Health promoting settings in the 21st century: New approaches and competencies to address complexity and inequity in an increasingly globalized world

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Published in
Frontiers in Public Health

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Health promoting settings in the 21st century: New approaches and competencies to address complexity and inequity in an increasingly globalized world

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Editorial on the Research Topic
Health promoting settings in the 21st century: new approaches and competencies to address complexity and inequity in an increasingly globalized world

The settings approach to health was initiated by WHO following the Ottawa Charter for Health Promotion and aimed to contribute to the implementation of its holistic concept in diverse settings. The movement started with Healthy Cities and was soon followed by health promoting schools, workplaces, hospitals and healthcare services, prisons, playgrounds, neighborhoods and other new emerging settings (1). Since then, settings-based health promotion programs, research and policies have continued to grow (2) and at the onset of the twenty-first century, a consensus was reached about the complexity of settings and how to introduce and sustain health promoting changes in settings (3).

The collection of articles in this Research Topic aims to collect and highlight new approaches and competencies to address complexity and inequity in an increasingly globalized world focusing on new developments in the settings approach and innovative approaches and ways of working and thinking in settings-based policy, practice, and theory. The articles describe a range of initiatives in different settings, from remote Australian communities through university campuses to prisons and sports federations, and methods and approaches, including individual and community-based strategies, guided by reflective practice and conceptualization of new frameworks for action.

For example, McRae et al. described a qualitative process evaluation of a *community*-led health promotion initiative set during the COVID-19 pandemic in 2020. The initiative involved producing a hip-hop music video ('HipHop2SToP') with youth in the Kimberly Region of Western Australia and showed that community-led and culturally appropriate initiatives could strengthen community ownership and create new ways of maintaining

relationships with remote Aboriginal communities. Likewise, Khazaee-Pool et al. in their research illustrate how social innovation in health and community-driven engagement acted as key strategy to address COVID-19 challenges in the multicultural society of Iran by increasing equity in health services access, especially among vulnerable groups and minorities.

In *universities*, Weaver et al. demonstrated how reflective structured dialogues can be used as a tool for addressing wicked public health problems, including polarization-related attitudes among university students on controversial divisive topics such as COVID-19, mental health, and racism. They showed that participation in conversations was strongly associated with improved attitudes related to openness, tribal identity, and moral disdain. Suarez-Reyes and Van den Broucke, in their global survey of participation of university community members in Health Promoting Universities, indicated that students were more involved in information delivery, the lowest level of participation, while professors were relatively more involved in consultation strategies and design, planning and decision-making, leaving room for improvement in terms of community participation. Doré et al. in their article on promoting the interruption of sedentary behavior among university students during online classes explored the use of videos with different message strategies as a tool for behavior change, although further research on effective communication and message strategies is needed.

In *prisons*, Tesler et al. report results from a cross-sectional study among Israeli inmates, showing that most participants failed to meet recommended physical activity levels and with half reporting that their physical activity levels decreased since being in prison. Participation in health promoting activities was associated with higher levels of activity and subjective health status and significantly higher among younger males, showing that health promotion activities may play an important role in addressing the challenges of maintaining inmate health.

The potential for organized sports to promote health was highlighted by Van Hoye et al. who in their article provide guidelines to support national *sports federations* to invest in health promotion. They elaborated how the settings-based approach to health promotion can be adapted to national sports federations by clarifying theoretical concepts, providing practical applications of potential interventions based on case studies, and guidelines and tools useful for implementation.

Jenkins et al. in their conceptual review of settings for the development of health literacy pointed to the need to identify and conceptualize *non-traditional and emerging settings* in the twenty-first century. They developed a conceptual model using a public library to propose four equity-focused antecedents to develop health literacy and located this within a "*super settings*" approach, where multiple settings work in synergy with each other.

Tong et al. in their article on developing a health literacy environment scale for Chinese *hospitals*, pointed to the complexities of an environment traditionally used to promote health literacy. They describe a process of rigorous scale development and validation resulting in a psychometrically sound instrument that provides a patient perspective for evaluating the environment which makes it easier for patients to access, understand, and use health information. Scale validation was also

the subject of the article by Lynn Ho et al. who assessed the family health climate in a multi-ethnic Asian population and adapted an instrument validated in Western populations for Singapore whilst accounting for language and cultural differences. The results suggest a good psychometric profile, including after the development of shorter versions of the scales.

COVID-19 also impacted the *digital environment*, with attention to digital health literacy and online teaching. Getachew et al. in their article on the digitalization of health during COVID-19, elaborate on the role of digital support for the prevention, diagnosis, and care at individual level, and data management, outbreak tracking and pandemic surveillance at population level. Questions were raised about its cost, compatibility with existing systems, disruption in patient-provider interactions and sustainability, in turn calling for more evidence on clinical utility and economic evaluation.

The COVID-19 pandemic also showed how *primary care* plays a central role in promoting health and preventing disease, even during health emergencies. Milani et al. in their perspective showed how in Italy local primary care centers called "Houses of Community" were used as a new model of care and the nearest access point to provide continuity of care and health and social integration. They pointed to the need for multiprofessional collaborative practices between services of care, local health districts and researchers, using participative approaches in research and action, and educational programs. Lev and Ron highlighted inequities in access to health care during the COVID pandemic, demonstrating the need not only to prevent the onset and progression of chronic non-communicable diseases and to promote healthy lifestyles, but also to prepare for new infectious diseases and their long-term effects on physical and mental health. In their perspective they argue for a broad-based approach to health promotion, prevention and preparedness (HPPP) at national and global level to strengthen government commitments to the Sustainable Development Goals.

Policies to curtail environmental determinants of unhealthy behavior were discussed in the article by Alebshehy et al. in a scoping review of policies regulating the *retail environment* to reduce tobacco availability. Through a search of WHO FCTC and COP decisions, scientific and gray literature, they identified measures to regulate the retail environment, the adoption of which in WHO FCTC related decisions would probably increase their implementation worldwide.

Li et al. in a methods article on contextual and environmental factors that influence health, report a within-subjects field experiment protocol focusing on the *street environment* as a routine setting for daily activities that integrated instantaneous assessments of the environment, physical activity and health outcomes. Using state-of-the-art environmental monitoring and biosensing techniques and focusing on physically active road users, an experiment was successfully executed in Texas, showing its feasibility of capturing health effects of physical activity in various urban environments by combining environmental, behavioral and physiological sensing.

Costa-Clemens et al. in their brief research report, describe a rapid site readiness project in Latin America to test clinical trial capacity building for COVID-19 vaccine and drug development,

which underscores the need for the availability of sufficient and well-trained *clinical trial sites*, especially in low- and middle-income countries.

Finally, Pescud et al. argued that while strengthening settings for prevention of chronic diseases is essential, leadership for systems change is crucial. In their article, they examined and described researcher practices for enhancing impact in prevention research using case studies. The results indicate that persuasive communication, compassion and deep listening, reflective practice, and research embeddedness can help create change within systems.

What all these studies show is that health promotion needs to be designed according to the needs and resources of the target population (group or community) and make use of nudging strategies, policy reinforcement and the reorganization of health and social action services. They show that there is investment in new approaches to increase competencies in order to address complexity and inequity worldwide. Health promotion and preparedness good practices are crucial to address the daily needs of groups and communities facing inequality, and even more so when catastrophic situations occur that affect entire populations and accentuate these conditions (4). Building health promotion competencies is essential and should be part of any training program aimed at building a skilled and competent public sector workforce (5, 6) and empowering university communities to lead this effort could bring countless benefits and return to society the investment made in training skilled technicians, thereby helping to achieve the sustainable development goals (4).

The collection of articles presented here also provide key insights into new approaches to address the different action areas of settings-based health promotion, ranging from individual to population level targets and from policy to practice, guided by sound research and reflection. The articles highlight the unwavering commitment of researchers and scholars to think and rethink twenty-first century health promotion, using the advances of digital technology, research and theoretical frameworks, focusing on equity in access to care and on pandemic prevention and preparedness, set against the backdrop of the COVID-19 pandemic. Lessons can be learnt from new settings-based models and programs, and we hope that the articles in this Research Topic will bring some food for thought and inspiration and that you will enjoy them as much as we did.

Author contributions

PD: Conceptualization, Writing – original draft, Writing – review & editing. NK: Writing – review & editing. IB: Writing – review & editing.

Funding

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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The validation of culturally appropriate scales to assess the family health climate in a multi-ethnic Asian population

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Background: The Family Health Climate (FHC) is a family environment attribute postulated to influence the health behaviors of family members. It can be measured by domain scales for physical activity (FHC-PA) and nutrition (FHC-NU), which have been validated and used to identify health climate patterns in families in Western populations. To extend the use of the scales to Asian settings, this study aimed to adapt and validate the instruments for use in the multi-ethnic population of Singapore, accounting for language and cultural differences.

Methods: In Part A ($n = 40$) to adapt the scales for the Singapore population, we performed cognitive interviews, face validity testing and pre-testing of the instruments ($n = 40$). Besides English, the scales were translated into Chinese and Malay. In Part B ($n = 400$), we performed exploratory and confirmatory factor analyses respectively on two random samples. We also tested for item discriminant validity, internal consistency reliability, construct validity, and measurement invariance.

Results: The findings from the cognitive interviews in Part A led to scale adaptations to accommodate cultural and linguistic factors. In Part B, EFA on Sample I resulted in a three-factor model for the PA scale (accounting for 71.2% variance) and a four-factor model for the NU scale (accounting for 72.8% variance). CFA on Sample II indicated acceptable model fits: FHC-PA: $\chi^2 = 192.29$, $df = 101$, $p < 0.001$, $\chi^2/df = 1.90$; SRMR = 0.049; RMSEA = 0.067; CFI = 0.969; TLI = 0.963; FHC-NU: $\chi^2 = 170.46$, $df = 98$, $p < 0.001$, $\chi^2/df = 1.74$; SRMR = 0.036; RMSEA = 0.061; CFI = 0.967; TLI = 0.960. The scores of family members demonstrated significant agreement on the FHC-PA (Sg) [ICC$_{(2,2)} = 0.77$] and FHC-NU (Sg) [ICC$_{(2,2)} = 0.75$] scales. Findings suggest good evidence for item discriminant validity, internal consistency reliability, construct validity, and measurement invariance. Short versions of the scales were also developed.

Conclusion: We adapted, translated and validated the scales for assessing the health climate of families in Singapore, including the development of short versions. The results showed good psychometric properties and the constructs had significant relationships with health behaviors and routines. Improving our understanding of family influences on individual health behavior will be important in developing multi-level strategies for health promotion and chronic disease prevention.

Introduction

Lifestyle behavior interventions are necessary to address the increasing trend of non-communicable chronic diseases (1). Yet intervening in the individuals' lifestyles alone may not be the most effective, for one's personal choices and behavior are also influenced by interactions with environmental factors (2). The family is one important environmental determinant for health behaviors, with studies showing that behavior-related risk factors tend to aggregate within families (3) and findings of spousal concordance for chronic diseases that point to the influence of shared environments, beyond that of shared genetic risk (4–6).

In a shared environment like the family, there are collectively-held opinions, attitudes, feelings, and behaviors that are attributes of life in the social setting, and which may be termed the "climate" (7, 8). The climate may arise in the group of family members through their frequent interaction with each other and the reciprocal influencing of each other over an extended period of time. Based on this concept, i.e., the Model of Family Reciprocal Determinism (9, 10), the Family Health Climate (FHC) has been defined as the perceptions and cognitions concerning health and health behavior that are shared among family members (11). The FHC may be seen as a health behavior framework for an individual family member, through the individual's experience of daily family life, the discussion of health-related topics and family expectations concerning health values, behavior routines and interaction patterns within the family. Through the FHC, references are provided to members for valuing and interpreting their own behavior and that of others, therefore the FHC is an aspect of the family environment that shapes the daily health behaviors of the family members (12–14).

Niermann et al. (11) developed a set of questionnaires to assess a family's health climate in the domains of physical activity (PA) and nutrition (NU). These scales have been tested and validated in the German population. They have provided promising results, as the FHC-PA and FHC-NU scores have

been found to be associated with individual variables like healthy eating, physical activity, food parenting practices and children's BMI (15, 16), suggesting relationships between family system influences on children and adolescent health behaviors. The findings also provided evidence for FHC as a family-level variable and can provide insight into how families influence each other's individual lifestyle behaviors. The recent identification of different clusters of families with specific co-occurring health behavioral patterns using the FHC scales (17) allows for targeted approaches to health promotion within the family. To date, the FHC scales have been applied largely in Europe and the USA and more recently validated for the Iranian and Turkish populations (18, 19). To apply the scales in Asian populations, there will be a need to adapt and validate the scales given sociocultural and language differences.

In this study, we aimed to adapt and validate the psychometric properties of the scales for the multi-ethnic population in Singapore. We hypothesized that there will be positive correlations of the respective FHC domains with family lifestyle behavior (frequency of family physical activities and family meals, encouragement for healthy lifestyles, and availability of healthy foods in the household) and to a lesser extent with individual lifestyle behavior (amount of physical activity and healthy food intake). We also hypothesized that there would a negative relationship between the FHC-NU scores and the household availability of unhealthy foods. Since the FHC scales had previously been shown to be a family level variable (11), we also hypothesized that at least moderate inter-rater agreement between family members on FHC scores.

Methods

The study had two parts: Part A included the translation of the FHC scales into Simplified Chinese and Malay, the testing of face validity and the pre-testing of the translated scales. Part B of the study comprised the testing of the item, scale and construct validity of the FHC scales. Short versions of the scales were also

developed. The study was approved by the institution's ethics review committee (CIRB Ref. 2020/2195).

Part A

Participants

Forty individuals were recruited through an institutional research panel mailing list and an advertisement posted on the institutional website. The inclusion criteria were: age minimum of 15 years, Singapore residents, and fluency in English, Mandarin or Malay. Exclusion criteria were mental or cognitive disorders, as this may confound the responses for the validation process.

FHC scales and procedures

The first round of face validity testing was performed on a group of English-speaking participants ($n = 10$). The semi-structured, cognitive interviews used a probing technique (20) and lasted approximately 1 hour each. We used the original English version of the FHC scales (11). In the FHC-PA scale, there are 14 items within three factors (*value, cohesion*, and *information*): the five items under *value* assess the importance of being physically active for the whole family; the five items under *cohesion* assess joint physical activities and having fun together during these activities, while the four items under *information* assess the extent to which the family searches for and shares information related to sports and exercise (11). The FHC-NU consists of 17 items within four factors (*value, cohesion, communication*, and *consensus*): the four items under value assess the family's emphasis on nutrition in daily life; the five items under *cohesion* assess the importance of eating together with other family members; the five items under *communication* assess family support for balanced diets, while the three items under *consensus* assess the agreement of family members regarding daily eating behavior (11).

Based on feedback from the first round of testing, we modified and adapted the items for better understanding amongst the local population. Translations were also made from the English version into Chinese and Malay using professional services [Translation authorization was obtained from the corresponding author of the FHC scales (11)]. Independent translators performed forward and backward translations for each language and differences were reconciled. The Chinese and Malay FHC scales were then presented to new groups of Chinese- and Malay-speaking participants ($n = 10$ respectively) for face validity testing (see Supplementary File 1 for the Chinese and Malay scales).

Lastly, pre-testing interviews with a new group of English-speaking participants ($n = 10$) were conducted with the locally adapted scales ["FHC-PA (Sg) and FHC-NU (Sg)"]. They were asked to respond to the items on the 4-point Likert scale and

elaborate on their understanding of the items and the sufficiency of the Likert scale. The four-point Likert scale rating was: 0 = "strongly disagree", 1 = "somewhat disagree", 2 = "somewhat agree", 3 = "strongly agree".

Data analysis

Face validity was analyzed based on participant qualitative feedback and interview transcripts. Specifically, we considered whether the vocabulary and phrasing of the items in the three languages could be understood linguistically and semantically. For each scale item, the study team discussed and made decisions together to modify the wording of the items if necessary.

After pre-testing the modified scales, we analyzed the qualitative feedback and interview transcripts to evaluate the adequacy of the 4-point response scale, as well as the cultural thought processes elicited by the items. Items were further modified, if necessary, based on consensus from among the study team.

Part B

Participants

Two hundred family dyads (i.e., 400 individuals) were recruited from the research panel of a survey vendor and from online advertisements placed on Facebook. The inclusion criteria were: age 15 years and above, Singapore residents, and living in the same household. Single-person households and tenants were excluded, as they do not share essential living arrangements, e.g., food preparation. A minimum sample size of 200 individuals, or at least 10 individuals per item for validation have been recommended in the literature (21–24). With a total of 33 items for the FHC (Sg) scales [16 items for Physical Activity (PA) and 17 items for Nutrition (NU)], our sample size met both criteria.

Procedures

Participants filled in the Singapore Family Health Climate scales [FHC (Sg)] and other self-reported measures related to physical activity and diet (described below) to test construct validity. This was done *via* an online survey platform. Data on the demographic characteristics of participants (age, sex, race, education, occupation, marital status, type of housing and household income) were also collected. English versions of the questionnaires were used.

Measures

Singapore family health climate scales

Following the results of Part A of the study, we used Version 1 of the Singapore scales (see Supplementary File 2). The FHC-PA (Sg) consisted of three factors (*value, cohesion*, and *information*) with a total of 16 items. The FHC-NU (Sg) consisted of four factors (*value, cohesion, communication*, and *consensus*), with a total of 17 items. The questionnaire used a four-point Likert scale rating of 0 = "strongly disagree", 1 = "somewhat disagree", 2 = "somewhat agree", 3 = "strongly agree". The range of possible scores for FHC-PA (Sg) and FHC-NU (Sg) were from 0 to 48 and 0 to 51 respectively, with higher scores indicating a better family health climate.

International physical activity questionnaire

We used the IPAQ, a 27-item questionnaire to assess the time spent by an individual on physical activity over the last seven days. The IPAQ has shown acceptable test-retest reliability and criterion validity across countries (25). We used the IPAQ scoring protocol for calculating physical activity-related energy expenditures (MET-minutes/week), focusing on the domain of recreation, sport, and leisure.

Diet screener

We used a 37-item diet screener (26) to assess the frequency of food eaten by an individual over the past year. It consists of items from the major food groups, such as grains, protein foods, dairy, fruits, vegetables, and foods high in sugar or fat, along with the types of drinks consumed. The diet screener has shown reasonable validity and good reproducibility when compared against the detailed Food Frequency Questionnaire in the Singapore population (26).

The Dietary Approaches to Stop Hypertension (DASH) scoring index (27) was used to calculate the intake of seven food groups: whole grains, fruits, vegetables, nuts and legumes, low fat dairy, red processed meats (reversed scoring), and sweet beverages (reversed scoring). Sodium was excluded from the total DASH score, as the diet screener may not accurately assess it, given the wide variation of sodium content in Asian dishes (26). DASH scores range from 7 to 35, with higher scores indicating higher consumption frequency of healthy food and/or lower consumption frequency from unhealthy food in comparison with other participants.

Family-related lifestyle behaviors

As part of construct validity testing, we probed family routines and support for healthy lifestyles and the availability of healthy foods (11). Specifically, we looked at the frequency of family engagement in physical activities or meals together, the frequency of encouragement by family members for partaking in physical activities or eating healthily, and the frequency of healthy and unhealthy foods made available in the household. A five-point Likert scale (1 = "Never" to 5 = "Very often") was used.

Data analysis

The dataset was divided into two samples to perform exploratory factor analysis (EFA) and confirmatory factor analysis (CFA), based on stratification of demographic characteristics: age [< or ≥ median age of sample (41 years)], sex (male, female), and education (below tertiary level, tertiary level and above). Within these stratifications, random allocation to the two samples was done using a random number generator, resulting in $n = 200$ for each sample. There was no missing data, as the online survey platform would prompt for missing responses. STATA version 16.0 (STATA Corp LLC, TX, USA) was used for EFA and CFA. The rest of the data analysis was performed using IBM SPSS Statistics for Windows version 26.0 (IBM Corp., NY, USA).

The suitability of running an EFA was assessed through the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy, yielding an acceptable KMO statistic ≥ 0.70 (28) and a statistically significant χ^2 value upon the Bartlett's Test of Sphericity (29). We then performed EFA on Sample I using principal axis factor extraction with oblique promax rotation (30, 31) to explore the underlying factorial structures in both FHC-PA and FHC-NU. The number of factors to be extracted was based on an initial eigenvalue threshold of 0.80 (31) and guided also by the structure of the original FHC factor model (PA: 3 factors, NU: 4 factors) (11). The criteria to retain items were: >0.40 for factor loadings, ≥0.4 corrected item-total correlations, and < 0.4 communality (32). Skewness and kurtosis for the PA and NU scales were within the thresholds of 0 and 7 respectively (33). Visual inspections of the Q-Q plots for the FHC-PA and FHC-NU scores were done to assess normality and outliers. All 200 observations for FHC-PA were kept. One outlier (>3 *SD*) from the FHC-NU scores was removed.

To verify the factor structures obtained, CFA was performed on Sample II using independent cluster models. The commonly recommended fit indices χ^2/df, TLI, CFI, SRMR and RMSEA were used to assess the overall goodness-of-fit. A good fit is indicated by $\chi^2/df < 5$, SRMR ≤ 0.08, RMSEA ≤ 0.06, CFI ≥ 0.95 and TLI ≥ 0.95 (34), while CFI ≥ 0.90, SRMR < 0.10 and RMSEA < 0.08 are considered adequate fits (34, 35).

We tested the assumptions of item scoring and the summated rating scales with the IQOLA Project Approach (36). The main assumptions tested were: (1) items in each factor contain a similar amount of information as the construct under examination; (2) items have homogeneous variances so that they contribute equally to the total score; (3) items are linearly related to the total score. Using both samples, we looked at the similarity of item means and standard deviations within each factor. We computed corrected item-total correlations after respectively removing items of interest from their respective factor scores to avoid inflated correlations. A threshold of 0.40 for the item-total correlations indicated item internal consistency. Item discriminant validity was tested by looking at whether item-total correlations were significantly higher

for the corresponding factor than for competing factors. We also measured the internal consistency reliability of the factor items, i.e., how much the items in the factor co-vary relative to their sum score. Cronbach's alpha with a threshold of 0.70 was used.

To test construct validity, we assessed the correlations of the FHC scores with related measures on family routines, family support for healthy lifestyle, availability of healthy foods, using Samples I and II. Interpretation of Pearson's correlation coefficient (37) were as follows: $r < 0.30$, weak; $0.3 \leq r < 0.49$, moderate; $0.50 \leq r < 1.00$, strong correlation.

To ensure that the scales are measuring the same constructs across demographic groups, tests of measurement invariance (configural, metric and scalar) for age, sex, and education levels were performed on both samples. Configural invariance would be supported through finding equivalent numbers of factors and similar loadings of items onto their respective factors (38). Metric invariance would be analyzed by constraining factor loadings to be equivalent in the groups and comparing the model fit with that of the configural invariance model (i.e., unconstrained model) (38). The following thresholds determined metric invariance (Chen, 2007): a change of ≤ -0.010 in CFI, together with a RMSEA change of ≤ 0.015 or a SRMR change of ≤ 0.030. Upon support of metric invariance, we proceeded to test scalar invariance by constraining item intercepts to be equivalent among the groups (38). The thresholds for scalar invariance were: a change of ≤ -0.010 in CFI, together with a RMSEA change of ≤ 0.015 or a SRMR change of ≤ 0.010 (39). If non-invariance was found, we would investigate the source of non-invariance by unconstraining item loadings or intercepts and retesting the model to achieve a partial invariance model (38).

Finally, to assess the FHC (Sg) as a family-level variable, we used intraclass correlations to measure the concordance of responses among family dyads. A two-way, random-effects ICC model based on average measures between the dyads was used to assess the absolute agreement of FHC (Sg) scores for each dyad. Mean estimations along with 95% confidence intervals (CI) were reported for each ICC. Interpretations of ICC values were as follows: ICC < 0.50, poor; $0.50 \leq$ ICC < 0.75, moderate; $0.75 \leq$ ICC < 0.90, good; ICC > 0.90, excellent agreement (40).

After testing the full scales, short versions were developed (see Supplementary File 3 for details).

Results

Part A: Face validity and pre-testing

The participants' mean age was 40 years ($SD = 12.5$; range 20–71 years old). 75% were female, 72.5% were Chinese, 25% were Malay, 2.5% were of other races, and 80% had tertiary education. A variety of family household types were

represented: 1-generation (12.8%), 2-generation (71.8%), 3-generation (15.4%), with an average of four persons living in one household.

The cognitive interviews elicited feedback on the wordings and understanding of the items, which resulted in the following changes: (1) Examples of physical activity and nutrition-related behavior were specified in the first item of each scale to orientate participants to the relevant contexts and to standardize thinking of what physical activity or nutrition might mean, especially in the local context. (2) Items that pertained to obtaining physical activity or nutrition information were updated to account for trends in searching for information online, e.g., "read newspaper or magazine articles" were modified to include both printed and online material. Similarly, "watch TV-programmes" was amended to "watch videos (e.g., on YouTube, Netflix, TV)" (3) Words and phrases were modified for better local understanding and interpretation of the scale items: The word "healthful" was changed to "healthy". "Leisure time" was changed to "free time". "It goes without saying" was simplified to "It is normal". The phrase "like being together" was changed to "enjoy our time together". The participants viewed physical activity and sports as distinct from each other; thus, we tested separate items with these words for uniqueness of contribution to our final scale. The original examples of sports provided were also changed from "bike tours and hikes" to "cycling, ball games, canoeing", as highlighted by some participants that the original examples were not commonly played sports by families in Singapore. The appending of the word, "healthy" to items on nutrition and diet served to orientate participants to thinking of "healthy diet" and "healthy nutrition", since there was feedback that the words "diet" and "nutrition" did not necessarily have positive meanings. Participants found it difficult to answer one of the original items under the *consensus* factor, "In our family, we rarely argue about food- or diet-related matters." Some participants felt that the word "argue" was too strong a word to use and carried negative connotations, while others felt that some families may not argue to avoid conflict despite not agreeing.

Modifications to the wording of the original four-point Likert scale were made for easier understanding while retaining the graded meanings: The original version (0 = "definitely false", 1 = "rather false", 2 = "rather true", 3 = "definitely true") was modified to the following (0 = "strongly disagree", 1 = "somewhat disagree", 2 = "somewhat agree", 3 = "strongly agree").

Two items were added to the FHC-PA (Sg) to reflect concepts that were measured in the original FHC-NU but not the original FHC-PA ("In our family, we encourage and support each other to be physically active"; "In our family, we usually agree on physical activities to do together"). At this stage, the FHC-PA (Sg) consisted of 16 items and the FHC-NU (Sg) consisted of 17 items. These "Version 1" scales can be found in

TABLE 1 Item descriptives, factors, and item parameters of FHC-PA (Sg).

Label	Item Description (In our family...)	Sample I ($n = 200$)		Sample II ($n = 200$)		Samples I and II ($n = 400$)
		M (SD)	a_{EFA}	M (SD)	a_{CFA}	r_{corr}
Val1	...we make it a point of being physically active during our daily life (e.g., taking walks, exercising, playing sports)	2.01 (0.74)	0.87	1.77 (0.74)	0.82	0.81
Val2	...it is normal to be physically active on a regular basis	1.98 (0.75)	0.93	1.78 (0.74)	0.88	0.86
Val3	...it is normal for us that we exercise on a regular basis	1.84 (0.83)	0.92	1.71 (0.81)	0.90	0.87
Val4	...it is normal to be physically active in our free time	1.88 (0.72)	0.54	1.72 (0.70)	0.80	0.73
Val5	...we agree that physical activities are part of our daily life	2.01 (0.71)	0.79	1.82 (0.74)	0.83	0.82
Val6	...we encourage and support each other to be physically active	2.09 (0.72)	0.57	1.93 (0.75)	0.73	0.70
Coh1	...we like spending time together doing physical activities	1.80 (0.78)	0.65	1.62 (0.79)	0.91	0.86
Coh2	...we enjoy exercising together	1.77 (0.81)	0.85	1.55 (0.83)	0.92	0.89
Coh3	...we have fun doing physical activities together	1.87 (0.79)	0.97	1.70 (0.80)	0.92	0.89
Coh4	...we find it very pleasant to be together doing physical activities	1.90 (0.75)	0.92	1.73 (0.81)	0.88	0.86
Coh5	...we like spending time together in sports (e.g., cycling, ball games, canoeing)	1.59 (0.89)	0.77	1.43 (0.87)	0.76	0.76
Coh6	...we usually agree on physical activities to do together	1.79 (0.78)	0.61	1.62 (0.83)	0.86	0.81
Inf1	...we watch videos (e.g., on YouTube, Netflix, or TV) on fitness, physical activities, or exercise	1.53 (0.91)	0.67	1.49 (0.87)	0.61	0.57
Inf2	...we actively look for the latest information on physical activity and exercise to stay up to date	1.41 (0.82)	0.81	1.20 (0.83)	0.88	0.80
Inf3	...we collect information (e.g., download/bookmark online information, cut out print articles) on fitness, physical activity, and exercise	1.32 (0.81)	0.85	1.17 (0.81)	0.89	0.80
Inf4	...we read articles (printed or online) on fitness, physical activity, and exercise	1.52 (0.80)	0.85	1.31 (0.88)	0.85	0.75

M, mean; SD, standard deviation; r_{corr}, corrected item-total correlations; a_{EFA}, factor loadings of exploratory factor analysis; a_{CFA}, factor loadings of confirmatory factor analysis; Val, Value; Coh, Cohesion; Inf, Information. Full range of Likert scale scoring for each item was used (Min = 0; Max = 3).

Supplementary File 2. The score range for the FHC-PA (Sg) was 0 to 48, while the range for the FHC-NU (Sg) was 0 to 51.

Part B: Factor structure and validity for item, scale, and constructs

The participants comprised 200 dyads from the same household and their relationships were: 43% parent-child, 37.5% couples, 19% siblings, and 0.5% aunt-nephew. 83% of the dyads lived in public housing and the remainder in private housing. 50.5% had household income between ≤ $7500. The mean age was 42 years (SD = 15.18; range 15–85 years old). 62.7% were female, 86.5% were Chinese, 6.0% were Malay, 6.3% were Indian, and 67.3% had tertiary education. There was a larger representation of female participants (62.7% vs. 51.1%) and those with tertiary education (67.3% vs. 32.4%), as compared to the population (41).

Exploratory factor analysis

Sample I data for both sets of scale items were suitable for EFA as shown by the following statistics: FHC-PA (Sg): KMO statistic = 0.93; Bartlett's Sphericity Test $\chi^2(120) = 2963.28$, $p < 0.001$. FHC-NU (Sg): KMO statistic = 0.92; Bartlett's Sphericity Test $\chi^2(136) = 2832.03$, $p < 0.001$.

FHC-PA (Sg) scale

Three factors with eigenvalues ranging from 1.16 to 8.93 were identified and extracted, accounting for 71.7% of the variance. The three factors corresponded to the original factors of cohesion, value and information. The factor cohesion, which consists of items on family members engaging in physical activities together and the level of enjoyment of physical activity experienced together as a family, accounted for 55.8% of variance (6 items, eigenvalue = 8.93). The factor value contains items that represent the importance of physical activity in the family, and accounted for 8.6% of variance (6 items, eigenvalue = 1.38). Lastly, the factor information, which contains items

TABLE 2 Item descriptives, factors, and item parameters of FHC-NU (Sg).

Label	Item Description (In our family…)	Sample I (n = 199*)		Sample II (n = 200)		Samples I and II (n = 399*)
		M (SD)	a_{EFA}	M (SD)	a_{CFA}	r_{corr}
Val1	…a healthy diet is important to us (e.g., type and amount of food, meal timings)	2.35 (0.66)	0.75	2.24 (0.64)	0.80	0.76
Val2	…we pay attention to eating healthily	2.24 (0.67)	0.85	2.18 (0.61)	0.89	0.84
Val3	…we eat healthily on a regular basis	2.10 (0.71)	0.78	2.07 (0.64)	0.82	0.80
Val4	…it is normal for us to choose healthy foods	2.13 (0.72)	0.70	2.10 (0.61)	0.84	0.81
Com1	…we are interested in articles (print or online) on healthy nutrition	1.86 (0.78)	0.42	1.71 (0.81)	0.59	0.58
Com2	…we remind each other to pay attention to a healthy diet	2.20 (0.69)	0.66	2.16 (0.65)	0.81	0.75
Com3	…we talk about which foods are healthy	2.13 (0.71)	0.92	2.09 (0.73)	0.84	0.82
Com4	…we encourage and support each other to refrain from eating/drinking unhealthy things	2.18 (0.69)	0.54	2.18 (0.69)	0.77	0.72
Com5	…we talk about how to eat healthily	2.14 (0.72)	0.82	2.12 (0.64)	0.87	0.80
Coh1	…we value spending time together during meals	2.37 (0.70)	0.79	2.32 (0.66)	0.81	0.81
Coh2	…everybody enjoys having meals together	2.42 (0.68)	0.85	2.30 (0.65)	0.86	0.85
Coh3	…eating together is a part of our daily family life	2.31 (0.73)	0.94	2.19 (0.72)	0.84	0.83
Coh4	…we enjoy meals most when we sit at the same table.	2.36 (0.72)	0.97	2.28 (0.67)	0.87	0.86
Coh5	…we try to eat together as often as possible	2.40 (0.67)	0.75	2.29 (0.65)	0.79	0.75
Con1	…we agree on diet and nutrition	2.11 (0.70)	0.77	2.01 (0.61)	0.82	0.70
Con2	…we usually agree on meals and food choices	2.20 (0.62)	0.81	2.11 (0.57)	0.75	0.70

M, mean; SD, standard deviation; r_{corr}, corrected item-total correlations; a_{EFA}, oblique rotation of factor loadings of exploratory factor analysis; a_{CFA}, factor loadings of confirmatory factor analysis. *One outlier was excluded from Sample I. Val, Value; Com, Communication; Coh, Cohesion. Full range of Likert scale scoring for each item was used (Min = 0; Max = 3).

on the use and collection of information materials relevant to physical activity in the family, accounted for 7.3% of variance (4 items, eigenvalue = 1.16). Factor loadings ranged from 0.54 to 0.97 (Table 1) and all items met the retention criteria. The two newly included items, which focused on encouragement and support to be physically active and agreement on doing physical activities together, loaded on the factors of *value* and *cohesion* respectively. A family that values the importance of physical activity would naturally encourage and support one another to engage in physical activity. Likewise, a family who is cohesive in terms of the climate on physical activity would likely agree more on exercising together.

FHC-NU (Sg) scale

An initial iteration identified two factors with eigenvalues 2.58 and 7.92. One item ("In our family, we rarely argue about food- or diet-related matters") was dropped as it had a communality >0.4 and did not meet the item retention criteria. To match the original structure, we specified four factors. The

retained items loaded into the four factors, with factor loadings ranging from 0.42 to 0.97 (Table 2), and corresponded well with the items under the original factors of *value, communication, cohesion* and *consensus*. 72.8% of total variance was accounted for by the four factors. The factor *value*, which contains items on the importance of nutrition, accounted for 49.5% of total variance (4 items, eigenvalue = 7.92). The factor *communication* covers items on family members actively communicating and encouraging each other about healthy diets, and accounted for 16.2% of total variance (5 items, eigenvalue = 2.59). The factor *cohesion* is concerned with the frequency and importance of having family meals together, and accounted for 4.3% of total variance (5 items, eigenvalue = 0.70). Finally the factor *consensus* relates to the agreement of family members on food-related matters, and accounted for 2.7% of total variance (2 items, eigenvalue = 0.43). Although the eigenvalues for the *cohesion* and *consensus* factor did not meet the 0.80 threshold, the two factors were kept for the following reasons: they were relatively distinct (the correlations between the

TABLE 3 Cronbach alpha coefficients and inter-factor Pearson's correlations of FHC (Sg) scales.

FHC-PA (Sg) Factors	Value	Cohesion	Information	
Factor 1: Value	(0.93)			
Factor 2: Cohesion	0.73	(0.95)		
Factor 3: Information	0.59	0.61	(0.87)	
FHC-NU (Sg) Factors	Value	Communication	Cohesion	Consensus
Factor 1: Value	(0.92)			
Factor 2: Communication	0.76	(0.89)		
Factor 3: Cohesion	0.42	0.45	(0.93)	
Factor 4: Consensus	0.57	0.55	0.55	(0.83)

Cronbach's alpha coefficients are presented in brackets along the diagonals.

FIGURE 1
FHC-PA (Sg) standardized factor loadings and inter-factor correlations.
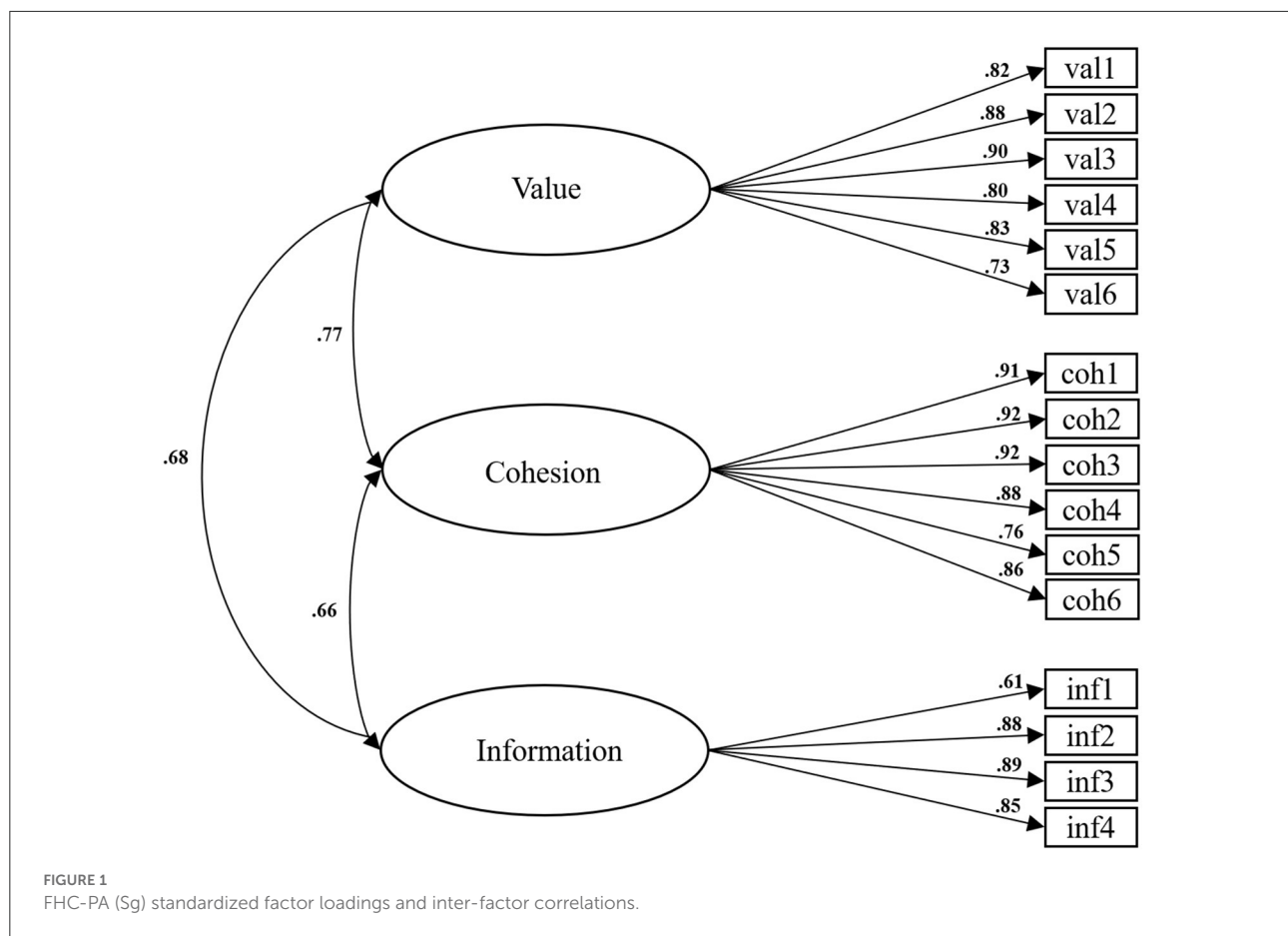
factors were smaller than their reliability coefficients (Table 3), indicating unique variance measured by the factors (42), their internal consistency was high (0.93 and 0.83 for *cohesion* and *consensus* respectively; Table 3), and their inclusion allowed us to follow the original interpretation of the FHC model more closely.

Confirmatory factor analysis

For FHC-PA (Sg), the fit indices ($\chi^2 = 192.29$, $df = 101$, $p < 0.01$, $\chi^2/df = 1.90$; SRMR = 0.049; RMSEA = 0.067; CFI = 0.969; TLI = 0.963) indicated an acceptable fit. Factor loadings, item-total correlations and inter-factor correlations are shown in Table 1 and Figure 1.
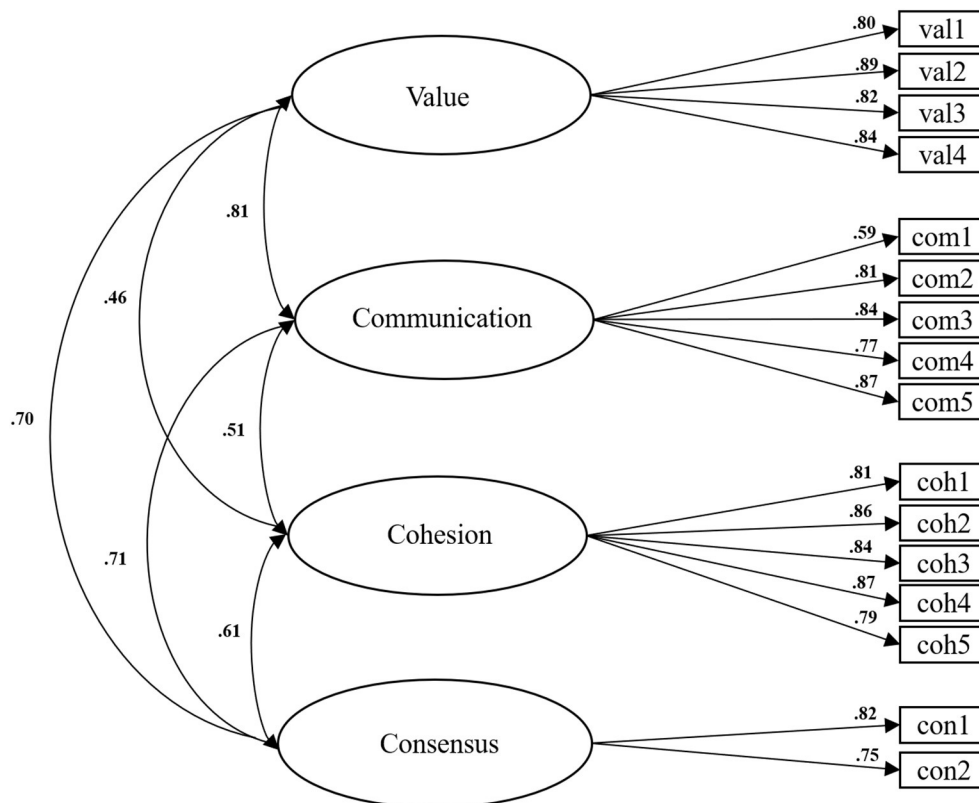
FIGURE 2
FHC-NU (Sg) standardized factor loadings and inter-factor correlations.

For FHC-NU (Sg), the fit indices ($\chi^2 = 170.46$, $df = 98$, $p < 0.01$, $\chi^2/df = 1.74$; SRMR = 0.036; RMSEA = 0.061; CFI = 0.967; TLI = 0.960) indicated an acceptable fit. Factor loadings, item-total correlations and inter-factor correlations are shown in Table 2 and Figure 2.

Testing of assumptions for item scoring and the summated rating scales

The assumptions were supported. Item means and standard deviations were relatively similar within each factor (Tables 1, 2). The standard deviations for the items were below 1 and relatively homogeneous. The corrected item-total correlations for FHC-PA (Sg) and FHC-NU (Sg) were all greater than the threshold of 0.4 (Tables 1, 2). Item-total correlations of items were highest for their own scale (factor) as compared to correlations with other factors (Tables 4, 5). Item discriminant validity for both FHC-PA (Sg) and FHC-NU (Sg) were met (Tables 6, 7). Internal consistency of the factors met the Cronbach's alpha threshold of 0.7 (Table 3).

Construct validity

From Table 8, it can be seen that FHC-PA (Sg) was strongly correlated with the frequency of family engaging in physical activity together ($r = 0.65$, $p < 0.001$), as well as higher frequency of family encouraging each other to exercise ($r = 0.57$, $p < 0.001$), supporting convergent construct validity. Total FHC-PA (Sg) was weakly associated with an individual's amount of recreational physical activity as computed by the total Metabolic Equivalent of Task (MET) per week ($r = 0.16$, $p < 0.001$).

FHC-NU (Sg) scores were significantly correlated with independent measurements concerning diet and nutrition on both the family and individual levels, supporting convergent construct validity for this scale (Table 9). FHC-NU (Sg) scores were moderately to strongly correlated with the frequency of family meals ($r = 0.44$, $p < 0.001$), the frequency of encouraging each other to eat healthily ($r = 0.62$, $p < 0.001$), and the availability of healthy foods at home ($r = 0.45$, $p < 0.001$). As hypothesized, there was a negative correlation with the availability of unhealthy foods at home ($r = -0.25$, $p < 0.001$). On the individual-level, higher total FHC-NU (Sg) scores were moderately correlated with higher DASH scores that indicate healthier diets ($r = 0.31$, $p < 0.001$).

TABLE 4 Item-total correlations of FHC-PA (Sg) scale.

FHC-PA (Sg)		Item-total correlations		
Label	Item description (*In our family…*)	Factor 1 (Val)	Factor 2 (Coh)	Factor 3 (Inf)
Factor 1 = Value (Val)				
Val1	…we make it a point of being physically active during our daily life (e.g., taking walks, exercising, playing sports)	0.81*	0.63	0.52
Val2	…it is normal to be physically active on a regular basis	0.86*	0.67	0.51
Val3	…it is normal for us that we exercise on a regular basis	0.87*	0.63	0.52
Val4	…it is normal to be physically active in our free time	0.73*	0.60	0.49
Val5	…we agree that physical activities are part of our daily life	0.82*	0.62	0.52
Val6	…we encourage and support each other to be physically active	0.70*	0.64	0.51
Factor 2 = Cohesion (Coh)				
Coh1	…we like spending time together doing physical activities	0.72	0.86*	0.58
Coh2	…we enjoy exercising together	0.68	0.89*	0.54
Coh3	…we have fun doing physical activities together	0.64	0.89*	0.50
Coh4	…we find it very pleasant to be together doing physical activities	0.66	0.86*	0.49
Coh5	…we like spending time together in sports (e.g., cycling, ball games, canoeing)	0.58	0.76*	0.53
Coh6	…we usually agree on physical activities to do together	0.66	0.81*	0.61
Factor 3 = Information (Inf)				
Inf1	…we watch videos (e.g., on YouTube, Netflix, or TV) on fitness, physical activities, or exercise	0.41	0.42	0.57*
Inf2	…we actively look for the latest information on physical activity and exercise to stay up to date	0.56	0.59	0.80*
Inf3	…we collect information (e.g., download/bookmark online information, cut out print articles) on fitness, physical activity, and exercise	0.51	0.55	0.80*
Inf4	…we read articles (printed or online) on fitness, physical activity, and exercise	0.54	0.51	0.75*

*Highest correlation among the factors. Item-total correlations have been corrected for overlap.

Measurement invariance

The tests of measurement invariance and their goodness-of-fits across sex, age and education levels are shown in Table 10. The mean scores and SDs for each scale and factor by the demographic groups can be found in Tables 11, 12. For the FHC-PA (Sg) scale, configural invariance was supported across sex, age and education levels. The metric invariance model (constrained factor loadings) was not significantly different from the configural invariance model (fully unconstrained) for sex ($\Delta\chi^2 = 21.7$, $\Delta df = 16$, $p = 0.15$) and education levels ($\Delta\chi^2 = 19.4$, $\Delta df = 16$, $p = 0.25$). Across age groups, the constrained and unconstrained models differed significantly in goodness of fit ($\Delta\chi^2 = 28.7$, $\Delta df = 16$, $p = 0.03$). Five items, which were all from the *value* factor, contributed to the fit differences. We tested for partial metric invariance by unconstraining the factor loadings of these items while the rest of the items remained constrained. Partial metric invariance was confirmed ($\Delta\chi^2 = 4.64$, $\Delta df = 11$, $p = 0.95$). For scalar invariance (comparing models with constrained vs. unconstrained item intercepts), it was supported for all groups: sex ($\Delta\chi^2 = 19.8$, $\Delta df = 16$, $p = 0.23$), age ($\Delta\chi^2 = 17.5$, $\Delta df = 16$,

$p = 0.36$), and education levels ($\Delta\chi^2 = 16.1$, $\Delta df = 16$, $p = 0.45$).

For the FHC-NU (Sg) scale, configural invariance was supported across sex, age and education levels. For metric invariance, the constrained and unconstrained models did not differ significantly for sex ($\Delta\chi^2 = 12.6$, $\Delta df = 16$, $p = 0.70$), age ($\Delta\chi^2 = 11.2$, $\Delta df = 16$, $p = 0.80$) and education levels ($\Delta\chi^2 = 10.6$, $\Delta df = 16$, $p = 0.84$), supporting metric invariance. Scalar invariance was also supported for sex ($\Delta\chi^2 = 16.0$, $\Delta df = 16$, $p = 0.46$), age ($\Delta\chi^2 = 18.2$, $\Delta df = 16$, $p = 0.31$) and education levels ($\Delta\chi^2 = 18.45$, $\Delta df = 16$, $p = 0.30$).

Intraclass correlations for family dyad scores

A good level of agreement was found between members of family dyads for FHC-PA (Sg) and there was a moderate level of agreement for FHC-NU (Sg). The average measure $ICC_{(2,2)}$ for FHC-PA (Sg) was 0.77, with a 95% CI from 0.70 to 0.83 [$F_{(199,199)} = 4.41$, $p < 0.001$]. For FHC-NU (Sg),

TABLE 5 Item-total correlations of FHC-NU (Sg) scale.

FHC-NU (Sg)		Item-total correlations			
Label	Item description (In our family…)	Factor 1 (Val)	Factor 2 (Com)	Factor 3 (Coh)	Factor 4 (Con)
Factor 1 = Value (Val)					
Val1	…a healthy diet is important to us (e.g., type and amount of food, meal timings)	0.77*	0.63	0.38	0.49
Val2	…we pay attention to eating healthily	0.85*	0.70	0.37	0.52
Val3	…we eat healthily on a regular basis	0.80*	0.66	0.35	0.52
Val4	…it is normal for us to choose healthy foods	0.81*	0.73	0.38	0.51
Factor 2 = Communication (Com)					
Com1	…we are interested in articles (print or online) on healthy nutrition	0.52	0.57*	0.32	0.42
Com2	…we remind each other to pay attention to a healthy diet	0.67	0.75*	0.40	0.46
Com3	…we talk about which foods are healthy	0.65	0.82*	0.36	0.46
Com4	…we encourage and support each other to refrain from eating/drinking unhealthy things	0.65	0.72*	0.40	0.47
Com5	…we talk about how to eat healthily	0.70	0.81*	0.42	0.50
Factor 3 = Cohesion (Coh)					
Coh1	…we value spending time together during meals	0.35	0.39	0.81*	0.50
Coh2	…everybody enjoys having meals together	0.41	0.42	0.86*	0.54
Coh3	…eating together is a part of our daily family life	0.33	0.38	0.84*	0.47
Coh4	…we enjoy meals most when we sit at the same table	0.34	0.39	0.86*	0.47
Coh5	…we try to eat together as often as possible	0.43	0.43	0.76*	0.46
Factor 4 = Consensus (Con)					
Con1	…we agree on diet and nutrition	0.59	0.56	0.49	0.71*
Con2	…we usually agree on meals and food choices	0.46	0.46	0.53	0.71*

*Highest correlation among the factors. Item-total correlations have been corrected for overlap.

the average measure $ICC_{(2,2)}$ was 0.75 with a 95% CI from 0.67 to 0.81 [$F_{(199,199)} = 4.00$, $p < 0.001$]. Moderate to good levels of agreement were also found comparing dyad scores for the individual factors of FHC-PA (Sg) and FHC-NU (Sg) (Table 13).

Discussion

Based on the original Family Health Climate scales developed by Niermann et al. (11), we have developed a culturally appropriate set of scales, including Chinese and Malay translations, for the multi-ethnic population in Singapore. We have tested the scales' psychometric properties and validated them from item to factor level and across demographic groups. The FHC (Sg) scores also demonstrated good inter-rater reliability within family dyads, supporting FHC (Sg) as a family-level variable.

Language and cultural considerations

Given the multi-ethnic population in Singapore, the FHC scales were translated into Simplified Chinese and Malay, as this would cover up to 96.1% of the population who spoke English, Chinese, Chinese dialect or Malay at home (43) [Tamil, the fourth national language is spoken by 2.5% at home, the majority of whom are also able to communicate in English, thus we did not translate the FHC scales into Tamil (43)] Since the original FHC scales were translated from German (11), face validity and pre-testing interviews of the FHC (Sg) scales were conducted to examine potential differences in understanding and interpretations, and account for cultural influences on language encoding or decoding processes. An example is the perceived negative connotation attached to the word "argue", in one of the items under the *consensus* factor, "In our family, we rarely argue about food- or diet-related matters". Participants felt the word "argue" was too negative and that including it would not serve the purpose of the probe, since some Asian families, despite

TABLE 6 Item-level discriminant validity testing for FHC-PA (Sg).

FHC-PA (Sg)

Label	Item Description (In our family...)	Mean	SD	Factor 1 (Val)	Factor 2 (Coh)	Factor 3 (Inf)
Factor = Val (Value)						
Val1	...we make it a point of being physically active during our daily life (e.g., taking walks, exercising, playing sports)	1.89	0.75	–	2	2
Val2	...it is normal to be physically active on a regular basis	1.88	0.75	–	2	2
Val3	...it is normal for us that we exercise on a regular basis	1.78	0.82	–	2	2
Val4	...it is normal to be physically active in our free time	1.80	0.72	–	2	2
Val5	...we agree that physical activities are part of our daily life	1.91	0.73	–	2	2
Val6	...we encourage and support each other to be physically active	2.01	0.74	–	1	2
Factor = Coh (Cohesion)						
Coh1	...we like spending time together doing physical activities	1.71	0.79	2	–	2
Coh2	...we enjoy exercising together	1.66	0.83	2	–	2
Coh3	...we have fun doing physical activities together	1.78	0.80	2	–	2
Coh4	...we find it very pleasant to be together doing physical activities	1.82	0.78	2	–	2
Coh5	...we like spending time together in sports (e.g., cycling, ball games, canoeing)	1.51	0.88	2	–	2
Coh6	...we usually agree on physical activities to do together	1.70	0.81	2	–	2
Factor = Inf (Information)						
Inf1	...we watch videos (e.g., on YouTube, Netflix, or TV) on fitness, physical activities, or exercise	1.51	0.89	2	2	–
Inf2	...we actively look for the latest information on physical activity and exercise to stay up to date	1.31	0.83	2	2	–
Inf3	...we collect information (e.g., download/bookmark online information, cut out print articles) on fitness, physical activity, and exercise	1.24	0.81	2	2	–
Inf4	...we read articles (printed or online) on fitness, physical activity, and exercise	1.41	0.84	2	2	–

Cutoff point for significance is 2 standard errors (1 SE = 0.05, 2 SE = 0.1). Levels of scaling success: 2: Item-factor correlation is significantly higher for hypothesized scale than for competing scale. 1: Item-factor correlation is higher for hypothesized scale than competing scale, but not significantly.−1: Item-factor correlation is lower for hypothesized scale than competing scale, but not significantly.−2: Item-factor correlation is significantly lower for hypothesized scale than for competing scale.

disagreeing, may not argue simply to avoid conflict. Asian cultures are known to be collectivistic and conflict avoidance is an associated characteristic, as compared to individualism in Western cultures (44). In line with the qualitative feedback received, we also found that this item had high communality and thus we eventually removed the item from the FHC-NU (Sg) scale.

Factor structure of the FHC (Sg) scales

Overall the factor structures and item loadings of the FHC (Sg) scales show that the intended concepts of the original FHC scales did not differ much for the Singapore population. All three original factors (*value, cohesion, information*) for the FHC-PA were replicated in the Singapore version even with the inclusion

TABLE 7 Item-level discriminant validity testing for FHC-NU (Sg).

FHC-NU (Sg)

Label	Item Description (In our family…)	Mean	SD	Factor 1 (Val)	Factor 2 (Com)	Factor 3 (Coh)	Factor 4 (Con)
Factor 1 = Val (Value)							
Val1	…a healthy diet is important to us (e.g., type and amount of food, meal timings)	2.29	0.66	–	2	2	2
Val2	…we pay attention to eating healthily	2.20	0.65	–	2	2	2
Val3	…we eat healthily on a regular basis	2.08	0.68	–	2	2	2
Val4	…it is normal for us to choose healthy foods	2.11	0.67	–	1	2	2
Factor 2 = Com (Communication)							
Com1	…we are interested in articles (print or online) on healthy nutrition	1.79	0.80	1	–	2	2
Com2	…we remind each other to pay attention to a healthy diet	2.17	0.68	1	–	2	2
Com3	…we talk about which foods are healthy	2.10	0.73	2	–	2	2
Com4	…we encourage and support each other to refrain from eating/drinking unhealthy things	2.17	0.70	1	–	2	2
Com5	…we talk about how to eat healthily	2.12	0.69	2	–	2	2
Factor 3 = Coh (Cohesion)							
Coh1	…we value spending time together during meals	2.34	0.69	2	2	–	2
Coh2	…everybody enjoys having meals together	2.35	0.67	2	2	–	2
Coh3	…eating together is a part of our daily family life	2.24	0.74	2	2	–	2
Coh4	…we enjoy meals most when we sit at the same table	2.31	0.71	2	2	–	2
Coh5	…we try to eat together as often as possible	2.34	0.67	2	2	–	2
Factor 4 = Con (Consensus)							
Con1	…we agree on diet and nutrition.	2.06	0.66	2	2	2	–
Con2	…we usually agree on meals and food choices.	2.15	0.61	2	2	2	–

Cutoff point for significance is 2 standard errors (1 SE = 0.05, 2 SE = 0.1). Levels of scaling success: 2: Item-factor correlation is significantly higher for hypothesized scale than for competing scale. 1: Item-factor correlation is higher for hypothesized scale than competing scale, but not significantly. −1: Item-factor correlation is lower for hypothesized scale than competing scale, but not significantly. −2: Item-factor correlation is significantly lower for hypothesized scale than for competing scale.

TABLE 8 Pearson's correlations for FHC-PA (Sg) with family- and individual-level physical activity behaviors.

	Items	Total FHC-PA (Sg)	Value	Cohesion	Information
Family physical activity behaviors	How often does your family engage in physical activities together?	0.65**	0.56**	0.67**	0.45**
	How often do family members encourage each other to engage in physical activities?	0.57**	0.56**	0.52**	0.38**
Individual physical activity behavior	Weekly amount of recreational physical activity (Total MET-minutes/week)	0.16**	0.16**	0.11*	0.15**

*$p < 0.05$; **$p < 0.001$. Numbers are rounded to 2 decimal places.

of two new items (Val6 and Coh6), which were mirrors of FHC-NU items. The original four factors for the FHC-NU scale were also replicated (*value, communication, cohesion* and *consensus*) (11). The fourth factor, *consensus* currently has two items, as the third item on "…we rarely argue about food- or diet-related

matters" was dropped, since it did not meet the item inclusion criteria and also received poor feedback during the cognitive interviews, as discussed in the section above. With two items remaining in the *consensus* factor, the removal of the factor altogether may be considered (45). We chose to retain the factor,

TABLE 9 Pearson's correlations for FHC-NU (Sg) with family- and individual-level nutrition behaviors.

	Items	Total FHC-NU (Sg)	Value	Communication	Cohesion	Consensus
Family nutrition behaviors	How often does your family have meals together each week?	0.44**	0.22**	0.25**	0.60**	0.29**
	How often do family members encourage each other to eat healthily?	0.62**	0.53**	0.59**	0.43**	0.44**
	How often are healthy foods (e.g., fruits and vegetables) available in the household?	0.45**	0.47**	0.37**	0.30**	0.33**
	How often are unhealthy foods (e.g., soft drinks, fried snacks) available in the household?	−0.25**	−0.34**	−0.20**	−0.10*	−0.23**
Individual nutrition behavior	Diet quality (DASH score)	0.31**	0.37**	0.30**	0.14**	0.18**

*$p < 0.05$; **$p < 0.001$. Numbers are rounded to 2 decimal places.

because firstly, the concept of consensus is important when considering the nutrition "climate" of a family. Since a "climate" encompasses opinions, attitudes, feelings, and behaviors that are shared within a social group (7, 8), the factor of consensus (the agreement of family members on daily eating behavior) is an important contributor to the climate concept. Second, the goodness-of-fits for this model met acceptable thresholds and surpassed the fits for models with the same items forced into three factors, or models that did not drop the item (The results of these EFAs are not reported here, but can be requested from the authors). Third, the two items on the consensus factor are highly correlated with each other ($r = 0.71$) and less correlated with other items (r from 0.46 to 0.59; Tables 4, 5) (32). Future studies should nonetheless consider generating additional items for the consensus factor to strengthen its construct.

Validity and reliability

Across various tests, the scales showed validity and reliability: The assumptions for item scoring and the summated rating scales were tested to be valid. There was internal consistency reliability for each factor, as shown by the high Cronbach alphas. Construct validity was supported: the FHC-PA (Sg) and FHC-NU (Sg) scores were strongly and positively correlated with independent measurements for family-level behavior concerning physical activity and nutrition (i.e., family routines for exercise and meals, the frequency of encouragement among family members for these behaviors, and the availability of healthy foods in the household). Conversely, the availability of unhealthy foods in the household was negatively correlated with the FHC-NU (Sg) score. These results show the close relationship of the FHC to health-related behavior of the family as a whole and provide support for the FHC as a family-level construct (11). The FHC is also expected to be

related, albeit less strongly, to individual health behaviors; this is because even though the health climate of a family should influence one's health behavior, it is a broad, collective attribute that is distinct from objective, specific measurements of physical activity and nutrition for the individual (11, 46). Indeed we found that though the correlations were significant, it was relatively weak for the FHC-PA (Sg) with individual physical activity levels, while the FHC-NU (Sg) was moderately correlated with individual diet quality. It would be important for intervention strategies to understand the mechanisms by which the FHC may percolate within the family to influence individual members' health behaviors.

Measurement invariance

Psychometric equivalence of the FHC-NU construct was found across age, sex and education levels, as demonstrated through configural, metric and scalar measurement invariance. For FHC-PA, there was similarly measurement invariance across the demographic groups, with the exception of partial metric invariance for age groups. The non-invariant items belonged to the value factor, meaning that the items do not contribute to the value construct in a similar degree across age. Caution may be needed when administering the FHC-PA (Sg) to a wide age range, even though the effects on the mean differences of the value factor are unlikely to be significant, given that simulations have shown that partial metric invariance generally has minimal effects (47).

Relationship of dyadic scores

The ratings between family dyad members for FHC-PA (Sg) and FHC-NU (Sg) had at least moderate to good

TABLE 10 Fit-indices of the models for testing of measurement invariance.

	χ^2	df	χ^2/df	CFI	RMSEA	90% CI	SRMR	BIC	m∧	$\Delta\chi^2$	Δdf	p	ΔCFI	Δ RMSEA	Δ SRMR	Decision
FHC-PA (Sg):																
Female (n = 251) and Male (n = 149)																
M1	476**	202	2.36	0.954	0.082	0.073–0.092	0.049	10100	–	–	–	–	–	–	–	–
M2	498**	218	2.28	0.953	0.080	0.071–0.089	0.068	10000	M1	21.7	16	0.152	−0.001	−0.002	0.019	Accept
M3	518**	234	2.21	0.952	0.078	0.069–0.087	0.069	9970	M2	19.8	16	0.231	−0.001	−0.002	0.001	Accept
< 41 years old (n = 194) and ≥ 41 years old (n = 206)																
M1	485**	202	2.40	0.953	0.084	0.074–0.093	0.050	10100	–	–	–	–	–	–	-	-
M2	514**	218	2.36	0.950	0.082	0.073–0.092	0.114	10000	M1	28.7*	16	0.026	−0.003	−0.002	0.064	Reject
M2a	490**	213	2.30	0.954	0.081	0.071–0.090	0.066	10000	M1	4.64	11	0.947	0.001	−0.003	0.016	Accept
M3	531**	234	2.27	0.950	0.080	0.071–0.089	0.115	9920	M2	17.5	16	0.356	0.000	0.000	0.000	Accept
Below tertiary (n = 131) and Tertiary (n = 269)																
M1	514**	202	2.55	0.948	0.088	0.079–0.097	0.056	10100	–	–	–	–	–	–	-	-
M2	534**	218	2.45	0.947	0.085	0.076–0.094	0.094	10000	M1	19.4	16	0.250	−0.001	−0.003	0.038	Accept
M3	550**	234	2.35	0.947	0.082	0.073–0.091	0.094	9950	M2	16.1	16	0.450	0.000	−0.003	0.000	Accept
FHC-NU (Sg):																
Female (n = 251) and Male (n = 149)																
M1	395**	196	2.01	0.961	0.071	0.061–0.081	0.047	8981	–	–	–	–	–	–	-	-
M2	408**	212	1.92	0.962	0.068	0.058–0.078	0.068	8898	M1	12.6	16	0.703	0.001	−0.003	0.021	Accept
M3	424**	228	1.86	0.962	0.066	0.056–0.075	0.068	8818	M2	16.0	16	0.456	0.000	−0.002	0.000	Accept
< 41 years old (n = 194) and ≥ 41 years old (n = 206)																
M1	395**	196	2.02	0.962	0.071	0.061–0.081	0.045	8500	–	–	–	–	–	–	-	-
M2	406**	212	1.92	0.963	0.068	0.058–0.078	0.076	8846	M1	11.2	16	0.800	0.001	−0.003	0.031	Accept
M3	424**	228	1.86	0.962	0.066	0.056–0.075	0.076	8768	M2	18.2	16	0.314	−0.001	−0.002	0.000	Accept
Pre-tertiary (n = 131) and Tertiary (n = 269)																
M1	369**	196	1.88	0.966	0.066	0.056–0.077	0.046	8971	–	–	–	–	–	–	-	-
M2	379**	212	1.79	0.967	0.063	0.052–0.073	0.066	8885	M1	10.57	16	0.835	0.001	−0.003	0.020	Accept
M3	398**	228	1.74	0.967	0.061	0.051–0.071	0.066	8808	M2	18.45	16	0.298	0.000	−0.002	0.000	Accept

All estimates are rounded off to 3 significant figures. *p < 0.05; **p < 0.001. M1 = Configural invariance model (Unconstrained). M2 = Metric invariance model (Fully constrained factor loadings only). M2a = Partial metric invariance model (Partially constrained factor loadings only). M3 = Scalar invariance model (Fully constrained factor loadings and fully constrained item intercepts). m∧, Model comparison for difference between model fits.

TABLE 11 Demographic group means and standard deviations for FHC-PA (Sg) scale and factor levels.

	FHC-PA (Sg)	Factor 1 (Val)	Factor 2 (Coh)	Factor 3 (Inf)
Sex				
Female ($n = 251$)	26.52 (10.00)	11.10 (3.96)	9.89 (4.44)	5.53 (2.82)
Male ($n = 149$)	27.52 (9.40)	11.52 (3.77)	10.64 (4.21)	5.36 (2.96)
Age				
Young ($n = 194$)	26.56 (9.07)	10.92 (3.40)	10.20 (4.21)	5.43 (2.92)
Old ($n = 206$)	27.21 (10.42)	11.57 (4.29)	10.14 (4.52)	5.50 (2.83)
Education				
Tertiary ($n = 269$)	27.09 (9.41)	11.35 (3.74)	10.31 (4.19)	5.43 (2.87)
Pre-tertiary ($n = 131$)	26.48 (10.53)	11.07 (4.19)	9.88 (4.71)	5.53 (2.88)

Standard deviations are indicated in brackets.

