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PRINCIPAL INVESTIGATOR: Dr. Gregory Gahm, Ph.D., PI

CONTRACTING ORGANIZATION: The Geneva Foundation
917 Pacific Ave, Suite 600
Tacoma, WA 98402

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INTRODUCTION

In-home tele-behavioral health treatments have the potential to address current health needs of Service Members, Veterans, and their families, especially for those that live in rural and underserved areas. The use of in-home, web-based treatment to address the psychological needs of Service Members and Veterans is not yet considered standard of care for the DoD. The safety and clinical efficacy of such treatments must be established before broad dissemination of these treatment programs occurs. This study is a two-group (web-based in-home BA vs. in-person BA) prospective randomized controlled trial. Both groups will be assessed at baseline, mid-treatment (Week 4), post-treatment (Week 8), and at a 3-month follow-up visit. The primary outcome variables are safety and hopelessness. Secondary outcome variables include depression, anxiety, PTSD symptoms, attitudes toward seeking mental health services, quality of life, and health care utilization, as well as treatment satisfaction, adherence, and compliance. A total of 120 participants will be recruited with an anticipated completion rate of 108 participants (54 per treatment group). Participants are Regular Service Members, National Guard Members, Reservists, and Veterans recruited at Madigan Army Medical Center and the Portland VA Medical Center.

BODY

The protocol was reviewed by The Human Research Protection Office (HRPO) and approved on 30 April 2012. The Portland VA site received HRPO approval on 26 September 2012. Currently, both sites are actively enrolling participants. Additionally, continuing review of this protocol, an annual requirement, was completed and approved by the Madigan IRB on 22 October 2013. The continuing review HRPO submission form was submitted on 07 November 2013.

Recruitment efforts for the In-Home Depression RCT have been a major focus over the period of review (formally beginning 08/2012). Combined across both sites, 208 potential participants have been referred to the study, 114 of which consented to participate and completed intake interviews. Of those, 87 were eligible for randomization, while 27 failed to meet inclusion criteria. Currently, 9 participants are in treatment, 26 have withdrawn, and 52 have completed the treatment phase. Of the treatment completers, 19 are currently in the follow-up period, and 38 have fully completed the follow-up period. Three treatment completers have been classified as lost to follow-up for the 3 month post-treatment assessment.

In the past year, the PTSD Pilot Study associated with the larger RCT has been successfully completed. Overall, we received 32 participant referrals, 25 of which consented to the intake evaluation. Of those, only 15 were eligible for treatment, and 10 agreed to participate in treatment. Eight of these 10 completed all 8 sessions, while 2 participants each completed 5 sessions before withdrawing from treatment. Nine participants completed the post-treatment assessment, and 6 completed the follow-up assessment. In January 2014, the focus of this project shifted to data analysis and final report preparation.

During the period covered by this review, the Madigan Healthcare System IRB approved four specific modifications to this project's research protocol. Three of these modifications involved the addition of new staff members to the project (approval dates 21 March 2013, 16 May 2013, and 22 October 2013). There was also a modification to allow study staff to recruit

from an additional MAMC department: The Department of Operational Readiness' Post Deployment Health Reassessment clinic (PDHRA). This modification was approved 16 May 2013. Finally, the protocol was amended on 15 July 2013 to allow follow up data to be collected remotely for participants that are no longer residing at JBLM. During the continuing review process at JBLM, a new medical monitor was also assigned to the study by the IRB.

Similar modifications have occurred with the PTSD Pilot Study as well. Specifically, this protocol was modified to allow for follow-up assessments to be conducted remotely for participants that are no longer residing at JBLM (approval date 06 August 2013), to add additional staff members (approval date 26 March 2013 and 14 May 2013), and to include the Department of Operational Readiness' PDHRA clinic as an approved site for recruitment. Continuing IRB review and approval for this study was completed and approved by the Madigan IRB on 29 January 2014.

Additional staff has been added to these protocols during this review period. These new staff members include three post-doctoral clinicians, one psychologist, and a research coordinator. Additionally, a new research coordinator at the Portland VA has been hired, and approval by the Portland VA IRB is underway (expected approval April 2014). Dates of hire are included below:

Katherine Stanfill, Ph.D., Clinician, hired 3 March 2013
Patricia Koenen-Woods, Psy.D. Clinician, hired 6 March 2013
Michael Audas, M.A., Research Coordinator, hired 8 July 2013
Michael Jenkins-Guarnieri, Ph.D., Clinician, hired 12 August 2013
Kristine Johnson, Ph.D., Clinician, hired 26 August 2013
Jennifer Green, B.A., Research Coordinator-Portland, hired 6 January 2014

Several staff have also left the project:

Karen O'Brien, Ph.D., end date 6 Dec 2013
Patricia Koenen-Woods, Psy.D., end date: 10 January 2014
Elizabeth Speidel, B.A., end date: 3 January 2014

Challenges

Referral based recruitment strategies have proved to be an on-going challenge. However, with a full staff, the addition of the PDHRA clinic, and consistent recruitment efforts to develop professional relationships with MAMC providers, we have been steadily recruiting participants and meeting our quarterly recruitment goals since October 2012. Additionally, a no cost extension request was submitted on 5 FEB 2014 and approved via email on 26 FEB 2014 in order to complete data collection, analysis, and dissemination. Receipt of the formal award modification is pending.

Network security changes made by the Army resulted in a 2.5 month period from July-September 2013 during which participants' attempts to access the Jabber video-conferencing software (In-Home Treatment condition) were blocked by the Army network. We have been able

to resolve this issue, but it did present a major challenge that interrupted the delivery of the treatment protocol during that time frame.

KEY RESEARCH ACCOMPLISHMENTS

Administrative and Logistical Matters

1. Personnel
 - a. The study is currently fully staffed with no expected turnover. Many of the staff changes in the past year were expected transitions resulting from post-doctoral fellows completing their commitments and moving on to permanent positions. No additional hiring is planned.
2. Equipment
 - a. All laptops have been configured according to the specifications required for the protocol, and all laptops and webcams are in working order. We currently have a 100% equipment recovery rate from participants who have had equipment checked out to them. All original MOVI/Jabber licenses obtained for this study are still active and being utilized.
3. Materials, supplies and consumables
 - a. Materials and required supplies, including study measures, were acquired in anticipation for participant enrollment and data collection. As these supplies are consumed, new supplies are ordered to keep the project running smoothly.
4. Institutional Review Board (IRB)
 - a. In-Home Depression RCT
 - i. Madigan IRB approves protocol modification on 21 March 2013.
 - ii. Madigan IRB approves protocol modification on 16 May 2013.
 - iii. Madigan IRB approves protocol modification on 27 August 2013.
 - iv. Madigan IRB completed Continuing Review on 22 October 2013.
 - b. In-Home PTSD Pilot
 - i. Madigan IRB approves protocol modification on 26 March 2013.
 - ii. Madigan IRB approves protocol modification on 14 May 2013.
 - iii. Madigan IRB approves protocol modification on 06 August 2013.
 - iv. Madigan IRB completed Continuing Review on 29 January 2014.

REPORTABLE OUTCOMES

The study team completed the pilot study on schedule and the results have been reported in a journal article that is currently under review. The results showed that the delivery of in-home behavioral health treatment was feasible, safe, and had positive treatment outcomes. Several other manuscripts related to these projects have been completed over the past year as well. Four have been accepted for publication, while 3 have been submitted to journals and are currently under review. References are included below:

Manuscripts accepted for publication:

Luxton, D.D., Pruitt, L.D., & Jenkins-Guarnieri, M. (In press). Clinical assessment. In: Tuerk, P.W., & Shore, P. (Eds.). *The Behavioral Telehealth Series*. New York, NY: Springer International, in press.

Luxton, D.D., Pruitt, L.D., & Osenbach, J.E. (2014). Best practices for remote psychological assessment via telehealth technologies. *Professional Psychology: Research and Practice*, 45, 27-35. doi: 10.1037/a0034547

Osenbach, J.E., O'Brien, K.M., Mishkind, M., & Smolenski, D.J. (2013). Synchronous telehealth technologies in psychotherapy for depression: A meta-analysis. *Depression and Anxiety*, 30, 1058-1067. doi: 10.1002/da.22165

Pruitt, L.D., Luxton, D., & Shore, P. (In press). Additional clinical benefits of home-based telemental health treatments. *Professional Psychology: Research and Practice*. doi: 10.1037/a0035461

Manuscripts submitted for publication:

Luxton, D.D., O'Brien, K.O., Pruitt, L.D., Johnson, K., & Kramer, G. (In submission). Suicide Risk Management During Clinical Telepractice. *International Journal of Psychiatry in Medicine*.

Luxton DD, O'Brien K, Pruitt LD, Stanfill K, Jenkins-Guarnieri MA, Johnson KA, Wagner A, Thomas E, Gahm G. (In submission). Design and methodology of a randomized clinical trial of home-based telemental health treatment for U.S. military personnel and veterans with depression. *Trials*.

Luxton, D.D., Pruitt, L.D., O'Brien, K., & Kramer, G. (In submission). A pilot study of In-home telehealth-based behavioral activation for post traumatic stress. *Behaviour Research and Therapy*.

CONCLUSION

None

REFERENCES

None

APPENDICIES

Luxton, D.D., Pruitt, L.D., O'Brien, K., & Kramer, G. (In submission). A pilot study of In-home telehealth-based behavioral activation for post traumatic stress. *Behaviour Research and Therapy*.

