Protocol and Statistical Analysis Plan

Title

A pilot trial of health coaching to improve functioning and reduce suicide risk among reintegrating Veterans

Contact

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Specific Aims/Purpose

This pilot study will examine the feasibility of study methods and acceptability of virtually-delivered (telephone or video) health coaching among a national sample of reintegrating Veterans. Veterans will be enrolled within 3 months of service separation and followed for 9 months, approximately capturing their first year of separation. This pilot is designed to obtain the necessary feasibility data on study methods, acceptability of the intervention, and measure selection that is needed to evaluate the move to a confirmatory efficacy trial. Implementation data will also be gathered. Participants will be randomized to receive ≤12 coaching sessions over four months plus printed materials with information on VA benefits or receive printed materials on VA benefits only. Participants will complete a baseline assessment and follow up assessments at 2, 4, and 9 months post-baseline.

Aim 1: Examine the feasibility of study procedures and acceptability of the health coaching intervention among reintegrating Veterans.

Aim 2: Evaluate measures of mediators and outcomes for suitability in a future confirmatory efficacy trial.

Aim 3: Determine barriers and facilitators of implementation of health coaching among reintegrating Veterans.

Research Design and Methods

Eligibility criteria. All previously active duty U.S. military service members and National Guard/Reservists separating from service to civilian life who did not receive a dishonorable discharge status within the prior three months will be potentially eligible. We will exclude Veterans who are 1. institutionalized (e.g., prison, psychiatric inpatient, nursing home; self-report), 2. unable to read or understand English, 3. cognitively impaired (≥10 on Short Blessed Test[1]), 4. experiencing psychosis (endorsing thought interference or hallucinations of the Psychosis Screening Questionnaire[2]), or 5. determined to be at acute risk for suicide (endorsement of suicidal ideation on the 9th item of the Patient Health Questionnaire-9 [PHQ-9][3] and categorized as "higher risk" on the P4 Screener[4]). We are excluding Veterans at acute risk for suicide because these Veterans are thought to be at high risk for a suicide attempt in the near term and require more aggressive treatment options. All study staff are experienced with IRB-approved assessment and referral protocols to ensure Veteran safety during screening and subsequent study visit contacts. Any Veteran expressing suicidal ideation during eligibility screening will receive resources and referrals appropriate to the level of risk.

Sample size. We will consent and enroll up to 100 Veterans in this study.

Enrollment and randomization. Study staff will conduct the consent process with interested Veterans. Consented and eligible participants will then receive a link via email to complete their baseline assessment online before being randomized to either Health Coaching arm or the VA benefits information only arm. Once the assessment is complete, the study coordinator will contact the study PI for randomization assignment. The study coordinator will then call participants to discuss their study arm assignment and schedule participants in the health coaching arm for their first coaching session. We will randomize using block randomization as opposed to simple randomization to ensure similarly sized treatment groups throughout recruitment. With fixed block sizes it is hypothetically possible for treatment assignment to be predictable if the study groups are unmasked (e.g., if the block size were 10, the assignment of the 10th person would be deterministic if the first nine were known); this selection bias is reduced by randomizing the size of the blocks[5], which will be our approach. Specifically, we will randomly select the block sizes to be 4, 6, or 8 with equal probability and, conditional on the block size, perform block randomization. To ensure similar baseline levels of depression in both

groups, we will stratify randomization by baseline PHQ-9 score. Specifically, we will perform separate randomizations for those with PHQ-9 scores of <10[6,7], and those with scores ≥10, which will ensure equal fractions of each in both treatment groups. The study coordinator will assign intervention group participants to one of two coaches, alternating between the coaches as participants are enrolled.