TABLE 12 Demographic group means and standard deviations for FHC–NU (Sg) scale and factor levels.

	FHC-NU (Sg)	Factor 1 (Val)	Factor 2 (Comm)	Factor 3 (Coh)	Factor 4 (Con)
Sex					
Female ($n = 251$)	35.00 (7.93)	8.69 (2.31)	10.51 (2.91)	11.59 (3.23)	4.21 (1.20)
Male ($n = 149$)	34.50 (7.80)	8.64 (2.50)	10.10 (3.10)	11.56 (2.90)	4.19 (1.13)
Age					
Young ($n = 194$)	34.52 (7.32)	8.52 (2.27)	10.19 (2.88)	11.66 (3.01)	4.15 (1.12)
Old ($n = 206$)	35.09 (8.37)	8.82 (2.48)	10.51 (3.08)	11.51 (3.20)	4.25 (1.22)
Education					
Tertiary ($n = 269$)	35.06 (7.57)	8.80 (2.33)	10.42 (2.91)	11.65 (3.02)	4.18 (1.17)
Pre-tertiary ($n = 131$)	34.32 (8.48)	8.41 (2.47)	10.22 (3.13)	11.44 (3.28)	4.25 (1.18)

Standard deviations are indicated in brackets.

levels of agreement within pairings ranging from parent-child, couples, siblings and aunt-nephew, as indicated by the intraclass correlations [$ICC_{(2,2)}$]. Taken together with our findings of strong correlations between the scale scores with relevant family-level behaviors, it adds support to the concept of FHC as a family-level variable (11, 16). These results also provide confidence that a single family member's FHC rating is likely to be representative of the other family members (11, 48, 49).

As an aspect of family life, it would be necessary to find out how a healthy FHC is developed and how it in turn influences individuals. Work on this has started, e.g., Wasche et al., 2021 (50) have explored the underlying processes and mechanisms which create the FHC that influences family members' health behaviors. Further work in different cultural settings is needed, where family systems are likely to be different (51). Understanding the role of the family in health promotion and the models and mechanisms involved in families with varied characteristics will allow us to better develop family-based interventions to improve the health climate, individuals' lifestyles and their health (52).

TABLE 13 Intraclass correlations (ICC) of FHC-Sg scales within family dyads.

	$ICC_{(2,2)}$	(Lower Bound–Upper Bound)
FHC-Sg (PA)		
FHC-Sg (PA) Scale (16 items)	0.77	(0.70–0.83)
FHC-Sg (PA) Factor 1 (6 items)	0.78	(0.71–0.83)
FHC-Sg (PA) Factor 2 (6 items)	0.75	(0.67–0.81)
FHC-Sg (PA) Factor 3 (4 items)	0.67	(0.56–0.75)
FHC-Sg (NU)		
FHC-Sg (NU) Scale (16 items)	0.75	(0.67–0.81)
FHC-Sg (NU) Factor 1 (4 items)	0.74	(0.66–0.80)
FHC-Sg (NU) Factor 2 (5 items)	0.71	(0.61–0.78)
FHC-Sg (NU) Factor 3 (5 items)	0.75	(0.67–0.81)
FHC-Sg (NU) Factor 4 (2 items)	0.67	(0.56–0.75)

All the ICC values ranged from moderate to good level of agreement (40). Samples I and II were used (n = 400).

Strengths and limitations of study

As far as we are aware, this is the first study on the family health climate in Singapore and Southeast Asia, a region with a unique mix of cultures and languages, which necessitates the adaptation and translation of the FHC scales. As the Malay and Chinese languages are also used in several other population groups around Southeast Asia, the adapted and translated scales may prove useful for studies on family health climates in the region. Furthermore, with studies highlighting the differences in health and lifestyle behaviors among the various ethnicities in Singapore (53), the FHC instrument can help identify key, actionable constructs of family climates that may be common to target in promotion of healthier lifestyles.

The limitations in the study include the following: The generalisability of the FHC (Sg) scales could be limited by the over-representation of female participants and those with tertiary education, as compared to the population (41). However, this was mitigated by the tests of measurement invariance, which indicated the equivalence of the constructs across sex and education levels. Measurement invariance was not tested across ethnicity, because the group sizes were statistically unbalanced (86% Chinese ethnicity, with Malays (6%), Indians (6%) and other races forming the remainder in the Part B sample), and this would affect the accuracy of the results (54). The length of time the sample of family dyads lived together could be a factor in the FHC scores, but as there was no data on this, we cannot yet assess the role of this factor. Future studies could also be done to confirm the factor structures, internal reliability and construct validity of the face-valid Chinese and Malay versions, which were not used in Part B. Finally, the study data was collected during the COVID-19 period, which could have disrupted to some extent family and/or individual lifestyle behaviors and routines. While it is unlikely that such changes will significantly impact the FHC scores, since the family health climate is likely to be developed over time through family processes (11, 16, 49), the correlations of FHC scores with family- and individual-level health behaviors and routines could have been underestimated due to the pandemic's disruptions to daily life.

Conclusion

This study has validated the use of the FHC (Sg) scales in English, together with Chinese and Malay translations, to enable assessments of the health climate of families in Singapore. Overall the results showed good psychometric properties, with the FHC constructs further shown to be family-level variables with strong relationships to family health behaviors and routines, and associated also with individual health behavior to a lesser degree. Short versions of the FHC (Sg) scales have also been developed for ease of use in future studies. Understanding the family influence on individual health behavior will be key in developing strategies for healthy lifestyle promotion and disease prevention.

Data availability statement

The datasets presented in this article are not readily available because of the stipulations from the local institutional review committee on data sharing beyond the approved study team members. Requests to access the datasets should be directed to: lynn.ho@duke-nus.edu.sg.

Ethics statement

The studies involving human participants were reviewed and approved by the Centralized Institutional Review Board (CIRB), Singapore Health Services. All subjects gave written informed consent, except in Part B of the study, where written informed consent was not required, as individuals had full choice to participate or leave the online survey at any point, and no personal identifiers were retained.

Author contributions

Y-CH conceptualized and designed the study. KD guided the study. Y-CH and JT acquired funding for the study. MC, CH, AL, KD, and Y-CH conducted the multi-language cognitive interviews. MC did project administration, data charting, and visualization. MC, Y-CH, and VL performed the data analysis. GL guided the analysis of the diet screener. Y-CH and MC wrote the first draft. All authors contributed to manuscript revision, read, and approved the submitted version.

Funding

Acknowledgments

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/fpubh. 2022.988525/full#supplementary-material

SUPPLEMENTARY FILE 1
FHC-PA and NU (Sg) Chinese and Malay Final Versions.

SUPPLEMENTARY FILE 2
FHC-PA and NU (Sg) Version 1.

SUPPLEMENTARY FILE 3
Development of FHC-PA and NU (Sg) Short Version.

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Leadership for systems change: Researcher practices for enhancing research impact in the prevention of chronic disease

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Introduction: Strengthening systems for chronic disease prevention is essential. Leadership for systems change is an important key to strengthening systems. Leadership in prevention research for supporting systems change remains a relatively abstract concept and there is limited empirical information about the leadership practices of prevention research teams when viewed through a complexity lens. In this paper we examine and describe some systems leadership practices for creating change through prevention research, as identified in a series of six case studies.

Methods: A qualitative approach incorporating semi-structured interviews, participant observation, and document review was used to facilitate an in-depth investigation of the research topic.

Results: Several researcher practices for enhancing research impact in the prevention of chronic disease were distilled from the data pertaining to how they sought to create change. These included persuasive communication, compassion and deep listening, reflective practice, and embedding themselves within the systems they sought to change.

Discussion: The findings provide insights that may assist prevention researchers and other practitioners dedicated to creating change in chronic disease prevention.

KEYWORDS

system, leadership, change, prevention research, chronic disease, research impact

Introduction

Chronic disease presents a considerable burden on population health at both local and global levels (1–3). Key elements to creating a stronger purpose-driven, chronic disease prevention system include focusing on health equity, dedicating sufficient resources and information, improving collaboration and implementation capacities, actively applying a systemic paradigm, and fostering leadership for on-going, adaptive systems change (4).

The goals of prevention research are many, but prevention research ultimately seeks to inform, support, and have impact on preventive action (i.e., interventions, programs, policies, and large-scale institutional and organizational change). The absence of a co-owned, purposeful prevention research system is often a limitation in supporting the impact of that research. The amelioration of this requires what we refer to in this paper as "systems leadership." Yet systems leadership in prevention research for supporting systems change remains a relatively abstract and opaque concept, and there is limited empirical information about the leadership practices of prevention research teams when viewed through a systems theoretical and complexity lens.

Our previous work has examined the importance in prevention research of integrating a systemic lens with an implementation focus linked to a theory of systems change. We have also explored the complementary interplay between systemic and systematic approaches in prevention research (5, 6). The broader practices of systems leadership have been described for other settings [e.g., (7–9)]. These include commitment to the viability of a whole system, deep listening, ability to see reality through the eyes of people very different from oneself, and openness and commitment to ongoing growth and learning (7, 8). It is also recommended that such practices be distributed throughout a team, organization, or larger group to create sustainable change and reduce the reliance on a single "heroic" leader (10, 11). These practices within a team provide an antidote to traditional ideals of leadership that have had minimal impact on solving complex problems (12).

In this paper we present practices described in six prevention research case studies (5, 6) to propose important elements of leadership for systems change. This analysis of interviews with researchers focused on addressing complexity in chronic disease prevention and identified recurring patterns in the qualities, perspectives, framing, and practices that were associated with a focus on creating systems change within the prevention system.

Materials and methods

Research design

We conducted a comparative case study using qualitative methods with the overarching goal of exploring how chronic disease prevention researchers address complexity in prevention research [see (6) for a full description of the study methods overall for the larger study]. A qualitative approach incorporating semi-structured interviews, participant observation, and document review was chosen to facilitate an in-depth investigation of the research topic (13). Ethics approval was granted by the Australian National University human research ethics committee–ref no 2019/653.

Recruitment

Case selection and participants

A purposive sample of six prevention research case studies was chosen. Cases had either been fully or partially funded by the Prevention Center or affiliated with the Center. Given the focus on complexity, the following criteria were used to recruit case studies: use of systems thinking (implicitly or explicitly), application of systems approaches and systems science methods/tools to a component of the work, application of traditional methods/tools to a component of the work, and or use of systems theories. The six cases focused on studies of liveability (making communities healthier places to live), rating and benchmarking the food environment, community-based childhood obesity prevention, intersectoral action to address inequities in healthy eating, embedding prevention research within health systems, and using dynamic simulation modeling as a decision-support tool for addressing childhood obesity [see (6)]. Each case study operated within its own system, which is generally defined as an interconnected set of biological, behavioral, social, environmental, and economic factors. Our focus was on cases where these either helped or hindered chronic disease prevention efforts, and influenced their change making focus.

Participants held positions in academic, government, and the not-for-profit sectors, and a handful held cross-sectoral roles; for example, working in both government and academia or academia and the not-for-profit sector. Participants' roles in the system, the types of change they were involved in (e.g., influencing policy, mindsets, and community actions), and their practices all appeared to operate in a complex and interdependent manner which enabled them to successfully influence or produce change within the systems in which they worked.

Data collection

Case study participants were recruited *via* a personalized email invitation with an information letter and consent form attached. Interviews were held over the phone or *via* zoom video, digitally recorded with permission, and transcribed verbatim style by a professional transcription service.

Data comprised two sets of qualitative interviews scheduled four to six weeks apart and associated project materials (available

online). In total, 29 interviews were conducted with 16 study participants. For the document review, we collated project information from relevant websites comprising peer-reviewed publications and findings briefs. This information served to complement the interview transcripts, thus providing a more comprehensive picture of the research work relating to each case study.

The first set of interviews served to introduce participants to the study purpose, explore the background and context of their research, and deeply understand how they carried out their work. Language associated with systems theory, such as feedback loops and stocks and flows, were avoided by the interviewer unless referred to and used by the participants. In the second set of interviews, the goal was to take a deeper look into how research teams and individual participants addressed complexity within their work. A systemic lens was applied to the interviews and guided by an adapted version of Foster-Fishman et al.'s (14) framework for understanding and changing systems. We chose this framework for its theoretical depth and breadth covering literature on systems thinking, community change, organizational change, as well as its successful previous application (14, 15). Key areas for exploration within the framework included systems norms, systems resources, systems regulations, and systems interdependencies (14). To suit the prevention research context of our study, we adapted the sets of questions within each of the key areas to elicit deeper insights into how prevention researchers responded to complexity in their work.

Data analysis

Data analysis occurred in a staged manner both within and across the case studies focusing on identifying the many ways in which teams addressed complexity. Further analysis was then conducted to explore leadership for systems change for the present study. Both inductive and deductive processes were employed throughout whereby Foster-Fishman et al.'s (14) framework was used to inform coding categories and theoretical sensitivity; Glaser and Strauss' (16) grounded theory principles informed the development of new codes and 15 reflexive thematic analysis informed the approach to coding. More details of the staged analysis can be found in Pescud et al. (6).

All interview transcripts were coded individually by a minimum of two authors (MP, LR, and or MI). The coding process was carried out using the Microsoft Word comment function and followed by memo writing within each transcript. Deductive codes were informed by a combination of literature on systems approaches, frameworks, models, and tools including the Intervention Level Framework, complex adaptive systems characteristics, community-based systems dynamics work, and systems change (14, 17–19).

Next, a structured framework analysis was carried out in Google Sheets to allow for comparisons across the case studies

and within categories. The framework was devised by creating broad categories comprised of several combined codes informed by the systems literature (14, 17–19) as well as the inductive codes (16, 20).

While a central part of the analytical process was exploring the broad research question of how prevention researchers address complexity in their work [see (6)], an important theme generated from the data analysis process related to leadership and its relationship with change making. This included the dependence of systems change on leadership capabilities that support change making within complex systems as well as leadership structures. We decided to explore the recurring theme of creating systems change by focusing in on a smaller number of categories within the framework as this was an important element of all interviews.

Research reflexivity

Our core team were LR and MP; at the time of the project, LR was Co-Director of the Prevention Center, while MP was a Senior Research Fellow at the Australian National University. Throughout the study, our team of co-authors contributed to our ideas, analyses, and writing. This occurred *via* in-person and virtual conversations and written feedback within draft manuscripts. We also drew from the systems literature to inform our work and analytical processes (14, 17–19, 21, 22). We acknowledge that the data we collected and interpretations made are informed by our team's worldviews, assumptions, beliefs, and experiences in the area, the research question and study design, and the overall goals of the Prevention Center to explore ways to apply systems thinking and systems science to the study of chronic disease prevention.

Results

Several researcher practices were distilled from the data pertaining to how they sought to enhance their research impact for the prevention of chronic disease. These practices included persuasive communication, compassion and deep listening, reflective practice, and embedding themselves within the systems they seek to influence. The key findings center on what participants reported to be the core drivers and motivations for their work and the way in which they described their approach in practice to the goal of creating change. The leadership practices reported are a combination of concepts that the participants described of themselves and what we as researchers observed through our analysis.

Persuasive communication

Being able to communicate in a persuasive manner was a capability and practice reported by participants for

influencing change. Persuasive communication was fostered through various practices including careful use of language, the ability to foster shared values and understanding, the rigorous use of research evidence, the ability to evoke the collective community, and having or creating legitimacy and authority.

Careful use of language

Participants spoke about the importance of adapting their use of language and style of communication to fit the needs of the various stakeholders with which they interacted. They spoke at length about the need to clearly communicate, which in many cases meant refraining from using jargon and learning to speak the language of different communities, be they policymakers, academics, or local community members. In some cases, however, the use of jargon was considered beneficial and was used as a way of ensuring all stakeholders within a room were on the "same page," thus enabling a shared understanding to be established when it came to the technical use of systems science terms. For example, when working with epidemiologists to build a dynamic systems model, content was explained in terms of prevalence, incidence, and duration, whereas when working with people with a lived experience of mental health issues researchers explained things in terms of pathways and how people flowed through systems, and where they went to get what they needed. Making the language relevant to different ways of thinking meant that the various stakeholders could critique the work in a meaningful way. In a dynamic simulation modeling project, the lead researcher described the importance of common language:

> We need a common language to help everyone feel they're on the same level and because system dynamics language is in talking about stocks and flows and pathways, it's new to everyone. It kind of levels the playing field a bit, which is a good thing in that environment.

Communication also went beyond verbal interaction to include physical attire and served to either break down power structures or reinforce them where appropriate to ensure communities and stakeholders were engaged. For example, one researcher reported that they would deliberately dress formally as an authority figure or casually in order to convey an easy-going attitude depending on who they were meeting. This was based on feedback from community leaders on what would work best to serve the community's needs.

Shared values and understanding

Participants described how important it was to link their research to a set of values that underpinned their work which also enhanced stakeholders' trust in their work and gave weight to the reasons why they were driven to work in their chosen

area. A "sense of living with principles" was something that was highlighted by participants as being key to their values-driven work. In alignment with their values, they reported consciously choosing a path that enabled them to achieve their goals. In those cases where values did not necessarily align with those they collaborated with, they ensured shared understanding was achieved so that all parties' needs were met through various means. For example, when working with a property developer, one researcher was keenly aware of the developer's goals to make money, while at the same time being part of the affordable housing solution. By recognizing that there was a shared value of helping humanity, they were able to create a working relationship based on mutual understanding and respect.

> I can't let my values of equity, and fairness, get in the way of knowing that they also want to make money. And I have no problem with that, as long as they're not screwing over other people… So, we share a common value of housing for all… He's just horrified that the largest, fastest growing homeless sector in Australia are women over 50. He said it's embarrassing, it's terrible, and we've got to do something about that. So, our basic value is humanity, and doing the right thing by humanity.

Rigorous use of research evidence

The ability to convey the merits of participants' programs of research and the methods they used was a key aspect of persuasive communication with stakeholders which also served to contribute to the development of trust between parties. Using rigorous research evidence and drawing upon the work of others was a necessary component for both gaining community support and informing their programs of work. In the case of those using innovative new methods within public health, such as established tools from system science, they spoke to the long and robust histories of use in other fields, in some cases spanning two hundred years of science.

> My broader vision has always been to use these methods that have been used for decades in infectious disease epidemiology to get them used in the broader public health sphere and the social and prevention agenda… Very rarely [have] the academics involved had any understanding of what this was, and the policymakers hadn't seen it before… while there was a long tradition in infectious disease in this work, there was not very much at all in chronic disease prevention.

Evoking the collective

Participants evoked a sense of the collective when they described their work. Their work was rarely described in terms of their individual needs; on the contrary, their

work was carried out within teams for the purpose of benefiting the wider community. They saw themselves as playing a leadership role within their teams and the communities within which they worked and influenced, but they did not emphasize any individualistic or personal needs and goals that weren't also linked with the collective. Further, the successful actions taken to achieve their goals were attributed to teams and communities working in collaboration, rather than being attributed to individuals. This aspect of communication also served to build trust as demonstrated in this quote from a lead of several community-based projects.

> Scientists are all trained to think that we're going to develop a tablet that solves the disease and we're going to do the study that's an RCT with 30 people in one arm and 30 people in the other, who all take the tablet at 10 am and no longer have Malaria and I'll get my Nobel Prize and get a building named after me. And that is never going to happen if you're going to solve complex problems because as soon as it works you shouldn't be in the photo, let alone have your name on it. Those wins belong to the people who deliver them. Our job is to help them find the way to do that.

Participants reported taking responsibility for their role within the systems in which they sought to influence and acted from a place of strong personal agency. From this position, the goal was for others to see themselves within the system too, and act from a place of agency for the benefit of the collective. Of importance is the seniority of study participants; many held associate professor, full professor, management, and or director positions, which under their positions meant they had the ability, power, and status to act with influence within systems.

Legitimacy and authority

In order to create change, participants explained that it was important to leverage, build, and demonstrate legitimacy and authority. Prior to being able to demonstrate it, however, it was necessary to align oneself with those who already had legitimacy and authority because they were established in their careers and had gained respect within their fields, as demonstrated in the following quote:

> He was the co-facilitator of the first modeling projects and he was deeply involved in those first applications. And since then, has been advocating strongly for the approach, to the point where all these people come to me and they say, "He said I needed to speak to you urgently about this approach that you're doing." So, he's great because he's well respected and he wears multiple hats for policy and academia and he saw the benefits on both sides.

Mentoring was an important aspect related to legitimacy and authority. Participants actively sought opportunities to be mentored by senior colleagues who embodied the traits they wanted to develop. These included learning how to work with the media, advocate for policy change, and facilitate community change-making workshops. Eventually, participants demonstrated legitimacy and authority themselves which translated to having greater leverage and capacity to influence and create change. Having been personally mentored also created an obligation and desire to mentor others as a way of paying forward the benefits they had been afforded through receiving mentoring themselves, as demonstrated by this quote from one researcher:

> He's been my mentor and I wrote a list of everything he's done for me and he said to me, "I'm not dead." I said, "I know you're not dead," and I only wrote three pages but they're just all the things you've done for me and I really appreciate it… So that's where mentors are so important, and if anyone ever wants to talk to me, anyone young, I always give them an hour, always, and I would do whatever I can.

Compassion and deep listening

Compassion was another capability and practice reported by participants for influencing change within systems. Compassion was closely related to deep listening and the development and maintenance of trust. Participants articulated the importance of being compassionate as a way of enhancing change efforts. They were keenly interested in the experiences of those living with conditions that lead to chronic disease. As well as gaining an in-depth understanding of community members' perspectives and experiences, they also sought to step into the shoes of the policymakers they aimed to influence. A key question they often asked was "what do you need?," thus, they actively took the time to imagine and hear what it was like to walk in another's shoes. A skill that enhanced their practice of compassion was deep listening without judgment and a sincere desire to learn. Because of this ability, they could act to address the needs of their community stakeholders and collaborators in their many and varied forms. Participants also shared that the practice of asking what was needed was key to establishing trust. Researchers were, however, able to ask what people's needs were because they held positions of power that enabled them to act upon people's needs.

> The target population, you look at them as a living being and you are thinking all the time about their behavior. So, we're asking, why doesn't a midwife ask this question of a pregnant woman in antenatal? And then we talk to them. And you just sit and listen and that's where you have the rich conversation. But she doesn't believe it and she doesn't have the skills or she's so pressed for time. And you can look at

the literature and they are all common barriers as to why a clinician doesn't ask. But if you go and listen to it in the flesh, you say, well I'm going to design my program, my training in a way that speaks to what that woman said, not what the literature says, time is a barrier. So, as soon as you make something abstract, you disconnect it from the human. You should never lose sight of the humanity of the person you are seeking to change. So, you should be engaged with them, you should be meeting with them.

Reflective practice

Engaging in ongoing reflective practice was another capability and practice reported by participants and observed through the analysis process for influencing change within systems. Reflective practice influenced deep listening which contributed to intellectual humility which in turn fed back into the practice of reflective practice. Each of these aspects fed into capacity building efforts within both research teams and in community stakeholders that facilitated the empowerment of communities.

Many of the participants were renowned experts in their fields of research in terms of content knowledge as well as methodological approaches. While they confidently stood by their work and its high quality, participants consistently demonstrated openness and receptivity to other ways of thinking and working. There was a recognition that there was no one way to create change. Intellectual humility was also present which was underpinned by personal practices, and in some cases, professional practices, of self or group reflection. An orientation toward continual learning and evolution of practice was fostered through reflection practices (both formal and informal) and deep listening.

I've learnt so much from these people and I've been grateful that they've been willing to help me from the beginning when I was very naïve, I didn't know anything at all. But I know a lot now, and I've known a lot from doing, and listening, and reading…I learn from them as much as they learn from me. And that's why a lot of our stuff gets picked up because I'm listening.

We build feedback into everything we do. So, to give you an example of that–if we were running a group model building session in a community, we'd have a couple of people from the last community and a couple of people from the next community in the room. We'd ask them to contribute in some way to the session, and then as soon as everybody's left the room regardless of the team that's there–we sit in a circle and say, "Okay, what went well? What can we improve on? What didn't feel right?" And we do it from least experienced to most experienced to break down power structures.

Embedding within systems

Participants reported being very deliberate about the extent to which they embedded themselves within the systems they sought to influence or change. It appeared that the use of compassion supported by deep listening enabled them to deepen their rapport and trust within relationships. This was a means by which to move closer to the inside of the "tent," therefore being more influential. In one institution that deliberately took an embedded approach, researchers sat in the same physical space as doctors, nurses, and patients. The purpose of this was to encourage stakeholder engagement. In addition, participants spoke about the need to foster strong relationships as a way of embedding themselves within a system or systems without the need to be physically present. They also mentioned using governance arrangements which meant that structurally, they had a defined role inside of a system in which they could create change through community empowerment.

I want my work to make a difference. So, I get in there, boots and all, but that's about engagement, it's about relating to your target audience as humans and then you design your interventions which relate to them, then you design your interventions to relate to the environmental context of them of where they fit.

Everyone can be caring, but it's actually about engaging with people. I sit and listen to people and find those gems about why they are doing something or why they are not doing something.

It appeared that governance structures combined with capacity building efforts worked to generate community empowerment which was key to systems change. Participants discussed the need to build capacity with policy stakeholders and partners as well as members of the lay community and the general public. By building capacity within these groups of collaborators, which was often facilitated by embedding within systems, participants were able to empower them to think and act in ways that ensured they thought and acted from a systemic perspective. From this place, they could ask appropriate questions to work toward achieving useful solutions to the problems they sought to solve. They were also upskilled in some instances with the use of software to better understand the systems in which they lived and worked and how to take effective action across the system to move toward transformative change.

So, the relationship is ongoing, but the relationship is adaptive as well because it's not a project-defined relationship. It's a mutual interest in tackling complex problems using system science. So, I reckon that's probably actually a massive difference because we're pigeonholed into a project starts, the

project ends, evaluate project paradigm, and if what you're looking for is inter-generational change, then that's not going to happen in a three-year stint.

We measured readiness to change and community capacity and they were clearly drivers of the results we were seeing and so we're not just building capacity outside of our four walls, we're building capacity within our teams as well.

Discussion

In this paper, we have drawn out the range of systems leadership practices present within a sample of prevention researchers, in many cases linking those practices to change making successes or research impact. This is the first time, in the Australian prevention research context, this grouping of practices for systems leadership to encourage systems change has been examined. The findings provide insights that may assist prevention researchers and other professionals dedicated to creating change in the chronic disease prevention space. While the findings are centered on the Australian context, they may have relevance internationally given the growing focus within academia to place more emphasis on research impact and the processes through which impact can be generated by researchers [e.g., (23)].

The findings from this study contribute to the existing body of systems leadership literature that demonstrates the need for those seeking to create change to hold a focus on the system as a whole, to practice deep listening, to practice compassion, and to step into the shoes of another, and engage in regular reflective practices to deepen their ongoing growth and learning potential (7, 8). Other systems leadership work in public health has centered upon the need to create a compelling call to action, a coalition of the willing, and a culture fueled by strong relationships, curiosity, and a deep understanding of the system of interest (24).

To effectively create change within complex settings, the focus is best centered on creating diverse teams, exploring various opportunities for interaction and the development of a collective mind, and shifting to sense-making from decision making especially when the trajectory of a system is unknowable (25). Systems leaders are not expected to have all of the answers when problem-solving; instead, they work through a process of co-production by engaging others to ask key and pertinent questions that allow for shared decision making and co-design of solutions (26, 27). Fawkes outlines some key propositions of systems leadership for systems change in the chronic disease prevention space, namely that leaders must enable dialogue; foster connections and promote innovation; allow and encourage leadership to occur as part of both formal and informal roles; respect various types of leadership including 'servant' or quiet styles; and work toward disrupting the status quo by creating a culture of

ongoing learning and growth and acknowledging uncertainty within systems.

Oliver and Cairney's systematic review (2019) explored how academics can most effectively influence policy change. They distilled eight main recommendations, all of which align with the leadership practices within our sample: (1) conduct high-quality research, (2) ensure research is relevant and accessible, (3) develop an understanding of policy processes, (4) routinely engage with policymakers humbly and flexibly, (5) make the decision to be either an advocate for particular issues or a knowledge broker, (6) build and nurture long term relationships with policymakers, (7) act like an entrepreneur or find a mentor who is, and (8) engage in ongoing reflection practices to ascertain what is working, what is not, and in doing so, being able to course correct. Our study adds to this list with the inclusion of deep listening and compassion, governance arrangements, and community empowerment, all of which were emphasized as key practices for creating change and generating impact.

Burgess (28) explains that academics who are successful at change making are driven 'by a passion greater than simply adding another item to your CV' (29), p. 12) and this was the case within our sample of prevention researchers. Participants were particularly passionate about ensuring their work was of a high standard and methodologically robust to foster change. This was important given that some methods (e.g., systems dynamic modeling) were considered innovative and relatively new to the prevention research context, therefore highlighting their long history as robust methods in other fields was necessary. Prior research indicates that conducting studies that are high quality while also communicating their strengths and weaknesses is key to having an impact by influencing policy (30, 31).

The need to communicate in a persuasive manner was emphasized within our sample. This meant learning the language of key stakeholders, adjusting communication styles to meet the needs of diverse groups be they senior government officials or community members, and avoiding jargon unless it was considered beneficial regarding technical use of terms and to ensure stakeholders were all on the same page. This aligns with the literature noting the importance of being able to adapt communication styles and formats to ensure relevance and comprehension (23). Something that was not however emphasized as much in our sample was the importance of storytelling for influencing policy, despite this being a well-documented necessity within the literature (32, 33). This omission is likely the result of our data collection tools not being specifically designed to explore leadership practices in depth.

Being able to situate research work within the policy and practice landscape was a key practice observed among participants. Instead of being focused first and foremost on situating research within an academic context, participants were primarily concerned with asking for,

understanding, and then addressing the needs of communities and policymakers to ensure their work was impactful. Thus, demonstrating a keen awareness of policy processes, contexts, and stakeholder goals [as per (23)]. Being able to step into the shoes of key stakeholders, be they patients, community members, or policymakers, was an essential part of this process and was facilitated by compassion and deep listening practices. Being humble, approachable, and accessible to stakeholders involved in change processes served to build rapport and trust, which contributed to ongoing fruitful engagement and relationships [(as per (34, 35))], and enabled them to become embedded within the systems they sought to change. Self-awareness appears to be an important antecedent to the development of these important change making skills (36), along with the guidance of a trusted mentor who has already embodied these practices across their career and can provide honest feedback for reflection.

Oliver and Cairney (23) recommend that researchers should be clear on whether they are an advocate for particular topics or knowledge brokers presenting a more neutral position. We do note however that this may not always be a choice available for researchers due to funding agreement rules and restrictions. We observed a strong lean toward advocacy and activism within our sample, especially given their change making focus when it came to chronic disease prevention. Moreover, to be effective as change makers, participants spoke at length about the need to establish legitimacy and authority in their focus areas. When they were early in their careers or branching into new fields, they strategically teamed up with respected personnel or sought out mentors to help them achieve their goals. Oliver and Cairney (23) note the importance of being entrepreneurial or collaborating with someone who is able to act on their behalf. Owing to the benefit of having been mentored themselves, participants mentioned choosing to act as mentors for others to pass on skills and foster networks for those new to their field. They also emphasized the importance of capacity building both within their research teams and their stakeholder groups.

When it comes to addressing complex and systemic problems there are calls for leaders to cultivate practices that interact to create systems of leadership; these have been referred to as "collective" (7, 37), "shared" (38), "collaborative" (39), "emergent" (40), "co-leadership", and "distributed" (11) leadership. Central to these concepts of leadership is the notion that leadership is a social process that is not reliant upon a single heroic leader but rather relies upon a systemic perspective of leadership whereby multiple actors take responsibility for change (10, 11). Distributed leadership, for example, calls for an emphasis on the attributes and behaviors of teams as opposed to individual leaders, while traditional forms of leadership typically focus on single leaders within organizations and systems (11). The topic of

distributed leadership was not identified within our discussions with participants, however, this was likely a result of the interview guide not being geared toward this specific topic. This may be a fruitful area for further exploration in future prevention research studies exploring leadership and change making.

Strengths and limitations

The findings reported here are qualitative, thus it is not possible to generalize the data collected and analyzed beyond the scope of the participants in the study. However, the information generated provides important insights that can assist prevention researchers to hone their leadership practices to foster greater impact in their work. Future research directions could explore a more explicit link between systems leadership practices and change making successes as well as how we can nurture systems leadership practices best suited to the prevention research workforce. Furthermore, future work could explore how leadership practices are distributed throughout teams and interact with the broader system and explore how the system supports or hinders their impact. Finally, we acknowledge that leadership is often a practice best judged from multiple perspectives within the system, therefore this may provide a beneficial area for further inquiry.

Conclusion

While we are not offering a prescription for becoming a systems leader, we are suggesting that prevention researchers reflect upon the set of practices we have distilled in this paper by considering their natural strengths and then setting about to enhance these. Drucker (41) suggests that there is little to be gained by developing weaknesses as these will be the natural strengths of others; instead, the most fruitful gains can be made by building upon pre-existing strengths. In alignment with the systems literature and (39) work, we recommend steering away from the idea of a single heroic leader with a myriad of systems leadership traits and instead advocate for the creation of interdependent systems of leadership within chronic disease prevention research whereby leadership practices are developed and distributed throughout teams [as per (10, 11)].

Data availability statement

The datasets presented in this article are not readily available because as per our ethics approval conditions, we are unable to share datasets outside of our research team. Requests to access the datasets should be directed to https://preventioncentre.org.au/.

Ethics statement

Author contributions

Funding

Acknowledgments

Conflict of interest

Publisher's note

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Policies regulating retail environment to reduce tobacco availability: A scoping review

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Background: In 2005, the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) entered into force. This treaty was developed in response to the global tobacco epidemic, and it includes measures to reduce both demand for and supply of tobacco. The measures related to demand reduction include raising tax, providing cessation services, promoting smoke free public places, banning advertising, and raising awareness. However, there are a limited number of measures for supply reduction, and these mainly include fighting illicit trade, banning sales to minors and providing alternatives to tobacco workers and growers. Unlike regulation of many other goods and services that have been subjected to retail restrictions, there is a lack of resources about restricting tobacco availability through regulation of tobacco retail environment. Considering the potential of retail environment regulations in reducing tobacco supply and consequently reducing tobacco use, this scoping review aims to identify relevant measures.

Methods: This review examines interventions, policies, and legislations to regulate tobacco retail environment to reduce tobacco availability. This was done by searching the WHO FCTC and its Conference of Parties decisions, a gray literature search including tobacco control databases, a scoping communication with the Focal Points of the 182 WHO FCTC Parties, and a databases search in PubMed, EMBASE, Cochrane Library, Global Health, and Web of Science.

Results: Themes of policies were identified to reduce tobacco availability by regulating retail environment: four WHO FCTC and twelve non-WHO FCTC policies. The WHO FCTC policies included requiring a license to sell tobacco, banning tobacco sale via vending machines, promoting economically alternative activities to individual sellers, and banning ways of sale that constitute a way of advertising, promotion, and sponsorships. The Non-WHO FCTC policies included banning tobacco home delivery, tray sale, tobacco retail outlets in or within a minimum distance from specific facilities, sale in specific retail outlets, and sale of tobacco or one or more of its products, in addition to restricting tobacco retail outlets per density of population and per geographic area, capping the tobacco amount allowed per purchase, limiting the number of hours or days in which tobacco can be sold, requiring a minimum distance between tobacco retailers, reducing tobacco products availability and proximity within a retail outlet, and restricting sale to government controlled outlets.

Discussion and conclusion: Studies show the effects of regulation of the retail environment in influencing overall tobacco purchases, and there is evidence that having fewer retails reduces the level of impulse purchasing of cigarettes and tobacco goods. The measures covered by WHO FCTC are much more implemented than ones not covered by it. Although not all widely implemented, many themes of limiting tobacco availability by regulating tobacco retail environment are available. Further studies to explore such measures and the adoption of the effective ones under the WHO FCTC decisions, could possibly increase their implementation globally to reduce tobacco availability.

1. Introduction

Tobacco use results in the premature death of up to half of its users causing eight million deaths every year. The poisonous habit leads to major comorbidities included heart attacks and strokes and is considered a major risk factor for many types of cancers (1). In 2021, the projected global prevalence of tobacco use was estimated to be around 20.4% by 2025 among those aged 15 years and older (2). In 2003, the World Health Assembly adopted the World Health Organization Framework Convention on Tobacco Control (WHO FCTC), which came into force in 2005. This treaty was developed as an evidence-based treaty and became one of the most rapidly and widely embraced treaties in United Nations' history with 182 affiliated Parties (3).

The WHO FCTC includes measures relating to the reduction of both demand for and supply of tobacco. The measures related to demand reduction include raising tax, providing cessation services, promoting smoke free public places, banning advertising, and raising awareness. However, there are a limited number of measures for supply reduction and these mainly include fighting illicit trade, banning sales to minors, and providing alternatives to tobacco workers and growers (3).

Although limited, there are some implemented and evaluated policies related to tobacco supply reduction, especially in the retail environment, documented in published literature. Some of these include restrictions on the numbers, location, and opening hours of tobacco retail outlets; restricting the amount of tobacco purchased by smokers over a given time; and loss of retail license following breaches of any of the conditions. Tobacco control experts have suggested that such policies are the new frontier in tobacco control with huge potential role in fighting the epidemic (4). Unlike regulation of pharmaceuticals and many other goods and services that have been subjected to a wide variety of restrictions, there is a lack of information and resources about restricting tobacco availability through regulation of the tobacco retail environment (5).

Considering the potential of retail environment regulations in reducing tobacco supply and consequently reducing tobacco use, this review aims to identify the implemented and suggested policies to reduce tobacco availability by regulating retail environment. The epidemiological agent-host-environment model provides a useful framework for tobacco control (6). In this review, the conceptual framework is that policies and regulations (environment) aiming to reduce supply in the retail environment (agent) will help in decreasing tobacco use at population level (host).

This review aims to address the lack of information and resources about restricting tobacco availability by undertaking a systematic search to identify and compile all implemented or suggested interventions, policies, and legislations designed to regulate tobacco retail environment to reduce tobacco availability. Considering the purpose of this study and the lack of knowledge in this topic area, this study is decided to be a scoping review to investigate available information about policies for restricting tobacco availability through regulation of the tobacco retail environment. A scoping review is useful for examining emerging evidence and providing an overview or map of the evidence. Therefore, it is an ideal tool to determine the scope of the policies investigated in this study (7, 8).

2. Methods

This scoping review examines interventions, policies, and legislations (hereinafter referred to all as policies) designed to regulate tobacco retail environment to reduce tobacco availability. For this review, retail environment means the context that allows direct interaction between customer and seller to buy tobacco. This study identified policies that limit tobacco availability by regulating such an environment. This means that policies that limit tobacco availability by other means than regulating the retail environment were excluded such as policies related to fighting illicit trade in tobacco products.

Although not pubished, a protocol for this review was developed and agreed by the authors of the study. The protocol is reflected in the searches described within the methods section of this paper. The authors used the PRISMA-ScR checklist of Tricco et al. (8) for guidance in the writing of this paper (8).

2.1. Searches

This study underwent four phases of search to identify relevant policies. First, we searched for tobacco retail environment policies in the two international tobacco control treaties: (1) WHO FCTC, adoped in 2003, and the decisions of the Conference of the Parties taken at its nine sessions (2006–2021) (9) and (2) the Protocol to Eliminate Illicit Trade in Tobacco Products (the Protocol), adopted in 2012, and the decisions of its two sessions of the Meeting of the Parties (2018–2021) (10).

In May 2021, a scoping communication, Annex 1, was sent electronically to all Focal Points of the 182 Parties to the WHO FCTC, facilitated by the Secretariat of the WHO FCTC (Convention Secretariat), to elicit what policies are implemented or planned, within their jurisdiction, concerning reducing tobacco supply (availability) through retail environment regulations. We also tried to reach out to countries which are not Parties to the WHO FCTC through the regional WHO offices as the aim of the study is to scope all policies whether they follow the WHO FCTC or not.

A gray literature search was conducted that included (1) a search within the "tobaccocontrollaws.org" tobacco control legislation database, which is established and maintained by the International Legal Consortium of the Campaign for Tobacco-Free Kids (CTFK), and it contains tobacco control legislations of 211 countries, and it allows research by policy; (2) a search within the tobacco control implementation hub of the International Union Against Tuberculosis and Lung Disease which includes resources, evidence and case studies of tobacco control policies; and (3) reviewing documents shared within tobacco control community networks.

Lastly, based on the previously outlined search results, we identified key terms to be used within the scope of the review relating to tobacco, retail environments, policies, legislations, and regulations. These key terms were used to run searches in five databases: "PubMed", "EMBASE", "Cochrane Library", "Global Health", and "Web of Science". The key terms run through the databases were:

- Tobacco and tobacco products: Tobacco OR Smok* OR cigar*
- Policies to reduce tobacco availability: Regulat* OR Polic* OR Legislat*

– Retail environment: Retail* OR outlet* OR sale* OR vending OR vendor OR store* OR shop*

2.2. Inclusion and exclusion criteria

In the search within the documents of the WHO FCTC, the Protocol and the gray literature, all papers documenting or suggesting examples of interventions, policies, and legislations to regulate tobacco retail environment to reduce tobacco availability were included. The inclusion criteria consisted of papers that are published in English or Arabic; in any country; at any time; on tobacco retail environment regulation; and with no restriction on the type of study included. All full-text, peer reviewed articles including commentaries and editorials, as well as relevant gray literature were included. In addition to the inclusion criteria, the main exclusion criteria included studies focussing on regulations of tobacco demand reduction, or studies focusing on tobacco supply reduction by other means than regulating retail environment.

In the writing of this paper, the responses by WHO FCTC Focal Points relate to policies already identified by the search methods outlined in the gray literature search or the search within the WHO FCTC and the Protocol documents were excluded to avoid the burden of going through a validation process for policies already identified by other means. The peer-review and public availability criteria were not applied to the resources obtained from the WHO FCTC Focal Points.

In the database review, the inclusion criteria consisted of papers that are published in English or Arabic; in any country; at any time; on tobacco retail environment regulation; and with no restriction on the type of study included. All full-text, peer reviewed articles including commentaries and editorials, as well as relevant gray literature were included. In addition to the inclusion criteria, the main exclusion criteria included studies focussing on regulations of tobacco demand reduction, studies focusing on tobacco supply reduction by other means than regulating retail environment, or meaures already identified by other means of search.

2.3. Ethics

The Ethics Committee of Bielefeld University has reviewed the application of this review according to the ethical guidelines of the German Association of Psychology, which correspond to the guidelines of the American Psychological Association. The Ethics Committee of Bielefeld University approved the study as ethically appropriate.

2.4. Analysis

All policies identified through searching the documents of the WHO FCTC and the Protocol documents were assessed for inclusion in the review based on the predefined inclusion criteria. This review identified four policies covered by the international treaties. The policies are discussed in the results section (3.1.1–3.1.4), and listed in Table 1.

TABLE 1   Policies identified in the WHO FCTC and related documents.

Document	Policy
Article 15 of the WHO FCTC	– Requiring a license to sell tobacco
Guidelines for implementation of Article 13 of the WHO FCTC	– Banning tobacco sale *via* vending machines – Banning ways of sale that constitute a way of advertising, promotion, and sponsorships
Article 16 of the WHO FCTC	– Banning tobacco sale *via* vending machines
Article 17 of the WHO FCTC	– Promoting economically alternative activities to individual sellers
Article 6 of The Protocol	– Requiring a license to sell tobacco

TABLE 2   Policies identified from WHO FCTC Focal Points responses.

Country	Policy
France, Italy, South Korea	– Restricting tobacco retail outlets per density of population
Belgium, Costa Rica, South Korea	– Banning home delivery of tobacco
Guyana, Ireland	– Banning tray/ mobile tobacco sale
Andorra, Spain	– Capping the tobacco amount allowed per purchase
South Korea, Spain	– Requiring a minimum distance between tobacco retailers
Chile, France, Georgia, Guatemala, Honduras, Lebanon, Portugal, Saint Lucia, Saudi Arabia	– Banning tobacco retail outlets in or within a minimum distance from specific facilities
Czech Republic, France, Netherland, Saudi Arabia	– Banning tobacco sale in specific retail outlets

TABLE 3   Policies identified from the CTFK database.

Category	Policy
Sales restrictions	– Requiring a license to sell tobacco – Banning tobacco sale *via* vending machines – Banning ways of sale that constitute a way of advertising, promotion, and sponsorships – Banning tobacco retail outlets in or within a minimum distance from specific facilities – Banning tobacco sale or one or more of tobacco products

The survey shared with the 182 WHO FCTC Focal Points was answered by 31 countries. Data was extracted from the answers and identified policies were described and presented in a tabular form and led to the identification of seven policies apart from the ones already covered by the WHO FCTC. New policies implemented or planned were included in the writing of the article as long as supporting evidence was provided by the WHO FCTC Focal Points or identified through gray literature, this led to the inclusion of responses from 19 countries in this review. The policies are discussed in the results section (3.2.1–3.2.7), and listed in Table 2.

The CTFK database were searched under the category of sales restrictions, and this led to the identification of an additional policy, which is banning tobacco sale or one or more of tobacco products. Moreover, information from the CTFK database was used as source on number of countries implementing other four

TABLE 4 Policies identified by databases and gray literature search.

Title	Authors	Setting	Study type	Policy
Papers identified through gray literature				
Regulating the tobacco retail environment: beyond reducing sales to minors	Chapman S, Freeman B.	Australia	Review (communication piece)	• Requiring a license to sell tobacco • Government controlled outlets • Restricting tobacco retail outlets per density of population • Capping the tobacco amount allowed per purchase
Reducing the availability of tobacco products at retail: policy analysis	Tilson M.	Canada	Policy analysis	• Requiring a license to sell tobacco • Banning tobacco retail outlets in or within a minimum distance from specific facilities • Restricting tobacco retail outlets per geographic area • Requiring a minimum distance between tobacco retailers • Government controlled outlets
Reducing the Density and Number of Tobacco Retailers: Policy Solutions and Legal Issues	Ackerman A, Etow A, Bartel S, Ribisl K.	United States	Policy analysis	• Banning tobacco sale in specific retail outlets • Banning tobacco retail outlets in or within a minimum distance from specific facilities • Restricting tobacco retail outlets per geographic area • Requiring a minimum distance between tobacco retailers • Restricting tobacco retail outlets per density of population • Banning tobacco sale in specific retail outlets
A comparison of three policy approaches for tobacco retailer reduction	Myers A, Hall M, Isgett L, Ribisl K.	United States	Cross-sectional	• Banning tobacco sale in specific retail outlets • Banning tobacco retail outlets in or within a minimum distance from specific facilities • Requiring a minimum distance between tobacco retailers
Policy coherence, integration, and proportionality in tobacco control: Should tobacco sales be limited to government outlets?	Smith E, McDaniel P, Hiilamo H, Malone R.	United States	Policy analysis piece	• Government controlled outlets
Reducing Tobacco Retail Density in San Francisco: A Case Study	Bright Research Group	San Francisco, United States	Case study analysis	• Restricting tobacco retail outlets per geographic area • Requiring a minimum distance between tobacco retailers • Banning tobacco retail outlets in or within a minimum distance from specific facilities • Banning tobacco sale in specific retail outlets • Promoting economically alternative activities to individual sellers
Evaluating the impact and equity of a tobacco-free pharmacy law on retailer density in New York City neighborhoods	Giovenco D, Spillane T, Mauro C, Hernández D	New York City, United States	Cross-sectional	• Banning tobacco sale in specific retail outlets
Global review of tobacco product flavor policies	Erinoso O, Clegg Smith K, Iacobelli M, Saraf S, Welding K, Cohen J	USA, Canada, Brazil, Ethiopia, Uganda, Senegal, Niger, Mauritania, EU (28 Member States), Moldova, Turkey and Singapore	Global systematic review	• Banning tobacco sale or one or more of tobacco products
The Khan review Making smoking obsolete	Khan J.	United Kingdom	Policy review	• Banning tobacco sale in specific retail outlets

(Continued)

TABLE 4 (Continued)

Title	Authors	Setting	Study type	Policy
				• Banning tobacco sale or one or more of tobacco products
Papers identified theough the database research				
Theoretical impacts of a range of major tobacco retail outlet reduction interventions: modeling results in a country with a smoke-free nation goal	Pearson A, van der Deen F, Wilson N, Cobiac L, Blakely T	New Zealand	Cross-sectional	• Banning tobacco sale in specific retail outlets • Banning tobacco retail outlets in or within a minimum distance from specific facilities
Vatican beats Italy 1-0 in the tobacco endgame	Gallus S, Cattaruzza M, Gorini G, Faggiano F	Italy	Commentary (communication piece)	• Banning tobacco sale or one or more of tobacco products
Tobacco retail policy landscape: a longitudinal survey of US states	Luke D, Sorg A, Combs T, Robichaux C, Moreland-Russell S, Ribisl K, Henriksen L	United States	Longitudinal study	• Limiting the number of hours or days in which tobacco can be sold • Requiring a license to sell tobacco • Banning tobacco retail outlets in or within a minimum distance from specific facilities • Restricting tobacco retail outlets per geographic area • Requiring a minimum distance between tobacco retailers • Banning tobacco sale in specific retail outlets
Banning tobacco sales and advertisements near educational institutions may reduce students' tobacco use risk: evidence from Mumbai, India	Mistry R, Pednekar M, Pimple S, Gupta P, McCarthy W, Raute L, Patel M, Shastri S	Mumbai, India	Cross-sectional	• Banning tobacco retail outlets in or within a minimum distance from specific facilities
Ending tobacco sales in pharmacies: A qualitative study	Jin Y, Berman M, Klein E, Foraker R, Lu B, Ferketich A	United States	Qualitative study	• Banning tobacco sale in specific retail outlets
A Comprehensive Review of State Laws Governing Internet and Other Delivery Sales of Cigarettes in the USA	Chriqui J, Ribisl K, Wallace R, Williams R, O'Connor J, Arculli R. A	United States	Systematic review	• Banning home delivery of tobacco
Altering the availability or proximity of food, alcohol, and tobacco products to change their selection and consumption	Hollands G, Carter P, Anwer S, King S, Jebb S, Ogilvie D, Shemilt I, Higgins J, Marteau T	High-income countries (predominantely USA)	Systematic review	• Reducing tobacco products availability and proximity within a retail outlet
Four policies to end the sale of cigarettes and smoking tobacco in New Zealand by 2020	Laugesen M, Glover M, Fraser T, McCormick R, Scott J	New Zealand	Policy review	• Banning tobacco sale or one or more of tobacco products

policies identified by the previous searches. The policy identified is discussed in the results section (3.2.12), and all policies in this review that the CTFK database included information on are listed in Table 3.

All documents/ studies/ interventions identified through database searches or gray literature (the Union database and documents received through tobacco control networks) were assessed by two reviewers independently for inclusion in the review based on the predefined inclusion criteria. Any disagreement was resolved through mutual discussion. Data was extracted and identified policies were described and presented in a tabular form (11). Quality assessment and appraisal was not deemed necessary due to this being a scoping review (7).

Summary of the database and gray literature results can be found in the PRISMA diagram below for clarification of number of articles included and excluded based on the mentioned criteria. The gray literature and database search led to four additional policies

being identified apart from the ones already identified by other searches. The policy identified is discussed in the results section (3.2.8–3.2.11), and all policies in this review that the databases and gray literature included information on are listed in Table 4. A PRISMA flowchart shows the records of documents identified is presented in Figure 1.

2.5. Synthesis

After the phase of identifying policies that limit tobacco availability by regulating retail environment as per Tables 1–4, similar policies were compiled and policies were categorized to either covered by the WHO FCTC (mainly for other purposes than limiting the availability), and non WHO FCTC policies. This synthesis led to a total of sixteen policies identified that are summarized in Table 5 and will be discussed below.

FIGURE 1
PRISMA flowchart.
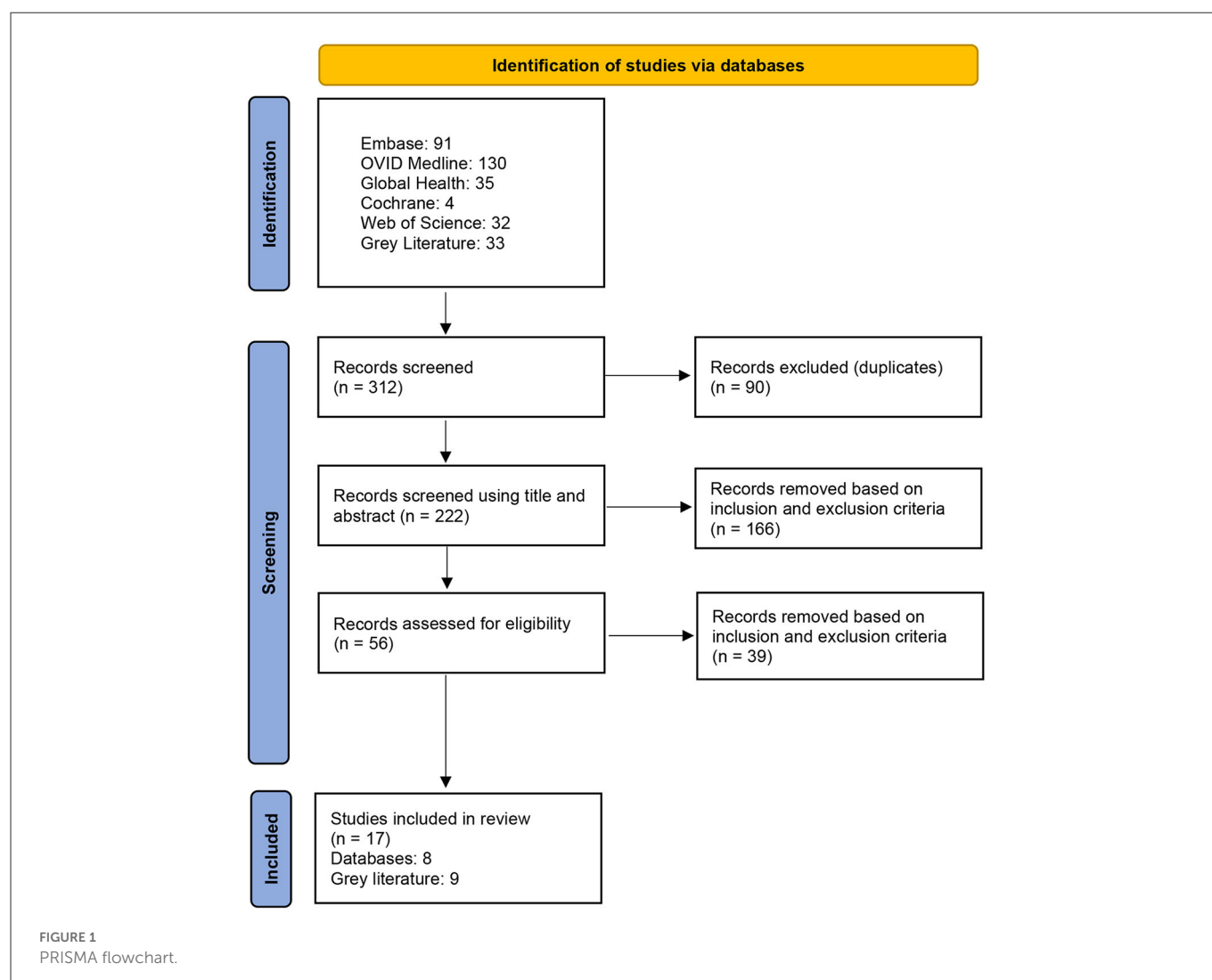
TABLE 5 All policies identified.

1. WHO FCTC policies
1.1. Requiring a license to sell tobacco
1.2. Banning tobacco sale *via* vending machines
1.3. Promoting economically alternative activities to individual sellers
1.4. Banning ways of sale that constitute a way of advertising, promotion, and sponsorships

2. Non-WHO FCTC policies
2.1. Restricting tobacco retail outlets per density of population
2.2. Banning home delivery of tobacco
2.3. Banning tray/mobile tobacco sale
2.4. Capping the tobacco amount allowed per purchase
2.5. Requiring a minimum distance between tobacco retailers
2.6. Banning tobacco retail outlets in or within a minimum distance from specific facilities
2.7. Banning tobacco sale in specific retail outlets
2.8. Restricting tobacco retail outlets per geographic area
2.9. Government controlled outlets
2.10. Limiting the number of hours or days in which tobacco can be sold
2.11. Reducing tobacco products availability and proximity within a retail outlet
2.12. Banning tobacco sale or one or more of tobacco products

3. Results

3.1. WHO FCTC policies

3.1.1. Requiring a license to sell tobacco

Article 15 of the WHO FCTC is mainly about policies to fight illicit trade in tobacco products. However, it flags the need for licensing to prevent illicit trade. The licensing requirement was further developed and explained in Article 6 of the Protocol to Eliminate Illicit Trade in Tobacco Products (3). Such policy could be a starting point to assess the density of tobacco selling points and then regulating them. The CTFK database shows that 52 countries have specific retail license to sell tobacco products (12). Out of the 31 countries responded to the survey, 13 countries reported that they have policies to revoke the license or to apply a fine in case of license condition violations (13).

There is evidence to suggest that high license fees will lead to decrease in number of tobacco retailers. A study done in Australia confirms this, estimating a 25% decrease in retailers (14). Making

licensing of tobacco retailers a policy and identifying a cap on the number of licenses would give the license a higher commercial value that will promote compliance to retail regulations as violation would risk losing that asset. Losing the license as a penalty could be also used as a way to decrease number of retailers (5). The policies of establishing and increasing license fees are adopted in many cities in the United States (15). Licensing requirements and strict conditions to be met to get a tobacco retail license, in addition to innovative practices in tobacco licensing, are discussed in policy documents (16).

3.1.2. Banning tobacco sale *via* vending machines

Article 16 of the WHO FCTC is mainly about protecting minors from having access to tobacco products. It requires the implementation of policies that ensure no access to vending machines by minors (3). The Article also requires prohibiting the introduction of tobacco vending machines to a total ban on tobacco vending machines. The guidelines for implementation of Article 13 of the WHO FCTC also require banning vending machines as they constitute, by their presence, a means of advertising and promotion of tobacco products (17). The CTFK database shows that 86 countries ban sale of tobacco products *via* vending machines, while 20 countries have some restrictions on vending machines that varies from banning them in places where minors are usually present to allowing them only in specific places such as hotels (12).

3.1.3. Promoting economically alternative activities to individual sellers

Article 17 of the WHO FCTC states that "Parties shall, in cooperation with each other and with competent international and regional intergovernmental organizations, promote, as appropriate, economically viable alternatives for tobacco workers, growers and, as the case may be, individual sellers" (3). The relevant practice to this Article so far is mainly about alternative solutions to tobacco growers. However, in Kenya's tobacco control act, individual sellers can be understood as sellers at retail environment as the law states "The Government through the relevant ministries shall put in place policies to promote, as appropriate, economically viable alternatives for tobacco workers, distributors, retailers and individual sellers" (18).

Introducing incentives that encourage retailers to stop selling tobacco, such as a subsidized program to help them sell more fresh fruit and vegetables, is a suggested policy to reduce tobacco retail density (4). A successful example to such policy is passing the San Francisco's Tobacco Retail Density Policy after the adoption of the Healthy Retail San Francisco ordinance which helped corner stores in shifting to the business of fresh and healthy affordable food. Such program secured an opportunity to find common ground with the retail association and led to a density policy solution that was supported by all stakeholders (19).

3.1.4. Banning ways of sale that constitute a way of advertising, promotion, and sponsorships

Article 13 of the WHO FCTC is mainly about banning tobacco advertising, promotion, and sponsorships. In its Guidelines for implementation (17), some regulations of retail environment were adopted. Although these policies aim mainly to reduce

the demand on tobacco, the authors believe that they can also reduce tobacco supply within the retail environment. These regulations include:

- Banning internet sale of tobacco. The CTFK database shows that 63 countries ban sale of tobacco products *via* the internet (12).
- Banning tobacco sale at educational establishments or at hospitality, sporting, entertainment, music, dance and social venues or events. The CTFK database shows that 76 countries ban tobacco sale in schools/educational facilities, 45 countries ban tobacco sale in stadiums/arenas, 31 countries ban tobacco sale in cultural facilities, and 26 countries ban tobacco sale in playgrounds (12).

3.2. Non-WHO FCTC policies

3.2.1. Restricting tobacco retail outlets per density of population

Possible models to decrease tobacco retail density could include a model where a restricted number of licenses is based on an agreed number of tobacco retail outlets per 100,000 population, and such licenses could be auctioned to the highest bidder (5). A population-based retailer caps is implemented in Hungary allowing only one store for every 2,000 residents (20).

France flagged 3,500 inhabitants as the number commonly required for opening a tobacconist shop (21). In South Korea, density of population does not limit the number of tobacco sellers, but local officials consider density of population in setting the criteria for certain distance between tobacco sellers (22). In Italy, municipalities with no more than 10,000 inhabitants are allowed to have one tobacco shop every 1,500 inhabitants, but there is also a policy that requires minimal distance between two tobacco sellers as per inhabitants' density. This required distance is 200 meters in cities with more than 100,000 inhabitants, 250 meters in cities with more than 30,000 inhabitants, and 300 meters in cities up to 30,000 inhabitants (23).

3.2.2. Banning home delivery of tobacco

Although banning tobacco internet sale is a requirement under the WHO FCTC, some countries expanded this to ban all types of distal sale and tobacco home delivery. Costa Rica prohibited tobacco sales to the consumer by telephone, digital, electronic, internet, mail, and other means (24). South Korea banned retailers from selling tobacco to consumers by way of postal sale or electronic transactions (22). Spain banned home delivery of tobacco products. Belgium banned all types of distal sales of tobacco (13). A review of state laws in the United States found that five states banned direct-to-consumer shipment of cigarettes (25).

3.2.3. Banning tray/mobile tobacco sale

A couple of countries banned tray/mobile sale of tobacco products. In Guyana no person shall go into any public place carrying any tobacco product, electronic delivery system, or component, in a tray, container or otherwise for the purpose of making sales or commercially displaying the product (26). Ireland prohibited the sale of tobacco products from mobile units/containers, from temporary or movable premises (27).

3.2.4. Capping the tobacco amount allowed per purchase

Capping amount allowed per purchase is implemented on other products. For example, in some settings the sale of paracetamol tablets is restricted by law to a maximum pack of 16 tablets without the supervision of a pharmacist (28). This is not the case for tobacco. Although many countries put a cap on the amount of tobacco to be purchased from duty free zones such as airports, this policy was not extended to be applied in regular retail environment. A review suggested restricting the amount of tobacco smokers could purchase over a given time to promote a gradual decrease in tobacco-use till quitting, this could happen by introducing an upper weekly limit to tobacco product purchases (5).

A couple of countries apply such policies but with very high amount allowed. Andorra prohibits the sale to individuals for an amount higher than 10,000 cigarettes. In the case of cigars the ban is for quantities exceeding 5,000 units (cigars or cigarettes <3 gram per piece) or 2,500 units (cigars or cigarettes <3 gram per piece). For waterpipe tobacco and smoking tobacco, the sale of more than ten kilograms is prohibited, these restrictions apply per sale and per person (29). In Spain, although there is no restriction on the allowed amount per purchase, the sale of tobacco products must be accompanied by their corresponding invoice or sale if the quantity is more than 800 cigarettes, 200 units in the case of cigars, 400 units in the case of cigarillos, or one kilogram of other tobacco products (30).

3.2.5. Requiring a minimum distance between tobacco retailers

A policy document suggested limiting the proximity of tobacco retailers to each other, with retailers not being allowed to sell tobacco products within 1,000 meters of another tobacco retailer (16). Having minimum required distance between tobacco retailers prevents clustering of tobacco outlets in certain areas such as economically disadvantaged districts (20). A study in the United States revealed that regulating the minimum allowable distance to 500 feet between tobacco outlets, if implemented, would reduce tobacco retailers' density by 22.1% (31).

Requiring certain distance between tobacco retailers is discussed in many of the United States cities and passed in a couple of them (15). California bans tobacco retailers from opening new stores within 200 feet of another store, that goes up to 500 feet in the unincorporated parts (20). The tobacco retailers density policy in San Francisco applied a standard of no tobacco sale permitted within 500 feet of another location permitted to sell tobacco (19). In South Korea, although the number of tobacco retail outlets per unit area is not limited, a certain distance must be maintained between retailers that differs according to criteria from one region to another (22). Spain has a policy that requires at least 150 meters distance between tobacco selling shops, and grants complementary status for tobacconists opening in rural zones (30).

3.2.6. Banning tobacco retail outlets in or within a minimum distance from specific facilities

The Guidelines for implementation of the WHO FCTC require banning tobacco vending machines; internet sale of tobacco; and tobacco sale at educational establishments or at hospitality, sporting, entertainment, music, dance and social venues or events. Some countries expanded this in their polices to either ban tobacco sale

in other facilities or to ban tobacco sale within a minimum distance from specific facilities. CTFK database shows that 65 countries ban tobacco sale in healthcare facilities (12). Portugal banned tobacco sale in many facilities including covered car parks and in the enclosures of automatic cash withdrawals (32). France banned tobacco sale in protected areas that includes perimeter of health, education and sports facilities or training, collective accommodation, and leisure establishments for young people (33).

A policy document suggested the establishment of safe routes policy by banning tobacco sale in designated access routes to schools, in addition to identifying specific distance from schools and youth-oriented facilities where tobacco sale is prohibited. The document suggested tobacco retailers should be at least 500 meters away from schools, community centers, sport or leisure facilities (16). A study in the United States revealed that restricting sales of tobacco products within 1,000 feet of schools, if implemented, would reduce tobacco retailers' density by 17.8% (31). A study in New Zealand suggested that elimination of outlets within 2 km of schools yielded an estimated lower smoking prevalence compared to no intervention (34).

Many places already banned tobacco sales near youth-populated areas (20). Prohibiting tobacco sales in locations where youth frequent are adopted in many cities in the United States (15). A number of countries banned tobacco sale from different facilities such as health, education, sports, childcare, religious, government, public, cultural and leisure facilities. The minimum distance required is varied such as 10 meters in Saint Lucia, 50 meters in Georgia, 100 meters in Chile and Honduras, 500 feet in San Francisco, 500 meters in Saudi Arabia and Guatemala, and 1,000 meters in Qatar (12, 13, 19).

3.2.7. Banning tobacco sale in specific retail outlets

Some countries banned tobacco selling in specific retail outlets. Czech Republic prohibits the sale of tobacco in food stores, catering establishments, and refreshment stands (35). A tobacco retailers density policy in San Francisco banned tobacco sales in restaurants, bars, or other tobacco shops that are not already permitted (19). A study in New Zealand suggested that permitting tobacco sales at only 50% of liquor stores resulted in large cost increase of getting tobacco (~$60/pack in rural areas) and yielded an estimated lower smoking prevalence than with no intervention (34). A recent review and policy document in the United Kingdom suggested banning tobacco sale in supermarkets (36).

Prohibiting sales in specific venues such as pharmacies is adopted in a number of places considering the conflict of interest for pharmacies to sell tobacco while offering medicine for tobacco-related diseases (20). Banning tobacco sales in pharmacies is a sensible public health policy with a proven positive impact of reducing tobacco sales density and smoking prevalence (37). This policy has been discussed in many of the United States cities (15). A study in North Carolina revealed that prohibiting sales of tobacco products in pharmacies or stores with a pharmacy counter, if implemented, would reduce tobacco retailers' density by 13.9% (31). A study in California and Massachusetts suggested that the process of adopting the tobacco-free pharmacy laws was smooth, with a few barriers (38).

