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Home-Based Telebehavioral Health for U.S. Military Personnel and Veterans With Depression: A Randomized Controlled Trial

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Objective: Evidence of feasibility, safety, and effectiveness of home-based telebehavioral health (HBTBH) needs to be established before adoption of HBTBH in the military health system can occur. The purpose of this randomized controlled noninferiority trial was to compare the safety, feasibility, and effectiveness of HBTBH to care provided in the traditional in-office setting among military personnel and veterans. ***Method:*** One hundred and twenty-one U.S. military service members and veterans were recruited at a military treatment facility and a Veterans Health Administration hospital. Participants were randomized to receive 8 sessions of behavioral activation treatment for depression (BATD) either in the home via videoconferencing (VC) or in a traditional in-office (same room) setting. Participants were assessed at baseline, midtreatment (4 weeks), posttreatment (8 weeks), and 3 months posttreatment. ***Results:*** Mixed-effects modeling results with Beck Hopelessness Scale and Beck Depression Inventory II scores suggested relatively strong and similar reductions in hopelessness and depressive symptoms for both groups; however, noninferiority analyses failed to reject the null hypothesis that in-home care was no worse than in-office treatment based on these measures. There were not any differences found between treatment groups in regards to treatment satisfaction. Safety procedures were successfully implemented, supporting the feasibility of home-based care. ***Conclusion:*** BATD can be feasibly delivered to the homes of active duty service members and veterans via VC. Small-group differences suggest a slight benefit of in-person care over in-home telehealth on some clinical outcomes. Reasons for this are discussed.

What is the public health significance of this article?
Behavioral activation treatment for depression can be feasibly delivered to the homes of active-duty U.S. service members and veterans. Small-group differences suggest a slight benefit of in-person care over in-home telehealth on some clinical outcomes. Telebehavioral health services provided to the home or other locations have the potential to address current and future health needs of military service members and veterans, especially for those who live in rural or underserved areas.

Keywords: telemedicine, telemental health, depression, military, veterans

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Home-based telebehavioral health (HBTBH) is the provision of behavioral health services directly to a patient's home with the use of telecommunications technologies. This method of providing care has the potential to benefit military personnel, veterans, and their families by improving access to care and by reducing the barriers that may impede treatment-seeking and engagement in care. A recent report from the RAND Corporation (Brown et al., 2015) notes that there are more than 300,000 U.S. military service members and 1 million family dependents in geographically remote locations that may benefit from telehealth services. Behavioral health care services provided directly in the home can reduce or eliminate travel burden to treatment facilities and may be especially convenient for service members and veterans who have limited mobility as the result of co-occurring chronic health conditions or physical impairments (Luxton, Pruitt, O'Brien, & Kramer, 2015). The option to receive care in the privacy of one's own home may also ease apprehension among military personnel who are concerned about stigma associated with seeking mental health care (Egede et al., 2009; Pruitt, Luxton, & Shore, 2014). These potential benefits of HBTBH have been recognized for some time within the U.S. Department of Defense the military health system's (MHS) model of care (Mullen, 2010), yet HBTBH is not presently recognized as a standard of care in the MHS.

The U.S. Department of Veteran's Health Affairs (VHA) has been a leader in establishing and expanding telebehavioral health (TBH) service options for veterans (Darkins et al., 2009; Strachan, Gros, Ruggiero, Lejuez, & Acierno, 2012). The feasibility and effectiveness of TBH has been supported by several pilot studies and randomized controlled trials (for a review, see Hilty et al., 2013). The majority of published TBH studies involving military veterans have focused on the treatment of posttraumatic stress disorder (PTSD) with evidence-based treatments including prolonged exposure therapy (Gros, Yoder, Tuerk, Lozano, & Acierno, 2011; Tuerk, Yoder, Ruggiero, Gros, & Acierno, 2010), Cognitive Processing Therapy (Morland, Hynes, Mackintosh, Resick, & Chard, 2011; Morland et al., 2014), or group anger management therapy (Morland et al., 2010), delivered to small outpatient clinics with fewer staffing resources. Other studies have specifically evaluated TBH treatments delivered to the homes of veterans (Egede et al., 2009; Yuen et al., 2015). For example, Egede and colleagues (2009) conducted an randomized controlled trial (RCT) that evaluated the effectiveness of behavioral activation treatment for depression (BATD; Lejuez, Hopko, & Hopko, 2001) to treat elderly veterans with major depressive disorder either in-home with videoconferencing (VC) technology or by traditional in-person services. The results showed that the treatment delivered by in-home video teleconference was as effective as by face-to-face therapy sessions. The VHA has also expanded its HBTBH program through larger pilot programs at the national level (Godleski, Darkins, & Peters, 2012).

While the expansion of HBTBH options in the VHA is promising, questions remain about the feasibility, safety, and effectiveness of home-based TBH treatments in the military setting. Particular questions concern the feasibility of using the military's information technologies (IT) infrastructure for VC and the applicability of general HBTBH procedures including safety and emergency management protocols. The safety of HBTBH is a primary issue to be evaluated given that care provided to settings without clinical staff on-site (e.g., the home) require additional safety planning and procedures to manage safety risks (Luxton, O'Brien, McCann, & Mishkind, 2012). Principal concerns involve how to appropriately plan for and manage risks including psychiatric emergencies (i.e., worsening of clinical symptoms, suicidal behavior) and medical emergencies that could occur without clinical staff on-site (Luxton, Sirotin, & Mishkind, 2010). There are no published trials with active-duty military personnel that have evaluated whether treatments provided via VC in the home are comparable in clinical efficacy to traditional in-office care. A preliminary pilot study evaluation (Luxton et al., 2015) tested the basic procedures and supported the technical feasibility of home-based care in the military setting. However, a direct comparison of HBTBH to traditional in-office care is thus needed to inform policy decisions regarding the adoption and expansion of HBTBH within the MHS and to add to the growing body of research on the effectiveness of TBH across diverse populations.

