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A Mixed Methods Study to Develop and Evaluate a Lay Health Worker Delivered Implementation Intervention to Decrease Engagement Disparities in Behavioral Parent Training

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Abstract

Introduction: Behavioral parent training programs (BPTs) are effective in preventing and treating early-onset conduct problems and child maltreatment. Unfortunately, pervasive mental health service disparities continue to limit access to and engagement in these interventions. Furthermore, challenges with parental engagement can impede the successful implementation of evidence-based practices (EBPs) in community settings that serve low-income, ethnic minority families. Lay health workers (LHWs)-- individuals without formal mental health training-- represent an important workforce to increase engagement, as they are members of the communities they serve. However, the mobilization of LHWs has not been well studied as an implementation strategy to extend the reach or effectiveness of EBPs in the United States. LHW-delivered implementation interventions that specifically support the engagement of Latinx parents in evidence-based BPTs have the potential to improve clinical and implementation outcomes.

Methods and Analysis: A community-partnered approach will use the Quality Implementation Framework[1] to tailor and implement a LHW-delivered implementation intervention that aims to promote Latinx parent engagement in BPTs. Steps from the QIF will guide study activities to: 1) conduct a mixed methods needs assessment to fit the implementation intervention to the local context, 2) adapt LHW delivered implementation strategies to promote parent access to and engagement in Parent-Child Interaction Therapy, and 3) conduct a hybrid effectiveness-implementation pilot trial to examine the feasibility, acceptability, and preliminary effectiveness of the LHW implementation intervention at increasing engagement.

Ethics and dissemination: Study procedures have been approved by institutional review board (IRB) at the University of California, Santa Barbara. Results will be shared with the community-

advisory group, at community-based meetings for other stakeholders involved in the pilot project, and submitted for publication in peer-reviewed journals.

Article Summary

Strengths and Limitations of this Study

- This study seeks to develop and test an implementation intervention to address the impact of underutilization and poor engagement in BPTs, which limit their clinical effectiveness and successful implementation and sustainment.
- This study aims to improve mobilization of LHWs, who may be able to offer cultural and linguistic bridges to reach diverse families, as a potential solution to address racial/ethnic disparities in engagement in BPTs.
- As a pilot, this study is limited in its sample size to determine the effectiveness of the implementation intervention.
- This study will be limited in its generalizability due to the small sample size, the focus on one BPT (Parent-Child Interaction Therapy), and the characteristics of the local context.

Keywords: Lay Health Workers, Implementation Strategies, Behavioral Parent Training, Mental Health Disparities

Introduction

Early onset conduct problems and child maltreatment have been shown to have enormous personal and societal costs, including long-term mental health and substance abuse problems, higher service utilization, and future abuse against women and children.[2–4] Given that behavioral parent training programs (BPTs) have been shown to be effective at preventing and treating both child maltreatment[5] and conduct problems,[6] large systems of care have invested millions of dollars in the implementation of these interventions.[7,8] Even with major implementation efforts, challenges remain with engagement and retention of families in BPTs.[9,10] Less than half of eligible families enroll in BPTs when they are available,[9] and attrition rates can exceed 65% in community settings.[11–13] The consequences of poor participation in BPTs are significant for individuals and service systems. Families who drop out of treatment are less likely to experience improvements in parenting skills or child disruptive behaviors.[14] Moreover, failed efforts to recruit and retain parents are costly for providers.[7,8,15] Frequent cancellations and no-shows leads to fewer billable hours for community agencies, which are often under immense financial pressure.[15,16] Further, when agencies have inadequate referrals for an evidence-based practice (EBP), such as BPTs, therapists may not learn to deliver the practice with fidelity.[7,8,17] In order to meet the public health potential of BPTs, implementation interventions are needed to support parental engagement. Implementation interventions, which are usually complex and multilevel, include strategies to enhance the adoption and ongoing implementation of clinical interventions at the organization, provider, and consumer levels.[18]

Addressing Mental Health Service Disparities

Accumulating evidence suggests that BPTs are effective in "real world" settings [19] and with Latinx, African American, and Asian families.[20–22] However, significant mental health

service disparities have been documented for racial and ethnic minority children.[23–25] For example, African American and Latinx children are almost 50% less likely than non-Latinx, White children to receive mental health services for externalizing disorders.[24] Negative attitudes, social norms about mental health treatment, and structural barriers to care (e.g., lack of transportation) all influence help-seeking amongst underserved parents.[26, 27] Beyond challenges that impact the demand for BPTs, systemic barriers limit the supply of these EBPs. Organizational factors that impact service delivery include challenges recruiting and retaining staff that can provide culturally and linguistically appropriate services. Further, mental health professionals often have competing demands on their time beyond their clinical services (e.g., billing, outreach), which limits the number of families they are able to serve.[28] As such, implementation interventions may need to be developed to improve engagement in BPTs for ethnic minority parents to achieve improved engagement.

Powell and colleagues[29] have identified multiple implementation strategies, which focus on increasing consumer engagement with EBPs, including: 1) increasing demand for EBPs, 2) intervening with consumers to enhance uptake and adherence, and 3) preparing consumers to be active participants in their treatment. These implementation strategies are consistent with evidence-based approaches to improve engagement in children's mental health care, which include assessment of barriers, accessibility promotion (e.g., providing child-care or services in the home), psychoeducation about services, and appointment reminders.[30,31] However, limited research has examined whether and how these consumer-facing strategies might increase the success of EBP implementation.

Lay Health Workers (LHWs) have been identified as an important paraprofessional workforce to address service disparities for underserved, low-resource communities.[32] LHWs

(which encompass a range of other titles including: *promotores*, community health workers, peer support partners, wellness navigators, and natural helpers) are individuals without formal mental health training, who have roles intended to increase their community's access to and benefit from services.[33,34] LHWs have the potential to address both demand and supply drivers of disparities in EBP delivery, as illustrated in Figure 1.[32] Demand for EBPs, or the willingness to access services and persist in care, is impacted by an individual's mental health literacy, stigma towards mental illness and help seeking, perceptions of treatment providers, and culturally based beliefs and preferences.[28,35] Systemic barriers to care may exacerbate disparities in seeking and accessing care. For example, undocumented immigrants are especially unlikely to seek mental health services due to fear of being reported to authorities and being discriminated against.[36] Since LHWs come from similar cultural and personal backgrounds as the individuals they serve, they may be especially adept at helping patients overcome distrust of health systems.[37] Regarding supply, the number of professional mental health providers who can deliver linguistically and culturally competent EBPs is inadequate.[38] Furthermore, bilingual, bicultural mental health professionals are frequently tasked with time-consuming demands that extend beyond providing psychotherapeutic interventions, to promote EBP engagement for their underserved communities, such as conducting outreach and case management.[17] The time spent on these tasks might limit the number of individuals they are able to serve. If LHWs are trained to deliver these auxiliary services, it could reduce the burden on mental health professionals and allow them to focus on activities that require advanced training and licensure, such as direct mental health services.[39] However, limited research has focused on how LHW-delivered strategies impact implementation and clinical outcomes of EBPs and if they successfully reduce disparities in engagement. Furthermore, research on LHWs has not consistently reported the

implementation supports (e.g., training and consultation) that are necessary for this non-professional workforce to deliver or support EBPs.[32,34]

The majority of mental health research with LHWs has been conducted in low- and middle-income countries, with emerging evidence that LHWs can improve mental health outcomes when they are tasked with delivering EBPs.[34,40,41] Given that LHWs have effectively addressed mental health disparities globally, it is imperative that this knowledge is translated to increase parity in mental health care for underserved children and families in the United States. LHWs likely will fulfill different roles in high-income countries as compared to low- and middle-income countries where LHWs typically deliver the EBPs using a task-shifting model.[34,40] Domestically, licensure and certification requirements frequently restrict EBP delivery to mental health professionals, requiring LHWs to have complementary and distinct roles within the provision of EBPs.[10,32] As trusted members of the community, LHW are particularly well suited to deliver implementation strategies that focus on promoting parent entry into and engagement in care (e.g., outreach and adherence promotion).[29,31,32] LHW models of care delivery show great potential to address mental health disparities domestically for underserved children and families; however, significant gaps in the literature limit our understanding of how to effectively mobilize LHW within community mental health services. The proposed study seeks to address these gaps through the development and evaluation of LHWs Enhancing Engagement for Parents (LEEP), an implementation intervention to improve engagement for low-income, Latinx parents into one BPT, Parent-Child Interaction Therapy (PCIT).[42]

