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Advancements and challenges in implementation science

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Advancements and challenges in implementation science: 2022

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SYSTEMATIC REVIEW
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Bridging the Silos: A Comparative Analysis of Implementation Science and Improvement Science

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Background: Implementation science and improvement science have similar goals of improving health care services for better patient and population outcomes, yet historically there has been limited exchange between the two fields. Implementation science was born out of the recognition that research findings and effective practices should be more systematically disseminated and applied in various settings to achieve improved health and welfare of populations. Improvement science has grown out of the wider quality improvement movement, but a fundamental difference between quality improvement and improvement science is that the former generates knowledge for local improvement, whereas the latter is aimed at producing generalizable scientific knowledge.

Objectives: The first objective of this paper is to characterise and contrast implementation science and improvement science. The second objective, building on the first, is to highlight aspects of improvement science that potentially could inform implementation science and vice versa.

Methods: We used a critical literature review approach. Search methods included systematic literature searches in PubMed, CINAHL, and PsycINFO until October 2021; reviewing references in identified articles and books; and the authors' own cross-disciplinary knowledge of key literature.

Findings: The comparative analysis of the fields of implementation science and improvement science centred on six categories: (1) influences; (2) ontology, epistemology and methodology; (3) identified problem; (4) potential solutions; (5) analytical tools; and (6) knowledge production and use. The two fields have different origins and draw mostly on different sources of knowledge, but they have a shared goal of using scientific methods to understand and explain how health care services can be improved for their users. Both describe problems in terms of a gap or chasm between current and optimal care delivery and consider similar strategies to address the problems. Both apply a range of analytical tools to analyse problems and facilitate appropriate solutions.

Conclusions: Implementation science and improvement science have similar endpoints but different starting points and academic perspectives. To bridge the silos between

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the fields, increased collaboration between implementation and improvement scholars will help to clarify the differences and connections between the science and practice of improvement, to expand scientific application of quality improvement tools, to further address contextual influences on implementation and improvement efforts, and to share and use theory to support strategy development, delivery and evaluation.

Keywords: improvement science, quality improvement, implementation science, comparative analysis, context

BACKGROUND

Within health care research and practice, implementation science has emerged as a vital multidisciplinary research field in the wake of the evidence-based medicine/practice movement. Both evidence-based medicine/practice and implementation science address the untapped potential to improve health and welfare of populations through wider and more systematic use of research findings and implementation of empirically supported ("evidence-based") practices (i.e., clinical interventions, programmes, services, etc.). The ambition is to reduce the research-to-practice gap; that is, the gap between what is known through research to be effective and what is actually practiced or used in various areas of society (1).

In parallel, the field of improvement science developed in the 2000s with similar aims of bridging the gap between ideal and actual care to improve health care quality and, thereby, patient and population outcomes (2, 3). Improvement science has grown out of the wider quality improvement (QI) movement, which entered health care widely in the late 1980s. QI involves process mapping and systems thinking and the use of measurement and tools to assess, plan, execute and evaluate changes to improve patient and population outcomes, system performance and professional development (4, 5). Whereas, the primary aim of QI is to enhance local performance, improvement science is aimed at producing generalizable knowledge within a scientific framework (6–8).

Implementation science and improvement science have similar goals of illuminating how to improve health care services and patient and population outcomes. Glasziou et al. (9) have argued that achieving this ambition requires integrating the "do (the) right things" orientation of implementation science (implementing evidence-based practices) with the "do things right" orientation of improvement science (making sure the practices are done thoroughly, efficiently and reliably). Still, despite a shared ambition, work within the two fields seems to progress largely separately, with limited exchange or cross-reference between researchers and practitioners (10, 11). The QI pioneer Don Berwick [(12), p. 1,182, 1,184] lamented that the evidence-based movement and QI "are often in unhappy tension."

The overlapping interest of implementation science and improvement science allows for common ground. Several scholars have argued that aligning the two fields could potentially improve treatment and care to benefit patient and population health (13, 14). For example, greater alignment could benefit implementation science scholars' ability to align their work with the terminology and tools such as Root Cause Analysis used by health care practitioners, many of whom have adopted QI approaches to address problems in health care delivery identified by such methods (15). Further, improvement science scholars might benefit from implementation science's growing menu of frameworks and models to categorise determinants of desired changes and provide guidance for implementation processes. Furthermore, research on collaboration between scholars in different fields suggests that bringing researchers with different backgrounds together can speed up research progress and generate new ideas and discoveries in shorter time periods (16, 17).

In this paper, we address the question: why do the two fields function independently and what are the opportunities to bridge the gap? To address this question, our first objective is to characterise and compare implementation science and improvement science as fields of scientific inquiry. Building on this, our second objective is to identify aspects of each field that potentially could inform the other so as to advance both fields. We begin by providing a brief overview of both implementation science and improvement science, using key literature. This is followed by a comparison of key aspects of the two fields, recommendations for how to address key differences, and a discussion of opportunities for cross-fertilisation.

METHODS

We used a critical literature review approach (18), which has been applied in past comparative reviews of related topics, such as knowledge translation (19) and large health care system transformation (20). Search methods included systematic literature searches in PubMed, CINAHL, and PsycINFO until October 2021 (using the search terms "improvement/implementation science," and "improvement/implementation research"); snowball techniques such as reviewing references in identified articles and books; and the authors' own cross-disciplinary knowledge of key literature. We further searched until October 2021 for relevant content in key disciplinary journals, including *Implementation Science*, *BMC Health Services Research*, *BMJ Quality & Safety*, *BMJ Open Quality*, *International Journal for Quality in Health Care* and *American Journal of Medical Quality*.

Comparative analysis is a method for comparing two or more topics to identify and analyse similarities and/or differences. The product has the potential to engender a deeper understanding of

each topic separately (21). The comparison of implementation science and improvement science used the following categories developed iteratively based on the research question (22):

(1) Influences: origins of the fields and knowledge sources drawn upon

(2) Ontology, epistemology and methodology: characteristics of the research

(3) Problem identification: key problem described in the research

(4) Potential solutions: strategies proposed to address the problem

(5) Analytical tools: theories, models, frameworks and other knowledge products and processes used to analyse, understand and explain problems, and to facilitate appropriate solutions

(6) Knowledge production and use: practice settings in which the research is conducted and users of the knowledge produced

The comparative analysis identified areas of convergence and difference across the fields. From this analysis, we identified and articulated opportunities for cross-fertilisation.

From the self-reflexive perspective on the current disciplinary "boundaries" of the two fields, the authors of the paper are engaged in implementation science and improvement science, with PN primarily involved in implementation science research, JT and BAG primarily involved in improvement science research, and MB, JL, and NS being equally engaged in both fields.

A BRIEF HISTORY OF IMPLEMENTATION SCIENCE

The birth of the field of implementation science is usually linked to the emergence of the evidence-based medicine/practice movement in the 1990s. This movement has popularised the notion that the effectiveness of health services depends on consistent application of the best available research findings and empirically supported ("evidence-based") practices (e.g., preventive, diagnostic or therapeutic interventions, services, programmes, methods, techniques, and routines) to achieve improved health and welfare of populations (23). Spread of the evidence-based medicine/practice movement has been facilitated by developments in information technology, especially electronic databases and the Internet, which have enabled practitioners, policy makers, researchers and others to readily identify, collate, disseminate and access research on a global scale (24). The movement also resonates with many contemporary societal issues and concerns, including the progress of New Public Management, which has highlighted issues of effectiveness, quality, accountability, and transparency (25).

Implementation science is commonly defined as the scientific study of ways to promote the systematic uptake of research findings and other evidence-based practices into routine practice to improve the quality and effectiveness of health services and care (2). The term implementation research is often used interchangeably with implementation science. Other terms in circulation to describe essentially similar research concerning how to put various forms of knowledge to use include knowledge translation, knowledge transfer, knowledge exchange, knowledge integration, and knowledge mobilisation (26, 27).

Although implementation science is a young research field in its own right, research on the challenges associated with how intentions are translated into effective actions to address society's problems has a long history. Many elements of today's implementation science can be traced to research on the spread and adoption of innovations. This research originated in sociology in the early 1900s (28). Everett M. Rogers collated different traditions and presented a conceptual apparatus for the spread and adoption of innovations in his ground-breaking book *Diffusion of Innovations*, which was first published in 1962. The theory originated from his own experience as a farmer and then as an investigator of the spread of agricultural innovations (29).

Today's implementation science is also related to research on policy implementation; that is, the study of "how governments put policies into effect" (30). This research rose to prominence in the 1970s during a period of growing concern about the effectiveness of public policy (31). A policy is a plan or course of action intended to influence and determine decisions and actions (32). This research emerged from the insight that political intentions seldom resulted in the planned changes, which led researchers to investigate what occurred in the policy process and how it affected the results (33).

Implementation science also has many connections with the study of research use (or research utilisation). This research grew out of the social science research field of knowledge utilisation in the 1970s, with Robert F. Rich and Carol H. Weiss being prominent scholars (the term "knowledge utilisation" has also been used as a collective name for all research relating to the use of knowledge). As early as 1975, nursing researchers were building on concepts and theories from knowledge utilisation in research to understand how nurses used research in their clinical practice (34, 35). Many researchers who were active in the field of research use subsequently developed broader research agendas within implementation science.

A BRIEF HISTORY OF IMPROVEMENT SCIENCE

The term "the science of improvement" was first used in a health care context by Langley et al. (36), in the 1996 edition of *The Improvement Guide*. However, approaches used in today's improvement practices date back almost 100 years. An important foundation for QI and, thereby for improvement science, was laid by Walter Shewhart in the 1920s and 1930s. A physicist, engineer, and statistician, he developed statistical methods to reveal key aspects of the quality of industrial processes (37). His work on tools such as control charts to understand and manage process variation and the Plan–Do–Study–Act (PDSA) cycle (originally called simply the Shewhart cycle or the Shewhart learning and improvement cycle) are foundational for QI and core concerns of improvement science. He summarised his work in his 1931 book *Economic Control of Quality of Manufactured Product* (38).

Shewhart worked at Western Electric Company's Hawthorne factory to assist its engineers in improving the quality of

telephone hardware. While at Hawthorne, Shewhart mentored both Joseph Juran and William Edwards Deming who went on to champion Shewhart's tools, not least the PDSA cycle (which was also referred to as the Deming cycle). Deming, a statistician, engineer and business consultant, recognised quality as a primary driver for industrial success and subsequently introduced QI tools to post-world War II Japanese industries, particularly the automobile industry (39). Deming's work was summarised in *Out of the Crisis* (40). Joseph Juran, similarly influential, highlighted the idea that quality can be managed through planning, control, and improvement, known as the Juran Trilogy, as outlined in his multiple-edition *Juran's Quality Handbook* (41). The trio of Shewhart, Deming and Juran are often considered the founders of the QI movement (7, 42).

Interest in applying QI approaches to improve health care increased in the 1980s. Concern about wide geographic variations in health care practice led the United States Congress to establish the Agency for Health Care Policy and Research (today the AHRQ, Agency for Healthcare Research and Quality). Twenty-one health care organisations in the United States participated in the National Demonstration Project in Quality Improvement in Health Care (NDP), a 1987 study to investigate the applicability of QI approaches to health care. Many of the organisations showed improved performance and the NDP was extended three more years before evolving into the Institute for Healthcare Improvement (IHI), a not-for-profit organisation that provides leadership and training in health care QI. From its inception, IHI leaders also promoted QI through influential academic writing (43–45).

Attention to quality problems in health care grew in the 1990s, but it was the landmark publication of *To Err is Human* in 1999 by the US Institute of Medicine (today the National Academy of Medicine) that brought quality problems in health care to widespread attention. According to the report, most medical adverse events result primarily from faulty processes and systems, not from isolated failures of individuals (46). This initial report was followed in 2001 by the follow-up report *Crossing the Quality Chasm* (also by the Institute of Medicine), which documented the substantial gap between actual and desired care, and proposed directions for closing it (47). Contemporaneously and also important was the policy report *An Organisation with a Memory,* which was published in 2000 by the Department of Health in the United Kingdom. It reported on the quantity and causes of adverse events in health care organisations and recommended that health care systems learn from safety incidents and act to improve safety (48). These reports provided political, policy, and funding impetus for developing QI into a research endeavour (8, 12, 49). Over the years, organisations such as The Health Foundation in the United Kingdom and the IHI in the United States have supported and disseminated QI and improvement science knowledge widely (50).

The 2000s saw the development of improvement science as a research field based on the recognition that QI needed a scientific knowledge base (51). There is no unified definition of the field and many different definitions have been proposed. Still, some core characteristics can be identified. Definitions typically build on definitions of QI but emphasise the scientific enquiry into health care improvement issues. Hence, these definitions emphasise the systematic and rigorous study of effectiveness; that is, "what works best" (52), when scientifically evaluated, of various QI strategies (5).

A fundamental difference between QI and improvement science is that the former concerns the practical application of knowledge for local improvement, whereas the latter aims at the accumulation of generalizable knowledge. QI generates knowledge for local improvement, and the results are not primarily intended to be generalised beyond the specific setting or population in question. In contrast, the ambition of improvement science is to generate new, scientific, generalizable knowledge (8, 10, 53). Hence, whereas QI focuses on optimising the local benefits of change, improvement science can be said to focus on maximising learning from, and for, improvement (52). The comparative analysis in this paper focuses on improvement science; references to QI are made when addressing aspects of QI that have direct relevance to improvement science.

COMPARATIVE ANALYSIS OF IMPLEMENTATION SCIENCE AND IMPROVEMENT SCIENCE

The comparative analysis of the implementation science and improvement science fields that we conducted centred on six categories, developed iteratively based on the research questions and analysis of the literature. We first describe findings concerning each of the six categories (summarized in **Table 1**) and then provide recommendations regarding how key differences might be addressed.

Influences

Implementation science and improvement science ultimately concern practice change. Improving the quality of a health care process or implementing an evidence-based practice implies the need to change aspects of current practice. Hence, describing and analysing change is important in both fields, but they draw on partially different sources of knowledge to achieve this. Improvement science has been informed by its roots in the management and manufacturing fields, and topics and disciplines such as quality, measurement, management, leadership, strategy, and organisational learning (7, 52, 54). Implementation science has different origins, being influenced by medical sciences (and the evidence-based movement), behavioural sciences and social sciences, perhaps most notably the fields of psychology, organisational behaviour, sociology, and political science (33).

An area of commonality in influence across the two fields is the relevance of psychology for understanding how the desired change can be achieved. However, how psychology is utilised in each field is different. Psychology in implementation science has been applied to analyse change and to identify the mechanisms of this change (55). In implementation science, change is usually considered in terms of behaviour change among health care practitioners (56); for example, the extent to which

TABLE 1 | Summary of similarities and differences between implementation science and improvement science across six thematic aspects.

Aspect	Similarities	Differences
Influences	Both fields ultimately concern practice change Both fields acknowledge the relevance of psychology for understanding how desired change might be achieved	The fields have different origins and draw on mostly different sources of knowledge
Ontology, epistemology, and methodology	The research characteristics of the two fields are largely similar, primarily belonging to the positivist tradition, but with some interpretivist features Both fields are highly applied in nature, with aspirations to inform practice	
Problem identification	Both fields describe a gap or chasm between current and optimal care and/or service delivery	For improvement science, the problem is related to the efficiency, safety, and/or quality of current practice; in implementation science the problem relates to delays in getting effective practices (clinical interventions, programmes, services, etc.) applied systematically in practice
Potential solutions	The two fields share multiple common strategies, although they use partially different terminology to describe them	Improvement science posits that quality improvement follows from successful change in the health care system and its processes. Implementation science assumes that implementation of evidence-based practices will reduce or eliminate the problem. The scope of change is broader in improvement science than in implementation science, because a QI initiative is not necessarily limited to application of scientifically supported evidence, but can also involve operations, service quality and efficiency
Analytical tools	Both fields use analytical tools to analyse problems and to identify possible solutions	Improvement science uses a range of QI tools, typically adapted for use in health care from the manufacturing industry and management, whereas implementation science emphasises the use of theories, models and frameworks as analytical tools
Knowledge production and use	Both fields produce knowledge that is both applicable for improved practice and sufficiently generalizable to contribute to scientific knowledge accumulation Both fields focus on studies in health care but also encompass research carried out in the broader health and welfare services	Health care practitioners and organisational developers are more likely to have QI and/or improvement science knowledge than implementation science knowledge

they act in accordance with an evidence-based practice, such as prescribing an antibiotic for a sore throat, adhering to a hygiene recommendation or providing advice on alcohol consumption. Social-cognitive theories from psychology concerning behaviour change are widely used in implementation science (57). These theories focus on individual cognitions (e.g., motivation, attitudes, beliefs, and self-efficacy) as processes that intervene between observable stimuli and responses in specific real-world situations (58).

In improvement science, psychology is part of Deming's System of Profound Knowledge, which is a holistic approach to leadership and management influenced by the theories of pragmatist C.I. Lewis (59). This system identifies the relevance of having knowledge about psychology, variation, the system and having a theory on knowledge to change organisations (42, 45). For Deming, psychology was essential for understanding the human nature of the people in organisations (5). Contributions from psychology that are important to improvement science include knowledge about differences in people and the relevance of both intrinsic and extrinsic motivation underlying behaviours, and how people can be attracted to change (36, 60).

Ontology, Epistemology, and Methodology

Despite their different backgrounds, the ontology and epistemology of the two fields can be positioned largely within a positivist tradition. Thus, they seek objectivity and use systematic approaches to undertake research. The researcher is assumed to have direct access to the real world, adherent with positivist beliefs concerning the nature of the world (61, 62). It is believed that it is possible to obtain objective knowledge and the research has a focus on generalisation, consistent with positivist notions about the relationship between the researcher and the reality (61, 62). Both fields study the use of strategies to actively influence and change current practice, to reveal assumed cause-and-effect relationships between controllable and editable independent variables and various outcomes (dependent variables).

Reflecting a positivist approach to methodology (63, 64), researchers in the two fields take a controlled and structured approach in conducting research by identifying a clear research topic, adopting a suitable research methodology and implicitly assuming that the role of the researcher is predominantly that of a detached, external observer. Still, interactive and participatory approaches are increasingly emphasised in implementation

science (65). Similarly, improvement science researchers acknowledge the importance of pre-understanding and action-oriented approaches to doing research (66, 67). This field has emphasised the importance of accounting for the personal experience, knowledge and intuition of those who are closest to the problem while recognising the need to frame and test these insights scientifically (42). This knowledge is referred to as subject matter knowledge, which is considered to be unique to each practice setting (45).

Both fields have a strong focus on measurement. Implementation science studies involve measurement, with the influence from clinical epidemiology, other medical sciences and the evidence-based movement evident in the preference for systematic reviews to determine the effectiveness of different implementation strategies (68, 69) (even if the strategies might have been applied in very different contexts). Overall, implementation science uses a wide range of research methods, both qualitative and quantitative, to understand and explain the conditions for implementation by identifying determinants, usually divided into barriers and enablers, for successful implementation and to evaluate the effectiveness of various strategies intended to facilitate implementation (1).

The origins of improvement science in industrial manufacturing provide an explanation for the importance of measurement in this field. The concept of "quality" in industrial production was initially bound up with standardisation, using statistics to understand and manage variation, and measurement was therefore recognised early on as critical to the identification and correction of deviations and deficits in the production process (70). Today, improvement science concerns efforts to use measurement for creating feedback loops to promote learning and gauge the impact of changes over time (36, 71).

Problem Identification

The two fields address a similar problem: that many patients or service users do not receive optimal care or treatment and that efforts to improve on this situation are often challenging, unsystematic, and meet with mixed success. Both fields start from a gap between current and optimal or desired care and treatment. The gap was famously referred to as a "quality chasm" in the US Institute of Medicine (47) report that inspired improvement science and as an "implementation gap" in implementation science (in contrast to an "evidence gap," which describes lack of evidence on the effectiveness of a practice). However, although the two fields describe a similar problem, the understanding of this problem and how knowledge of the problem can be obtained differ.

In implementation science, the problem is conceptualised as lack or insufficient use of evidence-based practices in current clinical care, which means that practice is not sufficiently informed by empirical research findings (1) and that (often hard won) research insights are left unused. Data on the deviations between current and evidence-based practice and determinants (barriers and facilitators) contributing to those deviations are key to understanding the problem and informing efforts to solve it (72).

Improvement science is premised on the assumption that there is a gap between the way care is being provided and optimal care delivery in relation to safety, efficiency, effectiveness, equity, patient centredness and timeliness, core dimensions of health care quality highlighted by the Institute of Medicine (47). Data on how care is currently being provided are essential to understanding the quality problem (3, 73).

The problem in improvement science can be identified based on clinical audits, quality registries or on local practice-based knowledge (74); for example, unwarranted variation in clinical practice and in patient outcomes, patient complaints about long waiting times in an emergency department, practitioners' experiences with increased incidence of pressure ulcers or performance benchmarking data that indicate avoidably, even unacceptably, high prescription of antibiotics. Hence, the specific problem can be identified by practitioners or researchers in a sort of bottom-up process in local practice settings. In contrast, the problem in implementation science is more likely to be defined by researchers or health care-related authorities, who identify a gap between current practice and a practice that is based on the latest available evidence (1). Thus, problem identification in implementation science studies tends to be based on more of a top-down process.

Scholars in both fields have increasingly engaged in discussions about how to address the influence of context on the gap between current and optimal care and treatment. Researchers in quality improvement have defined context as "everything else that is not the intervention" [(75), p. 605] or as one of three factors influencing the outcomes, the other two being the QI strategies and the QI tools (73, 76) (see below for further details regarding strategies and tools). This is somewhat similar to implementation science, in that the strategy to facilitate the implementation is not considered to be part of the context, instead being viewed as one of five determinant domains: (1) effectiveness of the strategy to facilitate implementation; (2) attributes of the implemented practice (e.g., the perceived complexity and relative advantage of the clinical intervention, programme, service, etc.); (3) features of the adopters (e.g., health care professionals' attitudes, beliefs and motivation concerning the implemented practice); (4) features of the patients or recipients of the implemented practice (e.g., their values and priorities); and (5) contextual influences (72, 77). Hence, implementation science researchers typically view this "everything else" quite broadly in terms of attributes of the implemented practice and features of the adopters and patients.

Potential Solutions

The two fields propose partially different means to solving the identified problems in current practice. Implementation science starts from the premise that implementation of evidence-based practices will address the problem and contribute to improved patient and population outcomes. Improvement science, meanwhile, examines whether and how QI in health care systems and processes can ameliorate the problems, thus improving clinical practice and patient and population outcomes.

The solutions studied in improvement science are typically called QI strategies, but they are also referred to as QI interventions or QI activities (66, 78). It is common in improvement science to distinguish between QI strategies and QI tools, the latter being instruments and processes used to define and analyse problems (15).

QI and improvement science share many strategies with implementation science. For example, researchers in both fields have referred to the taxonomy developed by the US Agency for Healthcare Research and Quality (AHRQ), consisting of nine types of "off-the-shelf" strategies, including audit and feedback, health care practitioner education, reminder systems, organisational change and financial incentives, regulation and policy (79). Numerous other strategy taxonomies have been developed in implementation science (80), but many of the strategies are essentially the same as in the AHRQ taxonomy. A recent review of both implementation and improvement science studies found they used many common strategies, although terminology differed (13). Hence, even though the problem is defined differently in the two fields, the potential solutions (i.e., strategies) to address the problem overlap markedly.

Analytical Tools

Both fields apply a range of analytical tools to understand problems, to inform and evaluate solution designs and efforts to facilitate their application in practice. Implementation science places great emphasis on the use of analytical tools in the form of theories, models and frameworks, both to describe and guide actual implementation endeavours (i.e., action models) and to analyse implementation (i.e., determinant frameworks) (72). Some of the theoretical approaches have been developed within the field by researchers from varying backgrounds (including psychology, nursing and sociology), e.g., Consolidated Framework for Implementation Research (77), Normalisation Process Theory (81), Organisational Readiness for Change (82), and the Theoretical Domains Framework (55). Other theories ("classic" theories) have been borrowed from other fields, such as psychology, sociology and organisational behaviour, and tend to be broader in nature (72).

A crucial element of improvement science is the wide range of generic QI tools, inherited from many years of QI work (15), that can be applied to quality and performance problems. Implementation science scholars also borrow some of these tools (13, 14, 80, 83), but they were not developed in this field.

Implementation science studies often investigate health care practitioners' behaviour change as an implementation outcome, emphasising the importance of using theory to understand and explain "what works, for whom and under what circumstances" (55, 84, 85). Similar approaches are entertained in improvement science (86–89). Both fields seek ways to determine cause-and-effect relationships.

Knowledge Production and Use

The two fields aim to produce knowledge that is applicable and useful in practice while simultaneously sufficiently generalizable for scientific knowledge accumulation. Implementation science studies are conducted in the wider health and welfare services (90, 91). Similarly to implementation science, improvement science research is carried out in health care settings, but studies also go beyond health care to encompass, for example, community-based services, education and social work. The wider QI movement encompasses many other environments, including manufacturing, software development, aviation and the military; that is, sectors that have systematically explored the most effective ways to reduce variability and improve quality (5, 92).

Both fields involve scholars who conduct research on improvement and implementation issues, and practitioners who are actively involved in "doing" QI work and carrying out implementation in real-world settings. However, health care practitioners are currently more likely to be knowledgeable in QI/improvement science than in implementation science (10). Knowledge used in (QI and) improvement science, including information about the numerous QI tools, is increasingly taught in health care practitioners' undergraduate, postgraduate and continuing professional education globally (93, 94). Furthermore, health care practitioners who are employed in organisational or health care development capacities also make use of this knowledge and enable it to be applied in health care practice (11).

In contrast, practitioners in health care and other areas tend not to be knowledgeable about implementation science (10). In fact, a gap has been noted between knowledge about implementation science (e.g., regarding key determinants or the most effective strategies) and the actual use of this knowledge in practice to facilitate implementation endeavours (95). Although there is a proliferation of "evidence-based skills" literature and courses, these tend to focus on how to critically appraise research studies and scientific evidence rather than on how to actually apply it effectively (96). Implementation science researchers have developed action models such as Knowledge-to-Action (97) and Quality Implementation Framework (98) to guide the translation of research into practice, but they are not as hands on or as widely disseminated or used as QI tools. Hence, knowledge produced in implementation science is still predominantly the domain of academia rather than health care practice and management. Paradoxically, there is a risk that valuable research about how to implement research is not being applied effectively in practice.

Recommendations to Achieve Increased Collaboration Between Implementation Science and Improvement Science

The comparative analysis shows that there are several similarities between the two fields, but there are also numerous differences that would need to be addressed to promote collaboration to allow the fields to learn from each other's approaches, expertise and experiences. The fields have different origins and draw on mostly different sources of knowledge, yet this does not constitute a problem since it can serve to broaden and deepen the understanding of the problem and solutions to produce more useful and indeed

deeper knowledge for research and practice. Both fields are inherently multidisciplinary, with scholars who are used to working together with others who might have different backgrounds, including clinicians, health care managers and people with lived experience if illness and care pathways. This suggests that collaboration with scholars and other stakeholders coming from the other field is not a barrier for cross-fertilisation.

The two fields are based on different premises as to what constitutes the problem. The starting point for improvement science is a need or opportunity to improve performance (e.g., efficiency, effectiveness, timeliness, equity), whereas implementation science is based on the recognition that current practice is not sufficiently evidence-based. Rather than viewing these two orientations as conflicting, we recommend that the two fields recognise them as complementary. In practice, problems often include aspects relevant to both perspectives. For example, long waiting times in an emergency department may result from both underuse of evidence-based triage tools and problems concerning care processes. Thus, implementation scientists would benefit from improvement science's process mapping or Root Cause Analysis methods, while improvement science would benefit from a consideration of existing tools that have demonstrated effectiveness in improving triage processes.

The potential solutions to the identified problems also differ between the two fields. The scope for solutions to achieve the desired practice is broader in improvement science than in implementation science simply because QI initiatives are not necessarily limited to application of scientific evidence. Implementation science is usually defined in terms of research on implementing evidence-based practices with convincing empirical support from clinical trials, preferably randomised controlled trials. In practice, however, this definition tends to be applied inconsistently as journals publishing implementation science studies also publish occasional studies involving practices that lack solid empirical support (99, 100). We argue that the focus on practices that are evidence-based limits the ability to assess how important the strength of the evidence is relative to other determinants for implementation success. For example, a highly structured clinical intervention with high efficacy shown in randomised control trials may be harder to implement than an intervention with less evidence, e.g., based on a number of small observational studies. Loosening conceptual restrictions of implementation science to evidence-based practices would introduce the field to the opportunities that are inherent in improvement science, which welcomes any reasonable approach to improvement. Obviously, such a development would considerably reduce the differences between the two fields.

Developing and implementing solutions to identified problems benefits from accounting for local knowledge of relevance for the implementation and/or improvement. In this regard, implementation science scholars could learn from improvement science by considering how local and tacit knowledge (e.g., of frontline health care practitioners) as well as "expertise by experience" (e.g., of service users) is accounted for in improvement efforts when designing tailored implementation strategies. The approach of improvement science coupled with existing knowledge about adaptation in implementation science (101) offers the potential for more tailored, context-sensitive implementation strategies instead of using "off-the-shelf" strategies.

It has been argued that improvement science scholars have achieved a better understanding of the complex concept of context than implementation science scholars (10, 11, 13). Implementation science frameworks that describe determinants of implementation success typically include context as one determinant alongside others, such as attributes of the implemented practice and health care practitioners' beliefs, attitudes, and motivation to change their practice (72). However, the treatment of the context in implementation science, as one of several determinants causally linked to implementation outcomes, implies a fairly reductionist approach to context that often fails to account for the inherent complexity of this concept. Determinant frameworks rarely provide a precise definition or clarify the meaning of the context. Most frameworks define the concept indirectly, in terms of specifying a number of components or dimensions that comprise the context; for example, organisational support, financial resources, culture, and leadership (102). Thus, in many ways, implementation science scholars are still struggling with the concept of context and how to address it in their research. We view this area as an important frontier for both fields to focus their efforts on, particularly in terms of tailoring effective approaches to differing contexts. Research in both fields seems to be heading in precisely this direction. Otherwise, they will remain stuck with the conclusion about the effectiveness of most strategies that "it depends," without being able to articulate how it does so, or how to adapt to such differences (103).

The two fields use partially different terminology for the solutions developed within each field. However, discussions about the meaning of concepts are not unusual *within* research fields as they evolve over time. For example, both implementation science and improvement science scholars have laboured over how concepts such as context, determinants, frameworks, strategies and interventions should be defined, with considerable within-field inconsistency in the use of many terms (66, 72, 78, 102). Differences in terminology can be a problem, particularly when implementation science scholars engage with practice settings, which are increasingly adopting QI approaches (14). As a result, health care practitioners are learning the language of improvement science. To be successful, implementation science scholars must engage with health care practitioners who are expected to adopt and use their evidence-based practices.

There are also differences with regard to what analytical tools are used in the two fields. We believe implementation science scholars should take a closer look at how improvement science researchers and practitioners use QI tools such as PDSA cycles, Six-Sigma, Root Cause Analysis and Failure Mode, and Effects Analysis (7, 15, 39). These tools can facilitate description and analysis of problems and support the development of relevant solutions. There are still relatively few implementation science studies that use the tools, but interest seems to be increasing, which is encouraging (13, 14).

The importance of using theory to understand the mechanisms of change appears to be more pronounced in implementation science than in improvement science. It has been argued that implementation science can offer valuable insights for improvement science into the how and why of change (11, 104). Improvement science scholars Ramaswamy et al. [(53), p. 15], stress the importance of "unpacking the black box of improvement" to learn what happens during the process of change. Although implementation science now has a strong focus on using theory to understand and explain change, early implementation science was critiqued on the basis of its limited use of theory (105, 106). However, the field has seen wider recognition of the need to establish the theoretical bases of implementation and the strategies used to facilitate implementation (72). A similar development has been advocated in improvement science (88). Increased collaboration between scholars in the two fields could facilitate more emphasis on theory use in improvement science to allow for better understanding and explanation of how and why certain improvements or not are achieved.

The two fields also differ concerning knowledge production and use. We contend that implementation science researchers could learn a great deal from some aspects of improvement science. In many ways, improvement science has a practitioner-friendly "how-to-do-it" orientation that facilitates the use of this knowledge in practice settings. QI/improvement science has been more successful in disseminating knowledge about basic QI principles and QI tools to health care leaders and practitioners, possibly because many accessible QI resources provide practical approaches that health care systems are in need of; that is, standardised ways to improve health care structures and processes that can be taught through training programmes (36, 44). Implementation science seems to have taken note, because recent years have seen a growth in the number of courses and programmes in implementation science directed at both practitioners and researchers, and publications providing more hands on, practical summaries of implementation science approaches; for example, the *Implementation Science Research Development (ImpRes) Tool* (107–112).

Knowledge produced in the course of QI is practice-based and held by practitioners, whereas knowledge generated in implementation science as well as improvement science is research based and therefore predominantly the domain of the academic community. The need to more clearly distinguish between QI and improvement science is a position taken by many improvement science scholars (6, 78, 104, 113, 114). Indeed, scholars have conveyed critique that the field is being held back by people who resist "the suggestion that science should play a more prominent role in improvement" [(104), p. 254] and therefore do not adopt a "more scientific approach to improvement" [(115), p. 83]. We believe such a development would open up more opportunities for collaboration between scholars in the two fields.

DISCUSSION

This comparative analysis study has sought to characterise implementation science and improvement science, analyse similarities and differences between the two fields, and provide recommendations how to address the differences so that improvement science potentially could inform implementation science and vice versa. At a higher abstraction level, we conclude that the two fields are remarkably similar, with a shared goal of using scientific methods to understand and explain how health care services can be improved for better patient and population outcomes. At lower abstraction levels, our comparative analysis identified some key differences and opportunities for enriching interaction between the fields.

Both fields ultimately concern practice change and describe a problem in terms of a gap or chasm between current and optimal care and treatment. Hence, it is not surprising that numerous scholars in both fields have argued for a merger or increased integration of the two fields. It was not uncommon in the early 2000s for scholars to conduct research in both fields. A 2012 discussion paper in *Implementation Science* (116) conveyed ambitions for a common science concerning research on how to improve health care, but these plans have since been laid to rest. More recently, Koczwara et al. (11), Check et al. (13) and Leeman et al. (14) have called for scholars who are proficient in both fields. A recurrent theme at many of the conferences the authors behind this study have attended is debate concerning whether and how the two fields differ and why there seems to be only limited collaboration—discussions that have prompted this paper.

Despite such calls for integration between implementation science and improvement science, they have not yet found adequate common ground. Why? After all, both fields ultimately are concerned with carrying out structured, rigorous and systematic scientific processes to build scientific knowledge to inform improvement of health and health care. In light of this study, we take the view that part of the continued separation between the two fields can be attributed to a failure to distinguish between QI and improvement science, with impressions of improvement science being influenced by views of QI as not being scientific (104, 117) and relying too much on "intuition and anecdotal accounts" [(15), p. 138]. Conversely, the challenges of applying implementation science in practice may perpetuate this separation.

We believe collaboration between the two fields will be more likely as improvement science matures as a scientific endeavour that is distinct from QI (even though QI tools might be used). Increased use of QI tools in implementation science and practice may also contribute to increased interactions between the two fields. Ultimately, integration will depend on a genuine interest among scholars (and indeed practitioners) to learn about each other's fields and collaboration to create favourable conditions for synergies. A comparative analysis like this is bound to identify many aspects that differ, yet the two fields have the same ambitions to produce scientific knowledge for improved patient and population outcomes; an inclusive approach to evidence-informed improvement through cross-field collaboration can achieve these ambitions more quickly and effectively.

CONCLUSIONS

Our comparative analysis identified both similarities and differences between implementation science and improvement science. The two fields have disparate origins and draw on mostly different sources of knowledge but have a shared goal of using scientific methods to understand and explain how health care services can be improved for better patient and population outcomes. The two fields describe a problem in terms of a gap or chasm between current and optimal care and treatment, and use similar strategies to address the problems. Both fields apply a range of analytical tools to understand problems and inform effective solutions, but implementation science is more focused on using tools (theories, models, frameworks) to disentangle the mechanisms of change to explain the how and why of practice change.

Increased collaboration between scholars (and practitioners) in the two fields, clarifying the differences between the science of improvement and its practice-oriented predecessor, QI, expanded scientific application and evaluation of QI tools, advanced analysis of ways to manage contextual influences on implementation and improvement efforts, and more coherent and shared use of theory to support strategy development, delivery and evaluation can all help move both fields forward and bridge the silos between them.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

AUTHOR CONTRIBUTIONS

All authors contributed to the conception, design, analysis and interpretation of data, and writing the manuscript.

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BRIEF RESEARCH REPORT
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Lessons Learned and Future Actions: Modifying a Stroke Specific Self-Management Program

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Background: Self-management programs have been shown to be effective at providing support to individuals who want to manage chronic health conditions independently. It has been shown that adapting self-management programs for different diagnostic groups, such as stroke, is essential.

Objective: To report modifications made during trial implementation, the barriers identified during the delivery of an evidence based, stroke-specific self-management program and minor data (including strategies made) from a small cohort of stroke survivors with multiple chronic conditions.

Methods: Prospective type III hybrid implementation-effectiveness trial for stroke survivors, with chronic conditions, living in the community, and interested in self-management. Modifications were reported by the following: (1) researcher reflections (2) barriers to implementation and (3) strategies used to address the barrier using the Consolidated Framework for Implementation Research (CFIR) guidelines from field notes.

Results: Twenty-five individuals consented (42% of eligible sample) at the time of acute stroke and five were interested in continuing at the 3-month call. Multiple barriers to implementation were identified, resulting in modifications. For example, before the group sessions began, the COVID-19 pandemic necessitated changes to the intervention delivery. The protocol was modified to an online mode of delivery. In total, there were seven modifications made.

Conclusions: The CFIR was a facilitative tool to report barriers and strategies and emphasized the importance of comprehensive reporting. The modifications to the study were an essential first step to address the research climate and needs of this stroke cohort. Next steps include continued research with a larger cohort to implement effective strategies and answer the clinical question of effectiveness of the adapted and modified intervention.

Keywords: stroke, implementation science, consolidated framework for implementation research, self-management, translational research

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INTRODUCTION

Despite comprehensive rehabilitation programs and supportive care, many individuals who have sustained a stroke cannot effectively manage residual stroke symptoms in addition to existing comorbidities in order to live independently at home and therefore must develop strategies to gain new knowledge, skills and confidence (1). In addition, lack of access to interventions and variable quality of care at different points in the post-stroke pathway are issues that prevent improvement (2). Self-management programs are effective at supporting and empowering individuals with chronic conditions (such as stroke), by teaching the skills necessary to actively and independently manage symptoms (1).

Many self-management programs have been developed and are being used by multiple patient populations. One example is the Chronic Disease Self-Management Program (CDSMP), an evidence-based self-management program that has been shown to be effective at improving overall health, health service utilization, and self-efficacy of individuals participating in the program (3, 4). The CDSMP curriculum has been adapted (prior to it being delivered) and modified (during delivery) for stroke survivors and used at multiple stages of stroke recovery (5, 6). These two studies demonstrated feasibility and improvements such as self-efficacy in the stroke group vs. the group that did not receive the intervention (5, 6). Another program added education on home, community, and work management, and yielded effective improvements in self-efficacy for health behavior management and participation (7). It is unknown whether further specific modification and tailoring of the program that not only focuses on the stroke symptoms but also on the coexisting health diseases that each person is experiencing will improve outcomes. Since most stroke survivors have multiple chronic conditions (8), specifically adapting the CDSMP to meet the needs of this cohort is a gap.

In 2019, we made adaptations to the CDSMP, using a visual analytic methodology and using medical records of stroke survivors with chronic conditions (9). These adaptions also included the development of clinical vignettes which were intended to be used to create tailored discussion opportunities and more personalized content for CDSMP future participants (9). The clinical vignettes relate to the weekly sessions' content and are situated within the curriculum during scheduled discussions and therefore keep the CDSMP fidelity (9).

After the adaptations were made, we intended to then conduct a type III hybrid implementation-effectiveness study to make any modifications as well as evaluate the impact of the adapted self-management program, assessing both clinical and implementation outcomes. The purpose being to expedite the translation of research findings into clinical practice by generating more effective implementation strategies and information for decision makers. Therefore, this report describes modifications made during trial implementation, barriers identified during the delivery of an evidence-based stroke-specific self-management program and presents minor data (including strategies made) from five participants.

METHODS

Study Design and Procedures

After full review, the stroke-specific CDSMP type III hybrid implementation-effectiveness (10) study was approved by the Institutional Review Board (IRB) at the University of Texas Medical Branch. Recruitment took place in the acute care hospital from August 2019 through February 2021 Medical records were used prospectively to screen new admissions and determine if inclusion criteria were met. Patients were approached to determine their interest in the study after discussion with their nurse. Consent and baseline 1 assessments were completed in participants' hospital rooms by the principle investigator (researcher). The process took ∼45 min. The assessment testing was repeated at two additional time points during the study (prior to the intervention and 2 weeks after). These assessments include multiple clinical outcome measures and are not reported in this manuscript. They are: (1) Southampton Stroke Self-Management Questionnaire (11), (2) Patient Reported Outcome Measure (PROMIS) self-efficacy (12), (3) PROMIS sleep disturbance scale (13), (4) PROMIS sleep-related impairment scale (13) and (4) visual functioning questionnaire (14).

Approximately 3 months after the consent and baseline 1 were complete, each person received a telephone call (see Appendix 1 for telephone script) from the study staff to complete a brief interview. This interview determined if the person still met the study's inclusion criteria, asked if they were interested in continuing the study, provided a timeline for when the second assessments needed to be completed, and identified the person's optimal day and time for when they could participate in the weekly group sessions. The study staff (occupational therapist) provided the following additional information during the call: information on the specific location for in-person sessions, parking information, including how to be compensated, and a reminder that family members were welcome to attend the group sessions. An honorarium was provided after the second set of assessments was completed. The study investigators and staff were trained in the CDSMP as group facilitators prior to the study being implemented. Over a 6-week period, the principle investigator and study staff lead the group members through the implementation of the intervention. The final assessments were completed after the last intervention group meeting (see **Figure 1**).

The principle investigator and study staff (researchers) took field notes before and during the intervention. Barriers to implementation were reported using the Consolidated Framework for Implementation Research (CFIR) which was done after the intervention through utilization of field notes. Researcher reflections were used to make modifications to the study protocol.

Participants

Participants for this study were required to meet the following inclusion criteria: diagnosis of an acute stroke, living with at least one chronic condition able to independently consent (in other words, each person was alert and oriented to person, place, and date), be community dwelling at the start of the intervention, and

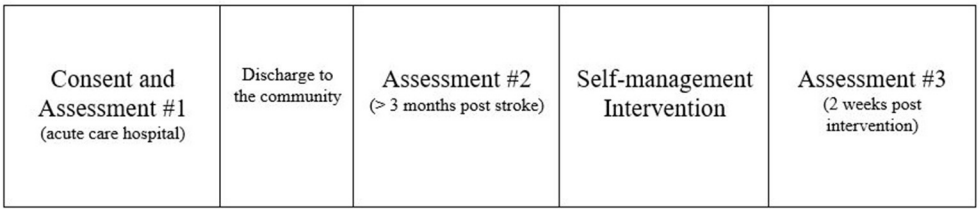

FIGURE 1 | Schematic of study design.

be over the age of 18 years. The chronic disease definition used to determine inclusion was: a medical condition that persisted more than 1 year and either requires ongoing medical attention and/or results in limitations in activities of daily living (15).

Intervention

The intervention for this study was the six-week CDSMP workshop, originally developed by Lorig et al. (4) and led by two trained CDSMP facilitators. The group sessions included six learning modules, one for each week of the workshop. Examples of the topics discussed were exercise, symptom management, nutrition, sleep and fatigue management, emotion management, communication training, health-related problem solving, and decision-making (4). This information was also published in the CDSMPBook, which was given to each participant to aid intervention delivery (16). The sessions were completed in group format one time per week and lasted ∼2 h.

Data Collection and Analysis

The principle investigator monitored the number of patients screened, eligible, approached, and enrolled as well as any study refusals, withdrawals, lost-to-follow-up, and adverse events. We used REDCap software system to obtain and store data, including demographics and assessment results. As explained above, the telephone questionnaire was used to determine personal reasons why consented participants were or were not interested in continuing the study. This information was kept in a password protected Excel file. This file was also used to collect any researcher field notes, which included comments noted verbally by patients during the intervention group sessions, and personal reflections.

The CFIR framework was incorporated to systematically define barriers as well as report strategies used to attempt to eliminate the identified barriers. The CFIR is comprised of five domains, which include: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved and the process of implementation (17). In addition, a total of 37 constructs related to the domains are indicated as either a facilitator or a barrier (17). For example, intervention characteristics is the first domain and includes constructs such as intervention source, adaptability and cost (17).

TABLE 1 | Five trial participants' demographics and characteristics.

Characteristic	Frequency
Male, *N* (%)	2 (40%)
Age, mean (SD)	58.96 (2.45)
Non-Hispanic ethnicity	5 (100%)
Race, *N* (%)	
Black or African American	2 (40%)
White	3 (60%)
Acute hospital length of stay, days (SD)	7 (2.45)
Discharge destination after acute care stay, N (%)	
Inpatient rehabilitation	1 (20%)
Home	3 (60%)
Skilled nursing facility	1 (20%)
Stroke location, N (%)	
Left stroke	3 (60%)
Right stroke	2 (40%)
Comorbidities, N (%)	
Previous stroke	1 (20%)
Hypertension	4 (80%)
Diabetes	2 (40%)
Hyperlipidemia	3 (60%)
Tobacco abuse	1 (20%)
Chronic obstructive pulmonary disease	1 (20%)
Mental illness	1 (20%)
Other	4 (80%)
Vision conditions, N (%)	
Glaucoma	1 (20%)
Cataract	1 (20%)
Visual field cut	1 (20%)
Visual acuity impairment	1 (20%)
Other vision impairment	3 (60%)

N, number; %, percentage; SD, standard deviation.

