Improving patient-provider communication to reduce mental health disparities (CDA 16-153)

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Please see the published study protocol paper for additional information.

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Proactive, Recovery-Oriented Treatment Navigation to Engage Racially Diverse Veterans in Mental Healthcare (PARTNER-MH), a Peer-Led Patient Navigation Intervention for Racially and Ethnically Minoritized Veterans in Veterans Health Administration Mental Health Services: Protocol for a Mixed Methods Randomized Controlled Feasibility Study
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Research Background

Low patient engagement in care and ineffective patient-provider communication are 2 major contributors to health care disparities [1-6]. Minoritized patients are less likely to be engaged in care, particularly in mental health care [5-7], which often leads to lower health service use [8-10], higher treatment dropout rates [5,11,12], and worse clinical outcomes [13]. Reasons for low engagement in mental health care vary but include perceived futility of treatment, inadequate access to care, lack of culturally sensitive treatment, low self-efficacy, and lack of trust in health care systems [14-16]. Minoritized patients are also more likely to experience poor patient-provider communication [1,17] and be excluded from treatment decisions [18]. Studies have found patient-provider interactions to be marked by conflicts, perceptions of discrimination, and provider dominance [18]. Ineffective patient-provider communication perpetuates racial health care disparities by contributing to poor care experiences [19-21], low treatment adherence [22], and negative health outcomes [23].

PARTNER-MH Intervention

PARTNER-MH incorporates peer support and patient navigation care models to deliver a manualized patient activation, engagement, and communication intervention to racially and ethnically minoritized Veterans in VHA outpatient mental health clinics. The aims of PARTNER-MH are as follows: (1) to engage racially and ethnically minoritized patients in mental health care, (2) to increase patient activation by giving patients the tools to become active

collaborators in their care, and (3) to improve patients' communication skills and participation in shared treatment decision-making.

Study Objectives

Aim 1 (primary aim) is to assess the feasibility and acceptability of PARTNER-MH in a VHA mental health care setting.

Aim 2 is to evaluate the preliminary effects of PARTNER-MH on patient activation, patient engagement, and shared decision-making (SDM). We hypothesize that patients randomized to the PARTNER-MH intervention group will report greater patient engagement, patient activation, and SDM than patients randomized to the control group.

Aim 3 is to examine patient-perceived barriers to and facilitators of engagement in PARTNER-MH as well as contextual factors, using the Consolidated Framework for Implementation Research (CFIR) [32], that may inhibit or promote the integration, sustainability, and scalability of PARTNER-MH.

Methods

Design Overview

This pilot study used a convergent mixed methods design [33] that involved a randomized controlled trial comparing the PARTNER-MH intervention with a wait-list control group with a sample of 50 racially and ethnically minoritized Veterans. The wait-list design was selected as a comparator for treatment as usual because it provides patients with the opportunity to participate in the intervention after the wait period, which facilitates recruitment into the study.

PARTNER-MH Interventionists

The interventionists for this pilot study are 2 certified VHA peer support specialists, selected through usual VHA hiring practices and assigned to the mental health service line, who have completed the PARTNER-MH training program. The training program consists of 40 hours of didactic sessions that cover topics such as patient navigation, patient engagement, social determinants of health, diversity and racial discrimination in health care, effective communication, and professional development.

Adherence to Intervention Protocol

Fidelity assessment was conducted quarterly using a sample of 8 patients in the active group (8/29, 28%) stratified by 2 peers. A total of 2 clinical psychologists from the study team used the PARTNER-MH fidelity 17-item checklist and audio-recorded intervention sessions or conducted live participant observations to assess fidelity. Fidelity assessment outcomes were then discussed with peers as well as the steps needed to reinforce or correct deviations from study procedures. In addition, peers receive weekly supervision to reinforce training information, address challenges, and provide support (aim 1).

PARTNER-MH Development and Intervention Structure

PARTNER-MH is a theory-driven, peer-led intervention that was developed using participatory approaches [34,35] guided by the CFIR [32]. Specifically, this process involved the active participation of racially diverse Veterans, peers, and peer supervisors throughout the development and pre-implementation phases of PARTNER-MH [36].