Parent-Child Interaction Therapy

PCIT has unique benefits and challenges related to engaging parents in treatment. The treatment model uses in vivo feedback (i.e., coaching) to overcome challenges that are inherent to teaching methods used in other BPTs (e.g., didactics, discussion) as it necessitates active participation and assesses learning in real time. PCIT requires that parents demonstrate a high-level of proficiency with the targeted parenting skills before they advance from the first phase of treatment, which focuses on enhancing the parent-child relationship, to the second phase of treatment, which focuses on effective and developmentally appropriate limit setting and discipline approaches, and then until they graduate from treatment.[42] Mastery-based criteria guarantees that all parents can successfully use the skills by the time they complete treatment; however, parents often drop out before they learn limit-setting and discipline skills,[11] which are necessary for long-term decreases in disruptive behaviors.[14] Furthermore, some research suggests that low-income, ethnic and racial minority parents require more practice and time in treatment to reach this level of skill proficiency.[20],[43],[44] Problems with family attendance, retention, and prolonged skill acquisition have downstream effects on PCIT provider implementation outcomes in systems of care. It can take up to three years for mental health professionals to meet PCIT certification requirements (i.e., achieving fidelity and graduating two cases).[45] Thus, low parental engagement results in provider attrition from training, which in turn compromises the sustainability of the intervention, and limits the return on costly investments made to implement PCIT in public service systems.[7,8]

LEEP seeks to improve the supply of and demand for PCIT in agencies that predominately serve low-income, Latinx immigrant families, and address engagement challenges that impact clinical and implementation outcomes (Figure 1). LEEP will be compared to PCIT implementation-as-usual to see if parental engagement and implementation challenges are

ameliorated. A community-partnered approach will focus on making LEEP a feasible and acceptable implementation intervention, with the following three aims:

Aim 1: Assess the current context of LHW mobilization in children's mental health services, to inform an implementation intervention (i.e., LEEP) focused on improving parental service entry and engagement in BPT.

Aim 2: Through community-partnership, develop a structure for the implementation of LEEP in publicly-funded, children's mental health settings.

Aim 3: Evaluate the feasibility of implementing LEEP in community mental health agencies through a pilot effectiveness-implementation trial.

Methods and Analysis

Conceptual Framework and Approach

The Quality Implementation Framework (QIF), which includes four phases to support high quality implementation, informs the three study aims and plans for scaling-up LEEP (Figure 2).[1] The first phase of the QIF focuses on various assessment strategies related to organizational needs, innovation-organizational fit, and a capacity or readiness assessment. In Aim 1, these assessments will be conducted through survey data and stakeholder interviews. Phase 2 in the QIF focuses on the development of implementation structures, which will occur during the second aim of this study through the input of a community-advisory group. The community-advisory group will collaboratively help to develop an implementation plan delineating tasks and timelines to establish infrastructure for LHW capacity building, including job descriptions, training plans, and measurement development. Phase 3 of the QIF includes three main activities that will take place during a hybrid type 2 effectiveness-implementation pilot stepped-wedge trial of LEEP. These activities include (1) providing implementation support strategies (e.g.,

supervision and consultation) to LHWs, (2) conducting a process evaluation to identify successes and barriers to implementation (e.g., implementation costs, number of families enrolled in PCIT), and (3) providing ongoing feedback to organizations about the impact LEEP is having on service outcomes. Finally Aim 3 activities will inform Phase 4 of the QIF, which focuses on learning from initial implementation experiences to inform future efforts to scale-up and sustain LEEP.

Aim 1: Assess the current context of LHW mobilization in children's mental health services, to inform the implementation of the LEEP model.

Participants. Surveys will be administered to LHWs employed or contracted by children's mental health agencies in two counties in California. Approximately 70 to 100 LHWs will be recruited to complete the quantitative survey. Based on a national survey of LHW[46] and California's demographics, LHW are expected to be Latinx, female, and have below a college level of education. Ten agency community mental health agency leaders and 25-30 LHW will be invited to participate in hour-long interviews to expand on the findings from the survey. As LHWs may be monolingual Spanish speakers, survey and interviews will be offered in Spanish or English.

Procedure. A mixed-method needs assessment will be conducted to understand how LHWs are currently mobilized in children's community mental health settings, with the purpose of adapting LEEP to fit within the local context. Surveys will provide a breadth of information and qualitative interviews will provide depth of information, to understand perceived barriers to parental engagement in children's mental health services, LHW roles and integration into services, and LHW knowledge about and attitudes towards BPTs and evidence-based engagement strategies.

Survey measures. Surveys will be collected via electronic or paper-and-pencil survey based on LHW preferences.

LHW characteristics.[47] A demographic questionnaire will provide information about the LHWs personal characteristics, including gender, race/ethnicity, country of origin, educational level, and years of experience as an LHW.

Cultural background questionnaire.[48] The Cultural Background Questionnaire is a 19-item self-report measure used to assess therapist generational status and acculturation, including cultural identity (i.e., U.S. identity and Heritage Cultural Identity) and language use.

Parental engagement.[49],[50] A questionnaire that was developed to measure provider's perceptions of and strategies for engaging fathers has been adapted to measure LHW's perceptions of barriers to engagement, strategies for engagement, and confidence in engagement for parents. Instead of solely investigating father engagement, the questionnaire included perceived barriers in engagement for parents in general, and the LHW's use of and confidence with engagement strategies for both mothers and fathers.

Attitudes towards BPT strategies. A four-item questionnaire was developed for this study to measure LHWs attitudes towards (e.g., *"It is important to teach parents how to…"*) teaching parents common strategies targeted in BPTs including play to improve the parent-child relationship, praise of positive behaviors, ignoring minor misbehaviors, and time-out as a form of discipline.

EBP questionnaire.[51] A questionnaire developed to measure service broker's knowledge of and referrals to EBPs has been adapted to identify if LHWs are aware of, making referrals to, and supporting families involved specifically in PCIT(e.g., *"Have you referred parents to Parent-Child Interaction Therapy (PCIT)"*).

Semi-Structured Interviews. Interview guides will include topics, questions, and probes related to LHW roles, training needs, and experiences and attitudes related to BPTs. Questions will investigate how LHWs became involved in mental health or family support services, descriptions of their job responsibilities, their perceptions of parenting practices targeted in BPTs, their formal and informal preparation for their position, and their training needs. Interviews with agency leaders will focus on how LHW are integrated into services, LHW training, outreach and engagement strategies and challenges with Latinx families, and financing strategies for LHW. A "funnel-approach" will be used with broad-open ended questions related to roles, trainings, and attitudes asked first, followed with specific probes to elicit details.[52]

Analysis. A QUAN + QUAL mixed methods design will be used, with quantitative and qualitative data collected simultaneously and given equal weight in analyses. Combined analyses will be used for *complementarity*, with the surveys providing a breadth of information and the interviews providing depth of understanding. Using recommendations for mixed-method design in implementation science, datasets will be merged with qualitative responses included next to quantitative ratings (i.e., triangulation) to analyze if the qualitative and quantitative data provide the same answer to the same question (i.e., convergence), and qualitative data will provide understanding to unexpected quantitative findings (i.e., expansion).[53] Interviews will be transcribed and entered into *NVivo*, software that aids the coding, organization, and retrieval of codes. An iterative process will be used where the coding team first develops a preliminary coding scheme and applies it to a sample text to ensure all relevant themes are captured. Once a final coding scheme is decided upon, coders will apply the final code list to all transcripts. Regular meetings with the coding team will be conducted to examine coding across analysts, resolve differences in coding, conduct iterative refinement of code definitions and the logic of

the coding tree, and collaborate on the development of themes. Qualitative themes will be identified through analysis of co-occurring codes and text analysis.[54,55]

Aim 2: Through community-partnership, develop a structure for the implementation of LEEP in publicly-funded, children's mental health settings.