RESULTS

A total of 352 patient medical charts were screened. Fifty-nine individuals met the inclusion criteria. Despite meeting the inclusion criteria, 18 individuals were discharged from the hospital before being approached and 16 individuals declined participation at initial approach. Consent and assessments were completed for 25 people (42% of the eligible sample).

TABLE 2 | Barrier assessment by domains of the consolidated framework for implementation research (CFIR) with modifications to remove the barrier.

Construct	Barrier	Strategy/modification to remove the barrier
Domain I: Intervention characteristics		
Adaptability	• Virtual technology was not available to participants: ○ Did not have computers or tablets ○ Did not have internet	• Phone option: ○ We suggested using phones and a conference call line (modification # 1) • Study staff either traveled to the participant's homes to provide the study materials or mailed information needed for participation (modification # 2)
Complexity	• Phone option: ○ Difficult for participants to follow the content because the workshop online use/following PowerPoint slides and when it was in-person, whiteboards and posters were used ○ Also, the workshop encourages participant engagement activities such as pairing off into smaller groups for discussions	We printed out all materials so that participants would be able to follow when on the phone (modification # 3)
Cost	• We did not anticipate the study changing into the virtual format; therefore, we did not purchase iPads for each participant and therefore had to resort to the phone • Also, when we changed to the virtual format, we did not anticipate that internet was not accessible to everyone	• Study investigator reapplied for funding
Domain II: Outer setting		
Patient needs and resources	• The COVID-19 pandemic affected patients' needs and resources because everything was shut down and then then eventually required new protocols to be followed • The phone method did not appear to meet patients' needs	• We called and informed participants that all aspects of research are postponed until further notice • We notified them that they would need to re-sign the consent form that has been modified to allow virtual participation • We ended up postponing the group due to low participation
Cosmopolitanism	• The evidence-based practice intervention being implemented in this study was designed by the Stanford Chronic Disease Self-Management group. We are required to follow the protocols they set, which is an in-person, over 6 member group	• One of the facilitators attended webinars hosted by Lorig et al., which was developed to roll out the virtual format that is required to be followed by all trained group facilitators. The materials (PowerPoint) were shared online (modification # 4)
External policies and incentives	• COVID-19 pandemic led to suspending all in-person research	• We stopped in-person research and then revised our Institutional Review Board (IRB) documents to use a virtual platform, and deliver the intervention via tele-health, in order to continue the study (modification # 5) • We used REDCap to virtually complete all assessments with participants (modification # 6)
Domain III: Inner setting		
Networks and communications	• All communication was done through leadership and then via email, which could easily not be shared or was missed because there were so many new policies and procedures related to the pandemic each day	• Study staff were required to pay close attention to all news briefs being put out by the University in order to determine when they could start revising and submit the IRB • Study staff would check in with leadership routinely to determine if any communication was missed or if there were new rules to follow
Implementation climate		
Compatibility	• Change in mode of communication was initially difficult because all research materials were on the University Campus • Recruitment took place on campus at the hospital	• We used REDCap to access patient information securely until we could return to campus • We followed all hospital protocols, including obtaining personally fitted N95 masks before returning to the hospital floor

(Continued)

TABLE 2 | Continued

Domain IV: Characteristics of individuals		
Knowledge and beliefs about the intervention	• The participants did not have any knowledge about the self-management program, even after sharing information during the consent process. A few decided not to continue with the group because they did not think it would be helpful to them	• We started to provided more information about the program through printed materials as well as verbally (modification # 7)
Domain V: Process		
Construct	**Barrier**	**Strategy/modification used to remove the barrier**
Planning	• Time involved in planning all aspects of the study • Time to get the IRB approved	• Lists, strategizing, participating in webinars • Completing the IRB approval process as early as possible

Out of the 25 patients, five (20%) indicated an interest in continuing the study, completed the second assessment battery and were scheduled to participate in the six intervention sessions. There were 11 withdrawals, of which was one of the five that indicated interest after the second assessment was completed, and 10 lost-to-follow-up. The demographics and characteristics of these five participants are reported in **Table 1**.

All participants completed the first session, however did not attend session two, even after study staff attempted to engage these participants in multiple ways (e.g., email, phone calls). Because the intervention was designed to be delivered in a group format, we paused the study to determine next steps. However, it is important to note that, even before this outcome occurred, the study staff identified multiple barriers and attempted to determine strategies to address these barriers during the implementation phase. **Table 2** describes the barriers encountered using the CFIR framework and reports the attempted strategies used to remove each barrier. For example, for the construct "External Policies and Incentives" that is noted in "Domain II: Outer Setting" (**Table 2**), the related barrier is the COVID-19 pandemic and the University mandate to suspend all in-person research. In response, we modified the in-person protocol to a format that can be implemented via a virtual platform, Zoom, a HIPAA compliant telehealth-based technology. This modification required a protocol amendment that was approved by the University's Review Board. There were seven modifications made in total during the implementation up to the time when the study was paused (see **Table 2**).

In addition, the researchers field notes summarized that participants did not participate after the first session for one to two reasons. Three participants disliked using the conference call line because they could not hear the other participants well. Four participants had difficulty with following the course content on the phone using the paper copy of the PowerPoint presentation. A researcher reflection included that the pandemic was occurring at the same time this intervention was attempting to be carried out and participants appeared to be overwhelmed.

DISCUSSION

This brief report seeks to discuss modifications made during trial implementation, the barriers identified during the delivery of an evidence based, stroke-specific self-management program and minor data (including strategies made) from five participants.

The CFIR provided structure to report barriers and specific strategies and/or modifications developed to remove the barriers. This method of reporting is not new and found to be effective in a clinical research environment (17). Also our findings were similar to another study that also found virtual efforts affecting clinical research activities and outcomes (18). Here we identified barriers such as the patients' lack of access to materials needed for telehealth. Another barrier was cost. We had purchased all materials necessary to complete the in-person workshops, but not for a virtual format. In addition to the participants in the group needing technology, including internet, we also needed a budget to deliver intervention materials to the participants because the CDSMP book was continued to be endorsed as a necessary material to be used even in the virtual environment.

Out of the seven modifications, there were two that were required and instructed by the original CDSMP team in order to maintain fidelity, as the transition to remote activities was not occurring just at our institution but worldwide (18). For example, we were required to use a PowerPoint presentation as the alternative for the physical white board charts that should be used when in the classroom environment.

There were a few lessons learned during the process of addressing barriers. For example, we attempted to use a phone option to address technology barriers, however, we did not determine prior to the modification if this was an appropriate strategy for all group members. The barrier that resulted in response to this modification was that the intervention had to pause because participants could not complete the activities required of the CDSMP. Also, a research reflection was that it was difficult to not be able to see participants' and any non-verbal gestures they might be making. Therefore, engagement and group participation became difficult. Another lesson learned

was that we should have asked the participants, in real time, their opinion about the strategy being used. For example, was it appropriate? This might have helped determine new ideas or different actions to take rather than having to pause the intervention due to lack of participation.

In conclusion, this study contributes to the literature by increasing the understanding of barriers, modifications used and lessons learned, as we navigated the initiation of a type III hybrid implementation-effectiveness trial for individuals with stroke and chronic comorbidities. Telemedicine, while it can potentially overcome geographic and transportation barriers (18) that are common for people with conditions such as stroke, could bring on barriers or additional challenges, as we experienced in this study. We plan to resume the study with a new cohort, to evaluate the CSDMP program, implement strategies to the lessons we learned, as well as report clinical and implementation outcomes.

DATA AVAILABILITY STATEMENT

The datasets presented in this article are not readily available because of patient confidentiality. Requests to access the datasets should be directed to the corresponding author.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by University of Texas Medical Branch. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

KH obtained IRB approval, and ran the study, collected data, and wrote the manuscript. AN analyzed the data. RK assisted with study implementation. MS assisted with all aspects of the paper. TR determined the study design, helped with IRB approval, and wrote/edited the paper. All authors contributed to the article and approved the submitted version.

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Expanding the reach of evidence-based mental health interventions to private practice: Qualitative assessment using a policy ecology framework

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Background: Evidence-based interventions (EBIs) for mental health disorders are underutilized in routine clinical practice. Exposure therapy for anxiety disorders is one particularly difficult-to-implement EBI that has robust empirical support. Previous research has examined EBI implementation determinants in publicly funded mental health settings, but few studies have examined EBI implementation determinants in private practice settings. Private practice clinicians likely face unique barriers to implementation, including setting-specific contextual barriers to EBI use. The policy ecology framework considers broad systemic determinants, including organizational, regulatory, social, and political contexts, which are likely relevant to EBI implementation in private practice settings but have not been examined in prior research.

Methods: Qualitative interviews were conducted to assess private practice clinicians' perceptions of EBI implementation determinants using the policy ecology framework. Clinicians were asked about implementing mental health EBIs broadly and exposure therapy specifically. Mixed methods analyses compared responses from clinicians working in solo vs. group private practice and clinicians who reported high vs. low organizational support for exposure therapy.

Results: Responses highlight several barriers and facilitators to EBI implementation in private practice. Examples include determinants related to organizational support (e.g., colleagues using EBIs), payer restrictions (e.g., lack of reimbursement for longer sessions), fiscal incentives (e.g., payment for attending training), and consumer demand for EBIs. There were notable differences in barriers faced by clinicians who work in group private practices compared to those working in solo practices. Solo private practice clinicians described ways in which their practice setting limits their degree of colleague support (e.g., for consultation or exposure therapy planning), while also allowing for flexibility (e.g., in their schedules and practice location) that may not be available to clinicians in group practice.

Conclusions: Using the policy ecology framework provides a broad understanding of contextual factors that impact private practice clinicians' use of EBIs, including exposure therapy. Findings point to potential implementation strategies that may address barriers that are unique to clinicians working in private practice.

KEYWORDS

policy, mental health, implementation, determinants, private practice

Introduction

Evidence-based interventions (EBIs) are infrequently used in routine clinical care settings. Prior research has largely focused on strategies to improve the implementation of EBIs in publicly-funded mental health settings. However, less is known about the implementation of EBIs in private practice mental health settings, where there is also a research-practice gap. Private practice settings represent a large sector of the mental health workforce (1), including a plurality (44.8%) of psychologists (2), and serve a large portion of people with private insurance. Treatment access disparities are particularly wide among individuals with public insurance, but privately-insured individuals also face significant barriers to accessing care (3, 4). Estimates indicate that ∼40% of youth with private insurance do not receive needed mental health services (5, 6) and that these families face significant barriers to receiving mental health care (7, 8). The number of unmet mental health needs, especially for anxiety and depression, has only been exacerbated as a result of the COVID-19 pandemic (9). Thus, identifying strategies to increase EBI use in private practice settings may improve access to care for a large portion of individuals in need of mental health services.

Existing research in private practice settings provides some evidence that there are unique challenges to EBI implementation that may be specific to this setting. For instance, in one study, private practice clinicians were found to hold more negative global attitudes toward EBIs than those working in public outpatient settings (10). One interpretation the authors provide for this finding is that private practice clinicians may have chosen this setting to allow them more autonomy and fewer mandates related to the types of interventions they are expected to deliver. Another study, focused on evidence-based assessment, found lower rates of evidence-based assessment use among private practice clinicians compared to clinicians in other settings (11). Supervisory practices reflect these general trends, with fewer references to EBIs and less supervision time spent discussing them among clinicians working in private practice settings (12). Prior studies have not specifically examined determinants of EBI use in private practice settings, which is a necessary first step to inform future work focused on supporting EBI implementation in this setting.

One intervention that is particularly underutilized is exposure therapy for anxiety, which has strong evidence for its efficacy but is rarely used in practice settings (13). A study of private practice clinicians working in Germany found that issues related to the practicability of exposure (e.g., feasibility of conducting exposures in session), negative beliefs about exposure, and distress for the therapist in delivering exposure therapy were barriers to its delivery (14). These findings are consistent with previous research indicating that therapists' negative beliefs about exposure are a primary barrier to its delivery (15–17). Although some interventions have been developed to directly address these negative beliefs (18), insufficient access to training in exposure is another commonly endorsed barrier (19). Even when therapists do receive training, actual use of exposure remains somewhat limited (20). Receiving consultation after training is one promising method that has been shown to increase use of exposure-based treatments (21). However, therapists in private practice have been found to use sub-optimal exposure techniques, such as assigning client self-directed exposure rather than conducting exposures in session (22). This may be due to difficulty accessing ongoing consultation, or a result of various other factors such as competing demands and limited organizational support.

Existing research on determinants of EBI use more broadly have identified an array of clinician- and organization-level barriers that interfere with implementation (23–26). For instance, organizational factors, such as proficient culture, leadership, and presence of champions influence the implementation of EBIs (27). Clinician-level barriers have also been identified as predicting EBI implementation, such as competing responsibilities and lack of training (28, 29). Even when clinicians do access training, one-time or even intensive trainings are not sufficient to lead to sustainable behavior change (30–32). In addition to these clinician- and organization-level considerations, there are also even broader contextual determinants that influence EBI implementation. In their "policy ecology" framework, Raghavan et al. (33) highlight the importance of considering multiple levels of the ecology of implementation, ranging from the organizational context to the larger social context in which implementation takes place, to ensure successful implementation of EBIs. This framework incorporates factors such as incentive strategies for policymakers

and payers to improve EBI implementation. According to the policy ecology framework, efforts to sustainably implement EBIs will require implementation strategies that expand beyond clinical factors and include a focus on systemic or ecological determinants. Such determinants have been increasingly studied in public sectors [e.g. (34)], but have not been specifically examined in private practice settings.

The policy ecology framework highlights four key levels that influence implementation, including the organizational context, the agency (regulatory) context, the social context, and the political context, as shown in Figure 1. The organizational context refers to the mental health practice in which treatment is delivered, which for private practitioners may consist of one individual or a large group practice. Specific considerations within organizations include: (1) the costs of delivery that organizations accrue (e.g., for ongoing supervision), which are typically not reimbursed, as well as (2) continuing education, which is often provided through or subsidized by organizations. Policy levers at the organizational level may include adjusting state licensing boards' requirements and expectations regarding continuing education to emphasize EBIs. However, therapists who work in private practice may face financial barriers to accessing continuing education and place less of an emphasis at the organizational level on implementing new EBIs (35). For instance, in an assessment of psychologists' use of outcome measures (36), clinicians in private practice settings were more likely to use outcome measures for clinical purposes, whereas clinicians in other settings (e.g., schools, community mental health, outpatient clinics) endorsed using these measures for clinical *and* business reasons (i.e., requirements by the work setting). Understanding how contexts for private practice clinicians may differ from other settings can inform the tailoring of implementation strategies.

The second level of the policy ecology is the agency (regulatory) context, which refers to payers (i.e., insurance companies) or states. Specific considerations within this level include: (1) fiscal incentives, such as pay-for-performance and public recognition for providing EBIs; and (2) payer restrictions, such as requirements for prior authorization or limits to the number and frequency of therapy sessions. In contrast with clinicians who work in publicly-funded agencies, private practice clinicians in the United States are not required to accept insurance. This is likely to have implications for how private practice clinicians interface with payers, including having more flexibility with the decision about whether to panel with insurance companies. If payers are to have an influence on the practice of private practitioners, they will likely need to incentivize providers to accept health insurance plans *via* strategies such as higher reimbursement rates, coverage of more sessions, and reduced administrative burden.

The political context level refers to legislative and advocacy efforts that may affect EBI use. From a consumer perspective, this may include efforts related to improving accessibility and affordability of mental health treatment for consumers. In public agencies, research has examined how policy mandates related to EBI use influence clinicians' behavior. In general, policy makers are urged to avoid strict policy mandates and instead consider how to balance EBI expectations with available support from a system (33, 34). One study demonstrated modest gains in cognitive behavioral therapy use following a system-wide initiative focused on supporting EBI implementation, a finding that was moderated by organizational culture (37). Given that many policy mandates may be less applicable to private practice clinicians, especially those who do not accept insurance, other issues at the political level may have more relevance. For instance, EBI training is not consistently required during pre-service training for doctoral and master's level clinicians (38). Existing accreditation standards for graduate programs may make it challenging to prioritize EBI training (39, 40). Thus, efforts focused on changing accreditation standards and increasing the emphasis on EBI-based training in pre-service settings may be one relevant lever at the political level that could influence private practice clinicians' behavior (39).

Finally, the social context level refers to public perceptions of EBIs, especially related to stigma and discrimination, as well as consumer demand for EBIs. A systematic review of parents' perceptions of barriers and facilitators to seeking mental health treatment demonstrated that parents frequently reported a lack of knowledge about where or how to seek treatment (41). Direct-to-consumer marketing is one approach that has been proposed to address stigma and increase consumer demand for EBIs (42), which in turn may motivate private practice clinicians to provide them.

Although the levels of the policy ecology framework were originally developed with public mental health settings in mind, the present study assesses how each of its levels might also apply to private practice mental health settings. To date, incentive strategies beyond providing training and technical assistance are rarely used (43) and limited research has examined the barriers to EBI adoption in private practice settings. The present study uses the policy ecology framework (33) to assess private practice therapists' perceptions of multi-level contextual factors that influence their use of EBIs broadly, and exposure therapy specifically. Exposure therapy was selected as a specific example of an EBI given that it has been one of the most difficult to implement (13, 22). Although an array of intervention-specific clinician- and organization-level barriers to exposure implementation have been identified, there may also be opportunities to engage implementation strategies at a broader ecological level to increase adoption and sustained use of exposure therapy. The primary aim of the present study was to conduct qualitative interviews with private practice mental health clinicians to identify incentive structures that may affect EBI implementation, with a particular emphasis on exposure therapy for anxiety disorders. Mixed methods analyses were used to examine differences between therapists in solo vs.

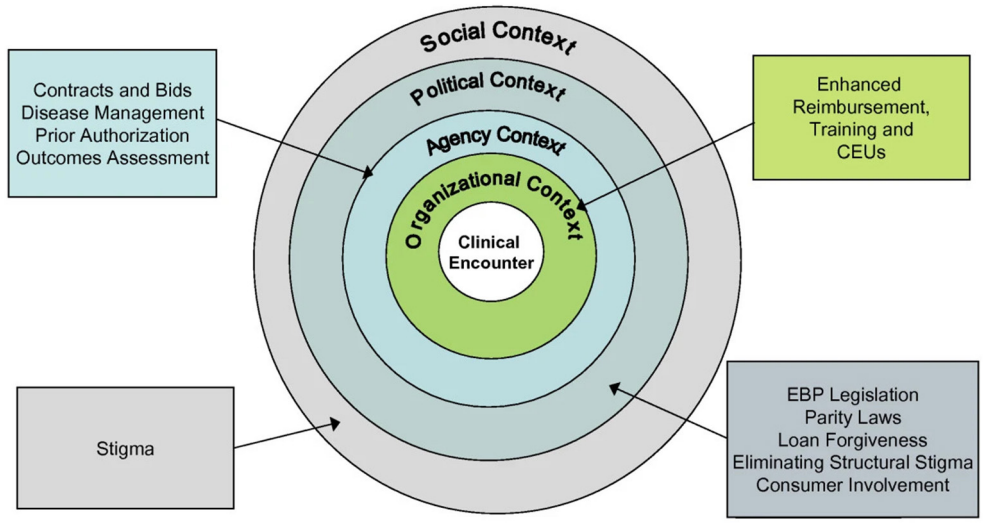

FIGURE 1
A policy ecology of implementation. Reproduced from (33); distributed under the creative commons attribution license.

group private practice settings, given that each practice structure is likely to present unique implementation considerations. In addition, we examined whether qualitative responses differed based on therapists' perceived level of organizational support for implementing exposure therapy.

Method

Participants

Participants include therapists ($N = 20$) with (1) an advanced degree in a mental health field who (2) work in private practice settings. Given that exposure therapy is a particularly difficult-to-implement EBI, we were interested in understanding responses from clinicians who had and had not sought out explicit training in exposure therapy. Thus, purposive sampling was used to identify approximately equal numbers of participants with and without previous training in exposure therapy. The final sample included $n = 9$ (45%) therapists who had previously participated in full day or longer training focused on exposure therapy and $n = 11$ (55%) who had never attended an exposure-focused training.

Measures

De-identified survey data were collected and stored using Research Electronic Data Capture (REDCap), a HIPAA compliant web-based survey platform (44, 45).

Demographics form

A demographics questionnaire assessed participants' age, gender, race, and education. It also assessed topics related to the participants' work setting, theoretical orientation, and level of familiarity with exposure therapy.

Organizational innovation-specific capacity for exposure (OISCE)

The OISCE (23) assesses therapists' perceptions of organizational policies and procedures for supporting exposure use in their clinical setting with responses rated from 0 (not at all) to 4 (extremely). The measure includes 17 items that cut across five domains of interest, including supervisory support, collaboration, organizational policies, resources, and emphasis on exposure.

Qualitative interviews

A semi-structured qualitative interview guide (see Supplementary Material) included prompts about participants' experience using EBIs in their practice, as well as their training and consultation needs for EBIs. Given that exposure therapy is a particularly underused EBI with strong evidence for its efficacy, therapists were also specifically asked about their use of and training in exposure therapy. In addition, participants were asked about barriers and facilitators to using exposure and other EBIs. Questions were developed based on the policy ecology framework (33), which includes factors at the organizational, agency, political, and social context levels.

TABLE 1 Participant demographic characteristics ($N = 20$).

Variable	*M* (*SD*) or *N* (%)
Age	46.25 (13.86)
Gender	
Female	18 (90%)
Male	2 (10%)
Race	
More than one race	1 (5%)
Southeast Asian	1 (5%)
White	18 (90%)
Ethnicity	
Hispanic or latine	0 (0%)
Not hispanic or latine	20 (100%)
Degree	
Doctorate	13 (65%)
Master's	7 (35%)
Exposure training	
Yes	9 (45%)
No	11 (55%)
Practice type	
Solo	11 (55%)
Group	9 (45%)
Professional discipline	
Clinical psychology	13 (65%)
Social work	3 (15%)
Marriage and family therapy	1 (5%)
Counseling	3 (15%)
Theoretical orientation[a]	
Cognitive behavioral	8 (40%)
Eclectic	4 (20%)
Feminist	3 (15%)
Family systems	4 (20%)
Humanistic	1 (5%)
Solution-Focused	1 (5%)
Strengths-Based	1 (5%)
Third wave	2 (10%)
Not reported	5 (25%)
Populations treated[a]	
Adults	18 (90%)
Children	13 (65%)
Couples	7 (35%)
Families	9 (45%)

[a]Participants could endorse more than one option; thus, totals are >100%.

Procedure

All study procedures were approved by the Lifespan Institutional Review Board (IRB). Participants with previous training were recruited by contacting therapists who completed prior studies at the Pediatric Anxiety Research Center (PARC) and agreed to be contacted for future research. Additional participants with and without previous training were recruited by sending emails to local (New England) professional listservs and contacting private practice clinicians on referral lists maintained at Bradley Hospital. Local private practice agencies who had publicly available contact information were also emailed and asked to distribute information about the survey to providers in their practice. Finally, participants who completed the qualitative interview were asked if they were willing to forward information about the study to their colleagues as part of a "snowball" recruitment method.

Recruitment of participants was informed by the Dillman Tailored Design Survey Method (46, 47). Initial contact included a phone call or email to potential participants, as well as two follow-up emails sent 1 week after the initial contact requesting participation in the study. Participants who indicated interest in the study were emailed a REDCap link to complete online quantitative measures prior to qualitative interviews. Then, participants were contacted to complete the qualitative interview. Our recruitment methods do not allow us to estimate how many people may have received information about the study. However, a total of 39 people initiated the survey questionnaires, and 24 of them completed the survey measures and provided their contact information. Four of those participants were either not available or did not respond to attempts to schedule the qualitative interview. All 20 participants who were scheduled for qualitative interviews completed them as scheduled. Interviews were audio recorded and conducted one-on-one with participants by phone until thematic saturation (i.e., no emergence of new concepts) (48) was reached. Completion of qualitative and quantitative measures took a total of ∼60–90 min. There was no additional follow-up with participants after completion of these interviews. Interviews were conducted by a female postdoctoral fellow (HEF) and a female advanced doctoral student who did not have previous relationships with the study participants. Participants were told that interviewers were affiliated with PARC and interested in understanding factors that affect clinicians' use of evidence-based interventions, including exposure therapy. The first author (HEF) has previous experience leading qualitative studies and provided training to the graduate student to conduct interviews. Interviews were transcribed using NVivo transcription services, checked by undergraduate research assistants, and spot checked by the first author (HEF).

Qualitative coding and data analysis

Qualitative interviews were analyzed in NVivo using content analysis (49) informed by Raghavan and colleagues' (33) policy ecology Framework. A priori codes included: (1) organizational context and its two subcodes: costs of delivery and continuing

education; (2) agency (regulatory) context and its two subcodes: fiscal incentives and payer restrictions; (3) social context; and (4) political climate. Coders included the first author (HEF) and a research assistant (LM) who received training in qualitative analysis from the first author. The coders collaboratively reviewed six transcripts to inform their iterative development of a codebook. They then independently applied codes to two transcripts to determine initial interrater reliability (*kappa* = 0.64). Finally, both coders independently coded transcripts with 20% overlap ($n = 4$ transcripts) to assess final reliability (*kappa* = 0.82). At each stage of coding, disagreements were resolved through discussion and consensus.

Thematic analysis of codes was conducted in Excel by the same authors who completed coding of transcripts (HEF and LM). Codes were examined collaboratively to identify patterns and key themes through discussion. Mixed methods analyses were used to integrate quantitative and qualitative findings using a convergent design in which quantitative and qualitative data were merged (50). Quantitative data (i.e., solo vs. group practice; high vs. low organizational support for exposure based on a median split on the OISCE) was entered into NVivo as attributes of each participant and used to categorize and compare themes among subgroups. Once exported into Excel, content analysis was used to identify themes for each code. Then, coders collaboratively created brief written summaries for each theme and for each quantitative variable (i.e., solo private practice, group private practice, high organizational support, low organizational support). These summaries were compared to identify differences in qualitative responses for each quantitative variable. All qualitative analyses adhered to consolidated criteria for reporting qualitative research (COREQ) (51).

Results

Participants were predominantly female ($n = 18$, 90%) and white ($n = 18$, 90%). The majority had doctorate degrees ($n = 13$, 65%) and worked in a solo private practice ($n = 11$, 55%). Scores on the OISCE indicated overall low levels of organizational support for exposure therapy ($M = 1.71$, $SD = 0.93$). Clinicians with high organizational support for exposure had scores above the median of 1.85, indicating responses of "somewhat" or above. See Table 1 for additional demographic information. Table 2 includes an overview of study codes, themes, and example quotes, as well as suggested implementation strategies to address barriers related to each theme.

Organizational context

Clinicians described varying levels of organizational support for EBI use. Among private practice clinicians, the "organizational context" refers to the individual practitioner, as well as the setting (e.g., geographical location, office space, proximity to colleagues) in which they work. Organizations that placed more emphasis on EBI use were described as facilitating EBI implementation. Specifically, organizations that offered EBI-consistent in-house training (e.g., through case conferences) fostered a "push for evidence-based interventions" (P1226). Many clinicians described working in organizations that support the implementation of cognitive behavioral therapy (CBT) principles while also emphasizing that "the patient's needs come first" (P1004) and that CBT should be applied flexibly. Some clinicians described their organizations as supporting EBI use conceptually, but not supporting specific aspects of EBIs (e.g., inability to hold sessions in the community or travel with clients during sessions). Supervisors were generally described as being supportive of EBI use. Similarly, clinicians endorsed that the presence of colleagues who also use EBIs can support EBI implementation.

Clinicians identified some organizational contextual factors that were specific to implementing exposure therapy. For instance, clinicians mentioned that having colleagues who understand and can help with exposure can facilitate exposure implementation. One clinician described, "when I had to do an exposure or when I've been asked to be part of an exposure, people in the office are really willing and able to be a part of that" (P1616). Clinicians also reported that space constraints affect their ability to conduct exposure work in the office. One clinician described, "I think that exposure therapy is best done if the clinician is able to go out with the person and there's more intensive therapy or if it's a home-based program. I don't feel like in private practice I would feel as comfortable" (P2605). Clinicians described that having businesses nearby that are willing to assist with exposures can facilitate the completion of exposure work outside of the office. Finally, clinicians noted that it is helpful to have knowledge of local providers who use exposure if they need to refer to a specialist, but that referral options are often limited [e.g., "There is nobody in (geographic region) who does hard core exposure stuff" (P1058)].

Mixed methods analyses

There were notable differences in descriptions of organizational support for EBI use between clinicians in solo vs. group practice. As might be expected, clinicians working in group practices more often reported that supervisor and colleague support are available to them, whereas clinicians working in solo practice hardly mentioned supervisor support for EBI use and varied more in their reports of the availability of colleagues who support EBI use. Clinicians in group practice more often mentioned that being busy (e.g., scheduling back-to-back sessions) makes it difficult to leave the office for exposure. However, as one clinician stated, "having a lot more people around, in my opinion, makes it easier to do exposure" (P2621). Clinicians working in solo practice more often described

TABLE 2 Reported barriers and facilitators and potential implementation strategies.

Code	Theme	Quotes	Implementation Strategy
Organizational context	Organizational policies that support or impede EBI use	"I think some of our higher-ups [...] they don't want us to depend on going out into the community if we don't have to" (P2037)	Adopt organizational policies that align with EBI implementation processes
	Supervisor support for or knowledge of EBIs	"I can imagine that in a group practice, unless it's an OCD group practice, I think people would have a hard time with [exposures that involved things like] smoke bombs, knives, gagging, sticking yourself with a straight pin that has been sterilized" (P8010)	Offer EBI training that is tailored specifically for supervisors
	Colleague support for or knowledge of EBIs	"When I had to do an exposure or when I've been asked to be part of an exposure, people in the office are really willing and able to be a part of that. That's obviously super helpful. Front office staff will even get involved" (P1616)	Support the development of peer consultation groups
Continuing education	Availability of consultation	"What I pick up in the workshop is the extent of what I learn. Or similarly, I went to a national training—a two day ACT training—and it was super interesting. But again, I have no ongoing supervision or education beyond my peer consultation groups" (P1613)	Provide supervisor consultation and/or facilitate peer consultation
		"When I was a postdoc, we had formal group supervision, which I loved. And then when I became a psychologist… you don't do it anymore" (P1616)	Encourage licensing board to allow for receiving consultation to count toward required CEUs
	Access to online resources	"Google Scholar can be overwhelming and unhelpful… especially if you don't have access to all the journal articles. If you're not in like a university setting"	Develop and distribute routinely updated educational materials such as online toolkits
	Compensation for training	"The hard thing with training, like you're both not getting paid for the time and you're paying [to receive the training]" (P3004)	Compensate clinicians for lost billable hours to attend training in EBIs (potentially with free CEUs)
Cost of delivery	Compensation for collateral contact and preparation time	"I feel like from a clinical perspective, there's not much incentive for clinicians to do exposure exercises outside the office. Which can be pretty limiting" (P1226)	Create a Decision flowchart to help prioritize session preparation and collateral contact
		"… We're like teachers and we prep and we have worksheets. Every client, I have to remember where I am in the protocol and what's next?" (8010)	
	Availability of supplies and exposure stimuli	"If you need the client to meet you at Wal-Mart [for an exposure], then do they need a cab voucher or is that something we can provide for them?: Do we need to set up people who are gonna ask them questions [for exposures]?" (P4025)	Allot funds for buying supplies Provide list of key supplies for exposures/EBIs
Agency (regulatory) context			
Payer restrictions	Ability to bill for longer and/or more frequent sessions	"I only take [Insurance Company name]. I used to take a wider range of insurances. [Now,] I take [only one Insurance Company] and I do sliding scale. I don't like people telling me what I can do" (P1526)	Create billable codes that permit longer and/or more frequent sessions for EBIs that have documented evidence of their benefits

(Continued)

TABLE 2 Continued

Code	Theme	Quotes	Implementation Strategy
		"A lot of the insurances... you really have to fight for more than a 45 minute session… So I just do 55 minute sessions anyway… So I just don't get paid for those" (P2804)	
	Payer knowledge about EBIs	"I can [bill for a longer session], but I know that I'm going to have an hour of my time wasted for a care management call with a person who doesn't even know what I'm talking about when I list the evidence-based treatments" (P8010)	Provide education to care managers about EBIs
	Cost to families	"If there was some sort of parent session that was supposed to coincide with the parent session, they would be like "oh can we just do it right after?" I [would say], "Yeah, but insurance isn't going to pay for that." So, then what? That's not fair to the family when time wise that would be the most feasible" (P2037)	Reduce cost of families Reduce discrepancies in reimbursement rates across different insurance companies and plans Increase transparency about reimbursement rates
Fiscal incentives	Training incentives	"Once you're a licensed clinician and you make a decent amount of money, it's so much easier to bill people than to do things where you're not getting paid. Or you'll have to pay money" (P1226)	Insurance companies recognize and label providers who are certified or have specialized training in EBIs
	Reimbursement for EBI use	"Well, I think everyone wants to be paid more, but my feeling is that if you're practicing, a licensed practitioner, you need to be using evidence-based practices" (P4610) "Oh, well, paying me more would be really motivating. Yes. I mean, if I could even if I could easily get paid for like the extra planning time or anything like that. That would be great" (P2804)	Insurance companies reimburse training in EBIs Provide enhanced rate of compensation for EBI use
Political context	None	N/A	N/A
Social context	Consumer education in EBIs	"Yeah, I know it's hard because a lot of clients don't know necessarily to come in and ask for exposure" (P3004)	Partner with community organizations and providers (e.g., primary care physicians) to provide education that meets communities' mental health education needs
		"I would guess-timate 15–20% [of clients] may know about evidence-based practice" (P4610)	Partner with patient advocates to provide education about EBIs
	Consumer demand for EBIs	"Some people come in and [exposure] is what they want. So that makes it easy" (P1616)	Use tailored marketing strategies to promote EBIs directly to consumers

leaving the office to meet with clients, although they still cited some barriers and restrictions. One clinician in solo practice mentioned that not having other clinicians in the office is a barrier to the completion of social exposures. Although they navigate around this by identifying social exposures that can be completed with just the clinician and the patient, they said, "it would be great to have other people, unfamiliar people, that [the patient] could interact with" (P4610).

There were also differences in descriptions of organizational support for EBI use for clinicians with high and low organizational support. Clinicians with high organizational support provided examples of the ways in which their

organization supported EBI use, including providing "in-house" continuing education and consultation on EBIs, as described in more detail below. Few such examples were given by clinicians with low organizational support. Clinicians with high organizational support noted the importance of supervisors for support and education in EBIs, whereas clinicians with low organizational support did not often discuss the role of supervisor support in EBI implementation. Clinicians with high organizational support spoke about how their colleagues give "a lot of feedback that is often guided by research or something people have done in their own practice" (P1226). They also described having colleagues to help with in-office exposures. In contrast, clinicians with low organizational support spoke about their setting feeling like "you're just here on an island" (P2605).

Continuing education

Clinicians described that the availability of organization-sponsored training (e.g., refresher courses on certain topics) would be helpful to facilitate EBI implementation. Clinicians described that having training "in-house" would facilitate training attendance, and that attending training with colleagues would facilitate group discussion after training. On the other hand, clinicians noted that informal training through case discussions within their practice may not be as helpful as formal trainings. One clinician described, "I would probably [want] a little more formal than what my practice is doing now in terms of training. I don't mind case conferences, but honestly, I don't always go" (P2621). The same clinician described that informal training is "helpful to some degree," (P2621) but may be less effective if the group is too large or more focused on "brainstorming" (P2621) rather than concrete suggestions. Clinicians indicated that compensation for attending training would facilitate training attendance and subsequent EBI implementation; they described that the cost of getting training includes both the actual cost of the workshop, as well as the lost income from not seeing patients during that time. Clinicians also said that receiving compensation in the form of continuing education units (CEUs) would facilitate training attendance. Clinicians highlighted the value of consultation to support ongoing EBI implementation after training. They described that it is easy to forget training content over time, and that isolated training workshops are often not sufficient to sustain EBI implementation without ongoing consultation. Clinicians indicated that both peer and expert consultation can be helpful, and that it is valuable to hear a diversity of perspectives through consultation.

Clinicians cited various sources through which they receive training. One common example was state-wide, discipline-specific organizations such as the Rhode Island Psychological Association as well as national organizations such as Anxiety and Depression Association of America (ADAA). Clinicians reported that training resources from professional organizations can be helpful, although the cost can be a barrier. Clinicians described online resources as a lower-cost (or no-cost) way of seeking training and continuing education, including professional mailing lists, listservs, special interest groups, Google Scholar, and Facebook groups. These resources were described as helpful to support EBI implementation, particularly when a clinician has a question about a specific clinical topic. Lastly, clinicians noted that being affiliated with an academic institution (e.g., as an adjunct professor) provides access to additional resources such as journal articles, training, and grand rounds that can facilitate continuing education and EBI implementation.

Mixed methods analyses

There were some differences in descriptions of continuing education between clinicians in solo vs. group practice. On one hand, clinicians in group practice reported that the presence of other clinicians made it more likely that they could find someone who could provide consultation. On the other hand, scheduling conflicts and busy schedules ("we joke we're passing ships in the night;" P6303) were described as practical barriers to receiving consultation from colleagues in group practice. Clinicians in solo practice cited specific professional organizations they have joined and specific conferences they have attended. For instance, one solo practice clinician described, "I joined… ADAA and I just started being very alert to opportunities" (P1058). Clinicians in both groups described being aware of training resources, but those in solo practice described more actively using resources outside of their organization. In terms of differences by level of organizational support, clinicians with high organizational support reported finding consultation that was helpful—even if it was outside of their organization ["In [name of professional group], we have a good amount of people you can always consult with" (P8907)]. In contrast, clinicians with low organizational support reported more mixed success in finding helpful consultation, as indicated by statements such as, "there are definitely times when I go, 'hmm I wish there was someone I could run this by'" (P4610).

Costs of delivery

In addition to the financial considerations related to payer restrictions, clinicians cited costs associated with EBI delivery. Clinicians described that collateral contact with clients, insurance companies, other providers, and hospitals can occupy a lot of time that clinicians are spending unpaid. Clinicians mentioned that they try to avoid collateral contact when possible (e.g., by not having an office phone), but that some collateral contact is unavoidable. Clinicians also highlighted that preparing before a session requires time and effort that is unpaid. Clinicians cited supplies (e.g., rewards for children) as a cost that they incur without reimbursement, and that having supplies available and/or reimbursement for supplies would

be helpful. Clinicians specifically described that conducting exposure in session requires additional preparation time, session time, materials, and ability to leave the office. One clinician said, "In order to use [exposure], there's a ton of prep work that goes into it" (P2605).

Mixed methods analyses

There were few differences in descriptions of cost of delivery between clinicians working in solo vs. group practice. Clinicians working in solo practice and clinicians with low organizational support mentioned wanting reimbursement for preparation time, as indicated with comments such as, "Money for planning time would change my behavior in that I would probably [treat] more children… because they're harder to plan for" (P2804). In contrast, clinicians in group practice or with high organizational support rarely mentioned this. Similarly, clinicians with low organizational support mentioned the cost of purchasing supplies ["I end up going out and buying things for kids (like) toys and prizes and all that" (P2804)], whereas no clinicians with high organizational support mentioned this.

Agency (regulatory) context

Payer restrictions

Clinicians described that payers generally want providers to use EBIs, particularly CBT. Respondents noted frustration that payers may prioritize the delivery of intervention components over allocating session time to build rapport. They reported that payers rarely provide reimbursement for longer (e.g., 60- to 90-min) or more frequent sessions, even though "45 min is not sufficient time" (P1226). Clinicians described that longer session time would be especially valuable for child patients and for conducting exposures in session. Clinicians indicated that they often opt to schedule clients back-to-back in order to maximize profit. They described variability in the amount of reimbursement provided by different payers, such that clinicians are less inclined to accept certain insurance providers who reimburse less for the same service. One clinician said that she only takes one insurance and "a sliding scale" (P1526). Clinicians also mentioned occasionally seeking certification in order to "re-negotiate reimbursement with insurance companies" (P8907). Lastly, clinicians indicated that high health insurance copays and deductibles are a barrier to families' treatment access.

Mixed methods analyses

There were no differences in descriptions of payer restrictions between clinicians who reported high vs. low organizational support; however, there were several differences between solo vs. group practice. Clinicians working in solo practice mentioned the administrative burden of dealing with insurance companies (e.g., authorization procedures, potential audits), which was not mentioned by clinicians working in group practice. Clinicians in solo practice also talked in detail about billing codes and dollar amounts from different insurance companies [e.g., "Insurance company name]'s low payment is a barrier… Even for a 90837 (billing code), it's significantly lower (than other companies)" (P1058)]. This topic was not discussed by clinicians working in group practice. Clinicians in solo practice made comments about what insurance companies want them to be doing (e.g., which billing codes to use, regulations related to frequency and duration of sessions) and more often indicated that they interpreted the billing guidelines more flexibility (e.g., billing for an in-office session even if part of the session took place in the community). Clinicians in group practice did not make comments about specific payers (e.g., which companies reimburse for what billing codes), but indicated an understanding of broad limitations of billing [e.g., "Insurance companies don't reimburse me for me to travel to (the client's) house and travel back" (P1226)].

Fiscal incentives

Clinicians described fiscal incentives that may incentivize EBI implementation. Clinicians had varied opinions about whether increased payment to deliver EBIs compared to other interventions would motivate them to implement EBIs; some clinicians reported that increased pay would motivate EBI use, whereas others said that they would use EBIs regardless of pay rate. Clinicians noted that payment for training would incentivize EBI use, given that cost is a barrier to attending training and that time spent in training is time spent not seeing clients. One clinician explained, "What complicates this is this kind of fee-for-service insurance-based care. Time is money. So every hour spent in a case conference or in a training session or whatever it may be is an hour less of a clinician seeing a patient" (P2621). Clinicians also mentioned that certification may in some cases incentivize training attendance. Some clinicians described that certification can provide specialized training, allow for opportunities to become a supervisor, and increase referrals to their practice, whereas others described that certification is not necessary in order to achieve specialized training, may be overly rigid and expensive, and may limit the type of referrals a provider receives. Clinicians reported that receiving CEUs is necessary but is not a primary motivator for how and why clinicians opt to attend training.

Mixed methods analyses

There were some differences in descriptions of fiscal incentives between clinicians working in solo vs. group practice, but no differences between clinicians with high vs. low organizational support. Clinicians working in solo practice indicated that they might be responsive to fiscal incentives (e.g., being compensated by insurance payers at a higher rate). For instance, one clinician said, "We live in a world that is monetized, so definitely increasing payment would [motivate

me to use EBIs]" (P8907). In contrast, clinicians working in group practice made statements suggesting that they use EBIs regardless of fiscal incentives, such as, "If insurance would pay an extra 10 dollars per session for using motivational interviewing or something. No, I don't care about that" (P2605). Lastly, clinicians working in solo practice discussed various benefits and limitations of certification, whereas only one group practice clinician mentioned certification and said that it did not affect their practice.

Social context

Responses related to social context included several themes, including consumer beliefs and education about EBIs, consumer demand for EBIs, and consumer reactions to EBIs presented in treatment. Clinicians noted that certain geographical locations may affect beliefs about certain interventions. For example, one clinician noted, "The whole town is crazy about internal family systems treatment" (P1058). Related to this, consumer demand for EBIs was described as variable and guided by clients' understanding about EBIs. Clinicians noted that consumers who are educated about EBIs may be more likely to request them in treatment, which may increase the likelihood that a clinician will implement them. On the other hand, many clinicians noted that families who do their own research may "come in… with some notions [about EBIs] that are accurate and some that are not" (P4610). Lastly, clinicians described that clients have mixed reactions to EBIs introduced in treatment. Some clients have positive reactions to research-based treatment "because people like to hear that things are going to work" (P6303), whereas others "might not be receptive or compliant to the treatment" (P1226) or may be "extremely resistant" (P8907) if they "just need like an open ended session and they just need to vent or they don't want the therapy to feel as formal as maybe it could be" (P1004). Clinicians described that getting client buy-in for EBIs can be difficult and noted the importance of tailoring the EBI to the individual for this reason.

Clinicians noted that consumers' understanding of and familiarity with exposure therapy varied, such that some clients "do their own research before coming in" (P4610) whereas others "don't necessarily know to come in and ask for exposure" (P3004). One clinician said, "I think the biggest problem that I encounter is that people are not compliant with it. Like people don't want to do it because it is too scary… but when we explain the rationale of these interventions to patients or clients, it makes perfect sense to them" (P1226).

Mixed methods analyses

There were minimal differences in perceptions of social context affecting EBI implementation for therapists in solo vs. group practice. Clinicians in group practice talked slightly more often about using psychoeducation to build client buy-in to EBIs. Differences by level of organizational support were also minimal. Clinicians with high organizational support more consistently described having clients ask them for certain types of treatment [e.g., "Some people come in and [exposure] is what they want" (P1616)]. Clinicians with low organizational support had more mixed views on whether people ask for certain types of treatment. For instance, one clinician said, "I think some adults … have done their homework and have heard that [CBT] is a recommended treatment modality for what they're coming for. But most of them are not [asking for CBT] because I see a lot of kids and teenagers" (P6303).

Political climate

No participants made comments about the ways in which current or past political climates have influenced their use of EBIs, including exposure.

