management, decision support, intervention mapping, intervention, mobile health, electronic health, treatment

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INTRODUCTION: BACKGROUND AND RATIONALE

Epilepsy is a neurological disorder involving recurrent seizures (1). It affects approximately 5 million people in the US (1). Epilepsy onset is not age dependent but incidence rates peak before 5 and after 60 years of age (2). Greater psychosocial impact is likely when seizure onset is in adolescence compared to younger ages (2). Epilepsy can have adverse social, physical, and psychological consequences, compromising a person's economic and social future. The direct costs of epilepsy care were estimated to range from $8,412 to $9,287 in 2013 and were markedly higher for sub-populations with uncontrolled or refractory epilepsy, or co-morbidity (3).

Epilepsy Self-Management (S-M)

People with epilepsy (PWE) have varied disease severity. Regardless, PWE are encouraged to manage their treatment and lifestyle to provide optimal quality of life. The Managing Epilepsy Well (MEW) Network defines epilepsy S-M as the "processes a person uses to optimize seizure control, to minimize the effects of having a seizure disorder, and to maximize quality of life in partnership with their health-care provider" (4, 5). This includes both S-M behaviors that are specific to epilepsy as well as S-M behaviors for chronic care that are applicable to most chronic conditions (2). Epilepsy specific S-M encompasses managing treatment (e.g., adhering to anti-seizure medication and clinical visit schedules), managing seizures (e.g., planning for, and responding to, seizure episodes), managing safety (e.g., monitoring and avoiding environmental seizure triggers), and managing co-morbid conditions (e.g., anxiety, depression). Chronic care S-M encompasses management of lifestyle issues (e.g., adjusting typical behaviors to avoid seizures and/or to mitigate their adverse consequences), partnering actively with the health-care team (e.g., information sharing), and pursuing independence (e.g., invoking support, resources, and services when needed) (2, 6). Knowledge and self-efficacy to perform S-M behavior are associated with epilepsy S-M (5, 7–10). S-M practice can be compromised by co-morbidities including depression, anxiety, and cognitive dysfunction. These can also act directly as internal precipitants of seizures (2, 11, 12). The emergence of S-M research in epilepsy has co-occurred with the development of the MEW Research Network. The development described in this paper occurred as a MEW Network collaborative project, supporting the Network's long-term objective to increase the number of adequately tested epilepsy S-M programs available to health-care providers (HCPs) and members of the epilepsy community. The aim of the Network is to contribute to applied research targeting the priority recommendations from the CDC Epilepsy Program and Living Well with Epilepsy 2003 to promoting S-M (5, 13). The Network's objectives are to: (1) "develop and implement a coordinated, applied-research agenda"; (2) conduct rigorous research that promote S-M and quality of life suitable for application in diverse settings including homes, communities, and clinics; and (3) to identify and collaborate with stakeholders outside of the network to implement these activities (5). The importance of S-M for PWE and programs available to assist S-M are discussed in the needs assessment section below.

Patient and Provider Collaboration

The Institute of Medicine (IOM) report, Epilepsy Across the Spectrum, promotes patient-centered care for epilepsy and related co-morbidities, including collaborative approaches (2). Partnership between the HCP, including clinicians, nurse educators, and community health workers and the patient (including the patient's family or significant others), is important in facilitating S-M adherence. Consistent with the patient-centered model of caring for people with a chronic disease HCPs are well positioned to help their patients in meet S-M goals (2).

Shared decision involves HCPs and patients making decisions together based on the best evidence available. This promotes a two-way communication that incorporates clinician expertise (i.e., disease, options, probabilities, and prognosis) and patient expertise (i.e., "preferences, values, attitudes to risk, and social circumstances") (14). Dual participation enables the best solution when varied options are available. Prompting patients before the clinical encounter can result in better shared decision-making and enable the transfer of more salient information from the HCP (14). Patient care plans or action plans can be useful, allowing patients to consider individual preferences on options and treatment goals prior to discussion. Systematic review indicates that shared decision-making can lead to better patient treatment adherence (15).

Health-care providers need to be able to clearly communicate the risks associated with epilepsy, the importance of S-M, potential side effects to treatment options, and resources and services that are available (2). Patients need to determine if the type and frequency of their S-M behavior adherence is appropriate; decide on S-M goals that they perceive as important and doable; and determine how to accomplish these behaviors in everyday life. Adoption of S-M behaviors can be undermined due to poor patient-HCP communication and/or a discrepancy in the perceptions about the patient's attitudes to, and S-M abilities, regarding their epilepsy. Conversely, by reinforcing patient S-M, HCPs can instill greater commitment to monitoring and improving behaviors (16, 17). There are challenges to effectively incorporating S-M assistance within a brief clinical visit that limits the time to assess a patient's S-M needs and adequately address them (18, 19).

Mobile Health (mHealth) Decision Support As an Intervention Channel

The IOM report also cited the need for new tools to enhance S-M decision-making (2). A decision-support system (DSS), broadly defined, is a tool to support the decision-making process. Typically, such tools are used in the context of less well-structured problems, enable the incorporation of varied models and analytic techniques, provide easy use by non-experts, and are flexible in accommodating changes in circumstances. Text- and video-based materials exist to assist patients and their HCPs in complex decision-making toward outcomes reflective of patient values and preferences (2, 13, 20–24). Electronic health (eHealth) applications are emerging that support daily S-M monitoring and decision-making for epilepsy (25). mHealth is a subset of eHealth that pertains to the "practice of medicine and public health supported by mobile devices such as mobile phones, tablet computers, and PDAs" (26). Clinic-based DSSs have focused on the technical aspects of diagnostic and pharmacologic decisions (27–33) and less on the personal or social aspects of patient care (34). Facilitating patient and HCP epilepsy S-M decision-making, therefore, represents a novel application of decision support.

The clinic-based Management Information Decision Support Epilepsy Tool (MINDSET) was developed to (1) engage adult patients with epilepsy (≥18 years) and their HCPs in managing therapy and lifestyle to prevent seizures and maximize quality of life (2), (2) provide easily followed goal-based action plans for patient decision support between clinic visits (35), and (3) document patient-centric quality indicators for epilepsy care (36, 37).

Management Information Decision Support Epilepsy Tool is a DSS founded on theory and empirical evidence. It is designed to increase awareness by adult patients and their HCP regarding the patient's epilepsy S-M behaviors, facilitate communication during the clinic visit to prioritize S-M goals and strategies commensurate with the patient's needs, and to increase the patient's self-efficacy to achieve those goals.

Interventional Mapping (IM)

Intervention mapping is a stepped framework to guide the development of behavioral change interventions that enable developers to systematically apply social and behavioral science theories (38). The 6 steps of IM are to (1) assess needs and develop a logic model of the problem, (2) develop matrices of behavioral change objectives for the program, (3) identify theory-based methods and practical applications to be applied in the program, (4) produce program components and materials, (5) plan for program adoption, implementation, and sustainability, and (6) plan for evaluation (38). IM is widely used to develop behavioral change interventions worldwide. A recent systematic review has demonstrated significant increase in the uptake of disease prevention behaviors associated with IM-based interventions when compared to placebo control groups (39). IM has been successfully applied in the domain of chronic disease S-M (39). However, few applications of IM have been reported in the context of managing epilepsy and, to our knowledge, none in the context of support for patient and provider epilepsy S-M decision-making.

The purpose of this paper is to describe the application of IM to develop and formatively evaluate MINDSET to be a clinic-based tool for adult patient (≥18 years) and provider decision-making regarding the patient's S-M. Plans for subsequent efficacy evaluation are briefly described.

METHODS: IM

The Development Timeline

IM steps 1 through 4 are the focus of this paper. Completion of these steps approximated 2 years of development time. The first 6 months of Year 1 involved completion of the logic model of the problem (IM Step 1) and defining program outcomes and objectives and the logic model of change (IM step 2). The remaining 6 months of year 1 involved program planning, developing the MINDSET design document (IM Step 3). The first 6 months of Year 2 involved producing a program prototype and the remaining 6 months of year 2 involved formative evaluation, including alpha- and usability-testing (IM step 4). Plans for implementation and evaluation (IM Steps 5 and 6) were commenced during the period of MINDSET formative testing.

IM Step 1: Logic Model of the Problem

Step 1 comprised establishing a planning group; conducting a needs assessment informed by the PRECEDE planning model that outlines the factors associated with the problem; defining the context of the intervention in terms of population, setting, and community; and stating program goals.

Task 1.1 Establish and Work with a Planning Group

Management Information Decision Support Epilepsy Tool development took place in collaboration with three neurology clinics varying in patient population, payer-base, epilepsy cases, and provider experience: Kelsey–Seybold Neurology Clinic (KS clinic) and their associated Education and Research Program, the Smith Clinic at Harris Health, and the University of Texas Physicians-Neurology Clinic (UT clinic). The clinics enabled access to patients and neurologists for a Patient-Provider Advisory Group (PPAG; described below) that provided ongoing input on MINDSET development through each step of the IM process and also provided a test-bed for formative assessment of MINDSET. These clinics were the test sites for the planned efficacy trial of MINDSET.

Collaborating Clinic Sites. The KS clinic operates within a large urban multispecialty medical organization comprising 21 clinics and over 325,000 diverse patients comprising primarily white (55%), African-American (23%), and Hispanic (19%) ethnicities who are mainly middle-class, employed, and with private insurance coverage primarily through HMO- or PPO-type plans. Patients with epilepsy are referred to the centralized KS neurology clinic. HCPs include general neurologists ($n = 5$), an epileptologist, and a nurse epilepsy specialist. The neurology department has an annual epilepsy case load of approximately 400 patients. The Epilepsy Education and Research Program was established at KS Clinic in 1987 with the goal to demystify epilepsy through patient and family education and training about epilepsy, its treatment, and management, and to develop and conduct research to improve the clinical management of epilepsy through participation in multicenter clinical drug trials and academic collaborations (3, 40, 41).

The *Smith Clinic at Harris Health* provides care to patients who are primarily Hispanic (40%), low-income, uninsured, and covered by Medicaid, and are referred from community health centers ($n = 12$) operated by a large public hospital system. Medical residents and students rotating through the clinic see up to 40 patients per clinic day under the supervision of attending faculty.

The UT clinic is a large urban multispecialty neurology clinic. Patients with epilepsy comprise white (56%), black (14%), Hispanic (4%), Asian (0.2%), and other/unknown (27%). Economic status and financial coverage for health care is diverse, predominantly commercially managed care (58%), and Medicare (31%). The clinic is a tertiary care referral center for neurological disorders, including the diagnosis of epilepsy and the management of difficult epilepsy.

Patient Provider Advisory Group. A PPAG was formed with representation from patients and HCPs from the three clinics and incorporated into the MINDSET research and planning team. The PPAG was consulted to review content (e.g., constructs, scales, and threshold scores for identifying "at-risk" patients);

assess functionality, flow, and "look and feel;" test usability; and review evaluation plans. Patients for the advisory group were invited to join the PPAG by co-investigator clinicians and nurses on the basis of their being representative of the patient population, over 18 years of age, English speaking, engaged in epilepsy management issues, and interested in contributing to the field. The PPAG included three neurologists, one nurse educator, and eight patients with epilepsy. The PPAG met in a conference room at the KS Clinic. Patient members received an incentive payment of $30 per meeting.

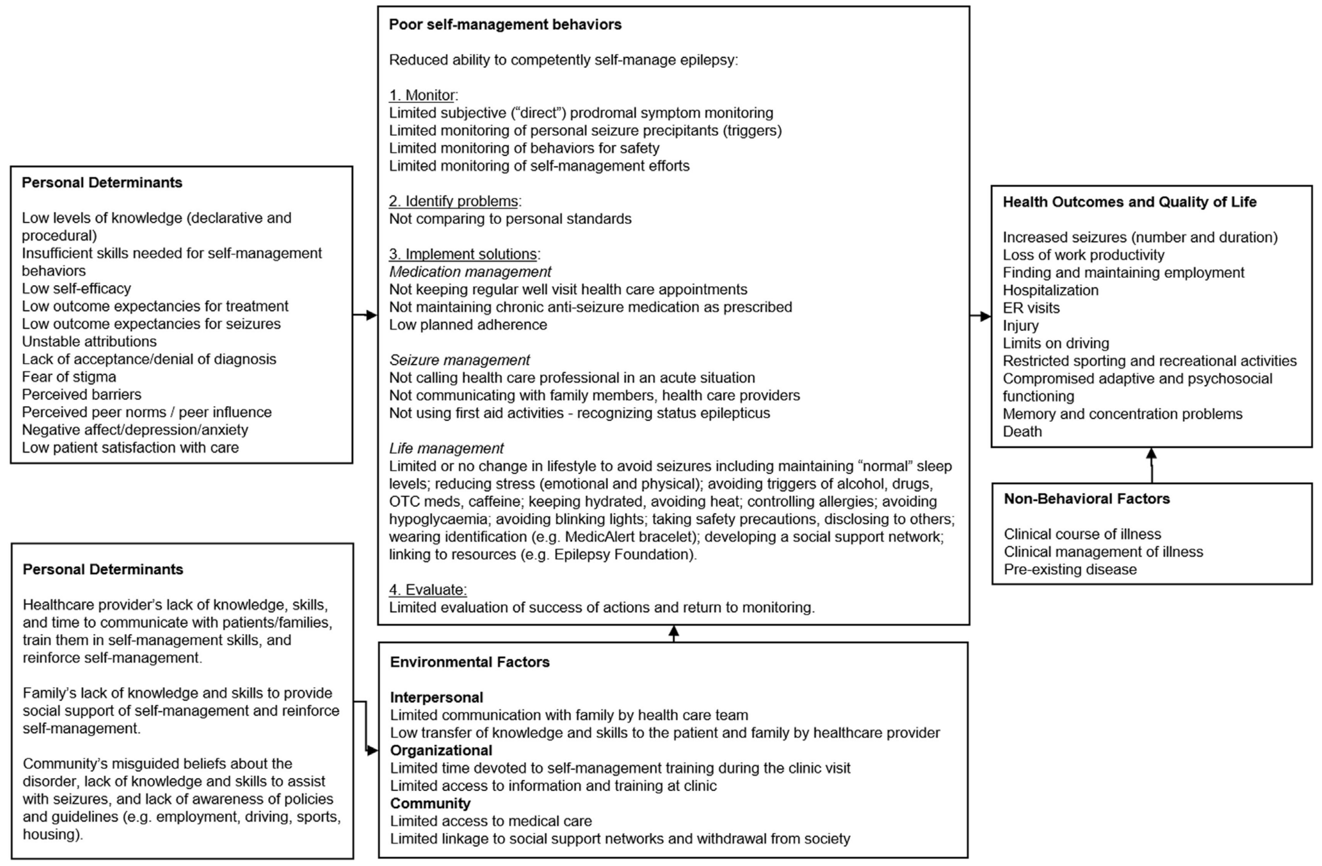
Task 1.2 Conduct a Needs Assessment to Create a Logic Model of the Problem

Information gathered to inform the development of MINDSET was obtained through literature review, quantitative enquiry with the PPAG, empirical investigation of the association of S-M antecedents with PWE in Houston clinics, and clinic-based system task analysis (described in Step 4). The needs assessment was designed to inform a logic model of the problem, to provide background information on challenges experienced by PWE in epilepsy S-M, and the potential for technology to assist patient and HCP decision-making regarding epilepsy S-M.

Literature Review. A decision support tool for identifying patient S-M needs based on clinical, behavioral, and psychosocial variables requires identifying S-M behaviors and the clinical, behavioral, and psychosocial antecedents related to poor S-M as well as to identifying what other instruments/tools might be available in the field. To develop a logic model of the problem, the literature review addressed the medical management of epilepsy, epilepsy S-M behaviors, determinants of S-M behavior, and environmental factors associated with S-M. Data on the S-M interventions, DSSs in support of epilepsy management, and perceptions of PWE toward technology-based applications were also reviewed to understand the empirical and clinical context. Theories and models applicable to chronic disease management amenable to, or applied to, epilepsy were also reviewed, as were practice guidelines for epilepsy management. The research team developed problem statements, identified relevant electronic publication databases of Medline, PubMed, and PsychINFO, formulated database search strategies, and recommended an approach to synthesizing the literature. Data abstraction forms were developed and pilot-tested before they were used to abstract data from the identified relevant studies. Abstracted data were used to create evidence and information tables for expert review. We considered articles published in peer-reviewed journals, including review articles and surveys as well as practice guidelines. Abstracts, poster presentations, and editorial publications were excluded.

Medical Management and the Pathophysiology of Epilepsy. As with many chronic diseases, patients with epilepsy may undergo benign or malignant courses, but all will be affected significantly in some way (21, 42). Most patients with epilepsy undergo basic serological tests, EEG, and imaging studies, and have treatment initiated with a single anti-seizure medication (referred to, henceforth, by the common term anti-epilepsy drugs or AEDs) appropriate for the type of seizure, and age and gender of the patient. If the first agent does not control the seizures or has unacceptable toxicity, switching to a second or third appropriate agent occasionally provides better results. Some patients have seizures incompletely controlled with a single agent, but the addition of a second medication only allows a further 15% seizure control. The choice of a specific AEDs for a given patient is a fairly complex process, which needs to consider the individual's tolerance for medication in general, seizure type, etiology of seizures, co-morbid conditions, concurrent medications, as well as non-medical factors such as employment and medication costs. Despite optimal pharmaceutical treatment, approximately 30% of patients will have recurrent seizures, and as many as 50% of patients with partial seizures will not attain complete seizure control with medication regimens. Patients who do not respond adequately to AEDs may be candidates for surgical treatment or other alternative regimens, including the ketogenic diet, vagal nerve stimulator, and control of precipitating factors (43). The pathophysiology of epilepsy varies between individual patients who may experience a number of different seizure types (e.g., generalized tonic-clinic seizures characterized by convulsions; absence seizures characterized by abrupt beginning and end, blank stares, and only a few second in duration; and complex partial seizures that are characterized by altered consciousness where there is no memory of the misplaced behavior demonstrated during the seizure) and varied stimulus onsets (43).

Epilepsy S-M Behaviors. For PWE, S-M comprises a number of adaptive behaviors that may assist in lowering seizures (44). S-M for PWE refers to a number of adaptive behaviors that may assist in lowering seizures. In recent years patient S-M has received more attention (2, 20). Behavioral risk factors contributing to seizures and co-morbidities include lack of adherence to AEDs, failure to monitor and protect against seizure triggers, lack of safety management to minimize the adverse consequences of seizures, failure to adhere to clinical visit regimens, and failure to adjust lifestyle behaviors to minimize risk of injury (2, 6, 45) (**Figure 1**). Epilepsy co-morbidities are associated with poor S-M and include cognitive dysfunction, depression, suicidal ideation, death resulting from a seizure or *status epilepticus*, and sudden unexpected death in epilepsy (SUDEP). Medication management (adherence), safety behaviors (e.g., cessation of driving), and daily activities (e.g., maintaining sleep and reducing stress and exposure to triggers of seizure triggers) may lower seizure frequency. The focus of seizure control is management of AEDs. AEDs require strict adherence and, even with this, may not completely control seizure activity in 30% of epilepsy patients (46). Compounding this is low AED adherence. Review data for claims indicates 39% of patients do not take their prescribed regimen (47). Failure to adhere to prescription is associated with increased likelihood of hospitalizations and ER visits (47). Poor adherence is related to significant adverse health effects and increased mortality (48, 49). Uncontrolled seizures place "challenging demands" on PWE and their family and strongly predict low quality of life (50), being related to injury, limits on driving, and restrictions on sporting and recreational activities. Other S-M activities, apart from AED adherence, can increase mood and quality of life. For example, self-monitoring can increase awareness of prodromal (early) fea-



Personal Determinants

Low levels of knowledge (declarative and procedural)
Insufficient skills needed for self-management behaviors
Low self-efficacy
Low outcome expectancies for treatment
Low outcome expectancies for seizures
Unstable attributions
Lack of acceptance/denial of diagnosis
Fear of stigma
Perceived barriers
Perceived peer norms / peer influence
Negative affect/depression/anxiety
Low patient satisfaction with care

Personal Determinants

Healthcare provider's lack of knowledge, skills, and time to communicate with patients/families, train them in self-management skills, and reinforce self-management.

Family's lack of knowledge and skills to provide social support of self-management and reinforce self-management.

Community's misguided beliefs about the disorder, lack of knowledge and skills to assist with seizures, and lack of awareness of policies and guidelines (e.g. employment, driving, sports, housing).

Poor self-management behaviors

Reduced ability to competently self-manage epilepsy:

1. Monitor:
Limited subjective ("direct") prodromal symptom monitoring
Limited monitoring of personal seizure precipitants (triggers)
Limited monitoring of behaviors for safety
Limited monitoring of self-management efforts

2. Identify problems:
Not comparing to personal standards

3. Implement solutions:
Medication management
Not keeping regular well visit health care appointments
Not maintaining chronic anti-seizure medication as prescribed
Low planned adherence

Seizure management
Not calling health care professional in an acute situation
Not communicating with family members, health care providers
Not using first aid activities - recognizing status epilepticus

Life management
Limited or no change in lifestyle to avoid seizures including maintaining "normal" sleep levels; reducing stress (emotional and physical); avoiding triggers of alcohol, drugs, OTC meds, caffeine; keeping hydrated, avoiding heat; controlling allergies; avoiding hypoglycaemia; avoiding blinking lights; taking safety precautions, disclosing to others; wearing identification (e.g. MedicAlert bracelet); developing a social support network; linking to resources (e.g. Epilepsy Foundation).

4. Evaluate:
Limited evaluation of success of actions and return to monitoring.

Environmental Factors

Interpersonal
Limited communication with family by health care team
Low transfer of knowledge and skills to the patient and family by healthcare provider
Organizational
Limited time devoted to self-management training during the clinic visit
Limited access to information and training at clinic
Community
Limited access to medical care
Limited linkage to social support networks and withdrawal from society

Health Outcomes and Quality of Life

Increased seizures (number and duration)
Loss of work productivity
Finding and maintaining employment
Hospitalization
ER visits
Injury
Limits on driving
Restricted sporting and recreational activities
Compromised adaptive and psychosocial functioning
Memory and concentration problems
Death

Non-Behavioral Factors

Clinical course of illness
Clinical management of illness
Pre-existing disease

FIGURE 1 | PRECEDE logic model of the problem for Management information Decision Support Epielpsy Tool (MINDSET) (101).

tures of seizures (e.g., "mood and premonitory triggers of blurred vision, hunger, thirst, tiredness") (44). Such self-prediction is associated with favorable mood and increased confidence in one's ability to accurately predict seizures (51).

Personal Determinants of S-M Behavior. A range of factors provide antecedents for S-M behavior (**Figure 1**). Poor S-M could be due to the patient's low levels of knowledge (declarative and procedural) and skill regarding epilepsy S-M behavior and goal setting, low self-efficacy or confidence to perform S-M behaviors, low outcome expectations (both in terms of causality of seizure onset as well as causality of treatment), and lack of attribution of S-M success to self-effort (particularly as this relates to patient control); lack of acceptance or denial of the diagnosis of epilepsy; fear of stigma related to epilepsy; perceived barriers to managing epilepsy, as well as unrealistic perceptions of how other PWE self-manage (2, 7–9, 11, 16, 52–62). Epilepsy is often associated with cognitive dysfunction, behavior problems, depression, and anxiety (12). Furthermore, seizures in epilepsy may be precipitated by psychological triggers such as stress and emotions such as anxiety and anger (12). Patient's perceptions of, and satisfaction with, health services and clinical care are associated with health care utilization, an important aspect of S-M (2). Many PWE lack the behavioral capability to monitor and self-regulate behaviors that affect seizure susceptibility indicating a need for effective S-M programs (2). Such behaviors include AED adherence, exposure to environmental stimuli, overuse of drugs and alcohol, stress reduction, and ensuring adequate sleep (2).

Personal Determinants of the Environmental Factors. Interpersonal, organizational, and community factors impact PWE. Personal determinants of environmental factors involve HCPs, families, and the community (**Figure 1**) (2). Epilepsy management is compromised when families lack knowledge and skills for providing support for S-M, and HCPs lack the skills to effectively communicate with patients and families to train them on, and reinforce them for epilepsy management behaviors (2, 12). This is compounded by the general community's misguided beliefs about epilepsy, lack of knowledge and skills to assist with seizures and support management, and lack of awareness of policies and guidelines regarding supporting PWE in important life functions, including employment, driving, sports, and housing (2).

S-M Interventions. Until recently, there were few evidence-based epilepsy educational programs (63). Reported results were encouraging. In a study among 100 adults with epilepsy with a two-day psycho-educational program (Sepulveda Epilepsy Education) significant effects were demonstrated that included greater serum

AED levels (indicating better drug adherence), decreased use of hazardous medical S-M practices, greater understanding of epilepsy, and decreased fear of seizures in treatment group compared to the comparison group (64). A study among adult Nigerian patients, a two-day modular didactic psycho-educational program focused on adjusting to epilepsy and related psychoneurotic traits, depression, and stigma demonstrated significant improvement in knowledge of epilepsy, neurotic disorders, and depression, in the treatment group compared to the comparison group (65). A modular didactic educational program (MOSES, Modular Service Package Epilepsy) evaluated on a sample of 242 participants, demonstrated greater tolerance of AEDs, fewer side effects, improved knowledge and coping, and greater satisfaction with therapy in the treatment group compared to the comparison group (56). Interventions were mainly psycho-educational with minimal focus on S-M as previously defined. Recent evidence-based interventions that target S-M behaviors and/or co-morbidities for adults (≥18 years) include WebEase (Web Epilepsy Awareness, Support, and Education), UPLIFT (Using Practice and Learning to Increase Favorable Thoughts), PEARLS (Program to Encourage Active Rewarding Lives), HOBSCOTCH (HOme Based S-M and COgnitive Training CHanges lives), and PACES in Epilepsy (Program of Active Consumer Engagement in S-M) (66). WebEase is a self-paced online website where PWE can choose from among medication, stress, sleep, and personal tracking diary modules that provide tailored activities for learning, self-assessment, and goal setting (assessed at 1-week intervals). A national RCT ($n = 148$) demonstrated significant improvement in self-efficacy and medication adherence for those using WebEase (67). Other interventions have greater focus on co-morbidities of depression [UPLIFT (68), PEARLS (69)] and subjective memory complaints (HOBSCOTCH) (70) or a niche priority population consumers with active epilepsy (with seizures occurring within the last year) (PACES) (71). Tools to optimize decision-making for S-M for patients and providers within the clinic visit had not been reported.

Decision Support and eHealth Applications in Epilepsy Management and Patient Perceptions. The Centers for Disease Control and Prevention (CDC) Epilepsy Program supported the development of e-Tools as one of several approaches to address the gap in available epilepsy S-M tools (1). This vehicle has the potential to overcome barriers to care that PWE face such as lack of transportation and stigma (1). Despite this, a review of the literature on informatics applications for epilepsy management revealed an only recently emerging research effort (25). Of the 68 studies reviewed in the domains of patient monitoring and prevention, education, and therapy or guideline application most were descriptive (describing models, system development, or system installation) with only eight studies testing effectiveness (the impact on patient or provider behavior) using prospective design (25). PWE are well positioned to use emerging eHealth applications in epilepsy S-M. Over 50% of PWE have access to the Internet in a variety of settings (i.e., home, work, school, library) (72–74) and a recent cross-sectional study (19) with adult PWE ($n = 183$) indicated that most participants had access to computers and the Internet (95 and 60%, respectively) and used them to find health information (99 and 57%, respectively). Participants reported "searching for general information on epilepsy (43%), medication (30%), specific types of epilepsy (23%), and treatment (20%)" and most reported that they "likely would use an Internet-based S-M program to help control their epilepsy" (19). Counter-balancing this is needs assessment survey data of adults with epilepsy in the Pacific Northwest ($n = 165$) (75, 76) indicating that a majority of patients prefer in-person (individual or group) program delivery, reinforcing the importance of this over purely distance delivery (phone or Internet).

While the patients in the PPAG were veteran self-managers and mostly exhibiting good seizure control they expressed frustration regarding their relationship with their HCP. This applied particularly to patients from a large inner city community health clinic where brief "face time" with clinicians and frequent and consistent turnover of fellows hampered the development of an ongoing therapeutic relationship. They considered a tablet-based DSS within the context of a clinic visit as a positive addition. Many were using the internet to acquire information on epilepsy and most wanted greater communication with their HCP. There was general agreement for the potential of the epilepsy DSS as a clinical tool in facilitating patient-provider communication.

Review of Selected Theories, Models, and Practice Guidelines for Chronic Disease Management. Social cognitive theory (SCT) and self-regulation models (77–79) were consistently reported in the literature in the context of S-M of epilepsy and other chronic diseases (80, 81) and associated with key psychosocial determinants, including knowledge, outcome expectations, and self-efficacy and skills previously described. A tenet of SCT is that behavior is determined by the interaction of personal, environmental, and behavioral influences (77). Personal influencers include cognitions, such as personal values, beliefs, skills, outcome expectations, and self-efficacy. Environmental influencers include social or physical factors (e.g., influential role models, social or normative support). *Self-regulation* is a potent SCT concept for organizing health education in the management of chronic health disorders (82, 83). It comprises primary subfunctions of behavior self-monitoring (including antecedents and consequences); judgment of one's behavior in comparison to optimal personal standards and environmental circumstances; and self-reaction (behavior to rectify drifts from optimal S-M) (84). The categorization of S-M behaviors in **Figure 1** are informed by this self-regulation framework (**Figure 1**). The term self-regulation refers to both the patient's management of his/her own care and the transfer of S-M tasks to the patient by the HCP as appropriate. Self-regulation has the potential of improving the patient's autonomy and increasing adherence to medical regimens, which can improve medical outcome. Self-regulation necessitates a more prominent role of the patient in first determining, and then monitoring, behaviors and environment, and then modifying therapeutic regimens accordingly in collaboration with the HCP. Self-efficacy and outcome expectations have been described as determinants of epilepsy S-M behavior (10, 16).

The 5-A's model of behavior change (81), quality-of-care criteria, and clinical guidelines for epilepsy (13, 31, 32, 85); informed MINDSET's scope, components, and relevance within a clinical context (described in Step 3). Motivational enhancement therapy protocols (86) provided a means of eliciting decision-making within an mHealth program. Both motivational interviewing and shared decision-making supports the ethical principle of self-determination (87) Motivational enhancement protocols used to elicit movement toward behavioral change had been used in previous decision-support studies (88, 89).

Empirical Study of S-M Determinants in the Target Population. To collect additional data on determinants of poor epilepsy S-M in their priority population, the planning team conducted surveys with PWE receiving care at two clinics in the Houston area ($n = 238$) (10). The objective was to examine variation in S-M across diverse patient populations and explore the association between personal psychosocial factors (knowledge, self-efficacy, depression, and stigma) with S-M. A cohort of 437 patients previously enrolled in the CDC-funded Epilepsy Care and Outcomes Study (41) completed a 45-minute S-M survey within the context of their regular clinic visit. The survey comprised scales previously reported in epilepsy-related research, including the Epilepsy S-M Scale, Epilepsy Knowledge Scale, Epilepsy Self-efficacy Scale, Outcome expectations, Shared Control portion of the Multidimensional Desire for Control Scale, Personal Resource Questionnaire 85 Part 2, Center for Epidemiologic Studies Depression Scale, and Modified Parent Stigma Scale, and Patient Satisfaction Questionnaire-III. The justification for these scales was recent research that had focused on assessing the association of these factors and epilepsy-related S-M behaviors. DiIorio et al. (90) determined the association of the assistance aspect of social support with regimen-specific support (41). Self-efficacy was significantly associated with outcome expectancy and anxiety in the predicted directions and anxiety was significantly negatively associated with S-M (90). DiIorio et al. determined that self-efficacy and patient satisfaction explained the most variance in medication management (16). Self-efficacy was associated with social support, stigma, outcome expectations, and depressive symptoms. Stigma was associated with depressive symptoms (16). The overall fit of the model was improved by adding the direct association between stigma and outcome expectations for seizures to S-M (90). DiIorio et al. (91) identified depressive symptoms and seizure severity as significant antecedents of self-efficacy for epilepsy S-M. Also significant were predictors of social support and stigma (91). Self-efficacy, social support, depression, and perceived stigma were significantly related to S-M regardless of demographics, seizure frequency, or socio-economic status ($p < 0.05$). These findings suggested that the difficulties with S-M faced by many patients with epilepsy are similar irrespective of a patient's background or characteristics and that the types of strategies to improve S-M appear similar regardless of population heterogeneity.

Task 1.3 Describe the Context for the Intervention, Including the Population, Setting, and Community

Management Information Decision Support Epilepsy Tool development was modestly focused on application for patients in the collaborating clinics (previously described). The heterogeneity offered in the clinic type (HMO, community clinic, and teaching hospital) and the patient population (demographics and epilepsy type) provided an excellent test-bed for development.

The family, significant others, and community sentiment regarding epilepsy were important environmental influences (**Figure 1**). Given the clinical setting, the priority environmental focus was the HCP. A caregiver component was considered, and though valid, represented an extension of project scope without universal relevance to PWE who may lack this social network, who are not accompanied to clinic visits, and who are not ready to involve others in their S-M. Broader community influencers, while important, were also outside the scope of the project.

Task 1.4 State Program Goals

Goals for MINDSET were to influence patient S-M behavior and to influence the mediating patient-provider communication regarding S-M. Respective patient and provider goals for MINDSET included:

1. Patients with epilepsy who use the MINDSET S-M DSS in the context of their usual clinic visit for three consecutive clinic visits over a 9-month period will report at least three fewer "at-risk" S-M behaviors (assessed by the Epilepsy S-M scale) compared to patients who do not use MINDSET.
2. HCPs who use the MINDSET S-M DSS in the context of their usual clinic visit will focus discussion on at least 3 "at-risk" S-M behaviors (assessed by the Epilepsy S-M scale) at every visit with every patient using MINDSET.

IM Step 2: Program Outcomes and Objectives—Logic Model of Change

Step 2 comprised: identification of expected outcomes, performance objectives (POs), and determinants for the behavior and environment; the development of matrices of change objectives; and the construction of a logic model of change for the program. This step enabled the triangulation of data obtained in Step 1 (from theory, empirical findings, and participant involvement) to inform a logic model of change.

Task 2.1 State Expected Outcomes for Behavior and Environment

Expected Behavioral Outcomes. Management Information Decision Support Epilepsy Tool was designed to positively impact S-M behavior for epilepsy that encompassed three domains: Medication management, seizure management, and lifestyle management.

The expected behavioral outcomes for PWE related to each domain were as follows:

- Take AEDs as prescribed by the physician (medication management).
- Prepare for, and respond to, seizure episodes (seizure management).
- Alter behaviors to avoid seizure onset and seizure-related injury (lifestyle management).

Targeted health and quality of life outcomes included decreased seizures (number and duration) and AED side effects and improved daily functioning resulting in improved work productivity, less injury, and reduced ER visits, hospitalization, or death attributable to epilepsy (**Figure 1**).

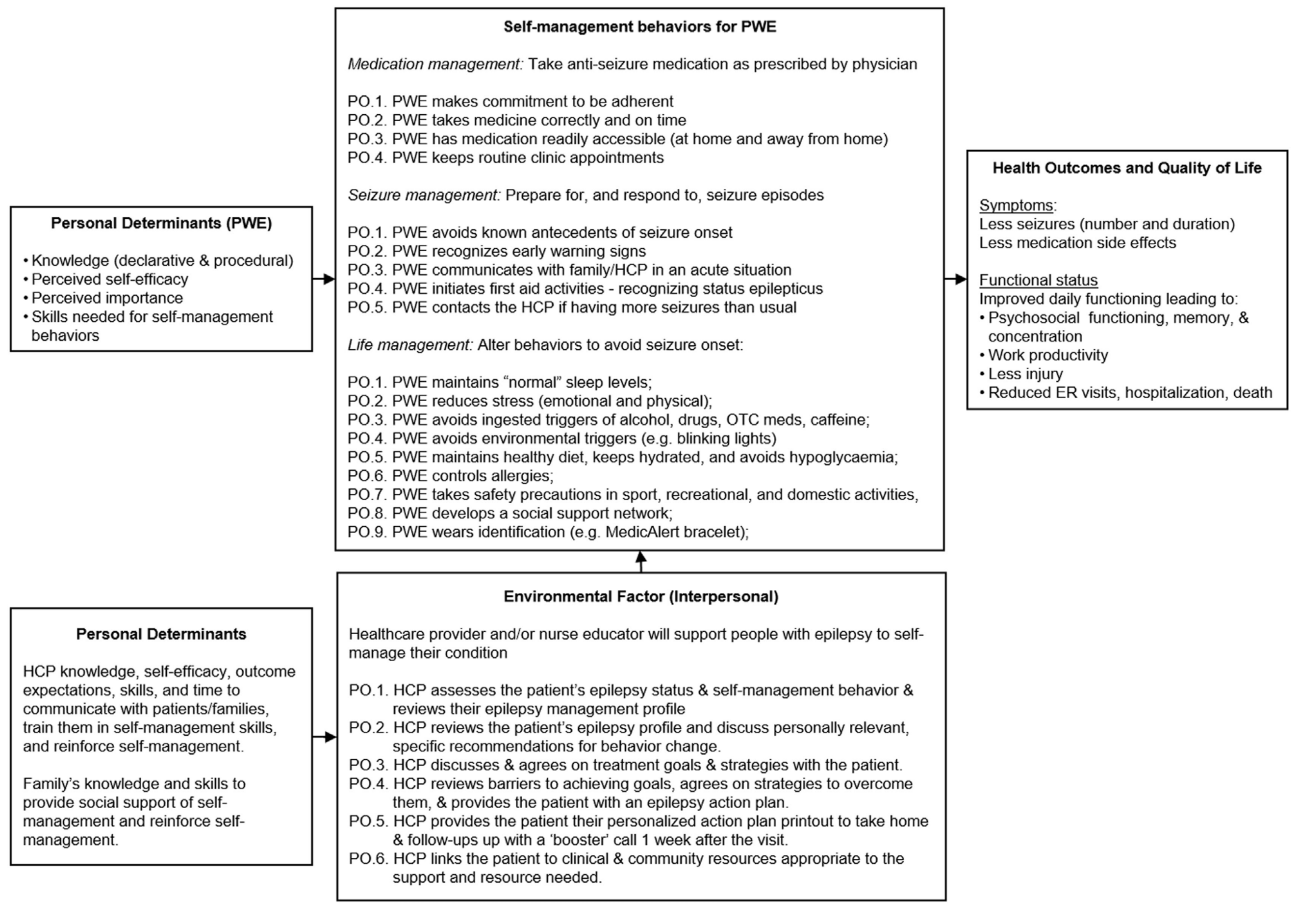
Expected Environmental Outcomes. Management Information Decision Support Epilepsy Tool was designed for use in the clinic visit so S-M assessment and intervention needed to become a minimally invasive component of the clinic flow. Rather than manipulate varied clinic environments (which would be prohibitive when considering future dissemination), the environmental outcome focused on the interpersonal level of the HCP (neurologist and nurse educator). Therefore, the environmental outcome was focused at a personal level:

- HCP and/or nurse educator will support PWE to self-manage their condition.

Task 2.2 Specify POs for Health-Promoting Behavior and Environmental Outcomes

POs for Epilepsy S-M. Performance objectives were described for each S-M outcome: medication management, seizure management, and lifestyle management. These are listed in **Figure 2** and were drawn mainly from review of existing literature and S-M measurement instrument domains (7). MINDSET and the patient action plan alert both the patient and HCP when change in S-M behavior is needed and cues them to decide on S-M priorities or goals based on available evidence and to agree on how best to achieve these S-M changes. The action plan provides the patient with an ongoing resource outside of the clinic visit on priority S-M performance objectives and strategies to achieve them (described further in Task 4.3 below).

POs for HCPs. The environmental focus for MINDSET was for the HCP to support S-M awareness raising and skills training (**Figure 2**). This included identification and review of S-M problems, and discussion with the patient to develop agreed upon S-M behavioral goals. The HCP's behaviors were structured in accordance with the 5 A's model and included requesting the patient complete data input into MINDSET, reviewing their epilepsy management profile, and acknowledging status (ASSESS); reviewing the patient's epilepsy profile, reinforcing past management successes, and discussing personally relevant, specific recommendations for behavior change (ADVISE); reaching agreement on treatment goals with the patient (AGREE); reviewing barriers to achieving goals and agreeing on strategies



Self-management behaviors for PWE

Medication management: Take anti-seizure medication as prescribed by physician

PO.1. PWE makes commitment to be adherent
PO.2. PWE takes medicine correctly and on time
PO.3. PWE has medication readily accessible (at home and away from home)
PO.4. PWE keeps routine clinic appointments

Seizure management: Prepare for, and respond to, seizure episodes

PO.1. PWE avoids known antecedents of seizure onset
PO.2. PWE recognizes early warning signs
PO.3. PWE communicates with family/HCP in an acute situation
PO.4. PWE initiates first aid activities - recognizing status epilepticus
PO.5. PWE contacts the HCP if having more seizures than usual

Life management: Alter behaviors to avoid seizure onset:

PO.1. PWE maintains "normal" sleep levels;
PO.2. PWE reduces stress (emotional and physical);
PO.3. PWE avoids ingested triggers of alcohol, drugs, OTC meds, caffeine;
PO.4. PWE avoids environmental triggers (e.g. blinking lights)
PO.5. PWE maintains healthy diet, keeps hydrated, and avoids hypoglycaemia;
PO.6. PWE controls allergies;
PO.7. PWE takes safety precautions in sport, recreational, and domestic activities,
PO.8. PWE develops a social support network;
PO.9. PWE wears identification (e.g. MedicAlert bracelet);

Personal Determinants (PWE)

- Knowledge (declarative & procedural)
- Perceived self-efficacy
- Perceived importance
- Skills needed for self-management behaviors

Health Outcomes and Quality of Life

Symptoms:
Less seizures (number and duration)
Less medication side effects

Functional status
Improved daily functioning leading to:
- Psychosocial functioning, memory, & concentration
- Work productivity
- Less injury
- Reduced ER visits, hospitalization, death

Environmental Factor (Interpersonal)

Healthcare provider and/or nurse educator will support people with epilepsy to self-manage their condition

PO.1. HCP assesses the patient's epilepsy status & self-management behavior & reviews their epilepsy management profile
PO.2. HCP reviews the patient's epilepsy profile and discuss personally relevant, specific recommendations for behavior change.
PO.3. HCP discusses & agrees on treatment goals & strategies with the patient.
PO.4. HCP reviews barriers to achieving goals, agrees on strategies to overcome them, & provides the patient with an epilepsy action plan.
PO.5. HCP provides the patient their personalized action plan printout to take home & follow-ups up with a 'booster' call 1 week after the visit.
PO.6. HCP links the patient to clinical & community resources appropriate to the support and resource needed.

Personal Determinants

HCP knowledge, self-efficacy, outcome expectations, skills, and time to communicate with patients/families, train them in self-management skills, and reinforce self-management.

Family's knowledge and skills to provide social support of self-management and reinforce self-management.

FIGURE 2 | PRECEDE logic model of change for MINDSET (101).

to overcome them, and providing the patient with an action plan (ASSIST); reviewing epilepsy S-M change at each visit by comparing MINDSET epilepsy profile with that of the previous visit, arranging referrals appropriate to existing co-morbidities in the patient profile, and linking patients to appropriate community resources to provide the support needed (ARRANGE). The briefness of clinic encounters made it challenging to adequately review S-M and such assessments had lacked formality. There was opportunity for relative improvement in the HCP *modus operandi* as it pertained to S-M intervention.

Task 2.3 Select Determinants for Behavioral and Environmental Outcomes

Information obtained from the needs assessment phase (Step 1) and Step 2 literature review informed the specification of determinants for the POs. After reviewing findings from the empirical literature, SCT and self-regulation models, motivational enhancement therapy, and our own formative research (Task 1.2 above), we identified knowledge, self-efficacy, perceived importance, and skills as important and changeable determinants of epilepsy S-M for PWE (**Table 1**). Similarly, we identified knowledge, self-efficacy and skills, and outcome expectations as important and changeable determinants of the HCP's behavior (**Table 2**).

Task 2.4 Construct Matrices of Change Objectives

Matrices were developed that cross-referenced behavioral POs with determinants to produce change objectives. The resulting cells of each matrix contained change objectives that stated what needed to change about a specific determinant (e.g., self-efficacy) for the patient to achieve a specific PO. Change objectives were produced for each relevant cell of the matrix. Example cells from the matrix for adherence to the prescription plan for AEDs are provided in **Table 1**. Similarly, a matrix was developed to describe the behaviors to be engaged in by the HCP that incorporated the MINDSET action plan into the clinic encounter (**Table 2**).

Task 2.5 Create a Logic Model of Change

A logic model provided an understanding of the types of functional components MINDSET would need to provide to impact both the patient's S-M behaviors as well as the HCP-patient discussion of S-M in the clinic visit (**Figure 2**).

IM Step 3: Program Plan

Step 3 comprised the generation of MINDSET's scope and sequence, the choice of theory and evidence-based methods, and the design of practical applications to deliver change methods.

Task 3.1 Generate Program Themes, Components, Scope, and Sequence

The theoretical framework for MINDSET is based in SCT (77), self-regulation models (77, 78) the 5-A's model of behavioral change (92), motivational enhancement therapy (86), quality-of-care criteria and clinical guidelines for epilepsy (13, 33, 34, 83), and formative studies (10, 93) drawn from the review of literature. The literature reviewed in Step 1 on decision support and S-M in epilepsy was particularly helpful in informing methods (10, 25, 94, 95).

The challenge was to develop a program to be able to fulfill five functional objectives involving both the patient and provider, without disrupting the flow of a typical clinic visit:

1. Increase patient awareness about their S-M behaviors.
2. Provide immediate feedback on S-M behaviors.
3. Provide a profile of the patient's S-M behavior for the HCP.
4. Provide tailored S-M behavioral goals for the patient and HCP, including a printable S-M Action Plan.
5. Increase the potential for patient-provider communication of S-M problems and goal setting.

Management Information Decision Support Epilepsy Tool's scope was contained to only relevant data necessary for the visit so as to not unduly intrude on the timing of events in the clinic flow and to not over-burden the patient. These objectives and our observation of the natural clinic flow suggested the scope and sequence of MINDSET. It was possible for the patient to enter and review their data in MINDSET in the waiting room prior to their visit, and then to provide this profile and the tailored action plan to the HCP for review and discussion in the clinic visit. MINDSET's scope and sequence are more fully detailed in Step 4.2 below. The original working title for the program was "Brainstorm." The PPAG advised against this title. While the notions of epilepsy as a brain-related disorder and thinking about management are apparent in this title the term "brainstorm" also has connotations with the erratic neural activity of a seizure and was considered too provocative by patients and providers. The MINDSET acronym, Management Information and Decision Support Epilepsy Tool, offered two contextually related meanings, that of the cognitive profile of the patient explored in the retrospective data input phase, and of "setting" one's mind which relates to the prospective action plan phase.

Task 3.2 Choose Theory and Evidence-Based Change Methods

Individual Behaviors. Theoretical and empirically based methods for S-M education, included chunking of information into a meaningful framework of S-M domains, self-assessment of S-M behaviors, feedback of a S-M profile to the patient to give an assessment of their S-M status, reinforcement for behavioral successes, goal setting to address those behaviors that were a problem for S-M, tailoring of goals based on the patient's individual profile, advance organizers and cue altering for S-M using behavioral strategies, self-monitoring of behaviors and environment, and facilitation and linkage to care/support as needed (**Table 3**). The research team selected methods based on (1) our previous work in decision support of chronic disease (96) and technology-based behavioral change interventions founded in self-regulation frameworks within varied health domains (97–99), (2) empirical evidence for use to impact the target determinants (exemplified in **Table 3**), and (3) the pragmatics of use in a tablet-based program. These methods and their related practical applications (Task 3.3) could all be delivered through repeated exposure to the MINDSET intervention in clinic visits over time. Their operationalization within MINDSET is described in Task 4.1 below.

Clinic Environment. Guidance on how MINDSET could align to existing guidelines, recommendations, and clinic flow was

TABLE 1 | Example cells from the matrix of change objectives for patient behavior.

Behavioral Outcome: people with epilepsy (PWE) will take AED (ASM) as prescribed by physician

Performance objectives (POs)	**Determinants**		
	Knowledge	**Perceived importance**	**Perceived Self-efficacy and skills**
PO.1. PWE makes commitment to be adherent	K1i. Describe how ASMs work K1ii. List consequences of non-adherence K1v. State reasons for taking meds as prescribed (will improve/maintain health, reduce likelihood of seizures, reduce likelihood of accidents or hospitalization)	PI1. State that it is important to take meds as prescribed to improve and maintain health status	SE/S1i. Express confidence and demonstrate ability to commit to ASM adherence SE/S1ii. Express confidence and demonstrate ability to understand how meds work
PO.2. PWE takes medicine correctly and on time	K2i. Describe why, how, and when to take meds correctly (name of pill, time, # pills, with/without food) K2ii. List situations that make taking meds on time difficult K2iii. List cues to action (memory aids) for taking meds correctly (e.g., by toothbrush, pill box, at mealtimes) K2iv. List ways to take meds discretely either at home or away from home K2v. Describe why and how to correctly make up for a missed dose(s) K2vi. State reasons to talk with physician if missing doses K2vii. List side effects	PI2 State that it is important to take meds correctly to improve and maintain health status	SE/S2i. Express confidence and demonstrate ability to take meds as prescribed SE/S2ii. Express confidence and demonstrate ability to take meds discretely if needed SE/S2iii. Express confidence and demonstrate ability to use cues/memory aids SE/S2iv. Express confidence and demonstrate ability to make up a missed dose(s) correctly SE/S2v. Express confidence and demonstrate ability to overcome side effects
PO.3. PWE has medication readily accessible (at home and away from home)	K3i. List personal medications K3ii. Lists places to store medication at home K3iii. List ways to carry medication when away from home K3iv. State how often prescription needs to be refilled K3v. If living alone, state how to refill prescription	PI3i. State that it is important to have medication readily available to reduce the likelihood of missing doses PI3ii. State that it is important to plan ahead to refill prescriptions to ensure constant supply of meds	SE/S3i. Express confidence and demonstrate ability to store medication appropriately at home SE/S3ii. Express confidence and demonstrate ability to carry medication outside of home SE/S3iii. If living alone, express confidence and demonstrate ability in filling prescription on time
PO.4. PWE keeps routine clinic appointments	K4i. State date/time of next appointment	PI4i. State that it is important to keep appointments so that the physician will be better able to monitor health and how well meds are working	SE/S4i. Express confidence and demonstrate ability in recording date/time of the next appt. and in keeping scheduled clinic appointments.

informed by the 5 A's model, quality assurance guidelines, and clinic task analysis. *The 5 A's Behavior Change Model.* The 5 A's Behavior Change Model (used with the Improving Chronic Illness Care Chronic Care Model) provided a framework for developing the scope, contextual fit, and application of MINDSET at the interpersonal (patient-provider interaction) level (81). A tenet of the model is that chronic illness patients have a S-M Action Plan covering the 5 A's elements (Assess, Advise, Agree, Assist, and Arrange). *Quality-of-Care Measures.* Quality-of-care measures for epilepsy management include an array of assessment, treatment, and counseling protocols representing the best practice recommendations (33, 34, 100). Published quality care measures for the clinical management of epilepsy were consulted to determine the context of use for the practice of medicine. Aligning MINDSET function within these protocols positioned it for ready acceptance for clinic use. *Clinic Task Analysis*. Task analysis was conducted to examine the clinic flow in each of the participating clinics to understand the on-site operation and to determine logical opportunities for intervention without compromising that clinic flow (101) (**Figures 3** and **4**). This involved shadowing patients through their clinic visit in each of the participating neurology clinics, examining data flow within the clinic for each patient, decision-making by HCP, interaction points between the patient and provider, and duration in each location.

TABLE 2 | Example cells from the interpersonal environment matrix for 0healthcare providers (HCPs).

Interpersonal outcome: HCP will support people with epilepsy (PWE) to self-manage their condition

Performance objectives (POs)		**Determinants**		
		Knowledge	**Outcome expectations**	**Self-efficacy and Skills**
ASSESS PO.1. HCP assesses the patient's epilepsy status and S-M behavior and reviews their epilepsy management profile	PO.1.i. Assess patient's epilepsy status, including seizure history, medication history, side effects, compliance, and barriers	K1i. Describe how to assess the patient's epilepsy status	OE1i. Expect that determining the patient's epilepsy status leads to more salient treatment goals and better control of epilepsy	SE/S1i. Express confidence and demonstrate ability to interpret the patient's status
	PO.1.ii. Assess patient's S-M for seizure, medication, and lifestyle S-M	K1ii. Describe how to assess the patient's epilepsy S-M behaviors	OE1ii. Expect that determining the patient's epilepsy S-M leads to more salient S-M goals and better control of epilepsy	SE/S1ii. Express confidence and demonstrate ability to interpret the patient's S-M
	PO.1.iii. Assess patient's attitudes (importance and confidence) regarding S-M behaviors	K1iii. Describe how to interpret the patient's perceived importance and self-efficacy to prioritize S-M goals	OE1iii. Expect that determining the patient's perceived importance and self-efficacy for epilepsy S-M leads to more salient S-M goals and better control of epilepsy	SE/S1iii. Express confidence and demonstrate ability to interpret the patient's perceived importance and self-efficacy
	PO.1.iv. Provide patient with personalized feedback on epilepsy status and S-M for review	K1iv. Describe how to ensure the patient has access to an action plan and how to print this for the patient	OE1iv. Expect that providing the tailored action plan to the patient for review will lead to more salient S-M goals and better control of epilepsy	SE/S1iv. Express confidence and demonstrate ability to be able to ensure the patient has access to an action plan and how to print this for the patient
ADVISE PO.2. HCP reviews the patient's epilepsy profile and discusses personally relevant, specific recommendations for behavior change	PO.2.i. Relate patient symptoms or lab results to their behavior, recognizing patient's culture or personal illness model	K2i Describe how including patient's input in goal setting leads to greater adherence to the treatment plan	OE2i. Expect that creating patient treatment goals leads to better control of epilepsy	SE/S2i. Express confidence and demonstrate ability to determine appropriate treatment goals from patient information
	PO.2.ii. Inform patient that management is more than just taking medications	K2ii List reasons to treat epilepsy as a chronic illness	OE2ii. Expect that explaining S-M goals for epilepsy management will help the patient to achieve the outcomes described	SE/S2ii. Express confidence and demonstrates ability to be able to persuade patients that better function is possible when epilepsy is well treated
	PO.2.iii. Provide specific, documented behavior change advice (action plan) in the form of a prescription	K2iii Show familiarity with the action plan	OE2iii. Expect that using the action plan will enable patient to better manage epilepsy	SE/S2iii. Express confidence in being able to use plan at each visit
AGREE PO.3. HCP discusses and agrees on treatment goals and strategies with the patient	PO.3.i. Review with patient prioritized goals in the patient's action plan	K3i. Describe how to review prioritized goals in the patient's action plan	OE3i. Expect that reviewing prioritized goals in the patient's action plan leads to greater adherence to the action plan	SE/S3i. Express confidence and demonstrate ability to review prioritized goals in the patient's action plan
	PO.3.ii. Discuss and agree on specific goals to achieve by the next visit	K3ii. Describe how to include patient's input in goal setting for shared decision-making	OE3ii. Expect that agreeing and meeting S-M goals will lead to better control of epilepsy	SE/S3ii. Express confidence and demonstrate ability to discuss and agree on appropriate treatment goals with the patient.
	PO.3.iii. Review recommended strategies with the patient needed to achieve targeted goals	K3iii. Describe how to include patient's input in strategies for shared decision-making.	OE3iii. Expect that agreeing on strategies to meet S-M goals will lead to a greater chance of achieving those goals	SE/S3iii. Express confidence and demonstrate ability to review strategies to achieve S-M goals with the patient

(*Continued*)

TABLE 2 | Continued

Interpersonal outcome: HCP will support people with epilepsy (PWE) to self-manage their condition

Performance objectives (POs)		**Determinants**		
		Knowledge	**Outcome expectations**	**Self-efficacy and Skills**
	PO.3.iv. Review barriers to meeting S-M goals: Ask patient, "What are your most challenging barriers?," recognizing physical, social and economic barriers	K3iv Describe how to review barriers to S-M goals using the action plan	OE3iv. Expect that reviewing barriers to S-M goals will lead to better S-M practice	SE/S3iv. Express confidence and demonstrate ability to be able to review barriers to S-M goals using the action plan
ASSIST PO.4. HCP reviews barriers to achieving goals, agrees on strategies to overcome them, and provides the patient with an epilepsy action plan	PO.4.i. Help patient develop strategies to address barriers to change (write on Action Plan form) (ask is there anything that would prevent you from doing these strategies?)	K4i. Describe how to review barriers and elicit patient's input in strategies to overcome barriers	OE4i. Expect that listing barriers and strategies to overcome them will lead to a greater chance of achieving S-M goals	SE/S4i. Express confidence and demonstrate ability to determine barriers and list strategies to overcome them
	PO.4.ii. Refer patient to evidence-based education or behavioral counseling – individual or group	K4ii. Describe how to refer the patient to evidence-based education or behavioral counseling	OE4ii. Expect that referring the patient to evidence-based education or behavioral counseling will lead to a greater chance of achieving S-M goals	SE/S4ii. Express confidence and demonstrate ability to refer the patient to evidence-based education or behavioral counseling
	PO.4.iii. Elicit patient's views and plans regarding potential resources and support within family and community	K4iii. Describe how to elicit the patient's views and plans regarding family support	OE4iii. Expect that eliciting the patient's views and plans regarding family support will lead to a greater chance of achieving S-M goals	SE/S4iii. Express confidence and demonstrate ability to elicit the patient's views and plans regarding family support
ARRANGE	PO.5. HCP provides the patient with their personalized action plan printout to take home and follows-up with a "booster" call 1 week after the visit.	K5. Describe the process to provide the action plan and conduct a follow-up booster	OE5. Expect that providing the action plan and booster follow-up call will lead to better epilepsy S-M behavior	SE/S5. Express confidence and demonstrate ability to action plan and follow-up booster call
	PO.6. HCP links the patient to clinical and community resources appropriate to the support and resource needed	K6. Describe the process to link patients to clinical and community resources	OE6. Expect that linkage to clinical and community resources tailored to patient needs will lead to better epilepsy S-M behavior	SE/S6. Express confidence and ability to provide linkage to clinical and community resources

Task 3.3 Select or Design Practical Applications to Deliver Change Methods

The planning team selected specific practical applications to operationalize the theory-based change methods in ways that fit the population and setting for the intervention. We designed MINDSET to be easy to use by physician and patient and portable to be able to accompany the patient through the clinic visit. A PC tablet-based tailored self-assessment approach appeared feasible for intervention delivery. Inclusion of data familiar and important to HCPs (e.g., seizure frequency and history, medication missed doses, and side effects) were included with the less familiar data on S-M behaviors for seizure, medication, and lifestyle management to provide added salience for use in the clinic setting. Clinic visit time constraints further suggested the advantages of tailoring data input such that patients would only enter their perceived self-efficacy and importance for "flagged" S-M problem behaviors. An action plan that could be printed in the clinic provided a vehicle for use by both patient and provider during the clinic visit as well as an ongoing reference by the patient between clinic visits.