Participants. A community-advisory group with 6-9 stakeholders will be formed to make sure that implementation supports match the unique local context. Agency leaders, PCIT therapists, and LHWs will be represented in the advisory group. Given the wide diversity of viewpoints, education levels, and ethnicities, efforts will be made to provide each participant with equal representation, opportunities for contribution, and honorariums.

Procedure. In line with the Model of Research-Community Partnership, which was specifically developed for research in children's mental health services, the formation of the partnership will focus on building relationships, trust, establishing a joint mission, and identifying roles and responsibilities of different partner members. This will provide the foundation to build a synergistic, collaborative relationship focused on developing and delivering LEEP, which in turn could improve the successful and sustained implementation of PCIT.[56] Using data from Aim 1 and in collaboration with the community-advisory group, the LEEP implementation intervention will be adapted from an existing protocol focused on LHW-delivered parent outreach and engagement strategies. This protocol was developed to increase access to PCIT in a low-income, Latinx community in the Southeastern United States, but has not been disseminated to other communities.[47] The implementation supports needed for LHWs to deliver LEEP also will be identified and put into place. Steps from the QIF will be used to guide the activities of the community-advisory group in adapting these materials and developing LEEP's implementation structure.[1] Advisory group meetings will include: 1) trust building

activities, 2) developing a shared mission statement, 3) providing feedback on adaptations needed for LEEP materials, 4) advisory group providing feedback and additional interpretation of survey and interview results from Aim 1, 5) development of an implementation plan that has specific tasks, roles, and a timeline for LEEP implementation, and 6) developing tracking systems to monitor LEEP implementation.

Aim 3: Examine the feasibility of LEEP on LHW, clients, and system level targets and outcomes.

In Aim 3, an effectiveness/ implementation hybrid design (Type 2) pilot study will integrate qualitative and quantitative data to examine the feasibility of delivering and scaling-up LEEP. Type 2 hybrid trials simultaneously measure the clinical effectiveness of an intervention, in this case PCIT, and the feasibility and utility of an implementation intervention, which is LEEP.[57] Pilot studies are limited in their ability to test effectiveness given small sample sizes, but they provide a critical phase of research design that can examine the feasibility of the approach to be used in a large-scale study.[58] A focus will be placed on measuring engagement outcomes at a client- and agency-levels to evaluate if LEEP is increasing the reach of PCIT services, service entry, and family treatment engagement.

Procedure. Three agency sites that provide PCIT will be involved in this pilot study, which will use a stepped wedge design. In a stepped wedge design, a period of baseline measurement will occur for all sites, in which PCIT will be implemented-as-usual. Then at subsequent time points each site will be randomized to LEEP and response to the intervention will be measured for client and implementation outcomes (Figure 3). At each agency, one to two LHWs (4-6 total) will be trained to deliver LEEP. Client and implementation outcomes will be collected during PCIT implementation-as-usual and LEEP implementation.

Participants. Four to six LHWs will be trained to provide LEEP. These LHWs will provide LEEP care extension services to approximately PCIT clients each (16-24 families). LHWs will be trained to provide informed consent for parents. Families that participate in LEEP or PCIT implementation-as-usual will meet criteria for receiving this BPT. This includes having a child between the ages of 2 to 7 and presenting problems consistent with disruptive behaviors, or risk for child maltreatment.

LEEP Intervention. The LEEP intervention will include components for LHWs to increase referrals for families to treatment, address barriers to care, and support parents use of skills taught in PCIT within community settings. LHWs will conduct community presentations about PCIT in locations with parents of young children (e.g., Head Start Centers) and health fairs to increase service entry. LHWs will be provided with electronic tablets with e-books that included scripts and videos to use in one-on-one meetings with parents before they enter into care and while they are receiving PCIT services. The e-books will have materials to help LHWs promote enrollment (e.g., parent testimonials), homework adherence, and skill practice (e.g., video demonstrations of the targeted parenting skills).

Effectiveness outcome measures. Given that PCIT is an assessment-driven BPT, clinical outcomes will be assessed using standard measures that are collected as part of the routine PCIT protocol. Parents will not complete any additional measures for this study.

Engagement. To assess if LEEP impacts engagement at the family-level, session attendance, the percentage of days that daily skill was completed, graduation from PCIT, and the number of sessions needed to graduate will be assessed.

The Dyadic Parent-Child Interaction Coding System (DPICS).[59] The DPICS is a behavioral observation coding system that was designed to measure the quality of interaction in

parent-child dyads, which has good interrater reliability. This study will use the DPICS categories, *Behavior Description, Labeled Praise, Unlabeled Praise, Reflection, Question, Negative Talk, and Indirect and Direct Commands,* to determine when the parent's skill acquisition.

Eyberg Child Behavior Inventory (ECBI). The ECBI (Eyberg & Pincus, 1999) is a 36-item parent-rating scale of disruptive behavior problems for children between the ages of 2 to 16. Parents rate the frequency of each disruptive behavior on a 7-point Likert scale ranging from *never* (1) to *always* (7), which are summed to yield the Intensity Scale and whether this behavior is a problem for them, with the total number of Yes responses yielding the Problem Scale.

Implementation outcomes. Using the implementation outcomes outlined by Proctor and colleagues,[60] this study uses mixed methods to understand the acceptability, appropriateness, feasibility, reach, and costs of delivering LEEP.

***LHW-level outcomes*.** To measure changes in LHW knowledge, perceptions of acceptability and feasibility of PCIT, and competence, LHW will complete pre- and post- self-report and behavioral measures (Table 1). Ongoing fidelity monitoring will be conducted throughout LHW's delivery of LEEP. Fidelity monitoring will include reviewing data capture of the ebook created for LEEP, which will include videos about PCIT and scripts for the LHWs to use with the families they serve. LHWs will also use the iPads that house the ebooks to audio record their sessions. Audio recordings will be used to monitor fidelity to the LEEP model, including addressing barriers to home practice, modeling PCIT skills, conducting skills practice with parents, and providing feedback for skills.

Implementation costs. Costs associated with delivering LEEP will be measured by calculating time estimates associated with all aspects of implementation, including LHW training and service delivery.

Agency efficiencies. To identify if LEEP impacts agency-efficiencies, with therapists increasing their billable hours, administrative claims will be calculated for PCIT therapists to measure the time spent in direct services.

Reach and penetration. At the agency level, reach of PCIT will be assessed by the number of clients that enroll in and graduate from PCIT. Using administrative claims data, penetration at the agency-level will be calculated as the percentage of children receiving PCIT in out of the number of children who are eligible for this EBP. Furthermore, the percentage of families that successfully complete PCIT out of the families enrolled will be calculated.