Discussion

This study examined an understudied area of implementation research by focusing on implementation determinants in private practice mental health settings guided by the policy ecology framework. Results from this study will inform future efforts to implement EBIs in private practice settings, where a large proportion of individuals seek mental health treatment. Responses from qualitative interviews highlighted the unique considerations for this setting and potential ways to tailor implementation strategies to increase clinicians' use of EBIs, including exposure therapy. Findings demonstrate how broadening our assessment of determinants by using a policy ecology framework may also inform future implementation strategies. Specifically, findings highlight the importance of tailoring implementation strategies to address organizational, agency, and social factors specific to private practice to increase EBI implementation in this setting. Participants did not specifically identify ways in which the political context, including state or federal policies, influenced their use of EBIs; however, political-level changes would likely influence some of the themes that were described by clinicians. Mixed methods analyses identified how EBI determinants may differ for solo vs. group private practice, as well as for organizations with high vs. low organizational support. Potential implementation strategies that address these policy ecology-informed determinants are discussed below and presented in Table 2.

Given evidence that organizational culture influences EBI implementation across various healthcare settings (27), we were particularly interested in understanding how organizational context functioned as a determinant of EBI implementation

in private practice settings. Studies of organizational culture and climate typically differentiate between individual and organizational levels of analysis (52). However, there are many private practice organizations that consist of only one individual. Thus, we sought to examine how individuals in such settings describe their organizational context and its influence on their EBI use. The range of responses about the level of organizational support for exposure (OISCE scores) among solo private practice clinicians (*range* = 0.00–3.06) highlights the fact that there are differences in organizational constructs even across settings that are comprised of one individual. Although it is possible that these variations reflect individual differences, they likely also reflect the larger context in which clinicians work (i.e., geographical setting, theoretical orientation of colleagues, funding structure). An example of an organizational characteristic more commonly noted by clinicians working in solo private practice organizations was that flexibility within their work setting may facilitate EBI implementation. For instance, they described having more control over their schedules and the location in which they deliver services. They also endorsed more flexibility in terms of treatment delivery, such as being able to meet clients in the community for sessions. In contrast to this, clinicians working in group private practice described having access to resources that are, by definition, not available in solo practice, such as colleagues to discuss cases with and staff who manage billing. Clinicians working in solo private practice offered ideas for implementation strategies that might address some of the barriers specific to this setting, such as building peer networks and forming external peer consultation groups to supplement the lack of colleague support. Future studies using social network analysis of clinicians in private practice may provide insights into how this is currently happening or ways in which existing networks could be enhanced to support peer consultation groups across providers (53).

For clinicians in both solo and group practice settings, there was variability in reports of organizational support for exposure implementation, which likely influences clinicians' perceptions of and use of EBIs (54). Overall, quantitative scores on the measure of organizational support for exposure (OISCE) in this sample were consistent with community settings (M = 1.21, SD = 0.86) and lower than anxiety specialty clinics [M = 3.62; SD = 0.34; (52)]. These relatively low scores suggest that existing organizational supports may be inadequate to support exposure implementation for many private practice clinicians. Consistent with the organizational factors expected to support exposure implementation (23), clinicians in practices with high organizational support described having more access to EBI training, as well as supervisory and colleague support for discussing cases. Improving access to training is likely to address multiple barriers, including: (1) increasing knowledge and (2) addressing misconceptions/beliefs about exposures that may interfere with their use (22). Group practices may benefit from ensuring that opportunities for training incorporate supervisors, consistent with recommendations from previous research [e.g., (55)]. This is likely to be more challenging for solo practices in which supervisors are unlikely to be present. As noted above, an alternative might be to create peer networks of expertise to connect clinicians across solo practices who aim to deliver EBIs. Evidence suggests that the presence of colleague or supervisor support for implementing EBIs may increase EBI use, even for clinicians who do not directly participate in EBI implementation initiatives (37). This further highlights the importance of fostering organizational cultures that support EBIs, which may look different for private practice compared to publicly-funded mental health settings.

Notably, even organizations that were described as supporting EBI use conceptually did not provide all of the necessary resources for clinicians to deliver them. Specifically, clinicians described organizational policies that restricted their ability to hold longer sessions or meet clients in the community to conduct exposures. Thus, organizations that are interested in implementing and sustaining EBI use may benefit from a regular review of organizational policies to ensure that they align with expectations that EBIs are prioritized. However, many organizational determinants stem from barriers that were identified at the agency or regulatory level, as discussed in more detail below. Even if organizations adopt policies that support EBI implementation, such as allowing clinicians to leave the office for therapy sessions or to travel with clients in the community, payer restrictions may interfere. Clinicians highlighted how factors such as the inability to bill insurance companies for longer sessions or for sessions conducted outside of the office can make it particularly challenging to implement EBIs, a common concern identified in previous research on implementation of exposure therapy (24). Creation of billing codes that permit travel and longer session lengths would likely address these barriers. This may be particularly warranted given growing evidence supporting home-based delivery of EBIs such as exposure (56–58). Providing increased education to care managers about EBIs may also facilitate the creation of such billing codes.

In this vein, responses related to the agency-context (i.e., payer restrictions and fiscal incentives) indicated that clinicians working in private practice may be disincentivized from engaging in activities for which they are not reimbursed. Clinicians described having difficulty attending training in EBIs, providing collateral contact, and conducting long enough sessions to meet clients' needs. Clinicians working in solo private practice also described being disincentivized from accepting insurance given variable or poor rates of reimbursement and the administrative burden of doing so (59). These findings are largely consistent with previous research examining EBI implementation determinants in other routine mental health care settings. For instance, Okamura et al. (60) found that EBI delivery in public sector mental health settings can incur

significant costs to therapists and organizations, which may serve to disincentivize implementation. The same is likely true of EBI use in private practice settings, especially given that private practice organizations do not receive public sector financial support. Costs associated with EBI implementation were also found to vary by intervention (61), which is consistent with our finding that exposure therapy has unique challenges to its implementation. Overall, respondents in this study indicated a strong desire for compensation for services they are already providing (e.g., collateral contact), but varied in their reports of whether compensation could motivate them to change their current practice and incorporate new EBIs.

Efforts to reduce discrepancies in reimbursement across insurance providers and compensate clinicians for training and for clinical services they are already providing (e.g., collateral contact) is one potential method to increase EBI use. Previous research examining stakeholder preferences related to implementation strategies has demonstrated that stakeholders across several groups (i.e., clinicians, supervisors, agency executives, payers) agree that financial incentives are the most useful category of implementation strategies (61, 62). In terms of specific financial incentives, payers would prefer to provide compensation for EBI delivery rather than preparation time (61). Providing an enhanced reimbursement rate for EBI use compared to other interventions may serve to encourage EBI implementation for some clinicians. However, in past research and in the current study, clinicians also identified a strong desire to be compensated for EBI preparation time and training, which has been rated as a less preferred option by payers (61). A potential lower-cost alternative to compensation for preparation time that might facilitate EBI implementation would be to allot funding for therapy supplies. This might be a more feasible incentive that payers could offer to support clinicians in implementing EBIs. Alternatively, the creation and dissemination of freely available and easily accessible (e.g., online) toolkits that incorporate active components, such as reminders, have been shown to support the implementation of EBIs [e.g., (63)]. Furthermore, advocates of "digital apothecaries," or online repositories for digital interventions (e.g., websites, mobile apps, digital tools) suggest that such resources may be particularly helpful for supporting private practice clinicians and their clients in using EBIs (64). Future implementation research should examine whether tailored online toolkits and digital apothecaries reduce barriers to EBI use and defray costs related to supplies. It is also worth noting that many clinicians mentioned that physical supplies are necessary when working with children (e.g., toys, games, prizes). In a group practice, it might be feasible for clinicians to pool funds for shared supplies. However, in solo practice this may be more challenging. Future implementation research should examine whether stakeholder preferences for financial incentives lead to meaningful behavior change, and whether lower-cost interventions such as providing supplies are effective at changing behavior or maintaining use of EBIs in private practice settings.

In addition to organizational- and agency-level factors, social context was also described as a determinant of EBI implementation. Specifically, clinicians reported that they may be more likely to implement EBIs if patients request them or respond positively to their introduction in treatment. This is consistent with prior research indicating that concerns about patient and caregiver reactions to an EBI (exposure therapy) are a common barrier to implementation (22). Consumer demand for and reaction to EBIs may be influenced by consumer education, geographical location, and culture. Respondents suggested that some patients may respond more negatively to exposure therapy compared to other EBIs. These findings are consistent with existing literature suggesting the need for additional efforts to increase consumer education about and demand for EBIs, including exposure therapy. Direct-to-consumer marketing strategies (42) aimed at increasing consumer demand for EBIs may incentivize more clinicians to use EBIs. Importantly, such marketing strategies may be most effective if tailored to specific subgroups of consumers (65). Thus, continued efforts are needed to examine how such direct-to-consumer marketing strategies should be tailored to consumers receiving services in public vs. private practice mental health settings.

Although clinicians were asked about determinants at the political level of the policy ecology, there were no themes that emerged in this category. One possibility is that considerations related to legislation were perceived by clinicians as too distal to have a direct influence on their behavior. Responses tended to focus on more proximal determinants of clinicians' use of EBIs in their current setting, such as the types of referrals they receive and the geographical location in which they work. While some participants mentioned whether their graduate training emphasized EBIs, they did not describe how this might be linked to political or administrative issues, such as accrediting requirements. Another possible explanation for the lack of findings in this domain is that private practice clinicians perceived the political context as being less relevant to their practice given their decision to operate in private practice settings; they may have selected this setting for its decreased regulatory requirements compared to publicly-funded mental health settings. More focused inquiry into how specific political issues, such pre-service training, loan forgiveness programs, and mental health parity might affect private practice clinicians should be the focus of future research.

The recommendations generated from our findings are a first step toward increasing EBI use in private practice settings. A key strength of this study is the application of an existing implementation framework (i.e., policy ecology framework) to a novel context (i.e., private practice mental health). Given the proliferation of implementation frameworks, applying existing frameworks to new contexts has been identified as a priority

for implementation research (66). Additional methodological strengths of this study include the use of purposive sampling to recruit clinicians with and without training in a difficult-to-implement EBI, exposure therapy. Similarly, the inclusion of clinicians working in different types of private practice settings (i.e., solo vs. group private practice) provides insight into EBI implementation in a range of settings in which clinicians might work.

Results should also be interpreted in the context of limitations. The small sample size and lack of ethnic and racial diversity of participants included in this study may limit the generalizability of the study's results. In particular, there are likely to be barriers faced by clinicians of color and their patients that may not be reflected in findings, such as the role of racial discrimination and bias, the need for resources in other languages, and other systemic considerations not represented in these results. Participants included in this study were clinicians located in New England, where clinical practice may differ from other geographical regions. For example, clinicians working in private practice in New England may accept public insurance, which differs from other regions of the United States. Additionally, all clinicians included were those who were willing to participate in a research study, and many had previously participated in a clinician training research study conducted by the same organization. Willingness to participate in a research study may suggest that these clinicians are open to research more broadly and may hold more positive attitudes toward EBIs than clinicians who are unwilling to participate in a research study. In addition, this study did not measure actual EBI or exposure use in clinicians' routine clinical practice. Future research should quantitatively assess whether the identified implementation determinants influence clinicians' EBI use. Finally, limited information was collected on the exact nature of previous training in exposure therapy, and clinicians likely varied widely in the amount of training they have previously received in EBIs.

Despite its limitations, this study provides novel information about the multi-level factors that influence the implementation of EBIs in private practice and supports the use of a policy ecology framework to inform the generation of setting-specific implementation strategies. Respondents in this study cited various organizational, agency-related, and social barriers to the implementation of EBIs in routine clinical practice, which informed suggestions for implementation strategies that may address these barriers. Future research should examine the feasibility, acceptability, and effectiveness of the suggested implementation strategies to increase EBI use in private practice. Future research should also examine the cumulative effects of multiple implementation strategies to target different ecological levels and maximize the likelihood of EBI implementation.

Data availability statement

The datasets presented in this article are not readily available due to the sensitive and potentially identifiable nature of interview transcript data. Requests to access the datasets should be directed to HF, hannah_frank@brown.edu.

Ethics statement

The studies involving human participants were reviewed and approved by Lifespan Institutional Review Board. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Author contributions

HF conceived of and designed the research study, acquired and analyzed the data, interpreted the data, drafted the manuscript, and substantially revised it. LM analyzed and interpreted the data and drafted sections of the manuscript. JF and KB helped conceive of and design the research study and substantially revised the manuscript. All authors approved the submitted version, have agreed to be accountable for the contributions, and attest to the accuracy and integrity of the work, even aspects for which the authors were not personally involved.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2022.892294/full#supplementary-material

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Mobile phone-based lifestyle support for families with young children in primary health care (MINISTOP 2.0): Exploring behavioral change determinants for implementation using the COM-B model

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Background: Obesity in childhood is a public health concern worldwide and mobile phone-based interventions (mHealth) has shown to facilitate obesity prevention. However, more research is needed on the implementation of digital tools in routine primary care. This study explored behavior change determinants for implementing a health promotion mHealth intervention (MINISTOP 2.0 app) targeting parents of 4-year-olds.

Methods: Secondary data from telephone interviews ($n = 15$) with child health care nurses working within primary child healthcare in Sweden was analyzed using directed content analysis and the COM-B model.

Results: Barriers for implementation included: limited knowledge about using technology and reservations about how and to what extent parents would use mHealth. Potential facilitators included nurses' openness to learn and try new tools, confidence in their role and engagement in reaching parents as well as beliefs that the app could improve practice by prompting dialogue and being a shared platform. Nurses expressed a strong professional identity and shared understanding of their practice, mechanisms that could potentially inhibit or facilitate implementation.

Conclusions: Findings suggest cautious optimism regarding implementing mobile phone-based tools in child primary healthcare in terms of capability, opportunity and motivation among stakeholders. Implementation strategies such as educational outreach visits and making the intervention testable among stakeholders could further facilitate implementation in this clinical context. However, more research is needed on behavior change determinants in different stages of real-world implementation.

KEYWORDS

implementation science (MeSH), implementation theory and research, primary healthcare, qualitative research, mobile Health (mHealth)

Introduction

Obesity in childhood is a public health concern worldwide. According to recent figures, around 38 million children under the age of five are overweight or obese (1, 2). Sweden also shows relatively high prevalence with ∼10–15% of 4-year-olds being classified as having overweight and obesity (3). Child primary health care is a key setting for obesity prevention through its reach among diverse populations and regular health visits throughout childhood from birth to school-age (4, 5). However, there are studies showing the complexity in implementing obesity prevention in routine child health care, primarily due to difficulties in getting parents on board (6–8), but also due to limited resources in health care organizations (9). Mobile phone-based interventions (so called mHealth) could facilitate obesity prevention in routine care through for example mobile applications aiming to promote healthy lifestyles among children and their families. mHealth in the area of health promotion have shown promising results on body weight and body mass index (10) as well as physical activity, smoking cessation and eating habits (10–15) and quality of care (16).

Although mHealth interventions could facilitate obesity prevention, it is unclear how these relatively novel tools can be implemented in daily routines and which determinants influence the adoption of mHealth tools in healthcare long-term (17). A systematic review showed that the most common barriers to implementing digital tools in routine healthcare were poor compatibility between the new tool and current workflow, unclear evidence of the technology, and poor organizational readiness to implement digital tools (18). A recent review on why health care professionals implement mHealth tools noted both technical aspects as well as social and organizational factors, such as the importance of ease of use, trustworthiness of the content and technical support, leadership support, peer influence and costs (17). However, the review had its focus on the implementation of mHealth targeting health services and care professionals, rather than patients per se.

Implementing mHealth in routine care can be understood as clinical behavior change e.g., child health care nurses recommend or use a mobile application during health visits. The Theoretical Domains Framework (TDF) and the COM-B model (19, 20) has been widely used in research to understand determinants of implementation in terms of behavior change. For example, the COM-B model (20) has been used to explore determinants of health behavior change among patient populations (21, 22) as well as to investigate barriers and facilitators for evidence based practice in healthcare (23). The TDF synthesize theories and constructs from 33 behavior change theories into 14 domains, argued to generate behavior. The COM-B model further consolidates these 14 domains into three overarching domains representing aspects that are argued to have to be present for a behavior to take place: "capability," that is, an individual's capacity and competency to engage in a behavior; "opportunity," which includes environmental factors that influence behaviors such as social support; and "motivation," which refers to the willingness to engage in a behavior including both conscious and subconscious processes (Table 1 for a complete list of COM-B domains and TDF constructs). In summary, although mHealth can be promising tools to facilitate obesity prevention and promote healthy behaviors among families, more knowledge is needed on how mHealth can be incorporated in routine practice. Investigating behavioral determinants among nurses for using mHealth is a critical first step in understanding mHealth implementation of family-facing mHealth technology.

The mHealth intervention "MINISTOP" is a mobile application that was initially developed targeting parents of 4-year-olds. The app ultimately aimed to reduce the prevalence of overweight and obesity by giving support to improve diet and physical activity (MINISTOP 1.0 app). The app showed promising results on dietary and activity behaviors in a randomized controlled trial (OR: 2.0; 95% CI 1.2–3.1; $p = 0.008$) (24, 25). MINISTOP 1.0 has thereafter been refined and modified to be used within Swedish primary child healthcare targeting parents of 2–3-year-olds [MINISTOP 2.0 app (26)].

Aim

To explore behavior change determinants for implementing a mHealth intervention (MINISTOP 2.0 app) for family nursing practice in primary healthcare.

Methods

Study design and setting

This study is a qualitative interview study with registered nurses working in child primary health care Secondary data (27, 28) from semi-structured interviews was analyzed using directed content analysis (29) and the COM-B model (20). The study is part of a larger research project aiming to develop and evaluate the effect of a mHealth intervention on health behavior change among parents of children aged 2–3 years [MINISTOP 2.0 trial (26)]. As part of the development of the app, interviews with nurses and parents were conducted and secondary data from interviews with nurses were used in this study. The app provides a 6-month behavior change program and includes the following features: information and practical tips provided in 13 themes with one theme released every 2 weeks (e.g., healthy snacks, fruits and vegetables, physical activity and screen time, food as rewards), a registration feature where parents can report their child's intake of fruits and vegetables, sweet drinks, physical activity and screen time and a library of healthy recipes and tips for physical activity indoor and outdoor. The parents also

TABLE 1 Key findings on the inductively generated themes within each domain (capability, opportunity and motivation domains) (20), describing the role that each theoretical domain plays both regarding current health promotion work in primary child healthcare practice and implementing mHealth.

Capability	
Psychological capability	*Knowledge* • Knowledge related to research evidence e.g., nutrition and health • Practice-based knowledge e.g., national guidelines • Tacit knowledge e.g., understanding of target group needs • Expressed need for training on specific mHealth tools before use in practice *Cognitive skills* • Competencies used when meeting patients • Communication skills e.g., using non-dramatic terminology • Inter-personal skills e.g., validating parents to create a safe space • Perceived opportunities in using mHealth tools to facilitate communication and access health data
Physical capabilities	Not apparent in data
Opportunity	
Social opportunity	*Social influences* • Social norms, social support and professional identity were highly prevalent • Shared understanding among nurses regarding practice routines • Shared understanding among nurses regarding using a biopsychosocial approach
Physical opportunity	*Factors in the environmental context and resources* • "Eco-system of support" around at-risk children e.g., dieticians, physicians and teachers • Expressed need for increased collaboration among stakeholders and access to specialized care • Perceived opportunities of mHealth tools e.g., reach diverse populations through tailored mHealth resources
Motivation	
Reflective motivation	*Social and professional roles* • Professional identity and responsibility to support and guide parents. • Roles and responsibilities of health care professionals and target group (parents) • Perceived need for mHealth tools targeting whole families including parents and children *Beliefs about capabilities* • Confidence to engage in health promotion work and use mHealth tools • Perceived need for induction to use specific mHealth tools *Optimism* • Confidence that health care professionals and families are able to use mHealth tools • Perceived opportunities of mHealth tools to offer a shared platform with families, accessing material in several languages and opportunities for continuous support, monitoring and follow-up of the children and their families. • Perceived misgivings about using mHealth e.g., ensuring long term use among families *Emotions* • Both negative and positive emotions regarding using mHealth tools in practice e.g., frustration and curiosity • Expressed emotional engagement among nurses in families' efforts to adopt healthy routines

receive feedback in graphs and messages once a week based on their registrations. The app has also been translated and adapted for Somali- and Arabic speaking families including a large series of audio files in Somali and Arabic. As it is a web-based app, it also has a user-interface where the nurses can register new users (parents) and through that interface they are also able to follow the parental dietary and physical activity registrations mentioned above. The research was performed according to the Consolidated criteria for Reporting Qualitative Research (COREQ) checklist (30) (see Supplementary material 1).

Swedish primary child healthcare is commissioned to work with health promotion and disease prevention in a structured way. As part of this work, routine health visits follow a national health program including regular consultations with a registered nurse. In addition to height, weight, cognitive and social development of the child, these regular visits are used as a platform for the promotion of health behaviors such as physical activity and a healthy diet.

Participants and procedure

In the original study, informants were recruited using convenience sampling with inclusion criteria: (1) currently employed at one of the participating centers and (2) willing to participate. An invite to take part in a telephone interview was sent out *via* e-mail by CA (co-author) during September 2019, and nurses registered their interest by replying to the e-mail. Invitation letters were sent to nurses ($n = 35$) at health care centers that had agreed to participate in the MINISTOP 2.0 trial (26). Recruitment was conducted from 24 primary care centers. A total of 15 nurses registered an interest to take part in interviews and were interviewed. The invitation letter consisted of information on the study including study aims, that participation was voluntary and that they could leave the study at any time.

Data collection

Secondary data (27, 28) from interviews with child health care nurses conducted within the research project described above was used. The aim of the original study was to explore nurses' perceptions of parents' needs and concerns regarding diet and physical activity and nurses' perceptions about how the MINISTOP 1.0 app could be refined to meet the needs of the target group. In the original study, data was collected through semi-structured telephone interviews using an interview guide (Supplementary material 2) developed by the research group that has expertise in nutrition, physical activity, behavior change, and qualitative methodology. The interview guide was generated to explore nurses' perceptions about the need of the target group and preferences for using a digital tool in routines. For example, the interview guide explored nurses' perceptions regarding current work routines, needs and concerns among target group and perceptions of the MINISTOP 1.0 app. Thus, the secondary analysis used an implementation perspective, which was not done in the original study. CA (female and PhD student) conducted all the interviews which lasted on average 1 h (range 37–90 min). Field notes were taken after interviews. Informed verbal consent was obtained and recorded at the beginning of each interview. Informants were told that the interviewer was a PhD student however no relationship was established between participants and the interviewer prior to study commencement. Only participants and interviewer were present during interviews.

Data analysis

Secondary data analysis was carried out using raw data from previously collected material. Directed content analyses (29) and the COM-B model (20) was used in data analysis. MN and KT conducted all the secondary data analysis including generating the codebook. A codebook based on the COM-B domains were used in data analysis (Supplementary material 3). Initially, key parts of COM-B were translated from English to Swedish i.e., domains (capability, opportunity, motivation and behavior). In Michie et al. (31), an extensive explanation is given of the connection between the TDF and COM-B [(31), p 87–93]. The authors point out that to identify what needs to change or when a more detailed understanding of the behavior is required, the TDF can be used to expand on COM-B domains identified in the behavioral analysis. To gain a richer understanding for the domains and how they could be operationalised for this particular dataset, constructs from the TDF were therefore also used when generating the codebook (31) (e.g., cognitive skills, beliefs about capabilities social influence etc.). Then, KT and MN individually generated codebooks based on the translated domains and constructs. The two codebook drafts were discussed and consensus about one final codebook was reached (see Supplementary material 3).

KT and MN performed the secondary data analysis separately using the codebook to ensure consistency. However, inter-coder reliability was strived for through regular meetings between KT and MN throughout the analysis process. Firstly, all the transcripts were read through to gain an understanding and impression of the data as a whole. Then, all data was reviewed for content and coded according to the pre-defined categories in the codebook. This coding phase involved identifying data that corresponded with, or exemplified, COM-B domains by using the codebook. Only data that corresponded to pre-defined categories were coded. Preliminary findings (sorting and coding of data) were discussed between MN and KT in an iterative process until agreement was reached. In a final step, KT and MN together drafted text that described each category including selecting citations that could illustrate the content. KT drafted the first version of the results section for this manuscript.

Results

The study aimed to explore determinants for implementing a parent-oriented mHealth intervention in health promotion practice in primary child healthcare. In total, 15 nurses from nine primary child healthcare centers took part in telephone interviews. The participants were on average 47 years of age (between 37 and 55) and had on average worked in their profession for 7 years (between three and 11 years). Implementation referred to nurses introducing the MINISTOP 2.0 app to parents of 4-year-olds within family nursing practice during routine health visits. The analysis explored how nurses perceived their current health promotion practice and used the COM-B model (20) to systematically map determinants in data. Results are presented below for each COM-B domain.

Behavior

In the interviews, the nurses described and reflected on what their current work routines entailed. Nurses expressed health promotion work to be continuous, preventative, and comprehensive, aiming to support families from infancy to school-age. The work included monitoring children's social, psychological, and physical health mainly through meeting families during scheduled visits and referring to specialists when needed. In their conversations with parents, they provided information about health risks related to overweight and obesity in childhood and guided parents through healthier living. This is the professional work in which the MINISTOP 2.0 app would be introduced. "*Within child health care all health visits are preventative … so we talk about growth curves and health behaviours in all visits at the clinic*" (Informant 7).

Capability

In the COM-B model, capability refers to psychological and physical capability to engage in a behavior. The data mainly included nurses exhibiting knowledge and cognitive skills to do health promotion work and to use mHealth in this practice. Thus, aspects of physical capabilities were not apparent in the data.

Nurses expressed extensive knowledge on the responsibility, approach, and routines of the primary child healthcare organization. Their knowledge encompassed both research evidence about for instance nutrition and health, practice-based knowledge about e.g., national guidelines and pedagogical tools as well as tacit knowledge about parents' everyday life and concerns. Furthermore, the nurses stressed the need to keep themselves updated to ensure quality of care. Nurses kept updated through their contact with parents, learning from cultural bridge-builders, other colleagues and searching the Internet. "*I have gained so much from them [bridge builders] . . . a lot. . . a culture competency which I didn't know. . . yeah didn't realise existed before I started here*" (Informant 11). In addition, nurses highlighted the importance of staying curious and open-minded about the meaning of food in different cultural contexts to be able to support parents. "*It is quite difficult to know I think . . . if I don't come from the same food culture as the person I meet. . . then I don't know exactly what they eat*" (Informant 14). Regarding using mHealth in practice, the nurses highlighted the need for training about specific tools to increase capability, including perhaps testing MINISTOP themselves before disseminating it among parents. "[sigh] *Yeah. . . you need training as well of course. . . and. . . guidelines on how . . . yes how to use it [mobile application] and that we get a united way of working is important*" (Informant 8).

Cognitive skills referred to the competencies the nurses used when meeting parents. These skills included for instance adopting a light-hearted approach, using non-dramatic terminology, and validating parents' concerns to create a safe environment for parents to share information. Using one's cognitive skills also involved to always assess the situation and the individual in front of you and changing communication techniques accordingly." *what experience does the parent have?//. . . the approach becomes who are you?...and what do you need from me?...these things I need to explore before I give advice*" (Informant 10). Thus, health promotion work was described as a two-way process with shared responsibility between professional and parent. Although nurses expressed confidence in their role, child obesity was described as a potentially sensitive subject that can provoke strong emotions among parents such as pride, obstinance, guilt and shame. "*Others blame themselves and believe that I have actually done wrong as a mother, yeah, and so there is some shame and guilt in this*" (Informant 9). Regarding their cognitive skills, the data suggested that there was a capability among nurses to use mHealth in current health promotion work. For example, nurses expressed that mHealth could be used together with parents and could facilitate communication by making the topic of obesity less dramatic. Also, the potential of accessing data on families continuously through the mobile phone was thought to enable monitoring long-term and ultimately improve the communication during visits.

Opportunity

Within COM-B, opportunity refers to social and physical opportunities to engage in a behavior. The data included aspects on social influences and factors in the environmental context relating to health promotion work and using mHealth in practice.

Data on social influences, conveyed that social norms, social support and group-identity were highly prevalent in nurses' health promotion work. This was illustrated by nurses' shared understanding and acceptance of practice routines and understanding of health whereby social, psychological, and physical health concerns were continuously monitored and addressed, from infancy to school-age. "*In child primary health care we work preventative at all visits. . . so we talk about this with children and growth curves and lifestyle. . . at all visits*" (Informant 7). Furthermore, nurses expressed that health promotion work is more than promoting healthy behaviors: it is also about parenthood and inducing confidence in parents to be able to follow through with health behavior change.

Regarding, environmental context and resources, nurses described a network of actors around at-risk children that could be potential resources in promoting health such as nurses, dieticians, physicians, specialists, interpreters and bridge-builders and teachers in nursery. "*What happens at home. . . what happens there. . . because of course we call them back after six months but what happens...in the family at nursery at the grandparents?*" (Informant 7). Nurses expressed that collaboration within this "ecosystem of support" can be challenging but also rewarding for instance through working with bridge-builders to learn about different food cultures. Nurses talked about needing more resources such as increased access to specialized care as well as hands-on tools and materials that could facilitate communication and dissemination of information. For example, nurses talked about opportunities with future mHealth interventions to be available in several languages including pictures which are valid across cultures. "*And especially if there is something we use these pictures. . . or if you have difficulties with the language or. . . then it is very good to have a picture*" (Informant 7). In some cases, nurses perceived that the pedagogic and information materials that they currently had access to were not up to date and that their methods of counseling were not attractive to the families they served. "*But the fact that there is no. . . that there...if we talk about*

balanced diet examples… everything is in Swedish… everything is adapted to how a Swedish plate looks like… not how it looks for Somali families or a family from China//here we have so much to learn… so much to learn" (Informant 13).

Motivation

Within the COM-B model, motivation refers to both reflective (conscious) and automatic (subconscious) processes to engage in a behavior. The data mainly included motivation in terms of social and professional roles, beliefs about capabilities, optimism, intention and emotions associated with health promotion work and using mHealth in practice. Thus, other dimensions of motivation that is described in COM-B such as reinforcement, goals and beliefs about consequences were not apparent in data.

Regarding social and professional roles, nurses conveyed a strong professional identity and responsibility to support and guide parents. Nurses also described boundaries for their responsibility, or ability to help, with families that despite several efforts, were difficult to reach. "*You know [sighing] sometimes you don't get there… sometimes there is no interest… sometimes you can't do it*" (Informant 14). Nurses highlighted that obesity often is a problem in the family as a unit whereby both professionals and parents have a responsibility. Relating to this, the nurses sought for mHealth interventions that targeted whole families rather than parents per se by for instance engaging children in the material. Furthermore, the nurses expressed that recruiting parents and supporting parents' long-term use of MINISTOP were important and part of their professional role.

Data on beliefs about capabilities included professional confidence to engage in health promotion work but also about using mHealth. Nurses were confident in performing health promotion work also stating that they perceived that their parent-and -child interaction skills developed over time. When asked to give their initial reaction on implementing a mHealth in this practice, nurses expressed that they would like to try out using the tool but that there could be a need for staff introduction and training to be able to integrate the tool fully in practice. "*What is needed is that everybody works with the app the same way… because sometimes we meet each other's children and… so it is important that everybody has the same training so we work the same way… refer similar cases*" (Informant 4).

Nurses expressed both optimism and challenges toward working with mHealth in routine practice. Apart from an optimism that both themselves and parents are technically savvy, nurses could identify additional benefits for example, the opportunity for parents to constantly access information and support as opposed to only when visiting the clinic. Nurses expressed that the mHealth intervention could facilitate the work with hard-to-reach families, especially parents of high-risk children and parents with poor reading and writing skills through alternative channels such as audio and video. "*It is actually those families… yes… if we look in general… if we look at our families here now… so issues around diet...around teeth … around overweight then it is problem in this group… that's where it is most difficult to reach… and of course you can influence… we can see… but can you reach… can you… can we use a tool that we use together then it would be easier… I believe*" (Informant 13). Other benefits mentioned were the potential of having a shared platform with parents, accessing material in several languages and opportunities for continuous support, monitoring and follow-up of the children and their families. Nurses also expressed misgivings about using mHealth, such as the added distraction for parents," *That… they use the app… exactly… when do I use the app… that's the point… as a parent… do I look at that instead of my child?*" (Informant 10). Other challenges described were achieving good communication in technical solutions, and difficulties in achieving long-term use among parents. "*Then it is this with the … the in-person meeting… to like still… whatever app you have… to be able to refer to the in-person meeting*" (Informant 10). As their advice on screen activity was usually about limiting the time spent with media, they worried about introducing another screen-dependent activity in the lives of the families they served. Although they indicated that modern families were very cognizant about using mobile phones in general, they also reflected on the risk of MINISTOP "disappearing" in the crowd of mobile applications that parents use every day. In general, the nurses expressed an optimism that MINISTOP would fit with current routines and feasibility to recruit families. "*It fits very well in our like when we talk about… diet and sleeping and screen time and activity and so on… this is exactly what we discuss at every visit*" (Informant 7).

The nurses described that the goal of monitoring health behaviors in families in their practice led them to take intentional charge of the conversations with parents in different ways. These intentions also led them to provide suggestions concerning the mHealth and the desirable functions for staff. Although they were used to using mobile phone applications in general, they were not very familiar with the MINISTOP application, but they stated that they welcomed new ways to manage their health promotion task. Nurses expressed that parents' intention to work with mHealth would depend on the characteristics of the intervention itself, but also on the health behavior interest of the family. They believed that mHealth would be useful for health promotion, but also that outside support was necessary to keep the issue at the top of the family's agenda.

The nurses expressed negative emotions like frustration, resignation and worry but also positive emotions such as excitement and curiosity regarding their work and using mHealth in practice. "*Yes… no but there is nothing that I feel at the moment… that no but… when I see this it feels really exciting I think… we can hope that the parents also think*

that…or will think [laughter]" (Informant 15). The nurses were emotionally engaged in the success and failure of their efforts to involve parents in the health promotion conversations, and disappointed when the child's health data indicated that results were lacking. As conversations about child obesity could lead to parental emotions such as shame and blame, nurses expressed that they experienced negative emotional stress in these situations. When asked to reflect on the use of MINISTOP by parents, the participants expressed feeling hesitation, but also excitement and curiosity, and they expressed that they looked forward to working with the app.

In summary, potential barriers for behavior change were limited knowledge and reservations among nurses regarding the use of the intervention among the target group. Potential facilitators for behavior change were nurses' openness, confidence and engagement in their professional role and beliefs that digital tools could improve practice.

Discussion

This study explored behavior change determinants for implementing an mHealth intervention (MINISTOP 2.0 app) in current health promotion practice in primary child healthcare. Determinants in terms of both barriers and facilitators for implementation were identified. Limited knowledge about MINISTOP and reservations about how and to what extent parents would use the intervention were identified as the main possible hinders. Potential facilitators were nurses' openness to learn and try innovations, nurses' confidence and engagement in their professional role and beliefs that mHealth could improve practice by prompting dialogue and being a shared platform. Finally, nurses expressed a strong professional identity and shared understanding of their practice, mechanisms that could potentially hinder or facilitate implementation of mHealth.

One of the potential barriers for implementing MINISTOP 2.0 was the capability among nurses to use the intervention. The COM-B model posits that the capability and motivation to engage in a behavior are interrelated, and would together with behavioral opportunities, contribute to adoption of mHealth (20). Although nurses expressed these hinders, our data indicated that nurses also exhibited capability (in terms of cognitive skills), opportunity and motivation to use and implement the MINISTOP in their daily routines. Indeed, well-known facilitators of practice change were observed such as nurses' openness to change and beliefs that the mHealth intervention would improve practice. In contrast, previous research in pediatric care has shown that poor buy-in and engagement among adopters together with limited time and information are typical barriers to implement mHealth (31). Innovations that are compatible with existing norms, values and ways of working have shown to easier engage adopters which could partly explain our findings. Indeed, the child primary healthcare context was found to be characterized by a strong professional identity, engagement, and long-term relationship with families. All these mechanisms have the potential to facilitate implementation of any innovation that is compatible with these notions and ethos (32). The nurses expressed that MINISTOP was compatible with their work for example by taking a preventative and holistic approach to health and offering information to parents.

Research on implementation has shown that an important determinant is how end-users perceive different attributes of the intervention so called innovation characteristics. Indeed, the central tenet of the Diffusion of Innovations theory (33) is that how attributes of a technology are perceived by stakeholders will influence implementation. Facilitating attributes include perceived relative advantage (the intervention is perceived to be superior to existing routines), complexity (an intervention is simple to use and understand), compatibility (an intervention matches established routines and norms), observability (potential benefits of an intervention is visible), and trialability (an intervention can be tested prior full-scale implementation) of an innovation (33). The possible barriers can be understood as the complexity and trialability of MINISTOP 2.0, that is, nurses expressed wanting more knowledge about the intervention and testing it before full-scale implementation. Effective implementation strategies to facilitate implementation could thus be educational outreach visits and making MINISTOP testable among nurses to promote familiarity (34). However, to fully facilitate the implementation of digital interventions in routine practice, implementation strategies need to target all barriers for change. Thus, strategies need to be systematically developed based on a thorough investigation of determinants specific for this particular context and intervention (31, 35).

Our findings echo existing literature on mHealth implementation. Indeed, a systematic review on mHealth adoption in healthcare highlighted perceived usefulness and familiarity, training and access to resources to be key determinants of successful implementation (17). Usefulness in the mHealth implementation literature typically refers to that mHealth interventions will not only fit current routines, but also make valuable additions to these. Our findings can add to the understanding of the usefulness of mHealth tools in healthcare, knowledge that is central for intervention development and implementation. In our data, nurses spoke about the usefulness of MINISTOP 2.0 in terms of the opportunities to monitor behavior over time and to create a shared platform incorporating multiple stakeholders. Nurses described how obesity prevention engaged a network of actors and that mHealth hold great potential in providing a shared platform in this work. A qualitative study on the use of mHealth in general practice similarly characterized usefulness as creating shared platforms for patients and healthcare providers (36). However, it can be a challenge for future mHealth designs to, on one hand,

include multiple stakeholders and, on the other hand, tailor content to specific target groups. mHealth interventions can be designed to be a platform where information is disseminated to patients, alternatively, mHealth can be designed as a dynamic tool, a place, where different stakeholders can communicate and share experiences continuously. In addition, the nurses voiced that they would like mHealth interventions to be a tool shared between themselves and parents. This could for example be done by parents registering their health behaviors, data that nurses would have access to, and used in consultations.

Methodological considerations

A strength of the study is the use of a theory-based codebook in data analysis which supported neutrality and consistency in the analysis process (37). Trustworthiness and scientific rigor were strived for in several ways (37). Researchers with varied research backgrounds and competencies were involved during study design, data collection and analysis which could have increased credibility. In addition, investor triangulation was used in data analysis to ensure dependability of the interpretation of data. The theory-based codebook enabled systematic data analysis which together with investigator triangulation could have increased dependability and confirmability. Furthermore, we have strived to increase transferability by providing detailed description of the procedure and thick descriptions of the results, illustrated by quotes from data. Transferability may have also been increased by the fact that healthcare centers, in which informants work, were located in diverse socioeconomic and geographical areas.

A potential challenge with using secondary data is that the interview material and the original interview guide may not adequately answer the study aim. Therefore, before starting data analysis, we read through the material to assess whether it included sufficient scope and depth to capture our study aim. We deemed that the data were sufficient to investigate conditions for mHealth implementation among nurses and offered valuable insights in this regard. However, including interviews with practice managers and regional managers could have strengthened the study. The study offers the perspective of registered nurses and knowledge on implementation in the healthcare visit setting. Future studies could include other groups of informants to enrich our understanding of implementation on other levels of the primary care organization.

The study explored future, potential, determinants for implementing an innovation in current practice, rather than actual experienced determinants. Perceived determinants prior an implementation is not necessarily the same as the ones that are later experienced during actual implementation. However, the nurses were experienced in health promotion work and showed extensive knowledge about obesity prevention and preconditions increasing the validity of the findings. Future research needs to investigate readiness to change and determinants among healthcare professionals with hands-on experience with mHealth implementation. This study adopted a point of departure in current practice routines to understand determinants for future implementation.

Conclusions

This study indicates cautious optimism regarding the preconditions for implementing mHealth in child primary healthcare in terms of capability, opportunity and motivation among stakeholders. Implementation strategies such as educational outreach visits and making the intervention testable among stakeholders could further facilitate implementation in this clinical context. However, more research is needed on the impact of behavior change determinants in different stages of real-world implementation.

Data availability statement

The raw data supporting the conclusion of this article can be made available by the authors on reasonable request.

Ethics statement

The studies involving human participants were reviewed and approved by the regional Ethical Review Board of Uppsala, Sweden (ref no 2019-02747; 2020-01526). The patients/participants provided their written informed consent to participate in this study.

Author contributions

ML is the principle investigator for the MINISTOP 2.0 trial, including this qualitative study. CA and HH performed the data collection in the original study. KT and MN conducted the secondary data analysis. KT drafted the first version of the manuscript with significant contributions from ML, CA, UM, MN, and HH. All authors read and approved the final version of the manuscript.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2022.951879/full#supplementary-material

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Systematic review of the development and effectiveness of digital health information interventions, compared with usual care, in supporting patient preparation for paediatric hospital care, and the impact on their health outcomes

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Background and aim: Elective surgery can be overwhelming for children, leading to pre-operative anxiety, which is associated with adverse clinical and behavioural outcomes. Evidence shows that paediatric preparation digital health interventions (DHIs) can contribute to reduced pre-operative anxiety and negative behavioural changes. However, this evidence does not consider their design and development in the context of behavioural science. This systematic review used the Theoretical Domains Framework (TDF) to evaluate the design and development of DHIs used to support children up to 14 years of age and their parents, prepare for hospital procedures, and determine any correlation to health outcomes. It also considered whether any behavioural frameworks and co-production were utilised in their design.

Methods: A search of the MEDLINE, EMBASE, PsycINFO, and HMIC databases was carried out, looking for original, empirical research using digital paediatric preparation technologies to reduce pre-operative anxiety and behavioural changes. Limitations for the period (2000–2022), English language, and age applied.

Results: Seventeen studies were included, sixteen randomised control trials and one before and after evaluation study. The results suggest that paediatric preparation DHIs that score highly against the TDF are (1) associated with improved health outcomes, (2) incorporate the use of co-production and behavioural science in their design, (3) are interactive, and (4) are used at home in advance of the planned procedure.

Abbreviations

AV, audio-visual; CASP, Critical Appraisal Skills Programme; CBCL, Child Behaviour Checklist; CSWQ, Child Surgery Worries Questionnaire; DHI, digital health intervention; DHIG, digital health intervention group; ENT, ear, nose, and throat; FACES, Wong–Baker Faces Scale; FLACC, Face, Legs, Arms, Cry, Consolability scale; IC, induction compliance; ICC, Induction Compliance Checklist; MESH, Medical Subject Heading; MRI, magnetic resonance imaging; m-YPAS, modified Yale Preoperative Anxiety Scale; PAED, Paediatric Anaesthesia Emergence Delirium; PBRS, Procedural Behaviour Rating Scale; PHBQ, Post-Hospitalisation Behaviour Questionnaire; PICOS, Population, Intervention, Comparison, Outcome, and Study; PPP, Paediatric Preparation Programmes; PPPM, Parents' Postoperative Pain Measure; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analysis; SAM, Self-Assessment Manikin; STAI, State-Trait Anxiety Inventory; TDF, Theoretical Domains Framework; VAS, visual analogue scale; YPAS, Yale Preoperative Anxiety Scale.

Conclusion: Paediatric preparation DHIs that are co-produced and designed in the context of behavioural science are associated with reduced pre-operative anxiety and improved health outcomes and may be more cost-effective than other interventions.
Systematic Review Registration: https://www.crd.york.ac.uk/prospero/, identifier: CRD42022274182.

KEYWORDS

digital technology, paediatric care, health outcomes, patient preparation, health information

1. Introduction

Over 500,000 children undergo elective surgery in the United Kingdom annually, with nearly 80% of these being planned day surgeries where the child is admitted and discharged on the same day (1). Anaesthesia, the surgical process, and the hospital environment can be overwhelming for children and their parents, with both often experiencing fear, stress, and apprehension. These emotions are associated with pre-operative anxiety (2, 3).

Heightened pre-operative anxiety can lead to poor anaesthesia induction, an increased risk of emergence delirium, pain, inconsolable crying, irritation, incoherency, and uncooperativeness (4). These frequently negatively impact the child's short- and long-term post-operative psychological and physiological outcomes and can trigger behavioural changes. These include aggression, sleep disturbances, eating problems, a more painful prolonged recovery (5–7), and longer-term maladaptive behaviours such as fear of healthcare professionals and medical environments, avoidance of treatment, separation anxiety, and persisting negative memories of anaesthesia (8, 9), all of which affect healthcare burden and costs.

Various pharmacological and non-pharmacological interventions have been used to reduce pre-operative anxiety in children and improve post-operative psychological and physiological outcomes. Pharmacological interventions include anti-anxiety and sedative drugs, but these commonly cause adverse effects such as drowsiness and can interfere with anaesthesia medication (10). Non-pharmacological interventions traditionally include routine hospital and procedural preparation information, hospital tours, child life specialists, therapeutic play interventions, music therapy, parental presence, clowns, games, and colouring books (10, 11). While non-pharmacological interventions are popular, they are not all readily available and cost-effective and some, like parental presence, have yielded mixed results (3, 11, 12). In addition, many are used as a distraction rather than a pre-operative preparation intervention.

