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Mixed-methods protocol for developing and implementing a culturally informed **FA**mily **M**otivational **E**ngagement **S**trategy (FAMES) to increase family engagement in coordinated care programs

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ABSTRACT

Introduction: Despite the proven effectiveness of coordinated specialty care (CSC) programs for first-episode psychosis (FEP) in the United States, CSC programs often have low levels of engagement in family psychoeducation, and engagement of racial and ethnic minority family members is even lower than that for non-Latino white family members. The goal of this study is to develop and evaluate a culturally informed FAmily Motivational Engagement Strategy (FAMES) and implementation toolkit for CSC providers.

Methods and analysis: This protocol describes a mixed-methods, multi-phase study that blends intervention mapping and the Promoting Action on Research in Health Services framework to develop, modify, and pilot-test FAMES and an accompanying implementation toolkit. Phase 1 will convene a Stakeholder Advisory Committee to inform modifications based on findings from phase 1 and 2. During phase 1, we will also recruit approximately 200 family members to complete an online survey to assess barriers and motivation to engage in treatment. Phase 2 we will recruit five family members into a three-month trial of the modified FAMES and implementation toolkit. Results will guide the advisory committee in refining the intervention and implementation toolkit. Phase 3 will involve a 16-month non-randomized, stepped-wedge trial with 50 family members from five CSC programs in community-based mental health clinics to examine the acceptability, feasibility, and initial impact of FAMES and the implementation toolkit.

Ethics and dissemination: This study received Institutional Review Board approval from Washington State University, protocol #17812-001. Results will be disseminated via peer review publications, presentations at national and international conferences, and to local community mental health agencies and committees.

Keywords: *Community mental health, Coordinated specialty care, Family engagement, First-episode psychosis, Implementation strategies, Motivation*

Trial registration: *ClinicalTrials.gov, NCT04188366, registered 28 December 2019,*

Strengths and limitations of this study

- This protocol demonstrates how to use a blend of intervention mapping and the PARIHS framework to develop, implement, and evaluate a culturally informed family engagement intervention and implementation toolkit.
- This study will examine the acceptability, feasibility, and initial impact of a family engagement intervention that addresses motivation as a mechanism for engagement in mental health services.
- If successful, the family engagement strategy can be utilized by community mental health clinics to increase engagement in services for youth and adults.

INTRODUCTION

Coordinated specialty care (CSC) programs in the U.S. ameliorate psychiatric symptoms and improve functioning and quality of life among youth and young adults experiencing first-episode psychosis (FEP).[1] CSC programs feature evidence-based practices such as individual or multi-group family psychoeducation.[2] There is considerable evidence demonstrating that family psychoeducation is associated with increased medication adherence, reduced relapse and rehospitalization, and improved functional status and family management of psychosis.[3-8] Family members have a key role in facilitating care and their participation in treatment is often associated with higher treatment engagement of individuals with FEP, particularly among youth.[9-15] Despite evidence for the effectiveness of CSC programs and family psychoeducation, and the importance of family member involvement in mental health treatment, the implementation of family psychoeducation in CSC programs has been low and is one the most challenging components of CSC according to providers.[16] For instance, in a large clustered randomized trial of NAVIGATE, a CSC program for FEP, 69% of family members did not participate in family psychoeducation.[17] These findings also revealed that non-Hispanic Black and Hispanic family members engaged in treatment at lower rates than non-Hispanic whites. We need to better understand and systematically address factors and underlying mechanisms, that affect the successful implementation of family-based interventions in mental health settings.

Previous studies suggest that low motivation and logistical, perceptual, and cultural barriers hinder treatment engagement and subsequently limit successful implementation of family interventions like family psychoeducation.[13,18-28] Logistical barriers include lack of financial resources, transportation problems, and inadequate clinics operation hours.[29-31] Perceptual and cognitive barriers include lack of interest due to religious beliefs, substantial burden, and perceived

lack of benefit.[23,26,32,33] At the provider level, improving clinicians training in cultural competence and providing culturally sensitive care increases treatment engagement and retention, while also mitigating cultural and perceptual barriers.[33,34] Although motivation has been identified as a mechanism for improving treatment engagement and retention among individuals with serious mental illnesses (e.g., schizophrenia),[35,36] research on engagement and family motivation has been limited. One study found that lower motivation was associated with greater perception of treatment barriers and lower engagement among family members of youth with conduct disorder.[37]

To address logistical, perceptual, and cultural barriers to engagement, several strategies and interventions have successfully improved family engagement for individuals with conduct disorder,[38] substance use disorders,[39-41] and those who access school programs.[42] Several of these studies have used techniques that enhance motivational and family engagement.[38,43] For example, Nock and Kazdin developed the Participation Enhancement Intervention composed of three major components: 1) describing the importance of treatment engagement, 2) motivational statements about engagement, and 3) addressing engagement barriers.[38] In their randomized trial family members receiving the intervention showed greater motivation and engagement than family members in the control condition. Other strategies that have led to increased engagement are telephone-based interventions addressing treatment barriers[44,45] and providing extrinsic motivators (incentives) for family involvement in mental health care.[42]

Study aims/objectives

The overarching purpose of this project is to assess the feasibility and acceptability of a brief provider-led FAmily Engagement Motivational Strategy (FAMES) and its accompanying implementation toolkit, and to examine its initial impact. This project has three phases: 1) survey family members regarding logistical, perceptual, and cultural barriers, and motivators that

influence engagement in CSC programs for FEP to inform modifications; 2) refine FAMES and the implementation toolkit for use in CSC programs for FEP using findings from Aim 1 and with input from key stakeholders, such as clients with FEP and their family members, CSC providers, and CSC organizational leaders; and 3) examine the feasibility, acceptability, and preliminary impact of FAMES in five CSC programs using a stepped-wedge design.

METHODS

Theoretical framework

This multi-site, mixed-methods project will be completed in three phases: 1) intervention development, 2) intervention modification, and 3) efficacy evaluation using a non-randomized stepped-wedge pilot trial design (Figure 1). We will apply core components of intervention mapping (IM) and the Promoting Action on Research in Health Services (PARIHS) framework, a collaborative implementation framework (Figure 1). IM is commonly used in implementation science to develop interventions and implementation strategies that are rooted in theory, build upon evidence, and incorporate stakeholder perspectives through an iterative process. IM is composed of six steps: 1) problem analysis (preliminary data), 2) review of theory-based methods and practical strategies, 3) development of the intervention, 4) modification of intervention methods and strategies, 5) development of the implementation plan, and 6) evaluation.[46] The PARIHS framework outlines factors necessary for the successful implementation of interventions into practice and has been extensively utilized to guide implementation. PARIHS is composed of three stages:[47-51] 1) the evidence stage gathers information related on stakeholder experiences, needs, and preferences to inform the intervention; 2) the context stage evaluates the acceptability, feasibility, and sustainability of the intervention among stakeholders; and 3) the facilitation stage is focused on the appropriateness of the intervention and provider skills.

Insert Figure 1 about here

Intervention components

FAMES will involve three distinct and revolving components - early, continuous, and motivational contact - that incorporate motivational techniques and the Diagnostic and Statistical Manual of Mental Disorders 5TH Edition (DSM-5) Cultural Formulation Interview (CFI).[52-54] The CFI will be used to identify the unique needs of family members within the context of their culture, enhance the provider-family relationship, and personalize treatment components of family psychoeducation.

