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Contents

Protocols

Protocol

Impact of Remote Symptom Management on Exercise Adherence After Video-Assisted Thoracic Surgery for Lung Cancer in a Tertiary Hospital in China: Protocol for a Prospective Randomized Controlled Trial

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Abstract

Background: Regular pulmonary rehabilitation exercises are crucial for patients with lung cancer after surgery. However, poor adherence to outpatient exercises is difficult to address due to inadequate supervision. The integration of remote symptom management through electronic patient-reported outcomes (ePROs) offers a potential solution to improve adherence by enabling more effective monitoring and intervention.

Objective: This study aims to evaluate the impact of ePRO-based remote symptom management on enhancing adherence to outpatient pulmonary rehabilitation exercises following video-assisted thoracic surgery for lung cancer.

Methods: In this single-center, prospective, randomized controlled trial, 736 patients undergoing minimally invasive lung resection will be recruited. All patients will use a smartphone app for perioperative management, allowing periodic PRO measurement and recording of exercise participation. Upon discharge, patients will be randomly assigned 1:1 into either an intervention or control group. The intervention group will complete the Perioperative Symptom Assessment for Patients Undergoing Lung Surgery (PSA-Lung) scale on the day of discharge and postdischarge days 3, 7, 14, 21, and 28. Alerts will be triggered at the provider side if any of the 5 core symptoms (pain, cough, shortness of breath, sleep disturbance, and fatigue) scored ≥4, prompting remote symptom management. The control group will complete the PRO measures without triggering alerts. The primary outcome is the rehabilitation exercise adherence rate. Secondary outcomes include postdischarge pulmonary complication rate, 30-day readmission rate, trajectory of symptom severity changes, exercise participation rate, and patient satisfaction.

Results: The enrollment of study participants started in December 2023 and is expected to end in March 2025. The final comprehensive analysis of the results is planned for May 2025, after all data have been collected and thoroughly reviewed.

Conclusions: This study is among the first to investigate the feasibility and effectiveness of ePRO-based remote symptom management in enhancing rehabilitation adherence after video-assisted thoracic surgery for lung cancer. If successful, this approach could significantly influence postoperative care practices and potentially be adopted in similar settings.

Trial Registration: ClinicalTrials.gov NCT05990946; https://clinicaltrials.gov/study/NCT05990946

International Registered Report Identifier (IRRID): DERR1-10.2196/60420

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KEYWORDS

thoracic surgery; rehabilitation medicine; patient-reported outcome measures; patient participation; telemedicine; eHealth; mobile phone

Introduction

Lung cancer remains a predominant cause of cancer-related morbidity and mortality worldwide. Specifically in China, the incidence rate reached 828,000 cases in 2016 [1]. Non–small cell lung cancer is the most prevalent subtype. With the increasing adoption of lung cancer screening, more patients are being diagnosed at early stages. Surgical resection is the gold standard for treating early-stage, non–small cell lung cancer, and the paradigm of enhanced recovery after surgery has been widely adopted in perioperative care [2].

While enhanced recovery after surgery effectively shortens inpatient stays, its benefits are often offset by inadequate outpatient management stemming from limited resources, which can adversely affect clinical outcomes and postdischarge quality of life [3]. One critical factor in postoperative recovery is adherence to pulmonary rehabilitation exercises. However, adherence rates are suboptimal due to insufficient supervision and guidance.

Following discharge, many patients face decreased exercise adherence rates, ranging from 50% to 70% according to studies focusing on patients with musculoskeletal disorders [4-6]. Several factors influence adherence, including self-efficacy, personal beliefs, sense of self-control, physical and psychological condition, clinical symptoms like pain, and perceived forgetfulness [7-11].

Moreover, many patients continue to experience symptoms such as coughing, pain, poor sleep, and breathlessness after discharge, which may substantially undermine their exercise adherence [12]. In the era of patient-centered care, remote symptom management through electronic patient-reported outcomes (ePROs) is emerging as a promising approach to improve outpatient quality of life and reduce postoperative complications [13-16]. By providing effective strategies for timely monitoring and managing patients' symptoms, ePRO-based interventions may help patients overcome barriers to exercise and enhance their self-efficacy and motivation, thus promoting exercise adherence [17].

There is a pressing need for research to investigate the impact of postoperative symptoms on exercise adherence and to evaluate whether ePRO-based remote symptom management can effectively improve adherence to outpatient rehabilitation exercises [18,19].

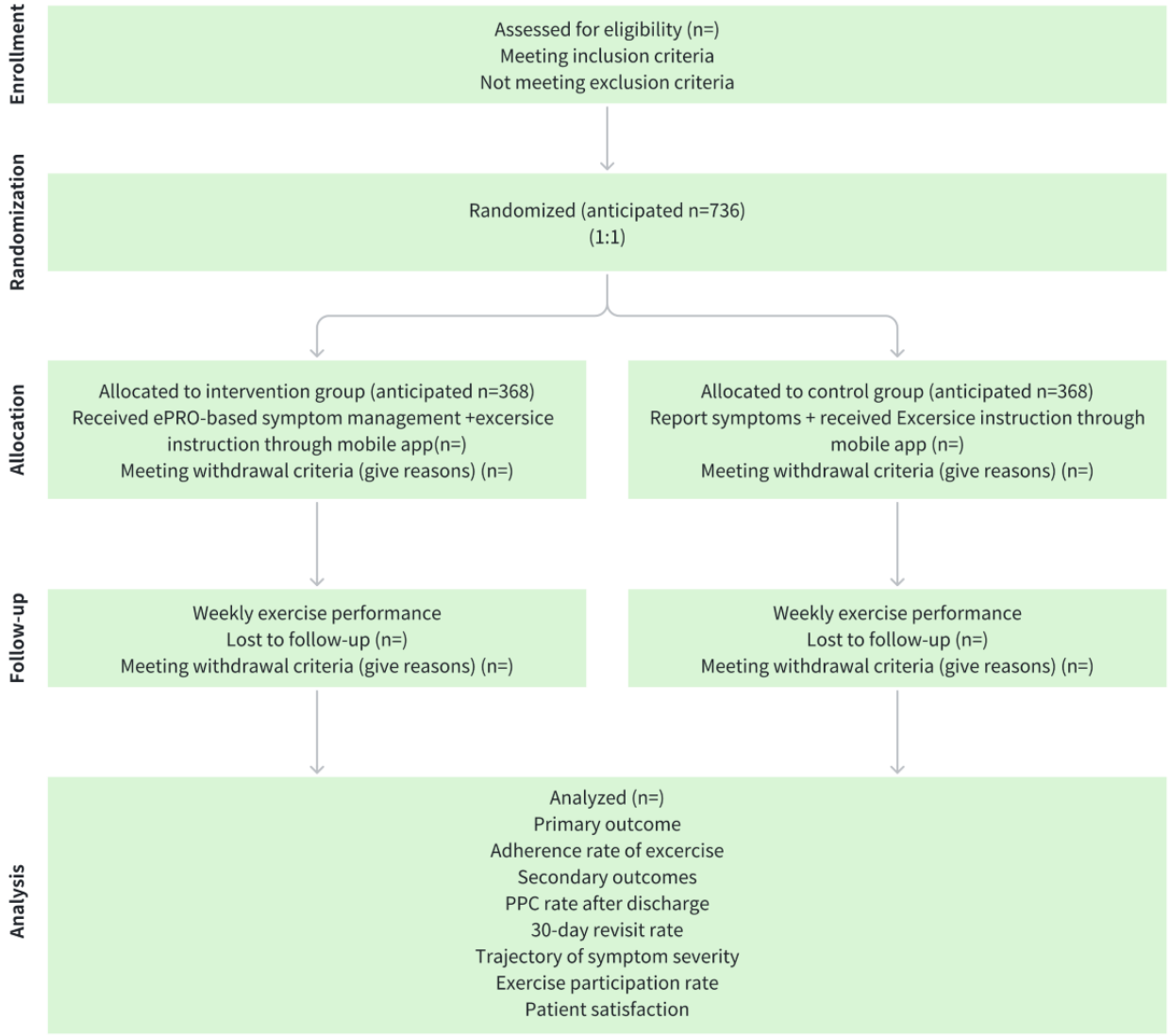
Therefore, this study aims to assess the feasibility and preliminary effects of remote symptom management based on ePROs on enhancing adherence to outpatient rehabilitation exercises after video-assisted thoracic surgery (VATS) for lung cancer. A prospective, randomized controlled trial study design is adopted to provide new strategies for rehabilitation management in patients with lung cancer. We hypothesize that remote symptom management based on ePROs can improve exercise adherence in patients with lung cancer after VATS compared with usual care.

Methods

Study Setting

This is a single-center, prospective, superiority, randomized controlled trial, consistent with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines [20]. Participants will be recruited from the Department of Thoracic Surgery, Zhongshan City People's Hospital, Guangdong, China, which performs approximately 600 lung cancer surgeries annually. The findings will be reported based on the CONSORT (Consolidated Standards of Reporting Trials) guidelines [21]. The study flowchart is shown in Figure 1. This trial has been registered on ClinicalTrials.gov (NCT05990946), where detailed information about the study protocol, inclusion and exclusion criteria, interventions, outcomes, and ethical approval can be found. The trial registration process was completed before the enrollment of the first participant.

Figure 1. Flowchart of this parallel-group randomized controlled trial. ePRO: electronic patient-reported outcome; PPC: postdischarge pulmonary complication.



Eligibility Criteria

Inclusion criteria for the participants are (1) being aged 18-75 years; (2) undergoing VATS, including lobectomy or segmentectomy; (3) being able to use smart devices and completing electronic questionnaires; and (4) providing informed consent. The exclusion criteria are (1) conversions to open thoracotomy during surgery, (2) preoperative Eastern Cooperative Oncology Group score >1, (3) received neoadjuvant therapy, (4) previous thoracic surgery history, (5) unable to exercise due to physical impairments, (6) continuous systemic corticosteroid use within 1 month, (7) unresolved toxicity above grade 1, (8) significant medical history, (9) uncontrolled comorbidities, (10) postoperative length of stay >14 days, and (11) other unsuitable conditions in the investigator's judgment.

Participant Recruitment

Patient recruitment will commence before discharge, including preoperative patients awaiting scheduled surgery. Eligible patients will be randomly assigned before discharge after confirming they can properly operate the smartphone app. After discharge, patients will be reminded to use the app for symptom and exercise logging. The app provides an incentive for participating in the 4-week rehabilitation program between discharge and the first postoperative clinic visit.

Randomization and Allocation Concealment

Each potential participant will be assigned a unique 3-digit screening number in sequence. Eligible participants will be randomly allocated 1:1 to the intervention and control groups.

Randomization will be performed using a central Interactive Web Response System (IWRS), which is deployed on a third-party platform (Huawei Cloud) and was developed by the Shuyu app development team. The IWRS uses a block randomization algorithm to generate the allocation sequence and ensure balance between the treatment groups. After confirming eligibility, the study site will enter participant information into the IWRS and receive the allocation. Withdrawn participants will retain their randomization number without re-enrollment. The randomization code will be securely stored in the IWRS throughout the study.

Blinding

Due to the nature of interventions, blinding of participants and care providers is not feasible. However, data collectors and statisticians will be blinded to group allocation. The data collectors, who are research nurses, will be trained to administer questionnaires and collect data consistently according to the study protocol. They will collect data at baseline through in-person interviews and then weekly for 4 weeks after discharge through telephone interviews.

Interventions

Participants will use the app "Shuyu" (Module type: TH001, Developed by Shanghai CinoCore Health Technology Co) for perioperative management.

Preoperatively, nurses will instruct app use and provide education. The app will assign individualized exercises and prompt logging. Patients will complete baseline PRO measurements. The Perioperative Symptom Assessment for Lung Surgery (PSA-Lung) was used for PRO assessments. The PSA-Lung scale includes 7 symptom items (pain, coughing, shortness of breath, disturbed sleep, fatigue, drowsiness, and distress) and 2 functional items (interference of activity and walking). Each symptom's severity was rated between 0 (the absence of symptom) and 10 (the worst imaginable symptom). Similarly, functional items were also rated on a scale between 0 (no interference) and 10 (complete interference). The PSA-Lung scale development team has verified its reliability and validity in patients who undergo lung cancer surgery, and the research results suggested adequate reliability and validity. The relevant articles have been submitted for publishing, and the preliminary results were announced at the 28th Annual Conference of the International Society for Quality-of-Life Research [22]. Permission to use the PSA-Lung scale in this study has been obtained from the scale development team.

Postoperatively during hospitalization, nurses will guide app-based rehabilitation, doctors will supervise exercises and PROs, and patients will complete daily PROs without alerts.

Before discharge, the care team will evaluate if patients can properly operate the app. Eligible patients will be randomly allocated into groups by the nurse entering the patient's screening number and discharge date in the provider app. Based on the pregenerated randomization code from the central system, this process will automatically allocate patients into the intervention or control group, unlocking the corresponding outpatient module.

After discharge, the app continues to offer postoperative education and exercise logging, sending daily reminders at 9 AM and follow-ups at 5 PM if logs are incomplete. Weekly phone checks by staff will confirm exercise log accuracy. Noncompliance or inaccessibility after 3 phone attempts will result in protocol violation and withdrawal.

Reminders for PRO assessments are set for 9 AM on the day of discharge and on postdischarge days 3, 7, 14, 21, and 28. A follow-up reminder will be sent at 5 PM if the assessment remains uncompleted. These assessments must be completed on the specified days, and the analysis will include patients who have logged exercises but have not submitted PRO assessments. For participants who are unable to continue using the ePRO system, a manual follow-up plan will be implemented to collect PRO data through telephone or email on the day following the scheduled assessment days to avoid conflict with system reminders.

Comparison

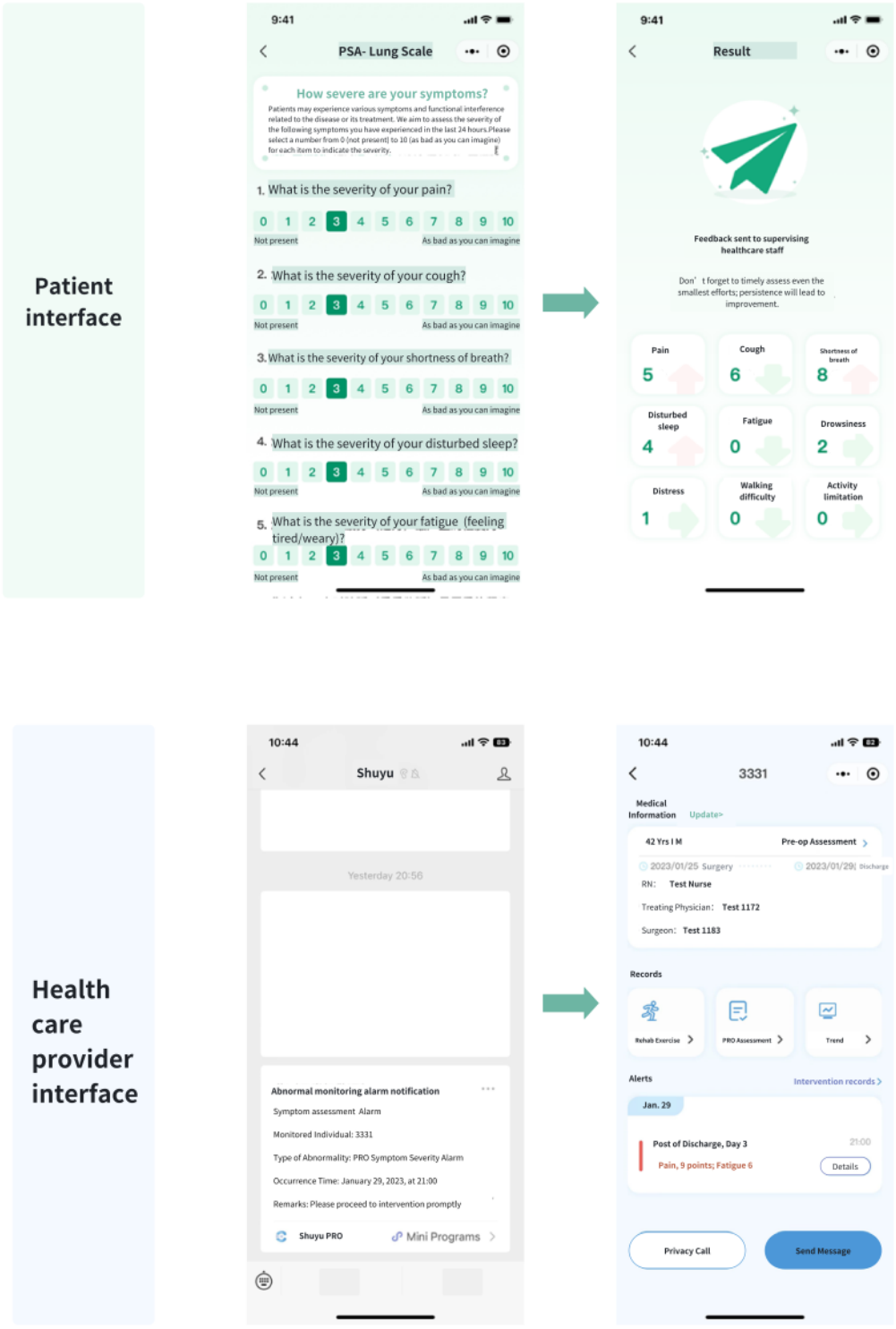
Intervention Group

The intervention group will be notified to complete the PRO measures on the designated days.

If any of the 5 core symptoms (pain, cough, shortness of breath, sleep disturbance, and fatigue) scored ≥4 in the ePRO questionnaire, alerts will be triggered on the provider end, prompting the assigned doctor and nurse to initiate remote guidance and intervention through the app through text or phone call within 24 hours following standardized procedures in the operation manual. Interventions will be based on PRO scores and include recommendations for self-management, medications, and clinic visits. In addition, patients who report any of the 5 core symptoms will immediately receive automated internet-based self-management suggestions generated by the system after submitting the PRO questionnaire.

The intervention will focus on the management of these 5 core symptoms since they were identified as critical symptoms for postoperative management in previous studies on remote PRO-based symptom management after lung cancer surgery in China [16]. Based on recommendations from the National Comprehensive Cancer Network and published studies, symptom scores ≥4 are considered moderate severity or above [23,24]. Therefore, a symptom score of 4 is set as the threshold for triggering alerts. Details of the patient self-reporting process and health care provider alert interface are shown in Figure 2.

Figure 2. Workflow of patient self-reporting via the shuyu app and healthcare provider alert interface.



Symptom management in the intervention arm will adhere to the latest guidelines and be standardized across providers through standard operating procedure manuals, as shown in Multimedia Appendix 1. In cases of severe symptoms, physicians may advise patients to temporarily pause or adjust their exercise plans to ensure safety.

Control Group

The control group will complete PRO measures on the same days without triggered alerts or self-management suggestions.

All patients, regardless of group assignment, will receive guidance on seeking medical attention through conventional means for severe symptoms. Severe symptoms are defined as individual symptom scores ≥6 on the PSA-Lung scale.

Withdrawal Criteria

Participants meeting the following withdrawal criteria will be removed from the analysis: (1) no primary lung cancer on pathology, (2) non-microscopically complete resection, (3) stage IV disease, (4) initiation of adjuvant therapy during follow-up, (5) severe protocol violation (nonadherence to instructions, random responses, etc), and (6) voluntary withdrawal.

Study Outcomes

Primary Outcome

The primary outcome is the rehabilitation exercise adherence rate over 4 weeks after discharge, defined as the proportion of patients completing the prescribed outpatient exercise regimen. Exercise completion will be ascertained based on patient self-reports through the app and verified through weekly phone follow-ups. Referencing exercise guidelines for cancer survivors from the American Cancer Society, ≥150 minutes of moderate to vigorous intensity physical activity per week (equivalent to 150 minutes of brisk walking) is considered adherent [25].

Secondary Outcomes

Secondary outcomes are listed in Textbox 1.

Textbox 1. Secondary outcomes and their measurement criteria.

- Postdischarge pulmonary complication (PPC) rate
  - Proportion of patients experiencing pulmonary complications within 30 days after discharge. Complications will be graded using the Clavien-Dindo classification [26], categorizing PPCs into 5 grades, as shown in Multimedia Appendix 2.
- 30-day revisit rate
  - Proportion of nonscheduled revisits within 30 days after discharge.
- Trajectory of symptom severity
  - Changes in symptom and interference scores on the electronic patient-reported outcome questionnaire from discharge to 30 days after discharge.
- Exercise participation rate
  - Number of days with exercise logged within 4 weeks after discharge. Any day with exercise logged is considered participation, regardless of whether the target duration is achieved.
- Patient satisfaction: score on the 4-item questionnaire including
  - Whether the app helped with rehabilitation and symptom control;
  - Overall satisfaction rating;
  - Whether the app caused daily life disruption; and
  - Likelihood of recommending the app to others. Each item is rated from 0 to 10.

Other Data

The study will record time intervals from alert to provider intervention in the app backend. Questionnaires and interviews will also survey provider acceptance of the app. Participant demographic information, tumor characteristics, clinical management, treatment outcomes, adverse events, and follow-up data will be collected at different time points. All adverse events will be evaluated and managed by thoracic surgeons.

Sample Size

The primary outcome is the rehabilitation exercise adherence rate, defined as the proportion of patients completing the prescribed exercise regimen. Adherence is defined as completing the prescribed exercise regimen, calculated from self-reported app data and verified through weekly follow-ups.

The sample size was calculated to detect a 10% difference in adherence rates between the intervention and control groups, with 80% power and a 2-sided significance level of .05. The control group adherence rate was assumed as 70% based on previous studies [27-30]. The 10% clinically important difference was determined through expert consultation, considering their practical experience and the potential impact on patient outcomes, despite limited direct literature support. The dropout rate was estimated as 20% from previous digital intervention trials (from 3.75% to 18.3%) [31-33]. Dropouts include discontinuation of app use and loss of follow-up.

Using a z test with a 10% proportion difference, 80% power, 5% type I error, and 20% dropout rate, the required sample size is 368 per group, 736 in total.

Data Analysis

Statistical analyses will be performed based on both the intention-to-treat principle and the per-protocol principle. The intention-to-treat population will include all randomly assigned participants, while the per-protocol population will include participants who provide baseline PRO data and measures for at least 2 additional time points, with at least 1 calculable weekly exercise duration logged. Participants meeting withdrawal criteria will be excluded from all analyses. Statistical inferences

will adopt 2-sided tests at a significance level of .05, with 2-sided 95% CI for estimation. The primary outcome, exercise adherence rate, will be compared between groups using the Pearson χ^2 test or Fisher exact test. Secondary outcomes will be analyzed as follows: PPC rate and 30-day revisit rate will be compared using χ^2 test or Fisher exact test; symptom severity trajectory, which involves repeated measurements, will be assessed using linear mixed effects models to account for within-subject correlation; exercise participation rate will be compared using Wilcoxon rank sum test; and patient satisfaction scores will be compared using the Student 2-tailed *t* test or Wilcoxon rank sum test. The time from alert to intervention and provider acceptance will be summarized descriptively. Baseline characteristics will be compared using 2-tailed *t* test, Wilcoxon rank sum test, χ^2 test, or Fisher exact test, as appropriate. Missing data will be handled through multiple imputation or maximum likelihood estimation methods.

Data Monitoring and Interim Analysis

A Data Safety Monitoring Board will be set up, including 1 clinical physician and 1 data manager, to conduct independent data monitoring. No interim analysis is planned considering the low-risk nature and short study duration.

Patient and Public Involvement Statement

Patients and the public will not be involved in the design, recruitment, or implementation of this study. Study results will be disseminated to applicants. As disseminating results to participants is not standard practice in China, we have no plans for participant-directed dissemination. Study participants will be informed that final results can be accessed through our future publications.

Ethics Considerations

The study protocol was approved by the Ethics Committee of Zhongshan City People's Hospital in December 2022 (approval K2022-285). All recruited patients will be required to give written informed consent. Any subsequent amendments to the protocol will be submitted for further review and approval. Study findings will be disseminated through peer-reviewed publications and conference presentations.

Results

The enrollment of study participants started in December 2023 and is expected to end in March 2025. An interim analysis is planned to assess the feasibility and preliminary effects of the intervention. The final comprehensive analysis of the results is planned for May 2025, after all data have been collected and thoroughly reviewed.

Discussion

Conclusions

This study primarily investigates the impact of outpatient symptom management on exercise adherence after minimally invasive lung surgery. Remote symptom monitoring based on ePROs provides an innovative approach to improve patient self-management and rehabilitation compliance. While previous digital interventions have focused on education and coaching, this study explores a new precision rehabilitation model that actively monitors patient-reported symptoms and provides timely medical feedback. Although symptom-related exercise interruptions may occur in both groups, the ePRO-based interventions are designed to help manage symptoms and provide personalized exercise guidance, which may potentially mitigate the impact of symptoms on exercise adherence.

Potential findings from this preliminary study include (1) providing initial evidence on whether ePRO-based remote symptom management can improve outpatient exercise adherence, which has been a neglected area in previous research; (2) demonstrating the feasibility and acceptability of implementing such a personalized symptom-exercise comanagement model in local patients; and (3) exploring its potential to reduce patient symptom burden and postoperative complications. The findings from this study will provide valuable insights into the barriers and facilitators of implementing ePRO-based symptom management in real-world settings, informing future efforts to expand and optimize outpatient care for postoperative patients. The planned analyses will also help elucidate the complex relationships between symptom alerts, symptom management, and exercise adherence in this context. Understanding these relationships is crucial for optimizing the design and implementation of integrated symptom-exercise management interventions for postoperative patients. If the findings support the feasibility and potential effectiveness of this innovative rehabilitation approach, it could inform future larger-scale studies and efforts to improve postoperative care for a broader patient population. The research framework and findings will contribute to advancing telehealth for patient-centered and digitally enabled care models.

Limitations

This study also has some limitations. First, the single-center design may limit generalizability. Second, the strict inclusion or exclusion criteria may restrict the eligible population, such as excluding patients unable to use smartphones or with poorer reading comprehension. Third, the eligibility criteria may cause selection bias and limit external validity, although stringent criteria and verification of exercise data are adopted. Further pragmatic trials in more heterogeneous populations are warranted to validate broader generalizability and effectiveness. Fourth, the lack of blinding for researchers and participants may introduce bias into the results. Fifth, the short follow-up precludes evaluation of potential long-term impacts on exercise habits.

In summary, this unblinded randomized controlled trial aims primarily to provide preliminary evidence on the effects of ePRO-based symptom management on outpatient exercise behaviors, evaluating the feasibility of this management approach. Larger studies in real-world diverse populations are needed to further validate its generalizability and effectiveness.

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Data Availability

The data sets generated during and/or analyzed during this study are available in the ClinicalTrials.gov repository. The protocol will be published on an open-access repository.

Authors' Contributions

All authors contributed to the design of this protocol. XY and JS initiated the project. XY drafted the protocol and will be responsible for manuscript preparation. JS, YL, and CY contributed to the study design and methodology and will provide critical revision of the manuscript. QZ was involved in the statistical design and will be responsible for data management and analysis. WJ, GL, and YC will contribute to research coordination, ongoing patient enrollment, outpatient research follow-ups, and data collection. All authors have read, refined, and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Standard operating manual for symptom intervention.
[PDF File (Adobe PDF File), 127 KB - resprot_v14i1e60420_app1.pdf]

Multimedia Appendix 2
Clavien-Dindo classification of surgical complications.
[DOCX File , 14 KB - resprot_v14i1e60420_app2.docx]

References

1. Zheng RS, Zhang SW, Sun KX, Chen R, Wang SM, Li L, et al. Cancer statistics in China, 2016 [Article in Chinese]. Zhonghua Zhong Liu Za Zhi 2023;45(3):212-220. [doi: 10.3760/cma.j.cn112152-20220922-00647] [Medline: 36944542]
2. Zhang W, Zhang Y, Qin Y, Shi J. Outcomes of enhanced recovery after surgery in lung cancer: a systematic review and meta-analysis. Asia Pac J Oncol Nurs 2022 Nov;9(11):100110 [FREE Full text] [doi: 10.1016/j.apjon.2022.100110] [Medline: 36158708]
3. Stone AB, Yuan CT, Rosen MA, Grant MC, Benishek LE, Hanahan E, et al. Barriers to and facilitators of implementing enhanced recovery pathways using an implementation framework: a systematic review. JAMA Surg 2018;153(3):270-279. [doi: 10.1001/jamasurg.2017.5565] [Medline: 29344622]
4. Kampshoff CS, van Mechelen W, Schep G, Nijziel MR, Witlox L, Bosman L, et al. Participation in and adherence to physical exercise after completion of primary cancer treatment. Int J Behav Nutr Phys Act 2016;13(1):100 [FREE Full text] [doi: 10.1186/s12966-016-0425-3] [Medline: 27612561]
5. Bassett S. Measuring patient adherence to physiotherapy. J Nov Physiother 2012;02(07):e124. [doi: 10.4172/2165-7025.1000e124]
6. Sluijs EM, Kok GJ, van der Zee J. Correlates of exercise compliance in physical therapy. Phys Ther 1993;73(11):771-782. [doi: 10.1093/ptj/73.11.771] [Medline: 8234458]
7. Argent R, Daly A, Caulfield B. Patient involvement with home-based exercise programs: can connected health interventions influence adherence? JMIR Mhealth Uhealth 2018;6(3):e47 [FREE Full text] [doi: 10.2196/mhealth.8518] [Medline: 29496655]
8. Mata J, Pecorelli N, Kaneva P, Moldoveanu D, Gosselin-Tardiff A, Alhashemi M, et al. A mobile device application (app) to improve adherence to an enhanced recovery program for colorectal surgery: a randomized controlled trial. Surg Endosc 2020;34(2):742-751. [doi: 10.1007/s00464-019-06823-w] [Medline: 31087175]
9. Granger CL, Irving L, Antippa P, Edbrooke L, Parry SM, Krishnasamy M, et al. CAPACITY: a physical activity self-management program for patients undergoing surgery for lung cancer, a phase i feasibility study. Lung Cancer 2018;124:102-109. [doi: 10.1016/j.lungcan.2018.07.034] [Medline: 30268446]
10. Lang S, McLelland C, MacDonald D, Hamilton DF. Do digital interventions increase adherence to home exercise rehabilitation? A systematic review of randomised controlled trials. Arch Physiother 2022;12(1):24 [FREE Full text] [doi: 10.1186/s40945-022-00148-z] [Medline: 36184611]

11. Jack K, McLean SM, Moffett JK, Gardiner E. Barriers to treatment adherence in physiotherapy outpatient clinics: a systematic review. Man Ther 2010;15(3):220-228 [FREE Full text] [doi: 10.1016/j.math.2009.12.004] [Medline: 20163979]
12. Liao J, Wang Y, Dai W, Wei X, Yu H, Yang P, et al. Profiling symptom burden and its influencing factors at discharge for patients undergoing lung cancer surgery: a cross-sectional analysis. J Cardiothorac Surg 2022;17(1):229 [FREE Full text] [doi: 10.1186/s13019-022-01974-9] [Medline: 36057613]
13. Barber EL, Garg R, Strohl A, Roque D, Tanner E. Feasibility and prediction of adverse events in a postoperative monitoring program of patient-reported outcomes and a wearable device among gynecologic oncology patients. JCO Clin Cancer Inform 2022;6(1):e2100167 [FREE Full text] [doi: 10.1200/CCI.21.00167] [Medline: 35427184]
14. Mata J, Fiore JF, Pecorelli N, Stein BL, Liberman S, Charlebois P, et al. Predictors of adherence to enhanced recovery pathway elements after laparoscopic colorectal surgery. Surg Endosc 2018;32(4):1812-1819. [doi: 10.1007/s00464-017-5865-6] [Medline: 28916861]
15. Lowery AE, Krebs P, Coups EJ, Feinstein MB, Burkhalter JE, Park BJ, et al. Impact of symptom burden in post-surgical non-small cell lung cancer survivors. Support Care Cancer 2014;22(1):173-180 [FREE Full text] [doi: 10.1007/s00520-013-1968-3] [Medline: 24018910]
16. Dai W, Feng W, Zhang Y, Wang XS, Liu Y, Pompili C, et al. Patient-reported outcome-based symptom management versus usual care after lung cancer surgery: a multicenter randomized controlled trial. J Clin Oncol 2022;40(9):988-996 [FREE Full text] [doi: 10.1200/JCO.21.01344] [Medline: 34995100]
17. Elshahat S, Treanor C, Donnelly M. Factors influencing physical activity participation among people living with or beyond cancer: a systematic scoping review. Int J Behav Nutr Phys Act 2021;18(1):50 [FREE Full text] [doi: 10.1186/s12966-021-01116-9] [Medline: 33823832]
18. Hughes KJ, Salmon N, Galvin R, Casey B, Clifford AM. Interventions to improve adherence to exercise therapy for falls prevention in community-dwelling older adults: systematic review and meta-analysis. Age Ageing 2019;48(2):185-195. [doi: 10.1093/ageing/afy164] [Medline: 30358800]
19. Ryan S, Ní Chasaide N, O' Hanrahan S, Corcoran D, Caulfield B, Argent R. mHealth apps for musculoskeletal rehabilitation: systematic search in app stores and content analysis. JMIR Rehabil Assist Technol 2022;9(3):e34355 [FREE Full text] [doi: 10.2196/34355] [Medline: 35916688]
20. Chan AW, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin JA, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ 2013;346:e7586 [FREE Full text] [doi: 10.1136/bmj.e7586] [Medline: 23303884]
21. Schulz KF, Altman DG, Moher D, CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. Ann Intern Med 2010;152(11):726-732 [FREE Full text] [doi: 10.7326/0003-4819-152-11-201006010-00232] [Medline: 20335313]
22. NA. 28th annual conference of the international society for quality of life research. Qual Life Res 2021;30(Suppl 1):1-177 [FREE Full text] [doi: 10.1007/s11136-021-02976-1] [Medline: 34642903]
23. NCCN clinical practice guidelines in oncology: adult cancer pain. National Comprehensive Cancer Network. 2023. URL: https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf [accessed 2024-09-18]
24. Wang XS, Zhao F, Fisch MJ, O'Mara AM, Cella D, Mendoza TR, et al. Prevalence and characteristics of moderate to severe fatigue: a multicenter study in cancer patients and survivors. Cancer 2014;120(3):425-432 [FREE Full text] [doi: 10.1002/cncr.28434] [Medline: 24436136]
25. Rock CL, Thomson CA, Sullivan KR, Howe CL, Kushi LH, Caan BJ, et al. American Cancer Society nutrition and physical activity guideline for cancer survivors. CA Cancer J Clin 2022;72(3):230-262 [FREE Full text] [doi: 10.3322/caac.21719] [Medline: 35294043]
26. Dindo D, Demartines N, Clavien P. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 2004;240(2):205-213. [doi: 10.1097/01.sla.0000133083.54934.ae] [Medline: 15273542]
27. Grau-Pellicer M, Lalanza JF, Jovell-Fernández E, Capdevila L. Impact of mHealth technology on adherence to healthy PA after stroke: a randomized study. Top Stroke Rehabil 2020;27(5):354-368. [doi: 10.1080/10749357.2019.1691816] [Medline: 31790639]
28. Chen HC, Chuang TY, Lin PC, Lin YK, Chuang YH. Effects of messages delivered by mobile phone on increasing compliance with shoulder exercises among patients with a frozen shoulder. J Nurs Scholarsh 2017;49(4):429-437. [doi: 10.1111/jnu.12308] [Medline: 28632975]
29. Svingen J, Rosengren J, Turesson C, Arner M. A smartphone application to facilitate adherence to home-based exercise after flexor tendon repair: a randomised controlled trial. Clin Rehabil 2021;35(2):266-275 [FREE Full text] [doi: 10.1177/0269215520962287] [Medline: 33040590]
30. Bennell KL, Marshall CJ, Dobson F, Kasza J, Lonsdale C, Hinman RS. Does a web-based exercise programming system improve home exercise adherence for people with musculoskeletal conditions?: A randomized controlled trial. Am J Phys Med Rehabil 2019;98(10):850-858. [doi: 10.1097/PHM.0000000000001204] [Medline: 31021823]

31. Zhang ZY, Tian L, He K, Xu L, Wang XQ, Huang L, et al. Digital rehabilitation programs improve therapeutic exercise adherence for patients with musculoskeletal conditions: a systematic review with meta-analysis. J Orthop Sports Phys Ther 2022;52(11):726-739. [doi: 10.2519/jospt.2022.11384] [Medline: 35960507]
32. Bennell K, Nelligan RK, Schwartz S, Kasza J, Kimp A, Crofts SJ, et al. Behavior change text messages for home exercise adherence in knee osteoarthritis: randomized trial. J Med Internet Res 2020;22(9):e21749 [FREE Full text] [doi: 10.2196/21749] [Medline: 32985994]
33. Bennell KL, Campbell PK, Egerton T, Metcalf B, Kasza J, Forbes A, et al. Telephone coaching to enhance a home-based physical activity program for knee osteoarthritis: a randomized clinical trial. Arthritis Care Res (Hoboken) 2017;69(1):84-94. [doi: 10.1002/acr.22915] [Medline: 27111441]

Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
ePRO: electronic patient-reported outcome
IWRS: Interactive Web Response System
PPC: postdischarge pulmonary complication
PSA-Lung: Perioperative Symptom Assessment for Patients Undergoing Lung Surgery
SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials
VATS: video-assisted thoracic surgery

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Protocol

Evaluating the Effectiveness of a Multimodal Psychotherapy Training Program for Medical Students in China: Protocol for a Randomized Controlled Trial

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Abstract

Background: Psychotherapy is central to the treatment of mental disorders, highlighting the importance of medical students and residents developing competencies in this area. Chinese medical residents have expressed a strong need for psychotherapy training, yet they are generally dissatisfied with the current offerings. This paper presents the protocol for an evidence-based, well-structured psychotherapy teaching program aimed at medical students and residents.

Objective: This study involves a randomized controlled trial of a 2-day multimodal intensive educational intervention designed to evaluate the effectiveness of a new psychotherapy teaching program for medical students and residents in China. The primary outcomes include participants' knowledge and utilization of psychotherapy, training program acceptability, self-reported self-efficacy, and motivation to apply psychotherapy.

Methods: This 2-arm randomized controlled trial was conducted at Sir Run Run Shaw Hospital. The study aimed to recruit approximately 160 medical students and residents, with about 80 participants in the intervention group and 80 in the control group. Both groups completed a baseline survey before participation, reporting their psychotherapy knowledge, utilization of psychotherapy, self-efficacy, and self-motivation. The intervention group received a 2-day multimodal intensive educational intervention (supervision-based online teaching), while the waitlist control group did not receive any intervention during this period. Both groups were followed up for 8 weeks, completing the same survey administered at baseline. At the end of the study, the control group received the intervention. The primary outcome measure was the change in trainees' psychotherapy knowledge before and after the intervention training. Secondary outcome measures included changes in the trainees' utilization of psychotherapy, self-reported self-efficacy, and self-reported motivation for psychotherapy. Additionally, training program acceptability was assessed. Analysis of covariance was used to analyze the primary outcomes. Pearson correlations and regression analysis explored factors associated with the knowledge score at baseline. The secondary outcomes, including participants' psychotherapy utilization, confidence, and motivation, were analyzed using the same methods as for knowledge. All tests were 2-tailed, with a significance level set at $P<.05$.

Results: A total of 160 participants were recruited and randomized between January 4 and 12, 2024. Baseline assessments were conducted from January 28 to February 1, 2024. The psychotherapy training program for the intervention group took place on February 3 and 4, 2024. Posttraining assessments were conducted starting April 1, 2024. Due to withdrawals, incomplete surveys, and data loss, we had a total of 113 participants: 57 in the intervention group and 56 in the control group. The amount of data varied across measures. The data analysis was finished in August 2024.

Conclusions: This study aims to evaluate the effectiveness of the multimodal psychotherapy training program for medical students in China. If this brief, cognitive behavioral therapy–based psychotherapy skill training proves effective, the potential mental health impact of its nationwide expansion could be significant.

Trial Registration: ClinicalTrials.gov NCT06258460; https://clinicaltrials.gov/ct2/show/NCT06258460

International Registered Report Identifier (IRRID): DERR1-10.2196/58037

(JMIR Res Protoc 2025;14:e58037) doi:10.2196/58037

KEYWORDS

multimodal teaching; psychotherapy training; Chinese medical students; randomized controlled trial

Introduction

Background

The delivery of psychosocial and psychotherapeutic interventions remains central to the treatment of many patients with psychiatric disorders (eg, obsessive-compulsive disorder, panic disorder, major depression, eating disorders, and addictive behaviors) and psychosomatic disorders (eg, hypertension, bronchial asthma, and rheumatoid arthritis) [1,2]. Cuijpers et al [3] conducted a large-scale network meta-analysis to examine the effects of various types of psychotherapies for adult depression, including cognitive behavioral therapy (CBT), interpersonal therapy, psychodynamic therapy, problem-solving therapy, behavioral activation, life-review therapy, and "third-wave" therapies, as well as nondirective supportive counseling. They found that all types of these therapies were more effective than care-as-usual and waiting list control conditions and that most therapies were more efficacious than placebo. Additionally, most therapies maintained significant effects at the 12-month follow-up compared with care-as-usual. A strong evidence base indicated that several psychotherapy modalities were effective for most mental disorders, whether used alone or in combination, primarily including behavior therapy, CBT, and interpersonal psychotherapy [4,5]. According to a systematic review and meta-analysis, the emotional change processes and mechanisms of psychotherapy were most strongly associated with specific CBT methods, such as fear habituation, emotion regulation and experience, and the habitual reorganization of maladaptive emotional perceptions [6]. Today, CBT is recommended as a first-line intervention for both the acute treatment and relapse prevention of various mental illnesses, including major depressive disorder, and most patients prefer psychological treatment over pharmacologic options [5]. Therefore, medical students in clinical rotations and residents working in psychiatric and psychosomatic departments should be required to develop competencies in psychotherapy, particularly in CBT [7]. However, there remains a significant treatment gap for mental disorders in China [8]. Despite the high prevalence of mental disorders in the country, medical professionals in psychiatric or mental health departments often have a comparatively low capacity to provide adequate care and lack qualified training in psychotherapy. Learning basic psychotherapy skills would benefit medical students, residents, and other health care providers (HCPs), including doctors and nurses, across all departments. These skills can be applied in clinical practice to enhance doctor-patient relationships [9]. A study conducted in Beijing found that after participating in a 2-year psychotherapy training program, medical doctors reported improvements in diagnosing and treating mental illness, as well as in doctor-patient communication and the development of strong doctor-patient relationships. Patients also demonstrated significant improvements in levels of depression and anxiety, the severity of physical symptoms, quality of life, and the patient-rated therapeutic relationship [9]. Therefore, psychotherapy training for medical students, residents, and other HCPs requires greater emphasis.

A narrative review indicated that medical residents in psychiatry have a strong need for psychotherapy training to enhance their competence, yet they generally express dissatisfaction with the current training programs [10]. Therefore, providing evidence-based and well-designed psychotherapy training programs is essential for equipping medical students and residents with a foundational understanding of psychotherapy and the necessary skills for clinical practice [11]. Compared with traditional methods, psychotherapy teaching that emphasizes skill practice and role experience is more popular and effective. For instance, a single-day simulation training program has proven effective in psychiatry for medical students, enhancing their knowledge, communication and interview skills with patients, and confidence in treatment [12]. Despite the critical importance of learning psychotherapy skills during medical school and residency, there is a notable lack of formal evaluation of psychotherapy teaching methods and their efficacy. Given the lack of access to psychotherapy, medical and psychological educators, along with program directors, should design high-quality curricula to teach medical students, residents, and other HCPs the essential knowledge and skills in psychotherapy. These curricula should be evaluated through well-conducted, methodologically robust randomized controlled trials (RCTs) [13].

Aim and Hypotheses

To evaluate the effectiveness of the multimodal psychotherapy training program for medical students in China, well-designed RCTs of psychotherapy teaching programs are urgently needed. The primary aim of this proposed project is to assess the effectiveness of a new multimodal psychotherapy teaching program for medical students and residents in China, which is designed to enhance their psychotherapeutic skills and improve their performance in entry-level clinical settings. The primary hypothesis was that, compared with a control intervention, the intervention group receiving the psychotherapy teaching program would acquire significantly more knowledge about psychotherapy after training. We also hypothesized that the

program would lead to an increase in the utilization of psychotherapy and be associated with improved knowledge in this area. The third hypothesis posited that trainees' self-reported self-efficacy and motivation to apply psychotherapy in clinical practice would increase significantly.

Methods

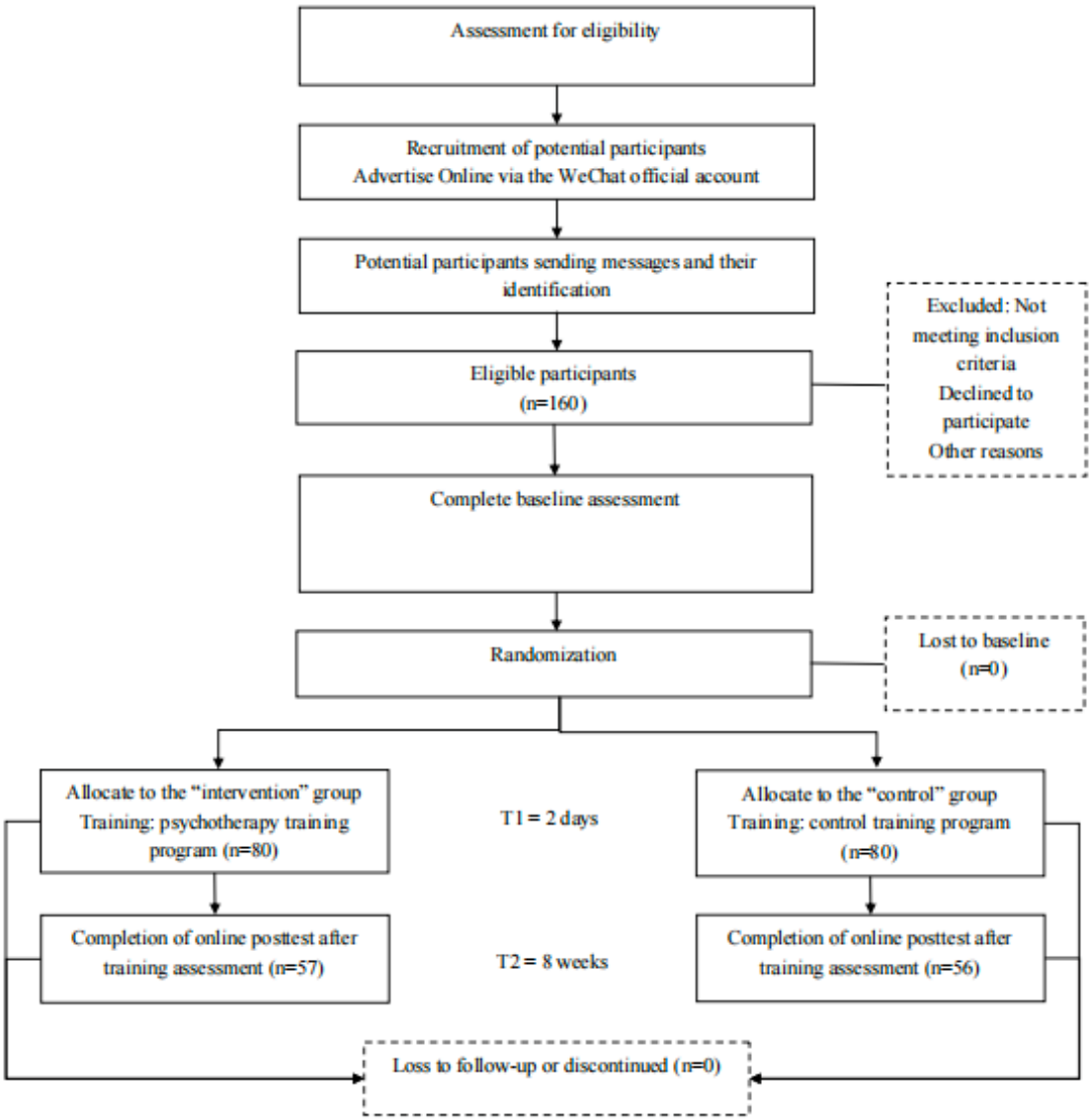
Patient and Public Involvement

Neither participants nor the public were involved in the trial's design, recruitment, or conduct of this study.

Study Design and Participants

This study was an RCT of a 2-day multimodal intensive educational intervention aimed at enhancing the clinical skills in psychotherapy of Chinese medical students and residents. The trial included a waitlist control group, with 8 weeks of follow-up for all participants. A detailed schedule of the study procedures is summarized in Figure 1.

Figure 1. Flowchart study design.



Study participants (n=160) primarily included medical students, residents, and a few other HCPs, such as doctors and nurses, in China. There were no specific restrictions for participants, although most were from Zhejiang University School of Medicine. An overview of participant eligibility criteria is provided in Textbox 1.

Textbox 1. Study inclusion criteria (participants who did not qualify for the criteria were not recruited to participate in this study).

- Medical students, residents, and other health care providers
- Aged 18 years or older
- Expressing an interest in psychotherapy
- Willing to receive randomization
- Willing to provide informed consent to participate in the study

Sample Size and Power Calculation

The sample size was calculated based on the primary outcome using G*Power [14] (version 3; Universität Düsseldorf). As the data were continuous variables and analysis of covariance (ANCOVA) would be used to compare differences between the 2 groups, an a priori analysis selecting ANCOVA as the statistical test was conducted to determine the required sample size. As only a few studies have examined the effectiveness of psychotherapy training for medical students, we were unable to reference effect size or other data as criteria. Therefore, a medium effect size for the primary outcome was estimated preliminarily. It was determined that 128 participants (64 in each group) would be required to achieve 80% power (effect size f=0.25; 1 – β=0.80; α=.05). To account for potential attrition, we aimed to recruit approximately 160 participants (80 in each group), ensuring that the proposed analysis would be sufficiently powered even if 25% of participants in each group were lost to attrition.

Randomization and Group Allocation

This study aimed to recruit approximately 160 participants, with about 80 in each group. The study coordinator randomized participants into the intervention and control groups using a random number generator in R software, maintaining a 1:1 ratio for allocation to the experimental and control conditions. Participants in the intervention group first received the experimental condition, which included the psychotherapy training program after the baseline assessment. The waitlist control group received the control condition, meaning they participated in the psychotherapy training program only at the end of the study. The timeline of the study was as follows: all participants underwent a baseline assessment, the intervention group received the training program, and the control group received a control training program. After 8 weeks, all participants were followed up, and finally, the control group received the intervention training program (Figure 1).

Recruitment

The researchers advertised the program online through the WeChat (Tencent Holdings Limited) official account of the Department of Psychiatry at Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, to recruit potential participants. They encouraged sharing the program details with medical schools and hospitals. Interested individuals could register by sending messages and their identification to the research assistants (Zitang Zhou and Luyao Zou). Research assistants then contacted the respondents to assess their eligibility, explain the study to each participant, and inform them about the allocation to either the control or intervention groups, where they would receive the psychotherapy training program.

Baseline and Posttraining Data Collection

Before randomization, demographic information and self-reported questionnaires were collected from all participants at baseline. This information included participants' sex, age, identity (student, resident, or HCP), education level (undergraduate or graduate degree), department affiliation (psychiatric or nonpsychiatric), and years of psychotherapy-related work. Additionally, outcome measurements were gathered, including trainees' knowledge of psychotherapy, utilization of psychotherapy, self-reported self-efficacy, and self-reported motivation, among others. The questionnaires on psychotherapy knowledge, utilization, and self-efficacy and motivation to engage in psychotherapy were specifically designed based on our training program. Outcome measurements were assessed again 8 weeks after training (Table 1). Data were collected online using WenJuanXing (Questionnaire Star), a Chinese platform that provides professional online questionnaire surveys and data collection for RCTs [15]. The hospital's data monitoring committee oversaw the data collection process, and personal information was deidentified to ensure confidentiality.

Table 1. Schedule of enrollment and posttraining assessments.[a]

Schedule	Baseline	8 weeks after training
Initial approach	✓	N/A[b]
Informed consent	✓	N/A
Eligibility screen	✓	N/A
Randomization	✓	N/A
Intervention/control initiation	✓	N/A
Demographic characteristics	✓	N/A
Knowledge	✓	✓
Self-reported self-efficacy	✓	✓
Self-reported motivation	✓	✓
Utilization	✓	✓

[a]This table illustrates the schedule of enrollment and posttraining assessments. Initial approach, informed consent, eligibility screen, randomization, intervention/control initiation, and demographic characteristics were evaluated and collected only at the baseline timeline. Psychotherapy knowledge, self-reported self-efficacy, self-reported motivation, and utilization were both collected at the baseline and 8 weeks after the training.

[b]N/A: not applicable.

Development of the Psychotherapy Training Program

The psychotherapy training program was primarily developed by an experienced psychotherapist (Tao Pei) and an MD-level psychiatrist (Yanhui Liao), both of whom have approximately 20 years of relevant experience. The details of the 2-day psychotherapy training program are outlined in Multimedia Appendix 1. The program included 2 days of intensive training followed by 8 weeks of follow-up, with guidance on applying psychotherapy in clinical settings.

