Protocol

Optimizing a Tool to Track Effectiveness and Responsiveness for Family Peer Support (Project OTTERS for Family Peer): Protocol for Mechanism Pathway Development and Measure Validation

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Abstract

Background: Family peers (FPs) have lived experience of parenting a child with mental health needs and specialized training to support other caregivers. They provide informational, emotional, affirmational, and instrumental support and are reimbursable by Medicaid in many states. While there have been positive results of FP support in randomized trials, there is little understanding of the mechanisms through which FP support improves caregiver and child outcomes. While observational coding is considered the gold standard for measuring psychosocial interventions, it has not been acceptable to FPs. This makes it necessary to explore other strategies for measuring intervention delivery.

Objective: This study will (1) identify common FP intervention components across a range of FP programs and models, (2) delineate potential causal mechanisms for FP success related to child and caregiver outcomes, and (3) develop a pragmatic measure to capture use of these common FP intervention components to support larger-scale testing.

Methods: This study will use intervention mapping to examine one-to-one FP support for caregivers of children aged 5-17 years in outpatient clinic, community, and home-based settings. We will survey 50 FPs and 50 caregivers across FP models. We will purposively select 48 participants to complete qualitative interviews (32 FPs and 16 caregivers). We will identify common

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FP components and their associated mechanisms and organize them in a logic model (aim 2). We will then create a corresponding tool to capture use of these components (aim 2), which we will validate with 200 FPs (aim 3). Of these FPs, 40 will complete up to 2 role plays of an FP encounter alongside the tool, which we will compare with observational coding. Another subset of 40 FPs and caregivers will be asked to complete a parallel self-report tool to report on the content of a selected session.

Results: The study was funded in September 2025 by the National Institute of Mental Health (NIMH). Recruitment for aim 1 began in August 2026, with 4 participants enrolled in August 2026. The project will end in August 2029. We will submit deidentified study data collected in aims 1 and 3 to the NIMH Data Archive for participants who consent to data sharing.

Conclusions: This study will advance our understanding of the common intervention components of FP support and associated mechanisms of change that go on to impact caregivers and children. This study will also result in a tool to measure this content across a range of outpatient programs and models. Results will inform a larger experimental trial to test the identified mechanisms of effective FP support.

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KEYWORDS

family peer; caregiver; child; mechanism of change; measurement

Introduction

Background

Our mental health system does not address the substantial mental health needs of youth [1-5]. Youth face many barriers to care, including trying to navigate complex behavioral health systems, long waitlists for services, and societal stigma and misinformation about the benefits of treatment [6]. Peer support, where individuals who share core characteristics or identities with those receiving services or support, is a promising strategy for overcoming these and other barriers [7]. Peer support has been successfully used with many populations with mental health needs [8,9]. In youth mental health, peer support often takes the form of family peers (FPs; also called family peer advocates, peer specialists, professional peer parents, parent support providers, or family peer providers), who have both lived experience parenting a child with mental health needs and specialized training to help others navigate similar experiences. By most recent published estimates, Medicaid reimburses for FPs in 33 states and across a range of settings [10].

Randomized controlled trials find that caregivers who receive FP support experience decreased parental stress [11,12], improved coping and cognitive adaptation [13], increased parental engagement with mental health services [14], increased parental feelings of efficacy and empowerment [15], increased parenting skills [16,17], and decreased likelihood of abuse or neglect [18] compared with control groups. FP support is also associated with improved family interactions with mental health and related services by reducing time to mental health diagnosis [19] and improved engagement with services [20,21]. Importantly, recent work finds improvements in youth psychiatric symptoms after parents receive FP support [14,17,20], underscoring the potential of FPs to have a positive impact on youth outcomes as well as broader family outcomes.

Despite this initial evidence that FP support positively impacts families, the literature does not delineate the specific intervention components that FPs deliver to families, nor how these specific interventions go on to impact mechanisms of change to ultimately impact family outcomes. This lack of delineation of what FPs deliver to families and how these specific delivered components impact family outcomes limits research efforts to demonstrate the effectiveness of FP support. FP support is a broad term used to describe both group and individualized interventions that range from highly manualized content to largely flexible structures with decision-making made by individual FPs. There is some consensus on the broad categories of FP support that may be delivered to families, which include informational, instructional, emotional, instrumental, and advocacy support [22]. However, within these broad categories, there is limited definition of how these skills are delivered or how to measure them. This delineation is important for 2 reasons. First, it is a necessary first step towards measuring the extent to which FPs use the specific intervention components, which is important to continue to demonstrate the effectiveness of FP interventions. Second, it will allow researchers to begin studying how specific FP intervention components are tied to mechanisms of action that affect desired change for caregivers and youth. This has the potential to increase the efficiency and effectiveness of FP support and research efforts by paving the way for matching family characteristics and needs to specific FP intervention components.

There are some challenges in determining the best ways to measure these common intervention components that FPs use in their work with caregivers. People working in FP programs hesitate to use established measurement methods such as audio and video recording [23] to capture FP session content [24] due to concerns about the invasiveness of these procedures. Thus, delineation and measurement of FP intervention component use must rely on alternative, pragmatic measurement methods while ensuring sufficient granularity to draw connections along theorized mechanistic pathways.

Study Objectives

The goal of this study is to identify common FP intervention components, link these to associated mechanisms of change that ultimately impact family outcomes, and develop and validate a pragmatic self-report tool to capture use of these common FP intervention components to support larger-scale testing. This project will focus on one-to-one FP support for

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caregivers of children aged 5-17 years in outpatient settings, including clinic, community, and home-based models. We will collaborate with an Advisory Board composed of FPs, caregivers who received FP support, FP trainers, and leaders from FP organizations to address these gaps. The study has 3 aims, which will be guided by principles from intervention mapping [25].