The primary aim of this trial was to evaluate the safety and feasibility of providing military service members and veterans with HBTBH care by comparing it to conventional in-office care. We selected BATD (Lejuez, Hopko, Acierno, Daughters, & Pagoto, 2011) as the target treatment for the present trial given that depression is one of the most prevalent psychiatric conditions among veterans and military personnel and it is the most frequent diagnosis associated with psychiatric hospitalization in both the active and reserve components of the U.S. Armed Forces (Armed Forces Health Surveillance Center, 2013; Bagalman, 2013). Prevalence rates for depression based on screening data have been estimated to be 12% among deployed service members (Gadermann et al., 2012) and 20% among Operation Iraqi Freedom/Operation Enduring Freedom veterans (Corson et al., 2013; Seal et al., 2009). Depression also frequently co-occurs with other conditions, such as PTSD and physical injuries among military personnel and veterans and can slow recovery and return to duty among those with comorbid conditions (Hoge, Auchterlonie, & Milliken, 2006; Hoge et al., 2004; Milliken, Auchterlonie, & Hoge, 2007). BATD aims to reengage depressed individuals in their lives through focused, values-based activation strategies. These strategies are intended to counter patterns of negative affect, inactivity, and withdrawal by reestablishing naturalistically reinforcing behaviors which in turn alleviate depressed mood and create stable patterns of activity and engagement. BATD is also presumed to be a compatible treatment for military personnel given that it is a problem-focused, direct intervention that may be perceived as less stigmatizing than other "emotion-focused" treatments (Egede et al., 2009).

A noninferiority design was used for this trial because it is well-suited for comparing novel adaptations of established treatments that have demonstrated efficacy (Greene, Morland, Durkalski, & Frueh, 2008). BATD has a strong empirical evidence base (Cuijpers, van Straten, Andersson, & van Oppen, 2008) and it has been evaluated in prior TBH studies with military veteran populations (Egede et al., 2009). Both active-duty service members and veterans were included to provide preliminary data regarding any unique differences between these populations and treatment settings. We hypothesized that in-home care would be no-worse than in-office care on clinical measures that reflect safety and clinical outcomes (measures of hopelessness and depression scores) and that participants in both groups would show improved hopelessness and depression scores at treatment end. We also predicted that

BATD delivered in home would be as safe as in-office treatment. Our assessment of safety also consisted of both qualitative analysis of any safety events requiring activation of our safety protocol as well as the evaluation of the relative clinical efficacy of HBTBH.

The study was approved by the institutional review boards (IRB) at Madigan Army Medical Center and the Veterans Affairs (VA) Portland HCS and reviewed by the Army Human Research Protection Office. The trial was partially funded by the Military Operational Medicine and Research Program and is registered on the U.S. National Institutes of Health Clinical Trials Registry (ClinicalTrials.gov Identifier NCT01599585; available online at https://clinicaltrials.gov/ct2/show/NCT01599585).

Method

Participants

A complete description of the trial methodology is available in a previous publication (Luxton et al., 2014). Participants were recruited at a large regional military treatment facility located at Joint Base Lewis-McChord (JBLM) in Washington State and at the VA Health Care System in Portland, Oregon (VAPHCS). Study patients at JBLM comprised active-duty, reserve, and National Guard service members. The study patients at the VAPHCS site were U.S. military veterans receiving health care services through the VA hospital.

Participants were included in the study if they met *Diagnostic and Statistical Manual of Mental Disorders* (4th ed., text rev.; *DSM–IV–TR*; American Psychiatric Association, 2000) diagnostic criteria for major depressive disorder or minor depressive disorder based on the Structured Clinical Interview for the *DSM–IV* Axis I Disorders (Research Version, Patient ed.; SCID-I/P; First, Spitzer, Gibbon, & Williams, 2002). The inclusion of both major and minor depressive disorder in the trial was intended to provide a more generalizable representation of patients typically seen at the sites. Clinical assessors were unaware of treatment condition throughout the trial. All participants had to have access to high-speed Internet available in their homes. The full study inclusion and exclusion criteria are shown in Table 1.

Table 1
Inclusion and Exclusion Criteria

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 kB/s 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
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 6 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

Note. SCID-I/P = Structured Clinical Interview for the *DSM–IV* Axis I Disorders (Research version, Patient ed.).

Procedure

Participant recruitment began in August 2012 and concluded in July 2014. Participants at both study sites were referred to the study by mental health care providers from outpatient mental health clinics as well as by self-referral (research flyers were placed in common areas around the hospital facilities). A study research coordinator conducted initial eligibility criteria screening via telephone. Eligible participants were then scheduled to complete informed consent procedures and an in-person interview (i.e., the SCID-I/P) with the study team's independent clinical assessor. Patients at the PVA site were given $20 for each of the first three assessment visits and $40 for completion of 3-month follow-up assessment. Patients at the JBLM site were not compensated for their time per U.S. Army regulations. Active-duty participants were provided with medical appointment permission slips to allow them time to attend treatment sessions outside of normal duties, including time to return home if randomized to the in-home condition.

The CONSORT chart in Figure 1 shows the progression of participants through the study phases. A total of 92 participants met all inclusion criteria and were randomized at the military site and 29 were randomized at the VA site. Participants were randomized to treatment condition in a 1:1 ratio using permuted blocks of size 10, stratified by baseline major or minor depressive disorder diagnosis and study site using Stata 12.1 (StataCorps, 2013). A suicide assessment and risk management standard operating procedure (SOP) used at Madigan Army Medical Center was used to assess and document current ideation, presence of a plan, suicidal intent, history of previous attempts and degree of impulsivity. Risk correlates (e.g., recent loss, financial problems), preparatory behavior (e.g., available means), and other risk factors (e.g., substance dependence) were also assessed and documented. The SOP was administered at the baseline assessment, the first treatment session, and readministered at each subsequent session if a patient endorsed current elevated risk per the SOP.