Intervention

Control Group

After providing consent, participants allocated to the waitlist control group received a message encouraging them to complete all questionnaires from baseline through to the final follow-up at 8 weeks. They were sent messages via WeChat to thank them for their participation and to remind them of the timeline for completing the study. Once they finished the posttraining measurement, a digital booklet of the psychotherapy training program was provided to them via WeChat or as a hard copy upon request. After the trial concluded, participants in the control group were offered the opportunity to receive the psychotherapy training program free of charge.

Intervention Group

All participants in the intervention group received the 2-day psychotherapy training program and were given a hard copy of the program booklet at recruitment. Additionally, supervision-based group meetings were held during the follow-ups at weeks 1, 2, 4, and 8, with each meeting lasting approximately 2 hours. During these follow-up meetings, instructors—including psychotherapists and psychiatrists—were available to answer any psychotherapy-related questions, encourage participants to practice psychological interventions, and provide further information to support the clinical application of psychotherapy.

Outcomes and Outcome Measures

Primary Outcome

Trainees' psychotherapy knowledge was assessed by participants using an 11-point scale (ranging from 0 to 10) before and after the 8-week period (Table 2). At baseline, 160 participants completed the self-reported psychotherapy knowledge questionnaire, and the results indicated a high internal consistency coefficient (Cronbach α) of 0.980 for the scores across the 17 items.

Table 2. Knowledge about psychotherapy.[a]

Variables	Measures (0-10)
Overview of psychotherapy	
Supportive psychotherapy techniques	
Overview of cognitive behavioral therapy	
Beck's cognitive therapy	
Identify automatic thinking and do cognitive conceptualization	
Cognitive conceptualization	
Evaluation of automatic thinking	
Reconstruction techniques for automated thinking1: Socratic questioning	
Reconstruction techniques for automated thinking2: pie charts, continuous spectrum, cost-benefit analysis, behavioral experiments	
Challenge automatic thinking	
Social skill training	
Problem-solving	
Behavioral therapy theory and behavioral conceptualization	
Behavioral activation	
Relaxation training	
Exposure therapy	
Competency structure of psychotherapists and the growth path of cognitive behavioral therapy therapists	

[a]This is the assessment of participants' knowledge about psychotherapy. Each item was rated on a 0-10 scale, where 10 means "knowing very well."

Secondary Outcomes

Training Program Acceptability

Program acceptability in the intervention group was measured using questions designed to assess acceptability, as detailed in Table 3.

Table 3. Questions for assessing the psychotherapy training program acceptability.[a]

Category and questions	Rating
General	
• Overall rating of the program	5=like very much; 4=like somewhat; 3=neutral; 2=dislike somewhat; 1=very dislike; 5=very likely
Appraisal	
• Appraisal of the program—the likelihood of applying the program for patients • Appraisal of the program—the likelihood of recommending the program to other medical students or other health care providers	4=somewhat likely; 3=neutral; 2=unlikely; 1=not at all likely
Acceptability	
• I would have been able to help patients to deal with mental problems with the program • The program made it easier to communicate and help patients during clinical work • The program disrupted my daily schedule • The program is easy to understand	5=strongly agree; 4=agree; 3=neutral; 2=disagree; 1=strongly disagree
Frequency	
• Frequency of using psychotherapy	1=almost never; 2=sometimes; 3=always

[a]This is the rating of the training acceptability assessment. The last item, "Frequency of using psychotherapy," was rated on a 1-3 Likert scale, where 3 indicates "always."

Utilization of Psychotherapy

The utilization rate of psychotherapy interventions for patients during the 8 weeks of follow-up was assessed using items from Table 4.

Table 4. The utilization rate of psychotherapy.[a]

Variables	Measures (0-10)
Supportive psychotherapy techniques	
Social skill	
Problem-solving skill	
Behavioral activation	
Relaxation training	
Exposure therapy	

[a]This is the assessment of participants' utilization rate of psychotherapy. Each item was rated on a 0-10 scale, where 10 means maximum utilization and 0 means minimum utilization.

Self-Reported Self-Efficacy and Self-Reported Motivation

Self-efficacy and motivation were measured using a visual analog scale on a 10-cm line, representing a continuum from "no self-efficacy or motivation" to "the strongest self-efficacy or motivation" (Table 5).

Table 5. Self-reported self-efficacy and motivation of psychotherapy.[a]

Variables	Visual analog scale
Self-reported self-efficacy	
Confidence in practicing psychotherapy	
Confidence in practicing supportive psychotherapy	
Confidence in practicing cognitive behavioral therapy	
Self-reported m otivation	
Willingness or motivation to practice psychotherapy	
Willingness or motivation to practice supportive psychotherapy	
Willingness or motivation to practice cognitive behavioral therapy	

[a]This is the assessment of participants' self-reported self-efficacy and self-reported motivation. Each item was measured by the visual analog scale on a 10-cm line that represents a continuum between "no self-efficacy or motivation" and "the strongest self-efficacy or motivation.

All secondary outcomes were reported as mean values. According to the baseline measurements of our study, 160 participants evaluated their psychotherapy utilization, confidence, and motivation using self-reported questionnaires. The internal consistency coefficients (Cronbach α) for these 3 questionnaires were 0.950, 0.961, and 0.936, respectively.

Procedures

Figure 1 and Table 1 summarize the schedule for enrollment and posttraining assessments. Participants were evaluated at baseline (0 weeks), before and after receiving the intervention training, and at 8 weeks after training. They were also asked to maintain a daily log of their utilization of the psychotherapy training program, which included activities such as providing emotional support and teaching patients breathing techniques for stress relief. Reminders were sent to participants who did not complete the 8-week posttraining questionnaires.

Withdrawal From the Program

All participants were free to withdraw from the trial at any time without needing to provide a reason. Following the intention-to-treat principle [15], participants who did not respond to the 8-week posttraining assessment were retained in the analysis according to the group to which they were randomized, regardless of whether they received the intervention. Participants who withdrew were excluded from the analysis, and their reasons for withdrawal were recorded. A complete case analysis was conducted, excluding any participants who withdrew at the posttraining assessment point.

Data Analysis

All data were automatically collected via WenJuanXing through a WeChat-based link. The data were downloaded from the WenJuanXing database into a user-specific Excel file. This study did not include interim analyses; data were analyzed only after all had been collected. The trial statistician blinded the intervention assignment in the data using R software (R Foundation for Statistical Computing) and SPSS (2013 release; IBM Corp.).

The primary hypothesis was that, compared with the control intervention, the intervention group receiving the psychotherapy teaching program would significantly gain more knowledge about psychotherapy after training. We also hypothesized that the program would lead to increased utilization of psychotherapy and be associated with improvements in knowledge. The third hypothesis posited that trainees' self-reported self-efficacy and motivation to apply psychotherapy in clinical practice would increase significantly.

Descriptive statistics were used to assess demographic and psychotherapy-related characteristics at baseline. Following normality and homogeneity of variance tests, ANCOVA was used to analyze the primary outcomes. In the ANCOVA model, the dependent variable was the change in the knowledge score. The fixed factor was the group (intervention group or control group), while the covariates included the mean score of psychotherapy knowledge at baseline and years of psychotherapy experience. Pearson correlations and regression analysis (both linear and binary regression models) were used to explore factors associated with the knowledge score at baseline and to assess the increase in psychotherapy utilization in both the intervention and control groups. The secondary outcomes—participants' psychotherapy utilization, confidence, and motivation—will also be analyzed in the same manner as knowledge.

A complete case analysis was performed, excluding any participants with missing information on the posttraining assessment. Additionally, a sensitivity analysis of the missing data was conducted to determine whether the missingness is random. Demographic information and scores for psychotherapy knowledge, utilization, confidence, and motivation at baseline were compared between the complete data group and the missing data group. All tests were 2-tailed, with a significance level set at $P<.05$.

Safety and Adverse Events

Throughout the psychotherapy training program, adverse events were closely monitored. Participants were encouraged to communicate any psychotherapy-related issues or adverse events encountered during their clinical work. We prompted each participant to report any adverse events experienced at each group meeting, and they could also report them at any time. If participants experienced severe adverse events, they were encouraged to seek support from a psychologist or psychiatrist.

We did not anticipate any training-related serious adverse events (SAEs), such as life-threatening incidents, during this trial. However, if any adverse events occur, we will document the SAE, record it on the SAE form, and submit it to the ethics committee of Sir Run Run Shaw Hospital (the principal investigator's affiliation) within 24 hours.

Ethics Approval and Consent to Participate

This study was approved by the ethics committee of Sir Run Run Shaw Hospital, an affiliate of Zhejiang University School of Medicine (2024 Ethics Approval File No. 2024-0066). The trial was conducted in accordance with the Declaration of Helsinki. Participants were provided with informed consent before the baseline assessment. After thoroughly reading and understanding the content of the consent, they received a link to electronically sign their name at the end of the informed consent form and submit it via WeChat. Each participant was informed about the study's purpose, procedures, measurements, potential risks, and benefits before recruitment. Informed consent was then obtained from each participant. Participation was entirely voluntary, and participants could withdraw from the study at any time. Coordinating researchers' contact information was provided to all participants for any inquiries or concerns.

Data Security

The authors utilized the professional version of WenJuanXing, which features high-level security management, alongside an applet on WeChat that ensures the secure and confidential protection of participants' data.

Results

This study recruited 160 participants from January 4 to January 12, 2024. The 2-day training program took place on February 3 and February 4, 2024, and the posttraining assessment was completed on April 1, 2024. Due to withdrawals, incomplete surveys, and data loss, we had a total of 113 participants: 57 in the intervention group and 56 in the control group. The amount of data varies for each measure. Data analysis was completed in August 2024. The results will be published in peer-reviewed journals. If found to be effective, the psychotherapy training program and the accompanying program booklet will be made freely available to the public by the end of the trial.

Discussion

To our knowledge, this will be the first RCT to evaluate the efficacy of a multimodal psychotherapy training program for medical students in China.

The strength of this study lies in its theoretical framework, primarily guided by cognitive behavioral theory. With a large sample size, this RCT evaluates the efficacy of the psychotherapy training program using multimodal teaching methods in China. If effective, this multimodal psychotherapy training program could be applied nationwide, significantly enhancing its potential impact on public health. Its expansion could help HCPs acquire the necessary psychotherapy skills to effectively manage patients' psychological issues.

There are several limitations to this study. First, the effectiveness of teaching and the quality of learning can be influenced by various factors, such as opportunities to implement psychotherapy practice, the intensity of clinical work during the follow-up period (including the impact of holidays), and the availability of continuing education resources. These factors cannot be adequately controlled in this study. Second, the 2-day training will take place at Sir Run Run Shaw Hospital, which may deter participants from other regions of China from attending the program. Third, there are only 2 main instructors (Psychiatrist YL and Psychologist TP) involved in this training program. While both have nearly 20 years of teaching and clinical experience, their individual teaching styles and characteristics may still influence the overall effectiveness of the program. Fourth, although this 8-week training program aims to enhance the acquisition of therapeutic skills, developing proficiency in psychotherapy is likely to be a more prolonged process. Fifth, all measures rely on participants' subjective assessments, which may be influenced by personal biases and expectations of improvement following the intervention training. Lastly, we submitted this protocol to the journal during the recruitment process.

In conclusion, this is the first RCT to evaluate the efficacy of a multimodal psychotherapy training program for medical students in China. If this educational program, which offers brief and short-term psychotherapy skills training, proves effective, its nationwide expansion could have a significant health impact. It provides evidence-based psychotherapy training—primarily in CBT—for medical students, and its dissemination will equip HCPs to better manage mental health issues, such as stress and depression. Therefore, it is crucial to develop effective psychotherapy training that emphasizes basic psychotherapy skills. The results of this training's effectiveness can offer valuable insights for the future development of training programs, enabling them to better meet the learning needs of medical professionals and enhance doctor-patient relationships.

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Availability of Data and Materials

Data sets from this study and the corresponding analysis code will be made publicly available at the conclusion of the study's analyses.

Declaration of Artificial Intelligence Use

Generative artificial intelligence was not used in any portion of the manuscript writing.

Authors' Contributions

YL designed the study, while YL and TP developed the program. YD verified the analytical methods. JT supervised the design of the work and revised the manuscript. All authors discussed and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The details of the 2-day psychotherapy training program.
[DOCX File , 26 KB - resprot_v14i1e58037_app1.docx]

References

1. Chaimowitz G, Weerasekera P, Ravitz P. Psychotherapy in psychiatry. Can J Psychiatry 2021 Nov;66(11):999-1004 [FREE Full text] [doi: 10.1177/07067437211040958] [Medline: 34871512]
2. Craighead WE, Craighead LW. The role of psychotherapy in treating psychiatric disorders. Med Clin North Am 2001 May;85(3):617-629. [doi: 10.1016/s0025-7125(05)70332-1] [Medline: 11349476]
3. Cuijpers P, Quero S, Noma H, Ciharova M, Miguel C, Karyotaki E, et al. Psychotherapies for depression: a network meta-analysis covering efficacy, acceptability and long-term outcomes of all main treatment types. World Psychiatry 2021 Jun;20(2):283-293 [FREE Full text] [doi: 10.1002/wps.20860] [Medline: 34002502]
4. Rosson S, de Filippis R, Croatto G, Collantoni E, Pallottino S, Guinart D, et al. Brain stimulation and other biological non-pharmacological interventions in mental disorders: an umbrella review. Neurosci Biobehav Rev 2022 Aug;139:104743. [doi: 10.1016/j.neubiorev.2022.104743] [Medline: 35714757]
5. McHugh RK, Whitton SW, Peckham AD, Welge JA, Otto MW. Patient preference for psychological vs pharmacologic treatment of psychiatric disorders: a meta-analytic review. J Clin Psychiatry 2013 Jun;74(6):595-602 [FREE Full text] [doi: 10.4088/JCP.12r07757] [Medline: 23842011]
6. Sønderland NM, Solbakken OA, Eilertsen DE, Nordmo M, Monsen JT. Emotional changes and outcomes in psychotherapy: a systematic review and meta-analysis. J Consult Clin Psychol 2024 Sep;92(9):654-670. [doi: 10.1037/ccp0000814] [Medline: 37166832]
7. Fefergrad M, Mulsant BH. Psychotherapy training in a competency-based medical education psychiatry residency: a proposal for a practical and socially responsible model. Can J Psychiatry 2022 Jun;67(6):423-427 [FREE Full text] [doi: 10.1177/07067437211063096] [Medline: 34935519]
8. Zhao X, Liu L, Hu C, Chen F, Sun X. Necessity and feasibility of improving mental health services in China: a systematic qualitative review. Int J Health Plann Manage 2017 Jul;32(3):363-371. [doi: 10.1002/hpm.2437] [Medline: 28639255]
9. Wei J, Fritzsche K, Shi L, Cao J, Bassler M, Müller AM, et al. Training in psychosomatic medicine and psychotherapy for medical doctors in China: a field report. Front Med (Lausanne) 2023;10:1119505 [FREE Full text] [doi: 10.3389/fmed.2023.1119505] [Medline: 37138758]
10. Salgado R, von Doellinger O. Psychotherapy training in psychiatry residencies: a review of trainees' perspectives. The European Journal of Psychiatry 2024 Oct;38(4):100263. [doi: 10.1016/j.ejpsy.2024.100263]
11. Truong A, Wu P, Diez-Barroso R, Coverdale J. What is the efficacy of teaching psychotherapy to psychiatry residents and medical students? Acad Psychiatry 2015 Oct;39(5):575-579. [doi: 10.1007/s40596-015-0345-6] [Medline: 25933647]
12. Younes N, Delaunay AL, Roger M, Serra P, Hirot F, Urbain F, et al. Evaluating the effectiveness of a single-day simulation-based program in psychiatry for medical students: a controlled study. BMC Med Educ 2021 Jun 16;21(1):348. [doi: 10.1186/s12909-021-02708-6] [Medline: 34134692]
13. Amsalem D, Gothelf D, Soul O, Dorman A, Ziv A, Gross R. Single-day simulation-based training improves communication and psychiatric skills of medical students. Front Psychiatry 2020;11:221 [FREE Full text] [doi: 10.3389/fpsyt.2020.00221] [Medline: 32265762]
14. Mayr S, Erdfelder E, Buchner A, Faul F. A short tutorial of GPower. TQMP 2007 Oct;3(2):51-59. [doi: 10.20982/tqmp.03.2.p051]
15. Montori VM, Guyatt GH. Intention-to-treat principle. CMAJ 2001 Nov 13;165(10):1339-1341 [FREE Full text] [Medline: 11760981]

Abbreviations

ANCOVA: analysis of covariance
CBT: cognitive behavioral therapy
HCP: health care provider
RCT: randomized controlled trial
SAE: serious adverse event

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Protocol

Research Participants' Engagement and Retention in Digital Health Interventions Research: Protocol for Mixed Methods Systematic Review

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Abstract

Background: Digital health interventions have become increasingly popular in recent years, expanding the possibilities for treatment for various patient groups. In clinical research, while the design of the intervention receives close attention, challenges with research participant engagement and retention persist. This may be partially due to the use of digital health platforms, which may lack adequacy for participants.

Objective: This systematic literature review aims to investigate the relationship between digital health platforms and participant engagement and retention in clinical research. It will map and analyze key definitions of engagement and retention, as well as identify design characteristics that influence them.

Methods: We will carry out a mixed methods systematic literature review, analyzing qualitative and quantitative studies. The search strategy includes the electronic databases PubMed, IEEE Xplore, CINAHL, Scopus, Web of Science, APA PsycINFO, and the ACM Digital Library. The review will encompass studies published between January 2018 and June 2024. Criteria for inclusion will be the presence of digital health care interventions conducted through digital health platforms like websites, web and mobile apps used by patients, and informal caregivers as research participants. The main outcome will be a narrative analysis with key findings on the definitions of participant engagement and retention and critical factors that affect them. Quality assessment and appraisal will be done through the Mixed-Methods Assessment Tool. Data analysis and synthesis will follow the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 flow diagram. Quantitative data will be qualified and integrated into qualitative data, which will be analyzed using thematic analysis and synthesis.

Results: The study expects to map and summarize critical definitions of participant engagement and retention, and the characteristics of digital health platforms that influence them. The systematic review is expected to be completed in June 2025.

Conclusions: This systematic review will contribute to the growing discussion on how the design of digital health intervention platforms can promote participant engagement and retention in clinical research.

Trial Registration: PROSPERO CRD42024561650; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=561650

International Registered Report Identifier (IRRID): PRR1-10.2196/65099

(JMIR Res Protoc 2025;14:e65099) doi:10.2196/65099

KEYWORDS

clinical research informatics; participant engagement; participant retention; clinical research; mobile application; digital platforms; mobile phone

Introduction

In 2022, over 100,000 health care mobile apps were available in Apple and Google app stores combined [1]. Digital health care has transformed care delivery through a diverse fleet of technologies, from mobile apps and wearable devices to biosensors and the Internet of Things [2]. It offers a myriad of innovative ways to provide treatments, monitor health conditions, assist, and empower patients with diverse needs to be more in charge of their health, and enable health care professionals to deliver better service [3]. Following the expansion of the digital health care range, digital health (DH) interventions have also increased exponentially (Textbox 1). DH interventions are interventions delivered through digital technology for the treatment or management of physical or mental conditions [4].

Textbox 1. Key concepts.

Digital health intervention

- Interventions are delivered through digital technologies such as smartphones, websites, wearables, video games, or text messaging [2,5,6]. A digital health intervention offers guidance, information, and support for a diversity of physical or mental health conditions through a digital platform. Also commonly referred to as health informatics or eHealth interventions [7]; they are designed to help people avoid, recover from, or cope with disease and disability or to improve the quality and safety of health care [8], for example, as self-help or self-guided eHealth interventions [9,10].

Digital health platforms

- Websites, web-based or mobile apps used to access digital health interventions.

Digital clinical research

- Clinical research is conducted through digital health platforms. It may include digital health interventions, digital data collection, and electronic Case Report Forms, among other resources. Only digital clinical research encompassing digital health interventions will be considered for this study.

Research participant

- Recipients of intervention; for example, patients or informal caregivers.

Participant engagement

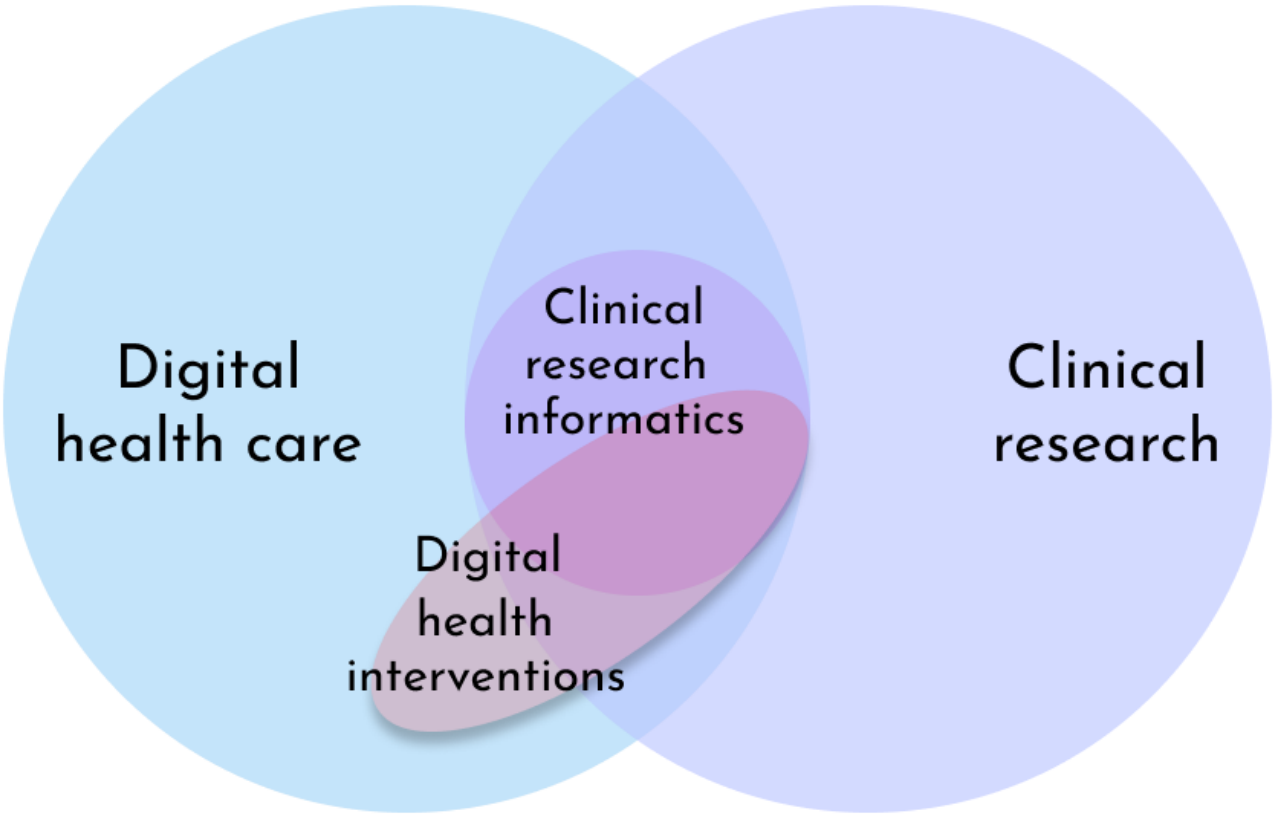
- Length and depth of participant's involvement with the digital health intervention.

Participant retention

- Duration and continuity of the participant's involvement with the digital health intervention.

Through online treatments, DH interventions promise to improve health care, enhancing accessibility, effectiveness, and personalization [2,11]. DH interventions are available in commercial applications, as easily accessible health care, and as part of clinical research (Figure 1). When conducted as part of clinical research, they share the same benefits as general digital health care. DH interventions also allow for the development of effective treatments for more patients [11], are more community-inclusive [12], decrease health disparities [13], and improve study generalizability and validity [14,15]. Successful clinical research generates evidence that, in turn, promotes health care improvements [16].

Figure 1. Digital health interventions are part of general digital health care and clinical research. The latter can be delivered through clinical research informatics or commercial health platforms and software.



In clinical research, DH interventions are designed following the principles of clinical research informatics (CRI) [4]. CRI is the use of informatics principles and techniques to conduct clinical research [4]. DH interventions have the potential to accelerate the process from initial research to "real world" outcomes, contributing to increasing scale and distribution, cost and resource optimization, and facilitating financial auditing processes [12,16-18]. These principles could also be applied to DH interventions.

Both engagement and retention of clinical research participants are crucial intervention research outcomes, but the concepts have varying definitions. Frequently, different terms for engagement are used interchangeably, like involvement, participation, acceptability, and completion rates, among others. Engagement can be described as the extent and manner in which people actively use a resource [19]. Perski et al [20] define engagement as two main concepts: (1) a subjective experience, meaning a state of focus and interest with a temporal dissociation, and (2) a behavior, described as usage over time. It is often connected to concepts like adherence, duration, and frequency that can be quantified through concrete measurements like opening or using a mobile app, frequency of times, or the duration of the use [21]. Participant retention, in turn, refers to the proportion of recruited participants who remained in the study until its end and at an optimal proportion that does not compromise the study's validity [22,23].

In DH intervention research, both engagement and retention can vary considerably. Intervention dropout from internet-based treatment for psychological disorders, for example, fluctuates between 30% and 50% [24]. While poor engagement or retention may be due to the intervention quality or outside factors, an often-overlooked component is the design of DH platforms. Appraising the DH platforms' design choices and how they impact participant engagement and retention could help make DH interventions better. In this context, there is an untapped opportunity to explore the practical factors that affect intervention success. This systematic literature review will focus on DH platforms' design choices concerning engagement and retention and their relationship with research participants' behavior.

The relationship between DH platforms and research participants is receiving growing interest, as evidenced by the increase in research. Studies have examined participant engagement and retention across various settings, for example, mHealth or web-based platforms [21,25], focusing on particular patient groups, for example, older adults with dementia or digital mental health interventions [26-29].

Still, a comprehensive literature review on the relationship between DH interventions and participant engagement and retention in digital clinical research has yet to be conducted. This review aims to fill the gap by studying DH platforms that have been used in digital clinical research. We will map the various definitions that capture the engagement and retention of research participants in DH interventions. We will further identify platform design factors and features that hinder or promote participants' engagement and retention. The key concepts relevant to the review are defined in Textbox 1.

Methods

This systematic review was submitted for registration with the International Prospective Register of Systematic Reviews (PROSPERO) on June 8, 2024 (CRD42024561650), to avoid bias in conducting and reporting findings. According to the study's progress, amendments will be made if necessary [30].

Review Question

The review question was elaborated using the Population-Exposure-Outcome (PEO) statement, as outlined in Textbox 2. We chose to apply the PEO as it is regarded as the more appropriate approach for qualitative inquiries [31]. It is also more suitable for the definition of associations between particular exposures and factors and related outcomes [32]. The overall review question is: What factors and aspects promote research participants' engagement with and retention in DH interventions in digital clinical research? This was further broken down into 2 specific research questions:

Research question 1: How are engagement and retention of research participants defined in DH interventions conducted for clinical research?

Research question 2: What user interface elements, interaction design, and platform characteristics influence research participants' engagement and retention in DH interventions?

Textbox 2. Population-exposure-outcome structure.

Population-exposure-outcome element and description
Population
Research participants who are patients, informal or family caregivers.
Exposure
User interface, interaction elements, and platform characteristics of digital health interventions conducted in clinical research.
Outcomes
Engagement and retention of research participants.

Methodology Choice Rationale

The choice to perform a mixed methods systematic literature review is due to the number of individual studies that have already been conducted in digital health care and DH interventions, providing substantial evidence for the review.

The methodology selected for this systematic literature review is the mixed methods systematic review (MMSR) [33]. It is a standard approach that allows to systematically combine qualitative and quantitative data [34]. By integrating the findings of effectiveness (quantitative data) with findings on participants' experiences (qualitative data), MMSR offers a comprehensive evaluation with balanced data insights [35].

We plan to carry out the MMSR as we expect both data types to be prevalent in the reviewed studies. By including both data types, we will adopt a holistic approach to defining engagement and retention. For instance, qualitative data can shed light on the context, patient and informal caregivers' experiences, and barriers to engagement and retention, which quantitative data alone may not fully capture.

Search Strategy

We will analyze studies that (1) offered a DH intervention; (2) used a DH platform component, such as a mobile app, website, or text-messaging process; (3) collected engagement and retention-related measurements–quantitative, qualitative, or both; and (4) presented a digital interface to the research participants—patients, and informal caregivers—to interact with the DH intervention. The DH platforms can be designed specifically for clinical research or not. Commercially available health applications will be considered if they are used for clinical research purposes.

The search strategy for this systematic literature review was developed in collaboration with Görel Sundström, a librarian from Uppsala University, and the researchers involved in this study, LT, AK, MH, and MIM.

The PEO statement was used to construct the search strategy (Table 1). The keywords refinement process involved different approaches: tests conducted by the librarian, consultation of referenced articles to analyze the keywords they used, and expert reviews conducted by the research team. The keywords selection process was performed to ensure the search would capture studies using various terminologies to address the same research questions (Multimedia Appendix 1).

Table 1. Preliminary Web of Science search strategy (to be adapted for the other databases).

Search number	Database search algorithm
User engagement, user retention, and metrics	
1	(“active user*” OR Attrition OR “Click rate” OR “Completion rate*” OR “Frequency of use” OR “Follow up” OR Login OR “log in” OR “Returning user*” OR “Session duration” OR “Sign in” OR “Study complet*” OR “Time spent” OR usage OR “User actions” OR “Use Rate*” OR “User metric*” OR “user session*”)
2	((Caregiver* OR “Healthy Volunteer*” OR “Research Subject*” OR participant* OR patient* OR subject* OR user*) NEAR/3 (accept* OR activit* OR adher* OR attitude* OR barrier* OR challeng* OR complian* OR discontinu* OR Disengagement* OR Dropout* OR Efficien* OR Effectiveness OR engag* OR evalutation* OR experience* OR Finish* OR involvement* OR interaction* OR obstacle* OR participation* OR perception* OR perspective* OR retention* OR satisf* OR visit* OR view*))
3	1 OR 2
Clinical research informatics and digital care	
4	(“Clinical informat*” OR “Clinical research informat*” OR “Clinical trials informatic*” OR CRI OR “digital care” OR eHealth OR e-health OR etherap* OR “e-Mental health” OR “Health informati*” OR iCBT OR “Internet Cognitive Behavioral Treatment*” OR “medical informatics*” OR mHealth OR m-health OR mtherap* OR m-therap* OR “Online Clinical Trial*” OR telerehabilitation)
5	((“clinical research” OR “clinical trial*” OR “medical research” OR health OR intervention* OR psychotherap* OR therap* OR “self-help program*” OR treatment*) NEAR/3 (Computer* OR cyber OR Digital OR electronic OR informatics OR Internet OR Mobile OR Online OR Smartphone OR “Technology Based” OR “Web based”))
6	4 OR 5
Design and aspects of software or digital platform	
7	(“Interaction design*” OR Interface OR Usability OR “User centered design*” OR “Visual design*”)
Combining all topics	
8	3 AND 6 AND 7

The search will be conducted across a range of electronic databases: PubMed, IEEE Xplore, CINAHL, Scopus, Web of Science, APA PsycINFO, and the ACM Digital Library. These databases are chosen based on their relevance to the research topic and their widespread use in academic and research communities.

In addition to the electronic database searches, the research team will use additional search methods to identify potential studies that may not be captured through the database searches. It includes hand search, which involves manually scanning relevant journals; back-forward citation tracking, where we examine the references of identified articles; and reference checking to ensure no valuable sources are overlooked during the review process.

This systematic literature review will not involve collecting sensitive personal data.

Study Selection Criteria

The PEO statement was used to outline the eligibility criteria for study inclusion and exclusion, delineating them by population, exposure, and outcomes (Table 2).

Table 2. Population-exposure-outcome inclusion and exclusion criteria.

PEO[a]	Inclusion criteria	Exclusion criteria
Population	Research participants, study participants, patients, informal caregivers, carers, caregivers, and users. No exclusion based on age or gender.	Researchers, physicians, doctors, nurses, social care workers, social workers, dentists, and health care professionals.
Exposure or environment	User interface and interaction design of DH platforms.	Engagement and experience related to the intervention or treatment itself. Experience with content quality (text and multimedia content).
Outcomes	Engagement and retention to the study.	Efficacy of the treatment, efficacy related to the intervention or treatment itself.
Study methods	Qualitative methods, quantitative methods, mixed methods.	Reviews (systematic, scoping, meta-analysis, etc)
Publication types	Formally published peer-reviewed journal articles, conference papers.	Grey literature, opinion pieces, protocols, reviews
Geographical considerations	Initially not limited to any geographical area.	

[a]PEO: Population-exposure-outcome.

Types of Studies

Qualitative Studies

Qualitative interviews, focus group discussions, usability studies, participatory research, participatory design, case studies, grounded theory research, thematic and content analysis of textual data, phenomenological studies, narrative research, and ethnographic observations.

Quantitative Studies

Randomized controlled trials, cohort studies, longitudinal studies, experimental studies, case-control studies, cross-sectional studies, and observational studies.

Mixed Methods Studies

Studies integrating qualitative and quantitative data collection and analysis methods within a single research design, encompassing but not restricted to convergent design, sequential explanatory design, and sequential exploratory design.

In the case of studies addressing the same DH intervention and cohort of individuals, only the study with more detailed data regarding engagement and retention-based measurements will be considered, unless the studies present different aspects of the 2 mentioned subjects.

Studies such as gray literature, editorials, letters, opinion papers, and theses and dissertations will be excluded.

Time Period

The study will consider articles published from January 2018 to June 2024. This 7-year publication window was chosen because of the rapid evolution in the technology and health informatics domain. The timeframe also covers DH intervention platforms developed before and after the COVID-19 pandemic [36].

Language

Due to resource constraints, the study will exclusively include articles published in English. The research team acknowledges that this approach limits the inclusion of studies performed in different parts of the world and published in other languages.

Study Screening

First, a search conducted by an independent librarian will identify potentially eligible studies based on predefined keywords that consider the inclusion and exclusion criteria. The results from this initial search will undergo deduplication: Duplicates will be identified and removed using EndNote (version 21; Clarivate), using the Bramer et al [37] guidelines. The remaining studies will then be imported into Covidence [38]. There, data will be screened in two steps: (1) title and abstract screening, and (2) full-text screening. During the first step, at least 2 reviewers will independently review the titles and abstracts, blinded to the authors' names, and each other's review decisions (ie, double-blinded) [38]. After, the potential articles will have their full text screened, filtered, and categorized according to the predefined inclusion and exclusion criteria. In the event of disagreements between the 2 reviewers, at either stage of the review process, a third reviewer (LT) will be consulted to reach a consensus.

Data Extraction

The data extraction will use a standardized data extraction form elaborated by the research team. The form is designed to capture study information such as (1) identification: study ID, authors, year, country, publication type, and analysis type (qualitative, quantitative, and mixed-methods); (2) characteristics: research participants' characteristics, age, sample size, intervention description, digital platform or software, and the medium used; (3) results: engagement and completion measurements, results and findings presented in qualitative and quantitative data, and measurement tools.

Other information may be added as the research team considers it relevant to the analysis. One reviewer will independently extract the data, and a second reviewer will check it for accuracy and completion. The extracted information will be organized in a previously formatted table in Microsoft Excel. Qualitative data regarding results and findings will also be collected. The qualitative data will be analyzed using NVivo (version 14; Lumivero) afterward.

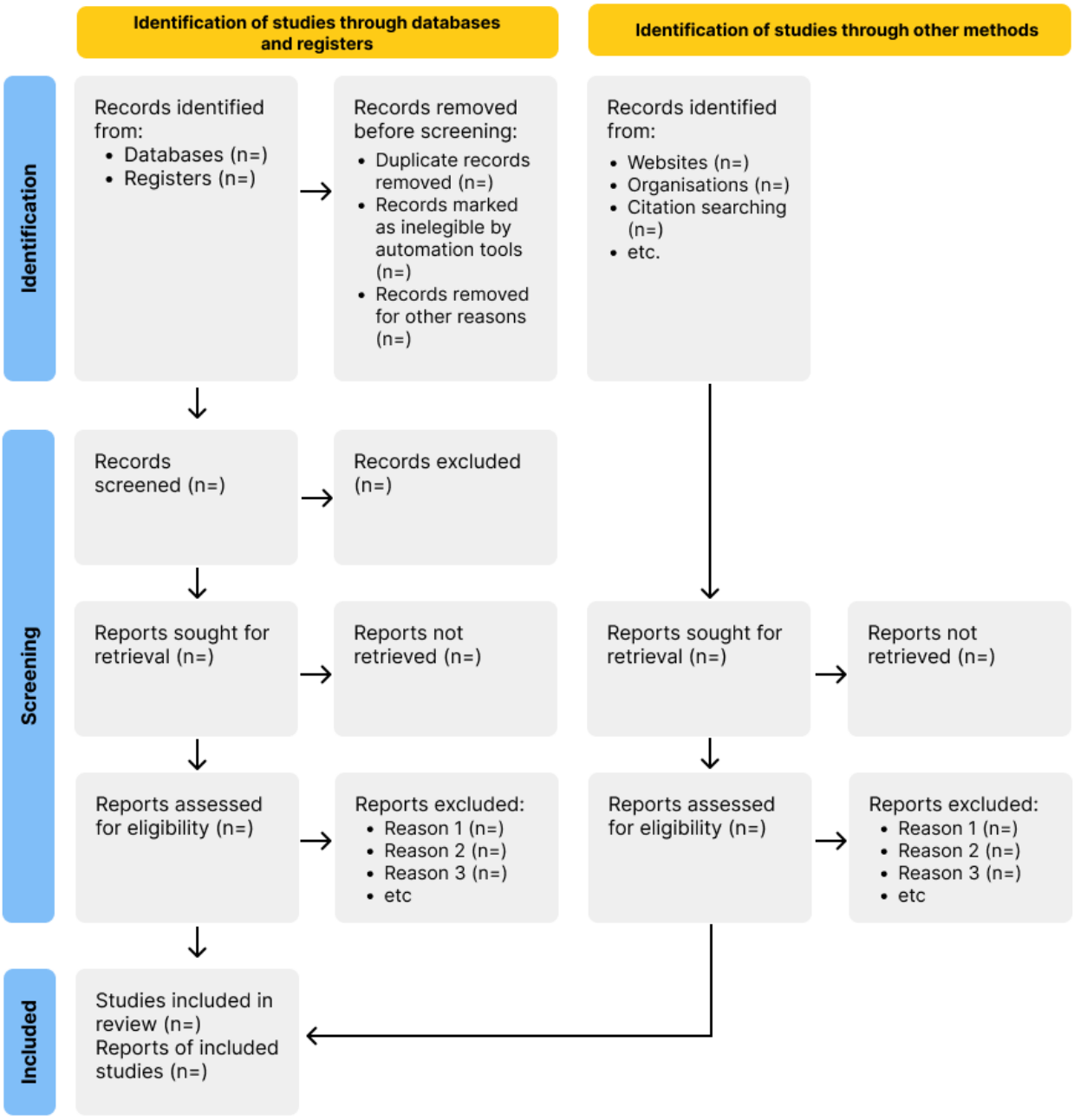
Quality Assessment and Appraisal

The study plans to use the mixed-methods assessment tool (MMAT) for quality assessment and critical appraisal [39]. MMAT provides a systematic approach to assessing quality criteria on a variety of study designs, such as qualitative studies, quantitative randomized controlled trials, quantitative nonrandomized, quantitative descriptive, and mixed-methods studies [40]. Using MMAT, we will evaluate the studies' clarity of the research question, appropriateness of the study design, data collection methods, data analysis, and interpretation of results.

Data Analysis and Synthesis

The study selection procedure will be visualized through the PRISMA 2020 flow diagram, as seen in Figure 2 [41].

Figure 2. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.



Data related to the identification of a given study and its characteristics will be organized in summary tables. As the review question stipulates the inclusion of a wide range of research designs, including qualitative and quantitative designs, the main results from our investigation will be organized into major themes and subthemes, and key findings on terms will also be presented. If significant differences and patterns arise, such as those related to health conditions, age, or digital literacy, thematic clusters for analysis will be delineated. Since the data will potentially arise from diverse study designs, quantitative data will be submitted to a data transformation process to be qualitized to be converted into qualitative data in the form of themes and categories and afterward summarized in a narrative synthesis to allow further integration with qualitative data [35,42,43]. Once qualitative and quantitative data are integrated, they will be compiled through a thematic analysis in order to identify the main concepts regarding engagement and retention. The codes for this investigation will be developed by one of the reviewers and checked by at least 1 member of the research team. The codes will be built using the Persuasive System Design framework developed by Oinas-Kukkonen and Harjumaa as a basis [44]. Kelders et al [25] have already applied this framework in the digital health area. A total of 2 independent reviewers will conduct the coding, and discrepancies and new codes will be discussed between the 2 reviewers. If no agreement is reached, a third reviewer will be consulted to reach a consensus. Afterward, the major themes and subthemes will be summarized in a narrative synthesis. One of the authors will compose the narrative synthesis, and a second author will assess and provide appraisal.

Dissemination Strategy

The results of this study will be disseminated as a scientific publication in a peer-reviewed journal and presented at conferences. Plain-language summaries will also be produced to share in various channels, such as social media, ResearchGate, and technology and health care websites.

Ethical Considerations

According to the Ethical Review Data (2003:460) by the Swedish Ethical Review Authority, ethical approval will not be required for this research.

Results

As of June 2024, the literature review has conducted 2 pilot searches to test and refine keywords and verify the initial quality of results. The results are expected to be published as a systematic literature review and submitted for publication in June 2025.

Discussion

Principal Findings

In light of the potential benefits of technology in clinical research, DH intervention design demands further investigation, to mediate the relationship between research participants and the technology. As highlighted by Johnson [45], connected technologies have provided many new opportunities in clinical research in recent years, such as increasing research awareness, recruitment options, and delivering interventions and treatments. Achieving a high rate of participation required to ensure the quality of an investigation is still a challenge. To meet these opportunities, CRI researchers and developers becoming more aware of the importance of developing adequate software for research participants to expand intervention. Although a "user-centric" approach has increased through participant-centered initiatives, digital clinical research is still on the journey to find ways to reduce the time and labor requirements that hinder participant involvement [14,46]. Offering a proper setting to a plurality of participants is fundamental to guaranteeing clinical research quality; otherwise, CRI risks increasing health care inequalities and disparities. DH interventions that do not consider socioeconomic factors such as financial situation, race, ethnicity, age, education, and digital literacy present higher chances of producing intervention-generated inequalities, increasing the digital divide, and may only benefit the already more advantaged populations [6,9,47].

Intervention researchers have long experimented with strategies for engagement and retention. Intervention factors like acceptability and feasibility of devices and technology, system usability, visual design, content, and adaption to literacy levels have been found to affect participant behaviors. These factors commonly influence access conditions by minimizing attrition but do not necessarily guarantee engagement, retention, and adherence. Importantly, engagement and retention may be promoted by factors that pertain to the particular characteristics of the digital platforms and software. Here are included platform usability and design, but also and others are research-based strategies, such as compensation, incentives, or rewards [21]. Interaction features can also incentivize participant's engagement and retention. These could be in the form of (1) gamification, (2) reminders or notifications, (3) social support provided within the DH intervention, (4) personalization, and (5) content tailored to participants' physical and cognitive abilities [21,25,26]. Understanding how platform design choices interact with participant behavior in DH interventions has become a crucial consideration for intervention research.

Limitations

Summarizing the key DH platform factors that affect participant engagement and retention given the variability of intervention designs, target participant groups and DH platform mediums may be challenging. Given the heterogeneity of the reviewed studies, we may have to focus only on some participant populations or DH platforms or include only broad trends in the narrative synthesis. Preliminary research, however, showed that concepts like personalization and fit to participants' conditions and needs are commonly important design factors, as discussed in previous literature [11].

Implications

We foresee that this review will serve as a useful resource to those developing DH interventions, but may not be versed in DH platform design. By summarizing key platform design characteristics that affect participant behavior on the platform and, by proxy, the intervention, the review will be particularly relevant to intervention researchers.

Conclusions

Systematic reviews are considered one of the most informative sources of research evidence and have supported decision-making in health care in recent decades [40,48]. Acknowledging the relevance of this resource, this review aims to contribute to the growing field of digital clinical research and patient-centered design, providing a comprehensive reference for developing more engaging and effective digital platforms and software for clinical research.

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Data Availability

Data sharing is not applicable to this article as no datasets were generated or analyzed during this study.

Authors' Contributions

LT, AK, and MH contributed to the idea conception. LT wrote the initial manuscript draft. Manuscript revision was performed by LT, AK, MH, and MIM, Visualization was done by LT. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
String searches.
[PDF File (Adobe PDF File), 135 KB - resprot_v14i1e65099_app1.pdf]

References

1. Butcher CJ, Hussain W. Digital healthcare: the future. Future Healthc J 2022;9(2):113-117 [FREE Full text] [doi: 10.7861/fhj.2022-0046] [Medline: 35928188]
2. Murray E, Hekler EB, Andersson G, Collins LM, Doherty A, Hollis C, et al. Evaluating digital health interventions: key questions and approaches. Am J Prev Med 2016;51(5):843-851 [FREE Full text] [doi: 10.1016/j.amepre.2016.06.008] [Medline: 27745684]
3. Kim HS, Kwon IH, Cha WC. Future and development direction of digital healthcare. Healthc Inform Res 2021;27(2):95-101 [FREE Full text] [doi: 10.4258/hir.2021.27.2.95] [Medline: 34015874]
4. Richesson RL, Andrews JE. Clinical Research Informatics. London, UK: Springer London; 2012.
5. Zhai S, Chu F, Tan M, Chi NC, Ward T, Yuwen W. Digital health interventions to support family caregivers: an updated systematic review. Digit Health 2023;9:20552076231171967. [doi: 10.1177/20552076231171967] [Medline: 37223775]
6. Jenkins CL, Imran S, Mahmood A, Bradbury K, Murray E, Stevenson F, et al. Digital health intervention design and deployment for engaging demographic groups likely to be affected by the digital divide: protocol for a systematic scoping review. JMIR Res Protoc 2022;11(3):e32538. [doi: 10.2196/32538]
7. Baumel A, Kane JM. Examining predictors of real-world user engagement with self-guided eHealth interventions: analysis of mobile apps and websites using a novel dataset. J Med Internet Res 2018;20(12):e11491 [FREE Full text] [doi: 10.2196/11491] [Medline: 30552077]
8. Sharpe EE, Karasouli E, Meyer C. Examining factors of engagement with digital interventions for weight management: rapid review. JMIR Res Protoc 2017;6(10):e205 [FREE Full text] [doi: 10.2196/resprot.6059] [Medline: 29061557]
9. Veinot TC, Mitchell H, Ancker JS. Good intentions are not enough: how informatics interventions can worsen inequality. J Am Med Inform Assoc 2018;25(8):1080-1088 [FREE Full text] [doi: 10.1093/jamia/ocy052] [Medline: 29788380]
10. Fleming T, Bavin L, Lucassen M, Stasiak K, Hopkins S, Merry S. Beyond the trial: systematic review of real-world uptake and engagement with digital self-help interventions for depression, low mood, or anxiety. J Med Internet Res 2018;20(6):e199 [FREE Full text] [doi: 10.2196/jmir.9275] [Medline: 29875089]
11. Inan OT, Tenaerts P, Prindiville SA, Reynolds HR, Dizon DS, Cooper-Arnold K, et al. Digitizing clinical trials. NPJ Digit Med 2020;3(1):101 [FREE Full text] [doi: 10.1038/s41746-020-0302-y] [Medline: 32821856]
12. Tan RKJ, Wu D, Day S, Zhao Y, Larson HJ, Sylvia S, et al. Digital approaches to enhancing community engagement in clinical trials. NPJ Digit Med 2022;5(1):37 [FREE Full text] [doi: 10.1038/s41746-022-00581-1] [Medline: 35338241]
13. Peters C, Castellano G, De Freitas S. An Exploration of User Engagement in HCI. 2009 Presented at: Proc Int Workshop Affect-Aware Virtual Agents Soc Robots Boston Massachusetts; 2009 November 06; New York, USA. [doi: 10.1145/1655260.1655269]
14. Carrion J. Improving the patient-clinician interface of clinical trials through health informatics technologies. J Med Syst 2018;42(7):120. [doi: 10.1007/s10916-018-0973-y] [Medline: 29845581]
15. Rosa C, Marsch LA, Winstanley EL, Brunner M, Campbell ANC. Using digital technologies in clinical trials: current and future applications. Contemp Clin Trials 2021;100:106219 [FREE Full text] [doi: 10.1016/j.cct.2020.106219] [Medline: 33212293]
16. Payne PRO, Embi PJ, Cimino JJ. In: Shortliffe EH, Cimino JJ, editors. Clinical Research Informatics. London, UK: Springer London; 2014:755.
17. Kahn MG, Weng C. Clinical research informatics: a conceptual perspective. J Am Med Inform Assoc 2012;19(e1):e36-e42. [doi: 10.1136/amiajnl-2012-000968] [Medline: 22523344]
18. Payne PRO. In: Richesson RL, Andrews JE, editors. The Clinical Research Environment. New York, NY: Springer; 2012.

