Connecting Women to Care: Home-based Psychotherapy for Women with MST Living in Rural Areas

NCT03429166

June 3, 2022
Data Plan and Analysis

Study Protocol Design Summary

1. Specific Aims

Military Sexual Trauma (MST) among women Veterans is a problem of epidemic proportion associated with significant mental health and functional impairment and substantial access to care barriers. Surveillance data indicate that one in four women Veterans reports MST when screened. Compared to women Veterans with other service-related stressors, those experiencing MST have greater mental health problems, are more likely to report difficulty in functioning in social, family and intimate relationships and are more likely to be unemployed and to report difficulties in finding a job. Nevertheless, women with MST engage less frequently in VA health care than other women Veterans. Barriers to care include distance from specialty services, financial difficulties, childcare and family responsibilities, and gender-related discomfort in male-dominated VA facilities. Research over the past decade has clearly identified the problems and concerns of women Veterans with MST but programs addressing their mental health needs and responsive to identified barriers are lacking. The current application addresses this gap.

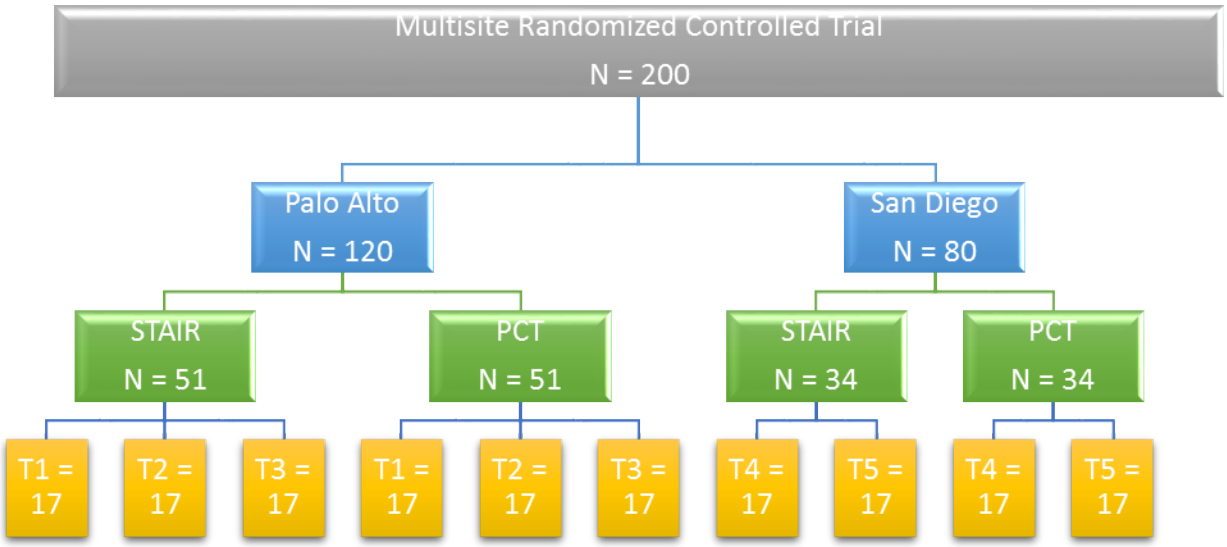
The VA conceptualization of care as patient-centered includes a commitment to program development that is guided by the needs and preferences of specific populations. It is important to note that MST is an *experience* not a diagnosis, and therefore VA intervention responses to MST need to take into account women's preferences and perceptions of their problems as well as their diagnostic status. Among the most frequently reported problems identified by women with MST is a sense of social isolation and limited social support. From a diagnostic perspective, PTSD is among the most common and impairing of psychiatric disorder associated with MST. Over two decades of research has indicated that low social support and PTSD are reciprocally related such that low social support contributes to risk for and severity of PTSD and that PTSD decreases social support resources that are necessary for maintaining work, family and other social roles. This reciprocal reinforcement may be particularly true of women living in rural areas who experience substantial social isolation. Supported by the Office of Rural Health, we evaluated a remotely delivered, evidence-based social skills intervention, Skills Training in Affective and Interpersonal Regulation (STAIR) which simultaneously addresses social concerns and PTSD symptoms to rural women Veterans with MST at their local VA clinic. Several studies in community samples have demonstrated the effectiveness of STAIR. Findings for the women Veterans were similar: significant improvements in PTSD symptoms, perceived social support and social engagement were observed, along with very high satisfaction with the program.

