Community-based family peer navigator programme to facilitate linkage to coordinated specialty care for early psychosis among Black families in the USA: A protocol for a hybrid type I feasibility study

Oladunni Oluwoye, Bryony I Stokes, Ekaterina Burduli, Liat S Kriegel, Kimberly E Hoagwood

ABSTRACT

Background  Approximately 70% of Black/African American family members report no contact with mental health providers prior to initial diagnosis and the receipt of services for early psychosis. Black families often encounter barriers and experience delays on the pathway to coordinated specialty care programmes for early psychosis.

Methods and analysis  This mixed-methods study will (1) develop and refine a family peer navigator (FPN) for Black families designed to increase access and engagement in coordinated specialty care and (2) pilot-test FPN for Black families with 40 family members with loved ones at risk for psychosis in a randomised trial to assess the acceptability and feasibility. Families will be randomised to FPN (n=20) or a low-intensive care coordination (n=20). Other outcomes include proposed treatment targets (eg, knowledge, social connectedness), preliminary impact outcomes (time to coordinated specialty care programmes, initial family engagement), and implementation outcomes (acceptability, feasibility, appropriateness).

Ethics and dissemination  Ethics approval has been obtained from Washington State University Institutional Review Board and informed consent will be obtained from all participants. This study will establish an innovative culturally responsive FPN programme and implementation strategy, and generate preliminary data to support a larger hybrid effectiveness-implementation trial. Study findings will be presented at conferences and in peer-reviewed journals.

Trial registration number  NCT05284721.

BACKGROUND

The pathway to care for early psychosis is a critical time period that involves various contacts with organisations, experiences and events that can impact the timely access to much needed services (eg, coordinated specialty care; CSC) and has residual impacts on treatment outcomes once the appropriate mental health services have been initiated. Often times, family members/support persons have a key role in the help-seeking process, pathways to care and during the treatment process for their loved one. The duration of untreated psychosis, which has been defined as the onset of psychosis to the initiation of CSC, is associated with pathways to care. Research has found that a longer duration of untreated psychosis is associated with poorer clinical and functional outcomes in CSC, the gold standard of treatment for first episode psychosis (FEP) in the USA. While, CSC has demonstrated positive impacts on treatment outcomes among youth in the early stages of psychosis, many families, especially Black families, are faced with inequities along the pathway to CSC that contributes to known racial disparities in service utilisation.

Black families experience unique difficulties on the pathway to CSC or other mental health services for psychosis.
by or a response to inequitable practices,11 these experiences often includes involuntary hospitalisation, multiple contacts with medical providers, interactions with law enforcement, seeking support from informal resources (eg, friends, family, religious leaders), all of which is shrouded by a lack of clarity and uncertainty.9 10 Further, roughly 30% of Black family members reported having contact with a mental health provider prior reaching CSC.11 The lack of contact with a mental health provider was seen to have a residual impact on quality of life among Black youth receiving services from CSC.12 Research has also shed light on racial disparities at intake, which serves as an indicator of experiences and events on the pathway to care where Black individuals in the early stages of psychosis start treatment with more severe psychiatric symptoms compared with their white counterparts.12 While receiving services, less than 40% of family members/support persons participate in CSC (ie, family education and support component) and Black family members/support persons engaged in CSC at significantly lower rates than white families.13 14 Connecting with Black families earlier and providing services are needed to increase access to services and improve initial engagement, which would potentially reduce disparities in service utilisation in CSC.

Family-focused navigator models emphasise connecting families to needed services while also providing support and resources to families. The availability of peer navigation for youth and their families is associated with the alleviation of barriers, increased access to appropriate mental health services, and reduced racial disparities in service utilisation.15–19 However, a systematic review on peer-led interventions identified that peer support or navigation interventions have not emphasised cultural factors.10 Despite the proven utility of navigator models in other fields (eg, diabetes, cancer), family navigator models have been underutilised in mental health settings and subsequently there have been limited studies in this area.20–22 Three studies identified core functions necessary for a family navigation process that include (1) assessment and treatment in a timely manner; (2) availability of guidance on services; (3) provision of at least some evidence-based treatment; (4) tracking and evaluating and (5) frequent communication.16 23 24

While the focus has generally been placed on providing navigator services during care, there is very little research on community-based navigator services prior to intake and on models that actively integrate culturally assessment tools.16 Thus, the purpose of this protocol is to describe the process of developing and refining a family peer navigator (FPN) programme to identify, screen and link community-dwelling Black families at clinical high risk for psychosis to CSC or appropriate mental health services. The feasibility, acceptability and preliminary impact of the FPN programme for Black families in a randomised pilot trial will also be evaluated.