Luxton DD, O'Brien K, Pruitt LD, Stanfill K, Jenkins-Guarnieri MA, Johnson KA, Wagner A, Thomas E, Gahm G. (In submission). Design and methodology of a randomized clinical trial of home-based telemental health treatment for U.S. military personnel and veterans with depression. *Trials*.

A Pilot Study of In-Home Telehealth-based Behavioral Activation for Post Traumatic Stress

David D. Luxton, PhD.^{a b}, Larry D. Pruitt, PhD.^a, Karen O'Brien PhD.^a, & Gregory Kramer, PhD.^a

^aNational Center for Telehealth & Technology, 9933 West Hayes St., Madigan Annex, Joint Base Lewis-McChord, WA, USA, 98431

^bDepartment of Psychiatry and Behavioral Sciences, University of Washington School of Medicine, 1959 NE Pacific Street, Box 356560, Seattle, WA, USA, 98195-6560

Corresponding Author:

Name: David D. Luxton, PhD

E-mail: david.d.luxton.civ@mail.mil

National Center for Telehealth and Technology (T2)

9933 West Hayes Street, Madigan Annex

Joint Base Lewis-McChord, WA 98431

Phone: (253) 968-3581

Fax: (253) 968-4192

Abstract

The purpose of this pilot study was to evaluate the feasibility of providing US military members with a behavioral health treatment delivered directly to the home using videoconferencing. Ten Soldiers volunteered to complete eight sessions of a novel Behavioral Activation (BA) treatment for Post-Traumatic Stress (PTS). The primary clinical outcomes included symptoms of PTS and depression. Attitudes about seeking mental health services, treatment satisfaction, treatment adherence, and treatment compliance were also assessed. The results showed a clinically significant reduction in PTS symptom severity and depression symptoms. Soldiers also indicated high levels of overall satisfaction with the treatment and there were not any adverse events requiring activation of emergency safety procedures. The findings from this pilot study suggest that home-based behavioral health treatments delivered by web-based videoconferencing are feasible and safe in the military setting. The findings also provide support for BA as an effective treatment strategy for PTS among military personnel.

Keywords: telemental health, home-based, behavioral activation, Post Traumatic Stress, military

A Pilot Study of In-Home Telehealth-based Behavioral Activation for Post Traumatic Stress

Home-based telemental health (HBTMH) is the provision of mental health care services directly to the homes of patients by using communications technologies. Home-based care may have particular benefits for the military community given that an increasing number of United States Department of Defense (DoD) healthcare beneficiaries are homebound or have limited mobility as the result of sensory, cognitive, emotional, or physical impairments, and various chronic health conditions (Armed Forces Health Surveillance Center, 2012). Further, some military members and veterans live in geographically remote locations or in areas that have a shortage of health care professionals and therefore must travel long distances to receive needed care. Perceived stigma associated with seeking care is another issue that has been noted as a particular problem in the military (Hoge et al 2004). The option to conveniently receive care in the privacy of a person's own home may help to address these issues.

In recognizing the benefits of home-based care, the United States' Veterans Health Administration (VHA) implemented a national home telehealth program (Godleski, Darkins, & Peters, 2012) that included veterans with PTSD, depression, and chronic medical conditions. A HBTMH pilot program (Shore, 2011) and several clinical studies (Strachan, Gros, Ruggiero, Lejuez, & Acierno, 2012; Strachan, Gros, Yuen, et al. 2012) have further demonstrated the benefits of home-based treatments for Veterans. The potential benefit of home-based treatment has also been recognized for some time within the DoD. For example, a 2010 Memorandum from the Chairman of the Joint Chiefs of Staff advocated that the Military Health System's model of care, "...must deliver options for mental health services in the comfort and security of the Service member's own home..." (Mullen, 2010). Despite the call for home-based care within the DoD, the Military Health System has not established the necessary policies and pathways for a home-based model of care to occur. While the existing empirical literature provides initial support and guidance for the safe and effective use of home telehealth services for appropriate populations (Luxton, Sirotnin, Mishkind, 2010), there remains a need to demonstrate that home-based care is technically feasible, safe, effective, and meets standards of care in the Military Health System before widespread implementation can be achieved.

The purpose of the present study was to test the feasibility of providing a Behavioral Activation (BA) treatment for PTSD (Jakupcak, Wagner, Paulson, Varra, & McFall, 2010) delivered via synchronous (real-time) videoconferencing to the homes of U.S. military members. BA is a well-established treatment for depression that counters patterns of avoidance and withdrawal with a pattern of engagement in valued activities through activity planning (Martell, Addis, & Jacobson, 2001). Given that avoidance and withdrawal processes also serve to maintain the symptoms of post-traumatic stress (PTS), BA has also been evaluated as a treatment for PTSD (Gros, et al., 2012; Jakupcak et al., 2006; Jakupcak, et al., 2010; Wagner, Zatzick, Ghesquere & Jurkovich, 2007). While previous studies have examined BA as a treatment for PTS with military veterans, our study is the first to test BA for PTS among a sample of active duty military members.

Method

This pilot study is part of a multisite clinical trial (ClinicalTrials.gov Identifier # NCT01599585) that is comparing the effectiveness of BA for depression delivered in-office versus in the home (Luxton et al., in press). While the RCT provides an opportunity to test the effectiveness of home-based BA for service members and veterans with depression, this pilot allowed us to test the feasibility of the technology, test safety management procedures, and evaluate a promising novel treatment for PTSD. We predicted that the BA intervention would result in a reduction in PTS and depression symptoms. We also included measures of anxiety and sleep quality as exploratory outcomes. The procedures of this study adhere to the principles and recommendations of the World Medical Association and the Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects. This study was approved by the Madigan Army Medical Center (MAMC) Institutional Review Board and the U.S. Army Medical Research and Materiel Command's Human Research Protection Office.

Participants

The sample consisted of 10 active duty members of the United States Army. All participants were referred to the study from medical and behavioral health clinics at a large Army medical treatment facility. The study inclusion and exclusion criteria were determined by initial screening interview. To be eligible for the study, participants had to have a score of 45 or higher on the Clinician Administers PTSD Scale (CAPS; Blake et al., 1995). The cut-off score of 45 has been used in other studies (see Schnurr et al., 2003). Participants taking any psychoactive medications had to have maintained a stable regimen for a minimum of 30 days prior to study entry.

All participants were men, between the ages of 21 and 45 years with a mean age of 31.8 ($SD = 7.44$) years. All were enlisted members of the United States Army with an average length of military service of 9.3 ($SD=5.21$) years. Fifty percent of the sample reported having some college education and ninety percent of the participants reported that they were currently married. Seven of the 10 participants resided in private housing off of the military installation in nearby areas.

Seventy percent of the sample had deployed to Iraq at least once in support of Operation Iraqi Freedom (OIF) and 60% had been deployed to Afghanistan in support of Operation Enduring Freedom (OEF). Two participants had also experienced other deployments besides OIF/OEF. The number of deployments that any single participant reported ranged from 1 to 4. All of the index traumas assessed on the CAPS were combat related and occurred during OEF/OIF deployments. All of these traumatic events met DSM-IV criterion A for posttraumatic stress disorder. On average, these traumas had occurred 6 (3.33) years prior to the patient presenting for treatment. The span of time since trauma exposure ranged from 2 to 11 years.

As part of the informed consent process, participants were provided with detailed information about how their identity and private health information would be protected, the limits of confidentiality, and the record keeping system used in the study. This included an overview of the telehealth equipment and instructions pertaining to setting up the treatment environment in a private area free from distractions. All participants completed a site specific release of information form so that a third party they identified as their emergency contact person could assist in cases of a clinical emergency. The requirements and processes for engaging with third parties were disclosed and discussed during the informed consent process.

Procedures

Study Personnel. Treatment providers included five clinical psychologists (4 licensed, 1 pre-licensed postdoctoral fellow). The post-doctoral fellow was supervised on a weekly basis, and group consultation occurred on an as-needed schedule, including consultation with a behavioral activation expert (Dr. Amy Wagner). All study treatment providers received training in BA.

Clinical Assessment. PTSD symptom severity assessments were completed by two doctoral level outcomes assessors. The outcomes assessors were trained in the administration of the CAPS and possessed prior experience with this measure. The CAPS, along with the self-report battery were completed at the baseline, mid-treatment, post-treatment, and three-month post-treatment assessments. All assessments were video recorded and reviewed by the supervisory psychologists for training purposes.

Treatment Protocol. The intervention consisted of 8-sessions of BA for PTSD. The treatment protocol is adapted from Martell, Addis & Jacobson's (2001) BA treatment that has been expanded by Wagner, Zatzick, Ghesquiere, & Jurkovich (2007) into an early intervention for PTSD and depression among injured survivors of trauma. The protocol places a strong emphasis on an outside-in approach to behavior change; rather than directly trying to change thought and feeling patterns (e.g. cognitive restructuring) BA promotes engagement in values-consistent activities despite the internal presence of painful thoughts and feelings. The treatment is guided by behavioral theory, with functional behavioral analysis being a primary treatment component (Dimidjian, Barrera, Martell, Muñoz, & Lewinsohn, 2011). Internal processes are not entirely disregarded in BA for PTSD; rumination and worry, as well as feelings of anxiety and panic, are common obstacles to the completion of scheduled activities, and are therefore addressed on an ongoing, as needed basis. In this protocol, rumination and worry are treated as behavior and are subject to the same functional analysis as overt behavior. The consequences of rumination are explored and participants are encouraged to accept anxious feelings in the service of valued activity.