IM Step 4: Program Production

Step 4 comprised refinement of the program's structure and organization, planning for program materials, drafting of messages and materials, and pretesting, refinement, and production of materials.

Task 4.1 Refine Program Structure and Organization

Management Information Decision Support Epilepsy Tool is provided on a tablet-based platform to provide S-M decision

TABLE 3 | Example of methods and practical applications used in MINDSET to impact the determinants (knowledge, self-efficacy, perceived importance, and skills) for adhering to prescribed medications.

Behavioral outcome: people with epilepsy (PWE) will take anti-seizure medicine as prescribed by physician.
Performance objective (PO) 2: PWE will take medications correctly and on time

#	Objective	Method	Practical applications
	KNOWLEDGE		
1	K2iii list cues to action for taking meds	Chunking	Epilepsy management is categorized into 3 domains to enable the patient to organize what is a complex array of behaviors. The domains are management for seizures, medication, and lifestyle. Cues to action for taking meds, therefore, occurs within the domain if medication management
3		Feedback, Information transfer, Consciousness raising	The patient profile and action plan indicate the patient's adherence status including "at-risk" medication management behavior, and how this has changed since the last visit (improved, worsened, no change), barriers to medication taking, self-efficacy, and importance
4		Reinforcement and remediation	The profile and action plan provide remediation that stresses the importance of medication management behaviors (e.g., strategies)
6		Tailoring	The patient profile and action plan are tailored to provide a list of S-M goals salient to the patient (based on data input) based on assessment of importance and self-efficacy. If the patient rates the medication adherence behavior as important and s/he has low efficacy to perform this behavior then the adherence behavior will be listed as a higher priority in the action plan
8		Advance organizing	The patient profile provides advice boxes and the action plan provides bulleted strategies on how to list cues to action for medication adherence
9		Cue to action	A cue is provided for the patient to discuss the medication adherence goal with the HCP during the clinic visit and a list of strategies related to memory aids is provided
	SELF-EFFICACY AND SKILLS		
10	SE2iii express confidence in ability to use cues/memory aids	Reinforcement and remediation	The profile and action plan provide reinforcement messages (congratulatory statements) to patients who have no flagged medication management behaviors
			The profile and action plan provide remediation stressing the importance of medication management behaviors
11		Goal setting	If medication adherence behavior is flagged as "at-risk" then this behavior is reframed in the action plan as a S-M goal
12		Tailoring	The patient profile and action plan are tailored to provide a list of S-M goals salient to the patient (based on data input) based on assessment of importance and self-efficacy. If the patient rates the medication adherence behavior as important and s/he has low efficacy to perform this behavior then the adherence behavior will be listed as a higher priority in the action plan
13	S2iii demonstrate ability to use memory aids	Planning coping responses	Patient and HCP review and discuss causes (barriers) for medication non-adherence and review the patient profile and action plan for recommended strategies
			Patient and provider agree on the patient's commitment to the medication adherence goal
14		Cue altering	Patient and HCP rehearse specific strategies and patient initiates cues to ensure adherence. For example, keeping a pill box in toiletry bag to cue packing meds before a trip and tagging refill dates on work schedules
15		Self-monitoring	Patient maintains a record of medication adherence
16		Facilitation/Linkage to care/support	Patient is linked to resources (e.g., Epilepsy Foundation) for more strategies
17		Repeated exposure	MINDSET is provided at each clinic visit
	IMPORTANCE		
18 19	PI2 state that it is important to take medications correctly to improve and maintain health status	Self-assessment	The patient inputs information on his/her medication adherence and medication management behavior and, if adherence is a problem, barriers to medication taking, self-efficacy, and importance
20		Reinforcement and remediation	The profile and action plan provide reinforcement messages (congratulatory statements) to patients who have no flagged medication management behaviors through
			The profile and action plan provide remediation stressing the importance of medication management behaviors
21		Goal setting	If medication adherence behavior is flagged as "at-risk" then this behavior is reframed in the action plan as a S-M goal.
22		Tailoring	The patient profile and action plan are tailored to provide a list of S-M goals salient to the patient (based on data input) based on assessment of importance and self-efficacy. If the patient rates the medication adherence behavior as important and s/he has low efficacy to perform this behavior then the adherence behavior will be listed as a higher priority in the action plan

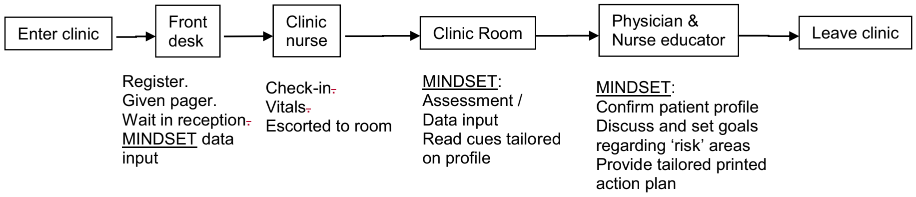


FIGURE 3 | Management Information Decision Support Epilepsy Tool (MINDSET) use within the clinic visit and top-level flow (101).

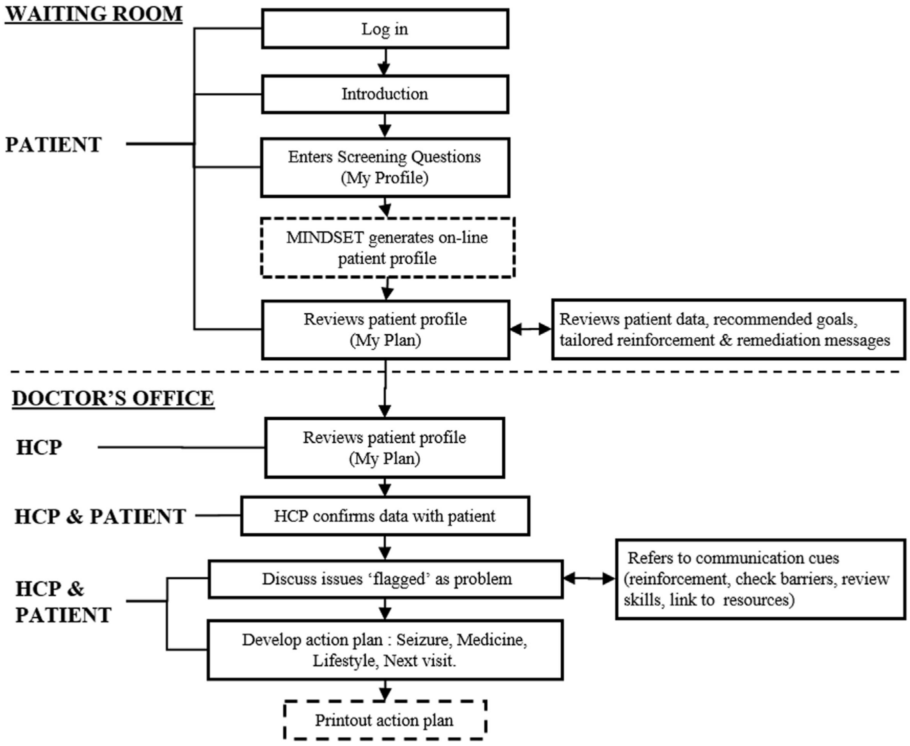


FIGURE 4 | Management Information Decision Support Epilepsy Tool (MINDSET) upper-level flow (101).

support to patients (≥18 years) and HCPs during their clinic visit and a printable action plan to provide decision support to patients outside the clinic (102). Originally mounted on an Archos 101 Android tablet platform (and subsequently on a Windows-based Dell platform), the use of MINDSET in the clinic comprises: (1) data entry by the patient; (2) data review by the patient and HCP; and (3) discussion by the patient and HCP of issues, goals, and strategies in conjunction with a tailored action plan (102). MINDSET was designed for the patient to enter data in the waiting room, prior to seeing their HCP. Data represented three epilepsy S-M domains: medication; seizures; and lifestyle. The method of chunking (**Table 4**, #1) informed us in distilling the complexity of epilepsy S-M into questions assessing 3 management domains and 13 S-M sub-domains including medication S-M ("current AED prescriptions, medication adherence, adherence barriers, side effects, and medication, S-M behaviors"), seizure S-M ("the patient's recent seizure history, including frequency and type, and seizure S-M behaviors"), and lifestyle S-M ("including mood, social life including sexual relationships, child care, employment, and driving, physical activity, safety, record keeping, social support, and clinic visits") (102).

Patient Data Entry for Assessment. Scales were embedded in MINDSET to provide assessment of the critical behaviors and determinants previously identified (**Tables 1** and **2**). A design specification was that MINDSET be minimally intrusive of clinic flow and patient burden. Therefore, an assessment battery was designed that collected information based on theory and empirical relevance, availability of a comprehensive and psychometrically valid scale, and clinical practice needs. For this reason, the determinant of knowledge was not assessed in MINDSET, though addressed in tailored messaging and action plan feedback. Furthermore, in response to the need for utility for use, assessment was tailored such that data were collected only when

TABLE 4 | Examples of theoretical methods and practical applications used in MINDSET.

#	Method	Definition	Practical applications
1	Chunking	Using stimulus patterns that may be made up of parts but that one perceives as a whole	Organization of the complexity of epilepsy S-M into sub-categories and domains. For example, the patient completes MINDSET S-M assessment by addressing behaviors related to seizure management, then medication management, then lifestyle management
2	Self-assessment, Consciousness raising, Information transfer	Providing information, feedback, or confrontation about the causes, consequences, and alternatives for a problem or a problem behavior	Providing the patient with an epilepsy S-M profile raises awareness of issues that had previously been ignored. Tailored advice messages on the printed action plan list examples of behavioral strategies to meet S-M goals (see **Table 7**)
3	Feedback	Giving information regarding the extent to which the individual is accomplishing learning or performance, and the extent to which the performance is having an impact	The patient's action plan provides an indicator for how a "risk" behavior has changed since the last visit (improved, worsened, no change)
4	Tailoring	Matching the intervention and components to previously measured characteristics of the participant	The patient profile and action plan are tailored on the S-M data provided by the patient. S-M goals are prioritized by flagged behaviors and patient ratings of self-efficacy and importance of the behavior. The patient's action plan is dynamically built in response to the patient's individual profile data
5	Reinforcement	Linking the behavior to any consequence that increases the behavior's rate, frequency and probability	The profile and action plan provide reinforcement messages to patients who have no flagged behaviors through congratulatory statements in the action plan
6	Advance organizing	Presenting an overview of the material that enables a learner to activate relevant schemas so that new material can be associated	The Action Plan delivers a S-M profile and goals in a logical format that mirrors the conceptualization of S-M within 3 domains to simplify understanding of what needs to be done. The MINDSET action plan provides recommended strategies to support S-M goals to prevent seizures
7	Goal setting	Prompting planning what the person will do, including a definition of goal-directed behaviors that result in the target behavior	Commitment to S-M goals that are agreed on by patient and provider. Flagged behaviors are reframed in the action plan as S-M goals (e.g., Make sure to get enough sleep)
8	Cues to action	Providing opportunities for learners to have personal questions answered or instructions paced according to their individual progress	Cues are provided for the patient to discuss "at-risk" (flagged) behaviors with the HCP during the clinic visit
9	Planning coping responses	Getting a person to identify potential barriers and ways to overcome these	Discussion of causes for non-adherence of anti-seizures medication and review of recommended strategies to derive ways to overcome barriers to adherence
10	Cue altering	Teaching people to change a stimulus that elicits or signals a behavior	A strategy is provided to introduce cues to pack sufficient anti-seizure when packing for a trip
11	Self-monitoring	Prompting the person to keep a record of specified behaviors	Recommended strategies for monitoring include record keeping (e.g., a symptom diary and seizure tracking) to enable better understanding of seizure antecedents
12	Facilitation/Linkage to care/support	Creating an environment that makes the action easier or reduces barriers to action	MINDSET provides linkage to community resources and support groups that are also printed in the action plan (e.g., Epilepsy Foundation)
13	Repeated exposure	Making a stimulus repeatedly accessible to the individual's sensory receptors	MINDSET is provided at each clinic visit

necessary for a given patient. For example, data on perceived self-efficacy and importance were only collected on a behavior if that behavior was flagged as "at-risk" (less than optimal adherence frequency), described in Task 4.2 and **Figure 5** below.

Assessment of S-M Behaviors. Self-assessment was an important method applied within MINDSET (**Table 4**). Assessment of S-M behavior was collected using the 38-item *Epilepsy S-M Scale* (7, 8, 16, 55) that delineates behaviors regarding medication adherence, seizures, information, safety, and lifestyle. Responses were entered using a button selection on a 5-point Likert scale ranging from "never" to "always." Perceived self-efficacy to perform S-M behaviors was assessed using a 33-item *Epilepsy Self-Efficacy Scale* (7). Responses were entered on a sliding scale (slider bar) adapted from motivational enhancement protocols (86) with a response set ranging from 0 to 10 with 0 being not at all confident (I cannot do at all) and 10 being extremely confident (Sure I can do) (8, 56). Self-efficacy items were completed for those behaviors flagged as "at-risk." Also adapted from the use of decision rulers from motivational enhancement protocols was the assessment of importance. Responses were based on a sliding scale from 1 to 10 with 1 indicating not important and 10 indicating extremely important (86).

Assessment of Medication Side Effects and Barriers to Adherence. Medication side effects represent an important clinical parameter to inform AED prescription as well as motivation for medication adherence. Side effects were assessed using a 19-item *Epilepsy Adverse Events* profile assessing reported problems during the previous four weeks from a list of 19 adverse effects (**Table 5**) (34, 103–105). The scale assessed reported problems during the previous 4 weeks from a list of 19 adverse drug

TABLE 5 | Items assessing medication side effects and barriers.

Anti-seizure medicine side effects (adverse effects scale)	Medication barriers (adapted from HIV scale)
• None • Unsteadiness • Tiredness • Restlessness • Aggression • Nervousness • Hair loss • Skin changes or rash • Blurred vision • Upset stomach • Concentration difficulty • Mouth/gum problems • Shaky hands • Weight gain • Dizziness • Sleepiness • Depression • Memory problems • Disturbed sleep	• I simply forgot • I don't like taking pills • I thought the drug was toxic or harmful • I felt depressed or overwhelmed • I felt sick • I wanted to avoid side effects • I was away from home • I was busy with other things • I had a change in my daily routine • I found it difficult to take pills at specified times • I slept through the dose time • I did not want others to notice me taking medication • I had too many pills to take • I ran out of medicine and didn't fill the prescription in time • I have difficulty storing/carrying meds • I have difficulty paying for meds • I have problems filling my prescription • Other

effects (**Table 5**). The original instrument used a 4-point Likert scale response set: 1. Never a problem; 2. Rarely a problem; 3. Sometimes a problem; 4. Always a problem (103). Barriers to AEDs were assessed using a list of 18 barriers to medication adherence (adapted from previous studies) and provided to patients reporting missed doses (**Table 5**) (88).

Assessment of Depression. Depression is a common co-morbidity of epilepsy that can compromise S-M practice. MINDSET was not initially designed to intervene on depression directly and S-M matrices were developed for patients who were physically and cognitively capable of S-M practice. However, the MINDSET planning team saw the potential of MINDSET providing neurologists with the benefit of rapid assessment. Depression was assessed using the 6-item Neurological Disorders Depression Inventory for Epilepsy (NDDI-E) Screening Tool that assesses the degree of depressive symptoms in the last week (106–108). Patients were "prompted to provide the answer that best described them over the last 2 weeks for 'everything is a struggle', 'nothing I do is right', 'I feel guilty', 'I'd be better off dead', 'I feel frustrated', and 'I had difficulty finding pleasure'. The response set was a 4-point Likert scale ranging from never to always or often (102)." "NIDDI-E scores of above 15 were considered positive for depression, with specificity of 90%, sensitivity of 81%, and positive predictive value of 0.62" based on the mini international neuropsychiatric interview (MINI) (102, 107, 108).

Patient Review of the S-M Profile. Immediate feedback is an important method applied in MINDSET (**Table 4**, #3). A profile is produced by MINDSET. The patient can review this in the waiting area and then share it with the HCP (**Figure 3**). The profile summarizes responses on medication, seizures, and lifestyle, and flags "at-risk" behaviors based on a comparison of the frequency of the behavior to benchmarks. As previously described, the patient rates his/her self-efficacy (confidence) and perceived importance to perform any S-M behavior that is flagged (**Table 4**, #4). Based on programmed benchmarks for behavior (frequency), self-efficacy (degree of confidence), and perceived importance, the profile provides a prioritized list of behavioral issues for discussion, goal setting, and action. The profile has accompanying tailored advice boxes to increase awareness about strategies to improve S-M behaviors. If the patient reports no problems with S-M behaviors (i.e., he/she has no flagged behaviors), reinforcement is provided in a text-based congratulatory message (**Table 4**, #5). The advice boxes are also available to provide anticipatory guidance (or advance organizers) in the form of specific behavioral strategies to consider in the future (**Table 4**, #6). When sharing MINDSET, both the patient and HCP can tab to a list of recommended action items and discuss the items and set goals (**Table 4**, #7). "The process of using MINDSET is designed to promote shared decision-making where a patient and HCP can assess the need for improvements (both medical and psychosocial) and make subsequent informed treatment and behavioral change decisions (102)." The applications, messages, and cues for discussion (**Table 4**, #8) are designed to impact determinants of knowledge, self-efficacy, perceived importance, and skills (**Table 1**).

HCP-Patient Review and Discussion of the S-M Profile and Action Plan. Providing patients with a decision aid to document S-M behaviors and guide future S-M goals is consistent with other approaches to chronic disease management (e.g., asthma) (109). For epilepsy S-M, such tools have focused on acute seizure management and not broader S-M domains inclusive of medication or lifestyle behaviors (110). MINDSET flow and function provides the HCP with an intuitive scaffold to progress through the management steps of assess, advise, agree, assist, and arrange (**Table 2**), allowing a rapid review of a patient's status, reviewing strategies to plan coping responses (**Table 4**, #9), to alter behavioral cues (**Table 4**, #10), to institute self-monitoring (**Table 4**, #11), and to link to family and community support as needed (**Table 4**, #12). The process of using MINDSET is reiterated at each clinic visit (**Table 4**, #13).

Task 4.2 Prepare Plans for Program Materials

A program design document provided the blueprint for MINDSET, informed by our understanding of patient characteristics, including knowledge, education, cognitive capacity, and time available for learning and discussion in the clinic setting (10). The team developed flowcharts to establish the function of MINDSET for the programmer, depicting the steps in the development of a tailored S-M action plan focused on AED adherence, seizure management, and lifestyle management (**Figure 5**). Flow charts and screen map mock-ups were developed as Powerpoint slides to depict MINDSET content, function, position of menu options, data entry components, patient profile display screens, and tailored feedback (bullets and cues). These "proof-of-concept" layouts illustrated what the patient and provider would see (the look and feel of the program).

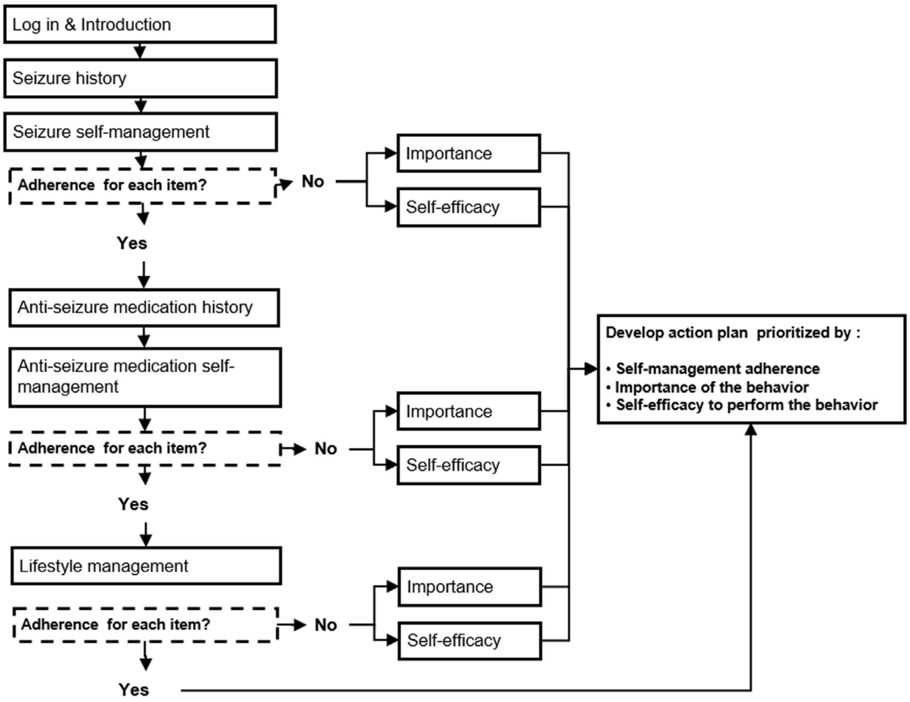


FIGURE 5 | Management Information Decision Support Epilepsy Tool (MINDSET) decision flow to produce a tailored action plan (101).

Initial mock-ups depicted the following: (1) screening assessment and (2) decision support for intervention on S-M (**Figure 6**). The screening assessment consisted of computer-based prompts for the patient to input data (based on the data acquired from the screening tool, see Section "Task 4.1 Refine Program Structure and Organization" above) (10). The decision support was designed to provide feedback to both the patient and the provider in the form of confirmation of the patient's profile on clinical and psychosocial variables; cues on discussion points during the clinic visit; and S-M goals and an action plan for after the clinic visit. The algorithm for prioritizing the S-M goals on the basis of patient self-report is illustrated in **Figure 6**. The development of flowcharts and screen maps was an iterative process and an essential one that helped guard against serious error or logical flows in the finished product. The design of an intuitive user interface was essential so that someone unfamiliar with the program could easily use it. A dedicated formative PPAG meeting, held at the KS Clinic conference room, provided a review and feedback on the design documents including content, design (interface) features, navigation, functionality, language, logistics of use and implementation in the clinic, orientation needs, and evaluation specifications. The aim was to uncover any concerns with these program elements as well as recommendations for improvement of MINDSET for PWE prior to programming. The PPAG was provided a simulated "walk through" of MINDSET from log-in through action plan review using projected screen "mock-ups" on Powerpoint slides. Flowcharts were used to illustrate MINDSET use in the context of the clinic visit. The PPAG had few concerns about the use of MINDSET within the clinics and the top-level flow of the program. Their concerns were mainly focused on clarity and completeness. Suggestions for improved clarify included defining medical terms (e.g., in describing seizure types) and specifying general terms (e.g., "wellness"). Suggestions for completeness included adding "choose all that apply" and "I don't know" options to data collection items; adding dosage amounts for assessment of medication adherence; and addition of items focused on negotiating independence and privacy. Design document revisions were made in response to PPAG consensus.

Task 4.3 Draft Messages, Materials, and Protocols

Programming followed a stepped sequence. At each developmental step all components of the program were taken one draft further toward completion, building upon the review of previous developmental steps. This process ensured that all elements of the program had been developed with the benefit of multiple reviews by the research team. Structured programming techniques were used to develop the program and reduce needed refinements. The Archos 101 Android tablet platform provided the first MINDSET hardware platform, later superseded by the Dell Latitude. Patients and providers interacted with MINDSET using a stylus or touch screen. The program was button and menu driven and designed for intuitive, easy navigation for both patient and provider with a limited depth of screens, ensuring providers could review the patient's entire profile in two stylus button presses and not need to "drill down" for data deeper than two screens.

Data input was in the form of pre-existing items from the previously validated surveys embedded in MINDSET (see Task 4.1 Refine Program Structure and Organization above). Tailored

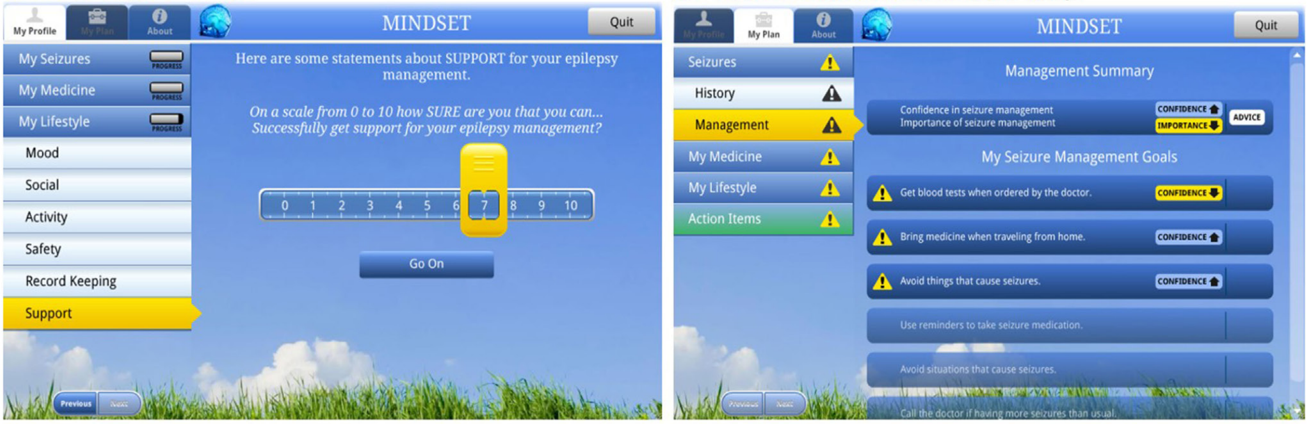
mind-set
-noun
1. an attitude, disposition, or mood.
2. an intention or inclination.

Here are some questions about your SEIZURE MEDICINES. Choose the answer that is most correct for you.

What side effects are you having from your seizure medicine? (Check all that apply)

MINDSET: Splash screen

MY PROFILE: AED side effect data entry



Here are some statements about SUPPORT for your epilepsy management.

On a scale from 0 to 10 how SURE are you that you can... Successfully get support for your epilepsy management?

Confidence in seizure management
Importance of seizure management

Get blood tests when ordered by the doctor.
Bring medicine when traveling from home.
Avoid things that cause seizures.
Use reminders to take seizure medication.
Avoid situations that cause seizures.
Call the doctor if having more seizures than usual.

MY PROFILE: Self-efficacy slider bar

MY PLAN: Seizure management goals

FIGURE 6 | Management Information Decision Support Epilepsy Tool (MINDSET) user interface (101).

TABLE 6 | Tailored Segue Messages Based on Confidence and Importance Feedback Exemplified for Medication Management.

Self-efficacy	Importance		HCP POs (Table 2)
	Low	High	
Low	You have reported that you are not confident that you can take your seizure medicine as your doctor has prescribed and don't think this is highly important to do *Advice*: Discuss this with your doctor and use the activities listed in your MINDSET action plan to help you	Congratulations on recognizing the importance of taking your seizure medicine as your doctor has prescribed. Despite this, your answers suggest that you are not confident of taking your medicine as your doctor prescribed *Advice*: Discuss this with your doctor and use the activities listed in your MINDSET action plan to help you	PO.1.iii. Assess patient attitudes (importance and confidence) regarding S-M behaviors PO.1.iv. Provide patient with personalized feedback on epilepsy status and S-M for review
High	Congratulations on being confident that you can take your medicine as your doctor prescribed. Despite this, your answers suggest that you don't think taking medicine is highly important *Advice*: Discuss this with your doctor and use the activities listed in your MINDSET action plan to help you	Congratulations on recognizing the importance of taking your medicine and being confident that you can follow your prescription plan *Advice:* Use the MINDSET program to help you and your doctor provider review all the aspects of your epilepsy S-M	

messages were created from permutations of these data. Segue messages confirmed the patient's self-efficacy (low/high) and perceived importance (low/high) regarding a particular flagged behavior and provided a cue to the need for further discussion and reference to the action plan (**Table 6**). Tailored messages in the action plan were guided by the 5-A's model: Confirming the patient's S-M profile (including citing the flagged behavior) and reinforcing S-M success (Assess), stating the behavior goal to mitigate the behavioral problem (Agree), providing strategies and recommendations specific to flagged behaviors (Assist) and cued discussion with the HCP (Advise) (**Table 7**).

Task 4.4 Pretest, Refine, and Produce Materials

Upon completion MINDSET was pretested and refined through an in-house alpha test and a usability test.

MINDSET Alpha Test for Functionality. An in-house alpha test was conducted by the MINDSET research team to ensure all program components and functions conformed to the intentions of the designers, functioned appropriately, and presented no anomalies ("bugs"). Research team members each completed MINDSET, simulating a patient with particular epilepsy S-M profiles. They completed logs recording any problems encountered that included incorrect logic, program bugs, syntax errors, or interface design problems. They completed the problem log by recording their location in the program, the user initiated events that preceded the problem, and a description of the problem (including screen captures where appropriate). Problems were collated and sent to the programming team for further troubleshooting and revision prior to usability testing.

MINDSET Usability Testing with PPAG. Patient Provider Advisory Group patients from three clinic sites (36–53 years of age, prescribed at least one AED, mainly female and ethnic minority) and 4 HCP from the planning team were asked to use the MINDSET prototype in "laboratory" conditions (a dedicated conference room at Kelsey–Seybold clinic) not associated with their regular clinic visit. Hypotheses for usability testing were that patient ratings on usability parameters (measured on a usability survey) would exceed an *a priori* benchmark of 70% agreement

TABLE 7 | Example Management Information Decision Support Epilepsy Tool (MINDSET) messaging and associated objectives for a patient who reports forgetting to take seizure medicine.

5-A steps	Message	Associated objectives
Assess: confirm status	*What you told MINDSET*: you [sometimes, always] forget to take your seizure medicine. You should feel proud of all the times you have taken your seizure medicine as your doctor has prescribed. Forgetting to take your medicine can cause seizures so make sure you talk to your doctor about this	*Change objective (HCP* **Table 2***)* PO.2.iii. Provide specific, documented behavior change advice (action plan) in the form of a prescription
Agree: make this part of your goal	*Your goal:* Make reminders to take your seizure medicine part of your daily activities	
Assist: develop strategies to overcome barriers, refer to evidence-based education, refer to resources, discuss with your HCP	*Your strategy:* Try these actions if you have problems remembering to take your seizure medicine: • Take your medicine with daily activities (breakfast, dinner, during TV show, before going to bed) • Use a pill container • Use a calendar or a set a daily reminder on your phone's calendar • Use a seizure diary to keep track of when you take medicine • Use electronic reminders, text or email, sent to you when it's time for your medicine. See "My Epilepsy Diary" or "Texting 4 Control" in the resource list of your action plan.	*Change objective (Patient* **Table 1***)* K2iii. List cues to action (memory aids) for taking meds correctly (e.g., by toothbrush, pill box, at mealtimes)
Advise: cue discussion to acknowledge, reinforce, and agree on strategies to meet S-M goals	Patient and HCP are cued to discuss this "flagged" behavior to: (1) acknowledge status (2) reinforce past successes (3) reach agreement on the goal (4) review and agree on strategies (5) review barriers to the selected strategies and how to overcome these	*Change objectives (Patient* **Table 1***)* • S2iii. Demonstrate how to use cues/memory aids • SE2iii. Express confidence in ability to use cues/memory aids *POs (HCP* **Table 2***)* • PO.4.i. Help patient develop strategies to address barriers to change (write on Action Plan form) (ask is there anything that would prevent you from doing these strategies) • PO.4.ii. Refer patient to evidence-based education or behavioral counseling – individual or group • PO.4.iii. Elicit patient's views and plans regarding potential resources and support within family and community
Arrange: printout and linkage	Messages printed in the action plan including community resources	*Associated change objectives (Patient* **Table 1***)* • K2iii. List cues to action (memory aids) for taking meds correctly (e.g., by toothbrush, pill box, at mealtimes) *Associated POs (HCP* **Table 2***)* • PO.5. Provide the patient their personalized S-M Action Plan and follow-up call to patient within a week after visit as "booster" for S-M Action Plan • PO.6. Link patients to clinical and community resources appropriate to support and resource needed

and that HCPs would rate MINDSET features (measured on a features checklist) as providing improvement to their current practice. After an orientation, patients were asked to access all elements of MINDSET (the screening tool, patient profile, recommendations, and action plan) and to verbally describe and interpret what they were seeing and doing. Any problems (as previously described for alpha testing) were recorded and collated. Patients then completed a usability survey assessing the functions of MINDSET and were interviewed on how MINDSET could be improved in terms of content, function, and interface design. Data were gathered on the patient's satisfaction with the user interface, ease of use (usability), acceptability, credibility, and applicability of the system to their needs using previously validated usability measures. HCPs were provided with a MINDSET tablet that had pre-loaded data on a patient whose profile indicated clinical and psychosocial S-M needs. Patients rated MINDSET favorably on usability parameters, providing 80 to 100% agreement that it was easy to use, likable, credible, understandable, and appealing. This exceeded *a priori* success criteria of at least 70% agreement (94, 95). Patients appreciated the opportunity to thoroughly review their epilepsy management: "It makes me look @ problems in my lifestyle/mood," and to receive advice: "I *love* the advice sections"; "the advice sections were really useful for me"; and to organize their thoughts prior to the clinic encounter ":… opportunity to remember everything to discuss with doctor"; "the information and seizure history for the doctor is great"; and "Helped condense my thought and organized any questions I might have." HCPs rated MINDSET as increasing the ease, thoroughness, accuracy, and communication in each of the S-M domains ("seizure history and management, medication management, lifestyle management, and providing an epilepsy action plan") (102).

Reported barriers to use of MINDSET included that the questions (behavior and self-efficacy) seemed repetitive; that patients required assistance due to technical difficulties with the tablet that delayed system responsiveness (distinct from a need to clarify data input questions); and that, while patients advocated the use of MINDSET, they suggested the need for patience for data entry due to the extensive data input in the My Profile section. Modifications were made in response to these issues. These focused on technical/functional fixes, on adjusting clinic expectations on the time commitment for data entry, and alerting patients to the apparent repetition of data input items. The usability data indicated that MINDSET showed initial promise in facilitating the operationalization of S-M constructs for screening, management, and education; the application of clinical guidelines; and was feasible for clinic use. The HCPs rated MINDSET favorably on thoroughness; but also rated it as requiring more time for the clinic encounter.

IM Step 5: Implementation Plan

Step 5 comprised describing potential program implementers, stating the outcomes and POs for implementation, constructing matrices of change objectives for implementation, and designing implementation interventions. An implementation intervention for wide scale adoption, implementation, and maintenance of MINDSET can be developed pending the intervention's demonstrated efficacy to enhance epilepsy S-M behaviors.

Task 5.1 Identify Potential Program Implementers

Management Information Decision Support Epilepsy Tool was designed for use by HCPs in specialty neurology clinics managing outpatients with epilepsy. Thus, potential adopters included specialty clinic directors or upper-level administrators; potential implementers included HCPs such as neurologists, epileptologists, and nurse educators.

Task 5.2 State Outcomes and POs for Implementation

Performance objectives for adoption were brainstormed by the research team with consideration of the decision-makers in neurology clinics, and informed by the IM framework (38), and characteristics for diffusion of innovation (111). These included that implementers recognize a need for MINDSET and its relative advantage, and make a formal commitment to use. Steps drafted to date include that the clinic director will: Assess the need for an epilepsy S-M program among clinic patients; review MINDSET and note objectives and relative advantages for program adoption; obtain feedback from clinic staff on potential barriers to/advantages of adopting MINDSET; solicit experiences from other clinics that have used MINDSET; agree to adopt MINDSET by signing a memorandum of understanding for its use.

Task 5.3 Construct Matrices of Change Objectives for Implementation and Task 5.4 Design Implementation Interventions

Critical opportunities for MINDSET implementation within the clinic flow were identified from clinic task analysis of collaborating clinics. This enabled us to understand environmental constraints. MINDSET was designed to accommodate regular clinic visits in varied clinic settings previously described (**Figures 3** and **4**). Matrices of change objectives for clinic directors, HCPs, and clinic nurses to adopt and implement MINDSET and the development of an implementation intervention are pending determination of its effectiveness.

Management Information Decision Support Epilepsy Tool will be more likely adopted if it is efficacious with minimal disruption to clinic activities or clinic overhead. The thoroughness of the S-M assessment may be associated with greater time commitments but this may, in turn, be offset by its provision of a detailed record of (potentially) billable behavioral counseling activities in the clinic. Integration of the MINDSET data base with existing medical record systems would also enhance its appeal to HCPs. Emerging potential uses for MINDSET exist beyond its original design including as a tool for clinic-based community health workers and as an electronic behavioral assessment with the National Epilepsy Education and Awareness Collaborative (NEEAC).

IM Step 6: Evaluation Plan

Step 6 comprised effect and process evaluation questions, developing indicators and measures of assessment, and specifying an evaluation design.

Task 6.1 Write Effect and Process Evaluation Questions

The primary question to be addressed in planning the evaluation of MINDSET was: Does the use of MINDSET by a PWE and their HCP during multiple clinic visits over a 9 month period, including the use of a printed action plan between visits, improve the S-M behaviors and confidence of patients? Stated as an alternative testable empirical hypothesis: PWE who use MINDSET in the context of their usual clinic visit for three consecutive clinic visits over a 9-month period, and a printed action plan between visits, will report at least three fewer "at-risk" S-M behaviors (assessed by the Epilepsy S-M scale) compared to patients who do not use MINDSET.

Planned process evaluation questions included assessment of factors that mediate the success of MINDSET as well as facilitating its implementation (**Table 8**). These include intervention exposure, impact on patient-provider communication, and information seeking other than MINDSET. Sufficient exposure to MINDSET relates to implementation fidelity, that the patient was exposed to all components and completed them through to action plan printout. Incomplete exposure compromises the quality of the efficacy trial. Time-on-task data (both patient and patient and provider use) informs expectations for future implementation (e.g., time commitments) for adopting clinics. Assessment of the quality of the patient and provider clinic encounter when MINDSET is used allows a determination of correspondence between MINDSET cues and topics subsequently discussed in the clinic encounter. Exit interviews allow for a protracted discussion of the HCP's experience in using MINDSET and recommended adjustments to facilitate its use and future adoption. Assessment of the degree to which the patients accessed other sources for information on S-M enables an accurate assessment of the degree to which MINDSET and the action plan (distinct from other sources) influenced S-M. Knowledge gained from clinic testing will inform implementation plans and program user manuals for those adopting MINDSET in the future.

Task 6.2 Develop Indicators and Measures for Assessment

From the outset the development of MINDSET focused on instruments and scales to assess patient's S-M status and to provide indicators of S-M success over time. For this reason, measures for evaluation can closely correspond to those embedded in MINDSET. *Planned impact measures* include the epilepsy S-M scale, epilepsy self-efficacy scale, NDDI-E, and adverse effects scale previous described (refer to Step 4: Program Production and **Table 8**). *Planned process measures* were developed to assess the process evaluation constructs previously described (**Table 8**).

Task 6.3 Specify Evaluation Design

The planned evaluation design for MINDSET involves an RCT with a sample of patients randomly assigned to treatment (MINDSET and usual care) and comparison (usual care only) groups ($n = 30$ per group) at three clinic sites over three visits to evaluate its efficacy.

Planned Patient Recruitment. A total of 60 patients from the KS clinic ($n = 20$), BT clinic ($n = 20$), and UT clinic ($n = 20$) (previously described) would be invited to participate. Participants would include patients with a diagnosis of epilepsy who are 18 years of age and older, who can speak English, who are willing and able to complete MINDSET, and who have no other medical disorders that could inhibit their ability to use MINDSET or practice S-M activities. Participation would be based on clinician and

TABLE 8 | Sample measures for pilot test.

#	Instrument (impact)	Description
SELF-MANAGEMENT (S-M) BEHAVIOR		
1	Epilepsy S-M Scale	38 Likert scale items. Internal consistency (alpha) = 0.81–0.84. Principal components analysis with varimax rotation yielded 5 factors (7, 8, 16, 54)
SELF-EFFICACY		
2	Epilepsy Self-efficacy Scale	Consists of 33 items using an 11 point rating scale, ranging from 0 (I cannot do at all) to 10 (Sure I can do). Items yield a total summative score. Content and construct validity have been assessed in a 25 item version of this scale with alpha coefficients ranging from 0.91 to 0.94 (8, 16, 54)
DEPRESSION		
3	Neurological Disorders Depression Inventory for Epilepsy (NDDI-E)	The scale is well validated, has high internal consistency (alpha = 0.80), test-retest reliability = 0.78 (106–108)
		Process measures
4	Intervention exposure	*Aim*: To monitor the extent of implementation and the degree and fidelity of MINDSET delivery. *Measure*: Data collected within MINDSET on selections and preferences made within the program and time-on-task.
5	Clinic encounter	*Aim*: To understand if the application of MINDSET influences patient-provider communication during the clinic visit. *Measure*: The patient will complete a clinic visit interaction checklist, clinic visit communication scale, and shared decision-making scale immediately after their clinic visit to assess quality of communication.
6	Exit interview	*Aim*: To understand the patient's and HCP's experiences with MINDSET, the most useful components and features, barriers to use, suggestions for improvement, and ratings on the MINDSET's perceived impact on epilepsy management. *Measure*: Patients and HCPs will complete an exit interview adapted from previously reported protocols.
7	Information seeking behaviors	*Aim:* Information seeking is an activity that may occur following completion of the pretest evaluation survey items (all patients) or in response to MINDSET (treatment patients) and can be an important mediating variable. *Measure*: Participants will be asked whether they actively sought information about epilepsy and where they looked for this information, e.g., Internet, Foundations, medical practitioners, or popular media sources (radio, television, or newspapers).

nurse educator referral and ideally reflect the diversity of gender and race-ethnicity, average age and SES for the respective clinic populations.

Planned Pilot Efficacy Trial of MINDSET. Each clinical site would recruit 20 patients to participate in the randomized pre–post treatment and comparison group study. Once enrolled the patients would participate during three regular clinic visits that would be scheduled three months apart. They would be randomly assigned to one of two groups (30 in each group, 10 from each site) for receipt of the treatment (MINDSET plus usual care) or comparison (usual care only) condition.

At the *first visit*, a MINDSET research staff member would meet the patient at the clinic to confirm participation, answer questions, and, if they agree to participate, obtain signed consents. Consent and study protocols are subject to approval by human subjects internal review boards at the contributing university and clinical organizations. All patients would then complete a contact sheet, and a demographic survey. They would then input data into the assessment section of MINDSET (My Profile) prompted by screening questions. This would include data on seizures, AEDs, and lifestyle, as well as S-M behaviors (Epilepsy S-M Scale) and self-efficacy (Epilepsy Self-efficacy Scale) related to these domains. Data input would take place in the waiting room and clinic room while waiting for the clinic appointment.

Group 1 patients would use MINDSET to review their epilepsy S-M patient profile (My Plan) that indicates S-M challenges ("risk"), provides behavioral goals and associated advice about content, provides recommendations for discussion with the HCP, and also provides information on associated S-M resources (e.g., available through the American Epilepsy Society, Epilepsy Foundation, and MEW Network). During the clinic encounter, the provider and patient would refer to MINDSET. The HCP would be provided suggested action items based on the patient's profile, could access the patient profile (My Plan) data and could confirm or modify these data after interviewing the patient. The patient and provider would have the opportunity to review recommended discussion points, goals for management, and the action plan. The provider will have the opportunity to provide the patient with a tailored printed action plan that reiterates the priority management goals discussed in the clinic encounter.

After completing initial assessment items in MINDSET, Group 2 patients would provide MINDSET back to the research staff member and continue their regular clinic visit in which they would meet with their providers as usual without the benefit of MINDSET information and prompting on discussion points and the action plan, and without the receipt of a printout of the action plan. Following the clinic visit both group 1 and group 2 patients would complete process measures of the clinic visit interaction checklist and clinic visit communication scale. All patients will then be provided $15 for their participation.

During the *second visit*, patients in Group 1 and Group 2 would again complete the assessment (My Profile) component of MINDSET. Group 1 patients would again use MINDSET to review their epilepsy S-M patient profile and recommended management goals (My Plan) and both HCP and the patient can use MINDSET to review and confirm data and develop the action plan. The HCP would also have access to any change in the patient data since the last clinic visit. Group 2 patients would again only complete initial assessment items in MINDSET, and then will provide MINDSET back to the research staff member and continue to the regular clinic visit. Again, following the clinic visit, both Group 1 and Group 2 patients would complete process measures (described below). During the *third visit*, both Group 1 and Group 2 patients would input their profile data using the assessment screening tool in MINDSET (My Profile). They will then return MINDSET to the research staff, complete a short exit interview.

Analysis. Comparisons of changes in scale scores on S-M and self-efficacy from O_1 to O_3 will be made and t-tests and one-way analysis of covariance of the changes will be used to address the evaluation hypothesis. The independent variable of interest in all cases will be group assignment: treatment or comparison. Measures of mediating factors including depression and pre-test scores will be used as covariates.

Limitations. This study represents a modest trial designed to be accomplished with available resources. While loss to follow-up is often an issue in such trials the small sample and previous success of the clinics in tacking and maintaining these patients indicates that a 20% attrition is realistic. A per-protocol analysis is planned in this efficacy trial to determine impact of the MINDSET intervention if received. Furthermore, because a limited number of providers (neurologists) are involved in the trial there is expected to be limited turnover and the capability of targeted training by the research staff. Despite this, any findings need to be interpreted in the light of acknowledged study limitations. We expect minimal between-patient contamination because the patients are not typically interacting with each other in these clinics. However, the study is subject to within-provider contamination because a limited number of providers will encounter both MINDSET (Group 1) and usual care (Group 2) patients. It is not possible to blind the provider in this type of trial because they are using MINDSET and the action plan with their patients. It is, therefore, possible that providers will be more attentive to lifestyle issues with all their patients, above what they might originally have been. The contamination will work against a Type I error, making any findings more robust. Further, the time constraints of a busy neurology clinic will likely limit providers to patient-specific cues (from the Action Plan) and not unduly influence general discussion. This remains to be determined. The trial has not been registered in a public trials registry.

DISCUSSION

Management Information Decision Support Epilepsy Tool is designed to address the need, identified in the 2012 IOM report, "Epilepsy Across The Spectrum," for substantial engagement by patients and their HCPs to manage therapy and lifestyle issues so as to prevent seizures and maximize quality of life (3, 22, 24). It also provides a called for "structured approach to addressing and documenting patient-centric quality indicators for epilepsy patient care" (3, 22, 24). In epilepsy care, DSSs have focused on diagnostic and pharmacologic support, consistent with historic applications of such systems in medicine (26–31). This reflects the focus and enquiry into the "technical aspects of care, in contrast to personal or social concerns" (32). The development and testing of MINDSET may lead to a new patient-centered decision-making tool to assist in identifying initial steps toward epilepsy S-M (4) to identify patients needing more assistance, and to provide ongoing decision support through action plans. It is also responsive to the Healthy People 2020 objective (HC/HIT-1.1) to increase the proportion of persons receiving easy-to-understand instructions about what to do to take care of their illness or health condition (109). To date, there is a lack of attendance to S-M needs in clinical settings despite the availability of evidence-based interventions to promote epilepsy S-M outside clinic settings.

The IM framework has facility in developing DSSs that promote patient and provider decision-making regarding S-M. Advantages of the framework include the imposition of a systematic approach, thoroughness in detailing needs and solutions informed by theoretical- and empirical literature, encouraging "downstream" thinking regarding implementation, evaluation, and dissemination, and ensuring that priority populations are consulted throughout. Challenges for the use of IM are the time resource required to complete the process with maximum "textbook" fidelity due to the tension with resource constraints in research projects. The MINDSET development presented here represents one case study application for decision support for chronic disease S-M in clinic contexts. In this capacity it is contributive as a guide for future development in analogous domains and populations and application. However, there are necessary limitations in this work that are a basis for future recommendations. Developers are encouraged to apply a systematic application of core processes with each development task. These include posing questions, brainstorming answers, review findings from published research, accessing and using theory, identifying and addressing the need for new research, and formulating the working list of answers. This will ensure a more complete and continuous data feedback loop throughout. Also advised is a timeline that indexes dialog with the priority population with each development task rather than, for example, a calendar meeting schedule which may fail to involve the priority population fully and at the time when input is most helpful.

By providing tools and procedures for identifying and assisting patients with S-M needs, this study will make a significant contribution to the CDC-MEW goal of promoting S-M and self-determination principles in the care of PWE. IM was conducive to providing an innovative technological application to facilitate the dissemination of knowledge from social and behavioral research on epilepsy S-M into clinical practice.

ETHICS STATEMENT

This study was carried out in accordance with the recommendations of local human subject research internal review boards at the University of Texas and the Harris County Hospital District (Harris Health) with written informed consent from all subjects. All subjects gave written informed consent in accordance with the Declaration of Helsinki. The protocol was approved by the local human subject research internal review boards at the University of Texas and the Harris County Hospital District (Harris Health).

AUTHOR CONTRIBUTIONS

The authors (RS and CB) have both been involved in the development of the MINDSET epilepsy decision support system from early needs assessment and descriptive studies through the structure and function of the program.

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METHODS
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Using Intervention Mapping to Develop Health Education Components to Increase Colorectal Cancer Screening in Puerto Rico

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Introduction: Colorectal cancer (CRC) is a leading cause of cancer-related mortality in Puerto Rico (PR). Although largely preventable through screening and treatment of precancerous polyps, CRC screening rates in PR remain low while CRC incidence and mortality continue to increase.

Methods: We used intervention mapping (IM), a systematic framework using theory and evidence to plan a health promotion intervention to increase colorectal cancer screening (CRCS) among Puerto Rican adults 50 years and older who are patients of Federally Qualified Health Centers (FQHCs) in PR.

Results: To inform the development of a logic model of the problem during the needs assessment phase, we determined the CRC incidence and mortality rates in PR using recent data from the PR Cancer Registry, conducted a literature review to better understand behavioral and environmental factors influencing CRC among Hispanics in general and in Puerto Ricans, and collected new data. We conducted seven focus groups to identify community needs and resources, specific sub-behaviors related to CRCS (performance objectives) and the determinants of CRCS. We then developed matrices of change objectives that would guide the content, behavioral change method selection, and the practical applications that would be included in the program. We selected two overarching methods: entertainment education and behavioral journalism and developed practical applications, materials, and messages containing several other methods including modeling, persuasion, information, and tailoring. We developed and pretested a Tailored Interactive Multimedia Intervention, newsletter, an action plan, and supplemental print materials for patients. We also developed a patient mediated provider prompt to increase provider recommendation and improve patient provider communication.

Conclusion: The use of IM for systematic planning produced a detailed coherent plan for the CRCS educational intervention. Guided by IM processes, steps, and tasks, we used community level information, existing literature, theory, and new data to develop health education materials that were well received by the priority population and will likely increase CRCS among FQHC patients in PR.

Keywords: intervention mapping, colorectal cancer screening, entertainment education, behavioral journalism, self-efficacy, program development, behavioral change, Federally Qualified Health Centers

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INTRODUCTION

In Puerto Rico (PR), colorectal cancer (CRC) is the second leading cause of death due to cancer among both men and women (1). Between 2010 and 2014, the age-adjusted incidence rate of CRC on the island was 31.3 per 100,000 population among women, and 48.0 among men (1). Colorectal cancer screening (CRCS) can reduce both, the incidence and mortality of CRC through early detection and removal of precancerous lesions (2). Currently, in PR, three types of CRCS tests are performed: fecal immunochemical test (FIT), fecal occult blood test (FOBT), and colonoscopy. The American Cancer Society and the US Preventive Task Force recommend regular CRCS between the ages of 50–75. In PR, Federally Qualified Health Centers (FQHCs) use either FIT or FOBT for CRCS. Patients with a family history of CRC and those who show risk factors are strongly recommended to have a colonoscopy, in accordance to the American Cancer Society guidelines (3). Nonetheless, the Behavioral Risk Factors Surveillance System reported that for the population over 50 years of age in PR, in 2014 only 18.5% had ever had either a FIT or FOBT and only 50.6% had ever had a sigmoidoscopy or colonoscopy (4). These screening rates are substantially lower than the goal targeted by the National Colorectal Cancer Roundtable (5), which aims to achieve 80% screening rate by 2018.

Both personal determinants such as low knowledge, fear of detection, and low perceived risk; and environmental factors such as lack of doctor's recommendation, lack of health insurance, and issues related to the local Health-Care System (i.e., high turnover rate among providers, low number of gastroenterologists, and increased patient ratio for primary care physicians) negatively influence CRCS in PR (6–10). Another organizational barrier that affects CRCS uptake is the fact that many clinics do not have an on-site laboratory and patients are required to visit an offsite laboratory to obtain and return FIT/FOBT kits; thus complicating the screening process (6).

Salient personal determinants that negatively affect CRCS among Hispanics in the U.S. and in PR include the following: lack of knowledge and misconceptions regarding CRC and CRCS, low health literacy, social norms and negative attitudes toward screening, low perceived risk of CRC, and perceived barriers such as a lack of time, perceived high cost of testing, or difficulties with transportation (6, 8, 11–17).

The Guide to Community Preventive Services (Community Guide) recommends one-on-one education in combination with small media and patient/provider reminders as strategies to increase CRCS (18). Although evidence suggests that these strategies are effective for fecal occult blood testing (FIT/FOBT), evidence regarding these approaches for increasing colonoscopy is still insufficient (19). Currently, there are few studies examining one-on-one education in combination with other communication strategies in the Latino population (12, 16, 20) and none with Puerto Ricans. The Puerto Rico Community Cancer Control Outreach Program designed a study to address this gap by developing and evaluating a health promotion program (*Salud por la Vida*) to increase CRCS in PR. The purpose of this article is to describe how we used intervention mapping (IM), a systematic planning framework, to guide the development of the program. This effort was carried out in collaboration with the PR Colorectal Cancer Coalition and the PR Primary Health Association, among others, using principles of community based participatory research. The research protocol and the data-gathering instruments were approved by the Institutional Review Boards of the UPR-MSC and the University of Texas Health Science Center at Houston. All study participants provided informed consent prior to enrollment to the study.

METHODS

Intervention Mapping

Intervention mapping is a systematic approach for the development of theory and evidence-based health promotion interventions and for planning their implementation (21). IM has been successfully employed to promote and increase screening practices for several types of cancers such cervical and breast cancer (22–27) and CRC (12, 28).

The IM process is composed of six steps; each one involves specific tasks (21) that guide the translation of relevant personal determinants and environmental factors into a health promotion program (29). We describe the first four steps (needs assessment, matrix of change objectives, selection of theory-based methods and practical strategies, and program production).

In step 1, we conducted a needs assessment based on the PRECEDE/PROCEED model (30) to identify the factors the program should address. In step 2, we identified the overall behavioral goal for the program and developed a matrix that combined the health-promoting behaviors and their determinants to create change objectives. During step 3, we paired change objectives with theoretical models and strategies to affect the selected determinants. Finally, we developed and pretested the program in step 4. Throughout the planning process, we used information obtained from the literature, and guided by behavioral theory, and new data to identify personal determinants and environmental factors influencing CRCS and to select the most appropriate methods and strategies to influence these (see **Table 1**).

Theoretical Underpinnings

To identify factors associated with the risk behavior and with the health-promoting behavior (CRCS in this case), IM suggests an integrated and iterative approach using theory and evidence. We used constructs from the Integrated Behavioral Model (32) which includes constructs from the most commonly used theoretical models in health promotion (i.e., Social Cognitive Theory, Theory of Reasoned Action, Theory of Planned Behavior, and the Health Belief Model). These constructs are as follows: severity, susceptibility, self-efficacy, attitudes, outcome expectations, perceived barriers and facilitators, and normative believes. Consideration of these constructs provided guidance for the identification and understanding of determinants related to CRCS and the selection of theory-based methods to achieve behavioral change.

TABLE 1 | Intervention mapping (IM) to develop health educational components to increase colorectal cancer screening in Puerto Rico (PR) (steps 1–4).

Step 1: Logic model of the problem	Establish a planning group Conduct a needs assessment based on the PRECEDE/PROCEED model: • Data from PR Registry • Review of empirical and theoretical literature • Focus Group Identify the factors the program should address
Step 2: Program outcome and matrix of change objectives	Identify overall behavior goal Specify health-promoting behaviors (performance objectives) Select determinants for behavioral outcomes Construct matrix of change objectives
Step 3: Educational components design	Identify theoretical and evidence-based change methods: • Entertainment education • Behavioral journalism • Patient activation method Select practical applications and strategies to operationalize the methods
Step 4: Educational components production	Design format, themes, and messages of the educational components: • Tailored Interactive Multimedia Intervention • Printed materials (newsletter, infographics, and action plan) • Provider prompt • Patient reminder support call Create drafts of the educational components: • In Spanish • Adapted to the Puerto Rican culture • Low health literacy Pretest the educational components Produce the final educational components

This table is informed by IM steps (31).