19. Nkyekyer J, Clifford SA, Mensah FK, Wang Y, Chiu L, Wake M. Maximizing participant engagement, participation, and retention in cohort studies using digital methods: rapid review to inform the next generation of very large birth cohorts. J Med Internet Res 2021;23(5):e23499 [FREE Full text] [doi: 10.2196/23499] [Medline: 33988509]
20. Perski O, Blandford A, West R, Michie S. Conceptualising engagement with digital behaviour change interventions: a systematic review using principles from critical interpretive synthesis. Transl Behav Med 2017;7(2):254-267 [FREE Full text] [doi: 10.1007/s13142-016-0453-1] [Medline: 27966189]
21. Amagai S, Pila S, Kaat AJ, Nowinski CJ, Gershon RC. Challenges in participant engagement and retention using mobile health apps: literature review. J Med Internet Res 2022;24(4):e35120. [doi: 10.2196/35120] [Medline: 35471414]
22. Frampton GK, Shepherd J, Pickett K, Griffiths G, Wyatt JC. Digital tools for the recruitment and retention of participants in randomised controlled trials: a systematic map. Trials 2020;21(1):478 [FREE Full text] [doi: 10.1186/s13063-020-04358-3] [Medline: 32498690]
23. Griffith Fillipo IR, Pullmann MD, Hull TD, Zech J, Wu J, Litvin B, et al. Participant retention in a fully remote trial of digital psychotherapy: comparison of incentive types. Front Digit Health 2022;4:963741 [FREE Full text] [doi: 10.3389/fdgth.2022.963741] [Medline: 36148211]
24. Bremer V, Chow PI, Funk B, Thorndike FP, Ritterband LM. Developing a process for the analysis of user journeys and the prediction of dropout in digital health interventions: machine learning approach. J Med Internet Res 2020;22(10):e17738 [FREE Full text] [doi: 10.2196/17738] [Medline: 33112241]
25. Kelders SM, Kok RN, Ossebaard HC, Van Gemert-Pijnen JE. Persuasive system design does matter: a systematic review of adherence to web-based interventions. J Med Internet Res 2012;14(6):e152 [FREE Full text] [doi: 10.2196/jmir.2104] [Medline: 23151820]
26. Gomez-Hernandez M, Ferre X, Moral C, Villalba-Mora E. Design guidelines of mobile apps for older adults: systematic review and thematic analysis. JMIR Mhealth Uhealth 2023;11:e43186 [FREE Full text] [doi: 10.2196/43186] [Medline: 37733401]
27. Ramdowar H, Khedo KK, Chooramun N. A comprehensive review of mobile user interfaces in mHealth applications for elderly and the related ageing barriers. Univ Access Inf Soc 2023;23(4):1613-1629. [doi: 10.1007/s10209-023-01011-z]
28. Ye B, Chu CH, Bayat S, Babineau J, How TV, Mihailidis A. Researched apps used in dementia care for people living with dementia and their informal caregivers: systematic review on app features, security, and usability. J Med Internet Res 2023;25:e46188 [FREE Full text] [doi: 10.2196/46188] [Medline: 37824187]
29. Borghouts J, Eikey E, Mark G, De Leon C, Schueller SM, Schneider M, et al. Barriers to and facilitators of user engagement with digital mental health interventions: systematic review. J Med Internet Res 2021;23(3):e24387 [FREE Full text] [doi: 10.2196/24387] [Medline: 33759801]
30. Stewart L, Moher D, Shekelle P. Why prospective registration of systematic reviews makes sense. Syst Rev 2012;1(1):7 [FREE Full text] [doi: 10.1186/2046-4053-1-7] [Medline: 22588008]
31. Bettany-Saltikov J, McSherry R. How to Do A Systematic Literature Review in Nursing: A Step-By-Step Guide. London: Open University Press; 2016.
32. Munn Z, Stern C, Aromataris E, Lockwood C, Jordan Z. What kind of systematic review should I conduct? A proposed typology and guidance for systematic reviewers in the medical and health sciences. BMC Med Res Methodol 2018;18(1):5. [doi: 10.1186/s12874-017-0468-4] [Medline: 29316881]
33. Harden A. Focus - Publ natl cent dissem disabil res. Mixed-methods systematic reviews: integrating quantitative and qualitative Findings. 2010. URL: https://ktdrr.org/ktlibrary/articles_pubs/ncddrwork/focus/focus25/Focus25.pdf [accessed 2009-07-29]
34. Stern C, Lizarondo L, Carrier J, Godfrey C, Rieger K, Salmond S, et al. Methodological guidance for the conduct of mixed methods systematic reviews. JBI Evid Synth 2020;18(10):2108-2118. [doi: 10.11124/JBISRIR-D-19-00169] [Medline: 32813460]
35. Lizarondo L, Stern C, Apostolo J, Carrier J, de Borges K, Godfrey C, et al. Five common pitfalls in mixed methods systematic reviews: lessons learned. J Clin Epidemiol 2022;148:178-183. [doi: 10.1016/j.jclinepi.2022.03.014] [Medline: 35341946]
36. Hu J, Li C, Ge Y, Yang J, Zhu S, He C. Mapping the evolution of digital health research: bibliometric overview of research hotspots, trends, and collaboration of publications in JMIR (1999-2024). J Med Internet Res 2024;26:e58987 [FREE Full text] [doi: 10.2196/58987] [Medline: 39419496]
37. Bramer WM, Giustini D, De Jonge GB, Holland L, Bekhuis T. De-duplication of database search results for systematic reviews in EndNote. jmla 2016;104(3). [doi: 10.5195/jmla.2016.24]
38. Harrison H, Griffin SJ, Kuhn I, Usher-Smith JA. Software tools to support title and abstract screening for systematic reviews in healthcare: an evaluation. BMC Med Res Methodol 2020;20(1):7. [doi: 10.1186/s12874-020-0897-3] [Medline: 31931747]
39. Hong Q, Fàbregues S, Bartlett G, Boardman F, Cargo M, Dagenais P, et al. The mixed methods appraisal tool (MMAT) version 2018 for information professionals and researchers. EFI 2018;34(4):285-291 [FREE Full text] [doi: 10.3233/efi-180221]
40. Hong QN, Pluye P, Fàbregues S, Bartlett G, Boardman F, Cargo M, et al. Improving the content validity of the mixed methods appraisal tool: a modified e-Delphi study. J Clin Epidemiol 2019;111:49-59 [FREE Full text] [doi: 10.1016/j.jclinepi.2019.03.008] [Medline: 30905698]

41. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71 [FREE Full text] [doi: 10.1136/bmj.n71] [Medline: 33782057]
42. Campbell M, Katikireddi SV, Sowden A, McKenzie JE, Thomson H. Improving conduct and reporting of narrative synthesis of quantitative data (ICONS-Quant): protocol for a mixed methods study to develop a reporting guideline. BMJ Open 2018;8(2):e020064. [doi: 10.1136/bmjopen-2017-020064]
43. Lizarondo L, Stern C, Carrier J, Godfrey C, Rieger K, Salmond S, et al. In: Aromataris E, Lockwood C, Porritt K, Pilla B, Jordan Z, editors. Mixed Methods Systematic Reviews. Australia: JBI Man Evid Synth JBI; 2024.
44. Oinas-Kukkonen H, Harjumaa M. Persuasive systems design: key issues, process model, and system features. CAIS 2009;24. [doi: 10.17705/1CAIS.02428]
45. Johnson SB. Clinical research informatics: supporting the research study lifecycle. Yearb Med Inform 2017;26(01):193-200. [doi: 10.1055/s-0037-1606503]
46. Kaye J, Curren L, Anderson N, Edwards K, Fullerton SM, Kanellopoulou N, et al. From patients to partners: participant-centric initiatives in biomedical research. Nat Rev Genet 2012;13(5):371-376. [doi: 10.1038/nrg3218] [Medline: 22473380]
47. Brewer LC, Fortuna KL, Jones C, Walker R, Hayes SN, Patten CA, et al. Back to the future: achieving health equity through health informatics and digital health. JMIR Mhealth Uhealth 2020;8(1):e14512 [FREE Full text] [doi: 10.2196/14512] [Medline: 31934874]
48. Bunn F, Trivedi D, Alderson P, Hamilton L, Martin A, Pinkney E, et al. The impact of cochrane reviews: a mixed-methods evaluation of outputs from cochrane review groups supported by the national institute for health research. Health Technol Assess 2015;19(28):100. [doi: 10.3310/hta19280]

Abbreviations

CRI: clinical research informatics
DH: digital health
MMAT: mixed-methods assessment tool
MMSR: mixed-methods systematic review
PEO: population-exposure-outcomes
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO: Prospective Register of Systematic Reviews

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Protocol

Trajectories of Change, Illness Understanding, and Parental Worries in Children and Adolescents Undergoing Internet-Delivered Cognitive-Behavioral Therapy for Functional Abdominal Pain Disorders: Protocol for a Single-Case Design and Explorative Pilot Study

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Abstract

Background: Functional abdominal pain disorders (FAPDs) are common in young people and are characterized by persistent or recurrent abdominal symptoms without apparent structural or biochemical abnormalities. FAPDs are associated with diminished quality of life, school absence, increased health care use, and comorbid anxiety and depression. Exposure-based internet-delivered cognitive behavioral therapy (ICBT) has demonstrated efficacy in alleviating abdominal symptoms and improving quality of life. However, a deeper understanding of effect mechanisms and identification of possible additional treatment targets could refine treatment.

Objective: This protocol paper aims to describe a study focusing on children and adolescents undergoing ICBT for FAPDs, aiming to further investigate the underlying mechanisms of effect.

Methods: Children (8-12 years), adolescents (13-17 years) with FAPDs, and their respective parents will be included for 10 weeks for ICBT. First, detailed trajectories of effect are examined through a randomized single-case design study involving 6 children and 6 adolescents (substudy 1). Following this, an open-ended explorative pilot study with 30 children and 30 adolescents explores potential illness-related cognitive biases and interoceptive accuracy before and after treatment (substudy 2). Finally, spanning across these 2 substudies, including all parents from substudies 1 and 2, we will assess parental distress and illness worries before and after treatment, and how these factors impact the treatment adherence and outcomes of the child or adolescent (substudy 3).

Results: Recruitment of participants began in June 2022 and is finalized for substudy 1 and ongoing for substudies 2 and 3. Recruitment is expected to be completed by January 2025, with final data collection during April 2025.

Conclusions: The findings have the potential to contribute to the ongoing improvement of specialized psychological treatment for FAPDs in young people.

Trial Registration: ClinicalTrials.gov NCT05237882; https://clinicaltrials.gov/study/NCT05237882; ClinicalTrials.gov NCT05486585; https://clinicaltrials.gov/study/NCT05486585; OSF Registries osf.io/c49k7; https://osf.io/c49k7

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KEYWORDS

functional abdominal pain disorders; abdominal pain; internet-based intervention; cognitive behavioral therapy; interoception; attentional bias; parental distress; single case study; children; adolescents; youth; study protocol; quality of life; treatment; medication; psychological treatment; psychology

Introduction

Functional abdominal pain disorders (FAPDs) affect up to 15% of children and adolescents and are characterized by recurrent or persistent abdominal pain and other debilitating gastrointestinal symptoms such as changes in defecation patterns and nausea [1,2]. The disorders are associated with reduced quality of life, high absence from school, and increased health care use [3]. Psychiatric comorbidities, especially anxiety and depression, are prevalent [4] and up to 40% persist in reporting abdominal symptoms into adulthood [5].

The pathophysiology of FAPDs is not fully understood but recent research suggests a biopsychosocial perspective where the complex interactions of physiological processes such as visceral hypersensitivity, psychological factors like emotional distress and anxiety, and social factors including family dynamics and environmental influences can contribute to the development and maintenance of gastrointestinal symptoms [6]. These factors combined are related to altered processing of sensory stimuli along the brain-gut axis with persistent or recurrent experience of abdominal pain and other gastrointestinal symptoms [7-10]. This altered processing can be understood within the framework of predictive processing, a theory suggesting that the brain consistently evaluates predictions regarding sensory inputs and discrepancies from these predictions [11]. Crucial factors contributing to the development of maladaptive predictive processes encompass cognitive biases marked by symptom-related fear and catastrophizing with an attentional bias toward pain or gastrointestinal stimuli [12-15]. This may be accompanied by the avoidance of situations expected to trigger symptoms [4,16-18] and changes in the interoceptive ability to sense, process, and interpret body signals [19]. Parental behaviors, such as solicitous responses, fearful communication about symptoms, and encouraging avoidance of situations that may provoke symptoms, can further influence the child's perception of bodily stimuli [20-23].

In summary, understanding the pathophysiology of FAPDs involves navigating a complex system of various factors and processes. Consequently, treatment may encompass different targets, including both child-specific and contextual, that is, typically parental-specific factors.

In line with this, cognitive behavioral therapy (CBT) is the treatment supported by the strongest evidence of effect [24-26], with its main focus on restructuring potential child symptom-related maladaptive cognitions, emotions, and behaviors, and often with parental involvement. Swedish studies have documented the efficacy of internet-delivered cognitive behavioral therapy (ICBT) aimed at children and adolescents with FAPDs and their parents [27-29]. The ICBT focuses especially on exposure exercises and parental management of their child or adolescent's symptoms. By enabling the child or adolescent to manage symptoms in previously avoided situations and thereby minimizing the gastrointestinal-specific fear, the treatment reduces the proposed visceral hypersensitivity, which over time leads to fewer abdominal symptoms.

Still, a proportion of the young patients do not improve from ICBT as the number needed to treat has been reported to be around 4, meaning approximately 4 patients must receive the treatment for 1 additional patient to experience adequate symptom relief [27,29]. Therefore, a deeper understanding of the mechanisms of change and the potential influence of additional modifiable factors on the treatment effect is required to improve treatment effects even more.

In the current study, we will evaluate translated versions of the Swedish ICBT for children and adolescents with FAPDs in a Danish context. The treatments target both children (aged 8-12 years) and adolescents (aged 13-17 years) and their parents, which provides a unique possibility to examine both child or adolescent and parental factors before and after treatment. The aims of the study are to (1) investigate the detailed trajectory of the effect of ICBT in children and adolescents with FAPDs, (2) explore potential illness-related cognitive biases and interoceptive accuracy in children and adolescents with FAPDs compared with healthy controls, and if these factors are changed after ICBT, and (3) explore if parental distress, illness worries, and behaviors may impact the child or adolescent's treatment adherence and outcome.

This protocol article is reported following the SPIRIT (Standard Protocol Items Recommendations for Interventional Trials) guidelines [30].

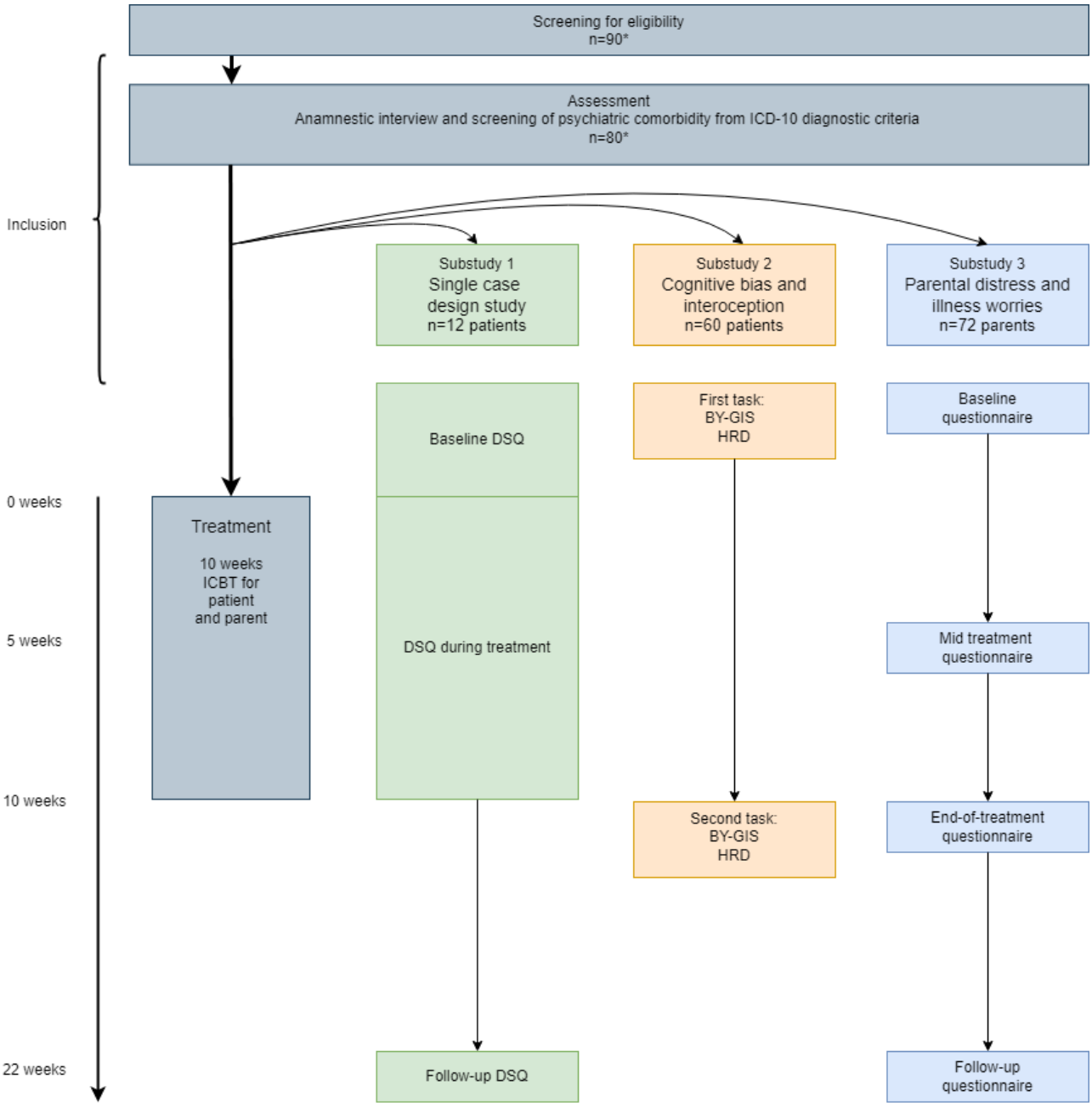
Methods

Study Design

The study includes 2 recruitment phases. The first phase concerns a single case experimental design (SCED) study (substudy 1) with a total of 12 patients (6 children and 6 adolescents, respectively). The second phase concerns an open pilot study on cognitive biases and interoceptive accuracy (substudy 2) with a total of 60 patients (30 children and 30 adolescents, respectively).

Consequently, a total of 72 children and adolescents, along with a corresponding number of parents, will undergo ICBT for FAPDs throughout the entire study. Parental distress and illness worries will be assessed before, during, and after the treatment in all included parents (substudy 3; Figure 1).

Figure 1. Overall study design. BY-GIS: biases in youth toward gastrointestinal-related stimuli; DSQ: daily short questionnaire; HRD: heart rate discrimination; ICBT: internet-delivered cognitive behavioral therapy; ICD-10: International Statistical Classification of Diseases, Tenth Revision.



Study Setting and Recruitment

Children and adolescents diagnosed with FAPD will be referred to the project from pediatric departments located at 4 hospitals (1 university hospital and 3 regional hospitals, respectively) as well as from private pediatric practitioners in the Central Denmark Region. Due to a slow referral rate of adolescents, we have been granted permission from The Central Denmark Region Committees on Health Research Ethics to expand the inclusion area to include additional regions (the North Denmark Region and the Region of Southern Denmark). We will maintain continuous communication with referring pediatricians to ensure sufficient participant enrollment. This will include in-person meetings, emails, and newsletters.

Eligibility Criteria

Eligible participants will be invited for an assessment interview at the Department of Child and Adolescent Psychiatry, Aarhus University Hospital Psychiatry. The assessment will include psychiatric comorbidities, such as neurodevelopmental disorders, mood disorders, and suicidal risk, systematically evaluated according to the *ICD-10* (*International Statistical Classification of Diseases, Tenth Revision*) diagnostic criteria. Assessments

will be performed by medical doctors who are either trainees or specialists in child and adolescent psychiatry.

Inclusion Criteria

First, age 8-17 years. Second, a primary diagnosis according to the ROME-IV criteria of one of the FAPD subtypes—irritable bowel syndrome (IBS) or functional abdominal pain not otherwise specified (FAP-NOS) documented by the child's regular pediatric physician [31]. The somatic evaluation includes recommended routine medical investigations, that is, growth, fecal calprotectin, and blood samples (TSH [thyroid stimulating hormone], total IgA [immunoglobulin A], IgA-tissue transglutaminase, complete blood count, C-reactive protein analysis, and liver enzymes). Third, stable dosage of regular FAPD-related medication such as laxatives, antidiarrheal medicines, or psychopharmacological medication during the past month.

Exclusion Criteria

First, another medical or psychiatric disorder that better explains the symptoms. Second, severe child psychiatric or social problems (eg, high level of suicidal ideation, school absence of more than 40% during the past month, or ongoing substance abuse). Third, ongoing psychological treatment. Fourth, insufficient language or computer skills (patients and parents). Fifth, severe family problems (eg, child maltreatment, parental substance abuse or severe psychiatric illness, and custody fight).

Intervention

Translation Procedure

For this study, the Swedish ICBT programs were translated into Danish. The translation procedure was stepwise; first, a direct translation was performed by native Danish speakers familiar with the Swedish language; second, a mutual discussion of the Danish translation took place within the research group, including a discussion of problematic sentences or wordings; third, remaining issues were discussed with the Swedish authors, and a final consensus on the Danish translation was reached. This translation was reviewed by both a Danish language expert and a clinician with experience with the patient group to make further refinements. Finally, in the last step, the revised translation was reviewed again by the Danish research group for final adjustments.

Design and Content of Treatment

The 4 distinct ICBT programs used in this study are targeted children (8-12 years), adolescents (13-17 years), and the parents of each group, respectively. The treatment lasts for 10 weeks and consists of 10 modules for children, adolescents, and parents of children (with a new module every week) and 5 modules for parents of adolescents (with a new module every other week). An overview of treatment content can be seen in Table 1. The programs include sections with videos, exercises, and quizzes designed to actively engage the child or adolescent in the treatment. Psychoeducation regarding FAPDs, detection of avoidance behavior, a brief mindfulness exercise called "SOL (Stop, observe, let go)" and graded repeated exposure exercises comprise some of the central components covered in the programs for both children and adolescents. The first modules of treatment introduce the above-mentioned concepts whereas later modules focus on repeated exposures. The purpose of "SOL" is Stopping, Observing how the stomach feels, and Letting go of the focus on the stomach and continuing with the activity. The parental programs emphasize supporting their child or adolescent's exposure, decreasing attention to their child or adolescent's abdominal symptoms, and prioritizing shared positive activities. Each module ends with planning of the homework assignments which are evaluated first thing in the next module.

Table 1. Overview of the content of treatment for each module.

Module	Children (8-12 years)	Parents	Adolescents (13-17 years)	Parents
1	• Introduction to the treatment format • Psychoeducation on FAPDs[a] (video) • Mapping "stomach behaviors" (control, avoidance, safety) • Setting treatment goals • Homework: Self-monitoring	• Introduction to the treatment format • Positive attention • Focus shift • Mapping common parental behaviors • Handling personal frustrations • Homework: Focus shift, breaks, involving peers	• Introduction to the treatment format • Psychoeducation on FAPDs (video) • Setting treatment goals • Homework: self-monitoring	• Introduction to the treatment format • Focus on positive attention and shared moments • Mapping common parental behaviors • Homework: Shared positive moments
2	• Psychoeducation on impact of thoughts and "SOL"[b] (video) • Constructing an exposure hierarchy. • Homework: Utilize "SOL" in everyday situations.	• Golden moments • Board game with rewards for exposure exercises. • Homework: Golden moments, focus shift, planning rewards"	• Mapping "stomach behaviors" (control, avoidance, safety) • Behavior analysis • Homework: Behavioral experiment (avoiding "stomach behaviors")	
3	• Behavior analysis • Psychoeducation on exposure exercises (video) • Homework: Exposure exercises.	• Supporting child's exposure exercises • Managing school absences • Homework: board game rewards, golden moments, focus shift	• Psychoeducation on impact of thoughts and "SOL" (video) • Toilet habits (frequent visits, urgency) • Homework: "SOL" and new toilet habits	• Psychoeducation on FAPDs (video) • Acknowledging and shifting focus to reduce symptom focus • Homework: Shared positive moments, letting go of parental behaviors, focusing on alternative adolescent behaviors
4	• Toilet Habits (frequent visits, urgency) • Behavior analysis • Homework: Exposure exercises, new toilet habits, "SOL"	• Parental stress and recreational activities • Homework: recreation, golden moments, board game rewards, focus shift	• Psychoeducation on exposure exercises (video) • Behavior analyses • Construct exposure hierarchy • Homework: "SOL," toilet habits, finish exposure hierarchy	
5	• Repetition • Behavior Analysis • Homework: Exposure exercises, toilet habits, eliminating safety behaviors, "SOL"	• Repetition • Mapping challenges • Homework: recreation, golden moments, board game rewards, focus shift	• Exposure exercises • Anticipatory anxiety • Emotional versus behavioral goals • Homework: Exposure exercises, "SOL," toilet habits.	• Encourage and support the adolescent's exposure • Psychoeducation on exposure exercises (video) • Homework: Shared positive moments, support and encouragement, support adolescent's exposure
6	• Positive analysis of new behaviors • Advancing exposure difficulty • Homework: Advancing exposure exercises, toilet habits, "SOL"	• Problem-solving with child • Homework: recreation, golden moments, board game rewards, focus shift, problem-solving	• Further details on exposure and rewards • Homework: Exposure exercises, "SOL," and toilet habits	

Module	Children (8-12 years)	Parents	Adolescents (13-17 years)	Parents
7	• Positive behavior analyses • Evaluation of Treatment Goals (from Module 1) • Homework: Exposure exercises, toilet habits, "SOL"	• Parental behavior analyses in child interaction • Homework: recreational, golden moments, board game rewards, focus shift	• Level up exposure exercises • Homework: Exposures exercises, "SOL," toilet habits	• Managing personal frustrations • Engaging in recreational activities • Listening effectively • Homework: Shared positive moments, support and encouragement, support adolescent's exposure, active listening, parental recreation
8	• Positive behavior analyses • Advancing exposures to a "Super Hard Day" • Homework: Exposure exercises, the "Super Hard Day," toilet habits, "SOL"	• Review of progress • Reward for efforts • Homework: recreation, golden moments, board game rewards, focus shift, parental reward	• Emphasis on more challenging exposures • Homework: Challenging exposure exercises, "SOL," toilet habits	
9	• Treatment repetition using quizzes • Progress evaluation • Homework: Final exposure exercises, toilet habits, "SOL"	• Progress evaluation • Challenge evaluation • Homework: recreation, golden moments, board game rewards, focus shift.	• Focus on how to further challenge oneself. • Homework: Exposure exercises	• Review of treatment • Parental behavior evaluation (comparison with module 1) • Future training and relapse prevention plan
10	• Treatment goal and exposure hierarchy evaluation • "Stomach behavior" evaluation (comparison with module 1) • Future training and relapse prevention plan	• Parental behavior evaluation (comparison with module 1) • Future training and relapse prevention plan	• Treatment goal and exposure hierarchy evaluation • "Stomach behavior" evaluation (comparison with module 1) • Future training and relapse prevention plan	

[a]FAPDs: Functional abdominal pain disorders.

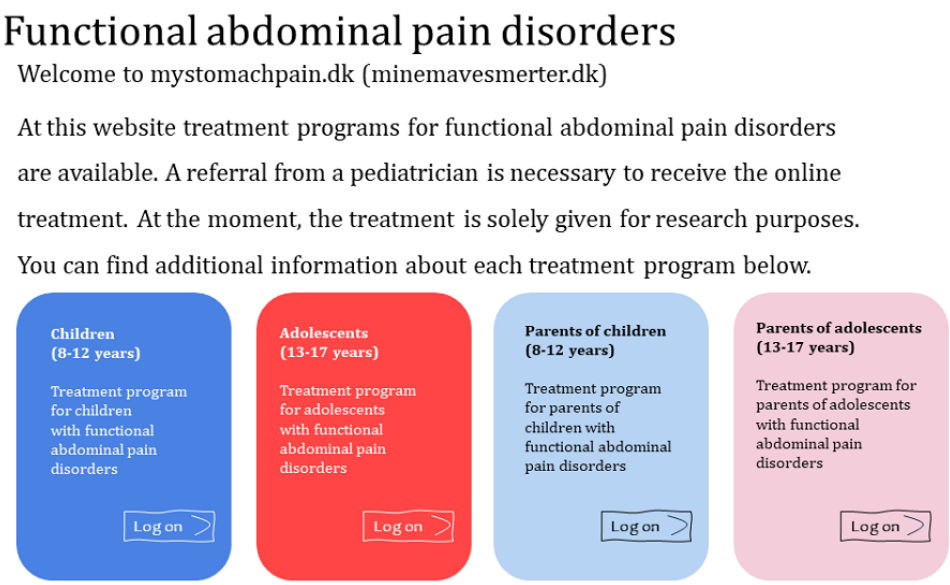
[b]SOL: Stop, observe, let go.

Modifications and Web Page

The Danish versions of the ICBT programs were pretested in 2 children and 2 adolescents with biweekly feedback from the patients and parents on overall experience and content (telephone interviews performed by a research assistant). Minor modifications were performed, mainly in the adolescent program where the IBS treatment was adjusted to include IBS and FAP-NOS. Furthermore, the mindfulness exercise "SOL" was integrated in the adolescent program to further support the process of labeling thoughts and sensations.

All treatment elements are delivered through a web page specifically designed for this study (Figure 2). Each family will choose 1 primary parent to participate in the treatment at the assessment. All 4 treatment programs are supported by a therapist who provides written feedback after each module. The affiliated therapists will be psychologists and medical doctors with knowledge of CBT. They will receive weekly supervision from Danish specialists in CBT and further supervision from the Swedish research team, who developed and tested the original programs.

Figure 2. Screenshot of the start page for the Danish treatment programs (all text is translated from Danish to English).



Measures

Measures in the Single Case Design Study (Substudy 1)

Children and adolescents will answer a daily short questionnaire (DSQ) throughout a pretreatment baseline period, randomized to last between 5 and 15 days, throughout the 10 weeks of treatment, and for a final 7-day follow-up period 3 months after treatment. The DSQ is an 8-item questionnaire, designed in line with the SCRIBE (Single-Case Reporting guideline In BEhavioural interventions) guidelines [32], addressing specific targets of the intervention, with items from different validated questionnaires for children and adolescents [32,33]. The full DSQ questionnaire is shown in Textbox 1. The primary outcome in the SCED study is the level of gastrointestinal symptoms assessed using 2 items from the Pediatric Quality of Life Inventory (PedsQL) Gastrointestinal Symptoms Questionnaire [34]. Secondary outcomes include illness worries, avoidance behavior, and level of pain acceptance as measured by the Visceral Sensitivity Index (VSI), irritable bowel syndrome behavioral response questionnaire (IBS-BRQ), and the Chronic Pain Acceptance Questionnaire – Adolescent Short Form (CPAQ-A8), respectively [35-37]. The items have been modified into questions concerning the last 24 hours and are rated on a 0-10 scale (“not at all” 0, “all the time” 10).

Textbox 1. Daily short questionnaire (DSQ).

During the last 24 hours, on a scale from 0 (not at all) to 10 (all the time)
1) Did your stomach hurt?
2) Did you feel discomfort in your stomach?
3) Did you worry about the problems in your belly?
4) Were you frightened when you felt discomfort in your belly?
5) Did you avoid going out in case you had belly problems?
6) Did you spent more time on the toilet than you ideally would like?
7) Did you do things that are important and things that are fun even though you have problems in your belly?
8) Has the most important thing been to keep your symptoms under control whenever you did something?

Measures on Cognitive Bias and Interoception (Substudy 2)

Cognitive biases will be assessed before and after treatment using a newly developed experimental design with a computerized web-based task: biases in youth toward gastrointestinal-related stimuli (BY-GIS) [38]. The BY-GIS task consists of a combination of a word task, which is a modified version of the Health Norms Sorting Task [39-41] and a picture task inspired by Gehrt et al [42]. The BY-GIS task is adapted to be appropriate for children and adolescents, featuring gastrointestinal-related stimuli (ie, words related to abdominal symptoms and pictures of food, leisure, and school situations). The BY-GIS task has 3 phases—encoding, free recall, and recognition. In the encoding phase, participants are asked to rate words and pictures presented to them. In the free recall phase, participants are instructed to recall as many words and pictures from the encoding phase as possible, and in the recognition phase, they are presented with words and pictures from the encoding phase along with new words and mirror images of the original pictures. They are then asked to mark which items have been presented to them before. The

development, test, and full procedure of the BY-GIS task are described by Bjerre-Nielsen et al [38].

Interoception will be investigated before and after treatment using a psychophysical measure of cardiac interoception, that is, the heart rate discrimination (HRD) task, developed by Legrand et al [43]. During the HRD task, participants have their heart rate monitored using a pulse oximeter while they are presented with auditory and visual stimuli from a computer and answer questions about their sensations of heart rate and subjective confidence in their answers. Thereby, the interoceptive performance (psychometric threshold, slope, and reaction time) and the metacognitive performance (confidence) can be measured. In collaboration with researchers from the Center of Functionally Integrative Neuroscience at Aarhus University, the task was adapted for a younger age group and pretested in 3 children and adolescents. Adaptations consisted of shortening the test by reducing the number of repetitions of trials, as well as replacing written instructions about the conduction of the test with direct oral guidance from a research assistant.

For both studies in substudy 2, we will perform parallel studies on healthy controls. The BY-GIS task was already tested in 96 healthy controls [38], and the interoception test setup will be performed in 60 healthy controls (all aged 8-17 years).

Measures of Parental Factors and Child Treatment Effects (Substudy 3)

To assess how parental distress, illness worry, and behavior impact the child's overall treatment effects in various domains and treatment adherence, all participating parents and children or adolescents in the ICBT programs will answer extensive questionnaires before assessment (T1: baseline), halfway through treatment (T2: mid-treatment), at end of treatment (T3: end of treatment), and 3 months after the end of treatment (T4: follow-up; Figure 1). Furthermore, the number of completed treatment modules will be obtained from the treatment web page after the end of treatment. The specific measures to be used are shown in Table 2 and described subsequently.

Table 2. Overview of questionnaires in substudy 3.

Outcome	Instrument	Time points and respondents[a]			
		T1	T2	T3	T4
Parental factors					
Parental distress	SCL-8[b] [44,45]	P	P	P	P
Parental illness worries	HAPYS[c] [46,47]	P	P	P	P
Parental illness behavior	ARCS[d,e] [48-50]	P	P	P	P
Child treatment effects					
Main measures					
Gastrointestinal symptoms	PedsQL Gastro[f] [34]	C, A, P	C, A, P	C, A, P	C, A, P
Pain intensity	Faces Pain Rating Scale – revised [51,52]	C, A, P	C, A, P	C, A, P	C, A, P
Additional measures					
Quality of life	PedsQL[g] [53]	C, A, P	C, A, P	C, A, P	C, A, P
Overall symptom load	CSSI[h] [54]	C, A, P		C, A, P	C, A, P
Depressive symptoms	MFQS[i] [55,56]	C, A		C, A	C, A
General anxiety	SCAS-S[j] [57,58]	C, A, P		C, A, P	C, A, P
Gastrointestinal anxiety	VSI[k]-short [35,59]	C, A	C, A	C, A	C, A
Avoidance and control behavior	IBS-BRQ-C[l] [36,60]	C, A	C, A	C, A	C, A
Illness perception	B-IPQ[m] [61,62]	C, A, P	C, A, P	C, A, P	C, A, P
Illness worries	CIAS[n,o] [63]	C, A	C, A	C, A	C, A
Pain acceptance	CPAQ-A8[p,q] [37]	C, A	C, A	C, A	C, A
Other measures					
Adverse events	Yes or no, and open question			A, P	
Treatment satisfaction	ESQ[r] [64]			C, A, P	
School absence	Hours past month	A, P	A, P	A, P	A, P
Work absence	Days past month	P	P	P	P

[a]Time points; T1: baseline, T2: mid-treatment, T3: end-of-treatment, T4: follow-up; Respondents: C: child, A: adolescent, P: parent.

[b]SCL-8: Symptom Check List-8.

[c]HAPYS: The Health Anxiety by Proxy Scale.

[d]ARCS: Adult Responses to Children's Symptoms.

[e]The monitor and protect subscales.

[f]PedsQL Gastro: Pediatric Quality of Life Inventory – Gastrointestinal symptoms.

[g]PedsQL: Pediatric Quality of Life Inventory.

[h]CSSI: Children's Somatic Symptom Inventory.

[i]MFQS: Mood and Feelings Questionnaire Short.

[j]SCAS-S: Spence Children Anxiety Scale – Short.

[k]VSI: Visceral Sensitivity Index.

[l]IBS-BRQ-C: irritable bowel syndrome behavioral response questionnaire – Child-adapted short version.

[m]B-IPQ: Brief Illness Perception Questionnaire.

[n]CIAS: Childhood Illness Attitude Scale.

[o]The fear factor subscale.

[p]CPAQ-A8: Chronic Pain Acceptance Questionnaire – Adolescent Short Form.

[q]One question from the pain willingness factor, one from activity engagement.

[r]ESQ: Modified Experience of Service Questionnaire.

Parental Factors

Parental distress will be assessed by the Symptom Checklist-8, an 8-item subscale from the Symptom Checklist Revised-90, screening for emotional symptoms. Items are rated on a 5-point scale from 0 “not at all” to 4 “a whole lot,” with a total range from 0 to 32. Higher scores indicate more emotional distress [44,45].

Parental illness worries will be assessed by the Health Anxiety by Proxy Scale (HAPYS), a newly developed questionnaire assessing parents’ worries about their child’s health [46]. The questionnaire covers 26 items about health anxiety by proxy, rated on a 5-point scale (from 0 “not at all” or “never” to 4 “a whole lot” or “most of the time”), with a sum score range from 0 to 104. In addition, there are 6 items about the impact of the worries rated on a 4-point scale (from 0 “no” to 3 “yes, severely”), with a sum score range from 0 to 18. Higher scores indicate a high level of health anxiety by proxy and the impact of the anxiety, respectively. HAPYS is a valid measure of health anxiety by proxy with good psychometric properties, including high internal reliability and known-groups validity [47].

Parental illness behavior will be measured by the Adult Responses to Children’s Symptoms, which is originally a 29-item questionnaire [48]. In this study, 2 subscales (monitor and protect subscales) comprising 15 items will be used. Items are rated on a 5-point scale from 0 “never” to 4 “always” with a score range from 0 to 60. Higher scores indicate a higher degree of monitoring and protective responses [49,50].

Child or Adolescent Treatment Effects—Main Measures

Gastrointestinal symptoms will be assessed by PedsQL gastrointestinal symptoms [34]. This is a 9-item questionnaire assessing gastrointestinal symptoms related to functional or organic gastrointestinal diseases, during the past month, on a 5-point scale from 0 “never” to 4 “almost always.” Scores are reversed and transformed into a 0-100 scale, with high scores indicating greater quality of life. Pain intensity will be assessed by the Faces Pain Rating Scale – revised (FPS-R) [51]. The FPS-R score includes 6 pictures of faces, each showing an increasing amount of pain and scored on a 2-step scale between “no pain” (0) and “worst pain” (10). The scale is validated in children and adolescents and found to be sensitive to change [52].

Child or Adolescent Treatment Effects—Additional Measures

Quality of life will be measured by the 23-item PedsQL [53], which is a widely used questionnaire to assess quality of life during the past month in children and adolescents. Items are scored on a 5-point scale from 0 “never” to 4 “almost always.” Scores are reversed and transformed into sum scores between 0 and 100, with high scores indicating higher quality of life.

Overall symptom load will be assessed by the Children’s Somatic Symptom Inventory. It measures somatic symptoms during the last 2 weeks using 24 items, rated on a 5-point scale from 0 “not at all” to 4 “a whole lot,” with a range in scores from 0 to 96. High scores indicate a high symptom load. The questionnaire is found to be reliable and psychometrically sound for children and adolescents with abdominal pain disorders [54].

Depressive symptoms will be measured using the Mood and Feelings Questionnaire Short. It comprises 13 items rated on a 3-point scale from 0 “not true” to 2 “true,” with a range from 0 to 26, where higher scores indicate more depressive symptoms. The questionnaire is found reliable for evaluating depressive symptoms in both clinical and community populations of children and adolescents [55,56].

Anxiety levels will be assessed with 2 different questionnaires—the Spence Children Anxiety Scale Short (SCAS-S) [57,58] for general anxiety, and the Visceral Sensitivity Index-Children (VSI-C) [35,59] for gastrointestinal-specific anxiety. SCAS-S contains 19 items which are answered on a 4-point scale from 0 “never” to 3 “always,” with a total range from 0 to 57, where higher scores indicate higher anxiety levels. The questionnaire is designed for use in children and adolescents, and the short version is validated for screening of anxiety levels in children and adolescents [58]. The VSI-C is a shortened child-adapted version of the VSI for adults [35], with 7 items answered on a 6-point scale from 0 “strongly disagree” to 5 “strongly agree,” with a range from 0 to 42, where higher scores indicate more GI-anxiety. It has been found reliable and valid in children and adolescents with FAPDs [60].

Avoidance and control behavior will be assessed by the IBS-BRQ–Child-adapted short version with 11 items, which is an adapted version of the IBS-BRQ for adults [36]. Items are rated on a 7-point scale from 0 “never” to 6 “always,” with scores ranging from 0 to 66, where higher scores indicate more avoidance. It has been validated for children and adolescents with FAPDs [60].

Illness perception will be assessed by the Brief Illness Perception Questionnaire [61,62], which is a 9-item questionnaire where 8 items are answered on an 11-point scale, and 1 item is an open-ended question. The total score range is 0-80, with higher scores indicating more severe illness perception.

Illness worries will be assessed by the Childhood Illness Attitude Scale with 11 items from the fear factor [63]. The questionnaire is developed and validated for children and adolescents. Items are answered on a 3-point scale from 0 “never” to 2 “most of the time,” with a total score range from 0 to 22, and higher scores indicate more illness worries.

Pain acceptance will be assessed by 2 items from the CPAQ-A8 [37]. One regarding pain willingness and one regarding activity engagement. They are both answered on a 5-point scale from 0 “never true” to 4 “always true,” the item on pain willingness is reversed scored, and higher scores then indicate higher pain acceptance.

Other Measures

Parents will provide information about school absence (hours last month) for children (aged 8-12 years) and about their work absence (days past month). Adolescents will provide information about their own school absence (hours last month).

Adverse events will be assessed by adolescents and parents of children using a binary (yes or no) question and an open-ended question to describe the potential event in detail.

Treatment satisfaction will be assessed by the Modified Experience of Service Questionnaire [64], which is a 13-item questionnaire with 10 items scored from "not true" to "certainly true" and 3 free-text items. The total score range is 0-20 with higher scores indicating a better experience with the treatment.

Sample Sizes

According to research design standards [65], a minimum of 3 replications are recommended in a SCED study (substudy 1). However, to achieve sufficient power for randomization tests, a higher number of potential randomizations is recommended [66]. The number of randomizations is influenced by both the number of participants and the number of possible starting points; hence, guided by Levin et al [67], we chose 6 participants in each group.

For substudy 2, we based our power analysis on potential differences in cognitive bias and interoception between cases and healthy controls on a previous similar study on cognitive bias in children and adolescents [40] and studies on interoceptive accuracy in adults with functional disorders [68-69]. Based on these study findings, calculations show that in order to detect a minimum effect size of 0.5 (Cohen *d*), 60 patients and 100 healthy controls are required for the cognitive bias outcome, and a minimum of 51 patients and 51 healthy controls for the interoception outcome to achieve 80% power at an α level of .05. The subsequent analysis of the possible impact of treatment on these 2 factors is more explorative and therefore no a priori power calculation is provided. The same concerns the last study on parental factors (substudy 3) as possible effect moderators. However, here the sample size is the largest possible, comprised of parents from substudies 1 and 2.

Data Collection and Management

The DSQ, the BY-GIS task, and questionnaires are set up in REDCap (Research Electronic data capture; Vanderbilt University) [70], hosted by Aarhus University, and distributed through SMS text message or email. REDCap is a secure, web-based software platform designed to facilitate data capture for research studies.

For the DSQ (substudy 1), a text message reminder will automatically be sent through REDCap 2 hours after the initial SMS text message. If the DSQ is not completed 2 days in a row, a research assistant will contact the family by phone. For the BY-GIS task (substudy 2) and the extensive questionnaire (substudy 3), REDCap will generate automatic email reminders 24, 48, and 72 hours after the initial email if they are not completed. If there is no response after 7 days, a research assistant will contact the family by phone.

The interoception task in substudy 2 will take place at the Center of Functionally Integrative Neuroscience at Aarhus University Hospital in a behavioral testing room, and data will be stored in REDCap.

Data Analyses

In substudy 1, visual inspection analyses will be applied to demonstrate the effect of the intervention on all outcomes [71]. In addition, within-case effect size measurements will be calculated using Tau-U [72] and between-case effect sizes will be determined using hierarchical linear regression models to account for the serial dependency of data [73]. A randomization test will be applied to test differences in means for the baseline versus treatment, and baseline versus follow-up periods, respectively [74].

In substudy 2, participants' descriptions reported in the recall phase of the BY-GIS task will be coded to their corresponding word or picture and category presented in the encoding phase (eg, picture-description "children and cake" coded as the birthday picture within the fun category). Coding for the first 20% of participants will be conducted by 2 independent raters (ESN and EB-N). If the consensus rating exceeds 90%, 1 rater will code the remaining cases independently. A third and experienced rater (TBG) may be consulted to resolve potential disagreements. Baseline data will be analyzed descriptively and compared with (1) data from a healthy control group who performed the same experimental test [38], and (2) end-of-treatment data, exploring potential differences in the outcomes from the encoding, recall, and recognition phases using *t* tests or nonparametric tests, depending on data variability in the samples.

Baseline measures of interoceptive performance and metacognitive measures will be analyzed descriptively and compared with (1) measures from a healthy control group and (2) end-of-treatment measures, using *t* tests or nonparametric tests, depending on data variability in the samples.

In substudy 3, the potential moderation of parental factors on treatment adherence (number of completed modules) and main measure (gastrointestinal symptoms) for children or adolescents will be investigated using negative binomial regression and linear mixed models, respectively, adjusting for baseline parental distress, illness worries, and illness behavior, respectively.

In addition, the potential effect of treatment on these parental factors and all other child or adolescent measures will be analyzed using linear mixed regression models.

An experienced statistician will provide statistical support for all analyses.

Ethical Considerations

The study will be conducted according to the guidelines of the Declaration of Helsinki. The study was approved by The Central Denmark Region Committees on Health Research Ethics (record 1-10-72-277-21, 1-10-72-80-22, and 1-10-72-142-22).

Written informed consent will be obtained from parents and adolescents (≥15 years) whereas children and adolescents (<15 years) will only give oral consent.

Children and adolescents will be compensated with a gift card (value 150 DKK [US $21.13]) for the first time participating in the interoception study. No other compensation will be provided.

Results

Recruitment of participants began in June 2022. Substudy 1 is finalized and expected to be published in 2025. Recruitment for substudies 2 and 3 is ongoing. By November 2024, 45 children and 24 adolescents have been included. Due to a skewed distribution in referrals, with a predominance of referrals on children, we continue to include children and adolescents until we have reached 30 adolescents. Inclusion is expected to be completed by January 2025 and data collection in March 2025.

Discussion

Principal Findings

With this study, we aim to explore previously sparsely investigated areas of ICBT for children and adolescents with FAPDs related to both child or adolescent and parental factors. This includes examining the detailed trajectory of effect, the presence of and potential changes in cognitive biases, and interoceptive inaccuracy after treatment, as well as investigating the potential role of parental distress, illness worries, and behavior as effect moderators.

Previous studies have demonstrated the effectiveness of Swedish ICBT programs in reducing abdominal symptoms and improving the quality of life in children and adolescents with FAPDs. Mediation analyses have shown that positive changes in symptom-specific avoidance behavior and fear mediate the treatment effects [17,18,27,29]. However, the detailed trajectory of treatment effects—specifically when and how possible changes occur during treatment for individual patients—remains unknown, and this will be investigated in substudy 1. This research could provide new insights into the mechanisms of change underlying treatment effects and could be clinically valuable for both therapists and patients.

To the best of our knowledge, this study is one of the first to assess cognitive biases and the ability to sense and interpret signals from the body (ie, interoception) in this patient group in comparison with healthy controls as well as to explore potential changes in these factors after treatment with CBT. Both factors are suggested to play a vital role in the predictive processing model, explaining the pathophysiology of FAPDs [11]. However, so far, they have mainly been studied in adults with various functional disorders [40,68-69,75-78]. By uncovering more knowledge about these factors, the results can potentially be used to further refine already established treatments. For example, this could involve adding biofeedback to train interoceptive accuracy or enhancing exposure exercises addressing specific cognitive biases that lead to fearful responses to gastro-related sensations and avoidance behavior.

Parental worries and anxious behaviors toward the child or adolescent's symptoms can impact the overall well-being of the child or adolescent. These factors are suggested to be part of the complex pathophysiology of FAPDs [9,20,21,48] and are therefore important to investigate further. Parental emotional distress has been found to negatively moderate the effect of ICBT for adolescents with chronic pain [79,80], whereby high levels of parental emotional distress lead to less improvement in disability for the adolescent. However, it is currently unknown how the level of parental distress impacts the effects of the ICBT programs for young patients with FAPDs [29,81]. A specific type of parental emotional distress is health anxiety by proxy, which is a recently described clinical phenomenon characterized by parents' excessive and distressing worries and rumination about their child's health, often involving fears of serious diseases being overlooked by medical professionals [82,83]. This fear may lead to frequent medical visits and investigations of the child [84]. In this study, we will use the newly developed HAPYS questionnaire [46,47] to assess parental health anxiety by proxy. To our knowledge, this is the first systematic examination of this specific type of parental emotional distress in parents of children and adolescents with FAPDs. Such type of parental anxiety may especially lead to symptom-related protective and monitoring behaviors, which are suggested to play a crucial role in the development, maintenance, and even aggravation of the child's FAPD and related health care visits [48-50]. The Swedish ICBT has been shown to effectively reduce such maladaptive parental behavior in both children and adolescents [28,29]. Still, the impact of parental emotional distress, particularly illness worries and related behavioral responses, on the effect of ICBT in children is less well-investigated [85] and no studies have yet been conducted specifically in relation to adolescents. This is why, in this study, we will explore parental distress, illness worries, and behaviors before and after ICBT and examine how these factors impact treatment adherence and treatment effects in both children and adolescents. By uncovering more knowledge about these parental factors, we aim to gain a better understanding of family dynamics and identify potentially important parental characteristics to focus on during treatment, thereby further improving its effectiveness.

The study has some limitations. In substudy 1, the generalizability of SCED study results has traditionally been questioned due to the low number of participants. However, our study adheres to guidelines that include multiple data points across different phases, randomization of the length of the baseline phase, and replication across several participants, thereby optimizing generalizability. Furthermore, participants are expected to answer daily questions for an extended period, which could induce some fatigue in responding and potentially affect reliability. Still, the inclusion of several close data points increases precision in analyses and helps buffer against occasional data loss. In addition, the setup was tested on 4 prestudy patients, who reported that the daily questionnaire was easy and quick to answer.

In substudy 2, we use the BY-GIS task, which is newly developed and has not been previously tested in patients. However, the task is developed based on well-known paradigms and previous tests, and it has already been tested in a sample of 96 healthy age-matched controls with good usability [38]. The interoception HRD measures participants' ability to sense their pulse, which is not directly related to gut sensations but falls within the broader perspective of interoception. However, studies in adults suggest altered interoceptive accuracy across different diagnoses of functional disorders and chronic pain,

which indicates that there may be a general hypersensitivity to inner sensations in this patient group as well [86]. Since this study is one of the first to investigate interoceptive accuracy in children and adolescents with FAPDs, we believe it is still valuable to use this well-known and widely used interoception measure.

Substudy 3 is an open pilot trial without a control group for comparison which means conclusions regarding the clinical effect of the treatment should be interpreted with caution. However, the substudy is explorative and primarily aims to investigate new and additional modifiable treatment targets on a parental level.

Conclusion

In conclusion, this study is expected to provide new and important information about the process of the effect of ICBT, increase our understanding of modifiable treatment targets within the framework of predictive processing in children and adolescents with FAPDs, and shed light on parental factors that are important for the child's treatment adherence and effect. Overall, this research can guide the further development of even more effective psychological treatments for one of the most prevalent chronic pain disorders in children and adolescents.

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Authors' Contributions

Conceptualization, methodology, and writing—review and editing were contributed by ESN, KHK, EB-N, TBG, ML, LF, MB, and CUR. Writing—Original Draft Preparation was contributed by ESN. Supervision was handled by KHK, TBG, ML, LF, MB, and CUR. Project administration was managed by ESN, EB-N, KHK, and CUR. Funding acquisition was handled by ESN, LF, and CUR. All authors have read and agreed on the published version of the manuscript.

Conflicts of Interest

None declared.