The primary tasks during the first two treatment sessions are (a) to provide psychoeducation about PTSD and the rationale for this treatment, (b) to identify values, priorities, treatment goals, and to translate those into scheduled activities, and (c) to establish a pattern of daily monitoring and planning of those activities. The goal of the remaining sessions is to support the ongoing implementation of BA strategies. During sessions 3-8, the treatment provider conducts functional analyses of avoidance behaviors that prevent participants from engaging in scheduled activities and reinforce progress towards goals. During sessions 7 and 8, the treatment provider also discusses relapse prevention with participants and encourages them to use BA principles on their own in the event that symptoms return.

Telehealth procedures. All participants were issued a Dell M6500 laptop computer, Tandberg Precision High Definition webcam, and auxiliary equipment (e.g. mouse, charging station and power cables). Participants were also provided with a username and password for access to the Jabber Video software that was pre-loaded on their laptops. Jabber Video was selected as the

video communications program for this study because its level of security and encryption is approved for use by the U.S. Army. Prior to the first treatment session, a treatment station set-up appointment was scheduled between participant and treatment provider to familiarize participants with the equipment, the Jabber Video software, and to test the network connection. Participants were required to use their home internet connections to login for treatment sessions (both Wi-Fi and cable connections were acceptable); in addition, participants were asked to initiate the Jabber Video connection with their assigned treatment provider at scheduled appointment times.

Some modifications to the original BA protocol were necessary in order to deliver the treatment remotely via telehealth technology. A treatment session checklist (see Luxton et al., in press) was administered at the beginning of each session for the purpose of reminding study clinicians of procedures and for documenting technical issues and patient safety management. Several modifications were also required for sharing homework and study handouts (BA worksheets, self-report questionnaires, etc.) such as use of screen shots of homework and handouts, and holding handouts up to the camera.

Measures. *Demographic questionnaire:* Participants provided demographic information including occupation/work status/income/living situation, branch of service/highest rank, pain rating (0-10), and medications.

Clinician-Administered PTSD Scale (Blake et al., 1995). The CAPS is a structured interview that assesses all DSM-IV PTSD criteria in terms of frequency and intensity. The CAPS Current and Lifetime Version, which measures a one month symptom-duration, was used for the Baseline and Follow-up assessments. The CAPS One Week Version, which measures a one week symptom duration, was used to assess participants after treatment sessions 4 and 8. PTSD severity as measured by the CAPS (total score) served as the primary PTSD outcome in the study.

PTSD Checklist – Military Version (PCL-M; Weathers, Litz, Herman, Huska, & Keane, 1993): The PCL is a self-report measure that evaluates all 17 DSM-IV PTSD symptoms across the three primary symptom clusters using a 5-point Likert scale. Internal consistency for the total score is high (.97) as are reliability estimates (.96). A total score of 50 typically serves as the threshold for identifying probable PTSD among those reporting military related trauma(s).

Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996): The BDI-II is the most commonly used self-report measure of clinical depression severity. It consists of 21 items that are rated on a 4-point scale which yield a range of scores from 0 – 63.

Beck Anxiety Inventory (BAI; Beck, Epstein, Brown, & Steer, 1988): The BAI is a self-report measure consisting of 21 items designed to discriminate anxiety from depression. It has high internal consistency (.92) and 1-week test-retest reliability (.75) and discriminates anxious from non-anxious diagnostic groups (Hewitt & Norton, 1993).

Pittsburgh Sleep Quality Index (PSQI; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989): The Pittsburgh Sleep Quality Index is a 10-item measure of sleep quality. This measure assesses both

the quality and quantity of an individual's sleep pattern over a 1 month period. Internal consistency for this measure has been found to be .80, with a reliability coefficient of .83 and test-retest reliability of .87 (Carpenter & Andryowski, 1998).

Safety Measures: Safety data collected included any adverse events, psychiatric hospitalizations, suicides and non-fatal suicide-related behaviors, number of times the patient support person was utilized during treatment, treatment adherence, and frequency of requests for patient or therapist technical support. Safety related data were recorded after each treatment session on the Treatment Session Checklist (described below). We also followed a suicide assessment and risk management Standard Operating Procedure (SOP) used at Madigan Army Medical Center to assess and document suicide risk. The SOP requires clinicians to assess and document current ideation, presence of a plan, suicidal intent, history of previous attempts and degree of impulsivity are documented. Risk correlates (e.g., recent loss, financial problems), preparatory behavior (e.g., available means), and other risk factors (e.g., substance abuse or dependence, DSM-IV Axis II diagnosis present) are also assessed and documented. The SOP was administered at the baseline assessment, the first treatment session, and re-administered at each subsequent session if a patient endorsed current elevated risk per the SOP.

Treatment Session Checklist (Luxton, et al, in press): This checklist is designed to collect information for the evaluation of clinical telehealth sessions. It is used to document safety information including current suicidal ideation, homicidal ideation, and other signs of risk (including the visual presence of a weapon at the patient's location). Clinical factors such as indicators of intoxication, disorientation, and severe emotion dysregulation are also included, as are questions assessing more general safety-related questions, such as, "Is anyone else at home today?" and "Do you feel that your environment is safe and private?" This checklist is also used to document telehealth equipment and connectivity status during each session as well as other environmental factors (e.g., adequate lighting, disruptions to the sessions).

Client Satisfaction Questionnaire (CSQ-8; Larsen, Attkisson, Hargreaves, & Nguyen, 1979): The CSQ-8 is an 8-item self-report measure of general satisfaction with psychotherapeutic treatment. Participants are asked to rate satisfaction on a 4-point scale. The CSQ-8 is scored by summing the individual item scores to produce a range of 8 to 32, with higher scores indicating greater satisfaction. Internal consistency and construct validity have been established and the measure is widely used in research (Attkisson & Zwick, 1982).

Results

Clinical Outcomes.

We examined clinical treatment outcomes based on similar procedures used in a pilot study of BA for PTSD that was conducted with veterans (Jakupcak et al., 2006). Table 1 shows the results of paired sample *t* tests (two-tailed) of clinical outcome measures and individual responses to the treatment. We calculated Hedge's *g* to represent effect size and used Cohen's (1988) definitions to interpret them. The criteria we used for reliable change (RC) was based off of previous research (Foa, Zoellner, Feeny, Hembre, & Alvarez-Conrad, 2002; Jakupcak et al, 2006) and was as follows: CAPS +/-9, PCL +/-5, BDI +/-5, BAI = +/-8, PSQI = +/-2. Additionally, for the

PSQI, a ≥ 2 point decrease, alone, is coded as “improvement,” but if that ≥ 2 points yielded a total score equal or less than 5 then it was coded as “recovered.” A total score of 5 is the upper limit for a “normal” sleep pattern on the PSQI, and a total score of 6 or more is indicative of sleep dysfunction (Currie, Wilson, & Curran, 2002).

As shown in Table 1., there was a trend of decreased symptom levels from pre to post treatment for all clinical measures. There was a statistically reliable decrease in PTS severity and symptoms as measured by the CAPS and the PCL-M with 5 participants showing improvement on the CAPS and 7 on the PCL. There was a statistically reliable reduction in BDI-II scores with 6 patients meeting criteria for clinical improvement. While there was not a reliable change in mean scores for the BAI, 5 participants showed improvement and one deteriorated. There was also not a statistically reliable change in the mean PSQI scores for the sample, however, 3 participants met criteria for improvement and 1 met criteria for deterioration.

The three cases who met criteria for clinical deterioration were not the same patient. Two of three patients completed all treatment sessions whereas the one patient who met criteria for deterioration on the PSQI dropped out of the study after 5 sessions (due to Army duties). There was not an observable pattern linking technical issues or any study specific factors that may have contributed to clinical deterioration.

Treatment Adherence and Satisfaction.

Two of the 10 participants did not complete all 8 treatment sessions; both withdrew from treatment following session 5. In both cases the participant reported that despite noticing that treatment had, anecdotally, led to improvements in their quality of life and PTS symptoms, participating in the treatment required too much time away from their Army duties. However, one of these cases had experienced frequent technical difficulties that may have been a contributing factor to their decision to withdraw from treatment. Treatment completers indicated high overall satisfaction with the treatment on the CSQ-8, ($M = 25.86$, $SD = 4.74$).

Technical Feasibility

A summary of the technical issues experienced during the pilot study are shown in Table 2. The most frequent technical issue was difficulty establishing a connection to the VTC server. This problem was typically resolved with additional sign-in attempts. The average length of these disruptions was less than 6 minutes. More serious connection difficulties developed during an Army-wide network security upgrade that caused the IP addresses associated with some of the laptops to be blocked from accessing the VTC software’s network. This occurred over a 2.5 month period during the study and necessitated multiple treatment sessions to be completed via telephone. One participant who completed the entire treatment protocol required 6 treatment sessions to be conducted by telephone. The second case completed three of five sessions over the telephone but withdrew from the study after sessions five. While technical issues with initiating and maintaining a VTC connection were more frequent than expected, they were managed effectively by study clinicians with simple troubleshooting steps and use of alternative contact methods per the study’s protocol.