RESULTS

IM Step 1: Needs Assessment

Data from the PR Registry (17) demonstrated that not only was there treatment delay for people with government health care as compared to those with other insurance coverage but survival was also lower. In addition, CRCS rates are lowest among individuals who had either no insurance or government health insurance, compared to those with other forms of insurance. Therefore, we focused on reaching these patients through a collaboration with FQHCs since their patients are primarily either uninsured or have government health insurance.

We completed an extensive review of empirical and theoretical literature to identify factors influencing CRCS in US Hispanic populations and PR. As mention earlier, we used the Integrated Model to guide exploration of potential constructs (determinants). We also identified determinants that were either correlates or predictors of CRCS among Hispanics from empirical studies. For example, a systematic review (33) assessed theory-based constructs associated with CRCS. These constructs included perceived susceptibility and severity, benefits and barriers, and self-efficacy from the health belief model (34, 35); attitudes, social norms and perceived behavior control from the theory of reasoned action and the theory of planned behavior (36, 37); self-efficacy from social cognitive theory (38); and decisional balance from the trans-theoretical model (39).

We conducted seven focus groups ($N = 51$) to explore barriers and facilitators of CRCS among Puerto Ricans living on the island. Inclusion criteria for focus group participants included: being a patient at a FQHCs, between the ages of 50–75, not being up to date with CRCS, and no previous diagnosis of CRC. We employed an adapted interview guide (13) that included questions regarding knowledge, attitudes, and beliefs about CRC and CRCS; as well as screening tests barriers and benefits. We also asked questions to clarify the process of obtaining a CRCS, information needs, and preferences for educational material. We transcribed the focus group recordings and used ATLAS.ti (version 7.5.10) for analysis. Members from the research team reviewed the transcripts (primary documents) independently and used constant comparative method (40) to identify themes and emerging topics. Two coders, one in PR (CV) and one in Houston (NFE), conducted an open coding identifying concepts and ideas using inductive methodology. The team reexamined the data according to differences and similarities, creating annotations in the form of memos. The resulting codes were classified into categories and subcategories (i.e., topics that were significant to respondents and are more generic concepts). Next, we continued with an axial coding that allowed us to clarify the relations between the different categories and subcategories. The team held weekly meetings to discuss coding and themes that had emerged. In most cases, coders identified the same themes. Any discrepancies in coding were resolved through team discussion. To assist in data reporting, we created categories of personal determinants and environmental factors that influence CRCS among Puerto Ricans living on the island (see **Table 2**).

Personal Determinants and Environmental Factors from Literature Review and Focus Groups

Based on the review of the empirical and theoretical literature we found that the following personal determinates influenced CRCS: low knowledge, perceived social norms, fear of finding CRC negative attitudes toward CRCS, perceived barriers, and low perceived risk (6, 8, 11–17). At the environmental level, substantial evidence from the literature pointed to lack of provider recommendation as a key environmental factor negatively influencing CRCS (6–10).

Results from the focus groups indicated that the following personal determinants influenced CRCS: lack of knowledge and misconceptions about CRC and CRCS; low risk perception about getting CRC; attitudes such as machismo, fatalism and procrastination; feelings of fear and embarrassment concerning the colonoscopy procedure, fear of test results, and perceived barriers such as lack of time and transportation problems. As in the literature, lack of provider recommendation was the primary environmental factor that emerged in the focus group findings. There was a high level of consistency in personal determinates and environmental factors identified through the literature review and focus groups.

TABLE 2 | Personal determinants and environmental factors influencing colorectal cancer screening (CRCS) among Puerto Ricans.

Categories	Subcategories
Personal determinants influencing CRCS	Knowledge about CRC/CRCS Misconceptions about CRC/CRCS Low perceived risk for getting CRC Attitudes: • Machismo • Fatalism • Procrastination Affective factors: • Fear (concerning the colonoscopy procedure) • Embarrassment (concerning the colonoscopy procedure) • Fear (of the results of the test) Perceived structural barriers: • Lack of time • Transportation problems
Environmental factors influencing CRCS (interpersonal)	Lack of provider recommendation

Preferences Regarding Educational Intervention Components

When asked about the type of information they would like to receive, focus group participants indicated they would like to know more about CRC and CRCS tests, type of coverage government issued health insurance provided for CRCS, and where they could undergo testing. Participants said that it would be both helpful and important if health-care providers informed them about these issues. Participant preferences for educational materials included videos or printed materials with attractive images containing simple vocabulary.

IM Step 2: Program Objectives

Based on the needs assessment, we defined the overall behavioral outcome: "Puerto Ricans ages 50 and older adhere to CRCS guidelines." Once the overall behavioral outcome was established, we formulated performance objectives (i.e., what participants need to do to complete CRCS) (see **Table 3**). We then identified determinants of the positive behavioral outcome (i.e., why participants would complete de CRCS) rather than lack of CRCS (as in step 1). We examined determinants derived from step 1 and re-reviewed the literature and focus group findings to identify factors that would positively impact CRCS. These included knowledge, perceived risk, decisional balance, outcome expectations, self-efficacy/skills, perceived norms, and attitudes. According to IM step 2, we then created a matrix of change objectives by placing performance objectives in the left column and determinants across the top of the matrix. Then, for each determinant and the corresponding performance objective we asked: what has to change in relation to the determinant so that our population of interest can achieve the desired performance objective? These change objectives were recorded in the cells of the matrix (see **Table 4**).

TABLE 3 | Behavioral outcome with associated performance objectives.

Behavioral outcome
Puerto Ricans ages 50 and older adhere to CRCS guidelines
Performance objectives
1. Make an appointment with the provider
2. Discuss CRC and CRCS with the provider
3. Request FIT/FOBT or obtain a referral for colonoscopy
4. Identify location to get screened
5. Make an appointment to get screened
6. Arrange transportation
7. Seek social support
8. Get screened for FIT/FOBT
9. Get screened for colonoscopy if recommended
10. Record and keep appointment to the discuss the results with the provider

FIT, fecal immunochemical test; CRCS, colorectal cancer screening; CRC, colorectal cancer; FOBT, fecal occult blood test.

IM Step 3: Program Design

We then identified theoretical change methods that are known to influence the determinants identified and conducted a literature review to help identify these methods as well as the practical applications or strategies to operationalize these. The intent of this step was to create strategies, materials, and messages that would address specific change objectives. We selected two overarching methods: entertainment education (38, 41, 42) and behavioral journalism (43). Entertainment education employs formats based on entertainment to introduce educational messages. In behavioral journalism, real-life role models who are identified as peers of the population of interest (with the same language and similar cultural and social norms) communicate the message (44, 45). These overarching methods also include other change methods including modeling, reinforcement, persuasion (Social Cognitive Theory), tailoring (Trans-Theoretical Model), anticipatory regret (Theory of Plan Behavior), consciousness raising (Health Believe Model), and providing cues to action (Theories of Information Processing). Strategies identified to operationalize these methods included testimonials and role-model stories about people talking with their provider about CRCS tests and overcoming barriers. We designed messages that include prompts for thinking about what might happen if they do not get screened and the regret that would accompany the decision.

Despite the importance of the organizational and provider level factors influencing CRCS identified during the needs assessment phase and our desire to create a multilevel intervention to address these factors, resources and project scope limited the ability of the team to do so. Nevertheless, since provider recommendation is an important and necessary component of any CRCS intervention, we decided to intervene using the patient activation method. This method is strongly associated with self-reported quality of care, a better doctor–patient communication, and increase CRCS rates (20, 46).

IM Step 4: Creating Educational Components

In this step, we designed, produced and pretested the educational materials guided by the matrix of change objectives,

TABLE 4 | Sample cells from matrix of change objectives.

Performance objectives	Overall behavioral outcome: "Puerto Ricans ages 50 and older adhere to CRCS guidelines"						
	Determinants						
	Knowledge	**Perceived susceptibility (risk)**	**Decisional balance (pros and cons)**	**Outcome expectations**	**Self-efficacy/skills**	**Perceived social norms (subjective norms)**	**attitudes**
PO8. Get screened FOBT/FIT (1) Pick up test from the lab or accept test from PCP (2) Read instructions (3) Complete test (4) Return test to lab	K8a. States that FOBT/FIT is recommended to be done annually for people over 50-year old K8b. Describes the steps to complete a FOBT or FIT K8c. Lists place where test should be returned	PR8. Perceives that he/she is at risk of getting CRC	DB8a. States the advantages of doing FOBT/FIT annually DB8b. Believes there are more benefits to CRCS than barriers DB8c. Describes ability to overcome barriers to doing FOBT/FIT annually	OE8a. Expects that if he/she gets CRCS they will reduce the risk of CRC or detect it early enough to be cured OE8b. Expects that going to pick up the test will result in getting one and getting tested OE8c. Expects that returning the test will result in quick information about outcome	SE8a. Expresses confidence in ability to pick up the test SE8b. Expresses confidence in ability to complete all steps SE8c. Expresses confidence in the ability to return the test	SN8a. Believes that other adults like them pick up the FOBT/FIT annually SN8b. Believes that other adults like them complete and return the test	ATT8a. Believes that CRCS is important ATT8b. Believes that early detected cancer can be cured ATT8c. Describes the importance of preventive behaviors such as screening to take care of one's own health
PO9. Get screened for colonoscopy Identify someone to go with you	K9a. States that colonoscopy is recommended to be done every 10 years for people over 50-year old K9b. Describes the steps to complete a colonoscopy including preparations K9c. Lists place where to go for colonoscopy K9d. Describes need to get a referral from doctor		DB9a. States the advantages of doing colonoscopy DB9b. Believes there are more benefits to CRCS and colonoscopy specifically than barriers DB9c. Describes ability to overcome barriers to doing colonoscopy	OE9a. Expects that if he/she gets a colonoscopy they will reduce the risk of CRC or detect it early enough to be cured OE9b. Expects that getting a colonoscopy will allow them to wait 10 years before having to get another one (if negative)	SE9a. Expresses confidence in ability to identify someone to go with him/her to appointment SE9b. Expresses confidence in ability to conduct preparations SE9c. Expresses confidence in ability to complete colonoscopy	SN9a. Believes that other adults like them identify person to accompany them to the appt SN9b. Believes that other adults like them get colonoscopy SN9c. Believes that other adults like them complete preparations correctly	ATT9a. Believes that colonoscopy is useful and important because it can identify cancer and polyps (pre-cancer) ATT9b. Believes that correctly completing prep contributes to a more accurate test ATT9c. Believes that the test results will give them peace of mind ATT9d. Believes that even if embarrassed the test is worth it ATT9e. Believes that cancer if detected early can be cured

CRC, colorectal cancer; CRCS, colorectal cancer screening; FIT, fecal immunochemical test; FOBT, fecal occult blood test.

methods, and strategies previously described. We reviewed the information obtained from the focus group analysis. Keeping in mind participants' preferences about informational needs and educational materials format, and guided by the change objectives from the matrices developed in step 2, we created a series of drafts that conveyed messages and content. We then modified drafts according to the format and type of educational material that would be presented. All developed materials were produced in Spanish and designed to be culturally relevant and appropriate for Puerto Ricans and individuals with low or no literacy skills.

The educational program consists of four components: a Tailored Interactive Multimedia Intervention (TIMI), printed materials (newsletter, infographics, and action plan), a provider prompt, and a patient reminder support call. The TIMI was created based on entertainment education criteria (41, 42) in collaboration with media professionals and was designed to be delivered on tablet computers. The TIMI consists of a video with tailored scripted scenes and testimonials; narrations, animations and interactivity. During development, we held two script readings, one with professionals and collaborators and a second one with community members to assess language suitability and cultural acceptability of the scenes, narrations, and testimonials. The main recommendations were to clarify and simplify medical language about CRCS and expand the conversation that occurs in the physician–patient scenes about CRC and CRCS. We modified scenes and the script based on recommendations from these activities.

To develop the newsletter, we followed behavioral journalism techniques (47). We conducted 10 in-depth interviews with participants who had completed CRCS and had characteristics similar to those of our target population. We conducted journalistic style interviews that included specific questions related to key performance objectives and determinants so that stories would reflect the most relevant information needed. We included both individuals who were up to date with screenings, or who had survived CRC because completion of the CRCS tests. During the interviews, we used open-ended questions to obtain quotes from participants to be incorporated into program materials. During analysis of these interviews, we selected keywords and expressions regarding how participants overcame CRCS barriers and asked about how they felt about the outcomes of screening. We used these to create stories about the benefits of CRCS and about how these individuals had overcome barriers to receive screening and protect their health.

We also developed an infographic and an action plan. These included images and messages with information about CRC and CRCS, steps to follow to complete CRCS tests, and mini-testimonials from people who completed CRCS.

As mentioned earlier, we created a provider prompt based on the patient activation method. This method enables patients to assume an active role in their health care (46, 48). Specifically, we used a patient mediated approach in which the patient gives the provider printed information about CRCS with questions or concerns they may have to prompt discussion; the prompt, a short summary of patient need for CRCS was printed from the TIMI following an interactive session. This also serves as a cue to action for the provider. We designed the prompt to be tailored to knowledge, attitudes, and barriers about CRCS that the participants reported during use of the TIMI.

We conducted focus groups ($N = 19$) and administrated a survey to test the appeal, acceptability, perceived relevance, cultural appropriateness, and motivation to obtain a CRCS of the TIMI and printed materials. Overall, participants found the educational components to be both attractive and culturally sensitive. Most participants indicated that their knowledge regarding CRC and CRCS increased and that they felt motivated to complete screening after viewing and reading the different materials. The only changes participants suggested were to reduce the length of the text in the printed materials and to incorporate information about CRC prevention. We used this information to refine the messages and the quality of the components.

DISCUSSION

In this article, we describe the development of an intervention to increase CRCS using IM. We described the first four steps used in the development process. The last two steps of IM, planning for implementation and evaluation, are currently underway and will be described in a subsequent paper. By using the process of IM, we ensured the systematic incorporation of theory and evidence from the literature and new data from the community participation to address the personal determinants and environmental factors using an ecological perspective. IM also guided the selection of the most appropriate methods and practical strategies, as well as the design and creation of the educational components of the program.

We found that entertainment education and behavioral journalism were two overarching effective methods relevant for addressing the identified personal determinants and environmental factors. These methods that are aimed at changing social norms attitudes, and self-efficacy (21) are particularly effective in reaching audiences that may have low literacy, or who are initially resistant or unwilling to process the message (43, 49). As strategies (practical applications) to operationalize these methods, we included testimonials, role-model stories and patient mediated provider prompts aimed at showing how to overcome barriers to complete the screening tests. The *Salud por la vida* program we developed using IM is a multicomponent intervention. Shokar et al. and Sabatino et al. both conclude that the use of multicomponent interventions is more effective for increasing CRCS testing uptake than the individual components by themselves (16, 50, 51). Likewise, a study with health promoters showed that participants who received a one-on-one educational intervention in combination with patient reminders for FOBT were more likely to get tested than those who just received the patient reminder (31). Another study with lay health workers reinforced the importance of testing small media approaches in combination with one-on-one educational interventions (12). The development of this intervention is expected to help to fill this gap by using multiple strategies to increase CRCS.

Using IM to design *Salud por la Vida* provided an organized, structured, and systematic approach to program development that helped guide (a) the identification of relevant factors influencing CRCS, (b) how and when to use theory and empirical evidence to make decisions about change methods, practical applications, materials, and messages, and (c) how to best engage the community in the planning process to ensure regular communication and feedback.

LIMITATIONS

Due to the qualitative nature of some of the activities of this study such as focus groups, results are not generalizable to all populations 50 years of age and older in PR. Nevertheless, participants were selected to represent the target population for the intervention, therefore, the identified determinants of CRCS are likely those most relevant. In addition, most of those who participated in the behavioral journalism interviews were of higher socioeconomic status and had a better access to private health insurance than the island's general population. Nevertheless, participants identified similar barriers to those documented for lower socioeconomic status. In addition, those with private health insurance recognized that their situation was different to that of the general population and related the experiences of friends and family members who do not have private health insurance.

ETHICS STATEMENT

The study, its components, and protocol were approved by the Institutional Review Boards of the UPR-MSC and the University of Texas Health Science Center at Houston.

AUTHOR CONTRIBUTIONS

MF, VC-L, LS, and SV: program conceptualization. MF, YS-M, VC-L, NF-E, CV, and AA: development of the program. YS-M and MF: manuscript development and primary writers.

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Development of the Social Network-Based Intervention "*Powerful Together with Diabetes*" Using Intervention Mapping

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This article describes the development of the social network-based intervention *Powerful Together with Diabetes* which aims to improve diabetes self-management (DSM) among patients with type 2 diabetes living in socioeconomically deprived neighborhoods by stimulating social support for DSM and diminishing social influences hindering DSM (e.g., peer pressure and social norms). The intervention was specifically developed for patients with Dutch, Turkish, Moroccan, and Surinamese backgrounds. The intervention was developed according to Intervention Mapping. This article describes the first four steps of Intervention Mapping: (1) the needs assessment; (2) development of performance and change objectives; (3) selection of theory-based methods and strategies; and (4) the translation of these into an organized program. These four steps resulted in *Powerful Together with Diabetes*, a 10-month group-based intervention consisting of 24 meetings, 6 meetings for significant others, and 2 meetings for participants and their spouses. The IM method resulted in a tailored approach with a specific focus on the social networks of its participants. This article concludes that the IM method helped our planning team to tailor the intervention to the needs of our target population and facilitated our evaluation design. However, in hindsight, the intervention could have been improved by investing more in participatory planning and community involvement.

Keywords: diabetes self-management, deprived neighborhoods, type 2 diabetes, social network, social influences and social support

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INTRODUCTION

People in lower socioeconomic groups, including ethnic minorities, are not only disproportionately affected by type 2 diabetes, they also have more diabetes-related complications and higher diabetes-related mortality compared with patients in higher socioeconomic groups (1–3). A recent study among ethnic minorities in the Netherlands shows that of those patients that were medically treated, only 37–53% had HbA1c levels on target (4). To the best of our knowledge, no comparable information on glycemic control in Dutch patients in lower socioeconomic groups in the Netherlands is known.

A poorer glycemic control, related to less adequate self-management behaviors, partly accounts for these increased risks (5). Properly managing type 2 diabetes requires a schedule of extensive self-management behaviors. These include an adequate use of medications, if applicable self-monitoring of blood glucose, eating healthy and being physical active, regularly checking and taking adequate care of the feet and dealing adequately with diabetes in every situation (6). Complying with and maintaining such complex health regimens seem to be challenging, especially for socioeconomically deprived patients (7–9).

Low incomes, a low educational level and living in a deprived neighborhood are associated with a lower prevalence of blood glucose monitoring and not knowing how to deal with extreme blood glucose levels (10, 11). Furthermore, especially the combination of smoking, physical inactivity and a lower consumption of fruit and vegetables is prevalent in socioeconomically deprived groups in the Netherlands (12–16). There is thus a need for effective interventions that improve glycemic control among socioeconomically deprived patients with type 2 diabetes.

There are multiple factors that influence self-management behaviors among socioeconomically deprived patients, such as a lack of knowledge, low health literacy, low risk perception, low outcome expectations, low self-efficacy, and specific socioeconomic barriers (lack of financial resources and environmental factors) (7, 9, 17–21). However, an increasing amount of studies shows that social interactions with friends and family members have a major impact on self-management behaviors as well.

Social support, the aid and assistance exchanged through social relationships and interpersonal transactions, can positively influence self-management, but significant others can also hinder self-management by interfering with or paying too much attention to self-management (22, 23). Socioeconomically deprived patients seem to have less access to supportive social networks, to generally have fewer sources of social support in their social environments and to receive less social support, which is needed for adherence (24–26). In addition, they are often confronted with social influences from their immediate social environments that hinder self-management (e.g., peer pressure, specific cultural beliefs and expectations, and fewer positive role models) (27, 28). Interventions that target social influences affecting self-management behavior, such as social support, might be promising. To the best of our knowledge, there are no interventions that focus simultaneously on social support and hindering social influences in this target population.

Therefore, we developed a social network-based intervention (*Powerful Together with Diabetes*) that aimed to stimulate social support for self-management and to diminish hindering social influences on diabetes self-management (DSM) among socioeconomically deprived patients. This target population often has poor reading and writing skills (20). Furthermore, using electronical devices and participating in online communities might be hindered by a low income and low health literacy (29, 30). Therefore, in our study design, we choose to focus on real-life social networks instead of focusing on online social networks.

We used IM to develop *Powerful Together with Diabetes* (31). The development was part of a 4-year project consisting of the development, implementation and evaluation of the intervention. We had 1 year for the intervention development and preparation for implementation. The study design, results of the process evaluation, and the effects of the intervention on outcome measures are described in a number of papers (32–34).

This article describes the first four steps of the intervention development. The development of the entire intervention is described in detail in the handbook and the materials, which are available from the author. The development of the most distinctive features of this intervention is outlined here including the specific focus on social support and social influences that affect self-management, particularly in patients from socioeconomically disadvantaged neighborhoods, and on examining the specific educational requirements of patients living in such neighborhoods.

MATERIALS AND METHODS

The first four phases of Intervention Mapping consist of the following: (1) conducting a needs assessment, (2) creating performance and change objectives, (3) selecting theory-based intervention methods and practical strategies, and (4) translating methods and strategies in an appropriately organized program. This section describes the methods used for the needs assessment.

Needs Assessment

The needs assessment consisted of a literature review and a qualitative study. The most current version of the IM handbook specifically focuses on participatory planning (35). However, at the beginning of this project in the IM handbook of 2006, this focus was less extensive (31). We encountered some barriers to participatory planning as advocated by the IM method. For example, we did not know the exact neighborhoods in which the intervention would be implemented due to difficulties with the recruitment of general practitioners (GPs). We planned to aim the intervention at a very specific target population (with suboptimal glycemic control) and did not want to create false expectations within a community. Therefore, we did not precisely know which community to address. Because of these barriers combined with time constraints, we choose to focus more on other aspects of the intervention development instead of on participatory planning.

Literature Review

The needs assessment started with a scoping review of the literature (unpublished) on social support and an exploration of theories related to self-management: the theory of self-regulation, different self-management theories, and the transactional model of stress and coping, relapse prevention, and social learning theories (36–40). The databases PubMed, Embase, PsycINFO, and Google Scholar were searched for articles describing the influence of social support on diabetes outcomes and DSM. A search was also made for intervention studies that aimed to increase or create social support for DSM.

The literature review provided a general overview of the most important factors related to self-management of people with type

2 diabetes, i.e., low outcome expectations, low self-efficacy, lack of knowledge on diabetes, and low risk perception (7, 9, 17–21). The review also revealed that not only social support but also other social influences in the immediate social environments of the patients (e.g., peer pressure, social norms, and role models) are important for self-management, especially in patients from socioeconomically deprived neighborhoods.

However, information was lacking on the precise nature of these determinants among our target population. For example, which social norms and role models are present in the social environment of these patients and how do these affect self-management behaviors? What form does peer pressure take and how is this related to self-management behaviors? How can these determinants be influenced? With the aim to address these questions, we then conducted a qualitative study to further examine the relation between social support and other social determinants on self-management behaviors. This qualitative study was conducted among people with type 2 diabetes from socioeconomically deprived neighborhoods, particularly Turkish, Moroccan, Surinamese, and Dutch patients.

Qualitative Study

During this project, we had 1 year for the intervention development and the preparation for implementation (recruitment of GPs and patients, writing our proposal for the medical ethical committee). In practice, we had 4 months for our needs assessment.

The qualitative study consisted of semi-structured in-depth interviews with health-care professionals and their patients. In addition, participant observations took place and we analyzed a forum held for people with diabetes. Because of time constraints, we decided that 24 in-depth interviews would be attainable. To further validate our findings, we also re-analyzed the in-depth interviews and focus group discussions with people with diabetes that were organized and conducted by fellow researchers.

Interviews

Semi-structured in-depth interviews were held with people with diabetes from lower socioeconomic groups ($n = 21$) and their health-care professionals ($n = 3$). They were recruited *via* a diabetes nurse who was working in a socioeconomically deprived neighborhood and *via* an advertisement placed on a diabetes forum. All three health-care professionals (two diabetes nurses and one general practice assistant) worked in socioeconomically deprived neighborhoods and were recruited with the help of GPs involved in this study.

The 21 patient interviews were conducted at the respondents' homes or, if preferred, at a local community center or health-care center (each interview lasted 60–90 min). For all interviews, a topic list was used which was revised in the light of emerging findings. Relevant topics (**Table 1**) included as follows: self-management in daily life, barriers and facilitators to self-management, interactions with health-care professionals, and the role of relatives/friends in self-management.

After patients had provided informed consent, the interviews were recorded, transcribed verbatim, and analyzed with MAXQDA software using framework analyses (41). In addition, a secondary analysis was performed on data from previous research (interviews and focus group discussions with people with diabetes from socioeconomically deprived neighborhoods). These interviews were held with Surinamese, Turkish, and Moroccan patients, as well as with patients from lower socioeconomic groups in general, and included topics similar to those used in our own interviews. Parts of these interviews were already coded in MAXQDA, which enabled us to incorporate the relevant codes into our own analyses; the remaining interviews were analyzed using framework analyses (21, 42–45).

Observations

The daily practice of a diabetes nurse working in a socioeconomically deprived neighborhood in The Hague was closely observed. Observations were also made during a 6-week intervention called "*Dealing with Diabetes*" that was organized for Turkish, Moroccan, and Dutch people with type 2 diabetes in socioeconomically deprived neighborhoods in Amsterdam. This took place by means of a participant, non-structured observation. One of our research group (Charlotte Vissenberg) observed all patient consultations with the diabetes nurse for 2 days from 0800 to 1700 hours in September 2008. The diabetes nurse saw (on average) 20 patients per day. The researcher sat in the nurse's office (unobtrusively at the back) and was introduced to each patient as a colleague who would observe the consultations. All patients were asked if they had any questions regarding this observation; moreover, each patient was guaranteed his/her anonymity and was asked to provide informed consent. None of the patients had any questions and none refused participation. During the group-based intervention "*Dealing with Diabetes*," the researcher (Charlotte Vissenberg) sat at the back of the room whilst the patients took part in the intervention.

During the observations, the researcher (Charlotte Vissenberg) wrote down everything that she saw and heard. After each consultation, she checked her findings with the diabetes nurse and the health promoter to ensure/optimize validity. These field notes were subsequently analyzed using thematic charting.

Analysis of Forums for People with Diabetes

Finally, we analyzed all the public content of forums held for people with diabetes. It appears that individuals (subjectively) report worse health and more often seek health information online, than individuals (subjectively) report good health. Furthermore, much information sought online is related to "sensitive" health topics that people prefer not to discuss with others (46). Kummervold et al. found that almost half of their respondents discussed personal problems online that they did not discuss with other people (47). Therefore, we analyzed all the public content of a forum organized for people with diabetes (48).

This forum was not specifically intended for patients from socioeconomically deprived neighborhoods and we doubted that these patients would participate in such a forum. However, we expected younger patients from our target population to participate, which might provide us with useful information as well. We selected www.diabetesforum.nl because it was organized by a professional organization (the National Diabetes Association),

TABLE 1 | Topic list for patients from a socioeconomically deprived neighborhood.

1. Living with diabetes

- When were you diagnosed with diabetes?
- What do you have to do to keep your diabetes under control on a daily basis?
- How did your life change since the diagnosis?
- What did you find difficult to change? What did you find the most difficult to get used to? Do you still experience difficulties with certain aspects of diabetes self-management (DSM)? Which aspects? Why?

2. Self-management

Medications

- Which medications do you take? When do you take these?
- How do you fit your medication use into your daily life? Do you find that difficult?
- Do you always manage to take your medications correctly and on time?
- Could you specify a situation in which you did *not* manage to take your medications? How do you deal with these situations?
- What do you need to take your medications correctly and on time (practical and social support)? What could your significant others have best done in this situation?

Insulin

- Do you use insulin? When?
- How do you fit your insulin use into your daily life? Do you find that difficult?
- Do you always manage to take your insulin correctly and on time?
- Can you specify a situation in which you did not manage to take your insulin? How do you deal with these situations?
- What do you need to take your insulin correctly and on time (practical and social support)? What can your significant others do for you in these situations?

Nutrition

- In what way(s) did you adapt your nutrition when you were diagnosed with diabetes? Did you find that difficult? Do you still find that difficult?
- Do you manage to eat sufficient healthy foods every day? Do you manage to eat regularly every day? Do you manage *not* to eat too many calories every day?
- Can you name some obstacles/situations in which it is difficult to manage healthy eating? (e.g., holidays, busy schedules, and bad mood)
- How do you deal with situations like these? In these situations, what do you need to be able to eat healthily? What can your significant others do for you in these situations?

Physical activity

- Do you exercise more since the diagnosis? How do you experience this?
- Do you manage to get enough exercise every day?
- Can you describe obstacles/situations in which it is difficult to exercise enough? (e.g., holidays, busy schedules, and bad mood)
- How do you deal with situations like these? What do you need to get enough exercise in these situations? What can your significant others do for you in these situations?

Smoking

- Do you smoke?
- Can you describe obstacles/situations that make it difficult for you to quit smoking?
- How do you deal with situations like these? What do you need so that you will not start smoking in these situations? What can your significant others do for you in these situations?
- Former smoker: are you ever tempted to start smoking again? In which situations? What do you need so that you will not start smoking in these situations? What can your significant others do to support you?

3. Role of significant others (family members, friends, acquaintances)

1. Which people are important for your DSM?
2. What is their role in your DSM? Do they help or support you? With what? How? How do you experience that?
3. For your DSM, what kind of support do you receive that you really appreciate? With regard to your self-management, what do you appreciate most about your family members and significant others?
4. What is it that these people do that makes them supportive of your self-management? What can they do that you find difficult? How do they support you?
5. Are you sometimes confronted with beliefs about diabetes that are incorrect? How do you deal with these beliefs? How do these beliefs affect you? Do you behave differently because of these beliefs?
6. Do you ever experience difficulties in managing your diabetes when you are with others? Could you describe such a situation? What happens in these situations? How do you feel in these situations? What do you need in these situations?
7. Does it ever happen that people in your immediate social environment do not take your DSM into account? Can you describe such a situation? What happens in these situations? How do you feel in these situations? What do you need in these situations?
8. Does it ever happen that family members or friends make it difficult for you to manage your diabetes? Can you describe such a situation? What happens in these situations? How do you feel in these situations? How do you deal with these situations? What do you need in these situations?

very active (lots of activity of members but also lots of new users) and was accessible to us.

Particular attention was paid to comments that indicated a lower socioeconomic background, e.g., related to educational level or profession, and to writing that included language that we recognized from our needs assessment phase.

We analyzed all public content from this forum from until April 2010. The content was analyzed using selective coding, focusing only on barriers/facilitators to self-management and the role of significant others (e.g., relatives and friends) in the performance of self-management. Additional analyses were performed using framework analysis (41).

RESULTS

We start this section with a description of the intervention lay out (step 4 of IM) followed by an explanation how we came to this specific intervention lay out (steps 1–3 of IM: the results of the needs assessment, performance and change objectives, the intervention methods and strategies).

The Intervention Layout

This section describes the way the intervention was set up for the participants. *Powerful together with Diabetes* is a group intervention that lasted 10 months and consisted of the following 32 meetings: (i) 24 for participants (10 per group), (ii) 6 for their significant others, and (iii) 2 social network therapy sessions, which was attended by the participants and their significant others. These three components are described separately below.

Meetings for Participants

Phase 1

Phase 1 focused on providing the participants with the basic tools to manage their diabetes. During this phase that lasted 3 months, participants came together every week for 2 h in a community center (within walking distance from their homes) under the supervision of a group leader. During phase 1, five topic were discussed: what is diabetes (one meeting), blood glucose levels (two meetings), medications (two meetings), diet (four meetings), and exercise (two meetings). The last two meetings entailed a module of choice and the celebration of the end of phase 1. Each meeting centered around one topic and started with drinking coffee and tea followed by interactive games, quizzes, and role-playing exercises combined with energizers (fun exercises to stimulate bonding between participants and to provide a break for participants to increase the attention span). At the end of the meeting, the participants walked with each other around the neighborhood. **Table 2** presents an overview of the topics.

In phase 1, recurring program components were as follows: question time, sharing positive news, sugar disease game, nutrition game, letter of the week, role-playing, energizers, exercising, weighing pros and cons, homework, cookbook, summarizing results, and complimenting the participants. These components were adapted to the gender and cultural background of the different groups (e.g., letter of the week for the Surinamese patients could be about combining medications with nostrums; for Moroccan and Turkish women, it could focus on the fear of becoming addicted). **Table 3** lists these program components.

Phase 2

Phase 2 focused on providing the participants with a set of (proactive) coping skills. Every meeting centered around one aspect of making an action plan: keeping a diary (two meetings), choosing a behavioral goal (one meeting), discussing problems and solutions (one meeting), identifying barriers and formulating solutions for these barriers (two meetings), practicing difficult situations (one meeting), discussing barriers and solutions and coping with these barriers (two meetings), making plans for the future (one meeting) and celebrating the end of the intervention (one meeting). Also in this phase, the meetings consisted of interactive games and role playing exercises alternated with energizers. At the end of the meeting, the participants walked with each other around the neighborhood.

In this phase, the meetings no longer took place every week. Gradually, more time was placed between each meeting thereby stimulating the participants to undertake activities together, without the group leader being present. The aim was to make participants more independent and to stimulate communication and exchange of social support/social influences outside of the regular meetings. The first two meetings were only 1 week apart; meetings 2–5 took place biweekly; meetings 6–9 took place once every 3 weeks and, finally, meeting 10 took place 4 weeks after meeting 9. **Table 4** presents an overview of the topics included in these meetings.

Recurring program components were homework, review of the last meeting and exchange of experiences, keeping a diary, group exercises, making an action plan, energizers, and walking with other group members (**Table 5**).

Review of the last meeting and exchange of experiences, the energizers, and walking with group members are described in **Table 2**. In phase 2, some of the energizers focused on remembering information from phase 1 through games and/or exercises (e.g., throwing a ball and naming a green food from the nutritional game when catching the ball). Instead of the group leader initiating walking together and determining how long it would take and where they would go, in phase 2 the participants were encouraged to take the initiative. Participants had to choose what they would like to do (e.g., swimming instead of walking) to make them feel more independent and to make walking (with group members) easier.

Meetings for Significant Others of Participants

For the meetings with significant others, each participant was asked to invite two persons that they considered important for their DSM. In each phase, three meetings were held for significant others during which the diabetic patients were *not* present.

Phase 1 focused on increasing practical knowledge about diabetes and its treatment. It also aimed to make the significant others believe that self-management is necessary and to create awareness about their important role in this self-management. Phase 2 focused on supporting a relative or friend with managing diabetes. The aim was to make the significant others aware that self-management is a shared responsibility between themselves and the patient, and to make them feel confident to support the patient (self-efficacy and skills).

Generally, we used the same program components that were used in the group meetings for participants. The program components were also alternated with energizers. Other program components (**Table 6**) included letting the significant others experience certain behaviors themselves to help them empathize with the participant.

Social Network Therapy Sessions (Participants and Their Significant Others)

In phase 2, both the participant and their significant others participated in two social network therapy sessions. Both sessions

TABLE 2 | Overview of the topics in the meetings for participants: phase 1.

Meeting	Topic	Content of meeting
1	What is diabetes?	• Getting to know each other (energizer) • Glucose, insulin and the origin of diabetes (sugar disease game) • Watching a DVD
2	**Blood glucose levels**	
2.1	Blood glucose levels	• Review of the last meeting and exchange of experiences • Collection of questions • Information about high and low blood glucose levels (sugar disease game) • Exchanging experiences and advice about recognizing and dealing with high/low blood glucose levels (letter of the week) • Exchanging advice and practicing together how to deal with fear of getting a high/low blood glucose levels (letter of the week and role-playing) • DVD • Walking with group members
2.2	Monitoring of blood glucose levels *(Meeting 1 for significant others)*	• Review of the last meeting and exchange of experiences • Collection of questions • Weighing the pros and cons of monitoring blood glucose levels because they might be too high (letter of the week) • Practicing and exchanging advice together about monitoring of blood glucose levels in company (letter of the week and role-playing) • Walking with group members
3	**Medications**	
3.1	Medications	• Review of the last meeting and exchange of experiences • Collection of questions • Weighing the pros and cons of medication use (letter of the week) • Exchanging experiences and advice about difficulties adhering to medication guidelines (role-playing) • Exchanging experiences and advice about how to deal with forgetting medications (letter of the week) • Information about medications (sugar disease game) • Walking with group members
3.2	Medications	• Review of the last meeting and exchange of experiences • Visit from a diabetic nurse: opportunity to ask questions about own medications (participants brought own medications to the meeting) • Exploring own medications with diabetic nurse: what are the different medications for? how to use these medications? • DVD • Information on influence of medications on blood glucose levels when exercising heavily, when ill, when forgetting medications (sugar disease game) • Walking with group members
4	**Diet**	
4.1	Diet 1 (*Meeting 2 for significant others*)	• Review of the last meeting and exchange of experiences • Collection of questions • Information about a healthy diet (nutrition game) • Doing groceries (information on labels/explanation of logos) • Walking with group members
4.2	Diet 2	• Review of the last meeting and exchange of experiences • Exchange of experiences and advice about barriers to eating healthy (letter of the week and role-playing) • Walking with group members
4.3	Diet 3	• Review of the last meeting and exchange of experiences • Exchange of experiences and advice about resisting temptations (letter of the week) • Practicing and exchanging advice together about resisting food in social situations (letter of the week and role-playing) • Eating at regular intervals (group discussion) • Walking with group members
4.4	Diet 4 (*Meeting 3 for significant others*)	• Review of the last meeting and exchange of experiences • Visit from a dietician: group members can choose between visiting a supermarket (how to pick healthy food from all the labels, how to read food labels), or adjusting their recipes to make them healthier • Recipes: cookbook • Walking with group members

(*Continued*)

TABLE 2 | Continued

Meeting	Topic	Content of meeting
5	**Exercise**	
5.1	Exercise 1	• Review of the last meeting and exchange of experiences • Weighing the pros and cons of physical activity • How much do I exercise (group exercise)? • How can we incorporate physical activity into our daily lives? • Walking with group members
5.2	Exercise 2	• Review of the last meeting and exchange of experiences • Exchanging experiences and advice on how to deal with peer pressure not to exercise (letter of the week) • Practicing and exchanging advice on strategies to overcome peer pressure regarding exercise (role-playing) • Walking with group members
6	Module of choice	• Review of the last meeting and exchange of experiences • Participants can choose one of the following modules: diabetes on holiday, diabetes and Ramadan, smoking and/or sexual problems
7	Celebration: end of phase 1	• Review of the last meeting and exchange of experiences • Looking back at phase 1 • Graduation phase 1: diploma

lasted about 25 min each and took place at the respondents' home or, if preferred, at the community center.

During the first social network therapy session, the participant and their significant others determined a behavioral goal the participant could work on. This behavioral goal had to be based on the action plan used in the meetings for participants. Also, together with the group leader, they identified facilitators/barriers to achieve that goal and considered ways that the significant others could contribute to achieving this goal. The session ended with compiling a list of specific agreements that stipulated who will do what, and when, to achieve this goal.

The second social network therapy session evaluated the things that went well and the things that need to be improved. If necessary, a new/adapted list of agreements was complied.

Training and Supervision of Group Leaders

Powerful Together with Diabetes was delivered by various group leaders. The Turkish and Moroccan groups consisted of separate groups for men and women, whereas both men and women were included in the Surinamese group. Each group was guided by a group leader who was matched with the participants on ethnicity and gender. The leaders of the Dutch groups were diabetes nurses, GP assistants, and nurse practitioners, whereas the leaders of the Moroccan, Turkish, and Surinamese groups were migrant health workers.

All group leaders received 4 h of training before phase 1 and another 4 h before phase 2. In these training sessions, they participated in some of the intervention components themselves. They were also trained to use the handbook of phases 1 and 2, how to use the materials for the participants and how to guide and stimulate group bonding during the intervention. During these training sessions, they were provided with all intervention materials they needed during that phase. During the interventions, all group leaders had regular telephonic contact with the researchers; these calls helped with questions about the intervention and also provided practical advice. In this way, any problems were quickly and efficiently solved.

Step 1: Needs Assessment and Development of the Logic Model

According to the IM method, we conducted a needs assessment to gain an understanding of the determinants underlying DSM and the target population of this study.

The results of the needs assessment are summarized in a logic model (**Figure 1**). A logic model describes the health problem, its impact on quality of life and its behavioral and environmental causes (35).

Our logic model is based on the results of the literature review and the qualitative study and outlines: (i) the personal and external determinants related to the self-management behaviors of the target population and (ii) also that of people in their immediate social environment. This section describes the development of the logic model.

Development of the Logic Model

The needs assessment yielded many determinants related to the self-management of our target population. To explore these determinants, two theoretical models were applied that matched and further explained the results of the needs assessment, i.e., the I-Change model, and the transactional model of stress and coping (39, 49). The overall layout of the intervention is based on the I-Change model (49), which helped to decide in what order the determinants arising from the needs assessment should be addressed. However, because the needs assessment showed that the social network plays an important role in DSM, we combined the social network model of Berkman and Kawachi (50) with the I-Change model (**Figure 2**). **Figure 2** shows the way we aimed for the intervention to address the determinants arising from our needs assessment. Our needs assessment showed that social influence might impact which

TABLE 3 | Program components: phase 1.

Program components	Description
Review last meeting and exchange of experiences (10–15 min)	At the start of each meeting, the group leader discusses how the period since the last meeting has been, and how the participants worked on their homework. Participants were stimulated to ask questions, exchange experiences, and help each other with their homework
Collection of questions (5–10 min)	To guarantee that the meeting fits the needs of the participants, the group leader starts with a short description of the meeting and writes down the participants' questions on this topic. At the end of the meeting the group leader checks whether all questions have been answered
Sharing positive news (5 min)	To make participants more open for new information, they share positive news of the previous week with each other (self-affirmation). This news can cover any topic as long as it was experienced as positive by the participant
Sugar disease game (15–35 min)	Many meetings include a knowledge game. Participants participate in a quiz or a game, often teaming-up and competing with each other. The group leader only provides the information that participants ask for themselves. The aim is to only provide information needed by the participants and prevent giving an overload of information. The information provided was supported with visual aids from the Netherlands Institute for Health Promotion and Disease Prevention (NIGZ)
Nutrition game (60 min)	Participants were divided into groups and given plastic cards with photographs of dishes and foodstuffs. The cards are divided into breakfast, dinner, lunch, snacks, beverages and others. Participants can place cards on three different piles: green (eat as often as you like), orange (eat to a limited extent), and red (try to avoid, eat very rarely). They were asked to place each of these cards on the correct pile. Afterward, participants discussed the correct place for the cards with each other
Letter of the week (20–45 min)	This is a fictional letter from "someone with diabetes" who has a problem that needs to be solved. Participants are invited to brainstorm about the problem and help the writer of the letter to solve their problem. The letter of the week was used to uncover participants' tacit views and provide them with solutions they might be able to use themselves
Role-playing 20 min (on average)	Every meeting included a role-playing exercise in which participants practiced together with some difficult situation. Participants could also provide role-playing scenarios themselves (e.g., difficult situations with which they were personally confronted). Each exercise ended with the exchange of advice and tricks/ideas the participants could use in their own lives
Energizers (5–15 min)	Energizers included passing a ball along and giving the person who fetches the ball compliments, balancing on a balloon to feel all the muscles in the body, playing "web of life" (a game that shows that everybody needs each other), keeping a balloon in the air, etc. The aim of these energizers is to stimulate bonding between group members and to refresh participants so that they are able to absorb new information again
Exercising with participants (30 min)	To show the participants how to exercise for 30 min and also let them experience this, each meeting the group leader walks with the participants for 30 min around the neighborhood (i.e., the participants' own neighborhood). The group leaders are instructed to walk among the participants, so they can talk to everyone
Weighing pros and cons (15–20 min)	To change outcome expectations, the participants brainstorm about the pros and cons of certain behaviors (e.g., refusing food at a party). This can be done through group discussions, sometimes using a whiteboard to count the pros and cons. The group leader aimed to emphasize the pros to stimulate positive outcome expectations
Homework	The participants get homework at the end of each meeting. They were often asked to pay special attention to certain things (e.g., when do you smoke more than usual?) or to try and meet other participants outside of the meetings
Cookbook	The recipes of all participants were collected and compiled in a cookbook, which was given to the participants during the intervention. The cookbook also contained information about choosing healthy ready-to-eat meals for those participants who did not cook
Summarizing results and complimenting participants (10 min)	To help participants feel they had spent their time well, had helped each other and learned a lot, at the end of each meeting the group leader summarizes what the participants have learned, and tells participants that he/she is proud of them

health information reaches individuals (before awareness). We also observed that patients that received information, cues to action and/or were aware of their risks, were still hindered by social influences in their social environments (perceived social support, social influences, and social engagement) to change and maintain their behavior which is why social influences appears twice in **Figure 2**.

The needs assessment also showed that our target population has inadequate coping skills; this represents a challenge for the implementation of self-management behaviors. This finding is in line with other reports on coping and socioeconomic position. Therefore, in our intervention, we decided to emphasize the items "Ability factors" and "Barriers" of the I-Change model. These were extended by replacing them with the transactional model of stress and coping. Again, because the needs assessment stressed the importance of the social network, we extended this model with the social network model of Berkman and Kawachi (**Figure 3**).

In short, the logic model assumes that our target population has a lower quality of life (increased disability/morbidity, increased pain/discomfort, and increased depression/anxiety) due to long-term health problems (high morbidity, diabetes-related complications, increased risk for cardiovascular disease, and negative psychosocial outcomes such as high depression rate/stress). These long-term health problems are related to

TABLE 4 | Overview of topics in meetings for participants: phase 2.

Meeting	Topic	Content of meeting
1	Diaries 1: physical activity, medications and blood glucose levels	• Discussing the pros and cons of keeping a diary • Keeping a diary for exercise, medications and blood glucose (group exercise) • Walking with participants • *Meeting 4 for significant others*
2	Diaries 2: nutrition and smoking	• Review of the last meeting: exchange of experiences • Comparing diary for exercise, medications and blood glucose with formal guidelines (group exercise) • Keeping a diary for nutrition and smoking (group exercise) • Walking with participants
3	Choosing a behavioral goal	• Review of the last meeting: exchange of experiences • Comparing diary for nutrition and smoking with formal guidelines (group exercise) • Choosing a behavioral goal, action plan part 1 (group exercise) • Walking with group members
4	Problems and solutions	• Review of the last meeting: exchange of experiences • Exploring barriers and thinking of solutions together, action plan part 2 (group exercise) • Walking with group members
5	Barriers in the immediate social environments	• Review of the last meeting: exchange of experiences • Exploring barriers *in the immediate social environment*, action plan part 3 (group exercise) • Special attention to feeling guilty about burden on significant others regarding the disease (letter of the week) • Walking with group members • *Meeting 5 for significant others* • *Social network therapy session 1*
6	Solutions for barriers in the immediate social environment	• Review of the last meeting: exchange of experiences • Exploring solutions for barriers *in the immediate social environment*, action plan part 4 (group exercise) • How to ask for help (letter of the week, brainstorming) • Walking with group members
7	Practicing difficult situations	• Review of the last meeting: exchange of experiences • How to respond to peer pressure (role-playing) • Asking for help, being assertive (role-playing) • Walking with group members • Homework: keeping diaries again
8	Barriers and solutions part 2	• Review of the last meeting: exchange of experiences • Comparing new diaries and old diaries, action plan 5 (group exercise) and discussing what goes well and what needs to be improved • Walking with group members
9	Coping with difficult situations	• Review of the last meeting: exchange of experiences • Thinking ahead and being proactive in solutions • Dealing with risky situations in the future, action plan 6 (group exercise) • Walking with group members • *Meeting 6 for significant others*
10	Plans for the future	• Review of the last meeting: exchange of experiences • What are we going to do in the future (group exercise) • Dealing with risky situations in the future, action plan 7 (group exercise) • Walking with group members • *Social network therapy session 2*
11	End of the intervention	• Review of the last meeting: exchange of experiences • Looking back at phase 2 • Graduation phase 2: diploma

poor self-management behaviors and ineffective coping skills caused by external determinants (social engagement/support/influences) and personal determinants (negative outcome expectations, perceived cultural norms and social expectations, moral norms, low risk perception, lack of practical knowledge, low self-efficacy, inadequate use of social network resources, and inability to expand social network with diabetes-related resources). It was also expected that the barriers (both external and personal) would be related to more distant determinants (such as unemployment, poverty, and marginalization) and other societal factors (in our original logic model) that might also influence long-term health problems. However, as Intervention Mapping stipulates focusing on the most important/changeable determinants, it was decided not to include these distant determinants but to consider them as the contextual environment in which the patients live. Although it is beyond the scope of this chapter to describe all the results of the needs assessment, the abovementioned determinants are in accordance with earlier studies on people with diabetes living in lower socioeconomic neighborhoods.

TABLE 5 | Program components: phase 2.

Program components	Description
Homework	In phase 2, the homework of the participants consisted of keeping their diaries, working on their behavioral goals and staying in contact with other participants in the weeks that had no intervention meeting
Keeping a diary	For this intervention, special diaries were developed for the participants to keep. They consisted of an outline of the days, which the participants could fill in. For filling in we used stickers, drawings or, if possible, writing. For example, for smoking we had stickers of little cigarettes, for physical activity stickers with a "10" on it (for 10 min) and stickers with different colors for the medications. The nutrition diaries could be filled in by means of writing or drawing
Group exercise (30–45 min)	The group exercises consisted of assignments the participants had to do in small groups (3 participants). Their aim was to let the participant practice and ask each other for feedback in a non-threatening environment, before sharing their experiences with the whole group. It also aimed to clarify what the participants were struggling with and to provide the group leader with guidelines for further explanations
Weighing pros and cons (15–20 min)	To change outcome expectations the participants brainstormed with each other about the pros and cons of certain behaviors (e.g., refusing food at a party). This was done through group discussions, sometimes using a whiteboard to count the pros and cons. The group leader aimed to emphasize the pros to stimulate positive outcome expectations
Action plan	The action plan consisted of 6 parts. It contained many pictures and consisted of outlines the participants had to fill in. Participants who could not write were teamed up with someone that could. The participants were not given all parts of the action plan at once, to prevent them from getting discouraged. They received a portfolio in which they added a part of their action plan each meeting; in this way they did not have to face all the work they still had to do, but could see their work growing Part 1: Choosing a behavioral goal, making it specific, determining who could help with this goal, and thinking of a reward when achieving this goal Part 2: Determining two important barriers to achieve the behavioral goal (some of the barriers were already listed in the action plan for the participants to mark). For each barrier, the participant has to create five solutions (together with group members) Part 3: Determining important barriers in the immediate social environment to achieve the behavioral goal and thinking of solutions Part 4: Thinking about ways significant others can help with diet, physical activity, taking medications, monitoring of blood glucose levels, and quitting smoking or smoking less Part 5: Updating action plan according to keeping a diary and comparing this diary with the one filled out in the beginning of phase 2 Part 6: Determining risky situations in the near future (the coming 2 weeks) and making plans to overcome these risky situations Part 7: Determining two new risky situations in the near future (the coming 2 weeks) and making plans to overcome these risky situations
Role-playing [20 min (on average)]	Every meeting contained a role-playing exercise in which the participants practiced together with a difficult situation from their action plan. The participants could also provide role-playing scenarios themselves (e.g., difficult situations they were confronted with themselves). Each exercise ended with the exchange of advice and tricks the participants could use in their own lives
Exercising with participants (30 min)	Continuing to walk for 30 min. Each time a different participant was responsible for the content of the exercise, or the route the participants took

Therefore, here we describe only the most distinctive/new features of the intervention, i.e., specifically focusing on the social support/social influences affecting self-management, and on the educational requirements of these patients from a socioeconomically deprived neighborhood.

The Social Network and Self-management Behaviors

Diabetic patients that receive a lot of social support are better able to manage their diabetes than patients that receive little social support (22, 51–54). However, the immediate social environment of patients can hinder DSM. For example, negative interpersonal relationships (distrust, criticism, and dominance) also have a major impact on health and health behavior (23, 54–56). Non-supportive behaviors from family members and friends result in lower therapy adherence or lower metabolic control, and too much support (albeit intended by significant others) can be experienced as a form of interference (57–63). These social influences might have a stronger impact on health than social support alone (22, 50). There are indications that this is especially the case among people with lower health literacy (64). This stresses the need to examine the impact of all influences of the social networks of patients on self-management behaviors.

The social networks of individuals in socioeconomically deprived neighborhoods often consist of persons that are in the same situation as themselves. For example, in the Netherlands, low-income households are often clustered in the same neighborhoods and work environments (65). Moroccan, Turkish and Surinamese immigrants often live in neighborhoods and work in environments consisting mainly of people with the same non-Western ethnic background (66). For people in socioeconomically deprived neighborhoods, the neighborhood they live in and their family members generally form the most important source of their social contacts (65).

TABLE 6 | Overview of the content of the meetings for significant others.

Meeting	Topic	Content of meeting
Phase 1		
1	Sugar disease and blood glucose levels	• Getting to know each other (introduction of participants) • Watching a DVD • Glucose, insulin and the origin of diabetes (sugar disease game) • Experiencing what it is like to measure blood glucose and thinking of ways to support someone with this (measuring blood glucose, followed by a group discussion) • Homework o Reading the leaflet "What is diabetes?" o If they do not know how to use glucagon: ask a relative/friend or pharmacy
2	Medication and physical activity	• Review of the last meeting: exchange of experiences • Importance of taking medications and of physical activity (letter of the week, and weighing pros and cons) • Brainstorming and exchanging advice about ways to support a relative/friend with taking medications and physical activity (group discussion) • Homework: o To be physically active (e.g., by participating in Netherlands in Motion)
3	Healthy nutrition	• Review of the last meeting: exchange of experiences • Discussing the importance of healthy eating (weighing pros and cons) • Information about a healthy diet (nutrition game) • Brainstorming and exchanging advice about ways to support a relative/friend with eating healthy (group discussion)
Phase 2		
4	Diaries	• Collection of questions • Practicing filling in a diary and discussing ways to support someone with filling in a diary (group exercise)
5	Behavioral goals and improvement points	• Review of the last meeting: exchange of experiences • Collection of questions • Choosing a behavioral goal (action plan: part 1) • Thinking about helpful and non-helpful behavior (group exercise, weighing pros and cons)
6		• Review of the last meeting: exchange of experiences • Exchanging experiences and advice on how to help someone with diabetes regarding different topics: diet, medications, physical activity, smoking, monitoring of blood glucose levels (letter of the week) • Module of choice (see **Table 2**)

Social relationships between people that are in the same difficult situation (e.g., situations characterized by exclusion, stigmatization, and/or poverty) are often strong because of these shared experiences. The social networks they reside in are often smaller and less open than those of people with a higher socioeconomic status (26). The social networks of people in socioeconomically deprived neighborhoods often consist primarily of bonding social capital (social interactions between members of a homogeneous social network) and lack bridging social capital (social interactions that allow social network members to access resources other than those in their own social networks) (26, 65, 67).

According to the social network model of Berkman and Kawachi, the social network influences health through the following five mechanisms: (i) social support, (ii) social influence, (iii) social engagement, (iv) person-to-person contact, and (v) access to resources and material goods (50).

Social support consists of emotional, instrumental, informational and appraisal support. Social influence consists of constraining/enabling influence on health behavior, social norms, peer pressure, and social comparison processes. Social engagement consists of physical/cognitive exercise, reinforcement of meaningful social roles, bonding/interpersonal attachment, and "handling and grooming" effects. Moreover, the social network approach assumes that not every social network is necessarily beneficial for the health of its members. Also, some social networks are better in promoting health than others, but not everyone has equal access to these social networks (26).

Small, closed, and dense social networks, like those of our target population, might positively influence health because the exchange of social support is often high (26). However, the strong interdependence between social network members can also prevent members from acquiring new information and "getting ahead" in life (65, 67, 68). Small social networks are also associated with lower therapy adherence and lower metabolic control (59, 69). In addition, this type of social network is known to impose strong social norms on its members; when these social norms are incongruent with health behaviors, these social networks often have an adverse influence on the health of its members (70).