Communities can also require that tobacco be sold solely by tobacco-only retailers as a method to control and decrease number of outlets selling tobacco (20). France allows only tobacconists to

sell tobacco and it bans a shop manager to apply for a license to open another one. France also prohibits the sale of tobacco in shopping centers and shopping malls next to supermarkets of more than 1,000 square meters. Saudi Arabia allows tobacco to be sold only in supermarkets not <100 square meters. Spain allows tobacco selling only to tobacconists or vending machines. Netherlands plan to ban tobacco sale in supermarkets by 2024, and to make tobacco sold only in tobacco specialty stores by 2030 (13).

3.2.8. Restricting tobacco retail outlets per geographic area

A policy to reduce number of retailers in a defined geographic area is the cap and winnow approach, which involves setting a limit at the number of existing tobacco retailers, then allowing lower number of new outlets than those who have failed to renew their licenses or have them revoked (20). A policy document suggested prohibiting tobacco retailers from locating in residential zones, and restricting the location of tobacco retailers to particular zones in a community (16).

Restricting retailers in certain zones such as residential zones is a policy discussed in many of the United States cities and passed in a couple of them. Limiting or capping the total number of licenses in a specific area is a policy discussed in many United States cities (15). A tobacco retailers density policy in San Francisco caps the number of tobacco sale permits in each of the City's 11 Supervisorial Districts at 45, limiting the citywide total to 495. The policy also added that tobacco sale permits will not be issued in locations that have never had a tobacco license in the past (19).

3.2.9. Government controlled outlets

Possible models to decrease tobacco retail density could include the nationalization of tobacco retailing involving a single network of government-controlled outlets (5). A suggested policy option in the literature is to restrict tobacco sales to a limited number of controlled outlets. A similar model has been used for the sale of alcoholic beverages before (16). A transition to government operated stores could solve the current contradiction between acknowledging and raising awareness of tobacco harms, while still allowing its sale. Such transition could allow governments to enforce better compliance to tobacco control policies and will provide governments with the tool to better regulate tobacco products and to move forward toward limiting tobacco availability (39).

3.2.10. Limiting the number of hours or days in which tobacco can be sold

A study in the United States discussed the planned and existing policies relevant to tobacco retail policy. It identified that a policy to limit the number of hours or days in which tobacco can be sold was planned/proposed twice in 2014 (15).

3.2.11. Reducing tobacco products availability and proximity within a retail outlet

The idea of altering the availability and proximity of tobacco products within a retail outlet was raised in a review about effects of availability or proximity of food, alcohol, and tobacco products to change their selection and consumption. The review didn't include studies particularly on tobacco, but the interventions mentioned included decreasing tobacco availability by providing a reduced range of types of tobacco product and making a lesser amount of cigarettes available in a shop. The intervention to decrease tobacco proximity was by moving tobacco products farther away from people to alter the degree of convenience and effort required for potential consumers to select or consume these products (40).

3.2.12. Banning tobacco sale or one or more of tobacco products

The scope of this review is about the retail environment regulations that affects all types of tobacco and not a certain targeted policy or endgame strategies, but its worth highlighting that some countries ban sale of all or certain types of tobacco. Endgame theories suggested different ways for phasing out tobacco products, such as allocating national sales quotas per manufacturer or importer, with annual 5% reduction of the allocated amount, and then be reduced by 5% every 6 months (41). A recent policy review in the United Kingdom suggested freezing the tobacco market and banning the introduction of any new tobacco products to make the market stagnant and to avoid the presence of new available or attractive tobacco products (36).

The CTFK database shows that 12 countries banned waterpipe sales, and 18 countries banned the sale of smokeless tobacco products (12). According to a recent review, 40 countries have active or pending policies that range from banning flavored tobacco, to banning flavor descriptors and images on packaging (42). In the Vatican, all sales of tobacco products were banned, a decision that was well received as a positive step toward counteracting practices that are harmful to the health of citizens (43). There is also evidence of the tobacco industry's opposition to such policies (44).

4. Discussion

4.1. Identified policies

This review identified 16 policies to reduce tobacco availability by regulating tobacco retail environment. The data synthesis and results' presentation followed the categorization of policies to either WHO FCTC polices or non-WHO FCTC policies because of the huge importance of the treaty in guiding the global performance in tobacco control. The identified policies can however be categorized to four main themes: policies that limit the number of tobacco retailers, policies that limit the ways of tobacco sales, policies that limit accessibility to tobacco products when they are available in the retail environment, and policies that ban tobacco sales.

Policies that limit the number of tobacco retailers included three policies covered by the WHO FCTC and six policies not covered by the treaty. The ones covered by the treaty are requiring a license to sell tobacco; promoting economically alternative activities to individual sellers; and banning tobacco sale at educational establishments or at hospitality, sporting, entertainment, music, dance and social venues or events. The ones that were not covered by the treaty are restricting tobacco retail outlets per density of population; requiring a minimum distance between tobacco retailers; banning tobacco retail outlets in or within a minimum distance from specific facilities; banning tobacco sale in specific retail outlets; restricting tobacco retail

outlets per geographic area; and selling tobacco only in government-controlled outlets to potentially limit the number of outlets.

Policies that limit the ways of tobacco sales included two policies covered by the WHO FCTC and two policies not covered by the treaty. The ones covered by the treaty are banning tobacco sale *via* vending machines and banning internet sale of tobacco. The ones that were not covered by the treaty are banning home delivery of tobacco and banning tray/mobile tobacco sale.

Policies that limit accessibility to tobacco products when they are available in the retail environment were not covered by the WHO FCTC. These policies are mainly three ones: capping the tobacco amount allowed per purchase; limiting the number of hours or days in which tobacco can be sold; and reducing tobacco products availability and proximity within a retail outlet.

Policies that ban tobacco sales included banning tobacco sale or one or more of tobacco products. This policy is listed under non-WHO FCTC policies, but it is worth flagging that the treaty decisions refer to banning flavored tobacco.

4.2. Importance of the topic

A global review documented that points of sale are used for tobacco advertisement even for children and youth by displaying of cigarettes near snacks, sweets and sugary drinks; placement of cigarette advertisements near the eye-level of children; advertisements and display of flavored cigarettes; and sale of single sticks of cigarettes (45). In Indonesia, a study about cigarette retailer density around schools and neighborhoods found that around 9.7% of the schools in Denpasar have at least one cigarette seller within a 25 meter radius and 96.8% within a 250 meter radius (46). A study done in two cities in India found that around 20% of tobacco vendors were observed operating within 100 yards of a school, with an average three or four tobacco vendors operating within 100 yards of each school (47). A study in India suggested that a tobacco sales ban near educational institutions could be expanded beyond 100 meters (48).

4.3. Tobacco industry position regarding retail environment

In 2020, the tobacco industry spent a million dollars every hour in the United States to make its presence known in the retail environment, with a total of $8.2 billion spent over the year (49). A study in Australia revealed that tobacco industry gave retailers cash and paid vacations with the objective of increasing market share and driving sales (50). Furthermore, it has also been documented that tobacco companies target retailers through competitive discounts, cash payments, prizes and gifts aimed at building positive relationships with them (51, 52). This relation allows the tobacco industry to influence the merchandising of tobacco products, which ultimately influences the sale and promotion of tobacco (51–53).

Tobacco industry gives particular interest to its relationships with tobacco retailers. A recent scoping review concluded that tobacco industry-retailers' agreements for pricing discounts and prime placement of products and advertising are prevalent around the world. Such agreements allow the tobacco industry to promote its

products and undermine tobacco control efforts in the retail setting. The review recommended banning such agreements. The importance of retailers' compliance to implementing tobacco control policies, in addition to the aim of limiting tobacco availability raises the idea of government-controlled outlets as a potential solution (54).

Tobacco companies oppose retail reduction policies, and in one letter sent by Japan Tobacco International to the Jordanian government, the company opposed the policy of declining to license tobacco sales within 200 meters from residency areas, mosques, educational facilities, and health facilities. The company stated in the letter that such policy equals in its severity a complete ban on tobacco sales. The company also opposed any restrictions on size or number of areas allocated to tobacco sales in commercial centers (55). It is reported in the media that the tobacco industry works to increase its presence in stores by increasing its field force (56).

4.4. Effectivness of policies

Studies show the effects of regulation of the retail environment in influencing overall tobacco purchases, and there is strong evidence that having fewer retails reduces the level of impulse purchasing of cigarettes and tobacco goods (4). For example, a Canadian study found that one-third of smokers would smoke less if they had to travel further to buy cigarettes, especially younger smokers (57). Similarly, another study in Australia found that even in the absence of tobacco products at the checkout counter, just the sight of tobacco retail outlets prompted impulse purchases (58, 59).

Policy analysis shows that reducing the convenience of obtaining tobacco products increases the cost to the smoker including the time, effort, and money spent to obtain tobacco. Therefore, policies that limit availability of tobacco will clearly affect the convenience of obtaining tobacco (16). A study in New Zealand suggested that with a law that required a 95% reduction in tobacco outlets, the cost of a pack of 20 cigarettes increased by 20% in rural areas and 10% elsewhere and yielded an estimated lower smoking prevalence compared to no intervention (34). A recent meta-analysis study concluded that decreased levels of tobacco density and proximity are associated with lower tobacco use (60).

4.5. Feasibility of policies

A study in the United States discussed the legal challenges for policies such as requiring minimum distance between retailers, limiting retailers in each geographic area, linking number of tobacco retailers to population size, and banning tobacco sales at or within a certain distance of certain places. The study concluded that courts are likely to reject constitutional challenges to carefully crafted laws that reduce the number of tobacco retailers (20).

This review shows that the policies covered by the WHO FCTC are more frequently implemented than the ones not covered by it. Overall, many policies of limiting tobacco availability by regulating tobacco retail environment are available. The WHO FCTC and its

Conference of Parties decisions provide a great opportunity for scaling up effective strategies, and bringing them to the attention of tobacco control at a global level, especially with the growing evidence of both public and experts' support for relevant policies (61, 62).

4.6. Limitations of the review

The authors recognize the limitation of the study considering the difficulties in reaching WHO FCTC Focal Points in all Parties, and in reaching tobacco control officials in countries that are not Parties to the WHO FCTC. In addition, the survey shared with the WHO FCTC Focal Points was only in English so all other languages were excluded. Furthermore, many of the policy documents are believed to be unpublished online and so were not included in this review.

5. Conclusion

Evidence on the effectiveness of supply reduction overall is available. Policies of regulating tobacco retail environment to reduce tobacco availability are effective, feasible, and already implemented. The extent of their implementation differs, mainly that the ones covered by the WHO FCTC are more widely implemented.

This review flagged that a wide range of policies not covered by the WHO FCTC are implemented by countries, however not much research is conducted to assess such polices or to evaluate the process of their implementation. This review documented the countries innovation in terms of policies to reduce tobacco availability by regulationg retail environment with overall 12 polices not covered by the WHO FCTC. There is a potential for these policies to be scaled up at global levels as a theme for tobacco control, a crutial step to do that could be a decision from the WHO FCTC Conference of Partices to require research and implementation of such policies.

Author contributions

RA conceptualized this review, gained the ethical approval, and collected the data through searching the WHO FCTC and Protocol documents, gray literature review, Focal Points survey study, and databases review and did the data analysis and synthesis and prepared the first draft of the manuscript. ZA did the initial database search and supported in the screening of databases results. MB supervised the implementation of this study and provided feedback during the manuscript preparation. All authors read and agreed on the final manuscript.

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/fpubh.2023.975065/full#supplementary-material

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Digital health in the era of COVID-19: Reshaping the next generation of healthcare

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COVID-19 is one of the most deadly diseases to have stricken us in recent decades. In the fight against this disease, governments and stakeholders require all the assistance they can get from various systems, including digital health interventions. Digital health technologies are supporting the tracking of the COVID-19 outbreak, diagnosing patients, expediting the process of finding potential medicines and vaccines, and disinfecting the environment, The establishment of electronic medical and health records, computerized clinical decision support systems, telemedicine, and mobile health have shown the potential to strengthen the healthcare system. Recently, these technologies have aided the health sector in a variety of ways, including prevention, early diagnosis, treatment adherence, medication safety, care coordination, documentation, data management, outbreak tracking, and pandemic surveillance. On the other hand, implementation of such technologies has questions of cost, compatibility with existing systems, disruption in patient–provider interactions, and sustainability, calling for more evidence on clinical utility and economic evaluations to help shape the next generation of healthcare. This paper argues how digital health interventions assist in the fight against COVID-19 and their opportunities, implications, and limitations.

KEYWORDS

digital health, technology, DHIs, COVID-19, pandemic

Introduction

The World Health Organization has suggested that countries keep maximizing the opportunities for digital health interventions (DHIs) to accelerate sustainable health development and universal health coverage. DHIs are applications of smartphones, health information technology, wearable devices, telemedicine, and personalized medicine to facilitate healthcare and attain intended health outcomes (1, 2). They enhance patient care by facilitating treatment adherence and monitoring, person-centered care, laboratory diagnosis, data management, disease surveillance, drug-safety monitoring, and professional development (3–5). Healthcare institutions are looking for digital health innovations to improve care quality by integrating various technologies. However, there are impediments that countries, especially those with limited resources, face when implementing digital health, calling for a good grasp of how to develop appropriate strategies to benefit the most of digital health-enabled patient-centered health systems (5, 6).

Even though COVID-19 has caused massive problems in the healthcare system, it has forced the majority of countries to bridge the DHI gap (7). Different studies across the globe assessed the potential of DHIs in the fight against COVID-19, including their role in service delivery, health literacy, disease surveillance, treatment and vaccination, and program follow-up (7–10). At the start of the pandemic, innovative digital health-based analysis of social media data and news reports assisted in forecasting the spread of the disease. Social media platforms and features open up new avenues for educating people including hard-to-reach, recruiting participants in therapeutic trials, and remote-delivering of healthcare. However, there are several digital health implementation challenges and opportunities across countries and territories that need to be compiled to inform policy and practice as the disease is not yet over. This perspective paper argues how digital health interventions assist in the fight against COVID-19 and their opportunities, implications, and limitations.

Opportunities for implementing digital health interventions in the era of COVID-19

The COVID-19 pandemic served as a veritable testing ground for emerging digital health concepts and practices. DHIs provide enormous support in the social distancing time that interrupted healthcare service delivery. The application of telemedicine has facilitated service continuity with great potential to protect both patients and care providers (11). Hospitals' closure forced the public to seek and practice alternative digital health solutions such as smartphones to connect with their clinicians and follow-up routine care (8, 12). The use of digital health for COVID-19 screening reduced the number of visits to emergency departments while also improving healthcare system organization (13). mHealth, telemedicine, eHealth, and a variety of other mobile applications rose to prominence during lockdowns and were widely used for diagnosis, clinical care, and patient follow-up, demonstrating their potential beyond serving marginalized and underprivileged communities (14).

Virtual communication platforms facilitated remote interactions between healthcare professionals and patients, as well as the creation of operational management dashboards for optimizing workflows, resources, and patient-centered care. Several healthcare institutions have been drawn to cloud technologies in order to implement discrete COVID-19-related functionality such as testing, diagnostics, monitoring, triage, and patient consultations. large numbers of research papers accessible through the COVID-19 Open Research Database can be analyzed quickly using machine learning to extract relevant knowledge about drugs that might be beneficial for the treatment of COVID-19. By generating data summaries from multiple sources, artificial intelligence platforms enabled real-time monitoring of patients in high-risk settings for COVID-19. Insurance companies use of health-tracking reward programs that encourage the application of wearable health technologies, though implementation has been straightforward.

We have included case studies from three different countries to demonstrate how DHI has been used to support the healthcare system during the pandemic.

Abbreviations: DHIs, digital health interventions.

Case 1: China

In response to the pandemic, a hospital in China's Guangdong province that is well-known for its smart services used an existing platform to launch COVID 19 responsive services. These included information hubs, e-Consultation and screening, remote symptom monitoring, and psychological support. The system was web-based and linked users from social media sites (WeChat Facebook/Twitter equivalent), a phone App, and a website. The hospital reported that they saw a drastic drop in outpatient visits during the pandemic lockdowns but recorded high usage of the online services even at the height of the pandemic. This implies that more people had been restricted access to physical health services but they still got the healthcare services through DHIs. They also reported that the system allowed them to better triage patients who needed emergency response by providing remote care and hence, reducing the workload on clinicians and encouraging social distancing (15).

Case 2: Kenya

A provider-to-provider (P2P) asynchronous telemedicine model developed and implemented during the second year of COVID-19 in Kenya facilitated the delivery of essential health services (16). Since 2011, the Addis Clinic telemedicine platform has been providing access to specialized medical experts for frontline healthcare providers treating patients in low-resource settings. Healthcare providers heavily used this digital health platform in Kenya during the outbreak, indicating they found it very useful to them during the outbreak. Despite some of the infrastructure and network connectivity challenges present in the country, the provider-to-provider telemedicine platform was a viable option for receiving clinical recommendations from medical experts located remotely and sustaining essential health services.

Case 3: Ethiopia

A COVID-19 e-health educational intervention in Ethiopia targeting healthcare workers delivered a series of three 1-h medical seminars on COVID-19 prevention and treatment. The study collected post-seminar evaluation data from the participants using a questionnaire. The findings demonstrated the promising potential of transitioning healthcare training and delivery from an in-person to a digital medium in low-resource settings like Ethiopia (17). COVID-19 had a significant burden on patients, healthcare providers, and the healthcare system in general in Ethiopia, where the Ethiopian government and its partners intervened to sustain healthcare services (18–20).

Case 4: Vietnam

Since the beginning of the COVID-19 pandemic, seven major digital applications have been implemented in Vietnam (21). They have been classified into four categories based on their main purpose, including surveillance and contact tracing, health communication, telemedicine, and Artificial Intelligence to support diagnosis and treatment. The eCDS software was primarily focused

on reporting case-based hospital admissions *via* an electronic system. Furthermore, two mobile apps (NCOVI and Vietnam Health Declaration) were created to record electronic health declaration forms for domestic and international travelers for case monitoring and surveillance (21).

Challenges and limitations to implementing digital health technologies

Despite a history of public health crises, data-sharing agreements and transactional standards do not exist uniformly between institutions, impeding a foundational infrastructure to meet data-sharing and integration needs for public health advancement. COVID-19 has revealed not only the need for data sharing but also the importance of serious evaluation and ethical considerations in the emerging field of digital health (22, 23). One of the main challenges in the biomedical research community and one of the contributors to international information sharing is maintaining control over the constantly generated data while simultaneously promoting their active use for generating scientific discoveries. Obtaining informed consent has been also a significant challenge in providing transparency about the kind of documents collected and which third parties able to access patient's data. Procedures were carried out remotely and/or *via* electronic consent during the pandemic; however, not all healthcare facilities were prepared to provide digital consent, prompting some scientists to create their own way of acquiring consent and electronic signature for participants in therapeutic trials. Issues such as potential participants' access to technology and an absence of user-friendly functionalities to interpret consent documents exacerbated the preceding problem of having complicated, lengthy, and technical consent documents in studies that used e-consent platforms.

There is a desperate need for strengthening resource capacity for effective implementation and evaluation of digital health technologies, taking into account the needs and priorities of countries (24–26). Inequalities in infrastructure and access to the internet and electricity are among the major challenges in the implementation and scale-up of DHIs in resource-limited settings. Digital health technologies were recommended to help patients adhere to their treatment; however, for optimal implementation

of such technologies, trials evaluating the effectiveness of remote treatment are critically needed (19, 27–29).

Digital health literacy in the general population often determines the acceptability and adaptability of digital health solutions in a given country and this has been witnessed in the era of COVID-19. Low levels of digital health literacy were found to have a significant association with an individual's COVID-19 precautionary practices, information accuracy, vaccine hesitancy, and subjective wellbeing (30–34). The lack of qualified and skilled professionals in digital health is one of the main barriers to digital health applications, especially in resource-constrained settings (35).

In many resource-limited countries, the lack of policies and strategies, governance structures standard operating procedures, and financial resources hamper the successful deployment and implementation of DHIs (35). Sufficient and sustainable financial mechanisms are not in place for large-scale deployment of approved DHIs. Significant number of such technologies are not culturally adapted to incorporate the local context and facilitate easy understanding by patients and providers (36). The move away from traditional face-to-face care and treatment to digital health-enabled remote care and monitoring was not straightforward and the pros and cons vary by country, program, and the type of digital health technology employed (37).

Discussion

During the COVID-19 pandemic, there were a large number of patients seeking healthcare, putting a significant strain on healthcare providers. As a result, remote patient monitoring and the use of mHealth applications became an essential part of healthcare delivery. Telemedicine for remote consultation and the use of health devices such as pulse oximetry was a pivotal DHI in the COVID-19 pandemic. As mentioned in the case studies, applications designed for patient surveillance and contact tracing were crucial in reducing the pandemic's impact. The pandemic brought all stakeholders' priorities in various aspects of digital health adoption in line, including expedited regulatory approval of clinical studies. However, the widespread use of DHIs has been hampered by a lack of infrastructure, equitable access to the internet and electricity, and evidence-based digital health standards and data governance systems.

In the COVID-19 era, electronic medical records provide large amounts of data that can be used to generate research evidence, but

TABLE 1 Implications of the paper for digital health interventions policy and practice in the era of COVID-19.

Current situation and problems	Suggested solutions
Lack of uniformity in data sharing among institutions	Creating standardized system
Unable to take proper consent during the pandemic	Preparing a digital signature for taking a remote consent
Difficulty using digital health technologies by healthcare providers and patients	Giving proper training
Poor infrastructure for DHI implementation	Political and stakeholders' commitment
Issues of confidentiality and privacy	Establishing standards for data governance systems and anonymization of the identification of the person
Lack of evidence and supporting strategies that describe in detail how DHIs can influence health outcomes, health system efficiencies, and service delivery cost-effectiveness	Conducting evidence-based researches

these data require quality assurance and valid sampling procedures. Such disadvantages reduce the quality of research driven by data captured through digital health. Privacy is a concern in the digitalization of health care, where data generated by digital health must be safeguarded. It is also important to clearly explain to all stakeholders how their data will be used and protected.

DHI implementation during COVID-19 faces some unique challenges in resource-constrained settings. There were reservations and uncertainties regarding the use, adaptation, and integration of DHIs into the wider scope healthcare system before COVID-19, which slowed information dissemination and prompt responses. In these settings, insufficient financial resources, electricity supply, internet connectivity, and a trained workforce impede DHI implementation during COVID-19.

Because of their diverse nature and types, the lack of homogeneous interventions creates a major obstacle in implementing DH interventions. Such distinctions may limit model generalization and understanding of DH effectiveness (13, 78). During the pandemic, most low- and middle-income countries faced serious issues with the practicability and desirability of digital technology by care providers. This is due to a shortage of training on new technology tools, insufficient technical assistance, internet connectivity problems, and also other administrative complexities. Thus, care providers in those countries find it difficult to adopt and use digital health solutions in the healthcare system. Acknowledging that many patients need recommendations or guidance, the use of digital technologies in providing guidance services has already been previously deployed in some countries and can be adopted as an alternative to physical visits in hospitals.

We can conclude from the preceding discussion that DHIs have enabled countries to mitigate the impact of the COVID-19 pandemic, paving the way for and reshaping the next generation of healthcare. COVID-19 has aided in the massive deployment of DHIs for immediate outbreak response. To better move the DHIs momentum forward and sustainably mitigate COVID-19, equitable access to approved digital health technologies, political commitment, collaboration, stakeholder cooperation, and workforce capacity building are required. Beyond COVID-19, there may be an opportunity to set an additional focus and implement policies throughout the health system to support the potential use of DHI solutions.

The implication of this paper for policy and practice is summarized in Table 1.

Data availability statement

Publicly available datasets were analyzed in this study. This data can be found here: https://osf.io/gvm2z/.

Author contributions

Acknowledgments

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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Settings for the development of health literacy: A conceptual review

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Advances in conceptualizing settings in health promotion include understanding settings as complex and interlinked systems with a core commitment to health and related outcomes such as health literacy. Traditional settings for the development of health literacy include health care environments and schools. There is a need to identify and conceptualize non-traditional and emerging settings of twenty-first-century everyday life. The aim of this conceptual review is to inform a conceptual model of a "non-traditional" setting for the development of health literacy. The model uses the example of the public library to propose four equity-focused antecedents required in a setting for the development of health literacy: the setting acknowledges the wider determinants of health, is open access, involves local communities in how it is run, and facilitates informed action for health. The review concludes that a settings approach to the development of health literacy can be conceptualized as part of a coordinated "supersetting approach," where multiple settings work in synergy with each other.

1. Introduction

The World Health Organization has long recognized that settings can be health-promoting or health-threatening: "[i]f health is everywhere, every place or setting in society can support or endanger health" (1) (p. 65). The Ottawa Charter for Health Promotion (2) views health as "created and lived by people within the settings of their everyday life; where they learn, work, play and love" (2) throughout the life course (3). "Settings for health" is used in this review as defined in the latest edition of the Health Promotion Glossary of Terms (4) (p. 30):

> The place or social context where people engage in daily activities, in which environmental, organizational and personal factors interact to affect health and wellbeing.

Health literacy is a domain of health promotion and enables people to access, understand, appraise, remember, and use information about health (5). Health literacy can be developed through interaction with, and is influenced by, settings such as health care environments (5) and schools (6) but there is increasing recognition that it can also be developed in "new" and emerging settings for health, such as online settings (social media and virtual reality) and hybrid settings (settings with physical and online manifestations; augmented reality) (7–11).

One of the Ottawa Charter's action areas focuses on creating "supportive environments" for health, but the Charter has not formally kept pace with the expansion of everyday settings for health (12) to include e.g., online settings (13), or "where people google" (14). More recently, the World Health Organization has referred to "enabling environments," which "support people to access, understand, appraise, remember and use information about health" (i.e., develop health literacy), "for the health and wellbeing of themselves and those around them, within the circumstances and demands of their daily lives" (15). A rapid review of settings for raising awareness of health inequities (16) has suggested several types of non-traditional settings for health: online, faith-based, night-time economy, green ("eco") and temporary pop-ups. Reviewing the settings approach from alternative angles and categorization, e.g., by opening hours, ecological footprint, and permanence, can revitalize the evidence base and ensure that it retains relevance.

The supersetting approach, or "settings approach 2.0" (17), is one such revitalization. It is a multisetting approach to health that emphasizes "the need for coordinated activities to be carried out in a range of different settings within a local community with the aim of attaining synergistic and sustainable effects" (3) (p. 30–31). This paper outlines a conceptual review of settings in the context of the settings approach in health promotion. The conceptual review informs a conceptual model of an example "new" setting, the public library, as a community-based setting for health and health literacy when part of a wider supersetting approach. The public library is selected as an illustrative example with four antecedents conducive to health literacy development. The antecedents are reported in more detail elsewhere (18); this review focuses specifically on the relevance of the settings concept to health literacy.

Community-based and informal education settings broadly accessible to people include "extended classrooms" such as "parks, shopping centers, community centers, or libraries" (19) (p. 146). The public library is the example case used in this paper, for several reasons. Within the field of public health, public libraries constitute a comparatively unique but under-utilized community partner, particularly in rural areas (20–22). Public libraries' reach is inclusive of otherwise marginalized communities, such as school-excluded children and the homeless. Conceptualizations of public libraries as responsive and active community hubs for health-related activities and information-seeking highlight their provision of flexible physical and virtual space, informal learning opportunities, and curation of free access to local and global health information services (23, 24). Library-based resources include the staff, some of whom will be trained information professionals with an understanding of health communication, infodemiology, and the determinants of health relevant to the communities they serve (25). Many public libraries have a consumer health librarianship function (26) and "routinely assist patrons with unmet health and social needs" (27) (p. 1).

Despite evidence internationally in support of the potential role of the public library in public health and, to some extent, health literacy (23, 28, 29), this setting constitutes a missed opportunity: it is not considered a "traditional" setting for health (30). The current conceptual review therefore uses the public library as an example to explore the potential of non-traditional or emerging settings for health and health literacy.

2. Methods

The importance of settings as a concept for the promotion of health is longstanding and there is a significant body of literature that explores the concept (31) and its practice (3), and yet its theoretical basis is contested (32, 33). A conceptual review examines the discursive scaffolding of a concept and contributes more nuanced understandings of the connections between that concept and empirical evidence (34). Revisiting the literature *via* a conceptual review can foster "revitalization of existing theory," or even "novel conceptual insights" (35) (p. 28).

A conceptual review of the settings-based approach was conducted using a systematic process of searching across databases and gray literature, and reading the retrieved literature critically to map and clarify this concept in its historical and social context (34). While the review was conducted systematically, it differs significantly from a systematic review. One such difference is the way in which a conceptual review is reported: there is no extension to PRISMA available for the conceptual review type, and therefore conceptual review reporting tends to be discursive in nature. The process incorporated five stages: establishing the parameters of the concept under review, integrating and synthesizing the evidence base (both conceptual and empirical), resolving inconsistencies and tensions, highlighting gaps in the existing literature, and outlining an agenda for future research (35).

The first stage involved defining the settings-based approach in health promotion and distinguishing it from related concepts by formulating and applying eligibility criteria to separate out instances of conceptual conflation and terminological confusion. The second stage used citation analysis of canonical or pertinent sources (3, 13, 17, 31, 33, 36) to comprehensively trace the development of the settings concept and its theorization. Inconsistencies and ambiguities, e.g., between definitions and operationalizations of the concept, were resolved systematically by grouping the amassed evidence into research "streams" that could be examined side-by-side (35). This examination led to the next stage: gap or "tensions" analysis, focused specifically on where an absence of evidence or the presence of tensions limited the ability of the settings-based approach to evolve and respond to twenty-first-century determinants of health. The conceptual tensions identified are reported in the Results.

3. Results

The results of the conceptual review are presented as themes that each reveal a tension in the narratives around settings and ways in which the concept has been clarified or developed, such as using complexity theory to represent settings as systems. Overlapping concepts identified from the literature are used to organize the results based on how the public library setting is understood: as a "setting for health," a "system," a "health-literate organization," or part of a supersetting approach. The results inform a conceptual model of the public library as part of a supersetting approach.

3.1. Settings for health and health literacy

The conceptual review provides insight into what is known about "settings." In health promotion policy and literature, "setting" is used in two ways: health promotion *in* a setting (where the setting serves as the location for individually-oriented lifestyle interventions), and settings-based health promotion (where the setting *is* the health promotion intervention) (3, 32). In the 2021 update to the Health Promotion Glossary of Terms (4), under a new entry for "environmental determinants of health," settings for health are referred to as providing the "structure for practical action" (p. 15). Action also appears under the "settings for health" entry itself, where the indicator that "people actively use and shape the environment" differentiates settings for health from "a setting as the basis for delivery of a specific service or programme" (p. 30).

The emphasis on "traditional" settings for health—"healthy cities; health promoting schools; healthy workplaces; healthy islands; health promoting hospitals; health promoting prisons and health promoting universities" (4) (p. 30)—can circumscribe applications of the settings-based approach. This selectivity is beginning to change with the induction of non-traditional settings, such as healthy stadia and airports, into the evidence base, "some through formalized initiatives led by the WHO and other bodies, others emerging through pilot studies and projects" (33) (p. 12); the public library is an ongoing example of the latter route (18, 21, 29).

3.2. Settings as systems

The settings-based approach understands settings as complex systems with inputs, throughputs, outputs, and impacts (32) in relation to a wider environment (including other settings). This complexity requires drawing on "multiple theories from multiple disciplines, rather than one overarching theory" (32) (p. 15) to consolidate knowledge of how settings-as-systems work. In the UK and other countries, the public library is organized and referred to as a "system" of distributed local branches.

Socioecological models identified in the conceptual review span theoretical stances and include a model of a non-traditional setting (a sports club) that shows the reciprocal interaction between setting- and individual-based factors for health at macro-, meso-, and micro-levels (37), and a model integrating a socioecological framework with health literacy at functional, interactive, and critical levels of enablement (38). Both make use of the visualization of health determinants as a "rainbow" of proximal and distal influences (39).

A further model identified in the review refers to an "equity-focused settings approach," or "settings praxis" (40) that attends to health determinants, addresses the needs of marginalized groups, catalyzes change in a setting's structure, and involves stakeholders. The model engages with complexity theory to view settings as complex, decentralized systems that are organic, non-linear and emergent. It takes the form of a conceptual framework with six guiding principles: a holistic (whole-system) orientation; "start where people are"; place-based and joined-up practices; in-depth sociopolitical analysis; an asset-based approach; and a capabilities approach to health. Collectively, these principles position settings-as-systems in which health literacy, in systems terminology, is an active throughput.

Work on healthy universities (32) suggests that investigations into settings should identify the extent to which the setting promotes health through its policies and expressed purpose (core business). However, a successful settings-based approach, viewed from a systems perspective, is one of homeostasis: an ideal state of healthful, dynamic equilibrium whereby health becomes "business as usual" so seamlessly that it is difficult to evidence and separate out the settings-based approach as a factor (41). Using the settings-based approach to guide identification of the antecedents that need to be in place to constitute a supportive and enabling environment for health and health literacy therefore requires overcoming the challenge of documenting a successful settings-based approach within the system (i.e., when health literacy becomes systemic) (41). It is not within the remit of this review to resolve the challenge of evidencing a successful settings-based approach, only to conceptualize, based on evidence, what such an approach might entail.

3.3. Health-literate organizations

Another concept in the literature is health-literate organizations (HLOs), which by design support people to "systematically orient their daily routines toward HL [health literacy]" (42) (p. 464). HLOs "equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others" (43) (p. 1,084).

The HLO concept has several related terms, including organizational health literacy, health literacy-friendly organizations (6, 44, 45), and "organizational health literacy responsiveness" (15). Organizational health literacy "comprises a settings-based approach aiming at changing organizational conditions to enhance health literacy of relevant stakeholders" (46) (p. 1). It is underpinned by a set of auditable attributes of a "health-literate" organization (44, 47). There is potential for health-promoting settings and health-literate organizations to:

> Work side by side (if not together), complementing each other [...] Settings that have adopted a health promotion approach can easily become health literate settings and vice versa, because structures and processes have already been reoriented and important changes (including awareness) have already been implemented (48) (p. 888–889).

Organizational health literacy responsiveness is defined as:

> The extent to which health workers, services, systems, organizations and policy-makers (across government sectors and through cross-sectoral public policies) recognize and accommodate diverse traditions and health literacy strengths, needs and preferences to create enabling environments that optimize equitable access to and engagement with health

information and services, and support for the health and wellbeing of individuals, families, groups and communities (15) (p. x).

To date, the HLO concept has been mainly used with health care environments (47), and recently schools (46). To approach the public library as a HLO, or facilitate the process by which it can become one, requires a reorientation in the literature toward non-traditional or emerging settings without (yet) an accepted "health-promoting" or "health-literate" prefix, nor their own set of HLO principles. Part of such a reorientation would need to consider the antecedents for a setting to be considered an active, enabling, and responsive HLO.

3.4. The example case of the public library as part of a supersetting approach

The settings-based approach is "explicitly determinants-focused" (13) (p. 46). When implemented in line with this commitment, the approach changes the way people's environments are organized (13) and involves people in this change. It shares the Ottawa Charter's set of tenets that health promotion practice be enabling, participatory, holistic, intersectoral, equitable, sustainable, and use multiple strategies for health in combination (49). Based on these tenets, and the framework for settings praxis identified in the conceptual review (40), a determinants- and equity-focused settings approach is proposed and presented in a conceptual model that aims to engage with the complexity of health promotion interventions.

Conceptual models provide a reference-point for theorizing settings-based approaches and a reminder to attend to the interconnection between macro-, meso-, and micro-levels of a setting that inform a socioecological, whole-system perspective (32). The conceptual model here posits four antecedents that would need to be in place in, for example, a public library as a supportive and enabling environment that optimizes individuals' equitable access to and engagement with relevant health information and services (5, 18).

The identified antecedents are as follows:
A public library…

1. Acknowledges the wider determinants of health
2. Is open access
3. Involves local communities in how it is run
4. Facilitates informed action.

Figure 1 shows the conceptual model.

The model makes use of the visual shorthand of a "rainbow," common to other models from the conceptual review (39), to represent the socioecological structure and operational levels of the public library. The library is shown as open to the wider environment (inputs from this environment include staff, funding, library branch facilities and resources; governance, policy, and school settings that influence library priorities; and additional potential partner settings for health). This is relevant to the tension between health promotion *in* a setting and a comprehensive settings approach: the partner settings depicted here are intended to

support a comprehensive approach. Further example settings could include sports clubs and healthy universities, based on their steady emergence in the settings literature as non-traditional settings for health and health literacy (7, 9, 37, 50–53).

All four antecedents are holistic (i.e., they span the system) and work intersectorally (with porous boundaries to facilitate partnership work with other settings). In the example of the public library, all four antecedents are in place and position the library as part of a wider network of settings (or systems, or HLOs). The model demonstrates the "connectedness" (17) (p. 10) of this setting vertically (macro–micro) and horizontally (intersectoral collaboration across settings). The public library is strengthened through the participation of individuals interacting with it and other everyday settings over the life course (54): a supersetting approach.

The supersetting approach is a socioecological approach that builds on local knowledge and resources, is context-sensitive, and emphasizes participation (55). It is intended "to mobilize local communities for public health action through coordinated and integrated engagement of multiple stakeholders in multiple community settings" (56) (p. 2). It welcomes complexity (57) and recognizes the need to combine bottom-up, micro-level actions for health with (managed) top-down, macro-level influences (55) (p. 61).

The supersetting approach, as an intervention strategy for comprehensive community interventions, works through coordinated engagement of multiple stakeholders in multiple settings to mobilize local resources and support collective community action (55). It has five core principles: integration (coordinated action across specific settings); participation (people are motivated to take ownership of processes of developing and implementing activities); empowerment (there are opportunities for equity-focused action on authentic, relevant issues); context-sensitivity (people's everyday life challenges are respected and considered when developing and implementing activities); and knowledge generation and sharing (knowledge produced from coordinated activities is used to inform future activities) (17, 55, 57).

Advances in the supersetting approach are linked to Scandinavian public health research. The demonstration project SoL (from the Danish *Sundhed og Lokalsamfund*, "Health and Local Community") marks the entry of the supersetting approach into the literature (17) and is the focus of several related papers. Citation analysis demonstrates that the public library is part of the historical development of the supersetting approach: *biblioteket* (library) appears as a label in a figure of the supersetting approach based on the 2014 original (58). By 2021, the presence of the library (joined also by "museum" and "sports club") in the illustrative figure of the supersetting approach has passed into the English-language supersetting literature (59), separately from the Danish project SoL.

The supersetting approach can be linked with the settings concept of "projectism" (31) (p. 200), i.e., when "the theoretical framework guiding the work may be rooted in systems thinking and organizational development," but practice is "constrained to smaller-scale project-focused work around particular issues" (60) (p. 56). Projectism is not incompatible with a comprehensive settings approach if the project—e.g., library-based health
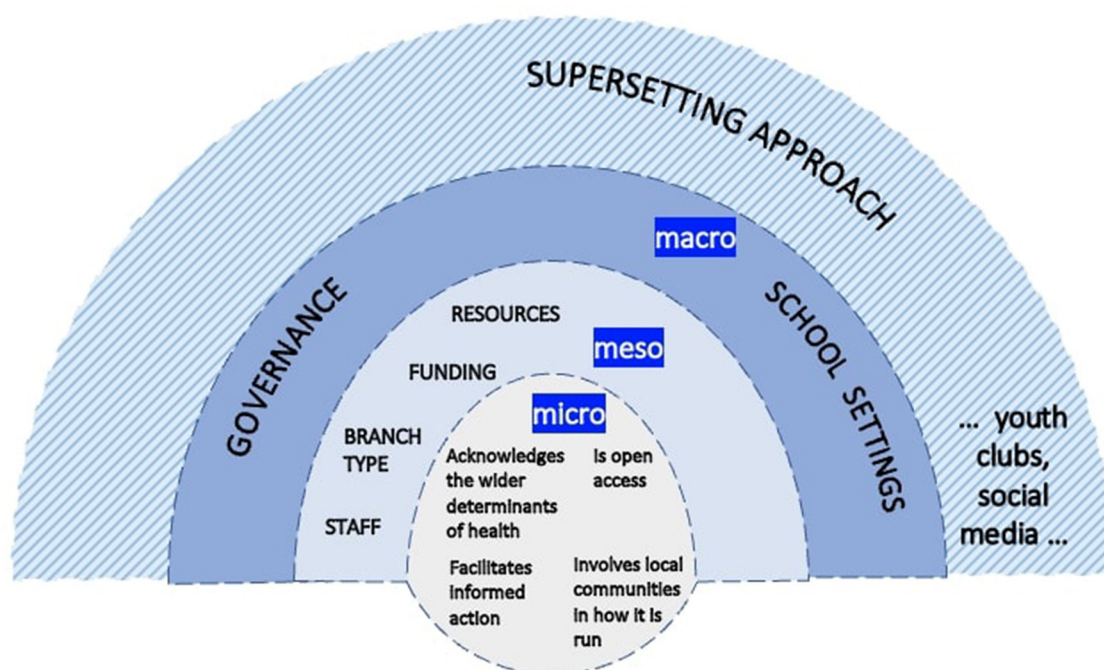
FIGURE 1
Conceptual model of the public library as part of a supersetting approach for health literacy development.

initiatives organized with partners—model "an inclusive and participative ethic" and "dynamic orientation" (21) (p. 893) commensurate with the supersetting approach.

4. Discussion

The conceptual review highlights how so-called non-traditional settings might support and enable the "project" of health literacy if this project is a collective endeavor, undertaken with support from other settings. It contributes a conceptual model of the public library (an example of a non-traditional setting) operating as part of a supersetting approach. The model theorizes the antecedents that need to be in place for the public library to be an enabling environment for health and health literacy in partnership with other settings, and points toward further areas for investigation.

To progress from health promotion *in* settings to active "settings for health," the conceptual review proposes a coordinated supersetting approach. The supersetting approach is increasingly discussed in the literature (61, 62), but the most up-to-date handbook available for settings-based health promotion has few sustained discussions of it; the most substantive discussion refers to schools:

> Actions in a school will be more effective when school activities are embedded in the local community, which will provide synergistic effects. This has been elaborated in the "supersetting" approach [. . .] that summarizes sustainable approaches to optimized health, wellbeing and quality of life, and involves mobilizing the local community (63) (p. 109).

Many of the settings listed by the World Health Organization as settings for health do not have all the modeled antecedents consistently in place, including Health Promoting Schools (HPS). HPS are frequently represented in the literature as promoting health (30) and health literacy (64) early in the life course, but are limited in the support they can provide for facilitating "practical action" on health (4): children are not routinely encouraged to actively shape the school environment much beyond e.g., school council activities (65, 66). The conceptual model therefore includes schools, based on previous research into the settings that significantly influence library-based health promotion (18), but supplements this traditional setting with other settings that have different strengths and weaknesses in relation to the antecedents and penetrate people's lives at different stages of the life course.

Considering that health literacy is a setting-specific social practice (5), focusing on health literacy as a complex throughput in settings, and integrating settings into a supersetting approach that spans the life course (54), may advance population health literacy development and ensure that the settings concept continues to be relevant and responsive to future determinants of health.

5. Conclusion

This review has synthesized research and gray literature on settings from the 1980s to date. The results delineate how, despite the longstanding importance of settings for health and the settings approach in the development of health promotion and World Health Organization strategy, theorizing about settings remains under-developed (67). The review highlights some key

conceptual challenges, including overlapping terms in the settings literature and theories from distinct disciplinary traditions (e.g., a systems perspective and health literacy responsiveness). The model developed from the conceptual review is helpful in providing a starter overview of antecedents to look for and in suggesting partnership opportunities between settings that collectively achieve the full complement of antecedents.

Understandings of the antecedents required so that settings can develop into settings for health and health literacy are advanced by a systems perspective and a supersetting approach that brings together multiple (traditional and non-traditional) settings to create and sustain supportive environments for health. This review has used the example of the public library to show the potential for a non-traditional setting for health, when part of a supersetting approach, to promote health and develop health literacy as "a whole-of-society endeavor—at the individual, community, and national level" that works "across sectors, not just health" (68). The direction of travel in a recent editorial in response to a World Health Organization report on health literacy development for the prevention and control of non-communicable diseases (5, 15), calling for "an integrative approach to develop health literacy interventions that involve a range of community-based organizations—not just medical centers—including schools, churches, sports groups, and workplaces" (68), is encouraging. But, in neither citing nor naming the supersetting approach that could potentially integrate such traditional and non-traditional settings, both the report and the editorial demonstrate the need to continue to review and refine the concept of settings.

Author contributions

Conceptualization and writing—review and editing: CJ, SS, and JW. Writing—original draft preparation: CJ. Supervision: SS and JW. All authors have read and agreed to the published version of the manuscript.

Funding

Acknowledgments

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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Contextual and environmental factors that influence health: A within-subjects field experiment protocol

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Background: Despite the growing research on environment-physical activity (PA) relationships, field experimental studies are limited. Such studies offer opportunities to focus on real-world environmental exposure and related PA and health outcomes, allowing researchers to better isolate the causal effect of exposures/interventions. Focusing on the street/pedestrian environment as a routine setting for people's daily activities, this research aims to develop and test a field experiment protocol that integrates instantaneous assessments of the environment, PA, and health outcomes. The protocol involves the use of state-of-the-art environmental monitoring and biosensing techniques and focuses on physically active road users (pedestrians and bicyclists) who are more directly exposed to their surrounding environment than others such as drivers.

Methods/Design: An interdisciplinary research team first identified the target measurement domains for the health outcomes (e.g., stress, thermal comfort, PA) and the street-level environmental exposures (e.g., land use, greenery, infrastructure conditions, air quality, weather) guided by the previous literature which was primarily observational. Portable or wearable measurement instruments (e.g., GPS, accelerometer, biosensor, mini camera, smartphone app, weather station, air quality sensor) were identified, pilot tested, and selected for the identified measures. We ensured that these measures are readily linkable using the time stamp and include eye-level exposures as they impact the users' experiences more directly yet missing in most prior studies relying on secondary, aerial-level measures. A 50-min experimental route was then determined to include typical everyday environments in park and mixed-use settings and to engage participants in three common modes of transportation (walking, bicycling, and driving). Finally, a detailed staff protocol was developed, pilot-tested, and used in a 36-participant within-subject field experiment in College Station, TX. The experiment was successfully executed, showing its potential to support future field experiments that can provide more accurate real-time, real-environment, and multi-dimensional information.

Discussion: Our study demonstrates the feasibility of capturing the multifold health benefits/harms related to walking and bicycling in varying urban environments by combining field experiments with environmental, behavioral, and physiological sensing. Our study protocol and reflections can be helpful for a broad spectrum of research addressing the complex and multi-level pathways between the environment, behavior, and health outcomes.

1. Background

Physical activity (PA) protects against various chronic diseases (1) and promotes overall health and wellbeing (2–4). Walking is a versatile and popular form of PA, especially among vulnerable and at-risk populations. The 2015 US Surgeon General's Call to Action to Promote Walking and Walkable Communities by the US Centers for Disease Control and Prevention not only recognizes PA as one of the most important preventive strategies to maintain good health but also emphasizes the significant roles of "places" in supporting walking and health (5).

With the growing recognition of the health-significant roles of the environment, there has been a steep increase in both the quality and quantity of empirical studies aimed at linking the environment and health outcomes. PA, especially walking, is among the most popularly studied health outcomes in this line of research. Literature has documented the neighborhood planning and spatial configurations that support PA or walking, such as higher development density, land use mix, street connectivity, and greenery coverage (6–9). Design attributes of the environment have also been linked with walking, including shade conditions, visual quality, and street/building design (10). In addition to these built environmental features, safety (from crime, traffic, and other injuries such as falls) and social environments (e.g., social support and social cohesion) have also been shown to be associated with walking (11, 12). However, studies have noted that significant heterogeneity exists in environmental factors that foster or hinder PA/walking depending on the target population (e.g., older adults, children, ethnic minorities) or settings (e.g., residential, commercial, forest areas; inner city, urban, suburban vs. rural communities), and these differences are not fully understood. Further, many prior studies rely on survey-based subjective measures, such as perceived availability of PA resources, visual quality, safety, and comfort (13–17). While such an approach is more feasible and appropriate for population-based studies, it is unable to provide the full and quantifiable exposure measures necessary to accurately measure their health impacts.

Further, most of the existing empirical evidence remains cross-sectional; thus, it cannot support causality or dose-response relationships between the environment and health outcomes. However, a small body of existing studies has used longitudinal or natural experimental designs (18, 19). For example, Pikora et al. have classified built environmental attributes into four categories: functionality, destination, safety, and aesthetics (20, 21). Characteristics of the urban environment, such as green space, may influence PA and the psychological and physiological conditions under which people engage in PA (22, 23). In the last decade, more natural experiments demonstrated that changes in pedestrian and public transportation infrastructures, such as cycling routes, bus and rail stops, and walking routes, are related to increased PA or walking (24). Both objectively measured and perceived

environmental characteristics have been utilized and compared in the literature (25). However, regarding the outcome of interest, most studies focused on behavioral dimensions such as mode, frequency, duration, and intensity of PA and a few limited health outcomes such as overweight/obesity, diet, and sleep physiology captured from self-reported surveys or one-time objective measures. The other domains of health, especially the instantaneous states of mood, affect, and thermal comfort during walking or other types of PA, remain understudied. Those conditions require laboratory or field experiments with rigorous real-time experimentation designs and protocols.

Laboratory experiments that examine PA or walking behaviors have typically used treadmills with simulated environments. For example, auditory and visual stimuli are presented as participants engage in various levels and/or types of PA, and their psychological and physiological conditions are assessed (26, 27). Although these studies have strong control over the intensity and duration of PA and can capture human physiological conditions and state mood during activities, the environmental stimuli used (e.g., images, projected views, video, audio, and virtual reality scenes) are often oversimplified representations of the actual pedestrian environment. Such simulated environments often fall short in delivering sensory dimensions other than vision and audition, and carry inadequate information related to heat, air pollution, and noise, which jointly influence pedestrian experience and health.

Field experiments provide opportunities for greater internal validity than observational studies, while maintaining greater ecological validity than laboratory experiments. By assessing outcomes in everyday environments, the results can be widely generalizable and policy-relevant. In the field, various physical and social environment attributes and atmospheric factors may influence pedestrian health outcomes (e.g., stress, safety, thermal comfort/risk). To date, most research has focused on the environmental factors associated with a single domain of health (e.g., physical activity, mental health, microclimate comfort). The potential synergy that walking and other forms of PA in pleasant urban environments (e.g., clean, safe, restorative, thermally comfortable) can bring, as well as the potential harms from being exposed to negative environmental conditions (e.g., air pollution, extreme heat, fall/crime/crash risks), remain inadequately investigated (28). Therefore, discussions about methods that can capture and synthesize various domains of the built environment and health through field experiments are essential.

Evidence exists from the previous literature that outlines the critical roles of land use, connectivity, and quantity and quality of greenness, as well as microclimate, air pollution, and noise exposure in pedestrian experience and health (29–31). Environmental attributes such as land use mix and greenness have been associated with the level of PA and walking (32, 33). Further, PA engaged in outdoor natural settings is related to increased emotional wellbeing and reduced tension, anger, and depression compared to activity indoors or outdoors in built spaces (34–36). As the urban outdoor environment creates complex and dynamic ambient conditions, microclimate factors such as temperature, humidity, and wind velocity have been investigated as determinants of pedestrian thermal comfort (37, 38). Air pollution exposure has also been revealed in recent studies as a major risk factor affecting the health and safety of pedestrians (30, 39). While pedestrians (and bicyclists) are

exposed to the multiple types and intensities of exposures while walking in diverse environmental settings, prior studies focused on addressing a single or limited number of exposure measures. Therefore, our knowledge is lacking regarding whether walking and biking in different environments under different exposures bring more benefits than harms, and what types of environmental features or conditions are needed to ensure sufficient health benefits (considering multiple domains of health) and sufficient protections from the potential harms.

A major barrier to addressing some of the important remaining questions in the environment–health relationship, especially in pedestrian environments, is the lack of measurement strategies to assess (a) the diverse range of environmental features, (b) individual exposure to those features, as one move through space and (c) the resulting human behavioral and physiological responses to such exposure, in a manner that is accurate, objective, real-time, and feasible and in which the individual data points from multiple instruments/sources are readily linkable. This research aims to develop a field experiment protocol that integrates the assessments of the environment, human activities and exposures, and human health outcomes using state-of-the-art environmental monitoring and biosensing devices. We focus on the street/pedestrian environment as a routine setting for people's daily activities and incorporate walking, bicycling, and driving as the most common types of activities in which humans naturally engage while in their everyday outdoor environments. This protocol can be used to support a wide range of future causal studies aimed at addressing whether and to what extent the exposure to the specific natural and built environmental characteristics impact, both positively and negatively, various health outcomes, such as safety, thermal comfort, mood, and stress.

2. Methods/Design

The Guided by a thorough review of the literature on environmental attributes pedestrian health outcomes (40), we identified the domains of variables requiring continuous real-time exposure measures to properly assess their health impacts on people using the environments for everyday activities. We then developed the study setting, participants, and protocol and selected a list of portable or wearable devices that can be used for field experiments in real-world ambulatory settings and that can generate valid, accurate, and real-time objective measures for environmental exposures (e.g., air pollution, heat, greenery), behavior outcomes (e.g., PA intensity, pace of walking/bicycling), and human health (e.g., physiological stress and thermal comfort) while engaging in common daily activities such as walking, bicycling, and driving (Figure 1).

2.1. Protocol development and staffing

The protocol of the within-subject field experiment and the measurements were developed through critical reviews of literature and several rounds of pilot testing. The team explored several candidate sites/routes for the experiment, conducted site visits and pilot testing, and finalized a 50-min study route. The experimental protocol was developed, pilot-tested, and finalized for implementation. Pilot testing involved five rounds with college

FIGURE 1
Conceptual framework.
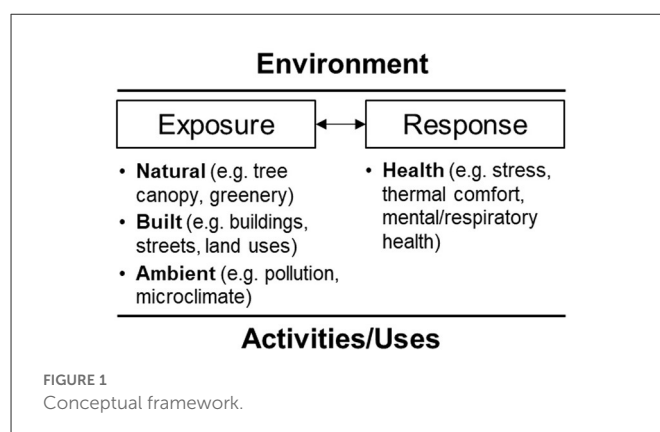
students. For the first few rounds, the team focused on testing the accuracy of the sensors and feasibility of using multiple sensors, as well as the route design to maximize the environmental exposure during the experiment and ensure reasonable participant time commitment and safety during the study during the last few rounds of testing. We modified the protocol after each round of pilot testing. Three research staff members were trained to administer this study. The detailed roles of the three researchers are described in Section 2.4.

2.2. Study setting

The study was conducted in College Station, TX, USA in spring 2021. The City of College Station had 120,511 residents as of 2020 (41), and it features a typical urban development pattern with traditional low- to medium-density residential and emerging mixed-use developments. It is anchored by a major public university and bounded by the City of Bryan. We selected two target sites within College Station for this field experiment, which represent typical settings frequently used for pedestrian/bicyclist activities in this type of community: one park (Thomas Park) with paths under canopy cover and one mixed-use housing area (North Point Crossing) with sidewalks along store fronts. The walking and bicycling segments in these two sites are connected with a driving route, completing a 50-min long experimental route which is described in detail later. Both areas are near but off the university campus, free of heavy traffic and noise, and had similar pedestrian foot traffic volumes during the hours of experiment.

2.3. Participants and recruitment

Participants were a convenient sample of students, faculty, or staff members from Texas A&M University recruited through the campus bulk email service. Individuals who were interested in participating contacted the research team to schedule the experiment. Participants were considered eligible if they met the following inclusion criteria: (1) 18 years of age or older; (2) able to walk, bike and drive without assistance; (3) have a smartphone; (4) have a valid driver's license and access to a vehicle; and (5) active at least 4 days per week. To adhere to the COVID-19 guidelines, participants were required to pass the COVID-19 pre-screening in order to participate in the

experiment. To take into account the age and gender differences in physical and physiological conditions, enrollment was stratified by age and gender. A total of 36 participants completed the experiment, of whom 10 were young adults (18–35 years old), 13 were middle-aged adults (36–55 years old), and 13 were older adults (over 55 years old). Half of the participants ($n = 18$) were female, of whom five were young adults, eight were middle-aged adults, and five were older adults. Our study coordinator contacted each eligible participant *via* email (and phone as needed) four times: first, to notify them of their eligibility and invitation to our study; second, to follow up with those who did not respond to the first invitation; third, to schedule the experiment time and location and share the study instructions; and fourth, the day before their scheduled time, to share the pre-screening COVID-19 checklist and remind them of the scheduled experiment. The study coordinator made sure to explain the overall study procedure, including walking, bicycling (using the bicycle provided by the research team), and driving (using the participant's own vehicle) activities.

2.4. Experimental route and procedure

In this 2×3 study, each participant was exposed to two types of urban environments (park and mixed-use), while completing three types of activities (walking, bicycling, and driving). Due to limitations of the linked trip in the field, a partial design without counterbalancing was developed, which involved walking in the park, bicycling in the park, driving in the park, walking in the mixed-use area, and driving in the mixed-used area. The experiments took place on sunny and partially cloudy days between 10:30 a.m. and 3:30 p.m. during a 2-month window in spring 2021 (late February to late April). This time slot was selected because of the favorable weather conditions for pedestrian activity and accurate microclimate measurements enabled by reduced diffused solar radiation around solar noon time. Each participant was assigned to the full predefined route involving walking, biking, and driving while wearing the location and physiological sensors and a compact camera attached to a cap, as well as carrying a smartphone with a trip-recording app. More information about these devices and their measures is further described in Section 2.5.

The 50-min experimental route (Figure 2) was designed to include short walking (10 min), biking (10 min) and driving (10 min) activities leading to a parking garage, and then a 10-min walking in the mixed land use area and another 10-min driving from the garage back to the starting point. These activities occur along the route through diverse land use conditions and along different road conditions (e.g., local street with and without sidewalks, collectors, and major arterials). This 50-min route is comprised of two portions. The first portion includes a 10-min walking and a 10-min bicycling in the park activities, which were considered an acceptable duration by most U.S. adults (42). For the second portion in the mixed-use area, driving and walking together took about 30 min to complete, which reflects the average commute time of 27.6 min reported by the U.S. Census Bureau (43). Walking and bicycling took place in the park and mixed-use housing areas, and the driving activities were along the roads with speed limits ranging from 20 to 50 mph.

The overall procedure of this study is shown in Figure 3. Upon arrival at the check-in point of the study site located under a picnic pavilion within Thomas Park, participants checked in with our Researcher 1 and received information about the study with an overview of the experiment. Participants were then instructed to move to the next station with Researcher 2, who explained the devices used in this experiment and instructed them to wear and adjust the devices for proper fit and high-quality data. Researcher 2 also went over the study route with the participant using both a paper map and a Google Maps link that was shared with participants to aid wayfinding. The participants were then escorted to meet with Researcher 3 to start the experiment. For the first portion with the 10-min walking and 10-min bicycling activities, participants were accompanied by Researcher 3 who pushed/rode a bike equipped with two additional pieces of equipment, a portable weather station and air quality sensor. Throughout the experiment in this first portion, participants were instructed to walk and bicycle at a pace that was comfortable to them, and the researcher kept a distance of approximately two meters behind the participants and did not intervene or talk to the participants.

After the first portion, participants drove to the mixed-use area, parked in a garage, and started the second portion, which include a 10-min walk along sidewalks in a mixed-use apartment complex and with store fronts. This portion was completed by the participants alone, again at a pace that was comfortable to them. Once they completed this short second walking route, they drove back to Researcher 1 in the check-in station, following a different driving route. The entire process including the check-in and check-out process took ∼60–65 min, and participants received a $20 gift card as a token of appreciation upon completion. This study protocol was approved by the Human Research Protection Program at Texas A&M University.

2.5. Instruments and measures

2.5.1. PA and trip characteristics
2.5.1.1. Accelerometry data
ActiGraph wGT3X wearable activity monitor (ActiGraph, Pensacola, FL, USA) was used to collect the accelerometry data that measure physical activity intensity and duration. The triaxial motion data were collected every 1/30 s, including vertical (Y), horizontal left-right (X), and horizontal front-back (Z) axes as well as the summary vector magnitude (VM). ActiGraph products have been recognized as the standard research-level device and are employed in more than 50% of research studies involving accelerometers (44). They show satisfactory validity and reliability and often serve as the gold standard for validating measurements from other physical activity monitors, such as smart phone-based sensors (45).

2.5.1.2. Classified travel data
Travel data were recorded using the Daynamica Smartphone App (University of Minnesota, MN, USA). This app integrates GPS sensing and machine learning algorithms to identify trips vs. activities and classify the trips based on the mode of travel. This app has been shown to be versatile with a user-friendly interface, and effective for various behavioral and transportation research purposes (46, 47). Raw data acquired from Daynamica included travel trajectory, travel and activity record, and travel mode.
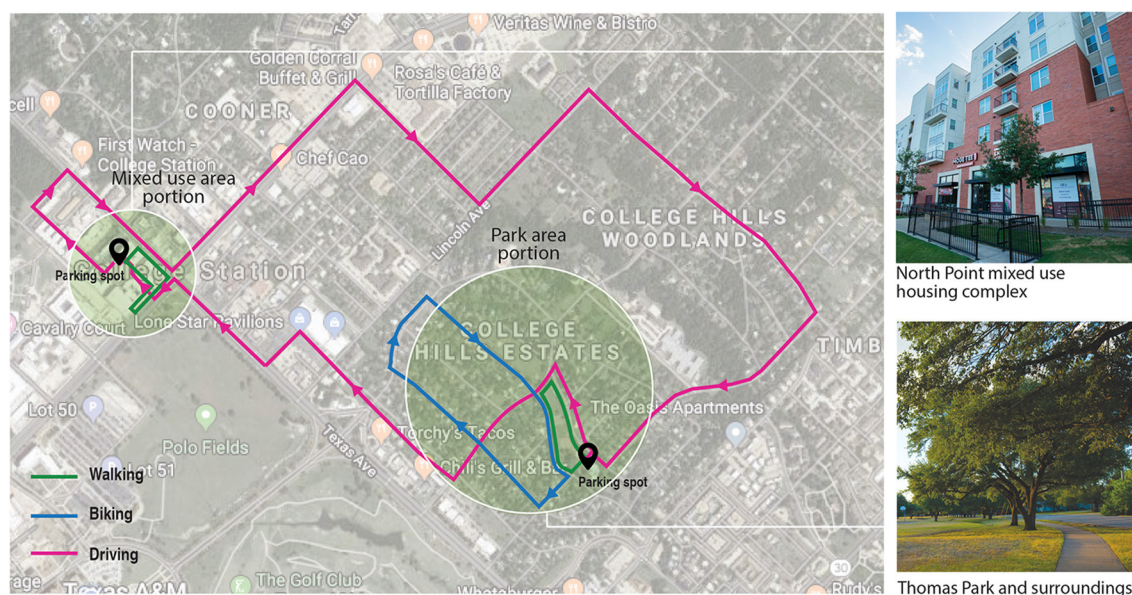
FIGURE 2
Predefined study route and mode of travel.
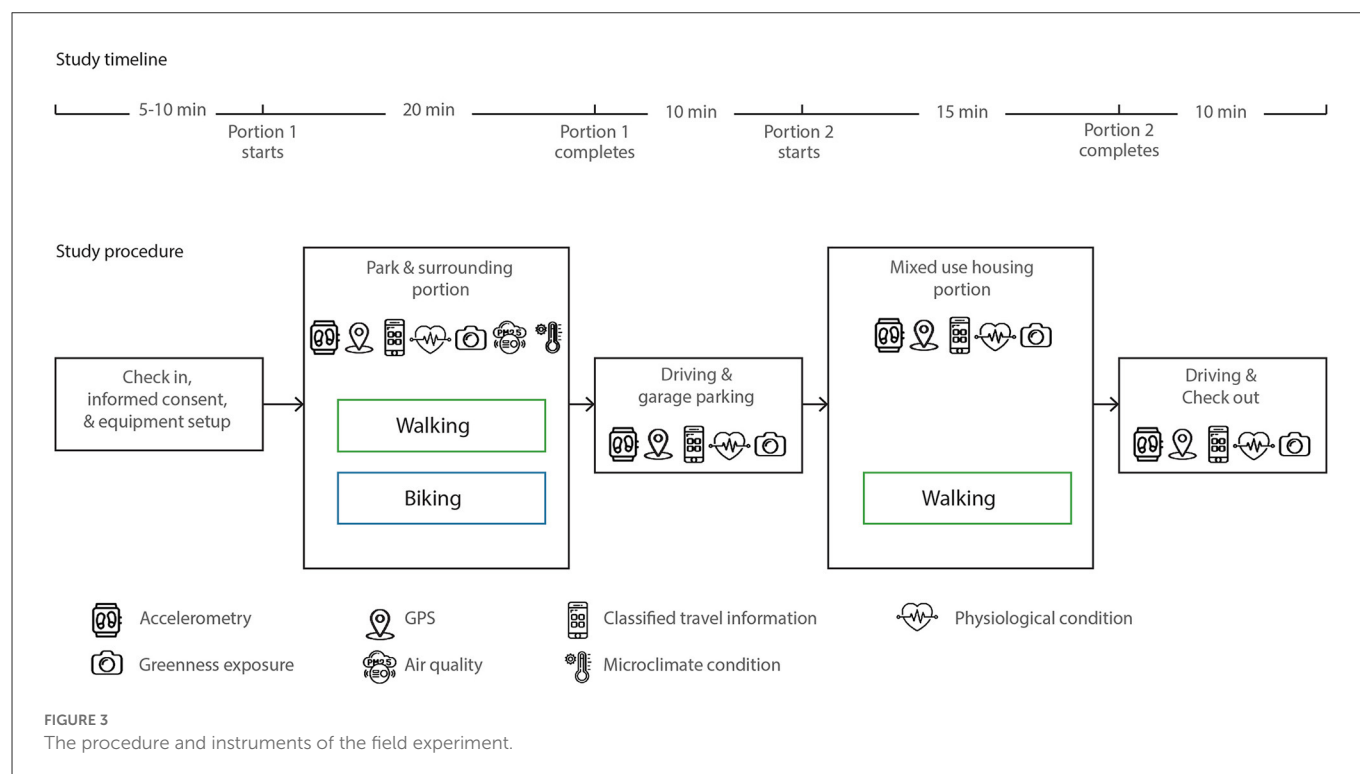
FIGURE 3
The procedure and instruments of the field experiment.

2.5.1.3. GPS locations

The Qstarz BT-Q100XT model (Qstarz, Taipei, Taiwan) was used, which logged the location every 15 s. This unit has an acceptable accuracy of 3 meters and has been used in many prior studies due to its durability, portability, and reliability (48, 49). As other instruments used in this study may not include a GPS sensor but do have time logs, the time-location pairs from the GPS logger serve to link the data across different measurements.

2.5.2. Biophysiological conditions for health measures

Real-time physiological data were collected using Empatica E4 wristbands (Empatica Srl, Milan, Italy), a validated device for unobtrusive biosensing (50, 51). The wristband combines four sensors for measuring blood volume pulse (BVP), galvanic skin response (GSR), peripheral skin temperature (ST), and triaxial accelerometry.

2.5.2.1. Blood volume pulse

BVP measures capture the peripheral pulse on a beat-by-beat basis and indicate the volume of blood in the capillary bed. A higher BVP amplitude suggests vasodilation of the capillary bed, and a lower amplitude indicates vasoconstriction. Heart rate variability (HRV) was derived from the BVP data, which represents the patterns of time intervals between successive heart beats. Time- and frequency-domain measures of HRV were extracted to monitor mental stress as related to human environmental exposure [52, 53].