Acceptability and feasibility. Qualitative interviews will be conducted with the LHWs, agency leaders, and ten parents total to assess their perceptions of LEEP including perceived acceptability, appropriateness, and feasibility, which are important early implementation outcomes.[60]

Analysis. This pilot trial is designed to evaluate the feasibility of implementing LEEP and develop tools to measure its clinical and implementation targets and outcomes. The trial is not powered to assess intervention effects. Analyses will focus on establishing the reliability and validity of measures of clinical engagement and implementation outcomes. Qualitative data will be analyzed using the same methodology described in Aim 1. Qualitative and quantitative data will be given equal weight in analyses with a focus on *convergence*, *expansion*, and *complimentarity,* with quantitative data used to measure outcomes and qualitative data to understand process.[53]

Discussion

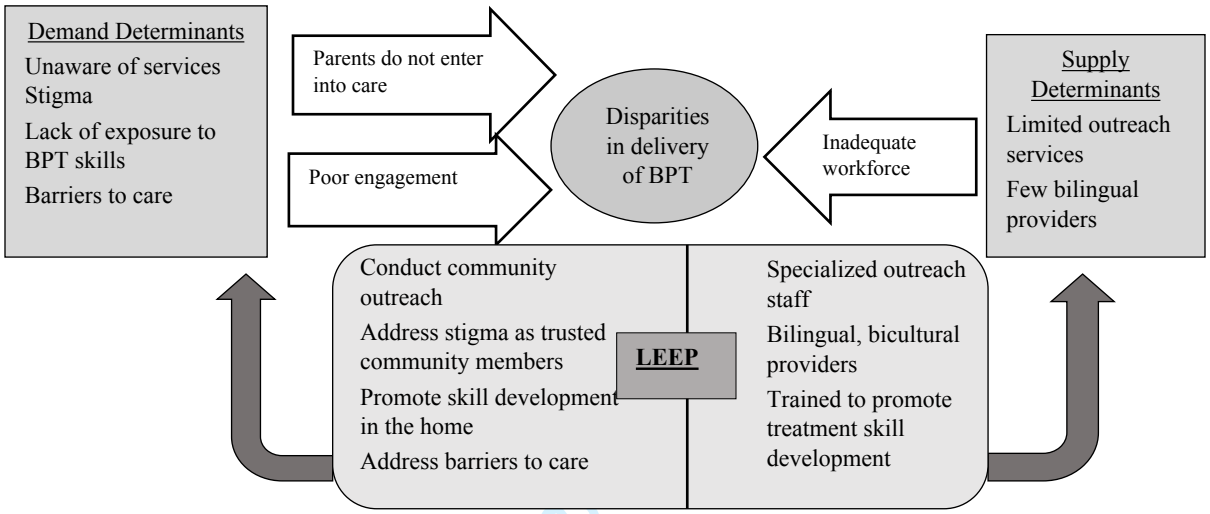
LEEP has the potential for a significant public health impact, by developing an implementation intervention to increase entry and engagement of Latinx parents into BPTs to improve clinical and implementation outcomes. Though LHWs have been identified as an important workforce to address mental health disparities, limited research has evaluated the best strategies to mobilize them to support evidence-based practice implementation in the United States.[34] As a pilot study findings will be limited in power and generalizability. However, the exploratory and development work in this study will provide data on the feasibility and acceptability of LEEP and its preliminary impact on client recruitment, adherence, and retention in PCIT, which will inform future scaling-up of the model.

Ethics and dissemination: Study procedures have been approved by the University of California, Santa Barbara IRB. Results will be submitted for publication in peer-reviewed journals. Furthermore, results will be shared with the community-advisory board and other stakeholders involved in the pilot of LEEP.

Table 1. Measures of LHW Training and Outcomes

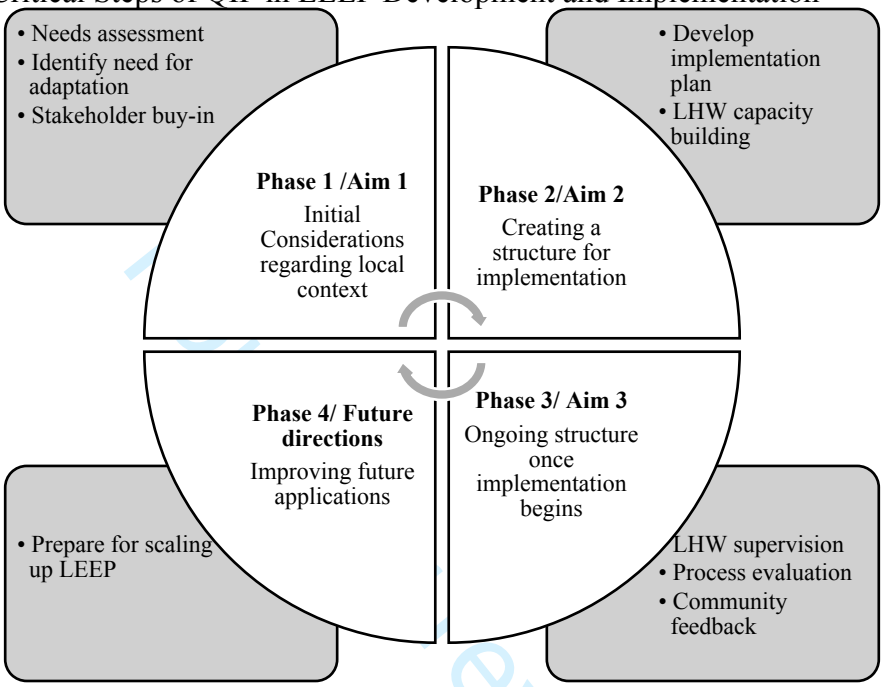
Measure	Description	Administration
Demographic and Background Form[47,48]	Characterizes personal and professional backgrounds of LHW	Aim 1: Survey Aim 3: Training
EBP Questionnaire[51]	Measures service brokers' awareness of and referrals to EBPs.	Aim 1: Survey
Parent Engagement Strategy Use and Confidence[49,50]	Assess use and confidence of engagement strategies with mothers and fathers.	Aim 1: Survey Aim 3: Pre-, Post-Training
Acceptability and Feasibility of PCIT[61]	Assess LHW perceptions of the acceptability and feasibility of PCIT	Aim 1: Survey Aim 3: Pre-, Post-Training
PCIT Knowledge Quiz [47]	A quiz that measures the knowledge of PCIT principles and practices.	Aim 3: Pre-, Post-Training
Dyadic Parent-Child Interaction Coding System[59]	A behavioral observation coding system that assesses parent-child interactions. It will be used to measure LHW's ability to model parenting behaviors.	Aim 3: Pre-, Post-Training
LEEP Fidelity Monitoring	Review of ebook data capture to see the LEEP resources being used and audio recordings of home sessions.	Aim 3: During consultation

Figure 1. LEEP's Approach to Address Supply and Demand Determinants of Disparities



Adapted from Barnett, Lau, & Miranda, 2018. LEEP seeks to address supply and demand drivers of demand for BPTs.

Figure 2. Critical Steps of QIF in LEEP Development and Implementation



Adapted from Meyers et al. (2012). The steps of the QIF inform each aim of the pilot study and plans for scaling.

Figure 3. Stepped Wedge Trial of LEEP Implementation

A stepped-wedge design will be used with the three sites implementing LEEP at separate time points.

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Author Statement

MLB is the principal investigator for the study protocol. MLB generated the idea and design of the study, and was the primary writer of the manuscript. ASL, JM, JL, MKK, and LS also made substantial contributions to study conception and design as mentors to MLB for this K01 award. All authors reviewed and provided feedback for this manuscript. The final version of this manuscript was vetted and approved by all authors.

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Competing interests

None declared

Ethics Approval

University of California, Santa Barbara IRB approved study procedures (Protocol number: 1-18-0919).

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	N/A
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	#3	Date and version identifier	N/A
Funding	#4	Sources and types of financial, material, and other support	28
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	28
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	1

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	28
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	13
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-9
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	9
Objectives	#7	Specific objectives or hypotheses	9
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	10
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	15
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	15
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return;	16

		laboratory tests)	
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	16
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	15
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	15
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	15
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
Blinding (masking): emergency	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during	N/A

unblinding		the trial	
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	16
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	N/A
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	17
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and	N/A

		whether the process will be independent from investigators and the sponsor	
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	18
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	15
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	N/A
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	28
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N/A
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	28
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	N/A

Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

BMJ Open

Developing and Evaluating a Lay Health Worker Delivered Implementation Intervention to Decrease Engagement Disparities in Behavioral Parent Training: A Mixed Methods Study Protocol

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Developing and Evaluating a Lay Health Worker Delivered Implementation Intervention to Decrease Engagement Disparities in Behavioral Parent Training: A Mixed Methods Study Protocol

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Abstract

Introduction: Behavioral parent training programs (BPTs) are effective in preventing and treating early-onset conduct problems and child maltreatment. Unfortunately, pervasive mental health service disparities continue to limit access to and engagement in these interventions. Furthermore, challenges with parental engagement can impede the successful implementation of evidence-based practices (EBPs) in community settings that serve low-income, ethnic minority families. Lay health workers (LHWs)-- individuals without formal mental health training-- represent an important workforce to increase engagement, as they are members of the communities they serve. However, the mobilization of LHWs has not been well studied as an implementation strategy to extend the reach or effectiveness of EBPs in the United States. LHW-delivered implementation interventions that specifically support the engagement of Latinx parents in evidence-based BPTs have the potential to improve clinical and implementation outcomes.