Social Network and Self-management Behaviors in Patients from Socioeconomically Deprived Neighborhoods

Five major themes related to the role of significant others in self-management behaviors emerged from the qualitative data of our needs assessment: (i) trying not to bother others, (ii)

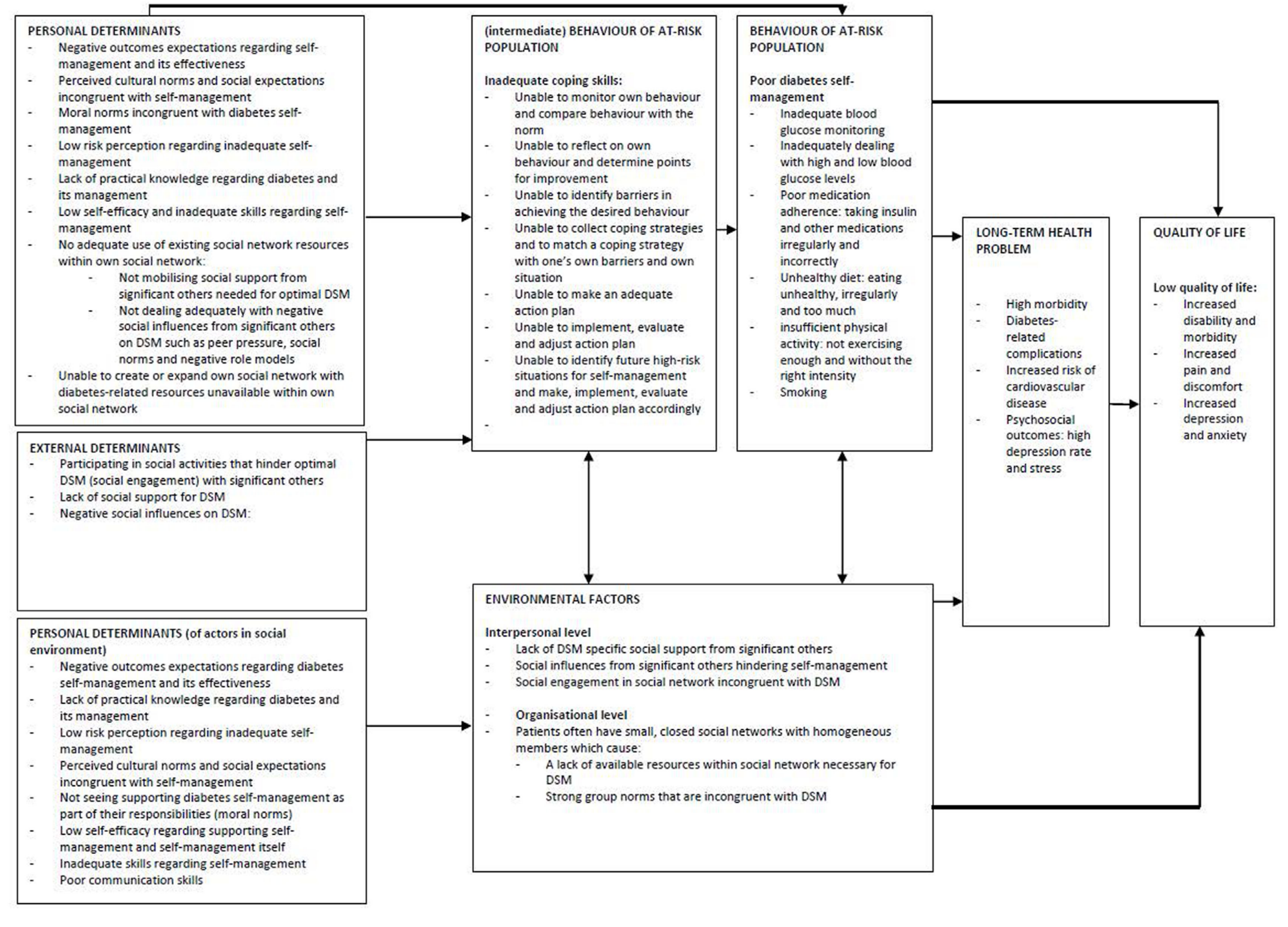

FIGURE 1 | Results of the needs assessment: the logic model.

trying not to stand out at social events, (iii) peer pressure at social events, (iv) social norms regarding medication use and physical activity, and (v) having no "allies" in the immediate social environment.

Trying Not to Bother Others

Most respondents indicated that they considered their diabetes to be their own responsibility and did not want to bother their significant others (mostly partners, children and friends) with their condition. Most respondents did not see any advantage in asking for social support and indicated that they were capable of managing their diabetes by themselves.

As a result, these respondents often felt "bad" in front of their significant others if they had to take their diabetes into account. For example, some respondents said that they felt sorry for their partners because they always have to set the alarm clock to take their insulin on time, even when their partner wants to sleep. They often did their best not to burden their significant others with their self-management. As a result, our respondents (as well as the participants in the diabetes forum) indicated that they always have to be the stronger person, which demands a lot of self-control.

> I often have to watch my husband eating a whole bowl of custard, cream and chocolate flakes. That's really difficult, but I don't want to put him under pressure – I'm the one who's sick, not him … (Patient).

The health-care professionals indicated that relatives often know very little about diabetes and/or the ways to help out with self-management, or they think they are being helpful whereas this is in fact perceived differently by the diabetic patients.

Not asking for support also affected the ability of the respondents to make changes in their self-management. For example, all women from the ethnic minority groups indicated that it is difficult to cook something different, or serve more healthy food, when their significant others do not like it and/or refuse to eat it.

> (…when serving brown rice instead of white rice): "Then they ask – what've you made now? Coconut?" (Patient).

Trying Not to Stand Out during Social Events

Most respondents were aware that they and their significant others shared the same unhealthy lifestyle. For most respondents,

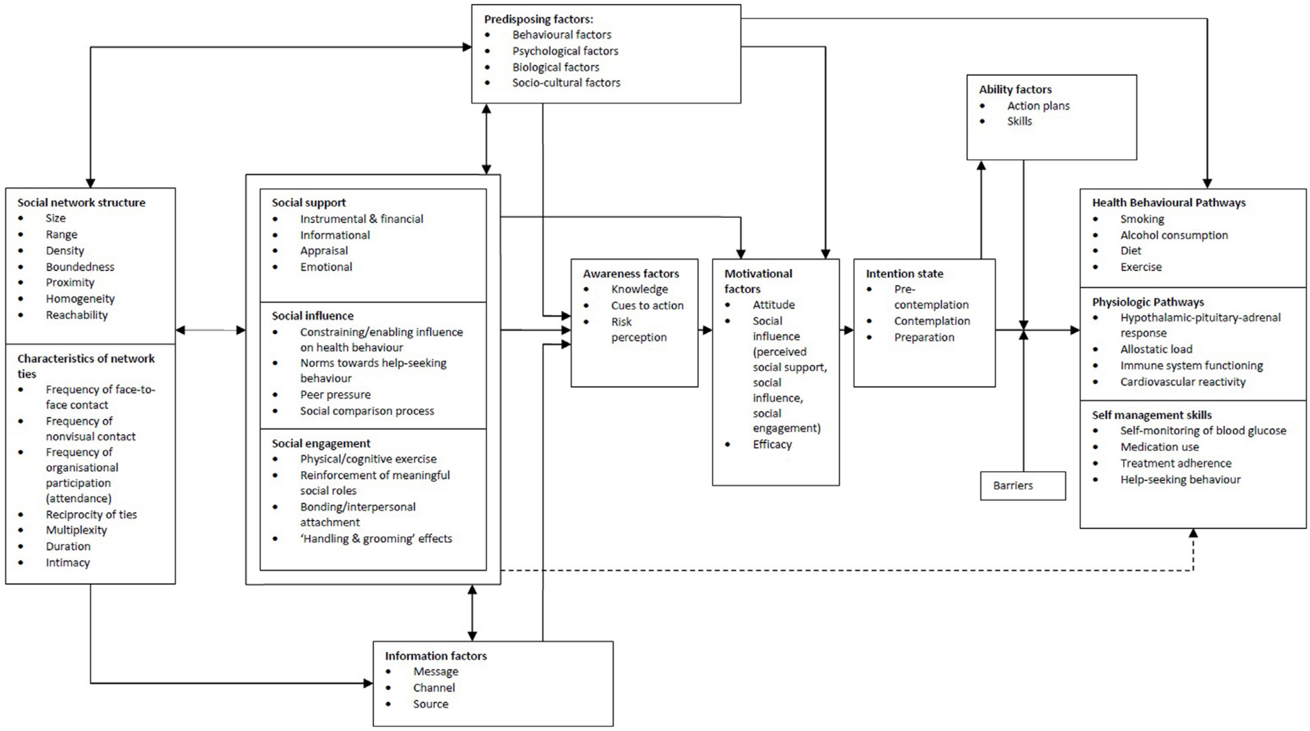

FIGURE 2 | The I-Change model combined with the social network model of Berkman and Kawachi (50).

adhering to the diabetes guidelines meant behaving differently from their significant others. Most respondents did not want to draw attention to themselves and their diabetes, i.e., they did not want to stand out in general and especially not during social events.

Particularly the combination of not wanting to bother others and trying not to stand out during social events proved detrimental for their self-management behaviors. When eating at the house of a friend/relative, patients tried to blend in with the others and would not ask the host to take their diabetes into account (e.g., to eat at a certain time, or to make/buy special foods). This often caused uncomfortable situations (e.g., not eating everything that was served, or having to ask for something to eat before dinner) and often required extra self-management skills (e.g., eating in advance, rearranging their insulin dosages).

Social parties were also experienced as being difficult. The respondents did not want to bother the host with questions about the ingredients or ask him/her to make something especially for them. Therefore, they often did not know what they can/cannot eat. Also, it is difficult to predict how often people might come around offering snacks and what these snacks might contain. This combination of not asking for support and trying not to cause a fuss also made going out to dinner difficult. Respondents said they sometimes had to wait too long for their food and, because they do not always know what the ingredients are, this makes injecting the right amount of insulin a challenge.

Trying to "blend in" also affected their medication use. Most respondents did their best not to inject insulin during social situations. Some said that the looks from other people made them feel uncomfortable, others said that their relatives did not like to witness an injection (fear of needles), and sometimes asked annoying questions, or interfered too much.

Peer Pressure at Social Events

The respondents reported a lot of peer pressure and temptations at social events that affected their diet. Most said that they found it unpleasant when everybody was eating, whilst they either cannot or should not eat that particular food.

The Turkish, Moroccan, and Surinamese respondents indicated that the food plays a central role in their daily life. Offering food is seen as a sign of hospitality and it is customary to prepare extra food for guests. Refusing food is seen as impolite. Although respondents knew that they should not accept all the food that is offered, they did not want to hurt anybody's feelings. Therefore, they often "act" as though they (temporarily) do not have diabetes, or try to avoid these situations as much as possible.

Almost all respondents had difficulty in resisting temptation and often felt under pressure to eat unhealthy/too much food, especially in the presence of negative role models.

> "… when you're at a party and other people with diabetes eat really unhealthy things". Or 'they' (people

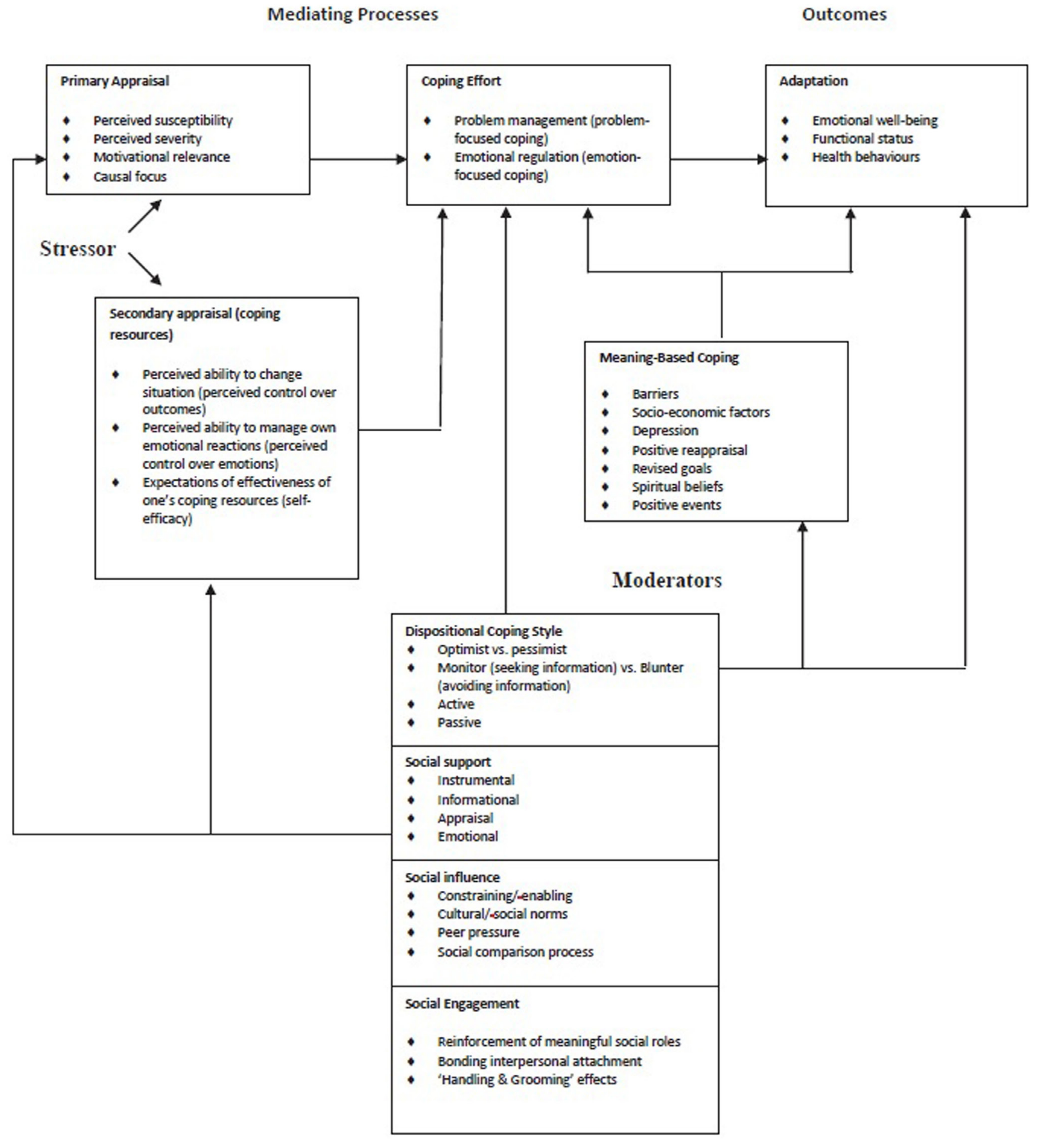

FIGURE 3 | Transactional model of stress and coping combined with the social network model of Berkman and Kawachi (50).

> at a party) say: "Well, this one and that one have got diabetes - and it's OK for them" (Patient).

The respondents handle these situations differently: some accept that their blood glucose levels will be too low or too high.

Social Norms Regarding Medication Use and Physical Activity

The needs assessment showed that social norms were especially prevalent in medication use. All respondents indicated that they prefer not to take any medication at all. Medications are often regarded as "chemicals" that are not good for their body. Most respondents did not see their medication use as something permanent and hoped that 1 day they could live without medication. This was confirmed by the health-care professionals who reported that patients often think that if they lose weight they can live without medication. Most respondents had a strong aversion to insulin and indicated that they definitely did not want to use insulin in the future.

> Then (when you have to use insulin) – that's when you're really sick (Patient).

According to the health-care professionals, Hindustani Surinamese persons often prefer not to take medications and have a strong tendency to see if they can manage without them. They fear that the medications will damage their kidneys; moreover, when they feel unwell they often skip their medication. Especially the use of insulin is experienced as a problem by these patients as it is associated with severe diabetes-related complications. We also observed that Surinamese patients sometimes try to "cleanse" their body by not using medications for a longer period of time. In addition, the interviews showed that Surinamese patients often get advice from other persons not to take their medications but to use "nostrums" (remedies from non-physicians) such as certain herbs or vegetables.

Turkish and Moroccan patients often have doubts about the medications prescribed by their physician. In Morocco and Turkey, physicians generally prescribe more medications and behave in a more authoritative way. Physicians in the Netherlands tend to ask more questions, which is interpreted by patients as lack of competance (3). The health-care professionals reported that, after the summer, these patients often arrive at consultations with a bag of (unnecessary) "new" medications they received from physicians in Morocco or Turkey. They also indicated that, among Moroccan and Turkish men, medications are sometimes associated with impotence.

During Ramadan, 60–80% of Turkish and Moroccan patients is non-adherent to their medications (71). Individuals who cannot participate during Ramadan due to illness are supposed to compensate by giving money to the poor. However, interviews with professionals revealed that this can be problematic when the individual involved has little/no money. According to the professionals, some alternatives, such as taking food to the poor, are also difficult because this is not socially accepted behavior in the Netherlands.

Social norms also affect physical activity. For example, Moroccan, and Turkish women mentioned they had no money to go to the gym, and that simply "walking around" was not an option for them. They were worried about what people in the neighborhood might think if they just "walked around" without going anywhere/without a valid reason. This situation was confirmed by the health-care professionals.

No "Allies" in the Immediate Social Environment

Most respondents said that they only knew a few people with diabetes and, often, they did not identify with them. For example, these acquaintances had different ways of dealing with their diabetes or were worse off than themselves, making it difficult to exchange ideas, ask questions, or share experiences. This affected multiple self-management domains. Also, quitting smoking was difficult because they were often surrounded by smokers and felt they were the only ones trying to quit.

> … just try stopping when you're living in a house with five smokers! (Diabetes forum).

Also, especially Dutch respondents said that they did not go to the gym (or go walking) because they had no one to go with, or had no one who thought it necessary to go to the gym.

Considerations Regarding Health Promotion in Patients from Socioeconomically Deprived Neighborhoods

The needs assessment also provided us with considerations related to health promotion in patients from socioeconomically deprived neighborhoods that needed to be taken into account when developing a group-based intervention for patients from socioeconomically deprived neighborhoods.

The respondents often had busy lives: they spend a lot of time taking care of their family (e.g., grandchildren and chronically ill relatives) and/or working. Some respondents felt stressed due to financial problems, or problems with raising their (teenage) children, or were worried about relatives living abroad. This was confirmed by the health-care professionals who reported that these patients often had difficult lives before the additional problem of developing diabetes.

> You're already having a tough time - then you also get one of the most difficult diseases that exist (Health-care professional).

Because of this, their disease was often given a low priority. Although they did what they had to do for their diabetes, most did not actively seek information about diabetes themselves. Some respondents expressed the desire for the diabetes nurse or the dietician to simply tell them what they had to do. According to the respondents, the diabetes regime is always complicated because one has to constantly think about the choices to be made and it is never simply "yes" or "no." The health-care professionals stated that these patients do not necessarily want lots of medical information about their disease, but mainly want to know what they *have* to do and what they *cannot* do.

Second, the interviews revealed that most respondents have a low level of education, i.e., the majority had attained no, or only one, diploma. They had little learning experience, or their learning experiences were mostly negative, e.g., being unable to follow the classes, or being bored during lessons. These respondents were not convinced that "education" would help them to better understand their diabetes; they said that they were not suitable to learn things, or that "learning was not really their thing." From our observations during the intervention "*Dealing with diabetes*" we knew that most participants had little experience with following classes. The more traditional educational methods (e.g., the teacher talks and the audience listens) did not seem suitable for this population, e.g., they had a short attention span and became distracted when they did not understand the information presented. Instead of asking questions, the participants generally chose to focus on something else (e.g., their telephones, or other participants).

Moreover, reading and writing was often a challenge for these respondents; this was confirmed by the interviews with the professionals. Also, the level of knowledge about diabetes differed between the respondents; some were unable to name one thing they had to do for their diabetes and could not recall whether they had ever heard of high/low blood glucose levels, whereas others could distinguish between their medications and also explain the basics of diabetes.

The needs assessment also revealed factors that might be important for the group process during the intervention. Most respondents were rather direct/blunt when we first met them ("rough diamonds"); however, this type of attitude can be problematic in a group where everybody needs to feel safe to speak freely. Moreover, it may be a challenge to find a balance between dealing with one's problems in daily life whilst also focusing on the aims of the intervention.

Conclusions of the Needs Assessment

In conclusion, patients from socioeconomically deprived neighborhoods generally have social networks that seem less beneficial to self-management because of their small size and the limited ability to acquire new information. Furthermore, the strong social norms these social networks impose on their members seem incongruent with self-management behaviors. Moreover, these patients receive little social support for self-management behaviors because they often lack sources of support in their social networks and are reluctant to ask for social support or show others that they need it. These patients find it difficult to deal with influences from their social network such as various temptations, peer pressure, negative role models, and social norms. Moreover, for these patients, some of their significant others are unaware that they can/should help, or they simply do not know how to help.

During interventions for patients from socioeconomically deprived neighborhoods, the following aspects should be taken into account: low outcome expectations regarding education and low motivation for education; a low priority for diabetes; a desire for practical information; reading and writing difficulties; differences in knowledge about diabetes and factors that might affect the group process during the intervention.

Step 2: Creating Performance and Change Objectives

The second step in IM is the development of matrices of change objectives that describe what needs to change in behavior and the environment to improve health and quality of life (35). We specified change objectives that describe what needs to change to achieve performance objectives, which in turn will lead to changes in behavioral and environmental conditions that will lead to accomplishing the program goals (35).

Formulating Program Goals

The needs assessment showed that our target population encountered influences that affected their self-management within their social networks (bonding social capital), including lack of social support, peer pressure, and social norms but also experienced difficulties in accessing other resources (bridging social capital) outside their social networks, such as new information, an ally/buddy, and other positive role models. In addition, they did not make adequate use of the social network resources already present in their social networks (asking for support, not dealing adequately with peer pressure, social influences and negative role models).

Therefore, based on the needs assessment and consultations with the experts, when we formulated program goals it was decided that our intervention should not only focus on the patient and their immediate social environment (bonding social capital) but also on bringing diabetic patients in contact with fellow patients (bridging social capital) thereby extending their social networks with diabetes-related resources. We aimed to extend the participants' social networks with more diabetes-related resources while simultaneously making their own social networks more diabetes friendly. Accordingly, the following program goals were formulated for the social network that should be achieved by participation in the intervention:

(1) Extend the participants' diabetes-related social networks, facilitating the exchange of social support and positive social influences with group members,
(2) Increase the participants' ability to handle social influences that hinder their self-management such as norms, peer pressure, and temptations,
(3) Increase the engagement and support of the participants' significant others in their self-management.

Performance and Change Objectives

This section focuses on the performance and change objectives that were formulated to achieve the program goals for the social network. The program goals for the social network were translated into performance objectives and change objectives. **Table 7** provides an overview of the performance objectives for the entire intervention. The health-promoting behaviors of the social network are formulated as performance objectives but also as change objectives: objectives for determinants supportive of self-management behaviors.

We organized two brainstorming sessions with five researchers who studied diabetes, nutrition, overweight and physical activity among patients in lower socioeconomic groups, or in minority groups. During these sessions, we checked the content of our performance objectives against their findings and experiences. Then, three researchers who had experience with Intervention Mapping, critically reviewed our performance and change objectives to see if they matched the Intervention Mapping conditions and were suitable to build our intervention on. Based on these meetings, our performance objectives were adjusted where necessary.

TABLE 7 | Performance and change objectives of the intervention *Powerful Together with Diabetes*.

Performance objectives	The participant	The participant in relation to their significant others	The significant others	The support group of the participants
Phase 1	1. Participant deals adequately with diabetes 1.1. Participants know the origins of diabetes 1.2. Participants know the basics about what happens in the body 2. Participant is therapy adherent with regard to medications 2.1. Participant takes his medications correctly and consistently every day 2.2. Participant takes his insulin correctly and consistently every day 3. Participant optimally manages his blood glucose levels 3.1. Participant self-monitors his blood glucose levels correctly and consistently 3.2. Participant adequately deals with high/low blood glucose levels 4. Participant has a healthy eating pattern 4.1. Participant eats sufficient healthy foods every day 4.2. Participant exercises regularly every day 5. Participant exercises enough 5.1. Participant exercises enough every day 5.2. Participant exercises with the right intensity every day 6. Participant does not smoke 6.1. Participant quits smoking	1. Participant tells significant others which obstacles he encounters with the correct and consistent intake of medications 2. Participant tells significant others which obstacles he encounters when managing blood glucose levels 2.1. Participant tells significant others which obstacles he encounters when monitoring blood glucose levels 2.2. Participant tells significant others which obstacles he encounters when dealing with high/low blood glucose levels 3. Participant tells significant others which obstacles he encounters when maintaining a healthy eating pattern 3.1. Participant tells significant others which obstacles he encounters when eating sufficient healthy foods 3.2. Participant tells significant others which obstacles he encounters when trying to eat regularly 3.3. Participant tells significant others which obstacles he encounters when trying not to eat too much each day 4. Participant tells significant others which obstacles he encounters when being physically active 4.1. Participant tells significant others which obstacles he encounters when exercising sufficiently 4.2. Participant tells significant others which obstacles he encounters when exercising with the right intensity 5. Participant tells significant others which obstacles he encounters when not smoking 5.1. Participant tells significant others which obstacles he encounters when trying to quit smoking	1. Significant others gather basic information on diabetes 1.1. Significant others attend the meetings that they are invited to attend 1.2. Significant others collect new information on diabetes 2. Significant others support the patient to take medications correctly and consistently 3. Significant others support the patient to take insulin correctly and consistently 4. Significant others support the patient to manage blood glucose levels 4.1. Significant others support the patient to correctly monitor blood glucose levels 4.2. Significant others support the patient to correctly deal with high/low blood glucose levels 5. Significant others support the patient to maintain a healthy eating pattern 5.1. Significant others support the patient to eat sufficient healthy foods 5.2. Significant others support the patient to eat regularly 5.3. Significant others support the patient to not eat too much 6. Significant others support the patient to be physically active 6.1. Significant others support the patient to exercise sufficiently 6.2. Significant others support the patient to exercise with the right intensity 7. Significant others support the patient to quit smoking	1. Participants in the support group continue to participate 2. Participants in the support group experience the atmosphere as positive and pleasant 3. Participants in the support group experience the meetings as fun and informative 4. Participants in the support group trust each other and feel safe with each other 5. Participants in the support group share experiences with each other 6. Participants in the support group listen to each other 7. Participants in the support group respect each other's opinions
Phase 2	1. Participant monitors his own behavior (medications, insulin, nutrition, physical activity and smoking) 1.1. Participant compares his own behavior with the norm	1. Participant tells his significant others what support he needs 2. Participant brainstorms with significant others about what needs to be changed to receive this support	1. Significant others see diabetes self-management (DSM) as a shared responsibility 2. Significant others regularly ask about how the DSM is going	1. Participants in the support group form a team

(*Continued*)

TABLE 7 | Continued

Performance objectives	The participant	The participant in relation to their significant others	The significant others	The support group of the participants
	1.2. Participant specifies goals for own behavior 2. Participant indicates obstacles to achieve goals 2.1. Participant indicates internal obstacles 2.2. Participant indicates obstacles in immediate social environment 3. Participant collects possible coping strategies to overcome obstacles when achieving goals 4. Participant chooses coping strategy that fits him and his problem(s) 5. Participant makes an action plan to implement the chosen coping strategy 6. Participant carries out the action plan 7. Participant evaluates the action plan and adjusts it when necessary 7.1. Participant evaluates the action plan 7.2. Participant adjusts the action plan when necessary 8. When experiencing a relapse, the participant interprets this positively (not as a failure) and goes back to 3 8.1. Participant interprets relapse positively 8.2. Participant goes back to 3	2.1. Participant brainstorms with significant others about what he can change about himself 2.2. Participant brainstorms with significant others about what they can change about themselves 3. Participant makes agreements with significant others about giving and receiving support 4. Participant implements the appointments with significant others 5. Participant evaluates the implementation of the appointments with significant others 6. Participant adjusts the agreements together with significant others when necessary 7. Participant asks for support of significant others when experiencing a relapse and goes to 2 7.1. Participant asks for support after a relapse 7.2. Participant goes back to 2 after a relapse	2.1. Significant others regularly ask the participants how the DSM is going 2.2. When the DSM goes well the significant others give the patient compliments 2.3. When experiencing obstacles, the significant others give positive feedback 3. Significant others brainstorm with the participant about the source of these obstacles 3.1. Significant others brainstorm with the participant about obstacles within the participant 3.2. Significant others brainstorm with the participant about obstacles outside the participant 4. Significant others choose a constructive strategy to overcome these obstacles together with the participant 4.1. Significant others choose a suitable strategy with the participant 5. Significant others make agreements with the participant 5.1. Significant others concur with the participant on agreements about asking for and receiving support 6. Significant others keep these agreements 7. Significant others evaluate these agreements and adjust them when necessary 7.1. Significant others evaluate the agreements together with the participant 7.2. Significant others adjust the agreements with the participant when necessary and go to 2.1 8. Significant others avoid using punitive remarks when the participants experience a relapse 8.1. Significant others avoid punitive remarks 8.2. Significant others go to 2.3	2. Participants in the support group participate in activities together to improve their DSM (besides the regular group meetings) 3. Participants in the support group keep on supporting each other with their DSM after the end of the intervention
	1. Participant identifies future risk situations for his DSM 2. Participant chooses the most suitable coping strategies to prevent these risk situations turning into a relapse 3. Participant makes an action plan 4. Participant implements the action plan before encountering high-risk situations 5. Participant evaluates his coping strategy and adjusts it when necessary 5.1. Participant evaluates his coping strategy 5.2. Participant adjusts the action plan when necessary and goes back to 4	Same as above	Same as above	

The performance and change objectives were formulated on the following four levels:

(1) the participant,
(2) the participant in relation to their significant others,
(3) the significant others,
(4) the participant's support group as part of the intervention.

Tables 8–10 provide an example of the change objectives for the performance objective "Patient adequately monitors his/her blood glucose levels," "Patient explains obstacles during monitoring of blood glucose levels to significant others," and "Significant others support patient with adequate monitoring of blood glucose levels" (levels 1–3). Because we anticipated challenges in the group process of the intervention (which was a key aspect of this intervention) we also formulated performance and change objectives for level 4, i.e., the participant's support group as part of the intervention (**Table 11**).

Step 3: Selecting Theoretical Methods and Practical Strategies

In this step, we selected change methods based on the performance and change objectives. Based on these change methods we created practical strategies that formed parts of the program lay out (35). For this intervention, the practical strategies and program components were developed together with a psychologist who has considerable experience in working with lower socioeconomic groups. When selecting theory-informed intervention methods/practical strategies and producing program components/materials, the literature and other ongoing lifestyle interventions were scrutinized for methods and strategies that would be suitable for our target population. These practical strategies/program components were submitted twice to a panel of migrant health workers with a Turkish, Moroccan, and Surinamese background ($n = 6$). In addition, panel members were consulted individually about the specific cultural groups in our target population. Finally, some of the intervention components were pre-tested among the target population by means of focus group discussions ($n = 3$) in which we "practiced" some of the intervention components.

The next section describes the ways we used our needs assessment to choose methods and strategies for the intervention.

Methods and Strategies Specific for Patients from Socioeconomically Deprived Neighborhoods

This section describes the ways we considered the results of the needs assessment regarding our methods/strategies for our target population. From the needs assessment we knew that our target population had little (or primarily negative) experiences with education. Therefore, when selecting our theoretical methods we aimed to make learning as much fun and as interesting as possible. The aim was to make our participants curious about diabetes-related topics and make participation a positive experience by focusing on the abilities of our participants rather than on their shortcomings.

One of our strategies included an inductive educational approach (72). In contrast to deductive education that stems from theory, inductive education is built from the students' experiences. Instead of telling students what they need to know from a theoretical point of view (deductive approach), we let the students practice with a problem they can relate to and slowly add information and theory to their understanding (inductive approach). Using this approach, the group leader can also investigate what the participants already know and which knowledge is incorrect or new (since the amount of foreknowledge about diabetes differed). Therefore, an inductive approach focuses on the abilities of the students and is closely connected with their interests (72). An example of the inductive approach is the game about nutrition: the participants had to solve a puzzle (what foods are green, which are orange and which are red?) together. The aim was to let them brainstorm together, focus on what they already knew, let them discover themselves what they did not know, and add to their knowledge and understanding where necessary.

To make learning as much fun as possible, it was important that the participants did not feel as though they were students but, nevertheless, felt that they benefited from each meeting. At the beginning and during the intervention, it was emphasized that they could help other participants with their own experiences and feedback (participatory problem solving). We did not use traditional educational strategies (such as teaching in front of a classroom) but non-traditional intervention strategies such as games and role-playing, with (fun or relaxing) energizers to optimize the attention span. The participants were encouraged to relate what they would "take home" from the intervention to help them realize what they had learned, or their particular significance for the other participants.

We also focused on self-affirmation by accentuating the personal qualities of the participants. This is a method to stimulate cognitive developments (72) and avoid dismissive/defensive reactions toward information perceived as a threat, and makes participants more perceptible for new information (73, 74). Practical strategies included giving each other compliments and constructive feedback, energizers, and sharing the positive news of the week at the start of each meeting.

To ensure a close connection to the interests of our participants, we involved them in the intervention through active learning to increase relevance and interest. This meant that the participants had direct influence on the topics and rehearsal situations addressed during the intervention.

Because most participants had a low educational background and problems with reading/writing, it can be difficult for them to learn/remember new information. Therefore, we used practical educational methods that enabled participants to remember the provided information and to practice real-life situations. Practical strategies included skills training with guided practice and feedback (practicing situations) and "chunking" (breaking up long pieces of information into easy to remember chunks). Also, a limited amount of information was provided at each meeting, and information from the previous meeting was always repeated at the latest meeting. In phase 2, the participants had to plan coping responses with the help of an action plan; this plan mainly consisted of the use of stickers and pictures.

TABLE 8 | Example of change objectives—the participant.

Performance objective	Personal determinants					External determinants	
	Attitude, outcome expectations	**Perceived (cultural) norms and social expectations**	**Moral norms**	**Knowledge**	**Self-efficacy and skills**	**Social Support**	**Social influence**
Participant monitors blood glucose levels correctly and consistently	Participant expects that monitoring his blood glucose levels correctly and consistently will provide more control and security Participant expects that he will understand his body better by monitoring blood glucose levels	Participant realizes that monitoring blood glucose levels is more important than trying to fulfill social expectations	Participant regards monitoring blood glucose levels correctly and consistently as a part of daily life	Participant knows why he needs to monitor blood glucose levels Participant knows why, how, and when he needs to monitor Participant knows that he has to monitor blood glucose levels before, during and after a day in the sun (holiday) Participant knows he has to monitor blood glucose levels more often during illness, or after a change in eating pattern	Participant feels confident that he can monitor blood glucose levels during social activities Participant feels confident that he can monitor blood glucose levels during special occasions Participant shows that he can attribute "bad" blood glucose levels as controllable Participant shows he can adequately deal with significant others who give him strange looks, or find it unpleasant when he monitors blood glucose levels	Significant others accept the monitoring of blood glucose levels by the participant Significant others indicate that the monitoring of blood glucose levels is necessary Significant others make sure the participant has a quiet place to monitor his blood glucose levels or Significant others find it normal that the participant monitors blood glucose levels in their company	Significant others accept that the participant regularly monitors blood glucose levels and support him

TABLE 9 | Example of change objectives—the participant in relation to their significant others.

Performance objective	Personal determinant				External determinants	
	Attitude, outcome expectations	**Perceived (cultural) norms and social expectations**	**Moral norms**	**Self-efficacy and skills**	**Social support**	**Social influence**
2.1. Participant tells his significant others which obstacles he encounters when monitoring his blood glucose levels	Participant expects that informing his significant others will not affect his autonomy, but will make monitoring blood glucose levels correctly and consequently easier The participant expects that informing his significant others will enable them to better support him when monitoring his blood glucose levels The participant expects that the burden he will put on his significant others will be acceptable	Participant realizes that his significant others might influence the management of his blood glucose levels: – Asking annoying questions – Giving funny looks or being disgusted – Acceptance of monitoring – Not being helpful with high or low blood glucose levels Participant realizes that his significant others cannot take his needs into account if he does not inform them Participant realizes that informing his significant others is more important than blending in with the others (i.e., acting as though nothing is wrong; acting as normal as possible) Participant realizes that informing his significant others is more important than being afraid of burdening them	Participants regards informing his significant others as a part of his responsibilities	Participant is confident to dare and to be able to inform his significant others about the obstacles he encounters when monitoring his blood glucose levels Participant is able to show how to inform his significant others about the obstacles he encounters when monitoring his blood glucose levels	Participants in the support group help with thinking about the best ways to inform each other's significant others about the obstacles they encounter when monitoring their blood glucose levels Significant others indicate that they are interested in the obstacles the participant encounters when monitoring his blood glucose levels	Participants in the support group encourage the participant to inform his significant others about the obstacles he encounters when monitoring his blood glucose levels Participants in the support group exchange positive experiences with informing significant others about the obstacles they encounter when monitoring his blood glucose levels Participants in the support group inform their significant others (positive example for other group members) about the obstacles they encounter when monitoring their blood glucose levels Significant others encourage the participant to tell them about the obstacles he encounters when monitoring his blood glucose levels

TABLE 10 | Example of change objectives—the significant others.

Performance objective	Personal determinants				
	Attitude, outcome expectations	**Knowledge**	**Perceived (cultural) norms and social expectations**	**Moral norms**	**Self-efficacy and skills**
4.1. Significant others support the participant when monitoring his blood glucose levels correctly and consequently	Significant others expect that the participant will be better able to manage his diabetes when he regularly monitors his blood glucose levels Significant others are receptive to new information about the monitoring of blood glucose levels	Significant others know that the monitoring of blood glucose levels is an important part of DSM Significant others know how and when the participant needs to monitor his blood glucose levels Significant others know that the participant needs to monitor more often when the participant's temperature is high, when the participant is ill, or when the participant alters his eating pattern	Significant others realize that the monitoring of blood glucose levels is more important than blending in with the others	Significant others regard supporting the participant with the monitoring of his blood glucose levels as part of their responsibilities	Significant others are confident that they can support the participant with the correct and consistent monitoring of his blood glucose levels Significant others can tell what kind of support the participant needs from them Significant others can tell how they can offer this support in the best way

TABLE 11 | Example of change objectives—the participant's support group.

Performance objective	Personal determinants				External determinants	
	Attitude, outcome expectations	**Perceived (cultural) norms and social expectations**	**Moral norms**	**Self-efficacy and skills**	**Social support**	**Social influence**
1. Participants in the support group continue to participate in the group meetings	Participants in the support group expect that participation will increase their control over their diabetes Participants in the support group expect that participation will motivate them to keep exercising, eat healthy and quit smoking	Participants in the support group believe that their group members will also keep on participating Participants in the support group feel that they are expected to keep on participating Participants in the support group realize that participating in the support group is more important than fulfilling other social expectations	Participants in the support group view participating in the support group as something that belongs to them Participants in the support group feel like part of the group	Participants in the support group are confident that they can keep participating in the support group Participants in the support group can show how to deal with negative remarks from significant others about participation Participants in the support group show how to conquer doubts and a lack of motivation to attend the group meetings	Participants in the support group support each other in dealing with negative remarks from significant others Participants in the support group support each other in dealing with doubts and a lack of motivation to attend the group meetings Participants in the support group give each other positive feedback when missing a meeting During each meeting, the group leader indicates how good it is that everybody is present Significant others facilitate the participant to attend the group meetings (taking care of the children, helping in the household, not nagging about the meetings, not prohibiting the participant to attend)	Participants in the support group keep participating (positive example for other group members) Significant others indicate that they appreciate that the participant keeps on participating

TABLE 12 | Theoretical methods and practical strategies.

General objective	Subgoals	Theoretical methods	Practical strategies
1. Extending participants' diabetes-related social networks, facilitating the exchange of social support and positive social influences with group members	– Participants positively influence each other (role models, positive peer pressure, positive group norms) – Participants encourage and support each other in adhering to their self-management during the intervention, and continue to support each other after the intervention has ended (advice, helping each other) – Participants continue to see each other after the intervention, and continue to do DSM-related activities together (e.g., exercising)	Skills training for providing and mobilizing social support Participatory problem solving Conscientisation methods Team building and human relations Stimulating communication and mobilizing social support	*Group meetings for people with diabetes: phases 1 and 2* – Participants took part in interactive games and energizers (short breaks during the intervention to keep the participants motivated and concentrated during the rest of the program: energizers often consisted of short exercises aimed at group bonding, e.g., throwing a balloon back and forth while giving each other compliments) in which they had to team-up with someone or form alliances. They were encouraged to open up to each other through these games and energizers – Participants were regularly invited to talk about their self-management problems and to ask group members for advice. To do this, the group members learned skills for giving constructive feedback – In small subgroups, participants did assignments in which they had to help each other (e.g., adjusting recipes together) to get used to giving and receiving social support – Participants had shared goals during the intervention such as making a cookbook together and attaining their diplomas – Participants were encouraged to phone and/or meet up with each other outside of the group meetings *Group meetings for people with diabetes: phase 2* – Periodic (first two weekly, then monthly) meetings were held. Participants were encouraged to continue seeing each other in between group meetings without the group leader
2. Increasing participants' abilities to handle social influences that hinder their self-management, such as norms, peer pressure, and temptations	– Participants critically evaluate the impact significant others have on their DSM – Participants are better able to deal with social influences that hinder their self-management, such as peer pressure (e.g., pressure to eat unhealthy foods or to overeat, or negative feedback when exercising or taking medications)	Influencing normative beliefs by making peer expectations visible Building resistance to social pressure to engage in risk behavior Modeling and vicarious reinforcement	*Group meetings for people with diabetes: phase 1* – Group discussions were held about social situations in which managing diabetes is difficult (in response to a DVD, a letter of the week, and of their own accord) – Participant practiced these strategies with group members during role-playing exercises *Group meetings for people with diabetes: phase 2* – An action plan was drawn up in which social influences and dealing with social influences played an important part (group meetings). Together with other group members, the person with diabetes came up with strategies and solutions to overcome these difficulties
3. Increasing the engagement and support of the participants' significant others in self-management	– Participants ask significant others for support – Participants indicate that their significant others are more involved in their self-management (providing more support or more enabling social influences) – Participants experience more enabling social influences	Self-reevaluation Stimulating communication and mobilizing social support Modeling Participatory problem solving	*Group meetings for people with diabetes: phase 1* – Participants were encouraged to tell their significant others they have diabetes (if they did not know) – Participants were encouraged to tell their significant others about the negative social influences and barriers they face (social network therapy) *Social network therapy session: phase 2* – Participants discussed solutions and strategies with their significant others to deal with negative social influences on self-management – Together with their significant others, participants agreed on an action plan in which the significant others play an active role in their self-management. In this action plan, the participant and his/her significant other(s) described the problem they would be working on and barriers and facilitators to overcome this problem. Finally, they agreed on some concrete appointments with each other to overcome this problem

(*Continued*)

TABLE 12 | Continued

General objective	Subgoals	Theoretical methods	Practical strategies
	– Participants experience fewer social influences from their significant others that hinder their self-management		*Group meetings for significant others: phases 1 and 2* – Significant others learned more about diabetes and the important role they play in the self-management of the patient with diabetes – To change their norms regarding self-management tasks, the significant others critically evaluated their own lifestyles through interactive games – Significant others did interactive assignments in which they distinguished helpful and non-helpful behavior with regard to self-management – Group discussions were held about ways to better facilitate the self-management of their relative with diabetes – Significant others learned ways to ask about their relative's self-management in a friendly, supportive way (group meetings for significant others)

Finally, to anticipate the varied and compelling priorities of our participants, the methods and strategies applied in this intervention focused on dealing with difficult situations that affected self-management; this was to promote/ensure long-term results. Therefore, the focus was on skills training with guided feedback. For example, participants exercised in their own neighborhood, and went to their own supermarket with a dietician to select healthy foods. Barriers that were encountered (e.g., an unsafe neighborhood, the higher costs of healthy food) were dealt with during these outings (e.g., exercising while shopping for groceries, finding alternatives that are also healthy, etc.).

Methods and Strategies for the Social Network

This section entails a description of the methods and strategies specific for the health-promoting behaviors of the social network. The needs assessment indicated that for interventions using group processes, it is important to consider how to shape these group processes for the participants. It is also important to consider how to balance dealing with personal problems and the goals of the intervention. Moreover, participants might have personal characteristics that can hinder the use of the group process during the intervention. **Table 12** presents an overview of the methods and practical strategies for the health-promoting behaviors for the social network.

For this intervention to be successful, it was important that the participants became a mutual support group, i.e., support each other and positively influence each other in self-management behaviors. Therefore, during the intervention we focused on the group process and on establishing a safe learning environment, by increasing trust and the exchange of emotions/experiences between participants. The methods used to achieve this included team building and human relations, stimulating communication and mobilizing social support, and skills training for providing and mobilizing social support. Participants made agreements about trust and also agreed to treat the experiences/stories shared within the group in a confidential way. They participated in interactive games in which they had to team-up and form alliances. During the intervention, they established shared goals (e.g., making a cookbook together), were encouraged to share personal stories (e.g., by relating their positive news of the week), and the energizers were aimed at getting to know each other, having fun together, and appreciating each other (e.g., by giving each other compliments). Group members practiced giving constructive feedback and giving/receiving social support before implementing this in real-life situations.

The second goal was to increase the participants' abilities to handle the social influences that hindered their self-management. Methods included the following: influencing normative beliefs by making peer expectations visible, building resistance to social pressure, modeling, and vicarious reinforcement. Practical strategies focused on making social influences on self-management visible by means of group discussions and stories about role models. Furthermore, strategies included helping fictional people with self-management problems, followed by giving advice to/asking advice from fellow group members. In phase 2, the participants made an action plan that focused on how to manage their diabetes within their social environments together with group members; in addition, they practiced the skills needed for implementing this action plan during role-playing exercises, followed by feedback from the group members and group leader.

Finally, the intervention aimed to increase the engagement and support of significant others in self-management behaviors. Methods to achieve this included self-reevaluation, stimulating communication and mobilizing social support, modeling, and participatory problem solving. Practical strategies included group meetings for significant others, in which the significant others learned the difference between supportive and non-supportive behaviors, communication skills, and how they might contribute toward self-management. Other strategies included the social network therapy sessions in which the patient and their significant others made an action plan together, which specified what each of them could do to achieve the joint goals.

DISCUSSION

Powerful Together with Diabetes primarily consists of non-traditional intervention strategies. The Intervention Mapping method focuses on matching theory and evidence based methods to the change objectives formulated in phase 2 of the intervention development and provides a state of the art overview of these methods (75). This helped our planning group to think out of the box, select the right methods and to create practical strategies that combined multiple methods at the same time.

Furthermore, the overviews of the change objectives and their matching methods and strategies facilitated our evaluation design. These overviews together with the data collected throughout the intervention period provided us with a thorough understanding of why certain aspects of the intervention worked while others did not.

However, lessons can be learned for future health promotion in this target population. First, though the intervention was appreciated and experienced as useful we noticed that the intervention did not fully fit the needs of the participants and seemed not totally in concordance with their daily lives. During the intervention, we realized we did not know the full extent of the problems those in our target population faced in their daily lives. Getting to know this target population takes time (76). Because of the nature and long time span of the intervention, we got to know the participants and their daily lives very well. Although the social network appeared to be a real problem for their DSM, this target population also faces other important problems. During the intervention, we noticed it did not fully meet the participants' needs and did not seem entirely consistent with their daily lives.

Our participants often had multiple conditions, were experiencing financial problems, marital problems, domestic violence, or were caring for sick relatives. These problems had a major impact on DSM, and the priority they gave to DSM. Although the intervention aimed to teach participants to deal with these problems so they could self-manage their diabetes, this was not always realistic. For example, if your husband or son is abusing you, it is very unlikely he will become a supportive partner in your DSM.

Intervention Mapping stresses, the importance of conducting a needs assessment before developing the intervention. A health-related needs assessment includes a study of the determinants of behavior and environmental contributors to health problems or health risks (75). To do this, IM increasingly stresses the importance of participatory planning. Important elements of the needs assessment are the involvement of a planning group with planners, implementers, and program participants, and the involvement of the community throughout the whole project. Community involvement is needed to prevent a top-down, outsider approach (75, 77, 78).

IM thus advocates collaboration between community members and health professionals from the start of a project. Other researchers have also reported this to be a positive factor that helped in the development, adoption, and evaluation of an intervention (79–82). According to some studies, it can be difficult for health promoters to include the concerns and issues of the community because of the extra time needed for community involvement, and the often top-down organization of intervention development and top-down funding for these projects (78, 83).

When we started our research project, there was less emphases on participatory planning than there is now in the most recent version of the IM book (31, 35). Besides this, we also experienced the abovementioned limitations (a lack of time and top-down funding). When conducting our needs assessment, we performed all of the research activities as if we were developing a social support (and later on, a social network-based) intervention for patients with suboptimal glycemic control, as stipulated in our research grant proposal. This was the focus of the literature search, the interviews, the analyses of previously conducted interviews, and the diabetes forum. We did consult a panel of migrant health workers with Turkish, Moroccan, and Surinamese backgrounds multiple times. However, due to financial and time constraints, we did this fairly late in the process (after our needs assessment was completed) and asked for feedback only on topics related to our chosen focus, the social network.

Other factors complicated community involvement as well. We did not know the exact neighborhoods in which the intervention would be implemented, and so where our participants would live (which community to address). Also, we planned to aim the intervention at a very specific target population (with suboptimal glycemic control) and did not want to create false expectations within a community.

In hindsight, we conclude that the intervention could have been improved by investing more in participatory planning. If we had involved the target population and their community from the start and asked them (with no predetermined focus) what they thought would be the best when it comes to management of their diabetes, we might have come up with a different intervention, one with closer connections between the lives of our participants and the intervention (77, 83, 84).

In some of the interventions that report positively on community involvement, the researchers involved the community before applying for funding. They chose the study design and applied for funding together with the community or based on the results gathered together with the community (79, 82). However, as funding programs are often clustered around specific themes or have a predetermined focus (e.g., "preventing overweight by influencing lifestyle factors" or "socioeconomic health disparities, prevention and reduction through integrated local policies") that provide a research direction, this might complicate involving communities without a predetermined vision (83, 85, 86).

In hindsight, it would have been better not to decide beforehand what the nature of the intervention would be, but to decide this based on an open needs assessment together with the target population and their community. Funding organizations might facilitate this community involvement by allowing for a longer planning period, and by allowing great flexibility in the area of focus and topics that will be investigated in one project (83, 87–89).

ETHICS STATEMENT

This study was approved by the Medical Ethics Committee of the Academic Medical Centre (AMC) in Amsterdam. The participants provided written informed consent for the study and the study procedures.

AUTHOR CONTRIBUTIONS

CV coordinated the study, developed the intervention, constructed the design, and drafted the manuscript. VN and KS developed the study, constructed the design, and revised the manuscript. PU, BM, and GN participated in the design of the study and revised the manuscript.

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Development, Implementation, and Evaluation of an Interdisciplinary Theory- and Evidence-Based Intervention to Prevent Childhood Obesity: Theoretical and Methodological Lessons Learned

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Overweight and obesity in children and adolescents is seen as a global health challenge and a priority for prevention (1). To solve such a health issue, we need full understanding of the related health behaviors (and underlying beliefs), and understanding of the biological mechanisms that cause or can prevent the issue. However, for overweight and obesity, drawing a full picture of the exact problem (and the subsequent solution) is difficult. In this paper, we describe how we used Intervention Mapping to develop a theory and evidence-based prevention program targeting overweight and obesity and how we investigated the 1-year efficacy of this program on body composition and physical activity of adolescents. A helpful tool, theoretical, and methodological lessons learned are given from our attempt to contribute to solving the obesity problem.

Keywords: overweight and obesity, children and adolescents, physical activity, motivation, body composition, intervention mapping

INTRODUCTION

We (and our children) are becoming heavier, overweight and obesity are established risk factors for chronic metabolic and cardiovascular diseases, and something has to be done to make people healthier. In this paper, we describe how we used Intervention Mapping to develop a theory- and evidence-based prevention program targeting overweight and obesity. We (1) developed a prevention program targeting overweight and obesity, (2) performed a literature study and several cross-sectional studies to investigate whether our proposed ideas were correct, and (3) investigated the 1-year efficacy of incorporating strength exercises in gym classes, combined with monthly motivational lessons to engage in physical activities after school, on body composition and physical activity behavior of adolescents. The developed intervention targeted first-year students in preparatory secondary vocational education (11–15 years of age). Teachers were the program implementers. One part of the intervention involved a 30% increase of strength exercises across the physical education (PE) lessons (about 15–20 min per lesson, or 3 h per week). The other part was based on Motivational Interviewing (2) and was facilitated by a trained mentor or PE teacher. Once a month, a 1-h lesson was used to increase motivation to be more physically active. The intervention period was between March 2015 and March 2016. Nine Dutch secondary schools were randomized into an intervention condition (four schools) or a standard curriculum control condition (five schools). Schools were recruited *via* school management and 695 adolescents participated. Measurements were taken before (T0) and directly after (T1) intervention [for a full overview of the intervention, see the open access design paper by Ten Hoor et al. (3)]. We found that strength exercises during PE classes in high schools improve body composition and probably promote physical activity. A helpful tool, we describe the development of our ideas, and theoretical and methodological lessons learned are given from our attempt to contribute to solving the obesity problem.

THE OBESITY PROBLEM—BIOLOGICAL AND PSYCHOLOGICAL PERSPECTIVES

As being too heavy (or becoming too heavy) is a consequence of an imbalance between energy intake (food intake), and energy expenditure (physical activity, exercise, but also resting metabolic rate, and the cost of ingestion/digestion), the common obesity-prevention adage is to eat less (and healthier) and to exercise more. However, to solve the obesity problem, it has repeatedly been proven that rapid weight loss is a "relatively easy," but often incomplete and often only short-term solution.

By eating less, preferable short-term changes in body mass adjusted for height (body mass index or BMI; used to determine weight status) can be achieved in younger adults, but several metabolic and hormonal mechanisms often cause a fast weight regain. By quickly losing weight by caloric restriction, one's energy expenditure also adjusts to a lower energy intake making long-term dieting a necessity for the maintenance of lost weight (4). At the same time, adaptive hormonal responses influence appetite and satiety (5). Another hypothesized cause of a fast weight regain is the screaming fat cell hypothesis: by quickly losing weight, the size but not the number of fat cells reduces. These adipocytes get "stressed," and try to compensate by an increased uptake of glucose and fatty acids (6).

The other part of "eat less, exercise more," i.e., being more physically active, might seem easier to achieve, except that it is not. Overweight youngsters can often not compete with normal weight youngsters when it comes to aerobic exercises (7) and are more vulnerable to injuries when engaging in aerobic exercises (8). Additionally, because children or adolescents who are overweight or obese often have less mastery experiences when engaging in aerobic exercises, many psychological theories predict disadvantageous physical activity outcomes for those people. With lower relatedness, competence, or autonomy when it comes to physical activity, Self Determination Theory (9) suggests that the motivation to be physically active is either absent (a-motivation), or extrinsically focused. Extrinsic motivation often results in potential short-term increases in physical activity, but not long-term. Based on negative past-performances, the Reasoned Action Approach (10) predicts lower physical activity attitudes, perceived norms, or self-efficacy, resulting in lower intentions to be physically active, and a decreased physical activity behavior. As a result of inferior physical activity performance compared with others, the Social Comparison Theory (11–13) suggests that this lower performance on a specific dimension (in this case: the physical activity dimension), will cause a shift in focus to other behavioral dimensions where superior performances can foster positive outcome expectations (e.g., being better in guitar playing, or geography). In conclusion, losing weight by eating less and being more physically active might be a short-term solution to being overweight or obese, but is often not the solution to overweight and obesity prevention and treatment, and its related diseases on the long term.

Biology and Psychology Combined

One could question if the focus in obesity prevention should be on weight or on health as overweight and obesity are seen as a threat to an individual's health. Impaired physical and psychological health has furthermore been associated with direct [health care (14)] and indirect (productivity or absenteeism) consequences on a societal level (15). All these negative implications might continue during and worsen throughout adulthood (16).

From a health perspective it is not weight but a healthier body composition (i.e., an increase in fat-free mass and/or reduction in fat mass percentage) that needs to be considered (17). Body weight adjusted for height (BMI) is commonly used to determine whether an individual has a healthy or unhealthy weight. Although BMI is a good and simple tool for risk estimates in large populations, it is not the right tool for individual metabolic and mental health evaluations (18) and might have stigmatizing effects on one's health in later life (19).

Overweight and obesity are seldom caused by the individual only but also by environmental factors (20, 21): from people influencing overweight and obesity at most proximal environmental levels like the parents or peers (22, 23), to societal levels [see, e.g., Borys et al. (24) for an overview of the EPODE approach].

Related to all previous arguments, we advocate that weight loss interventions should become health interventions. Focusing on weight and weight loss might have stigmatizing effects, adversely affecting an individual's psychological well-being (25, 26). Health care settings, including weight loss interventions are (unintentionally) a significant source of weight stigma. It is often believed that weight stigma triggers weight loss, but there is no evidence to confirm this belief (26). By focusing on health instead of weight, weight stigma might be reduced.

A NEW INTERDISCIPLINARY APPROACH

In our program, we assumed that there should be a focus on improving body composition for all youth, rather than only focusing on increasing leanness among those with overweight. Additionally, we suggested extra focus on mastery experiences within the field of physical activity, and optimal social comparison conditions. In other words, the aim was to focus on what people want to do to become healthier (or maintain health) instead of what they have to do.

In the proposed approach, the focus was on strength exercises in high schools to improve body composition in 12- to

15-year-old adolescents. From a physiological perspective, it is known that youngsters who are overweight or obese are generally stronger in absolute terms, i.e., they do not only have a higher fat mass but also a higher fat-free mass (27). Therefore, they are often better in strength-related exercises compared with aerobic exercises and they are often better in strength exercises compared with their normal weight peers, making them—under the right circumstances—more motivated to engage in resistance exercise and ultimately maintain a physically active lifestyle. Additionally, strength exercises can improve body composition. A higher fat-free mass will result in an increase in basal metabolic rate and total energy expenditure [see also Ref. (3, 28)]. In addition, a lower fat mass percentage improves several cardiovascular risk factors.

The intervention was executed in high schools. To reduce stigma, and to optimally use social comparison, the focus was not on weight or adolescents with overweight or obesity, but on health, and on all youngsters. The PE teachers integrated at least 15 min of strength exercises in their PE lessons (three times per week). This proportion was based on the feasibility of integrating strength exercises into the standard curriculum. To motivate students to be more physically active after school, and to improve the determinants of their physical activity behavior, we included a motivational intervention once per month [see also our design paper by Ten Hoor et al. (3); open access]. These motivational lessons were based on motivational interviewing (2) and facilitated by a trained mentor or PE teacher. In the first 5 months, an extra monthly online motivational lesson was given. Together with the feelings of competence and relatedness students experience during the PE lessons, the complete program, therefore, aimed to improve the three basic psychological needs required for autonomous motivation according to Self-Determination Theory (29).

MAIN EMPIRICAL FINDINGS

This program did not immediately start with the execution of this intervention. In considering strength exercises in health behavior change interventions targeting overweight and obesity, we followed the iterative steps of the Intervention Mapping protocol (21, 30). We systematically mapped what is known about the differential psychological consequences of strength vs. aerobic exercises. In a systematic literature research and meta-analysis (31), we found that strength exercises may have positive effects on a number of psychological outcomes in people who are overweight or obese. These effects, however, seemed often comparable to those of aerobic and diet interventions. The small and heterogeneous evidence base implied an urgent need for more research.