2.5.2.2. Galvanic skin response

GSR measures the changes in the activation of human sweat glands, which cause the conductivity of the skin to change. GSR or skin conductance data have been used in previous research to indicate arousal in response to various tasks and stimuli [52, 54]. Although GSR can reflect thermal conditions and levels of aerobic activity, it has been employed widely to detect emotional stress and arousal.

2.5.2.3. Peripheral skin temperature

We measured peripheral temperature from distal skin, which can reflect the heat exchanges between the human body and the environment. PA and stress exposure are related to elevated or decreased skin temperature [55, 56].

2.5.3. Environmental exposure measures
2.5.3.1. Built environment

The built environment (e.g., land uses, building height, street characteristics, maintenance conditions) was captured using street audits conducted by a trained auditor as well as existing geospatial data processed in GIS. The GIS analysis utilized existing secondary, mostly aerial, data from national and local sources such as planning/transportation departments, metropolitan transportation organizations, tax appraisal offices, and U.S. Census Bureau. Audits offered more detailed data at the street level which is complementary to GIS. We used a modified version of a previously developed audit instrument with an acceptable level of reliability [57]. The audits focused on assessing features such as pedestrian amenities (e.g., bench and trash can) along each road segment; sidewalk presence and condition (e.g., presence of sidewalk obstruction, sidewalk materials, completeness, connectivity, slope, width, surface condition, and sidewalk buffer) and street characteristics (e.g., width, number of lanes, posted speed, one-way street, traffic calming device, and crosswalk).

2.5.3.2. Natural/green environment

Green spaces along the experimental route were assessed using both aerial and street-level measures. Normalized difference vegetation index (NDVI) and tree canopy cover measures were derived from the National Agriculture Imagery Program (NAIP) aerial orthophotos. Human eye-level green exposure was measured using the video clips captured continuously using a mini camera attached to the cap that participants wore during the experiment. The camera captured 1,080 HD videos with a 120-degree viewing angle. Static images were then extracted from these videos at a sampling rate of 15 s, and various measures such as the Green View Index (GVI) values were calculated to quantify the level of exposure to greenery.

2.5.3.3. Air quality

Real-time air quality conditions were measured in terms of black carbon aerosols (BC) using the portable microAeth® AE51 (AE51) device (AethLabs, San Francisco, CA, USA). Black carbon aerosols have been shown to be related to all-cause mortality and morbidity [58, 59]. The device, which uses a 2.5 μm cut point cyclone, was set to log data at 15-s intervals with continuous readings throughout the experiment. This instrument has been validated [60] and used extensively in assessing personal environmental exposure, especially in urban outdoor environments where traffic conditions have heavy impacts on air quality [61, 62].

2.5.3.4. Microclimate condition

Micrometeorological conditions were measured using the MaxiMet Compact Weather Station GMX 501 device (Gill Instruments, Hampshire, UK). This device recorded real-time measurements of wind direction and speed, air temperature, relative humidity, solar radiation, and GPS locations. The instrument integrates temperature and humidity sensors under radiation shields, pyranometer, and ultrasonic wind sensor and outputs at 10-second intervals. It has been widely used in measuring outdoor meteorological conditions and human thermal comfort in indoor and outdoor locations [63, 64]. A complete list of the equipment used and measures made are presented in Supplementary material I.

2.6. Data processing and analysis

Once the data were captured, the next step is to run the quality checks and clean up the data from each instrument. Then, an important task is to identify strategies to link the data from different devices considering their varying units of measurement. While the units of measurement for human data are fine-grained, ranging from 4 to 64 Hz, environmental data are aggregated at larger spatial units such as street segments for audits and pixels and polygons for the GIS data. Other continuously measured exposure data (e.g., eye-level greenery data from the mini camera, microclimatic measures from the weather station, and the BC data from the air quality sensor) are measured at a time interval of 1–10 s. Those continuous measures are not as fine-grained as health outcome data, but they can be easily linked with the outcome data as both are consistently measured with the time stamp.

For this study, the GPS data points were used as the base/reference to sync the other data from other devices. To illustrate the data extraction, processing, and linking process in this section, we use the physiological stress and greenness as examples in this section as they are not well-addressed in previous literature. We also highlight the data linkage process for the audit data which involved additional steps, compared to most other data that already came with the time stamps.

2.6.1. Physiological stress

Raw physiological data were downloaded from the E4 unit using the "E4 manager" software provided by Empatica. Skin Conductance Level (SCL) and Skin Conductance Response (SCR) were extracted from GSR as indicators of physiological stress. Other measures included the HRV and ST data. Continuous Decomposition Analysis (CDA) of Ledalab software was applied to extract the SCL and SCR

values after outlier canceling and data smoothing of the raw GSR data in MATLAB software. Raw GSR data were split into six segments of consecutive GSR data by route portion (park and surrounding portion and mixed-use housing portion) and mode (walking, biking, and driving) before the smoothing and decomposition process was performed. The SCL and SCR data from this process were summarized and aggregated to the street segment level to link with the street audit data, and the average SCL and the number of SCR data within each street segment were also computed. Linking these data to other exposure/environmental data is straightforward as most of them are continuously captured with proper time stamps. However, due to the different time intervals across the devices, data extrapolations were sometimes needed before the data linkage. In addition, slight delays exist in physiological responses after the environmental stimuli. For example, SCR typically occurs within 1–5 s of a stimuli (65), we will test time series models to account for not only the explanatory variables at time T, but also T-1 through T-5.

2.6.2. Physical activity intensity

PA intensity is measured based on Energy Expenditure (EE) of each segment and can be used as an outcome or control variable in the multivariate analysis depending on the study purpose. A combination of Freedson VM3 (66) and Williams Work-Energy (67) algorithms was applied to measure EE, which classified PA intensity into light, moderate, and vigorous for each participant considering his/her weight condition. The weight condition is measured using Body Mass in kg, which was calculated based on the weight and height information collected from the survey administered prior to the field experiment. Count-Per-Minute (CPM) and VM were taken from the 60-s epoch data exported from Actigraph ActiLife v6.13.4 software. The classified PA intensity data are available at a finer level (e.g., 1–30 Hz) than the other data, and therefore can be extracted at any time intervals needed to link with other data and aggregated to the street segment level using the same approach as the stress measure.

2.6.3. Greenness

Greenness of the environment to which the participants were exposed was measured by several different methods based on the NDVI and tree canopy data. NDVI was created based on the Texas NAIP aerial imagery with the 0.6 m by 0.6 m resolution using an image analysis tool in ArcGIS Desktop 10.6.1 software. NDVI values were aggregated to the various spatial units of interest and negative values were set to zero to accurately reflect vegetation concentration. Four different street segment buffer distances (50, 100, 150, and 200 ft from the street centerline) were used to calculate these and other environmental measures, to further test and select an optimal buffer distance that may differ by the type of exposure/outcome variables. The unsupervised classification method, which is a machine learning technique outputting groupings of image pixels without labeled sample images, based on color infrared NAIP imagery was used to obtain the tree canopy data. Pixels of input infrared images were classified without labeled dataset. Region Group, Set Null, and Nibble functions were used to remove small, isolated cell groups from the classified output. In addition, the Boundary Clean tool was used to smoothen the class boundaries and clump the classified outputs. The remaining errors in tree canopy outcome were corrected manually,

and the final cleaned data were used to calculate the percentage of tree canopy area within the buffer.

For measuring the eye-level green exposure, Python codes were developed to quantify the green area of eye-level images extracted from the video clips using semantic segmentation based on the ADE20K dataset (68). A number of variables, including GVI and the percentage of green areas, will be calculated for each image based on the green area derived from the segmentation result. In addition to these variables derived from GIS and video clips, greenery-related variables were also captured from the street audit, including the presence and quality of street trees. Along with other environmental variables, greenness variables may be analyzed at the street segment level (to link with the audit data) or a more fine-grained level (to link with other continuously captured physiological data available at a finer level of detail).

2.6.4. Data linkage and analysis

To link the data with geospatial exposure measures, especially the street segment-based audit data, we used GPS points as the base reference to link other data. First, based on the GPS points plotted using ArcGIS, each participant's actual path taken during the experiment and their duration of stay at each location between segments were checked visually for quality assurance and erroneous data were removed. The audit data along the experimental route were captured at the segment level (including 67 segments ranging from 19 to 345 meters in length). A street segment is defined as a portion of a street between two street/driveway intersections that is fairly homogeneous in its land use and infrastructure conditions. Based on the GPS points plotted on top of each street segment line in GIS, the time stamp (used to link all the data in this study) of the start and the end location of each street segment was extracted to be linked with the stress, physical activity, and other time-stamped data. The linked data are then ready for various statistical analyses.

Our empirical study was a pilot effort by nature, due to the focus on the protocol development and feasibility test. However, the data collected for this study, with a sufficient sample size, can be used for various quantitative analyses using different analytical units. For example, data from Daynamica and E4 can be linked using the common timestamp for exploratory analyses. The potential units of analysis include timestamp and street segment, and the analysis can also be carried out for experimental treatment-control studies. At the timestamp level, environmental features such as GVI and microclimate conditions at the precise location and time will be linked to the PA and stress measures and analyzed using multi-level or mixed effect models to account for the within-subject variations in environmental exposure and pedestrian experiences across the different street segments and study portions. Time series analysis will be used to account for the delayed onset of physiological symptoms and cumulative effects of various environmental exposure during the experiment. At the street segment level, all measures of environmental characteristics and health outcomes will be aggregated to the street segment. At the treatment/control level, outcome variables will be further aggregated to compare the effects of the park vs. mixed-use environments, and repeated measures ANOVA or fixed effects models will be used.

3. Discussion

Despite the potential for field experiments and the need for protocols like the one we proposed in this paper, challenges do exist in carrying out such studies, requiring careful attention during the experiment and while contextualizing the results from such experiments. Below are the lessons we learned and the recommendations for future work.

3.1. Staff protocols and training

This protocol requires three research staff members and is somewhat labor-intensive as it utilizes several research-grade equipment for environmental and health monitoring. To reduce participant burden, we designed the protocol to ensure that the PA and health sensors were worn by participants while the environmental sensors were installed on a bike and pushed/rode by a researcher behind the participants. Although this may induce bias through the Hawthorne effect, walk along has been utilized in various types of study designs and this protocol ensures a concurrent environmental measurement that are accurate spatially and temporally.

An earlier testing with fewer staff members was inefficient and overwhelming, due to the aim of this study to more comprehensively capture both positive and negative environmental exposures with health implications. Multiple rounds of staff training sessions and a detailed staff protocol with a checklist for each staff member were essential to ensure consistent and complete data collection. Also, participants sometimes arrive earlier or later than their scheduled time, staff members had to cover each other's roles, and therefore it is important that all staff members are trained to handle both their own and the other staff members' tasks.

3.2. COVID-19-related challenges and protocol adjustments

The development of final protocols required multiple rounds of field testing and adjustments. Moreover, due to the additional challenges brought about by COVID-19, making it necessary to halt all in-person data collection activities during the early phases, followed by the strict "infection control plan" implemented by the University, the actual schedule of the data collection was delayed significantly. The field staff members had to be trained about the general and project-specific COVID-19 safety protocols, including social distancing, hand washing, surface disinfection, mask-wearing, and handling of potential participant issues (e.g., if they refused to follow our protocols), as well as strategies to minimize the transmission risk during each step of the experimental procedure. In addition, participants received a pre-screening health checklist before they arrived at the check-in station for the experiment. If they had any symptoms or close contact with someone who tested positive for COVID-19, the experiment was rescheduled to a later time after at least 2 weeks. These additional protocols have added extra burdens to the participants and the research staff, as well as raised concerns about the potential impact of mask-wearing on some of the physiological

measures. However, we anticipate such impacts would be manageable in this study given its focus on the within-subject variations.

Because of these COVID-19 related delays, the experiment was conducted during the springtime instead of the originally planned summer months, and the impact of hot ambient conditions critical to pedestrian behavior and health could not be captured. Therefore, the research team carried out another round of data collection during the following summer months. All previous participants were invited, but only 12 were able to participate in the second round. We further invited 19 new participants from the same participant pool meeting the same eligibility criteria to join this second round; thus, a total of 31 participants completed the second round of data collection during the summer of 2021.

3.3. Participant burden

To reduce threats to validity, our study used predefined routes and activities to control for extraneous factors, but following the complex study design strictly could increase participant burden. As participants had to change into different modes of travel during the experiment, the field staff had to make sure that participants understood all the predefined walking, bicycling and driving routes. Especially for the second experiment portion, the participants had to follow the provided map (both printed on paper and provided *via* Google Maps) on their own, as the COVID-19 protocol did not allow our staff members to ride in the same car with them. To ensure that the participants followed the correct routes, we used a smartphone app (Daynamica) to track their location in real time. If participants went the wrong way, they were asked to drive/walk the correct route again either immediately or at another time, which led to increasing the participants' burden. Riding a bicycle was also a challenge to some of the participants, especially older participants and those with heights and/or weights outside the typical range for a standard-size bicycle. When participants appeared to be experiencing difficulty with the bicycle, they were given the option to continue if they felt comfortable, skip the bicycling route, or join at another time when we could provide another bike that would be safer or more comfortable for them (e.g., a different size).

3.4. Confounding effects of the psychophysiological responses to the natural environment, thermal environment, and physical activity

Although the physiological measures of HRV, GSR, and ST have been used extensively as stress indicators, they are also sensitive to aerobic activities and ambient thermal conditions. For example, PA increases metabolic heat, body core temperature, and skin blood flows, which in turn increase sweat output and GSR values. Although overall levels of PA and thermal conditions can be controlled statistically, body part movements can cause changes in physiological signals that affect the results. In addition, the human body's heat generation and regulation depends on age, pre-existing health conditions, and climate acclimatization. Future experimental studies may consider controlling for one or more of these three

variables to further parse out the effects of various ambient and activity characteristics on physiological measures.

3.5. Capturing the level of human engagement with the natural environment during activities

Compared to the more extensive efforts made in previous studies about understanding the roles of the built environment for PA, natural environment has received limited attention. Although this study measures human exposure to the environment based on geographical location and visual field, they mainly capture the concentration of greenness in the environment. It is challenging to evaluate participants' level of PA and engagement with the natural environment. Previous studies have suggested that individuals' active vs. passive engagement with the environment and awareness of the natural elements and their benefits can affect the health benefits of nature (69). Video recordings may offer a way to help assess certain types of nature engagement, but the processing of such visual data for detecting those types of engagement requires advanced computational techniques and validation research.

3.6. Delayed and cumulative effects of environmental exposure

The current study employs continuous biosensing measurements and joins exposure and outcome data by time stamps. However, sympathetic activity, which is linked to stress responses, has a certain range of delay, which may show individual variations. In lab conditions, it is reported that the time delay between the onset of stimuli and heart rate response can be up to 5 s. Therefore, more research and adjusted time stamps may be appropriate in linking environmental stimuli and physiological outcomes. In addition, compared to instantaneous exposure, cumulative environmental exposure may play a stronger role in thermal comfort and affective outcomes. In our protocol, we propose to use time series models to statistically account for these delayed and cumulative effects. Future studies may further explore the appropriate cumulative exposure effect and the lagged effects between environmental exposure and human physiological responses by conducting sensitivity analysis.

3.7. Unplanned, extraneous factors influencing health outcomes

In field experiments conducted in real living conditions, unplanned extraneous factors, such as noise, traffic conditions, and social interactions among pedestrians, may influence pedestrian health outcomes. Our study used video cameras to capture the visual and auditory characteristics of the environment. Advanced sound processing and image segmentation techniques may help identify and control for certain unplanned factors in participants' visual environments. In addition, during the driving segments, participants used their own vehicle, and the characteristics of their vehicle (e.g., ride quality, noise insolation, controllability, comfort of the seat, temperature settings) may influence the participants' experience

and stress levels. Participants' familiarity with this area also may affect how comfortable or anxious they were during the experiment. Although our analysis mostly focusses on the walking and biking segments, such potential confounding factors should be considered and controlled for in future studies.

3.8. Summary

As the street environment receives increasing public health research and policy attention, experimental procedures that can be applied to ecologically valid settings and incorporate quantitative *in-situ* environmental and health assessments are needed. This research presents protocols for field experiments to help fill in some of the important knowledge gaps in this line of research, by offering opportunities to focus on a specific real-world setting to more accurately capture the environmental exposure and related PA and health outcomes, which can lead to better isolating the causal effect of exposures/interventions. The current research protocol is innovative as it (1) tests the effects of various environmental attributes on pedestrian/bicyclist health outcomes *in-situ*, (2) develops a framework for utilizing and synthesizing biosensing technologies for environmental health studies, and (3) discusses the caveats and nuances related to linking pedestrian health outcomes/responses with the immediate surroundings. Strategies proposed in this paper can be modified for settings other than streets, such as large parks and other types of public space. The methodological discussions can inform the development of large-scale studies using connected and wearable technologies to collect real-time data and real health risks that can be attributable to environmental factors.

In addition, results from such protocols can inform the development of tailored intervention strategies such as urban greening or green infrastructure development strategies to promote pedestrian health in warm climate regions where populations tend to bear higher health risks due to extreme heat and prevalent sedentary lifestyles. This protocol sets an example of a data-driven approach to document health-significant roles of the urban environments to which people are exposed on a daily basis. Results from research using this protocol can inform researchers, policy makers, and professionals of the specific and modifiable elements/structures of the urban environment associated with various health outcomes. For example, as cities invest resources in greening and revitalizing their neighborhoods, such efforts can be centered on improving the visual and thermal qualities of the urban space.

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.

Ethics statement

This research has been reviewed and approved by the Texas A&M Institutional Review Board (IRB2020-0060D). The patients/participants provided their written informed consent to participate in this study.

Author contributions

Funding

Acknowledgments

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/fpubh.2023.1019885/full#supplementary-material

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Development and validation of the health literacy environment scale for Chinese hospitals from patients' perspective

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Introduction: While the research on improving individual health literacy by promoting individual skills and abilities is increasing, less attention has been paid to the complexities of the healthcare environment that may influence patients' ability to access, understand, and apply health information and health services to make health decisions. This study aimed to develop and validate a Health Literacy Environment Scale (HLES) that is suitable for Chinese culture.

Methods: This study was conducted in two phases. First, using the Person-Centered Care (PCC) framework as a theoretical framework, initial items were developed by using the existing health literacy environment (HLE) related measurement tools, literature review, qualitative interviews, and the researcher's clinical experience. Second, scale development was based on two rounds of Delphi expert consultation and a pre-test conducted with 20 hospitalized patients. Using 697 hospitalized patients from three sample hospitals, the initial scale was developed after item screening and its reliability and validity were evaluated.

Results: The HLES comprised 30 items classified into three dimensions as follows: interpersonal (11 items), clinical (9 items), and structural (10 items) dimensions. The Cronbach's α coefficient of the HLES was 0.960 and the intra-class correlation coefficient was 0.844. The confirmatory factor analysis verified the three-factor model after allowing for the correlation of five pairs of error terms. The goodness-of-fit indices signified a good fit for the model (χ^2/df=2.766, RMSEA=0.069, RMR=0.053, CFI=0.902, IFI=0.903, TLI=0.893, GFI=0.826, PNFI=0.781, PCFI=0.823, PGFI=0.705). The item-content validity index ranged from 0.91 to 1.00, and the scale-content validity index was 0.90.

Conclusion: The HLES had good reliability and validity and provides a patient perspective tool for evaluating HLE and a new perspective for improving health literacy in China. That is, healthcare organizations make it easier for patients to access, understand, and use health information and service. Further studies about the validity and reliability of HLE should include other districts and different tiers or types of healthcare organizations.

1. Introduction

Individual health literacy is "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (1). Inadequate health literacy has become a significant global public health problem, although data on this are still unavailable. For instance, only 12% of American adults had proficient health literacy in 2003, according to National Center for Education Statistics (2). Similarly, a survey of the European Health Literacy Project (HLS-EU) revealed that 12.4% of participants had insufficient health literacy and 47.6% of participants had limited health literacy (3). Health literacy directly affects an individual's or community's health awareness and determines the choice of health decisions and actions. Individual health literacy correlates with social determinants of health, such as education, income, and environment, to influence health (4). However, individual health literacy changes dynamically. Even if individuals have adequate health literacy, it would be difficult for them to access, understand, and apply health information and health services to make health decisions in an unfamiliar environment and a jargon-filled doctor-patient communication process (5).

Most measures to improve health literacy are designed to enhance individuals' skills and abilities (6–8). However, recent studies (9–11) have shown that health literacy results from the balance between individual skills and abilities, and its demand has intensified owing to the complexities of healthcare systems (12, 13). Therefore, it is critical to make healthcare organizations "easier for people to navigate, understand, and use information and services to take care of their health" (5). The concept of health literacy environment (HLE) has been developed to leverage the role of healthcare organizations and healthcare professionals in promoting health literacy, to reduce the complexity of the healthcare environment and health inequities. According to Rudd et al. (14), HLE is "a healthcare facility that represents the expectations, preferences, and skills of those providing health information and services." In 2014, the Australian Commission on Safety and Quality in Health Care (ACSQHC) crafted two definitions for health literacy: individual health literacy and HLE. It defined HLE as the infrastructure, policies, processes, materials, people, and relationships that make up the health system and have an impact on the way people access, understand, appraise, and apply health-related information and services (15). Since the HLE concept was proposed in 2006, a growing number of agencies, institutions, and scholars have developed similar concepts, focusing on the role of healthcare organizations in promoting health literacy. Trezona et al. (16) defined Organizational Health Literacy Responsiveness (Org-HLR) as a healthcare organization's responsiveness to handle health literacy promotion through the system-level way to promote equitable access and engagement, meet the health literacy needs of people and the community, and support people to engage in decisions about their health. The *Healthy People 2030,* which was initiated by the United States Department of Health and Human Services (HHS), defined organizational health literacy (OHL) as "the degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and other" (17). Although these concepts were developed in different contexts, they all focus on reducing the complexity of healthcare organizations to make it easier for people to access, understand and use health information and health service.

Assessment shines a light on the barriers and enablers that may be impacting the quality of service (18). Identification of burdensome health literacy demands can be the first step in reducing barriers and providing more accessible and effective care (19). Through the literature review, we found that there is only one tool to measure HLE (14, 20). In 2006, Rudd and Anderson (14) developed the Health Literacy Environment of Hospitals and Health Centers (HLEHHC), the first HLE measurement tool in America, to assist administrators and medical workers in considering the HLE of their healthcare facilities and analyzing ways to reduce demands, to better serve their patients. The HLEHHC has five sections (Navigation; Print communication; Oral exchange; Technology; Policies and protocols) and 100 criteria. It is scored by the hospital's administrators, medical workers, and internal quality managers in a checklist format (1 = This is something that is not done; 2 = This is done but needs some improvements; 3 = This is done well). The total score is 300. A score ranging between 0–100, 101–200, and 201–300 represents "Begin a focused initiative to eliminate literacy-related barriers," "Augment efforts to eliminate literacy-related barriers," and "Continue to monitor and eliminate literacy-related barriers," respectively. In 2019, Rudd and Anderson (20) revised and updated the HLEHHC to create the HLEHHC version 2 (HLE2). The HLE2 is organized into five sections, and 135 criteria: (1) Organizational policies, (2) Institutional practices, (3) Navigation, (4) Culture and language, and (5) Communication: print materials, forms, websites, and patient portals. HLE2 is scored by the hospital's internal quality managers in a checklist format and patients in a 5-likert scale for the dimension of navigation. If the score is below 50%, it implies that actions are needed to begin a health literacy initiative to eliminate literacy-related barriers in this area, and if the score ranges from 86 to 99%, it represents the need to continue monitoring, to consider a study comparing baseline values with values at a later date, and to share experiences and findings with others. Although the HLEHHC and HLE2 have not been tested for reliability and validity, the former has been widely used in the Occident. In 2010, Smith et al. (21) used the HLEHHC to evaluate a rehabilitation center and a senior independent living facility and found that the measures in the Navigation, Print communication, and Oral exchange sections needed urgent improvement. In 2016, Oelschlegel et al. (22) conducted a systematic assessment over 6 months in a medical center in the United States. By analyzing 150 print patient education documents, interviewing nearly 300 patients, receiving feedback from 7 navigators, and measuring 77 administrators' knowledge of policies and protocols, the score obtained by the center was 218.57, suggesting that the it should continue to monitor and eliminate literacy-related barriers, among which the sections "Oral exchange" and "Policies and protocols" needed to be further improved. In 2017, Palumbo et al. (23) revised the HLEHHC and translated it into Italian. The study included three large public hospitals in Italy. The scores of the sections "Technology" and "Policies and Protocols" were low, and thus countermeasures were put forward to meet the special needs of people with low health literacy through the introduction of specific technologies and the settlement of policies and tailored protocols. Both the HLEHHC and the HLE2 have detailed and comprehensive evaluation content and mainly objective indicators. However, Unlike the HLEHHC, the HLE2 takes into account the importance of patient experience, and its invites patients to participate in the evaluation of the navigation which was not the entirety of HLE. As healthcare systems become increasingly

complex, patients may encounter difficulties finding and receiving health care services, using materials, navigation, filling forms, and offering consent for procedures (24–26). Evaluating HLE from the patient's perspective can directly and truly acknowledge the deficiencies of the hospital that need to be improved or the experience worth promoting in the process of assisting patients to obtain, understand, and use health information and service (19). Therefore, there is an urgent need to develop a HLE scale based on the perspective of patients.

The National Health Commission of the People's Republic of China reported that the health literacy rate in China is 25.40%, which means that only about one in four people in China has acquired basic knowledge and skills in health (27). Studies have also revealed that low health literacy is associated with poor health outcomes, including less frequent screening for diseases, high rates of disease and mortality, increased hospitalization rates, and medical costs (28, 29). To address the challenges of low health literacy, China's government and health administration departments have implemented a policy to improve health literacy and require healthcare organizations to assume corresponding responsibilities. In May 2014, the National Health Commission of the People's Republic of China initiated (30) the "*National Plan of Health Literacy Promotion Initiatives (2014–2020)*." This document recommended an establishment of a long-term and working mechanism that features leadership by the government, multi-departmental cooperation, and whole-society participation, and brings essential medical literacy promotion into the comprehensive assessment of healthcare organizations as well as the Health Promoting Hospital Initiative.

In 2019, the State Council, China's Cabinet, launched "*Actions to Build a Healthy China (2019–2030)*." This government document is an overall design and strategy for promoting the health of all people for more than 10 years. The *Healthy China Initiative* takes health literacy promotion as the prerequisite for the health of all people. At the same time, it requests healthcare professionals to advise health matters initiatively and to establish the performance appraisal mechanism for health promotion and education conducted by medical and healthcare organizations and professionals (31). It is the first time the State Council has requested healthcare organizations to promote health literacy.

In contrast to government documents, most healthcare organizations focus on treating disease rather than promoting health literacy. Few practices are related to HLE in Chinese healthcare organizations. Only one public hospital and one community healthcare center are engaged in health literacy promotion (32, 33). The former carries out health literacy promotion practices in four aspects: (1) developing organizational rules and regulations, (2) forming a health popular science team, (3) setting up a health popular science platform, and (4) innovating the form of health popular science activities. The latter practices health promotion by: (1) establishing a leading group of health literacy promotion, (2) improving management mechanisms, and (3) conducting staff training, evaluating action, and targeting health literacy promotion activities. The two healthcare organizations focused on improving the accessibility and radiation of health popular science knowledge. However, their practices should have included other HLE-related areas, such as reducing services' complexity and improving information comprehension.

Since the *Actions to Build a Healthy China (2019–2030)* was first published, the Chinese government has been releasing a document each year (from 2020 to 2022), setting out the annual work points of the *Healthy China Initiative*. In 2020, the government established "the performance appraisal mechanism for health promotion and education conducted by medical and healthcare organizations and professionals" as one of the high-priority annual tasks (34). The following year, 2021, the government endorsed this task as a key one to accelerate the implementation of the *Healthy China Initiative* (35). In 2022, the government continued the promotion of this task (36). This showed that the government attached great importance to the assessment of healthcare organizations for advancing health literacy promotion.

However, no government regulations or evaluation tools are currently available to assess the performance of health education and health promotion conducted by healthcare organizations and professionals in China. Only one study by Tong et al. (37) translated Kowalski et al.'s (38) health literate healthcare organization 10-item questionnaire (HLHO-10) into Chinese. The Chinese version of HLHO-10 (HLHO-10-C) had adequate reliability and validity. The HLHO-10-C was used to investigate 24 healthcare organizations in China and the results revealed that healthcare organizations had the highest scores for item 6 (communication standards) and item 9 (high risk) and the lowest scores for item 3 (workforce) and item 4 (inclusion of the served).

However, the HLHO-10 was developed in the context of Western countries and varies in the context of Chinese culture for the following reasons. First, some items may not be fully applicable to Chinese healthcare organizations. Such as item 5 ["are there communication standards at your hospital which ensure that patients truly understand the necessary information (e.g., translators, allowing pauses for reflection, calling for further queries)?"] and item 4 ["is individualized health information used at your hospital (e.g., different languages)?"]. Both items refer to providing translation services or health materials in patients' native languages. However, there are very few immigrants in China, so HLHO-10-C may not be applicable in the country. Second, in recent years, China has focused on constructing "Internet hospitals." The Internet hospital means applying Internet technology to the provision of health services and information by healthcare organizations, which is similar to telemedicine. It allows healthcare professionals to remotely provide medical services for patients, such as online consultation, prescription, and drug dispensation (39). HLHO-10-C may not evaluate the complexity of "Internet + Medical services" and the accessibility of Internet-based medical navigation devices (e.g., hospital navigation apps). Evaluating the Chinese policies and the current evaluation and practice of HLE in healthcare organizations, it is clear that there is an urgent need to develop a suitable tool for HLE, by evaluating and modifying the existing Health Literacy Environment Scale (HLES) to suit the Chinese healthcare organizations. The person-centered care (PCC) framework proposed by Greene et al. (40) reflects the personal, clinical, and structural dimensions of the patient experience. Therefore, we hypothesize that the PCC framework can be used to construct the HLES to accurately evaluate HLE from the perspective of patients. The purpose of this study was to (1) develop the HLES in China to evaluate the extent to which healthcare organizations and medical professionals can make health information and health services easily obtainable, processable,

and understandable for patients, and (2) test its construct validity, content validity, internal consistency reliability, and test–retest reliability.

2. Materials and methods

2.1. Phase I: definition of domains and designing of initial items

We used the PCC framework (40) as a theoretical framework for this study. The PCC framework attaches importance to the interaction between patients and the medical environment, in addition to focusing on patient-clinician interactions. The PCC framework has demonstrated good applicability in several studies and practices. To make the PCC framework practically applicable to various healthcare settings (such as healthcare organizations, private clinics, and emergency care centers), Greene et al. (40) classified it into three–interpersonal, clinical, and structural dimensions. The interpersonal dimension refers to the relationship between the service provider and the patient as well as their family members, and the interpersonal communication between them. The clinical dimension focuses on the way health services are delivered, particularly the process of making the clinical decision and providing coordinated and continuous services. The structural dimension involves existing facilities and equipment in the built environment where health services are provided, enhancing the accessibility of health information technology that patients use, and improving procedures to facilitate access to care. The PCC framework is closely connected to HLE construction, that is, focusing on the interaction between patients and the medical environment in the process of obtaining, receiving, and using medical services. At the same time, the PCC framework has been applied in several studies. For example, Prevost (41) used the PCC framework as theoretical guidance to design research tools and a cross-sectional observational investigation of patient perspectives on the accessibility of community paramedicine. Yuliati et al. (42) used the PCC framework to explore the role of case managers in patient-centered care and problems encountered. Therefore, this study used three dimensions–"structural," "interpersonal" and "clinical" –as the basic structure to evaluate HLE in healthcare organizations. Figure 1 shows the PCC framework that inspired this study, and Table 1 contains a list of the domain definitions of the PCC framework used in our study.

After determining the dimensions of the HLES, we generated items from the following four aspects. (1) Referring to current HLE-related evaluation tools that have adequate reliability and validity or have been widely used, items were extracted and modified in the following seven tools: Health Literacy-Sensitive Communication Scale (HL-COM), Health Literate Primary Care Practice Screener (HLPC), CAHPS® Health Literacy Item Set for Hospitals, Communication Climate Assessment Toolkit (C-CAT), The Health Literate Health Care Organization 10 Item Questionnaire (HLHO-10), Health Literacy Environment of Hospitals and Health Centers (HLEHHC) and Organizational Health Literacy Responsiveness self-assessment tool (Org-HLR Tool). (2) We searched for the following keywords referring to "health literacy environment," "organizational/organizational health literacy," "health literate (health care) "organization/organization." The search was performed using PubMed, Web of Science, Embase, EBSCO, and Chinese databases

FIGURE 1
Person-centered care framework in this study.
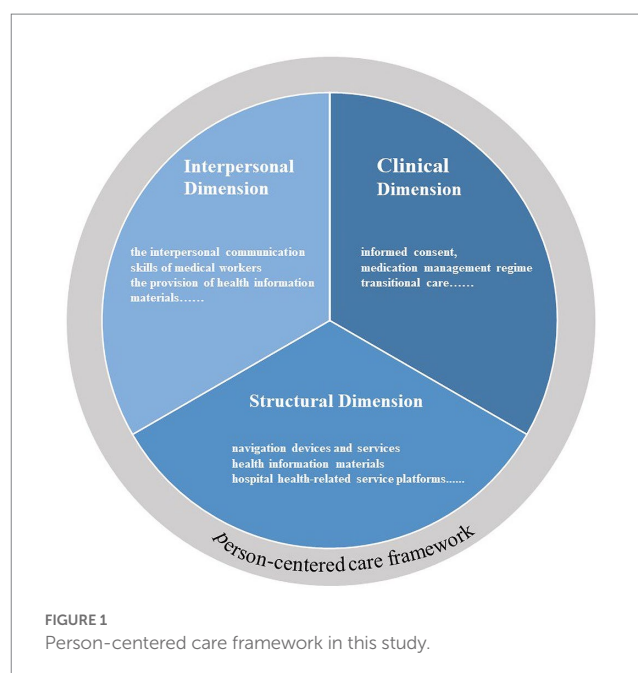
TABLE 1 The domains' definitions of the HLES.

Domains	Definition
Interpersonal dimension	The relationship between the service provider and the patient as well as their family members, and the interpersonal communication between them, such as the interpersonal communication skills of medical workers and the provision of health information materials.
Clinical dimension	In the process of delivering medical service, medical workers provide professional support and continuous care aimed to improve the accessibility and availability of medical information, such as paying attention to the health literacy of the population under high-risk situations (informed consent, medication management regime that may cause serious consequences, transitional care, and other clinical sessions), and ensuring that patients clear what medical insurance covers and what individuals have to pay.
Structural dimension	Navigable existing facilities and equipment in built environments of healthcare organizations, accessible health information platforms relying on information technology, as well as procedures to promote the acquisition of health services and information, such as navigation devices and services, health information materials, and hospital health-related service platforms.

such as National Knowledge Infrastructure (CNKI), Wanfang database, and China Science and Technology Journal database. We identified a total of 53 publications related to HLE (2 articles in Chinese and 51 articles in English). We extracted the content related to the construction of HLE to compile items. (3) We conducted qualitative interviews with hospital staff as well as patients and their families to explore the problems and improvement strategies of patients to obtain, understand, and use health information and medical services, to compile new items. Medical workers, patients, and patients' family members were recruited by purposive sampling.

Medical workers with over 3 years of work experience and who engaged in hospital management, health education, and health promotion, or clinical/nursing work were interviewed. The inclusion criteria of patients were: inpatients in internal medicine or surgery, aware of their condition, and able to communicate and comprehend. The inclusion criteria of the patients' family members were: aware of their condition, over 18 years old, able to communicate and comprehend; the exclusion criteria were: patients who were due to be admitted in the day of the interview; not participating in the accompanying process. A total of 23 participants (11 hospital staff, 9 patients and 3 family members) were included in the study. (4) Items were proposed based on the researcher's clinical experience.

An expert panel was established to develop an item pool and screen items preliminary. The experts had a minimum of 5 years of working experience, majoring in the fields of health management, hospital administration, and clinical medicine and nursing, with intermediate titles or senior titles. We organized two rounds of focus groups with seven experts. In the first round, the experts wrote and reviewed items and construct the scale pool. Then, each item was classified into three dimensions. In the second round, the experts combined similar items and removed items that are unrelated to HLE or could not be evaluated from the patient's perspective. Finally, we developed the initial scale containing a total of 57 items, including 16 items on structural dimensions, 16 items on clinical dimensions, and 25 items on interpersonal dimensions. The detailed item content and item source are shown in Appendix 1.

2.2. Phase II: development and evaluation of the HLES

This part included four steps: (1) revising the initial scale through Delphi to form the HLES-1 (the draft of pre-test); (2) revising the HLES-1 through pre-test to form the HLES-2 (the draft of pilot test); (3) screening items through pilot test and developing the HLES (final version); and (4) Testing the reliability and validity of the HLES.

2.2.1. Formed HLES-1 (the draft of pre-test) by Delphi

Using the Delphi method, we selected experts to evaluate and revise the initial scale to form the HLES-1 (the draft of pre-test). To meet the inclusion criteria, the experts had to have: (1) A minimum of 5 years of working experience in hospital administration, health education and health promotion, health management, clinical medicine, or nursing; (2) Intermediate or above professional titles. To obtain an adequate number, we invited at least 15 experts (43).

We compiled the initial scale with the expert consultation form and invited experts to fill it out. The contents of the expert consultation form included: (1) the five-point Likert Scale to rate the importance of each item with "1" indicating "not at all important" and "5" indicating "very important." The experts were invited to modify, delete, or add items in the scale; (2) the experts' demographic characteristics, and (3) the experts' judging basis and familiarity with the theme of our study. Depending on the consultation, we conducted 2–3 rounds of meetings with the experts. The Item Importance Score Mean (M) ≤ 4.00 or Coefficient of Variation (CV) ≥ 0.25 was deleted. Finally, we eliminated, adjusted, integrated, and added items to form

the HLES-1 (the draft of pre-test) based on the expert opinions and suggestions.

2.2.2. Developed HLES-2 (the draft of pilot test) by pre-test

The pre-test was conducted in July 2021 in three tertiary hospitals–the highest among a three-tier grade system for hospitals in Hangzhou, Zhejiang Province. The tertiary hospital is a medical services center within the region and plays a key role in the medical service system (44). It combines medical treatment, medical education, scientific research, and health prevention. In this study, a 2,400-bed tertiary general hospital, a 1,600-bed tertiary general hospital, and a 600-bed tertiary cancer hospital were included.

Considering that inpatients have more experience with medical services than outpatients and can evaluate HLE more accurately and comprehensively, we decided to select inpatients as study participants. We adopted a convenience sampling method in recruiting at least 20 patients for the pre-test. The inclusion criteria were: patients who were due to be discharged on the day of the survey or who had been in hospital for over 3 days; patients proficient in communication and comprehension. In this session, we used the HLES-1 as the research tool. Each item of the HLES-1 includes five responses consisting of a four-point Likert Scale level scale that includes strongly agree (4), agree (3), disagree (2), and strongly disagree (1), and another response ("not applicable") without scoring. We used field surveys to investigate patients one to one. After investigation, we asked the patients if there were any unclear expressions, ambiguity, and incomprehensibility in the questionnaire. Referring to the patients' feedback, we adjusted the scale items to form the HLES-2 (the draft of pilot test).

2.2.3. Developed HLES (final version) by a pilot test

The pilot test was conducted between August 2021 and January 2022. We adopted the same convenience sampling method and inclusion criteria used in the pre-test to recruit patients from the same three tertiary hospitals. Considering the requirements for factor analysis (45), the sample size was 10 times the number of items. In addition, some patients were unable to provide complete answers; therefore, we added about 20% of anticipated invalid samples.

Patients filled in the following three questionnaires: (1) Demographic information questionnaire, which included information on gender, age, marital status, education, monthly household income, residence, competent dialect, the number of hospital admissions, unit admitted to, and length of hospital stay. (2) HLES-2: The responses are the same as for the HLES-1. The total score is calculated by referring to the European health literacy survey (HLS-EU) carried out by the WHO regional office for Europe, and the original score of the scale is converted into the standard score. Appendix 2 shows the calculation method of the scale. (3) The Chinese version of Brief Health Literacy Screen (BHLS-C): BHLS-C was translated by Xue et al. (46) in 2022. The scale combines three of the optimal questions. Three questions are scored from 1 to 5. The total score of the BHLS-C adds each question's score together, ranging from 3 to 15. Patients with scores below 10 are identified as having inadequate health literacy, and patients with scores from 10 to 12 are identified as having marginal health literacy. The internal consistency reliability of BHLS-C was 0.742 and the criterion validity was 0.519.

We used field surveys to investigate patients in the hospital ward. Based on the results, we used item screening and factor analysis methods to develop the HLES (final version).

2.2.4. Test of the reliability and validity of the HLES

First, to analyze content validity, 16 experts majoring in health management, hospital administration, health education and health promotion, clinical medicine, and nursing were invited. The experts were asked to rate the relevance of each item using a four-point Likert scale (1 = not relevant, 4 = very relevant). Second, the internal consistency reliability and construct validity of the HLES were tested based on the results of the pre-test. In addition, to evaluate the test–retest reliability, 30 patients were randomly selected, and the questionnaire was administered on them twice within a two-week interval.

2.3. Statistical methods

Descriptive statistics were used to describe the sample characteristics and calculate the preference percentages. The homoscedasticity of variances among groups was contrasted with Levene's test. Student t-tests or Mann–Whitney U tests were used to compare mean values between two groups. One-way analysis of variance or Kruskal–Wallis tests were applied for the comparison of three or more independent mean values, based on whether there was a normal distribution or not.

First, frequency distribution, item discrimination test, inter-item and item-total correlations, and exploratory factor analysis (EFA) were conducted to reduce the number of items and identify the final version of the HLES.

The criteria for item screening were as follows: (1) Items with missing scores >20% were considered for elimination (47); (2) using an upper 27%-lower 27% method, the items with no statistically significant difference between upper and lower were deleted (47); (3) items with Pearson r ≤ 0.4 between the score of items and the total score of the HLES were deleted (48); (4) using principal component analysis and varimax-rotation method, common factors were generated and items with factor loading <0.4 were considered for elimination (49).

Second, we tested the validity of the HLES. Construct validity was evaluated by using confirmatory factor analysis (CFA). The criteria for model fit used were: Kline (50) recommended that χ^2/df in ranges of 1 to 3, Tucker Lewis index (TLI), comparative fit index (CFI), goodness-of-fit index (GFI), and adjusted goodness-of-fit index >0.9 as indicators of a good fit. Parsimony goodness of fit index (PGFI), parsimonious normed fit index (PNFI), and parsimony comparative fit index (PCFI) > 0.5 (51). Root mean square error of approximation (RMSEA) and root mean square residual (RMR) should be less than 0.08 for a good model fit (52). Content validity includes item-content validity index (I-CVI) and the scale-content validity index (S-CVI). I-CVI should be >0.78 and S-CVI > 0.90 (53, 54). Finally, we tested the reliability of the HLES. The internal consistency reliability was evaluated using Cronbach's α (55), and the threshold was 0.70 or greater. Test–retest reliability was conducted on 30 patients who completed the questionnaire twice within a two-week interval. The intra-class correlation coefficient (ICC) was also calculated and classified as follows: 0.5–0.74 as moderate, and 0.75–1 as almost perfect (56).

All data were analyzed at a 95% significance level using IBM SPSS 26.0 and AMOS 24.0.

2.4. Ethical approval

Approval to conduct this study was obtained from the Bioethics Committee of Hangzhou Normal University (Grant ID: 2022029).

3. Results

3.1. Experts' demographics and results of their consultation

A total of 16 experts participated in the consultation. A total of 10 experts (62.5%) had master's degrees or above, 11 experts (68.8%) had senior professional titles, and 12 experts (75%) had proficient experience (at least 10 years) in clinical medicine, nursing, hospital administration, or health management. The response rates of the two rounds were 100 and 84.6%, respectively. The expert judging basis coefficient (Ca) and familiarity coefficient (Cs) were 0.8600 and 0.9125, respectively. Therefore, the expert authority coefficient (Cr) was 0.886. The consistency judgment coefficient (Kendall's W) of the experts for the first and second rounds were 0.186 and 0.234, respectively ($p < 0.001$).

The first round of expert consultation (15 experts) evaluated the importance of the initial scale (57 items). The table of item importance score mean is shown in Appendix 1. There are 13 items with item importance score mean (M) ≤ 4 or CV ≥ 0.25. Meanwhile, the items were added, modified, or deleted based on the experts' suggestions. The first round of consultation results was as follows: 15 items were deleted, 24 items were modified, and 8 items were added. In the second round of expert consultation (13 experts), the item importance score mean (M) ranged from 4.182 to 5.000, and CV ranged from 0 to 0.171. All items satisfied the item importance score mean (M) > 4 or CV < 0.25. The second round of consultation results was as follows: two items were deleted and eight items were modified. Finally, the HLES-1(48 items) was developed for the pre-test.

3.2. Patients' demographics and results of the pre-test

A total of 20 patients with a mean age of 40.4 years (SD = 13.9) were included; 11 patients were men and 9 patients were women; 11 patients had high school degrees; 10 patients were selected from the internal medicine department and another 10 patients were selected from the surgery department. According to the patients' feedback, four items were modified and one item was deleted. Finally, the HLES-2 (47 items) was developed for the pilot test.

3.3. Patients' demographics and results of item screen in the pilot test

In total, 697 patients completed the survey, yielding a 96.0% (697/726) response rate. Among them, the majority (60.0%; 418/697) of the patients were investigated in the internal medicine department;

55.1% (384/697) were first hospitalized patients; the median length of hospital stay was 5 days, and 342 (49.1%) patients were hospitalized for 3–7 days. The mean age of patients was 53.5, ranging from 16 to 91 years; 384 (55.1%) were men and 92% were married; the majority of patients (39.0%) had an educational level with at least a junior high school degree. The monthly household income (CNY) of 279 (40.0%) patients ranged between 5,001 and 10,000 yuan. A total of 362 (51.9%) patients were living in the city; 283 (40.60%) patients were accustomed to only speaking their local dialect in daily lives. The results of the BHLS showed that 31.5% of the patients had inadequate health literacy, 23.7% of the patients had marginal health literacy, and 44.8% of the patients had sufficient health literacy.

A total of 10 items that did not meet the criteria were deleted through frequency distribution, item discrimination test, and inter-item and item-total correlations. The detailed results of the item screening above are shown in Appendix 3. The sample of 697 was randomly split into two samples, one for EFA ($n = 325$) and one for CFA ($n = 372$). EFA was performed on the remaining 37 items and the results showed that Kaiser-Meyer-Olkin = 0.955, and $\chi^2 = 9014.008$ of Bartlett's test ($p < 0.001$), indicating that EFA was suitable.

The results of the screen test and parallel analysis showed that extracted three common factors were the most suitable, and seven items that had a factor loading lower than 0.40 were further eliminated. The factor analysis of the remaining 30 items produced three latent variables, accounting for 59.8% of the cumulative variance contribution rate. The characteristic root values were 6.490 ("structural dimension"), 6.004 ("clinical dimension"), and 5.461("interpersonal dimension"), and the factor loading was between 0.403 and 0.816. The results of EFA are shown in Table 2. The final version of the HLES had 30 items remaining.

3.4. Results of reliability and validity of the HLES

The validity includes construct validity and content validity. CFA tested each of the three dimensions after conducting EFA to test construct validity. All 30 items were used as observed variables, and the CFA of the three-factor model (Figure 2) showed an acceptable fit after allowing for the correlation of five pairs of error terms (S15-S16, S2-S9, S1-S9, S1-S2, I6-I16). The full model exhibited enough fit statistics (χ^2/df = 2.766, RMR = 0.053, RMSEA = 0.069, CFI = 0.902, IFI = 0.903, TLI = 0.893, GFI = 0.826, PNFI = 0.781, PCFI = 0.823, PGFI = 0.705). The I-CVI of each item in the HLES ranged from 0.91 to 1.00, and the S-CVI/Ave of the total scale was 0.90.

The reliability of the scale was evaluated using two procedures, internal consistency and test–retest (Table 3). The Cronbach's α for the HLES was 0.960, and the Cronbach's α for the dimensions were 0.892 ("interpersonal dimension"), 0.915 ("clinical dimension"), and 0.923("structural dimension"). The ICC between the test and retest ranged from 0.661 to 0.721 in three dimensions, with ICC = 0.844 for the overall scale.

3.5. The score of the HLES in the three hospitals

The average score of the HLES was 59.3 ± 20.1 in total for the three hospitals. The three dimensions' average scores were 44.2 ± 22.2,

67.2 ± 21.6, and 66.8 ± 23.1 for interpersonal, clinical, and structural dimensions, respectively. Hospital A (63.51 ± 18.60) had the highest score in the HLES out of the three hospitals, while hospital C (56.51 ± 21.32) had the lowest score. The total score and dimension score of each hospital are shown in Table 4. As shown in Table 5, we found that the differences in the HLES scores according to patients' age, education, marital status, monthly household income, residence, competent dialect, and health literacy were statistically significant ($p < 0.05$).

4. Discussion

In this study, we developed the first scale for HLE that specifically reflected Chinese characteristics and had good validity and reliability. The HLES was developed based on the classical research procedure, and it was compiled and modified based on the unique local culture in China.

We tested the HLES for construct validity, content validity, internal consistency reliability, and test–retest reliability. EFA and CFA were used to evaluate the construct validity of the HLES. (1) Three common factors were produced by the EFA, that is, the "structural," the "clinical," and the "interpersonal" dimensions. These dimensions' characteristic root values were approximately 6, and the cumulative variance contribution rate was 59.8%. CFA was tested using structural equation modeling after conducting EFA. Except for the possible small sample size effect, the TLI and GFI was slightly less than the standard (57); other indexes were suitable, indicating that the model had an acceptable fit. The result shows that, overall, the test structure fits well with the default model, and the theoretical construction of the scale is reasonable. In addition, some error terms were correlated. This may be due to the relatively similar measurement content or expression of the items. For example, the error correlation between items S1/S2/S9 may be because the three items are designed to evaluate the navigation of the hospital and the navigation services of medical workers. The error correlation between S15/S16 may reflect the design of health information materials and use the same question stem; (2) We invited experts that majored in health management, hospital administration, health education, health promotion, clinical medicine, and nursing to evaluate the items. The analysis showed that the I-CVI > 0.78 and S-CVI > 0.90, indicating that the content validity of the scale was reliable; (3) The results showed that the Cronbach's α coefficient for the overall score was 0.960 and ranged between 0.892 and 0.923 for the domains, and (4) the test–retest reliability coefficient for the overall score was 0.844. These findings indicate that the scale had excellent reliability.

The theoretical framework of the scale was PCC, which is classified into three dimensions: interpersonal, clinical, and structural. In addition to current HLE-related measurement tools and content related to the construction of HLE from the literature, we also developed the items based on qualitative research and our own experience. For example, (1) the development of "Internet + Medical" in China. As of June 2021 (58), the internet penetration rate in China reached 74.4%, and the number of internet users in the country reached 1.05 billion, with about 99.6% of the citizens surfing the internet through mobile phones. This shows that the internet and mobile phone usage has become a carrier for Chinese patients in medical treatment and in promoting health information. Patients can

TABLE 2 Results of the third EFA (*n*=325).

Title item		Principal components		
		1	2	3
S1	Signs or route maps on the outside of the hospital helped me navigate or reach the hospital smoothly	0.638		
S2	Floor indexes, signposts, arrows, text, and other directions to different departments (e.g., Emergency departments, pharmacy, CT, etc.) helped me navigate smoothly	0.599		
S4	When I was hospitalized, I was taken by staff for examination and returned to my ward without navigating by myself	0.413		
S6	I could make an appointment online, by phone, or on-site	0.592		
S7	The hospital arranged the examination in a reasonable order, so I did not have to wait a long time	0.625		
S8	Medical workers informed or directed me to consult and seek guidance remotely via mobile phone	0.781		
S9	Navigator helped me solve the problems (such as informing the place of examination and selecting the department for medical treatment.)	0.633		
S11	Hospital information platforms (e.g., the hospital's WeChat official accounts platform and app) were designed to make it easy to find or use the functions I need, such as finding out what disease doctors specialize in treating, checking examination reports, and browsing health information	0.664		
S14	Health materials were available in a variety of formats (e.g., prints, drawings, videos, models) that allowed me to absorb health information in a preferred way	0.805		
S15	Health materials (e.g., brochures, posters, videos, and QR codes.) promoted health	0.778		
S16	The content of health materials (e.g., brochures, posters, videos, and QR codes) was easy to understand	0.793		
C1	Medical workers provided me with the disease information adequately		0.758	
C2	Medical workers explained the important results of the examination to me		0.606	
C3	Medical workers discussed with me the information about available treatment options (e.g., desired effect, risks, and costs) in order to involve me in decision-making		0.730	
C4	When signing medical documents (e.g., informed consent form, admission instructions), medical workers made everything clear		0.748	
C6	Guidance from medical workers (e.g., verbal communication, provision of medication labels) helped me take my medication correctly		0.522	
C7	Medical workers let me know emergency symptoms		0.585	
C8	Guidance from medical workers helped me obtain knowledge and skills to keep healthy (e.g., methods of self-monitoring my condition, proper diet and exercise, rehabilitation exercises, etc.)		0.569	
C9	Before the treatment, medical workers told me the approximate cost of the medical treatment		0.725	
C13	Medical workers gave me contact information so that I could contact them for medical help when needed		0.586	
I6	Medical workers had sufficient time for me to consult			0.816
I9	Medical workers encouraged me to ask questions			0.789
I10	Medical workers used simple language to explain medical information to me (e.g., using layman's terms and explaining medical terms through analogies)			0.403
I11	Medical workers asked me to explain back to them what they had told me (e.g., notice for examination/procedures, health instructions) to make sure I understood it			0.656
I12	When communicating about my condition, treatment, and health education, the medical workers gave me relevant written information (e.g., lists, brochures, and messages)			0.685
I14	When I finished communication, medical workers asked me if I had any other questions			0.442
I15	Medical workers asked me what I had learned about the disease before they gave me health advice			0.746
I16	Medical workers provided me with health information proactively (e.g., brochures, cards, and videos)			0.787
I17	Medical workers highlighted key information in the health materials to me (e.g., through verbal emphasis and marking)			0.429
I20	Medical workers used tools such as images or physical models to explain my condition or provide health advice			0.579

make an appointment for registration, payment, and inquiry using their mobile phones (59, 60). Moreover, they can communicate with healthcare professionals for medical consultations, and even browse disease awareness videos online on their mobile phones. Therefore, we added three items (S6, S8, and S11), accounting for 1/10 of the total items, to evaluate the complexity of navigation and appointment services, as well as the accessibility of obtaining health information. Meanwhile, there are three items (S14, S15, and S16) that specifically highlight the comprehensibility and usefulness of health videos and other material obtained by scanning QR codes. (2) Different from
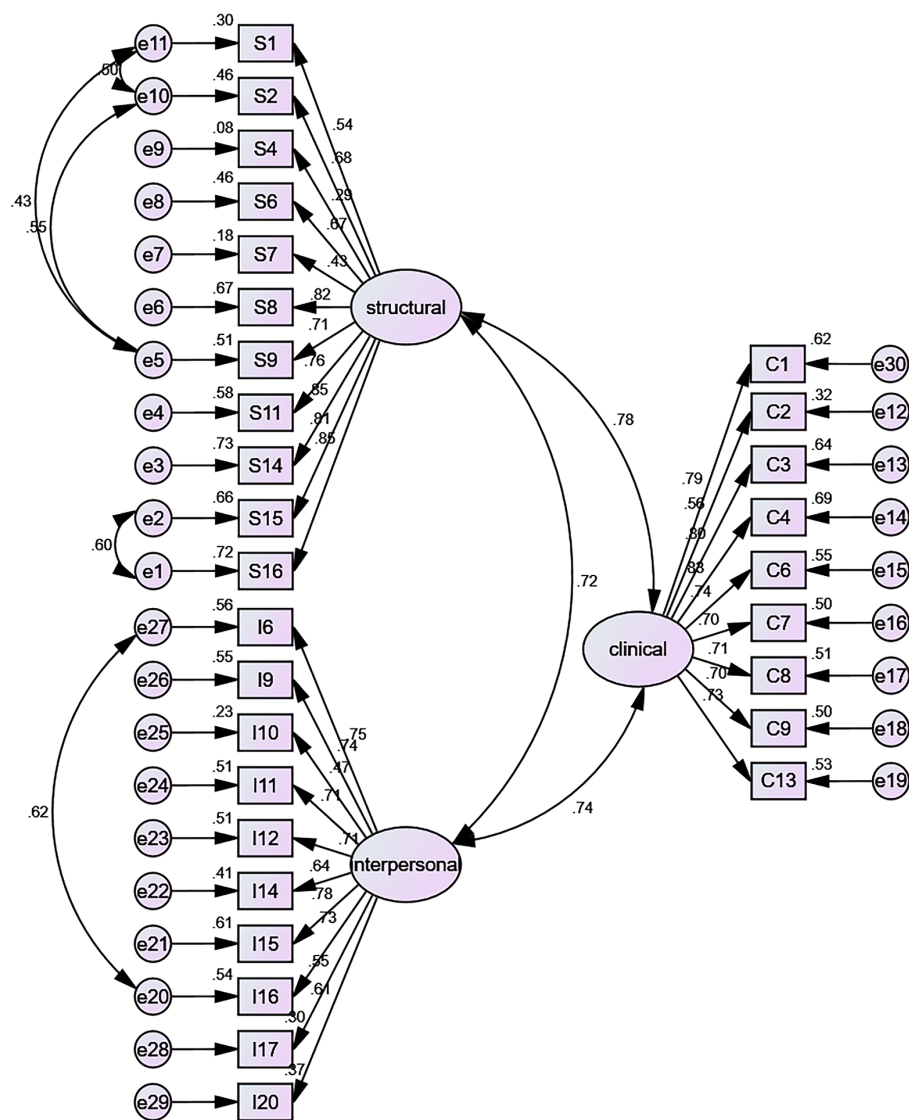
FIGURE 2
Confirmatory factor analysis.

TABLE 3 The results of internal consistency and test–retest.

Dimensions	Item	Cronbach's α	Test–retest
Interpersonal dimension	10	0.892	0.702**
Clinical dimension	9	0.915	0.661*
Structural dimension	11	0.923	0.721**
total scale	30	0.960	0.844**

*$p < 0.05$; **$p < 0.01$.

TABLE 4 The scores of the HLES in three hospitals.

Hospital	N	HLES		F-value	value of p
		Mean	SD		
A	251	63.51	18.60	8.871	<0.001
B	257	57.27	19.87		
C	189	56.51	21.32		

other countries, medical resources are relatively constrained in China owing to the country's large population. From 2018 to 2021, Chinese hospital beds (per 1,000 people) were 6.0, 6.3, 6.4, and 6.7 (61–63). While the data from the World Bank showed (64) that there were 8.0 hospital beds (per 1,000 people) in Grammy in 2017 and 13.0 hospital beds (per 1,000 people) in Japan in 2018. To solve this problem, Chinese hospitals have been built on an increasingly large scale in recent years. According to China's national health programs

development statistical communiqués in 2021 (62), there are 36,570 hospitals in China, with over 4,232 (11.6%) 500-bed hospitals as of 2021. Although to a considerable extent, the expansion of hospital scale can solve medical resource constraints, it also adds complexity for patients to access medical services. The visiting time of outpatients in China is longer than that in other countries. The mean visiting time of outpatients in China was 33 min in 2020 (65), in comparison to 14.5 min in the United States in 2012 (66), 17 min in Japan in 2013 (67), and 15 min in England in 2005 (68). In addition, most of the time

TABLE 5 Demographic characteristics of patients and the difference with the HLES.

Category		Patients (N=697)	The score of HLES (M±SD)	F-value/t-value	p-value
Ages (years)	≤35	99	72.2 ± 13.0	40.729[a]	<0.001
	36 ~ 45	95	68.9 ± 16.0		
	46 ~ 55	153	61.3 ± 18.1		
	56 ~ 65	195	53.7 ± 20.5		
	>65	155	50.2 ± 20.2		
Gender	Male	384	59.7 ± 19.6	0.529[b]	0.597
	Female	313	58.9 ± 20.7		
Education	Primary school and below	206	42.5 ± 18.4	119.938[a]	<0.001
	Junior middle school	219	60.3 ± 16.4		
	High school	127	68.2 ± 13.6		
	Associated college and above	145	73.9 ± 14.3		
Marriage	Married	641	58.1 ± 19.8	5.632[b]	<0.001
	Unmarried	56	73.5 ± 17.7		
Monthly household Income (CNY)	≤2000 yuan	41	30.5 ± 18.4	172.015[a]	<0.001
	2001 ~ 5,000 yuan	265	47.3 ± 15.9		
	5,001 ~ 10,000 yuan	279	68.1 ± 13.8		
	>10,000 yuan	112	76.3 ± 13.8		
Residence	Rural	335	50.9 ± 19.8	11.608[b]	<0.001
	Town	362	67.1 ± 16.9		
Competent dialect	Mandarin	249	68.0 ± 17.2	71.434[c]	<0.001
	Dialect	283	49.6 ± 19.8		
	Bilingual	165	62.9 ± 17.0		
Department	Internal medicine	418	58.2 ± 20.6	1.849[b]	0.065
	Surgery	279	61.0 ± 19.1		
The number of hospital admissions	First time	384	58.1 ± 20.6	1.509[c]	0.222
	Second time	122	61.7 ± 17.0		
	Third and above	151	58.3 ± 21.6		
Length of hospital stays (days)	<3	86	61.0 ± 20.9	2.506[c]	0.082
	3 ~ 7	342	59.5 ± 19.5		
	>7	169	55.8 ± 21.9		

[a]Welch F-value; [b]t-value; [c]F-value.

spent on outpatient visits in China is spent on navigating the hospital and waiting to be seen, while the time spent communicating with the doctor is very short. Therefore, in the development of HLE, optimizing navigation services is a challenge for Chinese healthcare organizations. In this study, five items (S1/S2/S4/S7/S7), accounting for 1/6 of the total items, were compiled to evaluate the complexity for patients to access medical services in the physical environment, the equipment of navigation staff, and navigation services.

Searching Chinese databases, we found that there is no HLE or related measurement tools. We only found one tool–HLE2–which evaluates the HLE in western countries (14). Patient-reported measures are important in quality improvement efforts because they provide patients' perceptions of regarding areas of high-quality care and aspects of care that need improvement (69, 70). However, the HLE2 cannot evaluate medical treatments from a patients' subjective perception, such as the process of doctor-patient communication, informed consent, clinical decision-making, and accessing or

browsing health materials. Therefore, it is difficult for the HLE2 to directly evaluate whether patients can successfully access, understand, and use health information and services. However, the HLES, as a patient perspective tool, can effectively evaluate those elements.

In addition, the evaluation contents of the HLES can be used as a reference for Chinese healthcare organizations to practice the indicators proposed in the *Actions to Build a Healthy China (2019–2030)* (31). "Healthcare professionals should actively provide health conduction during treatment" is an advocacy indicator in this action. Healthcare organizations can refer to the interpersonal, clinical, and structural dimensions of the HLES to appraise this indicator. In addition, "establishing the performance appraisal mechanism for health promotion and education conducted by healthcare organizations and professionals" is a binding indicator of the actions. At the same time, how to achieve and appraise this indicator is also the key work of the *Healthy China Initiative* in 2021 and 2022. The HLES can be used as one of the performance appraisal tools to evaluate

health promotion and education by healthcare organizations and professionals or to develop performance appraisal indicators.

This study has several strengths. First, the HLES has provided a patient perspective tool to evaluate HLE. Patient-reported measures are arguably one of the best ways to assess constructs that relate to patient-centeredness and evaluate the service quality in healthcare. However, Bremer et al. (71) summarized 13 HLE-related measurement tools in English, and only three of them evaluated HLE from a single patient perspective. Second, most of the strategies for health literacy promotion in China focused on individual competencies where health education is the most common method (30, 72, 73). However, improving health literacy is not just addressed by individual skills and abilities, it also depends on the complexities of the healthcare system (5, 17). This study provides a new perspective on improving health literacy in China, that is, healthcare organizations make it easier for patients to access, understand, and use health information and service, and provides a tool that has good reliability and validity for evaluating the role played by healthcare organizations in health literacy promotion (71). current research about HLE is mainly from developed countries such as the United States, Germany, and Australia, while our study provides research findings from developing countries. The HLES can be used by hospital managers to evaluate HLE regularly, and the results can provide a basis for the establishment and evaluation of quality improvement for health literacy promotion. Managers can formulate targeted health literacy promotion measures based on the three dimensions of HLES–Interpersonal, Clinical, and Structural—by incorporating health literacy promotion into medical workers training and formulating performance appraisal systems to improve medical workers' ability to practice health literacy (74, 75); formulating regimes for information support and services related to medication management, informed consent and clinical decision-making, and discharge (5); asking for navigation to be considered when designing or renovating health facilities. In addition, policymakers can use HLES to survey the hospitals under their jurisdiction. On the one hand, they can600-obtain benchmark data to issue policies and reduce the differences in HLE between regions; on the other hand, they can adopt targeted improvement countermeasures and provide corresponding resource allocation through the analysis of HLE influencing factors.

5. Limitations and future directions

The limitations of this study could be used to develop future research. First, this study was only conducted in Hangzhou, Zhejiang Province, located in the east of China. Although Hangzhou, with adequate medical resources, is representative of HLE measurement (76), subsequent studies need to validate the availability of HLE in other districts (e.g., western, northern, southern, and central China), considering the cultural differences among various ethnic groups and districts in China. Second, this study was conducted only in tertiary hospitals. The availability of the HLES could be subsequently validated in different tiers (e.g., primary and secondary hospitals) or types (e.g., nursing homes, and hospice care centers) of healthcare organizations. Third, a cross-sectional comparison should be conducted across different tiers and types of healthcare organizations to verify the discriminant validity of the HLES. Moreover, some error terms were correlated in CFA, so future research needs to further adjust the content and expression of the items, and expand the sample to test the fitted model. Finally, this study lacks criterion validity. The evaluation

of criterion validity needs to use both the "gold standard" scale and the testing scale to measure the concept, but there is no "gold standard" scale of HLE from the patient's perspective, and similar western scales lack Chinese translation versions and are not fully applicable to China's situation. Therefore, the criterion validity of the HELS will be further explored in a follow-up study.

Data availability statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics statement

The studies involving human participants were reviewed and approved by Bioethics Committee of Hangzhou Normal University (Grant ID:2022029). The patients/participants provided their written informed consent to participate in this study.

Author contributions

YT, YiW, and ZX conceived and designed the analysis. YT, YiW, and ZH critically reviewed the article content and wrote the paper mainly. YeW, SL, ZC, and MW were partially involved in writing the paper. ZX and SC collected the data. ZX performed the analysis. YT supervised the project. YT, YiW, and ZH are co-first authors and contributed equally to this manuscript. All authors read and approved the final manuscript.

Funding

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/fpubh.2023.1130628/full#supplementary-material

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Social innovation in health and community-driven engagement as a key strategy for addressing COVID-19 crisis challenges: insights and reflections from the multicultural society of Iran

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Background: Social innovation is one of the strategies for appealing to people and encouraging social cooperation and engagement in interventions during crisis periods. In this regard, community engagement is an operative and innovative community health approach for achieving successful health outcomes. There is limited information about the role and operational impact of social innovation on community engagement during the challenges posed by the COVID-19 crisis. In this study, we aim to contribute to the understanding of innovative social strategies to attract social participation in crises such as the COVID-19 pandemic by highlighting the experience of social innovative strategies based on community-driven engagement in Iran.

Methods: This qualitative study was conducted in seven provinces of Iran—Mazandaran, Zanjan, Golestan, Lorestan, Tehran, Kurdistan, and Khuzestan—from 4 September 2021 to 1 March 2022. A sample of Iranians (15−71 years) was selected by purposeful and snowball sampling methods to participate in the study, and 187 semi-structured telephone interviews were conducted. Participants were recruited from three levels of the community: community leaders, healthcare providers, and laypeople. The data collection tool was an interview guide, which was designed based on a review of the literature. The data were analyzed using conventional content analysis. Exploratory analyses were performed to identify social innovative strategies based on community engagement used during the COVID-19 crisis in Iran. The interviews continued until data saturation was reached.