References

1. Boronat AC, Ferreira-Maia AP, Matijasevich A, Wang YP. Epidemiology of functional gastrointestinal disorders in children and adolescents: a systematic review. World J Gastroenterol 2017;23(21):3915-3927 [FREE Full text] [doi: 10.3748/wjg.v23.i21.3915] [Medline: 28638232]
2. Robin SG, Keller C, Zwiener R, Hyman PE, Nurko S, Saps M, et al. Prevalence of pediatric functional gastrointestinal disorders utilizing the Rome IV criteria. J Pediatr 2018;195:134-139. [doi: 10.1016/j.jpeds.2017.12.012] [Medline: 29398057]
3. Varni JW, Bendo CB, Nurko S, Shulman RJ, Self MM, Franciosi JP, Pediatric Quality of Life Inventory (PedsQL) Gastrointestinal Symptoms Module Testing Study Consortium. Health-related quality of life in pediatric patients with functional and organic gastrointestinal diseases. J Pediatr 2015;166(1):85-90. [doi: 10.1016/j.jpeds.2014.08.022] [Medline: 25241177]
4. Newton E, Schosheim A, Patel S, Chitkara DK, van Tilburg MAL. The role of psychological factors in pediatric functional abdominal pain disorders. Neurogastroenterol Motil 2019;31(6):e13538. [doi: 10.1111/nmo.13538] [Medline: 30729663]
5. Sjölund J, Uusijärvi A, Tornkvist NT, Kull I, Bergström A, Alm J, et al. Prevalence and progression of recurrent abdominal pain, from early childhood to adolescence. Clin Gastroenterol Hepatol 2021;19(5):930-938.e8. [doi: 10.1016/j.cgh.2020.04.047] [Medline: 32344151]
6. Van Oudenhove L, Crowell MD, Drossman DA, Halpert AD, Keefer L, Lackner JM, et al. Biopsychosocial aspects of functional gastrointestinal disorders. Gastroenterology 2016;S0016-5085(16):00218-3 [FREE Full text] [doi: 10.1053/j.gastro.2016.02.027] [Medline: 27144624]
7. Levy RL, Langer SL, Romano JM, Labus J, Walker LS, Murphy TB, et al. Cognitive mediators of treatment outcomes in pediatric functional abdominal pain. Clin J Pain 2014;30(12):1033-1043 [FREE Full text] [doi: 10.1097/AJP.0000000000000077] [Medline: 24469611]
8. Youssef NN, Murphy TG, Langseder AL, Rosh JR. Quality of life for children with functional abdominal pain: a comparison study of patients' and parents' perceptions. Pediatrics 2006;117(1):54-59. [doi: 10.1542/peds.2005-0114] [Medline: 16396860]
9. Thapar N, Benninga MA, Crowell MD, Di Lorenzo C, Mack I, Nurko S, et al. Paediatric functional abdominal pain disorders. Nat Rev Dis Primers 2020;6(1):89. [doi: 10.1038/s41572-020-00222-5] [Medline: 33154368]

10. Simrén M, Törnblom H, Palsson OS, van Tilburg MAL, Van Oudenhove L, Tack J, et al. Visceral hypersensitivity is associated with GI symptom severity in functional GI disorders: consistent findings from five different patient cohorts. Gut 2018;67(2):255-262. [doi: 10.1136/gutjnl-2016-312361] [Medline: 28104632]
11. Henningsen P, Gündel H, Kop WJ, Löwe B, Martin A, Rief W, EURONET-SOMA Group. Persistent physical symptoms as perceptual dysregulation: a neuropsychobehavioral model and its clinical implications. Psychosom Med 2018;80(5):422-431. [doi: 10.1097/PSY.0000000000000588] [Medline: 29621046]
12. Beck JE, Lipani TA, Baber KF, Dufton L, Garber J, Smith CA, et al. Attentional bias to pain and social threat in pediatric patients with functional abdominal pain and pain-free youth before and after performance evaluation. Pain 2011;152(5):1061-1067 [FREE Full text] [doi: 10.1016/j.pain.2011.01.029] [Medline: 21420789]
13. Boyer MC, Compas BE, Stanger C, Colletti RB, Konik BS, Morrow SB, et al. Attentional biases to pain and social threat in children with recurrent abdominal pain. J Pediatr Psychol 2006;31(2):209-220. [doi: 10.1093/jpepsy/jsj015] [Medline: 15843503]
14. van der Veek SMC, Derkx BHF, Plak RD, Benninga MA, Boer F, Lindauer RJL, et al. Attentional bias to activity of different parts of the body in children with functional abdominal pain: an experimental study. J Pediatr Psychol 2014;39(4):438-449. [doi: 10.1093/jpepsy/jsu004] [Medline: 24566061]
15. Hermann C, Zohsel K, Hohmeister J, Flor H. Cortical correlates of an attentional bias to painful and innocuous somatic stimuli in children with recurrent abdominal pain. Pain 2008;136(3):397-406. [doi: 10.1016/j.pain.2008.01.007] [Medline: 18276076]
16. Drossman DA. Functional gastrointestinal disorders: history, pathophysiology, clinical features and Rome IV. Gastroenterology 2016;S0016-5085(16):00223-00227. [doi: 10.1053/j.gastro.2016.02.032] [Medline: 27144617]
17. Lalouni M, Hesser H, Bonnert M, Hedman-Lagerlöf E, Serlachius E, Olén O, et al. Breaking the vicious circle of fear and avoidance in children with abdominal pain: a mediation analysis. J Psychosom Res 2021;140:110287 [FREE Full text] [doi: 10.1016/j.jpsychores.2020.110287] [Medline: 33227558]
18. Bonnert M, Olén O, Bjureberg J, Lalouni M, Hedman-Lagerlöf E, Serlachius E, et al. The role of avoidance behavior in the treatment of adolescents with irritable bowel syndrome: a mediation analysis. Behav Res Ther 2018;105:27-35 [FREE Full text] [doi: 10.1016/j.brat.2018.03.006] [Medline: 29614378]
19. Hechler T. Altered interoception and its role for the co-occurrence of chronic primary pain and mental health problems in children. Pain 2021;162(3):665-671. [doi: 10.1097/j.pain.0000000000002099] [Medline: 33021565]
20. Thorgaard MV, Frostholm L, Walker LS, Stengaard-Pedersen K, Karlsson MM, Jensen JS, et al. Effects of maternal health anxiety on children's health complaints, emotional symptoms, and quality of life. Eur Child Adolesc Psychiatry 2017;26(5):591-601. [doi: 10.1007/s00787-016-0927-1] [Medline: 27909834]
21. Walker LS, Williams SE, Smith CA, Garber J, Van Slyke DA, Lipani TA. Parent attention versus distraction: impact on symptom complaints by children with and without chronic functional abdominal pain. Pain 2006;122(1-2):43-52 [FREE Full text] [doi: 10.1016/j.pain.2005.12.020] [Medline: 16495006]
22. van Tilburg MAL, Chitkara DK, Palsson OS, Levy RL, Whitehead WE. Parental worries and beliefs about abdominal pain. J Pediatr Gastroenterol Nutr 2009;48(3):311-317 [FREE Full text] [doi: 10.1097/mpg.0b013e31817c03ae] [Medline: 19274787]
23. Chow ET, Otis JD, Simons LE. The longitudinal impact of parent distress and behavior on functional outcomes among youth with chronic pain. J Pain 2016;17(6):729-738 [FREE Full text] [doi: 10.1016/j.jpain.2016.02.014] [Medline: 26993960]
24. Gordon M, Sinopoulou V, Tabbers M, Rexwinkel R, de Bruijn C, Dovey T, et al. Psychosocial interventions for the treatment of functional abdominal pain disorders in children: a systematic review and meta-analysis. JAMA Pediatr 2022;176(6):560-568 [FREE Full text] [doi: 10.1001/jamapediatrics.2022.0313] [Medline: 35404394]
25. Hua CH, Chen YL, Tao QF, Shi YZ, Li LW, Xie CR, et al. Dietary interventions for pediatric patients with functional abdominal pain disorders: a systematic review and network meta-analysis. Eur J Pediatr 2023;182(7):2943-2956. [doi: 10.1007/s00431-023-04979-1] [Medline: 37071174]
26. Rexwinkel R, de Bruijn CMA, Gordon M, Benninga MA, Tabbers MM. Pharmacologic treatment in functional abdominal pain disorders in children: a systematic review. Pediatrics 2021;147(6):e2020042101. [doi: 10.1542/peds.2020-042101] [Medline: 34045320]
27. Bonnert M, Olén O, Lalouni M, Benninga MA, Bottai M, Engelbrektsson J, et al. Internet-delivered cognitive behavior therapy for adolescents with irritable bowel syndrome: a randomized controlled trial. Am J Gastroenterol 2017;112(1):152-162 [FREE Full text] [doi: 10.1038/ajg.2016.503] [Medline: 27845338]
28. Bonnert M, Olén O, Lalouni M, Hedman-Lagerlöf E, Särnholm J, Serlachius E, et al. Internet-delivered exposure-based cognitive-behavioral therapy for adolescents with functional abdominal pain or functional dyspepsia: a feasibility study. Behav Ther 2019;50(1):177-188 [FREE Full text] [doi: 10.1016/j.beth.2018.05.002] [Medline: 30661558]
29. Lalouni M, Ljótsson B, Bonnert M, Ssegonja R, Benninga M, Bjureberg J, et al. Clinical and cost effectiveness of online cognitive behavioral therapy in children with functional abdominal pain disorders. Clin Gastroenterol Hepatol 2019 Oct;17(11):2236-2244.e11 [FREE Full text] [doi: 10.1016/j.cgh.2018.11.043] [Medline: 30502501]
30. Schulz KF, Grimes DA. Get in the spirit with SPIRIT 2013: protocol content guideline for clinical trials. Contraception 2013;88(6):676-677. [doi: 10.1016/j.contraception.2013.10.002] [Medline: 24230918]

31. Hyams JS, Di Lorenzo C, Saps M, Shulman RJ, Staiano A, van Tilburg M. Functional disorders: children and adolescents. Gastroenterology 2016;S0016-5085(16):00181-00185. [doi: 10.1053/j.gastro.2016.02.015] [Medline: 27144632]
32. Tate RL, Perdices M, Rosenkoetter U, McDonald S, Togher L, Shadish W, et al. The Single-Case Reporting guideline in BEhavioural interventions (SCRIBE) 2016: explanation and elaboration. Archives of Scientific Psychology 2016;4(1):10-31. [doi: 10.1037/arc0000027]
33. Vlaeyen JWS, Wicksell RK, Simons LE, Gentili C, De TK, Tate RI, et al. From Boulder to Stockholm in 70 years: single case experimental designs in clinical research. Psychol Rec 2020;70(4):659-670 [FREE Full text] [doi: 10.1007/s40732-020-00402-5]
34. Varni JW, Lane MM, Burwinkle TM, Fontaine EN, Youssef NN, Schwimmer JB, et al. Health-related quality of life in pediatric patients with irritable bowel syndrome: a comparative analysis. J Dev Behav Pediatr 2006;27(6):451-458. [doi: 10.1097/00004703-200612000-00001] [Medline: 17164617]
35. Labus JS, Bolus R, Chang L, Wiklund I, Naesdal J, Mayer EA, et al. The Visceral Sensitivity Index: development and validation of a gastrointestinal symptom-specific anxiety scale. Aliment Pharmacol Ther 2004;20(1):89-97 [FREE Full text] [doi: 10.1111/j.1365-2036.2004.02007.x] [Medline: 15225175]
36. Reme SE, Darnley S, Kennedy T, Chalder T. The development of the irritable bowel syndrome-behavioral responses questionnaire. J Psychosom Res 2010;69(3):319-325. [doi: 10.1016/j.jpsychores.2010.01.025] [Medline: 20708455]
37. Gauntlett-Gilbert J, Alamire B, Duggan GB. Pain acceptance in adolescents: development of a short form of the CPAQ-A. J Pediatr Psychol 2019;44(4):453-462. [doi: 10.1093/jpepsy/jsy090] [Medline: 30496433]
38. Bjerre-Nielsen E, Kallesøe KH, Nielsen ES, Gehrt TB, Frostholm L, Rask CU. A new experimental design to examine cognitive biases for gastrointestinal related stimuli in children and adolescents. Children (Basel) 2023;10(8):1327 [FREE Full text] [doi: 10.3390/children10081327] [Medline: 37628326]
39. Barsky AJ, Coeytaux RR, Sarnie MK, Cleary PD. Hypochondriacal patients' beliefs about good health. Am J Psychiatry 1993;150(7):1085-1089. [doi: 10.1176/ajp.150.7.1085] [Medline: 8317581]
40. Jungmann SM, Witthöft M. Medically unexplained symptoms in children and adolescents: illness-related self-concept and parental symptom evaluations. J Behav Ther Exp Psychiatry 2020;68:101565. [doi: 10.1016/j.jbtep.2020.101565] [Medline: 32171996]
41. Weck F, Witthöft M. Context effects in the evaluation of bodily symptoms: comparing three versions of the health norms sorting task. Journal of Experimental Psychopathology 2017;8(3):241-251. [doi: 10.5127/jep.054216]
42. Gehrt TB, Niziurski JA, Frostholm L, Berntsen D. Encoding and retrieval biases for health-related scenes in patients with severe health anxiety. Memory 2019;27(8):1110-1121. [doi: 10.1080/09658211.2019.1626437] [Medline: 31159637]
43. Legrand N, Nikolova N, Correa C, Brændholt M, Stuckert A, Kildahl N, et al. The heart rate discrimination task: a psychophysical method to estimate the accuracy and precision of interoceptive beliefs. Biol Psychol 2022;168:108239 [FREE Full text] [doi: 10.1016/j.biopsycho.2021.108239] [Medline: 34902450]
44. Christensen K, Bech P, Fink P. Measuring mental health by questionnaires in primary care -unidimensionality, responsiveness and compliance. Eur Psychiatr Rev 2010;3:8-12 [FREE Full text]
45. Fink P, Ørbøl E, Hansen MS, Søndergaard L, De Jonge P. Detecting mental disorders in general hospitals by the SCL-8 scale. J Psychosom Res 2004;56(3):371-375. [doi: 10.1016/S0022-3999(03)00071-0] [Medline: 15046976]
46. Ingeman K, Wright KD, Frostholm L, Frydendal DH, Ørnbøl E, Rask CU. Measurement properties of the Health Anxiety by Proxy Scale (HAPYS): a new questionnaire to assess parents' worries about their child's health. J Psychosom Res 2024;176:111555 [FREE Full text] [doi: 10.1016/j.jpsychores.2023.111555] [Medline: 38039620]
47. Ingeman K, Frostholm L, Frydendal DH, Wright KD, Lockhart E, Garralda ME, et al. A new measure of excessive parental worries about children's health: development of the Health Anxiety by Proxy Scale (HAPYS). Nord J Psychiatry 2021;75(7):523-531. [doi: 10.1080/08039488.2021.1900389] [Medline: 33724904]
48. Van Slyke DA, Walker LS. Mothers' responses to children's pain. Clin J Pain 2006;22(4):387-391. [doi: 10.1097/01.ajp.0000205257.80044.01] [Medline: 16691093]
49. Walker LS, Levy RL, Whitehead WE. Validation of a measure of protective parent responses to children's pain. Clin J Pain 2006;22(8):712-716 [FREE Full text] [doi: 10.1097/01.ajp.0000210916.18536.44] [Medline: 16988567]
50. Noel M, Palermo TM, Essner B, Zhou C, Levy RL, Langer SL, et al. A developmental analysis of the factorial validity of the parent-report version of the adult responses to children's symptoms in children versus adolescents with chronic pain or pain-related chronic illness. J Pain 2015;16(1):31-41 [FREE Full text] [doi: 10.1016/j.jpain.2014.10.005] [Medline: 25451623]
51. Hicks CL, von Baeyer CL, Spafford PA, van Korlaar I, Goodenough B. The faces pain scale-revised: toward a common metric in pediatric pain measurement. Pain 2001;93(2):173-183. [doi: 10.1016/S0304-3959(01)00314-1] [Medline: 11427329]
52. Huguet A, Stinson JN, McGrath PJ. Measurement of self-reported pain intensity in children and adolescents. J Psychosom Res 2010;68(4):329-336. [doi: 10.1016/j.jpsychores.2009.06.003] [Medline: 20307699]
53. Varni JW, Seid M, Kurtin PS. PedsQL 4.0: reliability and validity of the Pediatric Quality of Life Inventory version 4.0 generic core scales in healthy and patient populations. Med Care 2001;39(8):800-812. [doi: 10.1097/00005650-200108000-00006] [Medline: 11468499]

54. Walker LS, Beck JE, Garber J, Lambert W. Children's Somatization Inventory: psychometric properties of the revised form (CSI-24). J Pediatr Psychol 2009;34(4):430-440 [FREE Full text] [doi: 10.1093/jpepsy/jsn093] [Medline: 18782857]
55. Sharp C, Goodyer IM, Croudace TJ. The Short Mood and Feelings Questionnaire (SMFQ): a unidimensional item response theory and categorical data factor analysis of self-report ratings from a community sample of 7-through 11-year-old children. J Abnorm Child Psychol 2006;34(3):379-391. [doi: 10.1007/s10802-006-9027-x] [Medline: 16649000]
56. Eg J, Bilenberg N, Costello EJ, Wesselhoeft R. Self- and parent-reported depressive symptoms rated by the mood and feelings questionnaire. Psychiatry Res 2018;268:419-425. [doi: 10.1016/j.psychres.2018.07.016] [Medline: 30130708]
57. Spence SH, Barrett PM, Turner CM. Psychometric properties of the spence children's anxiety scale with young adolescents. J Anxiety Disord 2003;17(6):605-625. [doi: 10.1016/s0887-6185(02)00236-0] [Medline: 14624814]
58. Ahlen J, Vigerland S, Ghaderi A. Development of the spence children's anxiety Scale - Short Version (SCAS-S). J Psychopathol Behav Assess 2018;40(2):288-304 [FREE Full text] [doi: 10.1007/s10862-017-9637-3] [Medline: 29937623]
59. Labus JS, Mayer EA, Chang L, Bolus R, Naliboff BD. The central role of gastrointestinal-specific anxiety in irritable bowel syndrome: further validation of the visceral sensitivity index. Psychosom Med 2007;69(1):89-98. [doi: 10.1097/PSY.0b013e31802e2f24] [Medline: 17244851]
60. Lalouni M, Olén O, Bjureberg J, Bonnert M, Chalder T, Hedman-Lagerlöf E, et al. Validation of child-adapted short scales for measuring gastrointestinal-specific avoidance and anxiety. Acta Paediatr 2022;111(8):1621-1627 [FREE Full text] [doi: 10.1111/apa.16403] [Medline: 35545865]
61. Broadbent E, Wilkes C, Koschwanez H, Weinman J, Norton S, Petrie KJ. A systematic review and meta-analysis of the brief illness perception questionnaire. Psychol Health 2015;30(11):1361-1385. [doi: 10.1080/08870446.2015.1070851] [Medline: 26181764]
62. Broadbent E, Petrie KJ, Main J, Weinman J. The brief illness perception questionnaire. J Psychosom Res 2006;60(6):631-637. [doi: 10.1016/j.jpsychores.2005.10.020] [Medline: 16731240]
63. Thorisdottir AS, Villadsen A, LeBouthillier DM, Rask CU, Wright KD, Walker JR, et al. Measurement invariance across Genders on the Childhood Illness Attitude Scales (CIAS). J Psychosom Res 2017;98:34-39. [doi: 10.1016/j.jpsychores.2017.05.006] [Medline: 28554370]
64. Brown A, Ford T, Deighton J, Wolpert M. Satisfaction in child and adolescent mental health services: translating users' feedback into measurement. Adm Policy Ment Health 2014;41(4):434-446. [doi: 10.1007/s10488-012-0433-9] [Medline: 22829193]
65. Kratochwill T, Hitchcock J, Horner R, Levin J, Odom S, Rindskopf D, et al. Single-Case Intervention Research Design Standards. Remedial and Special Education 2012 Aug 15;34(1):26-38. [doi: 10.1177/0741932512452794]
66. Krasny-Pacini A. Single-case experimental designs for child neurological rehabilitation and developmental disability research. Dev Med Child Neurol 2023;65(5):611-624 [FREE Full text] [doi: 10.1111/dmcn.15513] [Medline: 36721909]
67. Levin JR, Ferron JM, Gafurov BS. Comparison of randomization-test procedures for single-case multiple-baseline designs. Dev Neurorehabil 2018;21(5):290-311. [doi: 10.1080/17518423.2016.1197708] [Medline: 27367902]
68. Ricciardi L, Demartini B, Crucianelli L, Krahé C, Edwards MJ, Fotopoulou A. Interoceptive awareness in patients with functional neurological symptoms. Biol Psychol 2016;113:68-74. [doi: 10.1016/j.biopsycho.2015.10.009] [Medline: 26528552]
69. Duschek S, Montoro CI, Reyes Del Paso GA. Diminished interoceptive awareness in fibromyalgia syndrome. Behav Med 2017;43(2):100-107. [doi: 10.1080/08964289.2015.1094442] [Medline: 26431269]
70. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, REDCap Consortium. The REDCap consortium: building an international community of software platform partners. J Biomed Inform 2019;95:103208 [FREE Full text] [doi: 10.1016/j.jbi.2019.103208] [Medline: 31078660]
71. Ledford JR, Lane JD, Severini KE. Systematic use of visual analysis for assessing outcomes in single case design studies. Brain Impairment 2017;19(1):4-17. [doi: 10.1017/brimp.2017.16]
72. Lobo MA, Moeyaert M, Baraldi Cunha A, Babik I. Single-case design, analysis, and quality assessment for intervention research. J Neurol Phys Ther 2017;41(3):187-197 [FREE Full text] [doi: 10.1097/NPT.0000000000000187] [Medline: 28628553]
73. Manolov R, Moeyaert M, Fingerhut JE. A priori justification for effect measures in single-case experimental designs. Perspect Behav Sci 2022;45(1):153-186 [FREE Full text] [doi: 10.1007/s40614-021-00282-2] [Medline: 35342872]
74. Heyvaert M, Onghena P. Analysis of single-case data: randomisation tests for measures of effect size. Neuropsychol Rehabil 2014;24(3-4):507-527. [doi: 10.1080/09602011.2013.818564] [Medline: 23865938]
75. Williams IA, Reuber M, Levita L. Interoception and stress in patients with functional neurological symptom disorder. Cogn Neuropsychiatry 2021;26(2):75-94. [doi: 10.1080/13546805.2020.1865895] [Medline: 33372576]
76. Pauli P, Alpers GW. Memory bias in patients with hypochondriasis and somatoform pain disorder. J Psychosom Res 2002;52(1):45-53. [doi: 10.1016/s0022-3999(01)00295-1] [Medline: 11801264]
77. Witthöft M, Kerstner T, Ofer J, Mier D, Rist F, Diener C, et al. Cognitive biases in pathological health anxiety: the contribution of attention, memory and evaluation processes. Clinical Psychological Science 2015;4(3):464-479. [doi: 10.1177/2167702615593474]

78. Brookes M, Sharpe L, Kozlowska K. Attentional and interpretational biases toward pain-related stimuli in children and adolescents: a systematic review of the evidence. J Pain 2018;19(10):1091-1101 [FREE Full text] [doi: 10.1016/j.jpain.2018.04.010] [Medline: 29733993]
79. Murray CB, de la Vega R, Loren DM, Palermo TM. Moderators of internet-delivered cognitive-behavioral therapy for adolescents with chronic pain: who benefits from treatment at long-term follow-up? J Pain 2020;21(5-6):603-615 [FREE Full text] [doi: 10.1016/j.jpain.2019.10.001] [Medline: 31606398]
80. Law EF, Fisher E, Howard WJ, Levy R, Ritterband L, Palermo TM. Longitudinal change in parent and child functioning after internet-delivered cognitive-behavioral therapy for chronic pain. Pain 2017;158(10):1992-2000 [FREE Full text] [doi: 10.1097/j.pain.0000000000000999] [Medline: 28777771]
81. Lalouni M, Ljótsson B, Bonnert M, Hedman-Lagerlöf E, Högström J, Serlachius E, et al. Internet-delivered cognitive behavioral therapy for children with pain-related functional gastrointestinal disorders: feasibility study. JMIR Ment Health 2017;4(3):e32 [FREE Full text] [doi: 10.2196/mental.7985] [Medline: 28798012]
82. Ingeman K, Hulgaard DR, Rask CU. Health anxiety by proxy - through the eyes of the parents. J Child Health Care 2024;28(1):22-36. [doi: 10.1177/13674935221095648] [Medline: 35510964]
83. Thorgaard MV, Frostholm L, Walker L, Jensen JS, Morina B, Lindegaard H, et al. Health anxiety by proxy in women with severe health anxiety: a case control study. J Anxiety Disord 2017;52:8-14. [doi: 10.1016/j.janxdis.2017.09.001] [Medline: 28950218]
84. Lockhart E. Health anxiety in children and parents. BMJ 2016;353:i2891. [doi: 10.1136/bmj.i2891] [Medline: 27222022]
85. Lalouni M, Bujacz A, Bonnert M, Jensen KB, Rosengren A, Hedman-Lagerlöf E, et al. Parental responses and catastrophizing in online cognitive behavioral therapy for pediatric functional abdominal pain: a mediation analysis of a randomized controlled trial. Front Pain Res (Lausanne) 2022;3:962037 [FREE Full text] [doi: 10.3389/fpain.2022.962037] [Medline: 36262179]
86. Locatelli G, Matus A, James R, Salmoirago-Blotcher E, Ausili D, Vellone E, et al. What is the role of interoception in the symptom experience of people with a chronic condition? A systematic review. Neurosci Biobehav Rev 2023;148:105142 [FREE Full text] [doi: 10.1016/j.neubiorev.2023.105142] [Medline: 36965864]

Abbreviations

BY-GIS: biases in youth toward gastrointestinal-related stimuli
CBT: cognitive behavioral therapy
CPAQ-A8: Chronic Pain Acceptance Questionnaire – Adolescent Short Form
DSQ: daily short questionnaire
FAP-NOS: functional abdominal pain not otherwise specified
FAPD: Functional abdominal pain disorder
FPS-R: Faces Pain Rating Scale – revised
HAPYS: The Health Anxiety by Proxy Scale
HRD: heart rate discrimination
IBS: irritable bowel syndrome
IBS-BRQ: irritable bowel syndrome behavioral response questionnaire
ICBT: internet-delivered cognitive behavioral therapy
ICD-10: International Statistical Classification of Diseases, Tenth Revision
IgA: Immunoglobulin A
PedsQL: Pediatric Quality of Life Inventory
REDCap: Research Electronic Data Capture
SCAS-S: Spence Children Anxiety Scale – Short
SCED: single case experimental design study
SCRIBE: Single-Case Reporting guideline In BEhavioural interventions
SOL: Stop, observe, let go
SPIRIT: Standard Protocol Items Recommendations for Interventional Trials
TSH: thyroid stimulating hormone
VSI: Visceral Sensitivity Index
VSI-C: Visceral Sensitivity Index-Children

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Protocol

Impact of Psychosocial and Palliative Care Training on Nurses' Competences and Care of Patients With Cancer in Cameroon: Protocol for Quasi-Experimental Study

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Abstract

Background: Cancer is a leading cause of global mortality, accounting for nearly 10 million deaths in 2020. This is projected to increase by more than 60% by 2040, particularly in low- and middle-income countries. Yet, palliative and psychosocial oncology care is very limited in these countries.

Objective: This study describes a protocol for the development, implementation, and evaluation of a psychosocial oncology and palliative care course on Cameroonian practicing nurses' knowledge, self-perceived competence, and confidence in palliative and psychosocial oncology care provision for patients with cancer.

Methods: A single group pre-posttest design, incorporating both quantitative and qualitative methods will be used. First, a psychosocial oncology and palliative care course for practicing nurses in Cameroon will be developed. This course will then be implemented with 50 practicing nurses purposefully selected from 2 oncology units in the Littoral region and 4 hospitals in the Southwest region of Cameroon. Finally, to assess the impact of the training program we will undertake a pre and posttest survey of nurses' palliative and psychosocial oncology competences, a pre and post training audit of patients' nursing records to examine nurses' practice of palliative and psychosocial oncology care and undertake a critical-incident interview of nurses' transfer of learning to practice. Descriptive and inferential statistics will be used to analysis quantitative data, while qualitative data will be analyzed using the framework approach.

Results: This study was funded in September 2023. The training program development was initiated in March 2024 and completed in June 2024. Baseline data collection commenced in May 2024 and as of September 2024, we had collected data from 300 patient record. Training implementation is planned for October-December 2024, and post intervention data will be started in October 2024 and continue till April 2025. Data analysis will commence in October 2024 and we aim to publish study findings in peer review journals by November 2025.

Conclusions: This study will improve our understanding of Cameroonian nurses' palliative and psychosocial oncology competency gaps. It will result in the development of a palliative care and psychosocial oncology course and in the training of 50 nurses in psychosocial oncology and palliative care in Cameroon. This study will inform strategies for future psychosocial oncology and palliative care training initiatives in Cameroon and other low- and middle-income countries.

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KEYWORDS

palliative care; psychosocial nursing; oncology nursing; nurses; quality improvement; training; competencies

Introduction

The global need for palliative and psychosocial oncology care continues to grow with the increasing prevalence of life-limiting conditions such as cancer [1,2]. In 2020, there were 19.3 million new cancer diagnoses and close to 10 million cancer-related deaths worldwide. As high as 1.9 million of these deaths occurred in low- and middle-income countries (LMICs) [3]. The number of people requiring palliative care globally has increased significantly in the last 2 decades, from 20 million in 2014 [4] to 56.8 million in 2020 [5]. Unfortunately, LMICs, especially those in sub-Saharan Africa, who have little or no psychosocial oncology and palliative care services harbor up to 80% of this global need [1,6-8]. The limited palliative and psychosocial oncology services in these countries has been associated with barriers such as the lack of competent health care providers with palliative and psychosocial oncology skills, the nonintegration of palliative and psychosocial care in the existing health care system [7,8], the lack of policies to support effective palliative and psychosocial care provision [7,9], and the presence of legislation that limits opioid prescription resulting in poor pain relief, among others [10]. There is therefore a need for strategies to overcome these barriers and facilitate the integration of palliative and psychosocial oncology care into the national health care systems in LMICs [7,11]. Providing educational opportunities to enhance the skills of health care providers in palliative and psychosocial oncology care is one important strategy to ensure that patients have early access to these essential health care services [5,6,12].

Patients and their families who receive a cancer diagnosis experience a high prevalence of pain, emotional, spiritual, and psychosocial distress [9]. The provision of palliative and psychosocial oncology care to these patients and their families will help prevent and relieve these problems [1,6,9] and is cost effective [13]. This is therefore priceless in LMICs where there are limited health care resources, and the cost of care is mostly borne by patients and their families who lack the needed financial resources [13].

With the increasing incidence of cancer in Africa, oncology capacity building opportunities are needed to enhance health care provider's competences and possibly ensure adequate management of patients and their families [14]. Palliative and psychosocial care are important components of quality cancer care that reduces distress, anxiety, and depression and improves patients' quality of life and survival [6]. However, it requires close monitoring and presence, which may not be feasible for an already overloaded oncologists [15]. Thus, nurses are in an ideal position to provide palliative and psychosocial care to patients with cancer, particularly in Africa, with huge shortage of oncologists and physicians [16]. Nurse-led palliative and psychosocial have been shown to improve access to palliative and psychosocial care for patients with cancer in resource limited settings [15,17].

The Need for Palliative and Psychosocial Oncology Care in Cameroon

In Cameroon, there is an upsurge of noncommunicable chronic disease morbidity and mortality [18]. Although cancer is likely underreported, there were approximately 19,564 new cancer diagnoses and 12,798 cancer deaths in Cameroon in 2022 [19]. Similar to most sub-Saharan African countries access to cancer care in Cameroon is limited, although cancer is a leading cause of premature death in the country [20]. There are 3 main cancer centers situated in 2 regions of the country, serving patients from all 10 regions of the national territory [21-23]. The majority of patients visiting these centers present with advanced cancer diagnoses due to delays in access to screening, diagnosis, and treatment [23]. With the limited number of oncology centers and specialists in the country, patients with cancer are often admitted in secondary level hospitals found in each of the 10 regions. Thus, patients with cancer are often cared for by nononcology professionals, particularly nurses. The Cameroon ministry of Public Health has developed a national cancer control plan to increase the number of cancer cases detected and treated early [23]. Thus, the need for strategies to promote early and timely access to psychosocial and palliative care. A study in Cameroon on psychosocial distress and quality of life of patients with cancer [22] found that majority of patients (n=83, 69.2%) presented with clinically significant distress. Financial difficulties, fatigue, transportation issues, and difficulties with work or school were the most reported problems. Up to half of the participants had moderate to severe anxiety and depression symptoms. The quality of life was fair, and there was a statistically significant negative relationship between psychosocial distress and quality of life of patients. These patients however lack access to much needed palliative and psychosocial care.

Palliative care was started in Cameroon in 2003 by the Cameroon Baptist Convention Health Services [24]. The literature reports the lack of a palliative care policy framework in the national cancer control plan [8,23], and limited accessibility to palliative care drugs, especially morphine [25]. These represent a huge gap in access to cancer care and is therefore a significant burden on the population. Training nurses to provide palliative and psychosocial oncology care to patients with cancer in Cameroon can improve access to care, patient experiences and quality of life. A few studies in Cameroon suggested that nurses lack knowledge about palliative care and have negative attitudes toward care of the dying [26,27]. However, there has not been any palliative and psychosocial oncology care training targeting practicing nurses in Cameroon.

Study Aim

The overall aim of this proposed study is to develop, implement, and evaluate the impact of a psychosocial oncology and palliative care course on Cameroonian practicing nurses' knowledge, and self-perceived competence and confidence in palliative and psychosocial oncology care provision for patients with cancer, using Kirkpatrick's framework [28] for training

program evaluation. Our specific aims are to develop a psychosocial oncology and palliative care training program for nurses in Cameroon, to implement the training program with 50 nurses who provide care to patients with cancer in selected health care facilities in the Littoral and South-West regions of Cameroon, to assess the impact of the training program on nurses' psychosocial oncology and palliative care knowledge and self-perceived competence and confidence in psychosocial and palliative care provision for patients with cancer after program completion, to assess the strengths and weaknesses of this training program and identify possible implementation challenges to inform future psychosocial oncology and palliative care curriculum initiatives in Cameroon, and to assess nurses' transfer of their learning from this training program in the care of patients with cancer and perceived impact on patient outcome.

Methods

Design and Methods

A single group pre-posttest intervention design will be used in this study and will incorporate both quantitative and qualitative methods of data collection and analysis. The study will be conducted in 3 phases: course development; course implementation, and course evaluation (Table 1). The Kirkpatrick's framework for training program evaluation will be used to evaluate the psychosocial oncology and palliative care training program. The Kirkpatrick's framework is selected for its unique focus on evaluating the outcomes of interventions beyond learners' satisfaction. It consists of four hierarchical evaluation levels including reaction, learning, behavior, and results. Patients and the public will not be involved in the design, or conduct, or reporting, or dissemination plans of the research.

Table 1. Summary of the phases of the study.

Study phase and objective	Activities
Phase 1: Develop a psychosocial oncology and palliative care course for nurses	• Engage nurse educators, palliative care experts and oncologist as course development team • Develop course through Delphi method • Inform course development with content from the psychosocial care competencies framework for nurses in Africa [6], the international psycho-oncology society's core curriculum [29] and a palliative care course for preregistration nurse training in Cameroon [26]
Phase 2: Course implementation	• Recruit nurses who care for patients with cancer in 6 hospitals from 2 Cameroonian regions • Deliver the course to 50 nurses over a 4 days duration through theoretical lessons and a practical session
Phase 3: Course evaluation	• Undertake a pre- and post-training assessment of nurses' palliative care knowledge, self-perceived competence and confidence in palliative care provision, and nurses' psychosocial oncology care competencies • Conduct a pretraining audit of nursing records of 300 hospitalized patients with cancer to assess nurses' baseline practice of palliative and psychosocial oncology care • Administer an end of course survey to evaluate the strengths and weaknesses of the course • After 6 months of training, undertake a posttraining audit of nursing records of 300 hospitalized patients with cancer nursing records to assess change in nurses' practice • After 6 months of training, conduct critical incident interviews with 18 nurses to assess transfer of their learning to practice

Settings and Sample

The study will be conducted in 6 health care facilities in the South-West and Littoral regions. This will include 2 oncology units in Douala in the Littoral region and 4 health care facilities in Fako in the South-West region. Patients in the Southwest region of Cameroon who receive a suspected diagnosis of cancer are referred to an oncology center in Douala, the neighboring town in the Littoral region. Thus, they travel long distances to access oncology care. Secondary level hospitals located in the Southwest region provide some consultation by a visiting oncologist. There are few health care providers in the Southwest region with palliative care training [30] and we do not know of any training in psychosocial oncology for nurses in Cameroon. A purposive sample of 50 nurses who work in hospital units that provide care to patients with cancer in the study hospitals from the oncology, medical, surgical, and intensive care units will be recruited, 9 nurses from each study site in the Southwest region and 7 nurses each from the oncology units in the 2 sites in the Littoral region. In a similar study in this setting [31], a power calculation showed that using a P value of .05 to determine a statistically significant result, 50 participants were required to give 98% power to find a significant difference in palliative care knowledge. In Cameroon, we have an estimate of 1 nurse per 1000 population [32]. In most secondary and tertiary level hospitals, there are about 10 nurses working in each of the targeted units. Thus, 50 nurses will be selected from an approximate population of about 220 nurses. Nurses who have worked in either the oncology, medical, surgical, or intensive care unit for at least 6 months will included in the study. We consider that 6 months of work in any of these units will allow the nurse to have encountered several patients with cancer and gathered relevant knowledge of their needs from which we can learn during the course and to which they can compare their post training competencies. The nurses have to provide consent and agree to participate during the entire training duration.

Participant Recruitment Strategy

Permission to conduct the study has been obtained from the directors and supervisors of nursing services of the study hospitals. We are requesting assistance from the general supervisors of nursing services in each study site to identify nurses who meet the inclusion criteria of the study. Interested nurses will register for the training by completing an application form. Selected participants will be contacted to complete the course registration process and consent. All participants will provide consent to participate. Personal identifiers, will only be collected to match pretest and post questionnaires. The questionnaires will be anonymized by coding and removal of any personal identifiers.

Data Collection

All data collection activities will be undertaken by trained research assistants (RAs), under the supervision of the principal investigators. We will train the RAs on how to use the survey instruments and how to conduct the individual critical incident interviews. We will undertake a mock data collection and role play of interviews with the RAs during the training, to ascertain they can undertake the exercise. The principal investigators will undertake validation checks of the data to ensure that data is precise, accurate and complete.

Study Activities and Data Collection Methods by Aim

Study Aim 1: Develop a Psychosocial Oncology and Palliative Care Training Program

We will develop a psychosocial oncology and palliative care training program for Cameroonian practicing nurses using the psychosocial care competencies framework for nurses in Africa [6], the International Psycho-Oncology Society's (IPOS) core curriculum [29] and the palliative care course developed for preregistration nurse training in Cameroon [26,27]. At the outset of the study, we will establish a curriculum development committee consisting of 3 members including an oncologists, a palliative care nurse, and psycho-oncologist. The research team will work with the curriculum committee to contextualize the competency framework and IPOS core curriculum for use in the training of nurses in Cameroon. This will be done in collaboration with the psychosocial oncology society of Ghana [7]. We will work virtually via email exchanges, using the Delphi strategy [33] and will organize 2 Zoom (Zoom Video Communications) meetings to finalize and validate the training program.

Study Aim 2: Implement the Training With Nurses

The training will be organized at the conference room of participating hospitals to facilitate nurses' participation. Thus, 6 training sessions will be implemented with participants in the 6 study sites. Each training session will last 4 days. Day 1 and 2 will entail classroom training sessions; day 3 will be clinical case studies and scenarios through role playing under the supervision of a palliative care nurse, oncologist, and clinical psychologist and day 4 will be experience sharing, action plan development, and training evaluation. The classroom sessions will include interactive lectures assisted by PowerPoint (Microsoft) presentations, pictures and videos, presentation of case studies, sharing of personal experiences and group discussions of concepts and experiences. An international facilitator will be invited to take part in the training and give an opportunity for others to present virtually during the training. For the clinical case studies and scenarios, participants will be shared in groups of 5 to work on different clinical case studies and scenarios followed by sharing feedback with the entire team. A similar approach has been used and shown to be an effective strategy in the training of nurses in psychosocial oncology [34]. Participants will be provided with printed copies of the palliative care toolkit by Lavy and Woodridge [35]. In addition, they will be provided with links to online resources including the free online resources by IPOS.

Aim 3: Assess the Impact of the Training Program on Nurses' Psychosocial Oncology and Palliative Care Competences

A pretest and posttest survey will be used to assess the impact of the course on nurses' psychosocial oncology and palliative care knowledge and self-perceived competence and confidence in psychosocial and palliative care provision. An advantage of a pretest and posttest assessment is that it can be used to enhance understanding of what change, particularly in factual knowledge or skill sets that could be credited to a training program. All 50 study participants will receive a paper-based pretest evaluation to determine their baseline psychosocial oncology and palliative care knowledge, and self-perceived competence and confidence in psychosocial and palliative care provision. The paper-based assessment will take place at the hospital on the first day of training. Posttest data will be collected on the last day of the training. A questionnaire has been collated and comprises of 3 subscales to collect the pretest and posttest data. These subscales include a researcher developed demographic information subscale, the Palliative Care Quiz for Nursing [36], Perceived Palliative Care Self-efficacy Questionnaire [37], and the psychosocial oncology knowledge subscales [34]. The demographic questionnaire will collect information on participants' characteristics including nurses' qualification, hospital and unit of work, gender, religious affiliation, and previous education about palliative care and psychosocial oncology. The validated Palliative Care Quiz for Nursing will be used to assess change in nurses' palliative care knowledge, the Perceived Palliative Care Self-efficacy Questionnaire will be used to assess self-perceived competence and confidence in palliative care provision. These instruments have adequate psychometric property and have been used to assess student nurses' palliative care competencies in the study setting. For the assessment of psychosocial oncology competences, we have adapted the instruments used in the study by Mahendran et al [34] in Singapore.

Aim 4: Assess the Strengths and Weaknesses of This Training Program

A course evaluation survey will be administered to participants to explore their experiences of the course, their perspective of its strengths and weaknesses, and their plans for transfer of their knowledge and skills from this course to practice, in the care of patients with cancer. This will include both close-ended and open-ended questions to give nurses the opportunity to expand

on their responses and provide all relevant information as they deem necessary. This survey instrument is under development by the team and will be administered by research assistants on the last day of each training session.

Aim 5: Assess Nurses' Transfer of Their Learning From This Training in the Care of Patients With Cancer

Individual critical incident in-depth interviews will be conducted with nurses to explore the transfer of their learning to practice, its perceived benefits to patients and implementation challenges. A random sampling technique will be used to invite 3 nurses from each study site for this interview. Thus, a total of 18 nurses will be interviewed. These interviews will be organized at month 6 following completion of the training for each hospital. An interview guide will be used and it is envisaged that the interviews will last for 1 hour and will be tape recorded. In addition, a pre- and posttraining audit of patient files will be carried out to assess the number of patients with cancer that nurses assessed for psychosocial distress and coping, depression, anxiety, and palliative care, the number they plan psychosocial nursing and palliative care interventions (cognitive behavioral therapy) for and the number that nurses referred or suggest referral to specialist mental health and palliative care services or psycho-oncologists. The pretraining audit will be conducted at baseline, using a checklist. We will select files of the 50 most recently discharged patients with cancer or patients who died during hospitalization from each study site. Thus, a total of 300 hospital files will be studied from the 6 sites. Six months after training implementation in each site, we will undertake the posttraining audit. We will randomly select 50 files of patients with cancer currently receiving or who received nursing care from trained nurses. In total we will study 600 files, 300 from baseline and 300 post training.

Data Analysis

We will evaluate changes in mean scores from pretest to posttest to assess the impact of the course on nurses' psychosocial oncology and palliative care knowledge, and self-perceived competence and confidence in psychosocial oncology and palliative care provision. A paired *t* test, will be used to calculate the change in nurses' psychosocial oncology and palliative care knowledge from pretest scores to posttest scores, and to examine the significance of this change. The between and within group variations of the pretest and the posttest scores in psychosocial oncology and palliative care knowledge before and after the training program will be assessed using ANOVA. The McNemars test will be used to assess changes from the pretest to the posttest in nurses' self-perceived competence and confidence in psychosocial and palliative care provision. Descriptive statistics (close ended responses) and content analysis strategy (open-ended responses) will be used to analyze data on nurses' evaluation of the benefits of the course on their psychosocial oncology and palliative care competencies, their experiences of the course and its strengths and weaknesses, and how they were able to use them in practice.

A framework analysis [38] will be used to analyze critical incidents where nurses implemented their learning in practice and their perspective of how that benefited the patients with cancer in their care. Themes will be used to describe these experiences. Finally, a content analysis of the change in nurses' practice in terms of the number and content of patients' assessment for psychosocial distress, depression, anxiety, and palliative care, the number of patients with psychosocial and palliative care nursing care plans and the number that were referred to specialist mental health or palliative care services by nurses before and after the training. All project team members, RAs, and program coordinator will be involved in data collection and analysis.

Ethical Considerations

Ethical approval for this study has been obtained through the University of Buea institutional review board (Ref-2023/2165-10/UB/SG/IRB/FHS). Participants will receive an information sheet regarding the study and will provide written consent for the study. Participation in the study will be voluntary and participants will also have the freedom to leave the study at any time without giving a reason to the study team. Data will be anonymized to ensure and no identifiable information will be stored. No compensation will be provided to research participants.

Results

This study was funded in September 2023. The training program development was initiated in March 2024 and completed in June 2024. We engaged 12 cancer care, psychosocial oncology and palliative care experts, and nurse educators in Cameroon (n=7), the United Kingdom (n=2), Ghana (n=1), Indonesia (n=1), and the United States (n=1) in a 3-round Delphi process for the development of a bespoke palliative care and psychosocial oncology training program. As of August 30, 2024, we had obtained administrative authorization from all participating hospitals. The collection of baseline data on nurses' practice of psychosocial oncology and palliative care as documented in the nursing records of patients with cancer was commenced in May 2024. As of September 19, 2024, we had completed an audit of the records of 300 hospitalized patients with cancer from all study sites. The implementation of the training program is planned for October-December 2024. Following course implementation, posttest data will be started in October 2024 and continue till April 2025. Data analysis will commence in October 2024 and will continue until June 2025. We aim to present study findings at national and international palliative care and psychosocial oncology conferences and publish papers in peer review journals by November 2025.

Discussion

Expected Project Outcomes

This protocol provides details of the steps for the development, implementation and assessment of the impact of a psychosocial oncology, and palliative care training program on Cameroonian nurses' palliative care and psychosocial oncology knowledge, self-perceived competencies, and practice. In this study, we are developing a palliative and psychosocial oncology course for nurses in Cameroon. We will pilot it with 50 nurses working in 6 hospitals in the southwest and littoral regions of Cameroon. We envisage that this training program will improve

participating nurses' palliative care knowledge and self-perceived competence and confidence in psychosocial and palliative care provision for patients with cancer. The implementation of this training program will enhance our understanding of the components and strategies for an effective palliative care and psychosocial oncology training program for nurses in Cameroon. We also hope that study findings will support future psychosocial oncology and palliative care training initiatives in Cameroon and similar contexts.

The field of psychosocial oncology is still developing in Africa [39] and therefore, initiatives to enhance health care providers' competences in this practice area are crucial especially in sub-Saharan Africa. Given the limited numbers of oncologist, psycho-oncologist, mental health experts and palliative care physicians and nurses in Cameroon, it is important to train registered nurses, who make the most of the health care workforce in Cameroon to provide palliative and psychosocial oncology care to patients with cancer and their families. This project builds on previously successful educational initiatives in palliative care for nursing students in Cameroon to enhance care of patients with life-limiting illnesses including patients with cancer [26,27]. Training nurses in palliative care and psychosocial oncology in other contexts have yielded positive impacts in terms of improvements in their knowledge and skills in palliative and psychosocial oncology care provision, with positive patient outcomes [15,34,40,41]. Similar outcomes are anticipated for this training in Cameroon.

Similar to this study, most studies have used both validated instruments such as the Palliative Care Quiz for nurses, and nonvalidated self-reported tools to evaluate the effective of training programs [15,40,41]. However, the use of self-reported tools is limited, with the possibility of recall bias, and social desirability bias [42]. Participating nurses may not recall past practices and may also tend to please the researcher and answer questions in ways they consider right rather than giving a true self-assessment of their competencies. Furthermore, nurses could overrate or underrate their competencies, resulting in a response shift bias [43].

The Kirkpatrick's model of training program evaluation used in this study provides us with a logical structure and process to measure participants' learning, satisfaction and transfer of learning to practice. It will provide us with an understanding of the specific areas for improvement within this training program, based on its strengths and weakness, thus informing program enhancement [44]. We aim to disseminate our study's findings in a peer reviewed journal and local and international conferences. In addition, during program implementation we will engagement with general supervisors of nursing services, nurse educators, and other health care professions education stakeholders in Cameroon. This has the potential to inform nursing education reforms and drive the long-term goal of curriculum revision to include palliative care and psychosocial oncology in the training programs of health professionals in Cameroon.

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Data Availability

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

Authors' Contributions

All authors contributed to the conceptualization, writing-review and editing, and approval of the submitted manuscript and will be accountable for its contents. NB and TN performed supervision. NB, TN, and BA performed data curation. NB, TN, BA, EVA, EME, NE, and ASA performed investigation and methodology. NB, TN, and BA handled project administration, managed resource and software and conducted validation. NB wrote the original draft.

Conflicts of Interest

None declared.

References

1. Palliative care fact sheet. World Health Organization. URL: https://www.who.int/news-room/fact-sheets/detail/palliative-care [accessed 2020-08-05]
2. WHO takes steps to address glaring shortage of quality palliative care services.: World Health Organization; 2021. URL: https://www.who.int/news/item/05-10-2021-who-takes-steps-to-address-glaring-shortage-of-quality-palliative-care-services [accessed 2021-10-05]
3. Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin 2021;71(3):209-249 [FREE Full text] [doi: 10.3322/caac.21660] [Medline: 33538338]
4. Worldwide Hospice Palliative Care Alliance. Global atlas of palliative care at the end of Life.: World Health Organization URL: https://www.iccp-portal.org/system/files/resources/Global_Atlas_of_Palliative_Care.pdf [accessed 2024-11-09]

5. Leave no-one behind: equity in access to palliative care.: ehospice URL: https://ehospice.com/editorial_posts/leave-no-one-behind-equity-in-access-to-palliative-care-by-claire-morris/ [accessed 2021-10-04]
6. Uwayezu MG, Nikuze B, Maree JE, Buswell L, Fitch MI. Competencies for nurses regarding psychosocial care of patients with cancer in africa: an imperative for action. JCO Global Oncology 2022(8):e2100240. [doi: 10.1200/go.21.00240]
7. Amonoo HL, Abdul-Rahim SA, Atobrah D, Addo-Mensah D, Longley RM, Jacobo MC, et al. Psychosocial oncology in sub-saharan africa: lessons from ghana. Psychooncology 2023;32(1):139-147. [doi: 10.1002/pon.5965] [Medline: 35584290]
8. Rhee JY, Garralda E, Namisango E, Luyirika E, de Lima L, Powell RA, et al. An analysis of palliative care development in africa: a ranking based on region-specific macroindicators. J Pain Symptom Manage 2018;56(2):230-238 [FREE Full text] [doi: 10.1016/j.jpainsymman.2018.05.005] [Medline: 29772280]
9. Worldwide Palliative Care Alliance. Global Atlas of Palliative Care, 2nd Edition. https://thewhpca.org/. 2020. URL: https://thewhpca.org/resources/global-atlas-of-palliative-care-2nd-ed-2020/ [accessed 2024-11-09]
10. Jayawardana S, Forman R, Johnston-Webber C, Campbell A, Berterame S, de Joncheere C, et al. Global consumption of prescription opioid analgesics between 2009-2019: a country-level observational study. EClinicalMedicine 2021;42:101198 [FREE Full text] [doi: 10.1016/j.eclinm.2021.101198] [Medline: 34820610]
11. Clark D, Baur N, Clelland D, Garralda E, López-Fidalgo J, Connor S, et al. Mapping levels of palliative care development in 198 countries: the situation in 2017. J Pain Symptom Manage 2020;59(4):794-807.e4 [FREE Full text] [doi: 10.1016/j.jpainsymman.2019.11.009] [Medline: 31760142]
12. Kaasa S, Loge JH, Aapro M, Albreht T, Anderson R, Bruera E, et al. Integration of oncology and palliative care: a lancet oncology commission. Lancet Oncol 2018;19(11):e588-e653 [FREE Full text] [doi: 10.1016/S1470-2045(18)30415-7] [Medline: 30344075]
13. Anderson RE, Grant L. What is the value of palliative care provision in low-resource settings? BMJ Glob Health 2017;2(1):e000139 [FREE Full text] [doi: 10.1136/bmjgh-2016-000139] [Medline: 28588999]
14. Sharma R, Nanda M, Fronterre C, Sewagudde P, Ssentongo AE, Yenney K, et al. Mapping cancer in africa: a comprehensive and comparable characterization of 34 cancer types using estimates from GLOBOCAN 2020. Front Public Health 2022;10:839835 [FREE Full text] [doi: 10.3389/fpubh.2022.839835] [Medline: 35548083]
15. van der Meulen IC, May AM, de Leeuw JRJ, Koole R, Oosterom M, Hordijk G, et al. Long-term effect of a nurse-led psychosocial intervention on health-related quality of life in patients with head and neck cancer: a randomised controlled trial. Br J Cancer 2014;110(3):593-601 [FREE Full text] [doi: 10.1038/bjc.2013.733] [Medline: 24280999]
16. Rosa WE, Buck HG, Squires AP, Kozachik SL, Huijer HA, Bakitas M, et al. International consensus-based policy recommendations to advance universal palliative care access from the American academy of nursing expert panels. Nurs Outlook 2022;70(1):36-46 [FREE Full text] [doi: 10.1016/j.outlook.2021.06.018] [Medline: 34627615]
17. Bassah N, Vaughn L, Santos Salas A. Nurse-led adult palliative care models in low- and middle-income countries: a scoping review. J Adv Nurs 2023;79(11):4112-4126. [doi: 10.1111/jan.15646] [Medline: 36965072]
18. Echouffo-Tcheugui JB, Kengne AP. Chronic non-communicable diseases in cameroon - burden, determinants and current policies. Global Health 2011;7(1):44 [FREE Full text] [doi: 10.1186/1744-8603-7-44] [Medline: 22112686]
19. Ferlay JEM, Colombet M, Soerjomataram I, Mathers C, Parkin DM, Piñeros M, et al. Estimating the global cancer incidence and mortality in 2018: GLOBOCAN sources and methods. Int J Cancer 2019;144(8):1941-1953 [FREE Full text] [doi: 10.1002/ijc.31937] [Medline: 30350310]
20. Bray F, Laversanne M, Weiderpass E, Soerjomataram I. The ever-increasing importance of cancer as a leading cause of premature death worldwide. Cancer 2021;127(16):3029-3030 [FREE Full text] [doi: 10.1002/cncr.33587] [Medline: 34086348]
21. Globocan (2020): new global cancer data.: Union for International Cancer Control; 2020. URL: https://www.uicc.org/news/globocan-2020-global-cancer-data [accessed 2020-12-17]
22. Ebob-Anya BA, Bassah N. Psychosocial distress and the quality of life of cancer patients in two health facilities in cameroon. BMC Palliat Care 2022;21(1):96 [FREE Full text] [doi: 10.1186/s12904-022-00981-w] [Medline: 35650571]
23. Ministry of Public Health Cameroon. National strategic plan for prevention and cancer control.: World Health Organization; 2020. URL: https://www.iccp-portal.org/system/files/plans/FINAL%20COPY%20OF%20PSNPLCa%20ENGLISH.pdf [accessed 2024-11-18]
24. D'Souza C, Djoumessi R, Lonlack C. Palliative care growing in Cameroon.: ehospice; 2014. URL: https://ehospice.com/africa_posts/palliative-care-growing-in-cameroon/ [accessed 2014-07-08]
25. Mapoko BSE, Frambo A, Saidu Y, Mbassi EDB, Atenguena E, Azemafac K, et al. Assessment of barriers to optimal cancer control in adult cancer treatment centres in Cameroon. Ecancermedicalscience 2023;17:1601 [FREE Full text] [doi: 10.3332/ecancer.2023.1601] [Medline: 37799946]
26. Bassah N, Cox K, Seymour J. Preregistration nursing students' experiences of a palliative care course in a resource-poor setting. Int J Palliat Nurs 2018;24(8):388-397 [FREE Full text] [doi: 10.12968/ijpn.2018.24.8.388] [Medline: 30141713]
27. Bassah N, Cox K, Seymour J. A qualitative evaluation of the impact of a palliative care course on preregistration nursing students' practice in cameroon. BMC Palliat Care 2016;15(1):37 [FREE Full text] [doi: 10.1186/s12904-016-0106-7] [Medline: 27036409]

28. Frye AW, Hemmer PA. Program evaluation models and related theories: AMEE guide No. 67. Medical Teacher 2012;34(5):e288-e299. [doi: 10.3109/0142159x.2012.668637]
29. Multilingual core curriculum in psycho-oncology english.: International Psycho-Oncology Society URL: https://www.ipos-society.org/module/english [accessed 2024-11-09]
30. Planning and implementing palliative care services: a guide for programme managers.: World Health Organization; 2016. URL: https://ahpsr.who.int/publications/i/item/planning-and-implementing-palliative-care-services-a-guide-for-programme-managers [accessed 2024-11-09]
31. Bassah NP. Impact of a palliative care course on pre-registration nursing students' palliative care knowledge. CAJPH 2019;5(2):58. [doi: 10.11648/j.cajph.20190502.11]
32. Tandi TE, Cho Y, Akam AJ, Afoh CO, Ryu SH, Choi MS, et al. Cameroon public health sector: shortage and inequalities in geographic distribution of health personnel. Int J Equity Health 2015;14(1):43 [FREE Full text] [doi: 10.1186/s12939-015-0172-0] [Medline: 25962781]
33. Hinman RS, Allen K, Bennell K, Berenbaum F, Betteridge N, Briggs A, et al. Development of a core capability framework for qualified health professionals to optimise care for people with osteoarthritis: an OARSI initiative. Osteoarthritis Cartilage 2020;28(2):154-166. [doi: 10.1016/j.joca.2019.12.001] [Medline: 31838047]
34. Mahendran R, Chua J, Peh CX, Lim HA, Ang ENK, Lim SE, et al. Knowledge, attitudes, and practice behaviors (KAPb) of nurses and the effectiveness of a training program in psychosocial cancer care. Support Care Cancer 2014;22(8):2049-2056. [doi: 10.1007/s00520-014-2172-9] [Medline: 24615706]
35. Coombes R. Palliative care toolkit developed for staff in developing countries. BMJ 2008;336(7650):913.1-91913. [doi: 10.1136/bmj.39556.505313.db]
36. Ross MM, McDonald B, McGuinness J. The palliative care quiz for nursing (PCQN): the development of an instrument to measure nurses' knowledge of palliative care. J Adv Nurs 1996;23(1):126-137. [doi: 10.1111/j.1365-2648.1996.tb03106.x] [Medline: 8708208]
37. Phillips JY, Salamonson Y, Davidson PM. An instrument to assess nurses' and care assistants' self-efficacy to provide a palliative approach to older people in residential aged care: a validation study. Int J Nurs Stud 2011;48(9):1096-1100. [doi: 10.1016/j.ijnurstu.2011.02.015] [Medline: 21377679]
38. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol 2013;13(1):117 [FREE Full text] [doi: 10.1186/1471-2288-13-117] [Medline: 24047204]
39. Kagee A. The need for psychosocial oncology research in sub-saharan africa: a review of the terrain. South African Journal of Psychology 2022;52(3):392-403. [doi: 10.1177/00812463221093842]
40. Chen X, Zhang Y, Arber A, Huo X, Liu J, Sun C, et al. The training effects of a continuing education program on nurses' knowledge and attitudes to palliative care: a cross sectional study. BMC Palliat Care 2022;21(1):56. [doi: 10.1186/s12904-022-00953-0] [Medline: 35473551]
41. Gupta M, Pruthi G, Gupta P, Singh K, Kanwat J, Tiwari A. Impact of end-of-life nursing education consortium on palliative care knowledge and attitudes towards care of dying of nurses in india: a quasi-experimental pre-post study. Am J Hosp Palliat Care 2023;40(5):529-538. [doi: 10.1177/10499091221108342] [Medline: 35703389]
42. Burchett DM, Sellbom M, Bagby RM. Assessment of response bias in personality disorder research. Personal Disord 2023;14(1):93-104. [doi: 10.1037/per0000608] [Medline: 36848077]
43. Schwartz CE, Rohde G, Biletch E, Stuart RBB, Huang I, Lipscomb J, et al. If it's information, it's not "bias": a scoping review and proposed nomenclature for future response-shift research. Qual Life Res 2022;31(8):2247-2257. [doi: 10.1007/s11136-021-03023-9] [Medline: 34705159]
44. Heydari MR, Taghva F, Amini M, Delavari S. Using kirkpatrick's model to measure the effect of a new teaching and learning methods workshop for health care staff. BMC Res Notes 2019;12(1):388 [FREE Full text] [doi: 10.1186/s13104-019-4421-y] [Medline: 31292006]

Abbreviations

IPOS: International Psycho-Oncology Society
LMIC: low- and middle-income country
RA: research assistant

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Complete Lifestyle Medicine Intervention Program–Ontario: Implementation Protocol for a Rural Study

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Abstract

Background: Sedentary lifestyles, poor nutritional choices, inadequate sleep, risky substance use, limited social connections, and high stress contribute to the growing prevalence of chronic diseases. Lifestyle medicine, emphasizing therapeutic lifestyle changes for prevention and treatment, has demonstrated effectiveness but remains underutilized in clinical settings. The Complete Lifestyle Medicine Intervention Program–Ontario (CLIP-ON) was developed to educate the rural population of Northern Ontario in lifestyle medicine to improve health outcomes and engagement.