In aim 1, we will identify common FP support intervention components and their associated mechanisms through surveys and qualitative interviews. In collaboration with our Advisory Board, we will expand an existing validated adherence measure [22,24,26] based on other FP quality measures [27] and Advisory Board input to capture components shared across FP models. This tool will be used to survey FPs and caregivers about components delivered or received during the first year of support, as well as perceived mechanisms of action and links between components and mechanisms. A purposive subsample will participate in qualitative interviews to provide deeper insight.

In aim 2, we will work with our Advisory Board across a series of meetings to (1) develop a logic model describing how common FP components engage mechanisms of change to impact outcomes, and (2) refine the aim 1 survey into a session-level tool for use in aim 3. Findings from aim 1 will inform both the logic model and the refinement of the measurement tool to capture component use and corresponding mechanisms.

In aim 3, we will validate the tool developed in aim 2. A total of 200 FPs will complete the revised measure following a selected session, along with measures of perceived mechanism targets and brief assessments of feasibility and acceptability. A subset of FPs will be selected for an additional procedure where they and a selected caregiver report on a session to gather corresponding FP and caregiver perspectives on components and associated mechanisms. For tool validation, a separate subset will be invited to complete up to 2 standardized role-play sessions (called walk-throughs) [24,28] with trained confederates. An overview of objectives, methods, analysis, and expected outcomes by aim is provided in Table 1. Detailed procedures for each aim are provided in the Methods section.

Table 1. Study procedures and expected products by study aim.

Aim	Objective	Method	Analysis	Expected product
Aim 1	Identify common intervention components of Family Peer support and associated target mechanisms across Family Peer models	• Advisory Board Meetings • Cognitive Interviews to refine survey (up to 4) • Surveys (50 Family Peers, 50 caregivers) • Interviews (16 caregivers, 32 Family Peers)	• Descriptive statistics on survey results • Qualitative Coding of open-ended Reponses • Qualitative Coding of qualitative transcripts	• Codebook of intervention components with links to mechanisms • Information on commonly used intervention components and mechanisms
Aim 2	Refine a logic model of change for FP support that maps common intervention components to target mechanisms and create a corresponding tool to measure use of the components	• Advisory Board Meetings • Cognitive Interviews to refine survey prior to distribution (up to 6)	• Building of logic model with Advisory Board using Aim 1 data	• Logic model of change for Family Peer support • Survey tool to capture use of common intervention components
Aim 3	Validate the self-report tool to capture use of common Family Peer intervention components developed in Aim 2 in preparation for large-scale mechanism evaluation	• 200 Family Peers complete tool • 40 also complete role-play to be able to compare tool to observational coding • Another 40 complete parallel tool on a session alongside caregiver	• Psychometric properties including internal consistency, factor analysis • Correlation matrix of common pairs of FP intervention components and associated mechanisms • Convergent validity of observational rating versus self-report for role-play • Examination of convergence of FP and caregiver response on identified sessions	• Validated measure to capture content of Family Peer support to be used in subsequent trials. • Comprehensive list of common intervention components and associated mechanisms

Methods

Study Setting

This study will recruit and enroll individuals across the United States delivering or receiving FP support in clinic, community, and home-based settings. We will exclude those working in or receiving support from higher levels of care (eg, inpatient settings). All participants will provide consent and can ask any questions of study team members before beginning any study activities. While final recruitment procedures will be refined in collaboration with the Advisory Board, mentors, and study consultants to aim for representation in terms of types of sites and training models within community, home, and clinic-based models, we anticipate recruitment to occur across 4-5 sites representing a range of FP training models and settings within

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the above-mentioned criteria. Study partners include several leading organizations in the provision and training of FPs, including the Family-Run Executive Director Leadership Association (FREDLA) and Families Together in New York State (FTNYS).

Advisory Board

All study activities will be conducted in collaboration with an Advisory Board. Informed by best practices for facilitated group discussion [29,30], the study Advisory Board will be composed of 8 members. Advisors include individuals who may fall into 1 or more of the following categories: FPs, those who received FP support, FP program administrators, and FP trainers and supervisors from diverse FP programs that support caregivers of children aged 5-17 years. The study's principal investigator (PI), JJ, will cochair the Advisory Board alongside an FP board member. We anticipate approximately 16 meetings over the course of 4 years. To minimize bias and ensure all voices are heard, Advisory Board meetings include methods like anonymous polling and small group discussion as well as broader group discussion. Advisory Board members will not participate in the research (eg, will not consent, collect data from, or view identifiable data from participants). They will be compensated US $50 for each meeting. We include individuals who represent a range of different FP organizations across the United States, including those that oversee, train, and credential the FP workforce.

Intervention Mapping

This study is guided by intervention mapping [25], a community-partnered planning framework for the development, implementation, and evaluation of health promotion interventions. It incorporates theory, novel data, and the perspectives of relevant community members in a 6-step iterative process. Intervention mapping emphasizes mechanistic understanding of intervention success by developing a logic model of change which posits how community needs are addressed by the designed intervention. It has been used to create new interventions and to modify existing interventions for new settings. Intervention mapping is an ideal fit for this study as it provides a systematic way to map common FP intervention components onto theorized mechanisms of change and outcomes while elevating key FP perspectives through the Advisory Board in the resulting logic model. The six intervention mapping steps are as follows: (1) build a logic model of the problem, (2) develop a logic model of change, (3) design the program, (4) refine program structure, (5) plan program implementation, and (6) plan program evaluation.