Safety Outcomes

There were not any adverse events during the pilot study or incidences that necessitated activation of our emergency protocol. At the baseline assessment, one participant endorsed thoughts of suicide but reported no desire or intention to act on those thoughts, and was therefore eligible for participation. At the midpoint assessment this participant continued to endorse thoughts of suicide. However, by the end of treatment those thoughts were no longer present, and suicidal ideation remained absent throughout the follow-up period. Two other patients (who did not indicate suicidal thoughts at baseline) reported single-occurrence endorsements of suicidal thoughts mid-way through treatment but did not report any plan or intent to act on those thoughts. Both of these patients no longer reported suicidal thoughts at post-treatment or follow-up assessments. None of the participants expressed any specific desire or intent to harm others and there were not any incidences that required notification of a patient's emergency contact person or emergency services. There was never a case where a patient deliberately terminated the VTC connection prematurely.

Discussion

This pilot study is the first to test BA for the treatment of PTS among active-duty U.S. military personnel and the first, to our knowledge, to report a test of a home-based synchronous telemental health intervention in the U.S. military. The overall results provide initial support for the feasibility of home-based telemental health treatments in the military setting. The results also showed positive treatment effects of this novel intervention on symptoms of both PTS and depression. While the results did not show statistically reliable overall reduction with the sleep quality measure (PSQI), this is not surprising given the small sample size of our pilot study. While the current pilot study is limited by its small sample size and lack of an in-clinic comparison group, the findings support the notion that it is possible to deliver a similar quality and standard of care (i.e., an established, evidence-based treatment) to the home as in the clinic. Our findings also support high levels of treatment satisfaction by the participants and the lack of any safety issues in this pilot provides additional data that mental health care can be delivered safely to service members in their homes when using workable safety standards and planning.

While we did experience several temporary technical issues that caused some inconveniences for both patients and our study care providers, these issues did not appear to be detrimental to the treatment process. The technological aspects of HBTMH were manageable and disruptions were typically corrected within several minutes of a problem. The technical problems were primarily caused by an unanticipated network security upgrade. The US military has unique network security requirements compared to most other settings. The optimal infrastructure for supporting enterprise-wide HBTMH VTC capabilities in this setting needs to be determined. An ideal capability would be to use a network infrastructure that meets DoD network security requirements but that also allows for the use of privately owned end-user equipment (personal computers and web cams).

Our pilot study supports the use of BA for the treatment of posttraumatic stress symptoms in addition to depression that is consistent with other recent studies (Gros, et al., 2012; Jakupcak et al., 2006; Jakupcak, et al., 2010; Wagner, Zatzick, Ghesquere & Jurkovich, 2007). These studies

suggest that BA may be an effective alternative treatment for PTSD, particularly if trauma processing therapies are not desired or available. Our pilot study thus adds to a growing body of research that supports BA as a transdiagnostic intervention and further suggests that BA is easily adaptable to delivery via telemental health technologies. Additional clinical trials are needed, however, to fully assess the clinical effectiveness of BA for the treatment of PTS.

In conclusion, HBTMH has the potential to greatly expand the range of services available to U.S. military members, veterans, and the general population. HBTMH can also help to reduce the costs associated with acute care visits by catching, monitoring, and treating emerging acute conditions that may not otherwise come to the attention of a provider until the individual is already hospitalized. This benefit could be significant for the Military Health System given that mental health disorders are the leading cause of hospital bed days and the second leading cause of medical encounters for active duty service members in the U.S. military (Armed Forces Health Surveillance Center, 2012). This pilot study can serve as a model to investigate and implement other forms of home-based health care and it provides decision makers with necessary preliminary data to make decisions regarding the expansion of HBTMH options for the U.S. Military community.

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Table 1. Treatment clinical outcomes

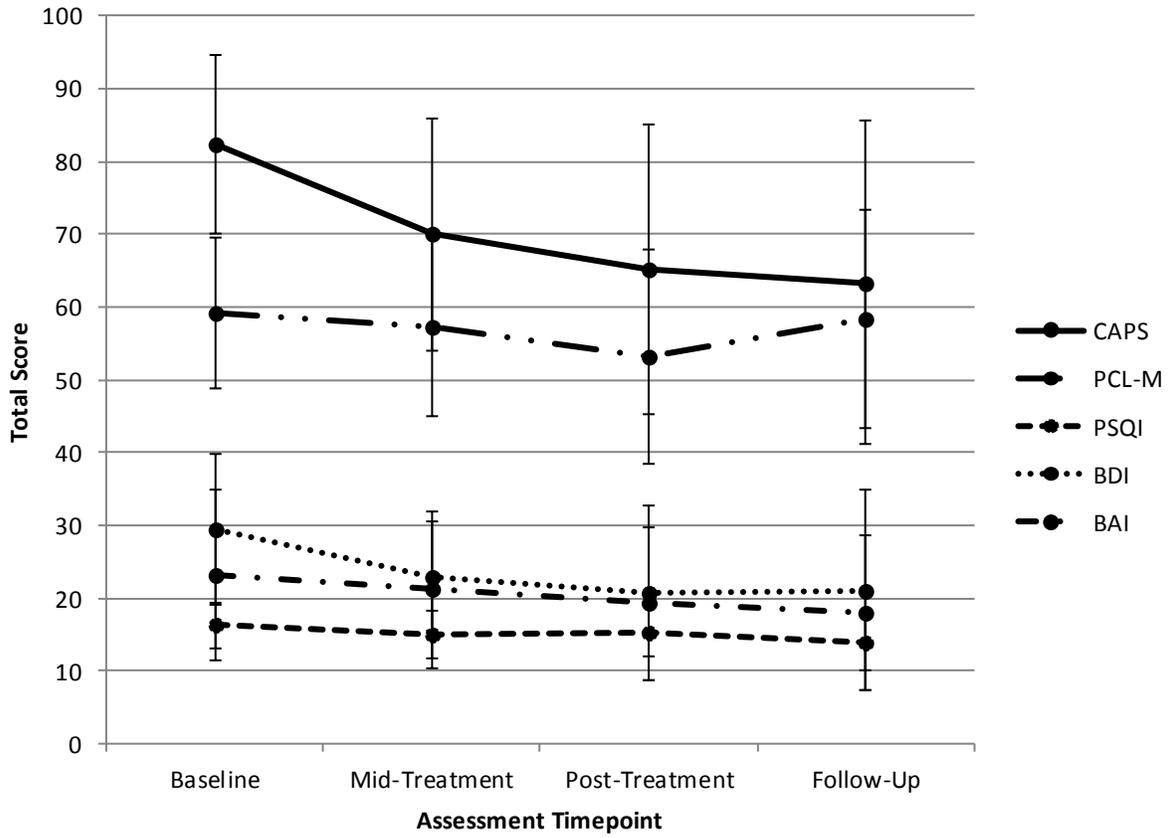
Measure	Baseline M (SD)	Post M (SD)	t(df)	Hedge's g	RC
CAPS	82.30(12.37)	65.11(20.74)	3.29 (8)*	0.95	5 improved 0 deteriorated
PCLM	59.20(10.40)	53.22(14.68)	2.53 (8)*	0.44	7 improved 1 deteriorated
BDI-II	29.50(10.32)	20.67(12.00)	2.95 (8)*	0.75	6 improved 0 deteriorated
BAI	23.20(11.66)	19.22(10.53)	2.15 (8)	0.34	5 improved 1 deteriorated
PSQI	16.20(3.05)	15.33(3.35)	1.71 (8)	0.41	3 improved 1 deteriorated

Note: CAPS = Clinician Administered PTSD Scale; PCLM = PTSD Checklist Military Version; BDI = Beck Depression Inventory; PSQI = Pittsburgh Sleep Quality Index; * p <.05

Table 2. Technical difficulties occurring across all 73 in-home telehealth sessions.

	Count (%)	Mean (SD)
Technical Issue:		
- Unable to immediately establish a VTC connection	31 (42.5)	
Time (Min.) to establish a connection		5.99 (4.27)
- Was the disruption severe enough to warrant phone contact	34 (46.6)	
- Patient was unable to be contacted by phone to follow-up	0 (0)	
Problem source for the 31 sessions where problems establishing a connection occurred		
Poor internet connection	3 (9.6)	
Software problems	1 (3.2)	
Hardware problems	3 (9.6)	
Server problems	17 (54.8)	
Other/Unknown	7 (22.6)	
- VTC connection lost mid-session due to technical issue	10 (13.7)	
Time (Min.) to re-establish a connection		4.71 (4.50)
Instances of being unable to reestablish a VTC connection	3 (30)	
Problem source for the 10 sessions where problems maintaining a connection occurred		
Poor internet connection	4 (40)	
Software problems	1 (10)	
Hardware problems	3 (30)	
Participant purposely terminated contact	0 (0)	
Other/Unknown	2 (20)	

Figure 1. Means and Standard Deviations of Clinical Outcome Measures.