Given these findings, the current study proposes to conduct a Hybrid Type 1 effectiveness-implementation design to assess the effectiveness of STAIR relative to a nonspecific active comparator, Present Centered Therapy (PCT) among women Veterans with MST, with dedicated resources to ensure engagement of those living in rural areas. We will evaluate remote delivery of the treatment to the home rather than a VA clinic. Recent research indicates that women Veterans prefer home-based video teleconferencing (HBVT) compared to clinic-based video teleconferencing (CBVT). In-home delivery may be of perceived value to women Veterans as it is responsive to the particular challenges of childcare and family responsibilities and the gender-related discomfort that can be experienced at a VA facility.

This proposal brings together the evaluation of a treatment as well as a delivery strategy each of which has strong face validity and supporting evidence indicating their relevance to women Veterans with MST, particularly those living in rural areas. If successful, the program will decrease social concerns and PTSD symptoms and increase use of mental health care in a highly burdened and underserved

Veteran population. The study has two aims:

1. To evaluate the effectiveness of HBVT-delivered STAIR compared to HBVT-delivered PCT via a randomized controlled trial. It is hypothesized that STAIR will be superior to PCT in reducing PTSD and related symptoms and in improving perceived social support, community engagement and social functioning. Assessments will occur five times: baseline (week 0), mid-treatment (week 5), post-treatment (week 10), 2 month follow-up (week 18) and 4 month follow-up (week 26).
2. To employ a multi-stakeholder mixed-methods evaluation of the delivery of STAIR via HBVT, based on two integrated frameworks: the Consolidated Framework for Implementation Research (CFIR) and the Replicating Effective Programs (REP). The evaluation will (a) elucidate facilitators and barriers of implementing STAIR via HBVT and (b) contextualize the quantitative findings of the clinical trial to enhance our understanding of both treatment processes and effectiveness.



2. Data Analysis for Effectiveness Trial

Preliminary analyses will include screening for normality, missingness, and equivalence of random assignment. Independent samples t-tests and chi-square tests of independence will be conducted to determine the presence of any significant baseline differences between key characteristics of individuals assigned to STAIR versus PCT. Baseline characteristics that differed by treatment condition or are associated with missingness will be used as covariates in the primary analyses. Analyses will be performed according to the intention-to-treat principle using the final sample derived from eligible participants.

To examine whether treatment condition predicted change in outcome variables, piecewise mixed-effects regression models will be estimated in R using package lme4. One slope estimates change during the treatment period, and a second slope estimates change from posttreatment through 4-month follow-up in order to assess maintenance of treatment gains. A COVID-19 pandemic status covariate will be created by cross-referencing the date of each assessment with the date that the state of emergency was declared (03/04/2020). Interactions between time and treatment condition will be the main parameters of interest to test our hypotheses.

Primary Hypotheses

Hypothesis 1.1. STAIR will be superior to PCT regarding improvement in PTSD at post-treatment and through 2 and 4 month follow-up as measured by the CAPS-5 and PCL-5.

Hypothesis 1.2. STAIR will be superior to PCT regarding improvement perceived social support at post-treatment and through 2 and4 month follow-up as measured by the ISEL.

Hypothesis 1.3. STAIR will be superior to PCT regarding improvement in social functioning as measured by increased social/community engagement and increased weekly social activities measured, respectively, by the WHODAS 2.0 and the SAM.

Hypothesis 1.4 STAIR will be superior to PCT regarding improvement in trauma-related symptoms including emotion regulation problems (DERS), depression (BDI) and posttraumatic maladaptive beliefs (PMBS) .