PARTNER-MH is a 6-month intervention that consists of individualized sessions with an assigned peer. Sessions are delivered in person, over the phone, or via videoconferencing, depending on patient preferences. Owing to the COVID-19 pandemic and restrictions on in-person visits, most of the sessions were delivered via telehealth. The PARTNER-MH sessions were delivered weekly for the first month, biweekly for the second and third months, and monthly thereafter. Peers and patients also met more often, as needed. The sessions lasted approximately an hour and were tailored to meet patient goals and needs related to engagement, access to services, care coordination, health care communication, and personal support. Peers used the PARTNER-MH handbook to guide and organize their sessions, but they also had the flexibility to use their lived experiences and training to inform the sessions. The flexibility of the PARTNER-MH structure also allowed patients to cover different modules at their own pace. Textbox 1 depicts the modules covered in the handbook and during the sessions.

Participants and Setting

PARTNER-MH was offered to racially and ethnically minoritized Veterans receiving mental health services from an outpatient mental health clinic at a large VHA medical center in the Midwest and associated community-based outpatient clinics. The program targeted Veterans

across psychiatric diagnostic categories who were relatively new to the broad array but somewhat complicated configuration of VHA outpatient mental health clinics, often requiring help to navigate mental health services. To be eligible for the study, participants must (1) belong to a racially or ethnically minoritized group, (2) be aged ≥18 years, and (3) have a new medication management or therapy appointment scheduled within 12 months before enrollment in the study or have recently re-established treatment after an absence of 2 years. Veterans are excluded if they (1) have mental or cognitive impairments that limited their ability to give consent (eg, having acute psychotic symptoms or being cognitively impaired during the consent or interview process), (2) have hearing difficulties that prevent participation in the interviews, or (3) received medication management services at the clinic for >12 months before enrollment in the study.

Recruitment

Participant recruitment for PARTNER-MH is complete. Multiple strategies were used to recruit participants to capture a diverse group of racially and ethnically minoritized patients. They included inviting eligible patients identified through electronic health records and sending them an introductory letter informing them about the study. The letter gave the participants a method for opting out of further contact. In the absence of such notification, 10 days after the letter's receipt was expected, study staff called the patient to explain the study in greater detail, conduct initial screening, and ask eligible patients whether they wished to participate. Other recruitment strategies included clinician referrals, patient self-referrals, direct advertisements, and snowball sampling (ie, asking enrolled participants to refer others). All eligible patients were given a research packet that included an invitation letter and a study information sheet.

Ethical Considerations

Approval was obtained from the Indiana University Institutional Review Board in November 2017 (1708628270) and the Veterans Affairs (VA) Research and Development review committee. Protocol modifications will undergo further review by the institutional review board, be communicated to the research team, and updated in the clinical trials registry.

Randomization and Protection Against Sources of Bias

Participants completed baseline assessment before being randomized into the study arms to ensure balance and reduce selection bias. Allocation to the treatment arm was carried out using a computer-generated randomization list with randomly varying block sizes of 4 and 8 to maximize allocation concealment. Furthermore, although blinding was not feasible for this project because of the study's limited staffing and the need to collect participant feedback on the feasibility and acceptability of the intervention, study personnel involved in screening and enrollment were masked to the computer-generated randomization assignment and were not included in delivering the intervention. Moreover, peers were not involved in data collection and did not have access to participants' assessment results.

Wait-list Control Structure and Overview

Participants in the wait-list control group received regular VHA mental health services (eg, individual or group psychotherapy, consults, and medication management) for the 6 months after enrollment. To overcome potential issues of contamination, where a peer could deliver PARTNER-MH services to control group participants, participants in the control group were encouraged not to use peer services unless they dropped out of the study. Chart reviews were conducted to assess contamination.

