Study Title: Pilot Study of Standalone and Peer Supported Online Problem Solving Program in Veterans with Untreated Mental Health Problems

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Project Title:	Pilot Study of Standalone and Peer Supported Online Problem Solving Program in Veterans with Untreated Mental Health Problems
RDIS Number:	CAS0014

Project Title*:	Pilot Study of Standalone and Peer Supported Online Problem Solving Program in Veterans with Untreated Mental Health Problems
Percent Effort Allocation*:	25%
Do you plan to start this project even if you do not receive sponsorship?*	No

Project Proposal

You must upload a scientific proposal (not an IRB Protocol) in order for the project to be approved. This proposal should include scientific descriptions of all activities that will be approved under this project (i.e., fellowships).

If you do not have a full proposal you may upload a Letter Of Intent instead. Please see the Guidelines for LOI Format.

Uploaded Project Proposal or Scientific (not IRB) Protocol*:	Proposal_60667.pdf

Project Summary/Abstract

Please limit the following sections to a **total of 150 words each**.

Objectives*

The overall goal of this research program is to improve mental health care in Veterans by increasing the availability of mental health care that is non-stigmatizing and easily available to Veterans who have untreated mental health problems, but choose not to seek or accept face-to-face VHA mental health care services. The specific aims of this pilot study are preparatory to a large-scale RCT to test the effects of Moving Forward (MF) with and without peer support (PS) on two populations of Veterans who have untreated mental health problems.

Aim 1: Test feasibility and acceptability of recruitment and data collection strategies to study MF + PS in two populations of Veterans with unmet mental health needs.
Aim 2: Obtain preliminary efficacy results on the impact of MF and MF+PS on problem-solving skills and psychological health in Veterans with unmet mental health needs.

Research Plan and Methods*

This pilot study aims to investigate the feasibility and acceptability of methods to study the impact of the online problem-solving training, Moving Forward, with and without peer support, in Veterans with untreated mental health problems. We will study 60 VHA primary care patients who are referred for mental health treatment but decline or do not attend a mental health intake session and 60 Veterans living in the community who have untreated mental health problems. We will adapt an existing guide for peer support for an online mental health program for use with MF, train a PS to support use of MF, and monitor fidelity to the guide throughout the study. All who agree to enroll will be referred to a study website, where they will be screened, provide informed consent, and complete baseline assessments of problem-solving skills and psychological health, which will include measures of quality of life, depression, anxiety, and PTSD. Participants will then be randomized to one of 3 conditions: a no-treatment control group, MF, or MF+PS. Participants in the two active intervention groups will be asked to complete the 8 MF modules over 4 weeks and spend an additional 4 weeks using MF. Mid-point and end-of-program assessments of problem-solving and psychological health will be completed, and use of the MF intervention will be objectively measured through the web site. Several indicators of feasibility and acceptability will be assessed to inform a large-scale RCT. User satisfaction, qualitative data on barriers and facilitators to use of MF and PS, and perceptions of usefulness of MF and PS will also be assessed. If results are encouraging, they will be disseminated and a Merit grant application for a large-scale RCT will be developed.

Clinical Relevance to the VA Mission*

The population of Veterans with mental health (MH) care needs is large and is projected to continue growing for another 15 years, but many of these Veterans go without care due to stigma, logistical challenges, and a high value on self-sufficiency. VHA has developed online, evidence-based, interactive programs aimed at fostering MH that may be more acceptable than psychotherapy and has established a peer support program, but these programs have not been the focus of rigorous research. If an online program can improve MH and

peer support can boost the program's use and effectiveness, peer support staff could be trained to coach a range of already available programs and deliver MH care to Veterans who decline other MH care. Results of this pilot study of feasibility and acceptability would inform a larger study of the impact on problem-solving and psychological health of a non-stigmatizing, online program - with and without peer support. If effective, peer supported online programs would improve the quality of care to Veterans with unmet MH needs.