Participants randomized to the in-home condition were provided with a Dell M6500 laptop computer and Tandberg Precision High-Definition Webcam. The lap-tops were preloaded with Jabber video software (Cisco Systems). This software was selected because its level of security and encryption is approved for use by the U.S. Army and the VAPHCS. Participants randomized to the in-home condition were scheduled for a brief test of the VC software and equipment prior to initiation of the first treatment session.

Treatment Protocol

An eight-session BATD protocol that has been successfully delivered both in-person and VC in the past was used as the study's intervention (Cuijpers et al., 2008). Session 1 was devoted to psychoeducation, the treatment rationale, and intro-

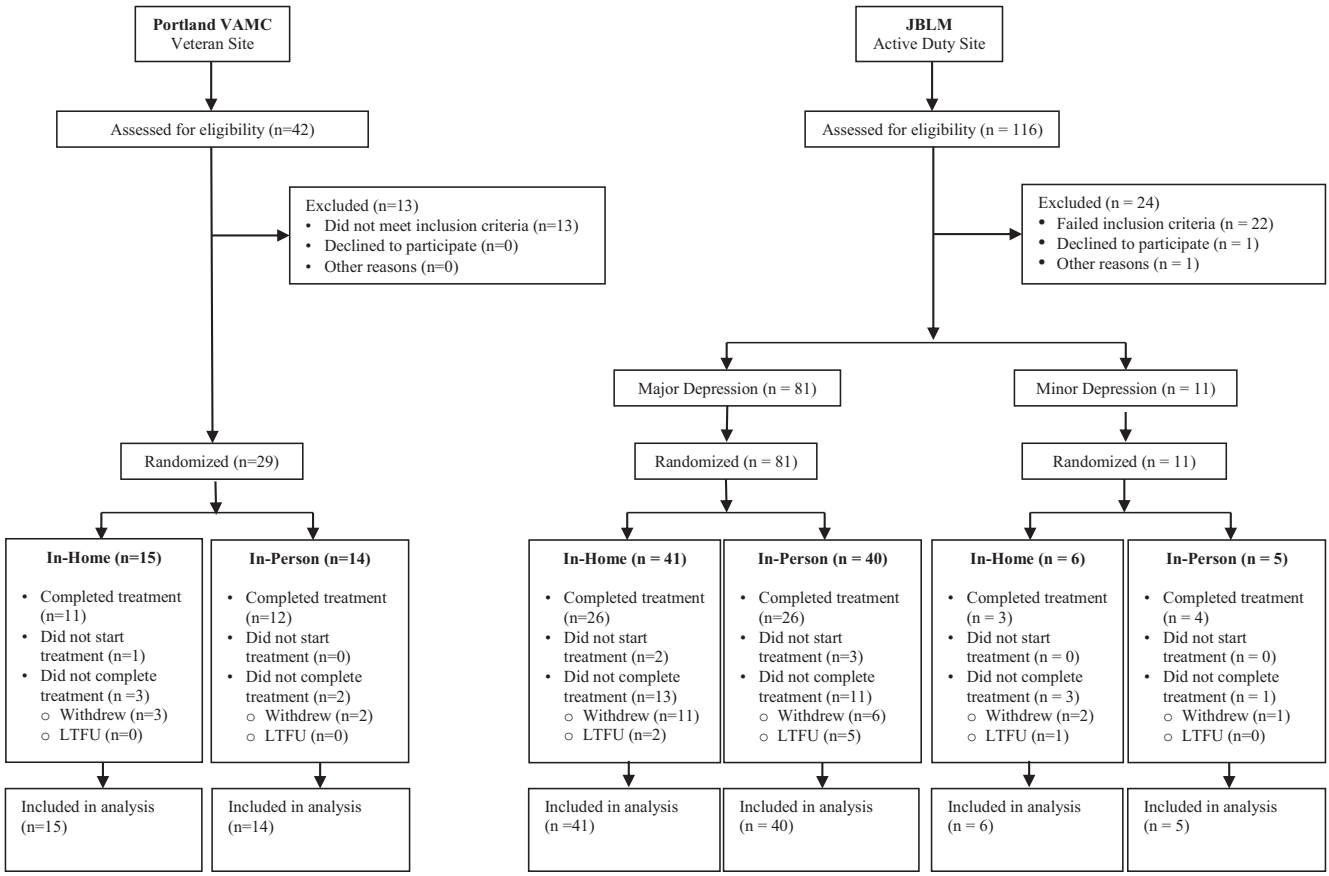

Figure 1. CONSORT diagram. VAMC = VA Medical Center; JBLM = Joint-Base Lewis McChord; LTFU = Lost to follow-up.

duction of the concept of daily activity monitoring. Session 2 focused on identifying goals/values across five different major life domains (i.e., relationships, education/career, recreation/interests, mind/body/spirituality, and daily responsibilities). Sessions 3 through 8 were focused on activity planning consistent with these goals/values. Activity planning is the process of collaboratively selecting and scheduling activities consistent with one's values that have a high likelihood of invoking positive mood or functional outcomes (i.e., are reinforcing to the individual). For example, if a patient identifies commitment to his or her marriage as a value, specific activities may involve scheduling a "date night," stopping to buy flowers on the way home from work, and helping with the dishes after dinner.

Both groups received the same BATD treatment for 50-60-min sessions every week for 8 weeks with clinical assessments conducted at baseline, 4-week midpoint, 8-week treatment completion, and 3-month follow-up. There were five treatment providers (4 at JBLM and 1 at PVA), all were doctoral-level mental health providers who received training from a BATD expert and consultant. Fidelity review was conducted by the BATD expert who reviewed video-recordings of a randomly selected 10% of all treatment sessions. The fidelity reviews confirmed an overall adherence of 98.19% for all clinicians providing treatment.