METHODS AND ANALYSIS

Study design
This hybrid type 1 feasibility trial aims to develop, implement and evaluate a culturally informed FPN programme in the Black community across three phases. The proposed study commenced in May 2022 and will end April 2025. Hybrid type 1 designed feasibility trials are suggested as a way to expedite the dissemination of information and bridge the gap from research to practice, especially when addressing inequities and disparities in care. In collaboration with a community advisory board (CAB), our development phases I and II use an exploratory sequentially mixed-methods design (qual→QUANT) to develop and refine the FPN for Psychosis programme and implementation strategy. Phase III uses an embedded designed (QUANT+qual) randomised pilot trial that will recruit 40 Black families at risk for psychosis. Phases II and III are registered on the ClinicalTrials.gov database (NCT05284721).

Patient and public involvement
Prior to the start of the study family members and/or support persons were not involved in the development of the research question, study design and outcomes selected. We will establish a well-rounded CAB, composed of 3–5 family members, who identify as Black and/or African American, with a loved one who had experienced FEP and enrolled in CSC to form the family advisory group. The family advisory group of the CAB will provide feedback on the cultural appropriateness to ensure relevance and to further modify the model after the prepilot. The family advisory board will be joined by 7–10 individuals involved with community-based organisations that often make referrals for mental health services and who serve Black families. The CAB will advise the research team and develop community support for the FPN programme, inform the development and modifications to the FPN programme and its implementation, assist in pragmatic solutions to address potential challenges experienced by families and FPNs, and collaborate in the dissemination of our findings. Monthly meetings will be held virtually or in-person. All CAB members will be compensated US$50 for each meeting attended.

The intervention: FPN programme
The FPN programme is composed of two major components extensive community-based outreach and family navigation and support.

Extensive community outreach
Extensive community outreach component involves assertive virtual and in-person outreach activities. In collaboration with the CAB, dissemination materials (flyers, infographics) will be developed covering topics deemed as important by the CAB and relevant to the Black community (eg, available resources, signs and symptoms of psychosis, de-escalation), and deployed to community-based organisations. Community presentations will be
offered and delivered to inform organisations and individuals about pathways to care for Black families (evidence and need), resources offered by the FPN programme and making referrals (ie, recruitment). In-person tables will also be set up at one-time community events or regular table-set ups will be coordinated with interested community partners to bring awareness to psychosis and make referrals to FPNs.

Family navigation and support
Family navigation and support component includes: (1) Introduction and assessment will occur over two phone or in-person sessions (based on family member preference). A modified cultural formulation interview for family members/support persons will be used and delivered longitudinally, to identify specific factors unique to each family. (2) Individual psychoeducation will occur over four sessions and supplemented with printed and digital materials. The sessions will focus on defining psychosis using terminology consistent with how the family originally defined psychosis during the first two sessions, coping skills that match those identified in prior sessions, introduction to CSC and other available mental health services, and re-emphasise the benefits to family involvement. (3) Brief check-in sessions will occur in weeks between psychoeducation sessions and occur using family member’s preferred method (ie, text message, email or phone). The purpose of the brief check-ins will capitalise on the strength of peer navigators’ roles and will allow the FPN to engage families, inquire about potential barriers and changes made after individual sessions, and provide updates on care coordination efforts. Individuals will be hired as FPNs if they: (1) have a family member with lived experience, caring for and managing a loved one who has experienced psychosis and (2) self-identify as Black and/or African American. On hire, FPNs will be enrolled in the 5 days certified peer counsellor training provided by Washington State Health Care Authority.

Training and supervision
Training will include an initial online self-paced training course covering the prior research that informed the development of FPN and overall goals, FPN programme components (extensive community outreach, family navigation and support, documentation), introduction of CSC, and an overview of commonly used software (eg, outlook, scheduling). To increase integration with CSC, training will also include an introduction to the New Journeys network data platform developed in REDCap, which will also be used for documentation and tracking. A comprehensive manual will also be provided to supplement the online training. FPNs will then participate in two 1:1 coaching calls for the delivery of the modified cultural formulation interview. After coaching calls, FPNs will be asked to identify an individual not related to them to participate in a live recording for them delivering the cultural formulation interview. Recordings will be reviewed by the principal investigator and trained research staff to assess readiness. Weekly consultation meetings with the principal investigator will occur to monitor adherence to programme components of (eg, cultural formulation interview) using a developed fidelity checklist, cover strategies to overcome potential barriers, the use of the REDCap-based informatics tool and data accuracy, and technical assistance.