In a related—additional—cross-sectional study (ten Hoor, Plasqui, et al., submitted)[1], we tested our chain of assumptions. This was in a different population, but provided some relevant data to inform the intervention with adolescents. We confirmed that overweight people have a higher fat-free mass compared with lean people. This was in line with biological insights. Additionally, we have shown that people with a higher fat-free mass are stronger (in absolute sense) compared with those with lower fat-free mass, and are better in strength exercises than they are in aerobic exercises. We have also confirmed that mastery experiences (in this case, resulting from successfully engaging in strength exercises as opposed to aerobic exercises) improve psychological outcomes. Finally, we have shown that overweight people enjoy strength exercises more than normal weight people, mediated by fat-free mass and muscle strength. This series of studies demonstrated the chain of relationships empirically.

Parents have a crucial role in their child's physical activity-related behavior. We therefore examined parental attitudes about physical activity behavior in general and aerobic and strength exercises in particular (28). Although strength exercises evidently have both physiological and psychological health benefits across all ages, they are erroneously considered to adversely affect health status in youngsters. We found that parents consistently reported a positive attitude toward aerobic exercises, but a less positive, neutral attitude regarding strength exercises. Parents indicated more often that their child was not allowed to participate in strength exercises than in aerobic exercises and considered strength exercises to interfere with optimal physical development. We suggested testing interventions to increase parents' understanding of the advantages of and possibilities (e.g., facilities) for strength training and the benefits of strength exercises on their child's health.

In a cluster randomized controlled trial (ten Hoor, Rutten, et al., submitted)[2], we examined the efficacy of a physical activity program combining strength exercises and motivational aspects in the school setting. We chose this setting to avoid parental influence on the strength exercise component. Within the school setting, and by not only focusing on adolescents with overweight or obesity but on all adolescents, social comparison was optimally used and negative stigma was minimized. With the strength exercise focus, we aimed to improve body composition (by improving fat-free mass), and mastery experiences of adolescents with overweight or obesity. The motivational aspects focused on improvements in physical activity motivations and physical activity behavior in daily life. After 1 year, this study resulted in favorable changes in body composition and physical activity behavior in the intervention group compared with a standard curriculum control group. All adolescents became less physically active after 1 year, which is seen often in youth (32, 33). However, the PA level in the intervention group decreased significantly less as compared with the control group. Our results also indicate that the use of strength training at school alongside a motivational intervention can induce a change in activity levels, also outside PE classes. Several meta-analyses have shown that any improvement in PA behavior may have large beneficial effects (34). Based on our findings in this last study, and earlier performed studies, we concluded that strength exercises might be a valuable contribution to a child's physical activity possibilities (e.g., facilities) and behavior.

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[1] Ten Hoor GA, Plasqui G, Schols AMWJ, Kok G. A benefit of being heavier is being strong.

[2] Ten Hoor GA, Rutten GM, Van Breukelen GJP, Kok G, Ruiter RAC, Meijer K, et al. Strength exercises during physical education classes in secondary schools improve body composition: a cluster randomized controlled trial.

THEORETICAL CONSIDERATIONS

In search for an obesity prevention program, many decisions were made. The development of our intervention was based on the Intervention Mapping protocol (21, 30). With this, we described the iterative path from problem identification to problem solving, or mitigation. The six steps of Intervention Mapping comprise several tasks, each of which integrates theory and evidence. The completion of the tasks within a step created a product that guides the subsequent step. The completion of all of the steps served as a blueprint for designing, implementing and evaluating our intervention based on theoretical, empirical and practical information.

An Interdisciplinary and a Socio-Ecological Approach

Interdisciplinary research, as stated by The Young Academy (35), is often seen as nothing more than a "multidisciplinary" combination of disciplinary perspectives. True interdisciplinarity goes a step beyond this; a crucial step. Interdisciplinary research characteristically involves a change in scholarly identity. This can be defined as "the interplay between the questions that researchers pose, the methods that they use, and the outcome measures that they employ" [(35), p. 7]. The authors state that "a change in scholarly identity can have both beneficial and adverse effects" and they have identified a number of major problems: the disciplinary focus of most funding bodies; the enormous time investment required to familiarize themselves with insights from outside their own discipline; cultural differences between disciplines; and friction with an academic infrastructure that is organized largely into disciplines, especially with regard to educational matters. There are good reasons to remove or at least minimize these obstacles. "Interdisciplinary research makes a major contribution to scientific innovation, leads to greater breadth and depth in individual disciplines, generates cross-disciplinary knowledge, and often plays a vital role in analyzing the major challenges facing society" [(35), p. 7].

In this project, we managed to avoid most of the problems as mentioned above and to profit from the beneficial effects of true interdisciplinarity. The primary investigator was trained as a biologist and psychologist and was able to integrate state of the art knowledge from both disciplines. The coinvestigators contributed from biological, human movement, physiological, child health care, social psychological, and health promotion sciences, without serious frictions. One binding factor was the societal relevance of challenges we faced (from different perspectives) related to obesity in youth.

Next to an interdisciplinary approach, we applied a socio-ecological approach. Socio-ecological models suggest that intervention development should include (or at least consider) all possible stakeholders: not only at the individual level but also at environmental levels (21): interpersonal, organizational, community, and policy levels. Including parents into the program was considered (interpersonal level), but this was not directly necessary. However, future research and interventions are needed (see also Section "Future Research and Implementation"). Although parents are less positive about strength exercises compared with aerobic exercises, and although they play an important role in a child's physical activity behavior, it was decided to initially work with high schools and PE teachers (organizational level) for three reasons: first, social comparison is part of typical classroom settings and therefore unavoidable in the school setting (36). Second, PE teachers are aware of the benefits of strength training, are able to teach, or emphasize, the right techniques, and are able to provide qualified supervision. The methods used to further prepare the PE teachers for the intervention are facilitation and participatory problem solving [see Bartholomew Eldredge et al. (21), pp. 378 and 391]. The teachers are instructed about the program, participate in workshops to improve their motivational speaking skills, and are provided with materials to make them able to include strength exercises in their lessons. Furthermore, the PE teachers received a book with strength exercises and games as inspirational material. This inspirational material was not only based on literature, but also on ideas from experts in the field, and from the PE teachers themselves Third, when adolescents participate in strength exercises in high school and have positive experiences, they could discuss this with their parents, possibly curving their parents' attitudes into a more positive direction. For the future, developments at the organizational and policy level will become relevant, such as training of PE teachers as well as activities initiated at the city level to promote exercise behavior in children and adolescents (see Future Research and Implementation).

Social Comparison Theory

We developed a program for adolescents with overweight or obesity, but involved non-overweight peers for social comparison purposes (interpersonal level; note that the non-overweight peers also benefitted from the program.) We did not suggest promoting "outperforming others," but promoting "mutual appreciation," both related to social comparison theory and self-determination theory. Outperforming others might relate to more controlled types of motivation, while a positive comparison with others for youngsters who are used to only experiencing negative comparisons might result in more autonomous motivations. The relation between social comparison and self-determination is an under-investigated area. Some authors [e.g., Ref. (37)] have suggested that stimulating social comparison may have detrimental effects on autonomous motivation. However, O'Keefe et al. (36) suggest that social comparison is part of typical classroom settings and therefore unavoidable. Moreover, Senko et al. (38) argued that normative-based performance goals often facilitate classroom achievement. Standage et al. (39) found that perceptions of competence and relatedness are more predictive of self-determined motivation than autonomy, but also that normative feedback that is repeatedly negative will lead to a-motivation. We think that, next to promoting autonomy [e.g., by giving youngsters choices (29)], positive social experiences of overweight youngsters with resistance exercises may increase their perceptions of competence, their self-worth, and in time, their intrinsic motivation for exercise. In the present intervention, having youngsters compete as teams in multicomponent exercises might have encouraged interpersonal appreciation of various skills (e.g., speed vs. strength). However, the relation between social comparison theory and self-determination theory has rarely been studied empirically (40).

The Theory of Expanded, Extended and Enhanced Opportunities (TEO)

Recently, Beets et al. (41) argued that the focus of physical activity interventions always should be on (1) expansion of opportunities to be physically active, (2) extension of available opportunities to be physically active, and/or (3) enhancement of the physical activity possibilities and/or opportunities (e.g., facilities). This TEO succeeds in making physical activity behavior more understandable and adds to the bigger picture of understanding obesity and obesity-related behaviors. In our program, we have added the idea of "Enriched Opportunities" of currently available physical activities: we replaced good physical activities by better ones (for people with overweight or obesity). This has been done, prior to expanding, extending, or enhancing the current physical activity opportunities.

METHODOLOGICAL CONSIDERATIONS

When schematizing our thoughts to solve the obesity problem, there is no straight line between the box "problem" and the box "solution." Moreover, in each step of the iterative process from "problem" to "solution," decisions were made, influencing subsequent steps in the process, or sometimes even impacting the entire direction (see our example below where we shift from the obesity clinic to a setting where social comparison played a larger role).

Study Populations

In our cross-sectional study (ten Hoor et al., resubmitted), linking the biological outcomes with the psychological outcomes, only young adults (18–30 years of age) were included, even though the main focus in the program was on young adolescents aged 12–15 years. This study was in a different population, but provided some relevant data to inform the intervention with adolescents. The measurements during this study were mostly gold standard measurements (VO_2 max test for aerobic capacity; underwater weighing for body composition; 1-Repetition-Max tests to measure maximal muscle strength), but also considered as being of high intensity, too invasive, difficult or not validated, or even health threatening for youth during growth (42). Less-reliable measuring instruments could have been used in young adolescents (as opposed to young adults). However, as we assumed that the mechanisms would have been the same in youngsters vs. young adults (combined with ethical considerations and easier accessibility), we chose to examine the relationships between the biological and psychological outcomes in young adults, with gold standard outcomes.

Initially, the idea of adding strength exercises to an adolescent's physical activity was focused on people with overweight or obesity only. Therefore, we first focused on performing our experimental studies in a clinical setting. During the process, and while the program ideas evolved, it was decided to shift our focus from the obesity clinic to a setting where social comparison played a larger role (see also theoretical considerations). Because of this shift, we were not able to perform a classic randomized controlled trial at the individual level, but were forced to cluster in groups of participants. With $\alpha = 0.05$, power = 0.90, and an assumed small-to-medium effect size ($d = 0.35$), 172 participants per group were needed for a classical RCT. However, in view of the clustering of students within schools and randomized assignment of schools (cluster randomized trial) a sample size of 600 was aimed at to adjust for the design effect arising from clustering (43). The sample size was further increased to 700 to accommodate 15% dropout (although all available data from all participants would be included into the analysis). Although our sample size was quite large, our study was underpowered both due to the larger than expected dropout or missingness and due to the clustered data structure (students nested within schools, randomization of schools; see also measurement issues).

Due to this shift to schools, and our adjusted aims, we did not focus only on adolescents with overweight or obesity but on all adolescents (all adolescents would benefit from the program if effective, including adolescents with a higher BMI). However, in this approach we were able to take baseline BMI into account as a covariate during our analyses to examine differential effects of the intervention due to weight differences. To recruit a population with a slightly higher BMI, we recruited mostly at schools with Lower Vocational Education. These schools are often characterized by adolescents from lower SES households and having a higher BMI. There is a possibility that the baseline characteristics and intervention effects are different when measured in other populations.

Measurement Issues

The shift from a clinical setting to high schools also caused a shift in the methods that were used for our evaluative measurements. Although gold standard techniques were preferred, these were often too expensive, or difficult to execute in larger populations. It was important to be able to measure both body composition and physical activity behavior (our primary outcomes), but also strength, aerobic capacity, and psychological determinants in large groups of 12- to 15-year-old adolescents in the school setting. All measurements were chosen by considering burden to the participants as well as validity and reliability.

Body Composition Considerations

Although there are many techniques to measure body composition [e.g., DXA, hydrostatic weighing, air-displacement plethysmography, deuterium dilution, and multicompartment models, see also (44, 45)], many of those techniques are costly, time-consuming, and logistically challenging to use in large groups of children and adolescents (45, 46). As with all techniques, these also rest on assumptions by which raw data are converted to final values (47) by use of hydration factors [e.g., Ref. (48), or fixed densities of fat- and lean mass (49)].

We used both the skinfold measures and the deuterium dilution technique. Skinfolds are a simple, safe, non-invasive, and widely used technique to measure body composition in larger groups of children and adolescents (46, 47). Originally, skinfold measures were used to estimate body density [using body density regression equations derived from gold standard techniques, see, e.g., Ref. (49, 50)], after which Siri's (51) equation was used to calculate fat- and fat-free mass. However, equations are population specific, and during maturation, the relation between skinfold thickness and one's subcutaneous adipose tissue distribution strongly depends on biological age (52–54). Measuring body composition by skinfolds is an indirect method. The measurement might suffer from additional errors while collecting the data. Wells and Fewtrell (47) described that intra- and interobserver error are low compared with between-subject variability, but higher in obese youngsters. The overall error further increases when (a) the collected skinfold values are converted to body density or (in this case) total body water, and (b) these data are converted to fat- and fat-free mass using hydration factors [see, e.g., Ref. (48)], or fixed densities of fat- and lean mass (49).

The more sophisticated method that we used is deuterium dilution (44, 55). We asked students to hand in a baseline urine sample, after which they drank 75 mL of deuterium-enriched water, increasing the deuterium body concentration with 100–150 ppm. At the end of the school day (a minimum of 4.5 h later), a second urine sample was collected. To calculate total body water, the two urine samples (baseline and enriched) are analyzed using isotope ratio mass spectrometry. From total body water, fat-free mass was calculated using age-specific hydration fractions of fat-free mass (48). Compared with underwater weighing (which is still considered a gold standard measurement), deuterium dilution is a reliable method to assess fat mass percentage in normal weight and obese subjects (56), showing the same changes in fat-free mass over time (57). The technique is not often applied in large studies as it requires specific expertise and equipment and is hence relatively expensive. However, this technique was most suitable in our study as it is accurate, non-invasive, requires minimal subject cooperation, and can be applied outside laboratory settings (47).

Strength Measurement Considerations

The most frequently used method to measure strength is the handgrip dynamometer because of its cost-effectiveness, simplicity, and portability (58). However, movement patterns performed during the execution of the handgrip test are not comparable to movement patterns of larger muscle groups, or performed in daily life or exercise training programs (59). To partly overcome this limitation, we evaluated the back–leg–chest (BLC) dynamometer as an effective, simple, and portable way to test total body strength [a simplified explanation: we asked students to stand on the base of the BLC dynamometer with flexed knees (ca. 30°) and asked them to lift a handle that was connected to the base with a continuous vertical motion by extending the knees, hips, and lower back—for a full explanation, see Ref. (60)]. The apparatus induced execution of static contractions, which are required less often in daily life compared with dynamic contractions. The BLC dynamometer provided reasonably reliable test–retest measurements of BLC strength in healthy adolescents and adults and was therefore considered as useful additional tool in our study (3).

Physical Activity in Daily Life Considerations

For physical activity in daily life, the Actigraph GT3X accelerometer (Actigraph, Pensacola, FL, USA) was used. The Actigraph GT3x triaxial accelerometer is a small device and measures acceleration in three directions (vertical, antero-posterior, and mediolateral). The Actigraph was chosen as it is the most validated triaxial accelerometer that is currently commercially available [see, for many references, Plasqui and Westerterp (61)]. Also, activity patterns can be determined as child-specific cut-off points for low-, moderate-, and high-intensity physical activity are available. Although this was a relatively simple measurement with a low burden to participants, compliance was lower than expected: some students forgot to wear the accelerometer (especially during weekend days), and some complained that they did not like to wear the elastic band with the device because it did not match their choice of clothing, it hurt their back or was irritating in another way.

Questionnaire Considerations

To keep the length of the included questionnaire relatively short, it was chosen to include questions relating to the Reasoned Action Approach, Self Determination Theory, and Social Comparison. Although it would have been interesting to include other clinical outcome measures (e.g., quality of life, self-esteem, mood, stress), this would have increased the length of the questionnaire substantially, and with that the burden on the participants.

Aerobic Capacity Considerations

To measure aerobic capacity, the shuttle-run test was used. For this test, students ran back and forth over a distance of 18 m (officially the distance for a shuttle-run test is 20 m, but because not all schools have a 20-m gym court, this test was taken over 18 m—therefore, comparisons within this study are valid, but the results cannot be compared with other studies). The running speed was determined by the interval between two sound signals ("beeps"). Every minute, the speed increased by shortening the interval between two beeps. When a student fails to reach the 18-m line at the sound signal two times in a row, the test stops for this individual. The shuttle-run test has a moderate-to-high validity for estimating maximum aerobic capacity and can easily be executed in larger groups (62). Submaximal and maximal tests using treadmill, or cycle ergometer, or tests where heart rate monitors were required were seen as unreachable in classroom setting. Compared with the Cooper test (where students are asked to run for 12 min and where the distance was used as proxy for aerobic capacity), the shuttle-run test was less likely to be influenced by weather conditions.

Missingness Because of the Intensive Measurements

Although both of our main outcomes (body composition and physical activity behavior) measuring techniques (deuterium dilution and accelerometry) are accurate, and acceptable in all age groups, the method is relatively expensive and thus not often applied in larger studies. A limitation was that, due to the nature of these measurements (i.e., two small urine samples are required), many students decided to not participate in this measurement (either at T0, T1, or both), causing missingness. While all available data were included into the analysis using a method that is valid under so-called missingness at random (MAR, missingness depends on observed variables such as age or pretest if posttest is missing), we cannot rule out bias arising from missingness not at random (MNAR, missingness depends on unobserved variables such as posttest if posttest is missing). Unfortunately, MNAR cannot be detected or adjusted for. At best, complex methods can be used to explore the robustness of results against various patterns of MNAR missingness (63).

FUTURE RESEARCH AND IMPLEMENTATION

We have processed evaluation data on secondary physiological and psychological outcomes, and are collecting data on teachers' experiences with our program. In addition, and for a long-term effective strength-based physical activity program, there are still several questions that need to be answered.

Future Research

Psychological Behavioral Determinants

From our systematic review and meta-analysis, we concluded that strength exercises are a viable alternative to or addition to diet and/or aerobic interventions when it comes to improving psychological outcomes, but more research is necessary. In the literature, studies reported only on a limited range of psychological outcomes. The reported psychological outcomes were mostly clinical outcomes or markers of quality of life. Measuring self-determination concepts as psychological constructs might give additional information about the effects of exercise training to be considered alongside that obtained from current clinical and quality of life measures.

Feedback and Body Composition

We also suggested giving feedback on body composition instead of weight loss to improve psychological outcomes. Pescud et al. (64) reported that feedback on body composition is useful as a "surrogate" for feedback on weight loss, which motivated participants to continue participating in strength training exercises. Gaining strength, and ultimately obtaining a healthier body composition, might lead to a higher resting metabolic rate, increased total energy expenditure, and a decreased chronic diseases risk (17). Thus, when participants in a strength training program become stronger, this could also lead to (long term) positive changes in body composition and health. However, these positive effects are often not reflected in reported short-term psychological outcomes of strength training as compared with other interventions. Related to this, two more recommendations for future research arise. First, as described under theoretical considerations, the relation between social comparison theory and self-determination theory has rarely been studied empirically (40) and needs to be further investigated. Second, valid and reliable methods to measure body composition should become more accessible to the public.

Parental Attitudes and Influence

In the study examining parental attitudes regarding strength training, we concluded that future interventions should increase parents' understanding of the advantages and possibilities (e.g., facilities) of strength training on their child's health and that strength training can be fun. Without parental support, it will be more difficult for (overweight) youngsters to engage in resistance exercises (65).

Tailoring

Further research is required on how possible program characteristics (e.g., intensities, quantities, form of exercise, feedback mechanisms) can be tailored to the individual (e.g., for the same exercise, an overweight adolescent lifts a heavier weight than a lean adolescent) or group level [e.g., girls may prefer different resistance exercises than boys (66)].

Replication

Lastly, future randomized controlled trials should replicate our findings and evaluate the immediate and long-term effectiveness of our approach. This can be done in high schools, but also in other settings and age groups (e.g., primary schools, clinical setting).

Implementation

Once an intervention has been created, a solid diffusion and implementation process is vital to ensure program success (21). Without implementation, the intervention will not have any chance of impact on determinants, behaviors, or health. The basic idea of our approach is simple and easily implementable. For future implementation infrastructures at schools (including the playgrounds) can be optimized, not only in high schools, but also in primary schools.

For the future, developments at the organizational and policy level will become relevant, such as training of PE teachers as well as activities initiated at the city level to promote exercise behavior in children and adolescents. PE teachers can be informed and educated about the background of the strength exercises, with guidelines and suggestions for practice. A work book with exercises is freely available but it was noticed that teachers themselves can easily come up with new ideas about strength exercises in the lessons the moment they understand the principle and find out that the students react positively, especially the students with overweight [see the additional file of our open access design paper by Ten Hoor et al. (3)].

Outside the school setting, different sports in which pure physical strength and/or body mass are beneficial (e.g., rugby, judo) could be systematically promoted as an alternative for youngsters with overweight. Fitness centers provide strength training possibilities but they are often not accessible for youngsters. In the future, schools may collaborate with fitness centers to create optimal circumstances, or schools themselves may provide fitness equipment for their students.

CONCLUSION

We developed, implemented, and evaluated an interdisciplinary theory- and evidence-based program that positively influenced body composition and physical activity. This might not be a direct solution to combat obesity, but it might help in the long term with the prevention of obesity-related health issues. We suggest adding strength exercises to children's and youngsters' physical activity possibilities: as long as strength exercises are performed under qualified supervision, they might have positive long-term health benefits.

AUTHOR CONTRIBUTIONS

GH, GP, AS, and GK conceived of, designed, and coordinated the study. GH drafted the manuscript. All authors read and approved the final manuscript.

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Developing a Return to Work Intervention for Breast Cancer Survivors with the Intervention Mapping Protocol: Challenges and Opportunities of the Needs Assessment

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Return to work (RTW) is an important step for breast cancer survivors (BCSs). However, they face many barriers that affect particularly women with low socioeconomic status (SES). Health care, workplace, and insurance actors lack knowledge and collaborate poorly. No intervention to date has proven effective to reduce social disparities in employment after breast cancer. The intervention mapping (IM) protocol is being used in France to develop, implement, and evaluate an intervention to facilitate and sustain RTW after breast cancer [*FAciliter et Soutenir le retour au TRAvail après un Cancer du Sein* (FASTRACS) project]. The research question of this study was to elicit the needs for RTW after breast cancer from various stakeholders' point of view. The aim of this study was to describe the process and the preliminary results of the needs assessment of the FASTRACS project. *Different methods* were followed to (a) establish and work with a planning group and (b) conduct a needs assessment to create a logic model of the problem. A planning group was organized to gather the stakeholders with the research team. A review of the literature and indicators was conducted to identify the magnitude of the problem and the factors influencing RTW. A qualitative inquiry was conducted with 12 focus groups and 48 individual semi-structured interviews to explore the needs and experience of the stakeholders. The *results* of these tasks were the proposition of a charter of partnership to structure the participative process, a review of the scientific evidence and indicators, and the description by the stakeholders of their needs and experience. Many stakeholders disagreed with the concept of "early intervention." They advocated for a better support of BCSs during their RTW, emphasized as a process. Anticipation, intersectoral collaboration, and workplace accommodation were mentioned to fit the needs of the BCS and their environment. A logic model of the problem was elaborated from these data. The ability of the model to consider specific characteristics of women with low SES is discussed, with a view to developing the FASTRACS intervention through the next steps of the IM protocol.

Keywords: intervention mapping, breast cancer, needs assessment, return to work, work rehabilitation, program development, participative research, social health disparities

INTRODUCTION

Breast cancer is the most common cancer in women worldwide (1), representing about 12% of all new cancer cases and 25% of all cancers in women. In France, an estimated 53,000 new cases were diagnosed in 2015 (2). Prognosis is good, with a standardized survival rate of 87% at 5 years from diagnosis and an estimated partial 5-year prevalence of 219,756 cases (2). Returning to work after a cancer is paramount, enhancing quality of life and financial independence and decreasing social costs (3). As the legal retirement age is to be postponed in many industrialized countries, the issue of return to work (RTW) after breast cancer is likely to affect a growing number of women worldwide.

The job status of French patients 2 years after the diagnosis of cancer is poor, with a decrease in the activity rate from 88.2 to 79.9% between 2010 and 2012 (4). In the Netherlands, the proportion of employed women who fully resumed working after breast cancer within 1 year of diagnosis has decreased, particularly in women over 50 years (from 59% in 2002 to 46% in 2008) (5). In the UK, a higher RTW rate (84%) was observed in the first year following treatment for breast cancer of health-care workers (6). A meta-analysis of 26 international studies from the US, Europe, and other countries showed that the unemployment rate is higher after breast cancer than after other cancers (35.6 vs 31.7%) (7). Even for women who succeeded in returning to work, a number of them still experience negative feelings while at work (8).

In the US, specific needs have been identified for certain categories of patients according to their race or income (9, 10), revealing social disparities in work resumption after breast cancer. In France, low-skilled women are more likely to lose their job 2 years later if they do not have job accommodation, whereas women with a management position are more likely to lose their job if they perceive a feeling of discrimination (4). In Denmark, a low socioeconomic status (SES) was identified as a risk factor for unemployment after breast cancer (11).

Although a fair amount of descriptive knowledge is available, intervention studies aimed at improving RTW after breast cancer have failed to prove their effectiveness (3). Despite the evidence of social disparities in employment after breast cancer, no intervention took into account their possible mechanisms which complexity needs clarification before proposing appropriate interventions (12, 13). A number of factors associated with a low social position are likely to act as causal and/or mediating factors of unemployment after breast cancer (heavy physical workload, low job latitude, temporary work contract, non-take-up of social rights, etc.). This might partially explain the failure of these interventions, which has also been attributed to the lack of conceptualization and the overmedicalization of a complex intersectoral issue (14). A recent review of 16 interventions addressing RTW after breast cancer showed that only one intervention referred to a theory linked to RTW (15). More than 80% of the interventions were provided by health-care professionals, and only 38% of the interventions were work-directed and offered other activities, such as coordination of services and information, as well as instructions for drawing up an RTW plan (15).

Furthermore, the implementation and routinization (sustainability) of interventions aimed at reducing social disparities usually fail to take into account the cultural and social specificities of the population they consider (16). In the field of complex interventions, it is therefore recommended to ensure a proper vision of the problem (theory of the problem) and of its solution (theory of action), not only from a scientific evidence-based point of view but also from the experience-based point of view of the actors in the field (target population and its environment) (17). The same has proven to be true in the specific field of work disability prevention, where it is recommended to base interventions upon explicit theories, in order to figure out their effective components with their relevant outcomes (14). It is also recommended to anticipate from the beginning the issues of implementation and sustainability, by involving the relevant categories of stakeholders (18, 19).

The intervention mapping (IM) protocol has been used for 15 years in different countries to develop, implement, and evaluate interventions in the field of health promotion (20, 21). It has been specifically used in cancer (22–24) and RTW (22, 25, 26). It develops a participative approach involving all the relevant stakeholders. It resorts to the theoretical frameworks in human and social sciences and requires a critical appraisal of the scientific literature (so-called evidence). Last but not least, the IM protocol relies on a global vision of the determinants of health, adopting an ecological perspective on the individuals within the different levels of their environment (interpersonal, organization, community, society, etc.) (16). In this respect, the IM protocol is acknowledged as an appropriate process to develop population-level health interventions likely to shift the distribution of health risk by addressing the underlying social, economic, and environmental conditions (27).

In view of its ability to help researchers face both theoretical and implementation issues in program development, the IM protocol was chosen in France by a research team in the frame of the *FAciliter et Soutenir le retour au TRAvail après un Cancer du Sein* (FASTRACS) project. The overall aims of the FASTRACS project are to develop, implement, and evaluate an intervention intended to facilitate and sustain RTW after breast cancer at a regional scale.

The aim of this study was to describe the process and the preliminary results of the needs assessment of the FASTRACS project during the first step of the IM protocol.

MATERIALS AND METHODS

Study Setting

The FASTRACS project is led by a multidisciplinary research team associating a skill mix in psychology (health psychology, social psychology, and work psychology) and medicine (occupational medicine, general medicine, oncology, and public health) from the University of Lyon, in the Auvergne-Rhône-Alpes region of France. The scale of the project is to develop, implement, and test a pilot intervention at the county scale of "Metropole de Lyon" (59 cities with 1,280,000 inhabitants distributed over 538 km^2). The strategic perspective at 5 years is to scale up and adapt the intervention in other counties of the same region if it is proven to be effective.

Needs Assessment Tasks and Methods

According to the IM protocol (21), the learning objectives and tasks of the first step of the protocol are (a) to establish and work with a planning group; (b) to conduct a needs assessment to create a logic model of the problem; (c) to describe the context for the intervention, including the population, setting, and community; and (d) to state program goals. The present study will focus on the two first tasks.

Planning Group

Members of the research team liaised with key stakeholders, defined as field actors or members of institutions involved in RTW after cancer on a regular basis, knowledgeable, influential, and eager to commit themselves in a working group on a sustainable basis. First, a theoretical sampling was followed according to the arena model in work disability prevention (28), from which four categories of stakeholders were identified: patients and associations, health-care professionals and facilities, workplaces, and regional institutions representing the government, the social insurance system, and organizations involved in work disability prevention and handicap. Second, a purposeful and snowball sampling was followed from the personal network of the researchers to select the members of the planning group.

Two meetings were organized with the research team and the 25 members of the planning group. The first meeting was the occasion to present each other, to give an overview of the FASTRACS project and the IM protocol, and to establish the basis of a charter of partnership. During small group discussions, participants were asked to answer the following three questions: (a) What are the most important values to me (as an individual and/or for my institution)?"; (b) "What do I need (as an individual and/or for my institution) in order to collaborate in the FASTRACS project?"; and (c) "What commitment(s) can I take in the FASTRACS project (as an individual and/or for my institution)?" The participants produced written answers which content fed the discussion during the meeting. Their qualitative content analysis performed afterward structured the draft for the charter of partnership. A second meeting was organized 1 year later to share preliminary results of the data analysis of the needs assessment qualitative inquiry (see below).

Needs Assessment: Literature Reviews

A first literature review was performed up to June 2013 and regularly updated. Its aims were to gather the evidence from empirical studies about the occupational prognosis, the effectiveness of RTW interventions, and the lived experience of RTW of BCS. A sensitive search strategy was adopted to explore Medline, Healthstar, and Web of Science databases with the search string: [breast cancer AND (work OR employ$)].ti. In order to be included, the studies had to fulfill the following criteria: (a) deal with any aspect of RTW and job retention, (b) after breast cancer, and (c) provide information about the occupational prognosis (cohort studies), the lived experience reported by the patients or other stakeholders (qualitative studies) or interventions developed to help them RTW (intervention studies). Discussion papers and studies exploring (occupational) risk factors of breast cancer were excluded. Surveys were considered on an individual basis depending on their interest for the research topic. A priority was given to literature reviews before considering original studies. Another systematic literature review was performed to identify and describe the content of the interventions developed with the IM protocol in the field of cancer (29).

Needs Assessment: Review of Indicators

Indicators were searched in the scientific and the gray literature to document the extent and the scope of RTW issues after breast cancer in France (incidence of breast cancer, occupational consequences, comorbidities, etc.). Indicators in the scientific literature were identified from the literature review. The gray literature was identified from 10 different websites of the French national cancer institute (Institut National du Cancer), French cancer patient associations (Ligue contre le cancer and Europa Donna), and databases and websites of the Ministry of Health (Score-santé database, etc). From these websites, six reports were selected with relevant indicators.

Needs Assessment: Qualitative Inquiry

A qualitative inquiry was conducted among the four categories of stakeholders (patients, health care, workplaces, and institutions) aimed at exploring in-depth and in context their perceived needs and field experience. The data collection proceeded by 12 focus groups (FGs) and 48 individual semi-structured interviews, according to interview guides. The guides' themes were based on the findings of the literature review and the clinical experience of the researchers. Some themes were common to each category of stakeholders to allow comparisons, and some other themes were specific to the stakeholder's category to explore its specificities. The participants were identified through the personal network of the researchers and the members of the planning group who helped access both field actors and members from institutions. The sampling method was the same as the one used to select the members of the planning group. Respondent characteristics are described in **Table 1**. Themes and location of the interviews and FGs are presented in Table S1 in Supplementary Material.

Data Analysis and Integration

The indicators retrieved from the scientific and the gray literature were categorized with an Excel™ spreadsheet. According to the IM protocol, indicators were sorted in the following categories: quality of life, health, and (occupational) environment.

For the qualitative inquiry, all interviews and FG meetings were recorded, transcribed, and anonymized (names of places and persons replaced by codes). The MAXQDA™ v11 and v12 software was used to conduct thematic qualitative content analysis. The analysis was performed by the researchers who conducted the interviews and FGs and the students they supervised. They were performed by different researchers investigating each stakeholder's category, i.e., the breast cancer patients (Marion Lamort-Bouché, Jean-Baptiste Fassier, Philippe Sarnin, and Guillaume Broc), the workplace actors (Philippe Sarnin and Sabrina Rouat), the health-care practitioners (Marion Lamort-Bouché, Jean-Baptiste Fassier, and Guillaume Broc), and members from institutions (Jean-Baptiste Fassier).

In a first step, the themes of the interview and FG guides were used as coding categories with a deductive perspective. In a second step, new categories were created to analyze the data which did not fit in the initial coding tree and to refine the analysis of the data in an inductive perspective.

TABLE 1 | Respondent characteristics and data collection mode.

Stakeholder's category	Respondent characteristics	Data collection mode	
		Focus groups (participants)	Interviews
Breast cancer patients			
	Women participating in a physical activity program after radiation therapy	3 (22)	10
Workplace actors (7 workplaces; 5 private/2 public sector; and 1 small, 3 medium, and 3 large size companies)			
	Former patients interviewed in their workplace		8
	Human resource directors		5
	Frontline managers		4
	Colleagues		5
Health-care professionals			
	General practitioners	3 (19)	
	Rehabilitation teams	3 (21)	
	Oncologists		20
Institutions			
	Social workers	2 (12)	5
	Insurance physicians	1 (4)	1
Total		12 (78)	48

Ethics

The needs assessment of the FASTRACS project received an ethical approval from the Comité de Protection des Personnes Sud-Est II (IRB no 00009118). All members of the planning group and participants to the qualitative needs inquiry received an information letter and signed a consent form.

RESULTS

Planning Group

The first task resulted in establishing a planning group representing the wide diversity of stakeholders involved in RTW of employees with cancer (**Table 2**).

Regarding the charter of partnership, the qualitative content analysis of the written report of the first meeting of the planning group allowed identifying common themes (values, needs, and commitments) shared by the different stakeholders and by the research team members. The detailed process and results of the charter of partnership will be published. A comparative table of the values, needs, and commitments of the different stakeholders is provided in Table S2 in Supplementary Material. Shared values were expressed in terms of "respect" (mutual trust, non-judgmental attitude, and confidentiality) both within the research project and toward future participating patients, "solidarity" (brotherhood, equity, and attention to social disparities), "employment" (sustained employment, healthy jobs, and work as a determinant of health), "scientific rigor", and "patient-centered program development". Shared needs were expressed in terms of "communication" (need for a clear and open communication from the research team) and "partnership" (mutual acknowledgment, equity, and shared decisions). Shared commitments were expressed in terms of "personal commitment" (personal network and experience), "communication" (about the project), and "time" (participate on a sustainable basis).

Needs Assessment: Literature Reviews

The first literature search in 2013 yielded 569 references from which 295 duplicates were removed. The remaining 274 records were screened and 213 were excluded on the basis of their title or abstract. Studies considered initially comprised cohort ($n = 16$) or register-based studies ($n = 4$), qualitative studies (15 original studies and 2 literature reviews), intervention studies (4 original studies and 3 literature reviews), and 17 surveys. This initial search was updated on a continuous basis with automatic alerts. The final evidence base comprised a number of original studies included in systematic reviews of cohort studies reporting on the occupational prognosis after breast cancer (30–32), reviews of qualitative studies reporting on the lived experience of breast cancer patients (33–35), and reviews of intervention studies aiming at RTW after breast cancer (3, 15, 36–38).

Factors Affecting RTW Rate and Time

According to cohort studies, factors affecting RTW rate and time are disease-related (prognosis, treatment, and symptoms), work-related (physical and psychological demands, social support at

TABLE 2 | Composition of the planning group.

Stakeholder's category	Affiliation	Number of participants
Patients and associations		
	Europa Donna (breast cancer patients association)	2
	Ligue contre le cancer (cancer patients association)	1
	Juris Santé (association promoting the rights of patients)	1
	Individual patient	1
Workplaces		
	Food retailer, private employer, and 6,000 supermarkets in France	1
	Public university hospitals of Lyon, public employer, and 23,000 workers	1
	Pharmaceutical industry, private employer, and 250 workers	1
	Insurance company, private employer, and 24 workers	1
	Ventilation, heating, and cooling, private employer; and 1,400 workers	1
Health-care professionals and organizations		
	General practitioner (private practice)	1
	Occupational physician (private employers)	1
	Medical oncologist (public hospital)	1
	Radiation oncologist (private hospital)	1
	Rehabilitation medicine (public hospital)	1
	Nurse manager (public hospital)	1
Institutions		
	Regional cancer agency (Cancéropole CLARA)	1
	Metropole de Lyon (County health administration)	1
	Health insurance (regional agency, CARSAT) – insurance physician	1
	Health insurance (regional agency, CARSAT) – social worker	1
	Health insurance (regional agency, CARSAT) – prevention engineer	1
	Regional health agency (Agence régionale de santé)	2
	Regional work administration (DIRECTTE) – occupational medicine inspectorate	1
	Local agency for job retention of handicapped workers	1
Total		25

work), and social and demographic (age, education, and income level) (9, 39–42). Disease-related factors are fatigue, cognitive impairment, hot flushes, lymphedema, and psychological distress (41, 42). The influence of chemotherapy on sick leave duration is paramount (43).

Social Support at Work

Social support at work from colleagues and/or employer is likely to ease RTW and job retention (44–46). In Finland, women were shown to require more social support, mainly from occupational health services, than men after cancer (47). Lack of social support and discrimination in the workplace are barriers to RTW and job retention (34, 45, 48, 49). However, it is hard to disentangle women's functional limitations after breast cancer from their feelings of discrimination at the workplace (50). Feelings of discrimination are mentioned in terms of undesired changes to the job, reallocation or reassignment, job stagnation, or deskilling (34, 50). A French study showed that women back at work after breast cancer perceived a lack of support from colleagues or employer (17 and 22%) and suffered from a feeling of being shunted aside (11%) (8). Discrimination at work increases job cessation by 10% in women after cancer, taking all forms together (50).

Work Adaptation

Beyond social support, work adaptation has a positive influence on RTW (51). However, a French survey showed that for 25% of cancer survivors their job was not being adapted (tasks and/or schedule) as desired (52). Despite the good RTW rate 3 years after breast cancer in France (82%), a study showed that 8% of women who returned to their previous job after breast cancer considered it inappropriate to their cancer-related symptoms, while 4% of those who had changed jobs within the same firm considered their new job inappropriate (8). A qualitative case study in France revealed great disparities in occupational adaptation after cancer, depending on the company's or the patient's strategies, with frequent underutilization of legal procedures intended to ease RTW and job adaptation for disabled persons (52). These results cast some doubt on stakeholders' awareness or willingness regarding disability prevention and legislation. On the other hand, they underline the importance of exploring cancer survivors' personal strategies for returning to work or not (34, 49, 53).

Information from Health-care Professionals

The paucity of appropriate information from health-care professionals about work resumption after breast cancer is mentioned in many qualitative studies as an obstacle to RTW (34, 45, 46, 48, 49). Health-care professionals act as if women should decide by themselves how and when to RTW, whereas women are in fact eager for counseling from them. Occupational health services could act as a resource on these issues (47), but occupational physicians (OPs) should provide better coordination and continuity of care in this respect (54).

Lack of Coordination

Lack of coordination between stakeholders is clearly mentioned in qualitative studies as an obstacle to RTW and job retention after disabling conditions (55–57) such as cancer (58). It was demonstrated, in Belgium, that different stakeholders followed different rules and objectives, with poor communication (58). In the UK, communication was identified as a key factor in easing RTW after cancer and even more in increasing job retention after return (59).

According to the synthesis of this evidence, RTW after breast cancer appears clearly as an intersectoral issue at the crossroads of the individual system of the patients, the health care, the workplace, and the insurance system. Furthermore, the RTW process and the work–life balance during and after the cancer journey can be thought of in a person–environment perspective, where different levels of the environment must be taken into account (interpersonal, organizational, and broader levels). Last but not least, social disparities in RTW and work retention after breast cancer were identified depending on the age, race, and education of the breast cancer patients. All these factors must carefully be taken into account when defining the logic model of the problem and the logic model of change of the intervention.

Needs Assessment: Review of Indicators

As compared to the literature review, the indicators from data of the gray literature give a national and local estimation of the burden in the French context.

Magnitude of the Problem

The number of employed women who had a breast cancer in the Auvergne-Rhône-Alpes region amounted to 1,500 women (aged 25–54 years) and 2,000 (aged 25–59 years) in 2014 (60, 61). At the county scale of the Metropole de Lyon, the number of employed women possibly concerned by RTW issues after a diagnosis of breast cancer in 2014 was around 430 (women aged 25–54 years) and 565 (women aged 25–59 years).

Job Status

A proportion of 74.7% of breast cancer women who had a job at the time of their diagnosis remained employed 2 years later (62). The mean duration of sick leave for employed women after a breast cancer was 9 months. The mean duration from diagnosis to job loss after a breast cancer was 9 months (62).

Impact of Cancer in the Workplace (Cancer Survivors)

After cancer, women felt more penalized in their job than their male counterparts (13 vs 7.5%). Overall, 18% of cancer patients declared being stigmatized by their employer after their cancer, with a reduction of their responsibilities (43% of the persons feeling discriminated), of acquired advantages (32%), with career/salary stagnation (24%), downgrading (21%) or unsolicited hour accommodations (12%), or mutation (8%). At the time of returning to work after cancer, 47% of the workers declared difficulties associated with fatigue and side effects of treatments, 26% with cognitive limitations (attention and memory), and 6% due to their medical follow-up.

Impact of Cancer in the Workplace (Colleagues and Employers)

As regards the colleagues, 43% declared that the absence of a worker due to the cancer disturbed the workplace organization and 35% their own work organization. As regards the employers, 47% hired a temporary replacement worker until the return of their ill worker and 39% distributed the workload to the colleagues. Three employers out of four declared direct costs associated with the absence of a worker after cancer (63).

Job Retention Measures

All cancers considered, one worker out of three declared the absence of any support measure from the workplace during his/her cancer treatments, and one out of four declared the imposition of a less interesting job. No indicator could be identified about the proportion of patients benefiting from a pre-RTW visit with their OP. A great majority of employers (95%) agreed with partial sick leave to facilitate RTW after cancer, but only 49% were aware of the possibility for a worker to benefit from the status of handicapped worker after cancer.

Social Disparities in the French Context

Lower educated women had a higher risk of job loss 2 years after a diagnosis of cancer if their job was not accommodated (62). All cancers considered, the risk of job loss was increased by 21.6% for workers with a lower level of education and by 6.9% for workers in small businesses (62). The proportion of patients who did not disclose their cancer in the workplace was higher for lower educated workers (24%) and workers in small businesses (40%) as compared to all cancer patients (17%) (63).

Needs Assessment: Qualitative Inquiry

The qualitative inquiry produced rich and varied results with a number of themes mentioned by the respondents, which will be published separately to allow a full description and discussion. The most salient results are summarized below.

Women Surviving Breast Cancer: Wanting a Better Work–Life Balance

Women with and after breast cancer had different motivations to RTW. These were related to financial issues, identity, social relationships, perceived utility in society, and the meaning of life. All the women had revised their personal priorities after cancer and wanted a better work–life balance. The possible timing of an intervention to help breast cancer patients resume work was carefully analyzed. The end of active treatments (chemotherapy and radiotherapy) was not mentioned by the participating women as an ideal timeframe. Rather, it was described as a golden period to take time for themselves before considering returning to work.

> No, no, I want to be cool… and I don't want to work full time any more. There is a time for everything. Enjoy life… When you could stay alive. (Breast cancer patient in a physical activity program)

The same period at the end of active treatments was paradoxically mentioned on several occasions as difficult for the women by health-care professionals.

> As long as you are ill, there is a programme, your life doesn't belong to you anymore. And one fine day, the doctor tells you: "It's over, it's all good. Thank you. Good bye (…)". There is feeling of abandon that is extremely important. (Psychologist, in a rehabilitation center)
>
> When they arrive here, they feel incapable of doing anything, they need help (…). They have been good little soldiers; they have done everything they were

> asked to do. And then they are told: "Here you are, it's over, you need to go on." And there they don't have strength anymore. (Physiotherapist, in a rehabilitation center)

Early RTW was never mentioned as a desirable outcome. Conversely, some women reported they had resumed work too early and not satisfactorily due to persisting problems and the constraints of their medical follow-up. Other women mentioned that participating in a physical exercise program after their radiation therapy delayed their RTW, but increased the awareness of their limits, decreased their unrealistic expectations, and possibly led them to resume work in better conditions with greater chances of sustainability. Many women expressed feelings of anxiety provoked by the perspective of returning to work.

> For me, it is not that cancer is marginal, but the big thing, that's it, it's work, the problem at work. (Breast cancer patient, in a rehabilitation center)

Important variations could be identified in the women's intention to RTW, which were analyzed according to the stages of change model (64). Some women were not considering returning to work (pre-contemplative stage), while some others were weighting (contemplative) or preparing (action) this perspective. Some women had resumed work (maintenance) or had a new period of sick leave (relapse). To sum up, it was not possible to identify a consensus on the appropriate timing of an intervention after breast cancer, due to the variation between women and the fluctuation of their intention to resume work according to different stages of change.

Workplace Actors: a Three-Phase Process

Three important phases could be identified from the workplace perspective. During the sick leave, the absence of the worker had to be compensated, either by hiring another worker or by increasing the workload of the colleagues. The links between breast cancer women and their workplace during active treatments varied from a complete interruption to women keeping in touch regularly. Very few women continued working during their treatments. At the time of the first RTW, all the workplace respondents agreed on the lack of preparation between actors [breast cancer survivor (BCS), physicians, and employer], while coordination was deemed necessary. It was emphasized that both colleagues and management needed information and training to support a woman returning to work after cancer. Possibilities of the workplaces depended on their size and awareness. After the RTW, persisting problems were mentioned for the BCSs (fatigue, cognitive impairments), the colleagues (work overload, lack of support, and job termination of the replacement worker) and the management (dealing with confidentiality).

Health-care Professionals: Wondering How They Can Contribute to RTW

Oncologists had different levels of commitment toward the work issues of their patients. All declared having insufficient knowledge about work. They did not know how to help their patients when they expressed their concerns about resuming work. Oncologists mostly emphasized the importance of individual characteristics of the women (motivation and temper) in returning to work. They systematically underreported potential barriers such as depression, anxiety, cognitive limitations, and job requirements. They acknowledged the role of general practitioners (GPs) and OPs but could not precise in what respect. Oncologists from different medical specialties (medical oncologists, surgeons, and radiation therapists) reported collaborating rarely with each other and with other physicians (GPs and OPs). Female oncologists seemed more aware of RTW issues and barriers of their patients than their male counterparts.

> When the chemotherapy is over, the radiation therapy is over, the surgery is over, and so, when the person is supposed to get back to a normal life, we consider that the job is done. (Medical oncologist)
>
> The issue of return to work? Very frankly, we don't discuss it, even with the social workers. (Medical oncologist)

For rehabilitation teams, physical activity programs after the radiation therapy were acknowledged as a period allowing the women to recover from a physical, psychological, and social point of view. RTW issues were rarely discussed during the programs. They were not considered as a priority and were left upon the women's initiative. In agreement with patients' views, rehabilitation professionals emphasized that delaying the RTW might lead to better results in terms of safety, quality of life, and sustainability.

> Most of the women want to take time for themselves rather than returning to work. (Physiotherapist, rehabilitation center)
>
> Still, they arrive at a time when everything is beginning, whereas for everybody, everything is over. Because it is then that something happens psychologically, when an emotional discharge may happen. (Psychologist, rehabilitation center)

General practitioners expressed that supporting their patients in returning to work was part of their role, but reported lacking of collaboration with social insurance physicians (SIPs) and OPs in this respect. Geographic disparities were mentioned, with patients having no access to occupational health services due to OPs shortage.

SIPs and Social Workers: Legal Constraints and Work Overload

Although all the SIPs felt concerned in helping women with breast cancer to RTW, they reported some limitations about their possibilities. Contrary to other medical conditions such as low back pain, they mentioned lacking guidelines to appreciate the risk of long-term work absence and disability after breast cancer. They had limited possibilities to exchange information with their social department due to legal constraints related to medical secrecy and privacy of personal data. However, some initiatives were taken at the regional and local levels of the social insurance agencies to better identify patients at risk of work disability, regardless of their specific medical condition.

The social workers of the social department of the national health insurance scheme (CNAMTS) had a clear mandate from their institution in work disability prevention. However, this mandate was only a little part of their other missions in the field of social work such as housing, education, autonomy of the elderly, etc. As a consequence, their possibilities in work disability prevention could be limited by work overload and lack of time. At hospital, social workers for the patients and their families shared their experience in different words. They reported difficulties to set standard criteria to identify socially deprived women. Rather, they insisted on the uniqueness of each situation and the need to consider the interactions of many factors such as financial resources, geographic isolation, social isolation, etc. Importantly, they expressed their reluctance to share information with OPs, by fear of negative consequences for the patients. As a consequence, they were also cautious about their advices to the patients regarding their OP.

Data Integration: Preliminary Logic Model of the Problem

The results from the literature review, the search of indicators and the qualitative field inquiry led to the proposition of an overarching conceptual framework able to integrate various determinants associated with RTW after breast cancer (**Figure 1**). At the individual level of the breast cancer patients, the framework represents various dimensions (social and medical factors, physical and mental health, behaviors and their determinants, and stages of change) likely to influence the RTW process and outcomes. At the level of the environment, the factors likely to influence the process and outcomes are sorted into dimensions corresponding to the main categories of actors (workplace, health care, social security, and personal systems), within the overall environment at a more distal level (political, cultural, economic, etc.).

These factors at the personal and environmental levels are likely to interact at different time points in the cancer journey of breast cancer patients. The timeline is schematized by the main events along the cancer journey (before cancer, diagnosis, active treatments with surgery, chemotherapy and radiation therapy, physical activity, and after cancer with the RTW process and outcomes).

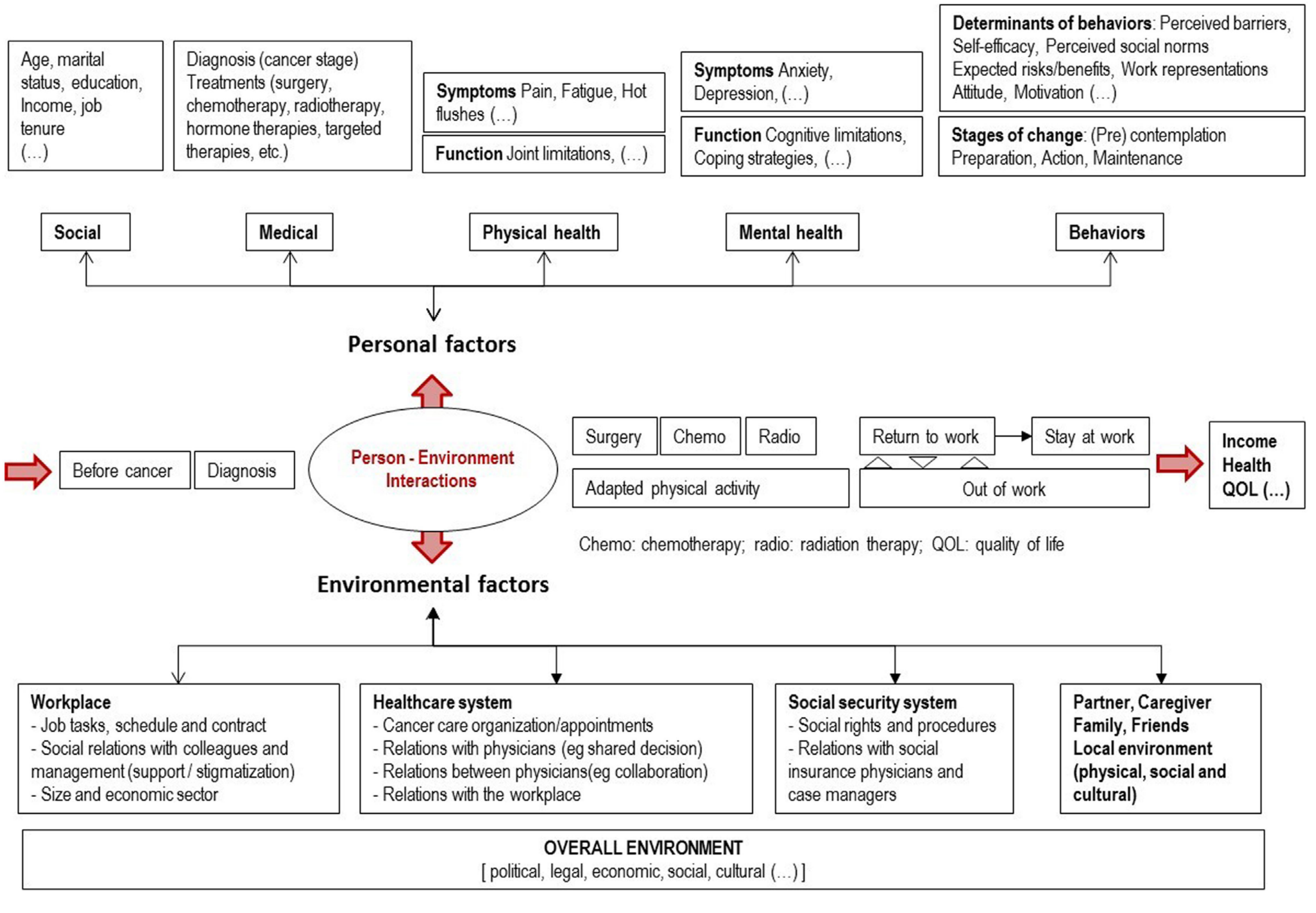

FIGURE 1 | Logic model of the problem.

DISCUSSION

The interest of this needs assessment study is to describe the process and the results of the different steps (planning group, literature review, review of indicators, and qualitative inquiry) leading to a preliminary logic model of the problem of RTW after breast cancer.

Summary of the Main Findings

Planning Group

The composition of the planning group represents faithfully the intersectoral nature of the problem. Despite the importance of the participative process in the IM protocol, only a few studies using this protocol in the field of cancer (29) and in the field of RTW (65) reported the association with a complete planning group from the needs assessment phase. This shortcoming has been discussed as a potential cause for the lack of relevance, acceptability, and/or efficiency of the studies developed (29). The elaboration of a charter to structure the partnership between the research team and the planning group is another original result, with no other example found in the literature on RTW.

Needs Assessment: Literature Reviews

The integration of results from cohort, qualitative, and intervention studies supported the formulation of an ecological view of the problem of RTW after breast cancer, which consequences are discussed below (preliminary logic model of the problem). Although this result was reported in previous studies (66, 67), it is worth mentioning since a majority of RTW interventions have focused on the individual level of BCSs rather than on their environment (15).

Needs Assessment: Review of Indicators

One main result of the review of indicators was to provide national and regional data to evaluate the magnitude of the problem. This is of particular importance in view to conduct the step 5 (implementation) and 6 (evaluation) of the IM protocol as regards the recruitment of the participants and the power calculation of the effectiveness study.

Needs Assessment: Qualitative Inquiry

The main finding of the qualitative inquiry is that "early RTW", although largely advocated for in the field of musculoskeletal disorders (28), was not supported by the data. This is in line with previous studies outlining that women after breast cancer consider different matters before RTW, with mental preparation colored by uncertainty and vulnerability (68). Similarly, the variations of women's point of view about RTW in this study are congruent with previous results showing that not all women change their view on life due to breast cancer (49). To our knowledge, it is the first time that the period following the active treatments is explicitly identified by BCS as a "golden hour" to take time for themselves, rather than to consider RTW. Paradoxically, the same period was described by several respondents as a "gap in the system" where women could be lost between the end of their active treatments and their RTW. An important implication in terms of RTW intervention is the necessity to adopt a tailored and responsive approach so as to adapt the propositions to each individual situation.

This finding supports the notion mentioned by many respondents that RTW should be viewed as a process, rather than a mere result. Once again, this echoes previous results that insist on the social and dynamic nature of RTW, with many interactions between the patient/worker and the actors of their environment at different phases of their cancer journey (58, 68). This result highlights the importance to adopt both a time-contingent basis and an ecological approach when developing an RTW intervention for women after breast cancer.

Preliminary Logic Model of the Problem

The conceptual framework elaborated from the data is not considered as the final version of the logic model of the problem for two reasons. In its current version, it is rather descriptive than explanatory, and hypothesis remains to be formulated about the direction, magnitude, and interactions of the many determinants on the process and outcomes of RTW after breast cancer. Second, this framework built by the researchers still needs to be discussed with the members of the planning group to make sure that it represents accurately their field experience.

This model presents the major interest to represent both an ecological view of the problem and to integrate the temporal dimension of the RTW process. As for the ecological view, BCSs are considered in their environment composed of various categories of stakeholders of the workplace, health care, insurance, and personal systems. This representation is in line with other "person-environment models" such as the arena model of Loisel et al. (28) and the Organizing model of practice for RTW in breast cancer developed by Desiron et al. after the International Classification of Functioning (67). Such models allow distinguishing more precisely different levels in the environment (micro, meso, and macro levels), corresponding to different determinants that may be targeted by an intervention (individuals, organizations, and wider structures of the political, legal, or economic context) (69).