Measures

The Beck Hopelessness Scale (BHS; Beck, Weissman, Lester, & Trexler, 1974) and the Beck Depression Inventory II (BDI-II; Beck, Steer, & Brown, 1996) served as the primary outcomes for the noninferiority objectives of the trial. The strong association between hopelessness and suicide risk (Beck, Brown, Berchick, Stewart, & Steer, 1990) made measurement of hopelessness a viable indicator of safety. The BDI-II also provides for an assessment of safety as significant symptom worsening could reflect adverse effects of the treatment modality. Other clinical outcomes including depression diagnosis, PTSD severity, and anxiety severity were analyzed as secondary outcomes along with assessment of technical and safety events during the trial. Safety events were not anticipated to occur with sufficient regularity to allow statistical hypothesis testing. All of the outcome measures and checklists administered in the trial are described below. Estimates of internal consistency reliability for scale measures, by assessment time and treatment group, are provided in the tables.

BHS (Beck, Weissman, Lester, & Trexler, 1974). The BHS comprises 20 true–false statements relating to feelings of hopelessness about the future. After reverse-scoring several items, sum

scores are calculated with a possible range of 0 to 20, with higher scores indicating higher levels of hopelessness.

BDI-II (Beck, Streer, & Brown, 1996). The BDI-II comprises 21 items with four response categories for each item. Sum scores are calculated with a possible range of 0 to 63, with higher scores indicating higher levels of depression symptom severity.

SCID-I/P (First et al., 2002). The SCID-I/P was used for initial diagnostic/screening purposes and at follow-up assessments for the presence of MDD. The SCID-I/P has excellent established interrater reliability (overall $\kappa = 0.85$).

Beck Anxiety Inventory (BAI; Beck & Steer, 1990). The BAI is a self-report measure consisting of 21 items designed to discriminate anxiety from depression. Similar to the BDI-II, the sum scores range from 0 to 63.

PTSD Checklist—Military version (PCL-M; Weathers, Huska, & Keane, 1991). The PCL-M is a self-report measure that evaluates all 17 *DSM–IV–TR* PTSD symptoms across the three primary symptom clusters using a 5-point Likert-type scale. A total score of 50 typically serves as the threshold for identifying probable PTSD among those reporting military related trauma(s).

Inventory of Attitudes Toward Seeking Mental Health Services (IASMHS; Mackenzie, Knox, Gekoski, & Macaulay, 2004). The IASMHS is a 24-item assessment of help-seeking attitudes. It includes the following three factors based on components of Ajzen's Theory of Planned Behavior (Ajzen, 1985): psychological openness, help-seeking propensity, and indifference to stigma. Test–retest reliability for the factors ranges from moderate to high. Convergent validity has been demonstrated by effectively differentiating those who would and would not use services. The IASMHS was completed at baseline, posttreatment, and follow-up.

Client Satisfaction Questionnaire (CSQ; Nguyen, Attkisson, & Stegner, 1983). 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, with a possible 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. The CSQ was administered at posttreatment.

Treatment session checklist (Luxton et al., 2014). Safety-related data were recorded after each treatment session on the treatment session checklist (see Luxton et al., 2014). This checklist is designed to collect information for the evaluation of clinical telehealth sessions. It is used to document pertinent safety information including current suicidal ideation, homicidal ideation, the presence of a firearm at the patient's location, and signs of intoxication, disorientation, and severe emotion dysregulation. There are also questions related to the in-home environment, 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 network connectivity status, lighting, and any disruptions to assess technical feasibility.

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

Sample Size

Sample size was estimated using a medium effect size value of Cohen's $f^2 = 0.15$, a one-tailed $\alpha = .05$, and $\beta = 0.80$ based on the BHS. This resulted in a requirement of 54 subjects per study group. Assuming a 10% attrition rate, this number was adjusted to 60 subjects per group with up to 150 participants approved by the IRB. Prior to start of the trial, only the BHS was specified as the primary outcome for the noninferiority analyses. Given that the treatment is for depression, the BDI was respecified from a secondary outcome to a primary outcome for additional noninferiority analyses prior to treatment condition unblinding and data analysis. The noninferiority margin (δ) was identified as a standardized difference of 0.50 (see Luxton et al., 2014). A recalculation of sample size for this outcome measure identified that with $\delta = 0.50$, an expected difference between groups (θ) = 0, a one-sided $\alpha = .05$, and $\beta = 0.80$, 49 subjects would be required per study group to reject the null hypothesis that any differences were greater than or equal to δ. These parameters are consistent with recommendations for noninferiority trials (e.g., Mohr et al., 2012; Nutt, Allgulander, Lecrubier, Peters, & Wittchen, 2008). However, Greene and colleagues (2008) have recommended $\beta = 0.90$ and a two-tailed alpha of 0.05, which we considered for post hoc analysis. The original target sample size was not changed.

Statistical Methods

We used linear mixed-effect regression models to estimate differences in the means of the primary outcome measures over time (Singer & Willett, 2003). We included treatment assignment in the model as a binary indicator and measurement time as a 4-level nominal variable. All analyses used the baseline assessment as the referent time point. Statistical inference on the difference between treatment groups at all assessment times post baseline was based on the treatment by time interaction terms included in the models. Primary inference was focused on the postassessment measurement time. We used the square root of the sum of the random intercept variance and the residual variance as the estimate of baseline variation for the purposes of standardization. Rejection of the null hypothesis was indicated by the upper bound of the standardized 90% confidence interval falling below 0.50. For both primary outcomes, we examined an intent-to-treat and a per-protocol (treatment completer) model. All models were estimated using restricted maximum likelihood in Stata 12.1 (StataCorps, 2013).

We also used the linear mixed-effects regression model to analyze the secondary outcomes of the BAI, the PCL-M, and the IASMHS. Because these measures were not hypothesized as measures for noninferiority, we used 95% confidence intervals to evaluate differences between the treatment groups. For the SCID-I/P assessment of major depressive disorder, the outcome used in analysis was a binary indicator for meeting or not meeting the criteria. As such, we used a population-averaged logistic model to compare the treatment groups in terms of change in the prevalence of the diagnosis over time. For the CSQ, we used a Student's t test to compare the means at posttreatment. There were no planned statistical analyses for descriptive data on the occurrence of adverse events and the initiation of the safety protocol data given the low expected rate of occurrence.