The use of pre-operative preparation interventions indicates that well-prepared children have reduced pre-operative anxiety and negative responses to surgery or medical procedures (13–16). Pre-operative preparation provides information about the planned procedure, hospital environment, and post-operative care and can encompass information on how to cope with emotions, stress, and anxiety (1). Bray et al. (17) and Fortier et al. (18) found that children wish to receive detailed pre-operative information, but it is frequently received through their parents, hampering their direct access and understanding. In addition, children want information that is engaging, easily accessible, and child-friendly. Digital health interventions (DHIs) such as audio-visual, video games, virtual reality (VR), computer or web-based programs or presentations, educational interactive multi-media applications, and smartphone, tablet, or computer applications (Apps) provide a platform for delivering child-friendly, engaging, and accessible pre-operative preparation information. Evidence (19–23) is growing into their use as pre-operative preparation for children and as an intervention to reduce paediatric pre-operative anxiety. However, this evidence does not consider the design and development of DHIs in the context of behavioural science.

Behavioural science is interested in aspects such as behavioural change, in this case, the design and development of paediatric preparation DHIs and their impact on children's emotional, behavioural, and clinical outcomes. Due to the lack of understanding between the preparation DHIs and behavioural change, this systematic review builds upon this research. It looks specifically at the design and development of paediatric preparation DHIs through the application of the Theoretical Domains Framework (TDF). It applies the 14 domains of the TDF to assess the components of DHIs and examines whether there is a correlation to improved outcomes. The TDF was developed from the synthesis of 33 behaviour change theories into a framework comprising 14 domains and 84 behaviour constructs, founded on the Behaviour Change Wheel (24). The Behaviour Change Wheel connects environmental and psychological factors to interventions, established on the COM-B system (Capability, Opportunity, Motivation, Behaviour) where behaviour is produced when capability, motivation, and opportunity interact (25). In building on the Behaviour Change Wheel, the TDF provides a validated framework, developed by behavioural scientists and implementation researchers, to evaluate behaviour change. It can be used to assess implementation issues, support intervention design, and analyse interventions (26).

1.1. Current literature

Children undergoing medical procedures, anaesthesia, and surgery experience significant psychological and physiological reactions. The unfamiliar environment, the equipment and routines, fear of separation, needles, and the medical procedure are well documented as sources of these negative reactions (27–29). These reactions lead to short- and long-term maladaptive behaviours such as irritation, aggression, incoherency, uncooperativeness, eating problems, and sleep disturbances (4) and fear of healthcare professionals or medical treatment (8, 9).

In addition, they are associated with poor anaesthesia induction compliance (IC) (30), emergence delirium (5), increased need for sedation or rescue analgesia (31), and prolonged pain and recovery (5). To address these psychological and physiological reactions, research has been undertaken on the use of pharmacological and non-pharmacological interventions to reduce pre-operative anxiety.

1.1.1. Interventions to manage pre-operative anxiety

Pharmacological interventions include anti-anxiety and sedation medications, such as Midazolam, Fentanyl, Ketamine, and Clonidine. These are used as effective pre-operative anxiolytic and sedation medications in children, which reduce pre-operative nausea and vomiting, enable satisfactory separation from parents and anaesthesia induction, and reduced the need for post-operative analgesics (32–35). However, they are associated with an increased incidence of respiratory depression, drowsiness, agitation, and paradoxical reactions (32–35).

Due to these adverse side-effects, non-pharmacological interventions have increasingly been used to manage pre-operative anxiety. Research on the use of parental presence is mixed. Some papers suggest it has been used to provide reassurance and comfort, eliminate separation anxiety and reduce the need for medications, while other papers suggest it can increase anxiety if parents themselves are anxious (36–39). Distraction techniques such as videos, singing, reading, colouring, playing games, or controlled breathing are often used to reduce anxiety and shift the focus away from the procedure concerned or the pain experienced (40–43). In addition, complementary and alternative therapies and remedies such as music therapy, art therapy, hypnosis, and clowns (33, 37, 44), cognitive behavioural therapy (37), child life specialists (15), and therapeutic play interventions (45, 46) have shown positive impacts on reducing pre-operative anxiety, enabling self-regulation of emotions and behaviours and acting as a support for children and their families. Other non-pharmacological interventions include preparation programmes such as hospital and operating room tours including exposure to medical equipment and staff (37, 47). Many of these non-pharmacological interventions have a low risk of adverse effects and are minimally invasive (37), but not all are readily available and cost-effective, as they can be time-consuming, requiring staffing resources and planning (11, 12).

Within the last 20 years, there has been increased research into the use of digital technologies such as DHIs to manage pre-operative anxiety either through distraction (7, 48, 49) or through preparation (3, 11, 50, 51). These DHIs include audio-visual, computer games or video games, VR, computer or web-based programs or presentations, educational interactive multi-media applications, and smartphone or tablet applications. Their versatility in being able to tailor pre-operative information for different procedures and child ages, as well as incorporate virtual tours of the hospital environment and operating room, provide information on medical equipment and staff, and use exercises, games, or activities to support understanding and emotional self-regulation, have made them increasingly popular pre-operative preparation interventions. Consequently, this also aids in addressing the findings from research into what children and their parents want from pre-operative information, specifically child-centred, easily accessible, engaging, and informative information with coping strategies (17, 18, 21, 52). Various systematic reviews (6, 19, 20, 53) have been undertaken to consider the effectiveness of DHIs in managing pre-operative anxiety and improving health outcomes. These show that DHIs, as distraction and preparation programmes, can have a positive effect on reducing pre-operative anxiety and negative behavioural changes. However, they do not consider the design and development of DHIs. This is specifically in the context of behavioural science, which includes aspects such as behaviour change, which is important in improving healthcare and health outcomes (24). This systematic review aims to address this gap by using the TDF to assess the design and development of preparation DHIs and the impact on children's health outcomes.

1.1.2. Theoretical domains framework

The TDF provides a validated framework, developed to provide a more accessible and usable tool to support improving the implementation of evidence-based practice. By bringing together a range of behaviour theories and key theoretical constructs, a simple and integrated framework is provided to inform and assess intervention design and implementation (54). The TDF originally included 33 theories and 128 key theoretical constructs, which were later simplified into a framework comprising 14 domains and 84 behaviour constructs. The revised TDF has been validated for use in assessing implementation issues, supporting intervention design, and analysing interventions (26).

This study aimed to evaluate the design and development of paediatric preparation DHIs used to support children up to 14 years of age, and their parents, to prepare for hospital procedures, and to understand their impact on their health outcomes. The primary objective was to evaluate the design and development of paediatric preparation DHIs against the TDF and ascertain whether any behavioural frameworks and co-production were used. A secondary objective, and in the context of the previous systematic reviews (6, 19, 20, 53), was to consider, compared with standard care, the extent to which paediatric preparation DHIs influenced the children's emotional and/or behavioural responses, and/or any impact on their clinical status and/or healthcare utilisation. Specifically, this study was interested in whether there was any correlation between the evaluation of the development of paediatric preparation DHIs and the reported results.

2. Methods

The study protocol is publicly available under registration number CRD42022274182 on the International Prospective Register of Systematic Reviews (PROSPERO). The inclusion and exclusion criteria (**Supplementary Table S1** in **Appendix A**) were built using the Population, Intervention, Comparison,

Outcome, and Study (PICOS) framework, which is a well-established framework for developing research questions and inclusion and exclusion criteria (55, 56). The population for this review constituted children up to 14 years of age, and their parents, without any cognitive impairments, who were prepared for hospital treatment using a paediatric preparation DHI. Studies were excluded if the DHI was solely aimed at parents or healthcare professionals. Children were excluded if they were aged 15 years and above in order to focus the review on the use of DHIs in younger children and early adolescents. The DHIs needed to be educational and focused on preparation for the procedure, providing information about the hospital environment, medical equipment, and healthcare staff roles and responsibilities. The type of digital interventions was broad, including audio-visual, VR, smartphone or tablet or computer applications, computer or video games, and websites or online programs or games. Any non-digitised health interventions, self-management applications, or digital interventions aimed at distraction were excluded. The studies that were included were randomised control trials, non-randomised control trials, and quasi-experimental studies such as before and after evaluations, to ensure the assessment of original, empirical research. The studies also needed to compare the DHI with usual care or be a head-to-head comparison of two DHIs. All other study types were excluded.

2.1. Search strategy and data extraction

The OVID databases that were selected were MEDLINE, EMBASE, PsycINFO, and HMIC. A mix of keywords and Medical Subject Headings (MESHs) was used to search for themes. The search was carried out in February 2022 using the complete syntax with truncation for each database as outlined in **Appendix B**. Limitations were added for the period (2000–2022), English language, and age.

2.2. Study selection

The preliminary search returned 931 records; 363 duplicate records were identified, and 176 records were removed. A total of 730 records remained, and these progressed to the stage of title and abstract screening (57). Two reviewers screened titles and abstracts for the 730 records for eligibility against the PICOS, resulting in 655 articles for exclusion, 41 articles for stage full-text screening, and 34 conflicts. After consultation with a third reviewer, 17 (58–74) articles remained for full paper review. The Cohen's Kappa score (75) for the screened title and abstract was 0.682, with a 95% proportionate agreement, and for the full paper review, a score of 0.907 was obtained, with a 96% proportionate agreement, demonstrating substantial agreement among the reviewers. **Figure 1** outlines the searching and screening process diagrammatically using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) (76) flow chart. **Appendix C** in the **Supplementary material** shows the full-text screening selection process questions.

Data relevant for extraction were considered against the aims and objectives of the review (77). **Supplementary Table S2** in **Appendix D** sets out the data extraction fields. For any randomised control trials, version 2 of the Cochrane Risk of Bias tool for randomised trials (RoB2) (78) was chosen, given that it is the standard recommended for Cochrane Reviews. For any non-randomised control trials or included quasi-experimental study designs, the Critical Appraisal Skills Programme (CASP) (79) was chosen, given its wide use in systematic assessment of the relevance and results of research.

The synthesis and analysis were first assessed, on the basis of the degree of homogeneity (80, 81), in terms of four aspects: patient characteristics, the intervention and comparators of the studies, the reported outcomes and timeframes over which they were measured, and the similarity of the results. If homogeneity is determined to be insignificant and heterogeneity significant, then a narrative synthesis would be undertaken on the study and participant characteristics, findings from the quality assessment, and the measurements used and reported outcomes. To meet the primary objective of this review, an evaluation of the development (design) of the DHIs was also undertaken. The results were then used to determine any correlation to the evaluation of the DHI development and findings from the studies using a measure of effect. DHI descriptions were evaluated using the information provided within the relevant studies, and where this was insufficient, related articles were sought out. For some studies, no related information was available, and the DHIs were, therefore, assessed using only the information provided in the included paper.

The digital health interventions in the studies are aimed at changing behaviour to reduce pre-operative anxiety through education, information, and coping strategies. The TDF was chosen to evaluate the design and development of the digital health interventions within the context of behavioural science, as it is a validated tool for assessing implementation issues, supporting intervention design, and analysing interventions (24, 26, 82). The DHI evaluation was undertaken using a scoring system against a 16-domain framework. The 16 domains constituted the 14 domains from the TDF (24) and two additional domains. The definitions of the 14 domains from the TDF were adapted from Cane et al. (24) and Smalley et al. (82) with two additional domains added. The additional domains identified as relevant in assessing the development of the DHIs, and added to create a modified TDF, were

1. input from one or more healthcare professionals, children, and parents, and
2. use of any behavioural frameworks.

During pilot testing of the modified TDF against a few studies, it was decided that the TDF's "social/ professional role and identity" domain was not applicable. This was attributed to its focus on the behaviours and displayed personal qualities in a social or work setting, whereas the TDF domains were being used to assess the design of digital intervention in respect of use

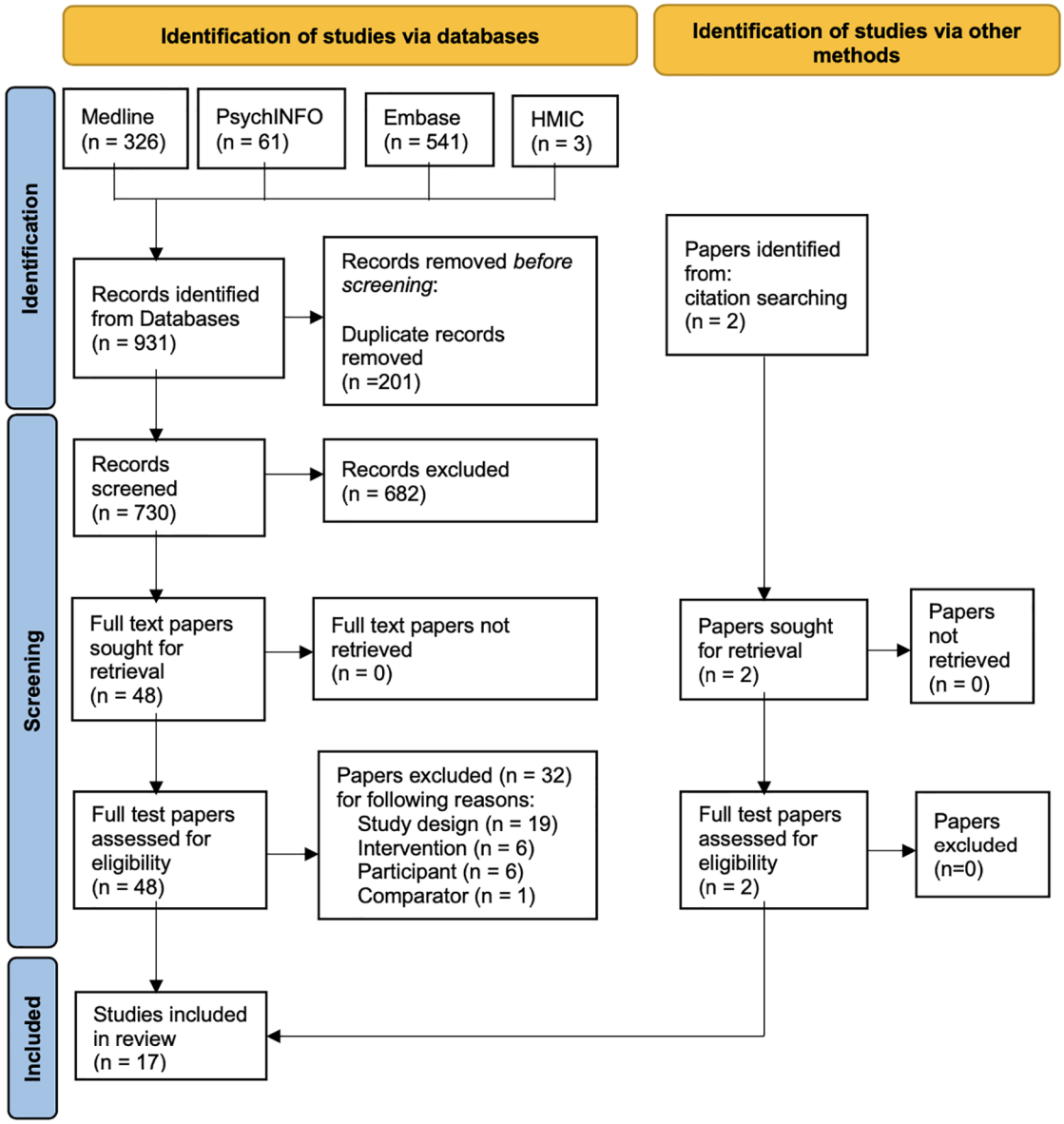

FIGURE 1
PRISMA flow chart (76) describing records obtained and reasons for exclusion.

by children and their parents. It was subsequently removed and the scoring for the evaluation of the DHIs was adjusted to be out of 15 domains.

For each domain in the modified TDF, the domain descriptions were used to develop a criteria checklist to guide the evaluation of the DHIs. The criteria checklist considered what information, activities, techniques, or actions the DHIs should incorporate to meet the domain descriptions. This was tested against a sample of the DHIs to refine the criteria checklist. Each DHI was then assessed against each domain criteria checklist and a score applied depending on whether the DHI fully met, partially met, or did not meet the requirements in the criteria checklist. Table 1 sets out the criteria checklist used to evaluate the DHIs against the modified 15-domain TDF. The scoring system applied to the 13 domains from the TDF was "1" if the DHI fully met the criteria, "0.5" if the DHI partially met the criteria, and "0" if either the DHI did not meet the criteria or insufficient information was provided. The scoring for the co-production domain (described in Table 1 as "input into the development of DHI") was "1" if the paper evidenced development involved healthcare professionals, children, and parents, "0.5" if the paper evidence development only involved one or two of these groups, and "0" if the paper did not evidence involvement from these groups. The scoring applied to the domain for use of behavioural and/or design frameworks in DHI development was "1" if the paper explicitly evidenced their use and "0" if the paper did not evidence their use. The scores were summed to provide an overall score out of 15 for each of the DHIs in the included studies, with those scoring higher assumed to have optimal design and

TABLE 1 Theoretical and additional domains of the modified TDF demonstrated in the digital health interventions.

Domain	Explanation adapted from Cane et al. (24) and Smalley et al. (82)	Criteria for DHI to meet fully or partially meet the domain.
Knowledge	Awareness of the existence of something, including a knowledge of the condition and the procedure, and what will happen	DHI provides detailed information about the hospital environment, the equipment (e.g., monitoring devices, pulse oximeter, anaesthetic mask, etc.), and the staff. It guides the user through the process from admission to the operating room. Domain is partially met if information lacks detail.
Skills	Ability or proficiency acquired through practice (e.g., skills, ability, competence, practice)	DHI includes an element that is interactive and aimed at developing an understanding of the pre-operative process and/or coping skills (e.g., modelling or breathing). Domain is partially met if not interactive but includes information or support on coping or post-operative care.
Emotion	A pattern of experiential, behavioural, and physiological reactions to deal with significant events or matters (e.g., anxiety, fear, stress)	DHI includes information about emotions, how the child might feel, how to cope with being anxious or scared, and the likely sensory aspects. Domain is partially met whether about coping with anxiety or some consideration of feelings.
Behavioural Regulation	Supports or activities aimed at managing or changing objectively observed actions (e.g., action planning, self-monitoring, breaking habits)	DHI includes activities or techniques aimed at changing behaviours, whether there are coping strategies, behaviour training, or breathing. Domain is partially met if modelling, with no activities or techniques.
Memory, Attention, and Decision Processes	Ability to retain information and selectively focus and choose among options (e.g., decision making, attention, and attention span)	DHI is interactive and may include prompts or challenges. Domain is partially met if DHI noted as taking account of children's memory and cognition but is not interactive. Also, partially met if DHI is short and provides information about how it is engaging.
Environmental Context and Resources	Circumstances of the environment that contribute (positively or negatively) to skill development, independence, and adaptive behaviour (e.g., organisational culture, resources, and environmental stressors)	DHI includes information on the hospital environment, staff, and equipment. Domain is partially met if all the information listed above is not provided.
Beliefs about Capabilities	Acceptance of one's true abilities, talents, or facilities (e.g., self-confidence, self-esteem, empowerment, self-efficacy, and perceived behavioural control)	DHI includes information or activities to help the child cope or manage behaviour or provides challenges. No partial scoring for this domain.
Beliefs about Consequences	Acceptance of true outcomes of behaviour in each situation (e.g., anticipated regrets and outcomes, beliefs, and consequences of actions)	DHI incorporates one or more of the following: (1) a step-by-step guide of what will happen and is involved, (2) what the outcome will be through information on the experience and how it might feel, and (3) using level progression or interactive games to check the level of understanding. Essentially, it provides sufficient information to create a level of understanding about the consequences of what will happen. Domain is partially met if the guide on what will happen is not a step-by-step one and does not include any other elements listed above.
Reinforcement	The increasing likelihood of desired behaviour by creating a stimulus and response dependency (e.g., incentives, rewards, punishments)	DHI is interactive or includes game elements to reinforce information. Domain partially met if the DHI can be used more than once.
Intentions	Consciously act in a certain way, or perform a certain behaviour	DHI includes feedback or rewards to drive action or behaviours or incorporates specific behavioural components. Domain is partially met if it includes exercises.
Goals	Outcomes or end states that an individual wants to achieve (e.g., setting a target, priorities, and action planning)	DHI requires specific action to progress levels, incorporates setting goals, and includes rewards. Domain is partially met if it includes actions to perform to achieve something specific.
Social influences	Interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours (e.g., social pressure, norms and support, group identity, and power)	DHI includes a parent element or considers familial influences on the child. Domain is partially met if it uses only famous characters or only partially considers familial influences.
Optimism	Confidence that desired goals will be attained (e.g., optimism, pessimism, identity)	DHI includes some form of reward or attainment. Domain is partially met if reward or attainment is indicated but not sufficiently detailed.
Input into the development of DHI	Does the DHI involve healthcare professionals, parents, and children in its development?	DHI is developed with the involvement of healthcare professionals, parents, and children. Domain is partially met if only one or two of these groups are involved in the development of the DHI.
Behaviour framework	Does the development of the DHI involve the use of any behavioural and/or design frameworks?	DHI is developed using a behaviour framework or tools or concepts. It considers the user and/or behaviour change. No partial scoring for this domain.

DHI, digital health intervention.

development through meeting more of the modified TDF domains. The scores were also summed to provide totals on how many of the DHIs scored fully (given a score of 1) or partially (given a score of 0.5) against each domain. These scores were then used to determine any correlation between the DHI designs and health outcomes.

To determine any correlation between the evaluation of the development of the DHIs and the reported outcomes, quantitative data was converted into a summary statistic. Specifically, this examined what outcomes were measured and how, whether there was a noticeable measure of effect, and how it correlated to the scoring from the DHI evaluation. To ensure that the data analysis met the requirement of systematic review transparency, established reporting guidelines were followed (83).

The effect size measure and direction was calculated where feasible using a standardised mean difference, Cohen's *d*, Glass's delta, and Hedges' *g* (84), or other appropriate statistical calculations such as a Chi-square *p*-value calculation (85). Where data are presented in studies using median and interquartile range (IQR) and where there is no evidence of significantly skewed data, median and IQR was converted to an estimated mean and standard deviation (SD), using an online calculator (86) developed from research by Wan et al. (87), Lou et al. (88), and Shi et al. (89, 90). Where estimate mean and SD can be derived, the results were used to calculate the effect size. Similarly, where the mean is provided but not SD, SD was calculated using the RevMan Calculator (91), with the subsequent effect size also calculated. **Table 2** outlines the scoring criteria to determine the direction of the effect.

3. Results

A total of 17 studies were included in this review, of which 16 were prospective randomised controlled trials (59–74) and one was a before and after evaluation study (58). Of the randomised controlled trials, five were triple-arm parallel randomised control trials comparing the DHI with a control and comparator and one a Solomon four-group design. The rest were all two-arm parallel randomised control trials. The studies were carried out between 2002 and 2020. The publication dates ranged between 2015 and 2021 for 15 studies, with two published before this in 2005 and 2009. **Supplementary Tables S5, S6** in **Appendix E** summarise the study characteristics, DHIs, and participant characteristics.

TABLE 2 Scoring criteria to determine the statistically significant direction of effect.

Effect size interpretation (Cohen's *d*, Glass's delta, or Hedges' *g*) rounded to two decimal places	Direction of effect	
	Positive	Negative
No overall effect (no significance) < 0.20	⟷	
Small = 0.20 to <0.50	↑	↓
Medium = 0.50 to <0.80	↑	↓
Large = 0.80 or more	↑	↓

Homogeneity was observed in parts of the 17 studies. However, when examining the four key aspects that Brown and Richardson (81) consider are required to determine homogeneity, the overall assessment was that there was significant heterogeneity. This was notable in respect of participant age.

3.1. Study characteristics and DHIs

The studies were mostly conducted in developed countries, with three in the United Kingdom (58, 65, 72), two in Canada (59, 62), four in South Korea (60, 61, 63, 70), and one each in the United States (71), Thailand (64), Portugal (67), Turkey (66), the Netherlands (68), Italy (69), and Japan (73). The study by Dehghan et al. (74) was conducted in Iran. Study durations varied, with six studies being conducted over 8 months or less, eight being between 10 and 18 months, two at 20 and 23 months, respectively, and one not stating the duration. All DHIs were utilised pre-operatively. The length of the DHIs ranged from 344 s (66) to a maximum of 45 min (59), with four studies (58, 64, 65, 72) not stating the length and the rest being between 4 and 15 min.

The DHIs trialled in the studies are divided into four main types—VR (59–61, 63, 68, 70, 74), audio-visual presentations (64, 66, 69, 73), web-based programs or presentations (62, 65, 71, 72), and educational interactive multi-media applications (58, 67). All DHIs incorporated a tour or information, in varying levels of detail, about the hospital environment and equipment, but only 11 studies (58–61, 63, 66–68, 70, 71, 73) explicitly stated that the information included details of the staff involved. Of the seven studies using a VR-based DHI (59–61, 63, 68, 70, 74), Stunden et al. (59), Eijlers et al. (68), and Ryu et al. (70) incorporated interactive elements, with the rest being informational video tours. The DHIs by Bray et al. (58), Wright et al. (62), Wantanakorn et al. (64), Fernandes et al. (67), and Fortier et al. (71) also incorporated interactive elements such as games and chatbots.

Except for five studies (63, 67, 68, 73, 74), all other studies used usual care in the control group, and this comprised standard verbal information and/or information leaflets. Of those studies using usual care, four were three-arm parallel randomised control trials and involved a comparator, and these were a Child Life Program (CLP) (59), handwashing game (65), voice recording (66), and cartoon strip (72). Park et al. (63) used the same video tour for the control group but without the mirror display for parents to watch simultaneously as their child as used for the intervention. Fernandes et al. (67) used a video game as a comparator and no intervention as the control. Eijlers et al. (68) and Wakimizu et al. (73) used audio-visual tour/information as the control, with the latter being the same as for the DHI intervention group but only viewed once a week in advance of the procedure. Dehghan et al. (74) used parental presence as the control.

The setting for the studies was linked to where the intervention DHIs were used. The majority were used once in the hospital either on the day before the procedure (64, 69) or on the same day as the

procedure (59–61, 63, 67, 68, 70, 72), with four of the same-day DHIs being one hour pre-operatively. Hatipoglu et al. (66) presented the DHI once, 1 week in advance of the procedure during hospital admission. The DHIs for the rest of the studies were used either at home (58, 62, 71) or both at home and in the hospital (65, 73), but for all five of these studies, the DHIs could be accessed by children and parents more than once. For the studies where the DHIs could be used at home, one (71) was made available a week before and up to 7 days after the procedure, three (62, 65, 73) were made available a week before the procedure, and one (58) 3 days before the procedure. It is unclear in the Dehghan et al. (74) study when the DHI was used relevant to the procedure, but it is assumed that the setting was in hospital post the randomisation of participants.

3.2. Participants

The total sample size across the 17 studies was 1,726 children, with sample sizes ranging between 40 and 200. The ages of the children ranged between 2 and 14 years, with three studies (65, 71, 73) including only younger children between the ages of 2 and 7 years. The reporting of sex across the studies was not consistent, with seven studies (59–62, 65, 68, 70) reporting the sex breakdown of only those included in the analysis and the rest reporting the sex breakdown of the children randomised. In total, of the sex breakdown reported, there were 980 males and 718 females. The only studies to report on child ethnicity were Wright et al. (62) and Fortier et al. (71). Eight studies (58, 59, 62, 64, 66, 67, 69, 73) included baseline information on the number of previous surgeries and/or hospitalisations by the children.

Inclusion criteria across all 17 studies were children within the studies specified age range, undergoing the relevant included procedures and without any cognitive impairments. Children were explicitly excluded from 11 studies (59–64, 67, 68, 70, 71, 73) with visual and/or developmental and/or auditory delays. Language was an exclusion in eight studies, with Stunden et al. (59), Wright et al. (62), Fortier et al. (71), and Campbell et al. (72) limited to English, Fernandes et al. (67) limited to Portuguese, Eijlers et al. (68) limited to Dutch, Liguori et al. (69) limited to Italian, and Wakimizu et al. (73) limited to Japanese. A history of seizures or epilepsy was an exclusion criterion in six (59–61, 63, 68, 70) of the seven VR DHIs, with Dehghan et al. (74) stating the only exclusion as "stress or special problems in using eyeglass or headphone in [virtual reality exposure therapy]" (p. 3).

Parents were included in 10 studies (58, 59, 62, 63, 65, 67, 68, 70, 71, 73). Six studies (58, 65–68, 71) reported baseline information on the educational socioeconomic status of the child's parents. Fortier et al. (71) also included information on parental income. Parental age was reported in seven studies (62, 65–67, 69, 71, 73) and parental ethnicity was reported only by Wright et al. (62).

The procedures that the children were undergoing across the studies were mostly for surgery, including elective and ambulatory surgery (60–63, 66–71, 74). The types of surgery differed across the studies, but the most noted were otolaryngology; ophthalmic; orthopaedic; dental; ear, nose, and throat (ENT); urology; herniorrhaphy; and tonsillectomy. The other procedures included tooth extractions (65, 72), magnetic resonance imaging (MRI) (59), and bone marrow aspirations (64). Bray et al. (58) included children undergoing both invasive (surgery, cannulation, and blood tests) and non-invasive procedures (x-ray or ultrasound). Wakimizu et al. (73) included only children undergoing herniorrhaphy.

3.3. Assessment of DHI development

There were 15 unique DHIs across the 17 included studies, with the same DHI used in three (60, 61, 63). The DHIs were scored against the 15 domains in the modified TDF, where 1, 0.5, or 0, respectively, meant that it either fully, partially, or did not demonstrate the domain. **Supplementary Table S7** in **Appendix F** provides the results of the DHI assessment against the 15 domains in the modified TDF, while **Table 3** offers a commentary for each.

3.4. Overview of the domains met in DHIs

None of the 15 domains was fully evidenced across all the DHIs, with 35% evidencing eight or more domains and 65% evidencing seven or fewer domains. The DHIs by Wright et al. (62) and Fortier et al. (71) fully evidenced the most domains, with 13 met in each. The first nine domains outlined in **Table 3** were met in each of these three studies, with differences occurring in the remaining six domains, namely, intentions, goals, social influence, optimism, co-production, and use of a behaviour framework. Stunden et al. (59) scored the next highest fully evidencing 11 domains, meeting the first nine and those for intentions and goals. Ryu et al. (70) scored the next highest, fully evidencing 10 domains, with all but that for emotion in the first nine being met, as well as goals and optimism. Dehghan et al. (74) did not evidence any domains fully, and the DHIs used by Huntington et al. (65), Campbell et al. (72), and Wakimizu et al. (73) fully evidenced only one domain and two domains each, respectively. This was attributed to insufficient information, as opposed to simply not meeting the domain. The remaining DHIs varied, with between three and nine domains fully evidenced. On average, the DHIs fully met 5.4 domains with a standard deviation of 4.17 and partially met 2.5 domains with a standard deviation of 1.19.

3.4.1. Domains for knowledge, beliefs about consequences, and environmental context and resources

The highest scoring modified TDF domains were for knowledge, beliefs about consequences, and environmental context and resources, with these being fully evidenced in 13, 11, and 10 DHIs, respectively. The domains for knowledge and

TABLE 3 Further details on the m-TDF assessment.

Included papers Domain	Bray et al. (58)	Stunden et al. (59)	Ryu et al. (60, 61), Park et al. (63)	Wright et al. (62)	Wantanakorn et al. (64)	Huntington et al. (65)	Fernandes et al. (67)
Knowledge	The platform provides information about the procedure, hospital environment including wards and operating theatres, the key healthcare staff involved, and the hospital equipment (p. 3). It uses a customisable avatar as a guide and chatbot.	VR movie and App provides information about the MRI procedure, the hospital equipment, and the staff involved (p. 3). It starts by introducing a radiologist and a peer in the reception area and then leads the user through an interactive guided tour of the hospital reception area, imaging room, and the steps of a head scan.	VR movie provides information about the procedure, hospital environment including the wards and equipment, and the staff (p. 99 and 1629, respectively). It takes the viewer through the process from admission to the operating theatre, and Pororo explains the process throughout in detail. It starts with Pororo changing into a hospital gown, having an IV catheter placed in his forearm, and then going into the operating room.	I-PPP includes two modules on education and information about the day surgery process and anaesthesia and anaesthesia protocol. Delivered *via* an interactive, virtual tour of the hospital including the admission area, day surgery room, holding area, operating room, and activities that take place in those locations. For anaesthesia, it covers what it is, the types, the purpose, and the process (p. 628).	Short, animated video in Mobile App provides patient information about the procedure including equipment used, and what to expect through the whole process from positioning, local anaesthesia, and sedation to the post-recovery process (p. 644).	Online web-based information over several screens/slides setting out a story of a 6-year-old child called Scott going through the process of the procedure, with child and parents "mouse clicking" through (From p. 159 plus additional paper Reynolds et al. (2012).	The App provides information on (1) hospital admission; (2) healthcare staff and hospital rules; (3) medical instruments; (4) medical procedures; (5) surgery room; (6) recovery room; and (7) aftercare and going home (p. 1192).
Skills	The platform uses a Q&A chatbot and games to create an understanding of the procedure and enable interactive engagement (p. 3).	The App includes elements to help the user learn how to interact with the virtual environment and cues to activate the next steps (p. 3).	The movie is not interactive only informative (p. 99 and 1629, respectively).	I-PPP includes a module on skills development through instructions regarding the continued practice of shaping and exposure to an anaesthetic mask (p. 628).	The game element is interactive, with breathing skills developed through the relevant game, but the movie element is purely informational.	Partially. Includes two videos that model appropriate coping behaviour and teach coping skills (p. 159).	The application uses interactive game activities after each level to guarantee that the information provided is understood by the child (p. 1192)
Emotion	Provides information on the sensory aspects of the procedure, and what the child may experience or feel to help reduce fear and anxiety (p. 3).	Through the inclusion of familiar sounds using narratives to support the child to cope with the loud and noisy MRI sound, to provide comfort, and thus to reduce stress.	Unclear if the movie addresses emotion. Reference made to Pororo emphasising that children will undergo the same process without difficulty, but there is no reference to considering anything that addresses dealing with fear, anxiety, etc. (p. 99 and 1629, respectively).	I-PPP includes a module on the identification of emotions and thoughts associated with day surgery experiences such as anxiety and worry (p. 628).	The game section is included in the App to support the child to cope with anxiety (p. 644).	Partially. Includes two videos that model appropriate coping behaviour and teach coping skills (p. 159).	The application uses a facial expression of the game character for the child to choose whether they are sad, happy, angry, or fearful (p. 1192). The application starts with a brief video explaining how to report emotions.
Behavioural Regulation	Provides information on coping strategies to manage behaviour (p. 3).	The App uses "staying still" to progress through the levels in the VR-MRI app, so drives behavioural regulation to achieve stillness (p. 7).	No information is provided.	I-PPP includes a module on behavioural training through shaping and exposure to an anaesthetic mask with a mask provided (p. 628)	The game section included in the App provides breathing exercises and coping skills (p. 644).	Partially. Includes two videos that model appropriate coping behaviour and teach coping skills (p. 159).	No information is provided to judge if the application supports any behavioural regulation.
Memory, Attention, and Decision Processes	Partially. Designed with children to ensure that it is engaging, acceptable, and effective. Also considers ease of navigation (p. 3).	User-led tour of hospital, staff, and equipment, through interactive hotspots designed to activate transition between rooms or sequences and the use of a stalling sequence to	Unclear. While the movie was short, being only 4 min long, it is not clear from the papers whether a child's attention and memory were factored into its development.	I-PPP is interactive and is initially provided sequentially, but once completed, the child and parents can return to any module (p. 628).	Unclear. It is not clear from the papers whether a child's attention and memory were factored into its development. No indication that the child could rewatch the video.	Unclear, as insufficient information is provided in the paper or other papers identified and reviewed.	The application uses interactive game activities after each level to guarantee that the information provided is understood by the child (p. 1192).

(*continued*)

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TABLE 3 Continued

Included papers Domain	Bray et al. (58)	Stunden et al. (59)	Ryu et al. (60, 61), Park et al. (63)	Wright et al. (62)	Wantanakorn et al. (64)	Huntington et al. (65)	Fernandes et al. (67)
		deal with any distractions (p. 3 and 4).					
Environmental Context and Resources	Provides information and images of the hospital environment (wards and operating theatres), equipment, and key staff (p. 3).	Provides information and images of the hospital environment, equipment, and staff. Also includes stimulations of sounds during an MRI (p. 3 and 4).	Provides information and images of the hospital environment, equipment, and staff. Includes scenes of having an intravenous catheter inserted, pressure cuff and pulse oximeters placed, and a facial mask applied for anaesthesia (p. 99 and 1629, respectively).	Module 1 is an interactive, virtual tour of the hospital including the admission area, day surgery room, holding area, operating room, and activities that take place in those locations (p. 628).	Partially. Provides information on the instruments used, and the images suggest some context of the hospital setting (p. 644), but not as detailed as with other applications/ tools, so partially met.	Partially. Appears to provide information on the procedure but is unclear on the level of information provided (p. 159).	The application provides information on healthcare staff and hospital rules; medical instruments; surgery room; recovery room (p. 1192).
Beliefs about Capabilities	Assumed through reference to what the child may experience and building of coping strategies—empowerment, self-confidence (p. 3).	Assumed through levels becoming more challenging to achieve as feedback mechanism is reduced and children are required to continue independently (p. 7).	Unclear. The video narration is noted to emphasise that all children undergo the same process without difficulty, but there are no references to coping, emotions, or feelings (p. 99).	I-PPP includes a module on coping instructions for parents to support their child (p. 628) and behavioural training (p. 628).	Breathing exercises and games help in coping with anxiety, help build self-confidence, and provide empowerment (p. 644).	Unclear as insufficient information is provided in the paper or other papers identified and reviewed.	Unclear as insufficient information is provided in the paper, and there is no indication of building confidence or esteem through coping.
Beliefs about Consequences	Understanding of the procedure and what the outcome will be through information on how it may feel or what may be experienced (p. 3).	Assumed through not progressing the levels because of not staying still (p. 7).	Taking the child through a narrative guided tour explaining the processes and showing what equipment is used (mask, ECG, blood pressure cuff, etc.) are deemed to support building an understanding of the consequences of the processes.	Assumed through a detailed virtual tour of hospital and experience, and behavioural component, specifically shaping and exposure to anaesthesia mask (p. 628) and practice of the skill module.	Assumed through the provision of information on the whole bone marrow aspiration process through a step-by-step guided video (p. 644) showing what happens by using cartoon children and healthcare professionals.	Unclear as insufficient information is provided in the paper or other papers identified and reviewed.	The use of the interactive game to confirm if the child has understood the information provided and an explanation of procedural information including rules.
Reinforcement	Use of interactive games.	Stalling of the sequence until the child's attention is refocussed appropriately (p. 4). Use of stillness as a measure to progress through levels (p. 7).	Simple 4-minute video taking the child through a guided tour from admission to the operating theatre, but there is no use of interactive tools, nor is there any implication whether the child could rewatch the video.	I-PPP is interactive and is initially provided sequentially, but once completed, the child and parents can return to any module (p. 628). Participants are encouraged to use the I-PPP more than once, particularly the behavioural component. Modules on the practice of skills, coping instructions, and emotions reinforce desired behaviour.	Breathing exercises and games to help in coping with anxiety and help reinforce behaviour to reduce anxiety (p. 644).	Unclear as insufficient information is provided in the paper or other papers identified and reviewed.	The application uses interactive game activities after each level to guarantee that the information provided is understood by the child (p. 1192)

(*continued*)

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TABLE 3 Continued

Included papers Domain	Bray et al. (58)	Stunden et al. (59)	Ryu et al. (60, 61), Park et al. (63)	Wright et al. (62)	Wantanakorn et al. (64)	Huntington et al. (65)	Fernandes et al. (67)
Intentions	Not demonstrated in the paper.	Uses interactive real-time feedback on the indicators of movement to support progression through the levels (p. 7).	No, due to the intervention being a video.	Assumed through behavioural components, specifically shaping and exposure to anaesthesia mask (p. 628).	Partially met through breathing exercises to promote specific behaviour.	Unclear as insufficient information is provided in the paper or other papers identified and reviewed.	Does not address this.
Goals	Not demonstrated in the paper.	Uses interactive real-time feedback on the indicators of movement to support progression through the levels (p. 7).	No, due to the intervention being a video.	Not demonstrated.	Not demonstrated.	Unclear as insufficient information is provided in the paper or other papers identified and reviewed.	Unclear as insufficient information is provided in the paper but suspect not.
Social influences	In a supplementary paper (081) covering information on parents being with a child or being supported by something familiar.	Unclear from the paper or methodology used in development.	Partially. The VR game incorporates a famous animated character to socialise the content in a child-friendly manner (p. 3).	Inclusion of a parent and child path in the program that would support discussion with the child (Wright et al. 2020, p. 306 and 307).	Not demonstrated.	Unclear as insufficient information is provided in the paper or other papers identified and reviewed.	Partially met through reference to information on parental separation (p. 1192).
Optimism	Not demonstrated.	Partially. Includes level attainment but unclear from the paper if level attainment is set out in advance for children to create optimism in achieving level 3.	No, due to the intervention being a video.	Not demonstrated.	Not demonstrated.	Not demonstrated.	Not demonstrated.
Co-production with: - healthcare professionals - children - parents	YES. Developed with all three.	PARTIAL: Developed with the research team, various healthcare professionals, and system administrators. No indication of development with the children or parents.	PARTIAL: The script for the movie is developed by an anaesthesiologist from Seoul National University Bundang Hospital, with doctors and nurses acting in the movie.	YES. Developed and tested with all three through separate studies (see Wright et al. 2017).	PARTIAL: The mobile App was tested with healthcare professionals and a small sample of children (p .645). No evidence that parents were involved.	YES: The paper notes that expert consultation and focus groups were used to develop the tool (p. 158 and 163), with this supported by information in Reynolds et al. (2012) and the study protocol.	PARTIAL: The paper notes that a pilot study involved 490 children and healthcare professionals to improve the application (p. 1192). No reference to the involvement of parents in the development of the tool.
Used a behaviour framework or	YES: Used a person-based approach as described by Yardley et al. (2015) [paper 082].	Unclear. Used an agile development methodology but unclear if a behavioural approach was used as part of this.	NO. No reference was provided to ascertain whether any behavioural frameworks were used.	YES. Wright et.al (2017) notes that cognitive behavioural intervention for anxiety disorders in children and behavioural preparation were used in developing the components of the I-PPP (p. 49).	Unclear. Reference made to the development team studying the characteristics and requirements of young children, but not to the use of behavioural frameworks or tools (p. 645).	Unclear as insufficient information is provided in the paper or other papers identified and reviewed.	Yes. The paper references the Social Learning Theory's theoretical framework (p. 1191) and that certain behaviours can be learned and reproduced, with modelling being effective to reinforce self-efficacy.

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environmental context and resources were the only two domains to have either been fully or partially evidenced for all 15 DHIs. The belief about consequences domain was fully or partially evidenced for 14 DHIs. Two DHIs did not fully meet the domain for knowledge. Liguori et al. (69) provided information on the operating room and equipment, lacking detail on the staff involved and the wider hospital environment, including what to expect before and after the procedure. Dehghan et al. (74) simply stated that "[the DHI] presented the simulated steps of going to operation room … [with] simulated sounds …" (p. 3). It was, therefore, deduced that while some information on the hospital environment was provided, insufficient detail was available on the whole experience and what elements were contained within the simulated steps to score fully. For the same reasons, these two studies were two of the five DHIs not fully meeting the domain for environmental context and resources. In contrast, Wantanakorn et al. (64), Huntington et al. (65), and Campbell et al. (72) all scored fully on knowledge but partially on environmental context and resources. Compared with the other 10 DHIs, the information in these DHIs lacked a wider environmental context and less detailed descriptions of all resources involved in the procedure.

The criteria to assess the beliefs about the consequences domain were dependent on the level of information provided to create an understanding of what the child would experience. Of the 15 DHIs, this domain was evidenced fully in 11, partially in three, and inconclusively in one. The DHIs scoring fully (58–64, 66–68, 70–72) either gave a step-by-step guide of what would happen, what and who were involved, and often what feelings or experiences may occur or used level progression or interactive games to check understanding. The three DHIs (69, 73, 74) scoring partially provided some information on what would happen but lacked information on feelings or experiences. Insufficient information was available on the Huntington et al. (65) DHI to score this domain.

3.4.2. Domains for optimism, intentions, goals, and social influences

The lowest scoring modified TDF domains were for optimism, intentions, and goals, with these being fully evidenced in 1, 2, and 3 DHIs, respectively. They were equally the lowest to score either fully or partially for all DHIs at 3, 5, and 4, respectively. The optimism domain was assessed on the basis of the inclusion of rewards or attainments in the DHI. It scored the least across all DHIs, with one (70) scoring fully because of awarding health points when the child advanced through the DHI levels and two (59, 71) scoring partially, as they separately incorporated level attainment and a completion certificate. The domains for intention, goals, and social influences were the next lowest scoring across all DHIs. Intentions were assessed on the basis of whether the DHI utilised feedback or rewards, goals if specific actions or behavioural changes were integrated, and social influences on whether something was aimed at parents or whether it used familial exposure or famous characters. The use of interactive real-time feedback to enable level progression and specific behavioural components scored two DHIs fully (59, 62), whereas the use of breathing or coping exercises partially scored three DHIs (64, 70, 71) for intention. The goals domain scored fully in three DHIs (59, 70, 71) that utilised feedback, level progression, and/or rewards and partially in one DHI (72). The social influences domain scored fully in four DHIs, with two specifically including a parental element in the DHI (62, 71) and two (58, 68) requiring parental involvement more broadly. Three DHIs scored partially on social influence either using famous characters (60, 61, 63, 70) or addressing parental separation (67).