Data Collection Methods, Data Management, and Monitoring

The data collection for this study is ongoing. Screening, enrollment, and survey data were collected and stored via VA REDCap (Research Electronic Data Capture; Vanderbilt University), behind the VA firewall. Outcomes were assessed over the phone at baseline and at 3, 6 (primary end point), 9, and 12 months. Outcome data also included qualitative interviews to evaluate participants' experience of the intervention and organizational factors that may impact its future implementation and the integration of the quantitative and qualitative data. Study participants were compensated with a US $35 gift card for each assessment except for the primary end point (at 6 months), for which they received a US $50 gift card. In addition, because of the COVID-19 in-person visit restrictions, participants received a US $10 gift card for each month they remained enrolled in the study to facilitate access to telehealth delivery of the intervention and retention. A brief exit survey was sent to participants who discontinued the

study to evaluate their experiences in the program. Participants' enrollment in the study was recorded in their medical records, which peers had access to. A data safety and monitoring board was also established to evaluate the data quality and safety of the study.

Aim 1 Outcomes

Aim 1 is to assess the feasibility and acceptability of PARTNER-MH in a VHA mental health care setting.

The feasibility of PARTNER-MH will be determined based on participants' recruitment, enrollment, and retention rates. Program acceptability for participants will be evaluated using session attendance, number of contacts with peer navigators, and the Patient Satisfaction Survey, which is an 11-item questionnaire rated on a 3-point Likert scale ranging from 1 (not at all) to 3 (very). Satisfaction with the peer was evaluated using a survey that included questions about the patient's relationship with the peer and views of support provided by the peer. Descriptive summaries of recruitment, enrollment, retention, and satisfaction rates will be reported. Participant feedback from qualitative interviews will also be used to inform the feasibility and acceptability of PARTNER-MH (aim 3).

Aim 2 Outcomes

Overview

Aim 2 is to evaluate the preliminary effects of PARTNER-MH on patient engagement, patient activation, and SDM.

Aim 2 has three main outcome measures: patient activation, patient engagement, and SDM. In addition, sociodemographic data (e.g., age, sex, race, ethnicity, education, and marital status) were collected at baseline. Tertiary and health-related outcomes that included communication self-efficacy, depression, mental health, and physical health functions were also assessed at all time points and are listed in the *Tertiary Outcomes* section.

Secondary Outcomes

The *Patient Activation Measure for Mental Health (PAM-MH)* [37] is a 13-item questionnaire that measures an individual's perceived ability to manage illness and health behaviors. The PAM-MH is reliable, valid, and sensitive to change and correlates with measures of improved self-management and health outcomes. The questions are rated on a 4-point Likert-type scale and then converted using Rasch analysis to a 100-point scale. The PAM-MH has strong test-retest reliability and internal consistency (Cronbach α=.91).

Patient engagement will be assessed using the *Altarum Consumer Engagement (ACE)* measure, a 12-item measure that consists of 3 subscales to reflect patients' commitment to everyday health behaviors, navigation skills in using health care services, and informed choice in treatment decisions [38]. The ACE is administered as a 5-level Likert scale. The subscale scores range from 5 to 25, and the total engagement score is computed by adding the 3 subscale scores and multiplying the sum by 4/3 to obtain a possible range score of 20 to 100. Higher scores represent higher patient engagement.

Finally, we will administer the *SDM-Q-9*, a widely used 9-item patient-reported SDM measure that focuses on the decisional process by rating providers' behaviors in medical encounters. For this study, we will ask participants to think of their most recent visit with their mental health provider. The scale shows good internal consistency (α=.94) and high face and structural validity [39,40]. The SDM-Q-9 is rated on a 6-point Likert scale. The items are scored from 0 to 5 on a 6-point Likert scale ranging from "completely disagree" (0) to "completely agree" (5). A simple sum score with possible values between 0 and 45 is obtained. Item means range from 2.9 to 3.81, and the mean sum of SDM-Q-9 is 3.15 (SD 0.9) [41]. In addition to the SDM-Q-9, we added four questions to evaluate patient participation in treatment decision-making: (1) To the extent that SDM took place during your visit, how much did you drive the process? (2) Thinking about your goal for the visit (what you wanted to be done), how much do you feel you accomplished? (3) How much did you feel heard during your discussion with your provider? (4) Did you experience any barriers that kept you from speaking up or participating in SDM during that visit?

