Official Title of the Study:
Improving Voluntary Engagement for PTSD Treatment among Service Members

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Not yet assigned

STUDY PROTOCOL

Objectives

This study will develop and test a brief motivational enhancement intervention for active duty Army and Air Force personnel who are experiencing symptoms of PTSD and who are not currently in treatment. The intervention is designed to prompt: (1) a willingness to participate voluntarily in a self-appraisal of PTSD symptoms, (2) increased perceptions of PTSD treatment effectiveness, (3) reduced perceptions of stigma associated with mental healthcare, (4) engagement in PTSD treatment or other self-help programs, and (5) reductions in PTSD symptoms. The proposed study will test the efficacy of this intervention against a comparison condition of treatment-as-usual – written referrals to treatment options.

Hypotheses

H1: Individuals receiving the MET intervention will report more PTSD treatment engagement at follow-up relative to participants in the comparison condition.
H2: Individuals receiving the MET intervention will experience fewer PTSD symptoms at follow-up relative to participants in the comparison condition.
H3: The effect of the intervention on PTSD symptoms will be mediated by PTSD treatment engagement.
H4: The impact of the intervention on PTSD treatment engagement at the 6-month follow-up will be mediated by decreased perceived stigma associated with PTSD treatment and increased perceived effectiveness of treatment for PTSD, both of which will be targeted by the MET intervention.

Methods

Design. In a randomized controlled trial, the experimental (MET) and control (TAU) interventions will be compared. Participants (N = 200) will be randomly assigned to receive the MET condition or TAU. Both interventions will be preceded by telephone-administered screening and baseline assessments. Telephone administered follow-up assessments at 1 week, 3, and 6 months will assess post-intervention change in pertinent intentions, treatment participation, behaviors, symptoms, and perceptions of stigma and treatment effectiveness.

Study Population. Study participants will be active duty Army and Air Force personnel stationed at Joint Base Lewis-McCord (JBLM). JBLM has a population of active duty personnel of approximately 46,496 (LTC Courtemanche, 2014). The demographic characteristics of the JBLM sample are expected to mirror demographic characteristics of Army and Air Force personnel in general. Participant selection will be equitable – inclusion/exclusion criteria are minimal and there are no limitations on age, race, ethnicity or sex included in the study.

Eligibility Criteria. Eligibility for enrollment and random assignment to the two conditions will be based on the following criteria: 1) current PTSD, 2) not currently being treated (counseling and/or medication) for PTSD, and 3) currently serving in the Army or Air Force. Exclusion criteria include: 1) non-fluency in English, 2) evidence of psychosis, 3) pending deployment that would preclude completion of follow-ups. Callers who do not meet eligibility criteria, but who are concerned about PTSD symptoms, will be provided the opportunity to speak with a counselor and to discuss their thoughts and concerns surrounding their symptoms. Counselors will provide

a 15-45 minute Motivational Interviewing (MI) session focused on their PTSD symptoms, and an exploration of options for ongoing support. Referrals to local treatment agencies and self-help options will also be available to the ineligible caller.

Relevant Scientific Background

Posttraumatic Stress (PTS) is associated with serious health and psychological effects. The health and well-being of military personnel, and consequently the capacity for optimal functioning of military units, are compromised by PTS. Rates of PTS are high among military personnel with post-deployment rates ranging from 5-20% (Hoge et al., 2004). Untreated PTS is associated with high rates of suicide, medical services utilization, relationship impairment, legal difficulties, decreased worker productivity, and decreased military readiness (Hoge et al., 2006; Hoge et al., 2007; Kline et al., 2010; Tanielian et al., 2008).

Interventions can lead to long-lasting reductions in PTS symptom severity. There are multiple effective interventions for PTS with a high degree of research evidence supporting their efficacy (Bisson & Andrew, 2005; Bradley et al., 2005), including trauma-focused cognitive behavioral therapies (e.g., Prolonged Exposure, Cognitive Processing Therapy and Eye movement Desensitization and Reprocessing) and pharmacotherapies (e.g., SSRIs) (Forbes et al., 2010; VA/DoD, 2004). However, while treatment can be effective, individuals may not seek treatment. Drop-out and medication noncompliance are common. Despite treatment options, the majority of military personnel affected by PTS do not present for treatment (Steenkamp & Litz, 2013). For example, less than 10% received the recommended exposure to PTSD treatment by attending 9 or more VA mental health treatment sessions in 15 weeks or less during the first year of PTSD diagnosis (Seal et al., 2010). For medications, on average, approximately 30% of those prescribed medications for PTSD also drop out (Ravindran & Stein, 2009).