While intervention mapping was primarily developed to systematically design and modify health promotion interventions, it can also be used to examine existing interventions [31]. Given that FP support is an already implemented intervention, we use intervention mapping to help us identify how its common intervention components target relevant behavioral determinants and associated beliefs that in turn may change behavior to impact broader family outcomes.

Conceptual Framework

To help identify relevant behavioral determinants that may be targeted by FP intervention components, we draw on both the theory of planned behavior (TPB) [32,33] and Yalom's therapeutic factors (YTF) [34]. The TPB has guided the development of many health promotion programs and is the basis for the Parent Empowerment Program, a leading FP model [35]. It seeks to identify determinants that influence the chance of human behavior change. The theory suggests the most proximal determinant of a behavior is one's intention (or motivation) to engage in that behavior. Intentions can be strengthened by increasing one's knowledge (eg, awareness) about a behavior, their attitudes (one's belief about the positive and negative consequences of performing a behavior), their subjective norms (one's belief of whether others would view engaging in the behavior favorably), and their self-efficacy (one's beliefs of their ability to carry out the behavior). Some work suggests that shared lived experience makes social norms and self-efficacy particularly impactful in peer support [36,37]. Finally, the link between intentions and behavior is moderated by having the skills and resources (ie, behavioral control) [32] to enact the behavior [38] and reduce the intention-to-behavior gap [39]; skills and resources strengthen one's ability to act on their intentions. The TPB therefore suggests determinants that may be targeted by FP support.

We also consider YTF [34] to theorize about how shared lived experience between FP and caregiver may affect the probability of caregiver behavior change. YTF posits how group interventions impact group members through elements unique to common lived experience. This includes instillation of hope, universality, and imitative behavior. These factors are likely mechanisms for one-to-one FP support due to perceived sameness between FP and caregiver [40,41]. While particularly salient for emotional support, we hypothesize these factors are active across common FP intervention components. These factors may enhance how FP intervention components act on behavioral determinants described above. Table 2 presents operationalized definitions of common intervention components derived from the review of existing FP programs by Hoagwood et al [22] alongside hypothesized target mechanisms and associated proximal outcomes.

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Table 2. Hypothesized mechanistic pathways to be expanded and refined in aim 1.

FP[a] component	Definition [22]	Hypothesized unique target mechanisms	FP proximal outcomes
Informational support	• Provide information about the biological bases of mental health needs, how services address needs.	• Increased knowledge about the child's mental health condition and services. • Attitudes towards potential utility of services.	• Initiate and sustain mental health services.
Instructional support	• Teach strategies (eg, caregiver coping, self-care, crisis management, problem-solving, and parenting skills). • Teach communication skills.	• Knowledge of the importance of engaging in core FP skills. • Self-efficacy to engage in FP-taught skills. • Knowledge of and self-efficacy to communicate with care team, child, and others.	• Caregiver implements FP-taught skills. • Improved communication with care team, child, etc.
Emotional support	• FP shares about personal experience and provides encouragement.	• Self-efficacy related to ability to navigate the experience of parenting a child with mental health needs and accessing necessary services. • Instillation of hope and sense of universality.	• Initiate and sustain mental health services. • Decreased isolation.
Instrumental support	• Provide tangible support (eg, respite, childcare, and transportation).	• Strengthening ability to act on intentions (address intention-to-behavior gap defined above).	• Initiate and sustain mental health services.
Advocacy support	• Provide information on laws relevant to advocating for child; teach skills to effectively advocate.	• Knowledge necessary to advocate for my child within the mental health system. • Self-efficacy to advocate for child's needs. • Attitudes about the importance of advocating.	• Caregiver implements FP-taught skills.

[a]FP: family peer.

In line with TPB and YTF, we expect all FP intervention components to act on social norms because the intervention is being delivered by someone with a common lived experience. Social norms include injunctive (what others expect one to do) and descriptive (what others have done) norms. We posit that all components act on intentions to engage in the target behaviors, except for instrumental support, which addresses the behavior-to-intention gap.

Intervention components are distinguished in the literature but may overlap and often are delivered together.

Aim 1: Identify Common Intervention Components of FP Support and Associated Target Mechanisms Across FP Models

Overview

Working with our Advisory Board, we develop and refine a survey that includes common FP intervention components and associated mechanisms, as well as a qualitative interview to distribute to FPs and caregivers who provided or received one-to-one FP support. We will survey 50 FPs and 50 caregivers to report on components delivered (FPs) or received (caregivers) and perceptions of each component's utility (ie, mechanism identification) in the first year of providing or receiving FP support. A subset of purposively sampled of 48 respondents will be invited to complete qualitative interviews to share in-depth qualitative data on intervention components, target mechanisms, and perceived effect on outcomes to inform aim 2. Purposive sampling criteria are described in the Participants and Procedures section.

Participants and Procedures

Participants for the aim 1 Survey will be recruited via pathways identified in the Study Setting section. Aim 1 participants will include trained FPs (including FP supervisors or trainers) and caregivers who have received FP support. FP participants must meet the following criteria: (1) have received formal training in providing FP support, (2) have provided at least one session of one-to-one FP support in the past 3 months to a caregiver of a child aged 5-17 years with mental health needs, (3) currently work in a program that represents outpatient care, (4) speak English, and (5) be at least 18 years of age. FP supervisors or trainers must meet the same FP inclusion criteria but only need to have provided one-to-one support in the past 6 months and engage in training or supervising others to provide FP support.

Caregiver participants must meet the following criteria: (1) received at least one instance of one-to-one FP support in an outpatient setting within the past 3 months, (2) identify as a primary caregiver of a child with mental health needs aged 5-17 years at receipt of FP support, (3) focus of FP support was related to child mental health need, (4) speaks English, and (5) is at least 18 years of age.