Tertiary Outcomes

Loneliness was assessed using the University of California Los Angeles Loneliness Scale Short Form, a 6-item scale with a 4-point Likert scale ranging from 1 (never) to 4 (often). It has demonstrated internal consistency (α.89-.94) and test-retest reliability (*r*=0.73) [42].

The *Perceived Efficacy in Patient-Physician Interaction-5 (PEPPI-5) scale* measures patients' self-efficacy in obtaining medical information and attention to their chief health concern from a physician [43]. The PEPPI-5 is 5-item scale scored on a 5-point Likert scale ranging from 1 (not confident at all) to 5 (very confident). Higher scores indicate higher levels of self-efficacy. The PEPPI-5 has internal consistency (α=.92) and adequate test-retest reliability.

The *Working Alliance Inventory-Short Revised* evaluates three key aspects of the therapeutic alliance between patients and their mental health providers: (1) agreement on the tasks of therapy, (2) agreement on the goals of therapy, and (3) development of an affective bond [44,45]. The *Working Alliance Inventory-Short Revised* includes 12 items rated on a 5-point Likert scale ranging from 1(never) to 5(always). It shows good psychometric properties in both outpatient and inpatient populations, with a reliability of Cronbach α>.90 and convergent validity with the helping alliance questionnaire (*r*>0.064).

The *Patient Health Questionnaire-9* measures the severity of depressive symptoms. The *Patient Health Questionnaire-9* includes 9 items and demonstrates high internal consistency and reliability (Cronbach α=.89) and good sensitivity and specificity for identifying cases of depression and assessing depression symptom severity [46].

The *Veterans RAND 12-item Health Survey* measures physical function, social function, role limitations owing to physical and emotional problems, mental health, energy and vitality, bodily pain, and the general perception of health. The *Veterans RAND 12-item Health Survey* uses 5-point ordinal response choices and provides two scores: the physical component summary score and the mental health summary score [47].

The *Perceived Discrimination in Healthcare Questionnaire* is a 7-item questionnaire that assesses a respondent's overall health care experiences rather than a specific experience based on their racial background. Respondents are asked to rate their experiences on a 5-point Likert-

type scale, with answers ranging from 0 (never) to 4 (always). This questionnaire has shown excellent reliability in diverse patient populations [48].

Veterans' trust in the VA is assessed using a 3-item questionnaire. Responses range from strongly

Planned Statistical Analyses for Aim 2

Power calculations are provided, but as a pilot, this study is powered only to detect large differences between groups. With a sample of 22 participants in the intervention group and 15 in the wait-list control group, we have 80% power at a .05 significance level to detect an effect size of 0.965 for tests between groups using 2-sided 2-sample *t* tests. With an estimated SD of 14 for PAM-MH based on previous studies, this sample size will allow detection of a PAM-MH difference of 13.5 between the 2 groups. Within the intervention group, the study can detect an effect size of 0.626 for tests between time points using 2-sided paired *t* tests, for a difference of 8.8 for PAM-MH changes. Similarly, in the wait-list control group, the study can detect an effect size of 0.778 and a difference of 10.8 for PAM-MH changes. To account for 25% attrition during follow-up, the study enrolled 30 intervention participants and 20 wait-list control participants. Figure 2 shows the participant flow.

The internal consistency of each scale for primary and secondary outcomes will be verified in this study sample using Cronbach α. Distributions of the scale scores will be examined to determine whether transformation of the data or nonparametric tests are required for the analyses. In this study, 2-sample *t* tests and Fisher exact tests for continuous and categorical variables, respectively, will be used to compare the demographic and baseline data between participants with and without complete data. Repeated measures ANOVA (RMANOVA) for the scale scores will be used to compare data among the assessments over time. The RMANOVAs will allow different correlations between each assessment time and will allow for the appropriate covariance structure to model the intraparticipant correlations; they will also include a random effect for peers to account for correlation among participants with the same peer. In this intent-to-treat analysis, the RMANOVAs will provide unbiased estimates under the missing-at-random assumption. A 5% significance level will be used for each test.