Early contact by email, phone, or text message will occur 14, 7, and 2 days prior to the first scheduled orientation appointment for family members. To facilitate ongoing engagement, *continuous contact* between providers (e.g., a licensed mental health counselors, social workers, or case managers) and family members will be made 12 to 16 days after each family appointment. During the early and continuous contacts, providers inquire about potential barriers participation in family appointments and other CSC appointments for their loved one. Providers will assess social support systems and remind family members of upcoming appointments. The *motivational component* will occur in person once per month, for a duration of approximately 20 minutes immediately prior to the family appointment. Providers discuss the barriers that were identified during the early and continuous contacts, work with family members identify pragmatic and tangible solutions to these barriers (e.g., extrinsic motivations), and develop a plan to overcome these barriers. Providers will prompt family members to create motivational statements (e.g., intrinsic motivations) that are goal-driven, with an emphasis on overcoming these barriers and promoting continued engagement. During development and modification phases, we will identify and determine possible changes to the components and delivery of FAMES.

Implementation toolkit components

During phases 1 and 2, we will develop an implementation toolkit, designed to be a resource for providers to facilitate the uptake and implementation of FAMES.[55] We anticipate that the FAMES implementation toolkit will utilize a combination of strategies (e.g., implementation guides, fidelity checklist, audit and feedback, technical assistance, internal or external facilitators) that can be amendable to a specific CSC program.[56]

Patient and public involvement

Patients, family members, and other stakeholders were not involved to the research question, study design, and outcomes measured. However, during this phases 1 and 2, a Stakeholder Advisory Committee will be convened, which will include two family members who have experience with CSC programs for FEP, a CSC provider (e.g., a licensed mental health counselor, social worker, or case manager), a former client who graduated from a CSC program, and a CSC administrator. The Stakeholder Advisory Committee will meet via videoconference two to three times per year in phases 1 and phase 2 to aid in the modification of FAMES. Findings from all phases will be disseminated to community mental health agencies and patient and family advisory groups.

Phase 1 – Intervention development

Design

Based on previously collected and published data that informed IM step 1 (problem analysis),[17] Self-Determination Theory (SDT) was chosen as an overarching theoretical framework to ensure that the intervention's underlining mechanism of motivation is targeted by incorporating specific components, an approach consistent with IM step 2 (review of theory-based methods and practical strategies).[57] SDT focuses on three fundamental human needs: autonomy (choice),

competence (self-efficacy), and relatedness (belonging). These are linked to a continuum of intrinsic motivations (internal drives to behave in a certain way such as core values and interests) and extrinsic motivations (external sources that result in external rewards such as awards).[58]

Aligned with the evidence stage of the PARIHS framework, approximately 200 family members of individuals with FEP will be recruited to complete a customized online REDCap or paper survey instrument to identify family members' needs and barriers to treatment and underlying proximal targets of change that may not have been previously identified. During IM steps 2 and 3, the Stakeholder Advisory Committee will meet several times throughout phase 1 to develop and discuss matrices of change objectives that are based upon data from IM step 1 and are informed by survey findings. These meetings will build on the intervention components, previously described, to ensure that intervention components adequately address needs, barriers, and proximal targets of change identified from survey findings in a feasible and practical way.

Inclusion Criteria

Survey eligibility criteria are: 1) aged 18 years or older; 2) family member (e.g., parent, guardian, aunt/uncle, spouse, grandparent, sibling, close friend) of an individual who has or had received services from an early intervention or CSC program for FEP in the US.

Data collection

Surveys will be directly entered into REDCap through an online survey link. The survey link will be distributed through national and local listservs and CSC programs. Potential participants will be informed that the survey will take approximately 25 minutes to complete and a unique return code will be provided for participants who are unable to complete the entire survey in one sitting. A list of measures included in the survey are outlined in Table 1.[59]

Insert Table 1 about here.

Data Analysis

Descriptive analyses will be conducted to assess family members' pathways to care, satisfaction with treatment, motivation for participation, and suggested areas for improving CSC programs. Regression analyses will be utilized to identify important components to services and to assess racial/ethnic group differences in treatment barriers, satisfaction, and motivations.

Phase 2 – Modifications

Design

Aligned with the context stage (pre-evaluation) of the PARIHS, FAMES and the developed implementation toolkit will be studied across a three-month time period among five family members from one CSC program using a combined quantitative and qualitative mixed-methods approach.[60] Phase 2 will include the completion of IM step 4 (modification of intervention methods and strategies) and step 5 (development of the implementation plan) using an iterative process where the Stakeholder Advisory Committee will provide suggestions that will inform modifications to FAMES and development of the implementation toolkit. Regularly scheduled, audio-recorded Stakeholder Advisory Committee meetings will occur throughout this phase and include the review of quantitative and qualitative data summaries from the three-month study. Suggested modifications identified from summaries will be compiled for the Stakeholder Advisory Committee to rate based on level of importance and feasibility and used to stimulate discussions on steps to refine intervention objectives and components. Similar to phase 1 steps to inform intervention components, the Stakeholder Advisory Committee meetings in phase 2 will also develop the learning objectives for the implementation toolkit and connect these objectives to a theory-based method and practical strategy that will be refined based on feedback from providers.

Setting

During phase 2, FAMES will be studied at one CSC program within Washington State's New Journeys network. New Journeys is a state-funded CSC program for FEP with nine locations distributed in community mental health clinics in rural and urban settings throughout Washington State.[61] Each New Journeys site employees four to eight mental health providers and currently serves a total of 300 clients with FEP. The New Journeys network serves approximately 55% racial and ethnic minorities; the average age of clients is 20 years; and 70% of clients reside with a family member or caregiver.

Inclusion Criteria

Eligibility for inclusion for family member participants in phase 2 include: 1) aged 18 years or older; 2) one family member (e.g., parent, guardian, aunt, uncle, spouse, grandparent, sibling, close friend) of an individual enrolled in a Washington State CSC program; and 3) has received no more than 3 months of services. Eligibility criteria for provider participants are 1) aged 18 years or older and 2) employed at a Washington State CSC program for more than two months.

Data collection and outcomes

To limit the burden on providers, self-reported measures for family member participants will be delivered directly to participants' mobile devices and email accounts using mobile and text message enabled capabilities linked to a customized REDCap database. Measures to assess satisfaction and practicality will be collected at baseline and monthly throughout the three-month study period. We will also measure the extent to which the intervention preliminarily impacts motivation. Measures to the assess toolkit, will be completed by provider participants will completed at baseline that will inform the implementation process in real-time and after the three-month study period that will be used by the Stakeholder Advisory Committee to improve the implementation toolkit. Separate qualitative interviews will be completed by family member and

provider participants at months 1 and 3 to solicit opinions on what components may, or may not be working, suggestions for improvement, and any lessons learned. All Stakeholder Advisory Committee meetings will be audio-recorded to capture qualitative comments. Key concepts from quantitative and qualitative data will be presented during Stakeholder Advisory Committee meetings. Suggested improvements and action items will be rated by members on the Stakeholder Advisory Committee, based on feasibility and importance.[62] These ratings will stimulate Stakeholder Advisory Committee meeting discussion points that will modify FAMES. These data will help us make improvements to the intervention delivery in real-time.

Quantitative data analysis

Descriptive analyses will be performed to assess satisfaction, motivation, practicality and implementation process. The mean score of ratings on practicality will be calculated and presented to the Stakeholder Advisory Committee.

Qualitative data analysis

All interview recordings will be transcribed verbatim and imported into NVivo 11, a qualitative data management software, a directed content approach will inform data analysis.[63,64] Coding will focus on satisfaction and areas for improvement. Qualitative data gathered from family member and provider participants will be coded, summarized, and presented to the Stakeholder Advisory Committee. The meeting recordings will be translated into actionable plans that will be re-presented to the Stakeholder Advisory Committee. To increase rigor, we will use member checks to confirm findings, keep detailed notes from each meeting, and establish an audit trail.[65,66]

Phase 3 – Stepped-wedge design pilot trial

Design

IM step 6 and the context (evaluation) and facilitation (appropriateness and skills) stage of the PARIHS informs phase 3. During this phase, we will conduct a non-randomized stepped-wedge pilot trial in five CSC programs in Washington State using a combined quantitative and qualitative mixed-methods approach.[60,67] Each CSC program will represent a cluster and serve as its own control (Figure 2). A two-month implementation transition period will occur at each CSC program and during which providers will be introduced to the intervention using the implementation toolkits and trained to conduct FAMES. A 12-month open cohort design will be utilized to recruit approximately 50 family members during the study period.