3.4.3. Domains for skills, reinforcement, emotion, behaviour regulation, beliefs about capabilities, and memory, attention, and decision processes

Except for emotions, these domains appertain to building skills or techniques to address behaviour and emotions, with this being achieved through interactive elements such as games, exercises, or activities. Emotion is linked both as a contribution to, and an outcome of, these domains. The scoring for the remaining modified TDF domains was mixed across the DHIs. The skills and reinforcement domains were evidenced fully in the same seven DHIs (58, 59, 62, 64, 67, 70, 71), as they integrated interactive games or actions, building skills, and understanding. However, five DHIs partially evidenced skills because of including modelling videos such as breathing exercises (65, 66) or information (68) or activities (72) or those that could be viewed multiple times (73), while only Wakimizu et al. (73) partially evidenced reinforcement. The domains for emotion, behavioural regulation, and beliefs about capabilities all scored fully in six DHIs, with the score being the same for four of them (58, 59, 62, 71). The full scoring DHIs for the other two in each of these domains differed, with Wantanakorn et al. (64) and Ryu et al. (70) fully evidencing behavioural regulation and beliefs about capabilities and Fernandes et al. (67) and Eijlers et al. (68) fully evidencing emotion. The domain for memory, attention, and decision processes scored fully (59, 62, 67, 70, 71) and partially (58, 66, 68, 69, 73) for five DHIs each.

3.4.4. Domains for co-production and use of behaviour frameworks

Of the 15 DHIs, 11 reported the design that involved co-production, with the remaining four (66, 69, 72, 74) not stating anything. The use of co-production to design and/or test the DHI with healthcare professionals, parents, and children occurred for five DHIs (58, 62, 65, 71, 73). Partial co-production with healthcare professionals and testing with children occurred for three DHIs (64, 67, 68) and with only healthcare professionals for two DHIs across four studies (59–61, 63, 70). The use of a behaviour framework was applied in the development of four DHIs across six studies (58, 60, 61, 63, 67, 71). Insufficient information was commonly the reason for the remaining six DHIs scoring 0 in this domain.

3.5. Study measurements, outcomes, and direction of effect calculations

All studies assessed the outcomes of the intervention, with these being self-reported by children and parents, observed by clinicians or researchers, or extracted from medical records. The primary and secondary outcomes included assessments across five categories:

1. emotions and feelings,
2. behavioural responses,
3. physiological responses,
4. clinical status, and
5. assessment of the DHIs' usability, satisfaction, and/or knowledge.

Supplementary Table S9 in **Appendix F** outlines the assessment types used in each category and the studies in which they were applied. These are further divided within these categories where feasible to show results with an effect and no effect for children and parents, with observations noted between the study findings and the assessment results of the DHI. **Supplementary Table S10** in **Appendix F** provides details of the primary and secondary outcome measures for each study, including when and how the outcomes were measured. The table includes, where feasible, the results of the effect size calculations and the main findings. This information is summarised in the following sections.

3.5.1. Emotions and feelings

Emotions and feelings were assessed using 10 different measures across 11 studies (58, 59, 62–65, 67, 68, 71–73), with most of these studies using a visual analogue scale (VAS) or the State-Trait Anxiety Inventory (STAI).

3.5.1.1. Effect demonstrated

Bray et al. (58) revealed that the child's self-reported VAS trait and state anxiety before the procedure were comparable between the DHI group (DHIG) and the control group. No significant difference or effect was found in either the trait ($p = 0.85$, $d = 0.07$) or the state ($p = 0.54$, $d = 0.14$) anxiety between groups. State anxiety on arrival at the hospital was significantly lower in the DHIG with a negative medium effect ($p = 0.008$, $d = 0.61$) compared with that in the control group. Similarly, Wantanakorn et al. (64) revealed that self-reported anxiety VAS scores significantly changed from one hour before the intervention ($p = 0.82$) to after its application ($p = 0.012$) within the DHIG, with a negative medium effect ($d = 0.6$). This suggests that the DHIs positively impacted levels of anxiety in these two studies. It is noted that both DHIs included interactive elements and scored fully in the domains for behavioural regulation, beliefs about capabilities, and reinforcement. However, Wantanakorn et al. (64) only partially scored for co-production and provided no evidence of the use of a behavioural framework, whereas Bray et al. (58) scored fully in both of these domains. Wright et al. (62) showed that parental self-reported STAI for trait anxiety (STAI-T) was similar between the DHIG and the two control groups 1 week before the procedure ($d = 0$ and $d = 0.03$). Parental self-reported state anxiety (STAI-S) increased pre-procedure and decreased post-procedure but with a notable increase in anxiety in the DHIG compared with that in the two control groups. A medium positive effect occurred between the DHIG and control group 1 ($d = 0.58$) and a small positive effect between the DHIG and control group 2 ($d = 0.48$) pre-procedure, changing to a small positive effect compared with control group 1 ($d = 0.43$) and no effect compared with control group 2 ($d = 0.15$) post-procedure. Fernandes et al. (67) assessed child worry and feelings by using the Child Surgery Worries Questionnaire (CSWQ) and Self-Assessment Manikin (SAM). The CWSQ results showed that children in the DHIG had significantly lower mean levels of worry compared with the two controls (no intervention and video game) across all parts of the questionnaire ($p < 0.001$). This translated into a large negative effect between the DHIG and each of the controls. In addition, the video game control group had lower levels of worries compared with the no intervention control group. SAM results showed no significant differences in valence (calmness) or arousal (happiness) between the groups before and after the interventions. Despite this, a small effect ($d = 0.25$) was calculated between the DHIG and control group 1 for valence post-intervention. For arousal in the DHIG compared with the control groups, a small effect occurred pre-intervention ($d = 0.20$ and $d = 0.4$) and a medium effect post-intervention ($d = 0.53$, $d = 0.64$). Parental anxiety in the DHIG was significantly lower with a negative medium effect compared with that in control group 1 ($p = 0.033$, $d = 0.53$) but comparable with no effect compared with that in control group 2 ($d = 0.08$). This DHI was developed using a behavioural framework and co-production with children and healthcare professionals. It also met the modified TDF domains for emotion and reinforcement, scoring fully across seven domains. Fortier et al. (71) parental self-reported STAI anxiety was significantly lower ($p = 004$) in the DHIG than in the control group pre-procedure and post-intervention, with a medium negative effect ($d = 0.65$). Anxiety remained lower in the DHIG at separation but was not statistically significant and had a small negative effect ($d = 0.25$). Wakimizu et al. (73) showed child anxiety using the Wong–Baker Faces Scale (FACES) at seven time points from before intervention (baseline) to 1 month after the procedure. The results show that children in the DHIG had lower anxiety at all time points compared with those in the control group. However, a clear small effect occurred only pre-operatively ($d = 0.45$) and 1 month after the procedure ($d = 0.27$), and a partial small effect occurred at 1 week after the procedure ($d = 0.2$). Wakimizu et al. (73) also found that parental anxiety using the STAI was lower in the DHIG at all time points with a negative medium ($d = 0.60$) effect post-operatively and a negative small effect ($d = 0.23$) at 1 week after the procedure, and all other time points showed no effect. Campbell et al. (72) found self-reported child VAS anxiety scores comparable ($p = 0.790$) before the intervention across all three groups (usual care control group 1, cartoon control group 2, and web-based click-through presentation DHIG). However, during induction and recovery, the observer-rated child VAS to determine anxiety levels shows a decrease in anxiety across all groups over time. A significant change was

noted between the DHIG and control group 1 at induction ($p = 0.014$) and between the DHIG and control group 2 at recovery (0.016). The effect could not be calculated because of a non-normal distribution of data. While the results of these two studies suggest that the DHI had some impact, albeit a small effect for Wakimizu et al. (73), it is noted that both scored poorly against the modified TDF, meeting two domains fully and four and three domains only partially. Neither was the DHI interactive nor did it include aspects related to emotions or behavioural regulation. Park et al. found that the Numerical Rating Scale (NRS) for parental anxiety decreased significantly ($p = 0.009$) in the DHIG post-intervention and with a negative medium effect (0.67).

3.5.1.2. No effect demonstrated

Stunden et al. (59) found no change in child anxiety before the use of the three group interventions and after the MRI simulation, with control group 1 using the Standard Preparatory Manual (SPM), control group 2 using the CLP, and the DHIG using VR-MRI. The results before preparation were SPM (median 0, IQR 1, SD 1.521); CLP (median 0, IQR 0, SD 1.240); and VR-MRI (median 0, IQR 1, SD 1.311) and those after MRI simulation were SPM (median 0; IQR 1, SD 1.738); CLP (median 0, IQR 0, SD 0.468); and VR-MRI (median 0, IQR 1, SD 0.434). It is noted that median anxiety levels increased slightly in the SPM group after preparation (median 1, IQR 2, SD 2.311) compared with CLP (median 0, IQR 0, SD 1.350) and VR-MRI (median 0, IQR 1, SD 0.819). In contrast to child anxiety levels, Stunden et al. (59) found no significant difference in parental anxiety across the three time points, although it did increase from before to after preparation and decreased again after the MRI simulation in both control groups. Of interest to these findings is that this study scored highly against the modified TDF despite not demonstrating the use of a behavioural framework; however, the RoB2 results were high due to the potential for allocation sequence knowledge, potentially influencing the results. Huntington et al. (65) also found no change in child anxiety using the Facial Image Scale (FIS) over time, with the results comparable among all three groups, with control group 1 using usual care, control group 2 using a handwashing game, and the DHIG using a web-based click-through presentation. Eijlers et al. (68) found no significant difference in child self-reported VAS anxiety between the DHIG and the control groups at all four time points, measured before the intervention ($p = 0.407$) and after ($p = 0.753$, $p = 0.735$, $p = 0.727$). Likewise, self-reported STAI and observed VAS parental anxiety were comparable between the control group and the DHIG immediately after child induction with no effect observed in the STAI results ($d = 0.01$). Campbell et al. (72) parent-reported Modified Child Anxiety Scale (MCDAS) scores indicated higher child anxiety levels than those self-reported by children but were not statistically significant among the three groups.

3.5.2. Behavioural responses

Behavioural responses were assessed using 11 different measures across 12 studies (60–66, 68–71, 74). All these 12 studies measured behaviour change using the Yale Preoperative Anxiety Scale (YPAS), with 11 of these using a modified YPAS (m-YPAS). Three studies (60, 68, 71) measured Paediatric Anaesthesia Emergence Delirium (PAED) and four studies (61–63, 70) measured IC.

3.5.2.1. Effect demonstrated

The DHIs used by Wright et al. (62) and Fortier et al. (71) were both web-based programs available for multiple uses in the week before the child's procedure at home. Both DHIs scored fully for co-production and use of a behavioural framework. Wright et al. (62) observer-rated m-YPAS child anxiety scores were lower in the DHIG [I-Paediatric Preparation Programmes (PPP)] than in the two control groups (usual care and I-PPP + parent). This correlated to a small negative effect ($d = 0.24$) between the I-PPP and the usual care groups in the holding area and to a medium negative effect ($d = 0.53$) and small negative effect ($d = 0.34$) between the DHIG and the usual care and I-PPP + parent groups, respectively. The lower anxiety levels in both the I-PPP and the I-PPP + parent groups to the usual care group suggest that the DHI positively impacted anxiety levels. When considered against the higher parental anxiety STAI-S scores in the control groups, it was possible that parental anxiety may have impacted child anxiety. Fortier et al. (71) found a significant difference in observer-rated m-YPAS child anxiety scores across groups and time. At separation to the operating room scores were comparable among groups, but in the DHIG, anxiety decreased at the entrance to the operating room ($p = 0.02$, $d = 0.59$) and again considerably during induction ($p = 0.01$, $d = 0.63$). Parental STAI anxiety scores followed a similar trend to that of the children. The DHI used by Hatipoglu et al. (66) was a video viewed once, a week before the procedure in the hospital. Compared with the two control groups (usual care and voice recording), observer-rated m-YPAS child anxiety was significantly lower in the DHIG ($p < 0.001$). A large negative effect was calculated between the DHIG and the control groups, respectively ($d = 3.34$, $d = 0.822$). The DHIs used by Wantanakorn et al. (64) and Liguori et al. (69) were used the day before the child's procedure. Both studies showed a significant decrease ($p = 0.001$, $p = 0.009$) in observer-rated m-YPAS child anxiety after the use of the DHI in the DHIG compared with the control group. A medium negative effect ($d = 0.6$) and large negative effect ($d = 0.9$) were calculated. Ryu et al. (60, 61, 70) and Park et al. (63) measured pre-operative child anxiety using the Korean m-YPAS. All these studies found a significant difference ($p = 0.022$, $p < 0.01$, $p < 0.001$, and $p = 0.025$, respectively) between the DHIG and the control group after the use of the DHI 1 h before the procedure, with negative effects of small ($d = 0.47$) and large ($d = 0.80$) in the first two. The effect could not be calculated for Ryu et al. (70) and Park et al. (63) because of the non-normal distribution of data. Dehghan et al. (74) reported that child anxiety was significantly different in all domains, except in arousal, in the two DHIGs. No effect size could be calculated because of the nature of the reported data. For induction behaviour and compliance, Ryu et al. (61) found significantly

lower Procedural Behaviour Rating Scale (PBRS) scores during induction in the DHIG ($p = 0.01$). Ryu et al. (61, 70) and Wright et al. (62) measured induction compliance using the Induction Compliance Checklist (ICC). A higher compliance was found in the DHIG than in the control groups ($d = 0.86$, $d = 0.52$, $d = 0.54$). Fortier et al. (71) measured emergence delirium using the PAED and found that it was significantly lower in the DHIG ($p = 0.04$), with a small negative effect ($d = 0.45$). Post-operative behaviour was measured by Hatipoglu et al. (66) using the Post-Hospitalisation Behaviour Questionnaire (PHBQ) 7 days post the procedure. They found a significant difference ($p < 0.001$) between control group 1 (usual care) and both control group 2 (voice recording) and the DHIG. The effect size between the DHIG was large to control group 1 ($d = 2.049$) and small to control group 2 ($d = 0.31$). In addition, they showed that anxious children had a 1.03 times greater risk of adopting negative post-operative behaviours.

3.5.2.2. No effect demonstrated

Eijlers et al. (68) found no significant differences in self-reported or observer m-YPAS anxiety scores between the DHIG and the control group after intervention use on the same day, with results comparable across all time points. Equally, no effect was noted where it could be calculated because of the normal distribution of data, with $d = 0.02$ at admission before intervention and $d = 0.01$ in the holding area after the intervention. Although the intervention was used a week before the procedure, Huntington et al. (65) found no significant difference in m-YPAS child anxiety scores between the DHIG and the two control groups overall. A small positive effect ($d = 0.21$) was calculated between the DHIG and control group 2 (handwashing game) both pre- and at induction. For induction behaviour and compliance, Ryu et al. (70) found PBRS scores during induction comparable between the groups ($p = 0.92$). Huntington et al. (65) found no difference in induction behaviour using observer-rated VAS between the DHIG and the control groups, correlating with no effect ($d = 0$, $d = 0.08$). Park et al. (63) ICC results found compliance similar between the groups ($d = 0.07$). Ryu et al. (60) and Eijlers et al. (68) also measured emergence delirium. Both found no significant difference in PAED scores between the DHIG and the control group ($p = 0.719$, $p = 0.266$). For behaviour, Ryu et al. (60) used the PHBQ-AS at one and 14 days post-operatively, finding no significant difference ($p = 0.671$, $p = 0.329$) among children in the two groups. Eijlers et al. (68) used the Child Behaviour Checklist (CBCL) at admission, and no statistical significance was found between the groups ($p = 0.251$).

3.5.3. Physiological responses

The study by Fernandes et al. (67) was the only one to measure physiological changes before and after the intervention and also after the SAM measurements. Blood pressure was similar, with no effect among all three groups, although mean values were lower in the DHIG. The heart rate was similar between the control groups and lower in the DHIG, with a small negative effect pre-intervention ($d = 0.45$, $d = 0.36$) increasing to a medium negative effect post-intervention ($d = 0.53$, $d = 0.63$) in the DHIG compared with the control groups.

3.5.4. Clinical status

Clinical status was assessed in five studies (59, 64, 65, 68, 71) with measures including pain level, length of stay, medication usage, head movement in MRI simulation, and MRI preparation and assessment time. Child pain was measured by Eijlers et al. (68) using the observer-rated Face, Legs, Arms, Cry, Consolability scale (FLACC) in recovery, and the Parents' Postoperative Pain Measure (PPPM) at home, and Fortier et al. (71) used an NRS. No statistical significance was found in any of these measures between the DHIG and the control group in both studies, with the results being $p = 0.410$, $p = 0.454$, and $p = 0.30$, respectively. For patient flow, Huntington et al. (65) measured anaesthetic induction time, recovery time, and ward time, finding no significant difference among the three groups. However, the DHIG had a slightly longer recovery time than control group 2 (handwashing game) with a small positive effect ($d = 0.31$) and spent less time on the ward compared with control group 1 (usual care) with a small negative effect ($d = 0.28$). Fortier et al. (71) similarly found no significance between the groups for surgery ($p = 0.708$) or recovery ($p = 0.26$) time. Medication usage for analgesic consumption was recorded by Fortier et al. (71) and Eijlers et al. (68) and for sedative drugs by Wantanakorn et al. (64), with all of them finding no significant difference between groups overall. Eijlers et al. (68) found that DHIG children undergoing an adenoidectomy and tonsillectomy needed significantly less rescue analgesic compared with the control group ($p = 0.002$, $d = 0.46$), and overall, a small effect ($d = 0.22$) was calculated between the need for rescue analgesia in the DHIG compared with the control group. Stunden et al. (59) used head movement in the MRI simulation to determine success with a threshold of 3–4 mm. They found no statistically significant difference in the number of participants scoring above the threshold ($p = 0.07$) nor among the three groups ($p = 0.27$). The chi-square p-value effect calculated a small effect ($d = 0.43$) in average successful MRI and a small negative effect ($d = 0.26$) between the groups, with the DHIG (VR-MRI) being on average less successful at 30% compared with control group 1 (SPM) at 47% and control group 2 (CLP) at 50%. Preparation time and assessment time were measured in minutes. Preparation time between the groups was significantly different ($p < 0.001$) and had a medium effect size ($\eta^2 = 0.57$), with the DHIG preparing the longest on average at 22.05 min. However, assessment time was comparable across the groups with no significant difference ($p = 0.13$).

3.5.5. Assessment of the DHIs' usability, satisfaction, and/or knowledge

DHI usability, satisfaction, and/or knowledge and understanding were assessed using seven different measures across eight studies (58, 59, 61–63, 65, 70, 73). Bray et al. (58)

measured procedural knowledge and satisfaction of children and parents or caregivers using the VAS. Procedural knowledge was measured 3–5 days before the procedure and on arrival at the hospital, increasing significantly for both children ($p < 0.001$) and parents or caregivers ($p = 0.01$) in the DHIG compared with the control group. The calculated effect was positively large for children ($d = 1.11$) and positively medium ($d = 0.59$) for parents and caregivers. Procedural satisfaction in children and parents was not statistically significant ($p = 0.10$ and $p = 0.72$) but was higher in the DHIG than in the control group, with a small positive effect in children ($d = 0.37$). Stunden et al. (59) measured child satisfaction using the VAS and found that children in control group 2 (CLP) and the DHIG (VR-MRI) were on average more satisfied than children in control group 1 (SPM) at 90%, 80%, and 73.5%, respectively. Huntington et al. (65) measured parental satisfaction using the VAS, reporting results only for those scoring 9 or 10 across the three groups, but they found no difference with the scores comparable. In addition, Huntington et al. (65) evaluated treatment by applying the Treatment Evaluation Inventory 48 h after the procedure and found that the DHIG had a higher odds ratio (OR) for satisfaction relative to control group 1 and control group 2 for whether they found the information helpful for their child to handle the visit (OR = 12; 95% CI 4.7–32, $p < 0.001$ and OR = 8.2; 95% CI 3–22, $p < 0.001$) and whether it improved their child's ability to cope (OR = 21; 95% CI 8–56, $p < 0.001$ and OR = 13; 95% CI 5–34, $p < 0.001$). Ryu et al. (61, 70) used an NRS to measure parental satisfaction and found no significant difference between the DHIG and the control group ($p = 0.198$, $p = 0.268$). Park et al. (63) did find a significant difference in NRS scores for parental satisfaction ($p = 0.008$). Wright et al. (62) measured parental satisfaction using the Client Satisfaction Survey and found that parents in control group 2 (I-PPP + parent) were more satisfied than their counterparts in control group 1 (SPM) and the DHIG (I-PPP). With regard to the DHIG, a small positive effect ($d = 0.20$) was calculated against control group 1 and a medium negative effect ($d = 0.50$) was calculated against control group 2. Stunden et al. (59) assessed how fun children found the interventions using the Smilyometer, with children in control group 1 (SPM) finding it "okay" and those in control group 2 (CLP) and the DHIG (VR-MRI) finding it "really good". They also assessed parental usability of the interventions using the Usefulness, Satisfaction and Ease of use (USE) questionnaire. No significant difference was found among the three groups, with control group 1 agreeing that it was somewhat useful but easy to use and learn and control group 2 and the DHIG agreeing that it was useful, easy to use, and learn. Bray et al. (58) used a 5-point Likert scale to measure self-reported child procedural involvement and a tick-box form against the parts of the App that the children looked at and liked. They found procedural involvement slightly higher in the DHIG than in the control group ($p = 0.03$), and of the 20 children who completed the form, they liked the different components. Wakimizu et al. (73) used a 4-point scale to measure parental satisfaction in the DHIG and found that the majority ($n = 66$, 91.7%) were satisfied.

3.6. Risk of bias assessment

The risk of bias across the 16 randomised control trials was generally concerning, with 68.8% having an overall result of some concern (60–63, 65–70, 73) and 31.1% an overall result of high risk (59, 64, 71, 72, 74). Risks were linked to the process for randomisation or the inability to confirm whether a pre-specified analysis plan was finalised before the results were unblinded for analysis. **Figure 2** provides an overall summary of bias as a percentage for the six domains.

Figure 3 provides a breakdown of the risk of bias for each study against the six domains, namely randomisation process (D1), deviations from intended interventions (D2), missing outcomes data (D3), measurement of the outcomes (D4), selection of the reported results (D5), and overall bias.

All studies used a random group allocation sequence, with this being computerised in eight studies (60–63, 66, 67, 70–72). The method of randomisation varied in the rest of the studies, including drawing lots, using concealed envelopes, allocating on bed numbers, or using an allocation ratio. Randomisation process bias (D1) for seven studies (60–65, 67) was low, with this being attributed to confirmed allocation sequence concealment and no noted baseline differences among the groups to suggest problems. Conversely, seven studies (66, 68–70, 72–74) were determined as having some concern due to insufficient information on the allocation sequence concealment but no notable baseline differences among the groups. Dehghan et al. (74) provided insufficient information to determine whether baseline differences among the groups suggested a problem with the randomisation process. Due to the potential for allocation knowledge to influence participant bias, the studies by Stunden et al. (59) and Fortier et al. (71) were determined to have a high risk of randomisation process bias, as both confirmed that blinding to allocation was not possible.

Bias due to deviations from intended interventions (D2) was low across 50% of studies. Of the five studies considered to have some concern of bias in this domain, three (59, 62, 63) were attributed to insufficient information on deviations from intended intervention groups. Ryu et al. (61) had one deviation from the DHI group due to dizziness using the VR, although the child was not reassigned and was excluded from the analysis. Fernandes et al. (67) reassigned 15 children after randomisation because of ethical concerns over children sharing the same ward and being in different groups. The potential bias from this change in the group was deemed to be of some concern but not high risk, as participants were unaware of their group allocation until receiving the intervention. Wantanakorn et al. (64), Campbell et al. (72), and Dehghan et al. (74) were considered at a high risk of bias in this domain because of insufficient information to determine whether participants, carers, and people delivering the interventions were aware of group assignment, whether any deviations from the intended groups occurred, and whether an appropriate analysis was used to estimate the effect of assignment to intervention.

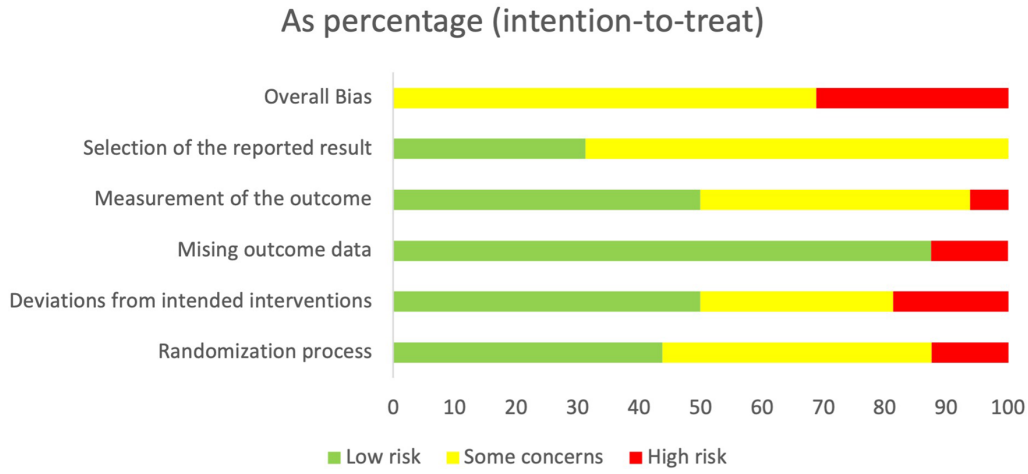

FIGURE 2
Risk of bias results as a percentage.

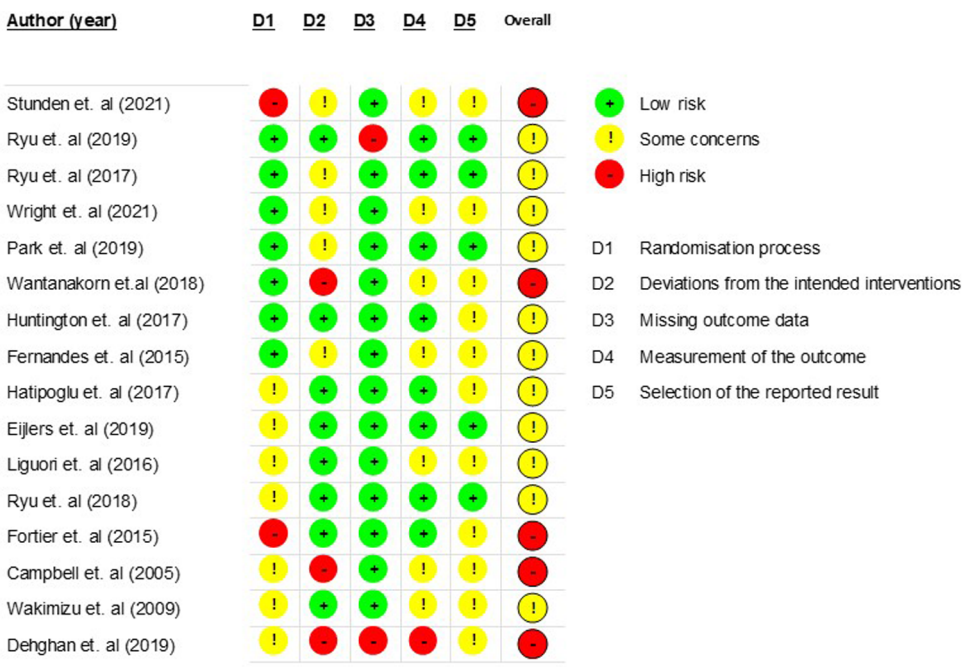

FIGURE 3
Risk of bias assessment for each included study.

Bias due to missing outcome data (D3) was low across 88% of the studies and considered high for two studies. Ryu et al. (60) excluded three participants from analysis because of a data collection failure, and given the small sample size, it was considered that this could have impacted the outcomes, thus having a potentially high risk of bias. Dehghan et al. (74) provided insufficient information on whether data were available for all or nearly all participants, thus also having a higher risk of bias.

Bias for measurement of outcome (D4) was deemed low in 50% of studies (60, 61, 63, 65, 66, 68, 70, 71) as the same appropriate outcome measures among the groups were used and the outcome assessors were blinded. In contrast, 43.8% of studies either provided insufficient information to conclude whether the outcome assessors were blinded (67, 69, 73) or provided evidence to suggest that they were not blinded (59, 62, 64), resulting in some concern of bias. Campbell et al. (72) likewise had some concern of bias in this domain, but this was due to an inability

TABLE 4

Included Papers Domain	Hatipoglu et al. (66)	Eijlers et al. (68)	Liguori et al. (69) [Online video (92)]	Ryu et al. (70)	Fortier et al. (71) [Kain et al. (93)]	Campbell et al. (72)	Wakimizu et al. (74)	Dehghan et al. (74)
Knowledge	Video recording that informs about the surgery and anaesthesia methods, what the duties of the anaesthesiologist are, what will happen, and what equipment is used and some of the hospital staff involved in the procedure, and what the operating and recovery rooms look like (p. 794).	The virtual reality storyline shows the child information about the hospital environment, staff, and equipment and what will happen from admission to recovery (p. 730). Different instruments can be explained by the child by pointing towards them creating an interactive explanation.	Partially. The video uses two clowns, Dr Cloud and Dr Wisp, who, funnily and engagingly, show the operating room and explain some of the equipment used (p. 2). It does not provide any information on staff or the wider hospital environment.	Virtual reality storyline with game elements explaining the pre-operative process through a 360-degree, three-dimensional virtual environment in a first-person perspective. It uses famous characters to explain the pre-operative process from putting on the hospital gown to being transported into the operating room and includes information on equipment and staff, how to use the anaesthetic mask, etc. (p. 3).	The intervention provides web-based information across four modules: (1) at home before surgery, (2) holding area and anaesthesia induction, (3) recovery room, and (4) at home after surgery (p. 908). Provides information on the hospital environment, staff, and equipment through videos and games.	The computer package provides information on the process before dental extraction. It includes details of the staff involved by clicking on each of their images and explains that the child is sent to sleep when "magic wind from a space mask" is applied to the face. It provides some information on recovery when Scott wakes up and feels "fizzy" and provides aftercare information (p. 833).	The video provides information across 12 scenes from pre-hospital preparation (1, 2, and 3) to arriving at the hospital and meeting the staff, preparing for surgery by changing and leaving the caregiver to walking to the operating room (4, 5, 6, and 7), to confirming the child's identity, and getting ready for surgery having equipment applied (8, 9, 10, 11, and 12). It provides information on the whole pre-operative process, hospital environment, and staff (p. 395).	Partially. The intervention uses VR-simulated steps, viewed through eyeglasses in front of a computer monitor, of going to the operation room, with headphones placed on the child's ears to stimulate the sounds of the virtual environment (p. 3). The paper states information provided on the ward and operating room but otherwise lacks details to meet this domain fully.
Skills	Partially. The movie is not interactive but only informative (p. 794); however, the paper states (p. 789) that visuals modelling body language, together with auditory information, are two key elements for effective learning methods.	Partially. The child can point at different instruments with a motion-tracked controller and the staff in the environment then explain what they are for (p. 730).	The movie is not interactive but only informative (p. 2).	The VR incorporates games to challenge the child to defeat the germ monster and awards "health points" each time the child advances to the next pre-operative step (p. 3).	Use of games and videos to build coping skills, modelling behaviour, and tailoring the experience to the child's fear levels by providing information about the surgical process; the child character Anna displays more or less fearful responses (p. 909–911).	Partially. At the end of the computer package, a list of activities is provided to support the prevention of tooth decay to achieve improved oral health (p. 833). However, insufficient information is provided to determine if other skills are addressed such as coping mechanisms.	Partially. The video is available for multiple reviews in advance of surgery during the week before, allowing the child to develop an understanding of the pre-operative process. However, the provided booklet for caregivers contains information on coping techniques, which the child did not have direct access to (p. 395).	Insufficient information is provided to judge if the VR-stimulated environment develops skills and is viewed only once lasting approx. 5 min (p. 1).
Emotion	Unclear if the movie addresses emotion. Reference made to a child asking about pain and being told that pain relief is used, but there is no indication of any emotional coping (p. 794).	The VR includes a video with a nurse explaining what kind of feelings the child may experience, for example, nausea (p. 730)	Partially. Dr Wisp explains that he is scared and shivering, and Dr Cloud tells him it is ok and that you do not need to feel like that (reference: video clip online).	Unclear if emotions are addressed in this VR game.	The intervention addresses emotion by tailoring the information provided and the fear responses of the character Anna to the child accessing the site (p. 911)	No information to suggest emotions are addressed in the detail provided in the paper. Appears to largely be informative about the process and staff involved.	The video description in the paper appears to not address emotions, with this being covered by the booklet for the caregiver (p. 395). Therefore scored 0 as it is not a part of digital intervention.	Insufficient information is provided to judge if the VR-stimulated environment addresses emotions.

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TABLE 4 Continued

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Behavioural Regulation	No information provided.	Does not appear that the VR includes any behavioural regulation and is purely informative.	The video does not address any behavioural regulation.	The VR game incorporates breathing practice (p. 3.)	The intervention provides techniques for the self-management of anxiety through deep breathing and guided imagery. This is aimed at helping to reduce anxiety and lessen feelings of nervousness (p. 909 and 910). Also uses distraction techniques to help the child manage anxiety (p. 910), and module 4 provides instruction on implementing behavioural strategies to minimise pain and distress (p. 910).	The computer package does not appear to address behavioural regulation.	The video description in the paper appears to not address behavioural regulation, with this being covered by the booklet for the caregiver (p. 395). Therefore scored 0 as it is not a part of digital intervention.	Insufficient information is provided to judge if the VR-stimulated environment addresses behavioural regulation.
Memory, Attention, and Decision Processes Memory	Partially. The paper states (p. 788 and 789) that behavioural programmes to teach coping skills through modelling need to consider the child's age, developmental stage, and previous experience. It is, therefore, assumed that this was factored into the development of this programme, but it is insufficient to fully meet the domain.	Partially. Two versions of the VR video were produced to address developmental differences in children aged 4 to 12 years, possibly considering memory retention ability and comprehension.	Partially. The video is short, approx. 6 min, simple, and engaging using humour and playfulness (p. 2 and online video clip).	The VR game is short, uses famous childhood characters from the animated film 'Hello Carbot' and has challenges and rewards to keep the child engaged (p. 3).	The intervention uses animated characters Billy Bot and his sidekick Tot Bot to help the child navigate through the modules, using videos, games, and humour to engage the child (p. 911). A memory game is included to introduce the child to the objects in the PACU. Additional printable resources are provided to reinforce learning from web-based modules. Website is available 5 days before surgery and up to 10 days after surgery and can be accessed 24 h a day, 7 days a week (p. 913)	Unclear. While the computer package seems to be short, it is not clear from the papers whether a child's attention and memory were factored into its development, nor how long it takes to navigate the package.	Partially. The video is short at approx. 9 min and provides a week in advance for children and caregivers to access as many times as they wish, enabling information to be absorbed in a relaxed environment (p. 395). However, there are no interactive elements for this tool.	Insufficient information is provided to judge if the VR-stimulated environment addresses this domain.

(*continued*)

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TABLE 4 Continued

Included Papers Domain	Hatipoglu et al. (66)	Eijlers et al. (68)	Liguori et al. (69) [Online video (92)]	Ryu et al. (70)	Fortier et al. (71) [Kain et al. (93)]	Campbell et al. (72)	Wakimizu et al. (73)	Dehghan et al. (74)
Environmental Context and Resources	The video recording shows the equipment, operating room, and recovery room. It also explains what to expect in terms of how the anaesthesia mask is used by demonstrating on a teddy bear. It includes the anaesthesiologist and nurse (p. 794).	The VR video provides detailed information and images of the hospital environment, staff, and equipment (p. 730).	Partially. The video includes information on the operating room and some of the equipment and explains the use of the pulse oximeter and anaesthesia mask, but there is no information on staff or the wider hospital environment, including the recovery process (p. 2 and online video clip).	The VR storyline and games provide detailed information and images of the operating room environment, equipment, and staff (p. 3).	The intervention provides information on the hospital environment, staff, and equipment through videos and games. It also uses a specific game to introduce the child to the objects in the operating room (p. 911).	Partially. The computer package includes information on staff and explains the use of the pulse oximeter and anaesthesia mask, but no information is provided on the wider environment or other equipment (p. 833).	The video provides information on the hospital environment, staff, and equipment (p. 395).	Partially. The intervention uses VR-stimulated steps, viewed through eyeglasses in front of a computer monitor, of going to the operation room, with headphones placed on the child's ears to stimulate the sounds of the virtual environment (p. 3). The paper states information provided on the ward and operating room but otherwise lacks details to meet this domain fully.
Beliefs about Capabilities	Unclear as insufficient information is provided in the paper, and there is no indication of building confidence or esteem through coping.	Unclear as insufficient information is provided in the paper, and there is no indication of building confidence or esteem through coping.	Does not address this domain. The video is purely information provision and does not incorporate any activities or interaction to enable building self-confidence, self-esteem, etc.	Assumed through the use of the challenging game to defeat germ monster (p. 3).	The games used are designed to "model, reinforce and practice strategies for keeping calm and reducing nervousness" (p. 911).	Does not address this domain. The computer package is purely information provision and does not incorporate any activities or interaction to enable building self-confidence, self-esteem, etc.	Does not address this domain. The video is purely information provision and does not incorporate any activities or interaction to enable building self-confidence, self-esteem, etc.	Does not address this.
Beliefs about Consequences	The movie explains that pain is managed by anaesthesia and that the child will fall asleep quickly and then awake after surgery with the parent in recovery. It shows how the anaesthesia will be administered through a vessel in the hand (p. 794).	Assumed through step-by-step storyline from admission to anaesthesia, including enabling interactive motion control to seek additional information on equipment (p. 730)	Partially. The video includes information on the operating room and some of the equipment and explains the use of the pulse oximeter and anaesthesia mask. These give a sense of the consequences, but they insufficiently address this domain to score a 1 (p. 2).	Assumed through the child advancing through a step-by-step pre-operative process and interaction of the operating room environment (p. 3).	Assumed using tailoring information to the child's level of fear, through the provision of information about the surgical process and use of video and games on objects in the operating room and PACU and placing of anaesthesia masks on animals (p. 911).	The computer package includes information about staff and some of the equipment and explains the use of the pulse oximeter and anaesthesia mask, giving a sense of the consequences. It also provides a list of activities to support the prevention of tooth decay to achieve improved oral health (p. 833).	Partially. The video includes information on the pre-operative process, including the equipment and staff, but insufficiently addresses this domain to score a 1 (p. 395).	Partially. The VR-stimulated environment includes information on the steps of going into the operating room but does not fully address this domain to score a 1 (p. 3).

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TABLE 4 Continued

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Reinforcement	A simple video explaining specific information about the pre-operative expectations, but there is no use of interactive tools, nor is there any implication whether the child could rewatch the video.	Although the VR video uses interactive motion–controlled gesturing, this is simply to enable the further provision of information, and there is no indication that any behaviour reinforcement is applied.	A simple video explaining specific information about the pre-operative expectations, but there is no use of interactive tools, nor is there any implication whether the child could rewatch the video.	The VR uses interactive game activities after instructions to challenge the germ monster; it also includes the choice of a facial oxygen mask to practice breathing (p. 3).	The use of deep breathing exercises, the use of memory games for introducing the child to the objects in the PACU, and placing the anaesthesia mask on animals all provide reinforcing behaviours (p. 911). Additional printable activities, including colouring sheets, are also provided.	A simple cartoon computer package explaining specific information about staff and some of the processes, but there is no use of interactive tools, nor is there any implication whether the child could rewatch the sequence.	Partially. The video is available for multiple reviews in advance of surgery during the week before, allowing the child to develop an understanding of the pre-operative process (p. 395).	Does not address this.
Intentions	Does not address this.	Does not address this.	Does not address this.	Partially. Using breathing exercises and interactive gameplay with rewards (p. 3).	Partially. Using breathing and coping exercises for both child and parents (p. 909 and 911).	Does not address this.	Does not address this.	Does not address this.
Goals	Does not address this.	Does not address this.	Does not address this.	The VR game element uses rewards when the child advances to the next step (p. 3).	Provision of certificate for completion of the program, advancement through the modules by playing games (p. 911).	Partially. At the end of the computer package, a list of activities is provided to support the prevention of tooth decay to achieve improved oral health (p. 833).	Does not address this.	Does not address this.
Social influences	Does not address this.	The VR video confirms that parents can stay with the child all the time until they are anaesthetised; it includes images of the parent and child wearing hospital gowns (p. 730).	Does not address this.	Partially. The VR game incorporates a famous animated character to socialise the content in a child-friendly manner (p. 3).	Parental modules of the site aimed at teaching parents coping and modelling behaviours, with this part accessed before the child site, which parents then go through with their child (p. 908 and 909).	Does not address this.	Does not address this.	Does not address this.
Optimism	Not demonstrated.	Does not address this.	Does not address this.	Assumed through rewarding "health points" when child advances levels (p. 3).	Partially met. Use of tailoring to create feelings of being safe and managing anxiety levels. Use of memory games to introduce objects in the PACU and provision of completion certificate.	Does not address this.	Does not address this.	Does not address this.
Co-production with: - healthcare professionals - children	No information is provided on the development of the video.	PARTIAL: A multidisciplinary team, consisting of child life specialists, child psychologists, a child	Beyond confirming that the video was produced in collaboration with the association of Soccorso Clown, it does not	PARTIAL: The study authors developed the video in collaboration with the VR game producing company,	YES: The programme was developed using a task force of anaesthesiologists, psychologists, surgeons, nurses, paediatricians, child	No information is provided on the development of the computer package, and	YES: The video was developed and edited by various medical staff (outpatient unit, surgical ward, and operation	No information is provided on the development of the VR-stimulated environment.

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TABLE 4 Continued

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- parents		psychiatrist, anaesthesiologists, a 3D acting director, and a 3D project manager, designed the script of the VRE (p. 2). The paper indicates that it is tested by children and adjusted to consider feedback, but there is no indication of parental involvement.	confirm if healthcare staff, children, or parents were involved. While this may be assumed, this is not stated.	with the study authors comprising healthcare professionals (confirmed *via* searching).	life specialists, parents, and children [p. 906, Kain et al. (2015) paper].	the referenced paper is not accessible.	department) and reviewed by families and experts (p. 395).	
Used a behaviour framework	No information is provided on the development of the video and therefore on the use of any behavioural frameworks.	Unclear. While various experts were used to inform development, including psychologists, it is unclear if any behaviour frameworks were used.	No information is provided on the development of the video and therefore on the use of any behavioural frameworks.	No information is provided on the development of the VR games and therefore on the use of any behavioural frameworks.	Yes. Paper Kain et al. (2015) states that the "conceptual framework and content of WebTIPS was examined by a behavioural medicine, interventions, outcomes expert panel" (p. 906).	No information is provided on the development of the computer package, and the referenced paper was not accessible.	No information is provided to determine of any theoretical frameworks were used.	No information is provided.

VR, virtual reality; App, smartphone, or tablet, or computer applications; 3D, three-dimensional; m-TDF, modified theoretical domains framework; PACU, Post Anaesthesia Care Unit; VRE, virtual reality exposure.

to align the sample size in the result data, meaning insufficient information was provided to decide whether measurement or ascertainment of the outcome differed among the groups. Although the same appropriate measures were used for the outcomes among the groups in Dehghan et al. (74), insufficient information was provided to determine whether the outcome assessors were blinded. As a knowledge of group interventions could lead to bias, and it was not possible to determine whether it was likely that the outcomes could have been influenced by this knowledge, it was considered that this study was at a high risk of bias.

Most studies (68.8%) had some concern for bias in D5 "selection of the reported results". This was due to an inability to confirm whether the outcome data were analysed following a finalised pre-specified analysis plan before unblinded outcome data were made available for analysis. This according to Cochrane RoB2 guidelines (94) means that there is an unclear risk for reporting bias. For 10 studies (62, 64–67, 69, 71–74), a trial protocol was not obtained, and although the studies generally set out the analysis plan, it was not viable to confirm whether it was finalised before unblinded analysis. Five studies had a low risk of bias in this domain, with four (60, 61, 63, 70) due to a finalised pre-specified analysis plan being reported in the trial protocol and one (68) due to the analysis plan being followed and the outcome assessors being blinded.

Medical trials entail a comprehensive understanding of clinical ethics, with those involving children complicated by stricter standards than those involving adults (95). In addition, paediatric medical trials entail a careful balancing of benefit against risk and a consideration of the evolving stages of a child's development and an informed parental, often family-centred, decision making (96). These stricter ethical standards and requirements, together with fewer eligible participants, result in paediatric medical trials being more challenging and less frequent (95, 97). The outcome is that paediatric medical trials are often not supported by class I evidence, having a higher probability of bias and lower external validity. These issues correlate with the studies included in this systematic review and the overall higher risk of bias.

4. Discussion

DHIs are increasingly being used to prepare children and their parents for hospital procedures, aiming to reduce pre-operative anxiety and improve health outcomes. It is evidenced that well-prepared children are associated with reduced pre-operative anxiety and that DHIs can be an effective preparation method (13–16). This study aimed to use the TDF to evaluate the design and development of these paediatric preparation DHIs, determine whether a behavioural framework and co-production were used, and understand their impact on health outcomes. The four main findings of this review are discussed within the context of the modified TDF and the

1. health outcomes observed,
2. co-production and use of behaviour frameworks,
3. type of DHIs, and
4. timing and location of the DHIs used.

4.1. Health outcomes observed

All studies included in this review assessed child anxiety either as an emotion or as a feeling or behavioural response. Compared with children in the control group(s), 14 studies (82%) showed that children using the DHIs were associated with lower anxiety levels and the DHI had a positive impact, with this corresponding to the result of the effect size calculations where they could be calculated. This differed for three studies (17%), which showed anxiety levels were similar and the DHIs had no or little impact and effect. Given that higher pre-operative anxiety is a predictor of negative behavioural changes, the results for measures such as emergence delirium, induction behaviour, and induction compliance were mixed, although they were considered only in a small number of the included studies. For the three studies (60, 68, 71) that measured ED, only one found its occurrence lower in children prepared using the DHI. For the studies looking at induction behaviour (61, 65) and induction compliance (62, 63, 70), one study found improved induction behaviour and two found improved induction compliance in children using the DHI. Some of these health improvements are linked to higher scoring within the modified TDF and the first finding of this study.