Methods and Analysis: A community-partnered approach will use the Quality Implementation Framework (QIF) to tailor and implement a LHW-delivered implementation intervention that aims to promote Latinx parent engagement in BPTs. Steps from the QIF will guide study activities to: 1) conduct a mixed methods needs assessment to fit the implementation intervention to the local context, 2) adapt LHW delivered implementation strategies to promote parent access to and engagement in Parent-Child Interaction Therapy, and 3) conduct a hybrid effectiveness-implementation pilot trial to examine the feasibility, acceptability, and preliminary effectiveness of the LHW implementation intervention at increasing engagement.

Ethics and dissemination: Study procedures have been approved by institutional review board (IRB) at the University of California, Santa Barbara. Results will be shared with the community-

advisory group, at community-based meetings for other stakeholders involved in the pilot project, and submitted for publication in peer-reviewed journals.

Article Summary

Strengths and Limitations of this Study

- This study seeks to develop and test an implementation intervention to address the impact of underutilization and poor engagement in BPTs, which limit their clinical effectiveness and successful implementation and sustainment.
- This study aims to improve mobilization of LHWs, who may be able to offer cultural and linguistic bridges to reach diverse families, as a potential solution to address racial/ethnic disparities in engagement in BPTs.
- As a pilot, this study is limited in its sample size to determine the effectiveness of the implementation intervention.
- This study will be limited in its generalizability due to the small sample size, the focus on one BPT (Parent-Child Interaction Therapy), and the characteristics of the local context.

Keywords: Lay Health Workers, Implementation Strategies, Behavioral Parent Training, Mental Health Disparities

Introduction

Early onset conduct problems and child maltreatment have been shown to have enormous personal and societal costs, including long-term mental health and substance abuse problems, higher service utilization, and future abuse against women and children.[1–3] Given that behavioral parent training programs (BPTs) have been shown to be effective at preventing and treating both child maltreatment[4] and conduct problems[5] for racially and ethnically diverse families,[6,7] large systems of care have invested millions of dollars in the implementation of these interventions.[8,9] Even with major implementation efforts, challenges remain with engagement and retention of families in BPTs.[10,11] A systematic review of engagement in BPTs found that at least 25% of families that are appropriate for BPTs do not enroll in treatment, and an additional 26% begin, but then drop out of treatment, with higher rates of attrition for low-SES families.[12] In fact, in community implementation of BPTs, attrition rates can exceed 65%.[13–15]

The consequences of poor participation in BPTs are significant. Families who drop out of treatment are less likely to experience improvements in parenting skills or child disruptive behaviors.[16] Moreover, failed efforts to recruit and retain parents are costly for providers.[17] Frequent cancellations and no-shows leads to fewer billable hours for community agencies, which are often under immense financial pressure.[17,18] Further, inadequate referrals negatively impacts the implementation of evidence-based practice (EBP), as therapists may not learn to deliver the practice with fidelity.[8,9,19] Challenges with engagement may be especially pronounced for racial and ethnic minority families, as mental health service disparities have been well documented.[20] For example, African American and Latinx children are almost 50% less likely than non-Latinx, White children to receive treatment for externalizing disorders.[21]

In order to meet the public health potential of BPTs and address service disparities, implementation interventions are needed to support parental engagement for ethnic minority parents. Implementation interventions, which are usually complex and multilevel, include strategies to enhance the adoption and ongoing implementation of clinical interventions at the organization, provider, and consumer levels.[22] Multiple implementation strategies have been identified that focus on increasing consumer engagement with EBPs, including: 1) increasing demand for EBPs, 2) intervening with consumers to enhance uptake and adherence, and 3) preparing consumers to be active participants in treatment.[23] These implementation strategies are consistent with evidence-based approaches to improve engagement in children's mental health care, which include assessment of barriers, accessibility promotion, psychoeducation about services, and appointment reminders.[24,25]

Addressing Mental Health Service Disparities

Lay Health Workers (LHWs) may be especially well positioned to deliver consumer-facing implementation strategies focused on addressing service disparities for underserved, low-resource communities.[26] LHWs, which include a range of terms, including *promotores*, family peer advocates, and wellness navigators, are individuals without formal mental health training, who have roles intended to increase their community's access to and benefit from services.[27,28] LHWs have the potential to address both demand and supply drivers of disparities in EBP delivery.[26] Demand for EBPs is impacted by an individual's mental health literacy, stigma towards mental illness and help seeking, perceptions of treatment providers, and culturally based beliefs and preferences.[29,30] Systemic barriers to care may exacerbate disparities in accessing care. For example, undocumented immigrants are especially unlikely to seek mental health services due to fear of being reported to authorities.[31] Since LHWs come from similar cultural

and personal backgrounds as the individuals they serve, they may be especially adept at helping patients overcome distrust of health systems.[32]

Regarding supply, the number of professional mental health providers who can deliver linguistically and culturally competent EBPs is inadequate.[33] The majority of mental health research with LHWs has been conducted in low- and middle-income countries, with emerging evidence that LHWs can improve mental health outcomes when they are tasked with delivering EBPs.[28,34,35] Though LHWs have successfully delivered BPTs as prevention interventions in high-income countries, using a task-shifting model,[36,37,38] licensure and certification requirements frequently restrict EBP delivery to professionals in mental health settings.[26] Therefore, LHWs in the United States may need to have complementary and distinct roles within the provision of EBPs.[11,26] For example, if LHWs delivered auxiliary engagement services (e.g., outreach and case management), it could reduce the burden on bilingual and bicultural mental health professionals and allow them to focus on activities that require advanced training and licensure, such as providing EBPs for more clients. [19,39]

One example of a LHW-delivered engagement program is the Parent Empowerment Program (PEP), which trains family peer advocates to work with parents to address their children's mental health needs and overcome barriers to care.[40,41] The majority of research on PEP has focused on evaluating the training of family peer advocates, as opposed to investigating the impact of the model on clinical outcomes for families, service utilization, or engagement in EBPs.[40–43] One randomized control trial evaluated the impact of PEP for Black and Latinx parents of children with autism. Parents who received PEP had significantly lower stress than parents who received treatment as usual. However, there were no group differences for service utilization. The researchers advocated that future research on programs like PEP should include

non-English-speaking families, who may have higher levels of need, and use qualitative research to better understand the strengths and areas of improvement for the model.[44] The proposed study follows these recommendations through the development and evaluation of LHWs Enhancing Engagement for Parents (LEEP), an implementation intervention to improve engagement for low-income, Latinx parents into one BPT, Parent-Child Interaction Therapy (PCIT).[45] LEEP seeks to follow recommendations by Chacko and colleagues (2016) based on their systematic review of parental engagement in BPTs by, "preparing parents for BPT, addressing practical barriers to engagement, assisting in aligning parent's involvement with their own goals for treatment" (p. 211) in order to impact initial and ongoing engagement in PCIT.