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For qualitative interviews, we will purposively sample 48 respondents, including 32 FPs (aiming for approximately half to be trainers or supervisors). They will be selected to reflect a range of intervention components delivered, mechanisms targeted, work settings, backgrounds, and years of experience reported. We will also invite 16 caregivers, selected to reflect a range of intervention components received, as well as settings in which seeking FP care and types of support received. We will sample primarily for diversity in FP work setting while aiming to achieve representation across backgrounds, including training model and years of experience.

Survey Development

All survey development procedures will be conducted in collaboration with our Advisory Board to ensure that surveys apply to the diversity of existing FP models and will support the logic model of the problem and change development. Final survey content and design will be determined in collaboration with the study Advisory Board.

The aim 1 survey will use tailored design principles [42], including clear and thoughtful survey development, efforts to minimize respondent burden through brevity, and structured follow-up contacts to maximize accessibility and completion rates. Prior to distributing the survey, we will gather Advisory Board feedback on individual items (including intervention components and mechanisms) as well as feedback on survey accessibility and length. They will report on any components or mechanisms that they think are missing, any that seem redundant, and any sources of confusion. They will also help refine wording to ensure that the survey is easily understood by both FPs and caregivers. These suggestions will be discussed with the research team and integrated into a revised survey that will be shared back with the Advisory Board for additional feedback and refinement prior to survey roll-out. The aim 1 survey will expand an existing validated measure of FP adherence, the family contact log [24,26] to capture content across FP programs and models. We will consult other existing FP quality measures like the family journey assessment [27] and tools used internally by FREDLA to be applicable to a wider range of FP programs. We will use this expanded measure to create both an FP-reported and caregiver-reported version.

We anticipate the final measure will focus on support provided or received in the first year of FP support. For the FP-reported version, FPs will first be asked to identify a specific session in the past 3 months conducted with a caregiver of a child aged 5-17 years they have been working with for a year or less. They will then be asked to report on the extent to which they discussed a range of topics and used a range of common FP intervention strategies with caregivers in that identified session. They will be asked how typical was of their sessions with caregivers, if they discussed any topics or used any intervention strategies in this session that were not included in the list and if they generally use any topics or intervention strategies not included in the list. They will then be presented with the list of strategies that they said they used in the session and asked to select the three most important strategies. Finally, they will be asked to rank the top three target mechanisms from a list provided that they targeted in this identified session. Throughout the survey, respondents will be able to free-respond to share on any intervention components or mechanisms they do not see in the survey. Respondents will also be asked to report on their demographic characteristics and workplace, as well as brief questions on the identified session. For the caregiver version, questions will be revised to instead focus on FP report received in the same format described above but with a focus on general receipt versus identification of a single session. As with the FP version, caregivers will have the option to share any intervention components or mechanisms not listed through a free response option. Caregivers will also complete brief questions about their and their child's demographics, their child's mental health needs, and the setting in which they received FP support. Each version of the survey will take ~30 minutes; all participants will be compensated US $35. Refer to Table 3 for full list of measures to be presented across study aims.

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Table 3. Quantitative measures by study aims.

Respondent group	Aim 1[a]		Aim 3			
	Family peer	Caregiver	Family peer main survey	Family peer parallel[b]	Caregiver parallel[b]	Family peer walk-through[b]
Description of data point	50 Family Peers will complete an aim 1 Survey	50 caregivers will complete an aim 1 survey	200 Family Peers will complete the main aim 3 survey.	Based on survey response, a subset of 40 of Family Peers will be selected to report on a session alongside an identified caregiver.	40 caregivers will be asked to report on a session alongside their Family Peer	Based on survey response, another subset of 40 of Family Peers will be selected to complete up to two walk-throughs (role plays) with a trained actor.
Measures						
Measure of Family Peer intervention component use	✓	✓	✓	✓	✓	✓
Acceptability and feasibility (AIM/FIM)			✓			
Demographic questionnaires	✓	✓	✓		✓	
Mechanism questionnaire	✓	✓	✓		✓	
Session information			✓	✓	✓	

[a]Qualitative interview not included here, this will occur in aim 1 with a subset of both Family Peers and caregivers.

[b]Denotes that this data point is only administered to a subsample.

To help ensure comprehensibility of survey, we will collect feedback on the draft tool up to 4 FPs individually using cognitive interviewing [43] procedures. We will use their responses to refine the survey prior to final administration. We will prioritize getting feedback from those who have not already provided feedback through Advisory Board. Respondents will be compensated US $50 for their time.

Qualitative Interview

In addition to the aim 1 survey, we will use qualitative interviews to gather in-depth information about common intervention components and perceptions of how each links to target mechanisms to deepen findings gathered from survey data (QUAN→qual approach [44]). To participate in the aim 1 qualitative interview, a participant must have participated in the aim 1 survey and been invited to participate based on their survey response, based on sampling criteria described in the Participants and Procedures section.

Interview guides for FPs and caregivers will be refined in collaboration with our Advisory Board. Interviews will first ask respondents general questions about the perceived impact of FP support, more specific questions about identified intervention components respondents reported they often used or received on the aim 1 survey, and ask FPs or caregivers to elaborate on how they operationalize these techniques in practice. Then, we will query respondents about intended mechanisms targeted by components used or received often and outcomes of interest. We will also include questions about how FPs disclose and address cultural factors in their work, and about how relevant contextual factors influence FPs' intervention decisions and families' response to FP recommendations.