Post hoc analyses. Post hoc analyses included the estimation of the primary outcome regression models with demographic covariates and with restrictions to just the active military sample or to participants with an initial diagnosis of major depressive disorder to examine the influence of sample heterogeneity on inference. We also examined the results of the primary outcome models using 95% confidence intervals (CIs) to determine if conclusions of treatment inferiority were warranted.

Missing data. Missing data occurred predominantly in a monotonic fashion as a function of treatment withdrawal or loss to follow-up. The regression models described above allowed us to retain all participants who provided data at baseline irrespective of data availability at subsequent assessment times. The assumption of this modeling strategy is that the data are at least missing at random. We used a logistic regression model to estimate the association between dropout and a vector of baseline outcome scores and demographic factors to evaluate this assumption. As a sensitivity analysis, we used latent curve models to estimate a selection model of dropout that assumes data missing not at random (Enders, 2010). In this model, we simultaneously estimated the growth curve parameters for the outcome from baseline to posttest using a linear specification of change over time and logistic models of dropout at the mid- and postassessment times. Antecedents of the dropout indicators were treatment assignment, the outcome score at that measurement occasion, and the outcome scores of the preceding measurement occasion. We used M*plus* 7.1 (Muthén & Muthén, 2012) to estimate the selection models.

Results

Study Completion

The demographic characteristics and outcome measures of the trial study participants are displayed in Table 2. A total of 40 participants completed all eight sessions in the in-home condition and 42 completed all eight sessions in the in-office condition for a total attrition rate of 32.23%. In the in-home condition, there were 16 withdrawals, three losses to follow-up, and three who did not begin treatment. In the in-person condition, there were nine withdrawals, five losses to follow-up, and three who did not begin treatment. The difference in proportions of subjects that did not complete treatment between the groups was not statistically significant (in-home = 35.48%, in-person = 28.81%, $\chi^2 = 0.62$, $df = 1$, $p = .433$). Baseline scores on the BHS and the BDI-II were not associated with dropout. None of the demographic variables were associated with dropout except race; however, the category that showed the strongest association with dropout was the "other" category which included only 10 participants. This evidence suggested that missing at random was a reasonable assumption for analysis.

Table 2
Baseline Demographic Characteristics and Outcome Measures of the Trial Study Subjects, by Treatment Assignment

Variable	In home		In person	
	n	%	*n*	%
Age				
19–24	12	19.35	10	16.95
25–29	16	25.81	12	20.34
30–34	13	20.97	11	18.64
35–39	4	6.45	9	15.25
40–49	6	9.68	8	13.56
50–65	11	17.74	9	15.25
Sex				
Male	52	83.87	47	79.66
Female	10	16.13	12	20.34
Race/ethnicity				
White, non-Hispanic	44	70.97	41	69.49
Black, non-Hispanic	8	12.90	10	16.95
Asian, non-Hispanic	3	4.84	1	1.69
Native American, non-Hispanic	1	1.61	0	.00
Hispanic, any race	3	4.84	7	11.86
Other/unknown	3	4.84	0	.00
Education				
High school	13	20.97	16	27.12
Some college	32	51.61	24	40.68
2-year college	8	12.90	13	22.03
4-year college	9	14.52	6	10.17
Years of military service				
1–2 years	9	14.52	14	23.73
3–4 years	14	22.58	12	20.34
5–8 years	15	24.19	12	20.34
9–20 years	21	33.87	19	32.20
21–34 years	3	4.84	2	3.39
Highest pay grade				
E1–E4	30	48.39	26	44.07
E5–E9	29	46.77	29	49.15
Officer	3	4.84	4	6.78
Any deployment history				
No	14	22.58	15	25.42
Yes	48	77.42	44	74.58

Note. Pay grades are separated by junior enlisted (E1–E4), senior enlisted (E5–E9), and officers.

Primary Outcomes

Table 3 displays the results for the intent-to-treat and per protocol analyses for both the BHS and the BDI-II. At posttreatment, participants in the in-person group had an average reduction of 6.21 points on the BHS (95% CI = −7.38, −5.05) and 17.63 points on the BDI-II (95% CI = −20.21, −15.06). Participants in the in-home group had an average reduction of 3.91 points on the BHS (95% CI = −5.25, −2.57) and 13.40 points on the BDI-II (95% CI = −16.36, −10.44). For both outcomes, the magnitude of decrease over time was less pronounced for the in-home group compared to the in-person group. After standardization of the difference between the groups at postassessment, we found that the upper bound of the 90% confidence interval included 0.50. The per protocol (treatment completer) analysis provided similar results; however, the point estimates were somewhat greater in magnitude than those from the intent-to-treat analysis. There were not any differences in baseline means on the primary outcomes between treatment completers and noncompleters (BHS: Completer [$n = 82$, M = 9.82, $SD = 5.94$], Noncompleter [$n = 39$, M = 9.36, $SD = 5.05$], $t = 0.42$, $df = 119$, $p = .679$; BDI: Completer [$n = 82$, M = 28.21, $SD = 11.80$], Noncompleter [$n = 39$, M = 29.51, $SD = 8.77$], $t = -0.68$, $df = 97.60$, $p = .497$). See Figures 2 and 3 for a graphic display of the point estimates and confidence intervals against the noninferiority margin.