Data Collection And Analysis

Yes

If Yes, please describe your plans for statistical analysis:
To address Aim 1, To accomplish Aim 1, we will collect data on the study measures and on these indicators:
enrolled per month; % of eligible who enroll
% of PS sessions achieving fidelity after training completion
% in control group who use MF during 8 weeks of study
% completing mid-way and post-study measures
Time using the online program, working with peer supporter
% of enrolled participants reporting problems using MF online
% of enrolled participants with complete data
% in MF and MF + PS who complete 6+ modules
% of those in MF + PS who have 4+ sessions with PS
% in MF and MF + PS who rate program as helpful
% satisfied/very satisfied with care, amount/type of PS contact
Post-training survey about barriers and facilitators to MF use, measures, usefulness of working with PSS, specific impact of PS on use of MF, and mpact on problem-solving skills.
Are target variable SDs in appropriate range for intervention?

We will also interview 40-50 Veterans and the Peer Support Specialist about barriers and facilitators to MF use, the study PS processes, and suggestions for improvements of the PS Guide for MF. We will also ask the PS about characteristics of Veterans who seemed to benefit the most or the least from MF and PS, modules of MF that were most and least difficult to support, and aspects of MF that the PS found confusing or unclear.

To address Aim 2, we will conduct analyses to determine whether a very broad confidence interval for an effect size (e.g., 90%) of MF + PS on problem-solving includes a small effect. MF alone may not have an impact due to lack of MF use and engagement, but we expect PS to increase MF use and engagement and MF + PS to improve psychological health. Multilevel Modeling will be used to test Condition X Time effects on problem-solving, engagement with the MF course, and psychological health. This approach has the advantages of a) permitting missing data, b) modeling within- and between-person differences in change across time, and c) inclusion of potential moderating variables in the model (e.g. usage). Power for a Condition X Time interaction for symptoms was estimated using GLIMMPSE 2.2.3 (64) to be .58, with on N =120, alpha = .05, 3 assessments, and pre- to post-intervention standardized effect size estimates of .80, .47, and 0 for the MF + PS, MF alone, and control conditions, respectively. Calculations were based on baseline mean and SD estimates from a study of VHA patients with depression symptoms (65) and effect size estimates from Greene et al. (34). A correlation will be calculated between participant age and positive impacts for problem-solving and for psychological health. We expect a small effect (r = -.1 to -.2). A large effect (r = -.5) would indicate that older Veterans are less likely to benefit from MF. Power to detect a large effect with N = 80 and alpha = .05 will be .99 (66).

Medical Subject Heading Terms (Keywords)

List three or more unique MeSH Keywords* to describe your project.
At least three must exactly match terms found in the MeSH terms browser.
Check your text for MeSH Terms.
Keywords will be an important aspect to finding your project in database searches, so be as specific as possible. Please check your spelling. Entries will be checked when you save the page, and those without a unique MeSH ID will be flagged. Click on the flag to view the MeSH database entry for that term in order to refine your entry.

Coaching	Problem Solving
Veterans	Mental Health
Stress Disorders, Post-Traumatic	Internet

PI Link

This is a voluntary opportunity for you to find and collaborate with your research colleagues at the VA based on shared research interests and techniques.
Read more about PI Link.
About PI Link Reports.
This information is **not required** for review or approval of your projects.
Please select at least one item in each category that applies to this project.

[n/a] I decline. I do not want to be considered as a potential collaborator or PI; nor as a potential beneficiary for additional resources.

Category A	I. Basic Research **X** II. Clinical Research III. Health Services Research
Category B	a. Animal Research b. Biochemistry/Cell Biology c. Bioengineering d. Bioinformatics e. Clinical comparative effectiveness - observational **X** f. Clinical comparative effectiveness - interventional **X** g. Devices/Technology h. Drug discovery i. Genomics/Genetics/Epigenetics j. Imaging k. Proteomics l. Metabolomics m. Tissue banking **X** n. Other, specify: online courses, peer support
Category C	1. Addiction 2. Aging 3. Cancer 4. Cardiovascular Disease 5. Chronic Inflammatory Disease 6. Cognitive Disorders 7. Hematology 8. HSR&D 9. Immunity 10. Implementation Science 11. Infectious Disease 12. Internal Medicine, Other 13. Metabolic Diseases/Obesity 14. Musculoskeletal Diseases 15. Neurological Diseases 16. Pain / Anesthesia **X** 17. PTSD 18. Pulmonary 19. Regenerative Medicine 20. Special Agent 21. TBI 22. Trauma, Rehabilitation & Orthopedics **X** 23. Other Mental Health, specify: depression, anxiety 24. Other, specify:
	Yes Share qualitative information about this project with other PIs in the reporting function.