For FP respondents, we will assess perceived impact of FP support using open-ended questions (eg, "How do you think receiving Family Peer support impacts families?"). To help operationalize intervention components, we will ask questions like: "When you provide informational support to a family, what does that look like?" To gather information about intended target mechanisms, we may ask questions like: "When you deliver emotional support, what are you hoping to achieve or what changes are you hoping to see in the caregiver?" To support respondents in engaging causal thinking, we may also use fill-in-the-blank statements such as "because" and "if-then" to follow up on specific intended mechanisms. Questions to gather information on outcomes of interest associated with mechanisms will rely on open-ended questions that specifically query areas of improvement seen in the literature (service engagement, changes in caregiver well-being, changes in parenting approach or caregiver-child relationship). We may also reference open-ended responses provided in their survey about mechanism targets. For caregivers, we will ask a directly corresponding set of questions. Interviews will take approximately 45 minutes; participants will be compensated US $50. Interviews will be recorded and transcribed for analysis.

Analyses

Consistent with a QUAN→qual approach [44], quantitative data will first be collected and inspected. Qualitative data will then be used to explore and hypothesis test what is learned in the quantitative data. In the quantitative survey data, we will identify intervention components commonly used by FPs and their perceived links to hypothesized mechanisms from FP and caregiver perspectives. We will conduct basic descriptive

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statistics on the survey data, inspect missingness, and characterize the demographics of the study sample. We will aggregate all open-ended survey responses reporting on intervention components and mechanisms, determine whether content is unique from items presented in the survey, and develop a set of codes to categorize them. We will map them onto the hypothesized mechanisms in Table 2 and generate more categories of potential mechanisms as needed. We will use qualitative analysis to contextualize quantitative results, analyze the open-ended questions, and elaborate on mechanistic pathways that emerge from the quantitative data.

To analyze qualitative results, we will rely on Rapid Qualitative Analysis (RQA) procedures. This approach provides an alternative to traditional qualitative analysis and has been shown to reduce time needed to complete analysis without sacrificing rigor [45-47]. Given the abbreviated window between collection of all aim 1 qualitative data and development and distribution of the aim 3 survey, the focused research questions, and the mixed methods nature of the data collected, we believe this project is well-aligned with RQA procedures [48]. We will first develop our summary template with domains corresponding to study questions informed by existing theory, identified intervention components from the survey, and mechanisms described in the survey. Once the template is fully developed, the first author and all other research team members involved in RQA will assess the template using three randomly selected transcripts. For training and calibration, we will also compare summarizing styles across team members and seek to understand and reconcile any areas of difference. We will continue this process until summaries look equivalent across research team members. The template will include space for other relevant content not reflected in current captures domains. Once the template has been verified and consistency across team members is established, we will divide up transcripts to summarize. Consistent with RQA best practices, the study PI will also audit 20% of the individually prepared remaining summaries using the original transcripts [48].

These summaries will then be placed into a matrix where they can be examined by respondent group. When possible, we will make efforts to complete summary templates immediately after study interviews [48]. Informed by the aim 1 survey, we will use qualitative results and synthesize results into a draft set of core interventions, intended target mechanisms, and links to proximal outcomes for aim 2. We will examine our matrix across and between respondent groups to see if components or mechanisms vary. We will also see if both qualitative and quantitative responses vary by FP background or work setting.

Aim 2: Refine a Logic Model of Change for FP Support that Maps Common Intervention Components to Target Mechanisms and Create a Corresponding Tool to Measure Use of the Components

Overview

Procedures for aim 2 will occur in conjunction with the study Advisory Board. We will present aim 1 data to the Advisory Board. Over a series of meetings, we will collaboratively refine a logic model of change delineating how each intervention component impacts change mechanisms and outcomes. The finalized logic model provides a comprehensive list of FP intervention components with intended mechanisms and informs the tool to be tested in aim 3.

Procedures

Guided by the IM approach of integrating data, theory, and community perspectives to build logic models, we will synthesize Aim 1 data into a summary of common intervention components, mechanisms, and qualitative descriptions to present to the Advisory Board for feedback. We will use visual displays of potential causal pathways using a program like Lucidchart [49] to improve comprehensibility. The focus of one Advisory Board meeting will be on refining the list of intervention components. We will present a comprehensive list of all intervention components identified across survey and qualitative interview results. We will provide accompanying example quotes to show how caregivers, FPs, and trainers describe them. We will ask for global impressions of the list, whether they think anything is missing and whether there are redundancies. We will refine the list based on feedback. At the next Advisory Board meeting, we will present the comprehensive list of target mechanisms endorsed across Aim 1 data with a focus on qualitative and open-ended responses grouped by theme. We will include example quotes of how FPs, trainers, and families perceive these mechanisms to be engaged. We will gather feedback on the links between the intervention component and mechanisms. Finally, at the next meeting, we will present a comprehensive logic model of change that presents each intervention component tied to the mechanism or mechanisms of change that are most strongly linked, and the outcomes of interest. We will briefly present the qualitative data on outcomes of interest for feedback. The Advisory Board will use this drafted logic model to create a comprehensive logic model of change. If there are disagreements among Advisory Board members, we will note these conflicting opinions and try to come to consensus in the meeting. If this is not possible, the PI will reexamine descriptive statistics from aim 1 data to see whether they suggest a direction. If direction remains ambiguous, we will keep both opinions represented in the logic model.

Informed by the final list of discrete interventions included in the logic model, we will create a comprehensive list of common FP intervention components that appear across protocols, how they are delivered, and theorized target mechanisms of change. The components will include clearly operationalized definitions informed both by qualitative interviews and Advisory Board meeting discussions. The list of common intervention components will comprise the first comprehensive list of FP intervention components across FP protocols, which may be used in future effectiveness studies of FP support. These components and their targets also will serve as the basis for: (1) the self-report measure of use of FP intervention components that will be developed for and evaluated in aim 3, and (2) the coding manual to code intervention component use within standardized walk-throughs (refer to aim 3) to validate the self-report tool.