3. Data Analysis for the Qualitative Investigation

Evaluation. We will conduct formative evaluations via the interview with three key stakeholder groups: administrative staff (n = 4), clinicians (n=5) and patients (n=30) across both sites. Aadministrative staff at each site including the project coordinators and TMH clinic leaders will be interviewed at the end of the study. The 5 cclinicians will be interviewed twice, the first time at the halfway point of the patient enrollment period, and again at the end of the trial after they complete their final case. This will allow us to identify challenges that might impede initiation of implementation and will also allow us to examine whether clinician perspectives shift after they gain additional experience with the technology and with the intervention. Lastly, we will interview a random sample of patients (n=30, 15 from each site) throughout the course of the study, at the end of their treatment experience to assess facilitators and barriers as related to the perceived benefit of the therapy, the experience of obtaining their treatment at home and the challenges and benefits of using the technology. We considered integrating a separate framework to guide patient interviews since patient-related constructs are underrepresented in many implementation frameworks including CFIR, but determined that CFIR constructs are relevant to, and can be adapted to apply to patients, and did so to facilitate the interpretation of the data. We will also collect quantitative data, using measures that have been identified as predictors of effective implementation or reflect constructs relevant to effective implementation. These include the clinician Perceived Characteristics of Intervention Scale (PCIS) and for the patient, the Clinical Satisfaction Questionnaire (CSQ-8) and the Working Alliance Inventory (WAI). The WAI will be helpful in assessing the strength of the therapeutic alliance under conditions of remote delivery of treatment (relevant to relative advantage, patient preferences, and clinician attitudes and self-efficacy).

Contextualizing Quantitative Data. The mixed methods evaluation data will be used to help contextualize the quantitative findings of the clinical trial to enhance our understanding of both treatment processes and effectiveness. For example, we might discover that clinicians who struggle to maintain fidelity (quantitative data) have lower scores on the Perceived Characteristics of Intervention Scale (PCIS) (quantitative), and are more likely to perceive STAIR as less compatible with veterans' needs (qualitative). Such a finding would have implications for selection of appropriate implementation strategies. We can also enhance our understanding of patient data. For example, we might wish to learn whether veterans who score

more highly on avoidance have different perspectives on receiving STAIR by telehealth to determine whether adaptations need to be made to the intervention or delivery format, or if specific implementation strategies may be needed to enhance engagement for veterans of this nature in future implementation efforts.

Analyses:. We will conduct formative evaluations via the interview with three key stakeholder groups: administrative staff (n = 4), clinicians (n=5) and patients (n=30) across both sites. Administrative staff at each site including the project coordinators and TMH clinic leaders will be interviewed at the end of the study. The 5 cclinicians will be interviewed twice, the first time at the halfway point of the patient enrollment period, and again at the end of the trial after they complete their final case. This will allow us to identify challenges that might impede initiation of implementation and will also allow us to examine whether clinician perspectives shift after they gain additional experience with the technology and with the intervention. Lastly, we will interview a random sample of patients (n=30, 15 from each site) throughout the course of the study, at the end of their treatment experience to assess facilitators and barriers as related to the perceived benefit of the therapy, the experience of obtaining their treatment at home and the challenges and benefits of using the technology. We considered integrating a separate framework to guide patient interviews since patient-related constructs are underrepresented in many implementation frameworks including CFIR, but determined that CFIR constructs are relevant to, and can be adapted to apply to patients, and did so to facilitate the interpretation of the data. We will also collect quantitative data, using measures that have been identified as predictors of effective implementation or reflect constructs relevant to effective implementation. These include the clinician Perceived Characteristics of Intervention Scale (PCIS) and for the patient, the Clinical Satisfaction Questionnaire (CSQ-8) and the Working Alliance Inventory (WAI). The WAI will be helpful in assessing the strength of the therapeutic alliance under conditions of remote delivery of treatment (relevant to relative advantage, patient preferences, and clinician attitudes and self-efficacy).

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