Insert Figure 2 about here.

Setting and inclusion criteria

In phase 3, FAMES will roll out sequentially in five CSC programs in Washington State's New Journeys network. Inclusion criteria for family members and provider participants in phase 3 will be with the same as the inclusion criteria detailed in phase 2.

Data collection and outcomes

The *primary outcomes* to be assessed are feasibility and acceptability of FAMES and the implementation toolkit. Primary outcome measures are described in detail in Table 1. The *secondary outcomes* will include measures related to the preliminary impact of FAMES on family engagement. These secondary outcomes will include engagement and retention, to be obtained by providers and entered directly into the REDCap database.[68] Motivation, family functioning, and cultural competence will also be captured using self-reported measures completed by family members. Primary and secondary outcome measures will be collected monthly during the control and intervention conditions. During the follow-up period for each program, family members will complete measures related to treatment motivation and family functioning at 1- and 3-months post-

intervention completion. *Exploratory outcomes* include implementation outcomes (e.g., adherence, exposure, quality, differentiation, responsiveness) will be tracked and assessed by external facilitators (i.e., research staff) throughout the implementation phase and during the intervention condition using audio/video recordings to monitor the delivery of FAMES across all CSC programs. At baseline and at 1-month follow-up provider participants will complete an organizational readiness measure that will assess key components of the PARIHS.[51] Providers will also be asked to complete an online self-report intervention component checklist in REDCap after each contact and session.[69]

Sustainability and uptake will be tracked by research staff during the follow-up period at 1- and 3-months post-intervention completion. Qualitative interviews will be completed by family member and provider participants at two iteration points during the study. The first will occur 1-month post-implementation and the second during the follow-up period, 1-month post-intervention completion to assess acceptability, feasibility, and key concepts of the PARIHS framework.

Statistical power

Our choice of sample size (n=50) needed given the stepped-wedge design to ensure adequate power to preliminary detect the initial impact of FAMES on improving engagement and motivation [70]. Accounting for an incomplete stepped-wedge design project with five clusters (i.e., community-based clinics) with an average recruitment of 10 family members per cluster, an intra cluster correlation of 0.10, and a significance level of 0.05, it is estimated that this will provide us with an estimated power of 0.84.

Quantitative data analysis

At the completion of the stepped-wedge trial in phase 3, we will perform descriptive analyses on the primary and secondary outcomes. We will also compare mean differences in

satisfaction scores from control and intervention conditions across all programs, using independent sample t-tests. We will utilize generalized estimating equation techniques to assess differences in engagement by comparing the control and intervention conditions, while controlling for potential confounders (e.g., time, site). To assess the mediation effect of motivation, cultural sensitivity, and burden on the primary engagement and retention outcomes, we will path analytic modeling (e.g., bootstrapped confidence intervals to evaluate indirect effects). If needed, we will use maximum likelihood, multiple imputation, or other sensitivity analyses, including "missing not at random" approaches, to account for missing data.[71]

Qualitative data analysis

The phase 3 qualitative analysis will also use key concepts derived from the SDT (e.g., autonomy, competence, relatedness, extrinsic and intrinsic motivations). Areas related to acceptability (i.e., satisfaction) will be utilized to develop and operationalize an initial coding scheme for data obtained from family member participants. Key concepts from the PARIHS framework such as organizational fit, relevance, range of flexibility, and style will be used to develop and operationalize the initial coding scheme for data obtained from provider participants.[72] Coding and analysis will be conducted independently by two coders through a series of iterative readings, noting text that corresponds to initial codes.[66,73,74] A kappa of .8 will be required for coders to code independently and codes will be continuously refined.[75] Notes will be used to develop a final codebook. To guard against biases of directive content analysis, an audit trail—documenting analytical decisions, analyzing cases that did not fit our coding scheme, and generating new codes not present in initial codebooks—will be maintained.[65]

Mixed-methods integration

A thematic matrix will integrate qualitative and quantitative data using a side-by-side comparison to examine feasibility, acceptability, and implementation outcomes.[76-78] We will answer questions such as: will the qualitative data collected from family member participants match the quantitative data collected regarding satisfaction and engagement? Qualitative data collected from provider participants using the PARIHS framework will be used to explain quantitative data collected on fidelity measures. Barriers and facilitators identified by family members and providers will identify similarities and differences between these stakeholder groups that will be linked to provide further explanation and to help contextualize results.

DISCUSSION

Despite previous research on engagement interventions in other populations and settings, little is known about strategies to engage family members in the context of CSC programs. Research has also suggested inequities in utilization of evidence-based interventions (e.g., family psychoeducation) among racial and ethnic minorities that directly impacts successful implementation. We will utilize a mixed-methods approach throughout the study to meld core components of IM and the PARIHS framework to develop, implement, and evaluate the culturally informed FAMES and implementation toolkit to address these inequities; evaluation will focus on acceptability, feasibility, and initial impact. Very little research has systematically utilized implementation science to address inequities in service utilization related to race and ethnicity within community mental health clinics. The study protocol described will actively identify and modify strategies to address logistical and cultural barriers that contribute to these inequities at the family, provider, and organizational levels. By utilizing a rigorous mixed-methods approach, this study will also provide a roadmap for implementation and local adaptation that may contribute important knowledge to the field of implementation science.

This study has several strengths, including the unique components of FAMES that will incorporate the DSM-5 CFI, which has only been previously focused on the assessment of individuals will now be tailored for families. This will allow clinicians to integrate culturally sensitive information to increase our understanding of family-related motivators related to treatment and that can then be incorporated into treatment planning for all racial and ethnic groups. The utilization of a stepped-wedge design provides the opportunity to offer FAMES to all CSC programs included in the study. It also presents an additional opportunity to assess whether FAMES has the potential to re-engage family members who over time have disengaged. In light of these strengths and potential impacts, family members' participation may be limited for programs that receive FAMES later in the trial. We will monitor family member participation during the control period with monthly program check-ins. As a pilot study, it is important to note that overall findings are limited by sample size and generalizability. However, this pilot project includes six CSC programs in rural and urban settings that will contribute to the iterative process of refining FAMES and its implementation various settings.

As the mental health field seeks to better understand motivations toward treatment in order to improve engagement and retention in CSC programs, this study will explore how to effectively engage and motivate families from various racial and ethnic groups. If successful, our findings will influence the scale up of FAMES to other CSC programs, while also potentially improving family engagement in other mental health services.

Ethics approval
Ethics approvals for this study were obtained from the Washington State University Institutional Review Board.

Patient consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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Authors' contributions
OO developed the concept, study design, and drafted the first version of the study protocol. DGD, SMM, RLF, MTC, MGM, and LJC contributed to the study design and revised subsequent versions of the study protocol. All authors have read and approved the final manuscript.