Parent-Child Interaction Therapy

PCIT has unique benefits and challenges related to engaging parents in treatment. The treatment model uses in vivo feedback to overcome challenges that are inherent to teaching methods used in other BPTs (e.g., didactics, discussion) as it necessitates active participation and assesses learning in real time. PCIT requires that parents demonstrate a high-level of proficiency with the targeted parenting skills before they advance from the first phase of treatment, which focuses on enhancing the parent-child relationship, to the second phase of treatment, which teaches effective and developmentally appropriate limit setting and discipline approaches, and then until they graduate from treatment.[45] Mastery-based criteria guarantees that all parents can successfully use the skills; however, parents often drop out before they learn the full range of parenting skills needed to decrease disruptive behaviors.[13,16] Furthermore, some research suggests that low-income, ethnic minority parents require more practice and time in treatment to reach this level of skill proficiency.[46–48] Extended treatment length can lead to long waitlists and fewer families seen in PCIT.[49]Further, problems with attendance, retention, and prolonged skill

acquisition have downstream effects on PCIT provider implementation outcomes. Clinicians can take up to three years to meet PCIT certification requirements (i.e., achieving fidelity and graduating two cases).[50] Thus, low parental engagement results in provider attrition from training, which in turn compromises the sustainability of the intervention, and limits the return on costly investments made to implement PCIT in public service systems.[8,9]

LEEP seeks to improve the supply of and demand for PCIT in agencies that predominately serve low-income, Latinx immigrant families, and address engagement challenges that impact clinical and implementation outcomes (Figure 1). PCIT is widely implemented in community settings, including in the county where the current study is being conducted. LEEP includes LHW-delivered implementation strategies to increase caregiver engagement as an extension of PCIT services, which will be provided by the licensed mental health professionals. LEEP will be compared to PCIT implementation-as-usual to see if parental engagement and implementation challenges are ameliorated. A community-partnered approach will focus on making LEEP a feasible and acceptable implementation intervention, with the following aims:

Aim 1: Assess the current context of LHW mobilization in children's mental health services, to inform the development of LEEP.

Aim 2: Through community-partnership, develop a structure for the implementation of LEEP in publicly-funded, children's mental health settings.

Aim 3: Evaluate the feasibility of implementing LEEP in community mental health agencies through a pilot effectiveness-implementation trial.

Methods and Analysis

Conceptual Framework and Approach

The Quality Implementation Framework (QIF), which includes four phases to support high quality implementation, informs the study aims and plans for scaling-up LEEP (Figure 2).[51] The first phase of the QIF focuses on assessing organizational needs, readiness, and innovation-organizational fit, which will be conducted in Aim 1 through survey data and stakeholder interviews. Phase 2 in the QIF focuses on the development of implementation structures, which will occur during the second aim with the input of a community-advisory group. The community-advisory group will collaboratively help to develop an implementation plan delineating tasks and timelines to establish infrastructure for LHW capacity building, including job descriptions and training plans. Phase 3 of the QIF includes three main activities that will take place during a hybrid type 2 effectiveness-implementation pilot stepped-wedge trial of LEEP. These activities include (1) providing implementation support strategies (e.g., supervision and consultation) to LHWs, (2) conducting a process evaluation to identify successes and barriers to implementation, and (3) providing ongoing feedback to organizations about the impact LEEP is having on service outcomes. Finally Aim 3 activities will inform Phase 4 of the QIF, which focuses on learning from initial implementation experiences to inform future efforts to scale-up and sustain LEEP.

Patient and Public Involvement

The research questions, study design, and outcomes measures were informed by public stakeholders, including agency leaders, PCIT therapists, and LHWs. No patients were involved in this process, though LHWs often have shared characteristics and life experiences given their social proximity to the individuals in the communities they serve.[52] The burden of the randomized control trial will be evaluated through the collection of feasibility and acceptability

data in qualitative interviews with participants. Results will be shared with participants in community-based events.

Aim 1: Assess the current context of LHW mobilization in children's mental health services, to inform the development of LEEP.

Participants. Surveys will be administered to LHWs employed or contracted by children's mental health agencies in two counties in California. Approximately 70 LHWs will be recruited to complete the quantitative survey. Based on a national survey of LHW,[53] LHW are expected to be Latinx, female, and have below a college level of education. Ten agency community mental health agency leaders and 25-30 LHW will be invited to participate in interviews to expand on the findings from the survey. Survey and interviews will be offered in Spanish or English.

Procedure. A mixed-method needs assessment will be conducted to understand how LHWs are currently mobilized in children's community mental health settings, with the purpose of adapting LEEP to fit within the local context. Surveys will provide a breadth of information and qualitative interviews will provide depth of information, to understand perceived barriers to parental engagement in children's mental health services, LHW roles and integration into services, and LHW knowledge about and attitudes towards BPTs and evidence-based engagement strategies. Data collection started in January 2017 and was completed in December 2018.

Survey measures. Surveys will be collected via electronic or paper-and-pencil survey based on LHW preferences.

LHW characteristics.[39] A demographic questionnaire will provide information about the LHWs' characteristics, including gender, race/ethnicity, country of origin, educational level, and

years of experience.

Cultural background questionnaire.[54] The Cultural Background Questionnaire is a 19-item self-report measure used to assess therapist generational status and acculturation, including cultural identity (i.e., U.S. identity and Heritage Cultural Identity) and language use.

Parental engagement.[55,56] A questionnaire that was developed to measure provider's perceptions of and strategies for engaging fathers has been adapted to measure LHW's perceptions of barriers to engagement, strategies for engagement, and confidence in engagement for parents. The adapted questionnaire includes perceived barriers in engagement for parents in general, and the LHW's use of and confidence with engagement strategies for both mothers and fathers.

Attitudes towards BPT strategies. A four-item questionnaire was developed for this study to measure LHWs attitudes towards teaching parents common strategies targeted in BPTs including play to improve the parent-child relationship, praise of positive behaviors, ignoring minor misbehaviors, and time-out as a form of discipline.

EBP questionnaire.[57] A questionnaire developed to measure service broker's knowledge of and referrals to EBPs has been adapted to identify if LHWs are aware of, making referrals to, and supporting families involved specifically in PCIT(e.g., *"Have you referred parents to Parent-Child Interaction Therapy (PCIT)"*).

Semi-Structured Interviews. Interview guides will include topics, questions, and probes related to LHW roles, training needs, and experiences and attitudes related to BPTs. Questions will investigate how LHWs view their roles in agencies and their communities, their perceptions of BPTs, their preparation for their position, and their training needs. Interviews with agency leaders will focus on how LHW are integrated into services, LHW training, and outreach and

engagement strategies with Latinx families. A "funnel-approach" will be used with broad-open ended questions related to roles, trainings, and attitudes asked first, followed with specific probes to elicit details.[58]

Analysis. A QUAN + QUAL mixed methods design will be used, with quantitative and qualitative data collected simultaneously and given equal weight in analyses, for the purposes of gaining breadth and depth of understanding (i.e., complimentarity), identifying if the qualitative and quantitative data provide the same answer to the same question (i.e., convergence), and using qualitative data expand on unexpected quantitative findings.[59] Interviews will be transcribed and entered into *NVivo*, software that aids the coding, organization, and retrieval of codes. An iterative process will be used where the coding team first develops a preliminary coding scheme and applies it to a sample text to ensure all relevant themes are captured. Once a final coding scheme is decided upon, coders will apply the final code list to all transcripts. Regular meetings with the coding team will be conducted to examine coding across analysts, resolve differences in coding, conduct iterative refinement of code definitions and the logic of the coding tree, and collaborate on the development of themes. Qualitative themes will be identified through analysis of co-occurring codes and text analysis.[60,61]

Aim 2: Through community-partnership, develop a structure for the implementation of LEEP in children's mental health settings.

Participants. A community-advisory group with 6-9 stakeholders will be formed to make sure that implementation supports match the local context. Agency leaders, PCIT therapists, and LHWs will be represented in the advisory group. Given the wide diversity of viewpoints, education levels, and ethnicities, efforts will be made to provide each participant with equal representation, opportunities for contribution, and honorariums.