Objective: This study evaluates the implementation and effectiveness of the CLIP-ON program for patients with chronic diseases in the Parry Sound area, focusing on lifestyle behaviors, health outcomes, enrollment, retention rates, and interdisciplinary team engagement.

Methods: This observational cohort study guided by the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, and Maintenance) includes pre- and postintervention assessments from participants and health care providers. A hybrid type II mixed methods design evaluates the intervention's effectiveness and implementation process in real-world settings through quantitative and qualitative data collection. CLIP-ON is tailored to the residents of the Parry Sound catchment area in Northern Ontario. Participants (≥18 years old) with chronic conditions such as prediabetes, type II diabetes, systemic hypertension, cardiovascular vascular disease, dyslipidemia, or high BMI (≥25) will be recruited through self-referral or provider referral. Approximately 10 participants per cohort will be enrolled in the CLIP-ON program, consisting of 22 weeks of weekly group sessions and monthly individual consultations with physicians, health coaches, kinesiologists, and registered dieticians either in person or through a web-based platform. CLIP-ON will cover the 6 pillars of lifestyle medicine through 14 group sessions followed by an 8-week supervised exercise program. Anthropometric and cardiometabolic variables will be measured before and after the program. Participants will be surveyed on lifestyle habits, wellness, perceived barriers, and program satisfaction at 3 and 6 months. Focus groups and dropout interviews with participants (n=10 per cohort) and providers (n=6 per cohort) will guide program

adaptations. Quantitative and qualitative data collected at baseline and follow-up will assess the program's implementation and identify barriers and opportunities for improvement.

Results: This study was approved by the Laurentian University Research Ethics Board (6021397) on July 6, 2023. The first cohort was enrolled in late 2023 and is still under evaluation. The second cohort began in mid-2024, and data collection is currently underway. A mixed methods analysis will be used at enrollment, program completion (22 weeks), and follow-up (6 months after program completion). Focus groups assessing the program's effectiveness and implementation will take place after the 22-week intervention. Data will be analyzed in early 2025.

Conclusions: This protocol provides insights into the implementation of this lifestyle medicine program and its impact on participants' health. The findings will guide future advancements and establish a scalable model for other communities.

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KEYWORDS

chronic disease; nutrition, exercise; sleep; relationships; stress reduction; self-compassion; risky substance use; holistic medicine; whole health; implementation; lifestyle medicine; rural medicine; web-based platform; substance use; feasibility; wellness; barriers; opportunities

Introduction

Background

Chronic diseases, also known as noncommunicable diseases (NCDs) such as cancer, cardiovascular disease, cerebrovascular disease, and diabetes, are among the leading causes of death in Canada, with their prevalence steadily rising [1]. Hypertension, the leading global risk factor for death and disability, remains uncontrolled in more than 50% of patients [2]. NCDs are responsible for over 74% of global deaths annually [2-4], significantly affecting vulnerable and low-income populations [5-7]. Despite clear benefits from improved lifestyle choices, including better nutrition, regular physical activity, and stress reduction, there remains limited research on the long-term sustainability of these changes and the role of physician intervention [5,7-9].

Sedentary lifestyles, poor nutritional choices, and increased stress play significant roles in chronic disease development [7,8,10], with type II diabetes affecting over 10% of the population worldwide [11]. Type II diabetes, primarily linked to cardiovascular disease, contributes to over 1 million deaths annually [7,12-14]. Chronic disease–related health care costs in Canada account for more than US $136 billion annually [15], emphasizing the need for lifestyle interventions to reduce this burden [1,14].

Lifestyle medicine is an interdisciplinary medical specialty that focuses on 6 key pillars such as dietary changes, regular physical activity, stress management, restorative sleep, positive social connection, and avoidance of risky substances such as alcohol and tobacco has been shown to improve outcomes in chronic conditions [16-18]. Moreover, with its patient-centered focus [6,19-21], lifestyle medicine addresses the root causes of disease, aligning with the P4 (Preventive, Predictive, Personalized, and Participatory) medicine approach [6,22,23]. Achieving optimal health through a maintained commitment to lifestyle medicine has been shown to reverse many stages of chronic disease, reduce hospitalization and hospital costs, improve chronic disease management, and promote better health outcomes [4,5,14,24-28].

Studies indicate that the adoption of evidence-based lifestyle medicine practices has gained traction, with numerous programs demonstrating effectiveness in improving health outcomes and promoting sustainable behavior change [9,29-31]. Other studies support the adoption of evidence-based lifestyle medicine practices across North America [9,20,32,33]. Such evidence highlights the potential for lifestyle medicine to be integrated into routine health care, paving the way for broader acceptance and implementation in various clinical environments.

However, despite these promising outcomes, effective implementation of lifestyle medicine in clinical settings remains challenging. A strong patient-provider collaborative relationship is essential for achieving adherence to treatment plans and informed health care decision-making [34]. The physician's role as a health coach is critical in this process, underscoring the importance of training clinicians in lifestyle medicine practices [5,12,16,35]. Yet, many physicians report a lack of confidence and skills in delivering lifestyle medicine effectively [20], especially in rural areas. During the COVID-19 pandemic, virtual and digital platforms, such as lifestyle management tools, were developed to support patients [10,36], which has proven to be crucial for equitable health care access [16,35]. These tools hold the potential to address barriers in underserved areas where health care resources are limited, particularly in rural settings.

In this context, it becomes essential to evaluate the real-world implementation of lifestyle medicine to identify both successes and challenges, ensuring that lifestyle medicine can be effectively integrated into routine health care. This is especially relevant in rural areas, where health care access is limited, and the burden of chronic disease is high. Parry Sound, a rural community in Northern Ontario with a population of 6879 and a catchment area of 42,824 (including 10% Indigenous residents) [26,29,36,37], experiences disproportionately high rates of diabetes (8%) and hypertension (20%) compared with the provincial average [27]. These factors make it an ideal location

for integrating lifestyle medicine into care. Incorporating traditional Indigenous teachings, which emphasize the interconnectedness of mind, body, spirit, and emotions, can bridge gaps between traditional Western medicine and Indigenous Healing Practices and improve population health outcomes [28,36,38].

Inspired by the New York Lifestyle Medicine program [36,38], in 2023 our medical and research team, in collaboration with the health care community in Parry Sound, developed an innovative and whole health program named the Complete Lifestyle medicine Intervention Program, Ontario (CLIP-ON). These comprehensive interdisciplinary aims are to educate participants on the 6 pillars of lifestyle medicine and inform them about their integration into daily life to mitigate chronic disease and enhance overall health. To facilitate the implementation of lifestyle medicine practices, various models and methodologies have been proposed [39]. Among these, the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, and Maintenance) serves as a valuable tool for evaluating the impact of lifestyle medicine interventions in diverse settings [40,41]. To the best of our knowledge, this is the first program in lifestyle medicine in a rural area in Ontario. Our overarching hypothesis is that the implementation of CLIP-ON will significantly improve lifestyle behavior, health outcomes, and participant engagement, with feedback from participants and health care providers informing real-time program improvements.

Primary Objective

To evaluate the implementation and effectiveness of the comprehensive web-based platform and in-person CLIP-ON program for patients with chronic disease in the Parry Sound area, focusing on its impact on lifestyle behaviors, health outcomes including cardiometabolic parameters, and participants' engagement.

Secondary Objectives

The secondary objectives of this study are (1) to assess the reach and adoption of the CLIP-ON program by evaluating participant enrollment, and retention rates and (2) to gather and analyze direct feedback from participants and health care providers to inform real-time program improvements and enhance the program's overall effectiveness.

Methods

Design

This protocol outlines an observational cohort study guided by the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, and Maintenance) and includes pre- and postintervention assessments from participants and health care providers (RE-AIM milestones Multimedia Appendix 1). A hybrid design type II mixed methods approach [42,43] will be used to simultaneously evaluate both the effectiveness of the CLIP-ON and its implementation process in a real-world setting. This will involve the collection and analysis of both quantitative and qualitative data.

The CLIP-ON program is an interdisciplinary lifestyle medicine intervention delivered both virtually and in person, specifically tailored for residents of the Parry Sound catchment area in Northern Ontario. Within this district are 3 First Nation Communities (Wasauksing, Moose Deer Point, and Shawanaga First Nations), each of which has requested access to CLIP-ON. The study design is summarized in Figure 1, and the participant's and health care providers' measurements are presented in Table 1. Following informed consent, each participant will have an initial appointment with a certified lifestyle medicine physician at West Parry Sound Health Centre before starting the CLIP-ON program. Participants will complete the Physical Activity Readiness Questionnaire (PAR-Q+) by the Canadian Society of Exercise Physiology [44] to identify risk factors during moderate physical activity. A Physical Activity Readiness Medical Examination (PARmed-X) [45] will also be completed for participants who had potential medical complications from exercise according to their response to the PAR-Q+. During this visit, they will undergo a medical review and physical examination. They will also receive a requisition for blood work to establish their baseline cardiometabolic data. Each participant will complete a baseline (intake Lifestyle and health) questionnaire on Google Forms with the assistance of a trained research staff member over the phone. This preprogram questionnaire will collect demographic and baseline information about their lifestyle according to the 6 pillars of lifestyle medicine. Cardiometabolic variables will be measured before and after the CLIP-ON intervention. Participants will be surveyed by phone at 3- and 6-months regarding lifestyle habits, wellness, perceived barriers, and program satisfaction. At the end of the program, web-based platform (through Zoom) focus groups with participants and health care providers will be conducted to discuss their experiences and provide feedback for program development. Focus groups and dropout interviews with patients (approximately 10 per cohort, anticipating a drop-out rate of 10% based on similar studies [29], and providers (approximately 6 per cohort) will provide iterative feedback, enabling program refinement. The 2 cohorts are planned, with potential for expansion based on the available funding. The study timeline is illustrated in Figure 2.

Figure 1. CLIP-ON protocol. The intake lifestyle and health progress questionnaire was inspired by the Lifestyle Assessment Short Form [46], the 36-Item Short Form Health Survey, and the Patient Health Questionnaire-9 [47,48]. The Physical Activity Readiness Questionnaire (PAR-Q+) [44] and PARmed-X [45] were used to measure physical activity readiness. The 6 pillars of health inspired by the American College of Lifestyle Medicine are nutrition, sleep, relationships, physical activity, risky substance use, and stress management [18]. Three- and 6-month health progress questionnaires were inspired by the questions used in the New York City Health [38,49,50], the Hospital lifestyle medicine program, and the Complete Health Improvement Program lifestyle medicine program at Vanderbilt University [51,52].

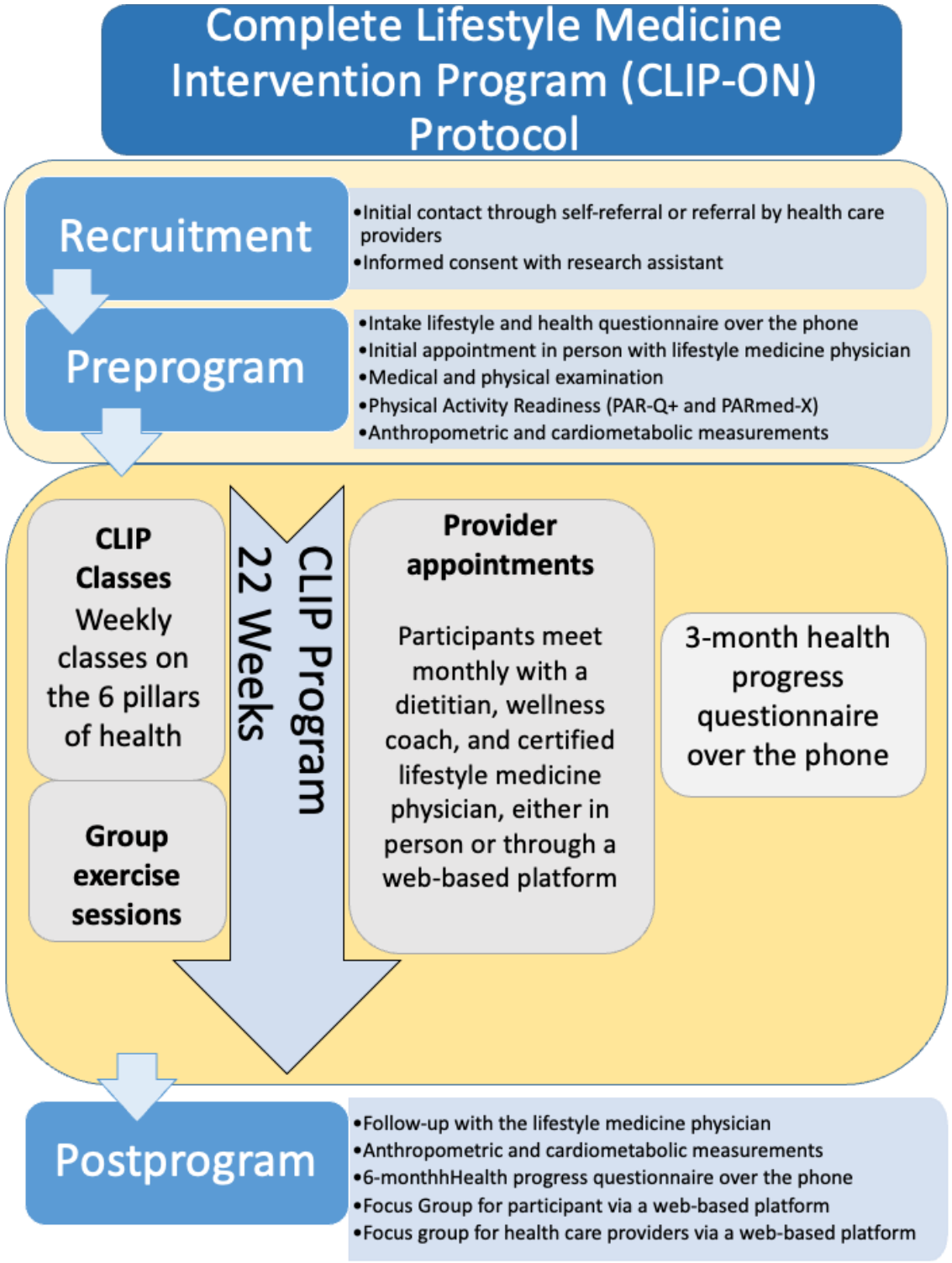

Table 1. Participants and health care providers measurements.

Measurement	Time	Variables	Details
Intake Lifestyle and Health Participants Questionnaire	Baseline, 6 months, and 12 months	Food consumption, motivation and confidence, neighborhood food environment, physical activity, media use and screen time, substance use, sleep, health, behavior, and well-being, and socio-demographics	Administered through phone or online, inspired by inspired by the Lifestyle Assessment Short Form [46], the short form survey instrument SF-36[a] and the PHQ-9[b] [47,48].
Health progress questionnaire[c]	3 months and 6 months	Similar to the intake questionnaire but includes additional questions on social support, satisfaction with the program	Conducted by phone with a research assistant
Anthropometric measurements	Pre- and postprogram	Health, weight, BMI, and waist circumference	Measurements taken by health care providers
Hemodynamic measurements	Pre- and postprogram	Blood pressure and heart rate	Measurements taken by health care providers
Cardiometabolic measurements	Pre- and postprogram	Hemoglobin, ions (calcium, magnesium, phosphate, sodium, potassium), Fasting blood glucose, Glycated Hemoglobin, cholesterol Lipid panels (total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, plasma, triglycerides) creatine glomerular filtration rate, Urine test: microalbumin, and albumin-creatine ratio	Blood and urine tests collected for analysis
Health care provider questionnaire	Preprogram	Provider social demographics, credentials, practice location	Completed before program involvement
Participants focus group	End of program	Experiences, benefits, challenges, program feedback, their thoughts on lifestyle medicine pillars addressed, and program continuation	Virtual focus group using a semistructured script led by an independent researcher or assistant
Health care provider focus	End of program	Feedback on recruitment strategies, their experiences, their thoughts on the content and materials provided, challenges encountered, future sustainability, suggestions for future program implementation cohort	Virtual focus group using a semistructured script led by an independent researcher or assistant

[a]SF-36: 36-item Short Form Survey.

[b]PHQ-9: Patient Health Questionnaire-9.

[c]These questionnaires include questions used in the Complete Health Improvement Program (CHIP) lifestyle medicine program at Linda Loma University and the New York City Health and Hospital lifestyle medicine program [38,49]. In addition, the Warwick, -Edinburgh Mental Well-Being scale guided the inclusion of questions pertaining to mental health [51,52]. Together, these existing surveys allow both quantitative and qualitative elements to be included in this study.

Figure 2. Timeline. It illustrates the key tasks throughout the study timeline. The first year focused on grant preparation, recruitment, preassessment, and intake questionnaires to prepare the first cohort. Year 2 emphasizes group sessions, individual appointments, end-of-program questionnaires, and postassessment for Cohort 1, while also initiating the same process for Cohort 2. Year 3 will primarily focus on data analysis and knowledge dissemination.

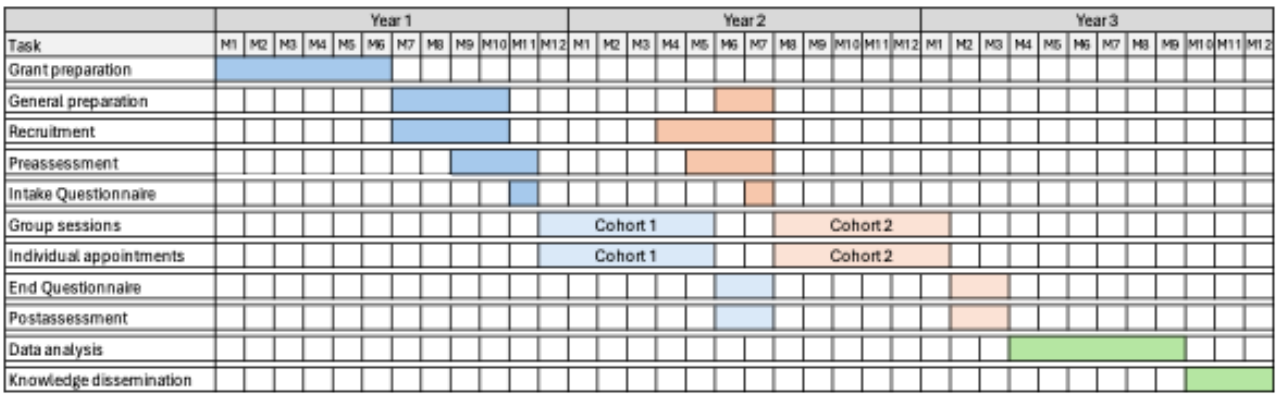

Figure 1 demonstrates participant flow throughout the CLIP-ON study, a hybrid lifestyle medicine program designed for rural Northern Ontario. The program addresses 6 pillars of health: healthy nutrition, regular physical activity, restorative sleep, stress management, avoiding risky substance use, and fostering positive relationships. Patients could meet health care providers in person or through a web-based platform. Group sessions and exercise classes during the 22-week program were available in 3 formats: in person, through a web-based platform, or as recorded sessions for later access. Intake lifestyle and health progress questionnaire inspired by the Lifestyle Assessment Short Form [46], the short form survey instrument SF-36 and the PHQ-9 [47,48]. Physical Activity Readiness Questionnaire: PAR-Q+ [44] and PARmed-X [45]. Three- and 6-Month Health Progress Questionnaire inspired by the questions used in the New York City Health [38,49,50] and Hospital Lifestyle Medicine program and the CHIP lifestyle medicine program at Vanderbilt University [51,52].

Participants

Inclusion Criteria

Adult participants (≥ 18 years) with chronic diseases such as prediabetes, type II diabetes mellitus, systemic hypertension, coronary heart disease, peripheral vascular disease, dyslipidemia, or health concerns related to excessive body weight (BMI≥25) will be recruited. Participants must reside in the Parry Sound, Ontario catchment area.

Exclusion Criteria

Participants with unstable medical conditions that prevent successful completion of program elements will be excluded. In addition, individuals who are unable to provide consent, do not meet the requirements of PARmed-X, and are unable to engage in a low-intensity, a professionally supervised exercise program will also be excluded.

Recruitment

Participants will be recruited through self-referral or referral by health care providers. Multiple avenues will be pursued to enhance recruitment efforts and reach a diverse population. Posters will be distributed throughout the Parry Sound community in high-traffic public locations such as grocery stores, coffee shops, libraries, and various departments within the Parry Sound Community Hospital. Pamphlets will be made available at health care provider clinics both within and outside of the hospital, including the Family Health Team and nurse-practitioner-led clinics. In addition, both posters and pamphlets will be distributed to local health care providers, who will be encouraged to share on social media (Facebook and Instagram [Meta]) in accordance with the ethical agreement to maximize outreach to the target population. These comprehensive recruitment strategies aim to ensure saturation of the rural environment and ensure equal opportunities for eligible participants to join the program.

Implementation Assessment

The CLIP-ON implementation assessment is guided by the RE-AIM framework which defines 5 dimensions: reach, effectiveness, adoption, implementation, and maintenance [40,41]. These dimensions will also help guide enhancements to the CLIP-ON program. Further details are provided in Multimedia Appendix 1.

Description of the CLIP-ON Program

Overview

The CLIP-ON program will consist of 22 weeks of weekly group sessions held at the local Parry Sound Bobby Orr Community Centre and monthly individual consultations, either in person at West Parry Sound Health Center or virtually, with an interdisciplinary team including physicians, a health coach, and registered dieticians. Participants will be encouraged to attend all 22 weekly classes and exercise sessions in person. However, a web-based platform option will be available for instances when they are unable to attend. Both the group class sessions and exercise sessions will be recorded for participants to access later. Each participant will receive a cookbook, exercise bands appropriate for their fitness level, and US $14.22 gift cards for local grocery stores as compensation for their time in completing program surveys and participating in focus groups.

Fundamentals of Lifestyle Medicine Group Class

CLIP-ON will cover the 6 pillars of lifestyle medicine through 12-14 group sessions on the Fundamentals of Lifestyle Medicine followed by an 8-week supervised exercise program developed and supervised by a kinesiologist. Table 2 outlines the topics covered in these group classes with a brief description of each. These classes will address the importance of the human microbiome and nutrition, fitness, positive relationship integration, stress and sleep management, and navigation of substance use toxicity and addiction. Concurrently, participants will discuss goal setting and planning with their lifestyle medicine physician, health coach, and dietician to incorporate knowledge and skills developed through the classes into their lives while motivating their success in the program.

Table 2. Topics and descriptions of each Fundamentals of Lifestyle Medicine group class.

Class topic	Class description	Providers
Introduction	An overview of what lifestyle medicine is and small group discussions for participants to meet each other.	Lifestyle medicine physician
Microbiome	Mostly focused on the gut microbiome, what it does, how every pillar can help build and maintain it, and what happens if we do not.	Lifestyle medicine physician
Nutrition	Two classes, one focused on explaining the recommendations of Canada's food guide, and another on discussing food preparation, practical cooking tips, and reading food labels.	Dietitian
Physical activity	Two Classes, one on the importance and benefits of physical activity and The Canadian Society of Exercise Physiologists' recommendations, and another class on how to move safely.	Kinesiologist
Sleep	Two classes, one on the benefits of sleep and what happens if we do not get enough sleep, another class on how to build our sleep hygiene, and an overview of insomnia and Cognitive Behavioral Therapy for insomnia.	Lifestyle medicine physician
Stress	Two classes, one on the impact of stress and the different ways it can manifest itself in our lives, and another class on stress management techniques.	Health coach
Social connections and positive psychology	One class on the impact of social isolation and the Positive Emotion, Engagement, relationships, Meaning, and Accomplishment (PERMA) [53,54] model of positive psychology for happiness and fulfillment.	Lifestyle medicine physician
Relationships with ourselves and others	One class on the concepts of Mindful Self-Compassion was developed by Kristin Neff and Christopher Germer, and Nonviolent Communication was developed by Marshall B. Rosenberg.	Lifestyle medicine and health coach
Risky substances and addictions	One class on the impact of addictions, the risk factors that can lead to addictive behaviors, and how to build our own resilience.	Lifestyle medicine physician
Conclusion	Discussion of takeaways and habit-building tips.	Lifestyle medicine physician

Exercise Group Class

An 8-week exercise program will be led by a registered kinesiologist and will follow the Fundamental Lifestyle Medicine group class session. The program will be structured yet adaptable to accommodate each participant's abilities and limitations. Before the exercise program, the kinesiologist will present the Education Sessions-Fitness Fundamentals, where they will explain why participants should exercise and how to be safe doing so. A booklet describing all activities will be shared with the participants that outline safe exercise guidelines, the rating of the Borg care of perceived exertion [44,55], when to stop exercising (symptoms and what to do), how to adapt the program, and exercises plan with picture of each exercise. The kinesiologist will then teach the entire exercise program in group sessions with the participants. Each session will last 1 hour and will follow this sequence warm-up, resistance training, cardio, flexibility, balance, core, and cool down. The exercise will use body weight resistance and a physiotherapy band appropriate for each person's capacity.

Enrollment

Participants will be screened according to the inclusion and exclusion criteria by the physician during their initial medical consultation. Eligible participants will be informed about the study's purpose, procedures, potential risks, and benefits during the informed consent process before enrolment. Participants will be made aware of their right to withdraw consent at any point during the study without any impact on their care.

Retention

The research staff and health care providers will strive to build strong rapport with participants encouraging them to attend the 22 weekly classes held in person at the local Parry Sound Bobby Orr Community Centre. If participants are unable to attend in person, a web-based platform option will be provided, along with access to recorded sessions. This approach ensured accessibility and adaptability to meet diverse patient needs. Attrition will be closely monitored, and for those who choose to leave the study, a structured exit interview with a research assistant will be conducted to gather feedback and identify potential areas for improving the program.

Ethical Considerations

This study received ethics approval from the Laurentian University Research Ethics Board (6021397) on July 6, 2023, and adheres to the guidelines stated in the Declaration of Helsinki. This study was registered at ClinicalTrials.gov (NCT06192251) in November 2023. Trained research staff informed participants of their right to withdraw themselves and the information collected on them up until the time of withdrawal, and informed consent was obtained. Patient data is available only to program health care providers and is segregated from research data. Participants are assigned a research code following the informed consent process, which links their research data through the study to allow appropriate analyses. Participant information is deidentified, and results will be published in this manner as well to ensure confidentiality.

Results

The first cohort of participants was enrolled in late 2023 and is still under evaluation. Data collection for the second cohort began in mid-2024 and is currently underway, with a projected end date in early 2025. A total of 16 participants have been recruited as of November 2024. Data analysis will be conducted in mid-2025, and we anticipate submitting the final manuscript by the end of 2025. A mixed method analysis [42,43] will be used to analyze the quantitative and qualitative data, collected individually at enrollment, program completion (22 weeks), and follow-up (6 months after program completion). Focus groups will be conducted after the 22-week intervention to assess the program's effectiveness and implementation.

Initial findings indicate that participants have gained knowledge about lifestyle changes, particularly in stress management and health behavior choices, and positively impacted their friends, family, and community by sharing their experiences. As more data is analyzed, it is anticipated that participants who commit to making changes will show improvement in their physical and mental well-being with the knowledge and practices learned from the classes and interdisciplinary health team.

In addition, initial participants included members of the local First Nation communities who raised concerns about accessibility for other First Nations such as challenges with significant travel and limited access to web-based platforms. In response to these concerns, there is confirmed interest in hosting a CLIP-ON cohort within these communities to ensure equitable access for all interested members.

Discussion

Expected Outcomes

We anticipate that these findings will support the long-term goal of establishing a lifestyle medicine program for rural Ontario communities that combines education, digital platforms, and interactions with an interdisciplinary health team. Its holistic, patient-centered approach to medicine strives to promote lifestyle changes that can prevent and treat chronic diseases, transform patient care in a manner that has been demonstrated to be successful in large urban centers and encourage its adoption and adaptation by health care providers across Canada. Our long-term goal is to demonstrate that CLIP-ON positively impacts community health and decreases health care use by reducing the impact of chronic illness.

Comparison to Previous Studies

CLIP-ON is the first lifestyle medicine program that will be conducted virtually and in-person in a rural Canadian community setting, while other Canadian lifestyle medicine interventions, such as Canadian Health Advanced Nutrition for Graded Exercise (CHANGE), have been implemented in large primary care settings in a physical format only [9,33]. This study will investigate the impact of incorporating all 6 pillars of lifestyle medicine as opposed to selected pillars [49-52,55-58]. It is also designed for patients with broad chronic diseases compared to other lifestyle medicine studies that focus on patients with specific chronic diseases [57,59-61]. Like the New York City lifestyle medicine program, CLIP-ON is built around all 6 pillars of health while providing individual support, goal setting, dietary recommendations, and monitoring support of an interdisciplinary health team [29,30,38]. However, Parry Sound's catchment area spans 9222 km^2 which is much larger than New York City's 790-km^2 urban setting [26,62]. The Parry Sound region includes 8 municipalities and townships and 4 First Nation communities housing over 42,000 residents who sometimes must travel long distances to access just primary care [26]. Therefore, understanding the unique challenges faced by rural Ontario communities will allow modifications to the program design that will be considerate of socioeconomic status, geographic and transportation barriers, preexisting patient-physician relationships, and cultural diversity.

The ability for participants to attend all programming virtually and in person was a core design to enhance program accessibility. This hybrid structure will also allow the onboarding of health care providers located throughout the province to engage in CLIP-ON more easily. Considering the vast catchment area of Parry Sound, limited transportation methods, and financial disparity within the region, it is understood that all participants may not have or have access to weekly transportation for classes. The research team will assist in identifying patient transport services to facilitate participant attendance at key program sessions wherever possible to enhance accessibility. A preexisting patient-physician relationship may result in discomfort for either participants or providers or introduce biased treatment towards some participants. Therefore, the research team will ensure that participants are matched with providers that they do not have an existing professional relationship with. Finally, special considerations will be incorporated for local Indigenous populations to be inclusive and respect their cultural requirements, including a land acknowledgment before every session and including providers with related experience and understanding of individual challenges and cultural differences.

These design elements distinctly position CLIP-ON as a whole health program designed to help all patients incorporate changes in various aspects of their lives in a setting where a lifestyle medicine program has yet to be introduced and piloted.

Strengths

CLIP-ON is the first lifestyle medicine program designed for rural communities in Ontario. This included extensive engagement with local health care providers and community members to understand their unique challenges and preferences. It incorporates specific design elements such as virtual programming, which increases program accessibility for patients facing geographic barriers so that they can attend classes, exercise sessions, and meetings with health care providers remotely. The hybrid delivery model provides flexibility, allowing patients to choose in-person or virtual participation, which is crucial for geographically isolated individuals. In addition, it enables the recruitment of remote health care providers, increasing the feasibility of building an interdisciplinary health team for the program. This flexibility offers CLIP-ON to be a sustainable, impactful, and scalable model of preventative health care.

The involvement of an interdisciplinary team of health care professionals, including physicians, dietitians, health coaches, and kinesiologists, provides a comprehensive care approach that addresses various facets of participants' health, enhancing the likelihood of sustainable health improvements. Furthermore, the program's use of the RE-AIM framework ensures that implementation is evaluated through a robust and credible scientific approach, facilitating future scalability and applicability to other regions.

Initial observations have noted that the group structure and interactions during lifestyle medicine classes and exercise sessions facilitate social connectedness within the first cohort. The program's focus on peer support and social interaction has led to increased participant accountability, as individuals share challenges and strategies within the group setting. Research shows that this peer support is often key to maintaining long-term behavior change [63]. Finally, the 2-cohort design of this study enables efficient incorporation of feedback from cohort one to enhance the program design for cohort two. The patient-centered approach, which integrates real-time feedback from participants and health care providers through focus groups and surveys, ensures continuous refinement of the program to meet participants' needs and further enhance satisfaction and engagement.

Limitations

This study has some limitations. Parry Sound's small core town population of 6879 combined with the geographic barriers associated with its vast catchment area and lack of public transit limited the initial recruitment to only 8 participants in the first cohort, as opposed to the anticipated 10-12 [25]. This small sample size may limit the statistical power of the study, making it difficult to establish significant findings that are generalizable to other rural communities. To mitigate this, we are actively exploring strategies such as broader outreach to health care providers within the catchment area and forming partnerships with community organizations to raise awareness of the program.

Initial feedback also suggests that some participants found the program duration of 6 months to be too short for achieving and maintaining meaningful lifestyle changes. Extending the program duration could allow participants more time to solidify lifestyle adjustments. In addition, longer follow-ups will support the long-term impact of lifestyle medicine on chronic disease management. To facilitate this, additional follow-up sessions and group support beyond the 6-month mark are being established to reinforce lifestyle habits. This could offer a more gradual transition toward self-management for participants.

The web-based platform, while increasing accessibility for most, may present technological barriers for older participants or those unfamiliar with using web-based platforms. This could potentially reduce engagement for certain segments of the population, especially if support for technology use is not adequately provided. To alleviate this, we have introduced a brief training session for participants on how to use the virtual platform, and technical support is now available throughout the program.

Future Directions and Dissemination Plan

We plan to conduct a follow-up assessment at 12 months and beyond to evaluate the sustainability of lifestyle changes and improvements in health outcomes among participants to provide valuable insights into the long-term impact of the CLIP-ON program. We will also explore the possibility of scaling the CLIP-ON program to other rural communities in Northern Ontario, considering adaptations based on the unique needs and cultural contexts of those populations. We will collaborate with local Indigenous communities to incorporate traditional health practices and teachings into the CLIP-ON program. This integration may enhance cultural relevance and improve health outcomes among Indigenous participants. We also plan to investigate the use of mobile health applications and web-based platforms to enhance participant engagement and accessibility such as tools for tracking progress, providing education resources, and facilitating communication with health care providers.

The results of this study will be shared locally through grand round presentations and with the hospital senior team and board members. There is a commitment from West Parry Sound Health Centre to support this study, and findings are regularly shared with senior leadership, the local education group executive, local primary care provider family health teams, and the Parry Sound Ontario Health Team. We will provide the results of the findings to each of these groups in an appropriate presentation at their request. In addition, we will share the results through publication and presentation within our Northern Ontario School of Medicine University and through presentation at the annual research conference.

Conclusion

This protocol paper will provide valuable insights into the implementation of a lifestyle medicine program, which will be evaluated for its impact on participants' health. The goal is to establish and disseminate an effective framework for secondary prevention, management, and in some cases reversal of common chronic diseases. By assessing the real-world implementation of this program, we aim to identify both successes and areas for improvement, ensuring the feasibility and sustainability of integrating lifestyle medicine into routine health care practices.

This comprehensive evaluation will not only guide future advancements in lifestyle medicine but also help establish a culturally inclusive and scalable model that can be adapted to benefit other communities, particularly those in resource-limited or rural settings.

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We confirm that no authors have potential competing interests, and all authors have equally contributed to each phase of the study, critically reviewed, and approved the manuscript.

Data Availability

The datasets generated during the study are available from the corresponding author upon reasonable request.

Authors' Contributions

MJ and CR are coprincipal investigators. All authors contributed substantially to the conception and design, data acquisition, data analysis and interpretation, drafting of the paper or critical revision for important intellectual content, and giving final approval of the submitted version. MJ, LA, and CR conceptualized the study. LA, MM, DF, NR, and JST provided administrative support. MJ, KB, MF, DF, SK, DL, CR, and EMC, participated in the development and teaching of the lifestyle medicine intervention. All authors contributed to the manuscript writing approval.

Conflicts of Interest

JST holds research grant funding from the Canadian Institute for Health Research, the Social Science and Humanities Research Council of Canada, and the Canadian Cancer Society. She was paid from the grant associated with this project to run the focus groups. All other authors declare no conflict of interest.

Multimedia Appendix 1
CLIP-ON (Complete Lifestyle medicine Intervention Program–Ontario): Phase I Program Evaluation Plan (RE-AIM Framework).
[DOCX File , 41 KB - resprot_v13i1e59179_app1.docx]

References

1. Public Health Ontario, CCO. The Burden of Chronic Diseases in Ontario. 2019. URL: https://www.publichealthontario.ca/en/Data-and-Analysis/Chronic-Disease/cdburden [accessed 2024-11-13]
2. GBD 2019 DiseasesInjuries Collaborators. Global burden of 369 diseases and injuries in 204 countries and territories, 1990-2019: a systematic analysis for the Global Burden of Disease Study 2019. Lancet 2020;396(10258):1204-1222 [FREE Full text] [doi: 10.1016/S0140-6736(20)30925-9] [Medline: 33069326]
3. World Health Organization (WHO). Non communicable diseases. URL: https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases [accessed 2024-07-02]
4. Sagner M, McNeil A, Puska P, Auffray C, Price ND, Hood L, et al. The P4 health spectrum - A predictive, preventive, personalized and participatory continuum for promoting healthspan. Prog Cardiovasc Dis 2017;59(5):506-521. [doi: 10.1016/j.pcad.2016.08.002] [Medline: 27546358]
5. Alexander S, Ostfeld RJ, Allen K, Williams KA. A plant-based diet and hypertension. J Geriatr Cardiol 2017;14(5):327-330 [FREE Full text] [doi: 10.11909/j.issn.1671-5411.2017.05.014] [Medline: 28630611]
6. Stauffer CM, McGlynn SM, Topor DR, Fiore L, Phillips EM. Evaluation of a whole health-lifestyle medicine curriculum for physician assistant students: a mixed methods analysis. Med Sci Educ 2022;32(1):57-61 [FREE Full text] [doi: 10.1007/s40670-021-01460-2] [Medline: 35186432]
7. Bodai BI, Nakata TE, Wong WT, Clark DR, Lawenda S, Tsou C, et al. Lifestyle medicine: a brief review of its dramatic impact on health and survival. Perm J 2018;22:17-025 [FREE Full text] [doi: 10.7812/TPP/17-025] [Medline: 29035175]
8. Doughty KN, Del Pilar NX, Audette A, Katz DL. Lifestyle medicine and the management of cardiovascular disease. Curr Cardiol Rep 2017;19(11):116. [doi: 10.1007/s11886-017-0925-z] [Medline: 28980137]

9. Marin-Couture E, Filion MJ, Boukari R, Jeejeebhoy K, Dhaliwal R, Brauer P, et al. Relationship between cardiometabolic factors and the response of blood pressure to a one-year primary care lifestyle intervention in metabolic syndrome patients. Metabolites 2022;12(9):861 [FREE Full text] [doi: 10.3390/metabo12090861] [Medline: 36144265]
10. Malecki HL, Gollie JM, Scholten J. Physical activity, exercise, whole health, and integrative health coaching. Phys Med Rehabil Clin N Am 2020;31(4):649-663. [doi: 10.1016/j.pmr.2020.06.001] [Medline: 32981584]
11. Government of Canada SC. Diabetes among Canadian adults. 2023. URL: https://www.statcan.gc.ca/o1/en/plus/5103-diabetes-among-canadian-adults [accessed 2024-07-02]
12. van Ommen B, Wopereis S, van Empelen P, van Keulen HM, Otten W, Kasteleyn M, et al. From diabetes care to diabetes cure-The integration of systems biology, eHealth, and behavioral change. Front Endocrinol (Lausanne) 2017;8:381 [FREE Full text] [doi: 10.3389/fendo.2017.00381] [Medline: 29403436]
13. Khan MAB, Hashim MJ, King JK, Govender RD, Mustafa H, Al Kaabi J. Epidemiology of type 2 diabetes - Global burden of disease and forecasted trends. J Epidemiol Glob Health 2020;10(1):107-111 [FREE Full text] [doi: 10.2991/jegh.k.191028.001] [Medline: 32175717]
14. Espeland MA, Glick HA, Bertoni A, Brancati FL, Bray GA, Clark JM, Look AHEAD Research Group. Impact of an intensive lifestyle intervention on use and cost of medical services among overweight and obese adults with type 2 diabetes: the action for health in diabetes. Diabetes Care 2014;37(9):2548-2556 [FREE Full text] [doi: 10.2337/dc14-0093] [Medline: 25147253]
15. Sporinova B, Manns B, Tonelli M, Hemmelgarn B, MacMaster F, Mitchell N, et al. Association of mental health disorders with health care utilization and costs among adults with chronic disease. JAMA Netw Open 2019;2(8):e199910 [FREE Full text] [doi: 10.1001/jamanetworkopen.2019.9910] [Medline: 31441939]
16. Mauriello L, Artz K. Digital lifestyle medicine: designing, delivering, and scaling for impact. Am J Lifestyle Med 2023;17(1):93-96 [FREE Full text] [doi: 10.1177/15598276211029219] [Medline: 36636393]
17. Phillips EM, Frates EP, Park DJ. Lifestyle medicine. Phys Med Rehabil Clin N Am 2020;31(4):515-526. [doi: 10.1016/j.pmr.2020.07.006] [Medline: 32981575]
18. American College of Lifestyle Medicine. Overview. URL: https://lifestylemedicine.org/overview/ [accessed 2024-01-04]
19. CDC. Health and Economic Costs of Chronic Diseases. CDC. 2023. URL: https://www.cdc.gov/chronicdisease/about/costs/index.htm [accessed 2024-01-04]
20. McDonald A. Incorporating lifestyle medicine into practice: a prescription for better health. Am Fam Physician 2022;106(3):229-230. [Medline: 36126001]
21. Klein D, Jeejeebhoy K, Tremblay A, Kallio M, Rheaume C, Humphries S, et al. The CHANGE program: exercise intervention in primary care. Can Fam Physician 2017;63(7):546-552 [FREE Full text] [Medline: 28701449]
22. Kushner RF, Sorensen KW. Lifestyle medicine: the future of chronic disease management. Curr Opin Endocrinol Diabetes Obes 2013;20(5):389-395. [doi: 10.1097/01.med.0000433056.76699.5d] [Medline: 23974765]
23. Flores M, Glusman G, Brogaard K, Price ND, Hood L. P4 medicine: how systems medicine will transform the healthcare sector and society. Per Med 2013;10(6):565-576 [FREE Full text] [doi: 10.2217/pme.13.57] [Medline: 25342952]
24. Trapp CB, Barnard ND. Usefulness of vegetarian and vegan diets for treating type 2 diabetes. Curr Diab Rep 2010;10(2):152-158. [doi: 10.1007/s11892-010-0093-7] [Medline: 20425575]
25. Government of Canada SC. Profile table, census profile, 2021 census of population. Parry Sound, Town (T) [Census subdivision]. 2022. URL: https://www12.statcan.gc.ca/census-recensement/2021/dp-pd/prof/index.cfm?Lang=E [accessed 2024-06-25]
26. Government of Canada SC. Census profile, 2016 census - parry sound, district [Census division]. Ontario and Ontario [Province]. 2017. URL: https://tinyurl.com/53a4m88m [accessed 2024-01-07]
27. Chronic Diseases - North Bay Parry Sound District Health Unit. URL: https://www.myhealthunit.ca/en/community-data-and-reports/chronic-disea.aspx [accessed 2024-01-07]
28. Redvers N, Blondin B. Traditional indigenous medicine in North America: a scoping review. PLoS One 2020;15(8):e0237531 [FREE Full text] [doi: 10.1371/journal.pone.0237531] [Medline: 32790714]
29. Albert SL, Massar RE, Kwok L, Correa L, Polito-Moller K, Joshi S, et al. Pilot plant-based lifestyle medicine program in an Urban public healthcare system: evaluating demand and implementation. Am J Lifestyle Med 2024;18(3):403-419 [FREE Full text] [doi: 10.1177/15598276221113507] [Medline: 38737881]
30. Babich JS, McMacken M, Correa L, Polito-Moller K, Chen K, Adams E, et al. Advancing lifestyle medicine in New York City's public health care system. Mayo Clin Proc Innov Qual Outcomes 2024;8(3):279-292 [FREE Full text] [doi: 10.1016/j.mayocpiqo.2024.01.005] [Medline: 38828080]
31. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Med Care 2012;50(3):217-226. [doi: 10.1097/MLR.0b013e3182408812] [Medline: 22310560]
32. Lifestyle Medicine Programs. NYC Health + Hospitals. URL: https://www.nychealthandhospitals.org/services/lifestyle-medicine-program/ [accessed 2024-06-25]

33. Marin-Couture E, Moulin JA, Thibault AS, Poirier P, Després JP, Gallant A, et al. Impact of lifestyle medicine interventions on the management of systemic hypertension in primary care: a Canadian randomized controlled trial. In: American Journal of Lifestyle Medicine. Los Angeles, Washington DC: SAGE Publications; 2024.
34. Lambrinou E, Hansen TB, Beulens JW. Lifestyle factors, self-management and patient empowerment in diabetes care. Eur J Prev Cardiol 2019;26(2_suppl):55-63. [doi: 10.1177/2047487319885455] [Medline: 31766913]
35. Wong VWH, Ho FYY, Shi NK, Sarris J, Ng CH, Tam OKY. Lifestyle medicine for anxiety symptoms: a meta-analysis of randomized controlled trials. J Affect Disord 2022;310:354-368. [doi: 10.1016/j.jad.2022.04.151] [Medline: 35523299]
36. Buxton A. NYC doctors to receive free plant-based nutrition training under $44M medicine program. Plant Based News. 2022. URL: https://plantbasednews.org/lifestyle/health/nyc-doctors-lifestyle-medicine-training/ [accessed 2023-01-24]
37. Parry sound, oN - demographics. Townfolio. URL: https://townfolio.co/on/parry-sound/demographics [accessed 2024-01-07]
38. Plant-Based Lifestyle Medicine Program. NYC Health + Hospitals. 2024. URL: https://www.nychealthandhospitals.org/services/plant-based-lifestyle-medicine- [accessed 2024-01-07]
39. Dissemination Implementation. URL: https://dissemination-implementation.org/ [accessed 2024-10-15]
40. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a 20-year review. Front Public Health 2019;7:64 [FREE Full text] [doi: 10.3389/fpubh.2019.00064] [Medline: 30984733]
41. Aim RE. Home-reach effectiveness adoption implementation maintenance. URL: https://re-aim.org/ [accessed 2024-07-21]
42. Achieving integration in mixed methods designs-principles and practices - PubMed. URL: https://pubmed-ncbi-nlm-nih-gov.proxy.lib.nosm.ca/24279835/ [accessed 2024-10-15]
43. Research Design. URL: https://collegepublishing.sagepub.com/products/research-design-6-270550 [accessed 2024-10-15]
44. Foley M. Canadian Society for Exercise Physiology (CSEP). URL: https://csep.ca/ [accessed 2024-10-15]
45. Warburton DER, Jamnik VK, Bredin SSD, McKenzie DC, Stone J, Shephard RJ, et al. Evidence-based risk assessment and recommendations for physical activity clearance: an introduction. Appl Physiol Nutr Metab 2011;36 Suppl 1:S1-S2 [FREE Full text] [doi: 10.1139/h11-060] [Medline: 21800937]
46. School of public health. Loma Linda University. URL: https://publichealth.llu.edu/ [accessed 2024-10-15]
47. 36-Item Short Form Survey (SF-36). RAND. URL: https://www.rand.org/health-care/surveys_tools/mos/36-item-short-form.html [accessed 2024-10-15]
48. The PHQ-9 - PMC. URL: https://www-ncbi-nlm-nih-gov.proxy.lib.nosm.ca/pmc/articles/PMC1495268/ [accessed 2024-10-15]
49. Shurney D, Hyde S, Hulsey K, Elam R, Cooper A, Groves J. CHIP lifestyle program at Vanderbilt University demonstrates an early ROI for a diabetic cohort in a workplace setting: a case study. Journal of Managed Care Medicine 2012;15(4):5-15.
50. Shurney D, Hyde S, Hulsey K, Elam R, Cooper A, Groves J. CHIP lifestyle program at vanderbilt university demonstrates an early ROI for a diabetic cohort in a workplace setting: a case study. Journal of Managed Care Medicine 2012;15(4):5-15.
51. Scottish Action for Mental Health. Wellbeing Assessment. SAMH. URL: https://www.samh.org.uk/about-mental-health/self-help-and-wellbeing/wellbeing-assessment-tool [accessed 2024-07-23]
52. Tennant R, Hiller L, Fishwick R, Platt S, Joseph S, Weich S, et al. The warwick-edinburgh mental well-being scale (WEMWBS): development and UK validation. Health Qual Life Outcomes 2007;5:63 [FREE Full text] [doi: 10.1186/1477-7525-5-63] [Medline: 18042300]
53. Keyes CLM. The mental health continuum: from languishing to flourishing in life. J Health Soc Behav 2002 Jun;43(2):207-222. [Medline: 12096700]
54. Ainsworth F. M. Seligman (2018). The hope circuit. A psychologist's journey from helplessness to optimism. Sydney: Penguin Random. Children Australia 2019 Apr 26;44(01):432. [doi: 10.1017/cha.2019.1]
55. Borg Rating Of Perceived Exertion. Physiopedia. URL: https://www.physio-pedia.com/Borg_Rating_Of_Perceived_Exertion [accessed 2024-10-15]
56. Jaqua E, Biddy E, Moore C, Browne G. The impact of the six pillars of lifestyle medicine on brain health. Cureus 2023;15(2):e34605 [FREE Full text] [doi: 10.7759/cureus.34605] [Medline: 36883088]
57. Walrabenstein W, Wagenaar CA, van der Leeden M, Turkstra F, Twisk JWR, Boers M, et al. A multidisciplinary lifestyle program for rheumatoid arthritis: the 'Plants for Joints' randomized controlled trial. Rheumatology (Oxford) 2023;62(8):2683-2691 [FREE Full text] [doi: 10.1093/rheumatology/keac693] [Medline: 36617162]
58. Medawar E, Huhn S, Villringer A, Veronica Witte A. The effects of plant-based diets on the body and the brain: a systematic review. Transl Psychiatry 2019;9(1):226 [FREE Full text] [doi: 10.1038/s41398-019-0552-0] [Medline: 31515473]
59. Beetham KS, Krishnasamy R, Stanton T, Sacre JW, Douglas B, Isbel NM, et al. Effect of a 3-Year lifestyle intervention in patients with chronic kidney disease: a randomized clinical trial. J Am Soc Nephrol 2022;33(2):431-441 [FREE Full text] [doi: 10.1681/ASN.2021050668] [Medline: 34893535]
60. Konieczna J, Ruiz-Canela M, Galmes-Panades AM, Abete I, Babio N, Fiol M, et al. An energy-reduced mediterranean diet, physical activity, and body composition: an interim subgroup analysis of the PREDIMED-plus randomized clinical trial. JAMA Netw Open 2023;6(10):e2337994 [FREE Full text] [doi: 10.1001/jamanetworkopen.2023.37994] [Medline: 37851444]

61. Islam NS, Zanowiak JM, Wyatt LC, Chun K, Lee L, Kwon SC, et al. A randomized-controlled, pilot intervention on diabetes prevention and healthy lifestyles in the New York City Korean community. J Community Health 2013;38(6):1030-1041. [doi: 10.1007/s10900-013-9711-z] [Medline: 23813322]
62. New York City. Britannica. 2024. URL: https://www.britannica.com/place/New-York-City [accessed 2024-07-21]
63. Latkin CA, Knowlton AR. Social network assessments and interventions for health behavior change: a critical review. Behav Med 2015;41(3):90-97 [FREE Full text] [doi: 10.1080/08964289.2015.1034645] [Medline: 26332926]

Abbreviations

CHANGE: Canadian Health Advanced Nutrition for Graded Exercise
CHIP: Complete Health Improvement Program
CLIP-ON: Complete Lifestyle medicine Intervention Program–Ontario
NCD: noncommunicable disease
P4: Preventive, Predictive, Personalized, and Participatory
PARmed-X: A Physical Activity Readiness Medical Examination
PAR-Q +: Physical Activity Readiness Questionnaire for Everyone
RE-AIM: Reach, Effectiveness, Adoption, Implementation, and Maintenance

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Protocol

Developing Guidelines for Conducting Stigma Research With Transgender and Nonbinary Individuals: Protocol for Creation of a Trauma-Informed Approach to Research

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Abstract

Background: Transgender and nonbinary individuals have received increasing attention within HIV research, with studies documenting the pervasive role stigma plays in creating and sustaining health inequities. However, the proliferation of HIV stigma research with this population has also raised concerns about research practices that may unintentionally stigmatize or retraumatize the very communities they are designed to benefit. Conducting stigma research is critical for generating accurate information about HIV epidemiology, risk and protective factors, and intervention strategies for transgender and nonbinary individuals. Yet, little research has directly examined the experiences of transgender and nonbinary individuals when participating in these studies or identified specific research practices (eg, recruitment materials or study framing, choice of specific survey measures, data collection protocols, and researcher behaviors) that may influence study participation, retention, and data quality. Equally important, research has not adequately examined the potential for unintended harm due to emotional distress experienced by participating in such research and what specific strategies might mitigate against potential distressful research experiences.