Note: CAPS = Clinician Administered PTSD Scale; PCLM = PTSD Checklist Military Version; BDI = Beck Depression Inventory; PSQI = Pittsburgh Sleep Quality Index

Design and Methodology of a Randomized Clinical Trial of Home-based Telemental Health
Treatment for U.S. Military Personnel and Veterans with Depression

David D. Luxton, PhD.^{a,b}, Larry D. Pruitt, PhD.^a, Karen O'Brien PhD.^a, Katherine Stanfill, PhD.^a, Michael A. Jenkins-Guarnieri, PhD.^a, Kristine Johnson, PhD.^a, Amy Wagner, PhD.^c, Elissa Thomas, LPN^a, & Gregory A. Gahm, PhD.^{a,b}

^aNational Center for Telehealth & Technology

^bDepartment of Psychiatry and Behavioral Sciences, University of Washington School of
Medicine, Seattle

^cPortland VA Medical Center

Corresponding Author:

Name: David D. Luxton, PhD

E-mail: david.d.luxton.civ@mail.mil

National Center for Telehealth and Technology (T2)

9933 West Hayes Street

Joint Base Lewis-McChord, WA 98431

Phone: (253) 968-3581

Fax: (253) 968-4192

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Abstract

Home-based telemental health (TMH) treatments have the potential to address current and future health needs of military service members, veterans, and their families, especially for those who live in rural or underserved areas. The use of home-based TMH treatments to address the behavioral health care needs of U.S. Military healthcare beneficiaries is not presently considered standard of care in the Military Health System. The feasibility, safety, and clinical efficacy of home-based TMH treatments must be established before broad dissemination of home-based treatment programs can be implemented. This paper describes the design, methodology, and protocol of a clinical trial that compares in-office to home-based Behavioral Activation for Depression (BATD) treatment delivered via web-based video technology for service members and veterans with depression. This grant funded three-year randomized clinical trial is being conducted at the National Center for Telehealth and Technology at Joint-base Lewis-McChord and at the Portland VA Medical Center. Best practice recommendations regarding the implementation of in-home telehealth in the military setting as well as the cultural and contextual factors of providing in-home care to active duty and veteran military populations are also discussed.

Keywords: telemental health, telehealth, home-based, depression, military, veterans

1. Introduction

There is mounting evidence supporting the clinical effectiveness of telemental health (TMH) treatments (Rabinowitz, Brennan, Chumbler, Kobb, & Yellowlees, 2008; Richardson et al. 2009) as well as patient and provider satisfaction with TMH (Boydell, Volpe, & Pignatello, 2010; Simms, Gibson, & O'Donnell, 2011). The evidence base supporting home-based telemental health (HBTMH) is also growing, and HBTMH services are expanding across diverse care settings including the VA Health Care System (Godleski, Darkins, & Peters, 2012). HBTMH treatment options have multiple benefits: They can improve access to care services, reduce the burden of travel expenses, eliminate wait times, and reduce time away from work to attend appointments. Stigma associated with mental health conditions is another barrier to care that may influence willingness to seek mental health treatment. The option to receive care in the comfort and privacy of the home is one way to combat this problem (Pruitt, Luxton & Shore, 2014).

Mental health treatments provided directly to the homes of U.S. military personnel are not considered a standard of care in the Military Health System (MHS). Clinical research is needed to test the feasibility, safety, and effectiveness of HBTMH treatments in the military setting in order to inform policies regarding the adoption and expansion of HBTMH. To address this need, we are conducting a randomized clinical trial (RCT) that compares Behavioral Activation Treatment for Depression (BATD; Lejuez, Hopko, Acierno, Daughters & Pagoto, 2010) delivered in-office to BATD delivered via webcams to the homes of U.S. military service members and veterans with depression.

Behavioral Activation for depression was selected as the treatment in our trial for several reasons. First, military personnel may be highly agreeable to BA as a treatment option. Behavioral Activation is based on a behavioral conceptualization of depression which posits that depression is an understandable response to negative life events and difficult environments (Kanter, Busch, & Rusch, 2009). This stance, that “depression makes sense,” renders BA less stigmatizing than other treatments because it does not assume weakness or disorder on the part of the patient (Turner & Jakupcak, 2010). Behavioral Activation is also an action-oriented treatment that that may be particularly acceptable to physically active military service members. Second, BA has considerable empirical support for the treatment of depression among both civilians (see Kanter et al., 2009) and Veteran populations (Egede et al., 2009) as well preliminary support as a treatment for PTSD (Jakupcak, Wagner, Paulson, Varra & McFall, 2010; Luxton, Pruitt, O’Brien & Kramer, 2014). Third, depression is a highly prevalent mental health condition in both the military and veterans populations and it is the most frequent reason for psychiatric hospitalization in both the active and reserve components of the U.S. Armed Forces (MSMR, 2013).

With this paper, we describe the design, methodology, and safety protocol for our in-progress Military Operational Medicine and Research Programs (MOMRP) grant funded multi-site clinical trial. The trial is registered on the United States National Institutes of Health Clinical Trials Registry, (ClinicalTrials.gov Identifier #NCT01599585) available online at: <http://clinicaltrials.gov/show/NCT01599585>. In addition to testing the effectiveness of a home-based treatment, the study tests the feasibility of existing technologies (i.e., webcams and laptop computers) that are readily available to service members and veterans for in-home care. The study also provides data on patient satisfaction with a home-based treatment and it advances the

knowledge base regarding the safety and risk management procedures of home-based treatments in both the military and VA settings.

2. Research design and methods

2.1. Study design

This RCT is a two-group non-inferiority design that compares the effectiveness of BATD delivered via web-cam to standard in-office BATD. The study is being conducted at the National Center for Telehealth and Technology (T2) located at Joint Base Lewis-McChord (JBLM; Fort Lewis, WA) and at the Portland Veteran's Administration Medical Center (PVA; Portland, OR). We followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines in developing the protocol, and our procedures adhere to the principles and recommendations of the World Medical Association, Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects, as well as all applicable Codes of Federal Regulation and Department of Army Regulations. The research protocols were approved by the Institutional Review Board (IRB) at each site and the protocols underwent separate review processes by the Army Human Research Protection Office (HRPO).

The study's conceptual design is shown in Figure 1. Eligible participants have an equal chance of being randomized to either the in-office or in-home treatment groups. All participants are provided with 8 sessions of BATD that is guided by a treatment protocol manual. Participants in both intervention groups follow the same assessment schedule with assessments at baseline, mid-treatment, 1 week post-treatment, and 3 months post treatment (see Table 1). Treatment clinicians are naïve to clinical assessment results. This design characteristic, along with the treatment fidelity process (described in Section 2.5), was implemented to prevent the study

clinicians from systematically altering treatment delivery due to potential biases in favor of or against either diagnostic group.

2.2 Setting

Joint Base Lewis-McChord (JBLM) is a large U.S. Army and U.S. Air Force base that is home to Madigan Army Medical Center (MAMC), a Regional Medical Center and teaching hospital that serves more than 108,000 beneficiaries across a network of military treatment facilities located throughout Washington State, Oregon, and California. The National Center for Telehealth & Technology is part of the Defense Centers of Excellence for Psychological Health & Traumatic Brain Injury and the Military Health System (MHS). It is co-located with MAMC on JBLM. The National Center for Telehealth & Technology's mission is to lead in the development and research of telehealth and health technology solutions for the military community. Study participants at T2 are comprised of active-duty, reserve, and National Guard service members who are eligible to receive health care through the MHS. The study participants at the PVA site are military veterans receiving health care services through the VA hospital in central Portland (Veterans Integrated Service Network [VISN] 20). These veterans reside throughout various towns and cities in Northwest Oregon and Southwest Washington State. The study teams at each site meet every two weeks via videoconferencing to assure parallel operations and assess study progress.

2.3 Participants and enrollment methods

Approximately 120 ($n = 90$ at JBLM; $n = 30$ at PVA) participants will be recruited with an anticipated treatment completion rate of 108 participants (54 per treatment group).

Participants are male and female members of the U.S. Armed Forces, Washington State Army

National Guard, and Army Reserves recruited from MAMC and the larger JBLM community, as well as veterans of the U.S. military recruited at the PVA site. Study eligibility depends in part on whether the participant has high speed internet access at home (384kbs or greater) as well as a private space in which to conduct sessions (complete inclusion and exclusion criteria can be found in Table 1). Participants that are randomized to the in-office treatment group are seen in a traditional face-to-face clinical office setting at T2 or PVA. Participants assigned to the in-home treatment group are issued a Dell Precision M6500 laptop computer, Tandberg Precision High Definition webcam, and auxiliary equipment (e.g. mouse, charging station and power cables) that they connect to their own private internet access (either wireless or wired connection). The laptops are password protected and functionality is restricted so that unauthorized software cannot be loaded onto them. The videoconferencing software being used is Cisco Jabber Video for Telepresence. This software has embedded encryption features that meet Health Insurance Portability and Accountability Act requirements and it is authorized for use by the U.S. Army. The primary referral sources for study participants are clinical providers within behavioral health, primary care, and operational medicine service programs at JBLM and PVA (e.g., psychologists, psychiatrists, physicians, social workers, nurse practitioners, and nurses). Military chaplains, affiliated with MAMC, also serve as a recruitment source. These referring professionals are not affiliated with the trial, but have been informed about referral procedures during informational presentations by study staff. Additional recruitment strategies include flyers and banners as well as the use of social media campaigns (i.e. Facebook, Twitter, and LinkedIn) that target treatment providers who could make patient referrals. Participant recruitment began in August of 2012.