Development and refinement phase
Qualitative interviews and focus groups
During phase I, we will conduct semistructured qualitative interviews and focus groups with approximately 25 key informants (eg, CSC providers and directors, community leaders, community organisations, families) to understand programme/agency-level factors and community-level factors. The Consolidated Framework for Implementation Research (CFIR) will be used as the organisational framework for the development of semi-structured interview guide to identify barriers, facilitators and additional needs associated with the integration of the FPN programme in CSC (CFIR domains: inner setting, individual, process) and within the community (CFIR domains: outer setting, individual, process, intervention). Interview guide can be seen in online supplemental materials. Trained research staff will conduct separate focus groups with key informants at the agency and programme level. Individual interviews will also be conducted with family members with lived experience caring for a loved with psychosis and community members.

All qualitative interviews and focus groups will be recorded, transcribed verbatim and imported into ATLAS.ti, a qualitative software to facilitate organisation, coding and analysis. The CFIR domains will be used to develop and operationalise the initial coding scheme. Additional codes will be developed independently through an inductive process to identify themes that emerge from the data that fall outside of CFIR domains. The research team will employ a direct content analysis approach to initially code transcripts. To ensure consistency, a final codebook will be developed after several meetings prior to the final coding of transcripts. Resulting categories and themes will be summarised and used to create a matrix of change objectives, which is a side-by-side table, to link and document strategies already being used, refine proposed strategies, and to potentially identify additional strategies.

Open trial
We will conduct a 4-month open trial with 10 help-seeking Black families who have mental health concerns, specifically psychosis, about their loved one. Inclusion criteria for participants include: (1) ≥18 years of age; (2) loved one who meets criteria for risk of psychosis with a total score of ≥3 on the Prodromal Questionnaire-Brief Version and (3) identify as Black and/or African American. Exclusion criteria include: (1) family member who have difficulties understanding the consent process that impact their ability to provide consent; (2) non-English-speaking adults without support person to translate and


Open access
(3) Black and/or African American families who have already been determined eligible for services by CSC. FPNs and research staff will conduct extensive community outreach, described above, to recruit participants for the open trial. Each participant will be screened and if eligible, research staff will explain the study, that participation is voluntary, and address questions that may arise. Participants that agree to continue will be asked to sign an informed consent form and complete the baseline assessments.

Individuals who are not eligible to participate in the study will be provided with a list of community resources including behavioural services and other community resources (eg, National Alliance on Mental Illness family-to-family). On completion of the baseline appointment with research staff, participants will be scheduled for their first session with an FPN. Participants will complete monthly measures to preliminarily assess changes in potential treatment targets, described below and complete an open-ended feedback questionnaire to assess what worked and did not work to inform potential changes. All project-specific data will be collected using REDCap.

During the open trial, we will also assess referral and recruitment procedures, the delivery of selected measures, training and supervision of FPNs and their preparedness. A structured log will be maintained by study staff to document barriers, challenges and solutions to implementation, as well as, number of meetings scheduled and attended, and other forms of contact (eg, email). We will create summaries from findings that will be presented to the CAB to solicit feedback to further refine the model and study procedures.

**Randomised pilot study phase**

**Setting and study participants**

The FPN programme will be implemented in two CSC, housed in community mental health outpatient agencies located in Pierce and King County in Washington State. During the randomised pilot trial, we will recruit 40 help-seeking family members who will receive either the FPN programme (n=20) or a low-intensive care coordination (n=20). Participant inclusion and exclusion criteria, as well as screening and informed consent procedures will be consistent with the open trial. After the baseline has been completed research staff will be randomised in REDCap on a 1:1 basis using a permuted block randomisation, stratified across site, age and sex. Screening, informed consent, randomisation and study assessments will be delivered by research staff and will not involve FPNs. A study flow chart of recruitment, assessments and randomisation is displayed in [figure 1](#).

**The active control condition**

Participants randomised to the active control condition will receive low-intensive care coordination that will consist of two brief psychoeducation sessions and materials (signs and symptoms of psychosis and an overview of CSC), two brief check-ins and linkage to CSC and provided a list of other services in the area. The active control condition will be delivered by research staff.

**The intervention**

Participants randomised the FPN programme will receive a modified version of the FPN programme, described above.

**Quantitative assessments**

**Table 1** provides a description of all the measures that will be collected and delivery time points over the duration of the study. Measures were selected based on existing data elements from the PhenX Early Psychosis and Social Determinants of Health Collection and/or had established validity and reliability among individuals with early psychosis and among racially and ethnically diverse groups. Assumptions will be delivered over the phone by research staff or participants will have the option of using REDCap email and messaging features (ie, Twilio), so that participants can complete them in their own time.