Results: Based on our findings, we distilled innovative strategies into 6 main themes and 37 categories: (1) information giving/sharing, (2) consultation, (3) involvement/collaboration, (4) health education and prevention, (5) empowering, and (6) advocacy. The results revealed that the participants were very driven to engage in the management and control of the COVID-19 crisis, even though they faced significant challenges.

Conclusion: The spread of the COVID-19 pandemic required social- and community-based responses. These reactions increased the possibility of fair access to health services, especially for vulnerable groups and minorities. As with other epidemics, applying the experience of the comprehensive participation of communities played an important and active role in the prevention and

control of COVID-19. In this regard, giving and sharing information, consultation, involvement/collaboration, health education/prevention, empowerment, and advocacy are the most important innovative strategies that might encourage the community to perform COVID-19 crisis management and control.

Introduction

The COVID-19 pandemic was sudden and shocking, resulting in severe changes that affected communities. The crisis was not a singular phenomenon but was influenced by sociocultural, political, and economic components of community settings, resulting in several negative impacts that could not be adequately handled by current and routine strategies. Therefore, the most effective global strategy was to use indigenous and native approaches that fit the sociocultural context to reduce the spread of infectious diseases. Approaches such as individual and community empowerment become relevant within cultural contexts to identify cultural factors that affect health and to remove obstacles and challenges related to health. Social innovations for health interventions can meet these challenges (1).

Social innovations are social goals linked to the successful lives of society to reach satisfaction through a well-organized, active, reasonable, and practical response to current needs (2). Social innovations are novelties that are communal, both in their approaches and in their objectives, and they target the detection of novel reactions to social complications and challenges by recognizing and offering novel facilities that grow the lives of persons in the community (3). The relationship between innovation and society is a complex issue (4). When culturally consistent solutions are combined with responsive care processes and existing local governance structures, opportunities for improving health and social innovation are created (5). Typically, reactions to public health crises include top-down government activities and community health organizations. This usually involves holding discussions with the community and using biosecurity methods, as well as considering their cultural diversity (2, 6).

Multicultural societies regularly display the necessity of culturally stable strategies for individuals during a health crisis and in confronting unequal health problems (7, 8). When such culturally stable strategies are merged with accountable care procedures and current local governance constructions, chances of progressing social innovation and health are generated (6). When encountering a health crisis or pandemic, societies noticeably request and look for descriptions as a reaction to their vulnerabilities and being in danger (7). Diverse cultural systems are expected to have varying disease perceptions during

a pandemic, leading to differing coping approaches (9). This becomes even more crucial in multicultural and multireligious contexts, such as Iran (10). Iran is an interesting example of a country with great diversity in ethnic, linguistic, religious, and cultural groups, including Persians, Kurds, Lurs, Mazandaranis, Gilakis, Azerbaijanis, Arabs, Balochi, and Turkmens. The nation is also home to several minority groups, including tribal Turkic groups, Talysh, Armenians, Georgians, Assyrians, Jews, Circassians, Russians, Koreans, and Iraqis (11). The differences and cultural diversity in Iran can pose different behavioral reactions during health-related crises in the community.

It is important for middle-income or low-income communities, especially those with diverse cultural and ethnic characteristics, to recognize how they will be influenced by a public health crisis and how to distinguish their barriers and challenges. One of the practical and useful public health approaches for strengthening social innovation in health in poor communities, growing health consequences, and certifying social support is to promote community engagement (CE) (3). CE is defined as "a procedure of rising interactions that allow a community to confront each member to consider health-related topics and increase health to attain good health effects and results." The concept of CE refers to fostering conditions and occasions for community members to have their opinions acknowledged in identifying the challenges and suggesting strategies to resolve the health difficulties they face (3). The risk of contracting the COVID-19 crisis cannot be entirely attributed to individual threats, as it also involves wider sociocultural and structural factors of health that lead to inequities in communities where at-risk people live, act, perform, and acquire (12).

For effective CE during a pandemic, such as COVID-19, there must be an environment with a common culture and purpose and sufficient levels of cross-cultural abilities in controlling the crisis, which may lead to the more effective implementation of pandemic strategies and possibly reduce the inequity that may be presented throughout the pandemic (13–18). In particular, the unequal burden of COVID-19 death was pronounced among multicultural populations in societies that have a history of providing unequal health services (13–16). Therefore, CE is vital for disclosing the opinions of those in the community using culturally appropriate strategies that are more likely to remain stable beyond the COVID-19 crisis. To perceive these communities, the role of culture is important if any strategy is to be accepted or stabilized (8). Culture is key to effectively informing the community about COVID-19 for CE, and it is also important for its universal response to CE (19). The community includes community leaders, community

networks or teams, health-controlling groups, persons, and main stakeholders (elderly, schoolchildren, youth, females, and others susceptible) (17, 20). In response to crises, an approach that entails full community participation is recommended, including the broad ability of all areas, such as trade, non-profit organizations (NGOs), groups, and the public (2, 17).

Previous studies have revealed the positive impacts of social innovations on the community-based distribution of health facilities and the mediating role of native strategies for infection prevention/control and CE. The positive effect of engaging communities to address neglected tropical diseases or planning for an influenza pandemic among disadvantaged groups has been reported (13–18, 20–23). In low- and middle-income states, CE has been a vital activator of dynamic reactions to direct communicable infections (24). CE was operative in responding to the 2014 Ebola epidemic in the setting of a poor health organization in Sierra Leone, where civic answer groups helped curb the native spread of the disease via contact finding, house-to-house appointments, health services, and community reporting (25, 26). Furthermore, CE promoted a significant reduction in children's deaths due to malaria in Ethiopia, as well as a decrease in HIV incidence among the people (24, 27).

Even when structures are present for engaging community participants in social innovations, the particular approaches implemented must reveal and be accepted in the native background, values, and legislation (21). The newness of COVID-19 has offered exclusive challenges that current models of facility supply may not be sufficiently designed to tackle (28). Therefore, it is essential to develop socially innovative strategies and approaches based on CEs to confront the challenges arising from the COVID-19 crisis (29). Thus, guided by the literature on social innovations (30) and CE (17, 31), this study explores how social innovations in health based on community-driven engagement can be leveraged to react to the health requirements, barriers, and challenges resulting from COVID-19 in the multicultural society of Iran. Until now, there has been little understanding of social innovation practical strategies for CE in confirming the adoption of government strategies for monitoring COVID-19 in multicultural societies, such as Iran. In the current project, we aim to fill this gap by highlighting the experience of CE during the COVID-19 crisis in Iran to provide insights that may enhance knowledge of social innovations through CE in multicultural societies.

Methods

The purpose of our qualitative study is to identify social innovative approaches that might increase community participation in response to the COVID-19 crisis.

Study design and setting

This was a qualitative content analysis study conducted from 4 September 2021 to 1 March 2022. We employed conventional content analysis, given the limited data in the field of study at that time of the study in the Iranian context; thus, there were no preconceived hypotheses. Semi-structured individual interviews

were used to gather data in the study. Each interview continued for not more than 40 min to avoid the mental fatigue and weariness of the interviewees. This study was conducted in seven provinces of Iran, including Mazandaran, Zanjan, Golestan, Lorestan, Tehran, Kurdistan, and Khuzestan, reflecting Iranian society's diverse cultural and linguistic features. Each of these provinces has a different language, accent, and cultural characteristics.

Participants

Participants were recruited from three levels of the community: community leaders, healthcare providers, and laypeople. Community leaders included community chair people, town, quarter, mayors/village headmen, school/university superintendents, religious leaders, business leaders, union leaders, imams, and other well-known community figures. Participants were also selected at the national level, including senior-level policymakers from two government offices ($n = 5$) and seven NGOs ($n = 9$).

To obtain different perspectives, participants were chosen by both purposeful (with maximum variation) and snowball sampling due to the necessity of sample diversity in terms of demographic characteristics and expertise (32). However, most participants in this study were recruited by purposeful sampling. In the selection of participants, the maximum variation or "heterogeneous method" was used to achieve varying levels of socioeconomic status, ethnic, linguistic, demographic, age, gender, level of education, and place of residence. Given the diversity of the culture and ethnicity of Iranian society, we tried to invite most of the ethnicities that covered both urban and rural communities for interviews. Snowball sampling was used on a case basis by encouraging recruited participants to invite others to participate in the study. At the launch of the study, the purpose of the study was explained to each participant. Interviewing with participants was continued until data saturation was achieved; that is, no new codes were discovered in the data.

Data collection

The data gathering technique in this research was telephone-based semi-structured individual interviews. At the start of each interview, the participants were asked about their demographic characteristics. An interview guide was used for the interviews, which was designed based on the literature review and the views of several professors in the fields related to the topic and research. The interviewing process is described in detail in Additional File 1.

Considering the dispersion of the study setting, the cultural and linguistic diversity of the research community, the high prevalence of COVID-19, and the time efficiency of the study, four researchers familiar with qualitative research methods were invited for administrative coordination to obtain the participants' contact numbers. In this regard, for the provinces of Khuzestan, Zanjan, Lorestan, and Golestan, which have various languages and dialects, native researchers who were also familiar with qualitative research methods were invited to participate in the study. The first author of this article conducted interviews in Mazandaran and

Tehran provinces, and the second author of this article conducted interviews in Kurdistan province due to familiarity with the local language of that region. The reason for this choice was that these people were familiar with the culture, language, and religious characteristics of the mentioned areas. After the administrative coordination of the different departments by each researcher in the selected provinces, the contact numbers of the individuals were collected to obtain permission and coordinate the time of the interviews.

In total, seven trained interviewers who were familiar with the culture of the selected provinces as well as qualitative research methods conducted semi-structured 40-min telephone interviews with 187 participants. Data collection lasted from September 2021 to March 2022. The interviews were conducted on Android smartphones that had the call-recording property. Telephone interviews were conducted due to the physical distancing protocol and the necessity of maintaining safety while conducting the qualitative study. Each interview continued for not more than 40 min to avoid the interview fatigue of the interviewees. Most of the interviews were held in Farsi (the official language of Iran). In cases where the participant preferred to speak his native (mother tongue) language or could not speak Farsi fluently, the interview was conducted in the native language of the same region (which was the reason for selecting interviewers familiar with the language of the selected provinces).

The participants were encouraged to discuss their experiences with innovative approaches that increased CE to control the COVID-19 crisis. Similarly, they discussed sociocultural and ecological components that might have had an effect on the level of CE regarding this crisis. The interviews focused on the following three main questions:

- How was your experience with engagement in the management and control of the COVID-19 pandemic?
- What strategy and procedure have you applied for engagement in the management COVID-19 pandemic?
- How have the strategies and procedures affected your engagement in this regard?

Based on responses to the questions, follow-up questions were asked. After each question, participants were invited to explain more about what they had reported. For example, they were asked, "What do you mean?" or "Explain more" for a deeper consideration of the participant's experiences regarding the topic.

To maintain the confidentiality of the participants' information, the interviews were numbered from 1 to 187. After 183 interviews, the data were saturated. The interviews were recorded and transcribed verbatim in Farsi. Considering that some of the interviews were conducted in the native language of the people of that area, after the interviews, the recordings were translated into Persian by the same interviewer. The transcripts and digital recordings were cross-checked.

Data analysis

Content analysis with a conventional approach was used to explore the information based on Graneheim and Landman's

approach, identify main themes, and compare patterns through several individuals (33). All interviews were audio-recorded after obtaining informed consent, and the audio-recordings were listened to carefully several times. The recordings were transcribed word by word into Persian. The researchers then read the interviews numerous times and discussed the best coding method. All recorded transcripts were converted into meaning units. Concepts of key words and expressions concerning the interviews' context were built. Concepts were displayed as codes after the completion of all interviews. The primary code was obtained, the meaning unit was summarized into a "condensed meaning unit," and the extracted codes were created in the next step. After the coding structure was identified, the interviewer entered the transcripts into MAXQDA software v12, which allowed the text to be coded and restored for ease of interpretation. The study group compared all transcript stages to categorize code relationships and differences. The researchers then explored the differences and reconciled them, and the final code was extracted. Similar codes formed subcategories, and the main categories were created from subcategories. Finally, the themes were obtained based on some related main categories. All audio files and transcripts are accessible to reviewers.

Rigor

The rigor of the data collection was confirmed by analyzing its credibility, transferability, confirmability, and dependability (34). In the current study, several features of trustworthiness were identified. Credibility was established through lasting engagement with information, member checking, and peer debriefing. We invited a second coder who was trained in qualitative study. We requested seven of our participants to review the transcripts, a summary of the interviews, and the developing results (member check); these participants were selected across the interviews. Confirmability of this study was achieved by sending content codes and themes to six researchers familiar with qualitative content analysis methods (peer checks). The transferability of the current research was ensured by providing a rich and complete explanation and a detailed report of the study method. The transferability of this study was ascertained by using the maximum variation sampling method (35). The dependability and credibility of the present data were confirmed by the obvious coding method and inter-coder confirmation (34). Additionally, data were analyzed using a thematic analysis method in Farsi, and the codes and study information were transcribed in English.

Ethical considerations

The study received ethics approval from the Mazandaran University of Medical Sciences Review Committee (Approval No/2021.06.23/IR.MAZUMS.REC.1400.250; Grant No. 11483). All participants were specified using aliases and were informed that their contribution to the current study was voluntary, they could withdraw at any time, their privacy would be maintained, and none of them would be recognizable in any publications resulting from

TABLE 1 Socio-demographic characteristics of participants (n = 187).

Characteristics	Values, n (%)	
Age (years)		
	15–34	69 (36.9)
	35–54	93 (49.7)
	≥55	25 (13.4)
Gender		
	Male	85 (45.5)
	Female	102 (54.5)
Education		
	Primary	37 (19.8)
	Secondary	45 (24.1)
	Higher	105 (56.1)
Occupation		
	Government's employee	67 (35.8)
	Freelance job	55 (29.4)
	Retired	14 (7.5)
	Unemployed	51 (27.3)
Ethnicity		
	Persians	43 (23)
	Mazanderanis	29 (15.5)
	Gilaks	17 (9.1)
	Kurds	19 (10.2)
	Lurs	12 (6.4)
	Azerbaijanis	18 (9.6)
	Talysh/Tats	9 (4.8)
	Baloch	14 (7.5)
	Turkmen	9 (4.8)
	Arabs	17 (9.1)
Current region of residence		
	North	44 (23.5)
	South	32 (17.2)
	East	37 (19.8)
	West	33 (17.6)
	Center	41 (21.9)

the study. Informed consent was collected from all participants before the interviews.

Results

In total, 187 Iranian people aged 15–71 years (41.5 ± 8.71 years) took part in the study. The characteristics of the participants are reported in Table 1. Overall, six major themes emerged from the analysis: (1) information giving and sharing, (2) consultation,

(3) involvement and collaboration, (4) health education and prevention, (5) empowering, and (6) advocacy. More information on the themes and categories is presented in Table 2. However, in the following section, we reflect on the participants' experiences of major themes.

Theme 1: Information giving and sharing

One of the themes produced in the current study was information giving/sharing. Here, information giving/sharing describes the exchange of data about the COVID-19 pandemic between various people and organizations (public, private, and non-governmental institutions and organizations) in different ways, such as the use of technologies. Based on the participants' comments, the five key strategies for sharing information related to the recent crisis were: (1) public awareness campaigns, (2) information management, (3) new technologies and telecommunication tools, (4) local advertising (with billboard/banners for training and TV messaging), and (5) media infrastructure (mass media and cyberspace).

During the COVID-19 crisis, information giving/sharing was used to raise information awareness about the COVID-19 disease, building awareness and sensitivity to accept health protocols, increasing perceived sensitivity, and advertising via social media. At the beginning of the COVID-19 crisis, rumors and misinformation were circulating via different communication channels. Therefore, one effective strategy during this crisis was accurate information management. This included accepting the worries of the community, offering occasions for conversation, and countering rumors, false information, and infodemic by social media, national/local media, and infographics.

> "In line with education and information in the field of COVID-19 disease and vaccination and the importance of awareness in this regard, all educational clips related to COVID-19 are available on Avay Salamat website at https://iec.behdasht.gov.ir (in the health campaigns section/Let's stay together). The site is loaded…" (Participant 14)

Participants reported that insufficient and sometimes inconsistent information provided by the government and health workers about COVID-19 caused them to feel anxious and distrustful.

> "The government was giving citizens one kind of information about COVID-19, and maybe private organizations, media, and even NGOs were giving another type of information and content about the way COVID-19 virus is transmitted. So, at the beginning of the COVID-19 epidemic, everything was mystifying and even contradictory." (Participant 56)

Another strategy used by the government and NGOs to inform the community was technology, especially in awareness campaigns about COVID-19. For instance, to inform people, the Association for Support of Children with Cancer (Taskin) carried out a campaign in the suburbs of Tabriz, with the participation of volunteers and the Tabriz Municipality. The

TABLE 2 Main themes and categories.

Main themes	Categories
Information giving/sharing	
	Public awareness and health literacy campaigns
	Correct information management
	New technologies and telecommunication tools
	Fliers and local advertising
	Media infrastructure
Consultation	
	Getting feedback from community
	Consultation with community leaders/stakeholders
	Setting up public and open consultation systems
	Launching a self-assessment system
	Comprehensive integrated system for psychosocial health services
Involvement and collaboration	
	Networking
	Lobbying between government and NGOs
	Multi-sectoral collaboration through COVID-19 committees
	Establishing platforms
	Social mobilization
	Shared leadership/decentralization/ability to control
	Managers' commitment
	Incentives and motivations
	Promoting a culture of participation
	Sensitizing, persuasion, and pressuring
	Stakeholder engagement
Health education and prevention	
	Prevention
	Risk communication
	Screening
	Quarantine
	Maintenance
Empowering	
	Jihadi, voluntary, and faith-driven actions
	Social trust building

(Continued)

TABLE 2 (Continued)

Main themes	Categories
	Social responsibility
	Community resiliency
	Strengthening society efficiency/finding talent
Advocacy	
	Leaders involvement (legislators; policy makers; decision makers)
	Partnership building and coalition
	Mass/virtual media and digital health
	Mobilizing the community groups
	Capacity building
	Legal and policy-making strategies

educational campaign of Halal Houses titled "Stay Together" was held with the participation of the International Committee of the Red Cross and the Health Education/Promotion Office of the Iranian Ministry of Health from December to March 2021. Other educational campaigns were "I Will Not Touch You," "Stay At Home," "Aware Society," "Neither to Sanctions Nor to Corona," "Let's Stay Together," etc. Furthermore, the director of public relations at a university of medical sciences said:

> *"We launched the "Ham-Ghasm" campaign with the aim of increasing community awareness and emphasizing the role of citizens in the management of Corona, so that we encouraged people to participate in controlling the disease … We tried to inform our fellow citizens that they should not leave their homes except in emergency moments …" (Participant 91)*

The communities were also informed through social media and virtual space, including smart SMS notifications and alerts (sending text messages to infected people who had violated quarantine and high-risk people). The educational messages about the coronavirus compiled by the Ministry of Health included information such as staying at home, wearing a mask, washing hands, social distancing, vaccination against COVID-19, and a respiratory mask educational guide.

Theme 2: Consultation

In this study, the purpose of consultation (based on the participants' viewpoints) included all the effective strategies used by the government and health system employees to increase interaction with the community, attract community participation, and reduce psychological pressure caused by the spread of the COVID-19 pandemic. This theme encompassed five sub-themes: (1) getting feedback from the community, (2) consultation with community leaders/stakeholders, (3) setting up open consultation systems, (4) launching a self-assessment system, and (5) a

comprehensive integrated system for psychosocial health services in the health network.

At the beginning of the COVID-19 pandemic, the use of counseling was not very active, although it was indicated as an effective and complementary approach by the government to reduce the psychological pressure caused by the disease, to reduce the socio-economic problems caused by it, and to increase community participation. In this regard, one of the participants noted:

> "I totally remember. At the beginning of Corona, my family was terrified. Everything was closed, and even counseling clinics were not safe [referring to the rapid spread of disease in gatherings and offices] … I had no faith in remote medicine and online counseling before this crisis … It was a novel and different [online consultation] for me … and we couldn't receive feedback physically at the clinic. So, I got the first consultation on Sky Room. This doctor recognized who I was, so we weren't completely unfamiliar with each other. Although it was a good experience for the first time." (Participant 64)

This form of CE occurred in some provinces of Iran during the COVID-19 crisis. One of the managers of the city health center defined their approach to attaining community reaction: "In cooperation with non-governmental organizations and religious leaders, we formed the community engagement forum so that we could have a good interaction with the people of the region … We used the local media to invite people." (Participant 11)

The other strategies were setting up the counseling line 1,480 and social emergency 123, setting up an internet phone line center (4,030) with 2,000 lines and the possibility of contacting families and following them up, and having comprehensive telephone counseling services for children/teenagers (e.g., mental health services and psycho-social support). The expert of the welfare organization said:

> "The number of calls to the voice of the welfare consultant at number, 480 has increased more than 50% compared to previous years, which is due to the spread of Corona and people's preference for free and remote counseling in this situation. The welfare counseling hotline is active in the fields of family counseling, mental disorders, depression, anxiety, and child problems, and clients raise their problems in this system." (Participant 81)

One of the effective strategies during the COVID-19 crisis was setting up a self-assessment system for psychological disorders (intelligent screening) for the community and the prevention of psychosocial harm caused by this crisis, which was run by the welfare organization. The general director of the welfare of one of the provinces said:

> "In this situation, society needs psychological interventions, social health, and preventive interventions more than ever, and in this regard, the smart self-assessment system (smart screening) of the country's welfare organization has been launched at http://corona.behzisti.ir." (Participant 17)

Phone hotlines were introduced as a possible means for people to record worries and receive a consultation, although the hotlines were occasionally disconnected and consequently provoked more frustration than benefits. Other practical measures included the launch of an integrated comprehensive system of psychological health and community facilities throughout the outbreak of COVID-19 for providing remote psychosocial consultation services and holding psychotherapy.

Theme 3: Involvement and collaboration

Collaboration refers to the commitment, cooperation, partnership, and participation of the community with the government in the management of COVID-19. Collaboration and involvement include improving the effectiveness of government through encouraging partnerships and cooperation within the government, across levels of government, and between the government and private institutions, as well as at the community level. It included all the ways and strategies that were synchronous or asynchronous, virtual, or in-person to increase the commitment to manage the COVID-19 crisis by the government and NGOs that were used. According to the opinion of the participants, 11 approaches of involvement and collaboration were used to increase community participation in the management of COVID-19: (1) networking; (2) lobbying between government/NGOs; (3) multi-sectoral collaboration through COVID-19 committees; (4) establishing platforms for community collaboration; (5) social mobilization; (6) shared leadership/decentralization/ability to control; (7) managers' commitment; (8) incentives and motivations; (9) promoting a culture of participation; (10) sensitizing, persuasion, and pressuring; and (11) and stakeholder engagement.

Crises similar to the COVID-19 epidemic focus on the worth of partnerships between government and community for durable crisis management achievement. Mainly in a disaster, governments must appeal to specialists with distinctive, cross-functional viewpoints to explain quickly varying, multipart complications that have long-term effects. The majority of participants agreed that crises such as the COVID-19 pandemic could be controlled by involvement and collaboration between community and government, including networking, collaboration, and lobbying between government and NGOs in a crisis, multi-sectoral collaboration through COVID-19 committees, establishing platforms for community collaboration, social mobilization and participation, using existing networks, managers' commitment, incentives, and motivations, promoting a culture of participation, health education and prevention, sensitizing, persuasion, and pressuring. One of the participants mentioned:

> "Community collaboration and involvement are when the public, patients, carers, amenity users, and other members of the public work in partnership with crisis management groups and apply their previous experience to participate in the plan, study, management, or dissemination of lessons learned." (Participant 94)

One of the key approaches to COVID-19 crisis management was women's willingness to collaborate in networks. One of the women said:

> *"Women have always been able to play multiple social roles. A group of women, regardless of their age and education, have started to form local networks by using the capacities of civil society and in preparing hot homemade food, masks, or disinfecting public places."* (Participant 82)

Participants were amazed at how respected their pre-existing unofficial networks (e.g., NGOs, local networks, social media, etc.) were in this way. They mentioned some effective elements in this regard, including knowledge networking, support management, dialogic loop of citizens on social media, customary/spiritual leaders, doctors, actors, and the college workforce.

> *"We mostly talked to each other via a phone messaging or video platform [WhatsApp]. We used the messaging platform in COVID-19 to exchange food and domestic substances during the lockdown, in which limited shops in our village locked down, and access to vital items became hard."* (Participant 88)

Most participants also emphasized cooperation with government organizations and native groups to develop effective collaboration through networks. One of the participants reported:

> *"We tried to tap into present networks, including traditional leaders, doctors, heads of councils, spiritual leaders, actors, teachers, university staff, sports players, and actors."* (Participant 23)

Other effective measures included collaborating and lobbying between the government and NGOs, charities, media, and labor unions to attract participation in this crisis management. A participant said:

> *"I believed that a major part of this stable situation in different provinces is due to the cooperation of NGOs and popular and jihadi groups in persuading community and faithful help."* (Participant 37)

Social mobilization, another strategy applied during the COVID-19 pandemic in Iran, was performed through the following activities: the cultural vow of masks, sending food and money to families whose businesses were closed, sending wedding/death expenses to the needy, and providing tablets and phones for underprivileged students. Designing sports and cooking clips/entertainment for families, launching innovative festivals, and designing applications were the effective measures taken by public and private organizations since the beginning of COVID-19 in Iran. Participants also recommended that the matching strengthening approaches of CE and trust building were important in managing the COVID-19 pandemic. According to one of the key informants' views:

> *"… The battle against COVID-19 was fought because of people's efforts and community mobilization. Although the government provided various strategies, the eradication of COVID-19 is*

achieved by mobilizing the community … If I don't desire to arise, who come? … We have a professional commitment and responsibility." (Participant 44)

Promoting a culture of participation was another strategy for solving difficulties in cooperation and involvement with communities, such as official cooperation.

> *"When the COVID-19 peaked, we held meetings via the village leaders. To prevent more spread of COVID-19 in the village, we assigned roles to people because village' people were familiar with the access points and recreation areas of the village. We bought handwashing equipment and masks with the financial support of the village council and benefactors and placed them at the entrance of the village and public places, including the bakery and 3 supermarkets of the village. Likewise, we put banners at the entrance of the village, stating that travel is prohibited."* (Participant 50)

Theme 4: Health education and prevention

The strategy of health education and health promotion in this study emphasizes all the individual, group, institutional, community, and systemic approaches that were used by the government, organizations, and society to improve the knowledge, attitudes, and behaviors in COVID-19 prevention. This strategy was tailored to the target population and community. This strategy aims to reduce health inequalities and discrimination so that all people in the COVID-19 era can fulfill their greatest health potential. This theme included five sub-themes: (1) prevention, (2) risk communication, (3) screening, (4) quarantine, and (5) maintenance.

Health communication emphasizes activities that can reduce the threat of COVID-19, such as how and what time to use a face mask, wash hands, and link to others, even though maintaining a suitable physical distance. In the offices, the body temperature of the employees was measured upon entering the building; masks were used, hands were disinfected, and a physical distance of 1–2 meters from other persons was maintained. One of the participants said:

> *"If someone has come from COVID-19 pandemic state, or having some COVID-19 signs, their boss demanded that they stay/go home, or go to clinic or healthcare center for checkup. The bosses also requested individuals not go to the COVID-19 pandemic area."* (Participant 18)

The COVID-19 screening included explaining the time and place the community could be screened, providing information about the costs of screening tests for COVID-19, and informing about safe activities. According to one of the participants' views:

> *"We attempted to know the procedures published by the National Headquarters of Administrating COVID-19 and the Ministry of Health in Iran [regarding types of diagnostic screening tests for COVID-19]. We discussed with other friends and relatives*

their experiences in performing screening tests with COVID-19 and then transferred this awareness and experience to family." (Participant 37)

During the quarantine phase, participants obeyed the rules and guidelines on the management and control of the COVID-19 crisis. They used masks in public spaces. Some university students did not return to their birthplace because of the distress of spreading to their relatives. Another participant reported that:

"I tried to track the new and updated quarantine guidelines during the COVID-19 era, and when the government announced a general quarantine, I only went out to buy essential items such as food and medicine. I was in the dormitory for 3–4 weeks and did not go to my hometown." (Participant 26)

Theme 5: Empowering

Community empowerment is a key concept and strategy that discusses the process of enabling communities to increase control over their lives during the COVID-19 pandemic. In this study, community empowerment addresses Iran's sociocultural, political, and economic elements, as well as the infrastructure health of the Iranian community, and includes building partnerships with other sections in building community-based preventive strategies during the COVID-19 pandemic. This theme is divided into five sub-themes: (1) Jihadi, voluntary, and faith-driven actions; (2) social trust building; (3) social responsibility; (4) community resiliency; and (5) strengthening society's efficiency/finding talent.

Social organizations can respond to the COVID-19 crisis through appropriate practices and innovative strategies. One of these cases involved the voluntary sector, such as NGOs, which played a key role in empowering individuals/communities and attracting their participation through various social and economic support. One of the members of the board of the parliament's industries and mines committee said:

"Identifying day laborers and women heads of families and helping them through support organizations such as Imam Khomeini (RA) Relief Committee is one of the necessities in the current situation. This is because, before the outbreak of Corona, due to the high rate of inflation, these people had financial problems. Before the spread of COVID-19, they faced many financial problems due to the high rate of inflation. In the current situation, they are dealing with much more difficult conditions due to the closure of daily wage businesses." (Participant 92)

Some of the jihadist and voluntary actions carried out to empower the community in the management of COVID-19 were performing different plans with the participation of local institutions (such as mosques, charity centers, NGOs, and health ambassadors), implementing culture-based plans (e.g., "Every Home Is a Health Base," "Jihadi camps," "Mosque-centered project," and "Health Improvement Plan for Women and Girls [prisoners]),

free visit, subsistence package, nursing home care, etc. One of the key informants stated:

"The "Every Home is a Health Base" plan has been held with the main aim of appealing community and NGO involvement in attempts to manage the COVID-19 crisis. This plan is a perfect sample of fetching community engagement, interdepartmental coordination, organizing based on the desires of neighborhoods, and the best use of the latent of the nation's healthcare system…" (Participant 87)

The participants stated that social trust building by the government plays an effective role in increasing CE. Examples of these approaches include having face-to-face interactions, cooperating with organizations trusted by society, and seeking support from neighborhood trustees. Some key informants stated that prior face-to-face communications were key to trust building, and some success they had in CE in the COVID-19 crisis reaction was due to previous efforts they had executed with them. Organizations resorted mostly to collaborating with communities if infrastructures such as the internet were accessible. One of the managers said:

"Trust was vital for community participation. We invited famous people such as celebrities, athletes, artists, scientific, cultural, religious, and social figures to city conferences." (Participant 11)

Another prominent point raised by many participants in increasing community empowerment and, as a result, increasing CE was social responsibility. One of the participants stated:

"In any case, all people are responsible for this crisis. It is not only the duty of the government … the government must guide and manage, and the people must participate. I used my personal van to disinfect the village's alleys at the start of the quarantine [during the Nowruz]." (Participant 39)

The COVID-19 pandemic has created many challenges for all societies. However, it had more negative effects on vulnerable people (e.g., women, children, aging, and patients) than other communities. Among these negative effects, reference elements included business closures, women's unemployment, domestic violence, and the price of essential items. Therefore, according to the suggestion of most of the participants, one of the effective strategies for empowering them is to increase the community's resilience. An imam of a local mosque explained:

"All the people of our village [the adolescents, the teachers, farmers, and village head], we together have collected money and dispersed lentils, rice, vegetables, detergent, etc. to the poor people. This is our social responsibility. Even the local baker covered some poor families in the village to receive as much free bread every day as they needed. Although these contributions are limited, they help to increase the resilience of poor families …" (Participant 37).

Theme 6: Advocacy

Advocacy has been used as one of the key strategies to promote community health during the COVID-19 pandemic. Advocacy for health as a combination of individual and social activities planned to achieve political commitment, social approval, policy support, and systems support for managing the COVID-19 crisis via CE. It takes into account actions and publications that affect public policy, public opinion, and laws. This theme consisted of six sub-themes: (1) leader involvement (legislators; policymakers; and decision makers), (2) partnership building and coalition, (3) mass/virtual media and digital health, (4) mobilizing community groups, (5) capacity building, and (6) legal and policymaking strategies.

In considering the role of communication during the COVID-19 crisis, advocacy is regularly mentioned as a key and important strategy of risk/health communication overall. This was a novel time when planning interventions with communities, patients, and other main stakeholders had never been key in expressing essential priorities, and community and patient desires. As the specific influences of the COVID-19 crisis were not similarly perceived, strategies must be community-detailed and addressed to the maximum key priorities. Health managers achieved support for plans by recognizing and involving local community leaders— religious leaders, head of the village council, head of the village, teachers, chiefs, elders, imams, vicars, and clerics—and consulting and cooperating with them as gatekeepers for access in a community. An NGO agent also restated the significance of employing local resources and communication techniques acquainted with the community:

"Although the new technologies were effective, they were not the answer alone … What was very effective was the cooperation of the local leaders … In our village, the village council members installed a loudspeaker on an agricultural tractor, and then the chairman of the council took necessary measures to inform the public about preventing the spread of the disease." (Participant 73)

Combining informal settings (e.g., public gatherings, festivals, sports events, indoors) and formal settings (meetings, seminars, and conferences) helped the government attract community participation. A member of a city council said:

"Our city council, in cooperation with the welfare department, launched a campaign of creative ideas as well as a children's painting festival about coronavirus and ways of managing it." (Participant 66)

Another practical advocacy strategy was partnership building and coalition. Most of the participants emphasized the key role of national and international NGOs, media, universities, public participation houses, and the clergy. A member of the NGO said:

"Face-to-face interactions are very important for the promotion of non-governmental organizations, but many of them were lost during this era. However, many virtual links and media campaigns were launched during this period with less cost and no need to travel. Coalition building is the key to success in non-governmental organizations. Today, we can easily communicate with many people from all over the world and involve people in health campaigns." (Participant 62)

Mobilizing community groups was another advocacy strategy for CE during the COVID-19 crisis. Participants listed some different methods in this regard, such as engaging community leaders, using trusted religious figures in neighborhoods to encourage people to inject vaccines, and involving key groups (athletes, actors, religious leaders, and neighborhood councils). Capacity building was another advocacy approach emphasized by interviewees. The participants mentioned several examples of community capacity building, including the Basij motor courier [Basij is a social institution with different functions to create the ability of people to help society when disasters and unexpected events occur. This institution plays a role in attracting, training, organizing, and employing public volunteers], financial support for women entrepreneurs, setting up mobile pharmacies, developing children's social skills (through campaigns, startups, online software, and competitions), and home workshops for fabric mask production. One of the participants said:

"At the beginning of Corona, my business was closed … But I saw a clip on the Internet that a person was making money with a motorcycle in China. I decided to deliver my wife's homemade food to customers using a motorcycle. For this purpose, I designed a page on Instagram and started promoting my work. I even bought the essential items that people needed and could not go out due to the quarantine and delivered them to the customers … This work is still going on … I helped the health of the community and started my own business. This is the power of the media." (Participant 41)

Finally, one of the most important strategies used during the COVID-19 crisis was legal strategies, such as crisis management, guidelines, government compensatory policies, and prohibitions/restrictions (control of borders and social distancing). A member of Iran's National Headquarter Against COVID-19 said:

"The government offered various strategies to limit the COVID-19, including ending trips, closing schools/universities, closing shopping mall, closing religious places, and banning religious meetings." (Participant 104)

Discussion

Overview

This study aimed to investigate social innovative strategies applied in Iran to increase CE in response to the COVID-19 crisis. The findings revealed several core concepts and strategies, including information giving/sharing, consultation, involvement/collaboration, health education/prevention, empowering, and advocacy. To identify the practical and innovative strategies that increase CE in a COVID-19 emergency,

hypothetical basics were explored, and field documents were analyzed by recognizing themes, categories, sub-categories, and codes, which could help legislators in key strategic decisions as well as in creating strategies applicable for future pandemics. When faced with public health crises, such as COVID-19, countries should adopt approaches to increase the motivation for community participation in disease reduction (36). For instance, the schedules taken in China showed that quarantine and social distancing were able to stop the rapid spread of COVID-19 (34). The operationalization of health actions at the individual and social levels requires the full participation of the community, such as repeated handwashing, social isolation, and flexible job schedules (36).

Theme 1: Information giving and sharing

We observed that correct, relevant, and up-to-date communication of health risks is a vital component of CE. In addition to improving community awareness and decreasing risky behaviors, this also contributed to promoting and maintaining trust. The findings highlighted that information giving/sharing regarding the COVID-19 crisis was done using public awareness campaigns, correct information management, new technologies and telecommunication tools, local advertising, and media infrastructure. Health professionals, government agencies, NGOs, and social media were trusted sources. An effective response in an epidemic is when accurate information about the burden of disease and death is told to society as soon as possible. This accurate dissemination of data allows the government and society to implement control and management methods quickly and on a large scale. Active communication and information sharing will similarly reduce the spread of "false information" and "infodemics" (37–39).

All three categories of participants believed that the dissemination of information was an effective approach in CE. The laypeople and healthcare providers believed that CE in crisis management could be increased when accurate statistics and information on deaths and the scope of the crisis were reported. Furthermore, the group of community leaders believed that while correct information should be published, it is not necessary to report all the details of the crisis to prevent fear, anxiety, and panic among the people. Key to fighting infodemics and advocating suitable communication will be recognizing and removing false news and gossips via the engagement of healthcare providers, community leaders, laypeople, and open channels for two-way communication between government authorities and community stakeholders. These leaders should be prepared to identify misinformation and to advocate correct, clear, and truthful information among communities, as well as to address and describe any modifications to the message.

Creating risk communication and disseminating information and crisis results to the community by health system reference groups can be effective. To successfully control the COVID-19 crisis or other health crises in future, comprehensive cooperation, strong government leadership, and multi-sectoral coordination are necessary to decrease misunderstandings and rumors and increase engagement with vulnerable people following capacity building, accurate communication, and resource mobilization. In this regard, digital health tools have been proposed as effective tools to support information sharing and communication, observation and monitoring, healthcare provision, and the expansion of vaccination (40). Digital health approaches can simplify the fast general sharing of data, encourage CE, and foster the participation and empowerment of people in implementation (41).

Theme 2: Consultation

Consultation was another innovative strategy employed for raising CE during the COVID-19 crisis by getting feedback from the community, setting up public and open consultation systems, launching a self-assessment system, and implementing a comprehensive integrated system for psychological and social health services. Among the three categories of participants, healthcare providers played the most important role in providing advice to the community. Some of their counseling efforts included preventive measures, the promotion of vaccination, compliance with health protocols, and psychological counseling. The second group, which increased community participation by providing advice, was community leaders. They also invited society in different ways to cooperate with the health system and the government in the management of COVID-19. The third category (laypeople) received various counseling services, and most of their opinions were about how counseling and feedback were received.

Marsh et al. reported that consultation needs a reliable public image, where truth suggests a reasonable, stable, and precise demonstration of the several different populations in the community (42). Such demonstrations can be from governmental leaders, religious leaders, or respected people in the community. For instance, some studies specified that they consulted with and required the consent of native leaders of the community, already future participants of the community (43–45). In Tindana's study, it became clear that consulting with the trustworthy people of the community is not only a conventional necessity for obtaining consent from the community but also an opportunity to increase insights into cultural morals that may affect the topic (46, 47). This seems to be an exclusive story of CE in the multicultural setting of Iran, where community construction is determined and accepted and where there is some community cohesion (48). Similarly, Tedrow et al. recommended keeping consultations and discussions with leaders of the community during a crisis fairly simple (49).

Theme 3: Involvement and collaboration

As Iran's COVID-19 epidemic grew, it became obvious that healthcare employees could not manage and control contact tracing or infection supervision. Community involvement is a manner of running straight with the community or via its agents to form a plan and perform the topic. The COVID-19 pandemic has helped as a modification originator in CE by using social innovative strategies in crisis management. The modifications were largely focused on

the introduction of technology, with improvised and scheduled novel procedures for active CE.

A range of strategies for involvement or collaboration with the community applied and our work initially to and during the COVID-19 crisis has drawn on these, including networking, collaboration/lobbying between government and NGOs in crisis, multi-sectoral collaboration through COVID-19 committees, establishing platforms for community collaboration, social mobilization, shared leadership/decentralization/ability to control, managers' commitment, incentives/motivations, promoting a culture of participation, sensitizing, persuasion, moaning, and stakeholder engagement. According to the participants' views, decentralization of the decision-making process to the local level is effective in reducing resistance and increasing CE. This can be done directly or work indirectly by ensuring that the community has an impact on the target. Inviting the community to cooperate should be within the capacity of the community if the community wants to be motivated to engagement (17, 50).

All three categories of participants believed that involvement and collaboration were key components of COVID-19 crisis management. However, the role of community leaders was more important than that of the other two groups. By using different approaches, community leaders tried to encourage people to cooperate with the government and the health system in following health protocols and principles during the recent crisis. They provided the right context for community participation through encouraging, persuasion, motivational approaches, social mobilization, multi-sector collaborations, and sensitization. Healthcare providers were in the second category. The biggest role of this group was in persuading and sensitizing society. Finally, people ranked third in using this strategy. The biggest role of laypeople (according to their statements in this study) was in social mobilization and cooperation with NGOs. However, there was also a group of people who had created many problems for the government and the health system by violating quarantine rules.

Theme 4: Health education and prevention

Most participants noted that health education and prevention strategies, including prevention, screening, quarantine, and maintenance, helped them to manage and fight against the COVID-19 pandemic, as well as engage the community. We believe these to be respectable suggestions that emphasize the fact that communities are becoming more aware of elements that endanger their lives. The use of web-based educational social media has been identified to help consider health emergencies and provide access to suitable evidence of troubling events (51). Public interventions may finally take on several practices. Given that the content is general information on restricted interactions by means of appropriate handwashing methods, screening passengers, and approving good quarantine approaches, these interventions can also be of vast advantage to the community (52).

All three groups of participants played an important role in providing health education to the community to manage the COVID-19 pandemic. The roles of each of the three study groups varied depending on the location and conditions. For example, laypeople participated more in complying with the principles

and instructions, complying with quarantine, and complying with the principles of risk communication. The healthcare providers contributed to attracting CE through various face-to-face and virtual training, screening, and vaccination. The community leaders also took an important step in increasing CE to control this crisis by establishing laws in offices and public places about mask-wearing and social distancing, national coordination, establishing quarantine, and providing a suitable platform for screening.

Theme 5: Empowerment

According to findings, jihadi/voluntary/faith-driven actions, social trust building, social responsibility, community resiliency, and strengthening society's efficiency/finding talent were some of the strategies applied to empower CE during the COVID-19 crisis in Iran. Community empowerment is the procedure that advances their properties and powers and creates the ability to reach access, allies, and networks to achieve management. Shared leadership was perceived to be of significance in increasing CE. Community empowerment should be planned, made, and directed in the community if it was to be operative and stable in decreasing the community's risk for COVID-19 and raising and maintaining their wellbeing and rights (53). The occurrence of the COVID-19 crisis as a pandemic has a socioeconomic and mental influence on the community. Consequently, to support the community in facing challenging periods due to the COVID-19 crisis is a public responsibility. Strategic policymaking is required to create a helpful, safe, and easy atmosphere for the community. Community empowerment considers the financial, sociocultural, and political elements that strengthen health, and creates cooperation with other regions in discovering answers. Health administrators and communities co-recognize complications and implement solutions by empowering community constructions or local organizations to provide variation (54).

The findings on this theme showed that the laypeople had a high level of compliance with the community leaders' and healthcare providers' actions on the management of the COVID-19 crisis at all levels, including readiness to be empowered by voluntary and faith-driven actions; building social trust; building social responsibility; building community resiliency; strengthening society efficiency; and finding talent. We found that community groups, religion groups, and key stakeholders (laypeople—youth, women, and the elderly) also participated in empowering and building trust. Trust and confidence are important elements of CE, and if communities lack confidence, they will likely abstain from their healthcare providers and guidance from government officials and community leaders (47, 55). We observed that risk communication, which is specified by interacting with native communities, deeply affected the desire to prepare for crises and the specified grade of community confidence and trust in, and finally compliance with, the government's preventive actions. Our findings also indicate that creating and supporting community cooperations, which are based on operative collaborations and constant communication, can be significant in creating and maintaining trust, finally helping CE. Consequently, reinforcing association and trust is recommended to ensure the stability of community health promotion programs in future.

Theme 6: Advocacy

Another important strategy for facilitating CE is advocacy through capacity building, coalition, leaders' involvement, mobilizing community groups, and legal and policymaking strategies. These were observed to be useful in guiding management, prevention, and control strategies and enabling the combination of these measures in the usual work of all groups. Operative advocacy is a vital means in the attempts to assist the most susceptible persons throughout the COVID-19 crisis. Although the COVID-19 crisis may have transformed how advocacy is implemented, collaborating with selected administrators and strategic decision-makers during this period of the COVID-19 pandemic was vital to obtaining funds and other support. The community background and the functioning of the elements can generally impact the success of CE, with innovative strategies being addressed in the broader structure of their implementation (56, 57). This may include promoting and building community capacity and advocative and supportive settings for engagement, advocating connections, and advocative policy and funding settings, as well as creating environments of respect, confidence, and shared subcultures, norms, and targets (17, 25, 58).

The participation of local leaders (laypeople) who had high levels of respect was very important in advocating for healthcare providers and government/community leaders in managing the COVID-19 crisis. Therefore, without their advocacy, participation, and cooperation, COVID-19 management measures would not be implemented properly. However, the role of the government and healthcare providers is not hidden from citizens. Notably, laypeople had an effective role in mobilizing local resources and volunteers and using social media devices such as Instagram and WhatsApp to gather and send preventing COVID-19 messages. However, these measures would not have been very successful without the advocacy of government agencies and community leaders.

The key concepts of the full community strategies are considerate community difficulty, identifying community abilities and necessities, raising connections with communities, constructing and keeping cooperations, empowering native acts, and persuading and reinforcing social substructures, links, and resources (59). Public strategies for CE include community involvement, mobilization, cooperation, and empowerment (3, 60), usually during the planning and implementation of interventions (17, 24). Particular applications of CE include awareness, increasing sensitization, consultation, building capacity via teaching and management, growing public consistency (constructing networking and reliance), and reinforcing relationships with health organizations. Regarding COVID-19 in Iran, the key CE actions included operative communication for socio-behavioral variation, observation, and contact tracing (17).

Strengths and limitations

In the current study, social innovative strategies for increasing CE were recognized using a qualitative method. Other innovative strategies for increasing CE in crisis management that has not been mentioned or reported in this qualitative study may be relevant. In future studies, mixed-method approaches can be applied. We acknowledge that the strategies identified and applied to increase CE based on the perspective of the study sample provided insights regarding the crisis across Iran. Although some strategies for increasing CE identified are related to multiple cultures and contexts, some may be culture dependent. There are different countries where there is a lot of study with a particular sociocultural, political, economic, and environmental perspective. Thus, those results may not be applicable and appropriate to other cultures, and the results may not be fully generalizable.

This relatively average-scale study aimed to discover social innovation strategies for increasing CE in combating COVID-19, focusing specifically on the multicultural society of Iran. The research provinces were purposively selected for practical and source reasons. We surmise that this sample delivered general viewpoints regarding the crisis across Iran. However, due to the remarkable diversity of pandemics and health crises, our findings may not be completely generalizable. More research is needed to investigate the impact of COVID-19 on large-scale communities as well as other vulnerable groups. Nevertheless, we collected and triangulated information from three groups of stakeholders and actors to combine themes generated from more than one source, thus controlling for the effect of bias.

Implications and recommendations for future studies

Our study underlines hopeful findings in the use of CE innovative strategies, recommending that for crisis management and control of pandemics, CE may be significant and influential in engaging with the public. Further study is needed to explore whether social innovative strategies of CE may be effective in the control and management of other kinds of health crises in all groups and cultures. Future publications and articles on the synergies of CE via social innovative strategies in health crisis management and control should place more emphasis on community involvement, advocacy, health promotion strategies, community consultation, community mobilization, and community empowerment. There is also a need to conduct further studies focusing on infectious diseases in this field. Even though some groups of communities (three groups of community stakeholders with different cultural characteristics) were interviewed, there are many more that may not have been studied, and their insights and experiences should be taken into account in future research.

Conclusion

The spread of the COVID-19 pandemic required social and community-based responses. These reactions increased the possibility of fair access to health services, especially among vulnerable groups and minorities. As with other epidemics, applying the experience of the comprehensive participation of communities played an important and active role in the management, prevention, and control of the COVID-19 crisis. In this regard, giving and sharing information, community consulting, involvement and collaboration, health education/prevention

approaches, community empowerment, and advocacy were the most important innovative strategies encouraging the community to perform COVID-19 crisis management and control. The findings of the present study offer the basis for advancing social innovation strategies for raising CE based on associations between government, NGOs, and the community, leading to sustainable progress in societies. However, the effort to build and strengthen community capacity must be placed within the scientific efforts made during the COVID-19 crisis.

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 authors.

Author contributions

MK-P designed the project, collected the data, analyzed the data, and wrote the first draft of the manuscript. TP participated in analyzing the data. MK-P and KP critically revised the final article. All authors read and approved the final manuscript.

Funding

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/fpubh.2023.1174385/full#supplementary-material

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Health promoting sports federations: theoretical foundations and guidelines

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Background: Researchers and policy-makers have highlighted that the potential for organized sports to promote health has been underexploited. Sports clubs have limited capacity to promote health due to their voluntary nature and have called for support from their national sports federations. The present article provides guidelines, based on the theoretical principles of health promoting sports clubs and an analysis of practical tools and proven strategies, to support national sports federations to invest in health promotion (HP).

Methods: A qualitative iterative study was undertaken, based on five 2-h meetings of a group of 15 international researchers in HP in sports clubs. Notes and minutes from meetings, as well as shared outputs were analyzed based on the health promoting sports club framework.

Results: Guidelines developed for national sports federations to promote health includes a definition of a health promoting sports federation (HPSF), a description of how the settings-based approach to HP adapts to national sports federations, as well as practical applications of health promoting sports club's intervention strategies. The analysis of existing tools also demonstrated that most tools are centered on a single dimension of health (social, mental, physical, spiritual or community), and often on a specific health topic. Furthermore, they do not cover HP as a continuous long-lasting process, but are generally short-term programs. The HPSF clarifies theoretical concepts, their practical implementation via case studies and outlines intervention components and tools useful for sports federations in their implementation of HP.

Conclusion: The guidelines developed in this study are intended to facilitate national sports federations to acknowledge/understand, reinforce/underpin and foster current and further investment in HP.

Introduction

Organized sports has largely been recognized and used by policy makers for its positive role as a powerful tool for the expression of political messages (1), and for facilitating wide-spread participation in sports and physical activity, with 12% of European citizens practicing sports in this setting (European Union, 2022). Research has also demonstrated that sport is a major contributor to the health of a nation (2). Specifically, evidence supports the contribution of sports participation to achieving international physical activity recommendations (3). Physical activity is largely recognized as a major health determinant (4, 5) contributing to improved health outcomes preventing non-communicable disease and improving mental, social and physical health (6). Nevertheless, the White Paper on Sports (European Commission, 2007) and the Global Physical Activity Action Plan 2018–2030 (World Health Organization, 2018) have both underlined sports clubs' underexploited potential to promote health. Sports clubs have been defined as "private, non-profit organizations formally independent of the public sector, including volunteer members and a democratic structure, having sports provisions as their main aim" (7). Sports clubs could go beyond facilitating physical activity, by becoming health promoting settings (8–10) and by considering their potential to foster social, mental, physical and community health (11) However, evidence shows that this will not happen without support (12). The path to move from passive sports clubs providing physical activity opportunities to active health promoting sports clubs (HPSC) is long (13), represented as five stages in the settings-based approach to health promotion (HP) (14). Progressing through these stages requires formalized and systematic efforts, strategic focus and related marketing tactics to implement HP programs in collaboration with health actors (15). Indeed, the HPSC model calls for action on organizational (orientation, guidelines, policies and their implementation), economic (human and financial resources), social (vision, values and social norms in the club) and environmental (built environment and material) determinants of health at seven levels (from individual to policy makers) (16). In this regard, sports club managers expressed the need to have guidelines and support from their national sports federation (NSF) to implement HP (17–19), as programs promoting health through sports tend to be more complex than traditional sports development programs. This complexity is due to a need to deal with fundamental economic, cultural and health issues rather than a sole reliance on sports provision to achieve health impacts and outcomes (1). Sports clubs search for answers on appropriate methods to integrate multiple strategies on social, organizational, economic and environmental determinants across multiple health domains (social, mental, physical, spiritual, community) (20). In this regard, the application of the settings-based approach does provide a proper way to answer, even if HPSC implementation also face unintended health effects or may threaten the integrity of the organization (21), due to this complexity. For example, previous work has documented how sports clubs were confronted with a paradox in terms of feasibly implementing the safety policy, where stakeholders stated this policy was essential to ensure safe practice, but the cost to the club of its adoption would affect their ability to survive (22).

To date, research in this area has primarily centered on developing the HPSC model (16), and investigating how club managers and coaches promote health (23, 24). Research on Australian interventions among community sports clubs have shown effectiveness on behavioral outcomes (25), as well as cost-effectiveness (26, 27). Nevertheless, scant research has targeted NSFs (28, 29), and focused principally on programs dedicated to health topics, such as, safeguarding children (30), doping prevention (31, 32) and injury prevention (33). The presence, albeit limited, and the narrow awareness of HP as a global concept in international or NSF has been demonstrated (34), and its alignment to sports federation business is crucial for further investment (28, 35). Such findings suggest a need to improve political lobbying, project and change management capacity within sports federations to develop HPSF (34).

To determine the theoretical and empirical gaps in HP in NSFs, the present article focuses on the creation of the Health Promoting Sports Federation (HPSF) Guidelines, to answer the research question: How to evaluate and foster health promotion implementation among NSFs? This article serves as a basis for the guidelines, by (1) offering a theoretical conceptualization of a HPSF, (2) providing evaluation indicators for a HPSF, (3) developing practical applications of the intervention components from the HPSC framework for NSFs, and (4) reviewing how existing tools to promote health are linked to HPSF.

Method

Design

A qualitative, iterative design (36) was used to develop the HPSF guidelines, based on five steps: (1) defining a HPSF and applying the stages of the settings-based approach to HP a to NSFs, (2) creating HPSF evaluation criteria, (3) analyzing HPSF intervention components, (4) synthesizing tools supporting HPSF and (5) establishing HPSF guidelines.

Participants

This work was led by an international research group, also acknowledged as authors in the present article, under the 'Sports Clubs for Health' working group of the health-enhancing physical activity network of the World Health Organization Regional Office for Europe. A project team, composed of the three first authors and the last author invited 20 researchers worldwide, renowned for their contribution to HP in sports, to take part in five 2-h virtual meetings (February 16th, March 26th, April 26th, May 24th, June 21st).

Participants gave their informed consent to take part in the study and were informed about the ethical implications of participating in the project, through an email in January 2022. Each participant engaged in at least three meetings, with a mean participation rate of 12 (min = 9 and max = 14) per meeting.

Data collection

The data was collected via feedback/notes and collaborative tools filled in by the first author during meetings, as well as by interactions and feedback through emails and an internal sharing platform between meetings. Agenda and minutes of each meeting were sent for approval, products generated from the meetings were shared for review and input from each participant was requested.

Step 1: defining HPSF and describing the stages of the settings-based approach to HP applied to NSFs

To develop the definition of a HPSF, the research group established an initial definition of a NSF that delineates its interconnections with other sport organizations in the pyramid sport setting, such as international sport federations (umbrella organizations for NSFs worldwide) and sport clubs, as well as the different organizational structures (sub-national level and local level). Then, using the definition of the settings-based approach to HP and of a HPSC (37) as a basis, the HPSF definition was derived. Furthermore, the different stages of the settings-based approach (14, 16) and the various descriptions of the relationship between sports and HP (38), which have previously been applied to sports clubs, were redefined in relation to NSF.

Step 2: creation of HPSF evaluation indicators

Evaluation indicators were identified based on two activities; an initial brainstorming session on criteria that could help to inform how HP was developed in sports federations, before a working meeting to classify these indicators based on the four already defined determinants of health from the HPSC model (16): (1) organizational determinants (NSFs guidelines about HP including policies, rules and regulations are provided to affiliated sports clubs), (2) social determinants (NSFs vision, values and philosophy are in relation to those of society), (3) environmental determinants (NSF offers support for safe, supportive and sustainable infrastructure, green spaces and playing fields for affiliated sports clubs), and (4) economic determinants (NSF provides financial and human resources for HP to affiliated sports clubs).

Step 3: development of HPSF intervention components

The intervention components (i.e., actions to be undertaken by NSF to develop HP) from the HPSC framework (16), that were previously classified under the responsibility of NSFs, were selected to ground the present work in an existing theoretical model, the HPSF framework (16). The research group first created a template of information needed for NSFs to implement each component, and determined the following: (1) how they were linked with NSFs' previous experiences and actions, (2) what was the purpose of their implementation, (3) how they should be implemented according to

the HPSF stages and (4) what role each stakeholder in the HPSC framework plays in its implementation. The template was discussed during two meetings, and then completed by the first author, with each component review by a member of the research group who had the highest level of expertise.

Step 4: review of tools supporting HPSF

To select tools supporting HPSF, a systematic search was conducted on the Erasmus+ website,[1] using the keywords "health promotion" and "sports." Inclusion criteria were: (1) to target HP or health topics in organized sports, (2) to include an English version, (3) to propose a tool (training, game, booklet, etc.) as an output, (4) to cover more than a single sport and (5) to constitute a practical document, not only policy recommendations. Exclusion criteria were (1) not targeting organized sports but physical activity in general, (2) no final tool availability in English language. An excel spreadsheet was developed for data extraction and circulated among the participants, to add details extracted from known tools based on the given inclusion criteria. When selected, the tool was fully reviewed by research group members, including website presentation, tool presentation and content. The review process for the tools was defined during two meetings. Meeting 2 focused on defining the templates for analysis using four categories: (1) description of the tool (weblink, language, link to HP, topic covered, date of release), (2) pedagogy of the tool (objectives, content, HPSF stage reached using the tool, person using and person targeted by the tool, type of tool, time estimated to complete and to implement, need for a trained person), (3) production and evidence (tool creation process, quality of evidence), (4) link with HP approach and theoretical framework (strategies of the Ottawa Charter and of the HPSC framework mobilized by the tool). Meeting 4 focused on discussing inclusion criteria for some tools where doubts had been expressed and adapting the template based on a review of the two tools. A double peer review process was undertaken on the chosen tools; a first draft analysis was produced for all tools by the first author and reviewed by a member of the research group.

Step 5: finalization of the HPSF guidelines

All of the different work sections were compiled into a single document. The design was reviewed by research group members, as well as external sports and health experts, including three French sports ministry members, two project managers from the French Public Health agency and three representatives from NSFs (France, Sweden, Luxembourg). The use and dissemination strategy were reviewed by the research group members during their last meeting.

Data analysis

Notes and productions were analyzed by the first author using a deductive approach, based on the HPSC framework as a theoretical basis (16). The data analysis was conducted between each meeting, based on participants' answers, as well as on the minutes from meetings sent to the research team. The results and output from each step were sent again to the research team/participants. They could

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1 https://erasmus-plus.ec.europa.eu/projects/search

provide their feedback before or at the beginning of the next meeting. After the five meetings, all notes were collated and reviewed twice by the first author (to become familiar with the content and to verify comments to include in the final guidelines). The research team read the final product and provided feedback twice. This feedback has been considered in the final guidelines. Data validity was addressed by having all participating researchers validate the final version of the guidelines (ensuring triangulation and respondent validation). In addition, a cross-country comparison of the guideline's applicability was undertaken based on participants' experience (triangulation of context) and an iterative constructive process of including existing literature on HPSC at each level, as well as during the case study search. Finally, data reliability has been facilitated by ensuring appropriate wording was used in the guidelines, and through collective validation of the final version of this article.

Results

Step 1: definition of a HPSF and of the settings-based approach stages applied to NSFs

The research group adopted the Institut National de la Jeunesse et de l'Education Populaire (INJEP; National Insitute for Youth and Popular Education) definition of sports federations: "National sports federations are responsible for planning and managing their sports at a national level, through an organization based on membership of affiliated clubs. A sports federation organizes and promotes the practice of it(s) discipline(s), from leisure activities to high level sports."[2] This definition was considered as the most inclusive of all types of NSF, including non-Olympic ones, as well as including different types of sports practice. After brainstorming the different activities and processes in place in NSFs, a HPSF was defined by the research group as a "national sports federation that considers health in its values, vision and leadership, as well as in its activities and training" (see Figure 1 for details). There are two primary aspects of a NSFs focus towards becoming health promoting: "to be a health promoting sports federation" (considering health in all policies, decision making processes, structures and activities) and "to support their affiliated clubs to become health promoting" (invest in programs, guidelines, toolkits, human resources helping affiliated club to promote health). Moreover, the application of the five stages of the settings-based approach to health promotion (14) can offer insight to NSFs on how to progress towards becoming a HPSF (see Table 1 for details).

Step 2: creation of HPSF evaluation indicators

The research group created nine categories of HPSF evaluation indicators through brainstorming (engagement from NSF, HP policy implementation, dedicated training on HP, dedicated HP programs,

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2 https://www.insee.fr/fr/metadonnees/definition/c1258

presence of safeguarding for members, presence of HP or prevention for (elite) athletes, financial investment, visibility, governance structure) and emphasized the need to ground them in a theoretical model (Ottawa Charter, Global Physical Activity Action Plan, HPSC model). For each category, work was undertaken to clarify the indicators, the questions used to evaluate them and the data sources an NSF could use. A final list of 18 indicators based on the four HPSC health determinants (nine organizational determinants, three environmental determinants, three economic determinants, and three social determinants; see Table 2 for details) were integrated into the HPSC model, which was approved during the second meeting. These indicators have been designed to work on the whole system of the NSF, impacting both policy framing and practice, as well as the decision-making process, as described in the settings-based approach to HP. Moreover, these indicators served as a basis for the case study analysis in chapter 2 of the guidelines (on case studies), and can be used as a self-evaluation grid to choose the strategies presented in chapter 3 (on implementation strategies) and the tools presented in chapter 4.

Step 3: development of HPSF intervention components

Intervention components were operationalized to support practice-based use. The final full description of each of the 26 intervention components can be found in the guidelines (Table 3 summarizes how each intervention component can be implemented by NSFs at each HPSF stage). The decision was made to retain the original formulation of the intervention components, as well as not to create a new one, to keep consistent with the HPSC framework and to develop a practical application of an existing theoretical model, rather than the creation of a new theory (Table 3). This work has raised the issue of describing actions that could be seen as an example to implement any health behavior and emphasize the progression from an individual change driver in a passive organization to an active organization fostering individual health and well-being. This question has been answered on choosing to either use the formulation mentioning a single health topic, which is limiting in regard to applying a holistic HP approach, or in choosing to use the umbrella concept of HP as a keyword for investment in multiple behaviors and health topics. Furthermore, as the intervention components belong to a strategy, we found the intervention components to be redundant, which was considered as acceptable, as NSFs will have to choose which to implement and will probably not target all of them at the same time.

Step 4: analysis of tools supporting a HPSF

Among the 117,501 Erasmus+ projects identified between 2015 and 2022, 336 projects included both HP and sports as keywords. Sixty projects were collaborative partnerships (staff training and youth exchange projects were excluded because no tool was produced). Among the 60 included projects, 26 targeted sports organizations and provided links to outputs or tools, leading to their inclusion in this review. In addition to the 26, the members of the research group provided links to additional tools they had identified as relevant.

FIGURE 1
Description of a HPSF.
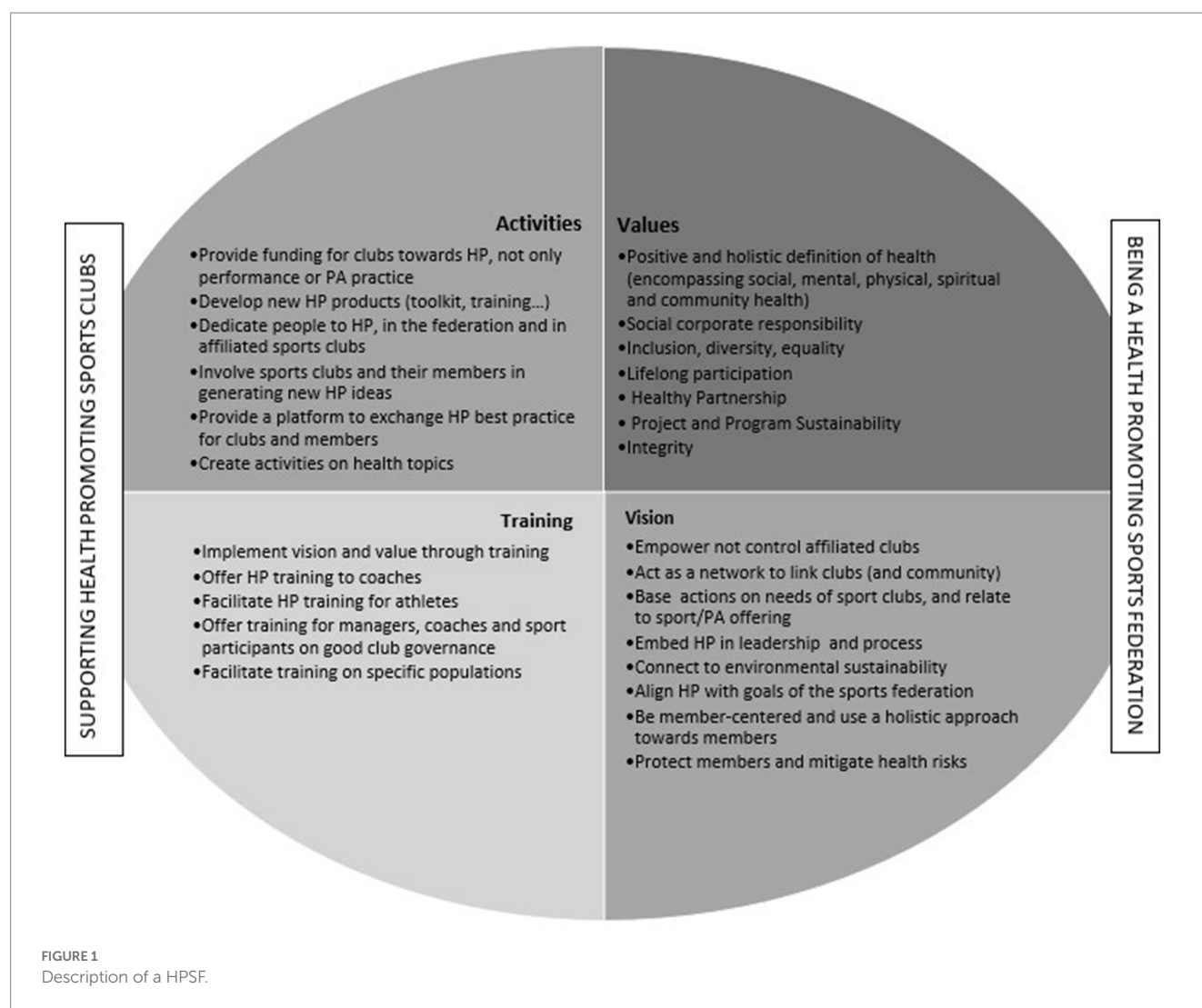
Eliminating duplicates and based on a full-text review, 28 tools were retained and presented in the guidelines. Reasons for exclusion of projects included: they were not directed towards sports federations ($n = 7$), tools were inaccessible ($n = 4$), content was not practical enough (n = 1), was not focusing on HP ($n = 5$), focused on a single sport ($n = 1$).