The first finding is that paediatric preparation DHIs scoring higher against the modified TDF are more likely to be associated with reduced anxiety and reduced negative behavioural changes, as they will provide detailed information on the planned procedure and encompass information on coping with emotions, feelings, and anxiety (1, 13). Bray et al. (58), Stunden et al. (59), Wright et al. (62), Ryu et al. (70), and Fortier et al. (71) were the highest scoring studies against the modified TDF, having fully met 10 or more domains with 8 of these in common. The eight domains that were commonly met were knowledge, skills, behavioural regulation, environmental context and resources, belief about capabilities, beliefs about consequences, and reinforcement. This is attributed to the DHIs including (1) detailed information on the hospital environment, staff, equipment, and relevant procedure; (2) interactive elements such as games, quizzes, rewards, actions, or activities; and (3) breathing or coping exercises or modelling videos. The children using the DHIs in four of these studies were associated with lower anxiety levels (58, 62, 70, 71), lower occurrence of emergence delirium (71), and higher induction compliance (62, 70). This finding indicates that DHIs that incorporate these domains and are used as preparation interventions could be associated with reduced anxiety levels and other negative behavioural changes. An anomaly to this finding is the study by Stunden et al. (59). Stunden et al. (59) did not find any impact on child anxiety levels nor any difference in the key measure for head movement in their randomised control trial. This inconsistency is not likely to impact the first finding of this review for two reasons: (1) the trial was conducted with a simulated MRI and paid volunteers; and (2) all children reported no anxiety at baseline. This contrasts with the other four studies where the DHIs were used in preparation for real paediatric procedures, and varying levels of anxiety were reported at baseline. Nevertheless, the design of this DHI is considered relevant to the evaluation against the modified TDF. This finding cannot be extrapolated to all studies that reported positive health outcomes, given that the DHI scoring varied against the modified TDF. Despite this, the lack of meeting this finding can be attributed to either one or more of the remaining three findings, or insufficient information available in the study paper to make a judgement, thus resulting in a zero score.

4.2. Co-production and use of behaviour frameworks

The second finding is that preparation DHIs scoring higher against the modified TDF are more likely to have used co-production and a behavioural framework in their design and development. Aufegger et al. (21) stated that children and their parents prefer "easily digestible, non-medical explanations as to what to expect during the treatment process [together with information] on how to prepare", whereas healthcare professionals suggest that information on policies, the hospital environment, staff roles and responsibilities, and patient flow timings are useful. In addition, Bray et al. (52) found that children valued coping strategy information as it enabled emotional self-regulation and provided more information about the procedure. Of the five DHIs scoring the highest against the modified TDF, three (58, 62, 71) fully met the co-production and behaviour framework domains. No information was provided in the papers by Stunden et al. (59) and Ryu et al. (70) to determine whether a behavioural framework was used, but both partially met the domain for co-production, having involved healthcare professionals in the DHI development. Fernandes et al. (67) used a behavioural framework and co-produced the DHI with healthcare professionals and children, with this DHI being the sixth highest scoring one. In the context of the findings from Aufegger et al. (21) and Bray et al. (52), the DHI in these studies all incorporated detailed information about the hospital environment, staff, equipment, and procedure, and the five highest scoring DHIs included interactive elements, coping strategies, or self-regulation feedback. The association between a higher modified TDF score and health outcomes is linked to the hypothesis in the primary objective of this review. Preparation DHIs that are co-designed and grounded in behavioural science can result in reduced pre-operative anxiety and improved health outcomes. However, further research is required to validate this finding.

The three higher scoring studies (58, 62, 71) that explicitly stated had used behavioural frameworks in designing and developing the DHIs were associated with lower levels of child anxiety, lower occurrence of emergence delirium, and higher induction compliance. In the context of theory-driven

intervention design, execution, and reporting, behavioural frameworks such as the TDF offer an approach to understand and/or explain what influences the success of intervention implementation. Through understanding and explaining what influences will contribute to successful implementation, interventions aimed at changing behaviours can be designed and developed accordingly. Similarly, this study suggests that behavioural frameworks, such as the TDF, can be used to assess an intervention design and development in the context of implementation evaluation, thus supporting refinement of the intervention design.

4.3. Type of DHIs

The third finding is that the type of preparation DHI plays an important role in achieving a higher score against the modified TDF, with this being intrinsically linked to interactivity and rewards or achievements. In a previous qualitative study (17), children wanted preparation information that is easy to access, comprehensible, engaging, and child-friendly, as they believed that all of this will aid in the alleviation of their worries. This builds on the previous two findings, reiterating the value of interactive DHIs that incorporate games, quizzes, rewards, actions, or activities. Here again, the top six and the seventh highest scoring DHIs against the modified TDF were all interactive, being an educational multi-media App (58, 67), a VR-MRI App (59), a video App with games (64), a web-based program (62, 71), and a VR video game (70). An anomaly to this finding is the educational multi-media App by Huntington et al. (65) that scored very low against the modified TDF. However, this is due to the lack of information in the study paper to fully assess the DHI. The remaining DHIs were mostly non-interactive video tours, VR information, or web-based click-through presentations. Consequently, a correlation was further identified between the domain for optimism and the domains for skills, reinforcement, intentions, and goals. This was observed in three of the highest scoring DHIs by Stunden et al. (59), Ryu et al. (70), and Fortier et al. (71). All these scored fully or partially in the optimism, intention, and goal domains, and all fully scored in the reinforcement and skill domains. Stunden et al. (59) used interactive cues (skills) and real-time feedback on movement within the MRI stimulation (reinforcement and intention) to encourage stillness (goal), and when this was achieved, the child advanced to the next level (optimism). Ryu et al. (70) and Fortier et al. (71) used interactive games (skills) and breathing and coping exercises (reinforcement and intention) to advance through the steps or modules (goals), receiving health points and a completion certificate, respectively (optimism). Both these DHIs used interactive game elements to reinforce behaviour, such as chasing the germ monster after instructions in the recovery room and placing the anaesthesia mask on animals. These findings suggest that integrating interactive elements (skills and reinforcement) with feedback or rewards (intentions) could be used to drive certain actions or behavioural changes (goals) by creating the desire (optimism) to achieve the feedback or reward. Furthermore, for two of the studies, it is associated with improved outcomes. An irregularity to this correlation was the DHI by Campbell et al. (72). It failed to meet the reinforcement, intention, and optimism domains, but it partially met the skill and goal domains through the provision of a list of activities to prevent tooth decay at the end of the web-based presentation.

4.4. Timing and location of the DHI used

The fourth finding is that the timing and location of the preparation DHI lends itself to a higher score against the modified TDF. Three of the highest scoring DHIs, by Bray et al. (58), Wright et al. (62), and Fortier et al. (71), were provided for use at home by children and parents, as many times as they liked, between a week and 3 days before the procedure. These three DHIs were also associated with lower anxiety levels in the children using the DHI, and for two, lower occurrences of emergence delirium (71) and higher induction compliance, respectively (62). This suggests that the use of the DHI in the comfort of the child's own home, within a few or more days before the planned procedure, may contribute to reduced pre-operative anxiety and improved health outcomes.

4.5. Strengths and limitations

This study's strength is that it evaluates the design and development of DHIs used in preparing children for hospital procedures, correlating this against effectiveness in improving outcomes. Previous systematic reviews (6, 19, 20, 22, 23, 98–100) have predominately focused on the type of health interventions used and their effectiveness in improving health outcomes and/or reducing pre-operative anxiety, stress, and pain. In addition, some of these reviews included non-digital health interventions (98–100) and those used for distraction (6, 100). This study has specifically evaluated DHIs used for preparation.

There are limitations to this study. The first and second limitations relate to the search strategy and data extraction. While the search strategy was considered comprehensive, it was limited to papers in English published within the last 22 years, with the period being to ensure the relevance of the studies. When snowballing references of included papers and previous systematic reviews, a few papers published before the year 2000 may have been relevant for inclusion.

The third was the inability to conduct a meta-analysis because of the presence of heterogeneity across the included studies. Consequently, effect sizes were calculated, but not all studies reported the mean and standard deviation. It was, therefore, necessary to convert the median and interquartile ranges into a mean and standard deviation to then calculate the effect size. However, due to insufficient information to determine proximity to a normal distribution, the results may potentially be skewed. Some data reported in the studies were not amendable to calculating the effect size, and for these studies, the results were only narratively synthesised.

Finally, the level of information contained within some of the study papers to describe the DHIs was minimal, with supporting resources not found. This was a factor in the inability to draw meaningful conclusions against many of the modified TDF domains.

4.6. Quality of the studies

The quality of the studies was predominately moderate, with five studies having an overall high risk of bias. However, when considering the individual risk of bias in each of the five domains, it generally ranged from low to some concern, with most of the concerns linked either to an uncertainty of, or to a confirmed lack of, blinding of participants or those assessing the data, or to a lack of information in the papers to make a judgement. This was within the domains for "randomisation process" and "selection of reported results", with the latter predominately linked to uncertainty on whether the analysis plan was finalised before results were assessed and the trial protocol not being readily available to verify, rather than the results being biased.

4.7. Implications for policy and future research

It is considered that this study is the first to use an adapted version of the TDF to assess the design and development of DHIs used to prepare children for hospital procedures. The four key findings from this study suggest that the TDF can be used to analyse the effects of preparation DHIs, and by using theory-driven behavioural science, their design can be redressed accordingly to improve health outcomes. While these findings contribute to this field of study, further research is required to validate the findings. Furthermore, research is required to understand the developmental costs of these preparation DHIs and whether they are cost-effective against the traditional form of pre-operative preparation.

5. Conclusion

The Theoretical Domains Framework is a validated tool designed to enable the evaluation of behaviour change and can be used to assess implementation issues, support intervention design, and analyse interventions. This study applied an adapted version of the Theoretical Domains Framework to assess the design and development of DHIs used to prepare children for hospital procedures.

The main findings from this assessment are that DHIs scoring highly against the modified TDF are

1. associated with positive health outcomes,
2. influenced by the use of co-production and behavioural science in their design and development,
3. interactive,
4. used a few days to a week in advance of the planned procedure within the comfort of the child's own home.

These four findings together are associated with reduced anxiety and reduced negative behavioural changes in the DHIs that scored the highest against the modified TDF. Furthermore, well-designed and developed DHIs that can be used in the child's own home and in advance of the planned procedure may be more cost-effective. This is in respect of the reduced staff time for on-the-day preparation and the potential longer-term reduced healthcare utilisation.

Paediatric preparation DHIs that are designed in the context of behavioural science and with co-development from healthcare professionals, children, and their parents are more likely to be associated with reduced pre-operative anxiety and have the potential for improving health outcomes. Furthermore, the use of paediatric preparation DHIs well in advance of planned invasive and non-invasive procedures may be more cost-effective than traditional preparation programmes such as Child Life Specialists or hospital tours that require staff time, resourcing, and planning around the child's procedure. By enabling pre-operative information to be provided digitally in the child's own home, these costs could be reduced. However, further research is required into the cost–benefit of this weighed against the developmental costs associated with the DHIs, particularly those that have shown to be more effective in reducing pre-operative anxiety.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

Author contributions

M-CD was involved in conceptualisation, methodology, investigation, data curation, formal analysis, writing—original draft, and writing—review and editing. CB was involved in conceptualisation and writing—review and editing. LA was involved in conceptualisation, methodology, formal analysis, and writing—review and editing. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2023.1103624/full#supplementary-material.

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Facilitating facilitators to facilitate—Some general comments on a strategy for knowledge implementation in health services

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Numerous endeavours to ensure that day-to-day healthcare is both evidence-based and person-centred have generated extensive, although partial, comprehension of what guarantees quality improvement. To address quality issues, researchers and clinicians have developed several strategies as well as implementation theories, models, and frameworks. However, more progress is needed regarding how to facilitate guideline and policy implementation that guarantees effective changes take place in a timely and safe manner. This paper considers experiences of engaging and supporting local facilitators in knowledge implementation. Drawing on several interventions, considering both training and support, this general commentary discusses whom to engage and the length, content, quantity, and type of support along with expected outcomes of facilitators' activities. In addition, this paper suggests that patient facilitators could help produce evidence-based and person-centred care. We conclude that research about the roles and functions of facilitators needs to include more structured follow-ups and also improvement projects. This can increase the speed of learning with respect to what works, for whom, in what context, why (or why not), and with what outcomes when it comes to facilitator support and tasks.

KEYWORDS

knowledge implementation, evidence-based practice, guidelines, internal facilitators, leadership, local facilitators

Introduction

To sustain safe healthcare with optimal quality, any breach between what procedures should be performed (commended by contemporary evidence) and what procedures are in fact performed needs to be closed (1). Scientists, decision-makers, managers, and clinicians seek support that will enable faster and better uptake of evidence-based healthcare. Consequently, quality improvement and knowledge implementation have progressed over the last decades, efforts that sometimes overlap and other times

counteract one another (2, 3). Although resources are now available that aid knowledge implementation, further efforts are needed to understand what really works. Using internal (also known as local) facilitators is encouraged (4), but more knowledge is needed about the engagement, training, and activities of facilitators and the outcomes of such efforts.

A tongue-twister sets the scene: a facilitator facilitates by facilitation. That is, a facilitator is any enabler of knowledge implementation. As such, facilitators come in various forms. For example, a facilitator for the uptake of an innovation could be a contextual element such as staffs' recognition of the need for and readiness to change routines. The term "facilitator" is also used for interventions dedicated to bridge barriers such as electronic reminders that enable the end-user's uptake and adherence to evidence-based practice guidelines (5, 6). Internal facilitators (IFs), a topic addressed here, are people assigned to facilitate knowledge implementation in their organisations (7–10). That is, IFs help others adopt and sustain the use of evidence-based practices.

Of all implementation theories, models, and frameworks, the integrated Promoting Action on Research Implementation in Health Services framework, i-PARIHS (previously PARIHS) is one of the most prominent when it comes to addressing the IF role and function (11). Yet, a previous analysis found this component infrequently addressed in for example empirical implementation studies (12). As the role of IFs has not received sufficient attention, no single formula exists for appointing, training, and supporting IFs (13). IFs can be and are often selected among staff, serving as singular entities or teams (14). IFs are commended because of their association with their organisations: their experience with and channels to the context where the knowledge implementation shall take place can be beneficial. IFs may be trained and work in different ways and with different approaches (15). Nevertheless, they are charged with promoting change that is supposed to benefit safer and better care. A better understanding of IFs should help implementation science and healthcare efforts. The purpose of this paper is to reflect how engagement and training of IFs, in relation to context elements can affect their activities and outcomes. Further, to present some recommendations for enhancing IFs role and function in knowledge implementation in healthcare.

Material and methods

In a number of previous and current implementation studies (**Table 1**), we have promoted IFs as the main vehicle for knowledge implementation. All studies have comprised interviews with the IFs themselves, managers, and fellow staff (with details available in the corresponding papers). Further, all such interviews have been semi-structured, following a similar, semi-structured guide. In this paper, we have applied a hermeneutic approach (24), to shape an overall understanding of the appointment, training, and performance of IFs (including: who were assigned and by whom; how many IFs were allocated; the layout and content of their training and support programs, plus; their activities and experiences).

Experiences and discussion

Internal facilitator recruitment

By default, the appointment of the IFs in our projects was initiated at the point of site inclusion (including the randomisation stage in cases of quasi-experimental or randomised trials). While recruitment of IFs should consider personal characteristics and interpersonal skills and confidence (8), we asked site managers to suggest IFs based on primary commands: assign IFs by means of identifying individuals (a) susceptible to clinical practice change, and (b) with authority among their peers. Consequently, all IFs across the commissioned implementation studies were local staff with an employment within their organisation, recruited by their site manager(s); to the best of our knowledge, none asked their staff to elect an IF. The IFs held typical positions for their professions and were assigned the IF role on a temporary basis for each unique knowledge implementation project. Some had a formal leadership role, and in some cases, both staff and managers were nominated to a local IF team. Many IFs in our cases had some or extensive prior training in and/or experience with quality improvement, but no one had prior knowhow of implementation science.

The IFs in the studies underpinning this paper were all willing to engage in this role. More exactly, most were genuinely keen to engage as IFs and recognised the importance of making changes in their organisation to improve the quality of care. A sense of pride being appointed to facilitate this process has transpired from the very start of each intervention. However, such commitment often diminished over time, regardless of if serving as IFs on a temporary engagement (for the particular implementation project) or having an everyday leadership position in addition to the IF assignment. This is despite the training and support programs offered: all our ventures have addressed the need to plan and perform both in times of tailwind and hardship, including a promotion of strategies to facilitate engagement over time. Rather, we propose such decline of enthusiasm is primarily a matter of focus and local support: it takes time to facilitate knowledge implementation. If—or more often when—other initiatives or requirements for change emerge in the local context, other staffs' and managers' attention to and engagement in the project the IF(s) are assigned often diminishes. IFs then seem to find it difficult to persist in what may be a slow pace of adoption and implementation. Particularly, when peers' interests turn to other novel initiatives, the IFs often waver. Furthermore, ensuring full adoption and addressing resistance to change is complex. This complexity means that the support of management is vital.

We have found that what a manager considers to be a staff's mandate might neither be what fellow staff nor the IFs themselves consider to be their authority. Rather, who has actual

TABLE 1 Overview of the studies informing this paper.

Research study	IF intervention timepoints	IF training and support	IFs	Type of data collection and analysis to map IFs
Primary leaders implementing stroke guidelines (PLIS) (16, 17)	February–May, 2013	A 4-month program including two workshops (1 day each) and two teleconferences between the workshops (90 min each, after 3 and 6 weeks) delivered to the IF teams.	Rehabilitation first-line managers (physiotherapists, occupational therapists, registered nurses, and physicians).	Individual interviews prior to and after the intervention; analysed with qualitative content analysis (18).
Onset prevention of urinary bladder issues in orthopaedic nursing and rehabilitation (the OPTION pilot (19, 20) and later cluster-randomised trial, addressing urinary incontinence and urinary retention, respectively (21) plus manuscripts in progress)	February–May 2014; May 2021–April 2022	Three full day seminars with all teams and two tele-conferences (separate per site); the ongoing RCT comprises a 12-month support program initiated and concluded in lunch-to-lunch seminars. In addition, monthly conferences via link plus opportunities for exchange via a project-specific website.	Registered nurses, assistant nurses, physiotherapists, and occupational therapists; teams of registered nurses, assistant nurses, occupational- and/or physiotherapists, nursing and rehab first line manager(s).	Individual interviews, prior to and following the intervention; analysed with qualitative content analysis (18).
Managers implementing oral care guidelines for frail older people in nursing homes (MOral) (22)	September–December, 2014	Three half-day seminars and workshops, and two teleconferences.	Registered nurses (first-line nursing managers).	Individual interviews, prior to and following the intervention; analysed with qualitative content analysis (18).
Preference-based patient participation in renal care (dialysis, and predialysis plus dialysis care, respectively) (23) plus manuscripts in progress	October 2019–March 2020	Lunch-to-lunch seminar with all teams; monthly meetings via link: each site team separate or all teams together in accordance with the IF's preferences.	Registered nurses.	Individual interviews, prior to and following the intervention; analysed with qualitative content analysis (18).

authority among peers, to what extent, and in what issues is delicate to detect. So, it is reasonable to propose that an IF rather needs the capacity to "establish and persist" in a given matter—i.e., whatever innovation (such as an evidence-based guideline or tool) the implementation process addresses. Perseverance is necessary for sustaining the often slow processes of knowledge implementation. Yet, it needs to come with an ability to detect if, when, and how an adaptation is needed—e.g., to adjust an implementation strategy if and when discovering it does not address a barrier, or if detecting additional elements of importance to the implementation process. This adjustment requires attention, confidence, and communicative skills. Such competences can be developed in IFs through implementation coaching, although IFs need a set of basic skills on which to build their further training (25).

Internal facilitator training and support

In our cases, coaching of IFs has comprised training and support programs. Such interventions for IFs lasted between 3 and 12 months. Training sessions focused on the implementation object, either evidence-based clinical practice guidelines and/or clinical tools. Furthermore, the IFs received material to support their and their peers' learning about the clinical innovation (i.e., the evidence to be implemented). In addition, the training focused on knowledge implementation. Consequently, both implementation experts and clinical experts served on the programs and helped guide the IFs (13). We name these external facilitators, EFs. All the programs (**Table 1**) suggested the IFs made plans for promoting the realisation of evidence by mapping local barriers and enablers and fitting implementation strategies to address these features. With the Promoting Action on Research Implementation in Health Services (PARIHS; later the integrated-PARIHS or i-PARIHS) framework as a common backdrop, the local context has been highlighted in seminars where the IFs discussed their plans and procedures along with plans to reinforce knowledge-to-action. This has been embedded with respect to their previous know-how of quality improvement.

All the studies also offered the IFs monthly interactions with the EFs, accommodating the IFs' own learning, making of plans, performance of tasks and actions, as well as addressing shared challenges and experiences (that is, both practical and intellectual support) (8, 11). These interactions were a mix of face-to-face meetings and telephone and/or teleconference support plus some digital support (via e-mail and/or a project specific website). We did not find much variance with regards to these arrangements, but the regular support was typically appreciated. However, we propose a variance occurs with respect to who is invited to these events. In some projects, the IFs were invited to joint meetings that included all IFs, in others we provided a mix of support for each site's IF(s) and joint meetings. In the former, IFs were occasionally unable to attend, but were offered site-specific encounters. In the latter, we invited the IFs to decide whether to have common or individual meetings. We found that early in IF support programs, local barriers and plans reinforcing site events need to be considered. Consequently, some meetings benefit from a joint setup between the intervention sites so the IFs can learn from each other. This common approach is particularly useful when all IFs have started to facilitate implementation. Yet, although each context is unique and therefore requires a tailored implementation, we found that over time the IFs tended to compare themselves with others in a competitive style. Therefore, we suggest a coordinated number of and structure for joint

meetings; these meetings should have an explicit agenda that emphasises learning from each other by sharing "what worked" only if accompanied by "in what context". That is, mutual meetings need to provide transferable experiences and activities. Unless feasible, individual support—i.e., site support—should be considered.

How much training and support IFs need is a critical issue. In previous implementation research, we experienced that longer training (5 vs. 3 days) and 2 years of monthly support (rather than 1 year) did not increase the impact of the IFs who were assigned to promote better incontinence care of frail older people (26). Rather, in a current RCT with an embedded process evaluation in orthopaedic care (**Table 1**), the IF teams appreciated the 1-year program although they were prepared for the progress to take longer (personal communication). It may take years for an IF support program to ensure guideline adherence with clinical outcome effects (27), emphasising the need to recognise context and sustained support (28).

Adding training and support to IFs to promote knowledge implementation is also a question of when and how the training and support takes place. In general, IF coaching in our studies was hampered by a lack of literature about clinical implementation, and we appreciate the recent publication of handbooks for scholars and clinicians (29, 30), in addition to training manuals (31). This literature should aid seminars and mutual discussions, enabling flipped classrooms and problem-based learning (32); though increasing the opportunities for better training and support of IFs, we recognise the need to have such guidance in one's native language (8). In all our cases, the IFs also needed (and were provided with) training on the clinical objective such as an evidence-based guideline or tool. We also commissioned material to sustain the IFs and other staffs' learning trajectories. Such needs have either been common, across all intervention sites, or local. Consequently, we have shared guidelines, sources of evidence such as scientific articles, video presentations with tutorials for the clinical issue. Further, we have provided templates for the IFs to assess and evaluate context barriers and enablers, including mapping the extent of evidence-based practice. Although appreciating having been trained with regards to the evidence, the IFs still hesitated to transmit clinical evidence to their peers. Again, we consider this in relation to their authority, which may be hampered by the fact that the IFs have either been a regular member of staff or a manager. In the first case, despite their training in an IF program, it can be difficult to speak with authority to their peers. In the latter, managers have described being dismissed due to their lack of clinical credibility.

Our studies had a limited number of IFs per site attending the intervention programs, although a broader distribution of teaching and training opportunities is proposed (33). Healthcare is often limited in how many people it can dedicate to facilitating change. Therefore, we propose at least introducing other staff and managers to the basics of knowledge implementation such as the enablers and barriers to knowledge implementation. This may encourage peers to engage in mapping their local conditions for knowledge implementation. Furthermore, a basic understanding of implementation strategies can avert obstacles such as resistance to change and deviation; a joint understanding of which efforts are promoted and why (i.e., to bridge everyday barriers) may promote acceptance among staff. We also propose a common, chief understanding of theories, models, or frameworks that recap and support knowledge implementation, which IFs ought to refer to as a result of their training (34). All IFs have attested that they wish they had known this before: this command would have saved them time and efforts when engaged in and/or promoting quality improvement.

Barriers and enablers for internal facilitators

In our cases, the IFs were primarily selected among the nursing and/or rehabilitation staff even though all cases required that physicians adopt evidence, such as guidelines and/or tools. In all four cases revisited, first-line managers were involved at some point. Even with some prior formal training in change management (either received as part of a leadership program or quality improvement courses), few first-line managers associated leadership with a facilitator role. Rather, most IFs had only through our programs learned about different leadership styles related to promoting change. Further, the IFs linked their own behaviours to facilitating knowledge implementation only after being guided to such connection (35). None of the IFs recognised any previous support in change-oriented leadership behaviours.

Although all IFs were selected because of their presumed capacity to promote change and hence enable knowledge implementation, they had few opportunities to address beliefs and routines of their peers and/or managers. Rather, when encountering such barriers, the IFs required support from their managers (36). Such support requires that all managers understand the basic principles of implementation processes and can both trust and envision change (37). We have found that IFs without the support of managers and managers without staff IFs on their team can only reach a certain point. Thus, we suggest that IF teams consist of both staff representatives and their first-line managers (including physician representatives when influenced by a change). Teams with representatives from both staff and management can better understand what is facilitating knowledge implementation, and what leadership facilitates change (38). The latter incorporates enabling the IFs to proceed and helps sustain the implementation through strategic performance of task-oriented, relations-oriented, and/or change-oriented behaviours (39).

Internal facilitators activities and performance

All our cases have promoted an elementary Plan-Do-Study-Act process to guide the IFs while progressing in their knowledge implementation assignments. This is similar to for example the Veteran's Affairs Implementation Facilitation Training (31),

likewise stressing the planning phase, and recommending a thorough assessment of the context elements that may or may not pose barriers and enable change, respectively. Drawing on the i-PARIHS framework (11), we have also employed the Ottawa Model of Leadership Implementation, including leadership behaviours promoting knowledge implementation. In addition, we have used the Consolidated Framework for Implementation Research (CFIR) to illustrate the implementation process (40). Moreover, both i-PARIHS and CFIR has served as means for capturing context and the elements and domains that can hinder or enable knowledge implementation. Furthermore, we believe that this should proceed by tailoring strategies to fit local facilitation needs, launched only when an appropriate implementation plan is in place. Nevertheless, we found that many IFs favour known methods of knowledge dissemination such as lectures for all staff (41). Early in an implementation process, these traditional approaches can help address the need for a shared understanding of the objective of the implementation (e.g., a clinical guideline) and the need for change. However, lectures in isolation only marginally facilitate adoption and sustainment of the change needed to embrace new or different procedures. Furthermore, teaching sessions do not facilitate de-implementation of what is no longer a best practice (42). We suspect the promotion of lectures for knowledge implementation is linked to a lack of grit and motivation for change, which is found in many healthcare organisations. A more careful initiation and completion of improvement initiatives is likely beneficial, including an evaluation of what has previously worked (or not), providing for more tailored knowledge implementation.

Mapping the context for barriers and enablers was important for all IFs we have trained and supported. In most cases, mapping has enabled both an understanding of upcoming impediments to change and why prior quality improvement efforts were or were not successful. However, even with barriers identified, we found that some obstacles are not addressed in the further implementation process. Quite often this relates to attitudes among peers and/or management, particularly a resistance to change in general or an unwillingness to adhere to a particular guideline or procedure. IFs propose that they cannot address such beliefs or behaviours regardless of whether they represent a staff or manager IF. Indeed, it is difficult to enable implementation whenever some or even several staff (or managers) resist the promotion of evidence-based practice. So far, we have promoted liaisons with key co-workers, also known as champions (43). We have also encouraged the IFs to adopt task-, relations-, and change-oriented behaviour, a focus that requires IFs to carefully assess their context and employment and evaluate their own actions with respect to source and outcomes (4) (This is certainly the case also for those of us serving as external facilitators.). Nevertheless, people are on their own trajectories when presented with and anticipating change (44), making facilitation a question of employing strategies that comprise a reasonable amount of coercion and enthusiasm. When implementing new guidelines, tools, etc. the IFs also need to prepare staff to address concerns raised by patients (or their next of kin) as a result of new healthcare routines and procedures. This way only, both evidence-based and person-centred healthcare services can transpire.

Co-design and co-production

Facilitating knowledge implementation should involve all end-users. Although recommended (45), patients were not engaged as IFs or placed on the IF teams in any of our cases (perhaps due to our programs not emphasizing this perspective). This may also be an effect of the often swift events taking place, by a lack of recognition of patients as resources, or not associating patient participation with opportunities for improvements (46). In the projects presented here, the IFs shared some previous experience of collaborating with patients (or their next of kin) in quality improvement initiatives. Since our training and support programs have not addressed potential patient facilitators or their representation on the IF teams, we consider this a topic for future development: any change in clinical practice that encourages the uptake and performance of previously not used but better knowledge and routines will require changes in attitudes and behaviours of individuals, teams, and entire organisations. Consequently, end-users like patients will be affected and therefore should be engaged (47). We suggest adding such elements to implementation and evaluations, investigating if and how co-design and co-production with patients facilitates knowledge implementation.

Contribution to the field

Knowledge implementation is crucial to evidence-based healthcare, but making changes is complicated when it comes to disseminating and adopting clinical guidelines, tools, and procedures. We suggest that IFs are key to such processes as they have the benefit of knowing their organisations and the people who need to be engaged to ensure knowledge implementation (and de-implementation). Furthermore, IFs have opportunities to adapt to the local context and translate the objectives and activities to others.

This paper adds to the growing understanding of who IFs are, their training and support, and what purpose they serve. Lessons learned include the importance of a careful recruitment process, and sustaining a long-term commitment to knowledge implementation, as outlined in **Table 2**.

Based on a summary of four studies and additional literature, we suggest that IFs best work in teams. In addition, such teams should engage staff representatives, managers, and presumably end-users such as patient representatives. The activities, performance, training, and support of IFs are complex issues that need further attention in implementation science and practice. Moreover, to the best of our understanding, IFs need more than just training and support. Rather, further attention when it comes to what IFs do and how much time they spend on knowledge implementation is needed.

Table 2 Overview of the overall understanding of facilitating facilitators to facilitate.

Lesson learned
Recruit internal facilitators (IFs) with caution, recognising their ability to reach out to fellow staff, management, patients, and other stakeholders of the knowledge implementation.
Identify IFs level of perseverance and ensure that it is sustained at times of high resistance to knowledge implementation and change
Certify that IFs map the barriers and enablers for knowledge implementation of the local context, and plan (and reschedule) actions to address these
Execute training and support programs for IFs with booster doses
Engage management to facilitate the facilitators in their facilitation of knowledge implementation

Based on our experience, a more careful engagement of professionals is needed to scaffold a solid and sober plan for knowledge implementation that sustains short- and long-term change while accommodating new needs as they arise. Although IFs with optimal features, prospects, and training are likely to facilitate implementation of evidence-based practice, further investigations into their collaboration with patients are needed. For example, future studies should investigate how to co-design knowledge implementation with patient representatives, focusing on if and how patients can facilitate more evidence-based and person-centred health services.

Data availability statement

The data analyzed in this study is subject to the following licenses/restrictions: Data identifying individuals are not available due to research ethics regulations, but details sufficing the Commentary are available upon reasonable request. Requests to access these datasets should be directed to ann.catrine.eldh@liu.se.

Ethics statement

Ethical review and approval was not required for this study in accordance with the local legislation and institutional requirements.

Author contributions

The manuscript was drafted and revised by the first author. All authors made a substantial contribution to the manuscript, throughout the writing process, and agreed its final version prior to submission. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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An external facilitation intervention to increase uptake of an adverse drug event reporting intervention

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Background: Adverse drug events (ADEs) are a leading cause of emergency department visits and hospital admissions in Canada. ActionADE prevents repeat ADEs by enabling clinicians to document and communicate standardized ADE information across care settings. We used an external facilitation intervention to promote the uptake of ActionADE in four hospitals in British Columbia, Canada. This study examined whether, how and in what context external facilitation influenced the uptake of ActionADE.

Methods: In this convergent-parallel mixed-methods study, an external facilitator used a four-step iterative process to support site champions using context-specific implementation strategies to increase the ADE reporting rate at their sites. We extracted archival data to assess implementation determinants before and after the implementation of the external facilitation and implementation strategies. We also retrieved data on the mean monthly counts of reported ADEs for each user from the ActionADE server. Zero-inflated Poisson models were used to examine changes in mean monthly counts of reported ADEs per user between pre-intervention (June 2021 to October 2021) and intervention (November 2021 to March 2022) periods.

Results: The external facilitator and site champions co-created three functions: (1) educate pharmacists about what and how to report in ActionADE, (2) educate pharmacists about the impact of ActionADE on patient outcomes, and (3) provide social support for pharmacists to integrate ADE reporting into clinical workflows. Site champions used eight forms to address the three functions. Peer support and reporting competition were the two common strategies used by all sites. Sites' responses to external facilitation varied. The rate of mean monthly counts of reported ADEs per user significantly increased during the intervention period compared to the pre-intervention period at LGH (RR: 3.74, 95% CI 2.78 to 5.01) and RH (RR: 1.43, 95% CI 1.23 to 1.94), but did not change at SPH (RR: 0.68, 95% CI: 0.43 to 1.09) and VGH (RR: 1.17, 95% CI 0.92 to 1.49). Leave of absence of the clinical pharmacist champion and failure to address all identified functions were implementation determinants that influenced the effectiveness of external facilitation.

Conclusion: External facilitation effectively supported researchers and stakeholders to co-create context-specific implementation strategies. It increased ADE reporting at sites where clinical pharmacist champions were available, and where all functions were addressed.

KEYWORDS

contextual factors, core functions and forms, adverse drug events, facilitation, health information technology (Health IT), implementation strategies

Background

Adverse drug events (ADEs)—harmful and unintended events related to medication use—are a leading cause of patient harm, and a burden on health systems (1–4). One in nine adult visits to the emergency department is caused by an ADE. Of those visits, one in three are repeat events (5). Repeat ADEs occur because clinicians may be unaware of patients' ADE histories when prescribing. Different health settings, such as hospitals, long-term care facilities and clinics, often use different clinical information systems that do not automatically exchange ADE information, leading to information discontinuity (5). Effective system-level interventions are needed to address this communication gap (6).

ActionADE is software that enables healthcare providers to document and share ADE information using standardized terminologies in a user-friendly electronic format (7–9). ActionADE (8) has been integrated with British Columbia's provincial medication dispensing database, PharmaNet, to automatically share ADE information documented in hospitals, where patients with severe and acute ADEs commonly seek care. This allows care providers in other health sectors (e.g., community clinics and pharmacies) across the province who have access to PharmaNet to access ADE information. Through systems integration, PharmaNet presents community pharmacists with standardized ADE alerts if they attempt to re-dispense a medication or medication of the same class for which the patient has an ADE recorded in PharmaNet. Preliminary data shows that ActionADE prevents repeat ADEs in 10.8% of patients with reports shared to PharmaNet (10), supporting the preliminary effectiveness of ActionADE in preventing re-exposure to culprit medication".

Noteworthy, valuable clinical interventions scarcely implement themselves. The use of effective strategies to implement evidence-based interventions into clinical practice is necessary to ensure that patients receive the benefit (11). Implementation strategies are methods or techniques used to improve adoption, implementation, sustainment, and scale-up of interventions (12). The field of implementation science has made significant progress to generate evidence for implementation strategies in the past two decades, with published reviews and taxonomies describing over 70 strategies, such as audit and feedback and educational outreach (12–16). Selecting the most appropriate implementation strategies for clinical interventions requires thorough understanding of implementation determinants (i.e., barriers and enablers) across multiple levels of stakeholders and settings in the dynamic and complex healthcare system (15, 17, 18) However, the literature offers limited evidence on methods for doing so effectively (17, 19, 20).

External facilitation offers a promising approach to align implementation strategy with determinants. External facilitation is a multi-faceted process whereby external implementation experts work with stakeholders to promote interactive problem-solving and knowledge exchange that supports the adoption and use of an evidence-based practice (21–23). Key components of external facilitation include assessing the contexts, assisting teams in identifying problems and developing implementation strategies, monitoring, and providing feedback around the change efforts (24–26). External facilitation has been effective in improving the uptake of various health interventions such as antenatal care (27), postpartum care, peer specialist service (28), opioid use disorder treatment (29), and psychosocial intervention for homelessness (30). There is growing evidence suggesting that external facilitation is effective in improving health intervention implementation (29). However, most studies did not provide clear and explicit descriptions of the facilitation process, which prevented others from repeating and adapting this approach. A systematic review synthesized evidence from 195 facilitation studies to identify the role and characteristics of facilitation, and found only six studies explicitly described the actual process (21). Moreover, we know little regarding context-specific effectiveness, particularly within multi-site interventions (25, 31). Previous multi-site studies found that the effects of external facilitation on intervention uptake were variable across sites, but the factors contributing to such variations has yet to be identified (28, 29, 32).

The objectives of this study were to examine whether, how and in which context external facilitation influenced the uptake of ActionADE. We aimed to address four research questions:

1. What were the implementation determinants that influenced uptake of ActionADE before the external facilitation?
2. What implementation strategies were used by each site to promote ActionADE uptake?
3. What were the effects of external facilitation on the mean monthly counts of reported ADEs per user?
4. What were the implementation determinants that influenced uptake of ActionADE during external facilitation?

Methods

Study design

We used a convergent-parallel mixed-methods design. We collected quantitative data from archival data and qualitative data from meeting notes during the study period. We analyzed quantitative and qualitative results separately and then triangulated the findings when interpreting the results (33).

Setting

Since December 2020, nine hospitals have adopted ActionADE, with four engaging in active change management to onboard new users and sustain reporting. After a 10-month pilot implementation (January to October 2021) to secure stakeholder buy-in, we initiated an external facilitation intervention to increase the uptake of ActionADE among frontline providers. We presented the characteristics of the four participating hospitals in **Table 1**. The four participating hospitals were Lions Gate Hospital (LGH), Richmond Hospital (RH), St Paul's Hospital (SPH) and Vancouver General Hospital (VGH). All are in the Greater Vancouver area within the Vancouver Coastal

TABLE 1 Site characteristics.

Site	# of beds and types	Population served	# of emergency department visits/year	Clinical areas covered by pharmacists	# of pharmacists	# of registered ActionADE users	Implementation team composition
Lions Gate Hospital (LGH)	268 beds, acute care, community hospital	Urban and rural	65,000	10	27	27	1 clinical pharmacist and 1 clinical pharmacy coordinator
Richmond Hospital (RH)	200 beds, acute care, teaching hospital	Urban	50,000	8	29	22	1 clinical pharmacist and 1 clinical pharmacy coordinator
St. Paul's Hospital (SPH)	548 beds, acute care, teaching hospital	Urban	123,000	25	69	69	1 clinical pharmacist and 1 clinical pharmacy coordinator
Vancouver General Hospital (VGH)	1,900 beds, acute care, teaching hospital	Urban	94,348	25	64	64	1 clinical pharmacist and 1 clinical pharmacy coordinator

Health Authority. All are acute care hospitals serving urban areas, and each had two pharmacists coordinating the implementation of ActionADE. LGH and RH are smaller urban community hospitals with fewer emergency department visits, fewer clinical areas covered by pharmacists, and fewer onsite clinical pharmacists. SPH and VGH are tertiary and quaternary urban teaching hospitals, respectively. All sites were involved in developing ActionADE, with pilot testing occurring at VGH.

External facilitation intervention

We conducted external facilitation between November 2021 and March 2022. External facilitation aimed to increase the use of ActionADE by supporting site champions to develop and use implementation strategies that fit their contexts. We hypothesized that the external facilitation process would lead to the use of context-specific strategies and increase mean monthly counts of reported ADEs per user.

A research team member (EL) with training in implementation science and knowledge about the implementation settings served as the external facilitator (EF) to provide strategic and methodological support to site champions. EF used a four-step iterative process guided by previous facilitation studies (**Figure 1**) (29, 34).

Step 1: formative evaluation

The formative evaluation aimed to identify implementation determinants (i.e., factors that influence implementation success or failure) (35) influencing pharmacists' use of ActionADE before the external facilitation intervention. To identify implementation determinants, the EF analyzed meeting minutes during the implementation planning and pilot implementation phases. The EF then categorized the identified implementation determinants according to the Consolidated Framework for Implementation Research (CFIR) (36). Next, the EF met with champions at each site to refine the list of identified implementation determinants.

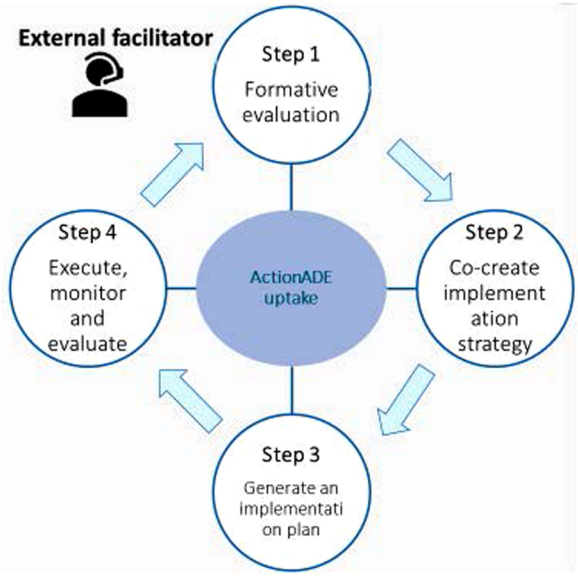

FIGURE 1
The four iterative steps of the external facilitation intervention for promoting uptake of ActionADE.

Step 2: co-create implementation strategies

To develop implementation strategies, the EF met with site champions to co-create a list of strategies targeting determinants identified in step 1. They then operationalized the strategies by specifying the name (10), purposes, action (the specific activities or processes that need to be enacted), the actors (who acts the strategy), and action target (target population of the actions) (37).

Step 3: generate an implementation plan

The EF developed, discussed, and refined an implementation plan with all site champions, which outlined the context, purpose, scope, timeline, target outcomes, and implementation strategies to increase the uptake of ActionADE. The plan was a living document for the EF to provide updates on ActionADE usage and document changes in implementation strategies and

contextual factors that influence implementation at each site. The EF shared the plan with the site champions electronically.

Step 4: execute, monitor, and evaluate

Site champions executed the implementation plan, while the EF and research team monitored the process and evaluated outcomes through bi-weekly emails and monthly meetings. The EF met with site champions monthly to review utilization statistics, revisit implementation determinants, and modify the implementation strategies, if needed. During the post-intervention period, the EF met with champions at each site to obtain feedback for the external facilitation intervention and discuss determinants identified at pre-intervention or that emerged during the intervention.

Outcome measures

Qualitative outcomes were implementation determinants reported before and after implementation of the external facilitation intervention, the functions and forms of the implementation strategies, and contextual factors influencing the uptake of ActionADE during the intervention. We extracted data on the implementation determinants before the intervention from meeting minutes documented between December 2020 to October 2021 (ActionADE pilot implementation period). The research team used a template for recording meeting minutes. A research team member recorded the date, time, purposes, and attendees of the meeting. The note-taker also recorded key discussion points, decisions, and action items. We extracted data on the implementation strategies used at each site and contextual factors from meeting notes documented between November 2021 and May 2022 (during the external facilitation intervention). These meeting notes captured opinions from research team members, patient partners, pharmacists at the participating hospitals, and site champions. Monthly meetings embedded within the external facilitation intervention offered a conducive environment for site champions to recall their implementation strategies. This approach was ideal for obtaining frequent feedback and specific perspectives on time-sensitive issues.

The main quantitative outcome was the mean monthly count of reported ADEs per user. We retrieved data on the mean monthly counts of reported ADEs for each individual user from the ActionADE server between June 2021 and March 2022 (10 months). We included data from pharmacists who registered for an ActionADE account before 1 June 2021 and held active employment without leaves at the same hospital throughout the study period.

Data analysis

We analyzed qualitative data by thematically summarizing the meeting minutes. We coded the implementation determinants and the contextual factors according to the Consolidation Framework for Implementation Research (CFIR) qualitative data codebook (38). To describe implementation strategies, we drew upon the concepts of functions and forms, a crucial concept to guide the development of complex, adaptable and scalable innovations (39, 40). Functions are the purpose of a set of activities, why it matters and how it produces changes in the expected outcomes. Forms are a set of activities used to meet the functions (37, 39, 41). For example, in the context of ActionADE, a function could be educating pharmacists on what to report in ActionADE. The form for the first site could be delivering information about ActionADE reporting criteria to pharmacists in a group presentation, while the form for the second site could be delivering the same information through a user manual. The EF shared a summary of the qualitative findings with research team members, and the team subsequently reached a consensus about the implementation strategies and determinants through discussion. Qualitative analyses were conducted using NVivo 11 qualitative data analysis software (QSR International).

For quantitative data, we used descriptive statistics to calculate the means and standard deviations. We measured the effects of the external facilitation on the mean monthly counts of reported ADEs per user using zero-inflated Poisson models. We selected this model because exploratory analyses showed that the distribution of participants' mean monthly counts of reported ADEs was overdispersed (i.e., mean and variance differ significantly) and contained an excess of zeros created by non-adopters (42). To account for these issues, the model optimizes the estimations by creating two regression equations: the logit component for predicting excess zero counts and the typical Poisson component for predicting differences in the occurrence of the count (42, 43).