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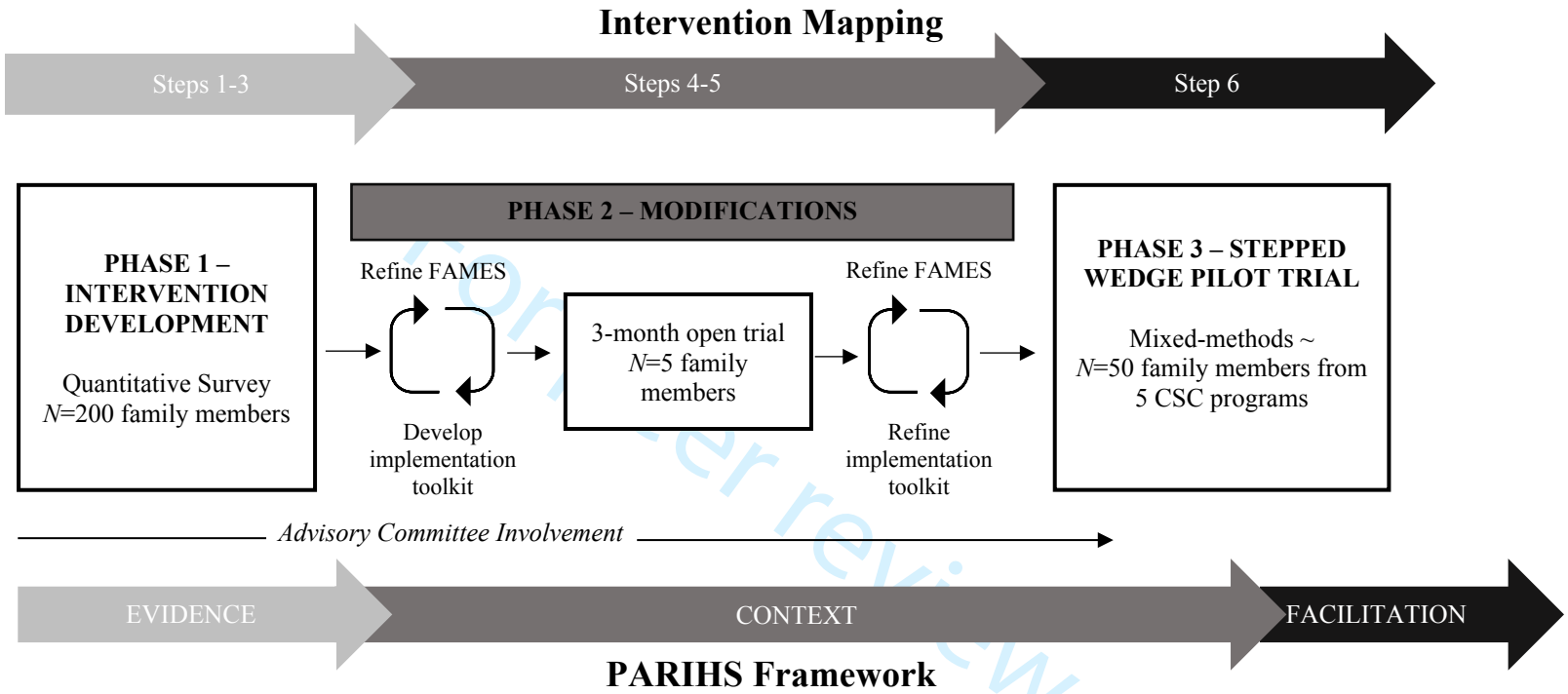

Note: Coordinated specialty care (CSC); Promoting Action on Research in Health Services (PARIHS)

Figure 1. Study design: Blend of intervention mapping and PARIHS framework

Cluster	Study Months															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
CSC program 1	T	T	I	I	I	F	F	F								
CSC program 2			T	T	I	I	I	F	F	F						
CSC program 3					T	T	I	I	I	F	F	F				
CSC program 4							T	T	I	I	I	F	F	F		
CSC program 5									T	T	I	I	I	F	F	F

Note: Black shading is the control period; T=implementation transition period; I= Intervention period; F=Follow-up/Sustainability period; dark gray shading is the follow-up period

Figure 2. Modified stepped-wedge pilot trial of FAMES

Table 1 – Outcomes and description of measures

Outcome	Quantitative Component - Measure Description	Qualitative Component
Phase 1- Intervention development		
	Barriers to Treatment Participation Scale,[79] a 58-item semi-structured questionnaire that gathers information about five areas: stressors and obstacles that compete with treatment, treatment demands and issues, perceived relevance of treatment, relationship with the therapist, and critical events. The *Iowa Cultural Understanding Assessment (ICUA)* is a 25-item measure to assess clients' perception of cultural competence of the treatment agency and staff.[80] To assess motivation about services, an adapted version of the 19-item *Treatment Self-Regulation Questionnaire* (*TSRQ*) will be used.[68] The 26-item *Youth Services Survey-Families* (*YSS-F*) from the PhenX Toolkit will be used to assess satisfaction in the following domains: appropriateness, participation, cultural sensitivity, social connectedness, and outcomes.[81-83] Scores >3.5 in each domain indicates positive experiences. Family members' demographics will be captured.	
Phase 2- Modifications		
Acceptability	Family member participants will complete the 8-item *Client Satisfaction Questionnaire* (CSQ-8) to rate overall satisfaction.[84-86] Possible total scores range from 8 to 32, with higher scores indicating greater satisfaction (>23 indicates satisfaction).	Semi-structured interviews
Practicality	Provider participants will complete a developed measure using a Likert scale to evaluate the practicality to the extent that the intervention could be implemented with the resources, time, and commitment available. The Organizational Readiness to Change Assessment (ORCA) tool consists of 77-items will be used to assess evidence assessment, contextual readiness and facilitation needs.[87] All items are scored on a Likert scale from 1=strongly disagree to 5=strongly agree.	
Phase 3- Stepped-wedge pilot trial		
Primary outcomes		
Feasibility	Provider participants will rate the appropriateness of the intervention and implementation toolkit (e.g., to what extent do you expect to be able to incorporate FAMES while working with family members? How useful were the components of the implementation toolkit?) Tracking the amount of external facilitator assistance needed to incorporate FAMES.	Semi-structured interviews
Acceptability	Family member participants will complete the CSQ-8, and the YSS-F will be used. Provider participants will rate satisfaction with toolkit and utility of individual items using a developed Likert scale.	Semi-structured interviews
Secondary outcome		
Effectiveness	Engagement will be assessed as the total number of contact hours with family members by email, phone, text, or in-person, and the total number of family psychoeducation appointments attended. Retention will be based on the percentage of families that dropout (family member declined or missed three consecutive appointments).	Semi-structured interviews
Motivation	Family member participants will complete the TSRQ.	
Family functioning	Family member participants will complete the 19-item *Burden Assessment Scale (BAS).*[88,89] Total possible scores range from 10 to 171 (higher scores indicating greater burden).	
Cultural competence	Family member participants will complete the ICUA.	
Exploratory implementation outcomes		
Readiness and Facilitation	Provider participants will complete the ORCA to assess local adaptation needs and key components of PARHIS framework.	Semi-structured interviews
Fidelity	The percentage of all completed items on all required intervention checklists.	Audio/video-recordings
Sustainability/Uptake	The total number of CSC programs utilizing all FAMES components and the number of programs using one or more FAMES components.	

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Developing and implementing a culturally informed FAmily Motivational Engagement Strategy (FAMES) to increase family engagement in coordinated care programs: Mixed-methods pilot study protocol

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Developing and implementing a culturally informed **FA**mily **M**otivational **E**ngagement **S**trategy (FAMES) to increase family engagement in first episode psychosis programs: Mixed methods pilot study protocol

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ABSTRACT

Introduction: Despite the proven effectiveness of coordinated specialty care (CSC) programs for first-episode psychosis (FEP) in the United States, CSC programs often have low levels of engagement in family psychoeducation, and engagement of racial and ethnic minority family members is even lower than that for non-Latino white family members. The goal of this study is to develop and evaluate a culturally informed FAmily Motivational Engagement Strategy (FAMES) and implementation toolkit for CSC providers.