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Using a systematic community-partnered approach [50], we will then adapt the self-report of intervention components tool from Aim 1 to align with the comprehensive logic model of change to be validated in Aim 3. This tool will ask FPs to report on the extensiveness of the intervention components they delivered in a specific session with a caregiver on a 4-point Likert scale. We will solicit feedback from the Advisory Board on the comprehensiveness of the tool and to ensure intervention components are described in easily comprehensible lay language for those working in outpatient settings, which may include community, home-based, and clinic models. After revisions, we will present the tool to 4-to-6 FPs individually and elicit feedback using cognitive interviewing [43]. These FPs will be external to the Advisory Board and will be compensated US $50 for their time. Interviewers will ask interviewees to complete the tool to identify any sources of confusion or response error, using "think aloud" procedures and "verbal probing" cognitive interviewing techniques [43]. Interviewees will also provide feedback on the operationalized intervention descriptions included in the tool and list of common intervention components. Results will inform measure refinements to address common sources of confusion or error until saturation is reached (ie, no additional areas of confusion are identified). We will present the revised tool for final feedback alongside the comprehensive list of common intervention components to the Advisory Board.

Aim 3: Validate the Self-Report Tool to Capture Use of Common FP Intervention Components Developed in Aim 2 in Preparation for Large-Scale Mechanism Evaluation

Overview

We will validate the self-report tool developed across aims 1 and 2. In total, 200 FPs will complete the tool following a recent session with a caregiver, along with brief measures of acceptability, feasibility, perceived target mechanisms, and demographics. We will evaluate psychometric properties including internal consistency and factor structure as well as acceptability and pairs of intervention components and mechanisms.

For additional perspectives on components and associated mechanisms, a subset of 40 FP caregiver dyads will complete a parallel report on a selected session. For validation, an additional 40 FPs will complete up to two standardized walk-through encounters with associated self-report tools, which will be compared to independent observational coding of their sessions. Aim 3 activities will result in refined materials necessary to use in future large-scale evaluations of FP programs.

Participants and Procedures

Aim 3 FP participants may include those who participated in Aim 1. We will also recruit additional FPs to meet our sample size goal. We will rely on the same recruitment methods from Aim 1. Aim 3 FP participants must meet the following criteria: (1) Have received formal training in providing FP support, (2) work in an ambulatory setting, (3) speak English, (4) be at least 18 years of age, and (5) have a caregiver on their caseload who meets the following criteria: caregiver of a child ages 5-17 with mental health needs, receiving individual support from the FP, received at least one session of FP support in past 3 months, and has been seeing the FP for less than a year.

Aim 3 surveys will be administered electronically and include: the developed self-report of common FP intervention components tool, acceptability of the tool, feasibility of the tool, a target mechanism questionnaire, and a demographics questionnaire. In line with validation procedures for other measures to capture fidelity to other intervention components [51], 200 FPs will complete the self-report tool finalized in Aim 2 for a selected session with a representative caregiver. We will then survey them about the acceptability and feasibility of the self-report tool to capture use of common FP intervention components in standard practice, using the validated 4-item Acceptability of Intervention Measure (AIM) [52] to report on acceptability and the 4-item Feasibility of Intervention Measure (FIM) to report on feasibility. Respondents will also answer the target mechanism questionnaire and select what they were trying to change with their intervention delivery from a list of target mechanisms (finalized in Aim 2 activities), based on items they endorsed in the tool. Respondents will also report on the perceived strength of the relationship between intervention component delivery and target mechanisms on a 4-point Likert scale from "not at all" to "a lot." We will collect demographics using the same items as in Aim 1. They will also provide brief deidentified information about the representative caregiver and family, the session, and any factors that affected intervention delivery. The research team will support prompt survey completion to foster session recall using reminders.

Parallel Caregiver and FP Survey Completion Participants and Procedures

For the Aim 3 Caregiver and FP surveys, we will purposively sample FPs by work setting and training background as reported in the Aim 3 survey. If selected based on the Aim 3 survey, FPs will be asked to identify a caregiver with whom they are working, who we will ask to complete the self-report tool a second time for a selected session. We will support FPs to identify caregivers of youth aged 5-17 years with whom they are currently working. Because services may differ for caregivers early vs later in their FP support, we will randomly ask FPs within this subset to invite either: (1) a caregiver within their first 3 months of FP service who has had at least 2 prior sessions, or (2) a caregiver with whom they have been working for 3-12 months to participate. While no formal consensus exists on the ideal length of time involved in FP support, studies suggest one-to-one FP support can range from 3 months to 9 months or longer in length [12,20,53,54]; thus, these windows were selected to differentiate early vs later phase content that might be delivered.

To recruit caregivers, selected FPs will be given a handout and link to provide to an identified caregiver with whom they are working. FPs will be instructed to select a session that is not a first or last session, as the content of these is likely to be distinct from the typical content of FP support. Once provided with the handout and link, the caregiver will have the option to speak with the study team or complete a consent form independently.

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Once a caregiver consents, they will be texted a link to their survey immediately after their indicated session. This survey will include the self-report tool to capture receipt of common FP interventions alongside the target mechanism questionnaire, session information, and brief demographic questions. FPs will also be texted a parallel survey link immediately after the selected session. If the caregiver does not consent prior to the session but does want to participate, while we will aim for survey completion within 48 hours of the session, they will be eligible to consent within a week of the session and have up to three weeks after the session to complete the parallel self-report tool. However, we will make all efforts to have consent obtained prior to the session to allow for reporting on content as close to the session as possible. There will be no recording of caregivers.