Given the heterogeneity of site characteristics and implementation strategies, we stratified the analysis by site. The model included the mean monthly counts of reported ADEs per user between June 2021 to March 2022 as the dependent variable and time as the independent variable. We treated time as a categorical variable, with 0 indicating the pre-intervention period (June 2021 to October 2021) and 1 for the intervention period (November 2021 to March 2022). We also tested a random effect term to account for repeated measurements nested within users. The random effects were not statistically significant in models for LGH, SPH and VGH. The model did not converge for RH's model likely due to a small sample size. Therefore, we removed the random effect term in the final models for RH. We validated the model by plotting the predicted and observed residual values from the models. The level of significance was set at $p < 0.05$. We conducted quantitative statistical analyses using SAS 9.4 (SAS).

The model produced two sets of estimates: a logistic component that yielded the odds ratios predicting the odds of having zero monthly counts of reported ADEs per user, a Poisson component that yielded the rate ratios (RRs) of the mean monthly counts of reported ADEs per user between the pre and during the intervention period after adjusting for excess zeroes by the logistic component (43). With a focus on the effects of the external facilitation on the mean monthly counts of reported ADEs per user, hereinafter, we presented and interpreted the RRs from the Poisson component only.

Results

Research question 1: what were the implementation determinants that influenced uptake of ActionADE before the external facilitation?

The formative evaluation identified four categories of implementation determinants that were common across sites: available resources, compatibility with workflow, relative priority and providers' knowledge and belief.

Available resources

All site champions noted lack of dedicated staff time as a major barrier to implementing ActionADE. They noted that staff shortages and turnover impacted reporting. Site champions at RH and LGH stated that they were smaller hospitals with fewer resources per patient compared to other sites.

Compatibility

Site champions stated that pharmacists had difficulties fitting ActionADE into their existing workflows. At the time of the study, pharmacists were unable to directly access ActionADE in the health information system being used without searching for it or receive visual reminders for ADE reporting through their local electronic medical records systems. Without streamlining the process, site champions felt that pharmacists were uncertain about the stage during care provision they should integrate ADE reporting into their workflow. When a patient transitioned between care areas (e.g., from the emergency department to an in-patient ward) there was no mechanism to support the handover of patients' ADE information across service locations.

Relative priority

At the time of the intervention new initiatives, such as COVID-19 vaccinations and training of new hires (due to the high staff turnover rate), competed with ActionADE implementation activities. With staff shortages, pharmacists were stressed, and experienced burnout and change fatigue. In this context, the site champions noted that pharmacists might have been less likely to prioritize ADE reporting.

Providers' knowledge and belief

Site champions noted that some pharmacists had questions about the types of ADEs to report (e.g., non-adherence, refuted allergy) and about specific data fields. Site champions noted that some pharmacists had not yet seen the impact of ADE reporting on patient care. Site champions suggested that these perceptions may explain why some pharmacists were reluctant to adopt the intervention.

Research question 2: what implementation strategies were used by each site to promote ActionADE uptake?

During step 2 of the external facilitation process, the EF and site champions co-created functions and forms for the implementation strategies based on the implementation determinants identified in step 1. The EF and site champions recognized the complexity of addressing implementation determinants related to available resources, relative priority and compatibility of ActionADE with other health information systems. Increasing the number of pharmacists and changing organizational priorities for ADE reporting were not feasible functions, and beyond the capacity of the research team. Similarly, more fulsome integration into other health information systems requires infrastructure from multisectoral collaboration (e.g., data standards, data privacy regulations and technological infrastructure), which could not be accomplished over the course of five months. Due to these constraints, site champions suggested improving pharmacists' education around the clinical impact that ActionADE could have on patient outcomes to motivate them to prioritize time for ADE reporting and providing social support for pharmacists to integrate ActionADE into clinical workflow. Table 2 describes the three functions co-created by the EF and site champions: (1) educate pharmacists about what and how to report in ActionADE, (2) educate pharmacists about the impact of ActionADE on patient outcomes and (3) provide social support for pharmacists to integrate ActionADE into clinical workflow. We operationalized social support as supports accessible to an individual through social ties to other individuals and groups, such as encouragement from a co-worker (44).

Site champions developed and used eight distinct forms to address the three functions (Table 2). Noteworthy, LGH, RH and SPH delivered forms meeting all three functions, while VGH addressed functions 1 and 3 only. All sites employed two common forms: peer support and reporting competitions. Peer support included site champions providing reminders, verbal encouragement and troubleshooting to pharmacists at their sites. Reporting competitions consisted of one individual-based and two team-based challenges in which pharmacists competed for prizes awarded to the top three reporters across sites individually or with a team of 2 to 3 members from the same site. Winners of the reporting competitions received gift cards to redeem for merchandise. Both forms encouraged pharmacists to integrate ActionADE into their clinical workflow by creating a social milieu for ADE reporting. Each site used slightly different forms to address the functions to fit their contexts. For instance, LGH employed educational meetings and materials to address function 1, while VGH used educational materials and 1-on-1 follow-up.

Each site operationalized the same form slightly differently. All sites used peer support but targeted different sub-groups. LGH focused on pharmacists in the emergency department; RH targeted pharmacists at different service locations; SPH targeted all clinical pharmacists, and VGH focused on less frequent users. Pharmacists were the action targets for forms. Site champions were the primary actors for most forms, with the research team

TABLE 2 Implementation strategies (functions and forms) used by each site during the external facilitation.

Determinant	Function	Form (Name of the strategy)	Form (Actor Actions and Action Target*)
Providers' knowledge about ActionADE (uncertain about what and how to use ActionADE)	1. Educate pharmacists about what and how to report in ActionADE	1.1 Conduct educational meetings	***LGH, RH, SPH:*** Research team delivered a 1-hour presentations covering why, what, and how to report in ActionADE, recent ADE examples, most reported drug types documented in ActionADE and a quick demonstration.
			VGH: not used.
		1.2 Develop and distribute educational materials	***LGH:*** Research team developed a new 1-page how-to guide. The champions distributed the materials on intranet
			RH: Not used
			SPH: Research team developed a new PowerPoint slide deck on how to access and use ActionADE. The champion presented it in a pharmacist meeting.
			VGH: Champions re-distributed lanyard cards (include access information) and previously developed ActionADE materials (i.e., user guide, demonstration videos Q&A fact sheets) *via* intranet.
Providers' belief, available resources, and relative priority	2. Educate pharmacists about the impact of ActionADE on patient outcomes.	2.1 Involve patients	***LGH, RH, SPH:*** A 1-hour presentation Patient partners shared ADEs experiences of family members and their perspectives on the importance of ActionADE on improving patient safety and quality of care.
			VGH: not used
Compatibility	3. Provide social support for pharmacists to integrate ADE reporting into clinical workflow	3.1 Peer support	***LGH:*** Champions encouraged, reminded, and assisted individual pharmacists to use ActionADE in the emergency department and during weekly meetings.
			RH: Champions to encourage, remind, and assist individual pharmacists to use ActionADE in different service areas and promoted ActionADE in weekly meetings.
			SPH: Champions encouraged, reminded, and assisted pharmacists to use ActionADE in regular pharmacist meetings.
			VGH: Champions met with individual pharmacists to encourage, remind, and assist them to use ActionADE.
		3.2 Identify and prepare additional champions	***LGH, SPH, VGH:*** Not used.
			RH: Champions trained casual pharmacists to support ADE reporting.
		3.3 Visual cues	***LGH, SPH:*** Not used.
			RH: Champions developed a poster associating ADE reporting with a routine practice –allergy reporting. The poster was displayed it in the pharmacy, on-call room, and medical room.
			VGH: Champions wore an ActionADE button on scrub, displayed ADE pharmacist's contact information on emergency department phones, and a ActionADE posters in the pharmacy.

*The action targets were individual clinical pharmacists unless specified otherwise. LGH, Lion's Gate Hospital; RH, Richmond Hospital; SPH, St. Paul's Hospital; VGH, Vancouver General Hospital.

assisting in the deployment. For instance, three site champions identified the need to develop and re-distribute ActionADE educational materials. The site champions were the ones who decided the content, format, and distribution channels of the educational materials. The research team supported them by sharing existing educational materials or tailoring new materials as requested.

Research question 3: what were the effects of external facilitation on the mean monthly counts of reported ADEs per user?

The analytical sample included 146 pharmacist users and 1,460 observations. The mean monthly counts of reported ADEs per user were 0.57 ± 1.24 at pre-intervention compared to 0.94 ± 3.23 during the intervention period. The mean monthly counts of reported ADEs per user were steady during the pre-intervention period and fluctuated during the intervention period across all sites; the counts for LGH, RH and VGH reached the peak during the intervention period (Figure 2).

Results from modelling showed that the rate of mean monthly counts of reported ADEs per user were significantly higher during the intervention period at LGH and RH, but null results were observed at SPH and VGH. The rate of mean monthly counts of reported ADEs per user during the intervention period was 3.74 times (RR: 3.74, 95% CI 2.78 to 5.01), 1.43 times (RR: 1.43, 95% CI 1.23 to 1.94) the rate for the pre-intervention period at LGH and RH, respectively. There was no difference in the rate between the pre-intervention and intervention periods at SPH (RR: 0.68, 95% CI: 0.43 to 1.09) and at VGH (RR: 1.17, 95% CI 0.92 to 1.49) (Table 3). Model validation plots showed that the observed and predicted values aligned closely, indicating that models fit the data well (data not shown).

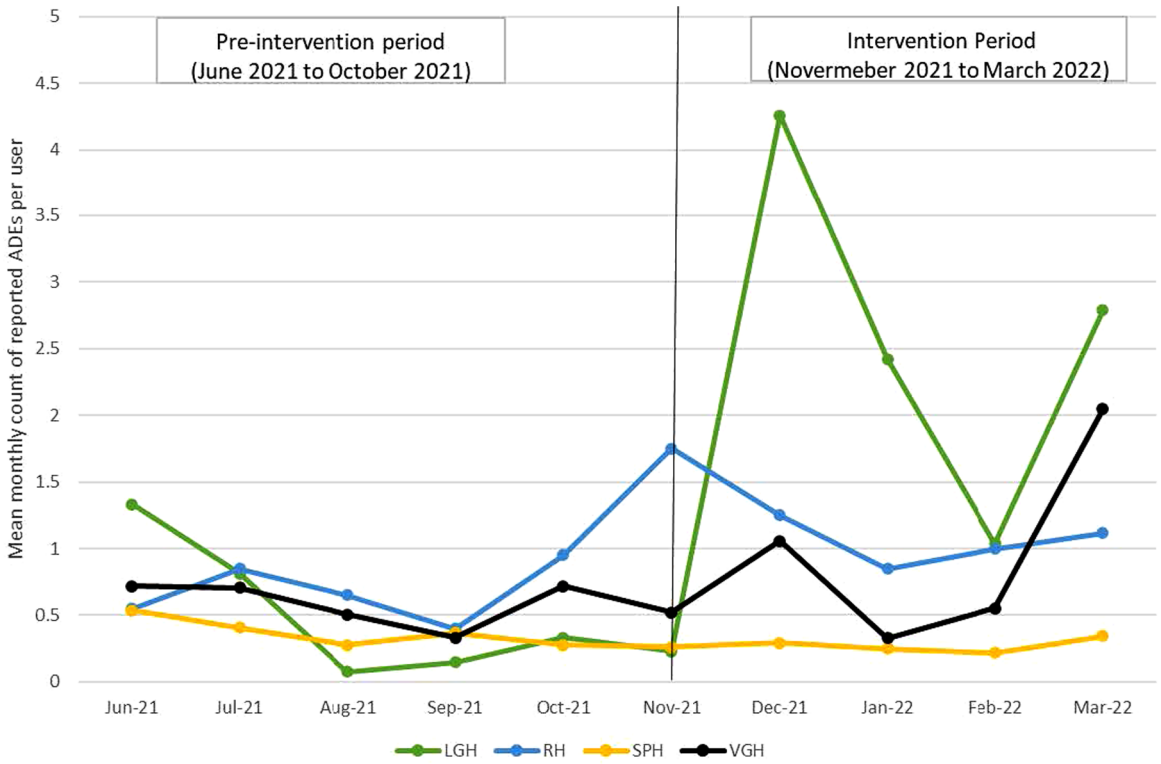

FIGURE 2
Mean monthly counts of reported ADEs per user at pre-intervention and intervention period by site.

Research question 4: what were the implementation determinants that influenced uptake of ActionADE during the external facilitation?

During and after the external facilitation, the EF discussed implementation determinants that may have influenced the ADE reporting rates and corresponding solutions.

Available resources

As with the pre-intervention period, lack of dedicated staff time was the most frequently discussed barrier. Due to a higher rate of staff turnover and sick calls during the COVID-19 pandemic, clinical pharmacists faced higher workloads. This issue impacted not only ActionADE use but other patient care activities more broadly. The SPH site champion noted that staff turnover issues had impacted the reporting rates significantly during the intervention period because one clinical pharmacist champion went on parental leave unexpectedly early right after the external facilitation intervention began. The other site champion had limited time to move implementation activities forward.

TABLE 3 Rate ratios of mean monthly counts of reported ADEs during the pre-intervention vs. intervention periods for the total sample and by site.

Variable	LGH	RH	SPH	VGH
	Rate Ratio (95% CI)	Rate Ratio (95% CI)	Rate Ratio (95% CI)	Rate Ratio (95% CI)
Time				
Pre-intervention period (Jun 2021—Oct 2021)	*Reference*	*Reference*	*Reference*	*Reference*
Intervention period (Nov 2021—Mar 2022)	3.74 (2.78 to 5.01)	1.43 (1.23 to 1.94)	0.68 (0.43 to 1.09)	1.17 (0.92 to 1.49)

Providers' knowledge and belief

Our qualitative data showed that discussions around providers' knowledge about ActionADE were less frequent after implementation of the external facilitation intervention. Site champions had noted that only a few pharmacists had questions about the eligibility of reporting for specific cases and duplicate reports. Regarding providers' beliefs, site champions reported that some pharmacists hesitated to use ActionADE because they feared that their reports would "scare prescribers" and take away necessary medications that should be re-dispensed.

Relative priority

Pharmacists were pulled into different initiatives during the intervention period, which may have influenced pharmacists' willingness and ability to use ActionADE. For example, the champion at LGH mentioned that pharmacists tended to prioritize treatment over preventive work. The champions at

SPH also noted that the hospital prioritized admitted patients and hired a team of pharmacists to review their medications. However, many ADEs were identified in patients who were discharged from the ED who were not prioritized for medication review by some sites. Site champions also mentioned low levels of physician engagement may have prevented pharmacists from prioritizing ADE reporting in a team-based approach.

Other determinants included discontinuation of reporting competitions that had been designed to create a social milieu to stimulate ADE reporting. Site champions also suggested that regular reporters' work rotation schedules led to fluctuating monthly ADE report counts over time. While pharmacists were on a rotation with dispensary shifts, they rarely saw patients and would not encounter ADEs.

Discussions

This mixed-methods study examined whether, how, and in which contexts external facilitation increased the uptake of ActionADE. Consistent with previous research, we found that external facilitation was effective in increasing the uptake of ActionADE, but effects varied by sites (28, 29, 32). We observed significant increase in ADE reporting at LGH and RH but null effects at SPH and VGH. The significant intervention effects at LGH and RH suggested external facilitation can be effective in improving intervention uptake by assisting clinical teams in developing tailored strategies based on the implementation determinants. The EF and site champions co-created three functions during the external facilitation process. They included educating pharmacists about what and how to report in ActionADE, educating pharmacists about the impact of ActionADE on patient outcomes and providing social support for pharmacists to integrate ADE reporting in the clinical workflow. The identified functions were similar to the recommended practices for implementing new digital services into the routine work of healthcare professionals by Nadva et al. (45). We added value to the existing literature by providing a menu of forms for each function, which future studies can adopt, test and adapt. Developing functions and the corresponding menu of forms is important for others to replicate an intervention or implementation strategy. Very few studies have provided explicit guidance on adapting an evidence-based practice to fit local contexts (46). Specifying the functions and forms of an intervention or implementation strategy provides other researchers or practitioners with explicit guidance and options about which adaptations to the intervention's form are allowable while preserving fidelity (46, 47).

The positive intervention effect was more profound in LGH than in RH. We did not observe differences in implementation strategies or determinants between the two sites. Thus, we attributed the variable effects to other factors not measured in this study. A potential factor could be the characteristics of individual users. Compared to RH, users in LGH appeared to be more responsive to the strategies, particularly during the months with patient partner presentations and reporting competitions. This speculation is consistent with previous research. Rycroft-Malone et al. (48) found that individual characteristics are prominent in the interaction between context and strategies. Staff members' learning skills and motivation significantly influenced the effectiveness of facilitation on research uptake. We attempted to survey users' perceptions of the implementation strategies, but the response rate was very low amid the pandemic. Future studies are needed to explore how user characteristics interact with determinants at different levels (e.g., organizations level) in influencing the process and effectiveness of external facilitation.

The null effects in the other two sites provided insights into the contexts in which external facilitation was less effective. We attributed the null intervention effect at VGH to the failure to address all the identified functions. VGH was the only site that did not address function 2, which was to educate pharmacists about the potential impact of ActionADE on patient outcomes. The null intervention effects at VGH suggested that all three functions identified through the external facilitation must be addressed to achieve the expected outcome. Gustavson and colleagues (29) examined the effects of external facilitation on increasing use of medication treatment for opioid use disorder in nine veteran health administration facilities. They observed a significant increase in program uptake in facilities who achieved almost all the implementation goals. Previous evidence also supported that perceived benefits of the intervention were an important determinant for changing clinical practices among healthcare professionals (36, 49, 50). Future studies with a larger sample size and experimental design are needed to verify this finding.

SPH used a similar set of forms as LGH and RH but did not result in a significant improvement in ADE reporting rate. Our qualitative data suggested that the leave of absence of a key site champion during the external facilitation intervention may have attributed to the null intervention effects. As mentioned by the SPH champion, the absence of the clinical pharmacist champion substantially limited the execution of implementation activities and engagement with other pharmacists. This finding was not surprising because previous research consistently indicated that use of program champions was a critical implementation determinant for healthcare interventions (51–53). Two randomized trials (54, 55) tested the impact of program champions on changing clinical practices in healthcare professionals. McCabe et al. (54) found that the presence of a formally identified, designated champions was associated with an increase in residential aged care staff sensitivity to depression among residents. Bentz et al. (55) reported that the presence of clinical champions associated with an increased rate of referral to a state-level smoking quit line.

One interesting finding was that the external facilitation could not address several essential implementation determinants (i.e., staffing shortages, competing demands) that were out of our team's control, but it nonetheless achieved a significant improvement in ADE reporting at two sites. A plausible explanation was that being able to address other determinants,

including providers' knowledge and belief, may have partially offset the negative impact from staffing shortages and competing demands. Previous studies suggested that implementation determinants interact synergistically to influence implementation success. A determinant that is perceived as less influential may be a preceding factor to improve another determinant (56, 57). For example, in ActionADE, improving pharmacists' belief might be a preceding factor to address staff shortage issue. Once pharmacists recognized the impact of ActionADE in improving patient outcomes, they may have been more motivated to prioritize their time for ADE reporting. However, we need future studies to verify these speculations. In the current study, we were unable to fully integrate ActionADE into the electronic medical record workflow due to resource constraints. Future work should assess the effectiveness of improved workflow integration compared to other strategies.

Reflections and lessons learned

When implementing ActionADE at multiple sites, adaptation to the local context was necessary to meet the diverse individuals' needs in order to avoid diminished intervention benefits (58). We found that external facilitation was an effective strategy to help implementation teams to identify the needs and focus of the adaptation. The functions and forms concept provided a new way of thinking when designing implementation strategies for a complex intervention undertaken in a complex health system. The function and form concept helped the team emphasize the intended function or purpose of the strategy instead of the dose (e.g., one or three training sessions). It also offered a practical tool for distinguishing between standardized and adaptable elements of the intervention or implementation strategies. However, conducting external facilitation was not without challenges. The external facilitation process was intense. It involved frequent communications with program champions, detailed records, and a rapid and timely evaluation-feedback loop. Nonetheless, the frequent contacts and in-depth evaluation of the contexts were beneficial for both parties to build a trusting relationship and co-create strategies that fit. The intense process was also necessary to keep the project on our site champions' agenda against other competing priorities. With the positive experiences, we decided to extend the facilitation intervention and continue to adapt and monitor changes in implementation strategies.

Our findings should be interpreted with the following limitations in mind. We conducted this study in four hospitals in one geographic location, limiting our findings' generalisability. Second, our qualitative data primarily captured the perspectives of the site champions, which may not be representative of all ActionADE users. We measured most of the implementation outcomes based on archival data. While this approach may not be able to explore a comprehensive list of implementation determinants, it provided a conducive and practical approach to capture longitudinal changes in providers' perceptions, contextual factors and implementation strategies. In this exploratory study, we did not assess fidelity of the implementation strategies. We need further studies to verify the effectiveness of the identified forms in addressing the functions and corresponding determinants.

Conclusion

This study offers new insights on whether, how, and in what contexts external facilitation promoted the uptake of clinical intervention. Our findings showed that external facilitation can be effective in promoting the uptake of ActionADE across multiple hospitals by assisting clinical teams in developing tailored strategies (functions and forms) based on pre-assessed implementation determinants. However, its effectiveness varied depending on the site's ability to deliver the identified strategies and the emergence of new determinants. Future studies are needed to examine the long-term success of external facilitation and strengthen the evidence base regarding factors influencing effectiveness of external facilitation.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The University of British Columbia Research Ethics Board approved all study procedures (H21–02973). This study involved the secondary use of de-identified archival data. ActionADE users were informed of and had to accept the app's privacy policy describing how de-identified data may be used for research purposes and presented in aggregate.

Author contributions

All authors contributed to the study's conception and design. EL: conducted the external facilitation, collected and analyzed the data and wrote the first draft of the manuscript. AC, CH, SS and KB: contributed to the refinement of the facilitation process. SS and KB: assisted with the external facilitation process. GL and SS: assisted in data collected. AC, CH: provided consultation to the statistical analysis and result interpretation. All authors contributed to the interpretation of the findings and commented on previous manuscript versions. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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Commentary: Designing healthcare for human use: human factors and practical considerations for the translational process

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A commentary on
Designing healthcare for human use: human factors and practical considerations for the translational process

by Edwards III GF, Zagarese V, Tulk Jesso S, Jesso M, Harden SM and Parker SH. (2023). *Front Health Serv.* 2:981450. doi: 10.3389/frhs.2022.981450

1. Introduction

Human factors' influence on health care practices is of heightened interest to the field (1), driving numerous efforts that pursue higher quality care by accounting for human behaviors, abilities, and limitations (2). Given implementation science's focus on achieving better care through promoting the uptake and sustained use of evidence-based interventions (3), and especially as human-centered design approaches to implementation are being increasingly embraced (4), an explicit connection between implementation science and human factors begs to be conceptualized. Edwards et al. offer a timely Perspective article that articulates this very connection, using implementation case examples to demonstrate how human factors interact with the design and implementation of evidence-based interventions (5). Notably, the article also provides a helpful list of specific human factors considerations to enhance an intervention's use, fidelity, and sustainability, presented in alignment with the widely-used Reach Effectiveness Adoption Implementation Maintenance [RE-AIM; (6)] framework's Adoption, Implementation, and Maintenance domains, respectively. The purpose of this commentary is to further contextualize the article's notions of human factors by discussing specific examples of their expected relevance to additional implementation science concepts, approaches, and foci, in the hopes of fueling continued discourse on integrating human factors considerations into implementation endeavors.

2. Human factors considerations for implementation frameworks

By outlining human factors considerations per RE-AIM's Adoption, Implementation, and Maintenance domains, Edwards et al.'s article illustrates the potential for human

factors considerations to work complementarily even with other implementation frameworks beyond RE-AIM. Especially for frameworks that are understood to be broad in their domain definitions (to be widely applicable across various interventions and implementation contexts), human factors considerations can help specify what the frameworks delineate as factors that influence implementation. For instance, the Integrated Promoting Action on Research Implementation in Health Services [i-PARIHS; (7)] framework consists of four domains (Innovation, Recipients, Context, and Facilitation), using which it posits that successful implementation of an innovation and its sustained use by recipients in a context are enabled by facilitation. The human factors considerations outlined in the article (e.g.: "In what ways does the intervention fit within the user's current work and workflow?" "How are individuals trained to complete the steps in an intervention?") directly align to i-PARIHS domains (e.g., Innovation and Recipients, respectively). Hence, an i-PARIHS-guided implementation effort can straightforwardly extend its use of i-PARIHS to specifically include relevant human factors considerations per domain. For example, the implementation effort's Innovation- and Recipients-related key informant interviews can include questions about the intervention's fit with current workflows and involved individuals' training status, respectively.

3. Human factors considerations for implementation adaptations

Edwards et al.'s article emphasizes the importance of human factors considerations particularly for adapting an intervention to fit the involved individuals' capabilities that they can exercise, given the system(s) in which they operate. This emphasis suggests that human factors considerations can meaningfully contribute to planning and evaluating adaptations that are made as the intervention is implemented. For instance, Iterative Decision-making for Evaluation of Adaptations [IDEA; (8)] is a tool that can be used to methodically decide whether and how to proceed with making adaptations to an intervention. A major decision point in IDEA involves assessing whether there is a need for adaptation based on existing knowledge (e.g., published data, input from involved individuals). Incorporating human factors considerations directly into this decision point can be one way to help ensure that human factors are accounted for in making decisions regarding adaptations. Namely, in seeking the knowledge upon which to make the decision, published data can be examined and individuals' input can be sought specifically regarding, for example, the extent to which the intervention fits with current workflows and individuals' training status.

4. Human factors considerations for implementation strategies

Many of the human factors considerations outlined in Edwards et al.'s article focus on human behaviors, abilities, and limitations as they relate to an intervention being implemented. Warranting further attention is how the considerations apply to devising the implementation strategy (or strategies) to be employed, for promoting the uptake and sustained use of the intervention. One way to incorporate human factors considerations into strategy design could be to augment Proctor et al.'s framework for specifying and reporting implementation strategies (9) with human factors considerations. Specifically, the Justification domain of the framework, defined as the "empirical, theoretical, or pragmatic justification for the choice of implementation strategies," can ask explicitly for human factors-related justifications (e.g., how the strategies account for current workflows and involved individuals' training status).

5. Discussion

Edwards et al.'s Perspective article provides essential conceptual building blocks using which the integration of human factors and implementation science can be pursued by the field going forward. This commentary aims to expand on the implications of the article by describing three potential ways in which the human factors considerations outlined in the article can be synergistic with existing ways in which frameworks, adaptations, and strategies are regarded in implementation science. Building from the article and this discussion, future works can systematically assess the impact of bringing human factors and implementation science together, studying the effectiveness, as well as costs and benefits, of incorporating human factors considerations into designing and implementing evidence-based interventions. In parallel with these assessments, also needed are efforts to more clearly delineate the overlaps and distinctions between human factors considerations and notions such as acceptability, appropriateness, and feasibility that have established definitions within implementation science (10). Especially given Edwards et al.'s explanation of incorporating the human factors perspective into implementation studies as "a minor but pivotal shift" to how most implementation studies are currently undertaken, this delineation is important to accurately understand the unique contributions of both the article and the human factors perspective more generally to implementation science.

Author contributions

BK conceptualized and wrote the commentary, inspired by Edwards et al.'s (5) article and valuable implementation research collaborations.

Conflict of interest

The author BK declared that they were an editorial board member of Frontiers, at the time of submission. This had no impact on the peer review process and the final decision. The author declares that this commentary was prepared in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Evaluating the translation of implementation science to clinical artificial intelligence: a bibliometric study of qualitative research

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Introduction: Whilst a theoretical basis for implementation research is seen as advantageous, there is little clarity over if and how the application of theories, models or frameworks (TMF) impact implementation outcomes. Clinical artificial intelligence (AI) continues to receive multi-stakeholder interest and investment, yet a significant implementation gap remains. This bibliometric study aims to measure and characterize TMF application in qualitative clinical AI research to identify opportunities to improve research practice and its impact on clinical AI implementation.

Methods: Qualitative research of stakeholder perspectives on clinical AI published between January 2014 and October 2022 was systematically identified. Eligible studies were characterized by their publication type, clinical and geographical context, type of clinical AI studied, data collection method, participants and application of any TMF. Each TMF applied by eligible studies, its justification and mode of application was characterized.

Results: Of 202 eligible studies, 70 (34.7%) applied a TMF. There was an 8-fold increase in the number of publications between 2014 and 2022 but no significant increase in the proportion applying TMFs. Of the 50 TMFs applied, 40 (80%) were only applied once, with the Technology Acceptance Model applied most frequently ($n = 9$). Seven TMFs were novel contributions embedded within an eligible study. A minority of studies justified TMF application ($n = 51$,58.6%) and it was uncommon to discuss an alternative TMF or the limitations of the one selected ($n = 11$,12.6%). The most common way in which a TMF was applied in eligible studies was data analysis ($n = 44$,50.6%). Implementation guidelines or tools were explicitly referenced by 2 reports (1.0%).

Conclusion: TMFs have not been commonly applied in qualitative research of clinical AI. When TMFs have been applied there has been (i) little consensus on TMF selection (ii) limited description of selection rationale and (iii) lack of clarity over how TMFs inform research. We consider this to represent an opportunity to improve implementation science's translation to clinical AI research and clinical AI into practice by promoting the rigor and frequency of TMF application. We recommend that the finite resources of the implementation science community are diverted toward increasing accessibility and engagement with theory informed practices. The considered application of theories, models and frameworks (TMF) are thought to contribute to the impact of implementation

science on the translation of innovations into real-world care. The frequency and nature of TMF use are yet to be described within digital health innovations, including the prominent field of clinical AI. A well-known implementation gap, coined as the "AI chasm" continues to limit the impact of clinical AI on real-world care. From this bibliometric study of the frequency and quality of TMF use within qualitative clinical AI research, we found that TMFs are usually not applied, their selection is highly varied between studies and there is not often a convincing rationale for their selection. Promoting the rigor and frequency of TMF use appears to present an opportunity to improve the translation of clinical AI into practice.

KEYWORDS

artificial intelligence, clinical decision support tools, implementation, qualitative research, theory, theoretical approach, bibliometric study

1. Introduction

Implementation science is a relatively young field drawing on diverse epistemological approaches and disciplines across a spectrum of research and practice (1). Its pragmatic goal of bridging know-do gaps to improve real-world healthcare necessitates this multi-disciplinary approach (2). A key aspect of implementation science is the application of theories, models or frameworks (TMF) to inform or explain implementation processes and determinants in a particular healthcare context (2, 3). In recent years TMFs addressing the implementation of interventions in healthcare organisations have accelerated and are pursued across a large and diverse literature which seeks to explore the factors shaping the implementation process (4). In line with the applications of TMFs, implementation researchers have variously employed qualitative research to explore the dynamic context and systems into which evidence-based interventions are embedded into practice by addressing the "hows and whys" of implementation (5). Drawing upon distinctive theoretical foundations, qualitative methodologies have offered a range of different analytical lenses to explore the complex processes and interactions shaping implementation through the recursive relationship between human action and the wider organisational and system context (4). Although this diversity of approach has allowed researchers to align specific research questions and objectives with particular context(s) at the policy, systems and organisational levels, at the same time it may pose challenges in informing the selection criteria for researchers to choose from the many TMFs in the field (6). This risks perpetuating or expanding implementation researchers' disconnect with practitioners, on whom implementation science's goal of improving real-world healthcare depends (7).

Healthcare interventions centering on clinical artificial intelligence (AI) appear in particular need of the proposed benefits of implementation science, as they are subject to a persistent know-do gap coined the "AI chasm" (8). Computer-based AI was conceived more than 50 years ago and has been incorporated into clinical practice through computerized decision support tools for several decades (9, 10). However, advancing computational capacity and the feasibility and potential of deep learning methods have galvanized public and professional enthusiasm for all applications of AI, including healthcare (11). The acknowledgment of this potential is formalized in the embedment of clinical AI into national healthcare strategic plans and by the recent surge of regulatory approvals issued for "software/AI as a medical device" (12–14). Despite this, there are few examples of clinical AI implemented in real-world patient care and little evidence of the benefits it has brought about (15, 16). This is in part because of the sensitivity of clinical AI interventions to technical, social and organizational variations in the context into which they are implemented and the paucity of research insights that go beyond the efficacy or effectiveness of the interventions themselves (17). TMFs offer a potential solution to this challenge as they allow insights from specific interventions and contexts to be abstracted to a degree through which they remain actionable whilst becoming transferrable across a wider range of interventions and contexts (18).

It is outside of the scope of the present study to directly assess the impact of implementation science on the translation of clinical AI to practice due to the bias and scarcity of reports of implementation success or failure (19). However, having been consistently proposed as an indicator of high-quality implementation research, the frequency and nature of TMF application to clinical AI research seem likely to influence the speed and extent of clinical AI interventions' real-world impact. To establish how the application of TMFs can most effectively support the realization of patient benefit from clinical AI, it will first be necessary to understand how they are currently applied. Given the early translational stage of most clinical AI research and the relatively low number of interventions that have been implemented to date, it seems unlikely that implementation science principals such as TMF usage are as well established as they are for other healthcare interventions. Implementation research focused on other categories of healthcare interventions has been characterized through descriptive summaries of TMF selection and usage. These studies act as a frame of reference, but to our knowledge none report on digital health interventions (20–22).

This bibliometric study aims to measure and characterize the application of TMFs in qualitative clinical AI research. These data are intended to (i) identify TMFs applied in contemporary clinical AI research, (ii) provide insight into implementation

research practices in clinical AI and (iii) inform strategies which may improve the efficacy of implementation science in clinical AI research.

2. Methods

Mobilising a definition of implementation research, e.g., research "focused on the adoption or uptake of clinical interventions by providers and/or systems of care", for a systematic search strategy is challenged by variation in approaches to article indexing and the framing which researchers from varied disciplines lend to their work (23–25). The present study aimed to mitigate this by targeting primary qualitative research of clinical AI. Qualitative research has a foundational relationship with the application of TMFs in implementation science and its focus on understanding how implementation processes shape and are shaped by dynamic contextual factors. Developing such an understanding requires an exploration of human behaviours, perceptions, experiences, attitudes and interactions. This approach was intended to maximise the sensitivity with which clinical AI implementation research using TMFs was identified whilst maintaining a feasible specificity of the search strategy (**Figure 1**).

This bibliometric study updates a pre-existent search strategy using AND logic to combine qualitative research with two other concepts; AI-enabled decision support including rule-based and non-rule-based tools and any healthcare context (17, 27). The earliest eligibility date of January 2014 was maintained from this prior work, marking the first FDA approvals for "Software as a Medical Device" (13), but the updated search execution included studies published up to October 2022. The five original target databases were maintained; Scopus, CINAHL (EBSCO), ACM Digital Library and Science Citation Index (Web of Science) to cover computer science, allied health, medical and grey literature (**Supplementary File S1**). Only English language indexing was required, there were no exclusion criteria relating to full-text language. The initial results were de-duplicated using Endnote x9.3.3 (Clarivate Analytics, PA, USA) and two independent reviewers (HDJH, MA) performed full title and abstract screening using Rayyan (28). The process was overseen by an information specialist (FB) and screening disagreements were arbitrated by a separate senior implementation researcher (GM). Eligible review and protocol manuscripts were included for reference hand searching only. Full-text review was performed independently by two independent reviewers (HDJH, MA), with the same arbiter (GM).

Two reviewers (HDJH, MA) extracted characteristics from articles independently following an initial consensus exercise. These characteristics included the year and type of publication, source field and impact factor, implementation context studied, TMF application, study methods and study participant type and number. For each study referring to a TMF in the body text, the stage of the research at which it had contributed and any justification for its selection was noted. The index article for the TMFs applied in eligible reports were sourced to facilitate characterization by a single reviewer (HDJH) following consensus exercises with a senior implementation researcher (GM). Nilsen's 5-part taxonomy of TMF types (process models, determinant frameworks, classic theories, implementation theories and evaluation frameworks) and Liberati's taxonomy of TMFs' disciplinary roots (usability, technology acceptance, organizational theories and practice theories) were applied to characterize each TMF along with its year of publication (29, 30).

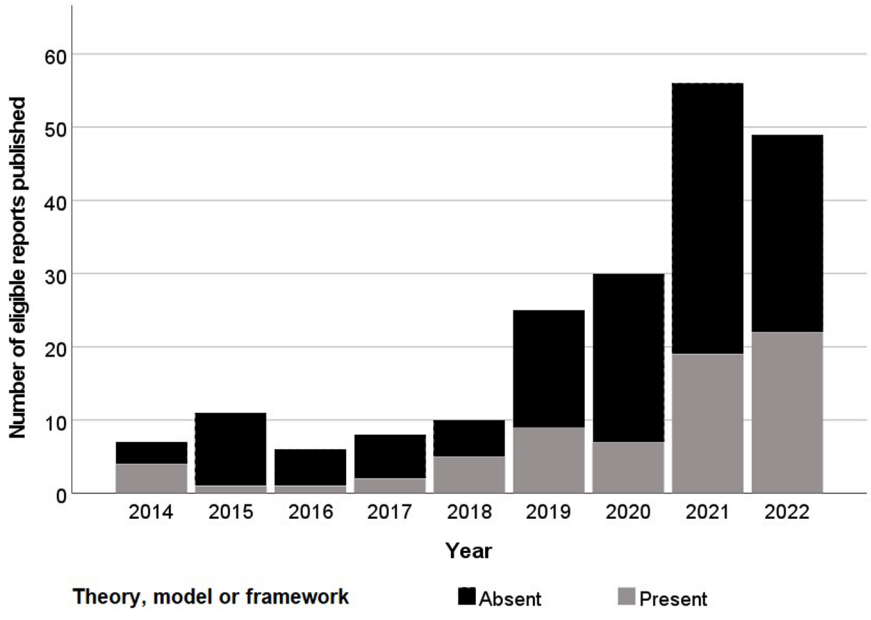

FIGURE 1
Histogram of year of publication of eligible reports and their application of a theory, model or framework.

3. Results

3.1. Eligible study characteristics

Following initial deduplication 6,653 potential eligible titles were returned by searches, 519 (7.8%) of which were included following title and abstract screening. Full-text screening identified 202 unique eligible studies (Figure 1). Three (1.5%) of these reports were theses with the remaining 198 (98.5%) consisting of articles in academic journals (Table 1).

TABLE 1 Characteristics of 202 eligible reports.

Characteristic	Category	Number of reports (%)
Scope of source	Clinical	90 (44.6%)
	Health service management	91 (45.0%)
	Health informatics	16 (7.9%)
	Other	5 (2.5%)
Context of AI application studied	Hypothetical	78 (38.6%)
	Simulated	46 (22.8%)
	Clinical	78 (38.6%)
AI type studied	Not specified	16 (7.9%)
	Rule-based	88 (43.6%)
	Machine learning	98 (48.5%)
Data collection method	Interviews	105 (52.0%)
	Focus groups	34 (16.8%)
	Survey	24 (11.9%)
	Observation	3 (1.5%)
	Mixed	36 (17.8%)
Participants	Clinicians	105 (52.0%)
	Patients and the public	26 (12.9%)
	Managers and leaders	2 (1.0%)
	Developers	2 (1.0%)
	Policy makers and	2 (1.0%)
	Mixed	65 (32.2%)

Excluding 2016, the frequency of eligible publication increased year-on-year, with a monthly rate of 4.9 publications averaged over January-October 2022 compared to 0.6 between January-December 2014 (Figure 2). Thirty-five different countries hosted the healthcare context under study, with the United States ($n = 56$, 27.7%), United Kingdom ($n = 29$, 14.4%), Canada ($n = 16$, 8.0%), Australia ($n = 16$, 7.9%) and Germany ($n = 11$, 5.4%) the most frequent countries studied. Six studies (3.0%) were based in countries categorized by the United Nations as having a medium or low human development index (31). Of the 172 studies focused on a single clinical specialty, primary care ($n = 48$, 27.9%) and psychiatry ($n = 16$, 9.3%) were the most common of 27 distinct clinical specialties.

3.2. Theory, model or framework characteristics

Seventy eligible reports (34.7%) applied at least one of 50 distinct TMFs in the main text (Table 2), 7 (14.0%) of these were new TMFs developed within the eligible article itself. Theory application was increasingly prevalent as studies focused closer toward real-world use, with studies of hypothetical, simulated or active clinical use cases applying TMFs in 26.9%, 34.8% and 42.3% of studies respectively. There was no significant difference between the frequency of TMF application before and after the start of 2021, the median year of publication (Chi squared test, $p = 0.17$). Twelve (17.1%) of the 70 reports drawing on a TMF applied more than one [maximum 5 (82)]. Of the 87 instances that a TMF was applied it originated from the fields of technology acceptance ($n = 36$, 41.4%), practice theory ($n = 21$, 24.1%), organizational theory ($n = 19$, 21.8%) or usability ($n = 11$, 12.6%) according to Liberati's taxonomy (30). Similarly, under Nilsen's taxonomy of TMFs the purpose of each TMF applied

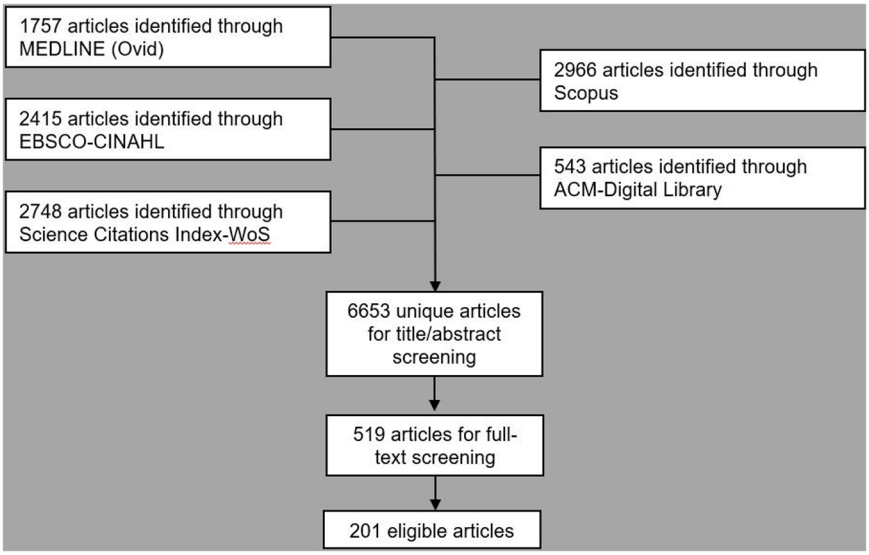

FIGURE 2
PRISMA style flowchart of database searching, de-duplication and title, abstract and full-text screening (26).

TABLE 2 Theories, models and frameworks applied by eligible reports.

Theory, model or framework	Year of index publication	Liberati classification (30)	Nilsen classification (29)	Frequency of use
Awareness-to-Adherence Model (32)	1996	Practice theory	Process model	1
Behaviour change technique taxonomy (33)	2013	Technology acceptance	Evaluation framework	1
Behaviour change theory (34)	1977	Technology acceptance	Classic theory	1
Behaviour change wheel (35)	2011	Technology acceptance	Determinant framework	5
Biography of Artefact (36)	2010	Practice theory	Classic theory	1
Consolidated Framework for Implementation Research (37)	2009	Organizational theory	Determinant framework	7
Clinical adoption meta-model (38)	2014	Technology acceptance	Evaluation framework	1
Clinical performance feedback intervention theory (39)	2019	Technology acceptance	Determinant framework	1
Disruptive innovation theory (40)	1995	Organizational theory	Classic theory	1
Dual process model of reasoning (41)	2009	Technology acceptance	Classic theory	1
Expectancy-value theory (42)	2000	Technology acceptance	Classic theory	1
Fit Between Individuals Task and Technology (43)	2006	Technology acceptance	Evaluation framework	1
Flottorp framework (44)	2013	Practice theory	Determinant framework	1
Framework for designing user-centred displays of explanation (45)	2020	Usability	Determinant framework	2
Framework of patient orientation to applications of AI in healthcare (46)	2022	Practice theory	Process model	1
Goal directed design (47)	1995	Usability	Process model	1
Heuristic evaluation (48)	1990	Usability	Determinant framework	2
Human-computer trust conceptual framework (49)	2000	Usability	Process model	1
Innovation-decision process framework (50)	2013	Organizational theory	Classic theory	1
Intention to use AI Model (51)	2020	Technology acceptance	Determinant framework	1
Iterative, collaborative development and implementation framework (52)	2021	Organizational theory	Process model	1
Kano model of satisfaction (53)	1984	Usability	Determinant framework	1
Methontology (54)	1997	Usability	Process model	1
Machine learning maturity model (55)	2021	Technology acceptance	Determinant framework	1
GPs' determinants of attitude towards AI-enabled systems (56)	2022	Technology acceptance	Process model	1
Non-adoption, Abandonment, Scale-up, Spread and Sustainability (57)	2017	Organizational theory	Determinant framework	2
Normalisation process model (58)	2007	Practice theory	Process model	1
Normalisation process theory (59)	2009	Practice theory	Mixed	4
Occupational therapy intervention process model (60)	1998	Practice theory	Process model	1
PESTLE framework (61)	1967	Organizational theory	Evaluation framework	1
Positions of perceived control (62)	2015	Practice theory	Evaluation framework	1
Process-oriented model of implementation pathways (63)	2020	Technology acceptance	Process model	1
Programme sustainability assessment tool (64)	2014	Practice theory	Determinant framework	1
Rasmussen behaviour model (65)	1983	Usability	Classic theory	1
Rogers' Theory of Diffusion (66)	1962	Practice theory	Classic theory	1
Shackel model (67)	1991	Usability	Determinant framework	1
Sittig and Singh sociotechnical framework (68)	2010	Practice theory	Determinant framework	6
Strong structuration theory (69)	2007	Organizational theory	Determinant framework	1
Systems engineering for patient safety 3.0 (70)	2020	Organizational theory	Determinant framework	1
Systems-Theoretic Accident and Process Analysis (71)	2011	Organizational theory	Evaluation framework	1
Technology acceptance model (72)	1989	Technology acceptance	Determinant framework	9
Theoretical domains framework (73)	2005	Technology acceptance	Mixed	3
Theoretical framing theory (74)	1999	Organizational theory	Classic theory	1
Theory of meaningful human control (75)	2018	Practice theory	Classic theory	1
Theory of planned behavior (76)	1991	Technology acceptance	Determinant framework	1
Two component model of attitude (77)	1961	Technology acceptance	Process model	1
Unified Theory of Acceptance and Use of Technology (78)	2003	Technology acceptance	Determinant framework	7
Usabilty criteria of Scapin and Bastien (79)	1997	Usability	Determinant framework	1
User-driven co-development of AI model (80)	2021	Practice theory	Process model	1
Work as done (81)	2015	Organizational theory	Classic theory	1

AI, artificial intelligence; GP, general practitioners; PESTLE, political, economic, sociological, technological, legal and environmental.

could be classified as determinant framework ($n = 49$, 56.3%), process model ($n = 18$, 20.7%), classic theory ($n = 10$, 11.5%), evaluation framework ($n = 9$, 10.3%) or implementation theory ($n = 1$, 1.1%) (29).