Planned Mixed Methods Analysis for Aim 2

As depicted in Figure 3, this study uses a convergent mixed methods design [33], which involves simultaneously collecting quantitative and qualitative data and giving equal weight to these data in analyses for the purposes of gaining breadth and depth of understanding (ie, complementarity), identifying whether the qualitative and quantitative data provide the same answer to the same question (ie, convergence), and using qualitative data to expand on unexpected quantitative findings (explanatory) [49-51]. Planned mixed data analysis will involve merging and comparing quantitative and qualitative data in parallel to interpret and explain the findings (QUAL+QUAN). This approach will enable us to triangulate our data by incorporating themes from the semi-structured interviews and results from the self-report measures to validate our findings, especially in the context of this feasibility study. Many of the constructs assessed in the quantitative measures will also be explored in the qualitative interviews, for example, intervention characteristics (patient engagement, patient activation, and communication). Moreover, we will use an explanatory mixed methods approach consistent with a randomized controlled trial to better understand the quantitative findings, the process of the intervention, and participants' experiences. The qualitative data will enhance the quantitative analyses by laying the groundwork to better understand the mechanisms of the intervention and facilitate its future implementation.

Aim 3 Outcomes and Analysis

Overview

Aim 3 is to examine patient-perceived barriers to and facilitators of engagement in PARTNER-MH, as well as contextual factors that may inhibit or promote the integration, sustainability, and scalability of PARTNER-MH using the CFIR [32].

We will use domains of the CFIR [32] to collect and analyze data to inform aim 3. The CFIR offers an overarching typology of five domains affecting intervention development and implementation: (1) intervention characteristics, (2) inner setting, (3) outer setting, (4) characteristics of individuals, and (5) implementation process [32]. Briefly, intervention characteristics include evidence of the intervention and its adaptability. Implementation takes

place within an inner setting—the program providing the service. The inner setting is affected by the outer setting—the broader treatment system. Characteristics of individuals such as their skills level also affect intervention delivery and implementation. The implementation process involves different strategies and tools that are used for putting a new practice in place.
Data collection for aim 3 will be guided by the CFIR using semistructured interviews. We will conduct interviews with patients and providers to obtain their perspectives on the intervention and on their experiences of participating in the PARTNER-MH program. Interviews will also assess organizational factors such as time and other resources that may affect the delivery and content of the intervention as well as the impact of the program on Veteran outcomes.

Aim 3 Study Participants

We will invite all 30 Veterans from the intervention group to participate in a qualitative interview. In addition, we will include a purposeful sample of 5 mental health staff members (prescribing and nonprescribing clinicians) with experience in working with peers and patients enrolled in the program.

Aim 3 Planned Qualitative Data Analysis

Interviews from aim 3 will be transcribed, deidentified, and entered into NVivo (QSR International), a qualitative analytical software program, to help organize the data. To facilitate the completion of qualitative data coding and analysis in a short time frame, we will incorporate several features recommended in rapid qualitative assessment [53]. First, we will impose some structure on the data being analyzed. The interviews will reflect CFIR constructs, which will allow for easier access to apply coding. Second, we will incorporate selected codes a priori, based on our prior research, to provide initial structure to the coding process, but will also allow for the expansion of the code list in which other meaningful ideas may emerge. We will use an inductive, interpretive approach that borrows concepts from grounded theory, to identify and explore emerging areas not covered by interview guidelines.

Through an iterative, consensus-building process, we will review transcripts to identify emergent themes consistent with techniques of immersion and crystallization [54]. We will independently read a few selected documents to identify possible areas of pursuit. We will create episode profiles for each transcript to facilitate in-depth understanding of each case and

identify emerging themes for cross-transcript comparison. We will meet to discuss our findings and develop a working set of codes to add to the structural codes mentioned earlier. We will repeat this process on fresh sets of documents until we have a set of defined codes that are stable and consistent. We will then code individual transcripts independently.

To facilitate the rigor of the data analysis process, we plan to hold regular meetings with the coding team to examine coding across analysts, resolve differences in coding, identify and resolve coding drift, and conduct iterative refinement of code definitions. We will maintain memos of our coding processes, coding decisions, and analyses. We will also continually assess and maintain consistency and consensus in our coding practices [50,55].