Walk-Through Participants and Procedures

To further validate the self-report tool, we will select another subset of 40 FPs based on their Aim 3 survey results to complete a standardized role play (walk-through paradigm. In selecting the subset of FPs for the walk-through, we will aim for a diverse sample in terms of work setting, training background, and whether the FP reports high, medium, or low use of intervention components on the Aim 3 FP survey. The walk-through is meant to simulate a prototypical session with a caregiver and relies on a trained FP to act as a standardized patient and role-play a caregiver who is receiving FP support [28]. We have selected the walk-through approach over video or audio recording sessions due to acceptability concerns related to recording. This method has been used with FPs to evaluate service delivery and has been found to be feasible and acceptable [24,28]. However, it is time-intensive and not suitable for scale-up, underscoring the importance of validating a pragmatic, self-report tool to capture use of common FP intervention components.

Selected FPs will be assigned to complete up to two randomly selected walk-through scripted vignettes that may represent different phases of treatment (eg, beginning, middle, and end of treatment), excluding first or last sessions. Walk-through scripts will include three possible scenarios adapted to ensure that they allow FPs to use the full range of common FP intervention components from the self-report tool. After the walk-through, each FP will complete the self-report tool to report on their own use of the common FP intervention components delivered in the walk-through. Walk-through recordings will also be coded by trained raters using a comprehensive coding scheme for all possible FP interventions delineated on a scale that parallels that of the self-report tool. To establish coding reliability, research team members including the PI, research assistant, and student worker will code alongside a trained FP and supervisor who is part of our Advisory Board. To be consistent with benchmarks for other observation coding scales [55], raters will be considered reliable and able to code independently after achieving intraclass correlation coefficients of >0.70 with the consensus code.

Analyses

We will examine the psychometric properties of the FP completed self-report tool to capture use of common intervention components, including internal consistency for the measure using Cronbach α. To examine response patterns, we will look at a histogram of all item responses. We will also conduct Exploratory Factor Analysis (EFA) to see which constructs appear and which intervention components are endorsed together. After data screening, we will create a correlation matrix of pairwise and partial correlations. To determine data factorability, we will look at the correlation magnitudes and their statistical significance. We anticipate many items will be highly correlated, indicating that they are endorsed as frequently delivered together in a session. We will look at Kaiser measure of sampling adequacy to ensure that it is greater than 0.6, indicating factor analysis suitability. If many correlations are significant and the Kaiser measure of sampling is adequate, we will extract factors via maximum likelihood factoring. For interpretability, we will rotate the factors using an oblique rotation (promax). To determine the number of factors, we will use a combination of parallel analysis with Glorfeld correction [56], minimum average partial [57], interpretability, and evaluation of the scree plot for where the eigenvalues begin to form a downward linear trend (the “elbow”). We anticipate at least 5 factors based on what is in the literature (Table 2); however, as noted above, it is possible additional key content areas may emerge based on aim 1 activities, so the final measure may include more factors. If a smaller number of factors is adequate, we will retain the most parsimonious factor model. In the interest of keeping the measure as brief as possible, we will inspect factor loadings, item thresholds/intercepts, and face validity to determine inclusion or removal. We will examine eigenvalues to determine the amount of variance explained by each factor and examine the variance accounted for by the factors. We expect the factor structure to account for at least 60% of the total variance [58]. We will examine if psychometric properties vary based on FP background or work setting. We will also examine if these variables impact components reported and associated mechanisms from the mechanism survey. High variability may suggest additional measure revisions necessary to ensure items translate across FP models. Finally, we will also examine feasibility metrics such as questions missed and time taken to complete measure, as well as results from the Acceptability of Intervention Measure (AIM) and Feasibility of Intervention Measure (FIM) [52].

Post hoc sample size adequacy will be determined by (1) evaluation of the loading standard errors, and (2) bootstrapped resampling and refitting of the factor structure to check its stability. The latter will involve Procrustes-rotating each solution to the full-sample target (to handle rotational indeterminacy, sign flips, and column reordering) and examining the distribution of loadings and frequency with which items change factor assignment with each resample.

We will examine convergent validity in the subsample of 40 FPs who complete the standardized walk-throughs by comparing results of coded recordings to the FP-completed tool from the walk-through encounters. We will use paired *t* tests to identify any differences between results from the walk-through and the self-report tool for each item. We will also examine responses collected from FPs about acceptability and feasibility of the measure and how long it took them to complete the measure.

We will also examine convergence of FP responses and caregiver responses for the subset of 40 dyads. We expect that

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FPs and caregivers may vary in their report of what occurred given that there is known variability in provider and client agreement on therapy session content [59,60]. We will analyze any area of discrepancy to inform understanding of common components as well as possible mechanisms.

Early-Stage Mechanism Validation

We will preliminarily validate the mechanistic pathways identified in aims 1 and 2 by creating a correlation matrix of items from the self-report tool of common FP intervention components and survey items from the target mechanism questionnaire. We will identify mechanisms most highly correlated with each intervention component. The most correlated variables will be selected for formal validation in a subsequent R01 proposal using prospective caregiver data to measure mechanisms. We will also specifically examine pathways identified in the logic model with these correlations. For example, if the logic model says advocacy support increases self-efficacy, we will examine the correlation between these items. We will consider correlations significant above a threshold of 0.30 to be evidence of preliminary validation of the association. Analyses are not intended to be fully powered; correlation magnitude will inform model refinement for fully powered testing in a subsequent trial.

Consistent with IM, we will present all relevant findings to the Advisory Board. We will discuss psychometric data, including discrepancies between observational coding, caregiver, and FP-report to determine if modifications to the FP self-reported tool are warranted before use in subsequent studies. We will also present preliminarily validated mechanistic pathways for feedback and revision.