Military personnel encounter more real and perceived barriers to seeking treatment than people in the general community, such as stigma, fear of a diagnosis appearing on one's service record, the perception that diagnosis would reflect negatively on one's unit, work interference, geographical distance, and the belief that treatment is ineffective (Gould et al., 2007).

A brief, telephone-delivered motivational enhancement intervention (MET) called a "check-up," has shown promise in promoting self-initiated behavior change as well as voluntary treatment entry, enhanced retention, and more successful outcomes for soldiers with substance use disorders (Walker et al., 2017). Why MET for PTS? Efficacious options for treatment are available for PTS and the military has invested considerable resources into scaling up access to care. However, rates of self-referral and retention are low among active duty military. Given the availability of effective treatments contrasted with the low rates of military personnel who present and complete treatment, figuring out how to connect individuals with PTSD symptoms into treatment and then helping them to stay engaged is a high priority. Adapting the "check-up" for application with military personnel experiencing PTS symptoms is warranted for three key reasons: (1) it has the potential of overcoming barriers to treatment seeking, i.e., stigma and apprehension of a negative impact on one's military career; (2) it has the potential of attracting voluntary participation; and (3) protocols for disseminating this low-cost intervention for use with deployed military can readily be developed and evaluated.

Summary. Adapting the "check-up" variant of motivational enhancement therapy for application with military personnel is warranted for three key reasons: (1) permitting anonymous participation through a telephone delivered intervention has the potential of overcoming a major barrier to treatment-seeking among those who are concerned about their behavior, i.e., stigma and apprehension that being identified as having PTSD will negatively impact one's military career and providing information about efficacy; (2) the nature of the check-up intervention as an opportunity to take stock of one's PTSD experiences without being pressured to change, and the use of an empathic counseling style in its delivery, have the potential of attracting voluntary participation among individuals who would otherwise be deterred by concerns of being judged negatively and of being pressured to enter treatment; and (3) if the check-up is efficacious in voluntarily recruiting untreated service personnel with PTSD and promoting treatment engagement, support group participation, or self-initiated behavior change, protocols for disseminating this low cost and brief intervention for use with deployed military can readily be developed and evaluated.

STATISTICAL ANALYSIS PLAN

The primary data assessed at baseline and follow-up points via interviews and questionnaires will be entered into SPSS for Windows data entry (DE) files. Out-of-range values and skip rules will be built into DE files to facilitate data entry. All data will be double entered into the DE files by two different people to ensure accuracy.

Following data cleaning, initial analyses will focus on assessing the psychometric properties of the assessments and constructing scale scores where appropriate. Univariate and bivariate descriptive analyses will be performed to examine distributions of and correlations among key study variables. In the event that variables show non-normal distributions (which could lead to violation of regression model assumptions), we will consider using generalized forms of models (e.g., Poisson or negative binomial count regression) or transformation of the outcome variable(s) of interest.

Hypotheses 1 and 2 evaluate whether MET participants will report more treatment engagement and fewer PTSD symptoms at follow-up than TAU participants. This study will 4 have repeated measures from baseline to 6 months follow-up yielding up to 800 observations. Given the nesting of observations within individuals, we will run linear mixed (also known as hierarchical linear or multilevel) models (Diggle, Heagerty, Liang, & Zeger, 2002) to test study hypotheses. Measures of PTSD symptoms (CAPS) and treatment engagement (TAQ) will be analyzed as outcomes in separate models. Fixed effects will include indicator variables for time (1-week, 3-months, 6-months) with baseline as the reference, intervention condition, and the interaction between time point and condition. The following represents the basic model:

Level 1: $Yti = \pi 0 + \pi 1(Time1wk)i + \pi 2(Time3m)i + \pi 3(Time6m)i$
Level 2: $\pi 0 = \beta 00 + \beta 01(Treat) + r00i$
$\pi 1 = \beta 10 + \beta 11(Treat) + r10i$
$\pi 2 = \beta 20 + \beta 21(Treat) + r20i$
$\pi 3 = \beta 30 + \beta 31(Treat) + r30i$

where *Yti* represents the continuous outcome for individual *i* at time *t; Time1wk*, *Time3m*, and *Time6m* are the indicator variables for study time points where baseline is the reference; *Treat* represents the variable for intervention condition; and *r00i* through *r30i* represent random subject specific deviations from the corresponding overall intercept or slope. Of particular interest are the coefficients $\beta 11$, $\beta 21$, and $\beta 31$, which describe the cross-level interactions between intervention condition and time. For analyses of PTSD symptom score as the outcome, we expect that these interaction terms will be negative and statistically significant suggesting that PTSD symptoms are lower at follow-up visits among those randomized to the MET intervention compared to those in the control group. We will consider inclusion of additional covariates such as gender, social support, and trauma severity to improve precision of estimates. We will also explore modeling time as a continuous measure to assess treatment differences on slopes over time. Similar mixed effects models will be used to test effects of the intervention on stigma/barriers to treatment (PSBCPP) and treatment expectancies (CEQ) as well as secondary outcomes such as anxiety and depression symptoms.

For analyses involving multiple outcomes, we will guard against Type I error by adjusting criteria for statistical significance for multiple testing (e.g., using global tests that test for an overall difference across outcomes while accounting for their inter-correlation or Benjamini-Hochberg corrections for the false discovery rate) where appropriate.

For hypothesis 3, we will test whether the effect of the intervention on PTSD symptoms will be mediated by PTSD treatment engagement. For hypothesis 4, we will test whether effects of the intervention on treatment engagement are mediated through stigma and treatment expectancies. We will evaluate the effect of the intervention on change in the outcome (e.g., PTSD symptoms) both before and after controlling for the putative mediator(s) (e.g., treatment engagement) using the method described by Krull and MacKinnon (1999; 2001). Reduction in the percentage of variance accounted for by the interaction effect after controlling for the mediator(s) will inform the degree to which the effect is mediated.

Missing Data and Attrition

Based on retention rates in our ongoing clinical trial, we expect no more than 20% attrition by 6-month follow-up in this proposed study. Linear mixed models provide unbiased estimates in the presence of missing data as long as it can be considered ignorable (Atkins, 2005). Missing data are ignorable if they are either missing completely at random or related to variables in the analysis, including earlier time points of the outcome (Graham, 2009). Little efficiency is lost in linear mixed models with 10%-20% missing data. As a safe-guard against the possibility of nonignorable missing data, we will use pattern-mixture models for non-ignorable missing data that directly assess sensitivity of findings to the presence of missing data (Atkins, 2005).

Sample Size and Power

This study was powered to detect differences in PTSD symptoms between the intervention condition and control group over time. We used a simulation-based approach to estimate power for this study (Gelman & Hill, 2007). Using R statistical software, 1,000 datasets were generated based on the linear mixed model equation provided in the Analysis Plan. Estimates for model parameters for standardized PTSD scores (e.g., baseline intercept, slopes for time, distribution of random effects) were guided by preliminary data from our ongoing clinical trial. We also specified missingness of 13% and 19% at 3- and 6-month follow-up, respectively, according to missing data patterns in the ongoing trial. The model was fit for each of the 1000 datasets. A number of simulation runs were conducted varying the size of the treatment effects and fixing the sample size to 200. The percentage of datasets where the treatment-by-time interactions were statistically significant provides an estimate of power. Based on these simulations, this study should have >.8 power to detect effect sizes of .36 or greater at any given follow-up visit. An effect size of .36 is at the lower end of the range found in the extant literature on treatment for PTSD in military samples. The conservative estimate seems appropriate given the non-treatment seeking nature of the population yet is still clinically meaningful. For instance, a .35 effect size translates to a mean difference of approximately 6 points between conditions on the PTSD symptom checklist based on data collected in our current ongoing trial.