Table 3
Intent-to-Treat and per-Protocol Analyses and Internal Consistency Reliability Estimates of the BHS and BDI-II Against a Noninferiority Margin of a Standardized Difference of .50

Outcome and time	In home			In person						
	n	*M* (*SD*)	α	*n*	*M* (*SD*)	α	*b*	90% CI	*B*	90% CI
Intent to treat										
BHS										
Pre	62	9.00 (5.12)	.88	59	10.37 (6.13)	.92	Ref.		Ref.	
Mid	48	7.21 (5.66)	.88	44	7.95 (6.26)	.94	1.29	−.30, 2.88	.22	−.05, .50
Post	45	4.89 (4.64)	.90	42	4.43 (4.94)	.92	2.30	.68, 3.92	.40	.12, .68
Follow-up	42	5.21 (5.10)	.92	36	5.53 (5.97)	.94	1.63	−.05, 3.32	.28	−.01, .58
σ = 5.77										
ICC = .64										
BDI										
Pre	62	27.60 (10.45)	.88	59	29.71 (11.33)	.89	Ref.		Ref.	
Mid	47	19.40 (11.77)	.93	44	20.20 (13.09)	.93	1.70	−1.81, 5.22	.14	−.15, .44
Post	45	13.82 (12.02)	.94	42	11.74 (12.08)	.95	4.23	.66, 7.81	.36	.06, .66
Follow-up	42	14.76 (12.89)	.95	36	15.00 (12.61)	.93	1.89	−1.84, 5.61	.16	−.16, .48
σ = 11.78										
ICC = .60										
Per protocol										
BHS										
Pre	40	8.58 (5.38)	.90	42	11.00 (6.27)	.93	Ref.		Ref.	
Mid	40	7.28 (5.67)	.87	42	7.55 (6.09)	.93	2.15	.43, 3.87	.39	.08, .70
Post	40	4.63 (4.42)	.89	42	4.43 (4.94)	.92	2.62	.90, .43	.47	.16, .78
Follow-up	38	4.82 (4.99)	.92	36	5.53 (5.97)	.94	1.90	.12, 3.68	.34	.02, .67
σ = 5.53										
ICC = .63										
BDI										
Pre	40	26.65 (11.80)	.90	42	29.69 (11.74)	.90	Ref.		Ref.	
Mid	39	18.97 (11.89)	.93	42	19.12 (12.04)	.92	2.74	−1.08, 6.56	.22	−.09, .54
Post	40	13.63 (12.47)	.95	42	11.74 (12.08)	.95	4.93	1.12, 8.73	.40	.09, .71
Follow-up	38	14.58 (13.18)	.95	36	15.00 (12.61)	.93	2.64	−1.29, 6.58	.22	−.11, .54
σ = 12.23										
ICC = .63										

Note. BHS = Beck Hopelessness Scale; BDI-II = Beck Depression Inventory—II; *b* = unstandardized difference between in-home and in-person treatment groups; CI = confidence interval; *B* = standardized difference between in-home and in-person treatment groups using the baseline standard deviation (σ); Ref. = reference; ICC = intraclass correlation (time nested within subject).

Secondary Outcomes

Table 4 presents the results of the analyses of the additional outcome measures. At baseline, 56 participants (90.32%) in the in-home group and 54 in the in-person group (91.53%) met SCID-I/P criteria for major depressive disorder. At posttreatment, there were 8 participants in the in-home group (17.78%) and 6 in the in-person group (14.29%) who met criteria for major depressive disorder. The difference in reduction of the number of participants meeting criteria for major depressive disorder was not statistically significant ($b = 0.33$, 95% CI = −1.22, 1.88). By the 12-week follow-up, 4 participants in the in-home group (9.52%) and 8 in the in-person group (22.22%) met criteria for major depressive disorder. This difference was also not statistically significant ($b = -0.89$, 95% CI = −2.54, 0.77). Participants in both treatment groups reported reductions in anxiety and posttraumatic stress symptoms and in mental health treatment stigma as measured by the IASMHS. There were no statistically significant differences between the treatment groups on these outcomes. Average scores on the CSQ suggested a high level of treatment satisfaction for both treatment groups. There was no statistically significant difference between the treatment groups on the CSQ.

Post Hoc Analysis

We did not identify a large change in the magnitude of the differences between the treatment groups when including demographic covariates in the model or when restricting the analytic sample to those at the MTF site and those with an initial major depressive disorder diagnosis. This suggested that the conclusions from the primary models were robust to the heterogeneity introduced by including veterans and participants with minor depression into the study sample. However, given the small number of veterans and participants in the sample, we were not able to formally test for effect measure modification in the association between treatment and the primary and secondary outcomes.

Using the 95% confidence interval (CI) as opposed to the 90% confidence interval allowed for a two-tailed test of noninferiority and inferiority. The 95% CI for the unstandardized difference on the BHS ranged from 0.33 to 4.20 for the intent-to-treat analysis and from 0.57 to 4.67 for the per-protocol analysis, both of which suggested that the in-home method of delivery was inferior to the in-person method of delivery. The post hoc power for the intent-to-treat analysis was 0.81. The

95% confidence intervals for the unstandardized differences on the BDI ranged from −0.03 to 8.50 and from 0.40 to 9.46 for the intent-to-treat and per-protocol analyses, respectively. Since the confidence interval for the intent-to-treat analysis covered 0, the results were inconclusive as to inferiority of the in-home method of delivery on treatment efficacy. The post hoc power for the intent-to-treat analysis of the BDI-II was 0.69. The results of the selection model are presented in Table 5. Dropout by the mid- and posttreatment assessments was not associated with treatment assignment, prior outcome scores, or the current outcome scores. Estimates of the treatment differences at mid- and posttreatment for the BHS and the BDI-II were similar to those presented in Table 3 for the intent-to-treat models. These findings further supported an assumption of data at least missing at random. There were seven participants who had adverse events that required reporting in the in-home group and four in the in-person group. None of these adverse events (e.g., a severe exacerbation of asthma symptoms) were determined to be related to study procedures. The safety protocol was initiated one time; this occurred for a military service member in the in-home condition who contacted his study provider and presented in-person to the research staff. The participant reported that he was experiencing distress and had underreported baseline level of suicidal ideation during the intake assessment. The patient was assessed by a supervisory psychologist and escorted to the emergency department for further evaluation as per the established safety protocol. Additional description of suicide risk management used in the trial is provided by Luxton et al. (2014).