Of the 28 tools, 16 were documents or leaflets, two were websites, one was a game, four were online trainings and five a combination of two or more types of tools (Table 4). Social health was considered in 13 tools, mental health in 12 tools, physical health in 8 and governance or capacity building in 5 tools, while 4 tools targeted more than one dimension of health action. Regarding the evidence used to build the tool, 18 were research based, 24 practice based and 5 built with stakeholders, whereas 3 tools included a combination of these. On average, tools targeted three of the five Ottawa Charter (39) strategies ($n = 11$ for building public health policies, $n = 25$ for creating supportive health environment, $n = 18$ for strengthening community action, $n = 20$ for developing personal skills and n = 8 for reorienting health services), where three covered all five strategies. On average, six strategies from the HPSC framework were developed in the identified tools (min = 1 and max = 13), with 16 based on planning, 17 on education, 18 on resources, 9 on feasibility, 11 on goals, 18 on

mobilization, 8 on monitoring, 15 on participative approach, 17 on partners, 15 on communication, 11 on dynamic, and 8 on experience.

Step 5: finalization of the HPSF guidelines

The final guidelines includes 151 pages, structured across four chapters: analyses and monitors HP in a NSF, is inspired by case studies and examples of NSF investment in HP, implements the HPSC framework, identifies tools to support HPSF and HPSC. The guidelines can be approached in different ways; however, it is recommended to proceed by reading the first chapter and application of the evaluation criteria and acknowledgement of the HPSF stage for the NSF. Then the case studies, intervention components and tools can be used to move on to the HP development in a sports federation, as each of them are linked to a specific strategy of the HPSC framework.

Discussion

The HPSF guidelines have been designed to clarify the theoretical concept of a HPSF and support its implementation

TABLE 1 Stages of health promoting sports federations inspired by (14).

	Stage	Core perspective	Definition	Action of national sports federation
0	Null			No communication on legal requirements related to health/reducing health risks.
1	Passive stage	The problem and solution rest within the behavior and actions of individuals	Safe sports offer fostered by sports federations	Promoting safe and secure sports activities (legal requirements to protect sports participants: doping, warming up, etc.). Sports clubs may independently undertake initiatives in HP.
2	Active stage	The problem lies within the behavior of individuals, some solutions lie in the setting	Sports federations promoting health	Promoting health benefits of sports for sports clubs and participants and signposting HP activities to sports clubs, but not actively engaging in HP programs.
3	Transmissive stage	The problem lies within the setting, the solutions lie in learning from individually-based projects	Health Promotion in Sports Federations	Sporadic HP events organized by the sports federation (event day), on a single health behavior or topic; Encouragement from sports federation to sports clubs to deliver club-based HP activities.
4	Organic stage	The problem lies within the setting, the solutions lie in the actions of individuals	Sports Federation Health Promotion programs	Dedicated programs developed by the sports federation to enhance sports club's activities around HP. The sports federation is actively involved in becoming a platform for sports clubs and external partners to meet for HP
5	Comprehensive approach stage	The problem and solutions lie in the setting	Health Promoting Sports Federation	HP is integrated in the vision, values, activities and training courses of the sports federation. Health is considered in the organizational structure and decision-making processes at all levels of the sports federation. The sports federation invests ongoing resources in HP in the long-term, to promote health beyond health topics. The sports federation collaborates with external partners on HP. The sports federation's policies are based on monitoring and evaluating previous activities.

through case studies, intervention components and tools. The guidelines are designed to act as a springboard for NSF to acknowledge, reinforce and further foster their investment in HP. This work is aligned with recent research efforts to clarify the theoretical tenets of a HPSC, as a previous literature review has shown that the application of the settings-based approach to HP has to be tailored to the context of the setting and core business (40) of the organization. For example, schools, universities and even cities have different characteristics compared to sports clubs (41), which are typically run by volunteers, have sports provision as their main aim, do not always own their facilities (13) and depend on NSF regulations, support and guidance (42). Moreover, a recent literature review showed a poor application of the settings-based approach in sports clubs, with programs principally targeting sports participants and lacking support for clubs to make organizational changes (8). The HPSF Guidelines consider the four determinants of health: organizational, social, environmental and economic, and go beyond traditional education program for coaches or health information for sports participants (43), supporting the implementation of more complex HP programs.

Another important aspect of these guidelines is that they constitute the first offer of theory-based intervention components to implement within NSFs, whereas previous studies have principally used observational studies or did not root their intervention in a theoretical framework. Nevertheless, no empirical data have been collected scientifically on the application of these intervention components, and there is a need to test their application and outcomes. In that regard, the creation of HPSF indicators, considering the whole system of a NSF, highlight key outcomes of

the development of HP by NSF, therefore providing a first attempt for a self-evaluation tool for NSF. In line with previous publications on the HPSC model (44), evaluation indicators can help to clarify the resources, activities, outcomes and impact of HP development by NSF, and could help government authorities, and local sports clubs to clearly call on their fulfillment by NSFs.

The analysis of existing tools showed that most of them are centered on a single dimension of health (mental, social, physical, spiritual and community), that they are often on a single health topic and that they do not cover HP as a process, more as a short-term program, that in turn, does not support sustained improvement to the health of sports club members. These findings are similar to results found in sports clubs, e.g., in Australia only 3% of the sports clubs had a policy on multiple health topics (45). In France, a case study on 8 exemplary HP projects has demonstrated that each project targeted a single health topic (24). Interestingly, creating a supportive health environment was the most targeted strategy of the Ottawa Charter (39), where reorienting health services was the least implemented. There is a need to move from interventions directly targeting sports participants towards a whole system approach (46). In regard to creating public health policy, efforts are still needed in sport on policy development, having been acknowledged in research as the biggest weakness of sports clubs (47). In addition, creating a supportive environment is the Ottawa Charter strategy which is the most aligned to sports clubs most developed HPSC strategies, like mobilization, resources, partners and education, which are also linked to identifying financial and human resource support to develop HP. This is in line with a request from sports clubs, identified in a previous concept mapping study among French sports clubs

TABLE 2	Indicators of a health promoting sports federation.

Indicators	Questions	Data sources
Organizational determinants		
Engagement from national sports federation (importance)	How important is HP for the national sports federation?	Policy document Board discourse Code of conduct
HP policy planning	What types of HP activities does the national sports federation commit to in the policy documents? How many HP activities does the national sports federation plan per year?	Policy document
HP policy implementation	How many HP activities does the national sports federation undertake per year, based on policy? How many sports clubs and their members take part in the activities? What are the characteristics of these clubs and individual members?	Policy document Annual Report
HP monitoring and evaluation	Are HP activities monitored? Are their outcomes and impacts evaluated? What are the HP perceptions of the sports clubs and members taking part in them?	Annual report, strategic monitoring and evaluation plan
HP programs	Does the national sports federation have dedicated programs related to health topics or HP? How are they implemented?	Website
Training on HP	How is HP embedded in mandatory coach training? Is there any specific training related to health topics or HP to clubs/club members??	Website, training course documents
HP decision making process	Who is appointed within the national sports federation for HP? Who is involved in the decision-making process about HP activities and how are decisions made?	Website, policy document, notes of (board) meetings
Participative approach	Can the sports clubs or club members be involved in the sports federation's decision-making process?	Description of the organization or human resources structure
Presence of safeguarding for members	Are there opportunities for sports clubs members to report misconduct to the national sports federation?	Code of conduct, critical incident plan
Environmental determinants		
Presence of HP or prevention measures for (elite) sports participants	Are specific HP regulations in place for training and/or competitions?	Website; code of conduct
Presence of a first aid kit, defibrillator	Are affiliated clubs equipped with a first aid kit and a defibrillator?	Annual report, survey, program description
Presence of guidelines for safe and sustainable environment	Are affiliated clubs encouraged to invest in safe and sustainable infrastructures and material?	Annual report, survey, program description
Economic determinants		
Financial investment (human and material)	How much does the national sports federation invest in HP? Is HP a priority in terms of resources?	Budget, annual report, human resources
Presence of corporate social responsibility investment	Does the national sports federation have a corporate social responsibility plan or activities?	Strategic plan, annual report
Presence of partnership with organization supporting HP	Does the national sports federation partner with HP organizations or HP professionals? Or with other organizations to invest in HP?	Strategic plan; programs description; website
Social determinants		
HP values	Does the national sports federation promote HP values (see figure above)?	Website, policy document, program description
Communication of HP	Is HP part of internal (within the national sports federation and affiliated clubs) and external (public and partners) communication strategies?	Mention of HP or health topics in newsletter, website, press release, on social media
Visibility of HP	Is HP explicitly mentioned in the communication and policy document of the national sports federation?	Social media, website

(19). A more challenging result concerns the few tools mentioning the experience and the monitoring of implementation strategies. The evaluation of HP in sports clubs is not undertaken nor encouraged in these tools, whereas previous work has shown that HP project managers in sports clubs lacked tools and methods to evaluate their actions (24) and a previous literature review has demonstrated the paucity of use of validated measurement to evaluate the application of the HPSC approach (8). As the settings-based approach is challenging to evaluate (48), robust methods to investigate the (cost) effectiveness of policy and practice at multiple levels, using multiple

TABLE 3   Application of the HPSF stages to HPSC intervention components (16).

Name of intervention components	Stage 1: safe sports offer fostered by sports federations	Stage 2: sports federations promoting health	Stage 3: HP in Sports Federations	Stage 4: sports federation HP programs	Stage 5: health promoting sports federation
COM3: Ensure internal club communication on HP	Inform sports clubs about legal requirements and let them communicate	Propose specific signage or message to communicate on HP within sports clubs	Organize specific event to disseminate on health topics and encourage clubs to signpost message on HP topics	Propose guidelines on how to create a communication plan on HP and communicate regularly on clubs' HP activities	Disseminate exemplar practices on sports federation's website, a specific hashtag in sports federation's communication, and a platform to share experiences and collect inputs from affiliated sports clubs
COM4: Ensure the club communicates with the external community on HP	Inform the community about legal requirements while entering sports facilities	Propose specific signage or message to communicate on HP	Offer a showcase of sports clubs' HP projects in the sports federation	Propose guidelines to support sports clubs to develop their external communication strategy	Disseminate exemplar practice on sports federation's website, a specific hashtag in sports federation's communication, and a platform and strategy to share information
EDU1: Support the managers and coaches to actively engage in gaining knowledge and skills to promote health	Remind the regulations of coaching certification to managers and coaches	Provide a list of readings and training enhancing coaches and managers HP skills and knowledge	Encourage coaches and managers to take part to training in HP, as well as propose list of reading, online resources and platform of exchange	Propose training in regard to delivering specific HP programs, to ensure a quality of delivery	Accredit public health organization training and support in coaches and managers training certification process and provide funding incentive
EDU2: Tailor the support to the managers and coaches individually in relation to the sports participants they coach (mentoring, courses, online tools)	Transfer legal requirements to coaches	Provide information (e.g., leaflets) on how coaches or managers can enhance their knowledge in managing specific health topics	Organize events or conferences on promoting specific health topics	Promote specific programs for different health topics, including different education options (e.g., online tools, leaflet, games)	Include specific programs in sports federation policy. Offer a shared experiences platform, online course.
EDU3: Encourage the managers and coaches to support each other to promote health	No action	Provide information on sports clubs' consultation process and advantage	Organize events in sports clubs and at local level to support collective dynamics on HP	Offer support and programs to help the development of sports clubs' participative approach and experience sharing	Request from sports clubs to have a HP commission and a representative at executive board. Have a mentoring system for coaches and managers
EDU4: Propose a variety of ways for the sports clubs to raise awareness about HP	Propose signage and posts on legal requirements for sports practice	Propose ready to use signage, posts on social network and press releases on HP	Propose events to raise awareness on HP	Propose a recognition for HP programs, as well as program promotion materials	Propose a labeling system on HP, including events, signage and community of practice
EDU5: Create tools and training courses to support HP in sports clubs	Propose training on knowledge about legal requirement for sports delivery	Provide specific training on health topics (managers, coaches, volunteers)	Provide lifelong training on HP (managers, coaches, volunteers)	Propose specific training for HP program delivery	Integrate HP training into all mandatory sports federation training, as well as a specific certification system (managers, coaches, volunteers)

(Continued)

TABLE 3 (Continued)

Name of intervention components	Stage 1: safe sports offer fostered by sports federations	Stage 2: sports federations promoting health	Stage 3: HP in Sports Federations	Stage 4: sports federation HP programs	Stage 5: health promoting sports federation
EXP5: Rely on existing, evidence-based HP tools	No action	Communicate on existing evidence-based tools	Provide a database of evidence-based tool, guidance on how to implement them	Base HP program on evidence base practices and tools	Have partnership with academics to root evidence-based research into sports federation strategic plan and stay informed about the last produced evidence
EXP7: Rely on other clubs' experiences when developing HP actions	No action	Provide example of good practice on sports federation website	Create an open working group and committee to support experience sharing (i.e., having an online platform)	Co-construct programs with sports clubs and pilot them before implementation, share piloting club's experience	Have a label program, which value sports club's investment and offer them to participate to a mentoring system of other clubs, as well as a library of these projects to be shared
GLS1: Define the goals of HP	Have goals based on the respect of legal requirements	Have goals on specific health topics (citizenship, injury prevention, doping) in the sports federation's strategic plan	Guide sports clubs on how to define their specific goals for HP	Consider HP as a specific goal, which covers different health topics and programs under an umbrella concept	Consider HP as a transversal goal in the policy development and have goals of integrating health in every decision-making process
MOB1: Mobilize sports champions to support the development of HP within your club	No action	Communicate on HP actions from high level athletes or exemplar sports clubs	Recruit an appropriate ambassador for a specific health topic program or projects and associate its image with the program Educate and support the champion on the health topic	Involve the champion in HP program and its dissemination, including participations at events	Encourage and support each champion to develop specific HP actions or programs in their clubs, by engaging them in program design, implementation and dissemination
MOB5: Mobilize local decision-makers and elected officials to promote health within the sports club	No action	Communicate to the local decision-makers sports clubs' activities in regard to HP	Organize events with local decision makers on HP	Set partnership with local municipality and policy-makers in terms of HP commitment and implementation	Through partnership, inscribe sports club's HP activities in local decision-makers policies and actions, as well as being members of specific interest group at local level
MON5: Review the HP policies of the sports clubs	Ensure sports clubs policy entails legal requirements	Communicate on the importance of reviewing HP policies of the sports clubs	Encourage sports clubs to review their HP policies, and communicate on guidelines to do it	Put a report system in place, where sports clubs can upload their development plan, especially the HP part	Provide guidance on how to review HP policies, good examples, use a report and accreditation system to acknowledge sports club's HP policies
MOT3: Take coaches' motivation for coaching and their future expectations into account	No action	Communicate on coaches' qualifications regulations and training requirements	Encourage clubs to find a balance on coaches' appointment to the group they will coach, taking their expectations into account	Provide guidance on how to retain volunteer coaches, establish good working conditions for coaches, as well as on training	Establish template for coaches' career plan and mentoring system for coaches

(Continued)

TABLE 3 (Continued)

Name of intervention components	Stage 1: safe sports offer fostered by sports federations	Stage 2: sports federations promoting health	Stage 3: HP in Sports Federations	Stage 4: sports federation HP programs	Stage 5: health promoting sports federation
MOT4: Strengthen coaches' autonomy to promote health	Inform coaches about legal requirements	Communicate on HP policies and activities of the NSFs	Organize events underlining coaches role towards HP	Provide guidance, training and program to support coach's investment in HP	Generate peer learning, working group and platform with resources for coaches to promote health
PAP1: Identify and call attention to HP actions of individuals	No action	Communicate on HP activities to sports participants	Organize events to recognize individual HP good practices	Propose empowerment program for sports participants, and make them visible to sports clubs	Offer a system in place to report exemplar action and offer an accreditation for exceptional individual's contributions towards HP
PAP3: Identify and call attention to management HP actions	No action	Communicate on health topics	Organize events to recognize club HP good practices	Ensure managers are able to recognize and value HP actions, and train them on empowerment	Offer a system in place to report exemplar programs and offer a label for exceptional contribution toward club's HP
PART1: Identify partners for HP (clubs, agencies, regional authorities, health professionals)	No action	Communication on HP organization name and mission	Propose guidelines on how to develop partnerships for promoting health topics	Propose a national partnership with HP actors, for the development of specific programs	Include national partners to support a health in all policy development and implementation, and their representatives at local level to foster sports club's HP development
PLAN6: Encourage sustainable HP actions	No action	Communicate on criteria for sustainable HP actions	Propose guidelines and support to apply sustainable HP criteria to program implementation	Ensure that each HP program entails a section on sustainability and its monitoring	Encourage clubs to provide input on the use of sustainable HP criteria for their actions, as well as strategies for scaling up their development plan. Have a dedicated section in sports federation policy and indicators to evaluate sustainability of policy evaluation
PLAN8: Plan future actions based on the evaluation of current actions	No action	Identify and communicate to sports clubs' members on previous actions and programs, which could be used by other sports federations or clubs	Propose guidelines on action planning in regard to specific health topics	Propose a systematic evaluation and reporting of sports club's HP actions, with success indicators for program implementation	Establish a monitoring system of sports club's HP actions, with an open access data base, where sports federations, clubs can get inspired by previous actions, as well as guidance on how to scale up specific actions
RES3: Review current skills and knowledge available to promote health	No action	Communicate a list of programs and training targeting health topics or HP	Provide guidance and checklist on skills requested to organize HP events	Identify sports federation employee profile, skills and knowledge to invest in HP	Have a directory of sports federation employees, as well as volunteers in sports clubs that could support HP implementation

(Continued)

TABLE 3 (Continued)

Name of intervention components	Stage 1: safe sports offer fostered by sports federations	Stage 2: sports federations promoting health	Stage 3: HP in Sports Federations	Stage 4: sports federation HP programs	Stage 5: health promoting sports federation
RES4: Identify and mobilize tools for HP development within sports clubs	No action	Communicate on tools that have been published to promote health in sports clubs	Propose guidance and tools to promote specific health topics	Provide a database of tools for HP, disseminate them and guide sports clubs to implement them	Evaluate the quality and transferability of tools, provide guidance on implementation, as well as training on how to use them
RES5: Identify the funding that can be used for HP actions	No action	Communicate on available funding stream from different organization	Guide sports clubs to identify funding on specific health topics	Provide a database of funding, deadline and guide sports clubs to draft funding application	Evaluate the relevance of funding, provide guidance on implementation, as well as training on how to apply and implement them
RES6: Establish a national resource site for HP within sports clubs	No action	Have a page dedicated to HP on sports federation website	Have a specific section on sports federation website, including case studies of good practice	Have a specific section on sports federation website, promoting national HP programs	Have a specific section on sports federation website, cases studies of good practice, tools, evidence and links to external websites, a forum for discussion
RES7: Establish a national spokesperson for HP within sports clubs	No action	Communicate the list of employees and function in the sports federation	Have different employees playing a role on specific health topic	Have a specific employee appointed for HP, linking people and programs to the HP concept	Have a board representative, as well as a specific commission being appointed for HP in the NSF
RES8: Create and host a regional and local network of HP mentors within sports clubs	No action	Sharing of sports club's managers contact details, when they propose HP actions	Have different employees playing a role on specific health topic	Share a profile of the sports clubs' managers who volunteer to support other sports clubs and offer an annual meeting	Have a meeting with mentors every three to six months, training provided on HP and evidence update, as well as link with national employees, to create a community of practice

strategies have already been used with health promotion interventions in sports clubs (26, 27).

The developed guidelines will be published on the World Health Organization's website. NSFs can use these guidelines to establish appropriate governance to support HP and embed it in existing policies and practice, identify tools and examples to support affiliated sports clubs to invest in HP, develop programs supporting HP in and through sports and provide evidence that the NSF is playing an enhanced role in society.

Strengths and limitations

The rigorous method and multiple steps used to create the HPSF Guidelines helped to produce a theory based and evidence informed tool, offering the opportunity to develop multi-levels and multi-strategies, in accordance with public health researchers' recommendations (49). Moreover, the final guidelines have been

reviewed by 3 practitioners beyond the group, to facilitate a transfer into practice.

Nevertheless, several limitations to the present study should be noted. First, no new literature review on how NSF undertake HP was conducted to evaluate the current state of the evidence, as well as barriers and facilitators to its implementation. Second, the present guidelines is created in English, limiting its use and dissemination in some countries and most of the researchers involved came from Europe, possibly limiting its application to Asia, Africa or North America. Third, NSFs were only involved in the final proof reading (50), as no co-construction process was undertaken through participatory research.

Conclusion

The article provides theoretical foundations, analysis of practical tools and strategies to support NSF investment in HP. It

TABLE 4 Analysis of the tools in regard to HPSF.

Name of the tool	Health topic	Type of tool	Type of evidence	Ottawa charter strategies	Intervention strategies
Stepping in: a bystander action toolkit to support equality and respect at work	Social Health: Gender Equity	Leaflet and website	Practice based evidence	Create supportive environment Develop personal skills Re orient health services	Planning Education Resources Feasibility Goals Mobilization Monitoring Motivation Participative approach Partners Communication
EU guidelines on dual careers of athletes	Dual Career (elite athletes)	Leaflet	Research and practice-based evidence	Build healthy public policy Create a supportive environment for health Develop personal skills	Planning Education Resources Monitoring
GAA Healthy Club Manual	Health Promoting setting	Leaflet	Practice based evidence	Build healthy public policy Create a supportive environment for health Strengthen community action for health Develop personal skills Re-orient health services	Planning Education Resources Dynamic Experience Feasibility Goals Mobilization Monitoring Motivation Participative approach Partners Communication
Good governance game	Good governance	Game and online training	Research and practice-based evidence and using a participative building approach	Create supportive environment for health Develop personal skills	Dynamic Mobilization Participative approach Communication
Sports diplomacy course	Sports Diplomacy	Online training	Practice-based evidence	Create supportive environment for health Strengthen community action for health Develop personal skills	Planning Education Resources Feasibility Goals Mobilization Monitoring Motivation Participative Approach Partners Communication
International safeguards for children in sports	Child protection	Leaflet	Research and practice based	Build healthy public policy Create a supportive environment for health Strengthen community action for health	Planning Resources Monitoring Motivation Partners Communication

(Continued)

TABLE 4 (Continued)

Name of the tool	Health topic	Type of tool	Type of evidence	Ottawa charter strategies	Intervention strategies
Mental health charter for physical activity and sports	Mental health	Leaflet	Participative building approach	Build healthy public policy Create a supportive environment for health Strengthen community action for health	Planning Education Resources Goals Mobilization Partners Communication
Mental well-being coaching toolkit	Mental well-being	Leaflet	Research based and practice based, using a participative building approach	Create supportive environment for health Strengthen community action for health Develop personal skills Re-orient health services	Education Resources Dynamic Experience Motivation Participative approach Partners Communication
Outsports tool	Inclusion and diversity in sports	Leaflet and game	Practice based evidence	Create supportive environment for health Develop personal skills	Planning Education Mobilization Motivation
Pro Safe Sports+ Training Kit	Prevention of sexual violence in sports	Leaflet, video clip, online resources center	Research and practice-based evidence	Create supportive environment for health Strengthen community action for health Develop personal skills	Planning Education Mobilization Motivation
Sports and sustainable development goals	Sustainable development	Leaflet	Research and practice based evidence, using a participative building approach	Build healthy public policy Create a supportive environment for health Strengthen community action for health	Planning Education Resources Dynamic Experience Mobilization Motivation Participative approach Partners
Sports for active citizenship toolkit	Participative approaches, active citizenship	Leaflet	Practice based evidence, using a participative building approach	Create supportive environment for health Strengthen community action for health Develop personal skills	Resources Dynamic Mobilization Participative approach
Sports for protection tool	Social inclusion, social cohesion	Leaflet	Research and practice based evidence, using a participative building approach	Create supportive environment for health Strengthen community action for health Develop personal skills	Planning Education Resources Dynamic Feasibility Goals Monitoring Motivation Participative approach Partners
Sports without Doping! A training tool for Anti-Doping Junior Ambassadors	Doping prevention	Leaflet	Research and practice-based evidence	Develop personal skills	Education

(Continued)

TABLE 4 (Continued)

Name of the tool	Health topic	Type of tool	Type of evidence	Ottawa charter strategies	Intervention strategies
Staying in side: how to stop match-fixing	Match fixing	Leaflet	Practice based evidence	Create supportive environment for health	Resources Partners Communication
The good sports program	HP	Website	Research and practice-based evidence	Build healthy public policy Create a supportive environment for health Strengthen community action for health Develop personal skills	Planning Education Resources Dynamic Experience Feasibility Goals Mobilization Monitoring Motivation Participative approach Partners Communication
Community sports for children and youth planning toolkit	Sports and physical activity	Leaflet	Practice based evidence	Create a supportive environment for health Strengthen community action for health	Planning Resources Experience Feasibility Goals Monitoring
Everyone wins community sporting clubs	Gender equality, diversity and inclusion	Leaflet	Practice based evidence	Build healthy public policy Create a supportive environment for health Strengthen community action for health Develop personal skills Re-orient health services	Planning Education Resources Dynamic Experience Feasibility Goals Mobilization Monitoring Motivation Participative approach Partners Communication
The**GenderEqualityTool** for Generation**Z**	Gender Equality	Online training	Research and practice-based evidence	Create a supportive environment for health Develop personal skills Re-orient health services	Resources Experience Mobilization Motivation Partners Communication
How to select mental health program providers for sports clubs	Mental health program provision	Leaflet	Research based evidence	Strengthen community action for health	Mobilization Partners
Integration of Refugees through Sports	Refugee integration through sports	Online training	Research based evidence	Create a supportive environment for health Strengthen community action for health Develop personal skills Re-orient health services	Education Mobilization Participative approach Partners

(Continued)

TABLE 4 (Continued)

Name of the tool	Health topic	Type of tool	Type of evidence	Ottawa charter strategies	Intervention strategies
IOC Mental Health in elite athletes tool	Mental health	Leaflet	Research and practice-based evidence	Create a supportive environment for health Develop personal skills Re-orient health services	Education Dynamic Motivation Partners
Keep youngster involved	Youth sports drop out	Game	Research and practice-based evidence	Create a supportive environment for health Strengthen community action for health	Mobilization Motivation Participative approach Communication
Sports and physical activity for people with mental health problems: a tool for the sports sector	Mental health	Leaflet	Practice-based evidence	Build healthy public policy Create a supportive environment for health Strengthen community action for health Develop personal skills	Planning Resources Goals Mobilization Partners Communication
STOP sports injuries	Injury prevention	Website	Research and practice-based evidence	Create a supportive environment for health Strengthen community action for health Develop personal skills	Education Resources Dynamic Experience Feasibility Goals Mobilization Monitoring Motivation Participative approach Partners Communication
Sports Clubs for Health	Physical Activity participation	Leaflet and online training	Research and practice-based evidence	Build healthy public policy Create a supportive environment for health Develop personal skills	Planning Feasibility Goals Motivation Communication
SUGAPAS	Health behavior	Online training	Research and practice-based evidence	Develop personal skills	Education Resources
Supporting mental wellbeing in community sports	Mental health	Leaflet, video and checklist	Research based evidence	Create a supportive environment for health Develop personal skills	Education Dynamic Feasibility Mobilization Participative approach Partners Communication

contributes to the development of HP in organized sports by providing a definition of HPSF, illustrating the application of the setting-based approach to HP to NSFs and providing intervention components linked with strategies in the health promoting sports club's intervention framework. The intervention components, guidelines and tools provide practitioners, including NSFs, clear and useful guidance on how to promote health. Future research needs to further evaluate the feasibility and acceptability of this theory based guidelines, their effectiveness in delivering health outcomes as well as their adaptability to different cultural contexts.

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.

Ethics statement

Ethical review and approval was not required for the study on human participants in accordance with the local legislation and

institutional requirements. The patients/participants provided their written informed consent to participate in this study.

Author contributions

AH, SG, AV, and MW have contributed to research design and method definition. All others authors have contributed to shared knowledge, toolkit evaluation, reading of successive version of the guidelines. AH, AV, and CW have secured the funding to generate these guidelines. All authors contributed to the article and approved the submitted version.

Funding

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.

Acknowledgments

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Health promotion programs in prison: attendance and role in promoting physical activity and subjective health status

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Introduction: Maintaining an inmate's health can serve as a challenge due to unhealthy background, risky behavior, and long imprisonment. This study aimed to analyze the prevalence of participation in health promotion activities among Israeli inmates and its association with their physical activity levels and subjective health status.

Methods: A cross-sectional study was designed to examine 522 inmates (429 males, 93 females). The data were collected by trained face-to-face interviewers and self-report questionnaires.

Results: Most of the participants (82.37%) did not meet the recommended physical activity level. Half of the participants reported that their physical activity levels decreased since they were in prison compared with 29.50% who reported that their physical activity levels increased. Physical activity and subjective health status were significantly higher among younger male inmates. Furthermore, participation in health-promoting activities was associated with higher levels of physical activity and subjective health status.

Discussion: Health promotion activities may play an important role in addressing the challenges of maintaining inmate health. Implications of the findings are further discussed.

KEYWORDS

prison, health promotion, physical activity, health promotion programs, subjective health status, inmates

Introduction

The health of inmates is a major concern among health service officials, as this population often suffers from high rates of substance use and exposure to violence. Moreover, inmates tend to come from backgrounds of poverty; low education; and poor professional skills, factors that are consistently associated with reduced physical and mental health (1). More specifically, compared to the general population, inmates suffer from higher rates of contagious diseases such as HIV, hepatitis B and C, and tuberculosis, a higher rate of mental health problems and disorders, and a higher risk of cardiovascular disease and some types of cancer (2). Along with

poor incarceration conditions and delays in medical treatment, such factors can lead to the deterioration in both physical and mental health (3–7).

Maintaining the health of people living in prison is not only a matter of equal rights and humanitarian justice, but is of paramount importance to public health; maintaining their health is also a legal requirement, not a luxury (4, 5). Many inmates serve short prison sentences and return to the community where they live (8); therefore, precarious health conditions may carry an additional burden on community health services (2, 3, 6) and the high prevalence of communicable diseases that are not monitored and treated among the inmates can constitute a real hazard to public health (7). Wider benefits of maintaining positive prison health include lowering the costs of incarceration, lowering public health expenditure, improving reintegration into society and reducing recidivism, reducing health inequalities, and reducing prison population size (6, 7). In this sense, the prison framework provides an opportunity for the health system to provide medical care for populations that are difficult to reach within the community (4, 5), while also promoting preventive medicine and encouraging healthy behaviors and lifestyles (3, 7). Prisons have the potential to significantly improve the health, well-being, and life chances of some of society's most marginalized and excluded members (9).

A review of legislation enacted to advance health and wellbeing in prison environments indicates that much more could be done to improve the health of inmates (6, 8). The prison population has grown in many Western nations in recent years, but the capacity of prison services has not kept up (3, 10). Where health promotion has been developed in prisons, it tends to follow a medical model, focusing on individual lifestyle choices rather than broader determinants of health (6–10).

A socioecological model of health, a salutogenic orientation concerned with what promotes well-being and makes people thrive, a systems perspective, and an emphasis on holistic change are all part of the approach, which recognizes that health is formed and experienced in everyday settings (10, 11). When employed in this situation, the settings approach prioritizes a comprehensive prison perspective, revisits ideas of control, choice, and empowerment, and makes use of a framework that is determinants-focused (9, 10).

The literature shows that health promotion programs can effectively improve inmate health. Health promotion activities such as structured physical activity, nutrition education, and smoking cessation programs were found to be positively correlated with the cardiovascular health of inmates during incarceration (12). Bilderbeck et al. (13) found that inmates who participated in yoga classes reported an increased positive affect and reduced stress and psychological distress levels; the inmates in the experiment group exhibited better cognitive performance than their counterparts in the control group. Other studies have found that yoga and mindfulness meditation improved the well-being and behavioral functioning of the participating inmates (14). Moreover, there is evidence that these health-promoting activities not only improve the well-being and the cognitive functioning of the inmates while incarcerated but also have the potential to reduce recidivism (15), whereas poor mental health during and after incarceration is linked to higher odds of recidivating (16).

In 2020, there were approximately 14,000 inmates located in 33 different prisons throughout Israel. About 30% of the inmates served conviction periods of no more than 2 years, and 40% of them suffered from some chronic medical condition (17). Since 2010, the Israel Prison Service has issued orderly procedures for the health promotion activities to be implemented within the prison population, including physical activity programs (e.g., aerobic exercises, strength training, availability of gyms, and various health education activities) (18).

The current study aimed to assess the prevalence of participation in various health promotion programs, levels of physical activity, and subjective health status among prison inmates in Israel. More specifically, we sought to examine how participation in health promotion programs as well as socio-demographic and imprisonment characteristics of the inmates are related to the inmates' level of physical activity and subjective health status.

Methods

A cross-sectional study was conducted from February–September 2019 in 11 prisons in Israel: three prisons in the Northern District, three prisons in the Southern District, and five prisons in the Central District. Data on socio-demographic characteristics, healthy habits, subjective health status, and prison situation variables were collected using a structured questionnaire. Data were collected by trained interviewers (in-person interviews).

Ethics statement

The studies involving human participants were reviewed and approved by the Institutional Ethics Committee of Ariel University (AU-HEA-RT-30315027). The patients/participants provided their written informed consent to participate in this study.

Participants and sampling

This study included inmates aged 21 years old and above. Inmates who were critically ill, unable to communicate and security inmates were excluded. A convenience sampling technique was used; 429 male inmates and 93 female inmates participated. Prior to the start of the study, ethical approval was obtained from the institutional review board (IRB) of the university. Informed consent was obtained from the participants by an external researcher who had no affiliation with the research team, ensuring impartiality and minimizing potential biases.

To assist with the data collection, five data research collectors and one supervisor were employed and trained on data collection procedures and ethics in a one-day training session. The English version questionnaires were translated to Hebrew and were then translated back to English to check their translation accuracy (19, 20). The questionnaire was pre-tested on 20 participants (5% of the sample size) in another prison in the region, and modifications were made to the questionnaire based on the evaluation. The internal consistency of the questionnaire was checked using Cronbach's alpha; the questionnaire had an alpha value of 0.83, showing a good level of internal consistency ($\alpha > 0.7$).

Instruments

The questionnaire was comprised of socio-demographic and imprisonment characteristics, a measure of engagement in physical activity, a subjective health status, and an evaluation of participation in health promotion programs according to a self-report on a scale of 1 to 5, where 1 indicated no participation and 5 indicated full participation. Following is a description of the variables.

Socio-demographic questionnaire – Data were collected on participants' age (18+), sex (male, female), country of origin, level of education, and marital status. Originally, marital status had six response options (single, in a relationship, married, separated, divorced, widowed). However, this variable was dichotomized into "not in a relationship" (single, separated, divorced, widowed) and "in a relationship" (in a relationship and married).

Imprisonment characteristics

Participants were asked to report on two imprisonment-related characteristics: years of detention and the number of family visits to the prison during the previous month. In the questionnaire, the latter options were: never, once, 2–4 times, and more than 4. This variable was also dichotomized to indicate "no visit" (never) and "at least one or more visits per month" (once, 2–4 times, more than 4).

Participation in health promotion programs

Participants were asked about their tendency to participate in seven health promotion activities: yoga, gym, meditation, Vipassana seminar, Jangling, smoking lectures, and a healthy nutrition seminar. A score of 0 was given to those who did not participate and 1 to those who did participate. Participants were grouped into individual inmates who did vs. did not participate in any of the above health promotion activities. The mean of the health promotion activities was also calculated. Finally, participants were asked whether they thought that there was a need for additional health promotion activities, namely nutrition groups, a variety of physical activity groups, and health lectures.

Physical activity – Participants were asked about their pre-prison and current weekly time spent in moderate to vigorous physical activity (MVPA), including rapid walking, slow walking, running, aerobic training, and gym training, including both aerobic and muscle strengthening activities. Total time spent in MVPA was calculated as the sum of the aforementioned five activities, classified as insufficient MVPA ($<150\,min/week$) and sufficient MVPA ($\geq 150\,min/week$), according to the physical activity guidelines for health benefits (WHO, 2018). To get greater benefits from MVPA, it is recommended by the World Health Organization to conduct more than $300\,min$ of weekly MVPA (WHO, 2020) Accordingly, the third category of the MVPA was created of those conducting $>300\,min/week$ with one or more activities from the above list. To learn about the effect of prison on participants' physical activity levels, they were asked to report their physical activity levels while in prison compared to their pre-prison levels. Response options were as follows: more active, same, less active, do not know.

Subjective health status (SHS) – SHS was evaluated by asking the following question: "How do you evaluate your health generally?" The scale included six levels, where 6 = excellent and 1 = very bad. This variable was also dichotomized to create two categories of SHS: "good-to-excellent" and "bad and very bad" health. The scale and the question were adopted from (21).

Data management and analysis

Assessment of normality

An assessment of the normality of the continuous data was conducted using Kolmogorov–Smirnov test. This test is commonly used for $n \geq 50$. The test's null hypothesis stated that data are from a normally distributed population. In the current study, physical activity levels and SHS did not normally distribute ($p < 0.001$). Therefore, non-parametric statistics were used when analyzing these variables.

Socio-demographic and imprisonment characteristics

Descriptive statistics (means, standard deviations, ranges, and percentages) for the socio-demographic and imprisonment characteristics were conducted.

Physical activity level and subjective health status

Participants' physical activity levels (minutes of weekly aerobic physical activity) is described using descriptive statistics. Physical activity levels are also presented visually using a boxplot figure. Percentage of participants who reported being more, same, or less physically active since being in prison was calculated as well. The percentage of participants reporting each of the five health status categories (excellent, very good, good, bad, very bad) was calculated and compared using chi-squared tests.

Participation and recommendations for health promotion programs

The percentage of inmates who participated, did not participate, or who were recommended to participate in one or more of the given health promotion activities were calculated. In the first step, participants were grouped into those meeting/not meeting physical activity recommendations and those with good-to-excellent health or bad-to-very bad health. Differences between those meeting/ not meeting physical activity recommendations and those with good-to-excellent health or bad-to-very bad health in the continuous variables were examined using the non-parametric Mann–Whitney rank-sum test. Differences between the groups in categorical variables were examined using chi-squared tests. In the next step, variables that statistically significantly differed between the two groups were further analyzed using two separate binary logistic regression models to determine the extent to which demographic characteristics, imprisonment characteristics, and attendance in health promotion programs predicted the physical activity level and SHS. In that respect, the dependent variables (physical activity level and SHS) were recoded as dummy variables (0 = not meeting physical activity recommendations or reporting bad and very bad health, and 1 = meeting physical activity recommendations or reporting good-to-excellent health).

Power analysis

Post-hoc power analysis was conducted separately for physical activity level and SHS using G*power (version 3.1). For physical activity level, using the Wilcoxon-Mann Whitney test (differences between two independents, namely, those achieving vs. not achieving the recommended physical activity level), two-tails, alpha err

TABLE 1 Socio-demographic and imprisonment characteristics of the sample ($n = 522$).

Variables			Mean (SD) [range] OR N (%)
Socio-demographic characteristics	Age, years: mean (SD) [range]		38.20 (12.83)
			[18.00–82.00]
	Sex: n (%)	Male	429 (82.20)
		Female	93 (17.80)
	Country of origin: n (%)	Native to the country	356 (74.01)
		Foreign	125 (25.98)
	Marital status: n (%)	Single	173 (33.70)
		In partnership	45 (8.80)
		Married	174 (33.90)
		Separated	19 (3.70)
		Divorced	88 (17.20)
		Widowed	14 (2.70)
	School, years: mean (SD) [range]		9.45 (3.26) [0.00–15.00]
	Educational level: n (%)	Never learned at school	28 (6.10)
		Only primary school	86 (18.70)
		Graduating school without diploma	88 (19.10)
		Basic diploma	120 (26.00)
		Professional diploma	56 (12.10)
		College diploma	12 (2.60)
		Technical or professional certification	23 (5.00)
		Professional degree/ course	48 (10.40)
Imprisonment characteristics	Years of detention: mean (SD) [range]		4.55 (1.55)
			[2.00–15.00]
	Family visitation in the previous month: n (%)	Never	158 (30.44)
		Once	161 (31.02)
		2–4 times	140 (26.97)
		More than 4	60 (11.56)

SD, standard deviation.

probability of 0.05, and with achieved mean effect size d = 0.40, the power achieved in the study was 0.90. For SHS, using the Wilcoxon-Mann Whitney test (differences between two independents, namely, those with good-to-excellent health vs. those with bad-to-very bad health), two-tails, alpha err probability of 0.05, and with achieved mean effect size d = 0.31, the power achieved in the study was 0.88.

The data were analyzed with the IBM SPSS statistics 25. In all statistical analyses, p-values lower than 0.05 were considered as statistically significant.

Results

Socio-demographic and imprisonment characteristics

Our study included 522 sample of Israeli inmates with a mean age of 38.20 + 12.83 years (males: $n = 429$, 82.2%). The average years of detention was 4.55 + 1.55 years (Table 1).

Physical activity level

Participants' MVPA levels varied considerably and ranged from 0 min to 1,210 min (median minutes: 0.00, 95% confidence interval:

0.00–5.00; Figure 1). Most participants did not meet the recommended physical activity level of at least 150 min of weekly MVPA (82.37%). In addition, 29.50% ($n = 154$), 15.51% ($n = 81$), and 49.80% ($n = 260$) of participants reported that their physical activity levels increased, remained the same, or decreased since they entered prison, respectively.

Subjective health status

The prevalence of excellent, very good, good, bad, and very bad SHS was 17.24 ($n = 90$), 18.58 ($n = 97$), 27.39 ($n = 143$), 23.18 ($n = 121$), and 13.60 percent ($n = 71$; chi-squared $= 5.33$, $p = 0.02$). Post-hoc test showed that more participants reported good health ($n = 143$, 27.39%) compared to those who reported very bad health ($n = 71$, 13.60%; chi-squared $= 25.04$, $p < 0.001$).

Participation in health promotion programs and recommendations for additional health promotion programs

Approximately 43% ($n = 226$) of study participants did not participate in any health promotion program. The most prevalent program was gym (35.63% participation rate) followed by
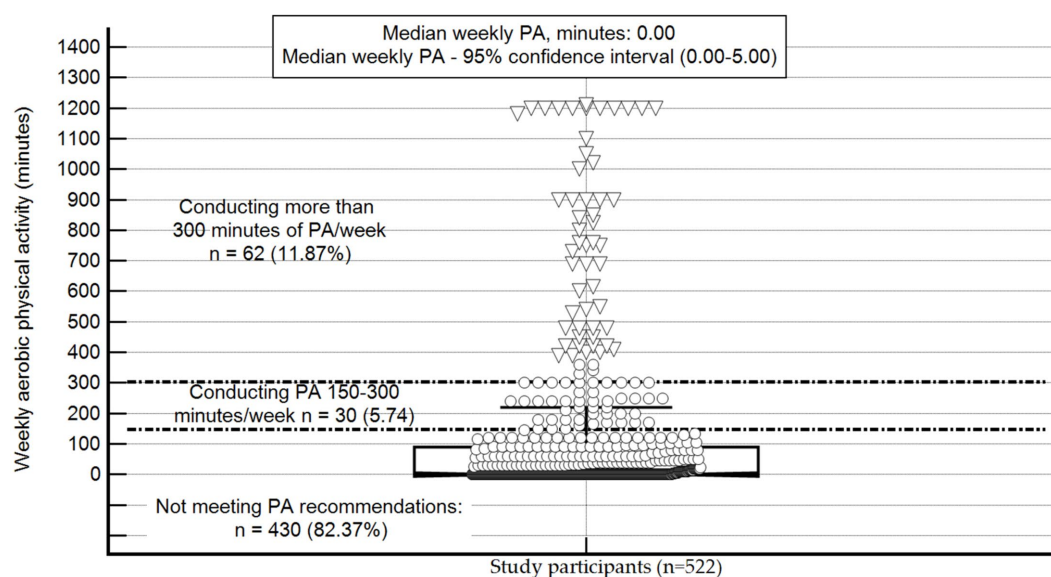
FIGURE 1
Physical activity level of study participants ($n = 522$), PA, physical activity; The central box represents the values from the lower-to-upper quartile (25-to-75 percentile); the vertical line extends from the minimum-to-the maximum value, excluding outside values (denoted in triangles). Non-outliers are denoted in circles. An outside value is defined as a value that is smaller than the lower quartile minus 1.5 times the interquartile range or larger than the upper quartile plus 1.5 times the interquartile range; the middle line represents the median; The area from the first horizontal line to the *X* axis (weekly aerobic activity of <150 min) represents individuals not meeting the recommended physical activity level. The area between the first and the second horizontal lines (150−300 min of weekly physical activity) represents individuals meeting physical activity recommendations. The area above the third horizontal line (>300 weekly minutes) represents people being sufficiently active to receive extra health benefits from physical activity.

meditation ($n = 119$, 22.79%) and yoga ($n = 115$, 22.03%). Activities with the least enrolled participants were: smoking lectures ($n = 76$, 14.55%) and healthy nutrition seminar ($n = 71$, 13.60%). The mean number of health promotion programs each participant was enrolled in was $1.29 + 1.59$. Approximately 80% of the participants recommended adding the following health promotion activities: a variety of physical activity groups ($n = 413$, 79.11%), health lectures ($n = 411$, 78.73%), and nutrition groups ($n = 407$, 77.96%).

Prediction of physical activity level and SHS

Overall, three variables significantly differed between participants who did vs. did not meet physical activity recommendations and those with good-to-excellent vs. bad-to-very bad health status (Table 2). More specifically, compared to those who met physical activity recommendations, those who did not meet the recommendations were older (Mann–Whitney $U = 1771.00$, $p = 0.01$) and participants with bad-to-very bad health were older (Mann–Whitney $U = 21,229$, $p < 0.001$). In addition, compared to females, the prevalence of meeting the physical activity recommendations and the prevalence of good-to-excellent health among males was statistically significantly higher (chi-squared $= 13.80$, $p < 0.001$; chi-squared $= 27.27$, $p < 0.001$ respectively). Finally, compared to those not participating in health promotion programs, the prevalence of meeting the physical activity recommendations among those who participated in health promotion activities was statistically significantly higher (chi-squared $= 11.39$, $p < 0.001$). Accordingly, the prevalence of good-to-excellent health among participants who did not

participate in health promotion programs was statistically significantly lower than the level found among those who participated in such programs (chi-squared $= 11.30$, $p < 0.001$).

For physical activity level, compared to males, the odds of females being physically active decreased by 77% (95% confidence interval: 1.24, 3.20). Similarly, compared to those not participating in health promotion programs, the odds of those participating in health promotion programs being physically active increased by 99% (95% confidence interval: 1.24, 3.20). For SHS, sex and participation in health promotion programs were also significant predictors with odds ratio equals 0.46 (95% confidence interval: 0.28, 0.75) and 1.66 (95% confidence interval: 1.13, 2.45), respectively. Unlike physical activity level, age also statistically significantly predicted SHS (odds ratio $= 0.96$, 95% confidence interval: 0.95, 0.97). For additional information, refer to Table 3.

Discussion

The present study assessed the prevalence of participation in various health promotion programs, level of physical activity, and subjective health status among inmates in Israel. We further examined the role of demographic and imprisonment characteristics and participation in health promotion programs in predicting physical activity level and subjective health status. Our findings show that inmate participation in health promotion activities was positively associated with physical activity level and subjective health status. Moreover, although most of the participating inmates (82.37%) did not meet the recommended physical activity level of at least 150 min of weekly MVPA, those who participated in any health promotion

TABLE 2 Differences in physical activity level and health status based on demographic, imprisonment characteristics, and participation in health promotion programs.

Variables			Physical activity level		Health status	
			Meeting physical activity recommendations		Self-reported health status	
			Yes: median (95% confidence interval) OR n (%)	No: median (95% confidence interval) OR n (%)	Good-to-excellent: median (95% confidence interval) OR n %)	Bad and very bad: median (95% confidence interval) OR n (%)
Socio-demographic characteristics	Age, years: mean (SD) ($n = 522$)		32.00 (30.00–37.00)	37.00* (35.00–38.31)	33.00 (32.00–36.00)	43.00* (39.35–46.00)
	Sex: n (%)	Male ($n = 429$)	88 (20.51)	341 (79.48)	295 (70.07)	126 (29.92)
		Female ($n = 93$)	4 (4.30)[†]	89 (95.69)[†]	35 (41.17)[†]	50 (58.82)[†]
	Country of origin: n (%)	Native to the country ($n = 356$)	67 (18.82)	289 (81.17)	240 (67.41)	116 (32.58)
		Foreign ($n = 125$)	18 (14.4)	107 (85.6)	81 (64.8)	44 (35.2)
	Marital status: n (%)	In a relationship ($n = 219$)	35 (15.98)	184 (84.01)	135 (61.64)	77 (35.15)
		Not in a relationship ($n = 294$)	55 (18.70)	239 (81.29)	194 (65.98)	93 (31.63)
	School, years: mean (SD) ($n = 461$)		10.00 (10.00–11.60)	10.00 (10.00–10.00)	15.00 (10.00–11.00)	15.00 (10.00–10.00)
Imprisonment characteristics	Years of detention: mean (SD) ($n = 522$)		4.500 (4.00–5.00)	4.00 (4.00–4.00)	4.00 (4.00–4.00)	5.00 (4.00–5.00)
	Family visitation in the previous month: n (%)	No visitations ($n = 158$)	22 (13.92)	136 (86.07)	93 (58.86)	57 (36.07)
		At least one visitation ($n = 361$)	70 (19.39)	289 (80.05)	237 (65.5)	115 (31.85)
Health promotion programs	Participation status: n (%)	Yes ($n = 296$)	66 (22.97)	228 (77.02)	218 (73.64)	78 (26.35)
		No ($n = 226$)	26 (11.50)[‡]	198 (87.61)[‡]	135 (59.73)‡	91 (40.26)‡

*Statistical significant differences between the two groups of physical activity level ["Yes" vs. "No" or health status ("Good-to-excellent" vs. "Bad and very bad")] ($p < 0.05$; 2-tailed) using independent t-tests [†]Statistical significant differences between males and females ($p < 0.05$; 2-tailed) using Chi-squared test; [‡]Statistical significant differences between those participating and not participating in health promotion programs ("Yes" vs. "No" groups; $p < 0.05$; 2-tailed) using Chi-squared test; SD, standard deviation.

TABLE 3 Summary of multiple binary logistic regression analysis for physical activity level and health status.

Dependent variable	Variables	Coefficient	Odds ratio	Wald	95% confidence interval	p
Physical activity level (reference, meeting physical activity recommendations)	Constant	−1.12	–	7.73	–	0.005
	Age, years	−0.01	0.98	3.40	0.96–1.00	0.060
	Sex (reference category: male)	−1.09	0.33	6.11	0.14–0.79	0.010
	Participation in health promotion programs (reference category: not participating)	0.69	1.99	8.22	1.24–3.20	0.004
	Model summary			Chi-squared = 23.36, $p < 0.001$, Nagelkerke $R^2 = 0.08$		
Health status (reference, good-to-excellent health)	Constant	2.06	–	37.11	–	< 0.0001
	Age, years	−0.03	0.96	23.36	0.95–0.97	< 0.0001
	Sex (reference category: male)	−0.77	0.46	9.52	0.28–0.75	0.002
	Participation in health promotion programs (reference category: not participating)	0.51	1.66	6.74	1.13–2.45	0.009
	Model summary			Chi-squared = 45.74, $p < 0.001$, Nagelkerke $R^2 = 0.12$		

activity had a better chance of meeting the recommended physical activity level. Likewise, the odds of reporting good health were 1.5 times higher among the inmates who participated in these programs compared to those who did not participate. These findings provide additional support to the growing body of research suggesting that health promotion programs and activities benefit inmate health and well-being (12–14), as well as the potential to reduce recidivism (15).

It has been generally claimed that the settings approach that the WHO Health in Prisons Program supports presents an opportunity to realize the potential of prisons to embrace health promotion and

truly fight health inequities, in spite of the inherent obstacles (8, 9). The fact that various health promotion programs provided in several prisons were found to be positively correlated with the health status of the inmates and their level of physical activity, emphasizes the importance of maintaining the health of the prisoners and minimizing future burden on public health services due to the onset and deterioration of untreated chronic physical and mental health conditions (3, 7).

Age and sex were the demographic variables that were found to significantly predict health status and meeting the physical activity

recommendations. Female inmates were less likely to meet the recommended physical activity levels and their reported health status was much poorer compared with male inmates. These findings corroborate previous research which indicates that women in prison have more disease burden (22) and need more health care services than men (6). Moreover, female inmates often come from at risk families and as such, they are more likely to suffer from poor mental health and higher rates of substance abuse compared to male inmates (22, 23). It is possible that the health promotion activities offered currently at the prisons are more focused on the needs of male inmates, which may lead to the deterioration of health problems experienced by female inmates (6). It is important to note, in Israel, as in many countries women report less physical activity as compared to men in the general population (23). Age was also negatively associated with both dependent variables: younger inmates were more likely to meet the recommended physical activity levels and to report better health than older inmates. Although a negative relationship between age and health is expected, compared to older adults living in the communities, older prisoners suffer from early-onset and more rapid progression of (23) many chronic medical conditions and untreated mental illness due to unhealthy lifestyle and inadequate health care (24, 25). These findings further stress the importance of developing and tailoring health promotion programs to the special needs of these two vulnerable groups of female inmates and older inmates (26, 27).

Years of detention, marital status, and family visitation were not found to be important factors in predicting inmate health status and physical activity levels. However, the direction of results may suggest that family visitation is associated with inmate health and activity levels. Indeed, research shows that family visits in prison can benefit the well-being of prisoners and motivate them to maintain good behavior during and after incarceration, however, it depends on the quality of interactions with the visiting family (4, 28, 29).

Finally, despite the positive and encouraging results of the health promotion programs in Israeli prisons, the current study also found that half of the prisoners reported that their level of physical activity had decreased since entering prison compared to 29.5% who reported that they had increased their level of physical activity since prison. Likewise, 43% of the inmates did not take part in any health promotion program. Given that most of the inmates expressed a desire for additional health promotion programs, these findings further stress the need to invest additional efforts and resources to encourage the widest possible participation of all inmates (9, 10, 30).

This study had some limitations that must be considered. The cross-sectional design precludes the inference of causality. While we know that those who participated in the health promotion program also reported higher level of physical activity, these may also be inmates who were previously healthier and more active prior to being in prison. Data were self-reported, which can be subject to bias. Convenience sampling does not represent the perception of all inmates who were in different stages of incarceration or in different stages of rehabilitation. Conducting face-to-face interviews by a trained interviewer can affect the data collection as a result of the relationship between the interviewer and the inmate. However, the sample size was sufficient to gather insights. Recommended future studies should include objective health measures and data, as well as a longitudinal design to evaluate the long-term effect of participation in health promotion programs.

Conclusion

The study findings emphasize the importance of providing in prison health programs to promote health activities and well-being perceptions to prevent chronic diseases in Israeli inmates. These findings underscore the importance of evaluating health behavior and SHS levels in prison settings. In addition, the significant association between participation in health promotion programs and subjective health status marks the need to explore the underlying factors for health promotion participation in prison. More positive health outcomes for male as opposed to female inmates and for younger as opposed to older inmates highlighted the specific needs of the different inmate population groups.

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 studies involving human participants were reviewed and approved by the Institutional Ethics Committee of Ariel University (AU-HEA-RT-30315027). The patients/participants provided their written informed consent to participate in this study.

Author contributions

Funding

Acknowledgments

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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Videos using different message strategies to promote the interruption of sedentary behavior in university students during online lectures – A pilot study

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Background: Sedentary behavior (SB) is highly prevalent among university students and has increased during COVID-19 pandemic. As SB is associated with negative health outcomes, appropriate prevention measures in the university setting are needed.

Objective: This pilot study aimed at investigating the effects of videos using different message strategies to interrupt SB in the collective of university students during online lectures.

Methods: During online lectures, university students (N=96) were shown one of three videos on the interruption of SB. The videos differed in their message strategies with regard to evidence type (statistical vs. narrative) and vividness (static vs. animated images). Demographics, health variables (SB intentions, SB attitudes) and selected media reception variables (identification, homophily, counterarguing) were examined as possible influence factors on the interruption of SB evoked by watching the video.

Results: Approximately half of the students interrupted sedentary behavior during watching the videos and students of the older age group (cut-off: median=22 years) interrupted SB significantly more often (p=0.046). The interruption of SB was predicted by SB intentions (p<0.05). Identification with characters significantly predicted the intentions to reduce SB (p<0.001), with a large effect of the overall regression model (R^2_{corr}=0.47).

Conclusion: Considering the increased digitalization in general and restrictions due to COVID-19 pandemic, videos seem to be a useful tool to interrupt SB among university students during online lectures. Narrative formats could facilitate the intention to reduce SB, which in turn could have a positive impact on the interruption of SB. However, further research on effective communication and message strategies is needed.

1. Introduction

Sedentary behavior (SB) is defined as any behavior in an awake state in sitting, leaned or horizontal position with an energy consumption less than 1.5 MET (metabolic equivalent) (1, 2). Populations of high-income countries spend a large extent of their daily time with SB (3). University students show an especially large extent of SB with sitting times of approximately 10 h per day (4, 5). Particularly common study activities, such as attending lectures, literature research, or writing assignments, are often spent in sedentary positions (4, 6, 7). Additionally, recent studies implicate that SB among university students further increased during the COVID-19 pandemic, whereas health beneficial physical activity simultaneously decreased (8, 9).

From a public health point of view, the above-mentioned extent of SB among university students and its increase during the COVID-19 pandemic are alarming because SB represents a clinically relevant risk factor which is associated with various physiological [e.g., (10–12)] and psychological [e.g., (7, 12, 13)] burdens and diseases, and may lead to an increased mortality [e.g., (11, 14)]. Therefore, effective measures to reduce SB in the university setting are needed. In this context, research suggests that not only the overall reduction of time spent with SB, but also regular interruptions of SB may be beneficial (6, 15) – even with short bouts of light physical activity (bodily movements produced by skeletal muscles that require energy expenditure of less than 3 MET, e.g., walking slowly or low impact exercises like light stretching) (16). The adaption of environmental conditions such as standing desks (17, 18) represents one commonly used option to regularly interrupt SB with light physical activity, but it may be limited due to financial restrictions and environmental constraints pertaining to workplace design and study conditions at home (6). Therefore, behavioral prevention approaches of health communication at the target group level of university students may be a promising approach to tackle the large extent of SB (6, 19).

Health communication aims to facilitate positive health outcomes by improving communication processes (20, 21). Among various distribution methods of health communication, especially mass media-based health communication is used in current times of increasing digitalization and it includes communication via different channels, such as (online) brochures and videos. In general, health communication uses different strategies, which refer to the overall approach to change health relevant parameters and can be organized in cognitive, affective, social, and behavioral categories (22). In particular, message strategies include clearly defined and manipulable characteristics of a message, which can have different effects on recipients' health outcomes (23).

One popular message strategy in health communication is the use of different evidence types – either statistical or narrative evidence. Statistical evidence is usually based on a large number of cases to disseminate information and appeals to the ratio of recipients (24–26). By contrast, within narrative evidence, cohesive stories with one or more protagonists are told (25, 26). Theories of narrative health communication assume that processes such as homophily and identification with media characters are effective mechanisms to reduce resistance against persuasive messages (such as counterarguing) and influence health behavior by changing health attitudes and intentions [e.g., (27, 28)]. Whereas homophily describes a cognitive evaluation of perceived similarity with a character (27), identification refers to a deeper process of adopting the perspective of a character (28). A recent meta-analysis indicates the effectiveness of both evidence types, but it remains unclear which strategy is more successful among which target group and in which setting (26).

Another message strategy used within health communication is the level of vividness. Vivid communication is conceptualized as "likely to attract and hold our attention and to excite the imagination to the extent that it is emotionally interesting, concrete and imagery-provoking, and proximate in a sensory, temporal, or spatial way" [(29, p.45)]. In literature, vividness has been manipulated in different ways, including the presence or absence of pictures and concrete or abstract pictures (30). A meta-analysis suggests that vivid information is more persuasive than non-vivid information (30). Concurrently, the *cognitive load theory of multimedia learning* assumes that the working memory of individuals is limited with separate channels for visual/pictorial and auditory/verbal material (31). Thus, the theory states that learning-irrelevant cues such as the use of too many different colors or a noisy voice-over should be reduced.

A systematic review of 28 studies suggests the effectiveness of video-based communication in modifying health behavior in general (32). Targeting university with video-based health communication, Conceição et al. (33) found an increase of fertility knowledge and in another study Conceição et al. (34) observed a reduction of depression stigma and an increase in help-seeking attitudes. In addition, a recent study indicated that videos are as effective as text formats in changing meningitis B vaccine knowledge, perceptions, and intentions (35). Particularly, when considering the increasing digitalization in general and the restrictions of regular university teaching caused by the COVID-19 pandemic, videos applied during online lectures seem like a promising approach to communicate health information to university students. However, evidence about the effects of different message strategies to promote the interruption of SB is lacking, particularly in the setting of online lecturing. Furthermore, it remains unclear, which characteristics of the heterogeneous target group of students (e.g., age or gender) are associated with the potential effects of these interventions. To determine the effectiveness of health communication interventions, it is further crucial to include psychological variables such as health intentions and attitudes in the investigation, as common theories, such as the *theory of planned behavior*, emphasize the relevance of these processes for the adaption of health behavior (36, 37).

Therefore, the present pilot study aimed at (1) identifying potential differences in the prevalence of the interruption of SB between video formats using different message strategies (evidence

type, vividness), gender, and age groups. (2) In a binary logistic regression analysis, it was further investigated, if the interruption of SB was predicted by the intention to reduce SB, the attitude towards SB, age, and gender. (3) Finally, leaning on theories about narrative persuasion (27, 38), it was examined if the intention to reduce SB and the attitude towards SB were predicted by identification and homophily with characters, as well as counterarguing.

2. Materials and methods

2.1. Study design

A three-arm parallel grouped study design was used to examine the effects of different video formats on the interruption of SB during online lectures. The study was conducted as part of the ongoing project "Healthy Campus Mainz" which aims at building and evaluating an evidence-based student health management program at the Johannes Gutenberg-University Mainz (JGU). For this purpose, the expertise of various professions (medicine, psychology, sports science, media science) is combined. Further information about the project is provided by Reichel et al. (39). The study was approved by the Ethics committee of the federal state of Rhineland-Palatinate (Number: 2021-15876-other research) and followed the Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects. Participants received no compensation.

2.2. Participants and procedure

Student participants were recruited *via* lectures in different disciplines (e.g., psychology, sports science, medicine) at the Johannes Gutenberg University (JGU) Mainz. Through personal contact, 23 lecturers were approached who enlisted further lecturers through word-of-mouth recruitment. Overall, the videos were shown in 16 lectures, which were divided into small and large ones to ensure equivalent sizes of the experimental groups. For this purpose, $n = 50$ was set as a cut-off to separate small practical seminars from large lectures. A cluster randomization subsequently was performed counter-balanced and separately for small and large lectures using BiAS for Windows version 11.10 (40). Courses were randomized to three experimental groups, each of them watching the video in one of three video formats (animated-statistical, animated-narrative, static-statistical) during online lectures. Videos were either incorporated in asynchronous lectures (e.g., pre-recorded lectures, on demand) or in synchronous lecture formats such as video conferences. After watching the videos, participants consented study participation and completed an online survey containing questionnaires on demographic, health, and media reception variables.

2.3. Video intervention

Since various evidence identified SB as risk factor in university students [e.g., (4, 5)], the "Health Express" has been developed as an intervention for the communication of health-promoting information and behaviors. The "Health Express" is a video-based intervention consisting of videos with a duration of approximately 3 min, which are

embedded into online lectures at the JGU. It aims at imparting evidence-based knowledge of SB and gives information about prevention strategies of SB in students' everyday life. The videos present health-promoting information in three different video formats, which vary in their message strategy using different evidence types (statistical vs. narrative) and level of vividness (static vs. animated). Please find the video links listed in (Supplementary Table 1).

Two video formats (animated-statistical, animated-narrative) are presented as animated videos using the same moving images depicting two student characters but with the voice-over in different evidence types. These video formats were developed by the study team using the online platform Powtoon (41). The animated-statistical video format uses statistical evidence by presenting information on a large number of individuals [e.g., number of JGU students fulfilling the World Health Organization's (WHO) recommendations for physical activity (42)]. By contrast, in the animated-narrative video format, the same information is presented in a narrative form: a dialog between the depicted university students is presented, one person describing barriers of reducing SB and the other person identifying possible solutions. No further information about the characters is given to facilitate identification for a wide majority of university students. As students are exposed to numerous visual and auditory cues during online lectures, it could also be suitable to use health communication with a low level of vividness. Therefore, the static-statistical video format (in contrast to the two other video formats) includes a lower level of vividness by using no moving images, and information in the style of statistical evidence is given through professional speakers.

2.4. Measures

The survey included questionnaires measuring demographics, health variables (interruption of SB, intention to reduce SB, attitude towards SB), and media reception variables (identification with characters, homophily with characters, counterarguing).

2.4.1. Demographics

Gender, semester, and subject were measured by means of categorical variables. As only few students reported to study another subject than psychology, medicine, or sports science, we summarized the remaining subjects to the category other. The mean and the standard deviation for semester and the continuous variable age were calculated. Additionally, we dichotomized age by means of the median (22 years) to be able to compare the age groups in the following analyses.

2.4.2. Health variables

The following single item was used to measure the interruption of SB: "Did you stand up during watching the video?" The answer format was binary ("Yes"/"No").

To measure the intention to reduce SB, the three items of Chevance et al. (43) were adapted to SB and translated into German ["I intend to reduce (my) sedentary behavior after watching the video."; "Even if I am tired, alone, or sick, I have set the objective of limiting my sedentary behavior after watching the video"; "Even if I have to work a lot for my study, I will limit my sedentary behavior after watching the video"]. The answer format was a 7-point Likert scale (from "I absolutely agree" to "I absolutely disagree"). Cronbach's alpha was $\alpha = 0.85$.

The questionnaire to measure the attitude towards SB was developed based on various studies (44–46), and translated into German. Within this scale, which included 3 items, the first was: "Reducing sedentary behavior would make me…" "…very satisfied" to "very dissatisfied." The remaining two items [e.g., "I consider the reduction of sedentary behavior as beneficial for my health.," and "It is not important for me to reduce my sedentary behavior (inversed)"] included a 5-point Likert scale answer format (from "I agree very much" to "I disagree very much"). Cronbach's alpha was $\alpha = 0.36$.

2.4.3. Media reception variables

To measure identification with characters, *Cohen's identification scale* (28) was used and translated into German. An exemplar item is: "During watching, I felt I could really get inside the characters' head." The answer format was a 5-point Likert scale (from "I agree very much" to "I disagree very much"). We measured a Cronbach's alpha of $\alpha = 0.84$.

Perceived homophily with characters was captured through a translated version of the dimension *attitude* of the *Attitude homophily scale* (47) (e.g., "The characters…" "… behave like me" to "…do not behave like me"). Cronbach's alpha for this scale was $\alpha = 0.84$ which is in line with reliabilities other studies established for this scale (48).

To measure counterarguing, the 4 items of the study of Nabi et al. (49) were translated into German. The answer format was a 5-point Likert scale (from "I agree" to "I disagree at all"). Nabi et al. (49) found a single factor index with a Cronbach's alpha of $\alpha = 0.80$.

2.5. Data analysis

Statistical requirements for every test were checked before analysis. Chi^2-tests were conducted to investigate differences in the prevalence of interruptions of SB between video formats, gender, and age. To investigate if the interruption of SB was predicted by the intention to reduce SB, attitude towards SB, gender, and age, a binary logistic regression was computed. If attitude towards SB, and intention to reduce SB appeared to be significant predictors in this model, the

prediction of these variables was analyzed in a further step using two multiple linear regressions with identification with characters, homophily with characters, and counterarguing as predictors. For this purpose, only animated formats were involved into calculations. Analyses were conducted using IBM SPSS (50).