As for the temporal dimension, the specificity of this model is to distinguish three main phases of the cancer journey: the phase of diagnosis, active treatments (surgery, chemotherapy, and radiotherapy), and after. RTW is considered both as a process and a possible outcome along this timeline, with the possibility of alternating periods at work and out of work, and eventually to stay at work or out of work in the long term. More distal outcomes are considered in line with the job status such as income (work-related), quality of life, health, or any other outcome of interest for the stakeholders. In this respect, the originality of this model is to avoid the risk of presenting RTW as the only desirable outcome. There is indeed the risk in the field of RTW research to reinforce a normative pressure toward RTW representing the global interests of the social protection system and the employers, whereas individuals may favor other choices than RTW and privilege a better work–life balance after breast cancer (35).

Overall, this model satisfies with the recommendations to (i) include psychosocial influences on individual's cognitions and behavior (individual level) (ii) consider the relationship between the stakeholders (proximal environment); (iii) acknowledge the legal and political dimensions (wider environment); and (iv) consider the temporal dimension of the RTW process (70).

Social Disparities

Several dimensions of the model include factors associated with social disparities. The women's position in the social hierarchy pertains to their social characteristics (e.g., education and income). Those factors are associated in the literature with other factors included in the logic model. As to the medical dimension, a lower SES is generally associated with a lower use of cancer screening services (71, 72) and a higher mortality (73). As to the determinants of behaviors, sociodemographic and economic factors influence the risk of weight gain after cancer, which may impact prognosis and risk of recurrence and of second cancer (74). As to the workplace environment, persons with a lower SES have physically heavier jobs with lower levels of autonomy and more temporary contracts (13, 75). As to the health-care system, they have a poorer access to specialized and standardized care (76). Social support is a key point to explain inequalities in waiting times between the first imaging procedure and the first treatment (77). There is qualitative evidence that socially deprived young women face many barriers and have unequal access to supportive care services after breast cancer (78). As to the social protection system, persons with a lower SES are more frequently concerned by non-take-up of their social rights, either by lack of information, demand, or attribution (52). In their personal environment, they usually have a lower social capital and are more frequently isolated socially and/or geographically. Finally, women with a lower SES are more likely to be on long-term sick leave and to lose their job after a breast cancer (9). The integration of these factors in the logic model of the problem allows formulating causal hypothesis about the possible mechanisms by which social disparities in employment after breast cancer take place. In the following steps of the IM protocol, this should allow developing an intervention with a greater cultural relevance, targeted to specific factors that contribute to social disparities. As an example, the intervention might propose social counseling to limit non-take-up of social rights, associated with a psychological approach to increase self-efficacy and/or a workplace component to ease job accommodation.

Strengths and Limitations

The first strength of this study pertains to the criteria adopted to ensure a genuine participative process between the research team and the planning group. This is a key feature of the IM protocol which importance is paramount to benefit from the field experience of the stakeholders. The composition of the planning group reflects the intersectoral nature of work disability prevention theorized in the arena model (28). Another strong feature of this study is the detailed description of the needs assessment with different data sources. The integration of the results allowed building an innovative logic model of the problem. Although preliminary, this model brings together an ecological view and a time-contingent specific perspective on the RTW process after breast cancer. It is expected to lead to a better understanding of the causal mechanisms of RTW outcomes along the timeline and to help develop an intervention that is culturally relevant to the needs of the different stakeholders.

Some limitations of the study pertain to the sampling of the respondents who participated in the qualitative inquiry. We cannot exclude a selective participation since most participants were found *via* personal connections of the researchers and snowball sampling. A possible consequence might be the underrepresentation of divergent point of views and the underestimation of barriers. However, the triangulation with other data sources (literature review and indicators) is likely to minimize this consequence in the case of a participation bias. The inquiry among institutions could not be done as expected due to bureaucratic complexity and some refusals to conduct individual interviews and FGs. This barrier could not be removed and the needs of the institutional actors could not be explored in their own view as it was the case for the other categories of actors. In this respect, it was not possible to triangulate the patients' point of views as regards the complexity of the social protection system and their difficulties to navigate the system (79). Also, despite important efforts, we included only two socially deprived women with breast cancer. This difficulty was considered as an important barrier to anticipate regarding the development of the future intervention and the way to reach lower educated persons. A possible strategy to remedy this shortcoming could be to spend more time in the field with associations and/or social workers to gain their trust and reach socially deprived persons.

Recommendations for Future Research

It is recommended from this study to investigate possible strategies to better involve socially deprived persons, and stakeholders from institutions. It is recommended to develop a transdisciplinary theoretical perspective to expand the potential of the preliminary logic model of the problem. It is recommended to investigate the interest and limitations of a charter of partnership to structure the collaboration between researchers and stakeholders in work disability prevention. Finally, it is recommended to investigate the relative advantage of rapid methods of needs assessments to render this step less time-consuming.

Next Steps of the FASTRACS Project

Several steps need to be carried out to complete the tasks of the needs assessment phase of the FASTRACS project. It is planned to define and adopt formally a charter of partnership by means of a Delphi consensus process associating the members of the planning group and the research team. The first version of the logic model of the problem proposed by the researchers (**Figure 1**) needs to be discussed with the members of the planning group to make sure it represents faithfully their experience of the problem. Last but not least, the objective of the intervention needs to be defined before moving to the next step of the IM protocol, that is, defining the logic model of change. It is expected to complete the step 2 (logic model of change), step 3 (theoretical change methods and their applications), step 4 (program plan), and step 5 (implementation) by August 2018. The evaluation step of the intervention is planned by means of a randomized controlled trial.

CONCLUSION

The IM protocol was used for the first time in France to develop an RTW intervention after breast cancer. The needs assessment tasks were carried out carefully and took longer than expected. Although the process was time-consuming, its results form a crucial basis for the intervention that will be developed. The logic model of the problem integrates actors of the workplace and health-care environment, contrary to previous interventions which were ineffective. A special emphasis was put to structure the participative planning group and its input to the FASTRACS project in the long run. The next steps of the IM protocol will be followed to develop, implement, and evaluate the FASTRACS intervention.

ETHICS STATEMENT

This study was carried out in accordance with the recommendations of the Comité de Protection des Personnes Sud-Est II with written informed consent from all subjects. All subjects gave written informed consent in accordance with the Declaration of Helsinki. The protocol was approved by the Comité de Protection des Personnes Sud-Est II (IRB no 00009118).

AUTHOR CONTRIBUTIONS

All the authors brought substantial contributions to the conception or design of the work or the acquisition, analysis, or interpretation of its data. All the authors revised the work critically and approved its final version to be published. They all agree to be accountable for all aspects of the work.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at http://www.frontiersin.org/articles/10.3389/fpubh.2018.00035/full#supplementary-material.

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Promoting Sustained Breastfeeding of Infants at Risk for Asthma: Explaining the "Active Ingredients" of an Effective Program Using Intervention Mapping

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Infants whose parents and/or siblings have a history of asthma or allergy may profit from receiving exclusive breastfeeding during the first 6 months of life. This is expected to diminish the chance of developing childhood asthma and/or atopic disease. Ongoing breastfeeding for 6 months seems challenging for many women. An educational program was developed using Intervention Mapping as a logic model to guide development and was found successful in improving breastfeeding rates at 6 months postpartum, improving knowledge and beliefs about breastfeeding for 6 months, after exposure to the program compared to controls. Intervention elements included an evidence- and theory-based booklet addressed during pre- and postnatal home visits by trained assistants. This paper elucidates the inner workings of the program by systematically describing and illustrating the steps for intervention development.

Keywords: breastfeeding, educational program, asthma, Intervention Mapping, program theory

INTRODUCTION

Complex behavior change interventions need evidence regarding the effectiveness of individual components to understand how these interventions work. The objective of this paper is to identify, guided by the Intervention Mapping (IM) protocol, the effective elements of an existing educational program, which were shown to be effective in increasing exclusive breastfeeding.

Exclusive breastfeeding during the first 6 months after birth is expected to diminish the chance of developing childhood asthma and/or atopic disease (1, 2). This effect may be particularly apparent in familial predisposed children (3, 4). Unfortunately, exclusive breastfeeding (entailing avoidance of solid foods[1]) appears to be a difficult behavior for women to perform and continue for 6 months. Only 18% of Dutch women succeeded in doing so in 2010 (7). In recent years, many programs have been developed to increase breastfeeding initiation and duration rates, employing diverse methods and theories, with variable results (8). Our multifaceted, theory-informed breastfeeding program, which combined two pre- and one postnatal home visits and a booklet, appeared to be effective

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[1] Exclusive breastfeeding is defined according the WHO definition (5). Nutritional advice is subjected to changes in scientific research outcomes. Currently, the postponement of solid foods is advised until 4–6 months after birth (6).

in promoting exclusive breastfeeding for at least 6 months in asthmatic families in 2005 (7). The intervention group, compared to the control group, entailed a significantly higher proportion of women that breastfed exclusively at 6 months, 48 versus 27%, respectively, providing evidence that written and oral advice about exclusive breastfeeding was effective in improving the exclusive breastfeeding rates at 6 months in asthmatic families. Moreover, significant improvements in knowledge and more positive beliefs regarding ongoing breastfeeding for 6 months were revealed in the intervention group compared with the controls, particularly directly after contact with the program. As anticipated, perceived self-efficacy and women's positive emotions toward breastfeeding increased and support for breastfeeding diminished in both groups over time. The intervention group reported perceiving more pressure to bottle feed and to be aware of more breastfeeding models than the control group (9).

Like educational or health promotion programs for other problems, it is difficult to know what parts of these programs have contributed to effectiveness or ineffectiveness. Failure to report adequately about the program theory, theory- and evidence-informed behavior change techniques, and practical delivery strategies hampers the growth of the science of health promotion. A number of researchers have called for better reporting (10, 11). Program development and description guided by IM (12) may help to explain what is "inside the black box" (13). IM has not only been used to develop effective health promotion programs but also to describe the intervention content (14, 15), see **Figure 1**. IM distinguishes six planning steps, with each step comprising several tasks.

In the first step, the planner puts together a planning group to assess the health problem, the behavioral and environmental factors influencing the health problem, and determinants of behavioral and environmental causes, which are then depicted in a logic model of the health problem. Step 2 specifies program outcomes and objectives in a logic model of change. In step 3, a coherent, deliverable intervention is designed. Theory-based intervention methods and practical applications to change (determinants of) behavior are selected, and program themes, components, scope, and sequence are generated. Step 4 comprises the actual production of the program. In step 5, a program implementation plan is generated. In step 6, a plan is generated for effect and process evaluations. Activities for steps 5 and 6 start as early as possible in the planning process. Although IM is presented as a sequence of actions, the authors see the planning process as iterative rather than chronological.

In this article, we use IM to describe the successive steps of the program development, especially the theoretical change methods and practical delivery applications used in our program to promote breastfeeding.

METHODS

Setting and Priority Population

The intervention described in this report and its evaluation was a sequel to a Dutch prospective birth cohort study called PREVASC (16). In this cohort, families had been advised on a variety of asthma control behaviors including breastfeeding to prevent

	Step 1: Needs Assessment - Logic Model of the Problem	• Establish and work with a planning group • Conduct a needs assessment to create a logic model of the problem • Describe the context including the population, setting, and community • State program goals
	Step 2: Program Outcomes and Objectives – Logic Model of Change	• State expected outcomes for behavior and environment • Specify performance objectives for behavioral and environmental outcomes • Select determinants of behavioral and environmental outcomes • Construct matrices of change objectives • Create a logic model of change
Evaluation	Step 3: Program Design	• Generate program themes, components, scope, and sequence • Choose theory- and evidence-based change methods • Select or design practical applications to deliver change methods
	Step 4: Program Production	• Refine program structure and organization • Prepare plans for program materials • Draft messages, materials, and protocols • Pretest, refine, and produce materials
Implementation	Step 5: Program Implementation Plan	• Identify potential program users (implementers, adopters, and maintainers) • State outcomes and performance objectives for program use • Construct matrices of change objectives for program use • Design implementation interventions Implementation
	Step 6: Evaluation Plan	• Write effect and process evaluation questions • Develop indicators and measures for assessment • Specify the evaluation design • Complete the evaluation plan

FIGURE 1 | Intervention mapping steps and tasks [adapted from Bartholomew et al. (12), p. 13].

asthma (and allergies) in high-risk infants. The primary care program further included hypoallergenic feeding as an alternative to breastfeeding, postponement of solid food, the introduction of house dust mite impermeable bed coverings, and smoking cessation. Mothers were included when 3–7 months pregnant. Adherence to the breastfeeding advice was low, a finding that called for refinement of the breastfeeding intervention.

Intervention Development

Intervention mapping guided the identification of determinants of breastfeeding (and postponement of solid foods), the formulation of intervention objectives, the choice of methods and practical applications for inducing a change in determinants and feeding behaviors, and creation of ideas for program implementation and evaluation. In this article, the first four IM steps will be illustrated in more detail.

1. *Needs assessment: the logic model of the problem*. Improvement of breastfeeding adherence was the interest of this project. Our needs assessment comprised two studies: a review of the literature and a qualitative study (17). Both studies aimed at increasing our understanding of the determinants both of early discontinuation of breastfeeding and of maintaining breastfeeding for 6 months. For the literature review, we searched Psychlit and Medline for publications on breastfeeding interventions and determinants of breastfeeding. The qualitative study entailed seven focus group interviews to explore the breastfeeding-related behaviors within 43 families in which either one of the parents and/or one of the children had physician-diagnosed asthma. Both successful and unsuccessful families in breastfeeding for 6 months were randomly selected from the Prevask study described above. There were six mixed groups (36 participants, 36 mothers, and 14 fathers) and one group consisted of solely fathers (7 participants), since they may think differently about breastfeeding and postponement of solid food, thoughts which might be overlooked in the presence of women.
2. *Program outcomes and objectives: the logic model of change*. We developed the program plan by specifying who and what will change as a result of the intervention. We combined performance objectives for each target group (women and partners) with chosen determinants to produce change objectives, the most proximal focus of an intervention.
3. *Program design*. Based on the change objectives, we sought theory-based methods and practical applications to change the factors that influence the target behaviors. An intervention method is a technique or procedure that is expected to change one or more factors that influence a target behavior of individuals, groups, or social structures while a practical application concerns the way methods are delivered to fit the context of the target population. We created a sketch of the program elements, their purpose and arrangement, the final program materials, and the program protocols.
4. *Program production.* All program components were pretested. We did this by presenting the booklet to eight women, by means of the plus–minus method. The plus–minus method involved asking participants to read the booklet from beginning to end and to indicate their positive and negative experiences in the margin with pluses and minuses, respectively. Pluses and minuses may be assigned to all sorts of text elements (from chapters to words) and for various reasons (e.g., comprehensibility, acceptability, interest, the relevance of the information). After that, we interviewed the participants to elicit the reasons for every plus and minus. We followed the interviews with a short semistructured questionnaire focusing on the macrostructure and a general evaluation of the text in the brochure (18).
5. *Program implementation plan*. This step includes program adoption and implementation (including consideration of program maintenance). We did not perform this step here because the program was implemented as a part of a research study by research personnel (efficacy study). Implementation after the RCT will focus on professionals and organizations specialized in pregnancy and/or breastfeeding, e.g., midwives and gynecologists, who have personal contact with pregnant women, which is important since preparation to breastfeed during pregnancy is considered prerequisite. These potential intermediaries will be approached to discuss their role in this breastfeeding program. In this way, providing the intervention materials to the target population and subsequent dialog occurs during health provider contacts and best resembles the RCT context.
6. *Evaluation plan*. The evaluation consisted of assessing the impact of the program provided on behavior adherence, exclusive breastfeeding for 6 months, using diaries as a source for the behavioral outcome in survival analysis. Furthermore, changes in related determinants of exclusive breastfeeding were assessed by a determinant-questionnaire filled-out by participants before and after the preventive program was provided and was compared with determinants in the control group. The analysis was performed to examine distal program objectives (e.g., knowledge, attitude, social pressure/support, self-efficacy, emotions). Process evaluation criteria were formulated (e.g., barriers to recruitment, participant maintenance in program and data collection, exposure to materials, and extent of reading them).

RESULTING PROGRAM

Step 1: Logic Model of the Problem

The needs assessment focused on barriers and facilitators to providing exclusively breast milk to newborns the first 6 months after birth. Thulier and Mercer (19) reviewed demographic biological and social variables associated with breastfeeding duration. Influential demographic factors that seemed beneficial for breastfeeding were non-black race, relatively older age, being married, higher educational level, higher social class, less exposure to free samples, and (active) distribution of formula. Biological variables supporting breastfeeding consisted of sufficient milk supply (enabling late introduction of solid food), no infant health problems (e.g., no preterm birth, no hospitalized infant), normal (pre-pregnant) maternal BMI, absence of physical challenges of breastfeeding (e.g., sore nipples, mastitis), maternal nonsmoking, multiparity/prior breastfeeding experience, and vaginal delivery. Beneficial social variables entailed the return to paid work after 6 months, positive family support (e.g., from fathers), and skilled professional support. Maternal knowledge, positive intention, interest, and enough confidence in breastfeeding were relevant psychological variables positively associated with breastfeeding.

The focus group interviews suggested that threats to the continuation of breastfeeding vary by three time periods—the prenatal preparatory phase, the postnatal initiation phase, and the postnatal continuation phase. In the prenatal phase, a woman and her partner may or may not have learned how to correctly breastfeed their child. Some parents became breastfeeding "experts" in solving breastfeeding problems that turned up during the initial 6 months after birth while others did not gain the knowledge and skills to deal with problems that arose after the birth. Interviews revealed that looking for solutions only happened when problems had occurred, which often resulted in breastfeeding failure since child feeding could not be postponed. Parents stated that they had lacked the self-confidence to stand up to "discouraging advice" from family and friends. Parents had to practically obtain a "fighting spirit" to maintain breastfeeding for 6 months.

The next critical period started after delivery. Certain problems, such as difficulty helping the baby to latch-on, sore nipples, and worries over whether the baby was feeding adequately, undermined efforts to breastfeed. Parents, who learned about breastfeeding prior to the birth and had been mentally exposed to thinkable risk scenarios, were better prepared to cope with such situations. In addition, parents talked about a strong perceived social pressure/criticism against breastfeeding and the postponement of solid food. This was considered a risk situation one really needed to be prepared for since this hindrance appeared rather unexpected. For the women, it was very important that their partners supported them.

The final precarious period was the return to work. Many women reported they did not prepare very well for the tasks during this period. For example, the mothers did not plan ahead with arranging for a breast pump and a room at work to express milk. Women who were not aware of these tasks and who did not know of the law regarding expressing milk during work time seemed to have been more vulnerable to quitting prematurely.

Step 2: Program Outcomes and Objectives; Logic Model of Change

Based on the needs assessment, we formulated four main program objectives regarding breastfeeding and postponement of solids until 6 months: Women will 1. Give exclusive breastfeeding for 6 months; 2. Postpone solid food for 6 months; 3. Recognize social pressure and cope with it; and 4. Recognize risk situations and cope with them. From these objectives, we developed performance specifications. These overall objectives were split into intermediate objectives such as acquiring information by reading the booklet as a preparatory action before delivery. We then combined these performance objectives with the determinants of breastfeeding that were under control of the mother and partner, and subject to change. Other, environmental factors, such as social norms or social support may directly influence the desired health behavior as well, but they are in this setting very difficult to address. We addressed only one relevant external agent, the newborn's father; a key person in breastfeeding support.

As an alternative to making other external agents direct targets of the program, we sought to address these environmental factors through change objectives for the women. For example, the social influence by grandmothers was dealt with through a change objective for the women dealing with perceived social influence and a change objective for the partner to support the mother when she is confronted with opinions against breastfeeding.

The performance objectives are mentioned in **Table 1** for the mother and **Table 2** for the partner combined with corresponding determinants. The cells in the matrix were populated by asking what needed to change in each performance objective for the mother or partner to accomplish the performance objective. These matrixes provided the map for developing intervention strategies. After we defined change objectives, the next step was to identify theoretical methods and practical applications that could be expected, according to theoretical and empirical evidence, to influence the change objectives from the matrices in Step 2 (20).

Steps 3 and 4: Program Design and Program Production

The eight women who pretested the brochure were multiparous women. Two of them had no experience with breastfeeding, three women breastfed an earlier child for 2–3 months, and three women breastfed an earlier child for more than 6 months. The results of the plus–minus method showed that the overall opinion about the brochure was very positive. The women thought that the brochure was interesting to read, attractive, and contained not too much or too little information. The used language appeared to be clear, and women appreciated examples and pictures. Despite the overall positive comments, the women had several suggestions to improve the brochure. Some women would like to have more information in the brochure about expressing milk and more focus on the social pressure of the environment. Other suggestions were a different title of the brochure and more pictures. We used information from these pretests to revise the program materials prior to implementation.

We present Steps 3 and 4 together so that the reader can readily understand the relations among theoretical behavior change methods, how the methods were delivered to parents and what specific topics and communication messages were conveyed. **Table 3** presents these elements and shows how the theoretical methods match the types of change objectives they were intended to influence.

To change the determinants in step 2 and enable the performance objectives, we used a number of theoretical change methods from different theories. For example, looking at the first row of **Table 3**, we used "Modeling," which is derived from Bandura's social cognitive theory (21). The key messages the model expressed, tied to this theoretical method, were: (1) you might encounter negative reactions in relation to postpone solid food for 6 months; (2) you can explain why you do it; (3) if you stick to your own opinion, the discussion will diminish;

TABLE 1 | Partial matrix of change objectives for women that exclusively breastfeed for 6 months (6 m-EBF).

Performance objectives before delivery	Knowledge	Skills and self-efficacy	Attitude	Perceived norm
The mother will				
Acquire information to prepare for 6 m-EBF from the booklet	Describe common misconceptions about 6 m-EBF Describe the relevance of 6 m-EBF for children predisposed to allergy or asthma Describe why the duration of EBF should be 6 months Describe why solid foods should be avoided in the first 6 months	Express confidence in giving 6 m-EBF (technically)	Expect that 6 m-EBF will decrease child's risk for asthma-allergies Describe the importance of preparation for exclusive 6 m-EBF	
Talk about 6 m-EBF intention with care providers (e.g., midwives)	Describe the relevance of 6 m-EBF for children predisposed to allergy or asthma			
Decide before delivery to 6 m-EBF after delivery	Describe health–social advantages of 6 m-EBF Describe benefits of EBF for mother and child Describe anticipated difficult (physical, social, and work) situations related to 6 m-EBF	Express confidence in dealing with people not in favor of 6 m-EBF	Expect that giving 6 m-EBF is hard but achievable Express favorable attitude toward the importance of 6 m-EBF for mother and child Expect that environment can be convinced about the need to postpone solid food	Expect that partner will agree and support 6 m-EBF Anticipate social criticism about 6 m-EBF Minimize unfavorable opinions of others
Document questions to be asked during the prenatal home visit by project staff	Describe questions to be asked during the prenatal home visit by project staff			
Start and continue 6 m-EBF after delivery (on demand)	Describe that EBF needs to be learned Describe that an EBF-child has its own feeding schedule Describe the signals that child wants to be fed Describe what to plan for to EBF at work Describe what to do with physical complaints of mother or child Describe sources of help	Express confidence in the ability to breastfeed	Be convinced that EBF will be enough for a child to grow on	Expect positive remarks/support about 6 m-EBF by partner Minimize unfavorable opinion of others
Counteract social criticism toward 6 m-EBF		Express confidence in the ability to recognize and counteract social criticism		Expect that recognizing social criticism as risk situation helps to minimize its impact on mother Expect that other women who BF and postpone solid food go through the same experience
Buy or hire and use a breast pump to express breast milk	Describe where to buy or hire a breast pump Describe how to use a pump to express breast milk	State confidence that they can express milk with a breast pump	State positive feelings toward expressing breast milk	
Transport, store, and prepare breast milk safely	Describe how to safely transport, store, and prepare expressed breast milk	Express confidence to adequately transport, store, and prepare expressed milk		
Monitor child development (length and weight)	Describe how to use the growth curve for EFB child Describe that the growth curve of an EBF child deviates from a bottle fed child	Express confidence in assessing child's progress in length and weight		Rely on the growth curve for EBF children when at infant well center that uses general population grow curves
Remind environment to not give solid food to a child		Express confidence that she can refrain others to give child solid food		Describe expectation that partner will support refraining others to give child solid food
Give solid food after 6 m-EBF	Describe how to introduce solid foods after 6 m-EBF			

TABLE 2 | Partial matrix of change objective for partners of women that provide exclusively breastfeeding for 6 months (6 m-EBF).

Performance objectives before delivery	Knowledge	Skills and self-efficacy	Outcome expectations	Attitude
Partner will				
Express appreciation to mother who intends to 6 m-EBF Acquire information to prepare for 6 m-EBF (including the postponement of solid food)	Describe health and social advantages of 6 m-EBF (and postponement of solid food) Describe anticipated difficult (physical and social) situations related to 6 m-EBF and postponement of solid food Recognize the importance of partner for successful 6 m-EBF and postponement of solid food	Express confidence in supporting mother that gives 6 m-EBF (technically) Express confidence in dealing with people not in favor of 6 m-EBF and/or postponement of solid food	Expect that 6 m-EBF will decrease child's risk for asthma-allergies	Express favorable attitude toward the importance of breastfeeding for mother and child Express favorable attitude toward the importance of postponement of solid food
Performance objectives after delivery				
Stand by mother who receives criticism because of 6 m-EBF Help to find solution for (physical) problems		Express confidence in dealing with people not in favor of 6 m-EBF Express confidence in supporting mother that gives 6 m-EBF (technically)		

TABLE 3 | Examples of objectives and methods for changing determinants.

Determinant knowledge and unsupportive social norms

Change objective	Methods	Parameters	Example
Performance objective Recognize and counteract social criticism toward 6 m-EBF *Knowledge change objective* Describe anticipated difficult (physical and social) situations related to 6 m-EBF	Information about others (dis-) approval	Positive and negative expectations are available in the environment	Application: experiential narrative in booklet Female model saying: "At one point I got to handle all kinds of comments from others. "*You cannot feed a child for 6 months only with breast milk*!" I found it very annoying that I constantly had to defend myself against all those people who think they know better. Even my family doctor started to tell me that I actually should start with adding fruit snacks at 4 months. Luckily, I was not be put out by it. I kept explaining every time why I choose for 6 months exclusively breastfeeding for my child. Most people still think it is abnormal what I do but, eventually, they stopped this discussion. It amazed me that I was considered being out of the ordinary because I opted for 6 months exclusively breastfeeding. I did not expect this."
	Resistance to social pressure	Commitment to earlier intention, psychological inoculation against pressure	
	Scenario-based risk information: scenarios can provide information on experiential stories about a potential future risk situation and/or how people have come to a solution (success frame)	Credible scenario with a cause and an effect; can be fictional or experiential stories. Most effective when individuals produce their own scenario or when several scenarios are offered	
	Modeling: providing a fitting model showing how beneficial behavior may be formed and is reinforced for the desired action.	Recognition, recall, self-efficacy and skills, support of model; bonding, relatedness with the model, coping rather than mastery model	

Determinants knowledge and attitude

Objective	Methods	Parameters	Application
Performance objective Provide breast milk on demand *Knowledge change objective* Know that an EBF-child has its own feeding schedule *Attitude change objective* Be convinced that EBF will be enough for a child to grow on	Self-monitoring Encourage individuals to keep a record of particular behaviors Self-reevaluation	The monitoring must be of target behaviors related to objectives. Preferable an objective standard should be used to assess target behaviors. The collected data must be processed, evaluated, aid decision-making, action selection, and execution. The reward must be reinforcing to the individual. Feedback	Mother is instructed in the text to monitor when she breastfeeds and how often per 24 h, to monitor weekly weight gain; to check volume and number of diapers and several other indicators to evaluate whether the child is drinking (e.g., growing) enough

(4) people will not change their attitude most times; and (5) do not be surprised, be prepared.

The key messages of the program were related to the central theme that exclusive breastfeeding (including the postponement of solid food) is the optimal and most normal/natural nutrition for newborns, but that it is hard work, and several barriers can make you quit before the intended 6 months. Therefore, preparation is needed. Presenting

TABLE 4 | Content of breastfeeding booklet discussed during home visits and content of the home visit manual.

Main topics per period discussed in the booklet		Main topics addressed during home visits' in manual
Introduction	• Introducing four target group representatives (three women and one man) who share their personal experiences in the booklet. Central theme: breastfeeding is a challenge; social criticism is common, so be prepared!	• Checklist of issues to be addressed during the phone call to make an appointment • Protocol first home visit (3–4 months of pregnancy): use the checklist of materials needed, use the checklist of topics to address, such as information on the study, on asthma prevention (hand over two asthma booklets), preventive measures to be taken to reduce house dust mite, smoke exposure, and for those without breastfeeding intention, information on hypo-allergic formula. Focus on pros and cons of breastfeeding and postponement of solid food, and breastfeeding intention • Protocol second home visit (seventh month of pregnancy): use the checklist of materials needed, discuss preventive measures taken, repeat information on pros and cons of breastfeeding and postponement of solid food, and breastfeeding intention. Bring social criticism to the attention • Protocol third home visit (2–4 weeks postpartum): use the checklist of materials needed, discuss preventive measures taken, inquire after breastfeeding behavior, repeat information on pros and cons of breastfeeding and postponement of solid food, and breastfeeding continuation. Inquire after experience with social criticism, preparation for work and experience with expressing milk/breast pumps
During pregnancy	• Why "breast is best" for infant and mother • Specific health benefits for families predisposed to asthma or allergy • Breastfeeding duration • Breastfeeding and the use of asthma medication • The special role of the father as a coach for the mother • What to do when no breastfeeding support is available in hospital • Breastfeeding and Cesarean section	
The first few weeks after delivery	• How breastfeeding works: good breastfeeding positioning, infant latching, frequency of feeding • Common breastfeeding myths • How to check if the child receives enough breast milk. • How to overcome sore and inverted nipples, breast engorgement and mastitis • Cow milk allergy and diet of the mother • What to expect from health professionals regarding advice on breastfeeding • Breastfeeding in public • Breastfeeding and anticonception • Coping with response from others	
A few months after delivery	• When to try the bottle with breast milk? • What if your child refuses the bottle? • Expressing milk, how does it work? • How to restore expressed milk • Breastfeeding/expressing milk during work time and the law • Alternatives to breastfeeding • Introducing solids after 6 months • Coping with response from others	
Additional	• Phone numbers of lactation, organizations/consultants, useful websites, and further reading options	

messages like this should increase the likelihood that readers process the content actively and stimulate an increase in their knowledge about the subject (22). Since knowledge alone is no guarantee for behavior change, it is important to provide the reader with the required skills to perform the behavior (21). Therefore, the booklet contained skill-based practical pictures (pictures with step by step guidance on how to latch a baby to the breast) alternated with the information on breastfeeding. Furthermore, we chose to combine written information with interpersonal communication. In our efficacy trial, the research staff created an opportunity for a dialog about breastfeeding and postponement of solid foods during the home visits (**Table 4**). For the broader implementation, the program is intended to be used in primary care, for instance, by midwives who see pregnant women frequently before and also sometime after birth. The home visitor and parents-to-be went through the written information together during the first home visit. Between the first and second visit, the women and their partner had the opportunity to read the brochure themselves and ask questions during the second visit. Moreover, the goal to create more equal partners in the conversation about breastfeeding (empowerment) could be addressed by this strategy. The interpersonal contact between the home visitor and parents was also aimed to review the information that had been read by the couples and to check understanding, clarify, repeat, and reinforce key messages (23).

Furthermore, risk awareness messages (your child might be predisposed to asthma) underlined the child's vulnerability to the threat (22), but at the same time, we presented an effective solution that women were able to perform (increase self-efficacy) breastfeeding exclusively for 6 months. This combination of awareness messages aimed at increasing threat perception and efficacy information is more likely to stimulate people to uptake the desired health behavior (24, 25). In our attitude strategy, we explicitly paid attention to existing beliefs for women with previous brief breastfeeding experience, since these women are at risk of not continuing for longer periods. For this group, we acknowledged that it was difficult to breastfeed, but being better prepared this time, they could do it. We included persuasive messages to accomplish positive breastfeeding attitudinal beliefs in first-time mothers. The models in the booklet were chosen for several reasons, but mainly to ensure that women identified with them. The four role models (selected by women of the target group for identification) illustrated the information and provided real-life experiences related to adherence to breastfeeding. These experiences were inspired by focus group stories. The goal was for the models to stimulate positive attitudinal beliefs, increase feelings of self-efficacy, but also to provide warning stories to prepare families for the social pressure they can expect and examples of coping responses (21). Another important step was to pretest the program in members of the target population before actual implementation of the intervention. The eight women who pretested the booklet were multiparous. Two of them had no experience with breastfeeding, three women breastfed an earlier child for 2–3 months, and three women breastfed an earlier child for more than 6 months. The results of the plus–minus method showed that the overall opinion about the booklet was very positive. The women commented that the brochure was interesting to read, useful and contained not too much or too little information. The language in the brochure appeared to be clear, and examples and pictures were appreciated. Despite the overall positive evaluations, the women had several suggestions to improve the brochure. For example, one woman liked to have more information about expressing milk and more examples on how to handle the social pressure of the environment in the brochure. Other suggestions were a different title of the brochure and more pictures.

Step 6: Planning for Evaluation

A description of the study design has been published elsewhere (26). At 6 months, the percentage of women breastfeeding exclusively was significantly higher in the intervention group than among the control group, respectively, 48 versus 27%; odds ratio 2.91; 95% confidence interval (1.10–7.71) ($p < 0.03$) (26). Substantial increases in knowledge and more positive beliefs regarding ongoing breastfeeding were revealed, especially directly after exposure to the program, in the intervention group compared with the controls. Perceived self-efficacy and women's positive emotions toward ongoing breastfeeding increased and perceived support for breastfeeding decreased in both groups. The intervention group reported a higher level of perceived social pressure to bottle feed and reported to know more other women that breastfeed than the control group (9).

Parents in the intervention group completed a questionnaire about the usefulness of the breastfeeding booklet and home visit. Almost all women (98%) read the booklet in whole or parts of it. The booklet was evaluated accessible, easy to read, and attractive. The overall appreciation of the program on a 10-point scale was rewarded with an 8.1 (range 6–10). The main comments reflected a generally positive view of the program.

DISCUSSION

In this paper, we described the development, theoretical behavior change methods, and content of a program that effectively increased the proportion of women who were able to sustain breastfeeding (26). The program was delivered through a combination of pre- and postnatal home visits and a corresponding theory-based booklet. The program increased the long-term duration of exclusive breastfeeding; the experimental group significantly outweighed the control group in days that their child received exclusive breastfeeding and more children in the experimental group received exclusive breastfeeding for 6 months (26). An explanation for the success of our breastfeeding program could be found in the significant impact on determinants of breastfeeding that were targeted by our program (27–30). Besides, during a meeting with parents in which they reflected on the program they had received, parents stated that the prenatal preparation for the unexpected negative attitudes and criticism from others had been helpful to continue breastfeeding. A recent study stressed the negative influence of social criticism on breastfeeding behavior as well (31). In the Netherlands, only one other study evaluated the effectiveness of a breastfeeding promotion program. This program aimed to increase the breastfeeding continuation until at least 3 months with a health counseling training for the caregivers in postpartum care, in order to enhance the cooperation between caregivers and continuity of care, and early signaling of breastfeeding problems and free lactation consultancy (OR 0.82, 95% CI 0.58–1.14) (32). Emphasis on educating the postpartum health professionals could be a wrong assumption since women chose early in pregnancy if they will breastfeed their child and can already benefit from prenatal support and education. Putting effort in preparing and educating the women starting from mid-pregnancy seems more logical than to train health professionals, which the women will see later in their pregnancy or in some cases even postpartum.

Many breastfeeding promotion programs to extend the duration of breastfeeding have been evaluated, but the majority of the studies are not comparable with each other due to several different basic assumptions (32–34). For example, most studies focus just on education or on support only or provide only written materials. Additionally, the timing points of contact moments fluctuate (pre- or postnatal or both), contact formats vary (the usage of group sessions or individual contacts, face-to-face, or just telephone contacts), and frequency of contacts differ (32). Two studies (35, 36), for instance, showed that only offering women written material was not successful, the difference between the success rate of the intervention and control group was only 7 percent after 6 months in one study (59 versus 52%), and 4% in the other study (48 versus 44%). Sikorski et al. (33) concluded in their systematic review that offering extra support leads to a higher proportion of women who breastfeed exclusively the first 6 months. The studies that were compared used different supportive strategies and trained volunteers or professionals to offer the breastfeeding support. A meta-analysis of four trials, which made use of the WHO/UNICEF training (a training to educate health professionals) showed significant benefit in prolonging exclusive breastfeeding (RR 0.70, 95% CI 0.53–0.93), but results were considered highly heterogeneous. Analysis of studies reporting a predominantly face-to-face intervention showed a statistically significant benefit (RR 0.86, 95% CI 0.78–0.94; eight trials, 2,044 women), whereas those using mainly telephone contact had almost a similar RR that was not statistically significant (RR 0.92, 95% CI 0.78–1.08, five trials, 1,168 women). Guise et al. (34) performed a systematic review and included studies, which originated in the primary care setting and contained a concurrent control group. They concluded that the effect regarding long-term breastfeeding practices (4–6 months) was the largest when breastfeeding education was combined with support. Hence, a recent Cochrane review on antenatal breastfeeding education to increase breastfeeding duration concluded that the evidence supporting any prenatal breastfeeding education to improve (1) the initiation of breastfeeding, (2) the proportion of women giving any breastfeeding or exclusively breastfeeding at 3 or 6 months, and (3) the duration of breastfeeding is still inconclusive (37). In addition, methodology problems in studies to evaluate breastfeeding interventions include short follow-up periods (less than 6 months), poor quality trials due to substantial baseline differences or lack of adjustment to confounders, and the vague definition of the outcome measure (7). In most reviews, the impact of whether educational interventions were based on behavioral change theory-based is largely ignored.

In conclusion, strong points of our program are the systematic development based on theoretical models, pre- and postnatal home visits, intervention starting in mid-pregnancy, and the supportive role of the home visitor, stressing partner support and resistance to social influence in combination with the written material.

The Use of IM

Intervention Mapping helps programs development and it also helps to describe existing interventions explaining what is "inside the black box" (12). In this project, IM guided a thorough analysis of the problem, program goals, and performance objectives, and determinants, which led to the development of an education program to promote exclusive breastfeeding by carefully describing the various steps and tasks of the IM protocol. IM is a complex and time-consuming process, reflecting the difficulty of changing (health) behaviors. For instance, during program development, describing performance objectives forced us to describe the sequence of actions that are needed to safely transport expressed breast milk from work to home, which led to a more detailed informational section (e.g., storage temperature, cleaning containers) than we would have written otherwise. Also, having to think about the core messages of our program helped us to better formulate the two major themes of the program "Exclusive breastfeeding is not easy at all, but if you prepare yourself during pregnancy, you can do it," and "Fathers' support is essential to succeed in exclusive breastfeeding." IM also forces developers to carefully consider methods and parameters of use. For instance, in our study, we let the target population select the pictures of the models the target group could identify with (parameter for use) instead of selecting them ourselves. Furthermore, our participatory approach to program development enabled us to identify the importance of the support the partners during our needs assessment, which helped us to consider mothers and partners as a breastfeeding team, instead of considering partners as an external influential person that might support mothers providing breastfeeding.

Above examples illustrate that IM can be complex, elaborate, tiresome, expensive, and time-consuming. However, IM also assists in bringing the development of interventions to a higher level, and it helps intervention planners develop the best possible intervention.

IMPLICATIONS FOR PRACTICE

At a national level, important organizations such as the professional organization for midwives and the health home care services adopted the national feeding guidelines for newborns to promote exclusive breastfeeding for the first 6 months. Also, the Dutch government promotes breastfeeding for 6 months because of the many proven health benefits for mother and child. Our effective breastfeeding promotion program was evaluated positively by participating families who graded the program with an eight on a scale from 0 to 10. We believe this program holds a promise for future care to coach women and their partner, pregnant of a predisposed child, toward adherence to breastfeeding for 6 months and improve health in high-risk newborns. Therefore, an attempt must be made to implement the program in the daily practice of health professionals, especially in prenatal care.

ETHICS STATEMENT

Medical ethics review committee Maastricht University Medical Center and Maastricht University.

AUTHOR CONTRIBUTIONS

IM and BG are the investigators of this study and developed the breastfeeding intervention. KB was the external consultant on Intervention Mapping. All authors contributed to writing the article submitted. KB passed away in February 2016.

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METHODS
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Using Intervention Mapping to Develop and Adapt Two Educational Interventions for Parents to Increase HPV Vaccination Among Hispanic Adolescents

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Introduction: Effective interventions to increase HPV vaccination are needed to reach national vaccination goals and to reduce later HPV-related cancer disparities. We used Intervention Mapping (IM) to develop and adapt a theory- and evidence-based educational intervention targeting parents of Hispanic adolescents to increase HPV vaccination.

Methods: We followed IM steps 1–6 to: (1) develop a logic model and identify modifiable factors associated with vaccination among Hispanic adolescents by conducting literature reviews, focus groups, and in-depth interviews with Hispanic parents; (2) develop outcomes, write performance objectives, and develop a matrix of change objectives; (3) develop and identify a program theme, program components, theoretical methods, and practical applications; (4) develop an intervention design plan; (5) develop implementation strategies; and (6) develop an evaluation plan. We completed Steps 1–6 for to develop an intervention targeting parents of females, and we followed the steps again to adapt the program once HPV vaccine recommendations included males.

Results: The program *Por Nuestras Hijas* (For Our Daughters) included two components: a print *fotonovela* and a tailored interactive multimedia intervention (TIMI). The program utilized the methods tailoring, targeting, framing, anticipated regret, modeling, skill building, and education and counseling to target the following determinants: parental knowledge, attitudes, self-efficacy, skills, perceived benefits/barriers, perceived susceptibility, perceived norms, and outcome expectations as modifiable factors influencing HPV vaccination. Lay health workers implemented the program in community clinics. A logic model of change guided evaluation planning. We later adapted the outcome and intervention content for parents of Hispanic adolescent males and changed the theme to *Por Nuestros Hijos* (For Our Children). Throughout the development and adaptation processes, we relied on theory, empirical evidence, and new data to make decisions.

Discussion: IM provided a systematic methodology for program development and adaptation. Tasks in each step built upon one another integrating findings from the literature, previous research, qualitative findings, and theory to develop two educational programs for parents to increase HPV vaccination. The systematic process allowed us to develop messages and materials targeting factors beyond HPV knowledge or awareness to create behavior change.

Keywords: HPV vaccination, Hispanic adolescents, intervention development, intervention adaptation, Intervention Mapping

INTRODUCTION

Persistent human papillomavirus (HPV) infection can lead to anogenital cancers, oropharyngeal cancer, and genital warts (1). In 2017, cervical cancer was the most prevalent HPV-related cancer with nearly 12,000 new cases per year in the United States (2). Cervical cancer disproportionality affects Hispanic women who have higher cervical cancer rates than their non-Hispanic counterparts and who have the second highest cervical cancer mortality rate after Black women (3, 4). Hispanic women also have lower cervical cancer screening rates than non-Hispanic women contributing to cervical cancer morbidity and mortality disparities (5).

The HPV vaccine can protect against the types of HPV that can lead to cervical cancer, other anogenital cancers, oropharyngeal cancer, and genital warts in both men and women. The Centers for Disease Control Advisory Committee for Immunization Practices (ACIP) recommends providers administer the HPV vaccine to adolescent males and females at ages 11–12 (6). While HPV vaccination rates in the United States have improved incrementally over the last several years, they remain below national benchmarks (7). Specifically among Hispanic adolescents, 68% of females aged 13–17 years, and 59% of males aged 13–17 years initiated the vaccine in 2015. However, only 46% of females and 35% of males completed the vaccine series (8). Theory- and evidence-based HPV vaccination interventions aimed at increasing series initiation and completion by targeting the multiple factors influencing vaccination rates are needed for Hispanic adolescent populations to reduce later cancer disparities (5, 9).

Theory- and evidence-based interventions have been shown to be more effective than non-theory based interventions (10). Intervention Mapping (IM) is a systematic framework for developing, implementing, and adapting theory- and evidence-based interventions (11). Cancer control and prevention researchers and program planners have used IM to develop interventions focused on sun safety and skin cancer prevention (12), smoking cessation (13) cervical cancer and breast cancer screening (14–19), and colorectal cancer screening (20). IM also provides a framework for developing implementation strategies for the adoption and implementation of interventions (21) and clinical guidelines (22) and for systematically adapting existing evidence-based programs (23).

This paper describes the use of IM to develop and adapt two interventions for parents aimed at increasing HPV vaccine uptake among Hispanic adolescents. These interventions were developed as part of a larger comparative effectiveness study to develop and evaluate a print vs. tailored intervention delivered by lay health workers in clinic settings. Initially, we followed IM to develop interventions focused exclusively on parents of Hispanic female adolescents to increase HPV vaccination among this population. The interventions, packaged as *Por Nuestras Hijas* (For Our Daughters), included a print *fotonovela* and a tailored interactive multimedia intervention (TIMI) delivered as an application on a tablet. *Fotonovela*s are brief print stories with pictures and dialog popular among Hispanic populations in conveying health information. Once recommendations changed and included HPV vaccination for boys, we used IM to adapt the interventions, repackaged as *Por Nuestros Hijos* (For Our Children).

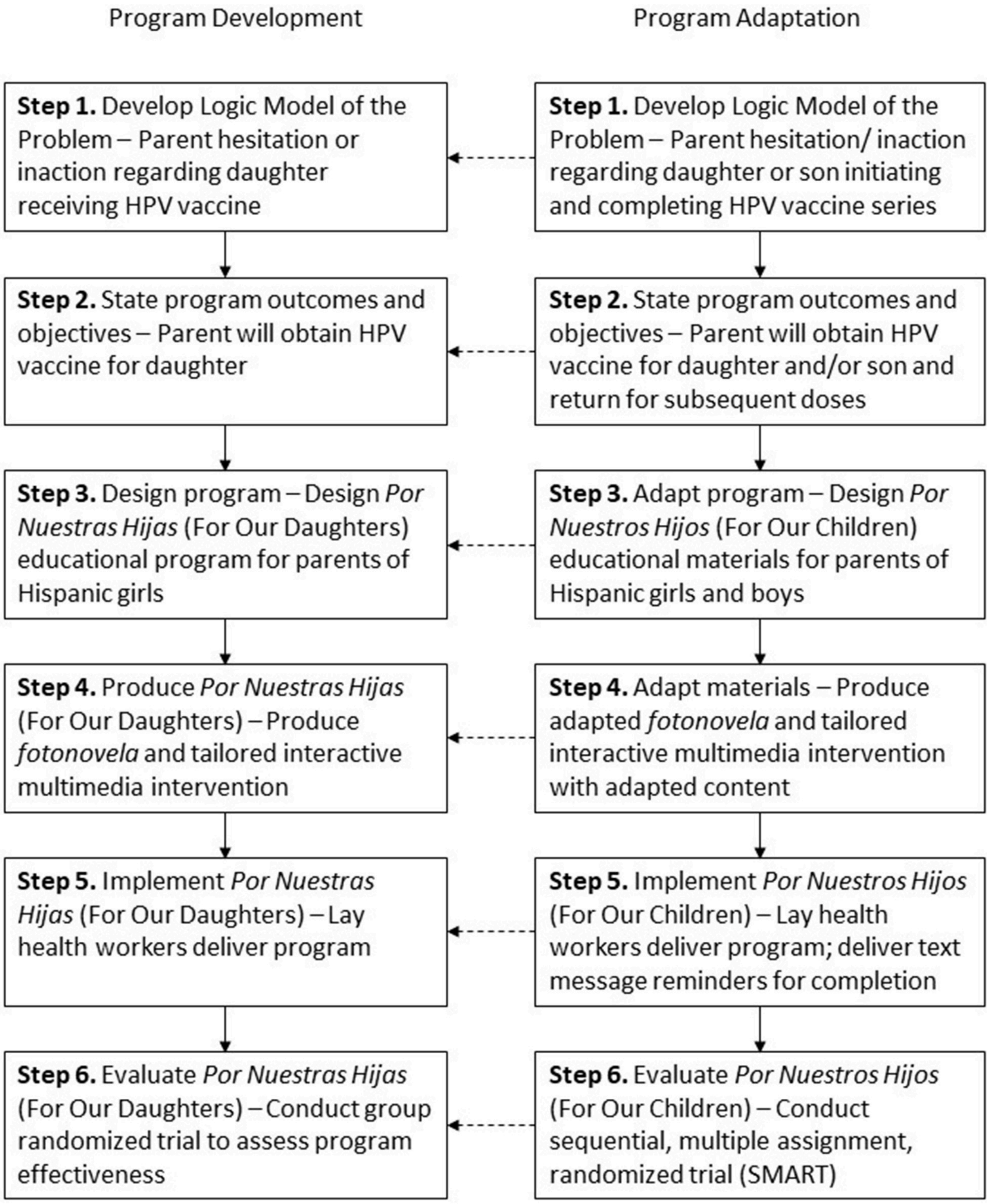
METHODS

Intervention Mapping guides program planners through six steps from needs assessment to program evaluation. The steps include: (1) developing a logic model of the problem, (2) identifying program outcomes and objectives, (3) designing the program, (4) producing the program, (5) planning for program implementation, and (6) planning for evaluation (11). Below we detail IM Steps 1–6 methods to develop and adapt two educational interventions for Hispanic parents of adolescents aged 11–17 years (**Figure 1**). While we briefly described the IM Step 6 in terms of evaluation planning, evaluation outcomes are not described as the effectiveness trial is currently ongoing. The University of Texas Health Science Center at Houston Institutional Review Board approved all research conducted during program development and adaptation.

Por Nuestras Hijas Program Development

Step 1. Develop a Logic Model of the Problem

The purpose of IM Step 1 is to conduct a needs assessment and develop a logic model of the problem (parent hesitation or inaction regarding adolescent child's HPV vaccination). To inform our needs assessment and logic model, we identified the following: (1) the burden of cervical cancer among low income or underinsured Hispanic women; (2) rates of HPV vaccination among low income and underinsured Hispanic female adolescents; (3) Hispanic parental beliefs, barriers, or attitudes toward the HPV vaccine amon; (4) and parental



* Dotted lines illustrate the need to compare adaptation methods to the original IM process and program

FIGURE 1 | PNH development and adaptation process.

decision-making processes for obtaining the vaccine for their daughters.

IM recommends first forming a planning group made up of community stakeholders, members of the target population, and potential program implementers who work collaboratively with intervention developers to identify health problems and work together to develop solutions (11). Our planning group consisted of academic researchers and intervention planners, community leaders, and a prominent *promotora* (health worker) association to help guide program development, implementation, and adaptation decisions.

The team conducted a literature review to identify factors related to parental acceptance of the HPV vaccine and parental beliefs and attitudes related to HPV vaccine decision-making. A medical librarian skilled in designing systematic reviews developed our search, which included MeSH terms related to HPV vaccination, parent decision-making and vaccinations, parental acceptance of the HPV vaccine, and parental beliefs and attitudes toward the HPV vaccine for their daughters. Studies conducted in the United States between 2001 and 2010 published in English were included in the search. Studies were not limited to those with Hispanic participants only.

Finally, focus groups and in-depth interviews were conducted with Hispanic parents of adolescent females aged 11–17 years to further understand parental acceptance of the HPV vaccine for their daughters and beliefs and attitudes related to the vaccination. Research staff placed recruitment flyers in local community centers and clinics serving predominantly Hispanic populations. Parent eligibility requirements included: (1) identify as Hispanic/Latina/o; and (2) report having a daughter aged 11–17 years. Bilingual facilitators trained in qualitative research methods conducted a total of four focus groups and two in-depth interviews. All focus groups and interviews were recorded and later transcribed for analysis. All participants completed informed consent documents prior to the focus group or interview, and all received a $25 gift card for participating.

Step 2. Identify Program Outcomes and Objectives—Logic Model of Change

The purpose of IM Step 2, is to state program outcomes and objectives and develop a matrix of change objectives to guide program development. During this step, we stated the overall behavioral outcome to be accomplished as a result of our intervention and developed a detailed list of performance objectives, or sub-behaviors needed in order to achieve the outcome (11).

To construct the matrix of change objectives, performance objectives were included as row headings and modifiable factors positively associated with vaccine decision-making (determinants) as column headings. IM Step 1 findings informed the selection of determinants for the matrix. We crossed performance objectives and determinants to produce change objectives. Change objectives describe what must change in the determinant in order for an individual to perform the performance objective (11). The matrix of change objectives served as a blueprint for further program development and guided the selection of intervention methods, practical applications, and messages. Step 2 elements were organized into a logic model of change illustrating the expected change mechanisms leading to the desired behavior—HPV vaccine uptake.

Step 3. Design *Por Nuestras Hijas*

The purpose of IM Step 3 is to develop a program theme, identify program components, map change objectives and determinants to theoretical methods, and develop practical applications to operationalize methods. Our team collaborated with the planning group to develop a theme for the intervention, identify program components, decide on tangible products for parents, and discuss how parents would interact with the intervention. Guided by tables of methods to address specific determinant in the Intervention Mapping text (11), the group selected theoretical methods to influence specific determinants. Theoretical methods are techniques for influencing determinants to ultimately create behavior change (11). We then developed practical applications, or the specific ways we would operationalize the theoretical methods. The setting (clinics), feasibility of delivery, literacy level of parents, and preferences for educational material were considered throughout this process.

Step 4. Produce *Por Nuestras Hijas*

For both program development and adaptation, a production plan guided the creation and adaptation of materials. The plan included detailed flowcharts, developed mock-ups, created content, and produced all materials. To produce materials, collaborators included an application design team, a graphic designer, a talent consultant and agency, a video production team, actors, video editors, and a photographer.

Step 5. Implement *Por Nuestras Hijas*

In IM Step 5 for both program development and adaptation, we developed implementation strategies to build lay health worker capacity to deliver the program. To do so, we completed IM Steps 1–4 again with lay health workers in mind. This included identifying specific steps lay health workers would have to do in order to implement the interventions, determinants that may influence lay health workers' abilities to implement, theoretical methods to influence those determinants, and materials needed to deliver the interventions.

Step 6. Evaluate *Por Nuestras Hijas*

As a first evaluation step in both program development and adaptation, we validated that program content was consistent with the program plan by comparing content with the matrix of change. Creating a table with all determinants, change objectives, theoretical methods, and practical applications enabled us to assess whether the interventions addressed each change objective.

Next, we designed a comparative effectiveness study to assess the intervention effect on increasing vaccination uptake among Hispanic adolescents. Previous IM Steps informed the evaluation in several ways. First, the matrix of change objectives guided measurement development since they clearly describe the specific changes expected because of the program. The logic model guided development of indicators and measures to identify predictors, mediators, and moderators of HPV vaccination.

The logic model of change also guided the evaluation of program implementation and informed our process evaluation. A complete description of the group randomized controlled trial including results is forthcoming. However, in short, thirty federally qualified health centers and community clinics to participate in the study. Lay health workers recruited participants from within the clinics and followed protocols to assess eligibility, obtain informed consent, administer surveys, and implement the interventions.

Por Nuestros Hijos Program Adaptation

Step 1. Develop a Logic Model of the Problem

During program adaptation Step 1, the aim was to identify factors associated with parental vaccine decision-making for males that may differ from those identified for parents of females. If significant differences existed, the program would likely require more extensive adaptations. Similar to methods in Step 1 for program development, we described the disease burden among the target population, parental barriers to obtaining the HPV vaccine for their sons, and the parental decision-making process for vaccinating sons.

An updated literature search was conducted in PubMed for studies assessing the following: (1) correlates of HPV vaccination in boys; (2) parents' acceptance or intention to vaccinate their sons against HPV; (3) parents' attitudes, knowledge, and acceptability of the HPV vaccine for male adolescents; and (4) barriers to HPV vaccination for male adolescents. The search was limited to US populations and to studies published in English through January 2015.

Step 1 also included three focus groups and five individual interviews with 20 Hispanic parents of males ages 11–17 recruited from local community centers and clinics. The purpose was to understand parental beliefs about the HPV vaccine for males and to understand parental decision-making to vaccinate their sons. Trained bilingual facilitators conducted the focus groups and interviews, which lasted between 60 and 85 min each. All sessions were conducted in Spanish. Facilitators obtained informed consent from each participant prior to each session, and all sessions were recorded and transcribed for analysis. Parents received $20 gift cards for participating.

Step 2. Identify Program Outcomes and Objectives—Logic Model of Change

Throughout the adaptation process, we considered whether the adapted intervention needed a new behavioral outcome and whether steps parents took to obtain the HPV vaccine for sons different from steps for obtaining the vaccine for daughters. All steps outlined above were followed to state the adapted behavioral outcome, identify adapted performance objectives, and create an adapted matrix of change objectives.

Step 3. Design *Por Nuestros Hijos*

During program adaptation, we reexamined the program theme, components, and theoretical methods, and practical applications to assess applicability to our new population. To ensure all content was relevant, we compared change objectives from the matrices for males to the materials previously developed for females. For example, if a change objective stated specific knowledge a parent should have, all materials were checked for that content. For all change objectives not addressed in the materials, we created new content.

RESULTS

For Our Daughters Program Development

Step 1. Develop a Logic Model of the Problem

The literature search resulted in 30 studies examining factors associated with HPV vaccination among adolescent females. Modifiable factors associated with HPV vaccination included knowledge, attitudes toward the HPV vaccine, self-efficacy and communication skills, perceived benefits of the vaccine, perceived barriers to vaccination, HPV risk perception, and concerns about HPV vaccine safety (24–26). Non-modifiable factors included income, parental history of sexually transmitted infections, mother's Pap testing history, and parental education level (25, 27–29). The literature review also elucidated information sources where parents learned about HPV and the HPV vaccine including pamphlets, brochures, the internet, television media, and health care providers (30).