Methods and analysis: This protocol describes a mixed methods, multi-phase study that blends intervention mapping and the Promoting Action on Research in Health Services framework to develop, modify, and pilot-test FAMES and an accompanying implementation toolkit. Phase 1 will convene a Stakeholder Advisory Committee to inform modifications based on findings from phase 1 and 2. During phase 1, we will also recruit approximately 200 family members to complete an online survey to assess barriers and motivation to engage in treatment. Phase 2 we will recruit five family members into a three-month trial of the modified FAMES and implementation toolkit. Results will guide the advisory committee in refining the intervention and implementation toolkit. Phase 3 will involve a 16-month non-randomized, stepped-wedge trial with 50 family members from five CSC programs in community-based mental health clinics to examine the acceptability, feasibility, and initial impact of FAMES and the implementation toolkit.

Ethics and dissemination: This study received Institutional Review Board approval from Washington State University, protocol #17812-001. Results will be disseminated via peer review publications, presentations at national and international conferences, and to local community mental health agencies and committees.

Keywords: *Community mental health, Coordinated specialty care, Family engagement, First-episode psychosis, Implementation strategies, Motivation*

Trial registration: *ClinicalTrials.gov, NCT04188366, registered 28 December 2019,*

Strengths and limitations of this study

- This pilot study will utilize an iterative mixed methods design to develop, implement, and evaluate a culturally sensitive FAmily Motivational Engagement Strategy (FAMES) in coordinated specialty care programs for first-episode psychosis.
- This protocol demonstrates the unique opportunity to blend intervention mapping and the Promoting Action on Research in Health Services (PARIHS) framework.
- Findings from a cross-sectional survey of family member experiences in Phase 1 will be used by a Stakeholder Advisory Committee to inform FAMES and further modified using clinician and participant feedback from Phase 2.
- Phase 3 involves a non-randomized stepped-wedge trial with coordinated specialty care programs to evaluate the acceptability and feasibility of FAMES.
- As a pilot, this study has a sample size and limited to the context of coordinated specialty care programs for first episode psychosis that limits generalizability.

INTRODUCTION

Coordinated specialty care (CSC) programs in the U.S. ameliorate psychiatric symptoms and improve functioning and quality of life among youth and young adults experiencing first-episode psychosis (FEP).[1] CSC programs feature evidence-based practices such as individual or multi-group family psychoeducation.[2] There is considerable evidence demonstrating that family psychoeducation is associated with reduced relapse and rehospitalization, and improved functional status and family management of psychosis.[3-8] Family members have a key role in facilitating care and their participation in treatment is often associated with higher treatment engagement and quality of life of individuals with FEP, particularly among youth.[9-16] Despite evidence for the effectiveness of CSC programs and family psychoeducation, and the importance of family member involvement in mental health treatment, the implementation of family psychoeducation in CSC programs has been low and is one the most challenging components of CSC according to providers.[17,18] For instance, in a large clustered randomized trial of NAVIGATE, a CSC program for FEP, 69% of family members did not participate in family psychoeducation and only 29% attended five or more appointments.[19,20] These findings also revealed that racial/ethnic minority families engaged in treatment at lower rates than non-Hispanic whites.[19] We need to better understand and systematically address factors and underlying mechanisms, that affect the successful implementation of family-based interventions in mental health settings.

Previous studies suggest that low motivation and logistical, perceptual, and cultural barriers hinder treatment engagement and subsequently limit successful implementation of family interventions like family psychoeducation.[13,21-31] Logistical barriers include lack of financial resources, transportation problems, and inadequate clinics operation hours.[32-34] Perceptual and cognitive barriers include lack of interest due to religious beliefs, substantial burden, and perceived

lack of benefit.[26,29,35,36] At the provider level, improving providers training in cultural competence and providing culturally sensitive care increases treatment engagement and retention, while also mitigating cultural and perceptual barriers.[36,37] Although motivation has been identified as a mechanism for improving treatment engagement and retention among individuals with serious mental illnesses (e.g., schizophrenia),[38,39] research on engagement and family motivation has been limited. One study found that lower motivation was associated with greater perception of treatment barriers and lower engagement among family members of youth with conduct disorder.[40]

To address logistical, perceptual, and cultural barriers to engagement, several strategies and interventions have successfully improved family engagement for individuals with conduct disorder,[41] substance use disorders,[42-44] and those who access school programs.[45] Several of these studies have used techniques that enhance motivation and family engagement.[41,46] For example, Nock and Kazdin developed the Participation Enhancement Intervention composed of three major components: 1) describing the importance of treatment engagement, 2) motivational statements about engagement, and 3) addressing engagement barriers.[41] In their randomized trial family members receiving the intervention showed greater motivation and engagement than family members in the control condition. Other strategies that have led to increased engagement are telephone-based interventions addressing treatment barriers[47,48] and providing extrinsic motivators (incentives) for family involvement in mental health care.[45]

Study aims/objectives

The overarching purpose of this project is to assess the feasibility and acceptability of a brief provider-led FAmily Engagement Motivational Strategy (FAMES) and its accompanying implementation toolkit, and to examine its initial impact. This project has three phases: 1) survey family members regarding logistical, perceptual, and cultural barriers, and motivators that

influence engagement in CSC programs for FEP to inform modifications; 2) refine FAMES and the implementation toolkit for use in CSC programs for FEP using findings from Aim 1 and with input from key stakeholders, such as clients with FEP and their family members, CSC providers, and CSC organizational leaders; and 3) examine the feasibility, acceptability, and preliminary impact of FAMES in five CSC programs using a stepped-wedge design.

METHODS AND ANALYSIS

Theoretical framework

This multi-site, mixed methods project will be completed in three phases: 1) intervention development, 2) intervention modification, and 3) efficacy evaluation using a non-randomized stepped-wedge pilot trial design (Figure 1). We will apply core components of intervention mapping (IM) and the Promoting Action on Research in Health Services (PARIHS) framework, a collaborative implementation framework (Figure 1). IM is commonly used in implementation science to iteratively develop interventions and implementation strategies that are rooted in theory and incorporate stakeholder perspectives. IM is composed of six steps: 1) problem analysis (preliminary data), 2) review of theory-based methods and practical strategies, 3) development of the intervention, 4) modification of intervention methods and strategies, 5) development of the implementation plan, and 6) evaluation.[49] The PARIHS framework outlines factors necessary for the successful implementation of interventions into practice and has guided implementation. PARIHS is composed of three stages:[50-54] 1) the evidence stage gathers information related on stakeholder experiences, needs, and preferences to inform the intervention; 2) the context stage evaluates the acceptability, feasibility, and sustainability of the intervention among stakeholders; and 3) the facilitation stage is focused on the appropriateness of the intervention and provider skills.

Insert Figure 1 about here

Intervention components

FAMES will involve three distinct and revolving components - early, continuous, and motivational contact - that incorporate motivational techniques previously used in other engagement interventions and constructs of the Self-Determination Theory (SDT).[41,55,56] The Diagnostic and Statistical Manual of Mental Disorders 5TH Edition (DSM-5) Cultural Formulation Interview (CFI) will be used to identify the unique needs of family members within the context of their culture, enhance the provider-family relationship, and personalize treatment components of family psychoeducation.[57-59]

Early contact by email, phone, or text message will occur 14, 7, and 2 days prior to the first scheduled orientation appointment for family members. To facilitate ongoing engagement, *continuous contact* between providers (e.g., a licensed mental health counselors, social workers, or case managers) and family members will be made 12 to 16 days after each family appointment. During the early and continuous contacts, providers inquire about potential barriers participation in family appointments and other CSC appointments for their loved one. Providers will assess social support systems and remind family members of upcoming appointments. The *motivational component* will occur in person once per month and occurs in sync with established monthly family psychoeducation appointments. It is anticipated that the motivational component will last a duration of approximately 20 minutes at the start of the family psychoeducation appointment. Providers discuss the barriers that were identified during the early and continuous contacts, work with family members identify pragmatic and tangible solutions to these barriers (e.g., extrinsic motivations), and develop a plan to overcome these barriers. Providers will prompt family members to create motivational statements (e.g., intrinsic motivations) that are goal-driven, with

an emphasis on overcoming these barriers and promoting continued engagement. During development and modification phases, we will identify and determine possible changes to the components and delivery of FAMES.