3. Results

Overall, $N = 118$ university students participated in the study. Of these participants, $n = 22$ indicated that they have already seen the video in another lecture or provided no data or only demographic data and thus were not considered in the analyses, resulting in a final sample size of $N = 96$ (animated-statistical group: $n = 29$, animated-narrative group: $n = 32$, and static-statistical group: $n = 35$). Participants were on average 23.54 years old ($SD = 3.93$), and more than half of the sample identified as female (62.5%). In Table 1, a description of the study sample in total and subdivided by video format is provided. The most common subject was psychology (45.0%). On average, participants studied in semester 4.77 ($SD = 2.46$), with 12% being in their first or second semester. Experimental groups did not significantly differ in gender [$\chi^2 (2) = 0.946$, $p = 0.623$, $V = 0.623$] or semester [$F (2, 91) = 2.139$, $p = 0.124$], but in study subject [$\chi^2 (6) = 67.816$, $p < 0.001$, $V = 0.000$] and age group [$\chi^2 (2) = 15.568$, $p < 0.001$, $V = 0.000$]. Table 2 presents descriptive data for the experimental variables, separately for gender and age groups.

3.1. Differences in interrupting sedentary behavior between video formats and demographic variables

Of all participants, 51% ($n = 47$) interrupted SB while watching the video, whereas 49% ($n = 45$) indicated that they did not interrupt SB. The prevalence of interruption of SB was 36% ($n = 12$) in the static-statistical group, 57% ($n = 16$) in the animated-statistical group, and 61% ($n = 19$) in the animated-narrative group. On a descriptive level, more men (61%, $n = 20$) than women (46%, $n = 27$) interrupted SB. However, there

TABLE 1 Demographic characteristics of the study sample.

Baseline characteristic	Animated-statistical		Animated-narrative		Static-statistical		Overall	
	n	%	*n*	%	*n*	%	*N*	%
Gender								
Male	9	31	12	37.5	15	43	36	37.5
Female	20	69	20	62.5	20	57	60	62.5
Study subject								
Psychology	16	55	7	22	20	57	43	45
Sport science			13	41	15	43	28	29
Medicine	13	45					13	14
Other			10	31			10	10
	N	*M*	*SD*	*N*	*M*	*SD*	*N*	*M*	*SD*
Age	29	25.0	2.90	32	23.1	4.21	34	22.7	4.16	95	23.5	3.93
Semester	29	5.52	1.82	30	4.6	3.34	35	4.29	1.89	94	4.77	2.46

n = absolute frequency; % = relative frequency.

TABLE 2 Descriptive statistics of experimental variables.

Variable	Overall			Female			Male			Chi²	≤ 22 years			> 22 years			Chi²
	N	M	SD	N	M	SD	N	M	SD	p	N	M	SD	N	M	SD	p
Identification	96	2.4	0.57	60	2.3	0.51	36	2.5	0.65	0.415	50	2.5	0.59	45	2.3	0.51	0.430
Homophily	95	3.5	1.12	60	3.3	1.04	35	3.7	1.23	0.434	49	3.6	1.17	45	3.3	1.04	0.989
Counterarguing	93	4.0	0.53	59	4.1	0.49	34	3.8	0.58	0.029*	47	4.0	0.59	45	4.01	0.48	0.879
Intention	92	3.1	1.00	59	3.1	0.87	33	3.2	1.21	0.567	47	3.3	1.02	44	2.9	0.96	0.222
Attitude	92	2.0	0.55	59	1.9	0.49	33	2.1	0.65	0.466	47	2.1	0.54	44	1.9	0.54	0.316

$*p < 0.05$.

TABLE 3 Prediction of the interruption of sedentary behavior.

Variable	B	SE	Wald	p	Exp (B)	95% CI
Intention	0.598	0.277	4.658	0.031*	1.818	[1.056–3.310]
Attitude	0.138	0.457	0.092	0.762	1.148	[0.469–2.812]
Age	−0.107	0.065	2.727	0.099	0.898	[0.791–1.020]
Gender	0.702	0.496	1.998	0.158	2.017	[0.762–5.338]

Chi²: χ^2 (4) = 14.071, $p = 0.007$. Model fit: $R^2 = 0.191$ (Nagelkerke). 95% CI for Exp (B).
$*p < 0.05$.

TABLE 4 Prediction of the intention to reduce sedentary behavior.

Variable	B	SE	B	T	p	95% CI
Identification	1.260	0.158	0.689	6.360	0.000**	[0.863–1.656]
Homophily	−0.003	0.102	−0.004	−0.034	0.973	[−0.208–0.210]
Counterarguing	−0.161	0.188	−0.083	−0.855	0.397	[−0.538–0.217]

ANOVA: F (3, 55) = 18.172, $p < 0.001$. Model fit: $R^2 = 0.470$ (corrected). 95% CI for B.
$**p < 0.001$.

was no significant difference between gender [χ^2 (1) = 4.565, $p = 0.172$, $V = 0.172$] or video format [χ^2 (2) = 4.565, $p = 0.102$, $V = 0.102$] in the interruption of SB. By contrast, age groups significantly differed in the interruption of SB [χ^2 (1) = 3.986, $p = 0.046$, $V = 0.046$], with more students of the older age group (62%, $n = 27$) interrupting SB while watching the video, compared to the younger students (40%, $n = 19$).

3.2. Prediction of the interruption of sedentary behavior

The binary logistic regression model to predict the interruption of SB by the variables intention to reduce SB, attitude towards SB, gender, and age was statistically significant [χ^2 (4) = 14.071, $p = 0.007$] and explained 19% of the variance (Table 3), indicating a small effect (51). Intention to reduce SB significantly predicted the interruption of SB ($p < 0.05$), while attitude towards SB ($p = 0.762$), gender ($p = 0.158$), and age ($p = 0.099$) were no significant predictors in this model.

3.3. Prediction of the intention to reduce sedentary behavior

As attitude towards SB was no significant predictor for the interruption of SB, regression analysis was only calculated with intention to reduce SB as the dependent variable. The included predictors of the model were identification and homophily with characters, as well as counterarguing. The regression model was significant [F (3, 52) = 18.172, $p < 0.001$] with a corrected R^2 of 47%, indicating a large effect (52). Identification was a significant predictor of the model ($p < 0.001$), whereas homophily ($p = 0.973$), and counterarguing ($p = 0.397$) did not significantly predict the intention to reduce SB (Table 4).

4. Discussion

Videos seem to be an appropriate measure of health communication to interrupt SB in university students during online lectures, since overall, approximately half of the participants stated that they interrupted SB during watching the video. The interruption of SB differed between age groups, but not between gender or video formats. The interruption of SB is predictable by a binary logistic regression, with intention to reduce SB as the only significant predictor of the model. The intention to reduce SB was in turn determined by identification with characters, and the model showed a high level of explained variance.

Referring to the first research aim, namely to identify potential group differences in the prevalence of the interruption of SB, age has been identified as relevant factor for the prevalence of SB (53–55). In general, SB seems to increase with growing age, but with exception for the SB of computer use (54, 55). Regarding the student population, Deliens et al. (56) found that "freshmen" showed more SB, what is congruent with the current finding that younger students significantly less often interrupted

SB. One explanation is that health risk behavior is more prevalent in younger adults and reinforced by the loss of parental control in the transitional phase of study begin (56). Furthermore, other research indicates that younger adults score higher at trait reactance evoked by the insecurity of the own autonomy (57), what possibly explains the resistance towards the promoted behavior within the video.

Although findings of our study showed no significant difference between video formats, descriptive data indicated a tendency towards animated video formats being more effective to promote the interruption of SB. This preliminary finding corroborates the findings of a meta-analysis, which found vivid information to be more persuasive than messages low in vividness (30). In addition, vividness of health communication interventions and identification with characters showed to be correlated (58), what hints to the effectiveness of using moving images presenting characters who facilitate identification. Another possible explanation for this preliminary result is that animated images may be more able to gain attention during online lectures which are demanding for students' concentration and additionally may be suitable for a topic requiring being active. Depicting possible differences between narrative and non-narrative video formats, the current results are incongruent with a recent study (59) which found that narrative videos were superior to non-narrative videos in reducing students' subsequent sedentary behavior while playing video games. In our study, narrative and non-narrative formats only varied with regard to the application of a dialog, but the same moving images were presented. As we did not conduct a manipulation check, potentially participants did not perceive the formats differently with regard to the extent of narrative elements and level of identification and no significant differences between formats could be observed.

With regard to the second research aim, namely to investigate if the interruption of SB was predicted by the intention to reduce SB, the attitude towards SB, age, and gender, a significant association between SB intentions and the interruption of SB was illustrated, which supports other study results (53, 60, 61). Prapavessis et al. (61) found that attitude predicted intention, what in turn determined the reduction of SB. Similarly, our study did not indicate a direct link between attitude and SB interruption, but a significant correlation between intention and attitude ($p = 0.343$, $p < 0.001$). This result is congruent with the *theory of planned behavior*, which states that attitude affects behavior indirectly through a correlation with intention, which subsequently influences health behavior (36).

In view of the third research aim, to examine if the intention to reduce SB and the attitude towards SB was predicted by identification and homophily with characters, as well as counterarguing, identification with characters was the only significant predictor of intention to reduce SB. Attitude towards SB was not predicted because it was no significant predictor of the interruption of SB in our analysis. With regard to these results, different studies that investigated the correlation between identification with media characters and health intentions indicated mixed results for different health behaviors. Whereas the study of Murphy et al. (62) did not find an association between the identification with characters of a narrative video and intentions to have a Pap test for cancer prevention, other research supports our finding that identification with characters of narrative health interventions predict health intentions (58, 63). In this context, results of Moran et al. (64) point to an indirect effect of identification on health intentions *via* social norms, although contrary to the hypothesis, the association between identification and social norms was negative. By contrast, other studies found a direct significant association between the identification and

health intentions (58, 65). Dillard and Main (58) observed a correlation with identification for intentions to have a colonoscopy and Moyer-Gusé et al. (65) for intentions to discuss sexual-transmitted diseases (STIs). In doing so, Moyer-Gusé et al. (65) emphasize the relevance of self-efficacy for the link between identification and health intentions. A recent meta-analysis investigating the effects of celebrity health communication supports the positive association between identification and health intentions (63). In general, narrative evidence interventions seem to be more effective to change health intentions, whereas statistical evidence interventions have a greater impact on health attitudes (26). Zebregs et al. (26) concluded that intentions involve a greater affective component than attitudes, thus emphasizing the effectiveness of increasing identification with characters to strengthen persuasion.

The current study has limitations. Some of the used measures were not validated, thus representing a possible source of bias. Results showed that Cronbach's alpha of the scale attitude towards SB was low, indicating an inappropriate measurement of this variable. As this is a pilot intervention, we conducted no power analysis to calculate the sample size, and thus the sample size could have been too small. Further, comprised university students mostly studied a health-related subject (psychology, sports science, medicine) what limits generalization of the findings. However, existing research suggests that the amount of SB is not linearly associated with moderate-to-vigorous-intensity physical activity (66). In fact, the extent of light-intensity physical activity (e.g., walking to the campus, to the bus station, or between lectures) and SB are inversely correlated (67), which indicates that everyday life physical activity might be more important to regularly interrupt SB than moderate-to-vigorous intensities of physical activity which predominantly occur in exercising or engaging in sports (68). As the investigation did not include a passive control group, the general effect of video-based interventions to promote the interruption of SB during online lectures could not be determined. Additionally, only the behavioral short-term effects on the interruption of SB were depicted and not the impact on general SB.

Future studies should ensure an appropriate sample size, an equal distribution of participants across all study subjects, as well as an investigation of long-term effects on SB, and an inclusion of a passive control group. Based on the current findings and theoretical approaches (36), future studies could analyze if SB intentions mediate the correlation between SB attitudes and SB behavior. In this context, it is important to include an objective measure for SB behavior and to develop and validate appropriate questionnaires of SB related constructs, particularly the attitude towards SB. Additionally, prospective studies could include other factors that might be relevant to the effectiveness of video-based interventions, such as physical acitvity habits (69), stress (70) as well as enviromental and social determinants (56, 71, 72). In general, future research should investigate different message strategies to promote the interruption and reduction of SB in university students. In doing so, placing a focus on the channel video and an application during online lectures could be useful. Based on the current results, future studies could consider possible differences in media reception variables such as counterarguing when examining narrative video formats. The acceptance and the feasibility of health communication interventions to reduce SB should also be analyzed among university lecturers to facilitate the implementation into (online) lectures. Within the use of narrative evidence to communicate health information, message strategies such as the use of animated vs. real characters could be examined. In this context, a recent study suggests that students increased their physical activity in response to influencers on Instagram

(73). Thus, influencers and relatable testimonials could be one opportunity to strengthen identification, increase SB intentions and reduce SB in college students. From a broader perspective, future research should investigate the effectiveness of health communication interventions for different health topics in the collective of university students, including the use of different message strategies and channels.

4.1. Conclusion and practice implications

Using a unique approach to compare different video formats for health communication during online lectures, this pilot study implies the suitability of short videos to interrupt SB during online lectures in the target group of university students. In doing so, the current results highlight the importance of tailoring these videos to the characteristics of the target group, particularly considering the age of the target group. When using narrative formats, identification with characters should be increased to facilitate the intention to reduce SB which in turn could have a positive impact on the interruption of SB. In particular, identification with videos' characters could be strengthen by using appealing characters who are similar to the student population regarding demographic, social and environmental factors. In this context, the use of a high level of vividness, e.g., by using moving images, could enhance the process of identification. In line with other research (74, 75), the videos could also be presented in other university settings and contexts, such as in face-to-face lectures, public university spaces or as reminders on university websites or via e-mail. Further research is needed to get more insights into relevant mechanisms and effective message strategies of video-based health communication interventions to reduce SB in university students as well as applicability to different university settings.

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 studies involving human participants were reviewed and approved by the Ethics committee of the federal state of Rhineland-Palatinate (Number: 2021-15876-other research). The patients/participants provided their written informed consent to participate in this study.

Author contributions

Funding

Acknowledgments

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/fpubh.2023.1108154/full#supplementary-material

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Participation of university community members in Health Promoting University (HPU) initiatives

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Background: Several universities around the world have adopted the settings approach to health to create a Health Promoting University (HPU) initiative. Health promoting initiatives are built on the values of health promotion, with participation being one of the most important. Despite the above, there is little information on how university community members participate in HPU initiatives. This study aims to describe the participation of university community members in HPU initiatives in universities around the world.

Methods: An online questionnaire was sent to representatives of universities that have implemented a HPU initiative. The questionnaire inquired about the level and nature of participation of university community members (students, professors, and administrative/technical staff) at different levels. Three levels of participation ranged from lower to higher levels were considered: (a) information delivery strategies; (b) consultation strategies and (c) involvement in design, planning and decision-making processes.

Results: At least the 50% of the universities implemented strategies so that all the members of the community could participate at all levels. Information delivery strategies were the most often used, with students being the main target group. Consultation strategies were aimed mainly at students and professors, whilst professors participated most actively in the design, planning and decision-making.

Conclusion: Different participation strategies are used in the HPU initiatives. Information delivery strategies, which represent the lowest level of participation, were the most often reported. Higher levels of participation were less used in the HPU initiatives. HPU initiatives should seek for strategies to provide more high-level participation to all university community members.

KEYWORDS

healthy universities, health promotion, settings approach, questionnaire, participation

1. Introduction

Numerous universities around the world have adhered to the Health Promoting University (HPU) initiative by applying the settings approach to health (1). By assuming this approach, universities work to create an environment that promotes the health and well-being of all those who are part of its community (2). The use of the settings approach is based on the values of health promotion, of which the participation of the community is one of the most important (3).

Participation is defined as a process in which people are enabled to become actively involved in defining the issues of concern to them, in making decisions about the factors that affect their lives, and in which those involved have the opportunity to influence and take part (4, 5). It means that the actions are carried out by and with people and not on or to people (6). As the university community is made up of students, professors, and administrative/technical staff, community participation in the context of HPU is when all of these groups have the opportunity to influence and participate in the HPU initiative. As such, promoting a high level of participation by students and administrative/technical staff in the decisions that affect their learning, working and social experiences is indeed one of the 10 key characteristics that a university must have in order to be considered as health promoting (2).

Studies on community participation in other settings have described that participation can occur at different levels, taking various forms. The prototypical "ladder" model proposed by Arnstein (7) presents participation as a continuum that moves from nonparticipation (no power) via degrees of tokenism (counterfeit power) to degrees of citizen participation (actual power). At the lower levels of this continuum are the strategies in which those involved do not have any kind of power or influence, and the intervention is only an effort by those who deliver a service to correct what they consider necessary to change. At the intermediate levels are the strategies where the community receives information, can be consulted about their needs, and may have the opportunity to give an opinion, but this opinion will not necessarily be considered to change the course of the initiative. At the highest level, the community can take control and responsibility for the operation of the initiative, being truly engage and empowered.

As a classic framework that presents a spectrum of ways that stakeholders can be engaged in decisions, Arnstein's ladder of citizen participation model has been used extensively in city planning, housing, health, and schools. In higher education, it has been used to assess the level of student engagement and participation in decision making. Despite critiques and adaptations of the model, a recent review and meta-synthesis of the literature concluded that the model has continuing value to conversations about partnership in tertiary education, along with other models (8). An alternative model to consider is that proposed by Davidson (9). This model recognizes the influence of contexts and proposes to understand participation in a non-hierarchical way, represented by a wheel distinguishing between four types of participation: information, consultation, participation and empowerment. It also allows to identify the nuances of the different types of participation. For example, information can be delivered in a minimal, limited or high quality. The same applies for other types of participation. Davidson's model has also been used to study participation in health promotion, more specifically in promoting the active participation of local people in healthy cities initiatives (5).

Whereas participation is considered a key principle of health promotion, the evidence that links community participation to improved health status is not very strong. The reason for this is that there is no standard definition of 'community' and 'participation', hence when causal links between community participation and improved health status are found, they are situation-specific and unpredictable, and thus not generalizable (10). Nevertheless, it is generally agreed that participation may include and can lead to community uptake, ownership and sustainability for health improvements.

In universities, the level of participation by members of the university community is embedded in the university policy. Like all settings-based initiatives, HPUs consider that a high level of participation by the different members of the university community is a key element. According to the Alicante Declaration on Health Promoting Universities (11), a document created after the 8th Ibero-American HPU congress in 2018, a HPU should support the active participation of the university community in general. Special attention should thereby be given to the motivation and encouragement of students for their relevant role in both the university and social environments, and to facilitating and recognizing their active participation and real representativeness.

However, this is often difficult to achieve in practice (12, 13). This may be because many activities undertaken to promote health in the university setting only imply low levels of participation, or because not all members of the community have the same opportunities to participate at all levels. The main strategies to involve members of the university community in health actions are based on the delivery of information about health and wellbeing. For that purpose, diverse channels can be used which reach all members of the university community, but many of the activities only address health issues that concern students, leaving the rest of the university community aside (14). The same occurs with consultation strategies, which only register the needs and opinions of some groups. A high level of participation, which is essential to HPUs, is only achieved if all members of the community meaningfully participate in the design, planning or delivery of the activities (14, 15). However, this can be impeded if important decisions are in the hands of a group that concentrates all power.

The participation of the university community members in HPU initiatives, or the strategies that are used to promote participation by the university community, have not yet been extensively investigated. To our knowledge, only two studies have addressed this issue. In a study of participation in HPU initiatives, Davies and Hall (15) found that such participation may be hampered in several ways. The most obvious reasons that limit participation are the lack of resources (human and economic) and time constraints, which both are barriers to including university community members in all levels of participation. In another study, Dooris et al. (16) found that the students' voice was often not considered when planning HPU activities. Both studies acknowledge the limited participation in HPU by members of the university community, but do not consider the strategies that are or can be used to enhance participation. Furthermore, both studies are concerned with universities in the United Kingdom, whereas the need and ways of participating in organizational processes can be very different depending on the national or cultural context.

A more extensive investigation of the participation of the university community members in HPU initiatives is therefore warranted. In this study, we investigated the participation in HPU programmes in universities around the world, and sought to explore the efforts that universities make to achieve the high levels of participation that are required for HPU initiatives.

2. Materials and methods

To explore the participation of the university community members, an online questionnaire survey was organized among universities belonging to HPU networks in different countries around the world.

The questionnaire was an adapted version of the questionnaire used by Dooris and Doherty (17), to explore the activities carried out by healthy universities in England. In addition to various questions regarding the implementation of HPUs (18) our version of the questionnaire included questions to explore the participation of university community members. Specifically, three questions asked how students, professors, and administrative/technical staff participated in the initiative. For each of the three groups, respondents could indicate the level or type of participation in their university by choosing amongst three options representing three levels of participation that are common to Arnstein's and Davidson's models of community participation: (a) information delivery strategies (no power); (b) consultation strategies (counterfeit power); and (c) involvement in design, planning and decision-making (real power). Respondents could also add details in written form about the strategies of participation.

The invitation to participate in this study was sent through various HPU networks (i.e., the English network, the Ibero-American network, and several national networks). The questionnaire was made available via LimeSurvey, and had to be completed by the coordinator of the HPU or another person directly related to the initiative. The representatives of each university had to (a) be directly related to the HPU initiative in the role of coordinator, director, or assessor; and (b) have been in that position for at least 1 year before the study. Using key informants as a source of information has been used in studies in similar and other settings (17). Representatives of the universities that did not respond to the invitation sent by the network were contacted directly. At least three email reminders were sent to each potential respondent. A total of 141 universities from 48 different countries received the invitation. Of those, 54 universities from 25 countries completed the questionnaire. Most of the respondents were from Europe ($n = 27$) and the Americas ($n = 24$), with a few additional participants from Africa ($n = 2$) and Australia ($n = 1$). The universities represented in the sample were both public ($n = 46$) and private ($n = 8$) institutions. Of the completed questionnaires, 32 were answered in Spanish, 21 in English, and 1 in French.

To derive information from the data, respondents' answers to the questionnaire were categorized according to the three levels of participation (information delivery, consultation and involvement) for the three main stakeholder groups, i.e., students, professors and administrative or technical staff. Descriptive statistics were calculated to report the number of universities that conduct information delivery strategies to students, professors, and administrative/technical staff. The same was calculated for consultation strategies and for design, planning, and decision-making. Additionally, open answers were summarized to serve as examples of strategies of participation at the different levels. The quotations serve to illustrate and reflect the words of the informants.

3. Results

Figure 1 shows the percentage of universities that implement each of the three levels of participation in relation to the three main group of stakeholders: information delivery strategies to students, professors or administrative/technical staff (A), perform consultation strategies with these groups (B), and involve them in the design, planning and decision-making of HPU initiatives (C), respectively.

Table 1 gives an overview of different HPU initiatives with the strategies that are employed to involve the three groups of stakeholders.

In the next paragraphs, each of the three strategies is outlined in more detail.

3.1. Information delivery

When asked how they kept community members informed about health, 50 of the 54 universities mentioned that they proactively informed students; 45 also informed professors, and 42 also administrative/technical staff about health and wellbeing (Figure 1A).

The information delivery strategies mainly involved mass events (e.g., workshops, health fairs, itinerant stands, etc.), carried out inside the campus, and organized by the university or by external agencies (NGOs, Ministry of Health, etc.). The topics covered a wide range including mental health, sexual health, healthy eating, recycling strategies, etc.
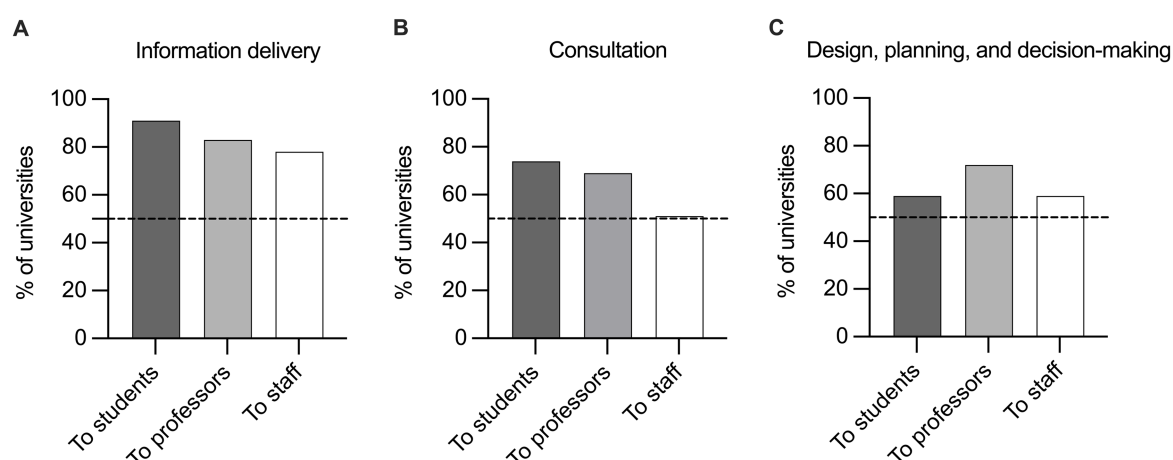

FIGURE 1
Percentage of universities addressing strategies of participation to students, professors or staff. The strategies are: **(A)** information delivery, **(B)** consultation, and **(C)** design, planning and decision-making.

TABLE 1 Examples of strategies of participation of the different groups of the university community at different levels.

Information delivery strategies		
Students	Massive information delivery activities are organized by the university or external health-related organizations. Preventive health checks	Workshops Healthy fairs (with certain periodicity) Talks Conferences
	Mandatory or elective workshops with health promotion topics that are part of the academic requirements or study plan	Life skills course
	Use of technology as a communication channel	Messages through social networks Sending information through institutional email Healthy messages on the University website Healthy messages on university computer screens
Professors	Massive information delivery activities are organized by the university or external health-related organizations. Preventive health checks. Attendance to events is hampered by lack of time and academic load	Workshops Healthy fairs (with certain periodicity) Talks Conferences
Administrative/ technical staff	Massive information delivery activities are organized by the university or external health-related organizations. Preventive health checks.	Workshops Healthy fairs (with certain periodicity) Talks Conferences
Consultation strategies		
Students	Surveys or questionnaires on health status and needs	Surveys on lifestyles or needs (once a year, once a semester) Risk profile as a result of surveys Participation is recognized but "partial" The surveys are organized by external organizations (ministry or health center) Participation in the definition of healthy policies
	Leaders or representatives of the student community are consulted about the needs	Student delegations (representatives, student union) student leaders
	Research	Participation in a focus group (in the framework of research) whose results can inform about the health situation and needs.
	Spontaneous and anonymous consultation methods	Other anonymous means such as consultation boards, or "clotheslines" of comments
Professors	Surveys or questionnaires on health status and needs	Risk profile as a result of surveys Surveys carried out by the occupational risk prevention service. Integral health survey
	Face-to-face consultation	Focus group (in the framework of an investigation) whose results can inform about the health situation and needs. Health talks Health reflection days Development groups by faculty
	Consultation about the learning environment	Health reflection days
Administrative/ technical staff	Surveys or questionnaires on health status and needs	Surveys carried out by the occupational risk prevention service
	Face-to-face consultation	Focus group (in the framework of an investigation) whose results can inform about the health situation and needs. Health talks
Involvement in design, planning, and decision-making		
Students	Participation in health steering committees	Student health advisory committee Seed funding for health-themed research
	Design of material and information	Design of educational material Contest on healthy initiatives
	Peer educators	Self-regulation of student residences Volunteer programs Scholarships and internships with health themes

(Continued)

TABLE 1 (Continued)

Information delivery strategies		
Professors	Participation in health steering committees	Professor health advisory committee
		Academic representation programs
	Activities design	Analysis of responses to health questionnaires
		Design of strategies according to specialty and experience
		Design and planning of activities.
		Evaluation of activities
		Seed funding with health issues
		Focusing lines of research on health promotion
Administrative/technical staff	Participation in health steering committees	Administrative staff health advisory committee
		Support in planning activities

"Students are invited to the development of different activities related to Health Promotion. A Health Fair is held every six months" (University in Colombia).

"Sometimes [professors] attend health fairs, respond to training programmes of recycling and storage habits" (University in Mexico).

"[The staff members] participate with the students in the events, responding to the habits that are promoted" (University in Mexico).

One university mentioned that professors' attendance at the HPU events might be hampered due to the lack of time they have and the academic workload.

Another information delivery strategy used by some universities was to give students the possibility to attend regular courses with health promotion topics. In general, these courses were aimed only at students and were required courses to complete a curriculum. In some cases, they involved elective courses, while others were compulsory.

"Students can register for a health promotion course as one of their academic requirements" (University in Nigeria).

Aside from attending mass events and courses, the Internet was also used as a communication medium for delivering health information. Health messages were sent through Facebook or institutional mail, or placed on the university's website.

"All are invited to participate through various media: university website, institutional mail, Facebook… we even put all kinds of healthy messages on the screens of all the computers of the university" (University in Mexico).

3.2. Consultation

Of the 54 universities that participated in the study, 40 indicated that they consulted students, 37 also consulted professors, and 28 also the administrative/technical staff (Figure 1B).

The most often used consultation format for all three groups was the questionnaire. These focused primarily on determining health status or exploring lifestyle habits, which were often assessed with a certain frequency (e.g., every semester or once per year). The results were used to determine the health topics that would be addressed in health promotion strategies. The questionnaires were mostly administered online, using either institutional mail or social media.

Another means of consultation used are face to face contacts with members of the three groups of the university community. In some cases, these were the official representatives (of the student bodies, professors and staff union). Students, in particular, were often interviewed for research on health and wellbeing in the university.

"[Consult student] is part of the ongoing research study, which aims to identify the key health issues to be addressed" (University in Ireland).

"They [students] are consulted with a health survey that is carried out on all newcomers to all professional careers" (University in Spain).

Some universities reported carrying out participatory diagnoses using less structured and more anonymous consultation mechanisms.

"Participatory diagnostic activities are carried out, such as "murals", where people can write their comments or experiences on the initiative" (University in Ecuador).

One university indicated that professors were not consulted about their needs or health problems, but were consulted on how the HPU initiative could support their educational goals and commitment of students. Many universities recognize that the group most consulted about their needs and health problems were the students, leaving teachers and staff out of the target of the strategies designed.

3.3. Involvement in design, planning and decision-making

Of the universities surveyed, 39 had mechanisms in place to involve professors in the design, planning and decision-making on

health; 32 of the universities indicated that they also included students and administrative staff in this process (Figure 1C).

The participation of the university community in the design and decision-making was facilitated through various mechanisms. The most often used strategy was to incorporate of the members of the community into the health committees.

> "We have a student health advisory committee who help guide our work" (University in Canada).

> "Some professors are part of the steering committee… some of them are specialists in different areas addressed by the initiative for example nutrition or physical activity" (University in Spain).

For the design of strategies and activities, some universities used seed funds to which all members of the community could apply. These funds were intended to fund healthy initiatives.

Other mechanisms that were used to involve students were the creation of peer health educators or health volunteer programmes that seek to train students in various health topics so they can promote healthy lifestyles among their peers.

> "[Students] can enroll in a training course for youth leaders in healthy habits" (University in Argentina).

> "They [students] participate as health promoters in the form of volunteers, professional practices, social service and internships" (University in Mexico).

In some universities the activities developed by peer educators or health volunteers were carried out on campus and also in university residences.

> "They lead campaigns to promote good living in university residences by carrying out self-regulation with codes of health behaviour among all inhabitants of the residences" (University in Colombia).

4. Discussion

The aim of this study was to document the extent to which participation is achieved in HPU initiatives, and the strategies that are used to that end. Participation is a fundamental principle that underpins health promotion. As such, it should be one of the cornerstones in health promoting initiatives that use settings approach. Like any community, the members of a university community have the right to participate in building a working and studying environment that provides good conditions for health (19). Yet despite the recognition of its importance, very little empirical information is available as to how the process of installing participation in HPU is carried out in practice (19, 20).

This study is one of the first to investigate this issue. The results show that the vast majority of universities deliver information on

health to all members of the community, that most also use consultation to obtain the opinions of the different university community members, and that more than half the universities try to involve all the members of the community in the design, planning and decision-making of the health initiatives.

Among the strategies that universities use to enhance the participation of the university community in working toward a healthy university setting, information delivery to all members of the university community is the most widely used. In this way, students, teachers and staff may all benefit from the initiative. This strategy has also been used in other health-promoting settings (21). Apart from Internet, the delivery of health information through massive health events such fairs, seminars, talks and courses is the most often used channel, and is believed to generate changes in the habits of university students such as eating habits, physical activity and combatting stress (22, 23). Since young people are active users of Internet and social networking sites, this channel represents an effective resource to disseminate health messages and reach students in the university context (24, 25).

To ensure that health related activities and initiative answer the needs of the community members, consultation strategies must also be put in place. The results of this study show that consultation is often applied, with self-report surveys being the most often-used method to consult students on health issues, along with face-to-face consultations. Online surveys are a pragmatic way to get the opinion of a large group of students, but it must be kept in mind that they are not always the most appropriate method to consult people, even when the access to internet is high (6). Consultation on health through discussion and focus groups can be a good alternative. Research by Holt et al. (26) demonstrated the importance of a consultation processes, and the value for students to have the opportunity to express themselves and be listened to. It is also important that feedback is provided after the consultation, but although such feedback would signal to the members of the university community that their ideas and needs are taken into consideration, feedback after a consultation process is not common practice in HPU (6).

Participation at a high level is a key factor for the success of any health promoting initiative (11). As such, involvement in the design, planning and decision-making processes should ideally be part of a HPU initiative at every stage (6, 27). This form of participation can be promoted through different strategies, directed at all university community members including students, professors, and administrative/technical staff. Strategies that were highlighted by the participants in this survey study are the provision of seed funding for the design and planning of activities, and training community members as health promoters. The latter may enhance participants' knowledge, skills and self-confidence, thus empowering them to become health promotion agents for their peers, friends and family (6). For students, health promotion training can be done through volunteer programmes. Volunteering facilitates the acquisition of wider life experience and is related to positive mental effects such as a higher sense of purpose, self-steem and quality of life. In addition, it facilitates the development of new job specific skill, soft skills and civic skills. Despite these advantages, students have been under-utilized and under-researched as potential volunteers in health promotion actions (28).

Previous research has shown that most HPUs develop strategies to obtain the support of the authorities of the university (29). This alignment with the authorities to develop a HPU initiative is considered as one of the most important determinants of their success (17). However, when a HPU initiative does not include the participation of all stakeholders, some groups that make up the university community may feel that the initiative is imposed on them, leading to lower acceptance (11). Promoting participation in a way that allows all members of the university community to have a voice in how the HPU initiative is conceived and implemented is an act of democracy and power sharing. However, university authorities may not want to change the existing power relations. This may be a reason why in many universities there is still a predominance of educational approaches to health promotion, rather than an approach that seeks organizational change. Questioning the power relationships within the university can be difficult to manage (30). Yet not providing members of the university community with possibilities to participate in decision-making at high levels may cause certain groups within the community to resist to the changes that a HPU initiative tries to establish (11). The results of the present study suggest that students and administrative/technical staff may be the groups that are most likely to show resistance, as they are the ones to whom universities offer less opportunities to participate at high levels.

It should be noted that there is not only a difference of status between groups of participants considered in this study, but also within these groups. Among the students, there are status differences between graduate and postgraduate students, between national and foreign students, or students in different years of study. Likewise, among academic staff there is a difference between tenured and tenure track professors or between those with full-time or part-time appointments. And among the staff there is a difference between technical staff, cleaning staff, and those who provide administrative services. Those within each group who have the least power and possibilities to participate in a HPU initiative may well be the most vulnerable to show a higher prevalence of health-adverse behaviors (30). Therefore, HPU initiatives, with the support of the authorities, should try to motivate all community members to participate, and achieve a balance between top-down commitment and bottom-up action as a way to advocate for health (31).

The study is not without limitations. A first limitation is that it only concerns a select sample of universities. Secondly, the data are based on self-reports by key informants, who answered the questions about the participation of the different groups within the university community - students, professors, and administrative/technical staff. Using key informants as a source of information has been used in other studies, but it inevitably produces a risk of bias. Moreover, the indirect way of data collection made it impossible to further refine these groups and distinguish for example between bachelor, master or PhD students, or between assistant, associate and full professors. As such, the information is concerns with larger categories that are relatively heterogeneous. It would have been useful to complement these self-reports with on-site observations and/or direct surveys with the different stakeholders, but this was not achievable within the scope and resources of the study. On the other hand, the heterogeneity of the stakeholder groups is not necessarily a weakness, as more detailed categories may have obscured larger trends. In future studies about participation in HPU, it would be interesting to analyse the differences in participation at all levels within each of these subgroups.

5. Conclusion

Despite these limitations, the study is one of the first to empirically document how the process of installing participation in HPU is carried out in practice. It showed that to date, the main form of participation in the HPU initiatives consists of the delivery of information. Consultation is also used, but mainly as a tool to know the health situation within the community, and to ask their opinions and needs. To make participation more meaningful, efforts should be made to ensure that consultation is accompanied by feedback. Participation of all members of the university community in the design, implementation and evaluation of HPU initiatives and in the decision-making processes is present in some of the initiatives, but needs more emphasis. To engage all those involved in HPU actions, they should not only have a voice, but also a vote (32). The type of participation toward which HPUs should direct their efforts, then, is that where members of the university community are involved in the design, implementation and evaluation of HPU initiatives and in the decision-making processes, in a meaningful way.

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 studies involving humans were approved by the Ethics Committee of the Psychological Sciences Research Institute, Université catholique de Louvain, Belgium. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

MSR was the principal investigator of the study and the major contributor to the study design, writing of the manuscript, and data analysis. SB contributed to the conception and planning of the study, supervised the data collection and analysis, and contributed to writing the manuscript. All authors have approved the final version of the manuscript and given their consent for publication.

Funding

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/fpubh.2023.1217177/full#supplementary-material

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How to promote changes in primary care? The Florentine experience of the House of Community

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Primary care (PC) has a central role in promoting health and preventing diseases, even during health emergencies. The COVID-19 pandemic has shown how strengthening comprehensive primary healthcare (c-PHC) services is key to ensuring community health. The Italian government decided to support PHC by investing resources from the Next Generation EU (NextGenEu) plan in the development of local health districts (LHDs) and local PC centers called "Houses of Community (HoC)". The Florence LHD (Tuscany)—in direct collaboration with the University of Florence—has represented the experimental context in which a c-PHC-inspired organizational model has been proposed and included the HoC as the nearest access point to PC services. Through multiprofessional collaboration practices, HoCs provide continuity of care as well as health and social integration. Different levels of action must coexist to initiate, implement, and sustain this new PC model: the organizational and managerial level, the experimentation of a new model of care, and the research level, which includes universities and LHD through participatory research and action approaches. This process benefits from health professionals' (HPs) participation and continuous assessment, the care for working relationships between HPs and services, an appropriate research methodology together with a "permeable" multidisciplinary research group, and educational programs. In this context, the HoC assumes the role of a permanent laboratory of experimentation in PC, supporting the effectiveness of care and answering what the Next Gen EU plan has been foreseeing for the rethinking of Italian territorial services.

KEYWORDS

primary health care (MeSH), House of Health, House of Community, collaborative practice, Participatory Action Research (PAR), interprofessional education (IPE)

1. Introduction

The COVID-19 pandemic revealed worldwide the inadequacies of healthcare systems mainly centered on hospital acute care, underlining the urgency to strengthen primary care (1). International organizations have been highlighting the central role of primary care in coping with health emergencies (HEs) (2), suggesting the importance of preserving the innovation of primary care services introduced in response to the COVID-19 pandemic (1). Further evidence supports the crucial role of a strong primary care system in ensuring effective and more appropriate answers to health needs in HE (3–5). Therefore, there is a clear indication toward experimenting with innovative models of providing health

promotion and healthcare in community and primary care settings. Despite the strength of the evidence on where to move and how to implement direction, vision, and strong ethical standing, these proofs are clashing with current healthcare management and the system as a whole, that is, the many obstacles to new forms of working organization, daily difficulties, and healthcare professionals' medical education (6–8).

However, examples of primary care centers inspired by the principles of c-PHC have developed in several countries in the pre-pandemic period, both in European contexts, such as Spain (9), Portugal (10), and Italy (11), and in non-European contexts, such as Iran (12) and China (13). The different experiences reported reflect the characteristics of different contexts.

In response to the changing health needs that emerged during the COVID-19 pandemic and in accordance with international evidence, the Italian Government defined a new model of primary care that improves the local health district (LHD) by introducing the House of Community (HoC).

The following subsections contain the theoretical background, the national legislative references, and the elements of the organizational local context in which the process described happens.

2. Subsections

2.1. Theoretical background (c-PHC)

According to the Alma Ata Declaration, *comprehensive Primary Healthcare (c-PHC)* addresses the main community health issues and involves all health-related sectors to achieve health equity, community, and individual participation in health promotion, and fight against health inequalities (14–16). It foresees the creation of a multiprofessional and multidimensional healthcare network, and the adoption of a model centered on comprehensive promotional, preventive, curative, and rehabilitative care, founded on actions addressed to the social determinants of health, intersectoral approach, and community participation. It aims to ensure the continuity of care by delivering people-centered and integrated care services (17) and providing intersectoral interventions (6). Interprofessional collaboration (IPC) is a recognized core element in taking care of complex health needs and an important and meaningful educational experience for healthcare professionals (HPs) and students (18–20).

This theoretical background represents the guiding principle of primary care strengthening in our local context. The Sections 2.2 and 2.3 introduce the elements of the primary care model in the Italian context and in the local context covered by the study.

2.2. Italian context

The Italian government is nowadays supporting the strengthening of primary care through the development of a new reference model of local primary care centers called the "House of Community" (HoC). The HoCs, realized within the public Local Health District (LHD), represent an evolution of the already existent *Casa della Salute (House of Health—HoH),* a type of primary care structure unevenly developed among Italian regions. The model of HoH aimed to further develop multidisciplinary collaboration, social and health service integration, continuity of care, and community involvement. Indeed, the Italian Government has recently decided to allocate funds from the Next Generation EU (NextGenEu) plan—the recovery plan designed and launched by the EU to emerge stronger from the pandemic—to specifically implement the HoC all over the Italian territory. The recent Italian Minister of Health Decree 77/2022 adopted the NextGenEu indications for the development of a new primary care organization. It introduced an innovative design of the LHD and described the HoC as a direct expression of a community-oriented model centered on the person, their social and family networks, and their living places. Therefore, the LHD constitutes the complex primary care services network in which the HoC represents the foundation of the new (functional and structural) model aimed at reinforcing the role of the community in the health system.

2.3. Local context: the LHD of Florence

The LHD of Florence—in the Italian Tuscany region—has been representing the site of a c-PHC-inspired model of primary care, supported by a specific reorganization analysis. In this model, the network of services within the HoCs (evolving from HoHs) is thought to ensure proximity and ease of access to the healthcare system. In fact, the HoCs act as decentralized centers for the management of public health services, located in the different neighborhoods of the city.

In this perspective and approach, HoCs (evolving from HoH) represent the nearest access point for the community to primary care services in the LHD. They provide welcome and service orientation, continuity of care, and social integration. To achieve these purposes, a multiprofessional team—composed of General Practitioners (GPs), nurses, and social workers, coordinated by public health doctors—interacts mainly with the other HPs and services of the HoC (medical specialists, administrative staff, physical therapists, mental health professionals, counseling center, vaccination center, nutrition service, addiction health service) and other LHD services. In this context, the activities of the multiprofessional team include the following:

- Weekly team meetings involving GPs, community nurses, and social workers aimed to define shared plans for patients.
- Joint home visits and cases/individual evaluations involving the team and, whenever necessary, other healthcare and social services.

- Structured and regular team meetings—called "*tavolo della complessità*" (complexity roundtable)—between members of the multiprofessional team to take charge and care of patients with complex needs.
- Collaboration with third-sector associations operating in the surrounding area.
- Engagement and networking with representatives of the community to organize and co-design the spaces of the structures and to define priorities and ways to collaborate in health and social services.
- Educational projects for master students and residents in different disciplines—mostly in public health, primary care, nursing, architecture, and urbanism. In these activities, HPs are involved in lessons using both classic and new interactive educational methodologies.

These collaborative practices require continuous remodeling to adapt to the changing context and evolving needs.

The new concept of HoC embeds these principles and aims to enhance community resources and participation. A cultural organizational change is required to realize this mandate and to support new and modified working practices concerning health promotion, care and relationships among HPs, social workers, and community actors. These changes must embrace the theoretical principles of c-PHC and must adapt to the health needs of the population in specific geographic and social contexts.

3. Discussion

3.1. Methods: how to define the model of HoC as the evolution of HoH

In our local context, the willingness and interest expressed by young HPs working in the HoHs have led to the definition of a Participatory Action Research (PAR) process (21) supported by the university and LHD. This approach represents the methodology within which the change takes place, in an ever-evolving process as the construction of the HoC itself is. Young HPs, HPs working in the HoHs, researchers, and students constitute a research group focused on overcoming the obstacles toward the flourishing of new community health services and delving into the underlying causes and dynamics. The group has strong motivation. Some HPs and public health researchers were students when the project was launched. This lets them pursue reflection actions and apply learned approaches and working practices (22). The focus is not on the results of each single research step in the management of care but also on the continuity of the process itself in reorganizing primary care services as community-oriented. Reflection on working practices encompasses specific instruments of conflict mediation and reflection and observation spaces during the daily current services, together with research methodologies to reflect on and learn from these practices, analyze and discuss them, and then define improvement actions (23, 24).

Along the process, multiprofessional education and community-based interventions have been organized from the perspective of assuming a transformative role (25, 26).

Starting from these premises, within the process described, different levels of action must coexist to build this model.

- **The organizational level**: The LHD, including the HoCs (evolving from the HoH), must ensure the provision of healthcare services, take care of health needs, and adjust the services provided according to the evolving needs. LHDs and HoCs must adapt to new guidelines and regulatory changes, extending their roles to management, planning, prioritization, organization of activities, monitoring, and evaluation.
- **The experimentation of new models of care**: It is associated with the demand to better answer health needs. Changing working practices toward more integrated actions requires organizational modification (27), team reflexivity on team roles and processes, and the definition of tools for monitoring and evaluating teamwork effectiveness and quality (28, 29). At the same time, the engagement of HPs is required to make this organizational culture change in a sustainable and participatory way (30).
- **The research level**: It complements the whole process by means of several research methods (research-action process, quantitative, and qualitative methodology) and different research issues: context and health needs deepening and analysis, community engagement, analysis of HPs' needs and perceptions of their work, and developing the enabling factors toward multiprofessional and collaborative practices. The research process supports the definition of monitoring and evaluating tools for implementing the new practices. It involves researchers, HPs, and students.

The three levels should coexist and be coherent in the theoretical, ethical, and political framework of c-PHC. Bottom-up experiences could not only trigger those changes and innovative working practices but also guide a research process embedded in making them sustainable and acceptable (31).

3.2. Lessons learned and sustainability of the organizational process

The following elements are relevant to make the described organizational changes sustainable:

- **Development of the ongoing process:** Within the research-action process, analysis, monitoring, and continuous evaluation, with the participation of HPs and other actors involved, should be an essential condition to combine the elements of the HoCs model (evolving from the HoHs), c-PHC oriented and to make it feasible with the characteristics of the contexts.

  - It includes the management of the macro-process and the different phases and the process direction toward the principles to which it aims to be implemented:
    Moreover, it should include a reflection toward:
  - Daily working practices: the implementation of collaborative integrated work needs the support of experimental working practices and integration between different levels (top management, middle management,

and professionals in the field). Identification and discussion of HPs' problems is the first step to finding solutions and making the changes happen (27).

    ◦ Ethical implications of working practices and organizational model: a continuous reflection on whether, or not, this kind of organization is able to answer complex health needs and reduce health inequalities and barriers to access to care (18, 32, 33);

    ◦ Research: the research process involves and is part of an existing context, and consequently, it modifies relationships and dynamics both inside the HoC and in the community (34).

- **Caring for the working relationships among HPs and services**: Within the institutional mandate and in the context of HoC, working practices of HPs and social workers can launch organizational changes to improve teamwork and relationships, with a shared willingness to build them (18, 28, 35–37). The efficacy of the multiprofessional teams benefits from a dedicated time frame and physical spaces to reflect (29) and discuss the status quo, obstacles, and solutions (23, 24).

    As a consequence, **the availability of specific competencies is also required.** Collaborative team meetings benefit from the presence of professionals with capabilities in leading groups (38–40). They could facilitate goal definition and how to get it, but also the communication process, and the achievement of shared decisions through conflict mediation, a shared "language," and values. Reflexivity and periodic assessment of the group process are required (41–43).

- **Appropriate research methodology together with a "permeable" multidisciplinary research group**: Research design has to match the experiences and needs of the HPs involved, students, and other research actors in defining priorities and reflecting on working practices. Both qualitative and quantitative methodologies using a participative approach are required (44).

- **Education**: Designing IPE and CBE programs within a real context is central to implementing an HoC based on the c-PHC framework with the following specific learning outcomes (20, 25): foster new collaborative models in PC and between HP relationships; define tools and ways to assess and monitor the impact of the new model; share and disseminate c-PHC culture; and, as mentioned above, assess, evaluate, and monitor the activity, improve the quality of health services and relationships between different HPs and comply with the most recent scientific evidence. This goal benefits from interprofessional group meetings that involve HPs from different disciplines, researchers, students, and members of the community.

4. Conclusion

In our context, HoCs play the role of a permanent laboratory of experimentation, in which HPs interact with researchers, students, and future HPs, as well as the community and surrounding environment (citizens, policymakers, third sector associations, etc.), to overcome obstacles toward the flourishing of community health services.

This process shall embody different levels—institutional, relational, and interpersonal—and areas—education, management, organization, and daily working practices—as well as specific research to support it. The simultaneous coexistence of these levels can be the key to transform the relationships between HPs and how they see themselves (17); students and trainees can experiment with a multidisciplinary learning space along with discussions with HPs from different disciplines and with community actors and also renewing work practice. Commitment and responsibility toward the community are the framework within which knowledge, skills, and techniques acquire meaning. The trigger and development of an ongoing process—within a context of primary care reorganization as one described—is desirable and applicable in any context in which organizational and cultural changes in working practices occur.

Future research calls for further evidence on the impact of this model on community health and HP satisfaction and on the sustainability of the process. Moreover, the comparison with similar experiences in other contexts could help identify enabling factors and obstacles to overcome and common lessons to share.

Considering the scientific evidence and ethical issues concerning primary care and the real inclusion of all stakeholders, the HoC becomes the place of practical implementation of integrated services that contribute to the improvement of community health.

Data availability statement

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

Author contributions

CM, GN, LB, GB, and MN contributed to the design of the work. GB, CM, and GN devised the project and the main conceptual ideas. CM and GN wrote the first draft of the manuscript. All authors provided critical feedback and commented the manuscript. All authors contributed to the article and approved the submitted version.

Conflict of interest

Publisher's note

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Reflective structured dialogue as a tool for addressing wicked public health problems

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Introduction: Attempts to address wicked public health problems can benefit from collaborative approaches to problem-solving, such as dialogue through structured conversations, that engage a wide range of stakeholders in deliberate inquiry to build trust and mutual understanding. This study seeks to assess the effects of participation in Reflective Structured Dialogue (RSD) on university students' polarization-related attitudes.

Methods: The BYU Campus Conversations project held 27 structured conversations with 139 participants on three divisive public health topics: COVID-19, mental health, and racism. The conversation structure encouraged students to share their personal experiences and learn from others in an environment that promoted vulnerability and confidentiality.

Results: Pre- and post-conversation surveys measured participant outcomes and found that participation in conversations was strongly associated with improved attitudes related to openness, tribal identity, and moral disdain. Over 95% of participants reported that they enjoyed taking part in the conversations and that it helped them better understand the experiences of others.

Discussion: The results of this project indicate similar conversations could be an effective tool in helping build understanding around divisive public health issues in university and community settings.

KEYWORDS

public health, community health, deliberative inquiry, reflective structured dialogue, higher education

1. Introduction

Political polarization and conflict over social issues are indelible features of American society. Since the beginning of the COVID-19 pandemic in 2020, critical public health-related problems have increasingly become the focus of many of the most heated debates in legislatures, communities, and schools across the country. In addition to disputes directly associated with the pandemic (e.g., masks, vaccines, school closings, etc.), the past 3 years have seen deepening societal rifts related to police violence, mass shootings, abortion, and other public health concerns. These polarizing issues can be characterized as "wicked" problems, i.e., complex social and political problems with dynamic root causes that are difficult to precisely delineate and that lack definitive and objective solutions, especially across different contexts (1). In contrast with typical problems in disciplines such as mathematics and chemistry, the nature of "wicked"

problems is likely to be viewed differently by each stakeholder depending on their values, perspectives, and biases (1, 2).

Polarization affects public health in at least two critical ways. First, polarization has been found to directly affect stress and anxiety, which can lead to a variety of poor health outcomes (3, 4). Second, and perhaps most crucially, polarization impedes collective problem-solving and increases social divisiveness—a factor that can be considered a determinant of health—which creates new and exacerbates existing health and social problems (5, 6). Thus, in order to build a foundation of understanding upon which today's wicked public health problems can be more effectively resolved, the public health community needs evidence-based approaches for promoting dialogue and reducing polarization around controversial issues.

As opposed to the much more common adversarial or expert-centric approaches typically relied upon by public decisionmakers, addressing wicked problems requires purposeful problem-solving approaches that involve cooperation and ownership from a broad range of stakeholders across multiple disciplines (7). Deliberative democracy is one form of problem-solving in which diverse groups of citizens gather, think critically, and generate solutions together (7). An essential component of deliberative democracy is the "deliberative inquiry" or "social learning" phase that, ideally, should come first and be separated from decision making (7, 8). While the deliberative inquiry phase is not in and of itself sufficient to resolve wicked problems, it can be a critical starting point. The purpose of this phase is to build a foundation of trust and understanding in which participants can learn from one another and begin to see each other as "collaborators facing a wicked problem" without pressure to reach an agreement (7, 8). Whereas polarization dismantles democracy by encouraging people to be more obstructionist and less deliberative (9), dialogue has been found to build understanding, integrate knowledge, and reduce fear and anger among diverse groups of stakeholders on difficult, interdisciplinary public problems (10). When people with opposing views can engage openly in dialogue, they have increased opportunities to work towards consensual problem solving by jointly defining problems and creatively identifying and implementing solutions that are more likely to be acceptable to various stakeholders with competing interests (11).

As institutions designed for learning and growth, universities are an ideal setting to serve as "critical spaces" in which students and scholars participate in deliberative inquiry on shared problems (12, 13). This can occur through a structured process of open and respectful dialogue where participants consider knowledge from various disciplines along with the underlying values that inform their views (12, 13).

Several organizations, primarily outside the field of public health, have developed structured approaches to creating space for deliberative inquiry through dialogue. Reflective Structured Dialogue (RSD) is a well-known method whose purpose is not to find solutions but to build a foundation of mutual understanding, empathy, and trust between participants upon which future solutions can be developed (14–18). Storytelling is a key ingredient in RSD, allowing participants to build trust and to offer differing points of view without being contentious (17, 19). RSD relies on careful preparation to craft conversation agreements (i.e., ground rules) and thought-provoking questions that facilitators use to encourage participants to reflect on and share their personal experiences related to the discussion topics. A shared commitment to the conversation agreements helps create an environment supportive of active listening, open-mindedness, and authenticity where participants can learn from one another. Due to

this carefully designed structure, RSD is uniquely suited to handle uneasiness and moments of disruption (18, 20).

While extensive research has documented the positive effects of various types of dialogue on polarization and conflict reduction, rigorous studies specific to RSD are more limited; however, the existing evidence related to RSD is promising. For example, a qualitative study showed that RSD can create and deepen positive connections, increase self-reflection and growth, improve communication skills, and help people understand different perspectives and viewpoints (15). Another case study found that RSD helped build trust and strengthen relationships between people that had opposing viewpoints on LGBTQ+ inclusion in a university setting (21).

Recognizing the scarcity of scientific evidence and the potential value of RSD in resolving wicked problems, the primary aims of this study were to assess the effects of participation in RSD—specifically about divisive public health-related topics—on university students' polarization-related attitudes. The study also sought to understand students' opinions about their participation in the RSD experience.

2. Materials and methods

2.1. Project description

In collaboration with Living Room Conversations, the Brigham Young University (BYU) Campus Conversations project was developed to create opportunities for dialogue around divisive public health-related issues among BYU students, with the objective of increasing mutual understanding, respect, and empathy in the campus community. The project was funded through a grant from the Heterodox Academy, a nonpartisan nonprofit organization whose mission is "to improve the quality of research and education in universities by increasing open inquiry, viewpoint diversity, and constructive disagreement" (22).

The project used an RSD approach to hold structured conversations about three specific public health topics chosen based on their relevance to the BYU community: COVID-19, mental health, and racism. The project team partnered with Living Room Conversations to create separate structured conversation guides for each of the three topics (see Supplementary material). The guides were tailored to the specific needs of the target population; for example, the conversation guide addressing racism was titled, "Race and Faith," and was designed to encourage students to reflect on their race-related beliefs and experiences at BYU, a religious institution where most students are members of The Church of Jesus Christ of Latter-day Saints. Each conversation guide was designed to last 90 min and included the following elements:

1. Introductions: participants share their names and why they chose to participate.
2. Conversation agreements: facilitator and participants read through a list of conversation agreements which all participants are asked to agree to follow before proceeding.
3. Getting to know each other: participants select a question from a list of introductory questions and take 2 minutes each to share their responses to help them introduce themselves to the rest of the group.

4. Exploring the topic: the facilitator reads a short paragraph introducing participants to the conversation topic. Participants (including the facilitator) take turns selecting a question from a list of topic-related questions and take 2 minutes each to share their responses with the group. After everyone has a chance to share, participants ask and answer follow-up questions. If time permits, participants repeat this process by selecting another question from the list.

5. Reflecting on the conversation: participants select a question from a list of final reflection questions and take 2 minutes each to share their responses with the group.

6. Closing: the facilitator thanks participants for their participation and reminds them to complete the post-conversation survey.

Table 1 summarizes key features of the different types of conversations. All conversations took place in small groups of four to seven people, including one to two student facilitators. Each student facilitator was a member of the project team and had received training from Living Room Conversations to guide the conversations. Some of the conversations were held in a large conference room (referred to here as "large group conversations") with three or more conversations taking place at the same time in separate small groups. Other conversations took place in smaller conference rooms (referred to here as "medium group conversations") with two concurrent separate conversations taking place at the same time in separate small groups. The rest of the conversations were held in small classrooms or homes (referred to here as "small group conversations") with only one conversation happening at a time. Different conversation types and sizes were used to assess whether participant outcomes differed by conversation features.

The large- and medium-group conversations addressed either COVID-19 or mental health while the small group conversations addressed the topic of racism. The large- and medium-group conversations required participants to attend only one conversation, but the small group racism conversations were conducted over a series of three conversations with the same group of participants, requiring the participants to attend all three conversations. Separate conversation guides on racism were developed and used for each of the conversations in the racism series. While most of the conversations were held in person on or near BYU's campus, two were held virtually via Zoom due to scheduling conflicts. Different conversation topics were used to assess whether participant outcomes differed by topic.

2.2. Participants

The project team consisted of two public health faculty, two public health graduate student project managers, and 12 public health undergraduate student facilitators. Conversation participants were current and recently graduated (within 1 year) BYU undergraduate and graduate students. Conversation participants were recruited in multiple ways, including via information booths, advertisements on university clubs' social media accounts, informational flyers, classroom announcements, and word-of-mouth.

2.3. Data collection and analysis

The project team developed the pre- and post-conversation surveys based on reviews of gray and academic literature on RSD-related activities. In addition to basic demographic questions, the surveys primarily used (with some modifications) previously tested questions from the Social Cohesion Impact Measure (SCIM) to measure outcomes related to participants' polarization attitudes towards other groups as well as to participants "bridging" mindsets and attitudes. The seven outcomes assessed in the survey included: openness (i.e., to new information and understanding), tribal identity (i.e., identity with one's group relative to other groups), intellectual humility (i.e., willingness to be wrong), respect (i.e., appreciation for differing opinions), empathy (i.e., ability to see things from other people's perspectives), animosity (i.e., negative feelings towards others), and moral disdain (i.e., perception that others are morally inferior). In total, 23 attitude questions with five-point Likert scale response options were included in both the pre- and post-conversation surveys. For most questions, the "preferred" answer was Strongly Agree; however, five questions were worded differently so that Strongly Disagree was the "preferred" response. The post-conversation survey also included 10 total Likert scale and open-ended questions regarding participants' overall experience with the conversations.

All participants were invited to complete the pre- and post-conversations surveys electronically using Qualtrics online survey software. After participants signed up to join a conversation, they received an email with a link to the pre-conversation survey. Participants were also given time to complete the survey at the beginning of the conversation if they had not previously done so. The post-conversation survey link was emailed to participants within a week following the conversation. To preserve anonymity, pre- and post-surveys were linked through unique participant IDs, and no personal information was tied to survey results. All participants who completed the pre- and post-surveys received a $10 Amazon gift card.

TABLE 1 Conversation features.

| | Size of conversation group | | |
	Small group	Medium group	Large group
Conversation location	Small classrooms or homes	Small conference rooms	Large conference rooms
# of simultaneous conversations of 4–7 People	1	2	3 or more
Topic	Racism	COVID-19 or mental health	COVID-19 or mental health
One-time or series of 3	Series of 3	One-Time	One-Time

The research team used Microsoft Excel to organize and analyze the data. Summary statistics for the demographic questions and each of the Likert questions were calculated, and two-tailed paired t-tests were conducted to identify statistically significant differences between the pre- and post-conversations surveys.

3. Results

A total of 139 study participants partook in one or more of 27 conversations. Of the participants, 118 completed both surveys and were included in the analysis; 108 were student participants, and the other 10 were student facilitators. Table 2 summarizes key demographic variables of the included participants. Ages ranged from 18 to 29 years old, with a mean of 22.4 years old. Most participants were either seniors (42.3%) or juniors (28%). There was a nearly equal split between male and female participants, and most participants (87.3%) identified as straight/heterosexual. Most participants were single (65.3%), followed by married (28.8%), engaged (5.1%), and divorced (0.9%).

Most participants (98.3%) indicated their religion as The Church of Jesus Christ of Latter-day Saints, the sponsoring religious institution of BYU. Most participants identified as White (69.9%). The second largest race/ethnicity represented was Asian American/Asian (11.9%), followed by Hispanic/Latino (6.3%), and Other (4.2%). Project participants were divided across the political spectrum. The greatest percentage of participants defined themselves as Moderately Conservative (35.6%), followed by Moderately Liberal (22.9%), Conservative (17.8%), and Liberal (11.0%).

Overall, the conversations appeared to be effective in improving participants' polarization and bridging attitudes. Tables 3, 4 show that 19 of 23 pre- and post-survey questions showed increases in the "preferred" response (Strongly Agree or Strongly Disagree, depending on question wording), and the pre-post differences for four of the 19 questions were statistically significant ($p < 0.05$).

The greatest statistically significant improvements between the pre- and post-conversation surveys were seen in the two questions related to the outcome of openness. Before the conversation, 42.9% of participants strongly agreed with the statement, "I enjoy having conversations with people holding differing opinions or perspectives"; after the conversation 58.8% of participants strongly agreed. Similarly, before the conversation, 52.1% of participants strongly agreed with the statement, "I am comfortable having conversations with people of different opinions"; after the conversation 66.4% strongly agreed.

The two other outcomes showing statistically significant improvements between the pre- and post-surveys were tribal identity and moral disdain. For tribal identity, before the conversation 18.6% of participants strongly agreed with the statement, "If people different than me are praised it makes me feel good," compared to 32.2% after the conversation. For moral disdain, before the conversation 19.5% of participants strongly disagreed with the statement, "I consider people with different opinions to be deceived," compared to 31.4% after the conversation. Questions measuring each of the other outcomes showed improvements between the pre- and post-surveys, but these improvements were not statistically significant.

Among the four questions showing either no change or a decrease in the preferred response between the pre- and post-conversation

TABLE 2 Participant demographics ($n = 118$).

	Count	Percentage
Gender		
Male	58	49.2
Female	60	50.9
Age		
18–20	17	14.5
21–23	74	62.7
24–26	20	17
27–29	7	6
Sexual orientation		
Heterosexual	103	87.3
LGBTQ+	10	8.7
Questioning	5	4.2
Religious affiliation		
The Church of Jesus Christ of Latter-day Saints	116	98.3
Agnostic	2	1.7
Political views		
Very liberal	2	1.7
Liberal	13	11
Moderately liberal	27	22.9
Moderately conservative	42	35.6
Conservative	21	17.8
Libertarian	6	5.1
Other	7	5.9
Race/ ethnicity		
White	100	69.9
Asian American/Asian	17	11.9
Hispanic or Latino/a	14	9.8
African American/Black	4	2.1
Native American/American Indian	2	1.4
Other	6	4.2
Current status in school		
Freshman	5	4.2
Sophomore	23	19.5
Junior	33	28
Senior	50	42.4
Graduate Student	7	6
Relationship status		
Not married or engaged	78	66.2
Engaged	6	5.1
Married	34	28.8

surveys, three measured the outcome of animosity while one measured the outcome of moral disdain. None of the pre-post differences for these questions were statistically significant. The greatest negative change (−3.4%) was for the statement, "I

TABLE 3 Strongly agree preferred statements.

Statement (outcome)	Difference between pre- and post-surveys (%)				p value *p < 0.05
	Disagree (somewhat and strongly)	Neither agree nor disagree	Somewhat agree	Strongly agree	
I enjoy having conversations with people holding differing opinions or perspectives (Openness)	−1.7	−5.9	−8.4	+16.0	0.026*
I am comfortable having conversations with people of different opinions (Openness)	−2.5	2.5	−14.3	+14.3	0.073*
If people different than me are praised it makes me feel good (Tribal Identity)	−1.7	−14.3	2.5	+13.5	0.010*
I can admit when my opinions or perspectives could be wrong (Intellectual Humility)	0.8	1.7	−13.5	+10.9	0.385
I respect differing opinions even when I do not agree (Respect)	0	−1.7	−6.7	+8.4	0.250
I can often see things from differing points of view (Empathy)	−0.8	0	−6.7	+7.6	0.240
I am comfortable having conversations with people of different political orientations (Animosity)	−3.4	−1.7	−1.7	+6.7	0.107
If I met someone who is different than me, I'd feel connected to this person (Tribal Identity)	1.7	−6.7	−0.8	+5.9	0.443
It's important to understand different people by imagining how things look from their perspective (Empathy)	0.8	−0.8	−5	+5.0	0.524
I am comfortable speaking with people different than me (Animosity)	−2.5	3.4	−5	+4.2	0.391
I am comfortable having conversations with people of different sexual orientations (Animosity)	−1.7	4.2	−5	+2.5	0.786
I am comfortable being around people different than me (Animosity)	0	−0.8	−1.7	+2.5	0.702
I am comfortable having conversations with people of different gender orientations (Animosity)	−1.7	5.9	−4.2	+0.0	0.862
I am comfortable having friends who are different than me (Animosity)	0	1.7	−0.8	−0.8	0.840
I would say that people different than me are generally good people (Moral Disdain)	−0.8	−0.8	3.4	−1.7	0.815
I am comfortable having conversations with people of a different race (Animosity)	−0.8	0	4.2	−3.4	0.885

am comfortable having conversations with people of a different race." Before the conversation, 84% of participants strongly agreed compared to 80.7% after the conversation.

The results from the questions unique to the post-conversation survey (see Table 5) further indicated the successful nature of the conversations. Over 50% of participants strongly agreed with seven of the ten unique post-survey statements. The most positive result was regarding the conversation being a positive experience, with 81.5% of participants strongly agreeing and 15.1% somewhat agreeing. The second most positive result was regarding the conversation helping participants understand the experience of others, with 78.2% of participants strongly agreeing and 18.5% somewhat agreeing.

The overall results were similar when comparing participant responses between different conversation types (series, non-series), topics (COVID-19, mental health, racism), and meeting sizes (small, medium, large). Few statistically significant differences were identified between these different conversation variations, which may be attributed to the smaller sample sizes of participants for each variation.