Study Duration

Please indicate a date by which you expect to complete this study, including data analysis and/or primary manuscript preparation. **In general, non-sponsored studies are expected to be completed within two years.***:	08/31/2019 Please briefly explain the proposed end date: Start date is currently unknown. Study may take 18 months to complete. Data analysis could take 6 months.

Study Location(s)

Will all study activities take place at VAPAHCS?*	Yes
If some activities will take place at other off-site location(s) (i.e. Stanford), list what activities will take place off-site and what activities, if any, will take place at VAPAHCS:	Request to contact veteran to invite participation and study administration will take place at VAPAHCS. Study will not include in-person interactions with participants.

Personnel Scopes of Practice

I am ensuring that every individual working on this project will maintain current privileges or Scope of Practice as appropriate for the duties to be performed.*	Yes

Research Data Storage Location(s)

Data collected/generated on a VA research project is a federal record and VA policy requires such data to reside within the VA (unless an Agreement permits off-site storage). This applies to all VA research data, including data generated/collected on animal, basic science and/or human subjects research.

Electronic Data*: If you will maintain research records in electronic form (e.g., spread sheets, enrollment logs) list where the records will be stored/maintained (server names, file names)	**VA Network** Server/folder: \\r01palhsm07.r01.med.va.gov\HOMEDIR$\vhapalcarlse **Non-VA Network** Institution Name: Stanford School of Medicine Server/folder: REDCap
Paper Data*: If you will maintain paper research records (e.g., lab note books, signed consent forms, completed surveys/questionnaires) list the physical location where the records will be stored/maintained (campus, building, room number)	**VA Location(s)** n/a (No paper data for this project)

VA Research Record Retention

I confirm all research records related to this project will be retained/destroyed in accordance with VHA policy. (VHA record retention policy requires Research Investigator Files be destroyed six (6) years after the closure of the research project)*	Yes

Project Uses at the VA

Does your project involve interaction or intervention with human subjects*:	Yes
Does your project involve the collection or use of individually identifiable data or specimens*:	Yes
If you are collecting human specimens (blood, other tissue), will specimens (including any leftover) be stored for future unspecified use? Please answer Yes if specimens will be stored off-site for any reason at a for-profit institution for greater than 3 months*:	No
Will this research use any human biological specimens/human data (identifiable or de-identified) originating from or being sent to an international site (not within the United States).	No
If this project involves human subjects, will you enroll or utilize data or specimens from children or minors?*:	No
Does your project involve the use of live animals*: https://ticklab.pavir.org/tickatlab	No
Does your project involve the use of Clinical Study Drugs*:	No
Does your project involve the use of Investigational Devices*:	No

Clinical Impacts at the VA

Will your project require the support of the Pharmacy for research purposes?* Answer "No" if your research DOES NOT require drug or will NOT be conducted onsite at the VA.	No
Will your research be conducted on a VAPAHCS clinical unit or the Ambulatory Care Center?*	No

Answer "No" if your research will be conducted on the Center for Clinical Research (CCR), or if it will be conducted in non-nursing areas, or if it WILL NOT be conducted onsite at VAPAHCS.	
Check "Yes" if the following are needed solely for research purposes and are not part of normal patient care, AND your research will be conducted onsite at the VA. Otherwise, check "No".	
Center for Clinical Research*:	No
Pathology and Laboratory Medicine*:	No
Imaging - Radiology and Nuclear medicine*:	No
Inpatient stays attributable solely to research*:	No Overnights per Patient:
Other clinically supported activity*: e.g., endoscopy, cardiac catheterization, EMG, etc.	No

Documents

Notes, comments or remarks

Return to Project Profile