**Qualitative assessments**

Phone-based exit interviews will be conducted with all participants in week 12, to explore treatment targets and potentially identify other mechanisms of change. Using a semistructured guide, we will explore experiences (eg, satisfaction, modifications) with FPN and providers, as well as contextual factors at multiple levels that may be barriers or facilitators to the model and implementation. At the completion of the randomised pilot trial, qualitative interviews will be conducted with CSC providers and administrators, and FPNs to assess the acceptability, feasibility and appropriateness of implementation processes and fit. All interviews will be audiotaped, transcribed, reviewed for accuracy and uploaded to ATLAS.ti.

**Quantitative data analysis**

Primary outcomes for the randomised pilot are feasibility and acceptability. Acceptability will be assessed descriptively by computing means, SDs and 95% CIs of the scores on selected measures. Mean differences in satisfaction scores between treatment groups at the 12 weeks will also be compared using independent samples t-tests. Feasibility will be examined by calculating rates of engagement and retention across 12 weeks. Reasons for disengagement will also be examined. Feasibility of study procedures will be characterised using N’s and percentages for recruitment processes, completion and reliability of measure responses, and follow-up rates. We will use an intention-to-treat approach, where all participants are included in analyses. All tests will be two sided with critical value $\alpha=0.05$. Necessary steps will be taken to ensure data completeness, however, ‘missing at random’ approaches (ie, multiple imputation, maximum likelihood) will be invoked if needed.

Secondary outcomes are preliminary effectiveness and treatment targets. For preliminary effectiveness (initial family engagement and access), a series of mixed effects
linear and logistic regression models with a fixed intercept for CSC to account for nesting of repeated measures and participants within CSC will be fit. Random participant and fixed site-level intercepts will be included to account for the nested data structure and to estimate intraclass correlation coefficients that characterise the proportion of variability in study outcomes accounted for at each level of analysis. An effect of time, a group-by-time interaction, and site will be added to each model to determine if the outcomes vary over time and differentially over time by group and site. Separate effect sizes and 95% CI will be calculated for number of appointments attended and number of contacts made between the participant and FPN. A Cox regression will be used to preliminary examine the number of days between referral to the FPN and the first CSC appointment. For each treatment target (knowledge, social connectedness, self-efficacy, alliance/communication, cultural sensitivity), we will explore the effect of the FPN programme on targets by calculating the effect sizes and 95% CI. Separate mixed linear models will be used to preliminarily test differences between conditions, baseline scores on each measure will be included as a covariate.