4. Discussion

This study shows that RSD is positively associated with improved polarization-related attitudes among university students. While not all changes were statistically significant, most survey questions showed positive changes between the pre- and post-surveys, with the biggest differences coming in questions related to outcomes of openness, tribal identity, and moral disdain. Nearly all students believed their experiences with RSD were positive, helped them understand the experiences of and feel more connected to others, and increased their empathy and compassion. Bethel and colleagues, who likewise employed the Living Room Conversations and RSD models in a study involving students from two different institutions, similarly reported that student participants found conversations to be meaningful and effective at increasing empathy, connection, and in providing insight into the lived experiences of others (23).

When asked to comment on their overall experiences, the open-ended responses from participants supported the quantitative findings. A representative comment from one student said, "I enjoyed being in a setting where people are encouraged to listen to others first

TABLE 4 Strongly disagree preferred statements.

Survey question (outcome)	Difference between pre- and post-surveys (%)				*p* value *p* < 0.05
	Agree (somewhat and Strongly)	Neither agree nor disagree	Somewhat disagree	Strongly disagree	
I consider people with differing opinions to be deceived (Moral Disdain)	−6.7	−10.1	5	+11.8	0.018*
I consider people with differing opinions to be uneducated (Moral Disdain)	−3.4	−3.4	−5	+11.8	0.103
I consider people with differing opinions to be misinformed (Moral Disdain)	0	−12.6	2.5	+10.1	0.165
I become angry when thinking about different people (Empathy)	3.4	−0.8	−9.2	+6.7	0.833
In a typical conversation I do the majority of the talking (Respect)	9.2	−9.2	−4.2	+4.2	0.591
I find it difficult to see things from a different point of view (Empathy)	−2.5	0	−0.8	+3.4	0.760
I consider people with differing opinions to be wrong (Intellectual Humility)	−0.8	0.8	−3.4	+3.4	1.00

TABLE 5 Post survey only statements.

Statement	% disagree	% neither agree nor disagree	% somewhat agree	% strongly agree
Participation in BYU campus conversations has been a positive experience	0.8	1.7	15.1	81.5
Participation in BYU campus conversations has helped me understand the experiences of others	0	2.5	18.5	78.2
Participation in BYU campus conversations has helped me feel more connected to others	0.8	6.7	27.7	63.9
Participation in BYU campus conversations has helped me gain new perspectives	0.8	6.7	28.6	63.0
Participation in BYU campus conversations has increased my compassion or empathy for others	1.7	6.7	27.7	63.0
Participation in BYU campus conversations has helped me see important issues from a different point of view	4.2	5.9	31.1	58.0
Participation in BYU campus conversations has increased my appreciation for perspectives different than my own	0.0	9.2	37.8	52.1
Participation in BYU campus conversations has increased my confidence in sharing personal experiences and perspectives	3.4	9.2	37	49.6
Participation in BYU campus conversations has increased my hope for the future	1.7	18.5	31.1	47.9
Participation in BYU campus conversations has increased my trust in others	3.4	16.8	35.3	43.7

without rebutting them. I usually do not talk about these kinds of topics due to being anxious about negative responses." Several students mentioned their desire to incorporate structured conversations into the university campus community in more permanent ways. For example, one participant wrote, "I believe this is important enough to be included in curriculum. I think that every BYU student should participate in such a discussion before they graduate."

Together, the quantitative data and participant comments suggest that, as in previous studies, RSD helped participants create connections and understand different perspectives (15, 21). This study also helps demonstrate how deliberative inquiry can contribute to student learning in higher education setting (12). These empirical findings are useful in supporting the theoretical justifications made about the value of RSD and other types of dialogue in building trust and understanding between diverse groups as a prerequisite to problem-solving (16–18). Successful consensual problem solving for wicked problems requires dialogue to create the conditions in which stakeholders with distinct interests can collaborate towards progress on solutions (11).

A potential limitation to this project is the lack of diversity among participants. Most participants identified as members of The Church of Jesus Christ of Latter-day Saints, as White/Caucasian, and as heterosexual. This demographic makeup was anticipated due to the demographics of BYU; however, such demographics should be considered when interpreting the project results and when seeking to generalize them to larger populations. A second potential limitation regarding generalizability is that this project was done with only university students that were to a large degree self-selected into the study. While the number and type of participants was chosen based on logistical concerns, a larger, more diverse sample in future projects would help increase confidence in the results and could potentially yield additional insights about conversation sizes, topics, etc. that were not observed in this project.

Structured dialogues, such as those used in this study, are more important now than ever as society becomes increasingly polarized along ideological, religious, racial, and other divides. While this is a relatively small demonstration project in a

somewhat unique context, the results are promising and lend strength to the argument that RSD can serve as a useful tool in university settings and in the larger context of addressing wicked public health problems in communities. Future projects should explore additional applications of RSD and use rigorous evaluation methods to better understand how to optimize outcomes.

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 studies involving humans were approved by Brigham Young University Institutional Review Board. The studies were conducted in accordance with the local legislation and institutional requirements. The ethics committee/institutional review board waived the requirement of written informed consent for participation from the participants or the participants' legal guardians/next of kin because Study posed minimal to no risk to participants.

Author contributions

CW, JB, PH, and JG contributed to conception and design of the study. CW, JB, LB, PC, SD, and MF recruited participants and collected data. CW performed the statistical analysis. CW and JB wrote the first draft of the manuscript. All authors contributed to the article and approved the submitted version.

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/fpubh.2023.1220029/full#supplementary-material

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Wake-up call for HPPP – health promotion, prevention, and preparedness

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The latest public health emergencies exposed urgent gaps in health promotion, prevention and preparedness (HPPP). Existing and new infectious diseases have gained far more prevalence than expected, and inequities in access to health care accounted for disturbing differences in the toll of these diseases in different populations. The COVID-19 pandemic not only demonstrated the need to prevent the onset and progression of non-communicable chronic diseases (NCDs) and promote healthy lifestyles, but also the need to prepare for new infectious diseases and their long-term effects on both physical and mental health. Preparedness was previously associated with natural disasters, with activities directed to developing emergency humanitarian action response resources. However, these actions are inadequate for the frequent natural disasters as the climate crisis intensifies. To reach effective actions in HPPP, we take a broad approach to HPPP components, identify the main stakeholders and suggest methods to change allocations for HPPP. We propose a call for action at global and national levels, involving strengthening the United Nations' Sustainable Development Goals and government commitment to HPPP.

KEYWORDS

public health, health promotion, prevention, health promoting settings, health policy

Introduction

Health promotion, prevention, and preparedness

The latest public health crisis presented a wake-up call for enhanced synergies across HPPP functions, and increased collaboration between major HPPP stakeholders. Health promotion aims to encourage healthy personal lifestyles as well as public environmental conditions to make this possible. Prevention is more complex as it generally includes three parts: primary prevention to prevent the onset or transmission of disease, secondary prevention to prevent severity after the onset of a disease, as well as complications of conditions, and tertiary prevention to prevent disability resulting from a disease or injury. These functions are the foundation for reducing the transmission of diseases and the onset and increase in severity of many chronic conditions. Preparedness is a set of activities, from recognition of the potential hazards and the preparation of resources to deal with epidemics, as well as emergency humanitarian action when needed. We have taken a broad approach to HPPP as effective implementation requires understanding of each component, their dependencies, and the role of the partners and stakeholders.

Wake up call for HPPP actions

The COVID-19 pandemic and the soaring rates of NCDs

The COVID-19 pandemic demonstrated that the spread of infectious diseases is still an enormous public health hazard. Older people were disproportionately impacted by the COVID-19 pandemic; in the US, adults aged 65 and over comprised about 80% of total COVID-19 deaths in 2020 (1). While older adults were labeled as the most vulnerable and urged to stay at home, we did not consider the known negative health outcomes of social isolation, as higher risk of dementia, coronary artery disease, and mortality (2). We failed to predict the negative impact of COVID-19 social isolation on mental health (3). In the working-age population, isolation and the loss of income led to increased domestic violence, substance abuse and depression (4, 5).

We see the urgency of preventing the spread of old and new infectious diseases and a continued need to promote healthy lifestyles and prevent the onset and progression of NCDs. We now recognize the negative interaction between the two groups; as reflected in more deaths and residual morbidity in people with risk factors such as obesity and multiple chronic conditions who were infected with different variants of COVID-19 (6, 7). While there are continuous efforts to prevent the onset and progression of NCDs, they are still considered an emerging global health threat, killing 41 million people annually (8). The pandemic has shown the need for preparedness, both for long-term care of people with NCDs and infectious diseases with long-term effects. We have been warned about future pandemics and should not repeat mistakes. Preparedness is not a concept for the future: it is required immediately to deal with the health care needs of the consequences of the COVID-19 pandemic and expectations of future pandemics.

Increasing natural disasters linked to climate change

Preparedness was previously associated with natural disasters, with activities directed to developing emergency humanitarian action response resources. First, through the establishment and reinforcement of United Nation's (UN) organizations, as the UN Disaster Assessment and Coordination Organization (UNDAC) which is part of the international emergency response system for sudden-onset emergencies, and the Office for the Coordination of Humanitarian Aid (OCHA), as well as the specialized agencies such as the World Health Organization (WHO), and the Red Cross. These agencies provide the operational guidelines for non-government disaster organizations, thereby coordinating all humanitarian emergency action at the time of the disaster and after. For example, as part of WHO's disaster preparedness and response efforts, the agency formed the *Disaster Management Guidelines: Emergency Surgical Care in Disaster Situation*. The comprehensive manual provides areas affected by natural disasters with guidance on the management of common injuries encountered in disaster situations (9).

However, these actions are inadequate for the more frequent natural disasters now linked to climate change. We see an unprecedented number of natural disasters with more displaced persons, and outbreaks of diseases associated with unsafe water and sanitation, such as diarrheal diseases which are the second leading cause of death in children under five worldwide (10). As climate change intensifies, wildfires are also on the surge, with a global increase in extreme fires of up to 14 percent by 2030 and 30 percent by the end of 2050 (11), causing increased pollution in large cities with preexisting major pollution issues and long-term adverse health consequences, especially among vulnerable populations (12).

Reaching effective HPPP measures

The first step for effective HPPP actions is to identify the factors, actors and methods to reach the HPPP goals, based on the evidence to date. For example, HPPP measures in maternity care are showing astonishing outcomes. The Maternal Mortality Ratio (MMR, maternal deaths per 100,000 live births) is a health indicator with one of the biggest variations, with a range of 3 in Finland and Norway, 19 in the USA, to a reported 1,150 in South Sudan and estimated 1,800 in Afghanistan (13, 14). The huge variation shows a clear example of how appropriate HPPP measures through health promotion as healthy nutrition, using appropriate vaccinations and scans to prevent and preparedness actions as can prevent morbidity and mortality in both mothers and infants.

To reach effective HPPP, the questions that need to be asked are who are the stakeholders, how to engage them, strengthen the partnerships, and allocate resources to these functions in the framework of a global commitment.

We identify the main stakeholders as

Governments, committed to reaching the Sustainable Development Goals (SDGs), are major stakeholders. Yet government programs tend to be vertical, with limited funding channeled through separate ministries. The Health in All Policies (HiAP) approach introduced a collaborative effort that integrates and articulates health considerations into policymaking across sectors to improve the health of all communities and people (15, 16). The mechanisms of HiAP are complex and have been found to work well in some local government contexts but less so at national efforts to enhance HPPP. Governments still need to be convinced of the effects and value of HiAP in progressing a cross-agency health promotion agenda. Governments that do use HiAP face the challenges in changing legislation and structures to facilitate policy coordination (17). The responsibility for HPPP indeed has to be collaborated between all ministries. In reality, implementation is generally delegated to local government until an emergency occurs, such as a cholera outbreak, and only then we may see collaboration between local authorities. Enforcement of regulations may be beyond the capacity of local authorities, with their own internal political pressures on licensing and inspection, as banning the sale of cigarettes and alcohol to minors. These harsh realities include the fact that many local authorities are underfunded and mismanaged.

The worst scenario is when the major source of financing for health care is out-of-pocket payments by patients. Governments in these countries may take responsibility for immunization against communicable childhood diseases but do not invest enough resources

and money on personal preventive care. Low-and mid-income countries are also less likely to spend funds on preparedness, despite the fact that housing, roads and bridges are often substandard and do not sustain the damage of natural disasters. Infectious diseases are far more transmissible in substandard housing with poor ventilation and inadequate water and sanitation facilities (18).

Improved legislation and regulation are urgent. Not all governments have the knowledge and tools to draft legislation and regulations on HPPP, allocate funds or find new fiscal space for the measures required. This is where the specialized UN organizations come in, through their resolutions, conventions and guidelines on monitoring indicators, such as in the SDGs. These organizations have the mandate to develop tools which can be followed by all countries – a fact that should not be ignored. The dissemination of these standards can also guide the multi-and bilateral donors in development aid in the framework of an informed policy backed by legislation.

The United Nations representing the collective body of member states, has developed tools to motivate governments to improve the quality of life of their citizens. The Millennium Development Goals (MDGs) and now the SDGs for 2030 serve as goals with explicit targets (19). These tools can guide the allocation of resources to achieve the goals.

Within the UN specialized organizations, the **World Health Organization** is charged with the development of public health provision through health promotion guidelines. WHO's work in the past was mainly directed at Ministries of Health. The UN undertakings of reaching the MDGs and now SDGs have led to some but not enough shift from vertical programs to a cross-cutting but not adequately coordinated approach.

The next UN body as a stakeholder is the **International Labour Organization (ILO)**, which has dealt with health promotion and prevention since its founding in 1919, through its conventions and standards. The major areas of these conventions with specific prevention approaches are maternity protection, health care under the social security framework, occupational safety and child labour. *Decent Work* is a later initiative of the ILO introduced in 1999, calling for creating jobs, guaranteeing rights at work, extending social protection, and promoting social dialogue (20). These four pillars of the *Decent Work* agenda became integral elements of the 2030 agenda for SDGs as Goal number 8 (19).

Social Security schemes are major stakeholders and probably have the most to gain from effective HPPP. But concern with their financial viability has grown as a result of some stagnation in economic growth and an increasing informal sector economy globally. Promotion and prevention are not adequately considered in cost control efforts of the schemes and there is little consideration of expenditure in one branch, such as health care, as savings in another branch, such as disability. The transfer of funds between schemes providing short and long-term payments could be a serious driver in our efforts to increase funds for HPPP23. For example, targeted health promotion on lifestyle, physical activity and nutrition may lead to healthier adults in working age needing less cash sickness benefits during sickness absenteeism.

To put it simply, we have a positive interaction of expenditure and savings between life contingencies. The expenditures on these contingencies are usually funded by separate contributions or sources and may be managed by separate organizations. While the transfer of

funds from one benefit branch or scheme to another may not currently be permitted by law, ways for collaboration and cooperation between the different partners, when the cost benefits are clear, and the outcome is a healthier and more productive population could be explored.

Multi and bi-lateral funding agencies have been major players through grants and loans for diseases with the highest risks of spread. The recipient countries have not always had the capacity to use the funds in an optimal and sustainable way. When the aid programs were successful, they have often been perceived as being good for the lowest-income populations, without due consideration of how these actions could benefit populations in other countries, both high and low-income (21).

There are additional stakeholders, such as private corporations and foundations, the academic community, non-government organizations dealing with specific diseases and patient associations. Their role may vary in different countries, but they should be considered in national plans.

Conclusion and recommendations

There is no "go it alone" in HPPP. At a global level, we propose that the UN broaden the scope of the SDGs, just as *Decent Work* was upgraded to a priority area in SDG 8. The areas covered here can be included in other SDGs. All the relevant specialized UN agencies need to be part of the effort to provide the impetus to countries to get back on track in reaching the SDGs after the delays noted at the United National General Assembly (UNGA) in September 2022 (22).

At the national level, governments have to commit to an ideology that leads to policy and legislation on appropriate HPPP.

The conditions for successful HPPP need to include

- Continued identification of effectiveness in HPPP measures. The promotion of routine tests for early detection of specific malignancies and relevant vaccination, such as the Human Papillomavirus vaccines against cervical cancer shown to be an effective HPPP measure that needs to be amplified in other areas as well.
- Adoption of mechanisms to recognize how expenditure by one authority or agency can impact on savings in other sectors, with collaboration between agencies to pool funds for HPPP.
- Recruitment of professionals outside the health field to enhance rational and logical thinking and undertake operations to increase responsibility and accountability in public health systems.
- Improved decision-making mechanisms, with input from successful private corporations and through the enlistment of trusted leaders from the cultural environment of the population, using appropriate communications mechanisms.
- Measures to link research findings to legislators and providers of health care.
- Advancements in the input from health professionals by the implementation of changes in basic as well as continued

education to improve knowledge and counseling on risk factors, such as food security and ecology.

- Involvement of relevant communications systems and social media in implementing the HPPP policies.
- The ability to evaluate and change policies and legislation in a timely manner to meet the new needs of changes in the disease pattern and demographic transitions.

As the timeline for the Sustainable Development Goals for 2030 is fast approaching enhanced collective efforts are crucial. Similarly to the Health in All Policies approach, success requires interaction between different sectors. The last of the SDGs is *Build Partnerships for the Goals*, and this is perhaps the greatest challenge. It requires giving up exclusiveness and sharing credits in a way that has not been done before for the good of all. Public health is about the good of all for a sustainable future.

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

VL and AR contributed to the conception and design of the paper and wrote the first draft of the manuscript. AR organized the structure of the paper and did the first edit the paper. VL did the second edit of the paper. All authors contributed to the article and approved the submitted version.

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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HipHop2SToP a community-led health promotion initiative empowering Aboriginal youth in the Kimberley region of Western Australia: a process evaluation

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Introduction: For millennia, Aboriginal people's ways of knowing, doing and being were shared through art, song, and dance. Colonisation silenced these ways, affecting loss of self-determination for Aboriginal people. Over the past decade in Australia, hip-hop projects have become culturally appropriate approaches for health promotion. When community led, and Aboriginal worldviews centralised, hip-hop workshops are more likely to be effective. In 2020, during the COVID-19 pandemic, a community-led health promotion hip-hop music video, 'HipHop2SToP' was produced involving young people in Dampier Peninsula communities address healthy skin and healthy living practices.

Methods: We report here a qualitative process evaluation of the HipHop2SToP project. Participants who had been involved in the planning and production of HipHop2SToP were selected using a purposive approach and invited either by email or face-to-face to participate in semi-structured interviews and share their experiences. Semi-structured interviews ranged from 30 to 60 min in duration and were conducted either face-to-face or virtually over MS Teams. Due to personal time constraints, two participants provided written responses to the semi-structured questions. All interviews were audio-recorded with consent and saved as a digital recording in a de-identified format. All audio recordings were transcribed verbatim and uploaded into QSR NVivo v12 along with written responses.

Results: As a health promotion project, the critical success factors were community-ownership and discovering novel ways to collaborate virtually with remote communities using Microsoft (MS) software. Highlights included observing the young people actively engaged in the project and their catchy lyrics and key messaging for environmental health and skin infections. COVID-19 presented some challenges. Gaps in communication, clarification of stakeholder roles and expectations, and post-production outcomes were also identified as challenges.

Conclusion: HipHop2SToP validates the need for Aboriginal community led health promotion programs. While creating some challenges COVID-19 also strengthened community ownership and created novel ways of maintaining relationships with remote Aboriginal communities. Future hip-hop projects would benefit from clarity of roles and responsibilities. Strengthening post-production outcomes by including a launch and well-planned, targeted communication and dissemination strategy will ensure the wider translation of important health messages and potential strengthen sustainability.

Introduction

For Millenia, Australian Aboriginal people's ways of knowing, doing and being have been shared through art, song, and dance (1). This oral tradition of story sharing, and expression of voice encompassed a wide range of knowledges, ensuring generations inherited a broad and interconnected understanding of their culture and environment (1, 2). Through the process and effects of colonisation, these ways of knowing, being and doing were silenced, affecting the loss of self-determination for Aboriginal people (3). In doing so, Euro-colonial epistemologies dominated institutions, systems, and research, perpetuating ongoing power imbalances and systemic racism (4, 5); thus health promotion has been based on Euro-colonial epistemologies and considered a colonial language denying the worldviews of Aboriginal people (6). In doing so, an authoritative dominance and control over Aboriginal people's lives has been fostered by way of instructing Aboriginal people on what they should and should not do for their own health, rather than give options to 'choose', inform and co-design the best messages for themselves (7, 8). Furthermore, these power dynamics and paradigms have marginalised already vulnerable populations (9, 10). Transcending post-colonial health promotion into strength-based programs among Aboriginal communities requires a paradigm shift that centralises Aboriginal worldviews. This transformation is essential for Aboriginal peoples' self-determination (6, 11) and reducing the burden of disease affecting their families and communities (12).

Reducing the burden of skin infections

The burden of skin disease remains high in Aboriginal populations, particularly, Aboriginal children who experience higher rates of skin infections compared to non-Aboriginal children (13). The two main skin infections of concern are scabies, an itchy skin infection transmitted between humans (14) via skin-to-skin contact and impetigo which often develops as a secondary bacterial infection from scabies or other broken skin or following minor trauma (15). In 2017 the World Health Organization (WHO) included scabies in the program of Neglected Tropical Diseases (16, 17), establishing a global drive for the promotion and implementation of scabies control programs in endemic countries. Acknowledging the broader social and environmental determinants of health and local conditions in which people are born and live is crucial for reducing the burden of skin disease (18). Engaging with, listening

to, and accepting guidance from community Elders to learn their wisdom, traditions, and unique Aboriginal worldviews is essential for effective programs (9). For non-Aboriginal organisations, adopting a critical lens to interweave the rich Aboriginal knowledge systems with biomedical knowledge and technology (19), is a positive approach for health messages to be delivered in culturally sensitive and relevant way. When done effectively, this approach can help increase participant engagement, facilitate active learning, raise awareness (20–22), and increase confidence and social inclusion for those involved (20–23). Over the last decade in Australia, this has been demonstrated in workshops and programs using hip-hop music as a means to engage Aboriginal young people (20, 21, 23–25). Creating hip-hop music and participating in workshops has provided healthy ways for Aboriginal young people to make meaning of themselves and their life experiences (23), and facilitate emotional regulation (26). Furthermore, hip-hop music has demonstrated its power for representing identity (27), and self-expression, in addition to providing therapeutic functions (23, 28) and maintaining traditional ways of knowing, doing and being through song and dance (24).

HipHop2SToP – community led health promotion initiative within the see treat prevent trial

Acknowledging the importance of Aboriginal community led programs, the purpose of this paper is to report on a community led health promotion hip-hop music initiative, namely HipHop2SToP implemented in four Dampier Peninsula communities. Under guidance from Woombooriny Amboon Angarriiya Partnership Initiative (WAAPI) Community Navigators[1] HipHop2SToP is an example of a community led, strengths-based approach to health promotion situated within a broader research project, See, Treat, Prevent (SToP) Trial: a randomised clinical trial aimed at reducing skin infections by 50% in children living in the Kimberley, Western Australia (29). In May 2019, SToP Trial activities commenced including face-to-face school-based skin surveillance; clinic

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1 At the time of HipHop2SToP, Community Navigators are community members working alongside family groups and leading community consultation, stakeholder engagement and co-design processes to enhance community mobilization around key social issues as well as facilitate culturally competent, integrated, and holistic service delivery.

treatments streamlined to include the latest evidence-based practice; and consultation with participating communities to co-design individualised health promotion initiatives. Well-recognised and popular music amongst the young people living in the Dampier Peninsula, a hip-hop music video was chosen by WAAPI community navigators, and supported by Elders as a culturally appropriate, and meaningful SToP Trial health promotion initiative to raise awareness on environmental health and skin infections. Community led and locally produced, HipHop2SToP was planned during virtual meetings and then produced face-to-face during the COVID-19 pandemic.

Hip-Hop subculture, music, and projects

Originating in the United States of America (USA), hip-hop music evolved as a self-expressive artform for many marginalised populations including African American youths (30–32). During the 1980s and 1990s, African American youths relished hip-hop music as an enlightened way of making sense of their world and the reality of life in their neighbourhoods and urban ghettos (30). The hip-hop subculture transcended into popular music industries, becoming a global language (32), and an example of how Indigenous populations globally utilised their cultural traditions of art, music, and dance as modern forms of storytelling. External organisations such as Indigenous Hip-Hop Projects (IHHP) have engaged with Aboriginal communities and young people across Australia, delivering workshops and producing music videos covering topics that include but are not limited to skin health (33), sexual (20) and mental health (21), and crime (34). These projects have facilitated a space for young people to actively engage and learn. For remote living Aboriginal young people involved in music workshops focused on sexual and mental health, hip-hop music helped to increase their social awareness and self-confidence, strengthen communities, and promote social change (20, 21). Further, the young people involved in the *beyondblue: the national depression initiative*, believed hip-hop music provided a means for reducing shame around mental health and increased their confidence to speak with peers and family regarding depression and anxiety (21). Similarly, high rates of participation in the sexual health focused hip-hop project was shown to increase young people's confidence and encourage them 'out of their shell' (20).

Desert Pea Media (DPM), a cross-cultural organisation, has worked with over 80 remote and regional communities in Australia delivering workshops and engaging with young people (25). Between 2019 and 2021, DPM delivered a series of mental health focused workshops in New South Wales and Queensland. These workshops created a safe space enabling young people to 'step up' and try something new. Participating in these workshops strengthened identity and increased the young people's sense of worth. Further, these workshops enabled open discussions about mental health among participants, breaking down the stigma often associated with this topic (22). Furthermore, studies in the USA report emotional and well-being benefits for participants involved in hip-hop summer camps (26, 28). These included social growth and awareness where the participants collaborated with their peers, experiencing joy in creating meaningful projects together.

Despite positive aspects and influence for participants, hip-hop workshops and projects have not been without criticism in terms of further exploitation and paternalism (35). Genuine collaborations in

all elements of hip-hop workshops can help mitigate this, and reduce the risk of power imbalances and colonial relationships when non-Aboriginal organisations work in this context (24). Hip-hop projects can help raise awareness on the subject of interest, however, concerns regarding sustainability and longer-term benefits have been reported on projects with limited community engagement and prior planning (20, 21). Furthermore, staff involved in hip-hop projects have reported issues regarding lack of clarity on roles and responsibilities (20). Well-designed projects with established aims and goals, and consideration for appropriate facilities and project timeframes are more likely to be effective (23). Aboriginal engagement and leadership throughout programs are key elements, as is respecting self-determination (11, 23, 24). Without these components, programs are less likely to be successful in translating health messages or influencing health outcomes.

COVID-19 and community leadership

COVID-19 is an important factor in HipHop2SToP, highlighting community strength and leadership in all elements of the project and the novel way the pandemic connected people using digital technology such as Microsoft (MS) Teams and Zoom when international and interstate travel restrictions were enforced by Federal and State governments (36). At this time, and following direction from Aboriginal leaders, remote Aboriginal communities were closed to all visitors (37). For the SToP Trial, COVID-19 travel restrictions meant all face-to-face school-based skin surveillance and engagement with communities were no longer an option, raising valid concerns that SToP Trial activities would cease indefinitely. This also created concerns around maintaining relationships with communities given the inability to meet face-to-face. Fortunately, online meetings using digital technology became normalised, and communities were receptive to yarning[2] (38) virtually via MS Teams.

Connecting virtually with the WAAPI community navigators and the process of planning the camp and music project has been reported in-depth elsewhere (39) however, bringing the young people together virtually to write the lyrics presented initial challenges due to the communities remaining closed. Fortunately, with support from the schools, eight virtual song-writing workshops prior to the camp were organised. These after-school virtual workshops were conducted in two Dampier Peninsula schools with SToP Trial team members in Perth, a local hip-hop artist in Broome and two hip-hop artists from Melbourne joining in via Zoom.

Lyrics for environmental health and skin infections

Aligning with the theme of skin health and environmental health, the young people learnt about the nine Healthy Living Practices (HLPs) (40) that guided key messages in the lyrics. Outlined in Table 1, these guidelines define the essential living conditions required

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2 Yarning is a culturally appropriate methodology for gathering data/ information through story sharing and engaging with Aboriginal people.

TABLE 1 Healthy living practices.

HLP 1	Washing people
HLP 2	Washing clothes and bedding
HLP 3	Removing wastewater safely
HLP 4	Improving nutrition, the ability to store prepare and cook food
HLP 5	Reducing the negative impacts of over-crowding
HLP 6	Reducing the negative effects of animals, insects, and vermin
HLP 7	Reducing the health impacts of dust
HLP 8	Controlling the temperature of the living environment
HLP 9	Reducing hazards that cause trauma

to ensure people are able to live healthy lives. Conception of the HLPs resulted from a request by Nganampa Health Council directors who provided health services to Aboriginal people in the Aṉangu Pitjantjatjara Yankunytjatjara (APY) Lands to '*stop people getting sick*'. The HLPs highlight the need for both 'health hardware' (41, 42) (e.g., functioning showers and taps, availability of a washing machine) and 'health software' (e.g., towels, soap, mattresses) within the home, while highlighting personal strategies one can employ to keep themselves free of infectious diseases. Although concepts from HLPs were embedded into the lyrics of the song, the young people created lyrics that were meaningful to them, including words such as Gubinge (Kakadu Plum) in the chorus. The young people also initiated a narrative, not related to skin health but about keeping heart, spirit, and connection strong and sung the words - '*Keep your 'Liyarn' strong, Hope you enjoy our song*' at the end of the song.

While the pandemic required innovative ways to plan the camp and produce HipHop2SToP, it also strengthened the community-driven approach and cultural integrity of the project through employing local people and contracting local organisations rather than externally outsourcing personnel. Over 20 community members (3 of whom were employed by the SToP Trial) supported the camp and provided supervision, 15 service providers and stakeholders facilitated workshops, and 41 young people attended the camp. While remote communities remained closed to non-essential visitors, travel within WA was permitted therefore a neutral location in the Dampier Peninsula that allowed face-to-face engagement was selected for the camp. With restrictions lifting to travel within WA, four staff from the SToP Trial and Kulunga³ teams who were involved in planning, were able to attend the five-day camp in person. There has been an influx of hip-hop projects in Australia in the past decade, of which several have been evaluated and contribute to the existing literature (20–24). We aim to add to the existing literature on hip-hop projects, highlighting the strengths of community leadership during COVID-19. Furthermore, there is limited research reporting locally produced hip-hop music videos in the Dampier Peninsula region of WA. Consequently, the current research project reports the perspectives of SToP Trial and Kulunga staff, community navigators

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3   Kulunga Aboriginal Units' role is to be the primary professional support service that links Aboriginal communities with researchers working at Telethon Kids Institute. Kulunga has a team based in Broome who oversee research conducted in the remote Kimberley communities.

and local organisation staff who were involved in the planning and implementation of the camp and HipHop2SToP music video. To achieve this aim, this project has two objectives:

1 To understand how project facilitators and challenges impacted planning and implementation of the music video.
2 To identify highlights and recommendations for future community led projects.

Methods

Underpinned by the philosophy of constructivism (43), we report here a qualitative process evaluation (44) of the HipHop2SToP community led health promotion initiative. Participants were selected using a purposive (45) approach and invited by TM either by email or face-to-face to participate in semi-structured interviews. These semi-structured interviews provided an opportunity for participants who had been involved in the planning and/or producing of HipHop2SToP to describe their experiences and share their perspectives on the strengths and challenges of the project. All participants were provided with information pertaining to the research project, assured of confidentiality, and advised that participation was voluntary prior to providing written informed consent. Semi-structured interviews ranged from 30 to 60 min in duration and were conducted by TM either face-to-face in Perth or Broome or virtually over MS Teams. Due to personal time constraints, two participants provided TM with written responses to the semi-structured questions.

All interviews were audio-recorded with consent and saved as a digital recording in a de-identified format. All audio recordings were transcribed verbatim and uploaded into QSR NVivo v12 (46) along with written responses. Each transcript was assigned a code number to protect participant privacy. Adhering to the question guide, the transcripts and written responses were coded independently following the broad topic areas and specific theme codes were added where new themes emerged from the data. Situated within the Patient, Provider and Practice (P3) framework (47), an inductive process was undertaken for themes emerging from the analysis. An appropriate framework to evaluate SToP Trial activities given the See, Treat, Prevent elements, the P3 framework facilitates triangulation of data from SToP Trial staff (practice and provider) and Kulunga staff (practice and provider), community navigators (patient, practice, and provider) and local organisation staff (patient, practice, and provider). The P3 framework not only conceptualises their personal worldviews (both Aboriginal and non-Aboriginal), but also considers the broader systems and policies. This is particularly important given the context of COVID-19, travel restrictions and community closures.

Ethics

This project was approved by the health ethics review committees at the Child and Adolescent Health Service (Approval number RGS0000000584), the Western Australian Aboriginal Health Ethics Committee (Reference number: 819), University of Western Australia (Reference RA/4/20/4123), Catholic Education Western Australia

(Reference number: RP2017/57) and Western Australian Department of Education (Reference number: D18/0281633).

Results

Eight participants were interviewed in this research project (seven females and one male), with four participants identifying as Aboriginal. Respondents included community navigators, researchers, and employees of local organisations, who described their own experiences of the HipHop2SToP project and reflected on the highlights and challenges of this initiative. Major themes emerging from the data revealed critical success factors as community-ownership; youth empowerment; and discovering novel ways to collaborate virtually using Microsoft (MS) and Zoom software. In addition to COVID-19 and associated travel restrictions and community closures; gaps in communication, clarification of stakeholder roles and expectations, and post-production outcomes were identified as challenges. Several participants discussed the key messaging and sustainability aspects of HipHop2SToP, highlighting local children continued to sing certain lines of the song and make the connection between healthy living practices and skin infections. Advice for future strategies included the importance of having appropriate mechanisms for directly employing local community members.

Strengths

Community leadership

All participants believed the critical success factor of HipHop2SToP was the role of the Dampier Peninsula communities in leading the project, under the guidance of the WAAPI community navigators. All participants recognised the effective leadership and guidance that community navigators provided to all stakeholders involved. While a research health promotion initiative, several participants articulated their appreciation for the culturally appropriate and respectful way that the research team worked alongside WAAPI, strengthening the integrity of the community led initiative.

> "I don't think that the outcomes would be the same and I don't think the promotional message would've got across as clearly … the community have a way of speaking to community and they have a way of gathering the community and here's a clear example of the need for it to be community driven". Local Organisation Staff

> "I think the key thing was the community control in planning and giving that directive and just, you know, the coordination from the ground." Community Navigator

> "I thought Telethon Kids staff worked really well with [the] navigators of the communities … they were given a lot of creative licence to lead [the video] work around the kind of loose general script on the purpose of the video to raise awareness around prevention of skin sores and skin health but letting the kids kind of define lyrics that they felt would resonate most about what seemed

to work really well and so the cultural integrity of the whole project was really solid because of that". Local Organisation Staff

Learning novel ways of working

While COVID-19 travel restrictions presented challenges for the planning and implementation of the camp and music video, COVID-19 also provided novel ways of working together despite the large geographical distance between stakeholders. From a research perspective, COVID-19 forced researchers to rely on and trust the community to facilitate HipHop2SToP, and this showcased the true power, resilience, and effectiveness of community led projects. This was reflected from a community navigator perspective, where COVID-19 had minimal effect as they continued to plan the project on the ground in their communities at a time when service providers and visitors were unable to visit. Responding to COVID-19 led to novel ways for all stakeholders to connect virtually via MS Teams software and enabled a community led approach to conducting research. This novel approach also enabled the young people to engage in virtual workshops after-school, putting their own ideas and cultural lens into the lyrics.

> "I think there was very minimal effect from the COVID and that's purely because of the community navigators holding a core position within community and having the capacity and resources to still engage with stakeholders out of the community and still having that position within the community to still do the community engagement." Community Navigator

> "Look I feel like we've learnt a lot during COVID and thankfully we have the sort of technology even on the Peninsula you know like in these beautiful remote areas, we were still able to connect with the kids who, who directed the writing of all the lyrics" Local Organisation Staff

> "All of a sudden with COVID times [meeting face-to-face was] no longer possible so a lot of the work for the HipHop2SToP video happened via MS teams meetings so I think that planning the song writing and bringing together people from Melbourne, and Broome and Perth as well as the communities together to write the song via MS teams was a uniquely COVID experience". Telethon Staff member

Challenges

Communication and clarity of roles

The community led camp and music project was a large collaboration involving approximately 100 people including the young people attending the camp. While those involved were able to meet virtually to discuss planning, the challenges of being unable to meet face-to-face were identified. Telethon Kids Institute and local organisation staff described difficulty at times navigating all the conversations and having clarity on the roles and responsibilities of all stakeholders involved. Clarity about the leadership of the camp and

the hip hop video (as a sub-activity of the overall camp) was challenging to establish and was re-negotiated frequently before, during and after the camp. Whilst this was a challenge, it was inevitable that this style of working together, across various organisations, geographical difference, age ranges and cultures would result in endless conversations to discover who needed to take responsibility for which aspects. Much of this also occurred during the week of the camp as emerging priorities led to daily changes. The wellbeing and needs of the young people remained central and enabled these conversations to facilitate productive resolutions and great outcomes for all.

> "I think over the course of the hip-hop there was probably over 100 different people involved from the kids, the 35 or so kids who were at the camp to the community leaders, to the CNs to the different agencies, with that many people involved there was certainly going to be some gaps." Telethon Staff member

> "I s'pose the distance between the home base of the SToP team which is really in Perth and then in Broome was hard to sort of get everyone in the same room to meet and talk, discuss it really, really in depth and yeah [being kept] in the loop with everything on my end was tough because there were conversations being had where we couldn't necessarily always be involved in and being sort of on the front line with it, it was yeah, tough trying to manage all of those conversations." Telethon Staff member

> "[In future] we have to get it right. We have to make sure that we map out who are all the stakeholders from the outset and make sure that we're continuously checking as to who is being consulted and who's being informed." Local Organisation Staff

> "I felt it was a great effort in the little time we had to plan. It was challenging to know who was leading the project at times and who was responsible for what." Local Organisation Staff

No official launch

Despite the critical success factor of community led project facilitation, COVID-19 and other priorities presented challenges post-production. Whilst acknowledging the difficulties with COVID-19 restrictions, participants described their disappointment with the post-production outcome overall, particularly with not having an official launch to celebrate what had been achieved during a challenging time. Despite this, access to the video via YouTube has ensured frequent viewings by individuals, school classes, community groups and the wider public. The video has been viewed >4,000 times on YouTube and other social media platforms.

> "There hasn't been the launch, and again post-production I feel like we had a great team, the sound guy did his job brilliantly which synced all of the video footage to the audio footage so post-production I think all worked well but there has not been an official launch". Local Organisation Staff

> "There was no one who took charge of finishing up the product and so I think that was a function of time, but I do think that we dropped the ball at that point in time and it was quite hard to manage the relationships as well as the ability to do a launch." Telethon Staff member

> "Yeah, again COVID-19 sort of restricted a lot of what [we] could and couldn't do in regard to accessing community and really trying to pump it up and pump up the ah the involvement with the kids you know, it would've been nice for us to have [an] official event to launch it you know and really make a spectacle out of it with the community but unfortunately restrictions were pretty hard and on and off in Perth as well." Telethon Staff member

Highlights

Learning about environmental health and skin infections

HipHop2SToP was a health promotion initiative and when asked about the healthy skin messaging embedded within the lyrics, several participants reported their joy in seeing the lyrics still resonating with the local Dampier Peninsula children. Participants believed the production of the music video facilitated a space for the young people to actively engage and learn practical ways to keep skin healthy. Key messages created by the young people were developed during the lyric writing workshops and reinforced throughout the week of production by the young people 'learning by doing'.

> "Yep, well in Aboriginal communities everyone knows that song and dance is the main way of us learning and learning by doing so if you got your own people on the screen doing things and singing about it, I think the message sinks in you know there's different forms, people like doing like art, music is an art." Telethon Staff member

> "Um so it made me very, very happy, it made my heart happy last week when I was told that a young boy was walking from the shower or to the shower singing 'gotta have a shower, to look after my power' and singing the lyrics of the song and that is really, that's just what we want, that was the outcome we wanted." Telethon Staff member

> "oh yeah absolutely, the lyrics were really clear, they were wonderful lyrics, and the messages were really clear, and I think it worked really well because you know they [the children] had their own spin on it, it was on their country, it was their culture, they were promoting having fun with their local cool hip hop artist but still the messaging was clear, in their own language and cultural kind of lens for it so it worked really well." Local Organisation Staff

> "... [I was] sitting in the clinic waiting room [and a parent commented to me] whatever you do you gotta keep this camp going because [the children] came back so excited and they just

can't stop talking about the music video and then they're actually singing it." Community Navigator

Empowerment and ownership

The success of having community leadership provided what the participants felt was a space for the young people involved in the camp and music project to be confident. While the interviewees had varying roles, when reflecting on the highlights of the camp and music project they all expressed their delight in observing the young people strengthening their confidence, exhibiting their creativity, engaging in all camp activities, and taking ownership of the music video.

"such a beautiful experience for myself and for the kids to see that, to have the experience of owning their own voices, I mean that's huge and also the confidence that is required to present yourself on the camera, are all confidence building skills" Local Organisation Staff

"I honestly, really loved the music workshops previous to the camp … the things that stood out to me as part of this whole process was the hip hop music video …, it was their idea [to meet] [Telethon staff and music artists] and it was like OK, we can do online stuff … that activity was really good to see the kids coming in, they were giving their own time straight after-school and just [the] expressions on their faces, you know that they were actually writing the song themselves and they were gonna sing it, helping produce it, so the idea, so that thing about empowering the youth is a big thing". Community Navigator

"I really enjoyed the hip hop video itself, seeing those kids working in different groups and then when it all came together and they started to sing in the final days and everyone was standing around listening to them, see like them having a lot of fun and we could see it all being pulled together you know you could really sense everyone's excitement that [we] pulled this off and so much professionalism around with [organisation name] the artist and all working together". Local Organisation Staff

"I think we all sort of got the same sort of highlight right towards the end you know when the kids really came out of their shell and were getting right into all of the activities especially the hip-hop". Telethon Staff member

Future strategies

Organisational processes, contracts, and systems

When discussing what could be done differently or improved on for future projects, participants reflected on lessons learnt, focusing on the importance of ensuring formal agreements were developed to clarify roles and responsibilities at the outset of the project. This was a factor of both the camp and music video being new initiatives that came together

with the additional challenges of travel restrictions during COVID-19. Despite the project evolving over many months of planning, all participants agreed that early attention to formal agreements would have strengthened the initiative. In addition, Telethon Kids Institute staff in particular discussed the need for having appropriate mechanisms for directly employing local community members. As the project was funded as a research activity, it was important to the researchers to employ local community members to lead the music video. However, this was challenging with the overlap of the camp led by WAAPI, and with most of the community members employed by this mechanism. Demonstrating reciprocity and respectful engagement in research is a high priority – and local employment is one strategy raised by local community members frequently to achieve this. This is why it was such a priority for the research staff to find ways to achieve this.

"I felt conflicted throughout the process and believe a clear agreement should have been negotiated and confirmed in writing rather than verbally." Local Organisation Staff

"I think the first and foremost one is really having at the [organisation name] a clear way in which we can appropriately employ research assistants as community navigators in community and I think that's been the goal of many of our discussions this year." Telethon Staff member

"[How to employ] the navigators directly because [they were] engaged through [organisation name] who we engaged with and for, on all accounts they we're employed as a [local organisation] employee so it was hard to know the line for them on where they fell under a Telethon Kids employee or whether they were still under a [local organisation] employee." Telethon Staff member

"I think we all learnt from this process about the importance of having clear communication about what we're doing as the activity but also about who is responsible and accountable." Telethon Staff member

Discussion

Our study provides unique insights into the facilitators and challenges experienced during the planning and production of the WAAPI community led HipHop2SToP music project during the COVID-19 pandemic. The critical success factor and major highlight for HipHop2SToP was the ground-up, community led approach that empowered local youth and communities. A community led approach to help reduce the burden of disease in Aboriginal communities has been well documented (12) and validated in our study. A strong sense of Aboriginal knowing, doing and being underpinned the philosophy of the youth empowerment camp and music video, strengthening the cultural validity and integrity of the project.

HipHop2SToP is an example of using the art of song and dance to move beyond Euro-colonial epistemologies and create inclusive approaches for where Aboriginal worldviews are centralised (22–24). Similar to the experience of the young people involved in a previous

sexual health project (20), the HipHop2SToP environment encouraged the youths 'out of their shells' to embrace their creativity. Interviewees indicated this art form provided a source of strength and engagement for health promotion messages, disseminated through a cultural and creative lens that has been used and evaluated for their contribution to health promotion (20, 21). Underpinned by environmental health and healthy skin science, the young people took ownership of the key messages, developing catchy lyrics that continue to resonate with the young people and communities of the Dampier Peninsula. Our findings move beyond the limited community engagement reported in some projects (20) and validate the need for community led health promotion where Aboriginal people's voices and culture are central to within the messaging to help facilitate ownership and strengthen sustainability (23, 24).

COVID-19 also highlighted and encouraged opportunities for local people to be employed and local organisations to be contracted rather than skills being externally outsourced, and a strong enabler of HipHop2SToP was the employment of local community members to support the camp and music project. While this was a strengths-based approach, our findings support the need for appropriate mechanisms for direct employment rather than outsourcing via third-party contracts, as this did result in confusion around roles, expectations, and responsibilities (20). We confirm virtual connection was an essential component of HiPHop2StoP but due to the large number of stakeholders and people involved, gaps in communication were experienced. Participants described it being difficult at times for everyone involved to know what was going on or how tasks were progressing. Aligning with previous research, clear communication and clarity of roles and responsibilities (20) from the outset should be emphasised for future initiatives. Establishing formal agreements between stakeholders when projects commence may help to mitigate these challenges.

Our findings also revealed participants' disappointment regarding post-production. Unlike previous Indigenous Hip Hop Projects where music videos are generally launched on the final day of production to celebrate the work, competing priorities of the media organisation producing HipHop2StoP along with COVID-19 travel restrictions, presented unfortunate circumstances post-production, leading to no official launch. Despite this, access to the video via YouTube has ensured frequent viewings by individuals, community groups and the wider public. The video has also been viewed in healthy skin educational workshops in schools across the region and shown at a range of cultural and scientific presentations about healthy skin.

Limitations and strengths

While a small sample size of eight participants, this study provides insights from stakeholders and breadth of experiences of those involved in the music project and camp. Unfortunately, given the continuing COVID-19 community closures, there were no formal interviews conducted with the young people involved in HipHop2SToP, however several anecdotal reflections from adults have been included here. This paper contributes unique insights to the body of literature describing community led approaches to health promotion and presents novel ways of planning and implementing projects during the COVID-19 pandemic.

There was an overwhelming sense of gratitude from the stakeholders involved in the HipHop2SToP project; firstly, for it to be community led with involvement from approximately 15 local stakeholders and secondly, to observe an initiative that they believed 'empowered' the young children of the Dampier Peninsula. While HipHop2SToP defied the challenges of COVID-19 travel restrictions, lessons learnt reveal the ongoing need for clear and effective communication in health programs in addition to developing appropriate mechanisms for organisations to employ local community members. HipHop2SToP is an exemplar of Aboriginal leadership ensuring a strong sense of culture emanated throughout HipHop2SToP and this evaluation research project. While future health promotion music projects may not experience the challenges of COVID-19 restrictions, they would benefit from adopting this community led approach and negotiating roles and responsibilities clearly from the outset. Strengthening post-production outcomes by including a launch and well-planned, targeted communication and dissemination strategy will ensure the wider translation of important health messages and likely sustainability.

To view HipHop2SToP please click on the lick at: https://www.youtube.com/watch?v=7eLLO9EuOiI.

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 studies involving humans were approved by Child and Adolescent Health Service (Approval number RGS0000000584), the Western Australian Aboriginal Health Ethics Committee (Reference number: 819), University of Western Australia (Reference RA/4/20/4123), Catholic Education Western Australia (Reference number: RP2017/57) and Western Australian Department of Education (Reference number: D18/0281633). The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Author contributions

TM: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – original draft. RW: Conceptualization, Supervision, Writing – review & editing. SE: Formal analysis, Writing - review & editing. HT: Writing – review & editing. JJ: Project administration. SS: Project administration. MM: Project administration, Writing - review & editing. NM: Project administration. JCo: Supervision, Writing – review & editing. JCa: Supervision, Writing – review & editing. AB: Funding acquisition, Supervision, Validation, Writing - review & editing.

Funding

Acknowledgments

Conflict of interest

Publisher's note

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Clinical trial capacity building in a pandemic—outcome of a rapid site readiness project in Latin America

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Background: Latin America (Latam) has a tradition of large-scale vaccine trials. Because of fluctuating demand, many sites have downsized their infrastructure. Therefore, BMGF launched a clinical trial site-readiness initiative early in the coronavirus-2019 (COVID-19) pandemic including Latam countries between August and September 2020. This survey evaluated clinical development performance measures pre/post initiative (September 2022).

Results: 20/21 prequalified sites participated in COVID-19 vaccine/drug development trials. 156 clinical trials (140 COVID-19 vaccine/drug trials) were initiated in the 2 years since prequalification, compared to 176 in the 5 years before. 33,428/37,810 participants were included in COVID-19 programs. The number of enrolled subjects/day across sites quadrupled from 15 (1−35) to 63 (5−300). The dropout rate was 6.8%. Study approval timelines were reduced from 60 (12−120) to 35 (5−90) days. Mean qualified staff was increased from 24 (6−80) to 88 (22−180).

Conclusion: Clinical trial sites across Latam were successfully prequalified to participate in COVID-19 developments. For the 100 days mission of vaccine availability in a new pandemic sufficient and well-trained clinical trial sites readily available are essential. This is only achievable if sites—especially in low/middle-income countries—are maintained active through a constant flow of vaccine studies.

KEYWORDS

site capacity building initiative, clinical trial site, COVID-19, Latin America, clinical development, success metrics

1 Introduction

Timely vaccine development is paramount in pandemic management (1). Clinical trials are the gold standard for evidence generation, ensuring unbiased estimates of vaccine efficacy and safety data for vaccine emergency use authorization (EUA) and licensing. The coronavirus-2019 (COVID-19) pandemic exposed the need to improve the clinical trial research capacity in Low-middle-income countries (LMICs). Given the severe acute respiratory syndrome 2 (SARS-CoV-2) epidemiology, population diversity, and a

long-standing tradition of large scale efficacy trials for global vaccine development [i.e., Cholera, Rotavirus, PCV, HPV, Dengue vaccines (2–6)], Latin America (Latam) was considered an attractive region for conducting vaccine trials during the SARS-CoV-2 pandemic. Unfortunately, because of fluctuating demand, many Latam sites engaged in previous large-scale trials had to downsize infrastructure, leading to an inability to engage quickly and efficiently at the beginning of the COVID-19 pandemic.

To support clinical trial site readiness and fast recruitment in the pandemic, the Bill & Melinda Gates Foundation (BMGF) launched, in August 2020, the COVID-19 site readiness initiative in Latam, Africa and Asia, to prepare sites and enhance their capabilities for conducting large scale COVID-19 vaccine trials. A grant was provided to the PDP partner "Instituto D'OR de Pesquisa e Ensino (IDOR)," as product development partner to prepare and qualify clinical trial sites for large scale COVID-19 vaccine trials in Latam. The project was implemented between August–November 2020 in 21 sites across 7 Latam countries (7). Sites which were qualified received grant funding to upgrade infrastructure, processes and resources for large trials in the midst of a pandemic. This paper discusses outcomes of the site readiness initiative.

2 Materials and methods

The aim of the BMGF project was clinical trial capacity building to ensure readiness for large scale COVID-19 vaccine development. Selection/qualification occurred between August–November 2020 and is described elsewhere (7). In short, potential sites were considered for inclusion if they had prior experience with vaccines or infectious disease clinical trials, were not yet involved in COVID-19 trials, could be qualified within 4 months including staff scale up, and were located in a country with EUA procedures in place. Of 34 potential sites from 10 countries, 22 sites in 7 countries were selected, trained and qualified. One site was qualified but, due to delays in regulatory site approval, was not included in the program. Qualified site information was shared on the COVAX website and directly with interested stakeholders.

Criteria of project success as defined by sponsor/principal investigator were:

1 ≥ 50% of qualified sites participated in COVID-19 vaccine development ≤4 months of qualification;
2 ≥1/4 of sites initiated their first COVID-19 study within 2020;
3 The number of trials at least doubled compared to the historical number;
4 Participant recruitment rate at least tripled compared to the historical number;
5 Dropout rate overall/by site of ≤10%;
6 Approval timelines, as an indirect measure of the site interaction with national regulatory authorities (NRAs) and institutional review boards (IRBs) ≤3 months;
7 Staff to meet trial demands (qualitative criterion).

To assess the outcomes of the site readiness initiative a follow-up questionnaire on key performance metrics was distributed by an external vendor in a Health Insurance Portability and Accountability

Act (HIPAA) compliant online format to the principal investigators of the sites involved, in September 2022, 25 months after project initiation.

A descriptive analysis and comparison of clinical development metrics pre/post project based on the follow-up questionnaire was performed.

3 Results

Twenty of the qualified 21 sites (95%) across 7 countries were included in the COVID-19 vaccine development program: Brazil 6, Colombia 5, Dominican Republic 1, Guatemala 1, Honduras 1, Mexico 3, Peru 3 (Table 1). All sites had their first COVID-19 trial initiated within 4 months after qualification;6 started their first COVID-19 trials still in 2020, meeting the predetermined project goals 1 and 2.

Over the 5 years prior to the award, the 20 sites were executing 179 clinical trials (mean 5, range 0–12 per site) compared to 156 new clinical trials initiated in the 2-year survey period. Goal 3 was not met but the inclusion period was much shorter; 140/156 were COVID-19 trials. Trial sponsors were diverse—multinational companies, local/global biotechs, academia and MoH's as were vaccine platforms tested: mRNA, DNA, viral vector, inactivated, and adjuvanted protein subunit vaccines. Of note, 11/16 non-COVID-19 trials—mostly phase II/III—initiated during the pandemic were for other vaccines: chikungunya, RSV, dengue, norovirus, influenza and Ebola.

The main goals of the site readiness project were rapid high number recruitment into the COVID-19 clinical vaccine development and quality execution. The mean number of enrolled subjects/site/day by the 20 sites quadrupled from 15 (range 1–35) to 63 (range 5–300), meeting project goal 4. The total number of participants enrolled was 33,428 (6 sites ≥ 3,500 participants), mostly in COVID-19 vaccine efficacy trials. The abovementioned other vaccine programs included an additional 4,382 subjects, for a total number of 37,810 enrolled subjects in the approximately 25 months from qualification to survey.

Dropout rate, a key performance indicator of protocol adherence and study site quality, was on average 6.8%: 13 sites had dropout rates of ≤5%; 4 > 5%—≤10%, and 3 > 10%. The overall goal of dropout rate of less than 10% was met despite the complexity of doing clinical studies during a pandemic;17/20 sites also met the individual site goal.

A core element of the training process of sites was early engagement of local stakeholders (NRAs, IRBs) and involvement in study plans to reduce review/ approval timelines. This was achieved: timelines went down to 35 days (range 5–90) compared to the historical 60 days (range 12–120). Goal 6 was met, although it has to be acknowledged that the emergency procedures in place during the COVID-19 pandemic were most likely the main driver.

The ability to have access to, hire and (re)train a sufficiently high number of staff in GCP/study procedures was critical for project success. Staffing increased from a mean of 24 across sites (range 6–80) to 88 (range 22–180) within 4 months (Figure 1).

4 Discussion

The COVID-19 fast vaccine development has substantially altered the course of the pandemic, saving millions of lives. A bottleneck in clinical development was the number of qualified trial sites able to

TABLE 1 Sites qualified during the readiness project and involved in COVID-19 trials.

|	Country	City	Site name
1	Brazil	Porto Alegre	Hospital de Clinicas de Porto Alegre (HCPOA)
2	Brazil	Natal	Instituto Atena de Pesquisa Clinica
3	Brazil	Belem	Instituto Evandro Chagas
4	Brazil	Santa Maria	Universidade Federal de Santa Maria (UFSM)
5	Brazil	Rio de Janeiro	Instituto D'OR de Pesquisa e Ensino (IDOR Gloria D'OR)
6	Brazil	Natal	Centro de Estudos e Pesquisas em Molestias Infecciosas
7	Colombia	Barranquilla	Clinica de la Costa
8	Colombia	Bogota	Centro de Atencion e Investigacion Medica (Caimed)
9	Colombia	Cali	Centro de Estudios en Infectología Pediátrica (CEIP)
10	Colombia	Barranquilla	Clinica de la Costa
11	Colombia	Bogota	Centro de Estudios en Infectología Pediátrica (CEIP)
12	Dominican Republic	Santo Domingo	Fundacion Dominicana de Perinatología Pro-BEBE -HMNSA
13	Guatemala	Guatemala City	Centro de Estudos Clinicos Salud Avanzada (CECLISA)
14	Honduras	San Pedro Sula	Demedica
15	Mexico	Mexico City	Centro de Atención y Investigación Medica (Caimed)
16	Mexico	Guadalajara	CidVID Investigación Biomédica (IBIOMED)
17	Mexico	Aguascalientes	CidVID Investigación Biomédica (IBIOMED)
18	Peru	Lima	Investigaciones Medica en Salud
19	Peru	Lima	Instituto de Investigazion Nutricional
20	Peru	Lima	Universidad Peruana Caetano Heredia

initiate and execute large efficacy trials rapidly in the most affected regions. The BMGF clinical trial site readiness program was important in enabling Latam sites to fill that gap and help generate scientific evidence for rapid vaccine EUA.

In Latam, 20 clinical sites from 7 countries were qualified in the project. Details were immediately shared globally for suitable site selection. After site qualification, the number of participants/site/day quadrupled compared to historical data, regulatory/IRB approval timelines were reduced to half, and the number of trained staff was built up in time and scale to meet demand. As an example, four Brazilian sites that qualified early in the readiness project were successfully involved in conducting a large efficacy phase III trial recruiting, together with 2 other sites, 10,416 participants in 3 months. Participant retention rate and protocol compliance was high. Data generated contributed to about half of the clinical data used to approve the ChAdOx1 nCoV-19 Oxford AstraZeneca vaccine for emergency use globally (8, 9). Likewise, project sites in Colombia and Brazil contributed almost half of the 30,000 subject efficacy trial of an adjuvanted recombinant subunit vaccine developed by the Chinese biotech Clover and funded by CEPI, which now has EUA in China (10, 11).

The reduction of approval timelines is probably mainly due to changes in policies by- and international reliance between regulatory agencies and of IRBs. However, site staff was trained to interact with and involve agencies early in the projects to better understand their requirements upfront. Rapid participant recruitment and protocol adherence are critical for every successful clinical trial. Delays or quality issues in a trial lead to delays in EUA or licensure with a consequence of unnecessary morbidity and mortality. Therefore, the

fast recruitment capability of the selected sites, with up to 300 participants enrolled per day, along with a low drop-out rate of just 1/15 participants in an ongoing pandemic reflect the success of the site readiness initiative. Comparisons of historical dropout rates are difficult as there are many confounders, such as trial duration, population, or number of invasive procedures. As the majority of participants were enrolled in efficacy trials with long-term follow-up, the benefit for the participant waned and adherence declined over the trial. National immunization policies changed during the study period. As participants were blinded, some opted to get COVID-19 vaccines from governmental sources. Another phenomenon contributing to drop-outs was vaccination tourism to the US due to easier vaccine access. Also, some participants did not adhere to the follow-up visits after being fully vaccinated to avoid social contact. However, from our own long experience with vaccine efficacy trials in Latam, a dropout rate of 6.8% in vaccine efficacy trials with long follow-up is reasonable. In another COVID-19 vaccine efficacy trial performed in Brazil and in sites which were not included in the site readiness project, the drop-out rate was more than double (12).

One of the cornerstones of quick recruitment is the training and qualification of new staff, which leads to high and fast participant enrolment, maintaining data quality and accuracy. Recruitment of staff was possible as there was a pool of individuals who had been involved in earlier projects but, because of instability in clinical trial demand, were made redundant. While recruitment was generally smooth, it still took substantial time to on-board the number of professionals needed to be up to the task. All re- or newly hired staff were highly motivated given the purpose for which they were hired. Our data show that most sites retained additional staff even after the
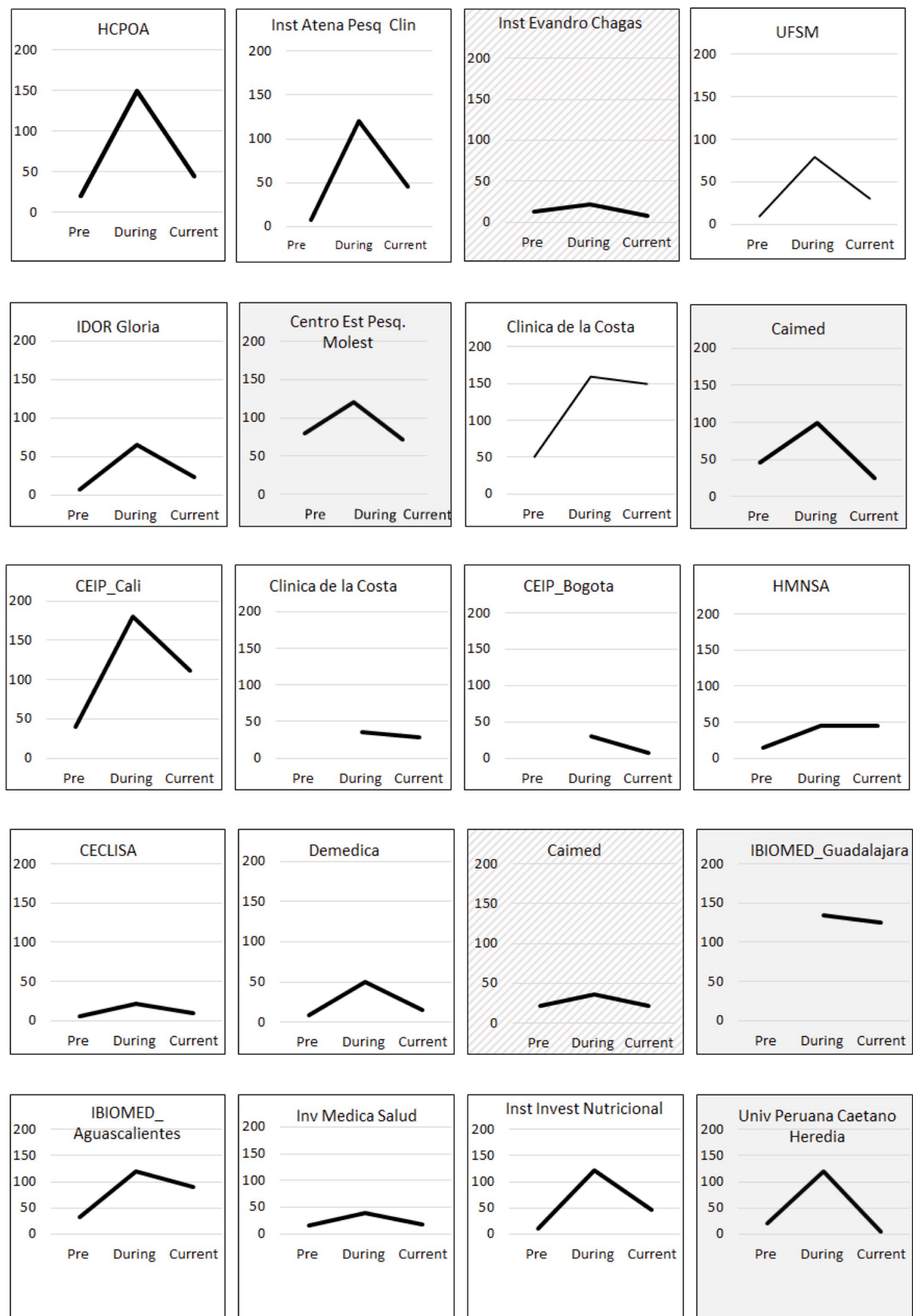
FIGURE 1
Total staff hired by site (y axis) before qualification (Pre), at the peak of demand during the COVID-19 pandemic (During) and by September 2022 (Current). Shaded and hashed boxes correspond to sites where current staff hired is lower or the same as before qualification, respectively.

peak in COVID-19 trials (during the pandemic) compared to before the readiness project (Figure 1).

An important lesson learned from this pandemic is that the retention of professionals in the regulatory and clinical trial environments in LMICs is key if we are to stand a chance to accomplish the ambition CEPI and governments to have vaccines available within 100 days of pathogen sequencing in a new pandemic. Clinical trial sites in LMICs, from where most likely novel pathogens will emerge, need to be kept "warm" by a constant flow of other vaccine studies in interpandemic times. This is a task and should also be a moral obligation for developing country vaccine manufacturers and even more so for the globally leading multinational companies (13).

There have been some positive trends recently with an increase in clinical trials including vaccines conducted in Latam. Data from clinicaltrials.gov shows that active vaccine trials in Latam went from 6 (2019–2020), to 16, 37 and 38 over the following 3 years. While encouraging, it is by far not enough to sustain infrastructures. The COVID-19 pandemic has underscored that the sustainability of clinical trial capacity in LMICs is crucial for the future, with increased focus on the preparedness for future epidemics and pandemics (14). As shown by our study, an improvement in clinical trial readiness has been achieved in Latam and needs to be maintained and cultivated, including the competitive timelines for regulatory and ethical approvals. Investments in local laboratory capacity building are mandatory, avoiding logistical challenges of shipping samples from Latam to labs in high income countries, which in the COVID-19 pandemic, with massive interruptions of air traffic, caused unnecessary delays. Finally, implementing a network of qualified sites with central/ shared governance for attracting large-scale trials stands out as a priority.

Limitations of the global BMGF project were different speed of site qualification by geography, which was mainly based on the differences in prior site experience and hence baseline status. The site readiness was constantly provided to the COVAX website to which manufacturers had access. As more sites were qualified in Latam, and earlier, the jump in recruitment in Latam was just a pragmatic approach of developers and not an indication of a genuine preference over other geographies.

A limitation to our study is that the original project design, implementation and follow-up were carried out by the same team, which may have led to biases. However, performance assessment against preset metrics was done by an external vendor and shared with the project team. Another limitation is that the direct impact of the project on approval timelines is not quantifiable. Most likely, the EUA's procedures were the main driver but the sites investigators facilitated the reviews and decisions by NRAs and IRBs through early and continuous interactions. Given site performance data is usually private and not publicly available, we could not adequately compare our outcome data with those of other sites outside our project. However, based on the experience of some authors, who have extensive large scale clinical development experience in the region, the project sites stand out with respect to time and quality metrics.

In conclusion, the BMGF site readiness project contributed to the successful inclusion of 20 qualified Latin American sites in COVID-19 clinical development, including vaccine efficacy trials, and thus providing scientific evidence for rapid vaccine EUA. This was important in the global context, and also regionally, by providing local data. The project was immediately accepted by potential sponsors as evidenced by the substantial increase in trials and subjects. High trial quality was maintained as evidenced by low dropout rates. For the 100 days ambition (14) for vaccine availability in a potential new pandemic, it is essential that sufficient and well-trained clinical trial sites are readily available. This can only be achieved if sites are maintained active not only in high income countries, but especially in LMICs through a constant flow of vaccine studies.

Data availability statement

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

Ethics statement

Ethical approval was not required for the study involving humans in accordance with the local legislation and institutional requirements. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent to participate in this study was not required from the participants in accordance with the national legislation and the institutional requirements.

Author contributions

SC, RC, and DS contributed to the conception and design of the study. DS organized the database. RC, DS, and IG wrote the first draft of the manuscript. All authors contributed to the article and approved the submitted version.

Funding

Acknowledgments

Conflict of interest

SC declares that she is Senior Advisor to the BMGF. She has various academic appointments including a professorship/chair at the University of Oxford, none of which constitutes a conflict of interest. RC is Member of the Board of Trustees of IVI and Senior Advisor to

the BMGF. He is Board Member/Chair of Scientific Advisory Boards of various vaccine related Biotech companies, none of which constitutes a conflict of interest. DS was employed by Wit I.C.T. Consulting.

The remaining author declares 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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