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## Peer mentorship to reduce suicide attempts among high-risk adults (PREVAIL): Rationale and design of a randomized controlled effectiveness-implementation trial



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## ABSTRACT

**Rationale:** Novel approaches to suicide prevention are needed to address increasing rates of suicide deaths. Research suggests that interventions led by certified Peer Specialists may improve suicide protective factors such as hope and connectedness; however, the effectiveness of a Peer Specialist intervention for reducing suicidal thoughts or behaviors has not previously been tested empirically.

**Design:** We describe the methodology of a randomized controlled hybrid effectiveness-implementation trial of a peer specialist intervention known as PREVAIL (Peers for Valued Living). The primary effectiveness aim is to determine whether the 3-month peer mentorship intervention compared to a minimally enhanced usual care condition reduces suicide attempts and suicidal ideation among adults at high risk for suicide who have been psychiatrically hospitalized. Secondary effectiveness outcomes include medically serious suicide attempts according to chart review and self-reported self-efficacy to avoid suicide. We also describe suicide risk management, supervision, and fidelity monitoring in the context of Peer Specialist providers and our methods for assessing implementation barriers and facilitators.

**Conclusion:** The PREVAIL trial will demonstrate novel methods for incorporating peer providers into a suicide prevention effectiveness trial with high-risk study participants. PREVAIL's hybrid effectiveness-implementation design aims to maximize the likelihood of rapid implementation in the community if shown to be effective.

### 1. Introduction

Peer specialists are individuals with a lived experience of mental health challenges who are trained and employed to provide support to others who are in earlier stages of the recovery process [41]. Research suggests peer specialists can potentially contribute to improved outcomes for peer support recipients by fostering hope and connectedness and reducing depression [7,16,17,56,73]. As such, clinical approaches to suicide prevention could potentially include innovative roles for peer specialists.

Though research on peer-delivered suicide prevention interventions is limited [23,34,51,63,64], the reality of community practice is that

peer specialists already serve populations that are at risk for suicide [16,67], suggesting a need for further research as well as guidance on best practices for implementing new interventions. With US suicide rates at their highest point in decades [10], developing and testing peer-led suicide prevention interventions is consistent with the National Strategy for Suicide Prevention, which states peers “can help promote hope and motivation for recovery; provide support for addressing specific stressors, such as the loss of a job; and help foster a sense of meaning, purpose, and hope.” [71].

In this paper, we present the protocol of a randomized controlled hybrid effectiveness-implementation trial designed to determine whether a peer mentorship intervention known as PREVAIL (Peers for

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Valued Living) reduces suicide attempts and suicidal ideation among individuals at high risk for suicide who have been psychiatrically hospitalized. Secondary aims seek to identify moderators of outcomes at the patient level and also, to identify potential barriers and facilitators to implementing and delivering PREVAIL to help to more quickly translate findings into practice [20]. We describe the intervention's theoretical basis, risk management approach, supervisory structure, and formative evaluation to assess implementation factors.

## 2. Materials and methods

### 2.1. Overview of study design

PREVAIL is a Type 1 hybrid effectiveness-implementation trial designed to maximize the likelihood of rapid implementation in the community if shown to be effective. We selected this design in the context of research showing that decades may pass before effective new interventions are implemented widely [20,38], in part due to failure to maximize real-world clinical utility in the research design [49]. Hybrid effectiveness-implementation trial designs address this problem of long delays between research and implementation by studying the barriers and strategies for future implementation concurrently with determining effectiveness [20,38]. Thus, our primary aim is to test effectiveness of PREVAIL within a randomized clinical trial and a secondary aim is focused on formative evaluation to identify potential barriers and facilitators to future implementation in clinical settings outside those participating in the current trial. Work by Chinman and colleagues [14] discusses the dearth of implementation research focusing on barriers and facilitators of peer specialist services, noting that previous outcome studies included in their reviews have not measured the fidelity of these services [13]. Our trial design remedies these gaps in the literature by including qualitative interviews to identify implementation barriers and facilitators, and by using a measure developed during the pilot phase to rate audio recordings of peer mentorship sessions for fidelity.

The addition of a formative evaluation can provide valuable insights about the role of context in implementation. For example, prior studies of peer support implementation identified confusion about the peer specialist's role within a clinical team as a barrier [12,27]. Formative evaluation conducted as part of this study will assess whether the PREVAIL training and protocols address this barrier, and whether other factors rise in prominence when accounting for the health system perspective (e.g., effect on readmissions) and the context of suicide prevention (e.g., acceptability of safety protocols) [24]. Even if PREVAIL proves not to be effective, assessing consumer, peer specialist, and provider stakeholder experiences may provide explanations for the null findings, guide future research on improved interventions, and inform ongoing initiatives to increase effectiveness of peer specialist involvement in suicide prevention.

The effectiveness component of the study is a single-blind randomized controlled trial of the PREVAIL peer mentorship for suicide prevention intervention compared to enhanced usual care among 490 participants at high-risk for suicide recruited from two inpatient psychiatric units. We will use the Consolidated Framework for Implementation Research (CFIR) [24] to structure interviews of approximately 40 stakeholders to elicit perspectives about actual and potential barriers and facilitators to implementation of PREVAIL.

### 2.2. Aims

The three primary aims in the PREVAIL trial are to (1) determine the effectiveness of the PREVAIL peer mentorship intervention for reducing suicide attempts and suicidal ideation among recently hospitalized adult psychiatric patients at high risk for suicide; (2) examine the mechanisms of peer mentorship by measuring the effects of PREVAIL on potential mediators, including hope and belongingness; and (3) identify barriers and facilitators in PREVAIL's implementation.

### 2.3. Sponsors

PREVAIL (R01MH115111-01) is supported by the National Institute of Mental Health (NIMH). The study protocol was approved by the Institutional Review Boards of the University of Michigan Health System and the Henry Ford Health System. The study convened a Data Safety and Monitoring Board (DSMB) composed of three members not otherwise involved with the project, which meets bi-annually to review data on adverse events, recruitment, and adherence to the protocol. PREVAIL is registered with clinicaltrials.gov (NCT03373916).

### 2.4. Eligibility, recruitment, and enrollment

#### 2.4.1. Participants in the PREVAIL intervention

The goal of study inclusion and exclusion criteria is to identify a broadly representative sample of adult inpatient psychiatric patients at high risk for suicide based on a suicide attempt or suicidal ideation prior to admission. Including only those with a suicide attempt would limit the generalizability of the intervention. Recruitment from inpatient units facilitates the initial in-person peer support contact in a safe setting and ensures some intervention has taken place prior to when patients are at maximal risk immediately following discharge [70].

Patients are eligible for the study if they: (1) are age 18 years or older, (2) are currently admitted to an inpatient psychiatric unit and have medical record documentation of suicidal ideation or suicide attempt at the time of admission, (3) have a Beck Suicide Scale score of 5 or higher with respect to the 1-week period prior to admission, (4) are fluent in English, and (5) are able to be reached reliably by telephone. The age and language criteria are necessary because peer mentors will be English-speaking adults. Patients are excluded if they are: (1) substantially cognitively impaired (according to the Mini-Cog [5,52]); (2) unable to provide informed consent for any reason (including incompetence); (3) identified by the attending psychiatrist as inappropriate for peer mentorship due to cognitive disorder, unstable psychosis, or severe personality disorder; (4) already receiving or intending to receive peer support services for suicide prevention (e.g., suicide attempt survivor support group) or services from a certified peer support specialist; (5) residing more than 50 miles from any peer mentor; (6) planning to be discharged to another inpatient or residential facility; or (7) receiving electroconvulsive therapy (which prolongs the hospital stay and complicates informed consent and peer interactions due to risks of memory impairment).

The study team will recruit participants from the psychiatric inpatient units of two Midwestern hospitals. One site admits approximately 800 patients per year, and the other site admits approximately 1200 patients per year. All patients admitted to each inpatient psychiatry unit will be screened for study enrollment via review of their electronic medical records and consultation with the attending psychiatrist. The research assistant will then approach those who meet initial inclusion criteria in order to describe the study, obtain informed consent, and complete the screening items not available from the medical record.

Informed consent will be obtained from all participants, and baseline measures will be completed at the time of enrollment, prior to study arm assignment. Randomization will occur using a minimization algorithm implemented by the U-M Consulting for Statistics, Computing & Analytics Research (CSCAR) center [1] that incorporates gender and recent suicide attempts, and will be stratified by study site. These three variables are known to be associated with our outcomes, and thus minimization randomization is used to minimize serious treatment imbalance in these factors. The three control variables are each used in minimization, and simulation studies have shown that adjusted analyses preserved type 1 error and increased power [77].

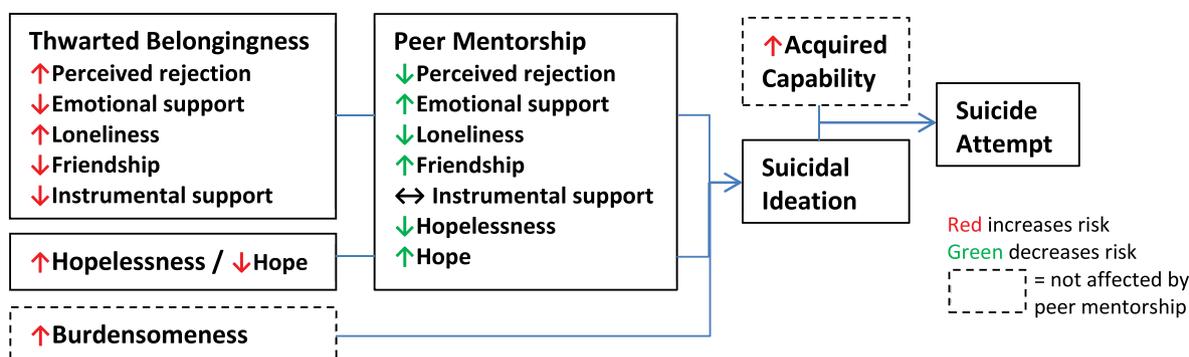


Fig. 1. Interpersonal theory of suicide constructs in relationship to peer mentorship.

#### 2.4.2. Participants in the formative evaluation

We will purposively sample approximately 40 patient care stakeholders, some of whom are involved in the PREVAIL implementation, and some of whom work in other settings likely to consider implementing PREVAIL if it proves effective [55]. Specifically, we will invite clinical leaders from the two inpatient units at which PREVAIL participants are recruited and from two inpatient units not affiliated with the current study; PREVAIL peer mentors; PREVAIL participants; and employed peer specialists without PREVAIL training. We will also sample leaders from county community mental health (CMH) services, as they are one of the largest employers of peer specialists in the region [46].

### 2.5. Intervention

#### 2.5.1. Theoretical basis of intervention

Our theoretical model for peer mentorship to prevent suicide attempts is based on the interpersonal theory of suicide (ITS) [40,74] and the postulated effects of peer support (Fig. 1). The ITS describes empirically-supported suicide risk factors in four categories: hopelessness, thwarted belongingness, burdensomeness, and acquired capability for suicide. The theory proposes that thoughts of killing oneself occur when thwarted belongingness, burdensomeness, and hopelessness co-occur, and that an acquired capability for suicide is important for the transition from ideation to making a suicide attempt. The ITS domains explain a greater portion of the variance of suicidal ideation and attempts than models using demographic characteristics and diagnoses [40]. While studies have not consistently replicated the theorized interactions between domains, the independent effects of the ITS domains have been found to be associated with suicide outcomes, thereby supporting the use of these constructs as intervention targets [15].

The selected theoretical model has significant implications for the intervention's design. While the effects of hopelessness and poor belongingness on suicide risk are well established according to several reviews encompassing dozens of trials [50,66,68,74], whether peer mentorship improves an individual's sense of belongingness or hopelessness has not been shown definitively, as most peer support trials have not included measures of these constructs [37]. In our review of 40 trials of peer support cited in 3 recent meta-analyses, 17 studies included measures of belongingness with 6 showing positive effects, and 4 studies included measures of hope or hopelessness with 3 showing positive effects [7,33,56]. In light of this evidence, the PREVAIL intervention explicitly includes content addressing protective factors such as belongingness, connectedness, and hope.

#### 2.5.2. Intervention description

During the pilot phase, the study team convened an expert panel to develop the intervention [57]. The intervention is informed by common elements found in many peer specialist interventions, especially sharing recovery stories and reflective listening, and tailors these elements to

working with individuals at high risk for suicide. The investigators then developed a series of semi-structured conversation guides for peer specialists that focused on hope, belongingness, and safety that were adapted from evidence-based practices. For example, establishing physical reminders of hope and safety plans are similar to elements of Wellness Recovery Action Planning (WRAP) [16] and cognitive behavioral therapy for suicide prevention (CBT-SP) [67]. Conversations regarding mindfulness exercises were adapted from dialectical behavioral therapy (DBT) [48], hopeful goal-setting conversations were informed by Hope Therapy [11,30], and a discussion of values as a link to goals was adapted from Acceptance and Commitment Therapy (ACT) [36]. The conversation guides are situated within semi-structured conversation templates called ILSM Guides: "Invite, Learn, Share, Motivate." The ILSM conversation guides are intended to assist the peer specialists in facilitating a discussion that balances disclosure and sharing with listening, and are situated within a Motivational Interviewing (MI) framework [53], incorporating the conversation guides described above and emphasizing reflective listening and "change talk" in forming and motivating recovery goals in partnership with peer support recipients.

Peer specialists are trained to use these conversation guides during a 3-day training program that involves extensive group discussion and role-play using the ILSM Guides. The training also includes guidance on sharing personal experiences related to suicide, emphasizing that peer specialists should describe their recovery from suicidal actions or thoughts, but not include graphic descriptions of self-harm or methods. Training introduces basic MI skills with the intention to reinforce those skills during ongoing supervision. It also covers the study's risk management algorithm, which is described later in this paper.

#### 2.5.3. Intervention delivery

Participants randomized to PREVAIL are given a short written description of each available peer mentor. Each peer mentor writes his or her own description, which includes demographic information, philosophy of peer support, and some discussion of prior mental health challenges. These descriptions are designed to improve fit between participant and peer mentor and provide the participant with agency in establishing the relationship, as one would have with natural supports. The study team provides minimal input on the initial peer mentor descriptions, mainly editing for length. If a peer is chosen substantially less often than others based on their description, the description will be subject to further review and suggested edits by the research staff.

The selected peer mentor then meets with the participant while he or she is still in the hospital. To establish "peerness," the peer specialists refer to their own suicide-related experiences during their first meeting with the peer support recipient. The first meeting also includes discussing logistics and describing the limits of confidentiality, particularly in the case of acute suicide risk.

Subsequent sessions are scheduled according to the participant's preferences, with a suggested maximum frequency of twice a week for the first two weeks, once a week for weeks 3 to 8, and every other week

for the last month. Allowable meeting locations include public places in the community (e.g., coffee shop, park), the participant's home, or a research clinic space. Meetings can also take place by phone, and brief contacts between meetings can occur via text message or e-mail if needed. To protect participants for whom an abrupt end to the peer relationship may be harmful, peer mentors may offer participants the option of 3 additional sessions over 4 weeks following the end of the 3-month intervention. Session duration is on average 1 h with at least 15 min discussing hope or belongingness consistent with the ILSM conversation guides.

Session content is flexible and allows for the peer mentor to provide general supportive listening, validation, and sharing. In delivering the intervention, the peer specialists may use whichever ILSM Guide feels most relevant to the peer support recipient's current presenting concerns and recovery. Group supervision meetings may help clarify which conversation guide might be most helpful. Session structure and content are intentionally flexible to allow for genuineness in the peer relationship, thereby increasing acceptability and implicit belongingness. One exception to this flexibility is that during the first session after hospital discharge, peer mentors are instructed to review the participant's suicide safety plan that was created during their inpatient stay and revise as necessary. The 6-week session is also a "check in" point for the peer mentor to gauge preferences for more- or less-structured conversations or sharing, and remind participants they are half-way through the intervention so they anticipate termination at 3 months.

As part of the study's risk management protocol (see Fig. 2), peer specialists ask about suicidal ideation (and recent suicide attempt behaviors, if ideation has been present) at each encounter. If the participant endorses suicidal ideation, the peer specialist asks whether the suicidal ideation or intensity is any worse than when last reported to a mental health clinician. If there has been any recent suicide attempt behaviors or worsening of suicidal ideation, the peer specialist will contact the PREVAIL on-call clinician – either a licensed clinical psychologist or a psychiatrist – while the participant is still present. The clinician then assesses the situation, possibly speaking with the participant directly, and determines next steps. In these cases, the study team may contact the participant's usual care clinician to relay what they have learned and what actions they have taken. Using this protocol, the peer specialists are not placed in the position of having to conduct more than a minimal risk screening, to make clinical judgments, or to manage acute suicide risk on their own.

All peer mentoring sessions are audio recorded. The research team analyzes these recordings for content and fidelity. The clinical supervisors also review these recordings and may play them during group supervision meetings for discussion and analysis.

2.5.4. *Certified peer support specialists*

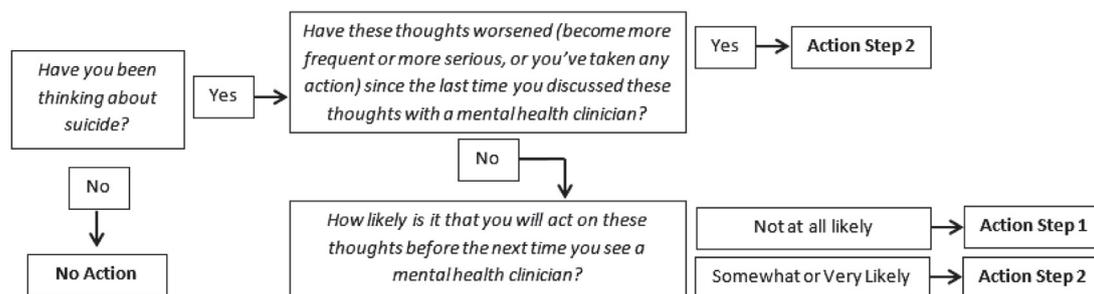
State-certified peer specialists are hired and trained to deliver the PREVAIL intervention. They are recruited through e-mail announcements to all state-certified peer specialists and through peer-facilitated social media (e.g. peer specialist Facebook page). Candidates are screened for their ability to discuss a lived experience of recovery from suicidal thoughts or a suicide attempt, preferably including inpatient treatment, and for having had at least one year of work experience as a professional peer.

2.5.5. *Group supervision*

Peer mentors attend a weekly group supervision meeting led by a clinical psychologist to review each active participant. The meeting allows clinicians to provide guidance regarding challenges the peer mentors may encounter that are beyond their training or experience, and also allows the peer mentors to provide one another with consultation and support. Peer mentors have the opportunity to review their audio recordings during supervision which provides an opportunity for self-reflection and additional feedback from the group. Group supervision also reinforces fidelity to the intervention by reviewing training materials, planning future sessions, and providing feedback on the use of ILSM conversations and general support skills.

2.5.6. *Enhanced usual care*

The investigators chose an enhanced usual care (EUC) control condition to address ethical concerns that high-risk study participants should receive some enhancement in care, to address concerns that comparing peer mentorship to usual care lacks equipoise, to increase expectancy and credibility among control participants, and to increase external validity by demonstrating the intervention is superior to another credible health system approach to suicide prevention [31]. The EUC condition consists of a caring message from the study team via e-mail or text message 24–72 h after discharge. An example message is, "We hope things are going well for you since you left the hospital. If you wish to reply, we'd be glad to hear from you." A list of local mental health resources is available if participants reply, and during the 3- and



**Action Step 1:** The Peer reviews the participant's suicide safety plan and ensures the participant has contact information for local mental health services and the telephone number for the National Suicide Prevention Lifeline.

**Action Step 2:** The Peer calls the study's on-call mental health clinician for further assessment and management with the participant still present. If the on-call provider is not available, the participant will be connected with the National Suicide Prevention Lifeline. The participant's regular mental health provider will also be notified.

Fig. 2. Suicide risk screening and management protocol.

6-month follow-up assessments.

The EUC condition is modeled on prior studies of caring letters and brief contacts by health professionals after suicidal crisis and national recommendations to provide post-crisis follow-up [9,43,47,54,72]. A research assistant trained in suicide risk protocols will address responses; after-hours responses will be automatically sent crisis resources. Participants randomized to the peer mentorship arm also receive EUC.

## 2.6. Study assessments

### 2.6.1. PREVAIL assessments

The primary outcomes to assess the effectiveness of the PREVAIL peer mentorship intervention are suicide attempts and suicidal ideation. Three- and 6-month outcome assessments occur through in-person meetings with research staff blinded to study arm assignment. In cases where in-person attendance is not feasible, research staff can complete the assessment over the phone or internet, though in these cases they first confirm the participant's location and availability of an emergency contact person in the event of acute suicide risk. If a participant does not complete an assessment within 45 days, that assessment will be documented as incomplete.

#### 2.6.1.1. Primary outcomes

- 1) We use the Columbia Suicide Severity Rating Scale (CSSR-S) administered at 3 and 6 months to detect any suicide attempts over the 6-month period. The definition of suicide attempt for the primary outcome will consist of any actual suicide attempt, aborted suicide attempt, or interrupted suicide attempt according to the CSSR-S. The CSSR-S will be administered by a trained research assistant, and all ambiguous classifications will be reviewed by the study team and resolved by consensus to maximize inter-rater reliability.
- 2) We use the Beck Scale for Suicide Ideation (BSI) [3] administered at baseline, 3 months, and 6 months to detect change in suicidal ideation over 6 months. The BSI is a scale consisting of 5 screening items and 21 test items. It assesses thoughts, plans, and intent to commit suicide. Each of the items are rated on a three-point scale (0 to 2). Total scores range from 0 to 48. While there are no established cut-off scores to create a severity classification, higher scores suggest greater suicide risk. For the primary outcome we assess current ideation (i.e., past week), but we also assess worst ideation since the last assessment (i.e., prior 3 months) as a secondary outcome.

#### 2.6.1.2. Secondary outcomes

- 1) We use the patient medical record from baseline to 6 months to detect medically serious suicide attempts, defined as any actual suicide attempt that results in medical hospitalization or more than 23 hours stay in an emergency department.
- 2) We use the Self Efficacy to Avoid Suicidal Action Scale (SEASA) [3] administered at baseline, 3 months, and 6 months to detect self-efficacy to avoid suicide. Prior studies have found that lower scores on the SEASA are associated with a higher incidence and greater severity of suicide attempts [22].

2.6.1.3. *Other pre-specified measures.* Exploratory analysis will also measure the effects of PREVAIL on the following outcomes measured at baseline, 3 months, and 6 months, and the potential role of changes in these factors as mediators:

- 1) Hopelessness, as measured by the Beck Hopelessness Scale (BHS), a 20-item measure of negativity and pessimism about the future. Scores range from 0 to 20, indicating the severity of self-reported hopelessness: minimal (0–3), mild (4–8), moderate (9–14), and severe (15–20) [2].

- 2) Quality of life, as measured by the Quality of Life Enjoyment and Satisfaction Questionnaire Short Form (Q-LES-Q-SF), a 14-item measure of satisfaction with a variety of life domains such as physical health, work, and social relationships. The scoring of the Q-LES-Q-SF involves summing the first 14 items to create a total score. The total score ranges from 14 to 70. Higher scores suggest higher levels of enjoyment and satisfaction with life [28].
- 3) Functional status, as measured by the Short Form 12 (SF-12), which covers domains including: (1) physical functioning; (2) role-physical; (3) bodily pain; (4) general health; (5) vitality; (6) social functioning; (7) role emotional; and (8) mental health. Summing factor-weighted scores across the subscales creates a summary score; the factor weights are derived from a US-based general population sample. Physical and Mental Health Composite Scores (PCS & MCS) are calculated using the twelve item scores and range from 0 to 100 in which a zero indicates the lowest level of health and a 100 indicates the highest level of health [39].
- 4) Perceived social support, as measured by the Multidimensional Scale of Perceived Social Support (MDPSS), which contains 12-item Likert scale items with three subscales to address different sources of support: family, friends, and significant other [78].
- 5) Depression, as measured by the Patient Health Questionnaire (PHQ-9), a measure of the severity of depression [44,45].
- 6) Hope, as measured by the State Hope Scale, a 6-item measure that contains two sub-scales reflecting respondents' personal capacity for change (agency) and knowledge regarding how to achieve change (pathways) [65].
- 7) Burdensomeness, as measured by the burdensomeness subscale of the Interpersonal Needs Questionnaire (INQ), a measure of the interpersonal theory of suicide construct of burdensomeness.
- 8) Perceived emotional support, as measured by the 8-item emotional support scale of the NIH Toolbox Adult Social Relationship Scales (ASRS) [21].
- 9) Perceived instrumental support, as measured by the 8-item instrumental support scale of the NIH Toolbox Adult Social Relationship Scales (ASRS) [21].
- 10) Perceived friendship, as measured by the 8-item friendship scale of the NIH Toolbox Adult Social Relationship Scales (ASRS) [21].
- 11) Loneliness, as measured by the 5-item loneliness scale of the NIH Toolbox Adult Social Relationship Scales (ASRS) [21].
- 12) Perceived rejection, as measured by the 8-item perceived rejection scale of the NIH Toolbox Adult Social Relationship Scales (ASRS) [21].
- 13) Self-reported utilization of health care services, as measured by the adapted Health Services Inventory [4].
- 14) Medication adherence, as measured by the Single-Item Self Rating (SISR) Scale for Medication Adherence [29].
- 15) Change in perceived meaning in life, as measured by the Meaning in Life Questionnaire (MLQ), a 10-item measure of the presence of and search for meaning in life [69].
- 16) Expectancy and credibility will be measured by the Credibility and Expectancy Questionnaire to assess for differences between the two study arms and the extent to which expectancy and credibility mediate the intervention and EUC effects [26]. This measure is only administered at baseline.

#### 2.6.2. Fidelity assessments

Fidelity to the PREVAIL intervention is monitored through formal fidelity ratings of a random sample of 20% of each peer mentor's audio-recorded sessions using the fidelity rating scale developed during the pilot study and further revised to improve inter-rater reliability. The measure, based initially on the Yale Adherence and Competence Scale [8], uses a 3-point scale (1: "inadequate", 2: "adequate", 3: "skilled") to rate the skill with which peer mentors (a) deliver ILSM conversations, (b) demonstrate general peer specialist skills such as listening, empathy, motivational enhancement, and self-disclosure, (c) ask about suicidal

ideation, and (d) avoid irrelevant topics. The measure also assesses whether or not the peer mentor provided medical advice, contradicted providers, or suggested a diagnosis or treatment, each of which are considered outside their scope. Incidents of inadequate fidelity are addressed in individual supervision with the peer mentor.

### 2.6.3. Formative evaluation data collection

We will conduct qualitative semi-structured interviews with up to 40 patient stakeholders (see Section 2.4.2) to identify potential barriers and facilitators to implementation of PREVAIL. Interviews will explore health system, peer mentor, and patient perspectives relevant to actual and future implementation. We will interview patients within a month of discharge from the intervention, and all others after the intervention to avoid co-intervention effects. We will develop semi-structured interview guides based on the CFIR (see [www.cfirguide.org](http://www.cfirguide.org)) [24], which will include open-ended exploration of implementation experiences, prospects for future implementation along with potential barriers, and exploration of potential implementation strategies. Interviews will explore access to training, costs, safety, and supervision concerns as well. Experienced interviewers will conduct and audio record the interviews.

Our formative evaluation will help explain outcomes, whether positive or negative, especially if we find differences (subjective or objective) between study sites. Insights gained through this component of our evaluation will help to inform recommendations on strategies to use in future larger-scale implementations and/or adaptations of PREVAIL.

## 2.7. Data management

Preliminary eligibility data will be collected from participant's electronic medical records and entered into a Microsoft Access database. Clinical data will be entered from the electronic medical record. This data will be linked by a coded identifier to direct identifiers (name, phone number, address, and medical record number) but stored separately. Outcome assessment data will be collected at baseline, 3 months, and 6 months using Qualtrics (Provo, UT) [58], a platform for creating and distributing online surveys, running on tablet computers. Data will reside in a secure local Qualtrics database until it is extracted to another secure platform for analysis. Qualitative recordings will be transferred from recording devices to a secure server space where they will be stored until the audio files have been transcribed and analyzed. Data will be erased from recording devices upon transfer to the server. Transcripts of the recordings will also be stored on a secure server space.

## 2.8. Data analysis plan

### 2.8.1. General approach

We will examine between-group differences at baseline, particularly in variables that are potentially associated with suicide attempts or ideation, including age, severity of suicidal ideation prior to admission, burdensomeness, hope, hopelessness, and belongingness. Balance is expected for sex and recent suicide attempt due to randomization by minimization.

We will examine the distribution of all study variables for extreme values, missing data, variances, possible coding errors, skewness and whether or how to categorize skewed data. We will describe means and standard deviations for the continuous measures and frequencies of dichotomous outcomes by study group for each assessment time for the entire sample and for each of the study sites, separately.

### 2.8.2. Primary outcomes

Primary analyses will determine the effectiveness of PREVAIL in decreasing the risk of suicide attempts and in decreasing suicidal ideation at 6 months post-randomization. The primary analytic cohort will be "intent to treat," such that all randomized participants will be included according to their original study arm assignment, regardless of

whether they subsequently drop out of participation. Secondary analyses will be conducted using a "per protocol" cohort where only participants who complete 6 or more encounters with a peer specialist will be compared to those assigned to the EUC arm.

To test for intervention effects at 6 months on the primary outcomes, a logistic regression model will be used for the dichotomous outcome of suicide attempt (as assessed by CSSR-S) and a multiple regression model will be used for suicidal ideation (as assessed by BSI). Each model will include the study arm as the primary predictor and will also include study site, gender, and prior suicide attempt, which were the balancing variables used in randomization. Outcomes at 6 months post-randomization will be our primary analysis in order to assess whether the intervention has lasting effects, but we will also assess immediate effects at 3 months.

We will also assess the intervention effects over time using longitudinal data for both suicidal ideation and suicide attempt. For suicidal ideation, we will use a linear mixed-effects model with ideation assessed at baseline, 3 months, and 6 months as the dependent variable. The model will allow the full use of all observed data despite missing outcomes at one or two assessment times and will give unbiased estimates as long as the missingness does not depend on the unobserved missing data (missing at random). For suicide attempt, we will use a generalized linear mixed-effects model with logit link for any suicide attempt in the prior 3 months as a binary response variable assessed at 3 and 6 months. These models will include participant as random intercepts to take into account the correlation of data within person over time. The models will allow estimation of the time-averaged effect of the intervention if the response to the intervention is immediate and lasting, or estimate the differential effect of the intervention over time if a significant interaction between time and intervention is found, such as different trends between the study groups. Whether we compare the time-averaged effects or the rates of changes between two groups, we will be guided by careful graphical exploration of the longitudinal data over time between the two groups.

### 2.8.3. Other quantitative outcomes and mediation analyses

The effects of the intervention on the secondary outcomes of self-efficacy to avoid suicide and medically serious suicide attempts will be conducted analogously to the primary outcomes. Effect of the intervention on the hypothesized mediators of hope (Hope Scale and Beck Hopelessness Scale) and belongingness (NIH Toolbox measures) will be assessed using multiple regression models based on a similar model as described under the primary outcomes. Our chief interest will be comparisons between treatment arms at 3 months (primary analysis) and 6 months (secondary analysis). We will use similar exploratory analyses to assess intervention effects at 3 and 6 months on functioning, quality of life, depression, patient activation, healthcare utilization, and medication adherence.

We will examine whether any improvements in the primary outcomes of suicide attempts or suicidal ideation are mediated through improvements in hope and belongingness in primary exploratory analyses. The role of functioning, quality of life, depression, healthcare utilization and medication adherence as mediators will be assessed in secondary exploratory analyses. To test whether a variable might be a mediator, we will first test the associations between the intervention arm and the mediator (described in above bivariate analyses), and then the mediator and the outcome of interest using bivariate analyses (e.g., hope at 3 months and suicidal ideation at 6 months). A variable will be considered a potential mediator if the variable at the 3-month assessment is associated with the intervention arm and with the outcome at 6 months. We will obtain a bias-corrected bootstrap confidence interval as an estimate of the confidence interval for the mediated effect.

Potential mediators (at 3 months) will then be included as covariates in multivariate regression models predicting the primary outcomes at 6 months (Fig. 3). If, as hypothesized, the intervention's effects on the primary outcomes are mediated through hope and belongingness (or

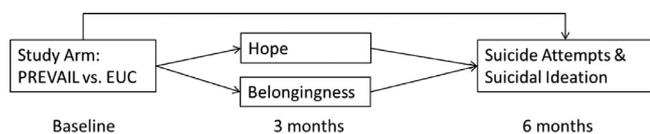


Fig. 3. Mediation model of intervention effectiveness.

other exploratory mediators), the variance in the 6-month outcomes explained by the intervention group will be less once the mediator variables are included in the models. Changes from baseline to 3 months will also be examined as potential mediators.

The intervention effects on any and number of readmissions to a psychiatric inpatient unit, emergency department visits, and outpatient mental health treatment visits (e.g., medication prescriber or psychotherapist) will be analyzed using generalized linear models with appropriate link function.

#### 2.8.4. Formative evaluation data analyses

Audio-recording of interviews will be transcribed verbatim, then de-identified. We will analyze the data using a qualitative content analysis approach, with both deductive and inductive coding [59]. We will create a draft codebook based on the CFIR, adapted to PREVAIL. To refine the codebook, two study staff members will independently read each of the interview transcripts, and in an iterative process, meet to develop and refine the coding scheme and code definitions collaboratively, more precisely specifying code definitions, adding new sub-themes and themes identified inductively from the transcripts, and including exemplar quotations from the data. Larger study team meetings will be convened periodically to review the coding as it develops and help achieve consensus on codes and their definitions. Interviews will then be coded by two members of the research team, with disagreements resolved through consensus. A qualitative analysis software package will be used to support coding and analyses. The study team will consider and interpret implementation findings based on site-specific memos that summarize data in each code and include analytic insights and decision rationale, which facilitates and enriches data interpretation [61]. Final study findings will focus on identifying the most important barriers to implementation and the most promising implementation strategies for overcoming those barriers.

#### 2.9. Statistical power

Based on our pilot study findings and those of other randomized controlled trials of psychosocial interventions that included suicide attempts as a primary outcome [6,35,60], we powered the study with the assumption that frequency of suicide attempts at 6 months will be 22% in the intervention arm vs. 36% in the control arm. We propose to enroll 490 patients in total, and assuming a 25% dropout rate, 368 (184 per group) are expected to provide primary outcome data. The proposed sample size is expected to provide 84% power to detect the desired difference between the two groups based on a two-sided 0.05 level test. For the primary outcome of suicidal ideation according to the Beck Scale for Suicidal Ideation at 6 months and measures of hope and belongingness at 3 months, our sample of 368 will provide 90% power to detect a standardized effect size (Cohen's  $d$ ) of .34. For the mediator analysis, the proposed sample size is expected to provide 80% power to detect a significant mediator assuming that the intervention explains about 2% of the variance of the mediator (corresponding to "small" effect based on Cohen's criteria), and about 7% of the variance of suicide ideation is explained by the mediator adjusting for the intervention effect, or vice versa based on joint significance testing for the mediation effect [32].

### 3. Discussion

High unmet needs and low treatment rates persist among adults with mental illnesses [18,76], and new approaches to suicide prevention are needed to address increasing suicide deaths [71]. Workforce innovations outside the traditional paradigm – that is, a paradigm in which a highly trained clinician provides care from within their office – are likely essential to alleviating the burden of mental illness on a population level [42]. Peer specialists are a growing, professionalized, and integrated workforce that can comprise one facet of a new mental health paradigm; one that can reach diverse populations in their own communities, fostering hope and belongingness through sharing their own recovery stories and providing instrumental support that is informed by lived experience.

Peer mentorship is a novel approach to reducing suicide risk by addressing poor belongingness and hopelessness, which are two suicide risk factors that are supported by theory, evidence, and advocates. Our study of peer mentorship will be the first effectiveness trial of a peer specialist-delivered intervention designed to reduce suicide attempts and suicidal ideation. It will also be one of the first studies to measure the degree to which a peer specialist intervention was delivered with fidelity [13]. Even as the peer specialist workforce rapidly grows, some clinical staff and administrators have voiced concerns about perceived issues such as peer worker fragility, potential for relapse, difficulties with documentation, and confidentiality [25]. In showing whether peer mentors can effectively deliver an intervention for high-risk adults, and in exploring whether implementation reflects the clinician concerns noted above, PREVAIL will contribute to an ongoing debate among clinicians about effective roles for peer specialists.

This study design grapples with, but does not fully resolve, different approaches to the role of peer support in healthcare contexts. Peer specialist interventions exist along a spectrum from unstructured mutual support to highly specified, directive practices [19,25]. In some qualitative studies, peer specialists have been found to experience intervention policies, practices, and assessment protocols as clashing with peer support values such as mutuality and equality [62,75]. In the PREVAIL intervention we attempt to balance competing elements of the peer specialist role through semi-structured, evidence-informed "conversation guides," while also providing flexibility for the peer mentor to select and customize the guides to ensure a good fit. The peer mentors are also encouraged to incorporate their individual approach to peer support, informed by their lived experience, alongside the semi-structured conversation guides. This autonomy, which is central to many conceptualizations of peer services, presents challenges for measuring fidelity, which we resolve through a flexible assessment approach that allows multiple paths to meet fidelity.

A safe and effective peer-based intervention to prevent suicide attempts could achieve wide-scale implementation, as the peer specialist workforce already supports high-risk individuals, and has enjoyed financial sustainability since the Centers for Medicare and Medicaid (CMS) published Medicaid reimbursement guidelines supporting their work in 2007. The hybrid effectiveness-implementation design will help speed translation of PREVAIL from clinical trial evidence to practice if it is effective. Finally, the study will determine whether the peer mentor intervention impacts the hypothesized intermediate outcomes of hope and belongingness, and the role these potential mechanisms play in subsequent suicide attempts and suicidal ideation.

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#### Conflict of Interest

The authors declare that they have no known competing financial

interests or personal relationships that could have appeared to influence the work reported in this paper.

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