3.3. Justification and application of theories, models and frameworks

The Technology Acceptance Model was the most frequent choice when a TMF was applied ($n = 9$, 12.9%), but 40 (80.0%) of the TMFs were only applied once across all eligible reports. Across the 87 instances of reports explicitly applying a TMF, 4 different modes of application emerged; to inform the study or intervention design ($n = 9$, 10.3%), to inform data collection ($n = 29$, 33.3%), to inform data analysis ($n = 44$, 50.6%) and to relate or disseminate findings to the literature ($n = 25$, 28.7%). The majority of instances in which a report applied a TMF carried no explanation or justification ($n = 51$, 58.6%). Five (5.7%) reports made isolated endorsement of the TMF's popularity or quality, e.g., "The sociotechnical approach has been applied widely…" (83). Thirty-one (35.6%) outlined the alignment of the TMF and the present research question, e.g., "our findings are consistent with disruptive innovation theory…" (84). Eleven (12.6%) reports discussed the disadvantages and alternatives that had been considered, e.g., "Because this model does not consider the unique characteristics of the clinical setting… we further adopted qualitative research techniques based on the CFIR [Consolidated Framework for Implementation Research] to further identify barriers and facilitators of the AI-based CDSS [Clinical Decision Support System]" (85).

4. Discussion

4.1. Principal findings

This study shows that a minority of clinical AI qualitative research applies TMFs, with no suggestion of a change in the relative frequency of TMF application over time. This appears to contrast with research funders and policy makers increasingly valuing more theory-based definitions of evidence and the consistent requirement for TMFs in related reporting guidelines and evaluation criteria (25, 86–88). Underlying this increasing appreciation of the contribution that TMFs can make, is a perception that specific research questions with unique configurations of complexity can draw on prior knowledge through the application of a well-matched theoretical approach (29). It is the great variety of unique research questions that may justify the ever-increasing variety of available TMFs. If considered matching of a specific research question's demands and a specific TMF's value is not taking place however, the ongoing proliferation of TMFs may only serve to further alienate practitioners trying to make sense of the shifting landscape of TMFs (7).

Within this study's relatively narrow eligibility criterion of qualitative clinical AI research, the variety and inconsistency of TMFs applied was striking, with 80% of the 50 TMFs encountered only applied once. This variation in TMF selection was also mirrored by the their varied purpose and mode of application. Across these applications of TMFs, a convincing rationale for their selection was usually absent. This heterogenous TMF selection coupled with little evidence of considered selection, suggests that current TMF application in qualitative clinical AI research usually fails to satisfy established definitions of good practice in implementation research (2, 25). If it is assumed that meeting these definitions of good practice would more effectively support implementation science's goal of bridging know-do-gaps, then it seems likely TMF application is currently under-delivering for efforts to translate clinical AI into practice. The observed heterogeneity in TMF selection is also set to grow, as 15% of the theories applied in eligible articles were novel. This may improve current practice in TMF application if these novel TMFs better serve the needs of research questions in clinical AI implementation. However, only 1 of these 7 novel TMFs has been applied within the other eligible reports of this bibliometric study and so there is a real risk of exacerbating unjustified heterogeneity in TMF usage (45).

4.2. Comparison with prior work

To the best of our knowledge, there are no other reviews of TMF application in qualitative implementation research of digital health. Smaller scoping reviews concerning specific disease areas and clinical guideline implementation, and a survey of implementation scientist practices are published, but their findings differ to the present study's in two important regards. Firstly, the heterogeneity of TMF application selection appears to be much greater in the present study, with half of guideline implementation studies applying at least one of the same 2 TMFs (20, 21). The preferences across implementation scientists in general also seem to differ from researchers working on clinical AI implementation as only 2 of the TMFs identified in the present study (Theoretical Domains Framework and Consolidated Framework for Implementation Research) appeared in the 10 most frequently applied TMFs from a survey of an international cohort of 223 implementation scientists (6). These differing preferences may be accounted for by the prominence of TMFs in qualitative clinical AI research from Technology Acceptance disciplines (40.9%), as described by Liberati's taxonomy, which do not have such natural relevance across implementation science as a whole (30). Secondly, the frequency with which any degree of rationale for TMF selection was described in the present study (42%) appears much lower than the 83% observed in guideline implementation research (21). Both of these differences seem to reflect the field of clinical AI and its nascent engagement with formally trained implementation scientists who have more established means of

selecting TMFs (6). Taken together, the heterogenous and unjustified selection of TMFs suggests superficial use or misuse of TMFs is common and that clinical AI research is yet to benefit from the full value of TMF-research question alignment experienced by other areas of implementation research (18, 25, 86–89). Given the potential of unjustified heterogeneity to lower the accessibility of implementation research to relevant stakeholders, avoidance of TMF application may be preferable to their superficial use or misuse (6).

There are a number of tools which have been designed, validated and disseminated to reduce the underuse, misuse and superficial use of TMFs demonstrated here and in implementation research generally (2, 90). To aid researchers in the rationalised selection of TMFs, interactive open access libraries and selection tools are available with embedded learning resources (91, 92). Following selection of a TMF, many of the authors of more prominent TMFs develop and maintain toolkits to support the appropriate and effective mobilization of their TMF to varied applications (93, 94). There are also reporting guidelines and quality criteria which support peer reviewers and academic journal editors in identifying quality research and incentivizing researchers to adopt good practices. Apart from occasional exceptions in the present study however, none of these tools were mentioned or used (86, 89, 95, 96). The present study adds to these resources for implementation researchers working in clinical AI by summarizing TMF use to date within the field, with examples of good practice (55, 56, 85). Paradoxically, it seems that the limitation on improving TMF application is not the presence of solutions, but their implementation.

4.3. Strengths and limitations

A strength of this study is the eligibility criteria, which facilitated the large number of eligible articles relative to pre-existent bibliometric studies of TMF applications in implementation research (20–22). The study also summarizes TMF applications in clinical AI research, a prominent and growing category of digital health implementation research which had not yet been subject to any similar bibliometric studies. Without clear incentives for authors to report the perceived impact, mode or rationale of TMF application, a lack of information in eligible articles for the present study does not exclude a theoretical foundation. This risk of over-interpreting negative findings is not unique to the present study but is a further limitation to hold in mind (97). A final limitation comes from the eligibility criteria for the present study which focus on qualitative research of clinical AI, to maximise the representation of TMFs among eligible articles at the cost of implementation studies which exclusively use quantitative methods. Whilst this does limit comparability to bibliometric studies of guideline implementation research or other areas, it appears to have succeeded in identifying a greater sample of TMF applications within clinical AI than found by alternative criteria in more established fields of research (20, 21).

4.4. Future directions

Firstly, the ambiguity over the value of ensuring that implementation research that is "theoretically informed", in a well-characterized and reproducible way, should be minimized through adequately resourced programmes of research. This is not in order to generate more TMFs, but to establish the impact of TMF application under current definitions of good practice. Without it, the challenge laid out in one of the first issues of the journal Implementation Science will continue to limit support from stakeholders influencing the implementation of TMFs: "Until there is empirical evidence that interventions designed using theories are generally superior in impact on behavior choice to interventions not so designed, the choice to use or not use formal theory in implementation research should remain a personal judgment" (19). A negative finding would also prevent future research waste in championing the proliferation and application of TMFs.

Secondly, if TMFs are proven to improve implementation outcomes then scalable impact within clinical AI and elsewhere cannot depend upon the oversight of implementation experts on any more than a small number of high priority implementation endeavors. Therefore, work to improve the accessibility and apparent value of existent TMFs and tools to promote their uptake should be prioritized (2, 91, 92). A focus on training and capacity building across a wider community of researchers and practitioners may also be beneficial (92, 98). Academic journal editors and grant administrators could be influential in endorsing or demanding relevant tools and guidelines, helping to improve the quality, consistency and transparency of theoretically informed clinical AI implementation research. Improved accessibility across existent TMFs would also help to tighten the relationship between frequency of application and efficacy of TMFs, helping to reduce the potentially overwhelming variety of TMFs available. If such a shortlist of popular TMFs emerged, with a clearer rationale and value for application, it could improve the accessibility of TMFs to a greater breadth of the implementation community. This could establish a virtuous cycle of improving frequency and quality of TMF application, mitigating against the researcher-practitioner divide described in implementation science (7).

5. Conclusion

Around a third of primary qualitative clinical AI research draws on a TMF, with no evidence of change in that rate. The selection of TMFs in these studies is extremely varied and often unaccompanied by any explicit rationale, which appears distinct from other areas of implementation research. In the context of the continual proliferation of TMFs and well-validated tools and guidelines to support their application, these data suggest that it is the implementation of interventions to support theoretically informed research, not their development, that limits clinical AI implementation research. Attempts to capture the full value of

TMFs to expedite the translation of clinical AI interventions into practice should focus on promoting the rigor and frequency of their application.

Author contributions

HH: contributed to the conception and design of the work, the acquisition, analysis and interpretation of the data and drafted the manuscript. MA: contributed to the acquisition and analysis of the data. PK: contributed to the design and conception of the work and revised the manuscript. GH: contributed to the interpretation of data and revised the manuscript. FB: contributed to the design of the work, the acquisition, analysis and interpretation of data and revised the manuscript. GM: contributed to the conception and design of the work, the data acquisition, analysis and interpretation of data and revised the manuscript. All authors approved the submitted version and all authors agree to be personally accountable for their own contributions and to ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated, resolved and the resolution documented in the literature. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2023.1161822/full#supplementary-material

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Expanding the evidence for cross-sector collaboration in implementation science: creating a collaborative, cross-sector, interagency, multidisciplinary team to serve patients experiencing homelessness and medical complexity at hospital discharge

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Introduction: Patients with medical and social complexity require care administered through cross-sector collaboration (CSC). Due to organizational complexity, biomedical emphasis, and exacerbated needs of patient populations, interventions requiring CSC prove challenging to implement and study. This report discusses challenges and provides strategies for implementation of CSC through a collaborative, cross-sector, interagency, multidisciplinary team model.
Methods: A collaborative, cross-sector, interagency, multidisciplinary team was formed called the Buffalo City Mission Recuperative Care Collaborative (RCU Collaborative), in Buffalo, NY, to provide care transition support for people experiencing homelessness at acute care hospital discharge through a medical respite program. Utilizing the Expert Recommendations for Implementing Change (ERIC) framework and feedback from cross-sector collaborative team, implementation strategies were drawn from three validated ERIC implementation strategy clusters: 1) Develop stakeholder relationships; 2) Use evaluative and iterative strategies; 3) Change infrastructure.
Results: Stakeholders identified the following factors as the main barriers: organizational culture clash, disparate visions, and workforce challenges related to COVID-19. Identified facilitators were clear group composition, clinical academic partnerships, and strategic linkages to acute care hospitals.
Discussion: A CSC interagency multidisciplinary team can facilitate complex care delivery for high-risk populations, such as medical respite care. Implementation planning is critically important when crossing agency boundaries for new multidisciplinary program development. Insights from this project can help to identify and minimize barriers and optimize utilization of facilitators, such as academic partners. Future research will address external organizational influences and emphasize CSC as central to interventions, not simply a domain to consider during implementation.

KEYWORDS

cross-sector collaboration, intersectoral collaboration, medical respite care, implementation science, people experiencing homelessness, care coordination, high-need

Introduction

Cross-sector collaboration (CSC) refers to the complex process of providing services through a collaborative framework of multiple agencies that a single agency could not achieve alone (1). Despite extensive use in organizational research and compelling demand to meet the care delivery for patients with medical and social complexity, CSC is a strategy that only recently began to emerge in health services implementation research. Previous studies documented that CSC has been employed in efforts to improve care transitions for people with serious mental illness (2), prevent infectious diseases (3), address obesity and non-communicable diseases (4), and advance health-promoting policy (5). Because of organizational complexity, differences in goals and financial models across agencies (6) and exacerbated social and clinical needs of patient populations receiving care requiring CSC (7), implementation and sustainability of CSC interventions remains poorly understood. Furthermore, the reliance on the traditional, disease- or illness-based biomedical care model in most of the US healthcare settings (8) often results in medical agencies leading CSC efforts, quality improvement, and innovation, which may compromise integration across agencies, reduce effectiveness, and hinder long-term sustainability of cross-sector interventions (9).

An example of a population with needs that demand collaborative care from cross-sector, interagency, multidisciplinary teams, is people experiencing homelessness at acute care hospital discharge. Compelling evidence from the last decade of health services research has demonstrated increasing medical and social complexity of people experiencing homelessness (10–13). In addition, the recent push toward community-based medical management means that patients are discharged from hospitals sooner, and with more complex treatment needs that they must manage at homes that they do not have (14). In parallel to patients' growing medical needs, our understanding of the impact that social factors play on their overall wellbeing and experience of care is also growing (15). We now know that social determinants of health play a larger part than we have historically accounted for in how and when patients access care, their trust in clinicians, whether they have the capacity to follow treatment plans, and if they will successfully transition to the community after acute hospitalization events (16). With high rates of housing insecurity, financial strains directly linked to healthcare cost, and demands of personal relationships and responsibilities, social factors often lead to patients' premature return to hospital. Studies show that lack of support at home, income limitations, and transportation demands are often more impactful in causing patients to decide to return to the hospital than clinical symptoms—realities that are exponentially worse in people experiencing homelessness at hospital discharge (17).

While several studies used the CSC approach to address care needs of complex patients, only a few demonstrated positive results (18). A prominent example is the study out of Camden, NJ which delivered community-based care coordination to high-need patients with patterns of high health services utilization (19). The study intervention, while rigorous in its attempt to address health and social needs, was primarily delivered from a single organizational entity, and lack of significant impact on rehospitalizations confirms the need for targeted CSC for high-need populations. In contrast, a growing body of health and social science literature from the National Institute of Medical Respite Care (20), a subsidiary of the Healthcare for the Homeless Council, attests to the multi-faceted and successful approach to care transition delivery, known as medical respite care. In the United States, medical respite programs provide support to individuals experiencing homelessness and medical complexity at the time of hospital discharge and have the capacity to facilitate linkages between health and social sector organizations (21, 22). However, little is known about implementation of medical respite programs, and the evidence of successful implementation is scarce.

The lack of insight into CSC in general, and as a specific strategy to facilitate care transitions for people experiencing homelessness, poses implementation challenges for programs reliant upon collaborative service delivery. The aim of this study was to outline barriers and facilitators to the implementation and sustainability of a program based on a team of cross-sector providers. The social services-based program serves people experiencing homelessness in Buffalo, NY.

Methods

Setting

The Buffalo City Mission (BCM) is Buffalo's largest homeless shelter, with capacity to serve 200 men, women, and children in their emergency and transitional shelters at two downtown locations, the Alfiero Family Center for men, and the Cornerstone Manor, for women and children. At the time of initiation of this collaborative project, the BCM was transitioning from an existing facility to a larger men's facility that included a 13-bed unit for medical respite care, to be called the Recuperative Care Unit (RCU).

The BCM receives referrals to its RCU program from regional acute care hospitals. Most patients come from the county acute care hospital. The hospital also maintained an existing contractual post-acute program for behavioral health patients requiring BCM services and county crisis services oversight. BCM staff only provides social services to the tenants and has formed partnerships with other collocated agencies to provide other necessary services: a Federally Qualified Healthcare Center (FQHC) primary care agency, and a behavioral health agency. Additional collaborative partners include specialty healthcare providers, transportation providers, and legal agencies as dictated by individual patient needs and located elsewhere in the city.

Participant sample

The study participants include project representatives from social, behavioral, and academic agency partners represented in **Figure 1** ($N = 10–15$ primary agencies), with individuals from a mixture of frontline, provider, academic, and administrative departments, and roles.

Through the support of a grant procured from the Robert Wood Johnson Foundation Clinical Scholars Fellowship (RWJF

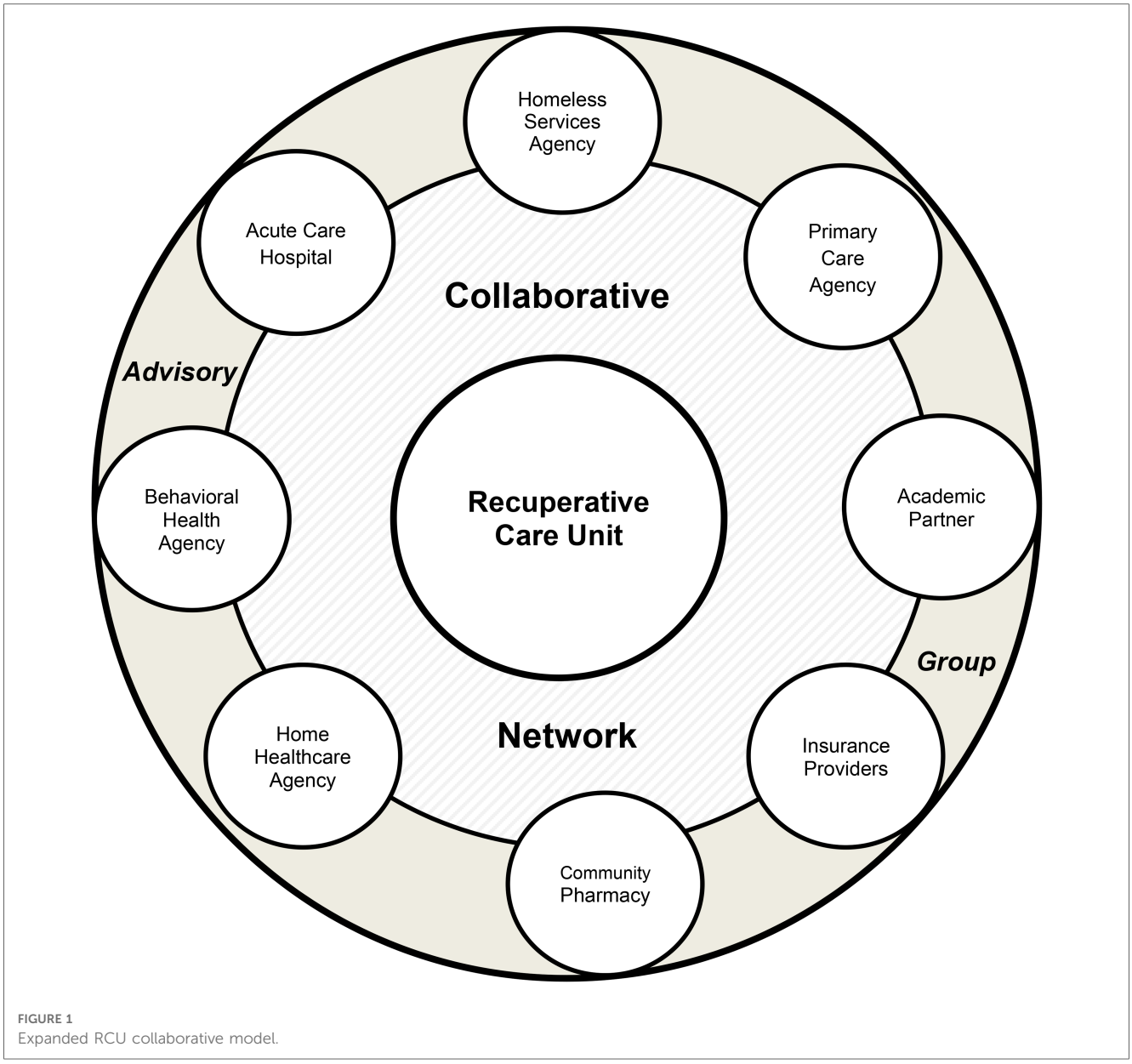

FIGURE 1
Expanded RCU collaborative model.

77883), a partnership between the Buffalo City Mission and the State University of New York at Buffalo School of Nursing (UBSON) was formed, followed by a collaborative, cross-sector, interagency, multidisciplinary team of partners making up the study sample (Figure 1) known as the Buffalo City Mission Recuperative Care Collaborative medical respite program (RCU Collaborative). The fellowship, which includes leadership enrichment and project management training (23), launched in September 2021, and scholars joined with organizational stakeholders to form the RCU Collaborative for the purpose of opening the medical respite program within a cross-sector framework.

Study design

To facilitate the creation of the collaborative, cross-sector, interagency, multidisciplinary team, the project stakeholders agreed upon a schedule of recurring meetings including a weekly case conference of frontline providers, a monthly advisory group of administrators, and *ad hoc* workgroups for operational and programmatic development needs (Table 1). Members from each partnered organization attended recurring meetings and were called upon for workgroup-specific tasks.

Data analysis

The study data were generated through informational interviews, review of regular meeting materials and operational procedures, and feedback from involved team members. The study team analyzed study data, identified reported barriers to implementation of collaborative, cross-sector, interagency, multidisciplinary team, and mapped them to appropriate implementation strategies using the Expert

TABLE 1 RCU collaborative meeting structure.

Meeting	Cadence	Description
Clinical Scholar	Weekly	Fellow-only think-tank meeting for reflection, cross-communication, and brainstorming
Advisory Group	Monthly	Cross-sector leadership stakeholder meeting for review and approval of workgroup and case conference output; new strategy and alignment
Operations Workgroup	Weekly	Frontline cross-sector group charged with policy, procedure creation
Case Conference	Weekly	Cross-sector clinical review of respite clients for purpose of care transition management through program
Learning Consortium	Monthly	National Health Care for Homeless Council Medical Respite Learning Consortium for new medical respite providers
CS Retreats	Quarterly	Quarterly RWJF Clinical Scholar leadership retreats to support professional development of fellows

Recommendations for Implementing Change (ERIC), a validated framework of implementation strategies (Table 2) (24, 25). The preferences were given to implementation strategies that were aligned with implementation facilitators identified by the study informants.

Results

The primary goal of this study was the creation of a new collaborative, cross-sector, interagency, multidisciplinary team delivering medical respite care to people experiencing homelessness after acute care hospital discharge, the RCU Collaborative. Below we describe barriers and facilitators to implementation of RCU Collaborative model of care (outlined with detail in Table 3) and propose implementation strategies to overcome these barriers by maximizing strengths and resources identified by the members of the Collaborative.

Implementation barriers

Organizational culture clash, disparate visions & workforce challenges

Unclear communication between primary partner leadership, complicated by historically strained relationships between partnering organizations, and unclear roles at the start of our initiative resulted in culture clash between organizational leaders. Additional barriers stemmed from differences in policy and procedure between organizations, which were tied to organizational culture, size, values, and understanding of healthcare service delivery. The lead homeless service agency functioned within a faith-based framework, with administrative restrictions on funding mechanisms that limited its operating strategies. Additionally, the reliance on relational workarounds and top-down administrative hierarchy for decision making in the lead social sector agency, caused barriers to formal operating procedure implementation with healthcare entities accustomed to more protocol-driven operating mechanisms (26). Extensive workforce turnover and leadership changes in the leading social sector agency led to persistent barriers to implementation and program growth. Additionally, the slow

TABLE 2 ERIC Implementation strategies by cluster with project-specific emphasis.

Implementation strategy cluster name	Implementation strategies
Use and evaluate iterative strategies	Asses for readiness and identify barriers and facilitators; Audit and provide feedback; Purposefully reexamine the implementation; Develop and implement tools for quality monitoring; Develop and organize quality monitoring systems; Develop a formal implementation blueprint; Conduct a local need assessment; Stage implementation scale up; Obtain and use patients/consumers and family feedback; Conduct cyclical small tests of change
Provide interactive assistance	Facilitation; Provide local technical assistance; Provide clinical supervision; Centralize technical assistance; Provide clinical supervision; Centralize technical assistance
Adapt and tailor to context	Tailor strategies; Promote adaptability; Use data experts; Use data warehousing techniques
Develop stakeholder interrelationships	Identify and prepare champions; Organize clinician implementation team meetings; Recruit, designate, and train for leadership; Inform local opinion leaders; Build a coalition; Obtain formal commitments; Identify early adopters; Conduct local consensus discussions; Capture and share local knowledge; Use advisory boards and workgroups; Use an implementation advisor; Model and simulate change; Visit other sites; Involve executive boards; Develop an implementation glossary; Develop academic partnerships; Promote network weaving
Train and educate stakeholders	Conduct ongoing training; Provide ongoing consultation; Develop educational materials; Make training dynamic; Distribute educational materials; Use train the trainer strategies; Conduct educational meetings; Conduct educational outreach visits; Create a learning collaborative; Shadow other experts; Work with educational institutions
Support clinicians	Facilitate relay of clinical data to providers; Remind clinicians; Develop resource sharing agreements; Revise professional roles; Create new clinical teams
Engage consumers	Involve parents/consumers and family members; Intervene with patients/consumers to enhance uptake and adherence; Prepare patients/consumers to be active participants; Increase demand; Use mass media
Utilize financial strategies	Fund and contract for the clinical innovation; Access new funding; Place innovation on fee for service lists/formularies; Alter incentive/allowance structures; Make billing easier; Alter patient/consumer fees; Use other payment schemes; Develop disincentives; Used capitated payments
Change infrastructure	Mandate change; Change record systems; Change physical structure and equipment; Create or change credentialing and/or licensure standards; Change service sites; Change accreditation or membership requirements; Start a dissemination organization; Change liability laws

Adapted and cited from (25).

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TABLE 3 RCU collaborative partners and care actions by transition phase.

Organization (Facilitator)	Phase 1		Phase 2	Phase 3
	Hospital discharge	Respite admission	Respite days 1–30	Respite discharge
Acute Care Hospital (Discharge Planners)	Completes online referral form/ sends clinical documentation; Schedules new patient visit at respite PCP; Refers patient to collaborative HHA/BHA	Troubleshoots post-discharge transition needs with HSA, PCP, AP	Participates in Weekly Case Conference Troubleshoots care needs with HSA, PCP, AP as applicable to hospitalization or prevention of readmission	Confirms discharge and conveys to internal billing management
Homeless Service Agency (Respite Case Managers)	Evaluates referral elements from ACP; Requests PCP; AP referral review; Requests ACH clarification/ documents/visit; Denies/accepts patient	Confirms PCP, HHA, BHA linkages, discharge elements Begins wraparound case management protocol	Provides 24–7 oversight/assistance to admitted patients; Generates and reviews daily census, individual patient plans; Facilitates necessary care escalation, coordination, disposition changes; Leads Weekly Case Conference; Leads Monthly Advisory Group	Transition patient to disposition decided upon by collaborative decision; Communicate with PCP, referred agencies for transition of care; Communicate with ACH to close billing for patient
Primary Care Agency (Physician's Assistant)	Reviews clinical elements of referral documents	Confirms new patient linkage and first visit with HSA	Facilitates post-discharge patient follow up within 7 days; Manages medical escalations 24–7 as necessary; Participates in Case Conference Group; Sends administrative representative to Monthly Advisory Group	Confirms disposition location and plan for care after transition
Home Health Agency (Home Health Providers)		Confirms new patient linkage and first visit with HSA	Facilitates nursing, PT/OT services; Participates in Case Conference Group; Sends administrative representative to Monthly Advisory Group	Confirms disposition location and plan for care after transition
Behavioral Health Agency (Behavioral Health Providers)		Confirms new patient linkage and first visit with HSA	Facilitates behavioral health/substance abuse services; Participates in Case Conference Group; Sends administrative representative to Monthly Advisory Group	Confirms disposition location and plan for care after transition
Academic Partners (Clinical Scholars)	Assists with patient referral review		Assists with cross-sector connections, troubleshooting; Assists with facilitation of Weekly Case Conference; Sends administrative representative to Monthly Advisory Group	Assists with patient data tracking
Case Conference Group (Frontline Facilitators)	Discusses new patient referrals	Troubleshoots post-discharge transition needs	Meet within first 7 days of patient admission (weekly recurrence); Address discharge gaps as necessary, health and social care needs; Assess rehospitalization risk/need for level care	Collaboratively decide upon patient discharges and transfers out of program
Advisory Group (Administrative Representatives)			Addresses policy & practice needs; Facilitates accountability across organizations; Serves as feedback and approval mechanism for frontline providers	

ACH, Acute Care Hospital; HSA, Homeless Service Agency; PCP, Primary Care Agency; HHA, Home Health Agency; BHA, Behavioral Health Agency; AP, Academic Partners

utilization of the respite program by regional organizations can be attributed to the impact of the COVID-19 pandemic, as regional acute care hospitals and health departments facilitated care transitions through external mechanisms, and shelter policy prohibited admittance of new patients who were actively infected with the virus.

Related ERIC strategy cluster: use and evaluate iterative strategies

An early element of the RCU Collaborative implementation aimed at restoring trust in relationships came with the creation of relational meeting structure, which fosters frequent and high-quality communication, facets of relational coordination inherent to successful cross-sector partnerships (1, 27), and an evidence-based strategy in care coordination programs for high-risk patients (28). The ERIC elements of *assess for readiness and identify barriers and facilitators* was done through an administrative-frontline dyad, the RCU Collaborative launched two key meetings to facilitate restored trust in relationships through consistent forums: the RCU Weekly Case Conference and the RCU Advisory Group (Table 1).

Another strategy from this cluster included *development of a formal implementation blueprint*, which included structures such as the RCU Weekly Case Conference, where cross-sector team members committed to meet via teleconference to discuss referrals, admissions and current RCU patients, fostered increased communication, discussion about discharge quality, and aligned efforts toward throughput and readmission reduction across the

RCU Collaborative. Following each patient for the 30-day period post-discharge, the case conference served as a conduit for relationship building because of the consistent audience across sectors, frequency of communication, and the shared burden of the care transition period with the discharging hospital.

In addition to the case conference, the RCU Collaborative leaders created a project hierarchy and meeting structure that included an approval mechanism forum called the Advisory Group, which was part of the strategy of *developing and organizing quality monitoring systems*. Comprised of partnering organization leaders, the Advisory Group served as a monthly mechanism for strategic decision-making, evaluation of cross-sector concerns, and approval of policies that were being drafted at the frontline level in a separate workgroup and from within the case conference. The dyadic pairing of Advisory Group members with frontline members of the case conference and workgroup provided clear structure for escalation and approval, and allowed frontline members to air concerns with each other, brainstorm solutions, and enact policy upon approval of collective leaders in the Advisory Board and within the relationships sustained by the meeting structure.

Related ERIC strategy cluster: change infrastructure

At the launch of the RCU Collaborative, the key element of shared policy structure, or according to ERIC, the infrastructure needed such as *membership requirements, mandate change,* and, *record systems*, that was addressed was the need to set guidelines for RCU patient eligibility criteria, and the process for referring patients to the RCU. This information was crucial to the movement of financial and contractual elements being driven by BCM leadership, and elements were generated within a workgroup comprised of leaders and frontline staff. Additionally, this strategy informed the creation of a robust data collection method that is practical, based on an evidence-based model (29), and rich in information that is often not extractable from health services data. Evidence was drawn from standards set by NIMRC, as well as existing readmission reduction literature, with a focus on Coleman's Care Transitions Intervention criteria (30, 31).

The referral process, an element of baseline process change pertinent to *membership requirements* specific to acute care hospital referral expectations, was the first shared policy and procedure element approved by the Advisory Group and represented a process that benefitted from the creation of a support tool, a key element to successful cross-sector collaborations drawn from Accountable Care Organization literature (32). The tool was comprised of a screening and acuity scale based on a published risk index (33), and performed by BCM when patients were referred by acute care discharging providers with unit-placement preference specified (**Figure 2**). As BCM RCU is located within the compound shelter facility that includes 30-day emergency shelter units and a transitional housing unit, the ability to rank referral acuity for admission to RCU as a shared process was a key policy decision. Once successfully implemented in paper form, the RCU Collaborative designed an online portal for referral, and executed go-live and affiliated training for easier management by both sectors. In tandem with creation of eligibility and referral process and requirements, the RCU Collaborative created a shared Policy & Procedure manual that addressed the elements of cross-sector respite care given to patients during the first seven to thirty days of stay.

Another key aspect of the shared policy and procedure work, which required cross-sector input, was the specified escalation procedures for discharge, clinical, behavioral, and mental health emergencies, which could fall into the ERIC strategy in this cluster, *mandate change*. Since the RCU was housed within BCM and did not offer or employ onsite clinical service providers, the RCU Collaborative created a collaborative algorithm with program partners to manage urgent needs. With the collective goal of avoiding rehospitalization or emergency room utilization, and optimize the nature of non-clinical RCU staff, the escalation policy

What is the patient's acuity score?
Review the referral document, select corresponding answers, and sum points to determine score.

	Normal 0 Points	Low 1 Point	Medium 2 Points	High 3 Points	Point Subtotal
Days in hospital?	[ ] 0 days	[ ] 1-2 days	[ ] 3-5 days	[ ] >5 days	
Hospital unit(s)?	[ ] ED/CPEP	[ ] OBS/EOB	[ ] Inpatient	[ ] Intensive Care	
Chronic condition(s)?	[ ] None (0)	[ ] 1	[ ] 2	[ ] > 3	
ED visits last 6 months?	[ ] None (0)	[ ] 1-2	[ ] 3-5	[ ] >5	
Additional needs?	[ ] None (0)	[ ] DME or O2	[ ] Indwelling device/wound	[ ] >5 medications/IV	
Total Acuity Score Enter sum of points above.					

FIGURE 2
RCU collaborative referral acuity score tool.

provided step-by-step instruction in a visual format. For example, if a patient was admitted without durable medical equipment listed on discharge instructions, the non-clinical staff would refer to the discharge escalation pathway, which specified how to contact a discharging provider to escalate a discharge need. Likewise, in the event of clinical emergency, the algorithm specified how to utilize the primary care partner, including in off-hours, to resolve non-emergency-level clinical issues that had formerly been deferred to emergency department care by shelter staff.

Finally, the RCU Collaborative established a means for tracking patients during the first year of the program, an example of ERIC strategy *change record systems*. This method was comprised of both automatic and manual extraction from the BCM electronic record known as the Client Record Online Service System (CROSS), a customized product of WellSky. Tracking included patient and programmatic demographics, descriptive metrics to establish population baseline of health and social risk factors, program quality improvement metrics, and the calculation of 7- and 30-day readmission rates.

Implementation facilitators

Clear group composition, academic partnerships & strategic linkages with hospitals

By linking administrative approval with frontline implementation and feedback, we adapted policies to the unique needs of our patients as they arose. This dyadic structure also improved our relational trust and creation of shared policy and procedure, which the collaborative depended on for facilitation of protocol-based, accountable communication and action across agencies. For example, acute care hospital leadership appointed specific middle-management and frontline staff to contribute to the weekly case conference of collaborative providers, which allowed for real-time information exchange on care transition quality and patient needs post-discharge; a rare snapshot that most acute care providers lack access to. This feedback mechanism extended across the entire care continuum from hospital discharge to patient transition out of the medical respite unit, which allowed for role normalization, consistent communication, and access to multiple record systems by network team members to inform a truly holistic dialogue about patient risk and care needs. Four academic-based research team members sponsored by the UBSON-based Robert Wood Johnson Foundation Clinical Scholars project, functioned as Implementation Facilitators in this project, defined by the updated CFIR framework as, "Individuals with subject matter expertise who assist, coach, or support implementation." (34) These members entered the project in Fall 2020 at grant initiation and included two of the authors (AA; SH). All participants in this group were White females with nursing degrees and greater than ten years of clinical and/or administrative experience.

Strategic linkages with acute care hospitals

Through a recurring weekly case conference that included all collaborating partners, and a recurring monthly oversight committee, our model structured a practical, important avenue for communication and feedback that mirrored real-time patient discussions often seen in acute care setting and incorporated representatives from acute care hospitals sending patient referrals as integral stakeholders in the RCU Collaborative. This facet is unique in care transition literature, but crucial to the success of the collaborative, cross-sector, interagency, multidisciplinary team. Our dyadic composition of frontline providers across the care transition continuum, paired with an oversight committee of leaders, was vital to our successes in clarifying cross-sector roles and implementation of the program.

Related ERIC strategy cluster: develop stakeholder interrelationships

Clarity of roles across involved organizations is a shared element in administrative theory on cross-sector collaboration, and the ERIC study (1, 24, 25). Although BCM and involved RCU Collaborative stakeholders had historical relationships in care transitions, early work included establishment of a visual model to establish cross-sector roles and connections (**Figure 1**). The model helped to *build a coalition* to align newly colocated program partners for input on collaborative capacities, and to begin the creation of procedural elements to outline how RCU care would be implemented, and what it would consist of (**Table 3**). For example, team discussions included licensing limitations for colocated providers in the RCU space, ensuring program expectations such as initial patient care appointments, facilitating communication during urgent situations to reduce rehospitalizations, and resolving discrepancies in discharges. During this time prior to program launch, new partners were added to the model, including stakeholders in community organizations, BCM departments such as dietary, housing coordination, and spiritual care, and home health care organizations. Although the visual model continues to expand and change throughout the course of the project, its value as a grounding tool for clarifying cross-sector organizational and individual roles, was seen early on.

A second strategy cluster element was the use of *academic partnerships* with the UBSON Clinical Scholar partners as boundary-spanning agents within the network. Brokers and boundary-spanners are agents within collaborative networks who work to connect disparate parties for the purpose of collective good (27, 35). The UBSON Clinical Scholars were four nurses working internally to the RCU Collaborative, connected through the RWJF grant elements. One (AA), a PhD student and experienced nurse administrator, performed research assistant duties as an internal member of the frontline BCM team, giving support to case managers and leadership in the creation of the administrative structure and policies. Another (SH), a PhD-prepared care transitions scientist and faculty member, liaised with RCU Collaborative leaders to facilitate the creation of project hierarchy and role clarity. Two additional members worked internally at the contracted acute care hospital, with a proportion of their salaried hours dedicated to the RCU Collaborative project. Their internal knowledge and access to the primary acute provider contributed to boundary-spanning capacities for establishing transitional elements such as discharge and referral criteria expected of hospital discharge planners

sending patients to the RCU, and to subsequent clarity of RCU care to hospital stakeholders.

Additional strategy cluster elements include opportunities both utilized and provided by the RCU Collaborative members that *promoted network weaving*. For example, a portion of members of the RCU Collaborative participated in the NHCHC Medical Respite Network Learning Consortium, and Clinical Scholar Fellows learned from leadership activities inherent to the CS program and coaching support. Additionally, BCM team members created materials about the RCU for the acute care hospital partners and rounded in the hospital to teach about eligibility criteria, referral processes, and typical respite stay. Finally, CS Fellows executed multiple "Lunch and Learn" sessions for BCM leadership on topics relevant to RCU such as data for quality improvement training, and financing respite care.

Discussion

Retrospective reflection of our program launch led to an understanding of the renewed importance of having a clearly defined, shared vision when engaging in a community-based implementation project across several interdisciplinary agencies. While this step is explicitly outlined in many determinant IS frameworks, including the original CFIR framework (34), in practice it is often omitted as unnecessary or too simplistic. Barriers related to how to operate and evaluate the program largely stemmed from varying data use standards among different agencies, differences in quality improvement practices across sectors, and the limitations of social sector record data, which relies heavily on elements required by the Housing and Urban Development documentation and varies in quality due to qualifications of shelter personnel. Additionally, the heavy healthcare influence of the academic partners initially caused barriers in protocol implementation in the social sector, leading to a leadership clash and need to reframe to integrate the healthcare paradigm into the social sector culture, not overtake.

Additional lessons learned include the extreme complexity of measurement and tracking outcomes across a collaborative, cross-sector, interagency, multidisciplinary team of providers using vastly different record keeping systems, some including paper. This stems from the lack of insight onto standardized outcomes for medical respite care, and care of people experiencing homelessness and other socially complex presentations. Conventional studies of high-need populations track readmission or utilization reduction, but this practice has since fallen out of favor considering the limitations when addressing patients experiencing extreme exclusion and may not present with typical healthcare utilization patterns (11). In our recent scoping review of care transitions models for high-need patients (36), we found that measurement of continuity was either absent or lacking from prominent studies. In the first year of operation, our medical respite program achieved a measurement of continuity by showing a 15% improvement in primary care provider linkage between admission to the respite program and first post-hospitalization visit within 7 days. This concrete quantification of continuity, which is the primary outcome of a large randomized controlled trial of complex care coordination for people experiencing homelessness in Toronto, Canada (37), and its marked increase because of our intervention, was relatively easy to track within our model, and indicates a direct benefit of this CSC model of care for a high-need population.

Our partner feedback showed that although patients were admitted to the respite program with clear clinical need during the initial period of care transition, the greatest long-term risk patients faced was in relation to predominantly high acuity social needs. The extension of acute care hospital collaboration into the post-discharge space ensured that discharge failures were remedied promptly so that social sector providers could facilitate wraparound treatment alongside collaborative primary care treatment. By understanding and quantifying our patients' social risk, our program is also able to optimize data collection of social determinants that is required but challenging for our acute care hospital partners to aggregate, a new facet of US-based Federal regulatory requirements.

Limitations

Our study is limited due to its small size, and nascent nature of our initial findings. Although our extraction of data from a social sector source is practical and offers an easily implemented framework for similar programs with limitations to health sector records, quality of data is limited. Although we possessed University at Buffalo Institutional Review Board approval to perform retrospective review of informal program data for the purpose of baseline measurement and quality improvement, hypothesis testing was not performed due to the small sample size. Additionally, our informal collection of observations on the implementation process could be bolstered by formal methods, such as through regular, formal focus groups and subsequent qualitative analysis.

Conclusion

This example of a collaborative medical respite program formation illustrates the potential for CSC implementation and adds to the call for further development of implementation strategies that address external organizational influences to better understand the external domain integral to CSC and thus to better meet the demands of our complex patients and agencies where they receive care (38). Our evaluation has demonstrated that by developing shared vision and corresponding workflow, providers from cross-sector agencies may gain clarity about their roles, and in doing so, improve long-term effectiveness and sustainability of the program through normalization of collaborative tasks.

Future research will focus on CSC as an integral facet of the intervention, not simply a domain to consider during implementation, and utilize innovative frameworks which specifically address CSC interventions as an imminent need in current patient care, such as the Consolidated Framework for Collaboration Research (CFCR) (39), a developing implementation

science framework focused on community engagement. Our collaborative model illustrates the importance of elements of CSC that bridge the vast spaces between sectors outlined in this emerging framework and similar body of literature, such as close attention to who is actively engaged (group composition), how a shared vision is implemented (structure and internal processes), and how to optimize relationships toward mutual empowerment (activities in community and collaboration). The intentional focus on community engagement of both CFCR and our model, instead of cross-agency competition for clients, could help strengthen further expansion of medical respite as an evidence-based model that requires CSC for successful implementation and leads to beneficial outcomes for our most vulnerable patients.

Data availability statement

The data analyzed in this study is subject to the following licenses/restrictions: Data was collected during program operations in a private institution and is not publicly available. Queries should be directed to Amanda Joy Anderson, ajanders@buffalo.edu.

Ethics statement

The studies involving human participants were reviewed and approved by University at Buffalo Institutional Review Board. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Author contributions

AA and SH contributed to conception and design of the study. AA organized the implementation findings. AA and SH performed the program evaluation and analysis of implementation findings. AA wrote the drafts of the manuscript. SH and KN wrote sections of the manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

The author KN declared that they were an editorial board member of Frontiers at the time of submission. This had no impact on the peer review process and the final decision.

The handling editor NS declared a past collaboration with the author KN.

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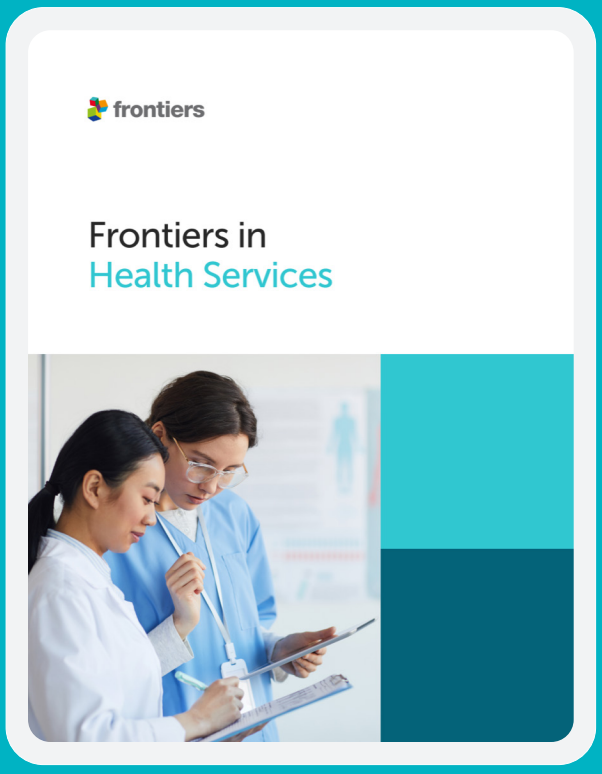

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