Implementation toolkit components

During phases 1 and 2, we will develop an implementation toolkit, designed to be a resource for providers to facilitate the uptake and implementation of FAMES.[60] We anticipate that the FAMES implementation toolkit will utilize a combination of strategies (e.g., implementation guides, fidelity checklist, audit and feedback, technical assistance, internal or external facilitators) that can be amendable to a specific CSC program.[61]

Patient and public involvement

Patients, family members, and other stakeholders were not involved to the research question, study design, and outcomes measured. However, during this phases 1 and 2, a Stakeholder Advisory Committee will be convened, which will include two family members who have experience with CSC programs for FEP, a CSC provider (e.g., a licensed mental health counselor, social worker, or case manager), a former client who graduated from a CSC program, and a CSC administrator. An announcement for client and family member representatives will disseminated through listserv and CSC programs. Preference will be given to client and family representatives who identify as a racial/ethnic minority and the first author will select members who are interested and have time to dedicate to attending meetings. The Stakeholder Advisory Committee will meet via videoconference two to three times per year in phases 1 and phase 2 to aid in the modification of FAMES. Findings from all phases will be disseminated to community mental health agencies and patient and family advisory groups.

Phase 1 – Intervention development

Design

Based on previously collected and published data that informed IM step 1 (problem analysis),[19] SDT was chosen as an overarching theoretical framework to ensure that the intervention's underlining mechanism of motivation is targeted by incorporating specific components, such as motivational statements, an approach consistent with IM step 2 (review of theory-based methods and practical strategies).[56] SDT focuses on three fundamental human needs: autonomy (choice), competence (self-efficacy), and relatedness (belonging). These are linked to a continuum of intrinsic motivations (internal drives to behave in a certain way such as core values and interests) and extrinsic motivations (external sources that result in external rewards such as awards).[55]

Aligned with the evidence stage of the PARIHS framework, approximately 200 family members of individuals with FEP will be recruited to complete a customized online Research Electronic Data Capture (REDCap) or paper survey instrument to identify family members' needs and barriers to treatment and underlying proximal targets of change that may not have been previously identified. During IM steps 2 and 3, the Stakeholder Advisory Committee will meet several times throughout phase 1 to develop and discuss matrices of change objectives that are based upon data from IM step 1 and are informed by survey findings. These meetings will build on the intervention components, previously described, to ensure that intervention components adequately address needs, barriers, and proximal targets of change identified from survey findings in a feasible and practical way.

Inclusion Criteria

Survey eligibility criteria are: 1) aged 18 years or older; 2) family member (e.g., parent, guardian, aunt/uncle, spouse, grandparent, sibling, close friend) of an individual who has or had

received services from an early intervention or CSC program for FEP in the US. Potential participants will be required to read an overview about the survey purpose and that participation is voluntary before being directed to survey questions.

Data collection

Surveys will be directly entered into REDCap through an online survey link. The survey link will be distributed through national and local listservs for family member support groups and CSC programs and an emphasis will be placed on CSC providers to identify family members who have discontinued participation. Potential participants will be informed that the survey will take approximately 25 minutes to complete and a unique return code will be provided for participants who are unable to complete the entire survey in one sitting. A list of measures included in the survey are outlined in Table 1.[62]

Insert Table 1 about here.

Data Analysis

Descriptive analyses will be conducted to assess family members' pathways to care, satisfaction with treatment, motivation for participation, and suggested areas for improving CSC programs. Regression analyses will be utilized to identify important components to services and to assess racial/ethnic group differences in treatment barriers, satisfaction, and motivations.

Phase 2 – Modifications

Design

Aligned with the context stage (pre-evaluation) of the PARIHS, FAMES and the developed implementation toolkit will be studied across a three-month time period among five family members from one CSC program using a combined quantitative and qualitative mixed methods approach.[63] Previous studies[37] that have utilized IM have ranged in sample size from 2 to 10

between Phase 2 will include the completion of IM step 4 (modification of intervention methods and strategies) and step 5 (development of the implementation plan) using an iterative process where the Stakeholder Advisory Committee will provide suggestions that will inform modifications to FAMES and development of the implementation toolkit. Regularly scheduled, audio-recorded Stakeholder Advisory Committee meetings will occur throughout this phase and include the review of quantitative and qualitative data summaries from the three-month study. Suggested modifications identified from summaries will be compiled for the Stakeholder Advisory Committee to rate based on level of importance and feasibility and used to stimulate discussions on steps to refine intervention objectives and components. Similar to phase 1 steps to inform intervention components, the Stakeholder Advisory Committee meetings in phase 2 will also develop the learning objectives for the implementation toolkit and connect these objectives to a theory-based method and practical strategy that will be refined based on feedback from providers.

Setting

During phase 2, FAMES will be studied at one CSC program within Washington State's New Journeys network. New Journeys is a state-funded CSC program for FEP with nine locations distributed in community mental health clinics in rural and urban settings throughout Washington State.[64] Each New Journeys site employees four to eight mental health providers and currently serves a total of 300 clients with FEP. The New Journeys network serves approximately 55% racial/ethnic minorities; the average age of clients is 20 years; and 70% of clients reside with a family member or caregiver.

Inclusion Criteria

Eligibility for inclusion for family member participants in phase 2 include: 1) aged 18 years or older; 2) one family member (e.g., parent, guardian, grandparent, sibling) of an

individual enrolled in a Washington State CSC program; and 3) has received no more than 3 months of services. Eligibility criteria for provider participants are 1) aged 18 years or older and 2) employed at a Washington State CSC program for more than two months. Potential participants will be provided with a detailed explanation of the study purpose, the voluntary nature of participation, and their right to withdraw from the study at any time. Research staff will obtain informed consent captured using REDCap e-consenting procedures.

Data collection and outcomes

To limit the burden on providers, self-reported measures for family member participants will be delivered directly to participants' mobile devices and email accounts using mobile and text message enabled capabilities linked to a customized REDCap database. Measures to assess acceptability and practicality will be collected at baseline and monthly throughout the three-month study period. We will also measure the extent to which the intervention preliminarily impacts motivation. Measures to the assess toolkit, will be completed by provider participants will completed at baseline that will inform the implementation process in real-time and after the three-month study period that will be used by the Stakeholder Advisory Committee to improve the implementation toolkit. Separate qualitative interviews will be completed by family member and provider participants at months 1 and 3 using open-ended targeted questions to solicit opinions on what components may, or may not be working, suggestions for improvement, and any lessons learned. All Stakeholder Advisory Committee meetings will be audio-recorded to capture qualitative comments. Key concepts from quantitative and qualitative data will be presented during Stakeholder Advisory Committee meetings. Suggested improvements and action items will be rated by members on the Stakeholder Advisory Committee, based on feasibility and importance.[65] These ratings will stimulate Stakeholder Advisory Committee meeting discussion points that will

modify FAMES. These data will help us make improvements to the intervention delivery in real-time.

Quantitative data analysis

Descriptive analyses will be performed to assess satisfaction, motivation, practicality and implementation process. The mean score of ratings on practicality will be calculated and presented to the Stakeholder Advisory Committee.