Procedure. In line with the Model of Research-Community Partnership, which was specifically developed for research in children's mental health services, the formation of the partnership will focus on building relationships, trust, establishing a joint mission, and identifying roles and responsibilities of different partner members. This will provide the foundation to build a synergistic, collaborative relationship focused on developing and delivering LEEP, which in turn could improve the successful and sustained implementation of PCIT.[62] Using data from Aim 1 and in collaboration with the community-advisory group, the LEEP implementation intervention will be adapted from an existing protocol focused on LHW-delivered parent outreach and engagement strategies. This protocol was developed to increase access to PCIT in a low-income, Latinx community in the Southeastern United States, but has not been disseminated to other communities.[39] The implementation supports needed for LHWs to deliver LEEP also will be identified and put into place. Steps from the QIF will be used to guide the activities of the community-advisory group in adapting these materials and developing LEEP's implementation structure.[51] Advisory group meetings will include: 1) activities to build trust and develop a shared mission statement, 2) feedback on adapting LEEP materials, 3) advisory group input on survey and interview results from Aim 1, and 4) development of a plan with specific tasks, roles, tracking for LEEP implementation. Phase 2 activities involving the community-advisory group began in December 2018 and will continue through March 2021.

Aim 3: Evaluate the feasibility of implementing LEEP through a pilot effectiveness-implementation trial.

In Aim 3, an effectiveness/ implementation hybrid design (Type 2) pilot study will integrate qualitative and quantitative data to examine the feasibility of delivering and scaling-up LEEP. Type 2 hybrid trials simultaneously measure the clinical effectiveness of an intervention,

in this case PCIT, and the feasibility and utility of an implementation intervention (i.e., LEEP).[63] Pilot studies are limited in their ability to test effectiveness given small sample sizes, but they provide a critical phase of research design that can examine the feasibility of the approach to be used in a large-scale study.[64] A focus will be placed on measuring engagement outcomes at a client- and agency-levels to evaluate if LEEP is increasing the reach of PCIT services, service entry, and treatment engagement.

Procedure. Three agency sites that provide PCIT will be involved in this pilot study, which will use a stepped wedge design. In a stepped wedge design, a period of baseline measurement will occur for all sites, in which PCIT will be implemented-as-usual. Then at subsequent time points each site will be randomized to LEEP and response to the intervention will be measured for client and implementation outcomes (Figure 3). At each agency, one to two LHWs (4-6 total) will be trained to deliver LEEP. Client and implementation outcomes will be collected during PCIT implementation-as-usual and LEEP implementation. The baseline measurement period began in January 2019. LHWs will be trained to deliver LEEP at the first site starting in July 2019 and will continue through March 2021.

Participants. Four to six LHWs will be trained to provide LEEP. These LHWs will provide LEEP care extension services to approximately PCIT clients each (16-24 families). LHWs will be trained to provide informed consent for parents. Families that participate in LEEP or PCIT implementation-as-usual will meet criteria for receiving this BPT. This includes having a child between the ages of 2 to 7 and presenting problems consistent with disruptive behaviors, or risk for child maltreatment.

LEEP Intervention. Based on community-advisory group feedback on the needs of the Latinx immigrant community and the agencies implementing PCIT, along with research on

parental engagement,[11] LEEP includes components for LHWs to 1) increase awareness of PCIT for Latinx immigrant families, 2) promote engagement once parents seek PCIT services, and 3) support parents' use of skills taught in PCIT throughout treatment. To increase knowledge of PCIT, LHWs will conduct community presentations in locations with parents of young children (e.g., Head Start Centers, churches). Parents will be referred to LEEP when they first seek services to promote engagement. LHWs will meet with parents in their home to discuss identify how PCIT aligns with their goals for treatment, address practical barriers to engagement (e.g., transportation), and introduce the relationship-enhancing parenting skills taught in PCIT. Once parents start PCIT, LHWs will provide home visits to promote skill practice and treatment adherence at the beginning of each treatment phase. Additional booster sessions will be provided based on the parent's progress in treatment. If parents have not reached mastery criteria after seven sessions, LHWs will conduct weekly home visits to reinforce skill use and address barriers to engagement. LHWs will be provided with electronic tablets with e-books that included scripts and videos to use in one-on-one meetings with parents before they enter into care and while they are receiving PCIT services. The e-books will have materials to help LHWs promote motivation (e.g., parent testimonials), homework adherence, and skill practice (e.g., video demonstrations of the targeted parenting skills).

Effectiveness outcome measures. Given that PCIT is an assessment-driven BPT, clinical outcomes will be assessed using standard measures that are collected as part of the routine PCIT protocol. Parents will not complete any additional measures for this study.

Engagement. To assess if LEEP impacts engagement at the family-level, session attendance, graduation from PCIT, and the number of sessions needed to graduate will be

assessed. Further, daily skill practice will be measured using the record sheets that parents complete over the week, which has been used in past studies on homework adherence.[65]

The Dyadic Parent-Child Interaction Coding System (DPICS).[66] The DPICS is a behavioral observation coding system that was designed to measure the quality of interaction in parent-child dyads, which has good interrater reliability. This study will use the DPICS categories, *Behavior Description, Labeled Praise, Unlabeled Praise, Reflection, Question, Negative Talk, and Indirect and Direct Commands,* to measure the parent's skill acquisition.

Eyberg Child Behavior Inventory (ECBI).[67] The ECBI is a 36-item parent-rating scale of disruptive behavior problems for children between the ages of 2 to 16. Parents rate the frequency of each disruptive behavior on a 7-point Likert scale ranging from *never* (1) to *always* (7), which are summed to yield the Intensity Scale and whether this behavior is a problem for them, with the total number of Yes responses yielding the Problem Scale.

Implementation outcomes. Using the implementation outcomes outlined by Proctor and colleagues,[68] this study uses mixed methods to understand the acceptability, appropriateness, feasibility, reach, and costs of delivering LEEP.

***LHW-level outcomes*.** To measure changes in LHW knowledge, perceptions of acceptability and feasibility of PCIT, and competence, LHW will complete pre- and post- self-report and behavioral measures (Table 1). Ongoing fidelity monitoring will be conducted throughout LHW's delivery of LEEP. Fidelity monitoring will include reviewing data capture of the ebook created for LEEP, which will include videos about PCIT and scripts for the LHWs to use with the families they serve. LHWs will also audio record their sessions to monitor fidelity to the LEEP model.

Implementation costs. Costs associated with delivering LEEP will be measured by calculating time estimates associated with all aspects of implementation.

Agency efficiencies. To identify if LEEP impacts agency-efficiencies, with therapists increasing their billable hours, administrative claims will be calculated for PCIT therapists to measure the time spent in direct services.

Reach and penetration. At the agency level, reach of PCIT will be assessed by the number of clients that enroll in and graduate from PCIT. Using administrative claims data, penetration at the agency-level will be calculated as the percentage of children receiving PCIT in out of the number of children who are eligible for this EBP. Furthermore, the percentage of families that successfully complete PCIT out of the families enrolled will be calculated.

Acceptability and feasibility. Qualitative interviews will be conducted with the LHWs, agency leaders, and ten parents to assess their perceptions of LEEP including perceived acceptability, appropriateness, and feasibility, which are important early implementation outcomes.[68]

Analysis. This pilot trial is designed to evaluate the feasibility of implementing LEEP and develop tools to measure its clinical and implementation targets and outcomes. The trial is not powered to assess intervention effects. Analyses will focus on establishing the reliability and validity of measures of clinical engagement and implementation outcomes. Qualitative data will be analyzed using the methodology described in Aim 1. Qualitative and quantitative data will be given equal weight in analyses with a focus on *convergence*, *expansion*, and *complimentarity,* with quantitative data used to measure outcomes and qualitative data to understand process.[59]

Discussion

LEEP has the potential for a significant public health impact, by developing an implementation intervention to increase entry and engagement of Latinx parents into BPTs to improve clinical and implementation outcomes. Though LHWs have been identified as an important workforce to address mental health disparities, limited research has evaluated the best strategies to mobilize them to support EBP implementation in the United States.[28] As a pilot study, findings will be limited in power and generalizability. However, the exploratory and development work in this study will provide data on the feasibility and acceptability of LEEP and its preliminary impact on client recruitment, adherence, and retention in PCIT, which will inform future scaling-up of the model.