Following referral, the study coordinator conducts a brief phone screen and schedules each potential participant for an individual meeting with an outcomes assessor to complete the informed consent process and discuss study procedures in detail. Participation is discussed as entirely voluntary without negative consequences for withdrawal. At the PVA site, participants receive \$20 for each of the first three assessment visits, and \$40 for completion of the 3 month follow-up assessment. Each participant's capacity to consent and answer any questions about study procedures is monitored during the course of treatment and during assessment visits as well.

After participants complete the baseline assessment (see section 2.7), those meeting eligibility criteria are assigned to treatment condition by the study coordinator (who is not condition-naïve) according to the pre-determined randomization schedule. In this way, each participant has an equal chance of being assigned to either of the two groups, while ensuring equal distribution of participants to the two conditions over the course of the study.

2.4 Clinician preparation and training

Assessments are conducted by condition-naïve outcomes assessors. Assessors are eligible to meet with patients after completing specific assessment training protocols (i.e., literature review, assessment training videos, DSM-IV TR review, taped practice sessions with expert review, and role plays). Study clinicians are credentialed healthcare providers at MAMC or PVA. All study clinicians are doctoral level clinical or counseling psychologists who have completed specific training requirements for both BATD as well as use of the TMH technology and equipment. BATD training consists of an extensive literature review (both theoretical and empirical), completion of mock sessions, and attendance at a two day intensive training

workshop led by Dr. Ron Acierno, Ph.D. who is one of the authors of the BATD protocol.

Training in TMH technology and equipment consists of test calls, troubleshooting practice, and equipment manual review. All training requirements are completed before a provider is allowed to actively treat study participants.

2.5. Behavioral Activation treatment protocol

BATD and other behavioral activation protocols originated from behavior analytic models of classical and operant conditioning (Mower, 1960; Pavlov, 1927; Skinner, 1938) and the behavioral component of cognitive therapy for depression (Beck, Rush, Shaw, & Emery, 1979; Lewinsohn, Biglan, & Zeiss, 1976; Lewinsohn & Gotlib, 1995; Lewinsohn & Graf, 1973). Behavior analytic theory posits that depression develops when learned behavioral contingencies fail to produce stable, diverse, and reinforcing environmental consequences (Kanter, 2009). This can occur in a wide range of contexts (e.g., trauma, loss, daily stressors) and is likely modulated by biological predispositions. When an individual's behavior no longer produces reinforcing consequences, a reduction in the frequency of the target behavior occurs. Often, this can occur in parallel with an increase in the frequency of other maladaptive behaviors associated with that response, including withdrawal, negative internal affective experiences, and ultimately, symptoms of depression. BATD aims to reengage depressed individuals in their lives through focused, values-based activation strategies. These strategies counter patterns of negative affect, withdrawal, and inactivity by reestablishing contact with naturalistically reinforcing consequences for adaptive behavior that alleviates depressed mood and creates stable patterns for accessing reinforcing consequences.

The BATD treatment protocol used in the present trial is based on a revised BATD treatment manual by Lejuez, Hopko, Acierno, Daughters, and Pagoto (2011). The protocol prescribes 8-sessions of BATD that can be delivered either in-person or by VCT. In the first session, participants are provided with psychoeducation about depression and introduced to the treatment rationale and the role and importance of daily monitoring for the duration of the treatment. In the second session, previous content is reviewed, followed by introductions to the concepts of values and activity planning. With regards to values, clinicians utilize a series of prompts and writing tasks to encourage participants to identify their personal values within five different major life domains (i.e., relationships, education/career, recreation/interests, mind/body/spirituality, and daily responsibilities). Values are defined as ongoing, meaningful patterns of action and are contrasted with goals, which have an endpoint. Participants then collaborate with clinicians to devise lists of activities that exemplify their values. For example, if a participant values spending quality time with his children, specific activities might include taking them to the park for a game of ‘catch,’ reading 3 short bedtime stories to them each night, and spending half of a hour helping them to complete homework at approximately 6:00pm each day. Activity planning is the process of collaboratively scheduling these activities in advance in order to maximize the potential for contact with naturally occurring reinforcement in a participant’s day-to-day life. In sessions three through eight, the treatment rationale is continuously reviewed, and participants are asked to schedule more and varied values-consistent activities using a daily planner of their choice (planners are provided for use with treatment, but patients are encouraged to utilize established planners or scheduling systems [e.g., their smartphone] to increase the chances of regular use). Final sessions are also used to address issues

related to termination, treatment progress, and ways to use what has been learned in treatment for relapse prevention.

The present study's treatment protocol also contains specific provisions for VCT-based treatment delivery such as equipment set-up, procedures for initiating the VCT sessions, and steps to take in the event of disrupted service. All clinical procedures for the in-office and in-home conditions are identical.

2.6 Treatment fidelity

To assure adherence to the treatment protocol, treatment providers complete session-by-session "Adherence Checklists" that highlight the key elements of each session as well as homework that is assigned. Treatment providers also participate in weekly individual and group supervision and they attend weekly cross-site (i.e., JBLM and PVA) case consultation meetings. To assess adherence to the treatment protocol, all treatment sessions are digitally recorded. Sessions at MAMC are video recorded onto DVD (although the video captures the clinician only along with audio for both clinician and patient), whereas sessions at PVA are audio recorded only (per VA policy). Ten percent of these session recordings are randomly selected and sent to an expert fidelity reviewer on a monthly basis (Dr. Ron Acierno). The fidelity reviewer was selected for his expertise in the delivery of BATD to service members and veterans via telehealth. The reviewer codes each session recording for compliance based on a treatment fidelity checklist delineating the essential therapeutic components that must be delivered in each session of BATD.

Description of the recordings and fidelity review is provided in the informed consent process at both study sites. VA study clinicians are also required to obtain participant consent for recording using the VA Form 10-3203, "Consent for use of picture and/or voice" in addition to

their IRB approved Informed Consent Form. At JBLM, the digital recordings are retained for 5 years after the publication of results. At PVAMC, in accordance with VA policy, digital recordings are retained indefinitely.

2.7 Safety management protocol

During the baseline assessment, outcomes assessors conduct a thorough suicide risk assessment to determine level of risk per MAMC standard operating procedure (see Luxton, Pruitt, O'Brien, Johnson & Kramer, 2014 for further description). Level of risk depends on a combination of risk correlates (e.g., substance abuse, significant psychosocial stressors); factors related to suicide desire and ideation (e.g., articulated reasons for living, passive thoughts of attempt); and resolved plans and preparation (e.g., available means, specific plans). Participants are asked to identify a third party (e.g., family member or friend) who may be able to assist in cases of emergency or imminent risk. At JBLM, service members are also asked to provide the contact information for their immediate commanding officers in case of emergency or elevated risk necessitating command notification, per Army regulation. This additional exception to confidentiality in the military setting is thoroughly reviewed as part of informed consent. Lastly, for participants randomized to the in-home condition, clinicians identify the best contact information for law enforcement and emergency services nearest each participant's home address for use in case of emergency.

Suicidal risk is re-assessed during the first treatment session (using the same standard operating procedure described above). The assessment is also conducted during subsequent assessment and/or treatment sessions for patients identified to be at greater than mild risk or if a participant indicates a change in the severity or frequency of suicidal ideation. For all

participants, regardless of their initial risk level determination, ideation and other signs of risk for self-harm are also monitored at each session by means of a treatment session checklist developed specifically for this study (see attachment 1). Relevant questions assess correlates of safety risk, alcohol or substance use, appearance of being disoriented or upset; reports of suicidal desire and ideation, and whether a weapon was observed. This checklist also includes questions that assess aspects of participant safety other than suicide risk. For example, some questions assess more general safety-related questions, such as, “Is anyone else at home today?”, whereas some questions are more specific, such as “Did the patient indicate intent to harm others?” Finally, in line with Luxton and colleagues’ (2010) definition of safety, this checklist also addresses matters of privacy and confidentiality (e.g., “Do you feel that your environment is safe and private?”), as well as technology, equipment and connectivity (e.g., “What number can I reach you at if we get disconnected?”, “Were there problems initiating/maintaining the webcam connection?”). The checklist also contains space for clinician comments.

If any study clinician or assessor becomes aware of any elevation in participant risk for suicide or violent behavior, established written safety protocols are followed according to the regulations of the site responsible for that patient. This may include developing a detailed safety plan with patients, modifying risk factors and removing lethal means for suicide or violent behavior, involving the third party identified by participants to help with enacting the safety plan, modifying risk factors, assisting with patient safety until the patient is transferred to emergency services, involving the patient’s commander and assigned unit, and transferring the patient to inpatient care. At the baseline assessment, high short term risk for suicide behavior would preclude participation in the study in favor of more acute, crisis-focused care. Elevated risk

during treatment is managed via consultation by the treatment team, who collectively determine whether the participant in question can be safely and effectively treated within the confines of the treatment protocol or whether more acute and/or intensive care is warranted.

All assessors and providers adhere to Federal Health Insurance Portability and Accountability Act regulations as well as their state (Washington/Oregon) and military/VA requirements of confidentiality, including exceptions and reporting of imminent risk of harm to self or others, including harm to vulnerable populations. The staff at T2 also complies with Army Medical Command (MEDCOM) regulations mandating that providers in the Military Health System must follow additional mandatory reporting requirements pertaining to substance use, sexual assault, and domestic violence which may necessitate notification of an individual's unit commander.