Study Arms

Health Coaching Intervention. Health coaching is a health behavior change modality that uses reflective listening, motivational interviewing, assessment, and accountability strategies to facilitate client-directed and values-based goal-setting, action planning, and goal achievement. Although health coaching involves some components similar to psychotherapeutic approaches (e.g., positive reinforcement, social support) and is congruent with effective psychotherapy approaches to behavior change (e.g., motivational interviewing, goal setting, values-based actions), it is fundamentally different from psychotherapy due to the truly equal partnership of the coach and client as well as the process of creating self-determined goals. Importantly, coaches do not conduct any clinical activities; they do not diagnose, discuss symptoms, make any recommendations for treatment/provide treatment, or perform procedures. The coaching process begins with a thorough exploration of the client's values, strengths, and resources towards articulating a personal mission or vision for their lives. They then self-assess across eight life domains: physical health, mental well-being, spiritual functioning, relationships, sleep/relaxation, personal development (i.e., employment), nutrition, and environment. Self-assessment involves ranking themselves on a scale from 1-5; noting where they are now versus where they want to be in each area. Goals and action steps are developed in service of the client's overall mission; the client chooses an area of focus, which may involve – for example – finding employment, increasing physical fitness, or improving social relationships. In each weekly session, the coach facilitates a conversation about the prior week's progress and helps the client problem-solve around barriers and identify resources to achieve their goals. In this process, the client can try out their action plan, see what works and what does not work, and then modify their action plan as needed. Intervention materials include a Personalized Health Inventory (used for self-assessment), a goal setting worksheet, activities that facilitate exploring values and strengths, and an Aftercare Plan. Participants will also receive the VA benefits information materials and resources (see also the Comparator section). Participants will receive weekly reminder calls and reminder emails for their sessions. Participants will then engage in up to 12 weekly, 30-40-minute, virtually-delivered (via phone, webex, or other VA-approved videoconferencing platform) health coaching sessions over the course of 4 months; sessions will be scheduled approximately weekly, with flexibility to accommodate the participant's schedule. Participants will have the opportunity to complete up to 12 coaching sessions as prior research indicates that four months is likely to be the upper limit on the time needed for participants to reach one goal.

Comparator (VA Benefits Information group). Participants in the VA benefits information group will receive a booklet of information on VA benefits and services. We chose this comparator to reflect the state of the science on health coaching, which has thus far been understudied, despite dissemination across VHA.

Data

Self-Report Assessments. Participants will complete assessments at baseline, mid-intervention (2 months post-baseline), post-intervention (4 months post-baseline), and follow-up (9 months post-baseline). The assessments will contain measures of the study's primary and secondary outcomes, mediators, moderators, demographics, and other sample descriptors (**See Table**

below). Data collection will be blinded; the research assistant facilitating assessment completion will remain blind to study condition.

Table. Self-report assessment schedule

CANDIDATE OUTCOME AND MEDIATING MEASURES						
Construct	**Source**	**Description**	Timepoint			
			B	2	4	9
Suicide risk (Suicidal ideation severity; primary outcome)	Depressive Symptom Index - Suicidality Subscale	The Suicidality Subscale of the Depressive Symptom Index (DSI-SS), is a 4-item self-report measure of suicidal thoughts, impulses, and plans, as well as control over suicidal thoughts during the past two weeks[8].	x	x	x	x
	Columbia Suicide Severity Rating Scale	The Columbia Suicide Severity Rating Scale (C-SSRS) is a brief measure of suicide risk severity with strong psychometric properties[9], and is widely used in VHA clinic settings.	*x*	*x*	*x*	*x*
Reintegration status (Functioning in adult life roles; primary outcome)	*Military to Civilian Questionnaire*	*The Military to Civilian Questionnaire (M2C-Q) is a multidimensional assessment of reintegration status, addressing challenges in employment, education, relationships, community, and heath. The M2C-Q was developed for use with Veterans, demonstrates strong construct reliability and validity, and it is sensitive to change over time[10,11].*	*x*	*x*	*x*	*x*
	Well-Being Inventory – Functional Status	The Well-Being Inventory (WBI) Functional Status items comprise a multidimensional assessment of functioning across social roles including work, education, relationships, and community. The WBI was developed for use with Veterans, demonstrates strong construct reliability and validity, and it is sensitive to change over time[12].	x	x	x	x
Engagement in VHA Care (exploratory)	CDW	Healthcare engagement (number of primary care, mental health, or other specialty visits) will be assessed for the three months prior to study enrollment (baseline) and at each timepoint (across the intervening months) to ascertain change in VHA care engagement and new engagement in VHA care.	x	x	x	x
Autonomy, competence, & relatedness (exploratory mediator)	Basic Psychological Need Scales	The three subscales of autonomy satisfaction, competence satisfaction, and relatedness satisfaction from the Basic Psychological Need Satisfaction and Frustration Scales[13] will be used to measure the degree to which participants experience these three constructs during the intervention period. Data will be used to explore the theoretical mechanisms of the intervention.	x	x	x	x
Identity coherence (exploratory mediator)	Purpose in Life scale	The Purpose in Life subscale of Ryff's Psychological Well-being Scales assesses the extent to which respondents feel a sense of purpose and direction in their lives[14]. This measure has been well-validated and widely used,[15] and is sensitive to change[16].	x	x	x	x
	Self-concept Clarity Scale	The Self-concept Clarity Scale measures identity clarity, or the degree to which respondents feel confident in knowing who they are[17].	x	x	x	x
	Life engagement test	The Life Engagement Test is a six-item measure of the extent to which respondents feel they are living with a clear sense of purpose[18].	x	x	x	x
INTERVENTION SATISFACTION						
Satisfaction with Health Coaching	Healthcare Climate Questionnaire	The Healthcare Climate Questionnaire measures the participant's perceptions of the degree to which their healthcare provider is autonomy supportive.			x	
	Acceptability of Intervention Measure	The Acceptability to Intervention Measure (AIM) (Weiner, 2017) is a four-item measure of the acceptability of an intervention from the participant's perspective.			x	
DESCRIPTORS *AND CANDIDATE MODERATORS*						
Perceived Stress	Perceived Stress Scale	The Perceived Stress Scale (PSS)[19] measures how unpredictable, uncontrollable, and overloaded individuals find their lives.	x			x