Qualitative data analysis

All interview recordings will be transcribed verbatim and imported into NVivo 11, a qualitative data management software. Due to its flexibility and ability to build on previous research identified in IM step 1 and phase 1, a directed content approach was selected for qualitive data analysis.[66,67] Using a directed approach to content analysis satisfaction and areas for improvement will serve as initial pre-determined coding categories. Qualitative data gathered from family member and provider participants will be coded, summarized, and presented to the Stakeholder Advisory Committee. The meeting recordings will be translated into actionable plans that will be re-presented to the Stakeholder Advisory Committee. To increase rigor, we will use member checks to confirm findings, keep detailed notes from each meeting, and establish an audit trail.[68,69]

Phase 3 – Stepped-wedge design pilot trial

Design

IM step 6 and the context (evaluation) and facilitation (appropriateness and skills) stage of the PARIHS informs phase 3. During this phase, we will conduct a non-randomized stepped-wedge pilot trial in five CSC programs in Washington State using a combined quantitative and qualitative mixed methods approach.[63,70] Each CSC program will represent a cluster and serve as

its own control (Figure 2). A two-month implementation transition period will occur at each CSC program and during which providers will be introduced to the intervention using the implementation toolkits and trained to conduct FAMES. A 12-month open cohort design will be utilized to recruit approximately 50 family members during the study period.

Insert Figure 2 about here.

Setting and inclusion criteria

In phase 3, FAMES will roll out sequentially in five CSC programs in Washington State. Inclusion criteria and consent procedures for family members and provider participants in phase 3 will be with the same as details in phase 2.

Data collection and outcomes

The *primary outcomes* to be assessed are feasibility and acceptability of FAMES and the implementation toolkit. Primary outcome measures are described in detail in Table 1. The *secondary outcomes* will include measures related to the preliminary impact of FAMES on family engagement. These secondary outcomes will include engagement and retention, to be obtained by providers and entered directly into the REDCap database.[71] Motivation, family functioning, and cultural competence will also be captured using self-reported measures completed by family members. Primary and secondary outcome measures will be collected monthly during the control and intervention conditions. During the follow-up period for each program, family members will complete measures related to treatment motivation and family functioning at 1- and 3-months post-intervention completion. *Exploratory outcomes* include implementation outcomes (e.g., adherence, exposure, quality, differentiation, responsiveness) will be tracked and assessed by external facilitators (i.e., research staff) throughout the implementation phase and during the intervention condition using audio/video recordings to monitor the delivery of FAMES across all

CSC programs. At baseline and at 1-month follow-up provider participants will complete an organizational readiness measure that will assess key components of the PARIHS.[54] Providers will also be asked to complete an online self-report intervention component checklist in REDCap after each contact and session.[72]

Sustainability and uptake will be tracked by research staff during the follow-up period at 1- and 3-months post-intervention completion. Qualitative interviews will be completed by family member and provider participants at two iteration points during the study. The first will occur 1-month post-implementation and the second during the follow-up period, 1-month post-intervention completion to assess acceptability (e.g., satisfaction, influence of intervention on engagement) feasibility, and key concepts of the PARIHS framework. Family members who discontinue study participation will be contacted asked to complete an exit interviews to assess acceptability (e.g., reasons for discontinuation (e.g., burden of the intervention, barriers).[73]

Sample justification

The sample size (n=50) was chosen based on literature regarding sample sizes for pilot/feasibility studies while remaining feasible within the context of present study.[74] While the trial is not designed to assess the effectiveness of FAMES the selected sample size will provide adequate power to preliminary analyses.[75] Accounting for an incomplete stepped-wedge design project with five clusters (i.e., community-based clinics) with an average recruitment of 10 family members per cluster, an intra cluster correlation of 0.10, and a significance level of 0.05, it is estimated that this will provide us with an estimated power of 0.84.

Quantitative data analysis

At the completion of the stepped-wedge trial in phase 3, analyses on the intent-to-treat sample will be performed (n=50). We will conduct descriptive analyses on the primary and

secondary outcomes. We will also compare mean differences in satisfaction scores from control and intervention conditions, using independent sample t-tests. Generalized estimating equations will be used to assess differences in engagement by comparing the control and intervention conditions, while controlling for potential confounders (e.g., time, site). To assess the mediation effect of motivation, cultural sensitivity, and burden on the primary engagement and retention outcomes, we will path analytic modeling (e.g., bootstrapped confidence intervals to evaluate indirect effects). If needed, we will use maximum likelihood, multiple imputation, or other sensitivity analyses, including "missing not at random" approaches, to account for missing data.[76]

Qualitative data analysis

The phase 3 qualitative analysis will also use key concepts derived from the SDT (e.g., autonomy, competence, relatedness, extrinsic and intrinsic motivations). Areas related to acceptability (e.g., satisfaction, intervention burden) will be utilized to develop and operationalize an initial coding scheme for data obtained from family member participants. Key concepts from the PARIHS framework such as organizational fit, relevance, range of flexibility, and style will be used to develop and operationalize the initial coding scheme for data obtained from provider participants.[77] Coding and analysis will be conducted independently by two coders through a series of iterative readings, noting text that corresponds to initial codes.[69,78,79] A kappa of 0.8 will be required for coders to code independently and codes will be continuously refined.[80] Notes will be used to develop a final codebook. To guard against biases of directive content analysis, an audit trail—documenting analytical decisions, analyzing cases that did not fit our coding scheme, and generating new codes not present in initial codebooks—will be maintained.[68]

Mixed methods integration

A thematic matrix will integrate qualitative and quantitative data using a side-by-side comparison to examine feasibility, acceptability, and implementation outcomes.[81-83] We will answer questions such as: "will the qualitative data collected from family member participants match the quantitative data collected regarding satisfaction and engagement?" Qualitative data collected from provider participants using the PARIHS framework will be used to explain quantitative data collected on fidelity measures. Barriers and facilitators identified by family members and providers will identify similarities and differences between these stakeholder groups that will be linked to provide further explanation and to help contextualize results.

ETHICS AND DISSEMINATION

Ethical approval was granted by the Washington State University Institutional Review Board (#17761). In accordance with the funders' policies, an independent Data and Safety Monitoring Board was established to assure safety of participants and data integrity. Findings from this study will be disseminated through publications in peer-reviewed academic journals and presented at local, national, and international conferences. To disseminate results of the study across a wider audience, key findings will be communicated through social media and other media outlets.

DISCUSSION

Despite previous research on engagement interventions in other populations and settings, little is known about strategies to engage family members in the context of CSC programs. Research has also suggested inequities in utilization of evidence-based interventions (e.g., family psychoeducation) among racial/ethnic minorities that directly impacts successful implementation. We will utilize a mixed methods approach throughout the study to meld core components of IM and the PARIHS framework to develop, implement, and evaluate the culturally informed FAMES

and implementation toolkit to address these inequities; evaluation will focus on acceptability, feasibility, and initial impact. Very little research has systematically utilized implementation science to address inequities in service utilization related to race/ethnicity within community mental health clinics. The study protocol described will actively identify and modify strategies to address logistical and cultural barriers that contribute to these inequities at the family, provider, and organizational levels. By utilizing a rigorous mixed methods approach, this study will also provide a roadmap for implementation and local adaptation that may contribute important knowledge to the field of implementation science.

This study has several strengths, including the unique components of FAMES that will incorporate the DSM-5 CFI, which has only been previously focused on the assessment of individuals will now be tailored for families. This will allow providers to integrate culturally sensitive information to increase our understanding of family-related motivators related to treatment and that can then be incorporated into treatment planning for all racial/ethnic groups. The utilization of a stepped-wedge design provides the opportunity to offer FAMES to all CSC programs included in the study. It also presents an additional opportunity to assess whether FAMES has the potential to re-engage family members who over time have disengaged. In light of these strengths and potential impacts, family members' participation may be limited for programs that receive FAMES later in the trial. We will monitor family member participation during the control period with monthly program check-ins. As a pilot study, it is important to note that overall findings are limited by sample size and generalizability. However, this pilot study includes six CSC programs in rural and urban settings that will contribute to the iterative process of refining FAMES and its implementation various settings.

As the mental health field seeks to better understand motivations toward treatment in order to improve engagement and retention in CSC programs, this study will explore how to effectively engage and motivate families from various racial/ethnic groups. If successful, our findings will influence the scale up of FAMES to other CSC programs, while also potentially improving family engagement in other mental health services.

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Authors' contributions
OO developed the concept, study design, and drafted the first version of the study protocol. DGD, SMM, RLF, MTC, MGM, and LJC contributed to the study design and revised subsequent versions of the study protocol. All authors have read and approved the final manuscript.

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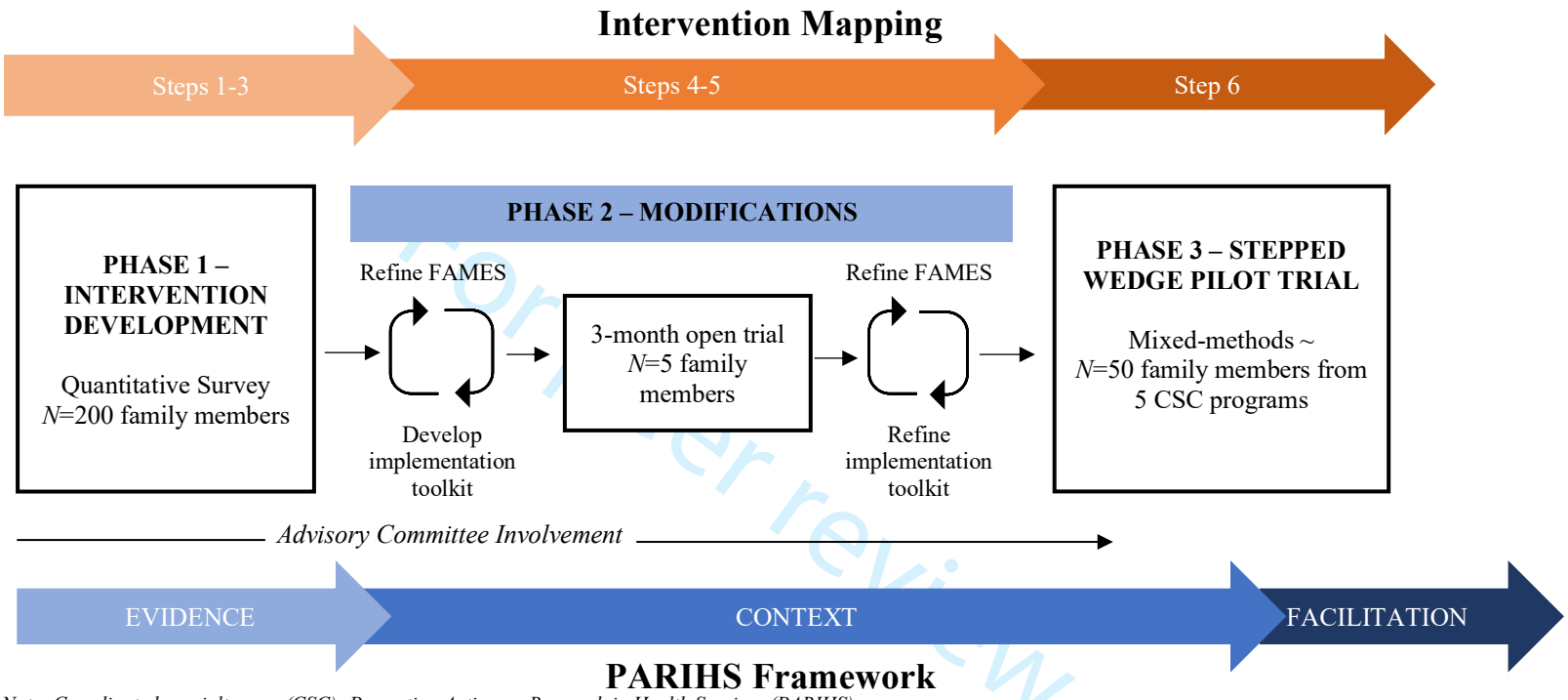
The authors declare that they have no competing interests.

Patient consent for publication
Not required.

Ethics approval
Ethics approvals for this study were obtained from the Washington State University Institutional Review Board.

Table 1 – Outcomes and description of measures

Outcome	Quantitative Component - Measure Description	Qualitative Component
Phase 1- Intervention development		
	Barriers to Treatment Participation Scale,[84] a 58-item semi-structured questionnaire that gathers information about five areas: stressors and obstacles that compete with treatment, treatment demands and issues, perceived relevance of treatment, relationship with the therapist, and critical events. The *Iowa Cultural Understanding Assessment (ICUA)* is a 25-item measure to assess clients' perception of cultural competence of the treatment agency and staff.[85] To assess motivation about services, an adapted version of the 19-item *Treatment Self-Regulation Questionnaire* (*TSRQ*) will be used.[71] The 26-item *Youth Services Survey-Families* (*YSS-F*) from the PhenX Toolkit will be used to assess satisfaction in the following domains: appropriateness, participation, cultural sensitivity, social connectedness, and outcomes.[86-88] Scores >3.5 in each domain indicates positive experiences. Family members' demographics will be captured.	
Phase 2- Modifications		
Acceptability	Family member participants will complete the 8-item *Client Satisfaction Questionnaire* (CSQ-8) to rate overall satisfaction.[89-91] Possible total scores range from 8 to 32, with higher scores indicating greater satisfaction (>23 indicates satisfaction).	Semi-structured interviews
Practicality	Provider participants will complete a developed measure using a Likert scale to evaluate the practicality to the extent that the intervention could be implemented with the resources, time, and commitment available. The Organizational Readiness to Change Assessment (ORCA) tool consists of 77-items will be used to assess evidence assessment, contextual readiness and facilitation needs.[92] All items are scored on a Likert scale from 1=strongly disagree to 5=strongly agree.	
Phase 3- Stepped-wedge pilot trial		
Primary outcomes		
Feasibility	Provider participants will rate the appropriateness of the intervention and implementation toolkit (e.g., to what extent do you expect to be able to incorporate FAMES while working with family members? How useful were the components of the implementation toolkit?) Tracking the amount of external facilitator assistance needed to incorporate FAMES.	Semi-structured interviews
Acceptability	Family member participants will complete the CSQ-8, and the YSS-F will be used. Provider participants will rate satisfaction with toolkit and utility of individual items using a developed Likert scale.	Semi-structured interviews
Secondary outcome		
Effectiveness	Engagement will be assessed as the total number of contact hours with family members by email, phone, text, or in-person, and the total number of family psychoeducation appointments attended. Retention will be based on the percentage of families that dropout (family member declined or missed three consecutive appointments).	Semi-structured interviews
Motivation	Family member participants will complete the TSRQ.	
Family functioning	Family member participants will complete the 19-item *Burden Assessment Scale (BAS).*[93,94] Total possible scores range from 10 to 171 (higher scores indicating greater burden).	
Cultural competence	Family member participants will complete the ICUA.	
Exploratory implementation outcomes		
Readiness and Facilitation	Provider participants will complete the ORCA to assess local adaptation needs and key components of PARHIS framework.	Semi-structured interviews
Fidelity	The percentage of all completed items on all required intervention checklists.	Audio/video-recordings
Sustainability/Uptake	The total number of CSC programs utilizing all FAMES components and the number of programs using one or more FAMES components.	



Note: Coordinated specialty care (CSC); Promoting Action on Research in Health Services (PARIHS)

Fig 1. Study design: Blend of intervention mapping and PARIHS framework

Cluster	Study Months															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
CSC program 1	T	T	I	I	I	F	F	F								
CSC program 2			T	T	I	I	I	F	F	F						
CSC program 3					T	T	I	I	I	F	F	F				
CSC program 4							T	T	I	I	I	F	F	F		
CSC program 5									T	T	I	I	I	F	F	F

Note: Dark blue shading is the control period; T=implementation transition period; I= Intervention period; F=Follow-up/Sustainability period; dark gray shading is the follow-up period

Fig 2. Modified stepped-wedge pilot trial of FAMES