2.8. Assessments and measures

After obtaining informed consent, the condition naïve outcomes assessor determines each person's study eligibility by asking a series of questions related to inclusion and exclusion criteria and conducts an abbreviated Structured Clinical Interview for the DSM-IV Axis I Disorders, Research Version, Patient Edition (SCID-I/P; First, Spitzer, Gibbon, & Williams, 2002) which focuses on the mood, psychotic, and substance use disorder sections. If eligible for participation, a demographics questionnaire is administered along with a set of self-report questionnaires which follow the assessment schedule outlined in Table 2. These self-report measures include: Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996), Beck Hopelessness Scale (BHS; Beck, Weissman, Lester, & Trexler, 1974), Beck Anxiety Inventory (BAI; Beck & Steer, 1990), Loneliness Scale (LS; de Jong Gierveld & van Tilburg, 2006), PTSD

Checklist – Military (PCL-M; Weathers, Huska, & Keane, 1991), Inventory of Attitudes Toward Seeking Mental Health Services (IASMHS; Mackenzie, Knox, Gekoski, & Macaulay, 2004), Client Satisfaction Questionnaire (CSQ; Nguyen, Attkisson, & Stegner, 1983), Computer and Audiovisual Technology Questionnaire (Technology Questionnaire; adapted by study authors from Egede et al., 2009), and safety measures (recording any clinical safety concerns and adverse events at each client contact). Additionally, a comprehensive suicide risk assessment is conducted at the initial meeting by the study assessor with ongoing monitoring by study therapists as part of clinical risk management (see section 2.10).

All standardized symptom inventory scales have been previously used in research with military populations and demonstrate adequate psychometric properties (e.g., validity and internal consistency reliability estimates calculated in data collected from samples with similar demographic profiles). Research on the Loneliness Scale has demonstrated sound psychometric outcomes in a large sample of adults (De jong Gierveld & van Tilburg, 2006), and Mackenzie et al. (2004) presented initial validity evidence for the IASMHS with strong psychometrics calculated from a sample of young adult, undergraduate students.

The outcome assessors remain condition-naïve throughout the course of the study to avoid bias the assessor may have toward any one particular treatment condition. Procedural and physical barriers are used to protect the assessor from being inadvertently exposed to information about the treatment condition to which participants have been assigned. For example, treatment and assessment sessions take place in different office spaces and efforts are taken to avoid scheduling both types of sessions at the same time. Assessors do not participate in regularly scheduled supervision and consultation of clinical cases, and are selectively excluded from

administrative meetings in which discussion of the treatment process might occur. The greatest risk to these barriers is the patient revealing the method of treatment delivery to the assessor at one of the non-baseline assessments. As such, instructions are provided to the patient at the outset of each assessment to avoid inadvertently revealing condition assignment.

2.9 Outcomes

The primary outcome variables (continuous measures) are depressive symptoms measured by the BDI-II and hopelessness measured by the BHS. In order to establish evidence for the safe use of web-based, in-home treatment with military personnel, we also conduct ongoing monitoring of patient safety during study participation. This is primarily assessed by study clinicians who document safety concerns and record any adverse events at each client contact. In addition, secondary analyses will assess treatment group differences in anxiety (BAI) and PTSD (PCL-M) symptoms, patient satisfaction with and attitudes towards treatment (CSQ, IASMHS), quality of life (LS), and healthcare utilization.

2.10 Statistical methods

We are using a non-inferiority design for this study because we expect the observed efficacy of the in-home BATD intervention will be no worse than that observed for in-person BATD. The non-inferiority design is especially useful for comparing interventions that have been modified or adapted for different modes of delivery to treatment as usual (Greene et al., 2008). Non-inferiority trials have also been previously used to compare telehealth interventions to conventional in-person care (e.g., Egede et al., 2009; Morland, Greene, Rosen, Mauldin, & Frueh, 2009; O'Reilly et al., 2007).

2.10.1 Power Analysis

We first determined the non-inferiority margin based on methodology used in similar studies as well as clinical considerations (Greene et al., 2008; Nutt, Allgulander, Lecrubier, Peters, & Wittchen, 2008). A 0.5 standard deviation change in scores has been used in clinical treatment research as an indicator of clinically significant improvement (e.g., Ready et al., 2008; Schnurr et al., 2003). This margin is consistent with clinically significant change in BDI-II total scores and standard deviations of approximately 10 points in both military (Williams et al., 2002) and civilian (Gibbons et al., 2010) samples. From a clinical standpoint, it is reasonable to consider a 5 or fewer point change in BDI-II scores as clinically unimportant, which also aligns with the 0.5 standard deviation criteria for significant change used in previous research. Thus, we set our non-inferiority margin at 0.5 SD and used a 2-sided test with a 90% CI following Mohr et al.'s (2012) approach. Power analyses following a standardized method (variance of 1) based on these parameters yielded a minimum sample size of 49 (D of -0.5 SD) participants in each treatment group to adequately power our non-inferiority analyses assuming an observed difference of 0 in the mean efficacy between the two study groups. Thus, we targeted our sample size for 120 assuming a 10% rate of drop-out.

2.10.2 Multilevel model

We will test the primary null hypothesis that differences in BDI-II scores between the two conditions (in-home vs. in-office BATD) will be greater than the set clinically relevant threshold or margin (labeled δ) using a multilevel (also referred to as *hierarchical* or *random effects*) modeling approach. The primary outcome measure is change in BDI-II scores and secondary analyses will include the BHS. We will include both individual and sessions as units of the analysis with participants nested within sessions. The baseline values for the outcome measures

will be included as covariates in the model. If the upper bound (with higher scores indicating a worse result) CI of the difference in BDI-II scores CI's lower bounds falls below the established δ , the null hypothesis will be rejected and the VCT treatment will be considered non-inferior to standard in-person treatment. Effect sizes will also be calculated and reported.

3. Discussion

With this paper we have presented the design, methodology, and protocol of a clinical trial that compares in-office to home-based Behavioral Activation for Depression (BATD) treatment delivered via web-based video technology for service members and veterans with depression. This trial is expected to yield important data that can help guide the development of treatment guidelines and standards of care (e.g., within the Department of Defense and the Veterans Administration) that aim to improve access to quality care for military service members and veterans. This trial will also demonstrate the limitations of home-based TMH care thereby allowing for further refinement of safety and technical procedures to maximize effectiveness and safety of this modality of care.

This study is generating important information about challenges and considerations when conducting research with active duty military service members and home-based TMH. Additional steps must be taken to meet requirements of multiple review boards and oversight committees, which may take more time and resources than is typically necessary for doing similar research in non-military settings. There is additional oversight regarding reporting of adverse events, verifying provider credentials, and accessing equipment, computing, and communications systems within the military. Further, participant recruitment strategies must be sensitive to varying perceptions regarding stigma associated with mental health treatment and

clinical research within the military culture and community. Retention efforts must be flexible in order to accommodate the high mobility of the military population given the potential for relocation and deployment. In this study, accommodations have been made to conduct follow-up assessments over the telephone since it is expected that some participants may have relocated (due to military assignment or discharge from service) during the period between completing treatment and the 3-month follow-up assessment. We hope that our methods presented here, and our future trial results, will help to guide additional research regarding home-based TMH treatments in the military and VA settings.

Factors associated with an active-duty military population also impact clinical practices and feasibility of home-based treatments in the MHS. Working within this system, clinicians must consider specific rules regarding the protection of privacy and confidentiality that may be different than what is encountered in civilian care settings. For example, military unit commanders are authorized to verify treatment attendance of their subordinates and clinicians must comply with requirements for mandated reporting to unit chain of commander that would exceed most state laws (e.g., all active substance abuse, any suspected incidence of domestic violence). Also, the process of patient safety (e.g., suicide risk assessment) must be adapted, as we have done, to fit local requirements.

We are also collecting treatment adherence data with our trial that will help us to determine what factors including scheduling may influence treatment outcomes. To date, we have been successful in working with patients to schedule treatment sessions during day-time hours. While home-based options may be ideally suited for patients who are already at home (due to medical leave, unemployment, etc.), we are finding that home-based options are feasible

in the military setting when sessions are scheduled in the morning before work or at the end of the day. In addition to being convenient for patients, time away from work and travel costs can be minimized because the service member does not have to leave work for a session at a clinic and then return back to work. Home-based TMH care may thus be an ideal solution for when travel to a military treatment facility or clinic is not feasible or if there is limited clinical space near where the patient works (i.e., in remote areas).

In conclusion, home-based mental health services have the potential to provide effective treatment to the many individuals who may not otherwise pursue mental health care, either due to logistical barriers or perceived stigma of receiving care. Home-based treatment options may be particularly useful in addressing the aforementioned barriers to care and can augment current treatment services provided in the MHS and VAHCS. The results of this clinical trial will provide basic information that is needed to inform policy decisions regarding the implementation of home-based behavioral health care in the U.S. military and further expansion in other settings including the VA Health System.