Findings from the focus groups and interviews confirmed that the modifiable factors identified in the literature search were applicable to our population. For example, Hispanic parents had low knowledge and awareness about HPV and the HPV vaccine, and parents expressed concerns about vaccine safety and side effects. Importantly, parents wanted information on how to speak with their daughter's provider about HPV and the HPV vaccine.

Our complete logic model of the problem included the behavior of interest (lack of HPV vaccination), the related health consequences (HPV-related cancers and genital warts), and determinants, or parental factors associated with the decision not to vaccinate (**Figure 2**).

Step 2. Identify Program Outcomes and Objectives—Logic Model of Change

The overall behavioral outcome focused on parents: Parent will obtain the HPV vaccine for daughter. We identified five performance objectives associated with the outcome (**Table 1**). Determinants to increase vaccination behaviors identified in Step 1 included knowledge, attitudes toward the HPV vaccine, self-efficacy and communication skills, perceived benefits of the vaccine, perceived barriers to vaccination, HPV risk perception, and concerns about HPV vaccine safety. The matrix of change objectives described the changes in determinants needed for each specified performance objective (**Table 2**).

Step 3. Design *Por Nuestras Hijas*

Program theme

The team developed the theme "*Por Nuestras Hijas* (For Our Daughters)" to convey a message of protection. Throughout the program, the theme was interwoven in two ways: (1) highlight that the HPV vaccine protects daughters from the human papillomavirus; and (2) highlight that parents protect their daughters from cancer by obtaining the HPV vaccine for them. The intervention follows the story of a mother gathering

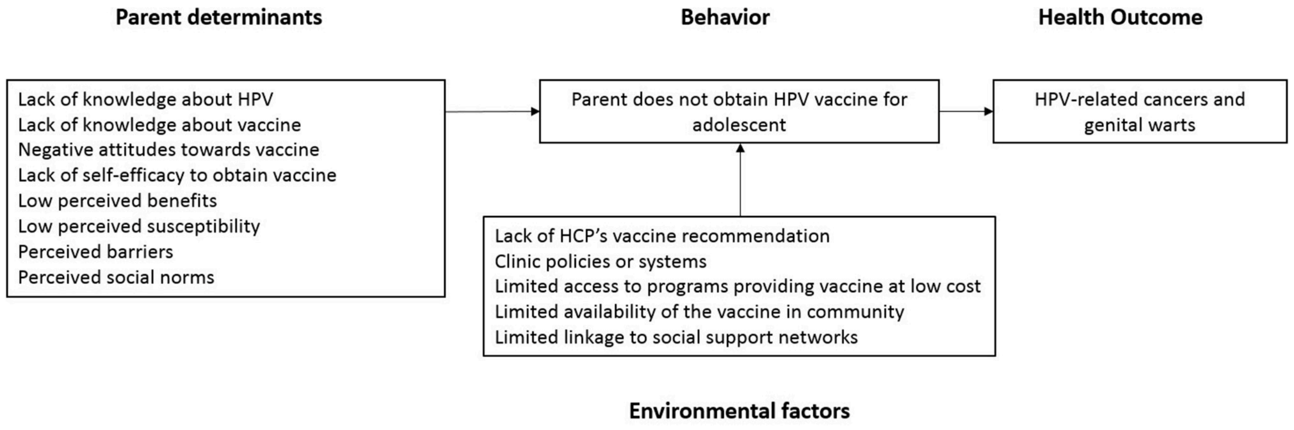


FIGURE 2 | Logic model of the problem.

TABLE 1 | Behavioral outcome with associated performance objectives.

Behavioral Outcome: Parent obtains the HPV vaccine for daughter

Performance Objectives:
(1) Parent considers and decides to vaccinate daughter against HPV
(2) Parent discusses HPV vaccine with health care provider
    a. Parent tells provider he/she is considering the HPV vaccine for daughter
    b. Parent asks the provider questions or communicates concerns, if any
    c. Parent tells provider he/she wants daughter to receive the HPV vaccine
(3) Parent identifies payment mechanism for vaccine
(4) Parent obtains the first dose for daughter
(5) Parent ensures daughter receives next two vaccine doses
    a. Parent makes follow-up appointments
    b. Parent writes down next doses schedules
    c. Parent and daughters attend appointments

information about the HPV vaccine and making the decision to vaccinate her daughter to protect her against cancer. This protective framework is effective for this population. Messages that specifically frame the HPV virus as a threat to daughters and mothers as protectors increase Hispanic mothers' intentions to vaccinate their daughters (31).

Program components

Based on our previous work (32), we developed two program components: a print *fotonovela* and a tailored interactive multimedia intervention (TIMI) delivered on a tablet. The two components conveyed the story of the mother in both video and print format. Print *fotonovela*s are illustrated brief stories with pictures and dialog accompanying the images. *Fotonovela*s are soap-opera style stories, popular in Spanish-speaking societies and are often used to describe and educate Hispanic audiences about health topics. They often employ theory and evidence-based methods such as social modeling and vicarious learning, and have been shown to be effective in helping individuals personalize health issues, identify with and internalize the information being presented, and engage in positive health behaviors (33, 34).

Theoretical methods

Tailoring and targeting, modeling, skill building, and education and counseling were identified as key theoretical methods to address determinants influencing Hispanic parents' decision-making regarding the HPV vaccine. Tailoring presents messages or interventions based on characteristics unique to an individual. Targeting is broader and involves developing messages and interventions for a subpopulation or group with shared characteristics (35, 36). These methods were operationalized as practical applications in multiple ways. First, program components were presented in English and Spanish and used actors resembling the audience (see IM Step 4). Next, self-tailoring and automatic-tailoring pause points were included throughout the TIMI. At self-tailoring points, parents chose information they wanted to see. For example, one pause point listed common questions parents have about the HPV vaccine. Parents were able to choose all of the questions they had, and the program tailored the subsequent content accordingly. Automatic-tailoring included pause points where the program asked questions based on specific determinants. Depending on the response, the application showed different messages.

We also incorporated framing and anticipatory regret in the intervention. Gain-framing and loss-framing may be used to emphasize the advantages or disadvantages of performing a behavior, such as vaccination (37). Using loss framing, we emphasized the negative consequences of not vaccinating to elicit anticipatory regret. For low-frequency behaviors such as HPV vaccination, loss-framed messages have been found to be associated with greater behavioral intentions (38). These framing methods targeted perceived susceptibility, perceived vaccine efficacy, and behavioral intentions.

Modeling, a method from the Social Cognitive Theory (39), targeted multiple determinants such as self-efficacy and skills, and reinforced desired behaviors outlined in the performance objectives. As stated above, the theme following the story of a mother as she decides to vaccinate her daughter. Scenes in the program showed the mother modeling behaviors aligned with the performance objectives that we wanted parents to emulate.

TABLE 2 | Intervention mapping partial matrix for the behavioral outcome "parent obtains the HPV vaccine for daughter."

Performance objectives	**Determinants**							
Parent will:	**Knowledge**	**Attitude**	**Self-efficacy**	**Skills**	**Perceived benefits/barriers**	**Perceived susceptibility**	**Perceived social norms**	**Outcome expectations**
PO1. Consider and decide to vaccinate daughter against HPV.	K.1.a. Recognize HPV is the most common sexually transmitted infection and can lead to cancer. K.1.b. Understand the link between HPV and cervical cancer. K.1.c. Recognize that there is an HPV vaccine to protect against HPV-related cancers. K.1.d. Recognize that daughter is eligible to receive the HPV vaccine. K.1.e. Understand that the vaccine is recommended for girls before sexual debut.	A.1.a. Believe that the HPV vaccine is important for daughters. A.1.b. Believe the HPV vaccine to be safe for their daughters. A.1.c. Believe that HPV infection can have serious consequences. A.1.d. Believe that the vaccine will not encourage sexual activity. A.1.e. Believe that not vaccinating will result in feelings of guilt and regret if daughter later develops cervical cancer.	SE.1.a. Demonstrate confidence in ability to process information about the HPV vaccine. SE.1.b. Demonstrate confidence in ability to decide whether or not to vaccinate daughter.	S.1.a.Express ability to process information about the HPV vaccine. S.1.b. Express ability to decide whether or not to vaccinate daughter.	Pbe.1.a. Recognize that the HPV vaccine can prevent HPV, cervical cancer, and HPV-related cancers. Pba.1.b. Understand that the benefits of HPV vaccination are greater than the barriers.	PS.1.a. Recognize HPV is the most common sexually transmitted infection, and daughter is susceptible once sexually active. PS.1.b. Recognize that daughter will be at risk for HPV and cervical cancer if not vaccinated.	SN.1. Believe that other parents are vaccinating their daughters against HPV.	OE.1.a.. Expect that the HPV vaccine will not produce negative results for daughters. OE.1.b. Expect the HPV vaccine can prevent cervical cancer and HPV. OE.1.c. Expect that the vaccine will not encourage sexual activity.
PO2. Discuss the HPV vaccine with health care provider (HCP). PO2.a. Tell HCP that they are considering the HPV vaccine for daughter. PO2.b. Ask HCP questions or concerns about their daughter receiving the HPV vaccine. PO2.c. Tell HCP that they want their daughter to receive the HPV vaccine.	K.2. Understand that they may have to initiate a conversation about the HPV vaccine with daughter's HCP	A.2.a. Believe that HCP will take time to discuss concerns about the HPV vaccine. A.2.b. View that discussing the HPV vaccine with HCP will address concerns. A.2.c. Believe that they have the right to initiate the discussion and ask questions.	SE.2.a. Feel confident that they can initiate a discussion even if it is not mentioned. SE.2.b. Feel confident that they can talk to HCP. SE.2.c. Feel confident about asking questions regarding the vaccine. SE.2.d. Feel confident about asking for their daughter to receive the HPV vaccine.	S.2.a. Demonstrate ability to initiate a discussion about the HPV vaccine with HCP. S.2.b. Demonstrate ability to communicate, listen and analyze the information that HCP will give them. S.2.c. Demonstrate ability to request the HPV vaccine for daughter.	Pba.2.a. Overcome feelings of fear and discomfort in order to initiate discussion with HCP about the HPV vaccine. Pbe.2.b. Believe that requesting the HPV vaccine from daughter's HCP will help daughter get vaccinated.	PS.2. Believe that their daughter could be at risk of HPV infection at some point in her life.	SN.2.a. Believe that other parents are discussing the HPV vaccine with their daughter's HCP. SN.2.b. Believe that other parents are requesting the HPV vaccine from their daughter's HCP.	OE.2.a. Expect that the HCP wants to discuss concerns. OE.2.b. Expect that discussing the HPV vaccine with HCP will address concerns.

Additional methods included education and counseling and skill building as we aimed to educate parents about the virus, the HPV vaccine, and how to request the vaccine for their adolescents. By identifying participant-specific barriers to initiation and completion through tailoring, the program provided tools and information necessary to build skills and overcome those barriers. For example, participants had the opportunity to write down questions they had for their provider after viewing content. Additionally, lay health workers clarified information that was unclear to participants and provided additional sources of information as needed.

Step 4. Produce *Por Nuestras Hijas*

Design documents shared with the TIMI design team included a flowchart, mock-up presentations, and scripts. A detailed flowchart of the TIMI included all tailoring points and detailed the placement of all video vignettes (**Figure 3**). Mock-ups of presentations with voiceover were created for TIMI graphic designers. Presentations included illustrations, such as abnormal cells leading to cervical cancer, a presentation on HPV prevalence, and information about free vaccination programs. Scripts were in both English and Spanish. Simple, direct sentences free of jargon were used to accommodate a low-literacy population.

Actors for the TIMI and *fotonovela* were bilingual Hispanic actors with experience in health-related productions. It was important to hire actors resembled our target population and to film in locations that were culturally appropriate for our target audience (e.g., community-based clinics serving predominantly low-income populations). A video production

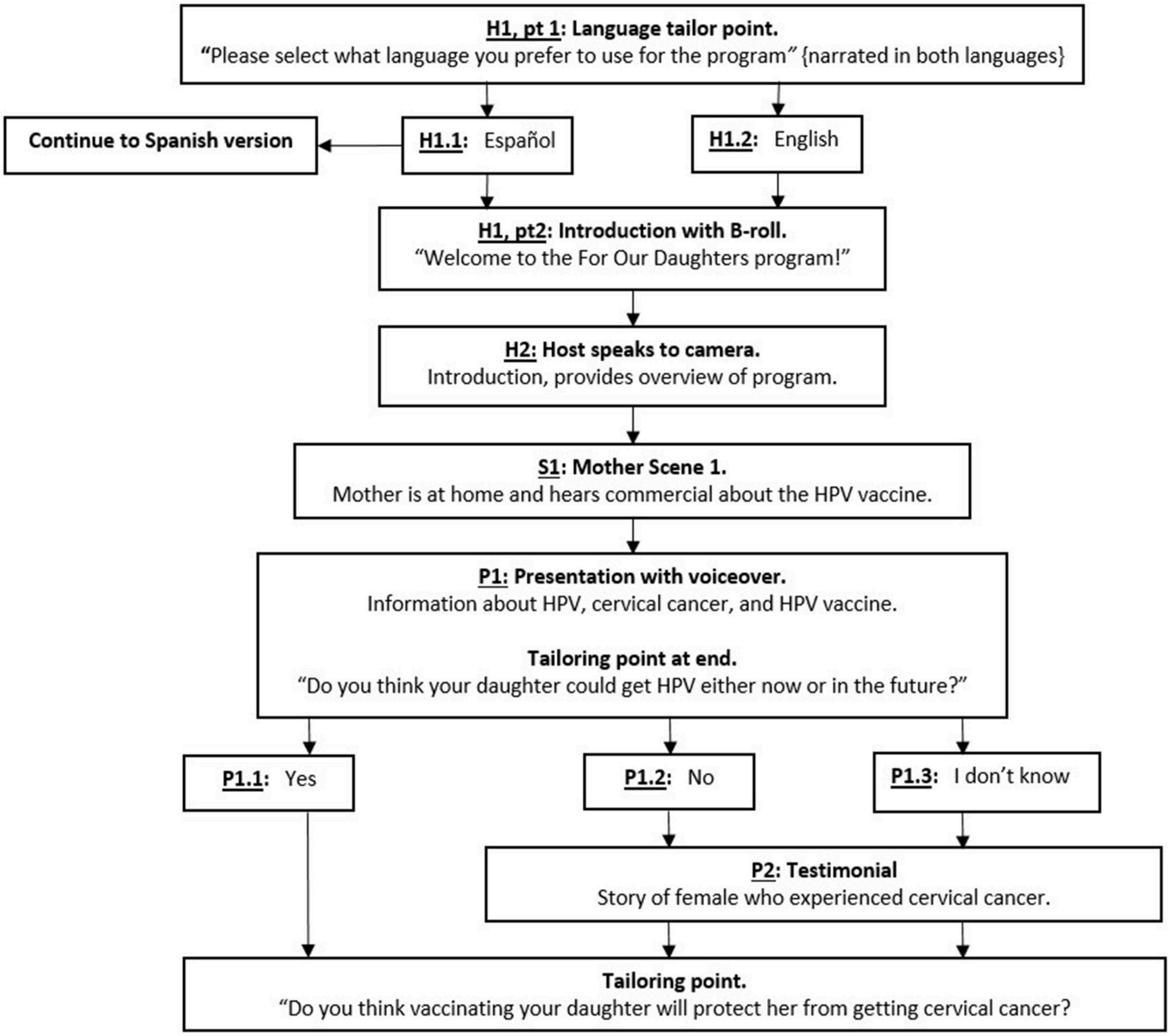


FIGURE 3 | Partial TIMI flowchart for parents of Hispanic adolescent females.

team with experience in health-related productions filmed and produced all scenes, and a graphic designer created presentations with voiceover for the TIMI. The design team received all material and created the tablet-based application (**Figure 4**).

We created a storyboard for the *fotonovela* based on scripts used in the TIMI. Similar to a comic book or illustrated novel, each page of the *fotonovela* contained short text bubbles along with a relevant image from a relevant video scene (**Figure 5**). In addition to the story of a mother learning about the HPV vaccine and deciding to vaccinate her daughter, the *fotonovela* contained the following content: (1) a list of resources available to help cover the cost of the vaccine; (2) information about HPV and the HPV vaccine; (3) a calendar to help parents keep track of dosing schedules; and (4) a place for mothers to write down questions about the vaccine to ask their health care provider.

The cost of developing the TIMI and *fotonovela* have previously been reported (40). As reflected in the development steps outlined here, a substantial proportion of personnel time was associated with program development. Cost analyses indicate that the personnel time cost to plan and create the *fotonovela*-based education (41%) was less than the iPad-based TIMI (67%) education intervention.

Step 5. Implement *Por Nuestras Hijas*

For implementation, the target behavior was "Lay health worker will deliver the educational interventions with fidelity," and performance objectives included (1) adopting the role of lay health worker, (2) locating eligible parents, and (3) conducting sessions with parents. Determinants included knowledge, skills and self-efficacy, attitudes, perceived norms, and outcome expectations. After completing the matrix of change objectives, we identified the following theoretical methods: information, modeling, feedback, reinforcement, and active learning for use in the implementation intervention. These methods were operationalized through presentations, activities, and practice sessions during a 2-day training session at *Pro Salud*, the lay health worker program headquarters. As a part of the training, medical experts presented information about HPV, the HPV vaccine, and cervical cancer. Each presentation ended with a question and answer session. The goal was to provide the lay health workers with a working knowledge of HPV, cervical cancer, and the HPV vaccine. We also used skills training and modeling approaches to prepare the lay health workers for their role in educating parents. Lay health workers learned how to use the program materials and how to respond to participant questions or concerns through both didactic presentations and facilitated practice session. Lay health workers took turns administering the program materials to build skills and self-efficacy. During this time, research staff circulated around the room to observe, assist, and offer feedback and reinforcement. Additional training topics pertained to evaluation efforts (see IM Step 6).

Step 6. Evaluate *Por Nuestras Hijas*

To assess content validity, we created a table mapping all program components back to change objectives and determinants (**Table 3**). The table illustrates the expected mechanisms of change. For example, in IM Step 1 we identified self-efficacy as a modifiable factor associated with behavior change to increase HPV vaccination. Parents needed increased self-efficacy to discuss the HPV vaccine with providers. In order to increase self-efficacy and to address each change objective associated with the determinant, the program included scenes with a mother modeling the behavior. As part of the content analysis, we went back to the table to ensure all appropriate change objectives were included in that scene.

FIGURE 4 | "*Por Nuestras Hijas*" screenshot.

We recruited 1,398 parents of adolescent females in participating clinics as part of the group randomized controlled trial to assess the effectiveness of the two interventions. Trained, bilingual data collectors approached parents in clinic waiting rooms, assessed eligibility, and obtained informed consent from those agreeing to participate. Data collectors administered baseline surveys to all participants and lay health workers administered the interventions to those in the *fotonovela* and TIMI study arms. We conducted follow up surveys and accessed patient vaccination records to assess vaccination status at 6 months after baseline. Results are forthcoming. During program development and implementation, we also assessed the cost-effectiveness of developing and implementing the interventions (40, 41). Finally, a sequential, multiple assignment, randomized trial to assess the effectiveness of *Por Nuestros Hijos* (described below) is currently underway.

Por Nuestros Hijos Program Adaptation

Step 1. Develop a Logic Model of the Problem

During the literature review, thirty-two relevant articles were identified after screening 1,032 title and abstracts. Similar to female adolescents, determinants for vaccinating adolescent males included parental knowledge, self-efficacy, skills, perceived benefits of the HPV vaccine, perceived susceptibility to HPV, perceived social norms, outcome expectations, and HPV vaccination attitudes. Parental intentions to vaccinate their sons were higher if they had daughters who were previously vaccinated against HPV (42, 43). Further, parents of males often believed their adolescent sons may soon become sexually active, and they

FIGURE 5 | *"Por Nuestros Hijos " fotonovela* scene.

TABLE 3 | Determinants and change objectives mapped to methods and practical applications.

Determinant	Targeted change objectives	Method	Practical application	Program component
Knowledge	(K)1.A. Recognize that there is an HPV vaccine	Modeling	Scene: Doctor discusses HPV vaccine with mother	Interactive multimedia/*Fotonovela*
	(K)1.B. Recognize that daughter is eligible to receive the HPV vaccine	Modeling	Scene: Doctor discusses HPV vaccine eligibility with mother	Interactive multimedia/*Fotonovela*
	(K)1.C. Understand the purpose of the HPV vaccine	Modeling	Scene: Doctor describes HPV vaccine as cancer prevention	Interactive multimedia/*Fotonovela*
	(K)1.D. Understand the link between HPV and cervical cancer	Education and counseling	Scene: Doctor describes link between HPV and HPV diseases	Interactive multimedia/*Fotonovela*
Attitude	(A)1.A. Believe that the HPV vaccine is important for their daughters	Modeling	Testimonials: Mothers discuss vaccinating daughter	Interactive multimedia/*Fotonovela*
	(A)1.B. Believe the HPV vaccine to be safe for their daughters	Modeling; Education and counseling	Scene: Doctor describes HPV vaccine as safe and effective	Interactive multimedia/*Fotonovela*
	(A)1.C. Believe that the HPV infection can have serious consequences	Modeling	Testimonials: Cervical cancer survivors describe experiences	Interactive multimedia/*Fotonovela*
Self-efficacy	(SE)2.A. Feel confident that they can initiate discussion with doctor even if HPV vaccine is not mentioned	Modeling	Scene: Mother has list of questions and asks doctor about HPV vaccine	Interactive multimedia/*Fotonovela*

believed vaccinating their sons could prevent the transmission of HPV to their female partners in the future (43–45). This finding was different from parents of females who perceived their daughters to be too young for the vaccine and not at risk for HPV because they did not perceive their daughters to be sexually active in the near future.

Focus groups and interviews revealed knowledge gaps about HPV-related cancers among males. Some parents were also unaware the HPV vaccine was available for males. Other knowledge gaps included parents confusing HPV with the herpes simplex virus (HSV) and parents now knowing condoms do not provide complete protection against HPV. Finally, parents reported receiving conflicting information about HPV from multiple sources. These results informed new content included in the adapted intervention.

Step 2. Identify Program Outcomes and Objectives—Logic Model of Change

The adapted program focused on a new outcome (HPV vaccination of sons). However, the target population, Hispanic parents, and the desired behavior, HPV vaccination, remained the same. Therefore, performance objectives were unchanged, and the matrix of change included most of the same change objectives. Minor changes included updating the knowledge change objectives to include male cancers and genital warts and removing change objectives regarding concerns about sexual disinhibition. For parents of daughters, we originally included content that assured parents daughters were not more likely to initiate sex at a younger age or to engage in risky sexual behaviors after vaccination. For parents of sons, we did not emphasize this point since it was not an identified barrier in the literature review or focus groups and interviews.

Step 3. Design *Por Nuestros Hijos*

Our original theme and program title *Por Nuestras Hijas* (For Our Daughters) was changed to *Por Nuestros Hijos* (For Our Children) to reflect that the program now contained information for parents of daughters and sons. The adapted program included the original story of a mother of a daughter and included a new story following a mother gathering information and deciding to vaccinate her son. The adapted program used the same program components, methods, strategies, and practical applications with one addition. Text message reminders, or cues to action, were added as a during *Por Nuestros Hijos* (For Our Children) to target HPV vaccine series completion behaviors.

Step 4. Produce *Por Nuestros Hijos*

To adapt the TIMI, we modified the original flowchart to include gender as an additional tailoring point. The flowchart depicted the two-arm program with one arm tailored for parents with daughters and one arm tailored for parents with sons. A third arm for parents with both daughters and sons is currently under development. We also revised the original scripts and multimedia presentations to provide information relevant to HPV-related cancers in males. As before, the program includes culturally appropriate actors. We followed the same process as in the development phase to produce the *fotonovela* aimed at parents of Hispanic males. Language in text message reminders to increase series completion were based on our previous work regarding linguistic agency and HPV vaccination intentions (31).

Step 5. Implement *Por Nuestros Hijos*

Our implementation plan for delivering *Por Nuestros Hijos* (For Our Children) did not change from *Por Nuestras Hijas* (For Our Daughters). Lay health workers continued to implement the program. The two primary adaptations to training content included: (1) providing information about HPV-related cancers affecting males, and (2) describing the updated ACIP recommendations to include HPV vaccination for adolescent males.

DISCUSSION

We used Intervention Mapping (IM) to systematically develop and adapt two interventions for parents of Hispanic adolescents to increase HPV vaccine uptake. We first followed IM to develop *Por Nuestras Hijas* (For Our Daughters), an intervention targeting parents of Hispanic females. The process relied on evidence and theory to drive development of the logic model of the problem, program outcomes and objectives, program design, program production, development of an implementation intervention, and evaluation. As guidelines changed to include HPV vaccination for males (46), we used IM to assess and adapt the original program to the needs of parents of Hispanic males. We repeated IM Steps 1–6 systematically assessing the original intervention and identifying key elements that needed adapting.

Our program adapted for Hispanic parents of adolescent males required minimal adaptations. IM can guide program planners in making adaptations that are more significant by systematically guiding decision-making throughout the process. This is helpful as program planners identify evidence-based interventions developed in one context and adapt them for another (23). Changes may include a new priority population, a different setting, or a new health behavior. IM then provides the framework to assess and adapt the building blocks of each intervention to determine the level of adaptation needed.

Por Nuestros Hijos required mostly surface-adaptations since the behavioral outcome, determinants, and performance objectives were similar to the original program. Surface adaptations are smaller adaptations that tailor a program to a new audience, but do not necessarily add new program components or address new determinants. In *Por Nuestros Hijos*, example surface adaptations included changing characters to include males, altering scripts to include HPV-related cancers related to males, and updating the HPV guidelines to include males. Some program planners may follow IM and find that deeper adaptations, or more extensive changes to the original program, are needed to adapt an existing program for a new population. For example, IM Step 1 may identify a new determinant relevant to the new target population. This would then add to the matrix of change objectives. Planners would then identify new methods to target that determinant, new practical applications, and new intervention materials addressing the new change objectives—activities associated with more extensive adaptations to the original program.

Further, IM assists program planners in identifying the most salient methods, applications, or program components critical to program effectiveness. For example, in *Por Nuestras Hijas* (For Our Daughters), we used modeling to address parental self-efficacy in asking the provider questions, requesting the vaccine, and scheduling subsequent doses. We also used modeling to address parental outcome expectations. In this way, and based on the IM logic model of change, modeling was a critical method for creating parental behavior change. Modeling was the mechanism through which we expected to increase self-efficacy, to create positive outcome expectations, and to ultimately increase vaccination behaviors. In adapting the program, we retained modeling as a method since determinants were identical, and we adapted the original scripts to include language relevant to parents of males to operationalize the method.

Interventions targeting multiple factors associated with a health behavior are critical to behavior change, and interventions specifically targeting HPV vaccination sometimes fail to address more than one factor associated with parental decision-making. Interventions to increase HPV vaccination among adolescents often provide only educational information or cues to action (e.g., reminder letters, text messages) for parents (47). Educational interventions and materials, including those produced by the CDC, aim to increase parental knowledge about HPV, HPV-related cancers, and the HPV vaccine (48). While it is important to increase parental knowledge, focusing solely on this factor may not be enough to change behavior, particularly for unmotivated parents (49). Systematically identifying and addressing multiple factors associated with HPV vaccination, such as attitudes, beliefs, or self-efficacy, allows intervention planners to move beyond simply providing information or cues to action to create behavior change.

The steps that guided program development and adaptation are applicable to a broad group of researchers, program planners, and public health professionals. IM was specifically designed for use in public health settings, not just academic research settings, providing public health practitioners the tools and resources to develop theory- and evidence-based interventions specific to their context (11). IM provides a systematic process, appropriate for any population or behavior of interest, that result in interventions targeting determinants specific to the population and behavior. Public health practitioners and health educators in health departments and hospital settings (50, 51), workplace settings (52), and community organizations (23) have successfully developed theory- and evidence-based interventions using IM. As exemplified by *Por Nuestras Hijas* (For Our Daughters) and *Por Nuestros Hijos* (For Our Children), IM provides a user-friendly, iterative stepped approach to facilitate development and adaptation guiding researchers and public health practitioners every step of the way.

Future studies should evaluate the *Por Nuestras Hijas* (For Our Daughters) and *Por Nuestros Hijos* (For Our Children) interventions to assess their efficacy in increasing HPV vaccination in Hispanic adolescents and in changing psychosocial determinants. These studies will provide important information regarding the effect the interventions on the knowledge, beliefs and attitudes that influence HPV vaccination along with information about the efficacy of the two program components. If the interventions are effective in increasing vaccination, they could be adapted for other populations using the process we outline in this paper.

There are limitations to our development and adaptation process using IM. Participants in the focus groups and interviews self-selected to be a part of our needs assessment work. Their attitudes toward the HPV vaccine may differ from those of other parents who did not participate. We therefore may not have captured all determinants relevant to our target population. While we conducted systematic reviews of the literature to also identify determinants, the qualitative nature of the needs assessment process may limit generalizability. Additionally, the program is limited in reach since participants were low income and underinsured Hispanic parents in an urban setting. The programs may not be effective among Hispanics in other settings, and messages may not resonate for other race/ethnicity populations. Further, while our team had resources to train and implement the intervention using lay health workers, clinics and other organizations utilizing this program in the future may not be able to employ this implementation strategy. This potentially limits program reach. Similarly, clinics or other organizations may not have capacity to implement text message reminders to target HPV vaccine series completion. Our development and adaptation processes and outcomes did not account for these differences in resources for future program adopters.

ETHICS STATEMENT

This study was carried out in accordance with the recommendations of UTHealth Science Center at Houston with written informed consent from all subjects. All subjects gave written informed consent in accordance with the Declaration of Helsinki. The protocol was approved by the University of Texas Health Science Center at Houston Institutional Review Board.

AUTHOR CONTRIBUTIONS

MF, SV, LS: Study and manuscript conceptualization; SR: Background, methods, results, discussion; AR, LS, and MF: Contributed to background, methods, results, discussion; DL: Contributed to methods.

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Systematically Developing a Web-Based Tailored Intervention Promoting HPV-Vaccination Acceptability Among Mothers of Invited Girls Using Intervention Mapping

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Background: Currently, the eHealth field calls for detailed descriptions of theory-based interventions in order to support improved design of such interventions. This article aims to provide a systematic description of the design rationale behind an interactive web-based tailored intervention promoting HPV-vaccination acceptability.

Methods: The 6-step Intervention Mapping (IM) protocol was used to describe the design rationale. After the needs assessment in Step 1, intervention objectives were formulated in Step 2. In Step 3, we translated theoretical methods into practical applications, which were integrated into a coherent intervention in Step 4. In Step 5, we anticipated future implementation and adoption, and finally, an evaluation plan was generated in Step 6.

Results: Walking through the various steps of IM resulted in a detailed description of the intervention. The needs assessment indicated HPV-vaccination uptake remaining lower than expected. Mothers play the most important role in decision-making about their daughter's immunization. However, they generally feel ambivalent after they made their decisions, and their decisions are based on rather unstable grounds. Therefore, intervention objectives were to improve HPV-vaccination uptake and informed decision-making, and to decrease decisional conflict among mothers of invited girls. Computer-tailoring was chosen as the main method; virtual assistants were chosen as a practical application to deliver interactive tailored feedback. To maximize compatibility with the needs of the target group, a user-centered design strategy by means of focus groups and online experiments was applied. In these, prototypes were tested and sequentially refined. Finally, efficacy, effectiveness, and acceptability of the intervention were tested in a randomized controlled trial. Results showed a significant positive effect of the intervention on informed decision-making, decisional conflict, and nearly all determinants of HPV-vaccination uptake ($P < 0.001$). Mothers evaluated the intervention as highly positive.

Discussion: Using IM led to an innovative effective intervention for promoting HPV-vaccination acceptability. The intervention maps will aid in interpreting the results of our evaluation studies. Moreover, it will ease the comparison of design rationales across interventions, and may provide leads for the development of other eHealth interventions. This paper adds to the plea for systematic reporting of design rationales constituting the process of developing interventions.

Keywords: HPV-vaccination acceptability, intervention mapping, eHealth, web-based intervention, design rationale

BACKGROUND

Too often design rationales of behavioral intervention programs are poorly described, leading to so-called "black box" evaluations (1). Currently, there is call in the eHealth field to open these black boxes. The scientific literature still provides detailed descriptions of *how* interventions are evaluated, but hardly ever of *what* exactly is being evaluated (2). Moreover, information about when and how decisions are made throughout the process of intervention development is often incomplete or even completely lacking (2, 3). Intervention development is a complex and laborious process which requires a large scale of decisions to be made along the way. This goes far beyond the decision about which behavior change techniques to include in an intervention (2, 3). We consider all of the decisions to represent valuable knowledge for the scientific community and for intervention developers who like detailed background about the conditions for (in)effectiveness of an intervention. Consequently, all decisions that were made during intervention development should be reported.

Hence, this article aims to provide a detailed, systematic description of the design rationale behind an interactive Web-based tailored intervention promoting HPV-vaccination acceptability. This paper encompasses all decisions that were made during the process of intervention development. A systematically developed and well described intervention enables the identification of active ingredients, improvement of existing interventions, future intervention development, and large-scale dissemination (1, 4). In addition, it facilitates comparison between interventions, for example for reviews and replication of studies (5–7). After all, the usefulness of systematic reviews depends on the quality of the studies included (3). Finally, it contributes to theory development by providing insight into causal mechanisms (3, 4, 7–9). We used the Intervention Mapping (IM) protocol, which provides a highly structured approach in describing an intervention program and its development (10).

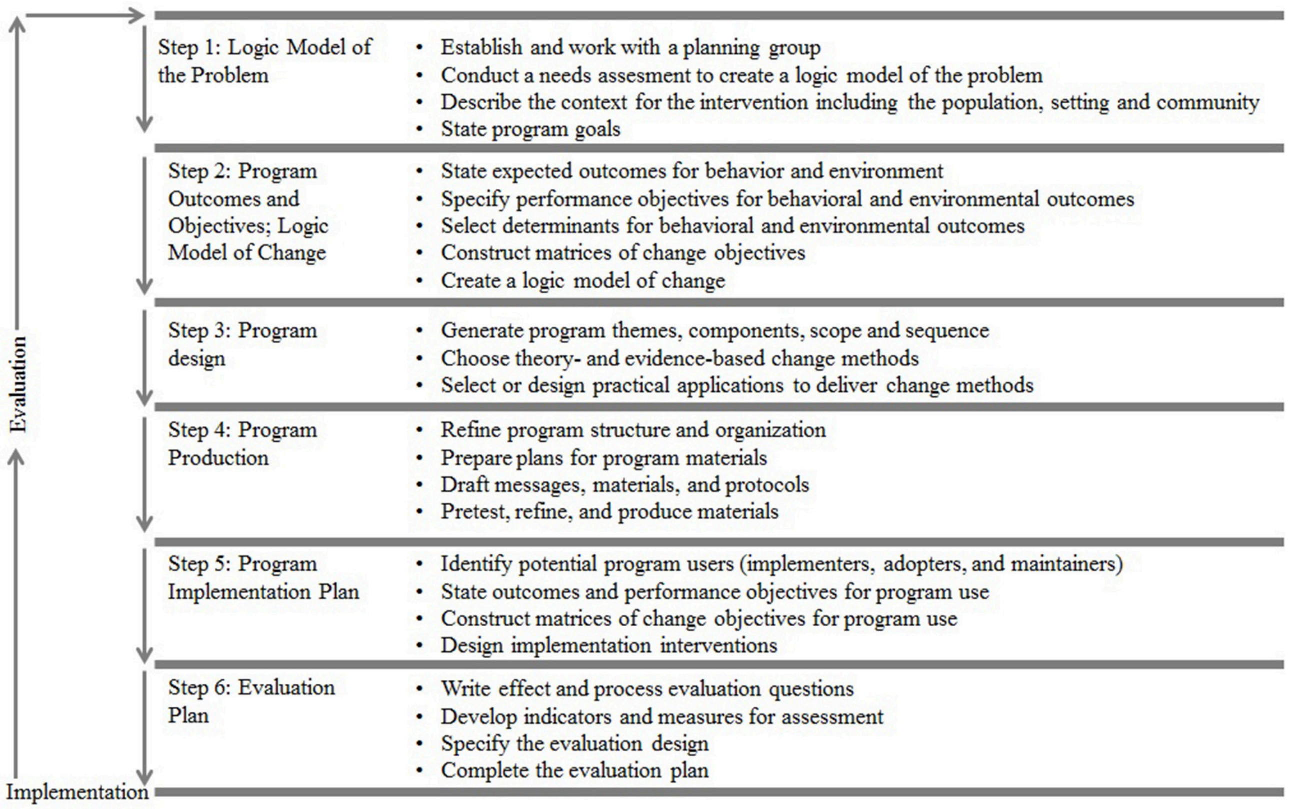
METHODS

IM is a systematic process for developing theory- and evidence-based health promotion interventions. The IM protocol describes the pathways from problem identification to solution (10). The six steps of IM comprises several tasks, each of which integrates theory and evidence. The deliverable of completing the tasks within a step serves as a guide for the subsequent steps. Although IM is presented as a series of steps, Bartholomew Eldredge et al. (10) emphasize that the planning process is iterative instead of linear, meaning that intervention planners move back and forth between the various tasks and steps. By explicitly reporting all decisions and considerations throughout the intervention process, IM makes the intervention development process transparent.

Step 1 concerns the conduction of a needs assessment and formulation of the overall goals of the intervention. In this step, the health problem, behavioral, and environmental causes of this problem, and related determinants are identified. The intervention goal is the desired outcome of the intervention. In Step 2, performance objectives and change objectives are formulated. Performance objectives (POs) specify the (sub)behaviors that must be performed by the target group in order to reach the intended goal. Change objectives (COs) outline the specifics of behavioral determinants to be targeted so the target group is enabled to reach the performance objectives. COs are formed by crossing the POs with the determinants. This results in a matrix which can be seen as the core of the design rationale. Step 3 is about the design of the intervention program in terms of generating program themes, components, scope and sequence. The scope is the breadth and amount of the program and the sequence is the order in which programs are delivered across time. This step also includes the selection of theory-based intervention methods and the translation of these methods into practical applications, taking into account the parameters for effectiveness of the these methods. In Step 4, the methods and practical applications are being translated into a coherent intervention program In Step 5, adoption, implementation, and sustainability of the intervention in real-life settings are planned. Finally, Step 6 entails the outline of the process and effect evaluation. The steps and tasks of IM are visualized in **Figure 1**.

RESULTS

Systematically walking through all of the steps of IM, resulted in a detailed description of the intervention. This description, in turn, provides insight into the theory- and research-based foundations of the many decisions that were made during the process of intervention development. Below, the study findings from each step of IM are described.



Step 1: Logic Model of the Problem
- Establish and work with a planning group
- Conduct a needs assesment to create a logic model of the problem
- Describe the context for the intervention including the population, setting and community
- State program goals

Step 2: Program Outcomes and Objectives; Logic Model of Change
- State expected outcomes for behavior and environment
- Specify performance objectives for behavioral and environmental outcomes
- Select determinants for behavioral and environmental outcomes
- Construct matrices of change objectives
- Create a logic model of change

Step 3: Program design
- Generate program themes, components, scope and sequence
- Choose theory- and evidence-based change methods
- Select or design practical applications to deliver change methods

Step 4: Program Production
- Refine program structure and organization
- Prepare plans for program materials
- Draft messages, materials, and protocols
- Pretest, refine, and produce materials

Step 5: Program Implementation Plan
- Identify potential program users (implementers, adopters, and maintainers)
- State outcomes and performance objectives for program use
- Construct matrices of change objectives for program use
- Design implementation interventions

Step 6: Evaluation Plan
- Write effect and process evaluation questions
- Develop indicators and measures for assessment
- Specify the evaluation design
- Complete the evaluation plan

FIGURE 1 | Intervention Mapping steps and tasks (adapted from Bartholomew Eldrigde and colleagues) (10).

IM Step 1: Needs Assessment

Worldwide, cervical cancer is the third most common cancer among women (11). Persistent infection by the human papillomavirus (HPV) appears to be the major cause of cervical cancer (12). In the Netherlands, yearly 600 new cases of cervical cancer are detected, of which 200 with fatal consequences (13). This is despite the presence of a national cervical cancer screening program for women aged 30–60 years (14). HPV-vaccinations of 12-year-old girls were expected to reduce the number of cervical cancer cases by 50% (13). Therefore, in 2008, the Dutch government decided to include the HPV-vaccination of 12-year-old girls in the National Immunization Program (NIP). However, HPV-vaccine uptake remains lower (53%) than expected (70%) (15). There is a need to improve this uptake is order to reduce the cervical cancer burden. Therefore, the primary goal of the intervention was to improve HPV-vaccination uptake among invited girls.

Most studies have confirmed that parents play a large role in decision-making about their daughters' HPV-vaccination [e.g., (16–18)]. A Dutch study showed mothers to play the most important role in the immunization decision of girls. There is a high percentage of consensus between mothers and daughters (79%) about the outcome (19).Therefore, mothers were selected as the target group for designing an educational intervention for promoting the HPV-vaccination uptake by their daughters In order to gain insight into determinants of mothers' HPV vaccination acceptability, we conducted a longitudinal study (20). The results showed that intention was the main and stable predictor of HPV vaccination uptake. Intention, in turn, was best explained by attitude, behavioral beliefs, subjective norms, habit, and perceptions about the relative effectiveness of the vaccine, they explained 83% of the variance in HPV-vaccination intention. Also relevant for the mothers' intention were anticipated regret, risk perception, self-efficacy, and knowledge. Additional determinants of HPV-vaccination acceptability found by previous cross-sectional studies were confidence in authorities, ambivalence, and processing of HPV-vaccination education (19, 21).

Furthermore, research showed that a substantial proportion of the mothers had not actively processed information about the HPV-vaccination (50%) and still felt ambivalent after they made their decision (25%) (19). This indicates that the mothers' decision is based on rather unstable grounds, which makes them vulnerable for arguments challenging their initial attitudes and/or intention. Informed decision-making is expected to make mothers less vulnerable for counter arguments (22, 23). Furthermore, decisional conflict is strongly related to informed decision-making, as one of the factors contributing to decisional conflict is feeling uninformed (24). A more informed decision is thus theoretically related to reduced decisional conflict (25).

Hence, the secondary goal of the intervention is to improve informed decision-making, reduce decisional conflict, and positively influence determinants of HPV-vaccination uptake.

In the Netherlands, the existing education about the HPV-vaccination consists of an introduction folder and a link to a website providing generic information. All girls at the age of 12 receive an invitation for the HPV-vaccination with the accompanying brochure and link to the website. But, this education needs to be improved because HPV-vaccination uptake remains lower than expected (15). Besides, Van Keulen et al. (19) showed that mothers indicated a need for more interactive, personal information about the HPV-vaccination over and above the general information. Mothers also expressed differential needs concerning the amount and scope of information. Topics of interest for future communication about the HPV-vaccination as indicated by mothers were for example, the pros and cons, potential long-term side effects, and the safety and effectiveness of the HPV-vaccination (19). Regarding the delivery mode of the information, mothers indicated a preference for internet (19). These preferences guided our decision to develop a web-based intervention, enabling us to provide mothers with interactive, tailored information about the HPV-vaccination (see Step 3).

IM Step 2: Program Outcomes and Objectives

Program Outcomes

Based on the identified problem and needs we determined that the primary outcome was to improve HPV-vaccination uptake among invited girls and the secondary outcome was to strengthen mothers' informed decision-making, reduce decisional conflict, and positively influence determinants of the HPV-vaccination decision. Below, we introduce POs, determinants of these POs, and accompanying COs for each outcome.

Performance Objectives

The expected intervention outcomes were subdivided into POs. The HPV-vaccination consists of two subsequent injections. In other words, the behavior has to be repeated only once (with an interval of 6 months). The POs are: (1) the mother makes a (informed) decision to have her daughter vaccinated against HPV; (2) the mother discusses her decision with her daughter and partner; (3) the mother guides her daughter toward receiving the first HPV-injection; (4) the mother guides her daughter toward receiving the second HPV-injection.

Behavioral Determinants

For each PO, we identified the reasons why mothers would take that action. These so called behavioral determinants were based on theory (e.g., the theory of reasoned action and socio-cognitive theory) (25, 26) and on empirical research (19, 20, 27). We selected determinants that met the criteria of importance and changeability (10). Importance of the determinants of PO 1 (i.e., deciding to get the HPV-vaccination) was based on the association (i.e., R2 effect size) (28) of the determinants with HPV-vaccination intention (21). For the POs 2–4 (i.e., discussing the HPV-vaccination and actually getting the first and second injection), importance was based on consensus among co-authors (RR, TP, MP, and HvK). Changeability (i.e., the strength of the evidence that the proposed change can be realized by the intervention), was also based on consensus among co-authors (RR, TP, MP, and HvK).

For the first PO, we returned to the needs assessment and selected the following determinants: attitude, beliefs, positive, and negative outcome expectancies, anticipated regret about both receiving and rejecting the HPV-vaccination, confidence in authorities, habit strength, risk perception having received (no) HPV-vaccination, subjective, and descriptive norms, relative effectiveness of the HPV-vaccination, ambivalence, and HPV-vaccination information processing (19, 21). Furthermore, according to Marteau et al. (27), an informed decision is based on sufficient and relevant knowledge, and a match between the person's values (i.e., their attitude toward the HPV-vaccination) and outcome behavior (i.e., whether mothers had their daughter vaccinated against HPV or not). Consequently, knowledge was selected as a determinant. Determinants that were selected for PO2 were attitude (29), and self-efficacy (26). Selected determinants for PO3 and PO4 were knowledge and beliefs (26). Determinants that were not selected were considered either unimportant (e.g., for PO1: self-efficacy) (19, 21) or unchangeable (e.g., for PO2: parenting style).

Change Objectives

For each determinant, we identified COs. COs are the active ingredients of the intervention and function as a blueprint of the theoretical design rationale. **Table 1** provides an overview of examples of the matrix of COs, the complete version can be found in **Additional File 1**.

IM Step 3: Program Design

Theme, Components, Scope and Sequence

The first task of Step 3 is to generate ideas for intervention theme, components, scope, and sequence. The product of this step is an initial plan that describes the program (10). We decided the intervention to be Web-based (see Step 1). The main theme of the intervention was "making an informed decision about the HPV-vaccination of your daughter." The various components were logically clustered for improving usability. This resulted in four menu options: (1) two-sided information about the HPV-vaccination, (2) a decisional balance, (3) practical information, and (4) frequently asked questions (See **Additional File 3** for screenshots of the four menus). The first menu enabled mothers to collect tailored information about the HPV-vaccination (e.g., such as information about the effectiveness of the HPV-vaccination). The various components were in line with mothers' preferences as indicated by earlier research (See "needs assessment") (10). In the second menu, mothers could weigh their personal values regarding the HPV-vaccination in the form of a decisional balance and values clarification tool. In the third menu, mothers could gather practical information such as how and where to receive the HPV-vaccination. The fourth menu listed frequently asked questions about the HPV-vaccination. Here we also added a "problems with the website" component, providing mothers with help.

TABLE 1 | Examples of change objectives (COs).

Performance objective	Determinant			
	Knowledge	**Attitude**	**Beliefs**	**Risk perception having received no HPV-vaccination**
1. Mother makes the (informed) decision to have her daughter vaccinated against HPV.	Mother explains that HPV is a virus. Mother explains that HPV is transmitted sexually. Mother explains that men can also be infected with HPV.	Mother evaluates the HPV-vaccination positively. Mother recognizes the health benefits of the HPV-vaccination.	Mother recognizes the importance of her daughter receiving the HPV-vaccination before they become sexually active (i.e., age 12). Mother recognizes that the vaccine has proven to be safe and effective.	Mother acknowledges the risk of her daughter becoming infected with HPV and developing cervical cancer later in life without the vaccination.
2. Mother discusses her decision to have her daughter vaccinated against HPV with her daughter and partner.		Mother evaluates communication with her daughter and partner positively.		
3. Mother guides her daughter toward receiving the first HPV-injection.	Mother knows where to get the first HPV-injection.			
4. Mother guides her daughter toward receiving the second HPV-injection.	Mother knows where to get the second HPV-injection.		Mother recognizes that the HPV-vaccination is most effective when her daughter gets fully vaccinated.	

Furthermore, mothers were able to visit the intervention multiple times. The first time they visited the website, they were provided with an explanation of how the website worked. Then, they were introduced to the first menu. We used a combination of a freedom of choice and a tunneled design (i.e., a "hybrid design") to guide mothers through the website (30). This means that mothers could choose themselves which component in which menu they wanted to visit (i.e., freedom of choice design). However, once they entered a component, they were guided through it in "tunnel fashion," with navigation being limited to "next" and "prior" buttons. The reason for choosing such a hybrid design is that we wanted to profit from the strengths of both approaches (30). Specifically, the tunnel design was expected to increase intervention adherence and engagement and acquisition of knowledge (31). The freedom of choice design was expected to promote mothers' autonomy, which is important when motivating behavior change (32, 33). Furthermore, the hybrid design matched the differential needs concerning the amount and scope of information expressed by the mothers (19). **Table 2** provides an overview of the scope and sequence of the intervention.

Theoretical Methods and Practical Applications

To identify theoretical change methods that help achieve the COs, we used an overview of methods provided by Bartholomew et al. (chapter 6) (10). The eHealth setting gave us the chance to apply effective strategies in an innovative way, namely by using computer-tailoring and interactions with virtual assistants (see sections below) (34). Computer-tailoring was selected as the main theoretical framework for development. Tailoring is a health communication strategy by which messages are individualized to personal preferences and needs (35). Meta-analyses have shown that tailored interventions are more effective than generic interventions in achieving behavioral outcomes [e.g., (36, 37)]. Beneficial effects of tailoring are attributed to improved exposure, information processing, appreciation, reading, and perceived personal relevance [e.g., (38, 39)]. Because computer-tailored interventions can reach large groups of people at relatively low costs, especially when delivered via the Internet, (40), they can have substantial impact at the population level (41). Also, tailoring matches the mothers' need for more interactive, personal information about the HPV-vaccination (Step 1) (19).

Computer-tailored feedback was used in three different ways throughout the intervention. First, it was used to tailor the feedback on participants' answers to statements and questions about specific aspects of the HPV-vaccination. For instance, mothers were first asked to estimate their daughters' chance to get an HPV-infection. Those who perceived this chance as low, received feedback which stated that this chance is rather high instead of low, whereas those who perceived the chance as high, received feedback that confirmed that the chance is indeed high. Second, computer tailoring was used to provide mothers the opportunity to weigh their personal values regarding the HPV-vaccination in a decisional balance. Another mean was the "value clarification" tool [a motivational interviewing strategy; cf. (32)]. Mothers were invited to list their central values for life, and were stimulated to relate these to the decision about vaccinating her daughter. Finally, computer-tailoring was used for guiding mothers through the website. The intervention kept track of the components that the mother had already visited by using logs. This enabled us, for instance, to highlight parts of the intervention which the mother had not seen yet. Also, if mothers were exposed to information that had already been discussed in another component, the intervention mentioned

TABLE 2 | Scope (components and main targeted determinants) and sequence of the intervention.

Menu[a]	**Component**[b]**: main targeted determinants**
Information about the HPV-vaccination	General information: *knowledge*
	Facts and stories: *beliefs, positive and negative outcome expectancies*
	From HPV to cervical cancer: *knowledge*
	Ways to protect against cervical cancer: *relative effectiveness*
	Side effects of the HPV-vaccination: *negative outcome expectancies*
	Importance vaccinating at young age: *positive outcome expectancies*
	Other mothers: *descriptive norm*
	Working mechanisms vaccination: *knowledge*
	Chance of getting HPV/cervical cancer: *risk perception having received (no) HPV-vaccination*
	Effectiveness and safety of the HPV-vaccination: *beliefs, positive outcome expectancies*
Weighing up the pros and cons	Decisional Balance: *attitude, ambivalence*
	Values clarification: *attitude, ambivalence*
Practical information	Talking about the HPV-vaccination: *attitude, self-efficacy, subjective norms*
	Where do I get the HPV-vaccination: *knowledge, planning, self-efficacy*
	2 instead of 3 HPV-injections: *knowledge*
Frequently asked questions	Frequently asked questions about the HPV-vaccination: n/a
	Frequently asked questions about getting the HPV-vaccination: n/a
	Problems with the website: n/a

n/a, not applicable.

[a] *Within and across the different menus, a freedom of choice design was used.*

[b] *Within the various components, a tunnel design was used.*

this in order to assure that the connection between the different types of information provided was clear.

We selected virtual assistants for delivering tailored feedback. A virtual assistant is an embodied conversational agent defined as a computer program with a human-like visual make-up and appearance on a computer screen (42). Virtual assistants were chosen to match the mothers' preferences for more interactive personalized feedback (19). They provide opportunities for two-way interactions, and can create a highly personal experience. Also, research has indicated that a social relationship between user and program is important (43, 44), as it supports the basic psychological need for relatedness (33, 45). This can be established by using virtual assistants (46–48). Also, several studies confirmed that the presence of a virtual assistant can further improve the effectiveness of the intervention (49–51). Specifically, the added value of using a virtual assistant over a text and picture-based website is that it improves recall of information (52), transfer of learning (53), amount of learning (54), self-efficacy expectations, literacy, and behavior change (49, 50, 55). In addition, the mere presence of such an animated interface agent has a positive effect on experiencing fun and engagement [e.g., (47, 50, 56)]. Two virtual assistants were visualized: a mother-like and a female doctor-like assistant as the combination of using an expert and a peer virtual assistant has been shown to be effective (57, 58). The main purpose of the virtual assistants was to provide mothers with social support, which is an important factor associated with positive health outcomes in general (59). The mother-like assistant was used to guide mothers throughout the website and helped weigh their personal values in the decisional balance. The doctor-like assistant was used to deliver feedback about the HPV-vaccination.

Table 3 provides examples of theoretical methods (column 2) for determinants identified in IM step 2 (column 1) for PO1 (i.e., mother makes the informed decision to have her daughter vaccinated against HPV). For each method, parameters for effectiveness were specified (column 3). We then translated theoretical methods into practical applications (column 4) that were appropriate for the population and the (Internet) setting. In **Additional file 2**, we also specify which POs and COs were targeted using which methods and applications in the various components. This can be seen as the most straightforward blueprint of the intervention. All COs were covered by the intervention.

The most important method aiming to reduce decisional conflict was the decisional balance (see **Figure 2**), which has proved a quick and efficient intervention by itself (63). Mothers were presented with a list of pros and cons of the HPV-vaccination by the mother-like assistant (left column). This list was based on pros (e.g., "the HPV-vaccination decreases the chance of my daughter getting cervical cancer") and cons (e.g., "my daughter is too young to receive the HPV-vaccination") that were considered most important to the mothers as indicated by the needs assessment (Step 1). For each pro or con, they indicated (1) whether they agreed (disagree/neutral/agree; middle column) and (2) how important the pro or con was to them (unimportant/neutral/important; third column). The latter was indicated by stars: the more stars, the more important the pro or con was to the mother. When mothers (dis)agreed, tailored feedback "popped up." This was done to ensure mothers based their answer on correct information (see **Figure 2**). Furthermore, mothers were given the option to add pros and cons that were not in the list. Based on pros and cons mothers marked as most salient, a decisional balance (top right of the screen) revealed their current position on a scale ranging between not-wanting (left side) and wanting (right sight) to get their daughter vaccinated.

IM Step 4: Program Production

We developed the intervention using Tailorbuilder© software. The virtual assistants were developed by a company called "Webspeaking." Individual responses and routing were linked to written and spoken feedback messages by means of computer software using if-then algorithms. The website was made available on computers and tablets and was OS-platform independent. Using an online questionnaire, mothers ($N = 375$) were asked about the preferred graphical appearance of the intervention (including the name of the intervention, the

TABLE 3 | Examples of selected methods, strategies, parameters and strategies for Performance Objective 1 "mother makes the (informed) decision to have her daughter vaccinated against HPV."

Determinants	Theoretical method	Parameter for use	Practical application
Beliefs, positive and negative outcome expectancies	Belief selection (TRA[a]) Active learning (ELM[b])	Requires investigation of the current attitudinal, normative and efficacy beliefs of the individual before choosing the beliefs on which to intervene Requires time, information and skills	"Facts & Stories": mother is asked by the mother-like assistant to indicate for various statements, whether they are either a "fact" (true) or a "story" (false).Then, the doctor-like virtual assistant elaborates on correct outcome expectancies, beliefs, misperceptions and omissions.
Attitude, ambivalence	Decisional Balance (MI[c])	Requires consideration and evaluation of behavior	"Weigh up the pros against the cons": Mothers are presented with a list of pros and cons of the HPV-vaccination by the mother-like assistant. Based on pros and cons mothers marked as most salient, a decisional balance reveals their current position on a scale ranging between wanting and not-wanting to get my daughter vaccinated.
Attitude, ambivalence	Value Clarification (MI[c]) Modeling (SCT[d])	Requires consideration and evaluation of values Attention, resemblance, self-efficacy and skills, reinforcement of the model, identification with the model, coping model instead of mastery model.	"What are your values?": Mothers are invited to list their central values for life. Optional, they can find examples of values of other mothers (e.g., being a good parent). They will then be stimulated to relate these to the HPV-vaccination. Here, examples of how these values were related to the HPV-vaccination according to other mothers, were available.
Risk perception having received (no) HPV-vaccination	Statistical risk information (HBM[e]) Consciousness raising (HBM[e]) Framing (PMT[f])	Can use feedback and confrontation; however, raising awareness must be quickly followed by increase in problem-solving ability and self-efficacy. Requires high self-efficacy expectations. Gain frames are more readily accepted and prevent defensive reactions	Mother-like assistant asks about mothers' perceived risk perception of her daughter getting infected with HPV and of her daughter developing cervical cancer. Tailored feedback on this perceived risk is then given by the doctor-like assistant. Finally, mothers are provided with statistical risk information (i.e., the probability rates of attracting HPV and cervical cancer).

[a] *TRA, theory of reasoned action (29).*
[b] *ELM, elaboration likelihood model (60).*
[c] *MI, motivational interviewing (32).*
[d] *SCT, social cognitive theory (26).*
[e] *HBM, health belief model (61).*
[f] *PMT, protection motivation theory (62).*

voices and appearances of the virtual assistants). A text-editor rephrased the written and spoken texts in order to maximize comprehensibility. A graphic designer made the website design and provided us with appropriate pictures to illustrate feedback, in order to make the website more appealing for this target group (See **Figure 3** for an example).

Experimental Pre-testing and Pilot-Testing of Prototypes

In order to anticipate an intervention that meets the requirements and preferences of the target group, we followed user-centered design procedures. This entails the iterative involvement of the end-users in the design process (64). We gathered feedback on different versions (static and interactive) or (parts of the) intervention, by online experimental pretests and focus groups, respectively. Experimental pretesting offers empirical support for the impact of strategies on determinants and serves as a guarantee for implementing adequate intervention materials (65, 66). We conducted three experimental online pretests. Since we did not find a clear consensus in the literature about the framing of risks, the first experiment ($N = 375$) was about testing the differential effect of providing statistical (i.e., probability rates) or/and narrative risk information (i.e., a personal story). Mothers were randomly assigned to one of four conditions in a 2 (statistical information: yes or no) × 2 (narrative information: yes or no) between-subjects factorial design. ANOVA revealed a significant main effect of statistical information on daughters' perceived susceptibility toward HPV [$F_{(1,\ 371)} = 7.56$, $p < 0.01$]. Mothers who received statistical risk information had a higher perceived daughters' susceptibility toward HPV ($M = 4.11$ on a 7-point scale, $SD = 0.10$) than mothers who did not receive statistical risk information ($M = 3.73$ on a 7-point scale, $SD = 0.09$). Thus, statistical risk information seemed most effective. We therefore decided to include statistical risk information to target risk perception with this intervention (Step 3).

In a second online experimental pretest ($N = 561$), we explored the best way to communicate about social norms; by providing negatively (i.e., discourage undesired behavior) vs. positively (i.e., encourage desired behavior) framed descriptive and/or subjective norms (67). It was suggested that the descriptive norm should be avoided in situations where the unhealthy behavior is prevalent (68). As for the HPV-vaccination, 39% of invited girls have *not* received the HPV-vaccination (15). Therefore, we also wanted to examine whether communicating a descriptive norm could have a potential adverse effect on

KEUZEHULP INENTEN TEGEN
BAARMOEDERHALSKANKER

Stelling	Uw antwoorden			Hoe belangrijk is dit voor u?
Mijn dochter is te jong om ingeënt te worden tegen HPV.	**Eens**	Neutraal	Oneens	★★★
Als mijn dochter zich laat inenten tegen HPV, dan zal zij in de toekomst onveilig vrijen.				
Als de overheid meisjes laat inenten tegen HPV dan ga ik er vanuit dat de inenting veilig is voor mijn dochter.				
Mijn dochter is nog niet seksueel actief, dus hoeft ze van mij de HPV-inenting niet te krijgen.	Eens	Neutraal	**Oneens**	★☆☆
Mijn dochter is al een tijd lang seksueel actief is, dus heeft het geen zin meer om haar te laten inenten tegen HPV.	Eens	**Neutraal**	Oneens	☆☆☆
De HPV-inenting verkleint de kans dat mijn dochter later baarmoederhalskanker krijgt.	**Eens**	Neutraal	Oneens	★★★
De meeste moeders in mijn omgeving laten hun dochter ook inenten tegen HPV.	Eens	**Neutraal**	Oneens	★☆☆
Mijn dochter wil zich niet laten inenten.	**Eens**	Neutraal	Oneens	☆☆☆
De persoon die meebeslist wil niet dat	Eens	Neutraal	**Oneens**	★★☆

12 jaar lijkt inderdaad jong. Uit onderzoek is gebleken dat de inenting het beste werkt nog vóórdat uw dochter met het virus in aanraking komt. Dus ruim voordat zij seksueel actief wordt.

FIGURE 2 | Screenshot of the decisional balance with a tailored pop-up and the mother-like virtual assistant on the website. *The plan for the decisional balance was developed in step 3; actual development of the balance was realized in step 4.

HPV-vaccination acceptability. Mothers were randomized into one of four conditions in a 2 (norm: injunctive vs. descriptive) × 2 (frame: positive vs. negative) between subjects factorial design with an additional control condition. We found no indication for using one type of framing norms over the other (p's > 0.05; mean HPV-vaccination intention scores ranging from 5.51 to 5.77, on a 7-point scale). We also did not find any adverse effects of descriptive norms on HPV-vaccination acceptability ($p > 0.05$). As negatively framed norms were expected to be more difficult to process (69), we decided to just include positively framed descriptive norm by communicating about the national HPV-vaccination uptake rate. Within the component "talking about the HPV-vaccination," mothers were taught how to deal with a potential contrasting subjective norm of important others (e.g., their daughter and partner).

Finally, being a relatively new vaccine, there remains uncertainty about potential long-term effects of the HPV-vaccination. This was also found to be a topic of interest among mothers for future communication (19). Therefore, in a third experimental pretest ($N = 695$), we investigated the effects of acknowledging vs. ignoring uncertainty about potential long-term effects of the HPV-vaccination. Mothers were randomly assigned to one of two conditions in which uncertainty about the HPV-vaccination was either (a) acknowledged or (b) ignored. Results showed that, compared to mothers who were exposed to information ignoring uncertainty, mothers who were exposed to information acknowledging uncertainty experienced more decisional conflict (acknowledged: $M = 3.42$, $SD = 1.84$, $p < 0.01$ vs. ignored: $M = 3.05$, $SD = 1.74$), were more ambivalent about their decision (acknowledged: $M = 4.04$, $SD = 1.86$ vs. ignored: $M = 3.42$, $SD = 1.89$, $p < 0.001$), and had a less positive attitude (acknowledged: $M = 5.07$, $SD = 1.50$ vs. ignored: $M = 5.69$, $SD = 1.38$, $p < 0.01$) and intention (acknowledged: $M = 5.26$, $SD = 1.73$ vs. ignored: $M = 5.85$, $SD = 1.45$, $p < 0.01$). These findings implicate *not* to communicate about long-term uncertainties. However, we chose to do so in the intervention, for the following reasons: first, the found effect sizes were small. Second, not communicating about long term uncertainties

Gezond leven beschermt niet tegen baarmoederhalskanker

Er is niet wetenschappelijk aangetoond dat gezond leven beschermt tegen baarmoederhalskanker.

Ook mensen met een gezonde leefstijl kunnen besmet worden met HPV en baarmoederhalskanker krijgen. Soms krijgt iemand met een gezonde leefstijl wel baarmoederhalskanker, terwijl iemand met een ongezonde leefstijl geen baarmoederhalskanker krijgt.

Het is wel zo dat mensen met een verzwakt immuunsysteem meer risico lopen om baarmoederhalskanker te krijgen van HPV. Zo lopen vrouwen van wie het immuunsysteem is verzwakt door HIV/AIDS meer risico. Ook kan roken het immuunsysteem minder goed laten werken. Dan is het voor het lichaam moeilijker om het HPV-virus op te ruimen.

FIGURE 3 | Screenshot of the doctor-like assistant providing feedback about the ineffectiveness of having a healthy life style (e.g., healthy eating, exercising) in protecting against cervical cancer with illustrations provided by a graphic designer.

brings along the risk of mothers searching information about this elsewhere. This can be quite dangerous as many rumors about potential long-term effects, for which no prove exists, can be found (e.g., on the Internet) (70). Reading these (false) rumors without any refutation being offered aside (71), could have more detrimental effects on HPV-vaccination acceptability than when we ourselves provide the (correct) information. The latter enables us to inoculate mothers with arguments that become accessible in case they are confronted with (new) information that might challenge their initial positive intentions (i.e., psychological inoculation) (22, 23). Finally, mothers themselves expressed a need for full disclosure, especially when uncertainties were ignored, which was also found in a previous study (19).

At a later stage, we conducted several focus groups ($N = 3$) among mothers to test interactive prototypes of the intervention to ensure compatibility with the preferences of the target group. A first prototype of the intervention was tested in two focus groups. After we revised the prototype according to the feedback from these two focus groups, a second prototype of the intervention was tested in a third focus group. The protocol was similar for all focus groups: after a general introduction, mothers were given a laptop and headset to individually navigate through the website. They were given the opportunity to give feedback on every page of the website about features they (dis)liked (e.g., the "look and feel" of the page(s), and the tailored feedback of the virtual assistants). Then, they were asked to fill out a written questionnaire assessing their subjective evaluation of the virtual assistants (e.g., the extent to which feedback matched their responses) and the website (e.g., their evaluation of the different menus). Finally, in a group discussion mothers could elaborate on their opinion about the intervention, and offer suggestions for improvement.

Feedback was first gathered from the first two focus groups. For instance, in the first prototype, there was a component targeting anticipated regret by using imagery (72, 73). Mothers were asked how much regret they would have if they did not vaccinate their daughter against HPV and their daughter developed cervical cancer later in life. However, we discovered that asking this evoked much resistance. We therefore decided to remove this component from the intervention. As an alternative, we decided to target anticipated regret indirectly (e.g., by giving information about the high prevalence of HPV). Furthermore, in the first prototype, the written and spoken tailored feedback were provided at the same time. Mothers indicated that, therefore, they experienced difficulties listening to the virtual assistant. Hence, we created a new prototype, in which the written feedback appeared once the virtual assistant was done providing the tailored feedback.

In the third focus group, mothers indicated that they would like to see which components they had already visited. We therefore created an adapted version of the website in which logs were used to register the pages mothers had already visited and subsequently used these logs to visualize which components were completed. This was done by turning them into a different color (i.e., orange, see **Figure 4**) In addition, the mother-like virtual assistant was used to give advice about components to visit next, in order to maximize exposure to the intervention. If the virtual assistant advised on a component, the component was highlighted by an orange circle (see **Figure 4**).

After revising the intervention according to the feedback from the third focus group, a final prototype was pilot-tested online using various devices to ensure it worked adequately. This was done among a sample of mothers ($N = 10$) and among members of the project group.

IM Step 5: Designing an Implementation Plan

To ensure future implementation and adoption of the intervention (step 5), we formed an advisory board of representatives of important linking agents (e.g., Public Health Services) and professionals involved in delivering the HPV-vaccination. We organized two advisory board meetings; they advised on the experimental pretesting, practicability, and feasibility of the intervention, the planned effect- and process evaluation, and implementation of the intervention within the NIP. The National Institute for Public Health and the Environment (RIVM), responsible for the national implementation of HPV-vaccination, was co-financier of the project and full member of the project team. RIVM would get full control and management over the website if the final intervention turned out to be effective.

IM Step 6: Creating an Evaluation Plan

In order to evaluate the efficacy and effectiveness of the intervention, we planned a randomized controlled trial (RCT). The RCT consisted of 2 arms: (1) a control and (2) intervention group. Mothers were randomly recruited from Praeventis, the Dutch National Immunization Register, and three Internet panels. The latter was to guarantee a suitable subsample for the planned efficacy trial (21The Praeventis sample enabled us to anticipate the naturalistic condition for future implementation of the intervention, which provided the opportunity for testing the intervention's effectiveness. The primary outcome measure was HPV-vaccination uptake, as registered by Praeventis Secondary measures were informed decision-making, decisional conflict, and determinants of HPV-vaccination acceptability. These were measured using a Web-based questionnaire.

Part of the RCT was a process evaluation assessed program adherence and the users' subjective program evaluation. At follow up, participants evaluated the information provided by the website (e.g., relevance, credibility), perceived user control (e.g., experienced degree of autonomy) and the functioning of the virtual assistants (e.g., fun, reliability). Mothers were also asked to rate the website and the virtual assistants on a 10-point scale, ranging from 0 (very bad) to 10 (excellent). Objective program use was evaluated by the logs keeping track of the pages the mothers' has visited. Two indicators were computed: "completeness" and "time." Completeness represents the total percentage of pages that a participant has visited while logged into the website, ranging from 0% (no exposure) to 100% (exposure to all pages). Time represents the total amount of time participants have spent logged into the intervention.

Results from the RCT are described in detail elsewhere (74). The main finding from the effect evaluation was that the intervention showed a significant positive effect on informed decision-making, decisional conflict, and nearly all determinants of HPV-vaccination uptake ($P < 0.001$). No differences in intervention effects were found between the two differential samples. The main finding from the process evaluation was that mothers evaluated the intervention as highly positive: mothers evaluated the website with a 7.6 (SD = 1.36) and the virtual assistants with a 7.4 (SD = 1.53). According to the computer logs, 2,509 (63%) of the 3,995 (100%) invited mothers logged on to the website. On average, mothers spent 22 minutes on the website (SD = 13 min).

DISCUSSION

In this article, we have provided a comprehensive and detailed description of how we systematically developed an intervention promoting HPV-vaccination acceptability using the IM protocol. This led to a highly innovative, interactive, Web-based, tailored intervention, in which tailored feedback was delivered by virtual assistants. Tailoring has only recently been applied to HPV-vaccination (57, 75–77). To our knowledge, only one of the existing tailored interventions was computer-tailored and this intervention turned out to be ineffective in promoting HPV-vaccination acceptance (75). Moreover, not only did we tailor the content of the intervention to the mothers' personal interest, but tailoring was also used to guide the mothers' personal pathway through the intervention. The latter is likely to have improved the usability of the intervention. The intervention accounted for tailoring on a variety of determinants. For example, not only did we tailor on perceived barriers (e.g., beliefs about adverse effects), like Gerend et al. (76) did, but also on other beliefs (e.g., beliefs about the daughters' sexual behavior and age in relation to the need for the HPV-vaccination), attitude, subjective norms, habit, relative effectiveness, anticipated regret, risk perception, self-efficacy, and knowledge. The use of virtual assistants in interventions promoting HPV-vaccination acceptance seems promising since results from the focus groups (Step 4) and the subjective program evaluation (74) showed that mothers appreciated them very well. But, we still consider the use of virtual

FIGURE 4 | Screenshot of the first menu with the mother-like assistant in which a suggested component is highlighted and visited components have turned into a different color.

assistants to be complex, especially in Web-based interventions in which both spoken and written feedback/information are provided.

The intervention appeared effective in promoting HPV-vaccination acceptability and informed decision-making, and appeared to have potential for broad scale dissemination and implementation (74). This intervention blueprint will aid in interpreting the results of our evaluation studies (74). In addition, it provides insight into causal mechanisms, which contributes to theory development (3, 4, 7–9). Moreover, it will ease the comparison of design rationales across interventions (e.g., for reviews and replication of studies) (5–7). Finally, it provides leads for the development of other eHealth interventions (1, 4).

Advantages of IM

We believe that using IM greatly contributed to the intervention being effective in promoting HPV-vaccination acceptability and informed decision-making among mothers of invited girls. First, by developing the intervention in a systematic manner, we ensured a solid theoretical and empirical foundation for the intervention [cf. (10)]. For decisions to be made about methods/applications that lack a solid ground of consensus in the research literature, we were able to pre-test the impact of alternative prototypes before finalizing and testing the full operational intervention.

Furthermore, according to IM, it is imperative that members of the target group are involved in the development of the intervention (10). However, currently, in many eHealth interventions, the design of the intervention is based on assumptions that are not validated with input from end-users. In fact, the importance of formative research and pretesting of materials is often being overlooked. The resulting intervention may therefore lack key features, and subsequent evaluations of the effectiveness of the interventions may be compromised (78). Therefore, we applied a user-centered design by extensively involving mothers in the intervention development from the beginning to the end (64). This was done by conducting focus groups and online experimental pretests, in which we gathered feedback from representatives of the target group. This iterative process of development and feedback guided our attempt to gradually improve the solution we had to offer for reaching the intended objectives. In other words, erroneous or inconclusive decisions can thoughtfully be changed or reversed in order to prevent the final intervention from being at odds with the objectives set beforehand. An example illustrating this is our decision to remove a component targeting anticipated regret from the intervention as it clearly evoked resistance as shown by the focus groups. Based on the feedback from the focus groups (Step 4), we changed the method targeting anticipated regret (Step 3), and pretested the intervention again (Step 4). Thus, we moved back and forth between the steps. Furthermore, not only did we fine-tune the content of the intervention to the mothers' preferences, but also the design of the website was chosen by the mothers. Hence, we adapted the entire intervention to the requirements and preferences of the mothers.

Next to maximizing the likelihood of success, using IM has made the process of intervention development explicit and transparent, providing a road map of the decision-making process and its main outcomes. This will suit the interpretation of strengths and weaknesses of the intervention when looking at the results from the outcome evaluation (Step 6) (74). It also enables the owner to improve the intervention where necessary and others to replicate the steps described when developing a similar intervention for different populations and/or settings (79).

Design Rationales in eHealth

Recently, it has been argued that eHealth researchers should publish descriptions of interventions and results from evaluation studies separately in order to gain a better understanding of what exactly is being evaluated, facilitate comparison between interventions, and extend the evidence base for the development of future interventions (80, 81). The current paper complies to this call and adds to the plea for systematic and detailed descriptions of design rationales in the eHealth field. Systematic descriptions may improve the quality of future systematic reviews that assess the link between design features and outcomes of an intervention (6, 82, 83). These reviews, in turn, can be used as a guide for eHealth researchers in designing future interventions with improved efficacy, reach, and user acceptability (81).

Limitations

Although we believe that using IM has greatly contributed to the intervention being effective in promoting HPV-vaccination acceptability, we agree with other authors that IM is a complex and time-consuming process (84–86). However, we are convinced that the development of the intervention was brought to a higher level by IM. Moreover, we believe that the experience we gained may improve efficacy of the process and make it less time-consuming in future intervention development. We can profit from this experience when developing similar interventions for a different population (e.g., an intervention promoting HPV-vaccination among Dutch boys).

Conclusion

In this article, we provide a detailed, comprehensive description of how we systematically developed an intervention promoting HPV-vaccination acceptability. Using IM led to an innovative and effective intervention using interactive Web-based computer-tailored education. This intervention blueprint will aid in interpreting the results of our evaluation studies. Moreover, it will ease comparisons of design rationales across interventions, and may provide leads for the development of other eHealth interventions. Overall, this paper adds to the plea for systematic reporting of design rationales constituting the process of developing interventions, and the development of a cumulative science of interventions in the eHealth field.

ETHICS STATEMENT

The study was approved by the Medical Ethical Committee (METC), the ethical committee of the VU Medical Center in Amsterdam. Informed consent was provided online for the online studies (i.e., the three experimental pretests, the online focus group and the RCT). For the focus groups, participants provided written consent.

AUTHOR CONTRIBUTIONS

MP contributed to study conception and design, acquisition of data, analysis, and interpretation of data, and drafting of manuscript. HvK, TP, and RR contributed to study conception and design, interpretation of data and revising the manuscript critically. AH and HdM contributed to study conception and design and revising the manuscript critically. HvV critically revised the manuscript. All authors approved the final version of the manuscript to be published.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2018.00226/full#supplementary-material

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Development of an Implementation Intervention Using Intervention Mapping to Increase Mammography Among Low Income Women

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Background: Although much work has begun to elucidate contextual factors influencing implementation, the specific processes that facilitate and hinder adoption, implementation, and maintenance of evidence-based interventions (EBIs) in clinical settings remains poorly understood. Intervention Mapping (IM) is a systematic process that facilitates planning and design for dissemination, implementation and maintenance of EBIs in practice. IM has been used to guide the design of many health interventions, focusing on program implementation. Less studied is its use to adapt and scale screening interventions within the healthcare clinic setting. This paper describes the development of an implementation intervention using IM to facilitate the adoption, implementation, and maintenance of an EBI designed to increase mammography adherence in healthcare clinics, the adapted Peace of Mind Program (PMP).

Methods: IM framework, Step 5, was used to guide the implementation intervention planning. IM guided identification of specific adoption, implementation, and maintenance performance objectives. We formed an implementation intervention planning group consisting of members of the academic team, our community partner and community health workers (CHWs) with substantial experience working on mammography screening programs in federally qualified health centers (FQHCs) and charity clinics.

Results: Results are presented by Intervention Mapping task for Step 5 (Program Implementation Plan). We describe how the consolidated framework for implementation research (CFIR) informed the selection of performance objectives, determinants, methods, and practical applications in the final implementation intervention.

Conclusions: This paper provides an example of the use of Intervention Mapping Step 5 and CFIR to create an implementation intervention to support EBI scale up of an evidence-based mammography intervention within a specific setting.

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Keywords: intervention mapping, implementation intervention, consolidated framework for implementation research, mammography, underserved women

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BACKGROUND

The research to practice gap is well-documented; only a fraction of evidence-based interventions (EBI) are integrated into practice settings and fewer still are sustained in practice over time (1–5). Although much work has begun to elucidate contextual factors influencing implementation, the specific processes that facilitate and hinder adoption, implementation, and maintenance of EBIs in clinical settings remains poorly understood (6, 7). Further, practitioners' knowledge and expertise is rarely effectively integrated into program design and testing, resulting in programs that may not fit well within the implementation context, or match the needs of the communities they were intended to benefit (4, 8–11). The development of effective implementation strategies should include participatory approaches and be guided by theory. Theory driven D&I interventions that consider individual and systems-level change, can improve the likelihood of adoption, implementation and maintenance of EBIs (12) and support policy and practice changes that improve health outcomes over time. However, few programs to date have used theory to inform their approaches. Davies et al. reviewed 235 D&I studies and found that only 23% used theory to inform the design of their strategies (13). Further, these D&I strategies rarely use multi-level approaches to increase EBI use (14).

There are both few programs available that target mammography adherence in underserved populations specifically and even fewer that use well-defined adoption, implementation and sustainment interventions for mammography EBIs in the U.S. (15). Underserved populations (women who lack insurance or who are underinsured and low-income) have increased risk for late-stage breast cancer diagnosis due to a combination of factors, including lower mammography screening rates overall, high rates of missed screening appointments and lack of timely referral to diagnostic evaluation and treatment in those who screen abnormal (12). Considering the second factor (missing appointments), it has been shown that women who missed screening appointments were more likely to be diagnosed at a later stage of cancer than women who attended their appointments outside of the other two factors (16). This highlights the need for EBIs that improve mammography appointment attendance in underserved women since these women have already addressed the first step of engaging with the healthcare system and scheduling a screening appointment. Gaps in understanding of how best to translate lessons learned from research for integration of EBI's into everyday use–taking into account the local setting and needs of the multiple stakeholders has left many effective mammography programs unused or applied with limited fidelity (17).

Well-designed dissemination and implementation (D&I) strategies are particularly important for the execution of multi-level interventions, which are typically used within complex practice systems such as health care settings to address differences in health outcomes (18). Intervention Mapping (IM) is a systematic process that facilitates planning and design for dissemination, implementation and maintenance of EBIs (19–22) in practice. Intervention mapping has been used to guide the design of many health interventions including a focus on program implementation (12). Less studied is its use to adapt and scale screening interventions within the healthcare clinic setting. This paper describes the development of an implementation intervention using Intervention Mapping to facilitate the adoption, implementation, and maintenance of an EBI designed to increase mammography adherence in healthcare clinics, the adapted Peace of Mind Program (PMP).

METHODS

PMP is a telephone-based EBI to increase mammography appointment adherence (attendance) in underserved women who have scheduled mammography screening appointments. PMP uses a scripted, tailored telephone counseling reminder call which was developed using the Transtheoretical Model of Change to counsel patients through barriers to appointment attendance, such as fear of screening or fear of outcome (4, 12, 23, 24). In addition, PMP engages the patient in active planning for their appointment, such as ensuring the correct paperwork has been completed and that required documents will be brought with the patient (e.g., proof of income) (4, 12, 23, 24). The PMP was designed for use in federally qualified health centers (FQHCs) and charity clinics providing access to mobile mammography services (4, 12, 23, 24). PMP had been previously adapted for underserved women and evaluated using IM [Int Map Adapt and found to effectively reduce appointment no-show rates from 44% (comparison) to 19% in the intervention arm (23, 24). The adjusted odds of a woman in the intervention group attending her appointment were 3.88. The adjusted odds of a woman attending her appointment in the intent-to-treat analysis were 2.31 (23, 24)]. However, previous implementations of PMP lacked a mechanism for taking the program to scale across multiple sites. Our previous studies had focused on development and evaluation of program components, but had not focused on structures necessary to take the program to scale. For this project, our aim was to develop an implementation intervention to support the implementation and scale-up of the EBI in 20 FHQCs and charity clinics in the Greater Houston region, Texas (24). The Intervention Mapping framework, Step 5 was used to guide the implementation intervention planning. Intervention mapping guided identification of specific adoption, implementation, and maintenance performance objectives (who had to do what to implement the intervention). It helps the planning group identify determinants of implementation; *why* clinics (decision makers and staff) or clients would adopt, implement, and maintain the PMP (19).

IM allows for integration of theories and frameworks to inform the implementation intervention. In our project we used CFIR to inform the planning process. The CFIR is a meta-framework which includes five domains [intervention characteristics, outer setting, inner setting, characteristics of individuals and process; (6, 25)]. Within these five domains are 39 underlying constructs that may influence implementation and development of clinical guidelines (6). CFIR was used to identify potential contextual factors that may influence the implementation and sustainability of the PMP as shown in **Figure 1**. Other theories that informed both the selection of determinants of implementations as well as methods for effecting change included Social Cognitive Theory, and Diffusion of Innovation (26, 27).

We formed an implementation intervention planning group to guide the process. The group consisted of members of the academic team, our community partner—the Breast Health Collaborative of Texas leadership and community health workers (CHWs) with substantial experience working on mammography screening programs in FQHCs and charity clinics in the Greater Houston area. Based on previous studies conducted by the team, the experience of planning team members in the community setting, and a review of the literature, we pre-determined that FQHCs and charity clinics were the primary stakeholders for adoption, implementation and maintenance. This project received approval from the Institutional Review Board at the academic institution, protocol number HSC-SPH-14-0269. Per Institutional Review Board review, written informed consent was not required. Women who later participated in the trial and received reminder phone calls gave verbal consent at the outset of the phone call.

RESULTS OF THE APPLICATION OF IM STEP 5 FOR PMP DEVELOPMENT

Results will be presented by Intervention Mapping task for Step 5 (Program Implementation Plan). We describe how CFIR informed the selection of performance objectives, determinants, methods, and practical applications included in the final implementation intervention.

Task 1. Identify Program Adopters, Implementers and Maintainers

We first identified what stakeholders would be involved in the adoption, implementation and maintenance of the PMP. We then held a brainstorming session with the planning group to answer key questions that would inform the development of the implementation intervention such as: (1) *Who will make the decision to adopt the PMP program in FQHCs or community clinics and who will these decision-makers need to consult?* (2) *Who will implement the program? Will the PMP program require different people to implement different components?* and (3) *Who will ensure that the PMP program is maintained as long as it is needed?* Following the brainstorming sessions, we completed detailed summaries to inform the following tasks and verified our implementers with clinic staff knowledge of FQHC and

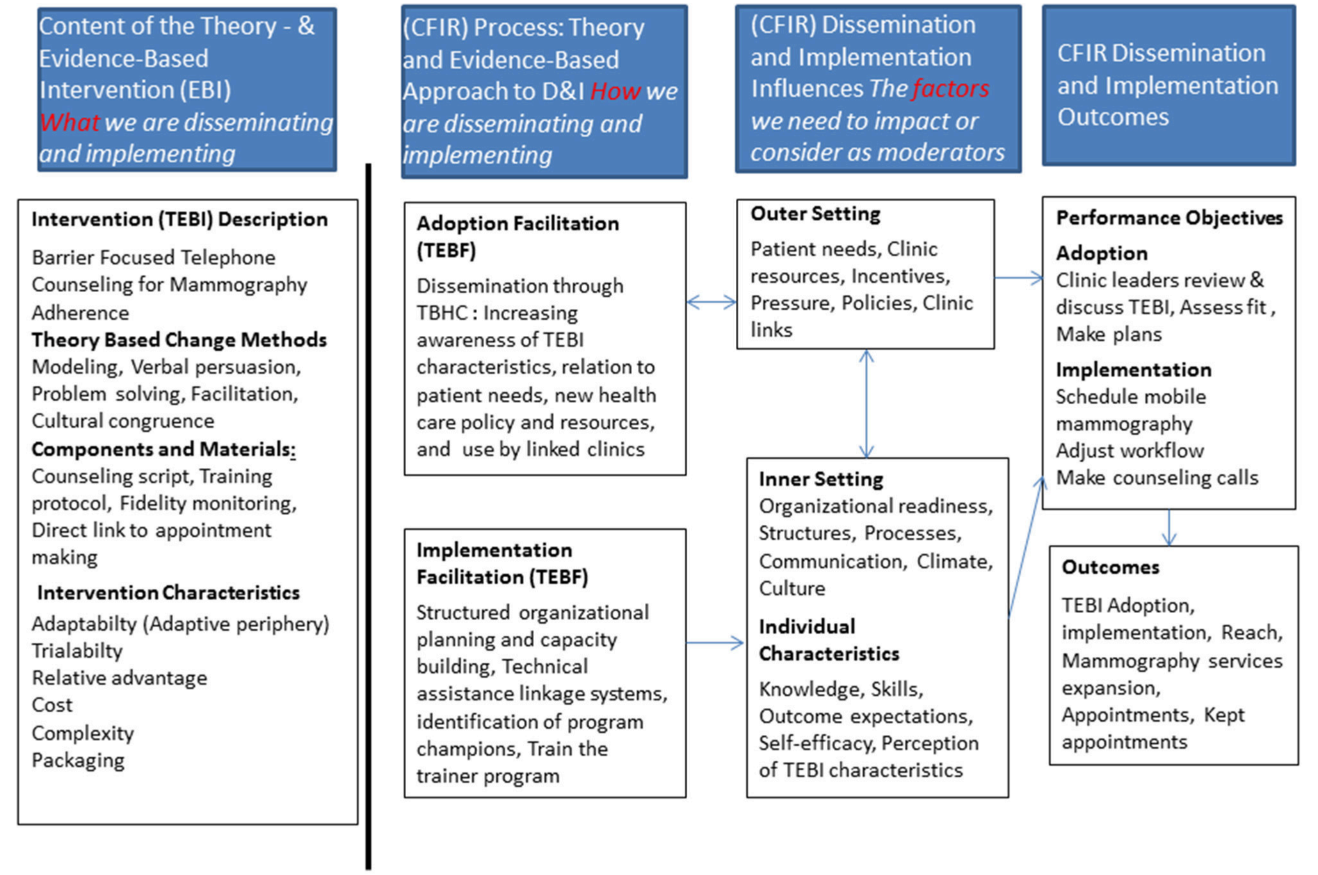

FIGURE 1 | Conceptual framework for development of PMP.

TABLE 1 | Adoption performance objectives and determinants.

Performance objectives	Attitudes about PMP (informed by CFIR domains: intervention characteristics and inner setting)	Knowledge (informed by CFIR domain: personal characteristics)	Outcome expectations	Self-efficacy	Normative beliefs (subjective and descriptive)
Clinic Decision Makers PO1. Agree to participate in the PMP	A.1.a. Perceive that the PMP is easy to adopt and implement A.1.b.Describe PMP as an improvement over what is done now A.1.c. Describe PMP as if the partners (UTSPH and BHC) are here to help A.1.d.Describe PMP as fitting with organizational goals and needs A.1.e. Believe that breast health needs of their patients and community are important. A.1.f. Describe PMP as effective and evidence-based	K. 1.a. Describe the components of the PMP program. K.1.b. Describe the rates of mammography in clinic including no show rates as a problem that needs to be addressed.	OE.1. Expect that the PMP intervention development partners will provide help with program implementation and resources OS.3. Expect this program will provide effective/improved outreach	SE.1.a. Expresses confidence in the ability to do what is expected by the PMP (increase screening capacity, implementation of the PMP, provide a program provide a program champion, assess and expand clinic resources) SE.1.b. Perceive that the clinic is capable of change SE.1.c. Describes the clinic as ready and able for change (perception of organizational readiness)	NB.1. Express belief that other clinics like theirs are agreeing to implement PMP
PO2. Agree to expand mammography services	A.2. Believes that expanding access to mammography service is important for meeting the needs of clients.	K.2.a. Describe the unmet need among clinic patients related to mammography Describe potential availability of staff to expand mammography services available. K.2.b. Describes the steps needed to expand the mammography services.	OE.2. Expect that increased and enhanced mammography services will decrease mortality from breast cancer	SE.2.a. Express confidence in ability to work with partners to increase screening capacity. SE.2.b. Express confidence in ability for clinic to arrange work flow to	NB.2.a. Express belief that other clinics are agreeing to expand mammography services NB.2.b. Express belief that leaders and other decision makers will encourage expansion. NB.2.c.Believes that other centers support new or expanded partnerships with mobile mammography providers NB.2.d.Express belief that providing financial assistance to underserved patients offered through PMP is normative
PO3. Agree to participate in evaluation	Express belief that the evaluation activities are an important element of the PMP program.	K.3.a. Describe the expected outcomes of the program. K.3.b. Describes the Describes the procedures for participating in the evaluation.	OE.3a. Expect that evaluation results will add value to clinic reporting OE.3.b.Expect that evaluation results will add value and status as compared to other clinics OS.3. Believe evaluation results will help clinic support program and garner future funding	SSI.SE.3a. Express confidence in ability to create records needed for evaluation SSI.IS.3b. Believe clinic is a learning environment	NB.3.Express belief that other clinics using PMP will participate in the evaluation.

(Continued)

TABLE 1 | Continued

Performance objectives	Attitudes about PMP (informed by CFIR domains: intervention characteristics and inner setting)	Knowledge (informed by CFIR domain: personal characteristics)	Outcome expectations	Self-efficacy	Normative beliefs (subjective and descriptive)
PO4. Provide a program champion for the PMP	AP.4.Believe that the program champion is an important element of the program.	K.4.a. Explains the role of program champion in PMP.	OE.4. Expect that a program champion will enable the PMP to be implemented and maintained	SSI.SE.4.Express confidence in the ability to recruit a program champion	NB.4. Lists other clinics like theirs that use champions to assist in practice change or program implementation.
PO5. Gain support from stakeholders reaction to the program (care providers, decision makers, navigators/schedulers, patients) (Informed by CFIR Outer setting domains constructs, e.g., patient needs and resources)	A.5.a. Expresses belief that gaining support from stakeholders is an important step in the success of the program. A.5.b. Describes importance of feedback from stakeholders in making revisions and refinements for practice	K.5.za. Describes key points to discuss with stakeholders regarding the PMP program.	OE.5.a. Expect that gaining support from stakeholders such as care providers, patients and managers will ensure the successful adoption and implementation of the program. OE.5.b. Expects that stakeholders who are consulted will develop feelings of acceptance and ownership of the program	SSI.SE.5 Express confidence in their ability to engage stakeholders and engender buy-in	

charity clinic structures. Based on our brainstorming sessions, the planning team determined that the clinic leader would be the adoption decision maker in our participating locations. Clinic leaders typically hold roles such as Executive Director or Chief Executive Officer and are decision makers. In order to adopt the program, the clinic leader would need to meet with the PMP team, review and sign an MOU and assign staff to participate in the program. Adoption performance objectives and determinants are summarized in **Table 1**.

Task 2. State Outcomes and Performance Objectives for Each Stage (Adoption, Implementation and Maintenance)

For this task, the planning group sought to identify who needed to do what in order to adopt/implement/maintain the program. The planning group met and brainstormed answers to key questions such as: "*What do FQHCs and charity clinics have to do in order to adopt PMP?*" "*What stakeholders does the planning group need to consult in order for PMP to be adopted?*" "*What levels of approval do the clinics need in order to adopt PMP?*" To better understand and clearly articulate the goals for implementation, we posed the following questions: "*What do the program implementers need to do to implement the essential PMP program components?*" To better understand and articulate maintenance of PMP over time, we needed to more clearly understand what would be required to sustain the program in the clinics. Thus we posed the following questions: "*What do they need to do to maintain the PMP program?*" Our planning team held a brainstorming session and free-listed performance objectives for each. The CFIR domain "process of implementation" was useful in informing potential answers to this inquiry and subsequent selection of implementation performance objectives (what had to be done to implement the intervention).

In the brainstorming session, a facilitator led the team through answering each question and probed the planning group around specific constructs from CFIR and social cognitive theory to make sure the responses were also informed by theoretical and contextual consideration. We determined that the implementation for the EBI would be led by two clinic staff members, the mammography program manager (or clinic staff manager) and a community health worker/patient navigator based on clinic leadership and staff structure related to their overall environment and specifically to their mammography programs. Performance objectives and determinants for implementation are summarized in **Table 2**.

Task 3. Create Matrices of Change Objectives

The next task, development of matrices of change objectives, included the description of very specific objectives for adoption, implementation, and maintenance. First, we identified the determinants for each stage in a brainstorming session where the PMP planning team answered the following questions: "*Why would adopters decide to use PMP?*"; "*Why would implementers do what is necessary to implement PMP?*", and "*Why would*

TABLE 2 | Performance objectives and determinants for implementation.

Performance objectives	Attitudes about PMP (informed by CFIR domains: intervention characteristics and inner setting)	Knowledge	Outcome expectations	Self-efficacy/ Skills	Social norms
Patient navigator PO1. Patient navigator agrees to implement the program and attends two-day PMP training.	A1a. Perceives that the PMP is easy to implement A1b. Perceives that PMP scripts are easy to use A.1.c. Perceives that RedCap online system is easy to use and an improvement over current practice. A.1.d. Describes training as though the PMP partners are here to help	K. 1.a. Describes the components of the PMP program. K.1.b. Describes the rates of mammography in clinic including no show rates. K.1.c.. Describes requirements of the PMP intervention	OE.1a. Expects that by attending the training he/she will be able to successfully implement PMP OE.b. Expects program champion and clinic leadership will reinforce and acknowledge them for completing the training successfully	SSE.1. Feels confident in ability to attend and learn from training. SSE1a. Expresses confidence to attend PMP training SSEc. Expresses confidence in the ability to do what is expected by the PMP (increase screening capacity, implementation of the PMP, provide a program champion, assess and expand clinic resources)	NB1. Expresses belief that patient navigators at other clinics like theirs are implementing PMP NB1b. Expresses belief that other patient navigators attend training to learn protocols to increase mammography appointment adherence.
PO2. Searches schedule for upcoming appointments	A.2.a. Believes that it is their role to identify upcoming appointments. A.2.b. Describes process of using data systems to identify upcoming appointments as important for PMP implementation.	K2a. Describe steps to searching schedule to identify upcoming appointments. K.2b.Describes the data system of the clinic and PMP program K.2c. Describes protections for patient information	OE.2. Expect that all scheduled women will be identified for receiving PMP.	SSE.2.a. Express confidence in and demonstrates ability to successfully identify all upcoming appointments	NB2a. Express belief that other patient navigators are searching schedules for upcoming appointments.
PO3. Conducts telephone barrier counseling PO3.a. Makes three attempts to reach patient via phone before appointment PO3.b. Asks staging question for PMP PO3.c. Uses active listening protocol when talking with patient PO3.d. Uses barrier scripts to respond to patient concerns	AP.3a.Describe PMP as a protocol-driven intervention AP.3b. Describe PMP as not too complex and fairly easy to implement AP.3c.Describe PMP as better than current practice	K3a. Describe process for conducting counseling. K3b. List staging questions for PMP. K3c. Describe active listening methods.	OE.3. Expect that the PMP will help women keep appointments better than current practice OE.3.a. Expect that mammography can help women detect cancer early when it is more curable OE.3.b. Expect that increasing mammography services and kept appointments will contribute to lowering mortality from breast cancer	SSE.3.Demonstrate skills for initiating conversation SSE.3.a. Demonstrate skills for determining women's intention for keeping appointment SSE.3b. Demonstrate skills for eliciting barriers and using barrier scripts SSE2.c. Demonstrate skills for supporting conversation with active listening SSE.d. Express self-efficacy for conducting telephone barrier counseling and specific skills	NB3a. Express belief that other patient navigators are conducting telephone barrier counseling. NB3b. Express belief that other patient navigators are asking staging questions. NB3c. Express belief that other patient navigators are using active listening with patients. NB3d. Express belief that other patient navigators use barrier scripts to respond to patient concerns.
PO.4. Champions oversee implementation efforts and provide feedback to navigators	A.4. Describes role in overseeing implementation as important and useful for ensuring fidelity	K.4.a. Describes daily and weekly activities associated with Champion Role. K.4.b. Describes steps needed to oversee implementation.	O.E. 4. Expects that through regular oversight and communication, the PMP program will be implemented effectively.	SSE.3. Demonstrates confidence and ability to oversee implementation of PMP.	NB.4. Believes that other individuals with similar positions in other clinics act as navigators to oversee and provide feedback.

(Continued)

TABLE 2 | Continued

Performance objectives	Attitudes about PMP (informed by CFIR domains: intervention characteristics and inner setting)	Knowledge	Outcome expectations	Self-efficacy/ Skills	Social norms
PO.5. Champions identify barriers and provide suggestions for overcoming them	A.5. Describes role in identifying barriers as important to the success of the project.	K. 5. Lists potential barriers to implementation and solutions that could address them.	O.E. 5. Expects that the early identification of barriers to implementation will lead to effective solutions that will facilitate continued program use.	SSE.5. Expresses confidence and demonstrates ability to identify problems during implementation and to work with other implementers to resolve them.	NB. 5Believes that other champions like them have a role that includes the identification and resolution of barriers.
PO.6.Champions interact with the research team and clinic leadership as necessary to share and address identified barriers	A.6. Believes that communicating with development and research team is an integral part of their role and important for success.	K.6. Describes protocol for effectively communicating with research team and clinic leadership to address identified barriers.	O.E.6. Believes that if they communicate with the research team and clinic leadership about implementation progress and any barriers, this will lead to effective solutions and program effectiveness.	SSE.6. expresses confidence and demonstrates ability to communicate with leadership.	NB.6. Believes that other Champions also communicate with the research team and with leadership about implementation progress and any barriers to be addressed.

implementers of PMP do what it takes to make sure the program is continued over time?" The CFIR also informed the selection of determinants. For example, the CFIR domain, "characteristics of the innovation" (also describe in Diffusion of Innovation) informed the selection of specific attitudinal determinants that were expected to influence both adoption and implementation. These included attitudes about the efficacy, potential fit, and importance of the PMP program. Following the selection of determinants, we created the matrices of change objectives by crossing the identified determinants with performance objectives asking the question: what needs to change in the determinants (e.g., knowledge, skills) for the implementer to accomplish this performance objective. The resulting cells of the matrix represent specific change objectives that form the blueprint of the implementation intervention. The maintenance of the EBI program as practice would require a commitment from the clinic leadership, program manager and community health worker/patient navigator. The performance objectives and determinants for maintenance are summarized in **Table 3**.

Task 4. Design Implementation Intervention Components

The final task for IM for developing implementation interventions includes choosing the change methods and practical applications, designing the scope and sequence for program components and production of materials for influencing program use. The program planning group began this task by considering the determinants and list of change objectives created in Step 3. Next, they reviewed the relevant research and practice literature to confirm, refute, or modify the provisional list of change methods and their practical applications. This task was completed over a period of 2 months where the planning group met in bi-weekly sessions to review the outputs from Step 3, review and discuss the literature and iteratively update the list of change methods and practical applications. To guide our process, we used a combination of the theories diffusion of innovations (28, 29) and social cognitive theory. We were also guided by the constructs of the consolidated framework for implementation research (CFIR) as shown in **Figure 1** through the selection of methods for the implementation intervention. We developed a PowerPoint presentation to keep the process organized which was updated at each team planning session and finalized. The presentation contained background information from the needs assessment, original program implementation and evaluation and brainstormed outcomes from each step of the IM process, serving as a complete record of project work which could be easily modified at each session and viewed by team members in remote locations (e.g., phone or internet connection).

The intervention change components (see **Table 4**), theoretical methods and practical applications for adoption, implementation and maintenance of the PMP program were developed to support the stated change objectives, including presentations, handbooks, training curricula, MOUs and newsletters. Examples of these program materials are available as a supplement to this article. Implementation of the program is

TABLE 3 | Performance objectives and determinants for maintenance.

Performance objectives	Knowledge	Outcome expectations	Skills and Self-efficacy (Personal characteristics)	Attitudes about PMP (characteristics of the innovation)	Feedback and reinforcement (observability)
Maintenance Outcome: **The clinic decision makers, program champions and patient navigators will maintain delivery of the PMP in their clinic.**					
The program champion will PO1. Discuss with decision makers the continuation of the PMP after funding	K.1.a. Describe processes that will help a program survive in an organization (e.g., inclusion in job descriptions, reward structures, budgets)	OE.1.a. Expect the program to continue to be value added to patients	SSE.1.a. Demonstrate skills for addressing management issues with decision makers SSE.1.a. Expresses self-efficacy for addressing management issues with decision makers	A.1. Describes early successes with the program as evidence of usefulness and reason to continue it. A1.b. Believes that it is important to maintain the program. A.1.c. Expresses continued satisfaction with enhanced services and improved no-show rates	FR.1.b. Ensure access to the RedCap system will be maintained for use by program partners
PO2. Work with decision makers to continue contractual arrangements for increased mammography services.	K.2.a. Describe relevant organizational and inter-organizational processes for writing and administrating contractual agreements	OE.2.a. Expect contractual arrangements are stable and will continue to function as specified OE.2.b. Expect that decision makers will support contractual agreements OE.2.c. Expect that contractual partnerships will contribute to an increase in mammography services	SSE.2.a. Demonstrates administrative skills to follow-up on contracts and work within the clinic administrative structure		FR.2.a. Express satisfaction with contractual partnerships
PO3. Assure that mammography and no show rates continue to be reported (and remain stable or on upward trend).	K.3.a. Describe how to query EMR for program-relevant information K.3.b. Describe how to visualize and share data from K.3.a. to appropriate clinic staff and partners	OE.3. Expect that continued monitoring and evaluation will contribute to likelihood of program continuation	SSE.3.a. Demonstrate administrative skills to monitor data SSE.3.b Express confidence in the ability to monitor, visualize, and present data	A.3.a. Describes how data and feedback on mammography is important to maintain or improved mammography rates and overall clinic performance	FR.3.a. Express satisfaction with enhanced mammography rates. FR.3.b. Express satisfaction with tools and methods for monitoring data
The decision makers (clinic director) will PO4. Approve steps to assure integration of the PMP into normal clinic routines.	K.4.a. Describe the process whereby the program champion will provide decision makers with feedback on PMP integration K.4.b. Describe steps the decision makers plan to take to support the continued use of PMP	OE.4.a. Expects that continued monitoring and evaluation will contribute to likelihood of program continuation OE.b. Expect that integration of PMP into clinic routine practices will lead to a sustained increase in mammography	SSE.4.a. Express confidence in the ability to maintain PMP as a part of clinic routine practices SSE.4.b. Demonstrate the ability to maintain a workforce that is skilled in utilizing PMP practices SSE.4.c. Demonstrate the ability to utilize feedback materials from the program champion to sustain a well-trained staff	A.4. Believe that approving the integration of PMP into normal clinic routines is an important part of their role in improving clinic practices and serving patient needs.	FR.4.a. Expresses satisfaction with enhanced mammography rates. FR.4.b. Express confidence and satisfaction in feedback provided by the program champion FR.4.c. Express satisfaction in how clinic staff utilize PMP practices in clinic routines

TABLE 4 | Peace of mind program implementation intervention plan.

Stage	Agent	Determinants/change objectives	Theoretical change methods	Practical applications
Adoption	Clinic Decision Maker	Awareness/Perceptions of PMP Outcome Expectations Skills and Self-efficacy Feedback and reinforcement	PMP program information Persuasion Role Modeling	Email blast to BHC members with PMP informational video and link to pre-adoption survey Webinar to BHC members covering evidence-based approaches to breast cancer prevention, PMP information and adoption steps Adoption meeting held with interested clinics Financial assistance to clinic Assistance with connecting to mobile providers to increase screening (as needed)
Implementation	All	Awareness/Perceptions Outcome Expectations Skills and Self-efficacy Feedback and Reinforcement	Cue to participate Communication Mobilization Organizational Consultation/Planning	Invite clinic staff to participate in stakeholder group (templates for invitation email) Email template for site visit (including requested participants) and site visit questionnaire Site visit planning meeting Program implementation guide, clinic handbook, stakeholder manual and computer assisted PMP scripts reviewed during participatory stakeholder meetings Implementation readiness checklist Stakeholder meetings to support implementation (continue after reminder calls begin). E-newsletter shared with stakeholders
Implementation	Program Champion Navigator	Awareness/Perceptions Outcome Expectations Skills and Self-efficacy Feedback and Reinforcement	Information Persuasion Skill building and guided practice Modeling Monitoring and feedback Technical assistance/capacity building Facilitation Vicarious reinforcement	Face to face training held over two 4 h sessions. Training was submitted to Texas for CEU certification for community health workers and social workers BHC navigators model EBI behavior and provide ongoing implementation support on-site PMP research team available via email, phone and training booster sessions as needed Paperwork processes to provide funds for patients needing financial assistance from PMP
Maintenance	Program Champion Decision Makers	Outcome Expectations Skills and Self-efficacy Feedback and Reinforcement	Information Persuasion Technical assistance	Face to face meeting to discuss maintaining program Program wrap up email with instructions for continued access to program scripts and contact info for technical support Continued access to online PMP scripts Technical support as needed via email or phone

supported through the use of a participatory stakeholder group, where clinic program staff participated in regular meetings with the PMP team to review program materials, address any needed adaptations and timeline adjustments, train in the use of the PMP scripts and online system, phase in implementation (clinic staff slowly take over ownership of the reminder phone calls) and ensure active troubleshooting of any program issues during implementation. Implementation is also supported through the use of bilingual community health workers and PMP materials which are available in multiple languages. Through the site visit, PMP staff collect information on language needs of program participants and translate materials accordingly. Implementation is also supported through the use of an online interface programmed in REDCap which guides the community health worker through each patient phone call starting from informed consent and through all intervention components. Using a simple interface, the community health worker is guided through the scripted intervention and advances to the next step by completing either pre-programmed check boxes or open-ended text boxes. The system collects data on informed consent, the patient's stage of readiness to attend their appointment, barriers counseled and logistical planning offered during the phone call.

The PMP was implemented over the course of three phases in each clinic. In phase one, the following steps were accomplished: (1) We conducted site assessments with each clinic to understand baseline processes in their mammography programs, (2) Clinic staff were invited to join the participatory stakeholder group, (3) Stakeholder meetings began and reviewed program materials and recommended adaptations to the implementation protocol as needed, (4) PMP training takes place, and (5) Implementation checklist is used to ensure readiness to start PMP phone calls. In phase two, the following steps are accomplished: (1) BHC navigators on-site, provide role modeling of phone calls and support clinic staff as the program begins, (2) Navigators transition reminder phone call scheduling and responsibility to clinic staff over a period of several months and then monitor calls to ensure fidelity, (3) Re-training is provided as needed during this phase and (4) Stakeholder meetings continue with a focus on troubleshooting any implementation barriers and creating e-newsletters to re-inforce program behaviors and highlight program successes. In phase three, clinics take more responsibility for the program and BHC navigators reduce on-site monitoring. Troubleshooting of implementation issues continues. Finally, as clinics move to maintenance, the PMP team holds a meeting with clinic leadership to discuss PMP maintenance plans and provides information on continued access to the PMP online system and technical support. To support maintenance, the PMP online system remains available to all participating clinics.

DISCUSSION

Poor rates of EBI adoption and low levels of implementation and maintenance, may lead to ineffective or less than expected impact on health poor outcomes when translating EBIs to practice in the community (19). The research to practice gap will persist until successful models are developed to support adoption, implementation and maintenance of EBIs within real-world settings. Practitioners and investigators have called for better descriptions of the development of implementation interventions to facilitate replication and refinement of EBI implementations and dissemination (30–32). However, there are few published studies which provide information on the process used to develop implementation interventions or how implementation science frameworks, such as CFIR, can inform implementation intervention planning (14, 31, 33). Neta et al. (22) note that despite many calls for research showing the process or frameworks used to develop implementation interventions, it is typically not at all apparent how planners took these issues under consideration while planning their programs (e.g., the "what" and "how") (22). The authors further note that systematic approaches, including IM, could address this need, especially when used in conjunction with theory (22). This paper provides an example of the use of Intervention Mapping Step 5 and CFIR to create an implementation intervention to support EBI scale up of an evidence-based mammography intervention within a specific setting (FQHCs and charity clinics). A recent systematic review of studies using CFIR found only two that had fully used the CFIR in the pre-implementation phase (34). We found that the inclusion of CFIR determinants in the planning process can facilitate critical implementation intervention design and development, increasing the likelihood of successful dissemination and implementation (34). The development of the implementation intervention resulted in the identification of key determinants that we then created specific strategies and methods for addressing through training and targeted messaging for adopters, implementers and for promotion of program maintenance. We further hypothesized that the use of a participatory stakeholder group would support implementation based both on our conceptual framework and from discussions in the brainstorming sessions about clinics' need for implementation support and to help ensure fidelity of implementation. One of the limitations to our participatory approach was balancing the amount of time required from our community partners to participate in brainstorming and planning sessions. Our team addressed this challenge by focusing our time with community partners on brainstorming activities. We spent additional time outside these meeting sessions working on transcription and translation of the brainstorming materials into EBI components which were then reviewed by our community members. An additional challenge was in getting all levels of FQHC and clinic staff to participate in these planning sessions. Clinic staff have many responsibilities and are not always able to take time away from the office for planning meetings, especially unpaid. We addressed this by working with a community partner who was knowledge of our local clinics and with community health workers who had previously worked in a number of the local clinics. In an ideal setting, we would have had clinic leadership directly participate in the planning sessions.

The Peace of Mind Program developed in this project was adapted from an existing EBI and previously tailored to our local community context for specific mammography barriers. In evaluating the EBI effectiveness, the implementation of the program had been highly tailored to that environment. Further, based on our knowledge of FQHCs and charity clinics in the Greater Houston area, we knew there was heterogeneity in the clinic environments, staffing and mammography program processes. Therefore, we hypothesized that adding a structured, theory-based implementation intervention more broadly relevant to FQHCs and charity clinics to the EBI would be necessary for successful scale-up within this specific context. A recent systematic review of the research-practice gap in primary care settings supports this hypothesis. Lau et al. (35) found overlap with EBI adoption, implementation and maintenance and CFIR constructs used in this project to develop the implementation intervention (what Lau et al. refer to as contextual factors). Additionally, the review highlighted that these "contextual factors" are often notably absent from research and frequently fail to be acknowledged, described or taken into account during implementation or program planning (35). The PMP is currently being evaluated using a non-randomized controlled stepped wedge trial in 16 FQHCs and charity clinics in the Greater Houston area. IM Step 6 was used to guide the development of the evaluation plan for PMP, including measures specific to adoption and implementation within clinics participating in the trial. A full description of the development of the evaluation plan for PMP is beyond the scope of this manuscript. For further information on the evaluation of PMP, we refer readers to Highfield et al. (24), which details the protocol for the PMP trial (24). Briefly, reach of PMP is being measured using Google Analytics tracking from BHC outreach events described above (e.g., email communications, webinars) and through the collection of participation logs for events. Adoption and implementation are being measured through the use of a validated survey of CFIR constructs which was adapted for this project. Implementation is also being measured through our REDCap interface, which tracks navigator's use of the EBI staging question. Evaluation results from the trial are expected in late

2018 and will be able to provide further insight into the effect of our implementation intervention on program implementation, maintenance, fidelity and outcomes (appointment attendance). While full evaluation of the program is underway and will be reported elsewhere, a total of 16 clinics with 24 operating sites, providing mammography services to over 4,500 women during our project period adopted PMP. These clinics served a diverse population of Caucasian, Hispanic, African American and Vietnamese women (all underserved). We anticipate that the program will lead to an increase in mammography screening in participating clinics as a result of the EBI components focused on assessing current screening goals, relationships with mobile providers and serving as a bridge between clinics and providers. Increases in screening in underserved women are important as screening serves as the first step in the pathway to breast cancer disparities (16).

In addition, we are monitoring appointment adherence (no-show rates) along with appointment cancellations, re-schedules, patients turned away for incomplete paperwork and other reasons why a woman may not ultimately complete her mammogram appointment. We believe that assessing the EBI against these additional factors will provide a more complete picture of screening outcomes and barriers. To our knowledge, this is the only paper to date which has applied Intervention Mapping in conjunction with the constructs of the CFIR framework and behavioral theories to develop a systematic implementation intervention for the scale up of a mammography EBI in FQHCs and charity clinics. While this paper is focused specifically on mammography screening, the approach we designed for implementation and the protocols and program materials could serve as a guide for others interested in developing similar programs.

CONCLUSIONS

EBIs which are tested and available for scale up may benefit from use of a structured implementation intervention process. In addition, this paper may provide useful insights for others interested in bridging CFIR, health behavioral theories and scaling up EBIs in community settings, particularly those related to mammography screening in healthcare settings and will facilitate use of the IM steps to support the systematic review and addressing of context specific needs for adoption, implementation and maintenance of EBIs into practice.

ETHICS STATEMENT

This study was carried out in accordance with the recommendations of UTHealth Committee for the Protection of Human Subjects. The protocol was approved by the UTHealth Committee for the Protection of Human Subjects. All subjects gave verbal informed consent in accordance with the Declaration of Helsinki.

AUTHOR CONTRIBUTIONS

LH conceptualized the study, carried out the study and lead the writing of the article. LE-B conceptualized and served as the mentor for the study. MV and MF assisted with study development and manuscript writing.

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