Health Satisfaction	Well-being Inventory	The health satisfaction subscale of the Well-Being Inventory, developed for use with Veterans, measures general mental and physical health satisfaction[12].	x			
Depression Symptoms	*Patient Health Questionnaire-9*	*The PHQ-9 is widely used and is a reliable and valid measure of depression severity[20]. Severity of depression will be used to stratify randomization.*	*x*			x
Sleep Disturbances	*PROMIS*	The Patient-Reported Outcomes Measurement Information System[21] (PROMIS) Sleep disturbance – Short form 4a assesses sleep quality.	*x*			
Alcohol use	*Audit-C*	*The Alcohol Use Disorder Identification Test (AUDIT-C)[22] is commonly used to assess alcohol use.*	*x*			
Pain-related Functioning	*PEG*	*The PEG (Pain, Enjoyment, General activity) scale[23] is a 3-item assessment of pain intensity and interference that is widely used and well validated.*	*x*			
Demographic		Items on age, race, ethnicity, gender, marital status, education, and employment.	x			

Qualitative interviews. The qualitative data will be used to supplement our understanding of the quantitative findings to inform subsequent trial design, but will also stand on its own to inform future implementation efforts[24]. We will conduct 40-60 minute, semi-structured interviews with 30 Veterans in the health coaching arm. Participants will be invited to participate in an interview, and we will seek to interview a selection of completers and non-completers at the end of their respective study period. The research associate, who has extensive qualitative experience, will conduct the interviews and transcribe audio recordings (the research assistant, blind to study condition, will not be involved in the qualitative interviews in any way). We will ask about their experience receiving coaching, perceived benefits (including goal progress and perceived impact on their health), and any negative experiences that may have occurred during the intervention. We will also ask for recommendations regarding the delivery and pacing of the intervention (schedule, number of sessions); we will ask for their thoughts on the feasibility and appeal of different modes of delivery (telephone, video, other); and how to best reach Veterans after service separation. Interviews will occur over the telephone or Webex (or other VA-approved videoconferencing platform).

Healthcare utilization & diagnoses. Diagnosis and healthcare utilization data will be extracted from the VA Corporate Data Warehouse (CDW) for four timeframes: between service separation and study enrollment, baseline through month 2, month 3 through month 4, and month 5 through month 9. These data will allow us to ascertain VA care engagement.

Analysis

Aim 1: Examine the feasibility of study procedures and acceptability of the health coaching intervention among reintegrating Veterans. Analyses for Aim 1 will be primarily descriptive. We will describe clinical and demographic characteristics of the sample, comparing those who enrolled to those who did not. We will calculate recruitment rate (based on number of Veterans contacted and enrolled) and intervention completion rate, reporting reasons of participant withdrawal in aggregate. We will consider a ≥30% enrollment rate of Veterans reached by phone and an ≥70% intervention completion rate (completion of at least one goal) fully successful. We will report acceptability from the Acceptability of Intervention Measure.