Qualitative data analysis
A directed content approach will be used to analyse transcripts from interviews with study participants. We will use constructs related to acceptability (eg, satisfaction with care coordination), and treatment targets such as self-efficacy, social connectedness and knowledge to develop and operationalise our coding scheme. We will use key concepts derived from the CFIR (eg, fit, resources, facilitation) to develop and operationalise the initial coding scheme for key stakeholder interviews. To guard against biases, we will generate an audit trail documenting analytical decisions and conduct peer debriefing meetings, and generate new codes not present in our initial frameworks.
<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Construct</th>
<th>Measure</th>
<th>Description</th>
<th>Time point</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary outcomes</strong></td>
<td>Feasibility</td>
<td>Engagement</td>
<td>The no of sessions attended by each participant, the total no of contact hours with participants, and the no of completed measures will be tracked.</td>
<td>Weekly</td>
</tr>
<tr>
<td>Recruitment</td>
<td></td>
<td>To assess the feasibility of the recruitment the no of family member participants recruited, and referrals received, categorised by where they originated and the no of family member participants who were eligible and agree to participate will be tracked.</td>
<td>Weekly</td>
<td></td>
</tr>
<tr>
<td>Retention</td>
<td></td>
<td>Will be assessed by the percentage of participants who dropout as defined by the participant asking to no longer receive services or missing three consecutive appointments.</td>
<td>Weekly</td>
<td></td>
</tr>
<tr>
<td><strong>Acceptability</strong></td>
<td>Satisfaction</td>
<td>The Client Satisfaction Questionnaire (CSQ) will assess overall satisfaction with services. The CSQ has 8-items and scores range from 8 to 32, with higher scores indicating greater satisfaction.</td>
<td>Months 3</td>
<td></td>
</tr>
<tr>
<td><strong>Secondary outcomes</strong></td>
<td>Preliminary effectiveness</td>
<td>Initial engagement</td>
<td>This will be measured by the participant’s attendance at, at least one family appointment within 30 days of a loved one’s intake in a mental health programme.</td>
<td>Follow-up (week 16)</td>
</tr>
<tr>
<td>Access</td>
<td></td>
<td>This will be measured by the no of days between the point of referral to a mental health programme and the receipt of mental health services.</td>
<td>Follow-up (week 16)</td>
<td></td>
</tr>
<tr>
<td>Treatment targets</td>
<td>Self-efficacy</td>
<td>The General Self-Efficacy (GSE) scale will assess perceived self-efficacy. The GSE has 10 items, rated on 4-point Likert scale from “not at all true” to ‘exactly true’. Total scores range from 10 to 40, where higher scores indicate greater perceived self-efficacy.</td>
<td>Baseline, Months 1–3, Follow-up (week 16)</td>
<td></td>
</tr>
<tr>
<td>Social connectedness</td>
<td></td>
<td>The Social Connectedness subscale of YSS-F will to assess social support. Scores range from 4 to 20 where higher scores indicate greater social connectedness.</td>
<td>Baseline, Months 1–3, Follow-up (week 16)</td>
<td></td>
</tr>
<tr>
<td>Knowledge</td>
<td></td>
<td>The Culturally-adapted Knowledge About Psychosis questionnaire assesses knowledge related to psychosis and culturally relevant information. Total scores range from 0 to 104 with higher scores indicate greater knowledge.</td>
<td>Baseline, Months 1–3, Follow-up (week 16)</td>
<td></td>
</tr>
<tr>
<td>Alliance/communication</td>
<td></td>
<td>The Scale to Assess Therapeutic Relationships (STAR) will assess therapeutic relationships. STAR includes 12 items and has three subscales: positive collaborations (score range 0–24), positive clinician input (score range 0–12), non-supportive clinician input (score range 0–12).</td>
<td>Months 1–3</td>
<td></td>
</tr>
<tr>
<td>Cultural sensitivity</td>
<td></td>
<td>The Cultural Sensitivity subscale of YSS-F will assess cultural sensitivity. Scores range from 4 to 20 where higher scores indicate greater sensitivity.</td>
<td>Months 1–3</td>
<td></td>
</tr>
<tr>
<td><strong>Implementation outcomes</strong></td>
<td>Feasibility</td>
<td>Adherence</td>
<td>A developed checklist will be used to measure the amount and percent of components delivered to the participants.</td>
<td>Weekly</td>
</tr>
<tr>
<td>Moderators</td>
<td>Demographics</td>
<td>Age, gender identity, biological sex, ethnicity, education, employment, marital status, religious preference, health insurance, relationship status.</td>
<td>Baseline</td>
<td></td>
</tr>
</tbody>
</table>
Mixed-methods integration
Quantitative findings will be integrated with qualitative findings, using a narrative approach, to examine feasibility and acceptability of the FPN programme and potential changes in treatment targets. We will use a thematic matrix to integrate the analysis of acceptability and feasibility data from participants and key stakeholder interviews. This matrix will enable us to compare side-by-side themes derived from these interviews and their relationships with satisfaction, engagement, and retention, noting themes that may help elucidate participants’ satisfaction and reasons for engagement or disengagement. A side-by-side comparison of barriers and facilitators identified will enable all the research team to identify similarities and differences between stakeholder groups.

ETHICS AND DISSEMINATION
The study was approved by Washington State University Institutional Review Board (phase I #19362 and phase II #19599). Consistent with funders’ policy, a data safety monitoring board will oversee the trial and any adverse events. Informed consent to participate will be obtained from all participants at each phase. The National Institute of Mental Health (NIMH) data archive will be used as the permanent repository for the final dataset, to be shared with qualified investigators for research via the terms and process established by the NIMH. Anonymised data from the study will be available from the authors after the trial has ended.

While there has been prior research to improve dissemination and access for mental health services for early psychosis among other historically underserved communities, this study will provide critical information on the level of dissemination and community engagement and evidence on the benefits of a culturally responsive FPN model. This model is designed to address known factors that contribute to inequities (eg, limited access, lack of representation) in the utilisation of mental health services that contribute to inequities (eg, limited access, lack of representation) in the utilisation of mental health services for early psychosis among black Americans in the RAISE-ETP trial. Schizophr Res 2022;216:523–5.


23. Markoulakis R, Chan S, Levitt A. Identifying the key features and outcomes of family navigation services for mental health and/or Addictions concerns: a Delphi study. *BMC Health Serv Res* 2019;19:137.