Of the 378 treatment sessions completed in the in-home group, there were 190 (50.26%) VC connectivity issues including the inability to initiate a Webcam connection (n = 137, 36.34%) and the inability to maintain a Webcam connection once initiated (n = 66, 20.31%). Overall, 135 (35.71%) treatment sessions required a phone call to resolve a technical issue or to complete all or a portion of the session's activities because of technical problems. Technical problems in the first two treatment sessions were associated with subsequent drop out over the first two treatment sessions (Session 1 odds ratio [OR] = 8.74, 95% CI = 1.09, 70.21; Session 2 OR = 6.27, 95% CI = 1.16, 33.80). The number of treatment sessions in which technical problems were experienced was not associated with the amount of change in either of the primary outcomes.

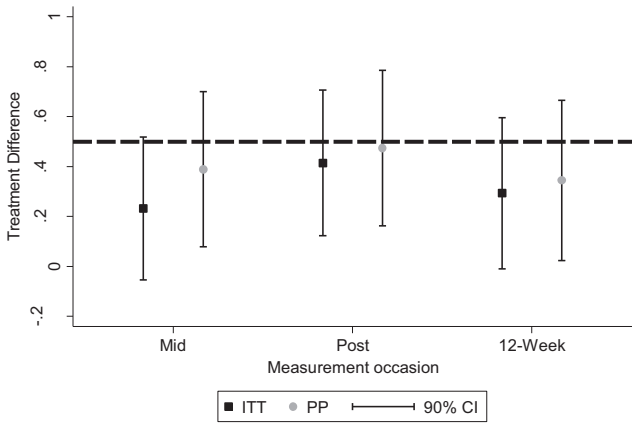

Figure 2. Intent-to-treat (ITT) and per-protocol (PP) assessment of non-inferiority on the Beck Hopelessness Scale at each measurement occasion using a 90% confidence interval (CI). Dashed black line is the non-inferiority margin.

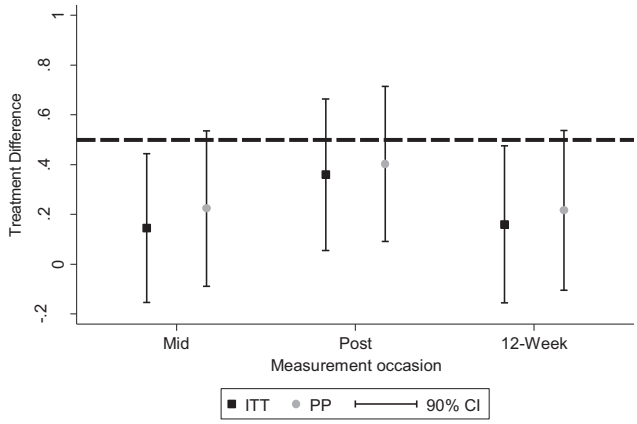

Figure 3. Intent-to-treat (ITT) and per-protocol (PP) assessment of non-inferiority on the Beck Depression Inventory at each measurement occasion using a 90% confidence interval (CI). Dashed black line is the non-inferiority margin.

Discussion

This study is the first randomized controlled trial of HBTBH conducted specifically in the U.S. military setting. The results provide important information about the feasibility, safety, and clinical efficacy of a HBTBH treatment that can inform policy decisions about the expansion of behavioral health treatment options for service members and for veterans.

The results of the present trial did not demonstrate noninferiority of HBTBH compared to in-person treatment based on BHS and BDI-II scores. The post hoc analysis that used a 95% confidence interval showed the in-home treatment modality was inferior and not noninferior according to the scores from the BHS. Also, because the 95% confidence interval for the comparison of the BDI-II included zero, we cannot make a strong conclusion about the inferiority of the treatment on this measure. We therefore cannot conclude from the noninferiority analyses that in-home BATD is as safe as in-office care based solely on the relative differences in BHS and BDI scores between these treatment conditions. It is important to emphasize that significant reductions in depression symptoms and hopelessness were observed across both groups. Similar improvement was also observed on measures of PTSD symptoms, and anxiety. While the absence of a nontreatment control (i.e., a waitlist control) precludes examination of whether improvement was directly attributable to treatment, the overall improvement in clinical outcomes suggests that at least part of the improvement was due to the BATD Treatment.

All safety procedures were successfully implemented and there was not any evidence of clinical worsening in the in-home condition to suggest that in-home care was less safe than traditional in-office care. These results provide evidence of the

Table 4
Intent-to-Treat Analysis and Internal Consistency Reliability Estimates of Secondary Outcomes

	In home			In person					
Outcome and time	*n*	*M* (*SD*)	α	*n*	*M* (*SD*)	α	*b*	95% CI	*B*
BAI									
Pre	62	15.48 (10.40)	.90	59	16.85 (12.92)	.94	Ref.		Ref.
Mid	48	12.21 (9.75)	.91	44	13.00 (10.98)	.93	1.29	−2.23, 4.82	.12
Post	45	9.71 (8.67)	.90	42	8.31 (9.11)	.92	3.13	−.46, 6.74	.30
Follow-up	42	11.10 (8.63)	.88	36	9.75 (8.95)	.92	3.10	−.64, 6.84	.29
σ = 10.56									
ICC = .65									
PCL-M									
Pre	62	43.15 (13.53)	.91	59	45.17 (14.75)	.92	Ref.		Ref.
Mid	48	37.60 (13.82)	.92	44	37.41 (16.24)	.95	2.20	−2.18, 6.58	.15
Post	45	33.16 (14.69)	.94	42	32.43 (16.58)	.96	2.14	−2.33, 6.61	.15
Follow-up	42	35.05 (14.57)	.93	36	34.39 (14.72)	.93	2.26	−2.39, 6.91	.15
σ = 14.67									
ICC = .72									
IASMHS									
Pre	62	35.23 (14.40)	.83	59	31.47 (14.33)	.83	Ref.		Ref.
Post	45	27.07 (14.98)	.87	42	21.88 (13.75)	.85	1.53	−3.46, 6.52	.10
Follow-up	42	28.33 (17.31)	.91	36	23.69 (16.57)	.90	.24	−4.97, 5.44	.02
σ = 15.16									
ICC = .68									
CSQ									
Post	45	28.76 (3.41)	.91	42	29.29 (3.98)	.92	−.53	−2.11, −1.05	−.14

Note. *b* = unstandardized difference between in-home and in-person treatment groups; CI = confidence interval; *B* = standardized difference between in-home and in-person treatment groups using the baseline standard deviation (σ); ICC = intraclass correlation (time nested within subject); BAI = Beck Anxiety Inventory; Ref. = reference; PCL-M = PTSD (Posttraumatic Stress Disorder) Checklist—Military; IASMHS = Inventory of Attitudes Toward Seeking Mental Health Service; CSQ = Client Satisfaction Questionnaire.

safety and feasibility of HBTMH in the MHS and VHA health care systems.