Objective: This study aimed to develop a set of empirically based trauma-informed guidelines for conducting HIV-related stigma research with transgender and nonbinary individuals to increase researchers' capacity to recruit and retain transgender and nonbinary individuals in HIV-related stigma research, enhance the quality of data collected, and reduce unintentional harm in stigma research methodology.

Methods: The study will engage in primary data collection using both qualitative and quantitative methodology. First, we will use in-depth qualitative interviews with 60 participants representing 3 participant groups: researchers, mental health clinicians, and transgender and nonbinary individuals who have participated in HIV-related and sexual health research. Second, the qualitative findings will be used to develop an initial set of survey items representing a preliminary set of guidelines. Third, we will engage 75 participants in a 3-round modified Delphi method, to refine the guidelines and promote their acceptability among key stakeholders.

Results: The study is funded by the National Institute of Mental Health starting in July 2022 and data collection began January 2023. The study's findings underscore the critical importance of adopting a trauma-informed approach to HIV stigma research with transgender and nonbinary individuals.

Conclusions: To make meaningful strides in stigma research, it is imperative to examine experiences of stigma that may happen within the research context and identify strategies for improving data quality and reducing unintentional harm in study recruitment, methodology, implementation, and dissemination.

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KEYWORDS

transgender; non-binary; HIV prevention and treatment; stigma research; trauma-informed

Introduction

Background

Over the past 2 decades, transgender individuals, particularly Black and Latina transgender women, have received increasing attention within HIV research [1-9]. Such research has consistently documented the pervasive role stigma plays in creating and sustaining health inequities among this population. However, this research proliferation has also raised questions about practices that may unintentionally stigmatize or retraumatize the very communities they are designed to benefit [4,10-15]. One area of particular concern is the measurement of stigma as part of HIV-related research with transgender and nonbinary individuals. First, there is concern that specific items within commonly used measures may unintentionally recreate or activate stigma. For example, many stigma and minority stress scales [16-19] include items that may be experienced as stigmatizing (eg, "Being transgender is disgusting to me") [19] or ask participants to recount and relive traumatic experiences (eg, history of physical and sexual violence, family rejection, and experiences of discrimination and harassment) to document their association with negative affect or health behavior [2]. There has been considerable debate within the larger field of trauma-related research as to whether recalling and answering questions about past trauma has negative or positive consequences for study participants [20-29]. However, there is surprisingly limited research within HIV science on the potential emotional impacts of participating in stigma research. Second, there are no evidence-based guidelines for person-centered, trauma-informed, and actively destigmatizing implementation of HIV stigma research. Conducting stigma research is critical for generating accurate information about HIV epidemiology, risk and protective factors, and intervention strategies for transgender and nonbinary individuals. Yet little research has directly examined the experiences of transgender and nonbinary individuals when participating in these studies, or identified specific research practices (eg, recruitment materials or study framing, choice of specific survey measures, data collection protocols, and researcher behaviors) that may influence study participation, retention, and data quality [30]. Equally important, research has not adequately examined the potential for unintended harm due to emotional distress experienced by participating in such research and what specific strategies might mitigate against potential distressful research experiences.

Impact of Stigma on HIV-Related Outcomes

Research documenting multiple and intersecting structural factors, including racism, sexism, transphobia, homophobia, and other systems of stigmatization, oppression, and traumatic victimization that contribute to the disproportionately high rates of HIV infection and HIV-related morbidity in this population [2-4,6,7,14,31-35]. One of the strengths of HIV research in this area has been its intersectional focus, [36] as well as the acknowledgement that stigma operates at individual, interpersonal, and structural levels. Intersectional approaches demonstrate the ways in which HIV-stigma and other sources of stigma occur simultaneously and interact to impact transgender and nonbinary individual's daily experience, health outcomes, and engagement with care. Research suggests that transgender and nonbinary individuals may experience this impact as traumatic, and support trauma-informed approaches that seek to mitigate retraumatization within the provision of care [37-43]. Transgender and nonbinary individuals health disparities have been directly linked to intersectional and multidimensional stigma processes [37,41,44,45], underscoring the extent to which this approach is essential for advancements in transgender and nonbinary individual–specific stigma frameworks, measurement, and intervention development.

Potential for Unintentional Harm

Within the fields of clinical psychology and neuroscience, there has been intense debate about the impact of research about traumatic experiences on study participants [20-29]. Some evidence suggests that such research might lead to traumatization or cause further harm to those with previous exposure to violence or abuse. One meta-analysis of studies about traumatic events found that approximately 25% (IQR 4.3%-50%) of adult participants reported distressing impacts (ie, unexpected upset, negative emotions, unwanted thoughts, or distress) as a result of research participation. Although, most people find that participating in trauma research is distressing, they also report that they find it worthwhile and meaningful [28]. Neuroscience research on memory reconsolidation suggests that the context and content of memory reactivation may determine its harmful or therapeutic impact. Data indicate that research participants anticipate or attribute negative impacts to study participation; in 1 large-scale study of traumatic experience, 94% of participants rated their participation as more than minimal risk, with participants that had greater previous exposure to trauma reporting higher levels of distress [46]. However, limited research within the field of HIV has directly examined the potential impact of stigma research itself on transgender and nonbinary participants.

Impact on Engagement in HIV Prevention and Care

Growing recognition of the importance of community partnership for HIV research with transgender and nonbinary individuals has led to a rise of studies that rely on community health centers or other service agencies for research recruitment and implementation [47-50]. It is well established that experiences of stigma within these settings may negatively impact transgender and nonbinary individual's willingness to receive needed health care, including HIV testing, treatment, or pre-exposure prophylaxis [37-39,51,52]. If stigmatizing or harmful research is conducted within these settings, there is the potential to reduce transgender and nonbinary individual's trust in the very organizations upon which they depend to access life-saving services. As such, it is essential to understand

whether and under what conditions HIV stigma research may result in unintentional harm or stigmatization of transgender and nonbinary individuals, and how harmful impacts can be reduced.

Impact on Recruitment, Engagement, and Data Quality

Evidence indicates that mistrust of research projects, study teams, or settings leads to difficulties with recruitment and retention of study participants and may be associated with false or misleading responses to study measures. Studies indicate that research mistrust is particularly strong among transgender and nonbinary participants, who may report feeling used or mistreated within HIV research contexts [53-55]. In 1 study, transgender women reported that research scripts and procedures can be experienced as microaggressions [55]. Critical HIV-related stigma research is likely to underperform and fail to provide much needed data on stigma processes if participants are discouraged from participating or alienated from the research enterprise by perceptions that stigma research is itself stigmatizing [56].

Need for Empirically Grounded Research Guidelines

Many HIV stigma studies report incorporating intentionally affirming components into their research practice, such as measures of self-esteem, community-connectedness, or other resilience factors [57,58]. However, there has been no systematic compilation of these strategies, or analysis of their potential use in reducing stigma experiences. This research gap results in a lack of consensus of what is meant by trauma-informed HIV stigma research, as well as gaps in how to best implement and evaluate stigma-reducing measures in HIV research practice. Outside of HIV research, there are models for patient-centered, trauma-informed health research [59] that could be adapted to better inform implementation strategies, but such adaptation needs to be grounded in empirical data from participants, researchers, and practitioners with direct experience in the field.

Theoretical Frameworks

This study is based on an interdisciplinary integration of minority-stress and trauma-informed theoretical frameworks to explain health inequity. Minority stress theory [60] is a strong epidemiological framework for explaining disparity but is less precise in specifying mechanisms of an individual stigmatized person's behavior, feelings, or experience. To complement this theory, we incorporate a conceptual framework developed specifically to support the mental health of TGNB individuals [61], which combines 2 trauma-informed care models to guide our research questions and analysis. The first, developed by Fallot & Harris [62,63], emphasizes five principles of interaction: safety, trustworthiness, collaboration, choice, and empowerment. The second, guiding principles of trauma-informed care created by the Substance Abuse and Mental Health Services Administration within the US Department of Health and Human Services, focuses on attention to cultural, historical, and gender issues that impact power relationships, privilege, and oppression [64]. This trauma-informed theoretical approach attends to the potential presence of trauma-related symptoms on the thoughts, feelings, needs, and reactions of TGNB research participants, and aims to actively disrupt retraumatization through the creation of interpersonal processes and settings that emphasize safety, trust, collaboration, empowerment, and choice. Rather than focusing on isolating and describing stigmatizing internal and external experiences that happen to a marginalized person, a trauma-informed approach to stigma research centers how those marginalizing experiences thwart a survivor's wellness, healing, and resilience [65]. Trauma-informed approaches are, therefore, inherently person-centered, and strengths-based in that they entail recognition of the signs and symptoms of trauma in an individual's behavior and guide clinical responses to minimize negative impact on the survivor's natural recovery process [64]. These characteristics are likely to support greater engagement, quality, and benefit of HIV research among transgender and nonbinary individuals [55].

Study Aims

The primary aim of this study is to develop empirically informed, trauma-informed guidelines for conducting HIV-related stigma research with transgender and nonbinary individuals. This work seeks to address critical gaps in the field by improving recruitment, retention, and data quality while reducing the potential for harm during research participation. Specifically, the study focuses on the following aims. First, this study aims at understanding participant experiences by conducting in-depth interviews with transgender and nonbinary participants who have engaged in HIV or sexual health-related research to explore their experiences, including factors that contribute to or mitigate distress, stigma, and harm. This aim seeks to uncover the nuanced challenges and opportunities for designing research that supports participant well-being. Second, this study aims to gather stakeholder perspectives by conducting in-depth interviews with researchers and mental health clinicians to identify current practices, challenges, and strategies for implementing trauma-informed and person-centered approaches in HIV stigma research. This aim emphasizes understanding the perspectives of professionals who interact with transgender and nonbinary populations in research and clinical settings. Third, this study aims to develop and refine trauma-informed guidelines by using findings from the first and second aims to create a preliminary set of trauma-informed research guidelines. These guidelines will be refined through a modified Delphi process involving transgender and nonbinary individuals, researchers, and mental health professionals to ensure their relevance, acceptability, and applicability across diverse research contexts.

By integrating qualitative interviews with a structured consensus-building approach, this study aims to establish actionable and evidence-based recommendations. These guidelines will enhance the ethical rigor and methodological quality of HIV stigma research, contributing to improved health equity and reducing unintentional harm in research practices.

Methods

Study Objectives

Our study is designed to address a critical gap in existing HIV stigma research with transgender and nonbinary individuals by examining experiences of stigma within the research context

and identifying strategies for improving data quality and reducing unintentional harm in study recruitment, methodology, implementation, and dissemination. This study will engage in primary data collection using both qualitative and quantitative data collection methodology. To accomplish the study aims we will first, conduct in-depth interviews with transgender and nonbinary individuals (n=30) to better understand how they understand and experience participation in HIV-related stigma research, including willingness to respond to questions about stigma and factors that may contribute to or mitigate potential distressing or stigmatizing experiences within the research context. Second we will conduct in-depth interviews with 2 groups: investigators who conduct HIV-related stigma research with transgender and nonbinary individuals, to better understand perceptions of and experiences with conducting stigma research with transgender and nonbinary individuals and compile existing strategies for mitigating harm (n=15) and mental health professionals (n=15) who provide care to transgender and nonbinary individuals to better understand ways in which experiences of stigma can be measured and studies can be conducted in a manner that is person-centered, trauma-informed, and actively destigmatizing. Third, we will develop a set of empirically informed guidelines for conducting HIV stigma research with transgender and nonbinary individuals. We will use a modified Delphi technique to engage a panel of transgender and nonbinary individuals, mental health providers, and researchers in a consensus building process to identify practical recommendations for person-centered, trauma-informed recruitment, measurement, and conduct of HIV-related stigma research with transgender and nonbinary individuals.

The sample sizes for this study were designed to ensure robust data collection and meaningful analysis across all phases. For aims 1 and 2, the sample size was chosen based on recommendations for similar qualitative inquires to ensure thematic saturation and demographic diversity [66-69]. In aim 3 the Delphi panel will consist of 75 participants (25 transgender and nonbinary individuals, 25 researchers, and 25 clinicians), aligning with best practices for achieving reliable consensus and providing robustness against attrition [68,70,71]. These sample sizes ensured methodological rigor, demographic representativeness, and the capacity to develop empirically informed, trauma-informed research guidelines.

Qualitative Interviews

Aim 1: Semistructured Qualitative Interviews With Transgender and Nonbinary Individuals

Overview

In aim 1, we will conduct a series of in-depth semistructured qualitative interviews with 30 transgender and nonbinary individuals.

Participants

Our sample will be stratified by gender identity and HIV status. We will ensure that >40% of participants will be aged 18-29 years and at least 70% people of color, due to the disproportionately high HIV infection rates among these populations and lack of access to HIV prevention and treatment services. Eligible participants will be aged >18 years; identify as transgender, nonbinary, or gender diverse; and have participated in an HIV prevention or treatment related research study.

Recruitment

Participants will be recruited through existing research panels, transgender health-related social media and listservs, and word of mouth. Interested participants will fill out an eligibility screener survey. For those who are deemed eligible, they will be provided a link to the study website [72] to schedule their interview at a day and time of their choice, with the study team member of their choice. Participants will be provided with a link to an electronic consent form on the study website, as well as the interview guide before the interview. The interviewer will review the consent form with the participant and obtain verbal consent before conducting the interview.

Interview Procedures

Interviews will be designed to last no longer than an hour and a half, and participants will be compensated US $80 for their time. All interviews will contain a core set of questions to assess how transgender and nonbinary individuals understand and experience participation in HIV-related stigma research, including decision-making processes around participation, perceptions of study purpose, risks and benefits, participants' willingness to respond to questions on stigma, factors that may contribute to or mitigate potential distressful or stigmatizing experiences within the research context, and opinions of the research after participation. Participants will also be asked to identify specific strategies to enhance researcher's capacity to design and implement stigma research that is person-centered, trauma-informed, and actively destigmatizing.

Aim 2: Semistructured Qualitative Interviews With Researchers and Mental Health Professionals

Overview

In aim 2, we will conduct a series of in-depth semistructured qualitative interviews with 2 groups, investigators who conduct HIV-related stigma research with transgender and nonbinary individuals (n=15) and mental health providers who provide care to transgender and nonbinary adults (n=15).

Participants

Investigators (n=15) will be stratified by career stage: early (n=5), middle (n=5), or late (n=5) stage investigators to represent a range of perspectives and experiences with conducting stigma research with transgender and nonbinary individuals. Our sample of mental health professionals (n=15) will include mental health clinicians with a master's degree in either social work, marriage and family therapy, or mental health counseling or a doctoral degree in clinical psychology (PhD or PsyD) who provide individual or group therapy to transgender and nonbinary adults (aged 18 years or older) and have training in providing trauma-specific or trauma-informed clinical practice.

Recruitment

Early, middle, or late-stage investigators with existing HIV-related transgender health research will be identified by Google Scholar and the National Institutes of Health (NIH) RePORTER. Investigators will be contacted by a study team

member by email and invited to participate in our study. Mental health professionals will be recruited through professional networks and word of mouth. Interested participants will fill out an eligibility screener survey. For those who are deemed eligible, they will be contacted by a study team member to schedule their interview. Participants will be provided with a copy of the study consent form. The interviewer will review the consent form with the participant and obtain verbal consent before conducting the interview.

Interview Procedures

Aim 2 will consist of 30 semistructured interviews with 2 groups, investigators who conduct HIV-related stigma research with transgender and nonbinary and mental health clinicians who provide counseling to transgender and nonbinary adults (aged 18 years or older). Interviews are designed to last no more than an hour and a half, and participants will be compensated US $50 for their time. *Interviews with investigators* will assess understanding experiences of conducting HIV-related stigma research with transgender and nonbinary individuals, including perceptions of study purpose, risks and benefits, question and measurement selection and creation, and factors that may have contributed to or mitigated against distressful or stigmatizing experiences within the research context. *Interviews with mental health professionals* will focus on identifying ways in which experiences of stigma can be measured in a manner that is person-centered, trauma-informed, and actively destigmatizing, including suggestions for using person-centered, trauma-informed language when developing questions or measures, and strategies to assist researchers around developing protocols and procedures to assess for and address potential distressful situations within the research context.

Development of Interview Guide (Aims 1 and 2)

The interview guide was developed through a collaborative, trauma-informed approach to ensure that all protocols and procedures reflected the study's goals and minimized potential harm to participants. This process involved a 3-step methodology with the transgender-identified research team. First, the team conducted an in-depth review of existing trauma-informed care models and adopted the framework developed by The Institute on Trauma and Trauma-Informed Care (ITTC) at the University of Buffalo, which emphasizes the principles of safety, choice, empowerment, collaboration, and trustworthiness. Second, components from ITTC's Trauma-Informed Organizational Change Manual [73] were adapted and integrated into the research procedures, including participant recruitment, consent, interview data collection, and analysis, to align all research activities with a trauma-informed approach. Third, the interview questions, prompts, and scripts were mapped to the ITTC framework to minimize risks of retraumatization and ensure a supportive environment for participants. Interview questions were refined to align with the study's 4 overarching research questions and tailored to the perspectives of the 3 participant groups, researchers, community stakeholders, and mental health clinicians, ensuring comparability and analytic integrity across the study phases (Multimedia Appendix 1).

Qualitative Analysis Plan (Aims 1 and 2)

Data collected in aims 1 and 2 will be analyzed using rapid qualitative analytic methods, [74-77] to identify key themes that best reflect the research decision-making process, perceptions and experiences of transgender and nonbinary individuals. We will assign four trained team members to summarize a subset of the interview transcripts independently, extracting key data into a summary template based on our framework and interview guide; triangulate key themes in the transcript through documenting observations, quotations, and reflections into the summary template; meet to compare and combine templates for each interview; and create a comprehensive matrix identifying common themes and contrasts across and within stakeholder groups.

Application of Knowledge Gained in Aims 1 and 2 to Aim 3

In preparation for aim 3, we will use the themes that were identified in the qualitative interviews to develop a preliminary list of survey items for use in the first stage of the modified Delphi process (aim 3) [78]. The use of qualitative interviews in a pre-Delphi phase [78-80] allows for all relevant stakeholder groups to guide the Delphi process by contributing to the development of the first round Delphi survey. To ensure that the Delphi survey items describe and capture the perceptions and experiences of all the stakeholder groups participating in aim 3, we will develop items using the language and narratives participants use during their interviews [78,80,81]. For example, the language used to describe and the meaning behind core concepts within stigma research may differ distinctly between stakeholder groups and could contribute to inaccurate measurement and interpretation of research findings. By integrating language from each stakeholder group into the Delphi survey we hope to better reflect the experiences of all relevant stakeholders involved in this process [79,82,83]. We will then compare the themes and associations derived from Aims 1 and 2 to better understand areas of concordance and discordance between stakeholder groups [78-81,84]. For example, it is possible that interview findings highlight similar domains across participant groups that are key to understanding and improving stigma research procedures, yet what is important to address within these domains may differ by stakeholder group. The use of qualitative interview findings will help further parse out and include survey items that address this complexity.

Aim 3: Development of Empirically Informed Guidelines for Conducting Stigma Research With Transgender and Nonbinary Individuals

Overview

To accomplish aim 3 we will use a 3-round modified Delphi method [85] to develop a set of empirically informed guidelines for conducting HIV-related stigma research with transgender and nonbinary individuals. The modified Delphi method will include 4 structured steps: panel formation, quantitative survey development, data collection and analysis, and guideline development [68,69,85,86].

Panel Formation

We will recruit 75 participants from the following 3 stakeholder groups, transgender and nonbinary individuals (n=25), researchers (n=25), and mental health professionals (n=25). Our sample size is based on previous studies which demonstrate that this sample size provides stable results robust to participant attrition or inconsistent responding [68,70,71]. Individuals who participated in aims 1 and 2 will be recruited to participate in aim 3.

Survey Development

Survey development will occur in 3 steps. First, the transcripts and codes from aims 1 and 2 will be reviewed to draft the initial survey items based on the most salient themes and domains pertinent to all aspects of the research process, including recruitment, measurement, retention, and dissemination. Each survey item will be designed to capture a single idea and be easily understood by participants. Second, we will develop a rating scale for the Delphi survey items that best capture the original content from aims 1 and 2. Third, we will finalize the items and organize the survey into the following 3 sections, Trauma-Informed Principles for Research Practice, Trauma-Informed Research Standards, and Trauma-Informed Research Competencies.

Quantitative Data Collection and Analysis

A survey will be administered online by REDCap (Research Electronic Data Capture) [87,88] at 3 time points (rounds 1-3). Participants will be compensated US $40 for their time after the completion of each survey. In each round, participants will be asked to rate each item on a 5-point scale indicating whether the item should be included in the research guidelines. Survey items will be categorized according to the decision matrix in Textbox 1, which has been widely used in previous studies [85,86]. In round 1, all items created by our study team will be included in the survey. At the end of each survey section in round 1, participants will be encouraged to provide feedback on items (ie, how to improve wording or messaging) and suggest novel items to include [68,85,86]. After round 1, we will analyze survey responses, including participant comments, and edit existing or draft new items to be included in the round 2 survey based on participant suggestions. In the second-round survey, participants will rerate items that receive a near miss in the first round and rate new items the research team crafted based on suggestions from participants in round 1. At the end of rounds 1 and 2, participants will be sent a report outlining survey results. Statements to be rerated will be displayed with the overall percentages for each rating and then by stakeholder group so participants can compare their response with others' responses. The report will allow participants to consider whether to retain or change their ratings in the next round. Finally, in round 3, only items rated for the first time in round 2 or received a near miss rating will be included in the final survey (Textbox 1).

Textbox 1. Decision matrix for developing expert consensus.

Endorsed

- If between 80%-100% of participants of each group rate a statement as either essential or important, it will be endorsed as a guideline.

Re-rated (near miss)

- If between 80%-100% of participants of each group rate a statement as either essential or important, it will be endorsed as a guideline.

Rejected

- If none of the above conditions are met, a statement will be rejected for inclusion as a guideline.

Guideline Development

At the end of round 3, the research team will create a document comprised of the endorsed items to be widely disseminated. Once the document is completed, participants will be invited to attend a 1-day virtual convening where we will present and discuss the final guidelines document as well as the goals and next steps for dissemination and implementation.

Ethical Considerations

Ethics Approval

The study received expedited approval from the City University of New York Human Research Protection Program (#2022-0280-Hunter).

Informed Consent

Participants were electronically sent a consent form and interview guide in advance to review at their own pace once their interview was scheduled. Before the start of each interview a trained study team member reviewed the consent form with participants and obtained verbal consent to participate. Before completing the Delphi survey participants affirmed that the agreed to participate.

Privacy and Confidentiality

All data were anonymized to protect participant identities.

Compensation

Participants were compensated US $40- US $80, depending on the study phase, to ensure fairness.

Results

The study was funded by the National Institute of Mental Health from July 1, 2022, to June 30, 2024. The study successfully achieved its specific aims. We successfully completed data collection and analysis for aims 1 and 2 recruiting 30

transgender and nonbinary participants (aim 1) and a total of 34 participants in aim 2 (17 researchers and 17 clinicians). As outlined above, we directly applied the knowledge gained to the development of the preliminary set of guidelines voted on in aim 3. The Delphi process for aim 3 is entering its final survey round, and we are actively preparing the finalized guidelines for dissemination (Table 1).

Table 1. Study timeline and progress by aims.

Phase	Planned timeline	Current progress
Aim 1: interviews	January 2023-June 2023	Completed (30 participants)
Aim 2: interviews	July 2023-December 2023	Completed (34 participants)
Application of knowledge gained from aims 1 and 2	January 2024-March 2024	Completed
Aim 3: Delphi survey	March 2024-June 2024	Ongoing (final survey round)

Discussion

Principal Findings

This study addresses a critical gap in HIV-related stigma research by developing trauma-informed guidelines to improve the quality of research involving transgender and nonbinary individuals. HIV stigma research has historically documented the pervasive role of stigma in shaping health inequities but has largely overlooked the unintended harms participants may experience within the research process itself. By using an interdisciplinary, trauma-informed approach grounded in qualitative data collection and a modified Delphi method, this study emphasizes principles of safety, trustworthiness, collaboration, empowerment, and cultural sensitivity. The findings aim to enhance participant engagement, reduce emotional distress, and improve data quality, thereby advancing ethical and effective research practices. Through active collaboration with community members, researchers, and clinicians, this project provides a model for addressing stigma while centering participant well-being and resilience.

The study's findings underscore the critical importance of adopting a trauma-informed approach to HIV stigma research with transgender and nonbinary individuals. Interviews with community members, researchers, and clinicians revealed the significant benefits of trauma-informed principles for enhancing participant trust, retention, and engagement while also improving the quality of collected data. Key findings include the following.

Higher Data Quality and Participant Engagement

Stakeholders across all groups emphasized that trauma-informed practices create safer and more supportive environments for participants, leading to more honest and comprehensive data. For instance, researchers noted that flexible interview formats and clear communication protocols increased participant willingness to share sensitive information.

Improved Team Dynamics and Research Outcomes

Researchers and clinicians reported that adopting trauma-informed principles, such as trustworthiness and collaboration, not only benefits participants but also enhances team cohesion and efficiency in implementing study protocols.

Ethical and Methodological Standards

The findings contributed to the development of trauma-informed research standards, including guidelines for ethical recruitment, harm minimization, and culturally sensitive data collection protocols. These standards prioritize participant autonomy and recognize the compounded effects of intersecting identities, such as race, gender, and sexual orientation.

Institutional Support Needs

Participants consistently highlighted the necessity of institutional support for implementing trauma-informed practices. Recommendations include increased funding, researcher training, and revisions to institutional review board protocols to ensure systemic integration of these practices into research frameworks.

Guidelines for Trauma-Informed Research

Preliminary guidelines developed through this study emphasize the integration of trauma-informed principles into every aspect of the research process. These include ensuring safety and dignity, using affirming language, and providing participants with opportunities for feedback and choice throughout their involvement in studies.

The findings collectively highlight the transformative potential of trauma-informed approaches for improving HIV stigma research practices. By addressing participant needs and mitigating harm, these practices ensure ethical rigor and enhance the impact of research on health equity for transgender and nonbinary populations.

Comparison to Previous Work

Previous research on HIV stigma has predominantly focused on documenting stigma and its health impacts without critically examining research practices themselves. Our study extends the NIH's Stigma and Discrimination Toolkit [89] by addressing the need for guidelines to reduce stigma within the research context. This complements existing frameworks and fills a critical gap. By focusing on the process rather than outcomes alone, this research provides a novel contribution to the field.

Strengths and Limitations

The study's strengths include a diverse, multidisciplinary research team with significant community representation, innovative use of the Delphi method, and the integration of trauma-informed principles. Limitations include the absence of a bioethicist on the team and potential challenges in generalizing findings to other populations beyond transgender and nonbinary individuals. Future research could explore the applicability of these guidelines in other contexts and populations.

Future Directions

Key next steps include developing researcher training modules and advocating for institutional review board and institutional policies that mandate trauma-informed practices. These guidelines could extend to other areas of health inequities research.

Dissemination Plan

This study prioritizes transparency and community engagement in disseminating findings. The dissemination plan aligns with trauma-informed principles by emphasizing accessibility, mutuality, and collaboration with the community and stakeholders.

Community-Focused Dissemination

A dedicated study website was created to provide participants and stakeholders with clear and accessible information about the study aims, process, and team. This platform has been instrumental in sharing updates, progress, and findings during the study period.

Two newsletters were distributed to participants and posted on the website to update stakeholders about study progress and preliminary findings. These newsletters ensured continuous engagement with the community and maintained trust.

Final study findings will be summarized in community-friendly formats, such as infographics and plain-language reports, and shared through newsletters and the website. This ensures that findings are accessible to diverse audiences, including those with varying levels of education and technical expertise.

Academic and Professional Dissemination

Findings have been shared at national and international conferences, ensuring visibility within academic and professional circles. Future presentations will focus on engaging institutional review boards, research institutions, and policy makers.

The trauma-informed research guidelines will be published in academic journals and policy briefs, targeting audiences involved in HIV research, social work, and public health.

Workshops and webinars will be conducted for researchers and community health organizations to facilitate the implementation of the guidelines. These sessions will provide practical strategies for adopting trauma-informed practices.

Collaborative Dissemination

The final guidelines will be shared during virtual or in-person gatherings with study participants and community members. These sessions will include opportunities for participants to provide feedback and discuss the next steps for implementation.

Findings will be disseminated through partnerships with community-based organizations and health centers. This approach ensures that the guidelines reach the people and institutions directly involved in HIV stigma research and care.

Sustainability and Long-Term Impact

Recommendations for integrating trauma-informed practices into institutional review board review processes, funding applications, and researcher training will be disseminated to key institutions. This will include targeted briefings and resource-sharing with institutional review boards and funders to encourage systemic change.

Training materials, including video tutorials and toolkits, will be developed to help researchers and institutions adopt the guidelines. These materials will be shared through academic and community networks. By using these dissemination strategies, this study aims to ensure that its findings are accessible, actionable, and impactful across diverse audiences, including researchers, policy makers, and the communities at the center of the research.

Conclusion

To make meaningful strides in stigma research, it is imperative to examine experiences of stigma within the research context and identify strategies to improve data quality while reducing unintentional harm in study recruitment, methodology, implementation, and dissemination. This study addresses these critical needs by developing empirically informed trauma-informed guidelines for conducting HIV-related stigma research with transgender and nonbinary individuals.

Grounded in interdisciplinary theoretical frameworks and extensive collaboration with transgender and nonbinary participants, researchers, and clinicians, this study highlights the transformative potential of trauma-informed approaches. These guidelines emphasize the principles of safety, trustworthiness, collaboration, empowerment, and cultural sensitivity, demonstrating their capacity to enhance participant engagement, foster trust, and mitigate risks of retraumatization. Findings further underscore the importance of systemic institutional support, including training programs, funding mechanisms, and policy revisions at the institutional level, to ensure the widespread adoption of these practices.

The study achieved its goals by developing and refining these guidelines through rigorous qualitative analyses and a modified Delphi process. By embedding trauma-informed principles into research methodologies, this work sets a new standard for ethical and effective research practices. These guidelines have the potential to increase researchers' capacity to recruit and retain transgender and nonbinary participants in stigma research, improve the quality of collected data, and reduce the unintended harms of research participation.

Next steps include broad dissemination of the guidelines through community-friendly formats, workshops, and academic publications. These efforts will ensure that the findings are accessible to a diverse range of stakeholders, including researchers, clinicians, policy makers, and community organizations. By reshaping HIV stigma research methodologies, this work contributes to advancing health equity and ethical research practices, with implications for other high-priority populations and fields of health disparity research.

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Data Availability

The datasets generated during and analyzed during this study are not publicly available to protect the identity of the participants, as some of the details mentioned in the qualitative interviews include information that could help identify the individual. Data are available from the corresponding author on reasonable request.

Authors' Contributions

AK contributed to conceptualization, methodology, writing original draft, writing review and editing, supervision, and funding acquisition. SAG managed methodology, writing review and editing, supervision, and funding acquisition. DB handled methodology and writing review and editing. ERC contributed to writing review and editing, project administration.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide for Aims 1 and 2 by participant group.
[DOCX File , 480 KB - resprot_v14i1e66800_app1.docx]

Multimedia Appendix 2
Peer-reviewer report from HIV/AIDS Intra- and Inter-personal Determinants and Behavioral Interventions Study Section, Risk, Prevention and Health Behavior Integrated Review Group (HIBI) (National Institutes of Health, USA).
[PDF File (Adobe PDF File), 143 KB - resprot_v14i1e66800_app2.pdf]

References

1. Baral SD, Poteat T, Strömdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. Lancet Infect Dis 2013;13(3):214-222. [doi: 10.1016/S1473-3099(12)70315-8] [Medline: 23260128]
2. Becasen JS, Denard CL, Mullins MM, Higa DH, Sipe TA. Estimating the prevalence of HIV and sexual behaviors among the US transgender population: a systematic Review and Meta-Analysis, 2006-2017. Am J Public Health 2019;109(1):e1-e8 [FREE Full text] [doi: 10.2105/AJPH.2018.304727] [Medline: 30496000]
3. Clark H, Babu AS, Wiewel EW, Opoku J, Crepaz N. Diagnosed HIV infection in transgender adults and adolescents: results from the national HIV surveillance system, 2009-2014. AIDS Behav 2017;21(9):2774-2783 [FREE Full text] [doi: 10.1007/s10461-016-1656-7] [Medline: 28035497]
4. Del Río-González AM, Lameiras-Fernández M, Modrakovic D, Aguayo-Romero R, Glickman C, Bowleg L, et al. Global scoping review of HIV prevention research with transgender people: transcending from trans-subsumed to trans-centred research. J Int AIDS Soc 2021;24(9):e25786 [FREE Full text] [doi: 10.1002/jia2.25786] [Medline: 34473421]
5. Herbst JH, Jacobs ED, Finlayson TJ, McKleroy VS, Neumann MS, Crepaz N, HIV/AIDS Prevention Research Synthesis Team. Estimating HIV prevalence and risk behaviors of transgender persons in the United States: a systematic review. AIDS Behav 2008;12(1):1-17. [doi: 10.1007/s10461-007-9299-3] [Medline: 17694429]
6. Poteat T, Reisner SL, Radix A. HIV epidemics among transgender women. Current Opinion in HIV and AIDS 2014;9(2):168-173. [doi: 10.1097/coh.0000000000000030]
7. Reisner SL, Murchison GR. A global research synthesis of HIV and STI biobehavioural risks in female-to-male transgender adults. Glob Public Health 2016;11(7-8):866-887 [FREE Full text] [doi: 10.1080/17441692.2015.1134613] [Medline: 26785800]
8. Stephenson R, Riley E, Rogers E, Suarez N, Metheny N, Senda J, et al. The sexual health of transgender men: a scoping review. J Sex Res 2017;54(4-5):424-445. [doi: 10.1080/00224499.2016.1271863] [Medline: 28140660]
9. Wirtz AL, Poteat T, Borquez A, Linton S, Stevenson M, Case J, ENCORE Study Group. Enhanced cohort methods for HIV research and epidemiology (ENCORE): protocol for a nationwide hybrid cohort for transgender women in the United States. JMIR Res Protoc 2024;13:e59846 [FREE Full text] [doi: 10.2196/59846] [Medline: 39190916]
10. Perez-Brumer AG, Oldenburg CE, Reisner SL, Clark JL, Parker RG. Towards 'reflexive epidemiology': conflation of cisgender male and transgender women sex workers and implications for global understandings of HIV prevalence. Glob Public Health 2016;11(7-8):849-865 [FREE Full text] [doi: 10.1080/17441692.2016.1181193] [Medline: 27173599]

11. Poteat T, Wirtz AL, Radix A, Borquez A, Silva-Santisteban A, Deutsch MB, et al. HIV risk and preventive interventions in transgender women sex workers. Lancet 2015;385(9964):274-286 [FREE Full text] [doi: 10.1016/S0140-6736(14)60833-3] [Medline: 25059941]
12. Radix AE, Harris AB, Goldstein ZG. How can we improve uptake of oral HIV pre-exposure prophylaxis for transgender individuals? Expert Rev Anti Infect Ther 2020;18(9):835-838. [doi: 10.1080/14787210.2020.1759418] [Medline: 32316773]
13. Scheim AI, Appenroth MN, Beckham SW, Goldstein Z, Grinspan MC, Keatley JAG, et al. Transgender HIV research: nothing about us without us. The Lancet HIV 2019;6(9):e566-e567. [doi: 10.1016/s2352-3018(19)30269-3]
14. Sevelius JM, Reznick OG, Hart SL, Schwarcz S. Informing interventions: the importance of contextual factors in the prediction of sexual risk behaviors among transgender women. AIDS Educ Prev 2009;21(2):113-1127 [FREE Full text] [doi: 10.1521/aeap.2009.21.2.113] [Medline: 19397434]
15. Scheim AI, Bauer GR, Bastos JL, Poteat T. Advancing intersectional discrimination measures for health disparities research: protocol for a bilingual mixed methods measurement study. JMIR Res Protoc 2021;10(8):e30987 [FREE Full text] [doi: 10.2196/30987] [Medline: 34459747]
16. Austin A, Goodman R. The impact of social connectedness and internalized transphobic stigma on self-esteem among transgender and gender non-conforming adults. J Homosex 2017;64(6):825-841. [doi: 10.1080/00918369.2016.1236587] [Medline: 27633046]
17. Bockting WO, Miner MH, Romine RES, Dolezal C, Robinson BBE, Rosser BSS, et al. The transgender identity survey: a measure of internalized transphobia. LGBT Health 2020;7(1):15-27 [FREE Full text] [doi: 10.1089/lgbt.2018.0265] [Medline: 31880493]
18. Reisner SL, Moore CS, Asquith A, Pardee DJ, Mayer KH. Gender non-affirmation from cisgender male partners: development and validation of a brief stigma scale for HIV research with transgender men who have sex with men (Trans MSM). AIDS Behav 2020;24(1):331-343. [doi: 10.1007/s10461-019-02749-5] [Medline: 31865515]
19. Rendina HJ, Cain DN, López-Matos J, Ray M, Gurung S, Parsons JT. Measuring experiences of minority stress for transgender women: adaptation and evaluation of internalized and anticipated transgender stigma scales. Transgend Health 2020;5(1):42-49 [FREE Full text] [doi: 10.1089/trgh.2019.0059] [Medline: 32322687]
20. Campbell R, Adams AE, Wasco SM, Ahrens CE, Sefl T. "What has it been like for you to talk with me today?": the impact of participating in interview research on rape survivors. Violence Against Women 2010;16(1):60-83. [doi: 10.1177/1077801209353576] [Medline: 19949229]
21. Draucker CB. The emotional impact of sexual violence research on participants. Arch Psychiatr Nurs 1999;13(4):161-169. [doi: 10.1016/s0883-9417(99)80002-8] [Medline: 10478494]
22. Griffin MG, Resick PA, Waldrop AE, Mechanic MB. Participation in trauma research: Is there evidence of harm? Journal of Traumatic Stress 2005;16(3):221-227. [doi: 10.1023/a:1023735821900]
23. Jaffe AE, DiLillo D, Hoffman L, Haikalis M, Dykstra RE. Does it hurt to ask? A meta-analysis of participant reactions to trauma research. Clin Psychol Rev 2015;40:40-56. [doi: 10.1016/j.cpr.2015.05.004] [Medline: 26051308]
24. Jorm AF, Kelly CM, Morgan AJ. Participant distress in psychiatric research: a systematic review. Psychol. Med 2007;37(7):917-926. [doi: 10.1017/s0033291706009779]
25. Labott SM, Johnson TP, Fendrich M, Feeny NC. Emotional risks to respondents in survey research. J Empir Res Hum Res Ethics 2013;8(4):53-66 [FREE Full text] [doi: 10.1525/jer.2013.8.4.53] [Medline: 24169422]
26. Legerski JP, Bunnell SL. The risks, benefits, and ethics of trauma-focused research participation. Ethics & Behavior 2010;20(6):429-442. [doi: 10.1080/10508422.2010.521443]
27. McClinton Appollis T, Lund C, de Vries PJ, Mathews C. Adolescents' and adults' experiences of being surveyed about violence and abuse: a systematic review of harms, benefits, and regrets. Am J Public Health 2015;105(2):e31-e45. [doi: 10.2105/AJPH.2014.302293] [Medline: 25521894]
28. Newman E, Risch E, Kassam-Adams N. Ethical issues in trauma-related research: a review. J Empir Res Hum Res Ethics 2006;1(3):29-46. [doi: 10.1525/jer.2006.1.3.29] [Medline: 19385821]
29. Peter E, Friedland J. Recognizing risk and vulnerability in research ethics: imagining the "What Ifs?". J Empir Res Hum Res Ethics 2017;12(2):107-116. [doi: 10.1177/1556264617696920] [Medline: 28421885]
30. Alessi EJ, Kahn S. Toward a trauma-informed qualitative research approach: guidelines for ensuring the safety and promoting the resilience of research participants. Qualitative Research in Psychology 2022;20(1):121-154. [doi: 10.1080/14780887.2022.2107967]
31. Brennan J, Kuhns LM, Johnson AK, Belzer M, Wilson EC, Garofalo R, Adolescent Medicine Trials Network for HIV/AIDS Interventions. Syndemic theory and HIV-related risk among young transgender women: the role of multiple, co-occurring health problems and social marginalization. Am J Public Health 2012;102(9):1751-1757 [FREE Full text] [doi: 10.2105/AJPH.2011.300433] [Medline: 22873480]
32. Lemons A, Beer L, Finlayson T, McCree DH, Lentine D, Shouse RL, Medical Monitoring Project. Characteristics of HIV-positive transgender men receiving medical care: United States, 2009-2014. Am J Public Health 2018;108(1):128-130 [FREE Full text] [doi: 10.2105/AJPH.2017.304153] [Medline: 29161069]
33. Neumann MS, Finlayson TJ, Pitts NL, Keatley JA. Comprehensive HIV prevention for transgender persons. Am J Public Health 2017;107(2):207-212. [doi: 10.2105/ajph.2016.303509]

34. Operario D, Nemoto T. HIV in transgender communities: syndemic dynamics and a need for multicomponent interventions. J Acquir Immune Defic Syndr 2010;55 Suppl 2(Suppl 2):S91-S93 [FREE Full text] [doi: 10.1097/QAI.0b013e3181fbc9ec] [Medline: 21406995]
35. Poteat T, Malik M, Scheim A, Elliott A. HIV prevention among transgender populations: knowledge gaps and evidence for action. Curr HIV/AIDS Rep 2017;14(4):141-152 [FREE Full text] [doi: 10.1007/s11904-017-0360-1] [Medline: 28752285]
36. Stockman JK, Anderson KM, DeSoto AF, Campbell DM, Tsuyuki K, Horvath KJ. A trauma-informed HIV intervention (LinkPositively) to improve HIV care among black women affected by interpersonal violence: protocol for a pilot randomized controlled trial. JMIR Res Protoc 2023;12:e46325 [FREE Full text] [doi: 10.2196/46325] [Medline: 37405824]
37. Goldenberg T, Jadwin-Cakmak L, Popoff E, Reisner SL, Campbell BA, Harper GW. Stigma, gender affirmation, and primary healthcare use among black transgender youth. J Adolesc Health 2019;65(4):483-490 [FREE Full text] [doi: 10.1016/j.jadohealth.2019.04.029] [Medline: 31303554]
38. Kosenko K, Rintamaki L, Raney S, Maness K. Transgender patient perceptions of stigma in health care contexts. Med Care 2013;51(9):819-822. [doi: 10.1097/MLR.0b013e31829fa90d] [Medline: 23929399]
39. Lacombe-Duncan A, Kia H, Logie CH, Todd KP, Persad Y, Leblanc G, et al. A qualitative exploration of barriers to HIV prevention, treatment and support: perspectives of transgender women and service providers. Health Soc Care Community 2021;29(5):e33-e46. [doi: 10.1111/hsc.13234] [Medline: 33237600]
40. Lange TM. Trans-affirmative narrative exposure therapy (TA-NET): a therapeutic approach for targeting minority stress, internalized stigma, and trauma reactions among gender diverse adults. Practice Innovations 2020;5(3):230-245. [doi: 10.1037/pri0000126]
41. Rich AJ, Williams J, Malik M, Wirtz A, Reisner S, DuBois LZ, et al. Biopsychosocial mechanisms linking gender minority stress to HIV comorbidities among black and latina transgender women (LITE Plus): protocol for a mixed methods longitudinal study. JMIR Res Protoc 2020;9(4):e17076 [FREE Full text] [doi: 10.2196/17076] [Medline: 32281542]
42. Sherman AD, Allgood S, Alexander KA, Klepper M, Balthazar MS, Hill M, et al. Transgender and gender diverse community connection, help-seeking, and mental health among black transgender women who have survived violence: a mixed-methods analysis. Violence Against Women 2022;28(3-4):890-921 [FREE Full text] [doi: 10.1177/10778012211013892] [Medline: 34167394]
43. Shipherd JC, Berke D, Livingston NA. Trauma recovery in the transgender and gender diverse community: extensions of the minority stress model for treatment planning. Cognitive and Behavioral Practice 2019;26(4):629-646. [doi: 10.1016/j.cbpra.2019.06.001]
44. Sevelius JM. Gender affirmation: a framework for conceptualizing risk behavior among transgender women of color. Sex Roles 2013;68(11-12):675-689 [FREE Full text] [doi: 10.1007/s11199-012-0216-5] [Medline: 23729971]
45. Wesp LM, Malcoe LH, Elliott A, Poteat T. Intersectionality research for transgender health justice: a theory-driven conceptual framework for structural analysis of transgender health inequities. Transgend Health 2019;4(1):287-296 [FREE Full text] [doi: 10.1089/trgh.2019.0039] [Medline: 31663035]
46. Collings SJ. A proposed model for evaluating the impact of participating in trauma-focused research. South African Journal of Psychology 2018;49(2):241-252. [doi: 10.1177/0081246318789537]
47. Akinola M, Wirtz AL, Chaudhry A, Cooney E, Reisner SL, American Cohort to Study HIV Acquisition Among Transgender Women. Perceived acceptability and feasibility of HIV self-testing and app-based data collection for HIV prevention research with transgender women in the United States. AIDS Care 2021;33(8):1079-1087 [FREE Full text] [doi: 10.1080/09540121.2021.1874269] [Medline: 33487032]
48. Lacombe-Duncan A, Logie CH. The ethical dilemmas of working safely with community researchers: lessons from community-based research with lesbian, gay, bisexual, transgender and queer communities. In: Peer Research in Health and Social Development. United Kingdom: Routledge; 2021.
49. Reisner SL, Deutsch MB, Mayer KH, Potter J, Gonzalez A, Keuroghlian AS, et al. Longitudinal cohort study of gender affirmation and HIV-related health in transgender and gender diverse adults: the LEGACY project protocol. JMIR Res Protoc 2021;10(3):e24198 [FREE Full text] [doi: 10.2196/24198] [Medline: 33646126]
50. Wirtz AL, Cooney EE, Stevenson M, Radix A, Poteat T, Wawrzyniak AJ, American Cohort To Study HIV Acquisition Among Transgender Women (LITE) Study Group. Digital epidemiologic research on multilevel risks for HIV acquisition and other health outcomes among transgender women in eastern and southern United States: protocol for an online cohort. JMIR Res Protoc 2021;10(4):e29152 [FREE Full text] [doi: 10.2196/29152] [Medline: 33900202]
51. Everhart AR, Boska H, Sinai-Glazer H, Wilson-Yang JQ, Burke NB, LeBlanc G, et al. 'I'm not interested in research; i'm interested in services': How to better health and social services for transgender women living with and affected by HIV. Soc Sci Med 2022;292:114610 [FREE Full text] [doi: 10.1016/j.socscimed.2021.114610] [Medline: 34923191]
52. King WM, Gamarel KE. A Scoping Review Examining Social and Legal Gender Affirmation and Health Among Transgender Populations. Transgend Health 2021 Mar;6(1):5-22 [FREE Full text] [doi: 10.1089/trgh.2020.0025] [Medline: 33644318]
53. Andrasik MP, Yoon R, Mooney J, Broder G, Bolton M, Votto T, HVTN 505 study team, NIAID HIV Vaccine Trials Network. Exploring barriers and facilitators to participation of male-to-female transgender persons in preventive HIV vaccine clinical trials. Prev Sci 2014;15(3):268-276 [FREE Full text] [doi: 10.1007/s11121-013-0371-0] [Medline: 23446435]

54. Owen-Smith AA, Woodyatt C, Sineath RC, Hunkeler EM, Barnwell LT, Graham A, et al. Perceptions of barriers to and facilitators of participation in health research among transgender people. Transgend Health 2016;1(1):187-196 [FREE Full text] [doi: 10.1089/trgh.2016.0023] [Medline: 28861532]
55. Reisner SL, Chaudhry A, Cooney E, Garrison-Desany H, Juarez-Chavez E, Wirtz AL. 'It all dials back to safety': a qualitative study of social and economic vulnerabilities among transgender women participating in HIV research in the USA. BMJ Open 2020;10(1):e029852 [FREE Full text] [doi: 10.1136/bmjopen-2019-029852] [Medline: 31959600]
56. Kaniuka AR, Zarwell M, Cramer RJ, Quinn K, Broaddus M, Patton A, et al. Perceptions of HIV research participation among gay, bisexual, and other men who have sex with men and transgender and nonbinary adults: results from a midwest pride event. J Empir Res Hum Res Ethics 2022;17(1-2):15-28. [doi: 10.1177/15562646211062707] [Medline: 34866467]
57. Goldenberg T, Kahle EM, Stephenson R. Stigma, resilience, and health care use among transgender and other gender diverse youth in the United States. Transgend Health 2020;5(3):173-181 [FREE Full text] [doi: 10.1089/trgh.2019.0074] [Medline: 32923667]
58. Watson RJ, Veale JF, Gordon AR, Clark BA, Saewyc EM. Risk and protective factors for transgender youths' substance use. Prev Med Rep 2019;15:100905 [FREE Full text] [doi: 10.1016/j.pmedr.2019.100905] [Medline: 31193847]
59. Shimmin C, Wittmeier KD, Lavoie JG, Wicklund ED, Sibley KM. Moving towards a more inclusive patient and public involvement in health research paradigm: the incorporation of a trauma-informed intersectional analysis. BMC Health Serv Res 2017;17(1):539 [FREE Full text] [doi: 10.1186/s12913-017-2463-1] [Medline: 28784138]
60. Meyer IH. Minority stress and mental health in gay men. Journal of Health and Social Behavior 1995;36(1):38-56. [doi: 10.2307/2137286]
61. Hall SF, DeLaney MJ. A trauma-informed exploration of the mental health and community support experiences of transgender and gender-expansive adults. J Homosex 2021;68(8):1278-1297. [doi: 10.1080/00918369.2019.1696104] [Medline: 31799893]
62. Fallot RD, Harris M. A trauma-informed approach to screening and assessment. New Dir Ment Health Serv 2001;2001(89):23-31. [doi: 10.1002/yd.23320018904] [Medline: 11291259]
63. Harris ME, Fallot RD. Using Trauma Theory to Design Service Systems. San Francisco: Jossey-Bass Wiley; 2001.
64. SAMHSA's concept of trauma and guidance for a trauma-informed approach.: Substance Abuse and Mental Health Services Administration; 2014. URL: https://tinyurl.com/2paw9yve [accessed 2024-12-21]
65. Herman JL. Trauma and Recovery: The Aftermath of Violence--From Domestic Abuse to Political Terror: Hachette uK. New York: Basic Books; 2015.
66. Livingston NA, Berke DS, Ruben MA, Matza AR, Shipherd JC. Experiences of trauma, discrimination, microaggressions, and minority stress among trauma-exposed LGBT veterans: Unexpected findings and unresolved service gaps. Psychol Trauma 2019;11(7):695-703. [doi: 10.1037/tra0000464] [Medline: 30998062]
67. Berke DS, Tuten MT, Smith A, Hotchkiss M. A qualitative analysis of the context and characteristics of trauma exposure among sexual minority survivors: Implications for posttraumatic stress disorder assessment and clinical practice. Psychol Trauma 2023;15(4):648-655 [FREE Full text] [doi: 10.1037/tra0001226] [Medline: 35254848]
68. Hart LM, Ferreira KB, Ambwani S, Gibson EB, Austin SB. Developing expert consensus on how to address weight stigma in public health research and practice: a delphi study. Stigma and Health 2021;6(1):79-89. [doi: 10.1037/sah0000273]
69. Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. Journal of Advanced Nursing 2008;32(4):1008-1015. [doi: 10.1046/j.1365-2648.2000.t01-1-01567.x]
70. Akins RB, Tolson H, Cole BR. Stability of response characteristics of a Delphi panel: application of bootstrap data expansion. BMC Med Res Methodol 2005;5(1):37 [FREE Full text] [doi: 10.1186/1471-2288-5-37] [Medline: 16321161]
71. Hall DA, Smith H, Heffernan E, Fackrell K, Core Outcome Measures in Tinnitus International Delphi (COMiT'ID) Research Steering Group. Recruiting and retaining participants in e-Delphi surveys for core outcome set development: evaluating the COMiT'ID study. PLoS One 2018;13(7):e0201378. [doi: 10.1371/journal.pone.0201378] [Medline: 30059560]
72. We are a group of researchers who aim to develop best practices for conducting research with transgender and nonbinary individuals in a manner that is person-centered, trauma-informed, and actively de-stigmatizing.: Hunter Alliance for Research and Translation URL: https://www.restart-study.org/ [accessed 2024-12-21]
73. Koury S, Green S. Trauma-informed organizational change manual. In: Institute on Trauma and Trauma-Informed Care. New York: State Office of Addiction Services and Supports (OASAS); 2021.
74. Brown DR, Hernández A, Saint-Jean G, Evans S, Tafari I, Brewster LG, et al. A participatory action research pilot study of urban health disparities using rapid assessment response and evaluation. Am J Public Health 2008;98(1):28-38. [doi: 10.2105/ajph.2006.091363]
75. McNall M, Foster-Fishman PG. Methods of rapid evaluation, assessment, and appraisal. American Journal of Evaluation 2007;28(2):151-168. [doi: 10.1177/1098214007300895]
76. Skillman M, Cross-Barnet C, Friedman Singer R, Rotondo C, Ruiz S, Moiduddin A. A framework for rigorous qualitative research as a component of mixed method rapid-cycle evaluation. Qual Health Res 2019 Jan;29(2):279-289. [doi: 10.1177/1049732318795675] [Medline: 30175660]
77. Watkins DC. Rapid and rigorous qualitative data analysis. International Journal of Qualitative Methods 2017;16(1):160940691771213. [doi: 10.1177/1609406917712131]

78. Keeley T, Williamson P, Callery P, Jones LL, Mathers J, Jones J, et al. The use of qualitative methods to inform delphi surveys in core outcome set development. Trials 2016;17(1):230 [FREE Full text] [doi: 10.1186/s13063-016-1356-7] [Medline: 27142835]
79. Keeley T, Khan H, Pinfold V, Williamson P, Mathers J, Davies L, et al. Core outcome sets for use in effectiveness trials involving people with bipolar and schizophrenia in a community-based setting (PARTNERS2): study protocol for the development of two core outcome sets. Trials 2015;16(1):47 [FREE Full text] [doi: 10.1186/s13063-015-0553-0] [Medline: 25887033]
80. Mathers J, Keeley T, Jones L, Calvert M, Williamson P, Jones J, et al. Using qualitative research to understand what outcomes matter to patients: direct and indirect approaches to outcome elicitation. Trials 2015;16(S2):O39. [doi: 10.1186/1745-6215-16-s2-o39]
81. Waters AM, Tudur Smith CT, Young B, Jones TM. The CONSENSUS study: protocol for a mixed methods study to establish which outcomes should be included in a core outcome set for oropharyngeal cancer. Trials 2014;15:168 [FREE Full text] [doi: 10.1186/1745-6215-15-168] [Medline: 24885068]
82. Hewlett S, Cockshott Z, Byron M, Kitchen K, Tipler S, Pope D, et al. Patients' perceptions of fatigue in rheumatoid arthritis: overwhelming, uncontrollable, ignored. Arthritis Rheum 2005;53(5):697-702 [FREE Full text] [doi: 10.1002/art.21450] [Medline: 16208668]
83. Sanderson T, Morris M, Calnan M, Richards P, Hewlett S. What outcomes from pharmacologic treatments are important to people with rheumatoid arthritis? Creating the basis of a patient core set. Arthritis Care Res (Hoboken) 2010;62(5):640-646 [FREE Full text] [doi: 10.1002/acr.20034] [Medline: 20461785]
84. Saketkoo LA, Mittoo S, Frankel S, LeSage D, Sarver C, Phillips K, OMERACT Connective Tissue Disease–Interstitial Lung Diseases Working Group, OMERACT Connective Tissue Disease-Interstitial Lung Diseases Working Group. Reconciling healthcare professional and patient perspectives in the development of disease activity and response criteria in connective tissue disease-related interstitial lung diseases. J Rheumatol 2014;41(4):792-798 [FREE Full text] [doi: 10.3899/jrheum.131251] [Medline: 24488412]
85. Jorm AF. Using the delphi expert consensus method in mental health research. Aust N Z J Psychiatry 2015;49(10):887-897. [doi: 10.1177/0004867415600891] [Medline: 26296368]
86. Hart LM, Jorm AF, Kanowski LG, Kelly CM, Langlands RL. Mental health first aid for Indigenous Australians: using delphi consensus studies to develop guidelines for culturally appropriate responses to mental health problems. BMC Psychiatry 2009;9:47 [FREE Full text] [doi: 10.1186/1471-244X-9-47] [Medline: 19646284]
87. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, REDCap Consortium. The REDCap consortium: building an international community of software platform partners. J Biomed Inform 2019;95:103208 [FREE Full text] [doi: 10.1016/j.jbi.2019.103208] [Medline: 31078660]
88. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42(2):377-381 [FREE Full text] [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]
89. Stigma and discrimination research toolkit.: (NIH) NIMH URL: https://www.nimh.nih.gov/about/organization/dar/stigma-and-discrimination-research-toolkit [accessed 2024-12-17]

Abbreviations

ITTC: Institute on Trauma and Trauma-Informed Care
NIH: National Institutes of Health
REDCap: Research Electronic Data Capture

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Protocol

Remote Lifestyle Intervention to Reduce Postpartum Weight Retention: Protocol for a Community-Engaged Hybrid Type I Effectiveness-Implementation Randomized Controlled Trial

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Abstract

Background: Maternal obesity is associated with significant racial disparities. People who identify as non-Hispanic Black and Latinx are at the highest risk related adverse short- and long-term health outcomes (eg, hypertension in pregnancy and postpartum weight retention). Remote lifestyle interventions delivered during and after pregnancy hold promise for supporting healthy weight outcomes; however, few are tested in groups of people who self-identify as non-Hispanic Black and Latinx or address the neighborhood-level and psychosocial factors driving maternal health disparities. Implementing remote lifestyle interventions within community-based programs that serve birthing people may optimize trust and engagement, promote scalability and sustainability, and have the broadest public health impact.

Objective: The goal of this trial is to test the effectiveness of a culturally adapted remote lifestyle intervention (Healthy for Two–Home Visiting) implemented within home visiting compared to usual home visiting services on postpartum weight retention among pregnant or postpartum individuals, in particular those who identify as non-Hispanic Black and Latinx. Facilitators and barriers to implementation of the intervention within home visiting will be examined.

Methods: We describe the rationale and protocol for this hybrid type I effectiveness-implementation randomized controlled trial. In this paper, we highlight the community-engaged approach and trial design features that enable the implementation of the intervention within home visiting and demonstrate its applicability to the target population. Participants will be 360 pregnant individuals with overweight or obesity enrolled between 20 and 33 weeks of gestation and randomized 1:1 to Healthy for Two–Home Visiting or usual home visiting services. The primary outcome is weight retention at 6 months post partum, calculated as 6-month postpartum weight minus earliest pregnancy weight (≤18 wk of gestation). The measures of implementation include intervention feasibility, acceptability, reach, adoption, and fidelity. Throughout the paper, we highlight the community input used to improve intervention effectiveness and study implementation and as a strategy to promote maternal health equity.

Results: This study was funded in June 2021, and recruitment began in April 2023. As of November 2024, we enrolled 90 participants. Data collection to assess the intervention's effectiveness is expected to end in June 2026. Implementation evaluation is expected to conclude in December 2026.

Conclusions: This hybrid type I effectiveness-implementation randomized controlled trial integrates a culturally adapted remote lifestyle intervention into early home visiting services to examine its effectiveness on postpartum weight retention compared to usual home visiting. We anticipate that the study results will enable an understanding of the drivers of successful implementation

within a community-based setting to maximize the future sustainability and dissemination of a strategy for reducing long-term obesity and other maternal health disparities.

Trial Registration: Clinicaltrials.gov NCT05619705; https://clinicaltrials.gov/study/NCT05619705

International Registered Report Identifier (IRRID): DERR1-10.2196/62847

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KEYWORDS

pregnancy; obesity; postpartum weight retention; remote lifestyle intervention; home visiting; mobile health; mHealth app; community-engaged research; implementation science; health disparities; maternal health

Introduction

Background

Maternal obesity is a persistent public health concern, with widening racial and ethnic inequities [1-3]. In the United States, 57% of women who self-identify as non-Hispanic Black and 47% of women who self-identify as Latinx, Hispanic, or of Spanish origin (hereinafter referred to as Latinx) have obese status compared to 38% of people who identify as non-Hispanic White [4]. Nearly 50% of pregnant people who identify as non-Hispanic Black or Latinx exceed the recommended guidelines for gestational weight gain (GWG), contributing to adverse maternal and infant health outcomes (eg, hypertension in pregnancy, preterm birth, and maternal mortality) [5-8], as well as an estimated economic impact of up to US $32 billion from conception through the offspring's first 5 years of life [9]. It is imperative to focus public health prevention efforts on non-Hispanic Black and Latinx pregnant individuals who are most susceptible to worsening obesity (ie, postpartum weight retention [PPWR]) [10-13] and other long-term health problems, including cardiovascular disease [14-17]. Pregnancy offers an opportunity to initiate healthy behaviors that limit GWG and its associated health risks because individuals are motivated to have a healthy baby [18]. This ideal window for health promotion extends to the period after birth when it is critical to sustain healthy changes and improve care transitions, especially among individuals with known barriers to health care access and quality [19]. These individuals have increased exposure to negative social determinants of health (eg, environmental, financial, cultural, and linguistic barriers; racism; limited health literacy; and inadequate insurance coverage), which impacts postpartum visit attendance [20,21] and further exacerbates health risk [22-24].

Counseling and lifestyle interventions during and after pregnancy are a recommended and well-established strategy for limiting GWG [25-28] and reducing PPWR [29-32], and their implementation is being tested in real-world settings; for example, our team is testing a remote health coaching intervention to limit GWG integrated into prenatal care clinics [33,34]. However, there are several evidence gaps. First, few interventions have been tested in racial and ethnic minority groups [32,35], with especially low representation of Latinx individuals [36]. Second, few interventions have been implemented and tested in community-based settings where pregnant and postpartum individuals considered high risk access safety net services. Finally, interventions that address health-constraining social factors that contribute to disparities in maternal health outcomes are limited [31,37,38].

Importantly, implementing effective remote lifestyle interventions within community-based programs that pregnant individuals access and trust may optimize their benefits, promote scalability and sustainability, and have the broadest public health impact. Home visiting is an evidence-based public health strategy targeting pregnant individuals considered high risk and families with children aged up to 5 years. Home visitors provide health education, promote positive parenting and early learning, and link families with needed community resources and social support [39]. Early home visiting has been shown to prevent child abuse and neglect, improve maternal and child health, enhance family socioeconomic status, and promote child development and school readiness [40]. Early home visiting is an ideal setting for delivering lifestyle interventions for pregnant and postpartum individuals because home visitors are uniquely positioned to address social and environmental factors impacting health behavior (eg, neighborhood food availability and walkability) [39]. A recent randomized trial testing a lifestyle intervention embedded in early home visiting services showed lower GWG and PPWR up to 12 months, greater achievement of 5% weight loss, smaller waist circumference, and reduced sugar intake at 12 and 24 months [41], as well as greater success in reducing access to sugar-sweetened beverages in the home up to 24 months [41,42].

Objectives

The goals of this paper are to (1) describe the design of this hybrid type I effectiveness-implementation randomized controlled trial testing the effectiveness of the Healthy for Two–Home Visiting (H42-HV) remote lifestyle intervention integrated into home visiting compared to usual home visiting services on PPWR among pregnant and postpartum individuals; (2) highlight the design features of this trial that enable its implementation within home visiting and the applicability of the intervention to the target population, in particular those who identify as Latinx and non-Hispanic Black; and (3) highlight our application of a community-engaged approach to the conceptualization and design of the study to improve intervention effectiveness and study implementation and as a strategy to promote maternal health equity.

Methods

Study Design, Aims, and Hypothesis

We designed this hybrid type I effectiveness-implementation randomized controlled trial to test the effect of the H42-HV lifestyle intervention integrated into home visiting from mid- to late pregnancy (20-33 wk) through 6 months post partum, compared to usual home visiting services, among pregnant and postpartum individuals with overweight or obesity. The primary outcome is PPWR calculated as 6-month postpartum weight minus prepregnancy (≤18 wk of gestation) weight. Additional measures of effectiveness include GWG and maternal health behaviors, wellness, and health care use. Our main hypothesis is that participants in the H42-HV arm will have lower PPWR than those in the usual home visiting services arm.

Hybrid type I effectiveness-implementation trials assess the primary outcome of clinical effectiveness and evaluate implementation strategies of the intervention as secondary outcomes to better understand facilitators and barriers to real-world dissemination. This hybrid approach could efficiently and in a timely fashion inform the pathways from translation of evidence into practice upon establishing the effectiveness of the intervention, guide future sustainability efforts, and facilitate greater subsequent public health impact [43,44]. To this end, the study will also examine home visiting organizational factors that could impact the implementation of the intervention. We will use the practical, robust implementation and sustainability model (PRISM) framework [45] and domains from the Consolidated Framework for Implementation Research (CFIR) [46] to assess intervention feasibility, acceptability, reach, adoption, and fidelity.

The protocol has been registered with ClinicalTrials.gov (NCT05619705).

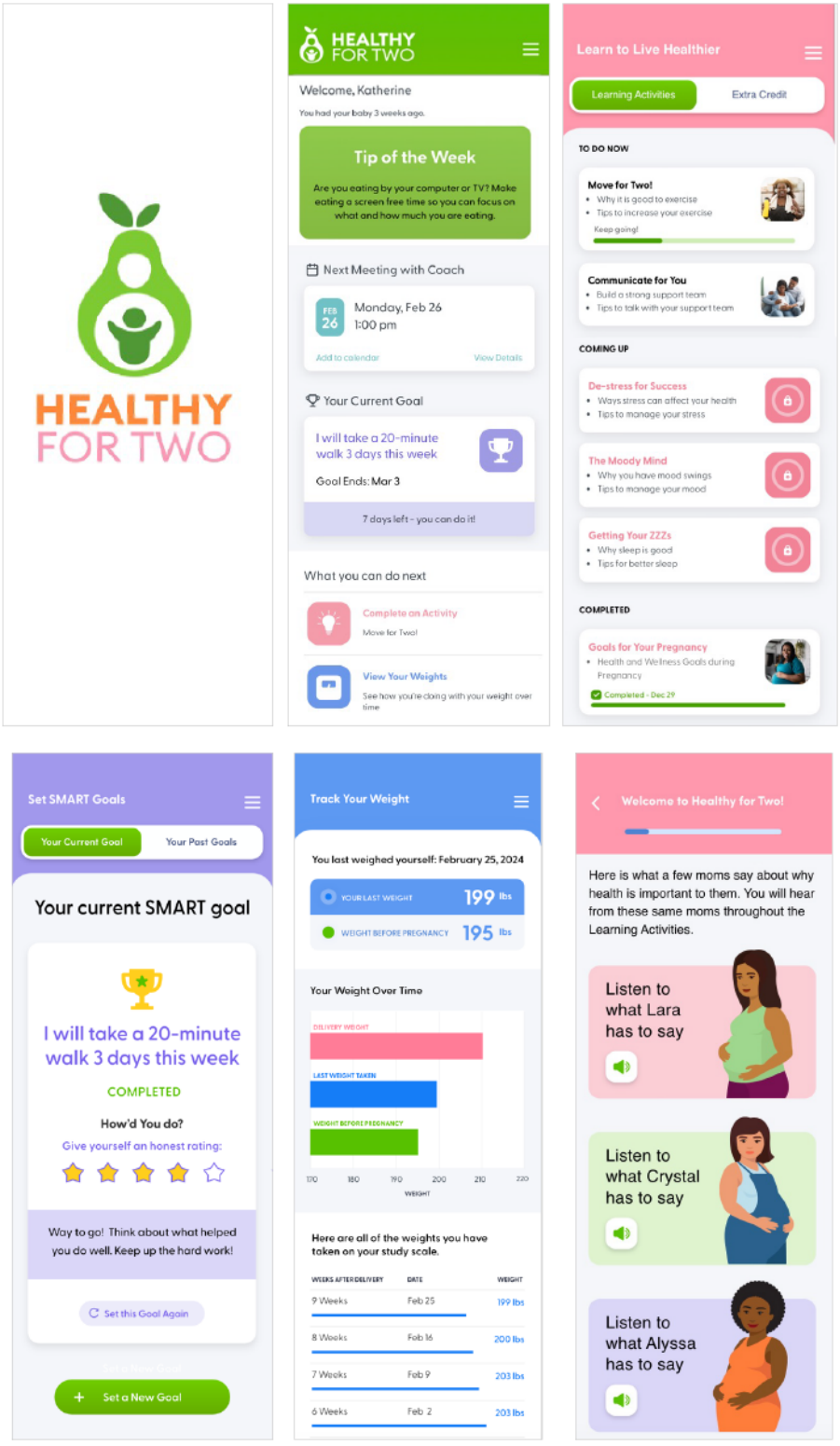
Application of a Community-Engaged Approach

We used a community-engaged research approach to inform the conceptualization and design of the study, including the adaptation of the H42-HV intervention and its integration into early home visiting services. On the basis of the continuum of community engagement in research [47], our level of engagement is best characterized as community participation because the community was actively engaged with a defined role in all stages of the research process. Prior studies clearly demonstrate the importance of early and sustained stakeholder involvement to develop and implement remote health interventions for underserved populations [48-50]. The study principal investigators (WLB and KMB) engaged home visiting stakeholders while developing the proposal and, once funded, used a variety of strategies to establish and sustain 2-way engagement, communication, and information sharing. All aspects of the study were enhanced by feedback from a diverse group of stakeholders who serve individuals identifying as Latinx or non-Hispanic Black, including regional and state leaders in home visiting and participating home visiting program managers and home visitors. Stakeholders also included current or recently pregnant individuals who identify as Latinx or non-Hispanic Black and participate in home visiting services.

During the conceptualization phase, we met with state and program leaders to gather information about the relevance of the intervention and its alignment with state and program public health priorities. We also explored the feasibility and acceptability of implementing the intervention within the home visiting setting. In the planning phase of the study, we established a translation and cultural adaptation team of primarily native Spanish-speaking maternal and child health professionals (ie, dietitian, midwife, and nurse) and health professional students (ie, those studying nursing and medicine) to translate and adapt the H42-HV intervention for Spanish-speaking individuals (the adapted version is called Sanos los Dos).

Once funded, we established a coordinating council with home visitors, leaders from participating programs, and Spanish- and English-speaking community members. Regular meetings with the coordinating council informed all aspects of the study protocol as well as implementation measures, recruitment processes, intervention adaptation, and safety protocols. We asked for specific feedback about the referral process, recruitment materials (flyers and videos), intervention approach and messaging, cultural adaptability, and community resource needs through semistructured one-on-one interviews (6 with home visiting program leaders and 7 with coordinating council members). We performed end-user testing of the H42 mobile health (mHealth) app (Figure 1). We conducted 6 interviews with parents and 2 with home visitors, applying a process known to impact the usability and engagement of culturally adapted digital health tools [49,51].

Figure 1. Healthy for Two mobile health app.



Overall, the feedback highlighted facilitators and barriers to the integration of the H42-HV intervention into home visiting programs and identified strategies for recruitment, adaptations to meet the language and cultural needs of individuals who identify as Latinx and non-Hispanic Black, and effective coordination between the home visitor and health coach. We describe how we addressed feedback from the coordinating council and the additional stakeholders in each of the following subsections.

Home Visiting Programs and Setting

In the formative phase of the trial, we engaged with 7 home visiting programs from across 5 counties in Maryland, United States, that serve predominantly pregnant and postpartum individuals who identify as Latinx or non-Hispanic Black, speak English and Spanish, and have low incomes and literacy levels. Once we launched recruitment, we invited additional early home visiting programs to refer participants to be screened and enrolled in the study. We did not limit ourselves to a particular

model of home visiting and included evidence-based and non–evidence-based models [39]; for example, the partnering home visiting models include but are not limited to Healthy Families America, Healthy Start, Nurse Family Partnership, and Babies Born Healthy. Depending on the model, home visitors are either nurses or paraprofessionals. Participating home visiting models enroll families in early pregnancy and follow them 6 months to 5 years post partum, but the frequency and intensity of home visits vary by model.

Participant Eligibility

As this is an effectiveness trial, we apply the broadest eligibility criteria to enhance generalizability [43,44,52]: age ≥18 years, singleton pregnancy between 20 and 33 weeks of gestation, and planning to enroll in home visiting services at 1 of the study's participating sites. We are focusing this study on individuals who are overweight or obese (BMI ≥25 kg/m^2) before pregnancy as they are at the highest risk for future cardiometabolic disease [53], and we are excluding conditions that may impact an individual's ability to medically or physically participate in the intervention if randomized to that arm (eg, advised not to exercise by provider or diagnosed with type 1 diabetes). Textbox 1 presents additional eligibility criteria.

Textbox 1. Eligibility criteria.

Inclusion criteria

- Age ≥18 y
- 20-33 wk of gestation
- Prepregnancy BMI ≥25 kg/m^2 (calculated based on self-reported prepregnancy height and weight)
- Able to provide informed consent
- English or Spanish speaking
- Intention to enroll in early home visiting services at a participating site
- Ability to complete telephone-assisted screening and electronic consent

Exclusion criteria

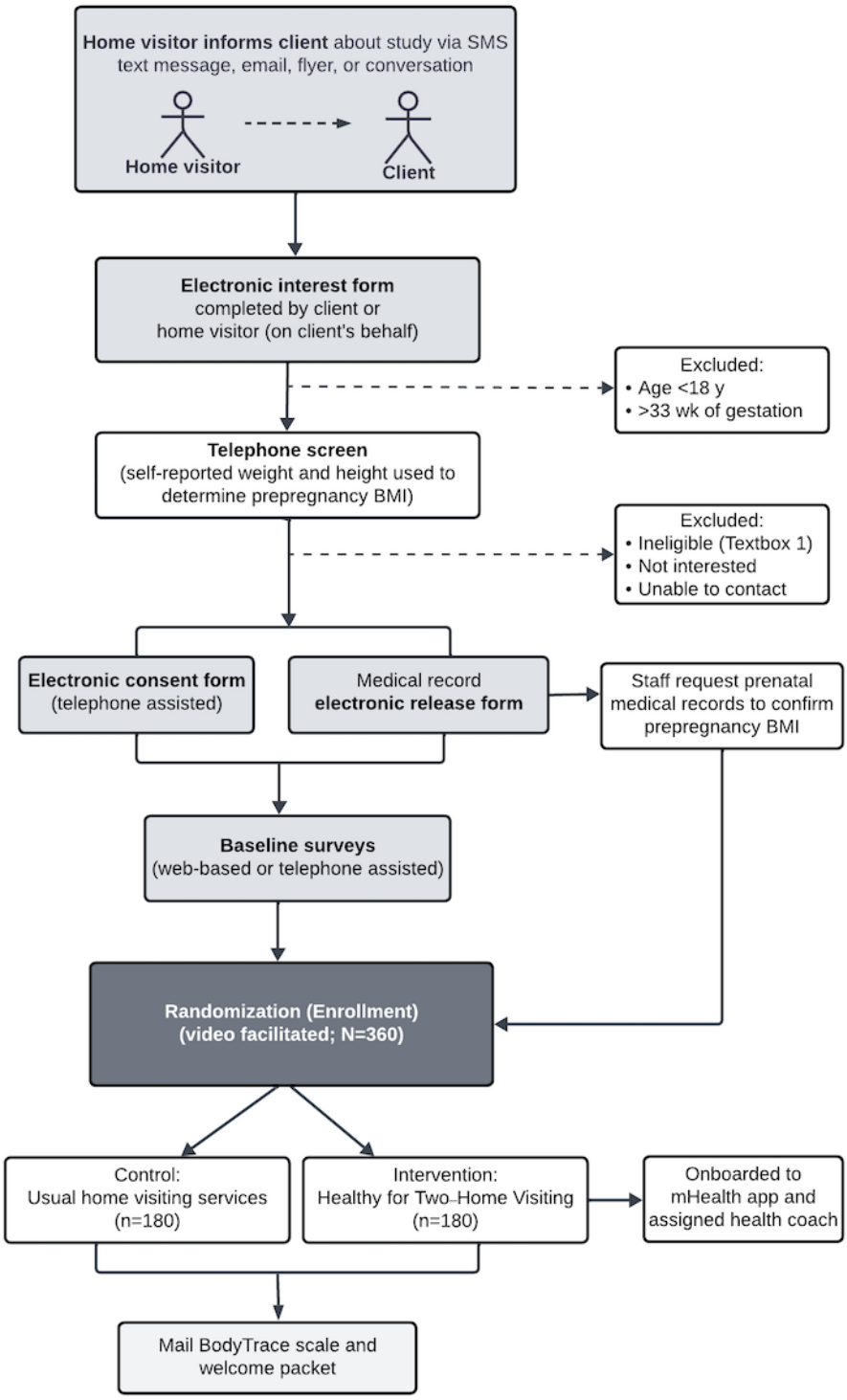
- Diagnosed with type 1 diabetes
- Pregnant with multiple fetuses
- Advised not to engage in exercise by medical provider
- Not cleared by the study's clinicians or home visiting program staff
- Planning to relocate outside of Maryland in the next year
- Active substance abuse (except marijuana)
- Psychiatric or substance use–related hospitalization in the past year
- Active eating disorder

Evidence shows that starting an intervention early in pregnancy has the greatest impact on pregnancy outcomes and GWG [54,55]. However, many home visiting programs rely on several steps to occur before services can begin, that is, entry in prenatal care, referrals from clinic, screening by outside agency for eligibility, and outreach by home visiting program. In response to input from participating home visiting programs, we selected a broad enrollment window during pregnancy (20-33 wk of gestation) and will continue intervention delivery through 6 months post partum. Given state and program leader feedback about the potential for home visiting enrollment in late pregnancy, we selected the primary outcome as return to prepregnancy weight or below because PPWR is a risk factor for future obesity.

Screening and Recruitment

With feedback from home visiting program partners (refer to the Application of a Community-Engaged Approach subsection), we designed the role of home visitors to be low touch and aligned with the procedures they already use in their program and visits. Figure 2 outlines the study design and recruitment procedures. Home visiting staff inform potentially eligible clients about the study via conversation, email, or SMS text message using a "toolkit" of different materials available in English and Spanish to accommodate program, staff, and client needs and preferences (eg, suggested dialogue, paper flyers or postcards, and an informational video lasting 2-3 min). All recruitment materials include a link and QR code to an "electronic interest form" (to be completed by clients or home visitors on their behalf) that requests basic eligibility information to preemptively exclude clients aged <18 years and >33 weeks of gestation, as well as additional details to facilitate the next steps of the screening process.

Figure 2. Study design and recruitment procedures. mHealth: mobile health.



Upon receiving a completed "electronic interest form," research staff reach out to the potential participant via telephone to further assess interest and screen for eligibility. After confirming eligibility, research staff complete a telephone-assisted electronic consent process that includes obtaining a signed authorization for the release of medical records, including prenatal and infant records as well as claims data. After consent is obtained, study staff immediately request prenatal clinic records for height and prepregnancy weight measurements to confirm BMI criteria, and participants complete web-based or telephone-assisted baseline data collection surveys. Once these steps are complete, consented participants meet virtually with staff for a video-facilitated randomization (enrollment) visit. At randomization, participants receive instructions for taking home weight measurements using a study-provided smart scale shipped to their home; intervention participants are oriented to the H42 mHealth app and provided the name of their health coach. In response to home visitors' interest in the result of each client they refer (ie, ineligible, unable to contact, or enrolled), we provide them with the option to "opt in" to live email updates on referral outcomes.

Randomization and Blinding

A total of 360 participants will be randomized 1:1 to the H42-HV arm or comparison arm. Randomization is stratified by home visiting program region+primary language served (ie, central Spanish or English, capital Spanish or English, eastern Spanish or English, southern Spanish or English, or western Spanish or English) and BMI (≥30 kg/m^2 vs 25-29.9 kg/m^2) and within each stratum using randomly varying block sizes of 2, 4, and 6. The randomization scheme was generated using Stata (version 17.0; StataCorp LLC) and imported into REDCap (Research Electronic Data Capture; version 14.0.31; Vanderbilt University) [56,57]. Assignment remains masked until a participant is randomized. Due to the nature of this lifestyle intervention, participants, home visitors, the intervention team, and the safety monitor will not be blinded to randomization assignment after randomization. Until the end of the trial, all nonintervention study staff and coinvestigators, including the principal investigators and data collectors, will remain blinded, with the exception of the lead biostatistician.

H42-HV: Intervention Design and Approach

Overview

The intervention was adapted from our previously designed and pilot-tested remotely delivered lifestyle intervention (called Healthy for Two/Healthy for You) to limit GWG and PPWR in a racially diverse population with low literacy [33,34]. The person-centered intervention uses a standard behavioral approach to weight management [58], teaching strategies aligned with social cognitive theory, such as self-monitoring, goal setting, and problem-solving [59]. The overarching goal of the H42-HV intervention is for participants to have lower PPWR 6 months after delivery.

Intervention Components and Adaptations

Overview

We used an iterative approach for translating and adapting intervention content and technologies using feedback from our key stakeholders (refer to the Application of a Community-Engaged Approach subsection). In addition to shifting intervention timing and focus to the postpartum period, we reframed messaging about program goals to achieving "overall health and wellness" versus a "healthy weight." Consistent early feedback from home visitors suggested that strong internalized weight biases among their clients may impact intervention engagement and acceptability. Weight stigma is pervasive in health care settings, has detrimental impacts on overall health and the use of health care services [60,61], and has more recently been regarded as a social determinant of poor birth outcomes [62]. Textbox 2 summarizes the adapted components of H42-HV.

Textbox 2. Healthy for Two–Home Visiting intervention components.

Person-centered health coaching (English or Spanish)

- 10 total telephone or video meetings (4 pregnancy, 6 postpartum) lasting approximately 30 min using a person-centered approach, plus 2 as-needed "boosters"
- Starts between 20 and 33 wk of gestation and continues through 6 mo post partum
- Coaches have access to a mobile health (mHealth) coaching interface to view participant app engagement and health progress (refer to the H42 mHealth App subsection)

Self-weighing via a home smart scale

- Participants self-weigh at least once weekly on a cellular-enabled home smart scale
- Paper and electronic "wellness journal" available to self-monitor diet and exercise

H42 mHealth app (hosts web-based learning and goal-setting activities, smart scale weight displays, and 2-way participant-coach messaging; promotes engagement via dynamic in-app messages and email reminders)

- Learning activities: 10 educational modules focused on diet, exercise, social support, stress, mood, and sleep. Learning methods include the following: simple, brief education on core topic; audio quotes from 3 ethnically diverse mothers describing personal challenges or successes and behavioral strategies that help them meet health and wellness goals; 5 simple multiple-choice quiz questions to reinforce key concepts; open-ended free-text questions, ranging from 4-9 total per learning activity, to promote goal-oriented thinking, problem-solving, and identification of barriers and successes.
- Add-on learning: videos and external links covering topics such as breastfeeding, gestational diabetes, and smoking cessation
- Goal setting activity: tool that aids participants in setting their own specific, measurable, achievable, relevant, and time-bound (SMART) goals and rating their progress
- Weight display: real-time view of home smart scale weights with feedback to support goal of returning to prepregnancy weight
- Coach-participant messaging: synchronous communication stream primarily used for scheduling and delivery of individualized intervention content (ie, PDF files, images, etc)
- Home page: personalized summary to facilitate intervention adherence (ie, date and time of upcoming coach meetings, most recent coach message, reminders to weigh) and engagement (ie, seasonal health or wellness "Tip of the week")
- Coach and coach manager interface: coach interface with dynamic access to participant weight data and engagement with app (ie, SMART goals, free-text entries); coach manager interface with real-time access to participant and group-level data for individualized case management and ongoing support and management of all coaches

Person-Centered Health Coaching

The cornerstone of the H42-HV intervention is *health coaching* using an evidence-based person-centered approach [63] aimed at enhancing participants' intrinsic drive to make health-related behavior changes (diet, exercise, and stress management). Participants complete up to 12 coach meetings (10 planned plus 2 as-needed "boosters") via video or telephone when they join the study (between 20 and 33 weeks of gestation) through 6 months post partum. Coaches aim to complete 4 meetings during pregnancy and 6 meetings post partum, with flexible cadence to account for varying enrollment dates. The frequency of coach meetings is consistent with similar interventions showing an effect on PPWR [29,33,64] and based on evidence that moderate- (ie, ≥6 contacts) to high-intensity (ie, ≥12 contacts) lifestyle interventions have the greatest effect on GWG [26,65]. Coaches receive enhanced training on weight bias and cultural sensitivity as well as supporting behavioral changes in the context of common social and environmental barriers such as food insecurity and neighborhood safety.

Health Behavior Tracking (Self-Weighing via Home Smart Scale)

Participants are instructed to weigh themselves weekly on a *cellular-enabled home smart scale* (Body Trace; BodyTrace, Inc) [66] that transmits live data to the H42 mHealth app and coach interface described in detail in the next subsection. Coaches emphasize that self-weighing is a core tool to assess progress, similar to monitoring one's exercise minutes and the type and amount of food and drinks consumed. Participants have the option to track and share diet and exercise behaviors with their coach as well as daily ratings of their mood and sleep using a simple paper "wellness journal" or "electronic wellness journal" delivered daily or weekly via SMS text message or email.

H42 mHealth App

Our team designed the *web-based mHealth app* (Figure 1) *and coach interface* based on intervention content tested in past trials [33,34]. The H42 mHealth app is accessible via mobile phone and delivers education tailored to a <6th-grade reading level [67-69] via interactive learning activities that provide guidance on making healthy lifestyle changes in the context of common environmental barriers (eg, eating healthy on a budget and low-cost ways to manage stress). Supplemental health topics (eg, breastfeeding, infant health, and depression) are also available because our formative research and work by others suggested that pregnant and postpartum people across races are more likely to use digital health tools that offer credible, perinatal-specific health information beyond nutrition and exercise [70,71]. The mHealth app contains a goal-setting activity, facilitates 2-way participant-coach communication, displays smart scale data, and promotes adherence and engagement via dynamic in-app messages and email reminders (Figure 1). End-user testing of the English and Spanish versions of the app completed in preparation for the trial (the testing involved 3 English-speaking and 3-Spanish speaking parents and 2 bilingual home visitors) generated reactions to app design and images, usability, interactive functionality, cultural appropriateness, and effectiveness. Consistent feedback gathered (and addressed) included preferences for a brighter color palette, more images, less text and fewer numbers, more traditional Latinx food options, larger-sized body types, simpler graphics (ie, bar graph vs line graph), and a stronger representation of family (ie, households with multiple children). If cost is a barrier, the study subsidizes web-based access (eg, by providing data cards).

The *coach/coach manager interface* provides dynamic access to participant smart scale weights and app activity (ie, goals and free-text responses) as well as food and exercise data for those who choose to track these behaviors using the "electronic wellness journal" that syncs data to the interface. The interface additionally serves as a documentation and scheduling tool. A coach manager interface provides individual and aggregate summary data to facilitate regular participant oversight, ongoing support, and the management of coaches and intervention adherence monitoring throughout the study.

Usual Home Visiting Services Comparison

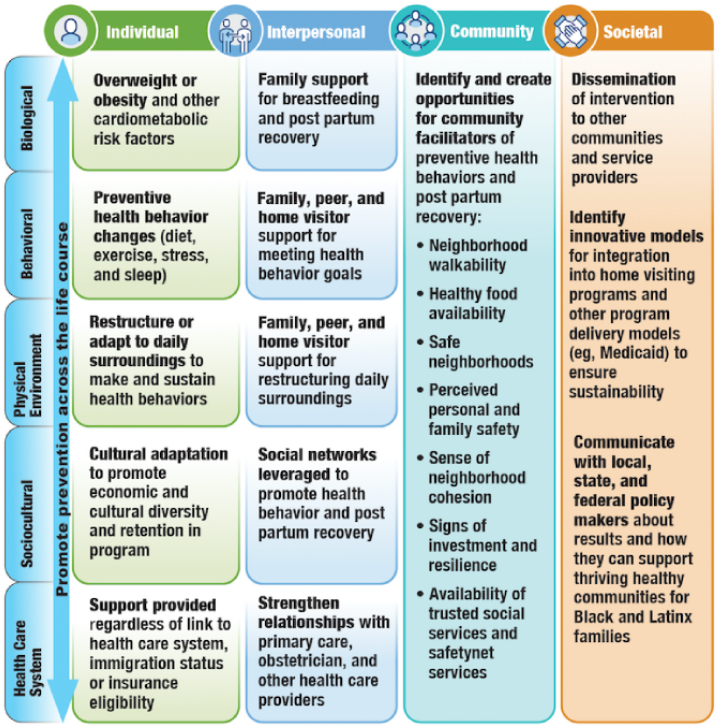
Participants randomly assigned to the comparison arm receive usual home visiting services per agency guidelines and requirements. In addition, we provide a brief, publicly available educational video on urgent maternal warning signs [72,73]. Private, staff-monitored Facebook groups are offered to disseminate information on healthy pregnancy and allow for community building and retention for both groups (usual home visiting services and H42-HV). Both groups are also provided county-specific resource lists with information on green spaces, food banks, mental health resources, medical centers, and intimate partner violence support. This resource list is available as an electronic map (using Google Maps) and a paper version.

National Institute on Minority Health and Health Disparities Research Framework Adaptation for the H42-HV Intervention

We adapted the National Institute on Minority Health and Health Disparities research framework [74] to depict the multilevel influences (individual, interpersonal, community, and societal levels) that embedding the remote intervention into early home visiting services has on health outcomes and disparities, including the social determinants of health (Figure 3). The H42-HV intervention impacts *individual-level* factors by promoting a healthy lifestyle in women with cardiovascular risk factors, regardless of insurance coverage or health literacy. While coaches provide education and strategies for making healthy changes (ie, adding fruits and vegetables to participants' diet), home visitors address context-specific barriers (eg, healthy food availability) and leverage context-specific assets (eg, local food banks) to increase success at achieving behavioral goals. At the *interpersonal level*, home visitors provide social support and connect participants with social support networks that promote a healthy lifestyle and provide tools to navigate family or peer norms, while health coaches teach participants effective communication skills to strengthen the support they receive from their existing network (eg, home visitors, health care providers, family members, and peers) and tailor this support toward making healthy changes. The H42-HV intervention addresses *community-* and *societal-level* influences by connecting participants with local resources and promoting

parent and infant use of health care services (eg, postpartum care and primary care). Ultimately, the study is designed to promote a holistic approach to reducing cardiometabolic health inequities among birthing people.

Figure 3. National Institute on Minority Health and Health Disparities research framework adaptation for the Healthy for Two–Home Visiting intervention.



Data Collection and Data Sources

Effectiveness Measures and Methods

Tables 1 and 2 summarize the methods of measurement and timing aimed at improving access and retention as well as minimizing participant burden (also refer to Figure 4). Early conversations with home visiting program leaders indicated that home visitors would not have time to collect study data; therefore, data collection procedures were designed to not involve home visitors. Data are collected through 4 methods: a cellular-enabled home smart scale, medical record review, web-based surveys via REDCap, and Medicaid claims data.

Table 1. Schedule of intervention effectiveness measures: electronic medical record review, smart scale, and Medicaid claims.

Measure	Pregnancy		Post partum			
	Baseline[a]	37 wk	Delivery[b]	2 mo	4 mo	6 mo
Maternal weight and height	Electronic medical record review	Smart scale	—[c]	Smart scale	Smart scale	Smart scale
Labor and delivery discharge summary from outside hospitals	—	—	Electronic medical record review	—	—	—
Infant weight and length from pediatric practices	—	—	Electronic medical record review	—	—	—
Maternal and infant health care use				Medicaid claims	Medicaid claims	Medicaid claims
Home visiting use and safety net services				Medicaid claims	Medicaid claims	Medicaid claims

[a]Baseline window: 20 to 33 wk of gestation.

[b]Delivery through 2 wk post partum.

[c]Not applicable.

Table 2. Schedule of intervention effectiveness measures: web-based surveys.

Measure	Pregnancy		Post partum		
	Baseline[a]	Delivery[b]	2 mo	4 mo	6 mo
Web-based surveys					
Demographics and medical history [75-78]	✓	✓[c]			
Dietary behaviors [79]	✓				✓
Physical activity [80]	✓		✓		✓
Depression and anxiety [81]	✓	✓	✓	✓	✓
Brief Perceived Stress Scale [82]	✓		✓	✓	✓
Brief Pittsburgh Sleep Quality Index [83]	✓		✓	✓	✓
Functional Social Support Questionnaire [84]	✓		✓		✓
Social determinants of health [76,78]	✓				
Everyday discrimination [85]	✓				
Tobacco, marijuana, and alcohol (PRAMS[d]) [86]	✓				✓
Pregnancy intention (PRAMS) [86]	✓				
Usual source of (maternal) care (PRAMS) [86]	✓				✓
Experiences with care (PRAMS) [86]		✓			
Infant care (PRAMS) [86]		✓	✓		
Postpartum visit attendance and support (PRAMS) [86]				✓	
Postpartum contraception (PRAMS) [86]				✓	✓
Breastfeeding intention and practices (PRAMS) [86,87]			✓	✓	✓
Use of community and safety net services: Supplemental Nutrition Program for Women, Infants, and Children (PRAMS) [86]			✓	✓	✓
Engagement with home visiting			✓	✓	✓
Safety survey		✓	✓	✓	✓

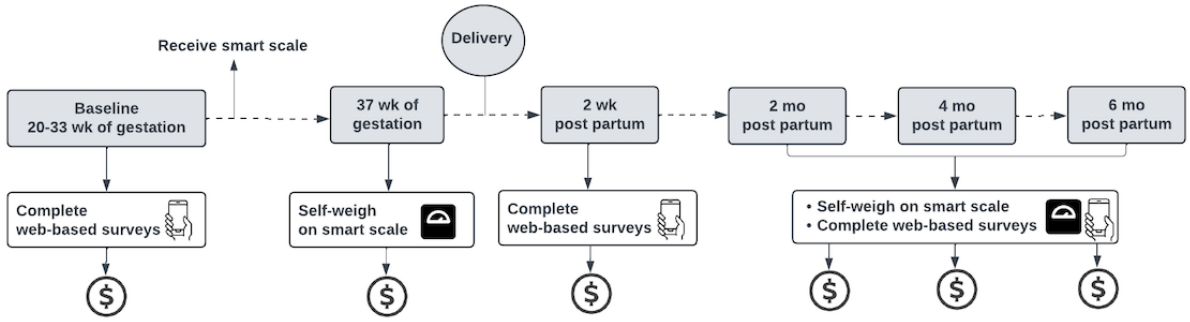
[a]Baseline window: 20 to 33 wk of gestation.

[b]Delivery through 2 wk post partum.

[c]Infant race and ethnicity collected at delivery.

[d]PRAMS: Pregnancy Risk Assessment and Monitoring System.

Figure 4. Data collection and retention.



Assessment and Verification of Maternal Weight Using a Smart Scale

Smart scale weights are collected at 4 time points: 37 weeks of gestation; and 2, 4, and 6 months post partum (Table 1). Participants are instructed to weigh themselves in light indoor clothes without shoes on their home smart scale (BodyTrace [66]). The smart scale transmits data to the study team via cellular connectivity (no Wi-Fi or cellular plan is required), which is ideal for rural client communities with intermittent Wi-Fi or those with reduced access to cellular data or inconsistent data plans. The BodyTrace smart scale was selected

because it demonstrates good concordance with in-person assessments [88,89] and has been used in several large weight management trials [90,91], including those with racially diverse populations with low incomes and literacy levels [92-94]. The scale is mailed to participants' homes after randomization, and brief SMS text reminders to weigh are sent at each study assessment time point (ie, "Time to step on your scale"). Staff monitor weight data transmitted to the study's REDCap server in real time and reach out to participants with no weight by the middle of each designated assessment "window," which ranges from –10 days to +10 days at designated study outcome assessment time points. Staff also monitor battery power and the strength of the cellular connection to assist participants with related issues, as needed. To mitigate the disruption that environmental factors (eg, potential for multiple users or scale displacement) can have on data quality, we programmed a dynamic weight cleaning procedure that requires participants to confirm questionable weights by responding to a 1-question survey sent via SMS text message. For intervention participants, this cleaning procedure ensures real-time accuracy of the weight graphs in the H42 mHealth app, as well as automated reminders, including in-app messages that prompt participants to weigh if a confirmed weight is not available after 7 days. After 14 days, coaches are notified to conduct personalized outreach to remind participants to weigh themselves.

Obtaining Medical Records and Abstracting Information on Prepregnancy Weight

Participants consent to pre- and postnatal medical record release for themselves and their infant from before pregnancy through 1 year post partum (Table 1). We use a secure electronic fax system (OpenText Fax; Open Text Corporation) to request medical records from prenatal clinics, offices, and hospitals. "Prepregnancy" weight is defined as the earliest measured weight obtained from medical records up to 18 weeks of gestation; when not available, we use self-reported weight. We also abstract height, parity, and comorbid conditions from medical records.

Web-Based Surveys

We used REDCap to build and design web-based surveys using standard instruments selected to minimize participant burden and enable completion at home (Table 2). Collectively, surveys take 10 to 20 minutes to complete, depending on the total number and length of those designated at each time point; staff-led telephone-assisted surveys are available, when preferred.

Demographics and Social Determinants of Health

Maternal and infant demographics and social determinants of health are collected using standard questions from the PhenX toolkit [78], the 2020 US Census Informational Questionnaire [75], and the Accountable Health Communities Health-Related Social Needs screening tool [77]. Additional common data elements, using standard and commonly used measures related to participant characteristics and social determinants of health, were incorporated, as required by the National Institutes of Health–Health Equity and Action Network for data harmonization at the National Institutes of Health Multiple Chronic Diseases Disparities Research Consortium [76]. Experiences with chronic, routine discrimination [95] are assessed using the 9-item Everyday Discrimination measure [85], which demonstrates good reliability (Cronbach α=0.88) and is shown to be a strong and consistent predictor of health and well-being [85].

Maternal Health Behaviors, Attitudes, and Experiences

Dietary intake is assessed as estimates of servings of fruits and vegetables, added sugars, whole grains, fiber, and calcium using the 26-item Dietary Screener Questionnaire [79], which demonstrates agreement with 24-hour dietary recalls [96]. Exercise frequency and intensity are measured using the 7-item International Physical Activity Questionnaire–Short Form, which has acceptable reliability (pooled ρ=0.76) and some agreement with the accelerometer standard (pooled ρ=0.30) in a diverse sample [80].

Mood is assessed using the 10-item Edinburgh Postpartum Depression Scale for postnatal depression, which illustrates moderately high validity (sensitivity=85%, specificity=77%) and split-half reliability (r=0.88) in the original sample of 60 mothers [81]; these results have been confirmed in other validation studies [97]. We measure stress using the 4-item Brief Perceived Stress Scale [98], which is a shortened version of the original 14-item scale [82] and has acceptable psychometric properties [99]. We assess sleep using the 6-item Brief Pittsburgh Sleep Quality Index [83], which shows good internal consistency (Cronbach α=0.79, McDonald ω=0.91) and adequate validity (sensitivity=76%, specificity=77%) in a large population-based sample [83]. Perceived social support is quantified using the 8-item Duke-UNC Functional Social Support Questionnaire [84], which has favorable test-retest reliability (r=0.50-0.85) and is significantly correlated with other social support measures [84].

Several questions from the standard and core measures of the Pregnancy Risk Assessment and Monitoring System (PRAMS) [86] assess pregnancy and breastfeeding intentions and practices, contraception, substance use (tobacco, marijuana, and alcohol), and experiences with or use of health care before and after birth.

Infant Health, Sources of Care, and Feeding Practices

Infant overall health, feeding, and sources of care are assessed using the PRAMS [86] and Infant Feeding Practices Survey [87]. The use of community and safety net programs (ie, Supplemental Nutrition Program for Women, Infants, and Children) is also measured using the PRAMS [86].

Engagement With Home Visiting Services

Engagement with home visiting services and the frequency of contacts with home visitors will be collected at all postpartum time points to assess the "dose" of home visiting during the study.

Intervention Satisfaction

Intervention participants complete a satisfaction survey at the end of the study using an adapted survey tool administered and reported on in previous trials [33,34].

Medicaid Claims Data

We will request Maryland Medicaid claims data for all consented participants with Medicaid to assess maternal and infant health care use outcomes (ie, attendance at prenatal care visits, postpartum visit, primary care visits, infant visits, and receipt of infant vaccines) via a data use agreement with the Maryland Department of Health (Table 2).

Implementation Process Measures and Methods

Overview

Measures to evaluate the implementation are based on the PRISM framework [45] and domains from the CFIR [46]. Table 3 outlines all implementation outcomes and measures.

Table 3. Implementation process measures and methods.

PRISM[a]+CFIR[b] domains	Implementation process measure	Data collection method (before, during, and after the trial)
Organizational perspectives	Home visiting program perceived usability, adaptability, and relative priority of the intervention	Surveys before and after program orientation; focus groups after the trial
Organizational characteristics (inner setting from the CFIR)	Home visiting program culture, management support and cooperation, systems, training, staffing, and incentives	Home visiting leader surveys before the trial
External environment (outer setting from the CFIR)	Home visiting program regulatory environment (policies and incentives); patient needs and resources	Home visiting leader surveys before the trial; county reports; census and county rankings database
Reach	Total number of clients enrolled out of those screened and eligible; total number of clients enrolled out of new pregnant clients enrolled in the home visiting program	Study recruitment and enrollment data; home visiting program leader surveys after the trial
Implementation (engaging, reflecting, and evaluating process from the CFIR)	Engagement of program leaders in implementation process; qualitative feedback on the progress and quality of the implementation	Coordinating council, formative interviews with home visiting program leaders, focus groups, and research team discussion and reflection throughout the trial
Adoption	Proportion of sites across the state that opt to participate in the study; adoption of training and recruitment procedures; level of involvement supporting intervention participants	Home visiting staff focus groups after the trial; review of study recruitment and enrollment data
Fidelity of the intervention (coach and participant)	Coach adherence to meeting guides and patient-centered approach; participant adherence to intervention components and perceived acceptability	Review of audio-recorded coach meetings during the trial; reports from data management systems; participant acceptability survey after completing the study

[a]PRISM: practical, robust implementation and sustainability model.

[b]CFIR: Consolidated Framework for Implementation Research.