Ethics and dissemination: Study procedures have been approved by the University of California, Santa Barbara IRB. Results will be submitted for publication in peer-reviewed journals. Furthermore, results will be shared with the community-advisory board and other stakeholders involved in the pilot of LEEP.

Table 1. Measures of LHW Training and Outcomes

Measure	**Description**	**Administration**
Demographic and Background Form[39,54]	Characterizes personal and professional backgrounds of LHW	Aim 1: Survey Aim 3: Training
EBP Questionnaire[57]	Measures service brokers' awareness of and referrals to EBPs.	Aim 1: Survey
Parent Engagement Strategy Use and Confidence[55,56]	Assess use and confidence of engagement strategies with mothers and fathers.	Aim 1: Survey Aim 3: Pre-, Post-Training
Acceptability and Feasibility of PCIT[69]	Assess LHW perceptions of the acceptability and feasibility of PCIT	Aim 1: Survey Aim 3: Pre-, Post-Training
PCIT Knowledge Quiz [39]	A quiz that measures the knowledge of PCIT principles and practices.	Aim 3: Pre-, Post-Training
Dyadic Parent-Child Interaction Coding System[66]	A behavioral observation coding system that assesses parent-child interactions. It will be used to measure LHW's ability to model parenting behaviors.	Aim 3: Pre-, Post-Training
LEEP Fidelity Monitoring	Review of ebook data capture to see the LEEP resources being used and audio recordings of home sessions.	Aim 3: During consultation

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Author Statement

MLB is the principal investigator for the study protocol. MLB generated the idea and design of the study, and was the primary writer of the manuscript. ASL, JM, JL, MKK, and LS also made substantial contributions to study conception and design as mentors to MLB for this K01 award. All authors reviewed and provided feedback for this manuscript. The final version of this manuscript was vetted and approved by all authors.

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Competing interests

None declared

Ethics Approval

University of California, Santa Barbara IRB approved study procedures (Protocol number: 1-18-0919 and 4-19-0167).

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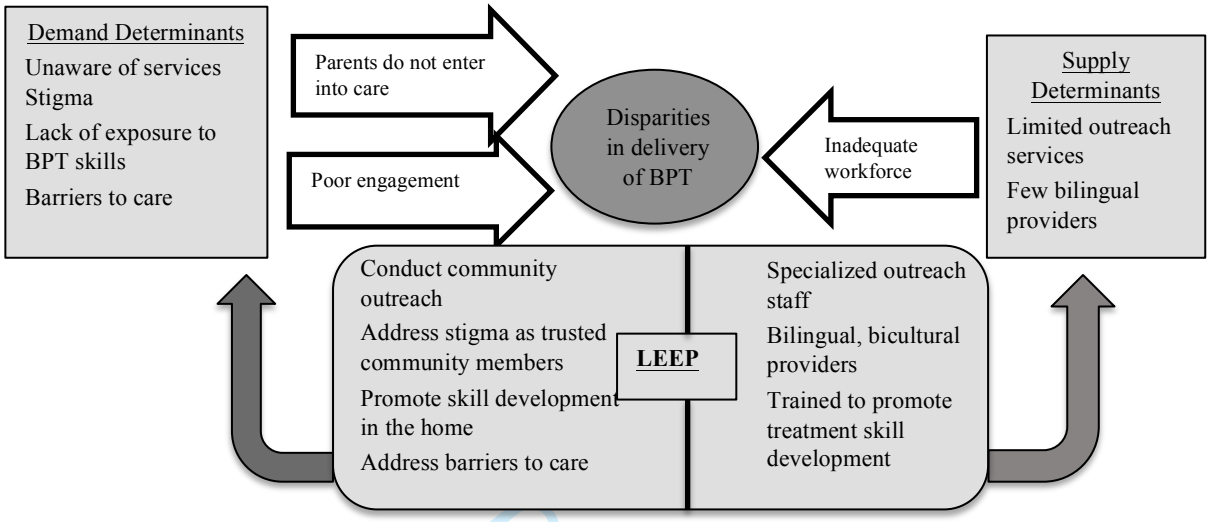
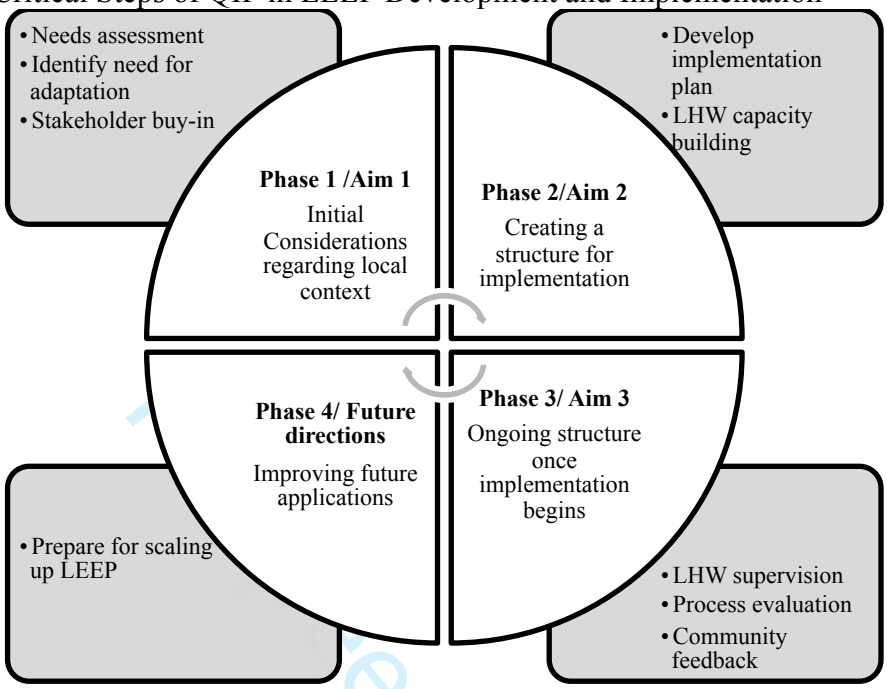
Figure 1. LEEP's Approach to Address Supply and Demand Determinants of Disparities



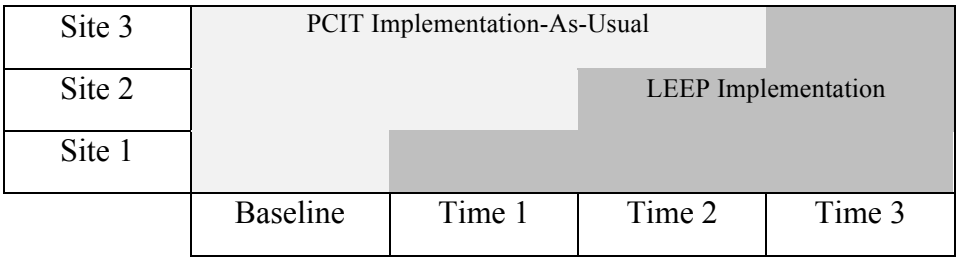
Adapted from Barnett, Lau, & Miranda, 2018. LEEP seeks to address supply and demand drivers of demand for BPTs.

Figure 2. Critical Steps of QIF in LEEP Development and Implementation



Adapted from Meyers et al. (2012). The steps of the QIF inform each aim of the pilot study and plans for scaling.

Figure 3. Stepped Wedge Trial of LEEP Implementation



A stepped-wedge design will be used with the three sites implementing LEEP at separate time points.

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	N/A
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	#3	Date and version identifier	N/A
Funding	#4	Sources and types of financial, material, and other support	27
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	27
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	1

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	28
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	13
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-9
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	9
Objectives	#7	Specific objectives or hypotheses	9
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	10
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	15
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	15
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return;	16

		laboratory tests)	
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	16
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	14
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	14
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	14
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
Blinding (masking): emergency	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during	N/A

unblinding		the trial	
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	15-16
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	N/A
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and	N/A

		whether the process will be independent from investigators and the sponsor	
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	18
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	14
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	N/A
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	27
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N/A
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	27
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Suppl

Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A