Ethical Considerations

All study procedures were approved by the University of Pennsylvania Institutional Review Board (IRB) in accordance with ethical research guidelines for human subjects (protocol 858162). Any modifications to the approved protocol, research strategy, or outreach materials will be submitted to the IRB per institutional procedures. All study participants will provide informed consent and can ask questions prior to engaging in any study activities. Any deviations from the protocol or adverse events will be documented and reported to the IRB.

Results

The study received NIMH funding in September 2025. At the end of August 2026, 4 participants have participated in the aim 1 survey. We anticipate aim 1 will be completed in November 2026, at which point we will prepare for study activities in Aim 2. We aim to have all study data collected inclusive of aims 1, 2, and 3 by August 2029. Per the terms of our grant award, we will submit deidentified study data collected in Aims 1 and 3 to the NIMH Data Archive for participants who consent to data sharing.

Discussion

Contribution to Existing Work

This study has the potential to significantly advance our understanding of how FP support impacts family outcomes through developing a mechanistic model of FP support, a comprehensive list of FP intervention components across the range of FP programs, and a self-report tool to capture use of these components applicable to the range of existing models in one-to-one FP support for caregivers of children ages 5-17 in outpatient settings, including community and home-based models. This will facilitate large-scale testing and support efforts to optimize FP support.

Design Considerations

We considered other approaches to learning about the content of FP support such as gold-standard audio and video recording followed by expert coding of behavior. However, based on feedback from community partners, this methodologically rigorous approach to characterizing FP content is unlikely to be acceptable or feasible within the FP workforce. Therefore, we prioritized developing a pragmatic, self-report measure that can be feasibly used in a larger trial and is likely for uptake in settings in which FP support is being implemented. We also considered including group FP support and FPs supporting a broader range of ages and for different amounts of time (ie, beyond the first year of FP support). The narrowed focus of this study will enhance our ability to delineate mechanisms and validate the self-report tool, which can then be tested within broader and varied FP contexts in future trials. Finally, we also considered pilot testing the comprehensive list of common FP components developed in Aim 2. FP support is already widely implemented with promising results to date. All common intervention components included will derive from the variety of extant FP protocols. It is most pressing to develop tools that can be used in the contexts in which FP support is already being implemented.

Limitations

Conducting this study requires balancing two needs: recruiting a sufficient number of participants within different programs and recruiting across the many different programs and settings in which FPs work. Even with careful planning, the final tool will not fully reflect all program types or geographic contexts due to the heterogeneity of FP support. Furthermore, it will not reflect the full range of FP models as it focuses on the provision of one-to-one FP support for caregivers of youth ages 5-17 in community, clinic, and home-based models. To increase the representativeness of study findings, we are engaging in ongoing collaboration with leading FP organizations across the United States and representation of geographic and programmatic diversity in our Advisory Board and recruitment efforts. Buy-in and feedback from these individuals will help ensure that our participant pool represents a broad range of models within the specifications above.

There are also several limitations related to measurement of intervention components and associated mechanisms in this study. First, we rely primarily on self-report data rather

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established gold-standard methods like observational coding to capture the content of FP support due to acceptability concerns of this alternate robust methods [24]. Although the study includes a subsample comparison to observational data, reliance on self-report remains a limitation of our study design. Second, we do not directly measure potential mechanisms of change, instead gathering FP and caregiver perspectives about mechanisms potentially engaged by FP support. Finally, this study exists within the context of a workforce motivated to demonstrate the value of FP support, which may make this measure particularly vulnerable to social desirability bias.

Finally, it is possible that the self-report tool may not initially demonstrate adequate psychometric properties. If this occurs, we will revise the tool in consultation with the study team and the Advisory Board before conducting the standardized walk-through, after which we will reassess psychometric properties and convergent validity.

Future Directions

Products from this study will allow for large-scale testing of the mechanistic pathways of FP effectiveness in subsequent trials for one-to-one FP support in community, home, and clinic-based settings. This study will result in a comprehensive list of treatment components, a self-report tool to report on use of these components, and a list of associated mechanisms to validate in larger trials incorporating data from caregivers and families from these types of programs. We also anticipate project outcomes to allow for larger-scale testing of discrete FP intervention components.

Given that this study focuses only on the provision of one-to-one FP support for caregivers of children aged 5-17 years within community, clinic, and home-based settings, future work should include collaboration with other individuals conducting similar work within other FP settings and levels of care to determine commonalities and differences across models.

Conclusions

FP support is a promising model already used widely across the United States. This study has the potential to advance the evidence base for FP support through rigorous delineation of intervention components tied to mechanisms and relevant outcomes common to the range of community and home-based models of FP support. Further, this project will result in a self-report tool to capture use of common FP intervention components applicable to this range of models. Both products are necessary prerequisites for larger-scale testing.

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Data Availability

The datasets generated or analyzed during this study will be available in the National Institute of Mental Health Data Archive (NDA) in accordance with the Data Submission Agreement for this study.

Generative AI Use

The authors declare that generative AI was not used in the preparation of this manuscript.

Authors' Contributions

JJ, EMB-H, DM, and KH conceptualized the study. JJ and SY wrote the initial draft of the manuscript. All authors reviewed the manuscript, provided feedback, and approved the submitted version. Manuscript content is the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Conflicts of Interest

None declared.

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Abbreviations

AIM: Acceptability of Intervention Measure
FIM: Feasibility of Intervention Measure
FP: family peer
FREDLA: Family-Run Executive Director Leadership Association
FTNYS: Families Together in New York State
IM: Intervention Mapping
IRB: Institutional Review Board
NIMH: National Institute of Mental Health
PI: principal investigator
RQA: Rapid Qualitative Analysis
TPB: theory of planned behavior
YTF: Yalom's therapeutic factors

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