The present study has several limitations that could be addressed in future evaluations of HBTBH. The sample size was insufficient to fully address the questions of noninferiority and inferiority/superiority of HBTMH.[1] Future evaluations would benefit from larger samples based on an established noninferiority margin and consideration of trivial differences in point estimates. The relatively low depression scores of both groups at baseline as well as the relatively low count of participants with minor depressive disorder and their inclusion at just one of the two sites are also limitations. Moreover, the inclusion/exclusion criteria limited the level of risk of the enrolled participants and the study was not powered to detect a sufficient number of safety events to make a statistical inference about safety solely based on the number of safety events. Much larger program evaluations of HBTBH provide an opportunity to further examine factors associated with patient safety and clinical outcomes with more diverse clinical profiles. The use of standardized metrics, such as those proposed by the American Telemedicine Association (Shore et al., 2014), are recommended to standardize data collected by clinics across the MHS including clinical outcomes, patient satisfaction, and preferences for TBH care.

The results also provide useful information about the technical and logistical feasibility of HBTBH in the military setting. The legitimate need to protect government information systems while connecting to external computer systems and commercial Internet service providers can create technical issues that need to be addressed before widespread implementation. This issue is of relevance to any health care system that utilizes a secured network. While the present evaluation provided a level of control over the technical aspects (supplied lap-top and camera), real-world applications of HBTBH need to consider use of personally owned equipment (Luxton et al., 2015). Also, clinical appointments were conducted during standard work hours (between the hours of 8:00 a.m. and 3:00 p.m., Monday through Friday). While these hours are typical for standard care in the VHA and MHS, and were appropriate for the execution of the study, this type of schedule does not capture the added flexibility and conveniences of HBTBH.

One of the many benefits of in-home care is the ability to provide clinical services without the patient having to depart from their home environment. In the present study, the military participants were very often at work before their appointment, went home for the appointment, and sometimes returned to work following their appointment. Future TBH programs, such as through the MHS's Telebehavioral Health Clinics, could employ providers on various shifts (after hours or in different time zones) so that care can be provided more efficiently to patients while at home.

[1] A post hoc sample size recalculation based on a power level of 0.90 and a two-tailed alpha of 0.05 (Greene et al., 2008) accounted for a difference between group means (θ) of up to 0.20, a margin of 0.50, and an intraclass correlation of 0.50 would have yielded a sample size of 176 subjects per treatment group. Since the observed mean differences for both outcomes exceeded a small effect size of 0.20, it is likely that we would still fail to reject the null hypothesis of inferiority in excess of the margin.

Table 5
Estimates From a Selection Model of Dropout on the BHS and the BDI-II

Model parameter	BHS *b* (*SE*)	BDI-II *b* (*SE*)
Intercept	11.73 (1.72)	31.77 (3.17)
In home	−1.32 (1.03)	−2.20 (1.98)
Slope	−4.26 (.85)	−10.93 (1.90)
In home	1.12 (.49)	2.11 (1.19)
Drop by midassessment[a]		
In home	−.13 (.44)	−.17 (.44)
Baseline	.02 (.05)	−.01 (.03)
Mid	−.05 (.05)	.02 (.04)
Drop by postassessment[a]		
In home	.65 (1.02)	.78 (.81)
Mid	.19 (.20)	.12 (.11)
Post	−.19 (.58)	−.08 (.11)

Mean difference	*b* (90% CI)	*B* (90% CI)	*b* (90% CI)	*B* (90% CI)
Mid	1.12 (.31, 1.93)	.20 (.05, .34)	2.11 (.15, 4.08)	.19 (.02, .37)
Post	2.24 (.62, 3.85)	.39 (.11, .68)	4.23 (.30, 8.15)	.38 (.03, .73)

Note. BHS = Beck Hopelessness Scale; BDI-II = Beck Depression Inventory—II; *b* = unstandardized regression coefficient; *B* = regression coefficient standardized to baseline standard deviation; CI = confidence interval.
[a] Modeled using a logistic link function and a binomial error distribution.

The present study adds to a growing literature base of studies that generally support the feasibility and effectiveness of providing behavioral health treatments to the home or other settings (e.g., clinics) via telehealth technologies. (Hilty et al., 2013). These studies have also generally supported evidence of patient satisfaction with TBH care (Jenkins-Guarnieri, Pruitt, Luxton, & Johnson, 2015). Conclusions regarding the feasibility, safety, and efficacy of TBH to the home or any setting should consider the extant data that is available, including future results from trials that are presently underway (e.g., Acierno, 2016). Also, economic evaluations of TBH, particularly HBTBH, are needed to assist with decision making regarding implementation of HBTMH in the MHS (Luxton, 2013).

In conclusion, TBH services provided to the home or other locations have the potential to address current and future health needs of military service members and veterans, especially for those who live in rural or underserved areas. While the results of the present trial did not demonstrate noninferiority of HBTBH compared to in-person treatment based on BHS and BDI-II scores, the overall results provide valuable information about the safety and feasibility of HBTMH in the MHS and VHA settings. The benefits of home-based care also extend to family members or other caregivers who may otherwise share the financial burden and inconvenience of assisting with travel to health care services. The value of home-based treatment lies in its potential to increase access to care for a population that has a well-documented history of low treatment-seeking behavior and other barriers to overcome (e.g., stigma, frequent relocations, deployment, and highly demanding work duty). The bottom line is that home-based care is a viable option, especially when traditional in-office care is less practical.

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