Aim 2: Evaluate measures of mediators and outcomes for suitability in a future confirmatory efficacy trial. The primary analytic goals of this aim are to evaluate our outcome and mediating measures for suitability in a future, fully-powered efficacy trial. This evaluation will entail quantifying the mean levels in this population, characterizing typical variation in our outcomes in this population, descriptive analyses of within-person change across time in the primary outcomes, and adjusted estimates of treatment effect sizes with 95% confidence intervals to be used for calibrating the sample size needs of a fully powered trial.

Outcome analysis will be conducted using an intent-to-treat approach. That is, randomized participants will be included in all analyses, regardless of their level of treatment engagement and every effort will be made to collect study outcomes even if Veterans are not engaged in treatment (e.g., follow-up staff will be blinded to study condition and engagement). Regarding missing data, we will evaluate the plausibility of the missing-at-random (MAR) assumption, which is not statistically verifiable, by investigating how missing values arise whenever possible; if MAR appears tenable, we will use multiple imputation by chained equations, which can handle different data types (numeric, categorical), arbitrary patterns of missing data, and can allow adherence to constraints (e.g., restrictions on variable range)[25]. If the MAR assumption is questionable, we will also consider complete-case-analysis (CCA), which produces unbiased regression coefficient estimates under certain types of non-random missingness that may be more plausible (e.g. when missingness depends on the covariate value, but is conditionally independent of outcome)[26]; in that case, we will consider using an augmented CCA approach that results in less lost information that traditional listwise deletion[27].

Aim 3: Determine barriers and facilitators of implementation of health coaching among reintegrating Veterans.

As our qualitative analysis of participant interviews will focus on improving reach and identifying implementation needs of the intervention, we plan to use a primarily descriptive thematic analysis approach that allows for both deductive (top-down) and inductive (bottom-up) identification of themes[28,29]. That is, we have specific topics we wish to explore, but are also seeking to uncover new, not yet identified, ideas from the data. For deductive coding, codes will be created for themes we seek to identify in the transcripts based on our research questions. To develop inductive, or bottom-up, codes, the research team will read and discuss transcripts. As each interview is transcribed, it will be read and discussed by the two analysts to generate codes to be included in the codebook. Once all interviews are transcribed and completed, the codebook will be finalized.

Using Atlas.ti® software, the two primary analysts will use the codebook to code individual text passages. We will build coder consensus prior to final data coding. To do this, the codebook will be applied to the same transcript by both primary analysts. The two analysts' coding results will then be compared and adjudicated using side-by-side comparison of transcripts. This process will be repeated on several transcripts until all code definitions are clear, and the analysts are applying them consistently. Final coding will involve double-coding each transcript. Once the data set has been completely coded, the analysts will review the coded data to identify core themes. Specifically, we will report on themes addressing barriers and facilitators to engagement in the intervention.

Risks/Benefits and Safety monitoring

Risks. The risk to participants is minimal, especially in consideration of the importance of the knowledge to be gained. This study will provide valuable information on the feasibility and acceptability of health coaching among reintegrating Veterans. Information from this study will inform development of a subsequent fully powered trial to examine effectiveness of health coaching. Data from this study may help to inform programmatic initiatives to improve reintegration success and reduce suicidal ideation or behaviors in reintegrating Veterans. For study activities involving administrative data extraction, risks could include breach of confidentiality via inadvertent disclosure of personal health information. All members of the research team have completed VA-mandated Data Security training, and every effort will be made to reduce the possibility of inadvertent disclosure.

Benefits. Participants may experience benefits from the coaching sessions, although these sessions will in no way be a substitute for clinical care. Participation in the study may also help benefit Veterans in the future by providing data on the use and implementation of health coaching.

Safety monitoring. There is a slight risk that participants could become upset during coaching sessions, interviews, or other contacts. We will take special precautions to minimize participant distress and to maximize safety. During the informed consent process and throughout participation in the study, we will ensure that participants understand they do not have to answer any question or discuss any topic that they do not wish to answer or discuss. If a participant reports suicidal ideation during a coaching session, interview, or on an assessment, we will seek immediate clinical consultation as per the study safety plan, and work with clinicians to ensure that the participant receives appropriate follow-up assessment. Unless a clinical assessment determines it is unsafe, the participant will continue with study activities. All study personnel will receive training in procedures for addressing and responding to suicidal ideation.

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