Organizational Perspectives

To support state and program leader feedback gathered during the conceptualization phase of the study (refer to the Application of a Community-Engaged Approach subsection), home visitors' perspectives of the intervention were assessed via survey before and after a 1-hour study staff–led orientation (an overview of study goals, design, and referral procedures) that they received before the trial. They rated the importance of, and the need for, resources to address various health-related topics (eg, nutrition and exercise) with their clients before the training and after they rated intervention acceptability, appropriateness, and feasibility [100]. At the end of the study, we will conduct 2 focus groups with home visitors from participating programs to further explore the perceived usability, acceptability, and adoption of the intervention. Interview guides will be developed using the PRISM framework [45] and include questions assessing facilitators and barriers to implementation.

Organizational Characteristics (Inner Setting From the CFIR)

Features of home visiting programs through which the implementation process will proceed and features that may support or impede the programs' ability to successfully implement the intervention (eg, structure, enrollment, staffing, service modality, and curriculum) were assessed before the trial using a survey completed by home visiting program leaders.

External Environment (Outer Setting From the CFIR)

The county-level economic, political, and social contexts within which the home visiting programs reside and which may affect their ability to successfully implement the intervention (eg, social determinants of health, obesity rates, demographics, reimbursements, and health and wellness resources) will be assessed before the trial using a survey completed by home visiting program leaders and publicly available data from county reports, US Census Bureau data [75], and a county rankings database [101].

Study Reach

We will quantify study reach as (1) the total number of clients enrolled in the study out of new pregnant clients enrolled in home visiting during the enrollment period and (2) the total number of clients enrolled in the study out of those screened and eligible for the study.

Implementation (Engaging, Reflecting, and Evaluating)

We will measure implementation through a combined strategy of gathering feedback from home visiting programs about the progress and quality of the implementation and holding regular debriefings with personnel and team about progress and experience.

Adoption of Intervention

We will track the proportion of home visiting sites across the state that opt to participate in the study and assess the level of involvement in study procedures and the intervention via survey and home visitor focus groups after the trial.

Fidelity of the Intervention: Coach and Participant Adherence (During and After the Intervention)

We will examine intervention fidelity and its impact on the primary outcome using common procedures applied in multicomponent remote lifestyle intervention trials [102,103]. Health coach fidelity to a participant-centered approach and standard meeting components (eg, reviewing successes and progress as well as setting goals) will be measured using an iterative quality assurance process of sampling and reviewing audio-recorded coach meetings. We will track participant adherence to each component of the intervention (coach meetings, mHealth app, and smart scale use) and intervention acceptability using an end-of-study survey.

Retention Strategies for Participants

On the basis of our experience with recruiting and retaining pregnant women, we will use several methods to achieve high retention, including rapport building, sending birthday and birth cards, and using email and SMS text message reminders based on each participant's preferred method of contact. Participants will be provided gift cards after each data collection visit: US $10 at enrollment; US $10 at 37 weeks of gestation; US $15 at 2 weeks post partum; and US $20, US $25, and US $30 at 2, 4, and 6 months post partum, respectively (Figure 4). As participants will be engaged in home visiting and consider the program part of their care, we anticipate low risk for loss to follow-up.

Methods for Ongoing Home Visitor and Community Engagement

Home visitor engagement will involve monthly recruitment updates shared with sites and site supervisors, raffle incentives, ongoing training opportunities on topics of interest, and brief one-on-one "check-ins" between a study team member and home visitor "site champion" aimed at quickly mitigating concerns or struggles pertaining to study procedures. Community engagement throughout the trial will involve quarterly newsletters to all stakeholders (ie, coordinating council members and state-level leaders), including home visitor and community member "spotlights" and participant success stories. In addition, each home visiting site will receive an annual financial incentive.

Analytic Approach

Sample Size and Power Estimates

With 360 participants, our objective is to determine the minimum detectable difference (MDD) for the primary outcome of PPWR between the 2 study groups. Our assumptions are as follows: a 2-tailed type I error rate of 0.05, a type II error rate of 0.10, and ≥70% follow-up for the main outcome of PPWR at 6 months. On the basis of the past experience [33] and published literature, we anticipate <30% loss to follow-up for 6-month weight measurements, consequential to various forms of dropout (eg, lost to follow-up). With this dropout rate and the assumption that the dropout is consistent with missing at random, we expect to randomize 360 participants (n=180, 50% per arm) to retain an effective sample size of 252 participants (n=126, 50%/arm) for our primary outcome. SDs for the MDD evaluation were informed by previous studies of similar combined diet-exercise lifestyle interventions to limit weight gain in pregnancy and promote postpartum weight loss [26,41,104,105]. Under these considerations, the resulting MDDs range from 2.3 to 3.6 kg with corresponding SDs for PPWR of between 5.5 and 8.8 kg.

Main Analytic Model for the Primary Outcome of PPWR

Analysis will follow the intention-to-treat principle. The main analysis will assess the between-group difference in PPWR (the difference between earliest pregnancy weight and weight at 6 mo post partum) using a mixed effects model characterized by a mean model relating the outcome to the predictors and a variance-covariance model addressing variance of all available longitudinal weight outcomes and correlation between outcomes measured over time within individual. The predictors in the mean model will include a group indicator (0 for the comparison arm and 1 for H42-HV) as well as 3 binary indicators for 2-, 4-, and 6-month postpartum visits, respectively, with baseline visit as the reference, and the corresponding group-by-visit interaction terms, adjusting for study sites (region and primary language served) and baseline BMI category used for randomization stratification, as fixed effects. The regression coefficient of the group by 6-month postpartum weight interaction term will estimate the intervention effect on the primary outcome, that is, mean difference in PPWR at 6 months between the intervention and control groups. We will use an unstructured variance-covariance model to allow full flexibility on outcome variances and longitudinal correlations for the repeatedly measured weight data. A model-based 2-tailed *t* test will be used to evaluate the intervention effect and derive the associated 95% CI. The Kenward-Roger approximation will be used to calculate the *df* for the *t* test, with $P<.05$ considered statistically significant [106].

Data from all randomized participants will be used in this analysis, with missing data included using a software-specified missing indicator. The main analysis will assume that outcome data are missing at random and use an observed data likelihood approach implemented through the mixed effects regression model, where baseline characteristics associated with the probability of missing outcome data will be further adjusted for in the mean model. Sensitivity analysis through multiple

imputation of missing outcome data under plausible missing-not-at-random scenarios will be conducted to evaluate the robustness of the findings from the main analysis conducted under the missing-at-random assumption.

Secondary Outcomes and Additional Analyses

Secondary outcomes include maternal, infant, and organizational process outcomes. For secondary maternal outcomes, available data from all randomized individuals will be included. Between-group differences in GWG (defined as the difference between the weight at 37 weeks of gestation and prepregnancy weight) and infant weights will be assessed using the same mixed effects modeling approach as described for the primary outcome, with separate models for each outcome. Between-group differences in the binary outcomes of diet, exercise, breastfeeding, and women's wellness measures (depression, sleep, stress, and social support) will be described between the H42-HV and comparison arms using standard cut points for the scales and modeled using logistic regression model–based longitudinal models implemented through a generalized estimating equations approach [107]. The mean models will similarly use the group indicator, visit indicators, and the corresponding group-by-visit interaction terms, adjusting for the variable used to stratify the randomization. Robust variance estimates will be used for statistical inferences to derive 95% CIs for the population-average estimates and corresponding *P* values. Conforming to recommended maternal postpartum care use and well-baby care use over time will separately be modeled using a similar generalized estimating equations approach as described for the longitudinal binary outcomes.

Exploratory Analyses for the Heterogeneity of the Intervention Effect

We will explore for potential moderators of intervention effects by conducting subgroup analyses based on baseline survey data (race, ethnicity, home visiting program characteristics, baseline BMI category [overweight or obese], language spoken at home, low English proficiency, income, and education level) and examining effect modification by adding appropriate interaction terms to the primary mixed effects model. We do not expect the intervention effects to vary across subgroups, and we will interpret carefully any observed heterogeneity, or lack thereof, given the exploratory nature of these analyses.

Safety Surveillance and Monitoring

For active surveillance, a safety medical officer will oversee the postdelivery review of medical records, including labor and delivery notes and infant discharge summaries. We will administer safety surveys after delivery and at 2, 4, and 6 months post partum to enable tracking of all maternal and infant hospitalizations, emergency department visits, and labor and delivery triage evaluations (Table 2). We have developed protocols to alert the team and manage high levels of depressive symptoms or interpersonal violence (Table 2). The Johns Hopkins Institutional Review Board is required to review all serious safety events. In addition, the study has a sponsor-approved data safety and monitoring plan, and oversight from the Mid-Atlantic Center for Cardiometabolic Health Equity Data and Safety Monitoring Board that meets twice a year to review study progress, intervention adherence, and adverse events (mild, moderate, and severe).

Ethical Considerations

The protocol received initial approval from the Johns Hopkins Institutional Review Board in June 2022 (IRB00307430) and was determined to be minimal risk. Standard continuing reviews occur yearly; protocol amendments are also reviewed and subsequently updated in the ClinicalTrials.gov registry. During the informed consent process (refer to the Screening and Recruitment subsection), participants are made aware of their right to privacy and confidentiality and are informed that all health information is deidentified or stored on secure servers. They are also advised that they can withdraw from the study at any time without consequence from the research team and medical or home visiting services, and if this occurs, Johns Hopkins may use any data collected before withdrawal. Participants will be provided gift cards after each data collection visit (for details, refer to the Retention Strategies for Participants subsection). In addition, each home visiting site will receive an annual financial incentive.

Results

This study was funded in June 2021, and recruitment began in April 2023. As of November 2024, we enrolled 90 participants. Data collection to assess the intervention's effectiveness is expected to end in June 2026. Implementation evaluation is expected to conclude in December 2026.

Discussion

Anticipated Findings

We designed this hybrid type I effectiveness-implementation randomized controlled trial to test a remote lifestyle intervention for weight management during pregnancy and post partum in a community-based setting that serves individuals who identify as Latinx and non-Hispanic Black. The goal of this hybrid trial is to evaluate the effectiveness of a newly adapted remote lifestyle intervention (H42-HV) and effectively integrate the intervention into early home visiting services to reduce PPWR. We hypothesize that participants who receive the H42-HV intervention will have a lower mean difference in PPWR at 6 months than control group participants. This would add to the limited evidence supporting the effectiveness of counseling and lifestyle interventions during and after pregnancy in minimizing GWG [25-28] and reducing PPWR [29-32] among racial and ethnic minority groups [32,35]. Furthermore, because few counseling and lifestyle interventions for pregnant and postpartum people have been tested in community-based settings, the use of implementation science methods will enable the gathering of important data about the facilitators and barriers to implementing the intervention in the early home visiting setting and among this population considered vulnerable. Early home visiting programs hold promise to be an ideal setting to integrate lifestyle interventions because of their unique ability to address relevant social and environmental conditions impeding healthy behaviors (eg, access to healthy foods and transportation), as well as support and improve transitions to

postpartum care. We anticipate that our study findings will demonstrate feasibility comparable to that reported in another trial of a lifestyle intervention embedded into early home visiting [41,42]. Through the implementation science approach, we will also provide evidence to support policy translation, including the expansion of H42-HV delivery into other US states' home visiting programs, and into Medicaid Managed Care coaching and case management programs as Medicaid coverage expands into the postpartum period in more states [108].

Strengths and Limitations

A major strength of the trial's design is the community-engaged approach, which began during the grant conceptualization and preimplementation phases to inform project design. Community-engaged research approaches have increased dramatically in the last few decades and are linked with statistically positive outcomes and success in recruiting and retaining racially and ethnically diverse populations experiencing marginalization [109-111]. Community-engaged research has many benefits, including ensuring intervention appropriateness, acceptability, and applicability [112-115]; ensuring that study methods and intervention are properly adapted to the population of interest [114,116,117]; and promoting trust, transparency, and bidirectional learning between research teams and stakeholders [112,118,119]. Adopting this approach has already guided key research design decisions, including (1) limiting the primary role of home visitors to the recruitment of study participants to minimize impact on workflow, (2) enrolling participants during mid- to late pregnancy (20-33 wk) to align with client enrollment in home visiting programs, (3) defining the primary outcome as weight retention at 6 months post partum to allow time for increased support during the postpartum period, and (4) focusing study goals and messaging on achieving "overall health and wellness" versus a "healthy weight" to minimize the effects that weight bias internalization may have on recruitment and intervention acceptability. Using remote data collection procedures was another important design consideration (ie, smart scale and access to prenatal medical records), given the transportation barriers of home visiting clients living in rural locations and anticipated challenges they might have in reporting their height and weight to confirm eligibility—an issue that was confirmed soon after study launch. We anticipate that the continued involvement of our coordinating council as well as other methods of community engagement will drive future decisions about the interpretation of data and dissemination of findings.

The iterative process of end-user interviews that informed the design, features, and functionality of the H42 mHealth app was especially valuable for adapting and improving it, including methods for incorporating weight goals and progress (ie, simple, colorful graph versus weight change statistics) and translating the interactive goal-setting activity for Spanish-speaking participants. Comprehensive measures of adherence to coaching, the H42 mHealth app, and the smart scale are a major strength of the study, given the growing complexity of remote lifestyle intervention packages and the critical need to differentiate the effects of unique components [27]. Similarly, access to robust engagement metrics for distinct mHealth app features (ie, interactive goal setting, coach messaging, access to weight data, comprehension quizzes, and educational videos) may build upon the patterns of website engagement characterized by Power et al [120] in a sample of individuals with low-income status who identified as Latinx; of note, in this particular study, website engagement was a strong predictor of weight retention at 6 months post partum.

The design of our study has limitations that could impact the interpretation of the results. First, control participants will have access to a scale for data collection, and regular self-weighing is a key component of behavioral weight management [58]. From a health equity and ethical perspective, we decided that we would refrain from instructing control participants not to weigh themselves outside of data collection and, instead, statistically control for the number of measured weights across the groups. Nonetheless, given the enhanced level of engagement with self-weighing in the intervention group (ie, reminders, ability to view progress on the app, and feedback from the coach), we expect the frequency of weighing in the control group to be significantly lower, and frequency is the strongest known predictor of overall weight change [121]. Another limitation is our limited ability to formally measure and control for the varying levels of support that the home visitors offer clients throughout the trial, which may differentially impact behavior change (eg, addressing access to healthy food and discussing a healthy lifestyle). This lack of control precludes our ability to measure intervention effectiveness for a Latinx and non-Hispanic Black, English- and Spanish-speaking sample considered high risk outside of the context of home visiting. Although home visitors were intentionally removed from intervention delivery, early feedback conveyed a preference among some home visitors to be actively involved, specifically with the ability to access SMART goals (assuming clients' permission). The differences in home visitor training (ie, nurse vs paraprofessional), curriculum, and the intensity of home visiting models in the trial (ie, frequency of visits ranging from weekly to 2 visits total during the first 6 mo post partum) may also differentially impact client success. We expect qualitative data on intervention adoption captured in focus groups after the trial to enhance our understanding of the potential role home visitors play in moderating intervention effects and will leverage these insights for future trial designs and intervention adaptions.

Conclusions

There is a critical need to develop effective lifestyle interventions for pregnant and postpartum individuals who identify as Latinx and non-Hispanic Black and experience the greatest risk for adverse pregnancy outcomes. This study has the potential to provide a high-quality assessment of the effectiveness of a remote lifestyle intervention for a Latinx and non-Hispanic Black population considered high risk and highlight facilitators and barriers to its implementation in a grounded service strategy specifically geared toward improving maternal and infant health. We expect the study to yield important findings that aid in refining future lifestyle intervention approaches for pregnant and postpartum people, particularly those who identify as non-Hispanic Black and Latinx, and facilitate scalability in community-based settings,

ultimately improving maternal and infant long-term health and promoting health equity.

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Data Availability

The datasets generated and analyzed during this study will be available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: KMB (lead), WLB (lead)
Data curation: LMM (lead), CDM (supporting)
Funding acquisition: KMB (lead), WLB (lead)
Investigation: KMB (lead), WLB (lead), LMM (supporting), CDM (supporting), LEA (supporting), JWC (supporting), NKJ (supporting), AS-U (supporting)
Methodology: KMB (lead), WLB (lead), LMM (supporting), CDM (supporting), JWC (supporting), NKJ (supporting), NYW (supporting)
Project administration: KMB (lead), WLB (lead), LMM (supporting)
Resources: AS-U (supporting)
Supervision: KMB (lead), WLB (lead), LMM (supporting), CDM (supporting), JWC (supporting), NKJ (supporting)
Writing (original draft): LMM (lead), KMB (supporting), WLB (supporting)
Writing (review and editing): LMM (lead), KMB (lead), WLB (lead), CDM (supporting), LEA, (supporting), JWC (supporting), NKJ (supporting), AS-U (supporting), KAC (supporting), NYW (supporting)

Conflicts of Interest

None declared.

Multimedia Appendix 1
Peer review report from the National Institute on Minority Health and Health Disparities Special Emphasis Panel - National Institute on Minority Health and Health Disparities - Centers for Multiple Chronic Diseases Associated with Health Disparities: Prevention, Treatment, and Management (P50) ZMD1 MLS (A1) (National Institutes of Health, USA.
[PDF File (Adobe PDF File), 226 KB - resprot_v14i1e62847_app1.pdf]

References

1. Driscoll AK, Gregory EC. Increases in prepregnancy obesity: United States, 2016-2019. NCHS Data Brief 2020 Nov(392):1-8. [Medline: 33270551]
2. Hales CM, Carroll MD, Fryar CD, Ogden CL. Prevalence of obesity among adults and youth: United States, 2015-2016. NCHS Data Brief 2017 Oct(288):1-8 [FREE Full text] [Medline: 29155689]
3. Alemán JO, Almandoz JP, Frias JP, Galindo RJ. Obesity among Latinx people in the United States: a review. Obesity (Silver Spring) 2023 Feb;31(2):329-337 [FREE Full text] [doi: 10.1002/oby.23638] [Medline: 36695058]
4. Flegal KM, Kruszon-Moran D, Carroll MD, Fryar CD, Ogden CL. Trends in obesity among adults in the United States, 2005 to 2014. JAMA 2016 Jun 07;315(21):2284-2291 [FREE Full text] [doi: 10.1001/jama.2016.6458] [Medline: 27272580]
5. Meyer D, Gjika E, Raab R, Michel SK, Hauner H. How does gestational weight gain influence short- and long-term postpartum weight retention? An updated systematic review and meta-analysis. Obes Rev 2024 Apr;25(4):e13679. [doi: 10.1111/obr.13679] [Medline: 38221780]
6. Ukah UV, Li X, Wei SQ, Healy-Profitós J, Dayan N, Auger N. Black-White disparity in severe cardiovascular maternal morbidity: a systematic review and meta-analysis. Am Heart J 2022 Dec;254:35-47. [doi: 10.1016/j.ahj.2022.07.009] [Medline: 35944667]
7. Yusuf HM, Koleilat M, Whaley SE. Prevalence and predictors of substantial postpartum weight retention among participants of the special supplemental nutrition program for women, infants, and children (WIC) in southern California. Am J Health Promot 2023 Jun;37(5):675-680. [doi: 10.1177/08901171221148840] [Medline: 36621898]
8. Zong X, Wang H, Yang L, Guo Y, Zhao M, Magnussen CG, et al. Maternal pre-pregnancy body mass index categories and infant birth outcomes: a population-based study of 9 million mother-infant pairs. Front Nutr 2022 Feb 17;9:789833 [FREE Full text] [doi: 10.3389/fnut.2022.789833] [Medline: 35252291]

9. O'Neil SS, Platt I, Vohra D, Pendl-Robinson E, Dehus E, Zephyrin L, et al. Societal cost of nine selected maternal morbidities in the United States. PLoS One 2022 Oct 26;17(10):e0275656 [FREE Full text] [doi: 10.1371/journal.pone.0275656] [Medline: 36288323]
10. Daundasekara SS, O'Connor DP, Berger Cardoso J, Ledoux T, Hernandez DC. Risk of excess and inadequate gestational weight gain among Hispanic women: effects of immigration generational status. Int J Environ Res Public Health 2020 Sep 04;17(18):6452 [FREE Full text] [doi: 10.3390/ijerph17186452] [Medline: 32899746]
11. Avorgbedor F, McCoy TP, Wideman L, Shriver LH, Buehler C, Leerkes EM. Racial disparities in neighborhood and household socioeconomic disadvantage predict postpartum weight retention. AJPM Focus 2022 Sep 09;1(2):100029 [FREE Full text] [doi: 10.1016/j.focus.2022.100029] [Medline: 37791241]
12. Siega-Riz AM, Herring AH, Carrier K, Evenson KR, Dole N, Deierlein A. Sociodemographic, perinatal, behavioral, and psychosocial predictors of weight retention at 3 and 12 months postpartum. Obesity (Silver Spring) 2010 Oct;18(10):1996-2003 [FREE Full text] [doi: 10.1038/oby.2009.458] [Medline: 20035283]
13. Kent-Marvick J, Cloyes KG, Meek P, Simonsen S. Racial and ethnic disparities in postpartum weight retention: a narrative review mapping the literature to the National Institute on Minority Health and Health Disparities Research Framework. Womens Health (Lond) 2023;19:17455057231166822 [FREE Full text] [doi: 10.1177/17455057231166822] [Medline: 37082834]
14. Fitzsimmons E, Arany Z, Howell EA, Lewey J. Differential outcomes for African-American women with cardiovascular complications of pregnancy. Curr Treat Options Cardiovasc Med 2020 Nov 03;22(12):64. [doi: 10.1007/s11936-020-00863-5]
15. Hoyert DL. Health e-stat: maternal mortality rates in the United States, 2022. Centers for Disease Control and Prevention. 2024 Feb 05. URL: https://stacks.cdc.gov/view/cdc/152992 [accessed 2024-02-09]
16. Petersen EE, Davis NL, Goodman D, Cox S, Mayes N, Johnston E, et al. Vital signs: pregnancy-related deaths, United States, 2011-2015, and strategies for prevention, 13 states, 2013-2017. MMWR Morb Mortal Wkly Rep 2019 May 10;68(18):423-429 [FREE Full text] [doi: 10.15585/mmwr.mm6818e1] [Medline: 31071074]
17. Tsao CW, Aday AW, Almarzooq ZI, Anderson CA, Arora P, Avery CL, et al. Heart disease and stroke statistics-2023 update: a report from the American Heart Association. Circulation 2023 Feb 21;147(8):e93-e21. [doi: 10.1161/CIR.0000000000001123] [Medline: 36695182]
18. Phelan S. Pregnancy: a "teachable moment" for weight control and obesity prevention. Am J Obstet Gynecol 2010 Feb;202(2):135.e1-135.e8 [FREE Full text] [doi: 10.1016/j.ajog.2009.06.008] [Medline: 19683692]
19. Creanga AA, Bateman BT, Mhyre JM, Kuklina E, Shilkrut A, Callaghan WM. Performance of racial and ethnic minority-serving hospitals on delivery-related indicators. Am J Obstet Gynecol 2014 Dec;211(6):647.e1-647.16. [doi: 10.1016/j.ajog.2014.06.006] [Medline: 24909341]
20. Ware KS, Thompson C, Renfroe K, Grabowsky A, Onuorah PO, Williams CH. Mapping the intersection of social determinants of health, postpartum visit attendance, and pregnancy-related deaths: a scoping review. Public Health Nurs 2024;41(3):374-382. [doi: 10.1111/phn.13290] [Medline: 38296814]
21. Wouk K, Morgan I, Johnson J, Tucker C, Carlson R, Berry DC, et al. A systematic review of patient-, provider-, and health system-level predictors of postpartum health care use by people of color and low-income and/or uninsured populations in the United States. J Womens Health (Larchmt) 2021 Aug;30(8):1127-1159 [FREE Full text] [doi: 10.1089/jwh.2020.8738] [Medline: 33175652]
22. Bazzazian S, Ozgoli G, Riazi H, Mahmoodi Z, Vafa M, Nasiri M. The relationship between social determinants of health and postpartum weight retention based on the World Health Organization model: path analysis. BMC Public Health 2023 Feb 14;23(1):323 [FREE Full text] [doi: 10.1186/s12889-023-15207-8] [Medline: 36788506]
23. Ditosto JD, Roytman MV, Dolan BM, Khan SS, Niznik CM, Yee LM. Improving postpartum and long-term health after an adverse pregnancy outcome: examining interventions from a health equity perspective. Clin Obstet Gynecol 2023 Mar 01;66(1):132-149 [FREE Full text] [doi: 10.1097/GRF.0000000000000759] [Medline: 36657050]
24. Bond RM, Phillips K, Ivy KN, Ogueri V, Parapid B, Miller SC, et al. Cardiovascular health of Black women before, during, and after pregnancy: a call to action and implications for prevention. Curr Cardiovasc Risk Rep 2022 Jul 23;16:171-180. [doi: 10.1007/s12170-022-00703-0]
25. Teede HJ, Bailey C, Moran LJ, Bahri Khomami M, Enticott J, Ranasinha S, et al. Association of antenatal diet and physical activity-based interventions with gestational weight gain and pregnancy outcomes: a systematic review and meta-analysis. JAMA Intern Med 2022 Feb 01;182(2):106-114 [FREE Full text] [doi: 10.1001/jamainternmed.2021.6373] [Medline: 34928300]
26. Cantor AG, Jungbauer RM, McDonagh M, Blazina I, Marshall NE, Weeks C, et al. Counseling and behavioral interventions for healthy weight and weight gain in pregnancy: evidence report and systematic review for the US preventive services task force. JAMA 2021 May 25;325(20):2094-2109. [doi: 10.1001/jama.2021.4230] [Medline: 34032824]
27. Raab R, Geyer K, Zagar S, Hauner H. App-supported lifestyle interventions in pregnancy to manage gestational weight gain and prevent gestational diabetes: scoping review. J Med Internet Res 2023 Nov 10;25:e48853 [FREE Full text] [doi: 10.2196/48853] [Medline: 37948111]

28. Mertens L, Braeken MA, Bogaerts A. Effect of lifestyle coaching including telemonitoring and telecoaching on gestational weight gain and postnatal weight loss: a systematic review. Telemed J E Health 2019 Oct;25(10):889-901. [doi: 10.1089/tmj.2018.0139] [Medline: 30523742]
29. Phelan S, Brannen A, Erickson K, Diamond M, Schaffner A, Muñoz-Christian K, et al. 'Fit moms/mamás activas' internet-based weight control program with group support to reduce postpartum weight retention in low-income women: study protocol for a randomized controlled trial. Trials 2015 Feb 25;16:59 [FREE Full text] [doi: 10.1186/s13063-015-0573-9] [Medline: 25887964]
30. Liu J, Wilcox S, Hutto B, Turner-McGrievy G, Wingard E. Effects of a lifestyle intervention on postpartum weight retention among women with elevated weight. Obesity (Silver Spring) 2022 Jul;30(7):1370-1379 [FREE Full text] [doi: 10.1002/oby.23449] [Medline: 35722816]
31. Yuhas M, Moore CF, Garay J, Brown SD. Improving maternal cardiovascular health in underserved populations: a narrative review of behavioral intervention trials targeting postpartum weight retention. Curr Atheroscler Rep 2022 Sep;24(9):689-699 [FREE Full text] [doi: 10.1007/s11883-022-01045-3] [Medline: 35781777]
32. Lim S, Hill B, Teede HJ, Moran LJ, O'Reilly S. An evaluation of the impact of lifestyle interventions on body weight in postpartum women: a systematic review and meta-analysis. Obes Rev 2020 Apr;21(4):e12990. [doi: 10.1111/obr.12990] [Medline: 31914234]
33. Coughlin JW, Martin LM, Henderson J, Dalcin AT, Fountain J, Wang NY, et al. Feasibility and acceptability of a remotely-delivered behavioural health coaching intervention to limit gestational weight gain. Obes Sci Pract 2020 Jul 16;6(5):484-493 [FREE Full text] [doi: 10.1002/osp4.438] [Medline: 33082990]
34. Bennett WL, Coughlin JW, Henderson J, Martin S, Yazdy GM, Drabo EF, et al. Healthy for two/healthy for you: design and methods for a pragmatic randomized clinical trial to limit gestational weight gain and prevent obesity in the prenatal care setting. Contemp Clin Trials 2022 Feb;113:106647 [FREE Full text] [doi: 10.1016/j.cct.2021.106647] [Medline: 34896296]
35. Michel S, Raab R, Drabsch T, Günther J, Stecher L, Hauner H. Do lifestyle interventions during pregnancy have the potential to reduce long-term postpartum weight retention? A systematic review and meta-analysis. Obes Rev 2019 Apr;20(4):527-542. [doi: 10.1111/obr.12809] [Medline: 30548769]
36. Haughton CF, Silfee VJ, Wang ML, Lopez-Cepero AC, Estabrook DP, Frisard C, et al. Racial/ethnic representation in lifestyle weight loss intervention studies in the United States: a systematic review. Prev Med Rep 2018 Feb 02;9:131-137 [FREE Full text] [doi: 10.1016/j.pmedr.2018.01.012] [Medline: 29616185]
37. Hill B. Expanding our understanding and use of the ecological systems theory model for the prevention of maternal obesity: a new socioecological framework. Obes Rev 2021 Mar;22(3):e13147. [doi: 10.1111/obr.13147] [Medline: 33000890]
38. Duran B, Oetzel J, Magarati M, Parker M, Zhou C, Roubideaux Y, et al. Toward health equity: a national study of promising practices in community-based participatory research. Prog Community Health Partnersh 2019;13(4):337-352 [FREE Full text] [doi: 10.1353/cpr.2019.0067] [Medline: 31866589]
39. Home visiting evidence of effectiveness review: summary. HomVEE. 2023. URL: https://homvee.acf.hhs.gov/sites/default/files/2023-11/homvee-summary-brief-nov2023.pdf [accessed 2023-09-15]
40. Michalopoulos C, Faucetta K, Warren A, Mitchell R. Evidence on the long-term effects of home visiting programs: laying the groundwork for long-term follow-up in the mother and infant home visiting program evaluation (MIHOPE). Office of Planning, Research and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services. 2017. URL: https://www.acf.hhs.gov/opre/report/evidence-long-term-effects-home-visiting-programs-laying-groundwork-long-term-follow [accessed 2023-09-15]
41. Haire-Joshu D, Schwarz CD, Steger-May K, Lapka C, Schechtman K, Brownson RC, et al. A randomized trial of weight change in a national home visiting program. Am J Prev Med 2018 Mar;54(3):341-351 [FREE Full text] [doi: 10.1016/j.amepre.2017.12.012] [Medline: 29455756]
42. Tabak RG, Morshed AB, Schwarz CD, Haire-Joshu D. Impact of a healthy weight intervention embedded within a national home visiting program on the home food environment. Front Public Health 2018 Jun 26;6:178 [FREE Full text] [doi: 10.3389/fpubh.2018.00178] [Medline: 29998092]
43. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Med Care 2012 Mar;50(3):217-226 [FREE Full text] [doi: 10.1097/MLR.0b013e3182408812] [Medline: 22310560]
44. Curran GM, Landes SJ, McBain SA, Pyne JM, Smith JD, Fernandez ME, et al. Reflections on 10 years of effectiveness-implementation hybrid studies. Front Health Serv 2022 Dec 08;2:1053496 [FREE Full text] [doi: 10.3389/frhs.2022.1053496] [Medline: 36925811]
45. Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. Jt Comm J Qual Patient Saf 2008 Apr;34(4):228-243. [doi: 10.1016/s1553-7250(08)34030-6] [Medline: 18468362]
46. Damschroder LJ, Reardon CM, Widerquist MA, Lowery J. The updated consolidated framework for implementation research based on user feedback. Implement Sci 2022 Oct 29;17(1):75 [FREE Full text] [doi: 10.1186/s13012-022-01245-0] [Medline: 36309746]

47. Key KD, Furr-Holden D, Lewis EY, Cunningham R, Zimmerman MA, Johnson-Lawrence V, et al. The continuum of community engagement in research: a roadmap for understanding and assessing progress. Prog Community Health Partnersh 2019;13(4):427-434. [doi: 10.1353/cpr.2019.0064] [Medline: 31866597]
48. Lee EW, McCloud RF, Viswanath K. Designing effective eHealth interventions for underserved groups: five lessons from a decade of eHealth intervention design and deployment. J Med Internet Res 2022 Jan 07;24(1):e25419 [FREE Full text] [doi: 10.2196/25419] [Medline: 34994700]
49. Naderbagi A, Loblay V, Zahed IU, Ekambareshwar M, Poulsen A, Song YJ, et al. Cultural and contextual adaptation of digital health interventions: narrative review. J Med Internet Res 2024 Jul 09;26:e55130 [FREE Full text] [doi: 10.2196/55130] [Medline: 38980719]
50. Ramasawmy M, Poole L, Thorlu-Bangura Z, Chauhan A, Murali M, Jagpal P, et al. Frameworks for implementation, uptake, and use of cardiometabolic disease-related digital health interventions in ethnic minority populations: scoping review. JMIR Cardio 2022 Aug 11;6(2):e37360 [FREE Full text] [doi: 10.2196/37360] [Medline: 35969455]
51. Alsswey AH, Al-Samarraie H, El-Qirem FA, Alzahrani AI, Alfarraj O. Culture in the design of mHealth UI: an effort to increase acceptance among culturally specific groups. Electron Libr 2020 Mar 27;38(2):257-272. [doi: 10.1108/EL-04-2019-0097]
52. Rothwell PM. External validity of randomised controlled trials: "to whom do the results of this trial apply?". Lancet 2005 Jan;365(9453):82-93. [doi: 10.1016/S0140-6736(04)17670-8] [Medline: 15639683]
53. Khan SS, Brewer LC, Canobbio MM, Cipolla MJ, Grobman WA, Lewey J, et al. Optimizing prepregnancy cardiovascular health to improve outcomes in pregnant and postpartum individuals and offspring: a scientific statement from the American Heart Association. Circulation 2023 Feb 14;147(7):e76-e91 [FREE Full text] [doi: 10.1161/CIR.0000000000001124] [Medline: 36780391]
54. Barroso CS, Yockey A, Degon E, Gautam Poudel P, Brown SD, Hedderson MM, et al. Efficacious lifestyle interventions for appropriate gestational weight gain in women with overweight or obesity set in the health care system: a scoping review. J Matern Fetal Neonatal Med 2022 Dec;35(25):6411-6424 [FREE Full text] [doi: 10.1080/14767058.2021.1914576] [Medline: 34034608]
55. Harrison CL, Bahri Khomami M, Enticott J, Thangaratinam S, Rogozinska E, Teede HJ. Key components of antenatal lifestyle interventions to optimize gestational weight gain: secondary analysis of a systematic review. JAMA Netw Open 2023 Jun 01;6(6):e2318031 [FREE Full text] [doi: 10.1001/jamanetworkopen.2023.18031] [Medline: 37326994]
56. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009 Apr;42(2):377-381 [FREE Full text] [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]
57. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, et al. The REDCap consortium: building an international community of software platform partners. J Biomed Inform 2019 Jul;95:103208 [FREE Full text] [doi: 10.1016/j.jbi.2019.103208] [Medline: 31078660]
58. Butryn ML, Webb V, Wadden TA. Behavioral treatment of obesity. Psychiatr Clin North Am 2011 Dec;34(4):841-859. [doi: 10.1016/j.psc.2011.08.006] [Medline: 22098808]
59. Bandura A. Health promotion from the perspective of social cognitive theory. Psychol Health 1998;13(4):623-649. [doi: 10.1080/08870449808407422]
60. Alberga AS, Edache IY, Forhan M, Russell-Mayhew S. Weight bias and health care utilization: a scoping review. Prim Health Care Res Dev 2019 Jul 22;20:e116 [FREE Full text] [doi: 10.1017/S1463423619000227] [Medline: 32800008]
61. Brown A, Flint SW, Batterham RL. Pervasiveness, impact and implications of weight stigma. EClinicalMedicine 2022 May;47:101408 [FREE Full text] [doi: 10.1016/j.eclinm.2022.101408] [Medline: 35497065]
62. DeJoy SB, Bittner K. Obesity stigma as a determinant of poor birth outcomes in women with high BMI: a conceptual framework. Matern Child Health J 2015 Apr 22;19(4):693-699. [doi: 10.1007/s10995-014-1577-x] [Medline: 25047786]
63. Wolever RQ, Simmons LA, Sforzo GA, Dill D, Kaye M, Bechard EM, et al. A systematic review of the literature on health and wellness coaching: defining a key behavioral intervention in healthcare. Glob Adv Health Med 2013 Jul;2(4):38-57 [FREE Full text] [doi: 10.7453/gahmj.2013.042] [Medline: 24416684]
64. Haire-Joshu D, Cahill AG, Stein RI, Cade WT, Woolfolk CL, Moley K, et al. Randomized controlled trial of home-based lifestyle therapy on postpartum weight in underserved women with overweight or obesity. Obesity (Silver Spring) 2019 Apr;27(4):535-541 [FREE Full text] [doi: 10.1002/oby.22413] [Medline: 30900408]
65. Harrison CL, Brammall BR, Garad R, Teede H. OptimalMe intervention for healthy preconception, pregnancy, and postpartum lifestyles: protocol for a randomized controlled implementation effectiveness feasibility trial. JMIR Res Protoc 2022 Jun 09;11(6):e33625 [FREE Full text] [doi: 10.2196/33625] [Medline: 35679115]
66. BodyTrace homepage. BodyTrace. URL: https://www.bodytrace.com/medical/ [accessed 2024-02-17]
67. Fernández HJ. Medidas sencillas de lecturabilidad. Consigna 1959;214:29-32.
68. Barrio-Cantalejo IM, Simón-Lorda P, Melguizo M, Escalona I, Marijuán MI, Hernando P. [Validation of the INFLESZ scale to evaluate readability of texts aimed at the patient]. An Sist Sanit Navar 2008;31(2):135-152 [FREE Full text] [doi: 10.4321/s1137-66272008000300004] [Medline: 18953362]
69. McLaughlin GH. SMOG grading: a new readability formula. J Read 1969 May;12(8):639-646.

70. Henrich N, Brinson A, Arnold A, Jahnke HR. Digital health needs and preferences during pregnancy and the postpartum period: mixed methods study. JMIR Form Res 2024 Jan 12;8:e48960 [FREE Full text] [doi: 10.2196/48960] [Medline: 38214971]
71. Ayyala MS, Coughlin JW, Martin L, Henderson J, Ezekwe N, Clark JM, et al. Perspectives of pregnant and postpartum women and obstetric providers to promote healthy lifestyle in pregnancy and after delivery: a qualitative in-depth interview study. BMC Womens Health 2020 Mar 04;20(1):44 [FREE Full text] [doi: 10.1186/s12905-020-0896-x] [Medline: 32131832]
72. Stierman EK, Watts T, Lawson SM, Bruce TM, Reed-Vance M, Bower KM, et al. Educating families on urgent maternal warning signs: learning from a pilot to improve training and tools for maternal and child home visiting programs. Health Promot Pract 2024 Jun 13:15248399241256691. [doi: 10.1177/15248399241256691] [Medline: 38872329]
73. Callaghan-Koru JA, Wahid I, Lawson SM, Bower KM, Wilburn CS, Creanga AA. Maternal warning signs education during home visiting: results from a formative evaluation in Maryland. Womens Health Rep (New Rochelle) 2022 Jul 11;3(1):633-642 [FREE Full text] [doi: 10.1089/whr.2022.0027] [Medline: 35982773]
74. Alvidrez J, Castille D, Laude-Sharp M, Rosario A, Tabor D. The national institute on minority health and health disparities research framework. Am J Public Health 2019 Jan;109(S1):S16-S20. [doi: 10.2105/AJPH.2018.304883] [Medline: 30699025]
75. 2020 Census informational questionnaire. United States Census Bureau. 2020. URL: https://www2.census.gov/programs-surveys/decennial/2020/technical-documentation/questionnaires-and-instructions/questionnaires/2020-informational-questionnaire-english_DI-Q1.pdf [accessed 2022-09-13]
76. NIH common data elements. Health Equity Action Network. URL: https://health-equity-action.org/nih-cde [accessed 2024-02-17]
77. Billioux AK, Verlander K, Anthony S, Alley D. Standardized screening for health-related social needs in clinical settings: the accountable health communities screening tool. NAM Perspectives 2017 May 30;7(5). [doi: 10.31478/201705b]
78. Hamilton CM, Strader LC, Pratt JG, Maiese D, Hendershot T, Kwok RK, et al. The PhenX Toolkit: get the most from your measures. Am J Epidemiol 2011 Aug 01;174(3):253-260 [FREE Full text] [doi: 10.1093/aje/kwr193] [Medline: 21749974]
79. Dietary screener questionnaire. National Cancer Institute Division of Cancer Control & Population Sciences. URL: https://epi.grants.cancer.gov/diet/shortreg/instruments/dsq-in-nhanes-09-10-self-administered-english-version.pdf [accessed 2022-09-13]
80. Craig CL, Marshall AL, Sjöström M, Bauman AE, Booth ML, Ainsworth BE, et al. International physical activity questionnaire: 12-country reliability and validity. Med Sci Sports Exerc 2003 Aug;35(8):1381-1395. [doi: 10.1249/01.MSS.0000078924.61453.FB] [Medline: 12900694]
81. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. Br J Psychiatry 1987 Jun;150:782-786. [doi: 10.1192/bjp.150.6.782] [Medline: 3651732]
82. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. J Health Soc Behav 1983 Dec;24(4):385-396. [doi: 10.2307/2136404]
83. Sancho-Domingo C, Carballo JL, Coloma-Carmona A, Buysse DJ. Brief version of the Pittsburgh Sleep Quality Index (B-PSQI) and measurement invariance across gender and age in a population-based sample. Psychol Assess 2021 Feb;33(2):111-121. [doi: 10.1037/pas0000959] [Medline: 33119375]
84. Broadhead WE, Gehlbach SH, de Gruy FV, Kaplan BH. The Duke-UNC functional social support questionnaire. Measurement of social support in family medicine patients. Med Care 1988 Jul;26(7):709-723. [doi: 10.1097/00005650-198807000-00006] [Medline: 3393031]
85. Williams DR, Yan Yu Y, Jackson JS, Anderson NB. Racial differences in physical and mental health: socio-economic status, stress and discrimination. J Health Psychol 1997 Jul;2(3):335-351 [FREE Full text] [doi: 10.1177/135910539700200305] [Medline: 22013026]
86. Pregnancy risk assessment monitoring system (PRAMS). Centers for Disease Control and Prevention. URL: https://www.cdc.gov/prams/index.html [accessed 2022-09-13]
87. Infant feeding practices study (IFPS) II. Center for Disease Control and Prevention. URL: https://www.cdc.gov/breastfeeding-data/studies/questionnaires.html?CDC_AAref_Val=https://www.cdc.gov/breastfeeding/data/ifps/questionnaires.htm [accessed 2024-11-26]
88. Gavin KL, Almeida EJ, Voils CI, Crane MM, Shaw R, Yancy WSJ, et al. Comparison of weight captured via electronic health record and cellular scales to the gold-standard clinical method. Obes Sci Pract 2023 Jan 12;9(4):337-345 [FREE Full text] [doi: 10.1002/osp4.656] [Medline: 37546286]
89. Ross KM, Wing RR. Concordance of in-home "Smart" scale measurement with body weight measured in-person. Obes Sci Pract 2016 Jun;2(2):224-248 [FREE Full text] [doi: 10.1002/osp4.41] [Medline: 27499884]
90. Madigan CD, Jolly K, Roalfe A, Lewis AL, Webber L, Aveyard P, et al. Study protocol: the effectiveness and cost effectiveness of a brief behavioural intervention to promote regular self-weighing to prevent weight regain after weight loss: randomised controlled trial (The LIMIT Study). BMC Public Health 2015 Jun 04;15:530 [FREE Full text] [doi: 10.1186/s12889-015-1869-0] [Medline: 26041653]
91. Krukowski RA, Hare ME, Talcott GW, Johnson KC, Richey PA, Kocak M, et al. Dissemination of the look AHEAD intensive lifestyle intervention in the United States Air Force: study rationale, design and methods. Contemp Clin Trials 2015 Jan;40:232-239 [FREE Full text] [doi: 10.1016/j.cct.2014.12.014] [Medline: 25545025]

92. Williams LB, Moser DK, Gustafson A, Waters TM, Rayens MK, Karle ER, et al. Reaching high-risk Black adults for diabetes prevention programming during a pandemic: the design of Fit and Faithful a randomized controlled community trial. Contemp Clin Trials 2022 Dec;123:106973 [FREE Full text] [doi: 10.1016/j.cct.2022.106973] [Medline: 36334705]
93. Katzmarzyk PT, Martin CK, Newton RLJ, Apolzan JW, Arnold CL, Davis TC, et al. Weight loss in underserved patients - a cluster-randomized trial. N Engl J Med 2020 Sep 03;383(10):909-918 [FREE Full text] [doi: 10.1056/NEJMoa2007448] [Medline: 32877581]
94. Waselewski M, Plegue M, Sonneville K, Resnicow K, Ghumman A, Ebbeling C, et al. Grocery delivery to support healthy weight gain among pregnant young women with low income: protocol for a randomized controlled trial. JMIR Res Protoc 2022 Aug 05;11(8):e40568 [FREE Full text] [doi: 10.2196/40568] [Medline: 35930351]
95. Essed P. Understanding Everyday Racism: An Interdisciplinary Theory. Thousand Oaks, CA: SAGE Publications; 1991.
96. Thompson FE, Midthune D, Kahle L, Dodd KW. Development and evaluation of the National Cancer Institute's dietary screener questionnaire scoring algorithms. J Nutr 2017 Jun;147(6):1226-1233 [FREE Full text] [doi: 10.3945/jn.116.246058] [Medline: 28490673]
97. Sultan P, Ando K, Elkhateb R, George RB, Lim G, Carvalho B, et al. Assessment of patient-reported outcome measures for maternal postpartum depression using the consensus-based standards for the selection of health measurement instruments guideline: a systematic review. JAMA Netw Open 2022 Jun 01;5(6):e2214885 [FREE Full text] [doi: 10.1001/jamanetworkopen.2022.14885] [Medline: 35749118]
98. Cohen S. Perceived stress in a probability sample of the United States. In: Spacapan S, Oskamp S, editors. The Social Psychology of Health. Thousand Oaks, CA: SAGE Publications; 1988.
99. Lee EH. Review of the psychometric evidence of the perceived stress scale. Asian Nurs Res (Korean Soc Nurs Sci) 2012 Dec;6(4):121-127 [FREE Full text] [doi: 10.1016/j.anr.2012.08.004] [Medline: 25031113]
100. Weiner BJ, Lewis CC, Stanick C, Powell BJ, Dorsey CN, Clary AS, et al. Psychometric assessment of three newly developed implementation outcome measures. Implement Sci 2017 Aug 29;12(1):108 [FREE Full text] [doi: 10.1186/s13012-017-0635-3] [Medline: 28851459]
101. Maryland. County Health Rankings & Roadmaps. 2021. URL: https://www.countyhealthrankings.org/health-data/maryland?year=2021&measure=Adult+Obesity [accessed 2022-09-13]
102. Bellg AJ, Borrelli B, Resnick B, Hecht J, Minicucci DS, Ory M, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. Health Psychol 2004 Sep;23(5):443-451. [doi: 10.1037/0278-6133.23.5.443] [Medline: 15367063]
103. Shaw RJ, Steinberg DM, Zullig LL, Bosworth HB, Johnson CM, Davis LL. mHealth interventions for weight loss: a guide for achieving treatment fidelity. J Am Med Inform Assoc 2014;21(6):959-963 [FREE Full text] [doi: 10.1136/amiajnl-2013-002610] [Medline: 24853065]
104. Ferrara A, Hedderson MM, Brown SD, Albright CL, Ehrlich SF, Tsai AL, et al. The comparative effectiveness of diabetes prevention strategies to reduce postpartum weight retention in women with gestational diabetes mellitus: the gestational diabetes' effects on moms (GEM) cluster randomized controlled trial. Diabetes Care 2016 Jan;39(1):65-74 [FREE Full text] [doi: 10.2337/dc15-1254] [Medline: 26657945]
105. Nicklas JM, Zera CA, England LJ, Rosner BA, Horton E, Levkoff SE, et al. A web-based lifestyle intervention for women with recent gestational diabetes mellitus: a randomized controlled trial. Obstet Gynecol 2014 Sep;124(3):563-570 [FREE Full text] [doi: 10.1097/AOG.0000000000000420] [Medline: 25162257]
106. Kenward MG, Roger JH. An improved approximation to the precision of fixed effects from restricted maximum likelihood. Comput Stat Data Anal 2009 May;53(7):2583-2595. [doi: 10.1016/j.csda.2008.12.013]
107. Diggle PJ, Liang KY, Zeger SL. Analysis of Longitudinal Data. New York, NY: Oxford University Press; 1994.
108. Status of state medicaid expansion decisions: interactive map. Kaiser Family Foundation. 2024 Nov 12. URL: https://www.kff.org/affordable-care-act/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/ [accessed 2024-11-26]
109. De las Nueces D, Hacker K, DiGirolamo A, Hicks LS. A systematic review of community-based participatory research to enhance clinical trials in racial and ethnic minority groups. Health Serv Res 2012 Jun 21;47(3 Pt 2):1363-1386 [FREE Full text] [doi: 10.1111/j.1475-6773.2012.01386.x] [Medline: 22353031]
110. Julian McFarlane S, Occa A, Peng W, Awonuga O, Morgan SE. Community-based participatory research (CBPR) to enhance participation of racial/ethnic minorities in clinical trials: a 10-year systematic review. Health Commun 2022 Aug 22;37(9):1075-1092. [doi: 10.1080/10410236.2021.1943978] [Medline: 34420460]
111. Salimi Y, Shahandeh K, Malekafzali H, Loori N, Kheiltash A, Jamshidi E, et al. Is community-based participatory research (CBPR) useful? A systematic review on papers in a decade. Int J Prev Med 2012 Jun;3(6):386-393 [FREE Full text] [Medline: 22783464]
112. Esmail L, Moore E, Rein A. Evaluating patient and stakeholder engagement in research: moving from theory to practice. J Comp Eff Res 2015 Mar;4(2):133-145 [FREE Full text] [doi: 10.2217/cer.14.79] [Medline: 25825842]
113. Frank L, Forsythe L, Ellis L, Schrandt S, Sheridan S, Gerson J, et al. Conceptual and practical foundations of patient engagement in research at the patient-centered outcomes research institute. Qual Life Res 2015 May;24(5):1033-1041 [FREE Full text] [doi: 10.1007/s11136-014-0893-3] [Medline: 25560774]

114. Wallerstein N, Duran B. Community-based participatory research contributions to intervention research: the intersection of science and practice to improve health equity. Am J Public Health 2010 Apr 01;100 Suppl 1(Suppl 1):S40-S46. [doi: 10.2105/AJPH.2009.184036] [Medline: 20147663]
115. Wallerstein NB, Duran B. Using community-based participatory research to address health disparities. Health Promot Pract 2006 Jul;7(3):312-323 [FREE Full text] [doi: 10.1177/1524839906289376] [Medline: 16760238]
116. Cargo M, Mercer SL. The value and challenges of participatory research: strengthening its practice. Annu Rev Public Health 2008;29:325-350. [doi: 10.1146/annurev.publhealth.29.091307.083824] [Medline: 18173388]
117. Westfall JM, Fagnan LJ, Handley M, Salsberg J, McGinnis P, Zittleman LK, et al. Practice-based research is community engagement. J Am Board Fam Med 2009;22(4):423-427 [FREE Full text] [doi: 10.3122/jabfm.2009.04.090105] [Medline: 19587257]
118. Getrich CM, Sussman AL, Campbell-Voytal K, Tsoh JY, Williams RL, Brown AE, et al. Cultivating a cycle of trust with diverse communities in practice-based research: a report from PRIME Net. Ann Fam Med 2013 Nov 11;11(6):550-558 [FREE Full text] [doi: 10.1370/afm.1543] [Medline: 24218379]
119. Frerichs L, Kim M, Dave G, Cheney A, Hassmiller Lich K, Jones J, et al. Stakeholder perspectives on creating and maintaining trust in community-academic research partnerships. Health Educ Behav 2017 Feb 09;44(1):182-191 [FREE Full text] [doi: 10.1177/1090198116648291] [Medline: 27230272]
120. Power JM, Phelan S, Hatley K, Brannen A, Muñoz-Christian K, Legato M, et al. Engagement and weight loss in a web and mobile program for low-income postpartum women: Fit Moms/ Mamás Activas. Health Educ Behav 2019 Dec;46(2_suppl):114-123. [doi: 10.1177/1090198119873915] [Medline: 31742447]
121. VanWormer JJ, Martinez AM, Martinson BC, Crain AL, Benson GA, Cosentino DL, et al. Self-weighing promotes weight loss for obese adults. Am J Prev Med 2009 Jan;36(1):70-73. [doi: 10.1016/j.amepre.2008.09.022] [Medline: 18976879]

Abbreviations

CFIR: Consolidated Framework for Implementation Research
GWG: gestational weight gain
H42-HV: Healthy for Two–Home Visiting
MDD: minimum detectable difference
mHealth: mobile health
PPWR: postpartum weight retention
PRAMS: Pregnancy Risk Assessment and Monitoring System
PRISM: practical, robust implementation and sustainability model
REDCap: Research Electronic Data Capture
SMART: specific, measurable, achievable, relevant, and time-bound

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