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3. Tables and Figures

Figure 1: Study flow chart

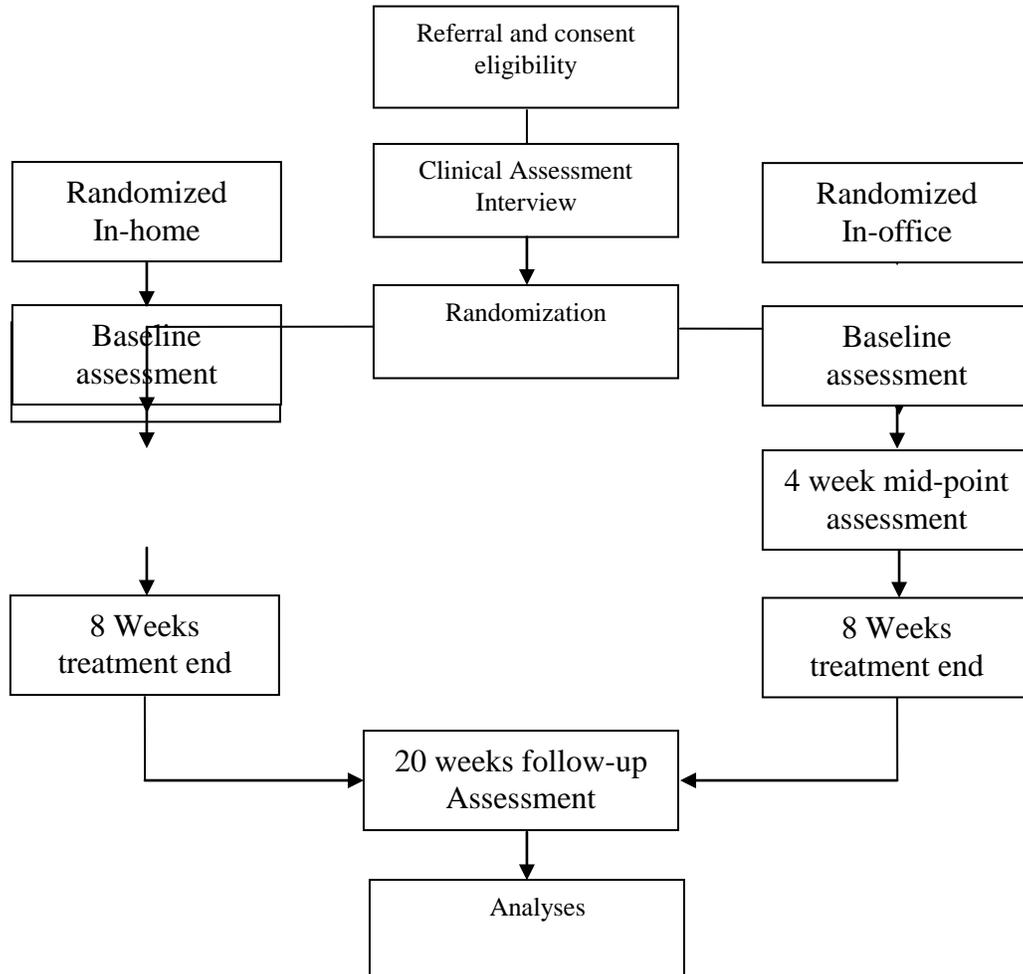


Table 1.

Inclusion and exclusion criteria for participant enrollment.

Inclusion Criteria

- (a) Met diagnostic criteria for Minor Depressive Disorder or Major Depressive Disorder, as determined by the SCID-I/P
- (b) High speed internet access at home (384 kbs minimum)
- (c) If taking psychoactive medications, has maintained a stable regimen for a minimum of 30 days prior to study entry
- (d) Informed Consent read and signed
- (e) Personal computer in-home (Portland VA only)

Exclusion Criteria

- (a) Currently undergoing psychotherapy for depression
 - (b) < 18 or > 65 years of age
 - (c) Active psychotic symptoms/disorder as determined by the SCID-I/P
 - (d) Dysthymic Disorder as determined by the SCID-I/P
 - (e) Current suicidal ideation with intent or recent (within six months) history of a suicide attempt
 - (f) History of Organic Mental Disorder
 - (g) Current substance dependence as determined by the SCID-I/P (lifetime substance dependence or substance abuse will not be excluded)
 - (h) History of violence or poor impulse control
 - (i) Significant ongoing stressors that require urgent crisis intervention
 - (j) Have a living arrangement that will not permit the use of a private space to participate in the study
-

Table 2.

Schedule of measures and survey instruments

Measure	Baseline			Midpoint					Post-Tx	3-month Follow-up
	Initial	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Final
SCID-I/P	X				X				X	X
BDI-II	X				X				X	X
BHS	X				X				X	X
BAI	X				X				X	X
LS	X				X				X	X
PCL-M	X				X				X	X
IASMHS	X								X	X
Safety Measures		X	X	X	X	X	X	X	X	X
CSQ									X	
Technology Questionnaire	X								X	

Note. SCID-I/P = Structured Clinical Interview for the DSM-IV Axis I Disorders, Research Version, Patient Edition; BHS = Beck Hopelessness Scale; BDI-II = Beck Depression Inventory-II; BAI = Beck Anxiety Inventory; LS = Loneliness Scale; PCL-M = PTSD Checklist – Military; IASMHS = Inventory of Attitudes Toward Seeking Mental Health Services; CSQ = Client Satisfaction Questionnaire; Technology Questionnaire = Computer and Audiovisual Technology Questionnaire.

Treatment Session Checklist

Participant ID: _____ Clinician: _____ Session Date: _____ Session #: _____

<p>Questions to be asked at beginning of session (in-home telehealth condition only)</p> <p>1. Is anyone else at home today YES NO (circle one) a. <i>If yes, who?</i> _____</p> <p>2. Do you anticipate any disruptions during our session today? YES NO (circle one) a. <i>If yes, explain:</i> _____</p> <p>3. Do you feel that your environment is safe and private? YES NO (circle one) a. <i>If yes, explain:</i> _____</p> <p>4. What number can I reach you at if we get disconnected? _____</p>
<p>Participant</p> <p>1. Was participant late to the session? YES NO (circle one) a. <i>If yes, how many minutes late?</i> _____</p> <p>2. Did the participant cancel session early? YES NO (circle one) a. <i>If yes, explain:</i> _____</p> <p>3. Was the session rescheduled? YES NO (circle one) a. <i>If yes, who was it rescheduled by?</i> _____</p> <p>4. Did the participant miss the session without giving prior notice? YES NO (circle one) a. <i>If yes, explain:</i> _____</p> <p>5. Did the participant appear disheveled? N/A YES NO (circle one) 1. <i>If yes, explain:</i> _____</p> <p>6. Did participant appear intoxicated? N/A YES NO (circle one) 1. <i>If yes, explain:</i> _____</p> <p>7. Did patient show any signs of suicidal ideation? YES NO (circle one) 1. <i>If yes, explain:</i> _____</p> <p>8. Did patient exhibit self-harm behavior during session? YES NO (circle one) 1. <i>If yes, explain:</i> _____</p> <p>9. Was there a suicide attempt since last session? YES NO (circle one) 1. <i>If yes, explain:</i> _____</p> <p>10. Did patient indicate intent to harm to others? YES NO (circle one) 1. <i>If yes, explain:</i> _____</p> <p>11. Did participant become upset/distressed during session? YES NO (circle one) 1. <i>If yes, explain:</i> _____</p>

Safety Protocol

1. Was the safety protocol initiated? YES NO (*circle one*)
2. Was it necessary to contact collateral? YES NO (*circle one*)
 - a. *If yes, check all that apply:*
 - Able to contact the collateral
 - Collateral responded to issue
 - The collateral was helpful
3. Was the police non-emergency line or 911 called? YES NO (*circle one*)
 - a. *If yes, check all that apply:*
 - The agency initiated an emergency response
 - The agency chose not to provide an emergency response
 - The agency was unable to provide an immediately emergency response (e.g., location)
4. Was a supervisor notified or consulted? YES NO (*circle one*)
 - a. *If yes,*
 - i. Name of supervisor: _____
 - ii. Date and time contacted: _____

Environment (in-home telehealth condition only)

1. Were there distractions at the patient's location (e.g., pets, children, cell phones)? YES NO (*circle one*)
 - a. *If yes, explain:* _____
 - b. *If yes, was this useful clinical information?* YES NO (*circle one*)
2. Was the session interrupted by another person? YES NO (*circle one*)
 - a. *If yes, explain:* _____
 - b. *If yes, was this useful clinical information?* YES NO (*circle one*)
3. Any weapons observed during session? YES NO (*circle one*)
 - a. *If yes, explain:* _____
 - b. *If yes, was this useful clinical information?* YES NO (*circle one*)
4. Did the participant's room have adequate lighting? YES NO (*circle one*)
 - a. *If yes, explain:* _____

Technology Issues (in-home telehealth condition only)

1. Were there problems *initiating* the webcam connection? YES NO (*circle one*)
- a. *If yes, how many minutes until connection made?* _____
- b. *Indicate source of problem (check all that apply)*
- Internet Connection (ISP Problem)
 - Software problem
 - Hardware problem (PC, webcam, microphone)
 - Unable to establish webcam connection
 - Unable to follow-up via telephone
 - Unable to contact the PSP

Describe: _____

2. Were there problems *maintaining* the webcam connection? YES NO (*circle one*)
- a. *If yes, how many minutes until connection made?* _____
- b. *Indicate source of problem (check all that apply)*
- Internet Connection (ISP Problem)
 - Software problem
 - Hardware problem (PC, webcam, microphone)
 - Participant purposely terminated contact
 - Unable to re-establish webcam connection
 - Unable to follow-up via telephone
 - Unable to contact the PSP

Describe: _____

3. Was it necessary to contact participant by phone? YES NO (*circle one*)

Other Information:

