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14. ABSTRACT Evidence of feasibility, safety, and effectiveness of home-based telebehavioral health (HBTBH) needs to be established before adoption. The purpose of this randomized controlled non-inferiority 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. One hundred and twenty one U.S. military service members and veterans were recruited at a military treatment facility and a Veterans Health Administration (VHA) hospital. Participants were randomized to one of two groups to receive either eight sessions of behavioral activation treatment for depression (BATD) in the home via videoconferencing (VC) or in a traditional in-office setting. Participants were assessed at baseline, mid-treatment, post-treatment and 3 months post treatment. Mixed-effects modeling suggested relatively strong and similar reductions in hopelessness and depressive symptoms for both groups; however, non-inferiority 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, and safety procedures were successfully implemented. 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.					
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Introduction

The primary aim of this trial was to evaluate the safety and feasibility of providing military service members and veterans with home-based telebehavioral health (HBTBH) care by comparing it to conventional in-office care. 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 (Seal et al., 2009; Corson et al., 2013). 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). We selected behavioral activation (BATD; Lejuez, Hopko, Acierno, Daughters, & Pagoto, 2011) as the target treatment for the present trial. Behavioral activation treatment for depression (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, Frueh, Richardson, et al, 2009).

A non-inferiority design was used, 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 telebehavioral health (TBH) studies with 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 additionally 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.

Key Words

Behavioral Activation (BA) Cognitive Behavioral Therapy (CBT)

Depression

Military

Post-Traumatic Stress Disorder (PTSD)

Randomized Controlled Trial (RCT)

Telehealth

Body

Overview (Pilot)

A preliminary study was conducted to evaluate the feasibility and safety of providing U.S. military service members with a behavioral health treatment delivered directly to the home using videoconferencing. Ten previously deployed soldiers volunteered to complete eight sessions of a novel behavioral activation treatment for posttraumatic stress disorder. The primary clinical outcomes assessed included symptoms of posttraumatic stress and depression. Patient safety data and attitudes about seeking mental health services, treatment satisfaction, treatment adherence, and treatment compliance were also assessed. Clinically significant reductions

in posttraumatic stress symptom severity and depression symptoms were observed. Soldiers indicated high levels of satisfaction with the treatment, and there were no adverse events requiring activation of emergency safety procedures. Technical problems associated with the network were observed but successfully mitigated. The results provided initial support for the feasibility and safety of telemental health treatments delivered by videoconferencing to the homes of soldiers. However, the optimal technical infrastructure to support expansion of synchronous videoconferencing capabilities to the home was identified as an issue but not resolved. The findings provide preliminary evidence for the feasibility, safety, and high user satisfaction with home-based telemental health in the military setting.

The objectives of the Pilot study were as follows:

1. Evaluate the safety of an in-home, web-based BA treatment as an intervention for PTSD.
2. Determine the effectiveness of in-home BA as treatment for PTSD delivered via a webcam.
3. Monitor PTSD symptoms to determine if there is an association between BA treatment and reductions in PTSD symptomatology.
4. Examine patient compliance, treatment satisfaction, and overall feasibility of the web-based intervention.
5. Identify best practices to guide the implementation of other web-based tele-mental health interventions.

The hypotheses of the Pilot study were as follows:

1. Participants in the in-home web care treatment condition will show improved PTSD scores at treatment end.
2. BA treatment for PTSD delivered in-home will be safe.

Participants

The sample consisted of 10 active duty members of the U.S. 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 an initial screening interview. To be eligible for the study, participants had to endorse experiencing at least one criterion A stressor and have a score of 45 or higher on the Clinician Administered PTSD Scale (CAPS). The cutoff score of 45 has been used in other studies (Blanchard et al., 1996; Weathers, Huska, & Keane, 1991). Participants taking any psychoactive medications had to have maintained a stable regimen for a minimum of 30 days prior to study entry.

Recruitment

Enrollment was open to all volunteers who met inclusion criteria. A total of 10 participants were recruited from among all service Members presenting at- or referred to- Behavioral Health Service clinics at Joint Base Lewis-McChord. Participants included service members from all Service branches; primarily Army, National Guard, and Reserves.

Additionally, participants that did not meet full criteria for inclusion in the IRB approved study “Comparing Virtual Reality Exposure Therapy to Prolonged Exposure in the Treatment of Soldiers with PTSD” (VRET; IRBnet # 112226-17, Gahm PI) were referred to this study for assessment. Participants in the VRET study were also selected from among all Soldiers presenting or referred to the Behavioral Health Service for treatment of PTSD.

All participants met diagnostic criteria for PTSD as assessed by the CAPS. The Diagnostic and Statistical Manual of Mental Disorders DSM-IV-TR research criteria for these disorders were used. This study required a CAPS score between 45 and 65 (moderate PTSD symptom severity). Participants must not have been undergoing any other treatment for PTSD.

Outcome Measures

Screening. Outcomes were assessed at the baseline, mid-treatment, post-treatment, and 3-month post-treatment assessments. All assessments were video recorded and reviewed regularly by a supervisory

psychologist. The following measures were assessed:

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 (CAPS; Blake, et al., 1996). 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 1-month symptom duration, was used for the baseline and follow-up assessments. The CAPS One Week Version, which measures symptoms over the past week, was used to assess participants after treatment sessions 4 and 8. PTSD severity, measured by the CAPS (total score), served as the primary PTSD outcome. Assessors were trained in the administration of the CAPS and possessed prior experience with this measure. Feedback was provided on an as needed basis to improve compliance with CAPS administration rules.

PTSD Checklist Military Version (PCL; Blanchard et al., 1996; Weathers, Huska, & Keane, 1991). The PTSD Checklist-17 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 (0.97), as are reliability estimates (0.96). The PTSD Checklist Military Version (PCL-M) is used here. 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, Streer, & Brown, 1996). The Beck Depression Inventory-II (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 and that yield a range of scores from 0 to 63.

Beck Anxiety Inventory (BAI; Beck & Streer, 1990). The Beck Anxiety Inventory (BAI) is a self-report measure consisting of 21 items designed to discriminate anxiety from depression. It has high internal consistency (0.92) and 1-week test–retest reliability (0.75) and discriminates anxious from non-anxious diagnostic groups.

Pittsburgh Sleep Quality Index (Buysse, et al., 1989). The Pittsburgh Sleep Quality Index (PSQI) 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 0.80, with a reliability coefficient of 0.83 and test–retest reliability of 0.87.

Safety measures. Safety data collected included any adverse events, psychiatric hospitalizations, suicides and nonfatal 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. We also followed the 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. Risk correlates (e.g., recent loss, financial problems), preparatory behavior (e.g., available means), and other risk factors (e.g., substance dependence) are also assessed and documented. The SOP was administered at the baseline assessment and the first treatment session and re-administered at each subsequent session if a patient endorsed current elevated risk per the SOP.

Treatment Session Checklist. The Treatment Session 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 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 was also used to document telehealth equipment and connectivity status, adequate lighting, and any disruptions to session.

Client Satisfaction Questionnaire (CSQ; Nguyen, Attkisson, & Stegner, 1983). The Client Satisfaction Questionnaire is an eight-item self-report measure of general satisfaction with psychotherapeutic treatment. (The instrument is reproduced with permission of C. Clifford Attkisson.) 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.

Clinical Outcomes

Clinically significant reductions in posttraumatic stress symptom severity and depression symptoms were observed. Soldiers indicated high levels of satisfaction with the treatment, and there were no adverse events requiring activation of emergency safety procedures. Technical problems associated with the network were observed but successfully mitigated.

Table 1. Pilot study results.

MEASURE	MEAN (SD)		t (df)	HEDGE'S g	RC
	BASELINE	POSTTREATMENT			
CAPS	82.30 (12.37)	65.11 (20.74)	3.29 (8) ^a	0.95	5 improved 0 deteriorated
PCL-M	59.20 (10.40)	53.22 (14.68)	2.53 (8) ^a	0.44	7 improved 1 deteriorated
BDI-II	29.50 (10.32)	20.67 (12.00)	2.95 (8) ^a	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

^a $p < 0.05$.
BAI, Beck Anxiety Inventory; BDI-II, Beck Depression Inventory-II; CAPS, Clinician Administered Posttraumatic Stress Disorder Scale; PCL-M, PTSD Checklist Military Version; PSQI, Pittsburgh Sleep Quality Index; RC, reliable change; SD, standard deviation.

Overview (RCT)

The purpose of this randomized controlled non-inferiority 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. One hundred and twenty one U.S. military service members and Veterans were recruited at a military treatment facility and a Veterans Health Administration (VHA) hospital. Participants were randomized to receive eight 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, mid-treatment (4 weeks), post-treatment (8 weeks) and 3 months post-treatment. Mixed-effects modeling results with Beck Hopelessness Scale (BHS) and Beck Depression Inventory II (BDI-II) scores suggested relatively strong and similar reductions in hopelessness and depressive symptoms for both groups; however, non-inferiority 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. BATD was demonstrated to be feasibly delivered to the homes of active duty service members and

Veterans via VC. Small group differences suggested a slight benefit of in-person care over in-home telehealth on some clinical outcomes.

The objectives of the RCT study were as follows:

1. Evaluate the safety of an in-home, web-based BA treatment as an intervention for depression.
2. Determine the effectiveness of in-home BA as treatment for depression delivered via a web cam.
3. Monitor PTSD symptoms to determine if there is an association between BA treatment and reductions in PTSD symptomatology.
4. Examine patient compliance, treatment satisfaction, and overall feasibility of the web-based intervention compared to in-person BA treatment.
5. Identify best practices to guide the implementation of other web-based tele-mental health interventions

The hypotheses of the RCT study were as follows:

1. In-home care would be no-worse than in-office care on clinical measures that reflect safety and clinical outcomes.
2. Participants in both groups would show improved hopelessness and depression scores at treatment end.
3. Treatment delivered in-home would be as safe as in-office treatment.

Participants

Participants were recruited at a large regional military medical 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 Edition (SCID-I/P; First, Spitzer, Gibbon, & Williams, 2002). The inclusion of both major and minor depressive disorder in the trial provided for 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.

Recruitment

Recruitment occurred primarily through referral from medical and behavioral health clinical providers at the study sites who were educated about the inclusion/exclusion criteria of the study. This occurred from a variety of clinics including outpatient behavioral health offices, Soldier Readiness Centers, Post-deployment Health and Readiness Assessment offices, Family Medicine Clinics, and Ministry and Pastoral Care offices.

Potential participants could also self-select to contact the study for consideration. Study information was posted on flyers at the medical centers at both sites. At JBLM, study information was also available on large banners posted at the base exit points. Information was also available online through a webpage created at the National Center for Telehealth and Technology (T2), which could be disseminated via T2's extant social media outlets.

Outcome Measures

Screening

Prior to randomization, patients were assessed on the following inclusionary and exclusionary criteria:

a. Inclusion Criteria –

- (a) Current Major Depressive Disorder or Minor Depressive Disorder
- (b) High-speed internet/network access at home (384kbs minimum)
- (c) Informed consent
- (d) Fluent in the English language

b. 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 for DSM-IV
- (d) Dysthymic Disorder
- (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 (lifetime substance dependence or substance abuse will not be excluded)
- (h) History of violence or poor impulse control causing potential risk to study staff or others
- (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

Clinical Outcomes

Beck Hopelessness Scale (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.

Beck Depression Inventory (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.

Structured Clinical Interview for DSM-IV (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 Major Depressive Disorder (MDD). The SCID-I/P has excellent established inter-rater reliability (overall kappa = 0.85).

Beck Anxiety Inventory (BAI; Beck & Streer, 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)

PTSD Checklist Military Version (PCL; Blanchard et al., 1996; 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, post treatment, 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 post treatment.

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.

Results

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 ten participants. This evidence suggested that missing at random was a reasonable assumption for analysis.

Primary outcomes

At post treatment, 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 post-assessment, we found that the upper bound of the 90% confidence interval included 0.50. The per-protocol analysis provided similar results; however, the point estimates were somewhat greater in magnitude than those from the intent-to-treat analysis. See Figures 3 and 4 for a graphic display of the point estimates and confidence intervals against the non-inferiority margin.

Secondary outcomes

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 post treatment, 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 twelve-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 military treatment facility (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 non-inferiority 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.

Dropout by the mid- and post-treatment assessments was not associated with treatment assignment, prior outcome scores, or the current outcome scores. Estimates of the treatment differences at mid and post treatment 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.

To improve the applicability of these findings to the Military Health System, and economic analysis of both delivery modalities was conducted. This analysis found that the total direct cost of HBTBH care was higher than IP care, but this was sensitive to whether patients already have access to computer technology suitable for video conferencing. Patients with access to computer technology may accrue less costs while maintaining quality health care for depression. However, if a large proportion of patients are without the necessary computer technology, the total direct costs of the HBTBH is largely driven by the need for government-supplied computer

technology. Health care policies centered on implementation of HBTBH care may benefit from an initial assessment of A/V coverage among beneficiaries.

Table 2. Intent-to-treat and per protocol analyses and internal consistency reliability estimates of the BHS and BDI-II against a non-inferiority margin of a standardized difference of 0.50.

Outcome and time	In-home			In-Person			b	90% CI	B	90% CI
	n	M (SD)	α	n	M (SD)	α				
Intent-to-treat										
BHS										
Pre	62	9.00 (5.12)	0.88	59	10.37 (6.13)	0.92	Ref.		Ref.	
Mid	48	7.21 (5.66)	0.88	44	7.95 (6.26)	0.94	1.29	-0.30, 2.88	0.22	-0.05, 0.50
Post	45	4.89 (4.64)	0.90	42	4.43 (4.94)	0.92	2.30	0.68, 3.92	0.40	0.12, 0.68
Follow-up	42	5.21 (5.10)	0.92	36	5.53 (5.97)	0.94	1.63	-0.05, 3.32	0.28	-0.01, 0.58
	$\sigma_s = 5.77$									
	$ICC = 0.64$									
BDI										
Pre	62	27.60 (10.45)	0.88	59	29.71 (11.33)	0.89	Ref.		Ref.	
Mid	47	19.40 (11.77)	0.93	44	20.20 (13.09)	0.93	1.70	-1.81, 5.22	0.14	-0.15, 0.44
Post	45	13.82 (12.02)	0.94	42	11.74 (12.08)	0.95	4.23	0.66, 7.81	0.36	0.06, 0.66
Follow-up	42	14.76 (12.89)	0.95	36	15.00 (12.61)	0.93	1.89	-1.84, 5.61	0.16	-0.16, 0.48
	$\sigma_s = 11.78$									
	$ICC = 0.60$									
Per protocol										
BHS										
Pre	40	8.58 (5.38)	0.90	42	11.00 (6.27)	0.93	Ref.		Ref.	
Mid	40	7.28 (5.67)	0.87	42	7.55 (6.09)	0.93	2.15	0.43, 3.87	0.39	0.08, 0.70
Post	40	4.63 (4.42)	0.89	42	4.43 (4.94)	0.92	2.62	0.90, 0.43	0.47	0.16, 0.78
Follow-up	38	4.82 (4.99)	0.92	36	5.53 (5.97)	0.94	1.90	0.12, 3.68	0.34	0.02, 0.67
	$\sigma_s = 5.53$									
	$ICC = 0.63$									
BDI										
Pre	40	26.65 (11.80)	0.90	42	29.69 (11.74)	0.90	Ref.		Ref.	
Mid	39	18.97 (11.89)	0.93	42	19.12 (12.04)	0.92	2.74	-1.08, 6.56	0.22	-0.09, 0.54
Post	40	13.63 (12.47)	0.95	42	11.74 (12.08)	0.95	4.93	1.12, 8.73	0.40	0.09, 0.71
Follow-up	38	14.58 (13.18)	0.95	36	15.00 (12.61)	0.93	2.64	-1.29, 6.58	0.22	-0.11, 0.54
	$\sigma_s = 12.23$									
	$ICC = 0.63$									

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; ICC = intraclass correlation (time nested within subject).

Table 3. Intent-to-treat analysis and internal consistency reliability estimates of secondary outcomes.

Outcome and time	In-home			In-person			b	95% CI	B
	n	M (SD)	α	n	M (SD)	α			
BAI									
Pre	62	15.48 (10.40)	0.90	59	16.85 (12.92)	0.94	Ref.		Ref.
Mid	48	12.21 (9.75)	0.91	44	13.00 (10.98)	0.93	1.29	-2.23, 4.82	0.12
Post	45	9.71 (8.67)	0.90	42	8.31 (9.11)	0.92	3.13	-0.46, 6.74	0.30
Follow-up	42	11.10 (8.63)	0.88	36	9.75 (8.95)	0.92	3.10	-0.64, 6.84	0.29
<i>$\sigma_s = 10.56$</i>									
<i>ICC = 0.65</i>									
PCL-M									
Pre	62	43.15 (13.53)	0.91	59	45.17 (14.75)	0.92	Ref.		Ref.
Mid	48	37.60 (13.82)	0.92	44	37.41 (16.24)	0.95	2.20	-2.18, 6.58	0.15
Post	45	33.16 (14.69)	0.94	42	32.43 (16.58)	0.96	2.14	-2.33, 6.61	0.15
Follow-up	42	35.05 (14.57)	0.93	36	34.39 (14.72)	0.93	2.26	-2.39, 6.91	0.15
<i>$\sigma_s = 14.67$</i>									
<i>ICC = 0.72</i>									
IASMHS									
Pre	62	35.23 (14.40)	0.83	59	31.47 (14.33)	0.83	Ref.		Ref.
Post	45	27.07 (14.98)	0.87	42	21.88 (13.75)	0.85	1.53	-3.46, 6.52	0.10
Follow-up	42	28.33 (17.31)	0.91	36	23.69 (16.57)	0.90	0.24	-4.97, 5.44	0.02
<i>$\sigma_s = 15.16$</i>									
<i>ICC = 0.68</i>									
CSQ									
Post	45	28.76 (3.41)	0.91	42	29.29 (3.98)	0.92	-0.53	-2.11, -1.05	-0.14

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; ICC = intraclass correlation (time nested within subject); BAI = Beck Anxiety Inventory; PCL-M = PTSD Checklist – Military; IASMHS = Inventory of Attitudes toward Seeking Mental Health Service.

Challenges

A summary of challenges throughout this project has been compiled for this report.

Year 1: The IRB and HRPO approval process was a major challenge due to frequent delays in the review/approval process that were outside the control of study staff.

Year 2: Madigan IRB and HRPO approval continued being a consistent challenge during year 2, namely because of delays in the review/approval process for both sites. However, approvals were obtained, and both sites began enrolling participants.

Additionally, referral-based recruitment strategies also proved challenging. However, the early phase of the recruitment period was spent developing relationships with providers who were willing to refer participants, and enrollment steadily increased to the point where our quarterly recruitment goals were being met consistently.

Year 3: 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 were able to partially resolve this issue, but it did present a major challenge that interrupted the delivery of the treatment protocol during that time frame.

Year 4: An important use of the data generated by this trial was the examination of economic costs/savings of home-based care. Finding the right group of health economic experts to conduct the appropriate analyses was challenging, but we were able to identify a productive and skilled research group at the University of Washington's Department of Pharmacy who were capable of completing this sophisticated analysis.

Key Research Accomplishments

- Main findings from this project were presented to leadership of the Military Health System (MHS) at the request for guidance on the use of Telehealth in the MHS.
- Main findings are under consideration for publication in the *Journal of Consulting and Clinical Psychology*.
- Findings from the Pilot Study have been published in the journal *Telemedicine and eHealth*.
- Main findings presented at the Military Health System Research Symposium (MHSRS) as a Plenary Presentation.
- Study staff was awarded a 2015 MHSRS Research Team Award.
- 6 other peer-reviewed publications and one book chapter have been published regarding this study.
- Results from the economic analysis will be presented at the International Society for Pharmacoeconomics and Outcomes Research annual conference.
- 4 additional publications are in development.

Reportable Outcomes

Peer Reviewed Publications:

Luxton, D.D., Pruitt, L.D., Wagner, A., Smolenski, D.J., Jenkins-Guarnieri, M.A., & Gahm, G. (In Submission). Home-based telebehavioral health for U.S. military personnel. *Journal of Consulting and Clinical Psychology*.

- Luxton, D.D., Pruitt, L.D., O'Brien, K., & Kramer, G. (2015). An evaluation of the feasibility and safety of a home-based telemental health treatment for PTSD in the US military. *Telemedicine Journal and eHealth*, 21, 1-7. doi: 10.1089/tmj.2014.0235
- Jenkins-Guarnieri, M., Pruitt, L.D., Luxton, D.D., Johnson, K. (2015). Patient perceptions of telemental health: Systematic review of direct comparisons to in-person psychotherapeutic treatments. *Telemedicine Journal and eHealth*, 21, 8. doi: 10.1089/tmj.2014.0165
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- Pruitt, L.D., Luxton, D.D., Shore, P. (2014). Additional clinical benefits of home-based telemental health treatments. *Professional Psychology: Research and Practice*, 45, 340-346. doi: 10.1037/a0035461

Solicited Book Chapters:

- Luxton, D., Pruitt, L.D., & Jenkins, M. (2015). Telebehavioral assessment. In Teurk & Shore (Eds.), *Clinical Videoconferencing in Telehealth*. New York: Springer.

Conference Presentations:

- Pruitt, L.D., & Luxton, D.D. (2015). A randomized controlled trial of home-based tele-behavioral health care for U.S. military personnel and veterans with depression. Plenary Presentation at the 2015 Military Health System Research Symposium, Fort Lauderdale, FL.
- Bounthavong, M., Pruitt, L.D., Smolenski, D.J., Gahm, G., Bansal, A., Hansen, R.N. (2016). Economic evaluation of in-home telehealth compared to in-person treatment delivery for managing depression. International Society of Pharmacoeconomics and Outcomes Research, 21st Annual International Meeting.

Conclusion

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 Veterans. The overall findings of this study support the feasibility of HBTMH for MHS and VHA beneficiaries. 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.

The results of the present trial did not, however, demonstrate non-inferiority 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 non-inferior 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 non-inferiority 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 non-treatment 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.

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 healthcare 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. Also, clinical appointments were conducted during standard work hours (between the hours of 8:00am and 3:00pm, 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.

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. 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). Home-based care is a viable option, especially when traditional in-office care is less practical.

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Appendices

Appendix 1: Bounthavong, M., Pruitt, L.D., Smolenski, D.J., Gahm, G., Bansal, A., Hansen, R.N. (2016). Economic evaluation of in-home telehealth compared to in-person treatment delivery for managing depression. International Society of Pharmacoeconomics and Outcomes Research, 21st Annual International Meeting.

Appendix 2: Luxton, D.D., Pruitt, L.D., Wagner, A., Smolenski, D.J., Jenkins-Guarnieri, M.A., & Gahm, G. (In Submission). Home-based telebehavioral health for U.S. military personnel. *Journal of Consulting and Clinical Psychology*.

Appendix 3: Luxton, D.D., Pruitt, L.D., O'Brien, K., & Kramer, G. (2015). An evaluation of the feasibility and safety of a home-based telemental health treatment for PTSD in the US military. *Telemedicine Journal and eHealth*, 21, 1-7. doi: 10.1089/tmj.2014.0235

Appendix 4: Jenkins-Guarnieri, M., Pruitt, L.D., Luxton, D.D., Johnson, K. (2015). Patient perceptions of telemental health: Systematic review of direct comparisons to in-person psychotherapeutic treatments. *Telemedicine Journal and eHealth*, 21, 8. doi: 10.1089/tmj.2014.0165

Appendix 5: Luxton, D.D., O'Brien, K., Pruitt, L.D., Kramer, G., Johnson, K. (2014). Suicide Risk Management During Clinical Telepractice. *International Journal of Psychiatry in Medicine*, 48, 19-31. doi: <http://dx.doi.org/10.2190/PM.48.1.c>

Appendix 6: Luxton, D., Pruitt, L.D., & Jenkins, M. (2015). Telebehavioral assessment. In Teurk & Shore (Eds.), *Clinical Videoconferencing in Telehealth*. New York: Springer.

Appendix 7: Luxton, D.D., Pruitt, L.D., O'Brien, K., Stanfill, K., Jenkins-Guarnieri, M.A., Johnson, K., et al. (2014). Design and methodology of a randomized clinical trial of home based telemental health treatment for U.S. military personnel and veterans with depression. *Contemporary Clinical Trials*, 38, 134-144. doi: 10.1016/j.cct.2014.04.002

Appendix 8: 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.

Appendix 9: Pruitt, L.D., & Luxton, D.D. (2015). A randomized controlled trial of home-based tele-behavioral health care for U.S. military personnel and veterans with depression. Plenary Presentation at the 2015 Military Health System Research Symposium, Fort Lauderdale, FL.

Appendix 10: Pruitt, L.D., Luxton, D.D., Shore, P. (2014). Additional clinical benefits of home-based telemental health treatments. *Professional Psychology: Research and Practice*, 45, 340-346. doi: 10.1037/a0035461

Abstract: Economic evaluation of In-Home Telehealth compared to In-Person Treatment Delivery for Managing Depression

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Target Conference: International Society of Pharmacoeconomics and Outcomes Research 21st Annual International Meeting, May 21-25, 2016; Washington, DC

Submission Deadline: January 14, 2016
300-word limit (current word count: 297)

OBJECTIVES: Despite the growing evidence supporting Home-based telebehavioral health (HBTBH) in improving mental health, there has not been an economic analysis comparing it to traditional In-person (IP) setting. The National Center for Telehealth and Technology recently completed a randomized controlled trial comparing the safety and efficacy of HBTBH among U.S. military personnel and Veterans with depression. We performed a trial-based economic analysis comparing HBTBH and IP care for depression.

METHODS: We performed a cost-minimization analysis on 121 patients with depression to assess the economic impact of HBTBH versus IP behavioral health care from the payer perspective (Department of Defense and Veterans Affairs) at 3 months. Sample population included US service members and veterans with a diagnosis of depression from Joint Base Lewis-McChord (Washington state) and veterans were enrolled from the VA Health Care System (Portland, Oregon). We also performed a scenario analysis assuming that all patients had access to personal video conferencing technology. One-way and probabilistic sensitivity analyses were performed to test the robustness of the model assumptions.

RESULTS: In the base-case analysis the total direct cost of HBTBH care was higher than IP care (\$68,483 versus \$21,561). This translates to an \$813 increase per patient. Assuming that patients personally owned computers could be used, HBTBH care was less costly compared to IP care (\$18,242 versus \$21,561). In one-way sensitivity analyses, the proportion of patients using personal computers was a major driver of direct costs. Probabilistic sensitivity analysis did not differ substantially from the base-case results.

CONCLUSIONS: Total direct cost of HBTBH care was sensitive to whether patients were able to utilize their personally owned technology. Using patients existing in home video conferencing technology accrues lower costs while maintaining healthcare quality. Health care policies centered on implementation of HBTBH care may benefit from an initial assessment of technology coverage among beneficiaries.

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

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DISCLAIMER: The views, opinions, and/or findings contained in this article are those of the author and should not be construed as an official Department of Defense position, policy or decision unless so designated by other official documentation.

HOME-BASED TELEBEHAVIORAL HEALTH

Abstract

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 (MHS) can occur. The purpose of this randomized controlled non-inferiority 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 (VHA) hospital. Participants were randomized to receive eight 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, mid-treatment (4 weeks), post-treatment (8 weeks) and 3 months post treatment. **Results:** Mixed-effects modeling results with Beck Hopelessness Scale (BHS) and Beck Depression Inventory II (BDI-II) scores suggested relatively strong and similar reductions in hopelessness and depressive symptoms for both groups; however, non-inferiority 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. **Conclusions:** 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.

Keywords: Telemedicine; Telemental health; Depression; Military; Veterans

HOME-BASED TELEBEHAVIORAL HEALTH

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 US Department of Defense (DoD) 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, Ryan, Kobb, Foster, Edmonson, et al, 2009; Strachan et al., 2012). The feasibility and effectiveness of TBH has been supported by several pilot studies and randomized controlled trials (for a review see Ferrer, Parish, Johnston, Callahan, & Yellowlees, 2012). The majority of published TBH studies involving military veterans have focused on the treatment of post-traumatic stress disorder (PTSD) with evidence-based treatments including prolonged exposure

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therapy (Tuerk, Yoder, Ruggiero, Gros, & Acierno, 2010; Gros, Yoder, Tuerk, Lozano, & Acierno, 2011), Cognitive Processing Therapy (Morland, Hynes, Mackintosh, Resick, & Chard, 2011; Morland, Mackintosh, Greene, Rosen, Chard, Resick, et al, 2014), or group anger management therapy (Morland, Greene, Rosen, Foy, Reilly, Shore et al, 2010), delivered to small outpatient clinics with less staffing resources. Other studies have specifically evaluated TBH treatments delivered to the homes of veterans (Egede et al., 2009; Yuen, Gros, Price, Zeigler, Tuerk, Foa, & Acierno, 2015). For example, Egede and colleagues (2009) conducted an 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,

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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, Pruitt, O'Brien, & Kramer, in press) 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 (Gadernann et al., 2012) and 20% among Operation Iraqi Freedom/Operation Enduring Freedom veterans (Seal et al., 2009; Corson et al., 2013). 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,

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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, Frueh, Richardson, et al, 2009).

A non-inferiority 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 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 additionally 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 at Madigan Army Medical Center and the 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 United States National Institutes of Health Clinical Trials Registry,

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(ClinicalTrials.gov Identifier #NCT01599585) available online at:

<http://clinicaltrials.gov/show/NCT01599585>.

Methods

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 Edition (SCID-I/P; First, Spitzer, Gibbon, & Williams, 2002). The inclusion of both major and minor depressive disorder in the trial provided for 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 2.

Procedures

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

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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 US 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 block randomization of size ten, stratified by baseline major or minor depressive disorder diagnosis 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 re-administered 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 pre-loaded with Jabber video software (Cisco Systems). This software was selected because its level of

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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 one was devoted to psychoeducation, the treatment rationale, and introduction of the concept of daily activity monitoring. Session two 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/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 minute 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.

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Measures

The Beck Hopelessness Scale (BHS; Beck, Weissman, Lester, & Trexler, 1974) and the Beck Depression Inventory II (BDI-II; Beck, Streer, & Brown, 1996) served as the primary outcomes for the non-inferiority 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

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assessments for the presence of MDD. The SCID-I/P has excellent established inter-rater reliability (overall kappa = 0.85).

Beck Anxiety Inventory (BAI; Beck & Streer, 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, post treatment, 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

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CSQ was administered at post treatment.

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 $\alpha = 0.05$, 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 non-inferiority analyses. Given that the treatment is for depression, the BDI was respecified from a secondary outcome to a primary outcome for additional non-inferiority analyses prior to treatment condition unblinding and data analysis. The

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non-inferiority margin (δ) was identified as a standardized difference of 0.50 (see Luxton, Pruitt, 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 $\alpha = 0.05$, 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 non-inferiority trials (e.g., Mohr, Ho, Duffecy, Reifler, Sokol, Burns, et al, 2012; Nutt, Allgulander, Lecrubier, et al 2008). However, Green 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 post assessment 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 model. All models were estimated using restricted maximum likelihood in Stata 12.1 (StataCorps, 2013).

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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 non-inferiority, we used 95% percent 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 post treatment. 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 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

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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 post-test using a linear specification of change over time and logistic models of dropout at the mid and post assessment 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 *Mplus* 7.1 (Muthén & Muthén, 2012) to estimate the selection models.

Results

Study completion

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 ten participants. This evidence suggested that missing at random was a reasonable assumption for analysis.

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 post treatment, participants in the in-person group had an average

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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 post assessment, we found that the upper bound of the 90% confidence interval included 0.50. The per protocol analysis provided similar results; however, the point estimates were somewhat greater in magnitude than those from the intent-to-treat analysis. See Figures 3 and 4 for a graphic display of the point estimates and confidence intervals against the non-inferiority margin.

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 post treatment, 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 twelve-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

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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 non-inferiority 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 post treatment assessments was not associated with treatment assignment, prior outcome scores, or

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the current outcome scores. Estimates of the treatment differences at mid and post treatment 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.

Discussion

This study is the first randomized controlled trial of HBTBH conducted specifically in the US 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 overall

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findings of this study support the feasibility of HBTMH for MHS and VHA beneficiaries. 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.

The results of the present trial did not, however, demonstrate non-inferiority 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 non-inferior 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 non-inferiority 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 non-treatment 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.

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 non-inferiority and inferiority/superiority of HBTMH.¹ Future evaluations would benefit from larger samples based on an established non-inferiority margin and consideration of trivial differences in point estimates. The relatively low depression scores of both groups at baseline, combined with high variability among participants may have also influenced the findings. Also, the

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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 healthcare 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. in press). Also, clinical appointments were conducted during standard work hours (between the hours of 8:00am and 3:00pm, 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

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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.

The present study adds to other research regarding the applicability of evidence-based treatments delivered via telehealth technologies. A growing literature base of studies have generally supported the feasibility and effectiveness of providing behavioral health treatments to the home or other settings (e.g., clinics) (Hilty et al, 2013). These studies have also generally supported evidence of patient satisfaction with TBH care (Jenkins-Guarnieri, Pruitt, Luxton, & Johnson, 2015). Evaluations of 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, Gros, Morland, Greene, Strachan, Egede, et al, 2013). Also, economic evaluations of TBH, particularly HBTBH, are needed to assist with decision making regarding implementation of HBTMH in the MHS (Luxton, 2013). Economic analyses with the present data are planned.

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. 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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HOME-BASED TELEBEHAVIORAL HEALTH

Table 1. 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	0.00
Hispanic, any race	3	4.84	7	11.86
Other/Unknown	3	4.84	0	0.00
Education				
HS	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

HOME-BASED TELEBEHAVIORAL HEALTH

Table 2. 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 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

Exclusion Criteria

- (a) Currently undergoing psychotherapy for depression
 - (b) b18 or N65 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
-

HOME-BASED TELEBEHAVIORAL HEALTH

Table 3. Intent-to-treat and per protocol analyses and internal consistency reliability estimates of the BHS and BDI-II against a non-inferiority margin of a standardized difference of 0.50.

Outcome and time	In-home			In-Person			b	90% CI	B	90% CI
	n	M (SD)	α	n	M (SD)	α				
Intent-to-treat										
BHS										
Pre	62	9.00 (5.12)	0.88	59	10.37 (6.13)	0.92	Ref.		Ref.	
Mid	48	7.21 (5.66)	0.88	44	7.95 (6.26)	0.94	1.29	-0.30, 2.88	0.22	-0.05, 0.50
Post	45	4.89 (4.64)	0.90	42	4.43 (4.94)	0.92	2.30	0.68, 3.92	0.40	0.12, 0.68
Follow-up	42	5.21 (5.10)	0.92	36	5.53 (5.97)	0.94	1.63	-0.05, 3.32	0.28	-0.01, 0.58
	$\sigma_s = 5.77$									
	$ICC = 0.64$									
BDI										
Pre	62	27.60 (10.45)	0.88	59	29.71 (11.33)	0.89	Ref.		Ref.	
Mid	47	19.40 (11.77)	0.93	44	20.20 (13.09)	0.93	1.70	-1.81, 5.22	0.14	-0.15, 0.44
Post	45	13.82 (12.02)	0.94	42	11.74 (12.08)	0.95	4.23	0.66, 7.81	0.36	0.06, 0.66
Follow-up	42	14.76 (12.89)	0.95	36	15.00 (12.61)	0.93	1.89	-1.84, 5.61	0.16	-0.16, 0.48
	$\sigma_s = 11.78$									
	$ICC = 0.60$									
Per protocol										
BHS										
Pre	40	8.58 (5.38)	0.90	42	11.00 (6.27)	0.93	Ref.		Ref.	
Mid	40	7.28 (5.67)	0.87	42	7.55 (6.09)	0.93	2.15	0.43, 3.87	0.39	0.08, 0.70
Post	40	4.63 (4.42)	0.89	42	4.43 (4.94)	0.92	2.62	0.90, 0.43	0.47	0.16, 0.78
Follow-up	38	4.82 (4.99)	0.92	36	5.53 (5.97)	0.94	1.90	0.12, 3.68	0.34	0.02, 0.67
	$\sigma_s = 5.53$									
	$ICC = 0.63$									
BDI										
Pre	40	26.65 (11.80)	0.90	42	29.69 (11.74)	0.90	Ref.		Ref.	
Mid	39	18.97 (11.89)	0.93	42	19.12 (12.04)	0.92	2.74	-1.08, 6.56	0.22	-0.09, 0.54
Post	40	13.63 (12.47)	0.95	42	11.74 (12.08)	0.95	4.93	1.12, 8.73	0.40	0.09, 0.71
Follow-up	38	14.58 (13.18)	0.95	36	15.00 (12.61)	0.93	2.64	-1.29, 6.58	0.22	-0.11, 0.54
	$\sigma_s = 12.23$									
	$ICC = 0.63$									

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; ICC = intraclass correlation (time nested within subject).

HOME-BASED TELEBEHAVIORAL HEALTH

Table 4. Intent-to-treat analysis and internal consistency reliability estimates of secondary outcomes.

Outcome and time	In-home			In-person			b	95% CI	B
	n	M (SD)	α	n	M (SD)	α			
BAI									
Pre	62	15.48 (10.40)	0.90	59	16.85 (12.92)	0.94	Ref.		Ref.
Mid	48	12.21 (9.75)	0.91	44	13.00 (10.98)	0.93	1.29	-2.23, 4.82	0.12
Post	45	9.71 (8.67)	0.90	42	8.31 (9.11)	0.92	3.13	-0.46, 6.74	0.30
Follow-up	42	11.10 (8.63)	0.88	36	9.75 (8.95)	0.92	3.10	-0.64, 6.84	0.29
<i>$\sigma_s = 10.56$</i>									
<i>ICC = 0.65</i>									
PCL-M									
Pre	62	43.15 (13.53)	0.91	59	45.17 (14.75)	0.92	Ref.		Ref.
Mid	48	37.60 (13.82)	0.92	44	37.41 (16.24)	0.95	2.20	-2.18, 6.58	0.15
Post	45	33.16 (14.69)	0.94	42	32.43 (16.58)	0.96	2.14	-2.33, 6.61	0.15
Follow-up	42	35.05 (14.57)	0.93	36	34.39 (14.72)	0.93	2.26	-2.39, 6.91	0.15
<i>$\sigma_s = 14.67$</i>									
<i>ICC = 0.72</i>									
IASMHS									
Pre	62	35.23 (14.40)	0.83	59	31.47 (14.33)	0.83	Ref.		Ref.
Post	45	27.07 (14.98)	0.87	42	21.88 (13.75)	0.85	1.53	-3.46, 6.52	0.10
Follow-up	42	28.33 (17.31)	0.91	36	23.69 (16.57)	0.90	0.24	-4.97, 5.44	0.02
<i>$\sigma_s = 15.16$</i>									
<i>ICC = 0.68</i>									
CSQ									
Post	45	28.76 (3.41)	0.91	42	29.29 (3.98)	0.92	-0.53	-2.11, -1.05	-0.14

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; ICC = intraclass correlation (time nested within subject); BAI = Beck Anxiety Inventory; PCL-M = PTSD Checklist – Military; IASMHS = Inventory of Attitudes toward Seeking Mental Health Service.

HOME-BASED TELEBEHAVIORAL HEALTH

Table 5. Estimates from a selection model of dropout on the BHS and the BDI-II

Model parameter	BHS		BDI-II	
	b (SE)		b (SE)	
Intercept	11.73 (1.72)		31.77 (3.17)	
In-home	-1.32 (1.03)		-2.20 (1.98)	
Slope	-4.26 (0.85)		-10.93 (1.90)	
In-home	1.12 (0.49)		2.11 (1.19)	
Drop by mid assessment ^a				
In-home	-0.13 (0.44)		-0.17 (0.44)	
Baseline	0.02 (0.05)		-0.01 (0.03)	
Mid	-0.05 (0.05)		0.02 (0.04)	
Drop by post assessment ^a				
In-home	0.65 (1.02)		0.78 (0.81)	
Mid	0.19 (0.20)		0.12 (0.11)	
Post	-0.19 (0.58)		-0.08 (0.11)	
Mean difference	b (90% CI)	B (90% CI)	b (90% CI)	B (90% CI)
Mid	1.12 (0.31, 1.93)	0.20 (0.05, 0.34)	2.11 (0.15, 4.08)	0.19 (0.02, 0.37)
Post	2.24 (0.62, 3.85)	0.39 (0.11, 0.68)	4.23 (0.30, 8.15)	0.38 (0.03, 0.73)

Note: BHS = Beck Hopelessness Scale; BDI-II = Beck Depression Inventory – II; CI = confidence interval.

^aModeled using a logistic link function and a binomial error distribution.

HOME-BASED TELEBEHAVIORAL HEALTH

Figure 1. CONSORT diagram

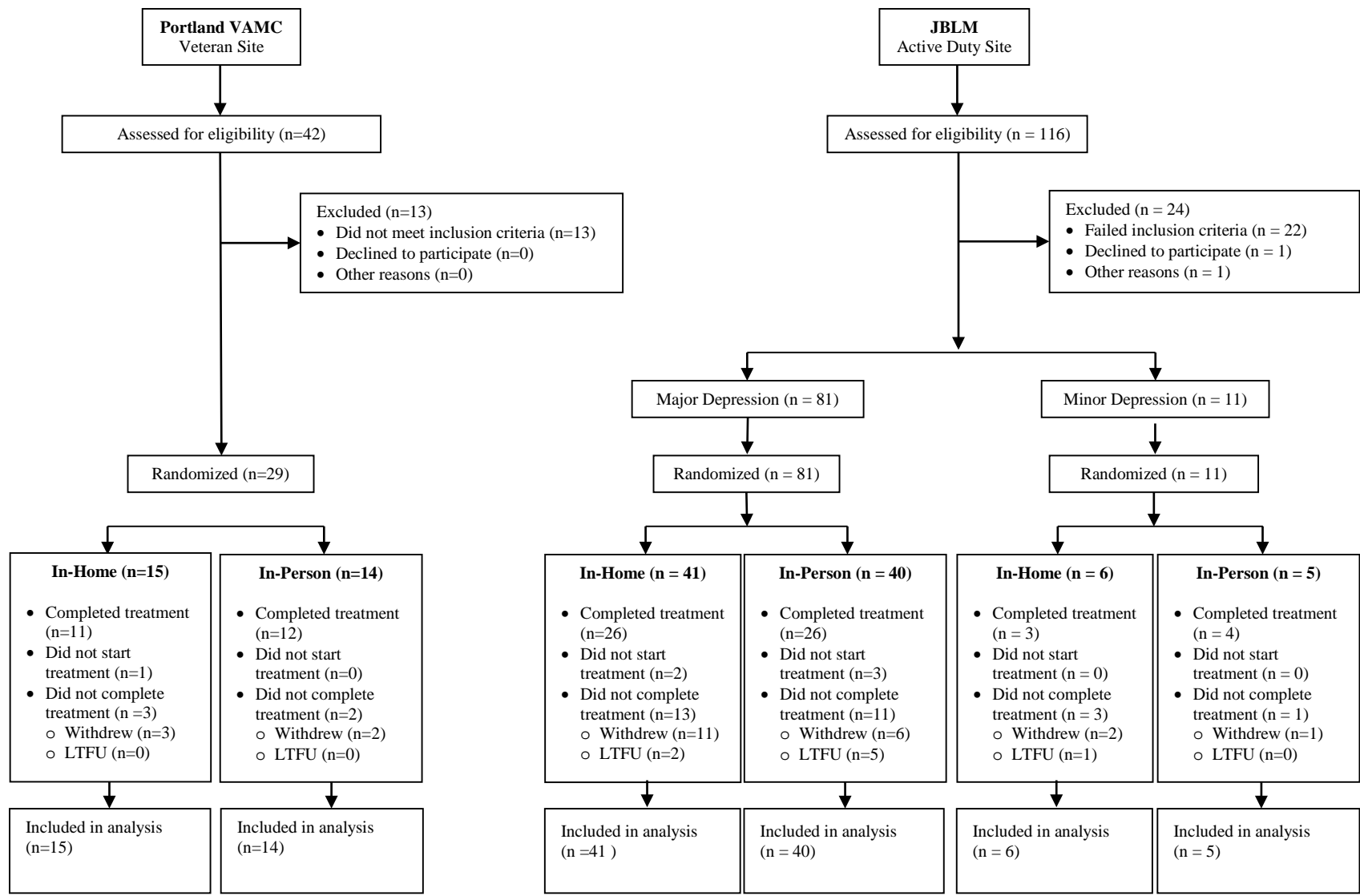


Figure 2. Intent-to-treat (ITT) and per protocol (PP) assessment of non-inferiority on the BHS at each measurement occasion using a 90% confidence interval (CI)

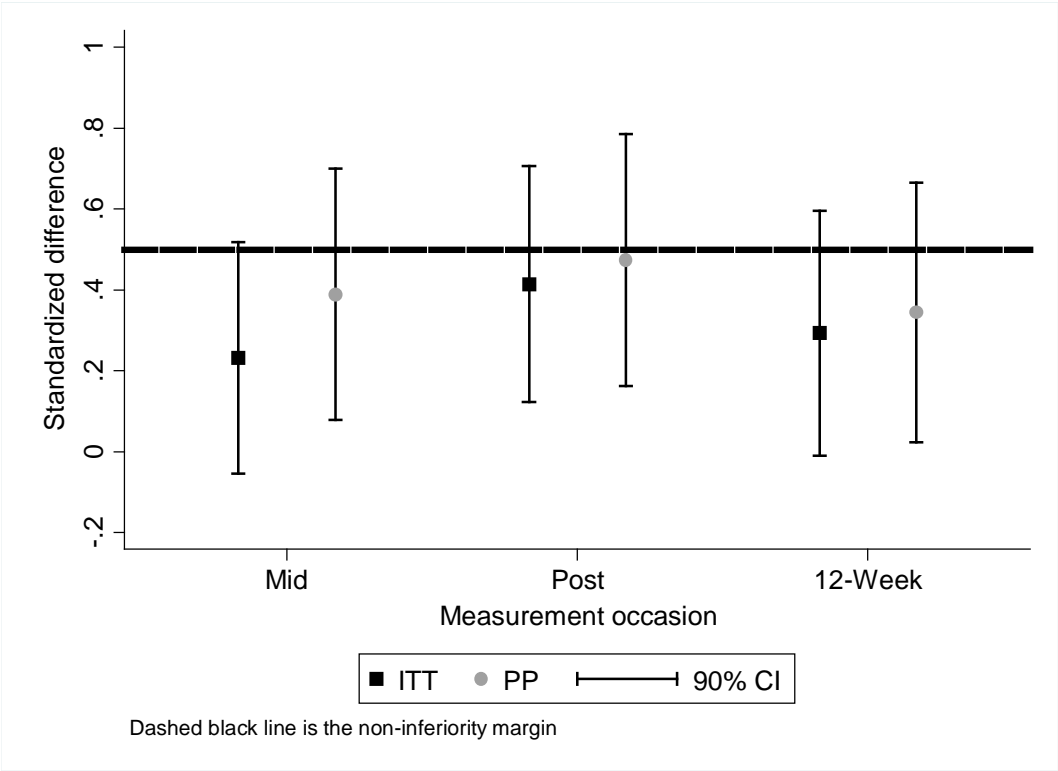
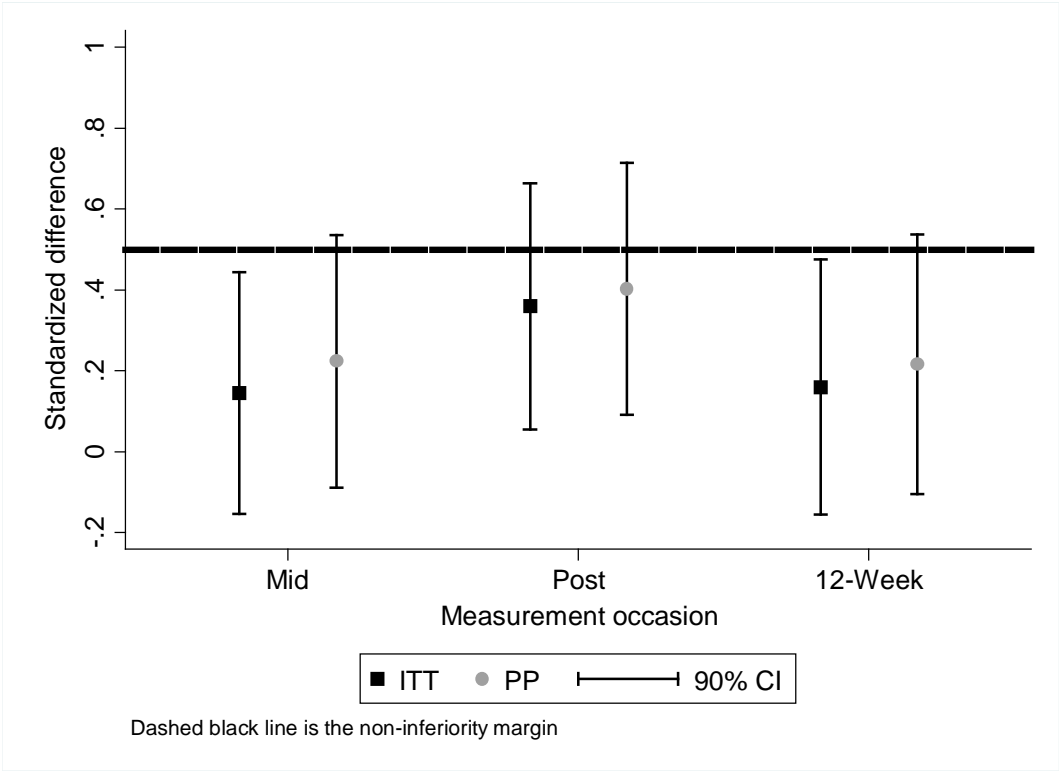


Figure 3. Intent-to-treat (ITT) and per protocol (PP) assessment of non-inferiority on the BDI at each measurement occasion using a 90% confidence interval (CI)



Footnotes

¹ A *post hoc* sample size recalculation based on a power level of 0.90 and a two-tailed alpha of 0.05 (Greene, Morland, Durkalski, & Frueh, 2008) accounted for a difference between group means (θ) of up to 0.20, a margin of 0.50, and an intra-class 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.

Original Research

An Evaluation of the Feasibility and Safety of a Home-Based Telemental Health Treatment for Posttraumatic Stress in the U.S. Military

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This study is the initial part of a clinical trial registered at ClinicalTrials.gov with clinical trial identifier number NCT01599585.

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Abstract

Background: Although home-based telemental health options have the potential to greatly expand the range of services available to U.S. military service members, there remains a need to demonstrate that home-based care is technically feasible, safe, and effective and meets the military health system's standards of care before widespread implementation can be achieved. The purpose of this preliminary study was to evaluate the feasibility and safety of providing U.S. military service members with a behavioral health treatment delivered directly to the home using videoconferencing. **Materials and Methods:** Ten previously deployed soldiers volunteered to complete eight sessions of a novel behavioral activation treatment for posttraumatic stress disorder. The primary clinical outcomes assessed included symptoms of posttraumatic stress and depression. Patient safety data and attitudes about seeking mental health services, treatment satisfaction, treatment adherence, and treatment compliance were also assessed. **Results:** Clinically significant reductions in posttraumatic stress symptom severity and depression symptoms were observed. Soldiers indicated high levels of satisfaction with the treatment, and there were no adverse events requiring activation of emergency safety procedures. Technical problems associated with the network were observed but successfully mitigated. **Conclusions:** The results provide initial support for the feasi-

bility and safety of telemental health treatments delivered by videoconferencing to the homes of soldiers. The optimal technical infrastructure needs to be determined to support expansion of synchronous videoconferencing capabilities to the home. The findings provide preliminary evidence of the feasibility, safety, and high user satisfaction with home-based telemental health in the military setting.

Key words: telemental health, home-based, behavioral activation, military, posttraumatic stress disorder

Introduction

Home-based telemental health (HBTMH) is the provision of mental healthcare services directly to the homes of patients with the use of communications technologies. The U.S. Veterans Health Administration has successfully implemented a national home telehealth program that included veterans with posttraumatic stress (PTS) disorder (PTSD), depression, and chronic medical conditions.¹ A HBTMH pilot program² and several clinical studies^{3,4} have also demonstrated the benefits of home-based treatments for veterans. The potential benefits of HBTMH have also been recognized for some time within the U.S. Department of Defense. 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..."⁵ Service members who are living in geographically remote locations or in areas that have a shortage of specialty healthcare professionals may especially benefit from HBTMH options. Moreover, some service members may be drawn to HBTMH because of the privacy it offers to those who are concerned about stigma associated with seeking mental health treatment. Despite the call for home-based care within the U.S. Department of Defense, and the benefits it may offer, the military health system has not established the necessary policies and pathways for a HBTMH model of care to occur.

The U.S. military has unique network and data security requirements compared with other settings as well as specific protocols and procedures for care that have not yet been tested for HBTMH. Although the existing empirical literature

provides initial support and guidance for the safe and effective use of home telehealth services for appropriate populations,^{6,7} there remains a need to demonstrate that home-based care is technically feasible, safe, and effective and meets the military health system's standards of care before widespread implementation can be achieved. The purpose of the present study was therefore to evaluate the feasibility of providing a behavioral activation (BA) treatment for PTSD⁸ delivered via synchronous (two-way) videoconferencing to the homes of U.S. military service 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.⁹ Given that avoidance and withdrawal processes also serve to maintain the symptoms of PTSD, BA has been evaluated as a treatment for PTSD.^{8,10-12} Although previous studies have examined military veterans, our study is the first to evaluate BA for PTS among active duty military members.

Materials and Methods

This study is an initial part of a multisite clinical trial that is comparing the effectiveness of BA for depression delivered in-office versus in the home.¹³ Although the randomized clinical trial provides an opportunity to test the effectiveness of home-based BA for service members and veterans with depression, this evaluation allowed us to assess the feasibility of the technology, to examine safety management procedures, and to evaluate a promising 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 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 U.S. 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 endorse experiencing at least one criterion A stressor and have a score of 45 or higher on the Clinician Administered PTSD Scale (CAPS).¹⁴ The cutoff score of 45 has been used in other studies.¹⁵ Participants taking any psychoactive medications

had to have maintained a stable regimen for a minimum of 30 days prior to study entry.

PROCEDURES

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 release of information form so that a contact person, of their choice, could assist in case of clinical emergency. The requirements and processes for engaging with third parties were disclosed and discussed during the informed consent process.

Study personnel. Treatment providers included five clinicians (four licensed psychologists and one postdoctoral fellow). The postdoctoral fellow was supervised on a weekly basis. All study providers participated in initial and annual BA training workshops.

Clinical assessment. PTS symptom severity assessments were completed by two independent, doctoral-level outcomes assessors. These assessors were trained in the administration of the CAPS and possessed prior experience with this measure. The CAPS, along with the self-report battery, was completed at the baseline, midtreatment, posttreatment, and 3-month posttreatment assessments. All assessments were video-recorded and reviewed regularly by a supervisory psychologist. Feedback was provided on an as needed basis to improve compliance with CAPS administration rules.

Treatment protocol. The intervention consisted of eight sessions of BA for PTS. The treatment protocol is adapted from a BA treatment manual¹¹ that has been expanded into an early intervention for PTSD and depression.⁸ The protocol places a strong emphasis on an outside-in approach to behavior change whereby values-consistent activities are identified, planned, and tracked. The treatment is guided by behavioral theory, with functional behavioral analysis being a primary treatment component.¹⁶

The primary tasks during the first two treatment sessions are (a) to provide psychoeducation about PTSD and the rationale for treatment, (b) to identify values, priorities, and treatment goals and to translate those into scheduled activities, and (c) to establish a pattern of daily monitoring and planning for 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 provider also discusses relapse prevention and encourages participants to use BA principles if/when symptoms return.

Telehealth procedures. All participants were issued a Dell (Round Rock, TX) M6500 laptop computer and a Tandberg (Oslo, Norway) Precision High Definition Webcam. Participants were also provided with a username and password for access to preloaded Jabber Video software (Cisco Systems, San Jose, CA). This software was selected 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 and the Jabber Video software and to test the network connection. Participants were required to use their home Wi-Fi or cable Internet connections to log-in for treatment sessions. Participants were instructed 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 checklist¹² was administered at the beginning of each session for the purpose of reminding study clinicians of procedures and for documenting patient safety and technical issues. 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. The following measures were assessed:

- *Demographic questionnaire.* Participants provided demographic information including occupation/work status/income/living situation, branch of service/highest rank, pain rating (0–10), and medications.
- *CAPS.* The CAPS¹⁴ 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 1-month symptom duration, was used for the baseline and follow-up assessments. The CAPS One Week Version, which measures symptoms over the past week, was used to assess participants after treatment sessions 4 and 8. PTSD severity, measured by the CAPS (total score), served as the primary PTSD outcome.

- *PTSD Checklist Military Version.* The PTSD Checklist¹⁷ 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 (0.97), as are reliability estimates (0.96). The PTSD Checklist Military Version (PCL-M) is used here. 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.* The Beck Depression Inventory-II¹⁸ (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 and that yield a range of scores from 0 to 63.
- *Beck Anxiety Inventory.* The Beck Anxiety Inventory¹⁹ (BAI) is a self-report measure consisting of 21 items designed to discriminate anxiety from depression. It has high internal consistency (0.92) and 1-week test-retest reliability (0.75) and discriminates anxious from non-anxious diagnostic groups.²⁰
- *Pittsburgh Sleep Quality Index.* The Pittsburgh Sleep Quality Index (PSQI)²¹ 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 0.80, with a reliability coefficient of 0.83 and test-retest reliability of 0.87.²²
- *Safety measures.* Safety data collected included any adverse events, psychiatric hospitalizations, suicides and nonfatal 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. We also followed the 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. Risk correlates (e.g., recent loss, financial problems), preparatory behavior (e.g., available means), and other risk factors (e.g., substance dependence) are also assessed and documented. The SOP was administered at the baseline assessment and the first treatment session and re-administered at each subsequent session if a patient endorsed current elevated risk per the SOP.
- *Treatment Session Checklist.* The Treatment Session Checklist¹³ 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 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 connectivity status, adequate lighting, and any disruptions to session.

- *Client Satisfaction Questionnaire.* The Client Satisfaction Questionnaire²³ is an eight-item self-report measure of general satisfaction with psychotherapeutic treatment. (The instrument is reproduced with permission of C. Clifford Attkisson.) 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.²⁴

Results

All participants were men, between the ages of 21 and 45 years with a mean age of 31.8 (standard deviation [SD] = 7.44) years. All were enlisted members of the U.S. Army with an average length of military service of 9.3 (SD = 5.21) years. Five of the 10 participants reported having some college education, and 9 of the participants reported that they were currently married. Seven of the 10 participants resided in private housing off of the military installation.

Seven of the 10 participants had deployed to Iraq at least once in support of Operation Iraqi Freedom, and 6 had been deployed to Afghanistan in support of Operation Enduring Freedom. Two participants had also experienced other deployments. The number of deployments that any single participant reported ranged from one to four. All of the index traumas

assessed on the CAPS were combat related and occurred during Operation Enduring Freedom/Operation Iraqi Freedom deployments. All of these traumatic events met DSM-IV criterion A for PTSD. On average, these traumas had occurred 6 (SD = 3.33) years prior to the patient presenting for treatment. The span of time since trauma exposure ranged from 2 to 11 years.

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.¹¹ 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 definition²⁵ to interpret them. The criteria we used for reliable change was based off of previous research^{11,26} and was as follows: CAPS, ± 9 ; PCL-M, ± 5 ; BDI-II, ± 5 ; BAI, ± 8 ; and PSQI, ± 2 .

As shown in Figure 1, there was a trend of decreased symptom levels from pre- to posttreatment 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 five participants showing improvement on the CAPS and seven on the PCL. There was a statistically reliable reduction in BDI-II scores, with 6 patients meeting criteria for clinical improvement. There was no reliable change in mean scores for the BAI; however, five participants showed improvement, and

Table 1. Treatment Clinical Outcomes

MEASURE	MEAN (SD)		t (df)	HEDGE'S g	RC
	BASELINE	POSTTREATMENT			
CAPS	82.30 (12.37)	65.11 (20.74)	3.29 (8) ^a	0.95	5 improved 0 deteriorated
PCL-M	59.20 (10.40)	53.22 (14.68)	2.53 (8) ^a	0.44	7 improved 1 deteriorated
BDI-II	29.50 (10.32)	20.67 (12.00)	2.95 (8) ^a	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

^a $p < 0.05$.

BAI, Beck Anxiety Inventory; BDI-II, Beck Depression Inventory-II; CAPS, Clinician Administered Posttraumatic Stress Disorder Scale; PCL-M, PTSD Checklist Military Version; PSQI, Pittsburgh Sleep Quality Index; RC, reliable change; SD, standard deviation.

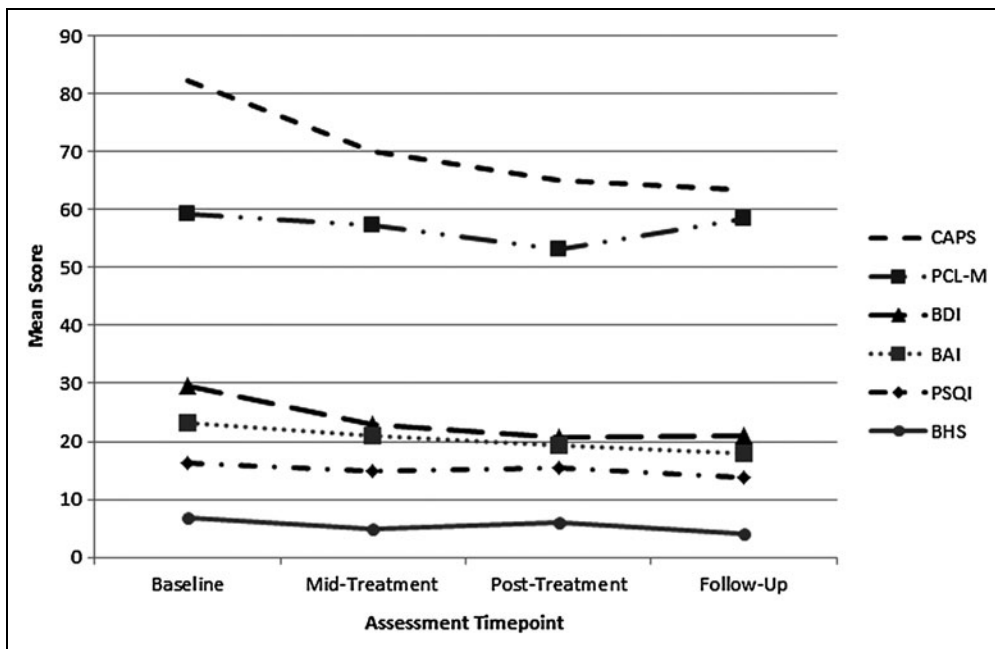


Fig. 1. Means of clinical outcomes measures at each time point. BAI, Beck Anxiety Inventory; BDI, Beck Depression Inventory; BHS, Beck Hopelessness Scale; CAPS, Clinician Administered Post-traumatic Stress Disorder Scale; PCL-M, Posttraumatic Stress Disorder Checklist Military Version; PSQI, Pittsburgh Sleep Quality Index.

one deteriorated. There was also not a statistically reliable change in the mean PSQI scores for the sample.

TREATMENT ADHERENCE AND SATISFACTION

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

TECHNICAL FEASIBILITY

As shown in *Table 2*, the most frequent technical issue was difficulty establishing a connection to the videoconferencing server. This problem was typically resolved with additional sign-in attempts. The average length of these disruptions was less than 6 min. More serious connection difficulties developed during an Army-wide network security upgrade that caused the Internet protocol addresses associated with some of the laptops to be blocked from accessing the video teleconferencing soft-

ware’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 experienced six treatment sessions conducted by telephone. The second case completed five treatment sessions, three of which occurred over the telephone. This participant withdrew from the study after session 5. Although technical issues with initiating and maintaining a videoconferencing 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 no adverse events during the 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 intent 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 midway 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 posttreatment or follow-up assessments. None of the participants expressed any specific desire or intent to harm others, and there were no incidences that required notification of a patient’s emergency contact person or emergency services. There was never a time when a patient deliberately terminated the video teleconferencing connection during a treatment session.

Discussion

This study is the first to examine BA for the treatment of PTS symptoms among active-duty U.S. military personnel and the

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		
Problematic 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 midsession due to technical issue	10 (13.7)	
Time (min) to re-establish a connection		4.71 (4.50)
Instances of being unable to re-establish a VTC connection	3 (30)	
Problem source for the 10 sessions where problems maintaining a connection occurred		
Problematic Internet connection	4 (40)	
Software problems	1 (10)	
Hardware problems	3 (30)	
Participant purposely terminated contact	0 (0)	
Other/unknown	2 (20)	
SD, standard deviation; VTC, video teleconferencing.		

first, to our knowledge, to assess a home-based synchronous telemental health intervention in the U.S. military. The overall results provide initial support for the feasibility of HBTMH treatments in the military setting. The results also showed positive treatment effects of this novel intervention on symptoms of both PTSD and posttraumatic depression that are consistent with other recent studies.^{8,10-12} Although 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 study. The results also suggest high levels of treatment satisfaction with HBTMH and the absence of any safety events provide additional data that mental healthcare

can be delivered safely to service members in their homes when using workable safety standards and planning.

Although 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 (primarily caused by the unanticipated network security upgrade) were usually corrected within several minutes of a problem. Our use of U.S. Army-approved and standardized laptops, software, and cameras helped assure technical compliance and control of potential hardware technical issues; however, this is also a limitation of the study. An ideal capability would be to use a network infrastructure that meets U.S. Department of Defense network security requirements but that also allows for the use of privately owned end-user equipment (i.e., personal computers, Webcams, mobile devices, etc.). Ultimately, the capability to use readily available privately owned equipment would be more convenient and economical for broad implementation. The optimal infrastructure for supporting enterprise-wide HBTMH videoconferencing capabilities in this setting needs to be determined.

In conclusion, HBTMH has the potential to greatly expand the range of services available to U.S. military members, veterans, and the general population. Although the current study is limited by its small sample size and lack of a control 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 in the military setting. This study can serve as a model to investigate and implement other forms of home-based healthcare, 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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Disclosure Statement

No competing financial interests exist.

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Patient Perceptions of Telemental Health: Systematic Review of Direct Comparisons to In-Person Psychotherapeutic Treatments

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Abstract

Background: Although there is growing empirical support for the clinical efficacy of telemental health (TMH) treatments, questions remain about how patient perceptions of the TMH treatment process may compare with those of traditional in-person psychotherapy treatments. **Materials and Methods:** Through a systematic review, we specifically examine measures of patient treatment satisfaction and therapeutic alliance in studies that included direct comparisons of video teleconferencing or telephone-based psychotherapeutic TMH treatments with in-person treatment delivery. We performed a comprehensive search of the PsychINFO and MEDLINE databases for articles published in the last 10 years (2004–2014) on TMH treatments that included in-person comparison groups, yielding 552 initial results with 14 studies meeting our full inclusion criteria. **Results:** The findings generally show comparable treatment satisfaction as well as similar ratings of therapeutic alliance. Some results suggested the potential for decreased patient comfort with aspects of group treatment delivered via TMH. **Conclusions:** We discuss implications for providing psychotherapeutic treatments via TMH and review practice recommendations for assuring and enhancing satisfaction with TMH services.

Key words: telemedicine, telemental health, telepsychology, video teleconferencing, treatment satisfaction, therapeutic alliance, literature review

Introduction

Telemental health (TMH) refers to “the provision of mental health and substance abuse services from a distance.”^{1,p.7} Telephone and video teleconferencing (VTC) are common synchronous telecommunication technologies that are used for providing direct psychotherapeutic treatments to patients. Research evaluating TMH treatments thus far has supported their efficacy in addressing a broad range of mental health concerns in many different patient populations.^{2,3} Psychotherapeutic interventions (e.g., behavior change through collaborative dialogue in a therapeutic relationship) delivered via TMH have demonstrated comparable efficacy to in-person treatment in rigorously designed randomized controlled trials, including treatments for posttraumatic stress disorder,^{4,5} depression,⁶ and anger management.⁷ Psychiatric services (e.g., medication management, symptom monitoring, and reducing side effects) delivered through TMH have also been shown to have comparable efficacy to in-person psychiatric care.^{8–10} Moreover, TMH treatments have been successfully delivered to a wide range of patient populations, including children and adolescents,¹¹ adults,¹² older adults,¹³ military veterans,¹⁴ and ethnically diverse populations.¹⁵

Although there is mounting empirical support for the clinical efficacy of treatments delivered via TMH, questions remain in the literature about patient perceptions of TMH services, especially regarding patient satisfaction with remote treatment and potential differences in therapeutic alliance and rapport compared with traditional in-office treatment delivery.^{2,16} Patient satisfaction with and perceptions of the therapeutic relationship are highly relevant for the adoption and acceptance of TMH services among both TMH providers and patients. The American Telemedicine Association Telemental Health Special Interest Group defined patient satisfaction as the “patient’s subjective satisfaction and experience with the TMH service provided.”^{17,p.285} Patient satisfaction with treatment may be an important variable in evaluating intervention programs,¹⁸ and therapeutic alliance has been shown to be a key factor related to psychotherapy outcomes.¹⁹

Previous reviews of TMH treatments in general (including psychotherapeutic intervention, telepsychiatry, etc.) have generally found high levels of patient satisfaction ratings.^{3,20} Research focused on telepsychiatry interventions has specifically found comparable levels of patient satisfaction between in-person and TMH delivery of services.^{9,10} However, these results may not generalize well to other types of treatment, as psychiatry is most often concerned with medication management during brief, intermittent meetings, whereas psychotherapeutic treatment relies on a therapeutic relationship and detailed discussion of patient concerns and intervention strategies that develop over multiple sessions. Therefore, aspects of and expectations for patient satisfaction may differ significantly between these two types of TMH treatment, and it may be helpful to consider them separately. Although existing research has generally found high levels of satisfaction with TMH psychotherapeutic interventions,^{2,21} no reviews to date have investigated patient satisfaction with psychotherapeutic treatment compared with in-person delivery. This is an important contribution to the literature given that “we do not know whether patient satisfaction with tele-mental health would remain as high in the presence of alternative mental health services.”^{20,p.328} In addition, there have been some indications that satisfaction with TMH may be reduced, largely due to the potential for technical difficulties in TMH equipment and poor connection quality (e.g., low Internet bandwidth).^{2,20}

Therapeutic alliance is another important factor that has been shown to be associated with psychotherapy outcomes.¹⁹ Therapeutic alliance, also called working alliance, was defined by Bordin²² as consisting of three aspects: agreement and collaboration on goals for therapy work, the tasks patients are engaged in, and the interpersonal bond between patient and therapist characterized by mutual trust and attachment. Low satisfaction and weaker therapeutic relationships in remote TMH treatment may deter people from engaging in treatment. For example, frustration with setting up or using the technology and concern about privacy may discourage patients from seeking out or engaging in TMH treatment. Providers and their choices about treatment modalities used may also be impacted by their own attitudes toward and perceptions of TMH.²³ For example, in a study that surveyed mental health professionals, Perle et al.²⁴ found lower general levels of acceptance toward technology-mediated interventions compared with face-to-face services, which also varied widely by type of psychiatric diagnosis. Some researchers have begun to address these issues more directly, with some emerging support for comparable patient ratings of working alliance for in-person and e-therapy (text-based) treatment.²⁵ Similarly,

Stiles-Shields et al.²⁶ reported comparable working alliance scale scores from both clients and providers in the face-to-face and telephone cognitive behavioral therapy (CBT) conditions in a sample of individuals struggling with depression.

Although preliminary research has begun to illuminate these central questions about patient perceptions of TMH treatments, more information is needed to fully evaluate TMH-based treatments and to also identify best practices that assure optimal delivery of care. The literature has echoed these calls for direct comparison between satisfaction levels for psychotherapeutic TMH treatments and face-to-face conditions, as well as the establishment of standard measures of client satisfaction for research in this area.^{2,23} Thus, we sought to conduct a systematic review of TMH research literature to evaluate studies that directly compare psychotherapeutic TMH treatment with equivalent in-person services to synthesize findings regarding patient satisfaction and therapeutic alliance. We also review the factors reported to influence patient satisfaction with TMH-based treatment services and discuss best practices for assuring and enhancing satisfaction with TMH services.

Materials and Methods

LITERATURE SEARCH

We conducted a comprehensive review of published research articles in the telemedicine and TMH literatures by performing a systematic search of the PsycINFO and Ovid MEDLINE databases. We followed a systematic strategy of combining the search terms “telemedicine,” “telemental health,” “telehealth,” “teleconferencing,” or “videoconferencing” with every one of the following terms in combinations using Boolean logic operators (e.g., AND, OR): “mental health,” “psychotherapy,” “therapist attitudes,” “client attitudes,” “client satisfaction,” and “treatment.” Restrictions for all searches included the following: English language, publication date range between 2004 and the third week of February 2014, empirical research involving adults, and publication in peer-reviewed journals. This search yielded 552 potentially relevant articles for evaluation. In addition, we performed a hand search of literature in relevant journals, consulted with experts about relevant TMH publications, and reviewed references cited in articles, review articles, and meta-analyses obtained in the initial search; these procedures yielded 20 additional sources that were included in the full review.

INCLUSION CRITERIA

We established the following inclusion criteria for reviewing the identified subset of studies, all of which had to be met in order to be included in our full review: (1) study design

included both TMH and in-person treatment groups; (2) TMH intervention composed of direct, synchronous communication with a mental health provider; (3) TMH treatment was primarily concerned with a psychological treatment involving a psychotherapeutic relationship (not exclusively psychiatry); and (4) outcome variables included measure of treatment satisfaction and/or therapeutic alliance.

FULL REVIEW AND ARTICLE ABSTRACTION

The first author (M.A.J.-G.) reviewed the titles and abstracts of the 552 articles for relevance and potential fit with our inclusion criteria (Fig. 1). This process yielded 101 articles eligible for full text review to determine if these studies explicitly met our inclusion criteria; we also reviewed fully and applied the inclusion criteria to the 20 articles obtained from hand searching and related methods performed during the review process. The first two authors (M.A.J.-G. and L.D.P.) independently evaluated the full text of these articles using a standardized criteria form and discussed any inconsistencies regarding inclusion decisions to form consensus. This process identified 18 studies focusing on psychotherapeutic TMH treatment; however, upon further inspection and contact with the study authors, four studies were re-analyses of data previously used in other studies already included in our review and so were excluded. Thus, 14 articles were included in our final review. We abstracted relevant information from these studies using a coding form, including sample size, telepsychology modality, diagnoses treated, client population, type of intervention, satisfaction and therapeutic alliance measures, and any other factors related to patient perceptions of treatment. These articles are summarized in Table 1.

Results

STUDY DESCRIPTIONS

Nine of the studies used randomized controlled trial designs, of which four were noninferiority trials. The remaining five studies relied on nonexperimental designs such as active control group designs without randomization, posttreatment quit-rate comparisons,²⁷ or multiple baseline through random assignment.²⁸ Study samples were drawn from both rural and urban populations from the United States (n=9), Canada (n=4), the United Kingdom (n=1), and Australia (n=1); all studies targeted adults. Most of the studies involved treatments delivered via VTC (n=13), whereas two studies were telephone-based TMH. Although most of the sample sizes could be considered small (for unique samples: median=46; mean=84.2), the nonexperimental group VTC-based smoking cessation study of Carlson et al.²⁷ included 554 people. The most common therapeutic orientation evaluated was CBT (11 studies).

PATIENT PERCEPTIONS OF SATISFACTION AND ALLIANCE

Four studies used custom scales developed for individual investigations, whereas others used standardized measures such as the Working Alliance Inventory,²⁹ the Session Evaluation Questionnaire,³⁰ or the Charleston Psychiatric Outpatient Satisfaction Scale-VA.¹⁸ Findings indicated no statistically significant condition effects for those studies that directly compared patient ratings of satisfaction with psychotherapeutic treatment between in-person and TMH conditions.^{4,7,31-35} Similarly, six analyses found no significant differences between modalities on patient ratings of therapeutic alliance.^{31,34,36-39} Four other studies reported no significant differences for related process measures or custom measures capturing some element of the treatment experience related to therapeutic relationship or client perceptions of treatment.^{4,7,37,39}

Four studies reported a statistically significant difference between conditions on more relationally oriented measures such as alliance between client and therapist. The in-person condition patients of Morland et al.⁷ reported higher ratings for group therapeutic alliance during anger management treatment compared with patients in the TMH condition. Although the study of Greene et al.⁴⁰ is a later analysis of the randomized controlled trial of Morland et al.,⁷ both will be discussed here given the distinct finding of Greene et al.⁴⁰ based on

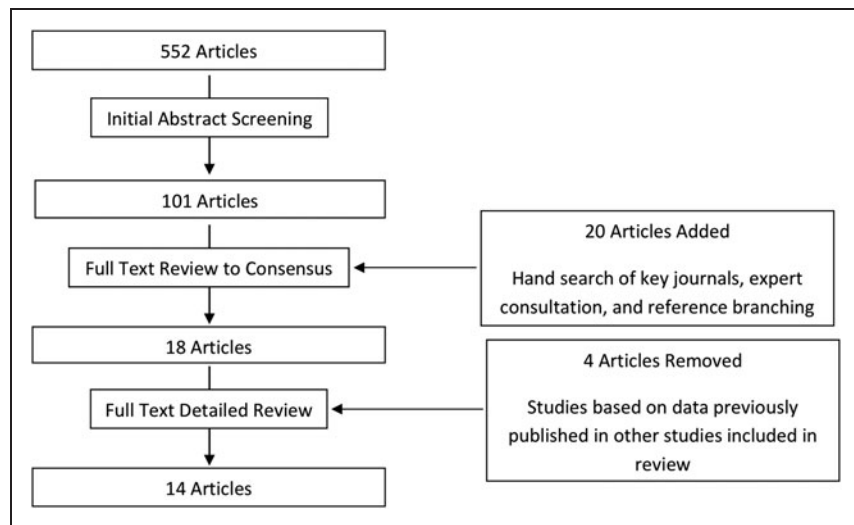


Fig. 1. Flow diagram detailing study selection for review.

Table 1. Characteristics of Included Studies

REFERENCE (YEAR)	SAMPLE SIZE (M)	PATIENT POPULATION	STUDY DESIGN	TARGET CONDITION	TMH MODALITY	THERAPEUTIC MODALITY	MEASURES	RESULTS/NOTES
Bouchard et al. ³⁶ (2004)	21	Canadian adults (half rural, half urban)	Randomized pre-post design with nonequivalent control group	Panic disorder with agoraphobia	VTC	Individual CBT	WAI; adapted treatment credibility questionnaire	WAI subscale scores reported for telepsychology group and concluded that no statistically significant differences between conditions were found posttreatment
Carlson et al. ²⁷ (2012)	554	Canadian adults (rural at remote sites; urban at in-person sites)	Posttreatment quit-rate difference comparisons	Tobacco use	VTC	Group smoking cessation (prominent CBT elements)	Custom telehealth and program evaluation questionnaires	Overall, relatively high satisfaction for both groups, with some reported disruption in participant experience due to the technology
Dunstan et al. ²⁸ (2012)	6	Australian adults	Multiple baseline	Depression and anxiety	VTC	Individual CBT, motivational interviewing, or interpersonal psychotherapy	Qualitative data collected from patients and providers	Satisfaction with modality from qualitative descriptions appeared generally positive.
Ertelt et al. ³⁷ (2011) ^a	116	U.S. adults	RCT	Bulimia nervosa	VTC	CBT	WAI	No statistically significant differences between treatment conditions for patient WAI ratings; provider WAI ratings were statistically significantly greater for the in-person condition. No differences observed in patient ratings for treatment suitability or success expectations
Frueh et al. ⁴ (2007)	38	Male U.S. veterans	RCT	PTSD	VTC	Group social and emotional rehabilitation CBT program	CPOSS-VA; TCS; SDPS	For process outcomes, only one difference found for greater comfort in talking with therapist for in-person group; overall satisfaction was comparable along with multiple additional process question responses. No attendance differences; greater homework completion for in-person group; differential dropout rates
Germain et al. ³⁸ (2010) ^b	46	Canadian adults	Nonexperimental active control group design	PTSD	VTC	Individual CBT	SEQ; WAI; DCCS; VTS; VT-Q	No statistically significant differences found on patient WAI scores between conditions, with Task and Bond subscales showing improvement over time for both modalities
Himmelhoch et al. ³¹ (2013)	34	U.S. adults attending HIV clinic	RCT	Major depressive disorder	Telephone	CBT	SIMH; WAI	No differences between groups for number of sessions attended, satisfaction scores, or WAI scores

continued →

Table 1. Characteristics of Included Studies *continued*

REFERENCE (YEAR)	SAMPLE SIZE (N)	PATIENT POPULATION	STUDY DESIGN	TARGET CONDITION	TMH MODALITY	THERAPEUTIC MODALITY	MEASURES	RESULTS/NOTES
King et al. ³² (2009)	37	U.S. adults	RCT	Substance use	VTC	Group relapse control therapy	Patient satisfaction survey; items on preference for modality of group intervention	Comparable satisfaction ratings between conditions, with high overall ratings; strong preference reported for VTC condition compared with on-site group intervention (often citing privacy and convenience); no difference in attendance between conditions
Lovell et al. ³³ (2006)	72	United Kingdom adults	RCT	OCD	Telephone (with some face-to-face contacts)	CBT (exposure and response prevention therapy)	CSQ-8	Satisfaction scores between conditions were comparable and at high levels for both groups.
Morgan et al. ³⁴ (2008)	86 (for psychological services)	U.S. adult male correctional inmates	Nonexperimental active control group design	Majority mood disorders and psychotic disorders	VTC	Psychotherapy focused on adjustment to institution, adaptive coping, and managing mental health symptoms	CSQ-8; WAI; SEQ	No statistically significant differences between in-person and telepsychology treatment groups on WAI, SEQ, or CSQ-8 scores
Morland et al. ³⁵ (2004)	20	U.S. male veterans	RCT	PTSD coping skills	VTC	PTSD coping skills group	Custom client and clinician satisfaction questionnaires	Comparable client satisfaction scores between groups after both 4 and 8 weeks of treatment, with satisfaction levels rising between mid- and posttreatment for both conditions; no statistically significant differences between conditions on clinician satisfaction scores; comparable number of sessions attended
Morland et al. ⁷ (2010)	125	Rural U.S. adult male veterans with PTSD	RCT	Anger management secondary to PTSD	VTC	Group anger management	CPOSS-VA; GTAS; TCS	No statistically significant differences between groups for patient satisfaction, process outcomes, or treatment credibility; alliance scores higher for in-person treatment group
Morland et al. ³⁹ (2011)	13	U.S. male military service members and veterans	RCT	Group CPT for combat trauma	VTC	CBT (group cognitive processing therapy)	GTAS; TCS	No difference in alliance ratings or expectancy
Tuerk et al. ⁴⁴ (2010)	47	U.S. veterans	Nonexperimental active control group design	PTSD	VTC	Prolonged exposure therapy	VTC acceptance measure	High acceptance rate for TMH; rates of treatment noncompletion within expected ranges

^aResults based on the study and sample of Mitchell et al.¹²

^bResults based on the study and sample of Germain et al.⁴³

CBT, cognitive behavioral therapy; CPOSS-VA, Charleston Psychiatric Outpatient Satisfaction Scale-VA; CSQ-8, Client Satisfaction Questionnaire; DCCS, Distance Communication Comfort Scale; GTAS, Group Therapy Alliance Scale; HIV, human immunodeficiency virus; OCD, obsessive-compulsive disorder; PTSD, posttraumatic stress disorder; RCT, randomized controlled trial; SDPS, Service Delivery Perceptions Scale; SEQ, Session Evaluation Questionnaire; SIMH, Satisfaction Index-Mental Health; TCS, Treatment Credibility Scale; VT-Q, Videoconferencing Therapy Questionnaire; VTC, video teleconferencing; VTS, Videoconferencing Telepresence Scale; WAI, Working Alliance Inventory.

Group Therapy Alliance Scale⁴¹ subscales. Greene et al.⁴⁰ reported lower Group Therapy Alliance Scale Self-Leader alliance subscale scores in the VTC condition, suggesting lower perceived connection between individual patients and the group therapist. However, they also noted that patients in the VTC group reported relatively high levels on the Likert scale used (mean was 4.2 out of a possible 5 points). Similarly, participants in the in-person condition of Frueh et al.⁴ reported greater comfort in talking with the group leader. Lastly, Ertelt et al.³⁷ reported that providers not involved in treatment who rated sessions of individual CBT treatment for bulimia nervosa indicated higher Working Alliance Inventory ratings for the in-person group compared with VTC delivery. However, it is important to note that the actual patient ratings were comparable between conditions. Although insufficient data were available to make firm conclusions, the only significant differences in the studies reviewed involved higher patient ratings of alliance and comfort in group treatment models for in-person treatment.

THERAPEUTIC ORIENTATION AND TREATMENT FORMAT

Across CBT studies, there was strong support for comparable levels of patient satisfaction between conditions, particularly for individual psychotherapy. Results also suggested similar satisfaction and patient-provider alliance scores across the limited sample of non-CBT interventions,^{28,32,34,35} although additional research is needed for other therapeutic orientations (e.g., interpersonal psychotherapy, motivational interviewing). Three of the four studies included in this review that found differences between TMH and in-person conditions were evaluations of group interventions. This suggests that psychotherapy format may be a significant factor in patient perceptions of the treatment experience.

DIAGNOSTIC CATEGORY

Across these categories, the results consistently supported the conclusion that both in-person and remote care demonstrated high overall levels of patient satisfaction. Although some interesting deviations from this pattern exist, the evidence suggests that the presenting problem does not strongly influence satisfaction ratings for the method of treatment delivery. The most commonly investigated diagnostic categories included depression ($n=3$) and posttraumatic stress disorder ($n=6$), and studies focused on these two disorders found comparable ratings of treatment satisfaction between remote and in-person modalities.

Frueh et al.⁴ reported that individuals receiving in-person care showed higher levels of comfort for talking with their therapist compared with those in the remote care condition at

their postassessment. However, this difference may be more related to the group treatment format.

In two studies focused on substance-related issues,^{27,32} the authors noted that patient dissatisfaction arose when experiencing technical difficulties with the TMH equipment. It is interesting that King et al.³² reported that patients receiving group relapse prevention treatment over TMH reported an increased perception of privacy compared with those participating in in-person treatment. This may have been because TMH participants could not see images of one another and only audio was shared between participants. In the study on group treatment for anger management,⁷ the in-person group produced higher ratings of therapeutic alliance than the VTC group.

Lastly, although patients in the study of Mitchell et al.¹² had comparable alliance scores between remote and in-person conditions, their treatment providers rated their own levels higher for in-person treatment delivery. These authors suggest that this finding may have resulted from providers being more focused on how to apply the treatment across a novel modality, whereas patients were more focused on the content of the intervention itself, regardless of modality.

Discussion

The results of this systematic review show that, in general, patient ratings of satisfaction with psychotherapeutic interventions and therapeutic alliance in treatment are comparable between remote TMH and in-person delivery. However, it is also important to note that the research conducted to date has generally involved small sample sizes, which may limit conclusions. Other treatment factors such as rapport and provider expertise, as well as patient factors such as personality variables and treatment preferences, are also likely to be important variables associated with patient satisfaction and therapeutic alliance. In addition, the efficacy of the specific treatment protocols used to guide treatment may be connected to patient perceptions of treatment and, ultimately, their satisfaction with the treatment process and clinical outcome, regardless of the means through which treatment is delivered. Furthermore, in the studies reviewed that showed different satisfaction levels between modalities, these findings appear to be associated with more modifiable factors such as the use of group treatment or technological factors that influence VTC quality. These results imply that additional preparation and focus on patient experience in treatment may be useful in group treatments delivered via TMH. Additionally, providers should follow established guidelines, such as those published by the American Telemedicine Association,¹ in selecting and setting up the technology to be used in synchronous psychotherapeutic TMH treatment.

Care providers must work with patients to weigh the pros and cons of using TMH services and determine what alternatives may be appropriate (e.g., traveling to a distant clinic for services). In some scenarios, it may be that treatment through TMH allows for the greatest access to care while also risking reduced satisfaction and engagement with treatment due to external factors such as Internet bandwidth. However, this risk may be warranted when the alternative to TMH is to travel great distances (e.g., to a metropolitan center), increasing the time and cost of seeking and receiving treatment—especially among populations who live on a fixed income, whose healthcare requires travel to a specific center (e.g., Veterans Administration Medical Center), or who cannot afford the luxury of taking time off work, arranging childcare, and commuting to and from an appointment on a recurring basis. Previous research has highlighted the importance of patient preference and choice of treatment, as these factors have relationships with both patient satisfaction and clinical outcomes.⁴² Because of these considerations, future research must begin to consider the patient's choice as a contributing factor in both the efficacy and satisfaction associated with treatment delivered via TMH and whether responses to treatment are modulated by one's match between the desired mode of treatment delivery and the received mode of treatment delivery.

Further research is needed to more fully assess the role of intervention format (e.g., group therapy, individual therapy) in patient satisfaction and therapeutic alliance given the small number of studies available from which to draw inferences. Additionally, investigations seeking to understand how individuals engage with telehealth treatment are needed, as well as research on perceptions of treatment experience for people with other specific psychiatric diagnoses. Richardson et al.²⁰ emphasized shortcomings in the research literature on patient satisfaction with TMH services by highlighting the need for evaluating satisfaction with the TMH modality as a distinct construct from general satisfaction with treatment. Researchers should define patient satisfaction with treatment carefully, as some have questioned whether findings suggesting comparable satisfaction ratings are primarily based on the treatment program instead of being tied to the modality being used (i.e., VTC). As our review highlights, researchers have been inconsistent in the types of satisfaction measures used across studies, making it more difficult to objectively compare studies and evaluate patient satisfaction as an outcome. Use of these standard satisfaction measures can be useful not only for research, but should be part of all TMH services programs to help inform program evaluation and improvement. The assessment of provider satisfaction with TMH may also be useful for making improvements to TMH programs.

PRACTICE RECOMMENDATIONS

Several studies examined for this review suggest that training for clinicians on TMH delivery of psychotherapeutic services could be implemented to increase clinician comfort and confidence with this modality, which in turn may affect patient satisfaction.^{34,37,43} It is also important to explain the TMH process and expectations with patients and to encourage questions and discussion of concerns before, during, and after TMH sessions. Similarly, it can be useful to emphasize the practical aspects of TMH delivery, such as technical support with computer equipment and specific instruction on using the computer and software involved³² as well as remote room setup and adequate lighting.¹² Clinicians may also need to adapt their delivery to overcome potential barriers in remote modalities, for example, by repeating discussion of psychoeducational content and directing attention toward related materials (e.g., handouts) in treatment.³⁵

Appropriate involvement of an assistant or mental health professional available at the remote treatment site may also affect patient satisfaction and can be an important resource for clinicians in managing suicide risk.¹² Local assistants can be used to increase engagement in groups and facilitate practical aspects of treatment such as transmitting forms or assessments to the clinician.^{27,39} Facilitators may also be instrumental ensuring that technical problems are minimized by testing equipment and connections as well as assisting with troubleshooting procedures.

Conclusions

The quality of patient satisfaction and the therapeutic alliance are essential to both the effectiveness of TMH-based treatments and to the acceptance of TMH services among both patients and care providers. Consistent use of standardized measures of patient treatment satisfaction in research studies and in general clinical practice is a necessity to accurately assess these important variables. TMH-based services continue to show great promise for addressing barriers to care, including geographic limitations and shortages of healthcare providers. The application of best practices that help to improve patient satisfaction and to optimize the quality of other therapeutic process variables with TMH will serve to expand the wider adoption of TMH services and assure the best possible quality of care.

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SUICIDE RISK MANAGEMENT DURING CLINICAL TELEPRACTICE*

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ABSTRACT

The effective assessment and management of suicidal patients is an essential component of telehealth-based care. With this article, we describe how we have implemented procedures for the ongoing assessment and management of suicide risk in a clinical trial that compares in-office treatment to home-based treatment delivered via web-cam to U.S. military service members and veterans with depression. We describe our safety protocol and how it was adapted from current recommended best practices, published guidelines, and local requirements for managing patient safety during home-based telepractice. We conclude with discussion of other key safety issues associated with telepractice. The topics discussed are relevant to all mental health practitioners who are interested in clinical telepractice services.

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Key Words: suicide risk, patient safety, risk management, telehealth, telemedicine

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INTRODUCTION

The effective assessment and management of suicidal patients is a critical component of both conventional in-office care and telehealth-based care. There are aspects of telepractice, however, that require additional considerations for managing the safety of patients who are or become high risk for suicidal behavior while under care. In clinically supervised settings (e.g., a provider's office, clinics, hospitals, etc.), clinical staff are typically available to assist during a clinical crisis by coordinating emergency services, providing consultation, or escorting a patient to the emergency department. The same is not necessarily true when care is delivered to settings that do not have clinical supervision at the remote site (e.g., a patient's home). Thus, management of suicide risk and patient safety during telepractice involves additional considerations and requirements. A particular concern is what to do in situations where a patient expresses intent to harm him/herself at the end of a telehealth session or before unexpectedly disconnecting from the session [1]. In order to effectively manage this type of crisis or other emergency situations (e.g., medical emergencies), it is necessary for telehealth providers to have a pre-planned process in place.

The assessment and management of patients' suicidal behavior while under care can be a very difficult and stressful experience for mental health clinicians [2, 3]. In the case of clinical telepractice, stress and anxiety can be exacerbated by the fear of having less control of the situation, unfamiliarity with safety procedures, technology issues, and concerns about liability [1]. The issue of potential liability is of particular concern for many mental health practitioners because inadequate suicide risk management can result in licensure complaints and/or malpractice lawsuits. Due to the ethical and legal responsibilities mental health practitioners have toward patients, liability can occur from even the briefest of patient contacts. The use of technology to deliver care (e.g., video conferencing, e-mail, web chat) introduces additional ways that a professional relationship can form and with it raises responsibilities to assess and manage suicide risk. The anxiety and concern about liability issues among individual practitioners and healthcare organizations as a result of these additional methods of delivering care can present a barrier to the wider adoption of telehealth-based services.

Several organizations, such as the American Psychological Association (APA) and the American Telemedicine Association (ATA) have issued guidelines that include provisions for patient safety management during telepractice [4, 5]. The American Psychiatric Association does not have its own telepractice guidebook, although the association refers its constituents interested in telemedicine to the ATA guidelines [6]. Clinical best practices regarding safety management specific to telemental health have also been published [7, 8], as have telemental health guidebooks that address patient safety [9]. Although the available guidelines, extant telepractice literature, and the general suicide risk management literature [2, 10-14] provide frameworks for effective risk management, the

literature is limited in detailed information regarding real-world implementation of suicide risk assessment and management protocols for telehealth-based services, particularly to clinically unsupervised settings such as the home.

With this article we address this limitation by describing how we have translated safety guidelines, practice recommendations, and local requirements into ongoing assessment and management of suicidal risk as part of a clinical trial that compares in-office treatment to care delivered to the home via web-cam to patients with depression. We describe our safety protocol, suicide risk assessment and management procedures, and how we have applied our safety protocol to mitigate risk during telepractice. We recognize that our protocol is limited by the specific clinical setting and population (clinical research at U.S. military and VA Hospitals); however, the principles and issues that we describe have applicability to other clinical telepractice settings. We do not elaborate on the issues surrounding licensure and liability as these have been adequately covered elsewhere [15].

CLINICAL TRIAL DESCRIPTION AND SAFETY PROCEDURES

The clinical trial (ClinicalTrials.gov Identifier #NCT01599585) is being conducted at the U.S. Department of Defense's National Center for Telehealth and Technology (T2) located at Joint Base Lewis-McChord (JBLM) in Washington State and at the Portland VA Healthcare System in Oregon. The aim of the trial is to compare in-office to home-based delivery of an abbreviated (eight-session) version of the revised Brief Behavioral Activation for Depression protocol (BATD-R) [16]. BATD-R is a behavioral reinforcement-based treatment that has received extensive empirical support as a treatment for depression [17]. Patients in our trial include both U.S. military personnel and veterans who either self-refer or are referred to the study by behavioral health providers at each respective site. While home-based telemental health treatments are already being expanded in the VA Health System, home-based telemental healthcare is not presently the standard of care in the U.S. military. Thus, the primary purpose of the trial is to examine the feasibility, safety, and effectiveness of home-based telemental health in the military setting to inform policy for broader implementation of home-based treatments. The study protocol adheres 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. This study was approved by the Madigan Army Medical Center Institutional Review Board and the Army Human Research Protection Office.

For our trial, eligible participants are randomized to either the in-office or in-home treatment groups. All participants are provided with eight sessions of BATD that follows a treatment manual [17]. Participants in both intervention

groups follow the same assessment schedule with clinical assessments at baseline (before first treatment session), mid-treatment (week 4), 1-week post-treatment, and 3-months post-treatment. A detailed description of the trial's methodology is published elsewhere [16].

Safety Protocol

The essential components of our safety protocol planning steps and processes are shown in Table 1. The safety protocol was designed in accordance with the professional guidelines and best practices literature available at the time [5, 7] and is consistent with the most recent applicable guidelines from both the American Telemedicine Association [18] and American Psychological Association [4]. Our safety protocol was made into a formal written plan that is part of our trial's research protocol.

The development of our safety protocol began with review of applicable local regulatory requirements and guidance. Our study clinicians (clinical psychologists) are credentialed providers at Federal facilities; Madigan Army Medical Center (MAMC) and Portland VA Medical Center (PVAMC). Thus, the standard operating procedures (SOP) of the Army and PVAMC were reviewed and included in our plan. This review included examination of duty-to-warn and mandated safety reporting requirements. For active-duty military personnel, their command must be notified when the service member's safety is a concern. Thus, these patients are asked to provide command contact information. The use of support persons is a recommended approach to telehealth safety planning [5, 7]. Depending on the type of clinical setting, an additional support person to assist with coordination in emergencies could include another treatment provider, other designated staff at the patient site, a family member, or a local community contact who knows the patient and agrees to remain reachable during telehealth sessions [19]. Thus, we ask patients at both sites to identify another person (e.g., family member, partner, or friend) who can be notified in case of an emergency. Patients at both sites are asked to complete a site specific release of information form so that the third party can assist in cases of emergency or imminent risk. These processes are discussed with our patients during the informed consent process upon entry into the clinical trial.

Screening and Assessment

Telepractice guidelines uniformly urge clinicians to determine appropriateness of each patient for telehealth care prior to initiating services [4, 5]. "Appropriateness" varies across contexts based on several factors including technology considerations, patient needs and preferences, and administrative regulations [1, 7]. In mental health care, suicide risk assessment is a critical aspect of determining appropriateness for varied treatment modalities. In our trial, suicide risk assessment begins during the initial in-person screening of patients. We first administer

Table 1. Overarching Safety Plan Steps and Process

Safety planning step	Process
Practice within institutional rules, regulations, and state laws	<ul style="list-style-type: none"> • Review local and health systems regulations. • Providers receive training and supervision on pertinent institutional and legal regulations for providing telehealth-based care.
Determine appropriateness of telehealth-based care	<ul style="list-style-type: none"> • Conduct pre-treatment clinical assessment and suicide screen to determine risks, contraindications, etc.
Ensure adequacy of home-environment, technology, and devices	<ul style="list-style-type: none"> • Test infrastructure for adequate bandwidth. • Assess quality of environment (e.g., sound, lighting, privacy, etc.) and equipment (e.g., computer, microphones, cameras, etc.). • Ensure tech support plan and materials (troubleshooting guides). • Plan for maintaining privacy at patient's end.
Conduct site assessments and establish procedures	<ul style="list-style-type: none"> • Obtain alternative contact numbers from patient. • Obtain patient's local emergency contact information and confirm with EMS agency (using non-emergency line). • Identify local collaborators (e.g., Patient Support Person) that can be called to support patient safety during crisis. • Obtain needed authorizations to release information. • Provider ensures that he/she has access to a secondary phone line in the clinical room during appointments. • Have secondary staff available during appointments to coordinate with EMS, if needed.
Discuss roles and responsibilities with patient	<ul style="list-style-type: none"> • Discuss technical troubleshooting with patient and have an agreed upon method for re-establishing contact during service disruption (e.g., via telephone).
Evaluate patient risk during and after treatment	<ul style="list-style-type: none"> • Monitor psychiatric symptom levels. • Assess for presence and/or change in suicidality. • Monitor relevant changes in patient's home environment. • <i>(If indicated by risk level)</i> Develop multi-step safety plan and provide patient with a copy of the plan. Lead a direct and candid discussion about patient's access to firearms or other lethal means, and generate strategies to restrict access. Determine how transportation, if necessary, will be handled and whether to utilize a local collaborator. • <i>(If indicated by risk level)</i> Try to remain connected to patient via VTC while coordinating involvement of EMS by telephone. Involve secondary staff and notify third parties as warranted.

Note: This list is based on that presented by Luxton and colleagues [7].

the Structured Clinical Interview for the DSM-IV Axis I Disorders, Research Version, Patient Edition (SCID-I/P) [20] to determine initial study eligibility and to screen for current suicidal ideation and past self-injurious events. Potential patients are ineligible for the trial if they report a suicide attempt during the past 6 months or if they have current ideation with stated intent. These exclusion criteria may eliminate the highest risk patients that are encountered in other clinical settings; however, these exclusion criteria were deemed necessary for this study because home-based care is not the standard of care in our setting (and thus deemed experimental by our IRB).

As part of our overall safety plan, we use the Standard Operating Procedure (SOP) for the Assessment and Management of Suicide and Homicide Risk in Active Duty Service Members that is used at MAMC [21]. This official SOP was updated during the course of our study, therefore we updated our procedures to remain consistent with the SOP. The SOP is based on information from several sources including the VA/DoD Clinical Practice Guidelines for Assessment and Management of Patients at Risk for Suicide [22], U.S. Air Force Guidelines for managing suicide behavior [23], and several other DoD policies and procedures. The same SOP guides assessments completed in-person or during telehealth sessions.

The SOP specifies a five-step process. Step one consists of a screen for the presence of suicidal, violent, or homicidal ideation, intent, or behavior. If the screen suggests presence of any risk, a full assessment interview is administered (step two) that assesses for frequency, intensity, and duration of ideation, content of thoughts and/or plans, impulsivity, history of suicidal and violent behavior, and other warning signs, risk, and protective factors. At the third step, clinicians integrate all information gathered from the assessment interview and compare that information to the SOP's guidelines in order to arrive at and document the current level of risk (i.e., not at elevated risk, low risk, intermediate risk, or high risk). The general descriptions of the levels of risk and associated clinical interventions specified in the SOP are shown in Table 2. In step four, clinicians are to document and provide rationale for the clinical responses provided. Finally, in step five of the risk assessment, clinicians develop and document safety plans with all patients with any elevation of risk. Safety plans can vary based on idiographic factors; however, the SOP encourages use of a safety plan to assist patients in identification of healthy coping strategies to be used when distressed, people to contact for additional support, ways to reduce risk in their environments (i.e., limiting substance use and restricting access to means), emergency/crisis response contact numbers, and making a commitment to living and to engage in treatment.

In our trial, the suicide risk assessment SOP is administered both at the intake/screening assessment and again during the first treatment session. It is also administered during subsequent assessment and/or treatment sessions as needed. That is, if a patient were to indicate a change in the severity or frequency of

Table 2. Determination of Suicide and Homicide Risk Level

Risk level	Criteria used to determine risk ^a	Clinical response ^b
Not at elevated risk	Denial of recent violent or suicidal ideation, intent, plans, or preparations. No history of violent behavior or suicide attempt in the previous 2 years.	No change necessary in routine outpatient clinical practice. Provide contact information for emergency responders. May consider devising safety plan for highly distressed patients.
Low risk	Endorsement of recent violent, homicidal, or suicidal ideation without intent to act or devise. Frequency and duration of ideation is low. No evidence of preparations or difficulty controlling impulses. No violent behavior or suicide attempt in the previous year.	Establish a safety plan with patient that addresses coping strategies, contact information for social supports, means restriction and limiting of substance use, and emergency contact information. Elicit a commitment to living and to engaging in treatment.
Intermediate risk	Endorsement of current homicidal or suicidal ideation without intent to act or difficulty controlling impulses. Frequency and duration of ideation is moderate to high. No recent violent behavior, suicide attempt, or preparations.	Take precautions of low risk and consider increasing frequency and/or intensity of contact to ≥ one time per week. Engage in peer consultation to share and track decision-making process and determine need for internal and external reporting/disclosures and means restrictions.
High risk	Endorsement of persistent homicidal or suicidal ideation with a plan or intent to act on a plan, and difficulty controlling impulses. Or, recent violent act, suicide attempt, or preparations.	Engage lower level precautions (including development of detailed safety plan with means restriction) and increase treatment intensity. Strongly consider implementing emergency response to arrange for safe transport of patient for evaluation and possible inpatient hospitalization. Initiate reporting/disclosure processes as indicated.

Note: The contents of this table are based on the MAMC risk assessment SOP [20].
^aIn addition to these criteria, clinical judgment is used to integrate additional known risk factors (e.g., agitation, significant psychosocial stressors, hopelessness) and protective factors (e.g., interpersonal connections, help seeking, optimism) to ultimately arrive at and document a current risk-level determination. Further, if a patient has greater than one previous suicide attempt or violent act, risk level automatically advances at least one level.
^bThese clinical responses reflect the minimum indicated response. Clinical judgment is always part of risk evaluation and clinicians may elect to engage a higher level of intervention if deemed appropriate.

suicidal ideation, the treatment provider would again assess for suicide risk per the SOP. If a patient is assessed to be at not elevated or low risk, s/he would not be assessed again until the final treatment session. Patients at or above intermediate risk are assessed during each treatment session until level of risk decreases below the intermediate risk threshold.

Patient Monitoring and Telehealth Session Checklist

As part of the clinical assessment battery in our trial, patients are asked to complete the Beck Depression Inventory-II (BDI-II) [24] during the clinical outcomes assessments and to complete the Patient Health Questionnaire (nine item) [25] before each treatment session. During telehealth sessions, patients provide their responses to the self-report items verbally and the clinicians record the responses in the patient's treatment folder (clinical chart notes). These assessment measures provide a method for regular monitoring of clinical symptom levels and the presence of and/or change in suicide risk throughout treatment.

For all patients, regardless of their initial risk level determination, ideation and other signs of risk for suicide and violence are documented by study clinicians via a treatment session checklist. Our telehealth treatment session checklist was developed in part to provide clinicians with specific patient safety and suicide risk assessment, monitoring, and documentation procedures. The complete checklist used in the current study is published elsewhere [16]; however, its components and rationale are summarized as follows. The checklist begins with a verification of patient location and contact information. Prior to the first session, study clinicians obtain contact information for local emergency services based on patient's place of residence. Patients are also asked whether they feel that their home environment is safe and private. Additional questions assess whether the patient appeared intoxicated or otherwise disheveled, distressed, or upset; suicidal desire and ideation, such as whether the patient showed any signs of suicidal ideation or self-harm behavior; and plans and preparatory behavior, such as whether a weapon (firearm) was observed in the patient's home.

Risk Escalation and Continuity of Care Procedures

For the purposes of our trial, if a study clinician observes a significant elevation in patient risk for suicide or violent behavior, the clinician is to immediately notify a supervisory psychologist who assists in determining what additional steps of the safety protocol are appropriate. Although determining the most appropriate clinical response for a given patient requires consideration of multiple factors, our safety protocol specifies minimum levels of intervention to be offered at each risk level. For example, at any time an assessment yields a risk level determination beyond no elevated risk, clinicians are expected to collaboratively develop a detailed safety plan with the patient, which may include identification of

safe coping strategies, working with the patient to remove lethal means (e.g., storing firearms in secured locations) and involving support persons with the plan.

While safety plans are familiar to many clinicians, providing patients with a copy of the plan during telepractice necessitates additional consideration. In our trial, telehealth patients are provided with blank copies of our safety plan at their in-person intake assessments so that the plans are available for use throughout treatment. In the event a telehealth patient does not have a blank copy of the safety plan, clinicians collaborate with the patients via telehealth in the drafting of a safety plan and then, once drafted, review the contents with the patient and allow the patient to indicate their comfort and agreement with the plan. Clinicians then mail a hard copy and/or scan and e-mail a copy of the plan to the patient. As with conventional in-office care, if a patient is assessed to be at high risk during a telehealth session, clinicians are expected to consider coordinating an evaluation of the patient for possible hospitalization. By gathering contact information for local emergency services and command, and identifying an emergency contact on behalf of the patient at the outset of telehealth services, our safety protocol is designed to enable clinicians to efficiently and effectively coordinate safe transport and evaluation of high risk patients.

We also have preplanned procedures in place to assure continuity of care for when patients complete treatment, are referred but do not enroll in treatment, or if they leave treatment early. To begin, we work with each patient to establish a continuity of care plan. This involves discussing with patients what may be the best options for them given their preferences and clinical needs. We also facilitate coordination with the initial referring care providers or other mental health professionals as appropriate. In addition, we provide all of our patients (regardless of risk level) with a list of local community mental health resources that they may keep as a reference. We follow-up with patients and/or the referring care providers when necessary and document as appropriate. Our continuity of care process helps to assure patient safety after they leave our care.

SUMMARY

Our safety protocol and suicide risk assessment procedures include gathering patient information so that we can make informed risk assessments and enact indicated, effective responses to psychiatric emergencies. While the patients in our study may be at somewhat lower risk for suicide than other clinical patient populations because of our prescreening criteria, we have encountered patients ranging from low to high risk. The majority of our patients in the in-home treatment condition ($n = 20$ at the time of this writing) began and ended treatment identified as “not at elevated risk” for suicide. The next most frequent risk category for our in-home patients has been low ($n = 6$ at initial treatment session). In each of these cases, the patient endorsed a history of suicidal thinking with limited frequency, intensity, and duration, with no or limited plans and no

preparatory behavior, and few other risk factors identified. We have had three patients receiving care in the home who were identified as intermediate risk for suicide during their initial risk assessment. For each of these cases, the steps to take in the event of increased suicide risk were discussed with the patients. We have also experienced one case that escalated from “low” to “high risk” and one patient that was assessed to be “high risk” during our initial assessment. For both of these cases a “warm hand-off” was made to a supervisory clinician for further risk assessment. Given the high level of risk in these cases, the clinician discussed voluntary hospitalization with these patients and, on both occasions, the patients agreed that presenting to inpatient behavioral health for evaluation was the best option. Per U.S. Army regulations, the study staff contacted the Soldiers’ unit commanders and requested escorts to transport the patients to the ED. One evaluation resulted in inpatient admission; the other did not, although it did result in increased intensity of care. In all cases, we have successfully managed suicide risk by following pre-planned recommended procedures. Our work demonstrates that with appropriate planning and training, patient safety can be effectively managed during telepractice, even when patients are in settings that are not supervised by clinical staff (e.g., their own home).

One of the principal concerns regarding safety management during telehealth is how to effectively manage a suicidal patient when the telehealth connection is lost or disconnected during a clinical encounter. In our trial there have not been any situations where technology failures caused any difficulties with risk assessment, monitoring, or intervention procedures. However, consistent with practice recommendations and guidelines, we are careful to collect alternate methods of contact in case the videoconferencing connection is lost. We also identify a support person who can assist in an emergency. It is also important to tailor safety plans to the specific situations that may be encountered, particularly if patients are located in another geographical or jurisdictional area. Having knowledge of the requirements for civil commitment and *Tarasoff* type duty to warn/protect and incorporating these elements into your safety plan is essential. Even at a local level, simple safety procedures, such as what number to contact for emergency response services may vary based on geographic region.

Suicide risk assessment should be an ongoing process as risk levels are fluid and risk determination is based on integration of multiple pieces of information and clinical judgment [2, 26]. While assessment guidelines and checklists may enhance the standardization of the assessment process and reduce errors, suicide risk is conceptualized as existing along a continuum from no significant risk to imminent risk and it is the clinician who is ultimately charged with integrating present and historical information, considering the duration and severity of explicit and implicit risk factors, and differentially weighting risk and protective factors to arrive at a clinical determination [2, 26]. Maintaining a comprehensive risk management or safety protocol that guides the assessment process, encourages consultation with colleagues and supervisors, and informs clinical

decision making can reduce patient and clinician anxiety, enhance accuracy and reliability of the assessment, and thereby, supports patient safety [27].

Safety planning with patients during telepractice may also carry additional clinical benefits [28]. For example, the process of working collaboratively with patients to establish a safety plan for telehealth encounters may provide the patient with increased confidence and therefore contribute to improved comfort and acceptance of the treatment process. Discussion of technical procedures as well as initial testing of telehealth equipment may also help to facilitate a collaborative therapeutic relationship. In some cases, the involvement of a family member or other supportive person during technical set-up and as part of safety planning may help facilitate patient support and overall treatment adherence. Of course, it is necessary to consider the preferences of patients, their autonomy, and privacy risks when involving others in their care. Telehealth capabilities also provide increased access to care, especially for patients who reside in remote or underserved areas. For these patients, access to care via telehealth services may be critical for ongoing treatment of suicidality, including assessment, intervention, medication management, and follow-up care.

In conclusion, telehealth is a growing area of practice that provides opportunities to increase access to care, improve convenience, and expand the range of clinical services. The effective assessment and management of patients experiencing a psychiatric crisis raises important legal, operational, and clinical issues that telepractitioners must be cognizant of. These issues, however, should not dissuade practitioners from clinical telepractice. With appropriate safety planning, training, and familiarity with published guidelines, telepractice is as feasible as traditional in-office clinical care delivery.

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Clinical Assessment

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DISCLAIMER: The views expressed are those of the author and do not reflect the official policy or position of the Department of Defense of the U.S. Government.

Purpose: This chapter addresses the barriers, solutions, and best practices for conducting clinical assessments with videoconferencing technologies (VCT). Specific attention is given to the process of determining the appropriateness of VCT-based assessments as well as recommendations for preparing, optimizing, and conducting clinical assessments. The exchange of assessment materials, data security, and recommendations for assuring the integrity of assessment instruments are covered. The benefits of telehealth-based assessments and future prospects for advancements in this area of telebehavioral health practice are also discussed.

Context: The information is relevant to clinicians and clinical managers because unfamiliarity with practice guidelines, best practices, and technical capabilities presents a critical barrier to competent, ethical, and effective clinical assessment services.

Tasks: Specific procedures include establishing an appropriate setting for VCT assessment, conducting informed consent for remote services, selecting appropriate measures, managing safety, and providing assessment feedback.

Tools: The chapter provides useful information for selecting compatible assessment measures and procedures, understanding the interaction between culture and service-delivery via VCT, practicing within legal and professional boundaries, and developing a working knowledge of the technological aspects of VCT-based clinical assessments.

Introduction

This chapter addresses best practices for conducting clinical assessments with videoconferencing technologies (VCT). As with in-person clinical assessments conducted in conventional office settings, telehealth-based assessments can be used for diagnostics, screening, symptom monitoring, evaluations of treatment progress and outcomes, and to provide further understanding of client contextual factors and needs. Clinical assessments can be conducted with various VCT platforms that are available today including professional videoconferencing systems, webcams, and camera enabled mobile devices (i.e., smartphones and tablets devices). It is critical for clinicians and clinical managers to be familiar with the best-practices for VCT-based assessments in order to assure that they are conducted appropriately and remain clinically useful. Practitioners also need to know whether a particular measure or assessment

technique is appropriate for use with VCT and they need to become familiar with the proper administration procedures to assure competent and ethical practice.

The chapter begins with discussion of the decision-making process regarding whether to conduct clinical assessments remotely. The considerations associated with clinical appropriateness, culture, and acceptability, legal, regulatory, safety considerations, and practitioner competencies are reviewed. The issues associated with selecting appropriate assessment instruments while considering the evidence base for various measures and techniques are discussed. Best practice recommendations for preparing and optimizing assessment conditions and the procedures for conducting assessments, including methods for the exchange of assessment materials are discussed. An overview of technological considerations along with data security and best practices for assuring the integrity of assessment instruments is also provided. The chapter concludes with a discussion of the benefits of telehealth-based assessments and future prospects for advancements in this important area of telebehavioral health practice.

Determining the Appropriateness of VCT-Based Assessment

The appropriateness of VCT-based clinical assessment must be determined as an initial step. This involves a decision-making process that begins with the determination of the objectives for the clinical assessment based on purpose, setting, and clinical needs of the patient. As with in-person assessment, this process should be guided by evidence-based practice that, as described by the American Psychological Association, involves “the integration of best available research and clinical expertise in the context of patient characteristics, culture, and preferences.”¹

While the decision-making process is similar to clinical assessment conducted in conventional office settings, there are specific issues associated with telehealth-based assessments that need to be considered. The patient’s attitudes towards and experience with technology are important factors,² as are the clinician’s competency and level of comfort with conducting clinical assessments via telehealth technologies.³ There are also aspects of the specific setting where services are to be provided that need to be evaluated. These include considerations regarding safety and privacy as well as the infrastructure and the technology needed to conduct VCT-based assessments. These aspects are especially critical when providing services to clinically unsupervised settings, such as to a patient’s home. This is because clinical staff cannot directly assist with setting up the assessment conditions or with on-site safety management in the event of a medical emergency or clinical crisis (e.g., indication of imminent intent to harm self or others). In these settings, the clinician must work with patients to establish appropriate assessment conditions, evaluate potential safety risks, and establish safety procedures such as the involvement of a Patient Support Person (PSP).⁴⁻⁵

In each of the following sections, the issues associated with determining the appropriateness of VCT-based assessment are reviewed in greater detail. While several of these issues are discussed in other chapters of this series, they are presented here in the specific context of VCT-based clinical assessment.

It is important to note that while these issues should be considered prior to initiating VCT-based clinical assessments, they are also essential to incorporate and re-evaluate throughout the assessment process.

Clinical Appropriateness

Patient clinical characteristics (e.g., diagnosis, cognitive abilities, etc.) are necessary for practitioners to take into account as these may influence whether VCT-based assessment procedures are appropriate or feasible. For example, it may not be appropriate to conduct an assessment with VCT with a person who is experiencing delusional beliefs that involve technology because of potential iatrogenic effects. Clinical assessment via VCT may also not be the best option if the safety of the patient or that of collaterals (i.e. family members at home) is a concern due to a known history of suicidal or violent behavior. It is therefore necessary to evaluate and assess whether VCT-based assessments are appropriate via review of treatment records or other patient data (if available). It may also be appropriate to consult with other practitioners who have been directly involved with treatment of the patient, especially in clinical settings where the person conducting the assessment is someone other than the primary care provider. Suicide risk assessments may be incorporated into prescreening procedures along with assessment of other patient characteristics such as vision or hearing limitations.

Clinical contraindications may also be discovered during the course of the assessment process. For example, it may be discovered that a patient has a cognitive deficit or problems with vision not previously identified that may influence the validity of assessment results. In those cases, clinicians should consider the pros and cons of continuing the assessment, and as with any conventional in-person assessment, document and disclose how those factors may have influenced assessment results.

Culture and Acceptability

Acceptability of assessment procedures can influence the accuracy of any assessment as well as a patient's compliance with and motivation toward the demands of a particular assessment.⁶ Just as a patient's cultural background is relevant to the procedures and interpretations of a given assessment tool,⁷ a patient's culture is also relevant to their acceptability and level of comfort with remote assessment and the VCT medium.⁸

Familiarity and comfort with technology can vary based on individual experiences and cultural backgrounds and these variables may influence patients' acceptability of VCT-based assessments. Familiarity with VCT technology has become more commonplace due in part to the popularity of media services and videoconferencing software (e.g., Facetime, Skype); however, significant portions of the population may still be unfamiliar with these technologies. In particular, older adults represent a growing population of mental health consumers⁹ who may benefit from clinical services delivered via VCT.¹⁰⁻¹¹ This population may be less familiar with VCT technologies, however, and they may prefer traditional in-person interactions based on their expectations for clinical care and previous experiences to which they have become accustomed.¹² Similarly, expectations and accepted norms for specific aspects of interpersonal interactions can vary considerably in different cultures. Another example is the

norm of eye contact, which may vary across cultures. In Native cultures, for example, direct eye contact may be considered disrespectful and rude.¹³ Thus, clinicians need to consider cultural expectations associated with eye gaze when using VCT technologies as this is important for both establishing rapport, and preventing misinterpretation of behaviors during a clinical assessment (e.g., mistaking a consistently downward eye gaze as a symptom of depression).

As noted by Luxton and colleagues,¹⁴ technical difficulties, especially those that interrupt the interaction between the patient and care provider, can reduce satisfaction with VCT-based services. Problems with network connectivity, low bandwidth speed, sound echo/feedback, and an inability to transmit written material (e.g., self report questionnaires) between users have been specifically identified as sources of frustration.¹⁵⁻¹⁶ The loss or distortion of non-verbal behavior and other patient characteristics may also negatively impact the acceptability of TMH assessment.¹⁷ However, solutions to these issues are increasingly available (e.g., faster internet speeds/video compression, head sets, adjunct technology such as fax/document scanners, software that allows screen sharing) but come with financial costs that may not always be practical. Assessment of potential technical problems and limitations (e.g., network bandwidth, etc.) is recommended prior to initiating VCT-based assessments.

Also important for the initial decision making process is the practitioner's own comfort level and experience with technology and its use during clinical assessments. While it is likely not necessary for the clinician to be an expert regarding how the technology works, it is important for the clinician to be adequately competent with using it and confident that he or she can effectively troubleshoot technical issues if they occur during an assessment session. Access to troubleshooting guides and a plan to involve external technical support or in some cases a Patient Support Person (PSP) to assist with technical issues is recommended and should be considered before initiating VCT-based assessments.

Clinicians and clinical managers must remain mindful of the cultural factors, patient comfort with technology, and both patient and provider familiarity with the technical aspects of remote service delivery. Clinicians should also provide a clear rationale to patients for why VCT is being used. This rationale should include discussion of the benefits that VCT-based clinical services can offer as well as limitations, risks (e.g., security of data transmissions), and any potential difficulties that may be encountered when using the VCT medium.¹⁸

Modai and colleagues reported that there is a positive correlation between a person's regular use of VCT and their acceptability of it, suggesting that experience using VCT in clinical practice may strengthen the user's opinion of that modality.¹⁹ Moreover, the perceived expertise of the clinician as well as the distance required to receive an in-person alternative (i.e., travel burden) may also influence acceptability.²⁰ Fortunately, across diverse clinical populations and services there are consistently positive ratings of user satisfaction and acceptance with VCT, which are either equivalent or in some cases superior to ratings of in-person services.^{10, 11}

Legal, Regulatory, and Safety Considerations

Licensing and legal issues also have great bearing on the decision to conduct clinical assessments remotely. State laws specific to the practice of telemedicine may vary greatly, and many jurisdictions require practitioners to be licensed in the same state in which the patient is located for treatment.²¹⁻²² This has the potential to limit delivery of psychological assessment services depending on practitioner license and client location, with the exceptions of practitioners working within a federal jurisdiction (e.g. VA medical centers) who may be able to provide telehealth services across state lines to other federal sites. These issues become increasingly challenging in parallel with the complexity of a patient's situation. For example, a patient in treatment at home may be travelling to another state for business or vacation during a scheduled follow-up assessment. Thus, it is essential that clinicians verify where the patient is physically located and become familiar with both the laws governing the jurisdiction in which they plan to conduct assessments and the jurisdiction in which their clients are located.

Mandatory reporting and involuntary commitment laws, for example, can differ between states and practitioners should follow the laws established by the jurisdiction in which the patient is physically located when carrying out legal duties and safety planning.²² There may also be laws specific to assessments conducted remotely and regulations governing delivery of results. For example, federal legal precedent has established VCT as an acceptable means of suicide risk assessment in involuntary commitment contexts,²³ although states may establish more stringent protections than federal law, and some states have granted citizens the right to appear in person instead of via VCT.²⁴ Given the remote nature of VCT interventions and the increased number of clinically relevant factors involved, safety considerations should be a priority throughout the assessment process. In order to manage risk effectively, ensure patient safety, and comply with legal responsibilities, practitioners must integrate a working knowledge of practical legal issues into their decision-making along with consideration of client background and contextual factors.

Clinician Competencies

The practice of TMH involves specialized knowledge, skills, and professional standards.²⁵⁻²⁶ Clinicians must assess their own level of skill and competence as part of the process of deciding whether they should conduct telehealth-based assessments. Competencies include specific knowledge and skills required to administer assessment measures and tests via VCT, familiarity with clinical best practices for conducting TMH sessions, safety management, as well as legal and ethical standards. Clinicians must also be technically proficient with the specific equipment, software, and network connection to be used during the assessment sessions in order to minimize potential technology problems.^{5, 27} This requires a working knowledge of clinical guidelines for practical aspects of using VCT equipment (e.g., bandwidth, camera position) as well as clinical skills relevant to VCT-based assessment such as administration protocols for remote assessment.

Clinicians and clinician managers should become familiar with published practice guidelines by professional organizations such as the American Psychological Association²⁸ and the American Telemedicine Association.^{29, 4} Additional training in clinical telepractice and review of relevant scientific literature are also important aspects of maintaining culturally and clinically competent practice.

Although some continuing education is currently available through several for profit and nonprofit organizations (e.g., American Psychological Association, American Telemedicine Association), researchers have proposed more formalized training models for use in graduate programs and professional workplace settings. For example, Godleski has proposed training programs for TMH psychiatric services³⁰ and Colbow presented curriculum content with a component involving supervised experience with TMH technologies.²⁵ Clinicians should also develop the necessary basic knowledge, skills, and experience required to effectively use and troubleshoot VCT equipment.

Selecting Appropriate Measures and Procedures

Just as with clinical assessments made in conventional in-person settings, practitioners must consider whether the measures and procedures for the administration and scoring of assessment instruments are appropriate for the specific application and patient population. This includes consideration of available validity and reliability data regarding specific measures and procedures. Luxton and colleagues noted that just because the validity and reliability of a particular instrument or procedure has been established for in-person administration, it does not mean that those qualities of an assessment will hold when it is administered over VCT.³ The decision to administer any particular measure via VCT must therefore be based on available psychometric data as well as information regarding procedures for modifying measures and procedures for remote administration.

Several available published reviews provide useful information regarding the validity and reliability of clinical assessments conducted via telehealth technologies. For example, Hyler and colleagues conducted a review and meta-analysis of 14 studies that compared face-to-face to TMH psychiatric assessments.³¹ Five of the studies used objective assessment measures (e.g., clinical rating scales), two studies used subjective measures (i.e., satisfaction measures), and seven studies used the combination of objective and subjective measures. The meta-analytic results indicated that objective assessments were comparable to in-person assessments in regard to diagnosis or symptoms assessment. The Telemental Health Standards and Guidelines Working Group³² also reviewed and reported data regarding the psychometric properties of remote telehealth-based assessments. These authors highlighted evidence that supported the use of standard objective measures via TMH, such as the Hamilton Depression Rating Scale, with some caveats about the negative effects of low bandwidth on reliability for symptom rating scales.³³⁻³⁴ They also noted support for the reliability of structured clinical interviews.^{20, 35} A later systematic review by Backhaus and colleagues¹⁰ supported these conclusions and showed that the majority of studies they evaluated (69%) utilized “at least one standardized measure with well-accepted psychometrics” (p. 118), including rating scales such as the BDI-II³⁶ and the Structured Clinical Interview for the DSM-IV Axis I Disorders, Research Version, Patient Edition (SCID-I/P).³⁷

The BDI-II³⁶ is a commonly used measure reported in published TMH treatment research¹⁰ that has evidence for its comparability in computer and paper forms.³⁸ Evidence of the reliability and comparability to in-person assessments for structured clinical interviews and psychiatric evaluations conducted via VCT have also been reported.^{35 39} Cognitive measures have been administered via VCT as

well, and patients have generally indicated acceptance of and satisfaction with the assessment process.⁴⁰⁻⁴¹ A small number of studies have investigated the agreement between neuropsychological tests conducted in-person and via VCT⁴⁰⁻⁴¹ and generally found adequate comparability, with some evidence for greater reliability with measures that primarily use verbal instructions.⁴¹

Researchers have highlighted a gap in the literature base regarding VCT-based assessments.²⁵ Some have pointed out the need to establish separate psychometric norms²⁶ whereas others have recommended the develop of assessments specifically designed for use with TMH technologies.¹⁰ Special cautions for neuropsychological measures have been suggested given the underdeveloped protocols for adapting established measures as well as the paucity of research on delivery through VCT, which may influence testing procedures, accuracy of assessments, and interpretation of results.^{26, 42} For example, the established normative performance data for the Halstead-Reitan Neuropsychological Battery were developed well before the advent of the personal computer, thus, it may be inappropriate to use these data to gauge performance on tests if administered remotely via VCT. Colbow suggested that similar caution be applied to cognitive testing and personality assessments due to the lack of data regarding the use of standardized measures that are administered electronically.²⁵ Grady and colleagues noted that research on personality assessment delivered via VCT is nonexistent and that “there is no information about projective testing over VCT (p. 138)” while neuropsychological testing is feasible but “may lack the same degree of resolution that [face-to-face] assessment provides” (p. 138).³²

It is important to note that assessment objectives and the client’s needs may require a particular type of assessment that lacks an established evidence-base for the use of VCT administration or that is not currently feasible for remote administration.^{40, 3} Thus, clinicians should consider the available alternatives for clinical assessment and what may best meet the needs of the particular situation. In some cases, remote assessment via VCT may be the only feasible method and therefore the best available option to a particular patient. This may be true for populations that live in remote areas, such as parts of Alaska, which may become inaccessible or very treacherous to travel through during substantial portions of the year. A home-bound elder that risks a life threatening fall by traveling to a clinic is another example of a situation in which VCT assessments may be the best choice.

In summary, clinicians who are interested in conducting assessment via VCT must consider the evidence base supporting specific measures and their use with this medium. Recommendations for appropriate adaptation of measures and administration procedures should also be considered. Recent research reviews support the use of many popular clinical rating scales, structured interviews, neuropsychological measures, and satisfaction measures administered via VCT. There are, however, limitations to the available data that will require additional study. The need for separate norms for existing tests as well as measures designed specifically for TMH administration has been recommended.

Preparing and Conducting Assessments

Informed Consent Process

Behavioral health clinicians who intend to provide VCT-based assessment services must consider the requirements of informed consent. While most of the informed consent components are consistent with the requirements for in-person mental health services, there are also unique aspects associated with not being in the same room as the patient as well as the use of technology. An initial consideration is the need to confirm the patient's identity remotely in order to assure patient privacy and to prevent service delivery to non-patients.⁴ Unless the clinician and patient have previously met in-person, presentation of supporting documents (e.g., driver's license, insurance information, etc.) via VCT may be necessary. Once initial positive identification has been made, visual confirmation of patient identity during subsequent VCT sessions should be adequate. The issue of positive identification may be complicated, however, when only audio (e.g., telephone) is available. It is therefore important to discuss expectations for establishing identity during the informed consent process. Also, as with any clinical service, practitioners should clearly identify themselves and their credentials during the informed consent process.⁴ The process for doing this may be accomplished with technological solutions such as displaying credentials over VCT or electronically on a website. The requirement for assuring patient identity and communicating credentials may vary by jurisdiction and thus clinicians and clinician managers should become familiar with applicable laws and guidelines.

The informed consent process should also include a discussion of the potential risks and relevant issues for the modality through which those services will be delivered.^{4, 28, 43} In regards to VCT-based clinical assessments, clinicians should discuss the ways that the modality may differ from alternative options as well as the unique risks and benefits.²⁸ Of particular relevance is disclosure of confidentiality and privacy measures and expectations associated with the electronic storage and transmission of assessment data and results. Practitioners should also discuss with the patient that there is a possibility that the accuracy of the assessment data collected could be influenced by the quality of the VCT connection or other disruptions. This is especially important in circumstances where assessment performance will be used to make lasting decisions about a patient's care, entitled benefits, or legal status.

In summary, there are several unique aspects of telehealth-based clinical assessment that clinicians must consider during the informed consent process. Clinicians must also be sure to provide ample time to address any questions that the patient may have regarding VCT-based clinical assessment. Given the evolving laws and guidelines, practitioners must also remain current on laws and practice standards that have impact on the overall informed consent process.^{4, 28}

Optimizing Assessment Conditions

When preparing for a remote assessment, the practitioner must prepare, or oversee preparation of, the rooms at both ends of the connection. In addition to assuring that all assessment materials, scoring materials, measurement, and timekeeping tools are in place, the clinician must also verify that their VCT equipment is capable of meeting minimal technical standards (e.g., appropriate bandwidth speeds) and is readied for use (e.g., microphone and speakers volume set, camera lens cap removed, camera properly positioned, etc.). Practitioners should also assure that their clinical space is adequately lit and that the background provides adequate image clarity.⁴⁴

The room at the patient's end of the connection must also be prepared. In situations where VCT services are provided to a remote clinic space, support staff may assist with preparation of the assessment space. This includes making sure the room is private and comfortable and assuring that the assessment materials (i.e., writing instruments, forms, and questionnaires) are available and prepared. When clinical support staff is unavailable, such as during home-based assessments, the patient may be asked to prepare the room or ask a PSP for assistance. For some types of clinical assessment, clinicians may also need to mail assessment materials to the remote location ahead of time. Clinicians must verify that patients have adequate materials and space available to complete the assessment (e.g., writing tools, desk space, etc.).

One of the primary factors that may influence the validity and reliability of remote assessments conducted via VCT is the fact that the client and practitioner are not physically in the same room.³ This has obvious bearing on procedures for administering assessments as well as what information can be assessed during clinical assessment procedures. In particular, the lack of in-person presence can limit what information can be assessed. Often, a patient's nonverbal cues provide useful information about their emotional state, symptom severity, and even risk behaviors. Olfactory data can provide relevant information regarding a patient's alcohol and substance use, as well as hygiene. Clinical impressions and conceptualizations can be influenced by body posture and language (e.g., foot tapping, hand wringing), minute changes to facial expression, and other non-verbal emotional responses such as facial flushing, tearing up, and eye-gaze direction, which may be absent during VCT assessment depending on the camera position and resolution as well as the quality of the transmission. For example, when administering the Brief Psychiatric Rating Scale (BPRS),⁴⁵ the practitioner may need to ask additional questions regarding the somatic manifestation of symptoms in order to most accurately determine the rating that best describes a patient's symptoms for domains such as anxiety, tension, mannerisms and posturing, motor retardation, and excitement since observation of the patient's full body may not be possible.

Psychomotor and other medically relevant symptoms may need to be observed during psychological assessments as well, in which case the practitioner can query them directly (e.g., to assess gait problems, the patient may need to be asked to stand back from the camera and walk across the room). Furthermore, the observation of *how* an examinee approaches a test or measure may be critical for making an accurate assessment. For example, along with measuring the accuracy of an examinee's copy and recall drawings of the Rey-Osterrieth Complex Figure,⁴⁶ it is important to examine the process by which a patient completes their drawing. With a camera capturing only a patient's face, the provider may not have access to this information. In this situation, and other similar situations, the remote location may need multiple cameras so that the practitioner is able to view the patient's desktop surface where they are completing assessment tasks.

In some cases, in-person assessment procedures may need to be modified or adapted to allow for accurate VCT assessment. Practitioners are cautioned, however, to carefully review the instructions or administration manuals of the planned measures and tests to ensure that the appropriate procedures

and environmental conditions for standardized administration are maintained in a way that does not threaten the reliability or validity of a given assessment. Rather than viewing a patient's responses across a table, it may be necessary to ask a patient to hold their responses to a paper and pencil assessment up to the video camera for viewing (e.g., self report measures). Patients may also need to be asked to use larger handwriting if small screen sizes or poor image quality disrupt the provider's ability to view their responses. Alternatively, it may be helpful to ask the patient to read their responses out loud in scenarios where video is not used or if the connection quality is poor. Practitioners should monitor their pace, annunciation, and volume of speech to ensure that patients receive the directions clearly. Patients should be asked to paraphrase instructions back to the practitioner to ensure clear receipt of a task's demands. While it is advisable to do this regardless of assessment medium, it may be particularly important to do so when making use of VCT as occasional fluctuation in bandwidth may briefly distort audio transmissions.

Technology Specific Considerations

There are several factors associated with the use of technology that may influence the reliability and validity of clinical assessment when videoconferencing. Eye gaze angle, the angle between the eye and the camera and the eye and the center of the display, is one issue that has been discussed depth.⁴⁷ Users of VCT tend to make eye contact with the image on the screen rather than with the camera.⁴⁸ This tendency may lead the person on the other end of the connection to the impression that the person is avoiding eye contact. Eye contact between a patient and clinician is important because it provides visual cues to which the participants can respond and is also a marker for interpersonal skill and social ability.^{47,49} Eye contact is also an important source of clinical information for determining the presence of psychological states (e.g. delirium) or particular disorders (e.g., Autism Spectrum Disorder). When eye contact is ambiguous, interpretation of facial expressions and affect may become difficult. Eye gaze angle may also influence satisfaction with using VCT.⁴⁷ Cameras should be positioned in a way that allows the images of both parties to appear straight-on and centered in their respective monitors so that both appear to speak eye-to-eye with each other.⁴⁴ Additionally, improved eye contact can be realized by increasing the horizontal distance of participants from the videoconferencing unit.⁴⁷

Patients may shift position or the video camera may accidentally be shifted from the optimal angle during the course of an assessment. It may therefore be necessary to make adjustments to the camera position or to the patient's physical location in relation to the camera. This can be accomplished by asking the patient to make adjustments to camera angle or their physical position. Some VCT camera systems include a remote tilt-and-zoom and panning feature that may make sense to use. It is also recommended to use the 'picture in picture' function, available on many VCT devices, to provide the clinician with visual verification of proper framing. As noted by Luxton and colleagues,³ it is also advised to check-in with patients throughout the assessment process to make sure that they can see and hear clearly. It is important to remember that technological limitations may influence how well the patient understands the practitioner (not just how well the practitioner understands the patient).

Audio quality is another important factor. Low microphone input volume or speaker output volume may make it difficult to understand questions, responses, and instructions. Jones and colleagues⁵⁰ found that inadequate audio quality can influence the ability to accurately gather information from the patient. For example, the observation of vocal properties (e.g., shakiness, inflection, and tone), as well as whether an individual may be crying, can be an important source of information regarding emotional states, and a low-quality audio connection may hamper observation of this information. Volume levels should therefore be established and tested at the outset of the interaction, and must be weighed against the possibility that the audio could be overheard by others. As with conventional office settings, the use of a white-noise machine outside the assessment room door may make sense.

Additionally, the transmission lag (the time it takes for the audio or video signal to travel from one user to the other) may influence the natural flow of conversation during assessments. A longer-than-normal pause after asking a question before the patient answers can be expected in some cases. Each speaker may need to pause every few sentences to allow enough time for the other person to respond. Each should speak at a slightly slower pace so that the normal indications from the listener (e.g. a brief comment or raised hand) can be transmitted and received before the speaker continues on to their next statement.

Even if the camera is positioned perfectly and audio quality is just right, a poor network connection can still interfere with the capabilities and quality of an assessment. A variety of factors can contribute to network connection problems, including low quality equipment, an overloaded computer (e.g., too many programs running at one time), inadequate bandwidth, and user inexperience with VCT.^{14, 31, 50} For example, Hyler and colleagues found that both patients and practitioners reported a preference for in-person assessment when the available VCT was hampered by low-bandwidth.³¹ Interestingly, when high-bandwidth VCT was available it was preferred over in-person assessment, even when the assessments being employed required detailed observations of the patient's behavior. Additionally, Zarate and colleagues noted that both patients and practitioners found high and low quality VCT acceptable, but that higher quality VCT resulted in a greater degree of reliability between assessments.⁵¹ Although there is some guidance available regarding minimum recommended bandwidth requirements for TMH (e.g., 384 Kbps for downlink and uplink^{4, 29}), what is or is not adequate in any given application will depend on a variety of factors, including requirements for the type of assessment, environmental conditions, and the technology itself.

It is also possible that the use of technology (e.g., web cam, personal computer, microphone) may distract or require extra attention that may influence the assessment session. For example, when conducting a clinical interview over a web cam, the patient may become distracted by inconsistent connections, error messages, or other technical anomalies.⁵² Shifts in a patient's attention may influence testing or assessment scores, potentially decreasing performance in domains requiring sustained attention and concentration. Additionally, lengthy or complex assessment procedures can be quite demanding on patients. While longer and more in-depth assessments generally provide the greatest reliability, participant dropout is also much more likely.⁵³ Overly long assessments may not be suited for VCT assessment.⁵⁴ Exposure to a new medium of interaction (VCT) for persons who are not experienced

with it may add additional stress or frustration, especially if technical problems occur.¹⁵⁻¹⁶ Given this, clinicians must remain mindful of the patient's degree of frustration and how likely it is that providing a given assessment in a novel manner may affect a patient's performance or patterns of responding.

Despite the many factors that can influence VCT transmissions, efforts should be made to maximize quality. While it may seem difficult initially to manage all of the various components, with practice the preparation necessary for a high-quality VCT interaction can become seamless and routine. It is important for clinicians and clinician managers who plan to use VCT to obtain training and experience with the technology prior to offering these services. Practice sessions are highly encouraged, including the simulation of common technical difficulties.

Privacy and Assessment Data Security

Risks to confidentiality can occur at both the patient and clinician ends of the VCT transmission. Precautions should therefore be taken to assure that the environments at both ends are private and secure during assessment sessions. Doors, windows, and window coverings should be secured to prevent audio and visual content from traveling outside of the assessment space. VCT equipment volume should be adjusted to a level where the patient can adequately hear the practitioner (and vice versa) but is not so loud that others outside of the room can overhear the interaction. For in-home telehealth-based clinical assessments, the patient may need to negotiate with their family members or roommates for private time and space for assessment sessions. As noted earlier in this chapter, patients may also be concerned about the security of the clinician's environment, such as whether the interaction is being recorded and who has access to it, and if anyone other than the practitioner is present in the room "off camera." Clinicians should assure adequate time and opportunity for patients to ask questions and to address any concerns that the patient may have about the process.

Some have suggested that allowing the patient some time to get accustomed to this new medium is beneficial, which may include taking physical steps to aid in this process (e.g. having the practitioner use the camera to tour them through their office).²⁶ Privacy and data security are also important aspects of a TMH informed consent process, as special attention must be given to privacy and the limits of confidentiality in TMH contexts given the transmission of VCT sessions over some type of network²⁶ which always carries some security risk. In addition, questions about the safety and storage of assessment documents and electronic records can be discussed as part of a comprehensive informed consent process.²⁶

Safety Planning

Given the unique factors involved in TMH assessment, careful consideration of patient safety and planning for risk management procedures must be in place when delivering VCT services, including clinical assessments. Practitioners must prepare the necessary resources and establish adequate means for managing a patient's distress and risk for self-harm or violence during TMH assessment, and all of these procedures should be discussed as part of the informed consent process. This should include

guidelines for troubleshooting technical issues, methods for contacting the patient in the event of connection or equipment failure (e.g., telephone), and contact information for emergency response services accessible from the patient's physical location.^{5,21} Contingency plans are especially important in the case of suicide assessment delivered via VCT, as communication with clients may be interrupted and the assessment may lead to further action and immediate triage that will involve third parties such as law enforcement in order to manage suicide behavior risk appropriately.²¹

When providing home-based TMH services, especially with patients who have little experience with technology, in-home with technology novel to the patient, a technical support specialist may be useful in delivering the equipment, setting up the technology correctly, and providing training on its proper use. Family members or close friends may be useful in assisting patients with operating the VCT equipment, and can also be instrumental as a local collaborator for emergencies to help with risk management.^{5,55} Furthermore, third parties can be useful in the assessment process by providing additional information about the patient, offering a unique perspective on client concerns and presenting symptoms, and utilizing their knowledge of the client to inform treatment plans.⁵⁶ However, Luxton and colleagues noted that TMH assessment in a client's home may not be appropriate for some patients, especially when encountering the increased safety risks for cases with a history of self-harm or harm to others.⁵

Exchange of Assessment Materials and Providing Assessment Results

When providing VCT-based assessments, informed consent documents, privacy policies, self-report questionnaires, assessment related task forms, and other materials, such as assessment results, need to be exchanged between clients and practitioners in a manner that is efficient and secure. In some cases, these types of documents may need to be mailed, faxed, or checked-out from a satellite location. The exchange of assessment-associated documents can also be conducted electronically. For example, email can be used to deliver documents remotely to a tablet computer provided to the patient for a digital signature and captured as an electronic record. The informed consent process can also be completed using websites and digital signature technology, for example through the comprehensive electronic informed consent and participant management database Research Permission Management System.⁵⁷ Harmell and colleagues have developed a web-aided multimedia consent procedure that may be more effective than traditional forms of consent among a sample of individuals with schizophrenia.⁵⁸ This web format did not affect comprehension among non-psychotic individuals, which was excellent regardless of format, suggesting that web-aided, multimedia informed consent may be most appropriate for those with comprehension impairments.

If a third party is involved during the assessment process, such as a family member, a signed release of information form may be needed. Releases can be faxed or mailed to clients in a self-addressed and stamped business envelope or signed at an initial in-person meeting, and practitioners must plan for these procedures and discuss them with clients as part of an ongoing informed consent process. Regardless of how assessment materials are to be exchanged, patients should be made aware of the risks that this may pose for their confidentiality based on the mechanisms used.

As with conventional in-person assessment, assessment results can be provided verbally over VCT. Written feedback can also be provided using technologies, such as VCT software that provides display of digital documents, or in conjunction with other internet technologies (e.g., opening the report on the practitioner's computer and using a "screen share" option, encrypted e-mail or document transfer, logging into a secure web-portal on a secondary computer, etc.).

Practitioner's must utilize clinical judgment and incorporate available scientific knowledge regarding the appropriateness of providing assessment feedback via VCT,²⁸ a process which may vary significantly for different tests, patients, and practice guidelines. Interpretation and explanation of results in TMH contexts must incorporate such factors as possible adaptations to administration protocols, interference from technology and hardware functioning, and distracters in the patient's physical environment.²⁸ Just as practitioners can note in written reports the potential limitations of adapting tests for TMH that were originally developed for in-person administration,²⁶ verbal feedback provided via VCT should also specify these same limitations where appropriate. Assessment measures may also have specific instructions for providing feedback based on results in their technical manuals, and different jurisdictions may establish minimum requirements for feedback of assessment results, similar to the requirement for in-person delivery of HIV testing results in the field of preventive medicine. Providing feedback via VCT may not be appropriate for every client, and practitioners should utilize clinical judgment carefully in order to assure the safety of patients and collateral people who may be in the patient's physical environment. For example, providing verbal feedback via VCT for a client with a complex personality disorder may significantly increase the likelihood of self-harm or aggressive behavior. In conclusion, clinical decisions about providing assessment feedback via VCT should be integrated into the larger decision-making process about the appropriateness of remote assessment and the unique factors relevant to this aspect of TMH practice.

Conclusions

Clinical assessment via VCT or other telehealth technologies provides many benefits to both patients and clinicians. VCT-based assessments can help overcome barriers to care by providing access to clinical services in rural or underserved areas, increasing the availability of practitioners familiar with the nuances of a particular culture or population, and allowing access to providers who specialize in particular areas of assessment. Clinical assessment via VCT can also be a solution to language barriers by connecting patients with practitioners who are familiar with the patient's language or by connecting hearing impaired patients to clinicians who are capable of conducting clinical assessment via American Sign Language. Clinical assessment via VCT also allows clinicians to expand their practice and provide services that they otherwise would be limited by due to their geographical location.

Further technological advances will continue to expand the capabilities of clinical assessment via VCT. As stated earlier in this chapter, the video camera capabilities on modern mobile smart devices (smartphones and tablet devices) have brought a whole new way to provide VCT services. Further adoption and integration of assessments delivered via mobile devices can also be expected in the years ahead.⁵⁹ The advantages of these tools are that they can augment traditional VCT clinical assessments

by providing continuous sensing and unobtrusive monitoring of behavior and symptoms that can be tracked over time. In some examples, the devices can provide real-time feedback to users or results from assessments can be uploaded to practitioners for review and monitoring. Further, many modern mobile devices have the capability to connect to external hardware devices, such as biofeedback sensors, for monitoring physiological signals. Smartphone apps can also be programmed to respond to critical items in self-assessments to auto-detect significant distress and, when appropriate, offer one-touch contact to a support hotline.⁵⁹ Moreover, other emerging technologies, such as the use of virtual reality environments and the application of artificial intelligence to assessment systems will further expand capabilities.⁶⁰

The use of VCT for conducting clinical assessment can be expected to become more common in parallel with the overall growth and expansion of TMH practice. The increasing availability of telehealth technologies and the budding evidence-base in support of their use for remote clinical assessment will continue to advance capabilities. As outlined in this chapter, there are many factors that clinicians and clinician managers need to consider in order to assure optimal VCT-based clinical assessments. All of these issues can be effectively addressed given attention to available best-practices and appropriate training.

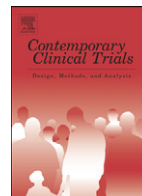
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Design and methodology of a randomized clinical trial of home-based telemental health treatment for U.S. military personnel and veterans with depression[☆]

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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.

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1. Introduction

There is mounting evidence supporting the clinical effectiveness of telemental health (TMH) treatments [31,33] as well as patient and provider satisfaction with TMH [5,35]. 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 [11]. 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 [40].

Mental health treatments provided directly to the homes of U.S. military personnel are not presently the standard of

[☆] **DISCLAIMER:** The views expressed are those of the authors and do not reflect the official policy or position of the Department of Defense of the U.S. Government.

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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; [14]) 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 [13]. 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 [37]. Behavioral Activation is also an action-oriented treatment 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 [13]) and Veteran populations [7] as well preliminary support as a treatment for PTSD [12,20]. 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 [27].

With this paper we describe the design, methodology, safety management, and treatment protocols for an in-progress Military Operational Medicine and Research Programs (MOMRP) grant funded multi-site clinical trial of HBTMH treatment. 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 HBTMH treatment, the study provides data on patient satisfaction with a home-based care and it advances the knowledge base regarding the safety and risk management procedures of home-based treatments in both the military and VA settings. The study also tests the feasibility of readily available synchronous videoconferencing technologies (i.e., webcams and laptop computers) to provide care to military personnel and veterans in the home. This paper should be particularly useful to researchers who are interested in the technical aspects of implementing clinical telehealth research in the military, VA, and other health care settings. The paper also highlights the procedures for applying a two-group non-inferiority trial design to establish a novel or alternative mode of treatment delivery as standard of care.

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-camera 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 Veterans 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 Fig. 1. Eligible patients have an equal chance of being randomized to either the in-office or in-home treatment groups. All patients are provided with 8 sessions of BATD that is guided by a treatment protocol manual. Patients 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 blinded 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

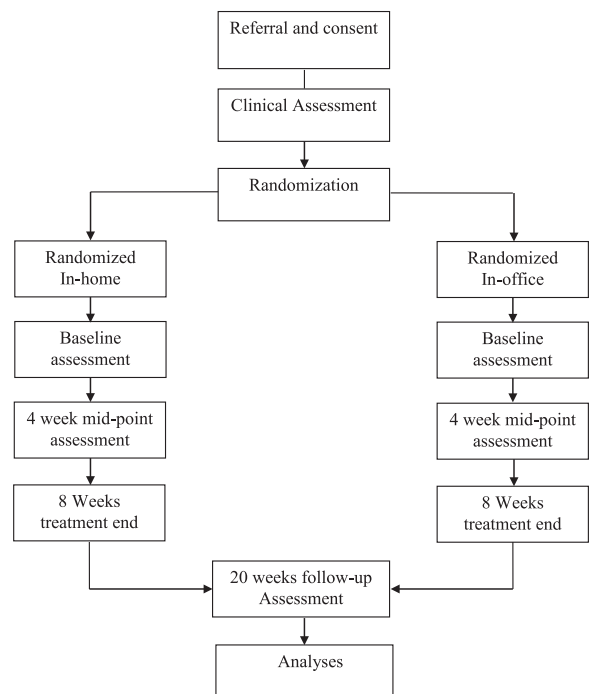


Fig. 1. Study flow chart.

Table 1
Schedule of measures and survey instruments.

Measure	Initial	Baseline			Midpoint				Post-Tx	3-month follow-up
		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.

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 patients 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 patients 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) patients will be recruited with an anticipated treatment completion rate of 108 (90%; 54 per treatment group). Patients are male and female members of the U.S. Armed Forces recruited from MAMC and the larger JBLM community as well as U.S. military veterans recruited at the PVA site. Study eligibility depends in part on whether the patient has high speed internet access at home (384kbs or greater) as well as a private space for treatment sessions (complete inclusion and exclusion criteria can be found in Table 2). Patients that are randomized to the in-office treatment group are seen in a traditional face-to-face clinical office setting at T2 or PVA. Patients 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 lap-tops 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 patients 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 on JBLM 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. Patient recruitment began in August of 2012.

Following referral, the study coordinator conducts a brief phone screen and schedules each potential patient 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, patients receive \$20 for each of the first three assessment visits, and \$40 for completion of the 3 month follow-up assessment. Patients at the JBLM site cannot be compensated for their time per US Army regulations. Each patient'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 patients complete the baseline assessment (see Section 2.7), those meeting eligibility criteria are assigned to treatment condition by the study coordinator (who is not blinded to condition) according to the pre-determined randomization schedule. The treatment condition is determined for both sites by using a computer generated table with a block ($n = 10$) randomization algorithm. This procedure allows each patient to have equal chance of being assigned to either of the two groups while assuring equal distribution of patients to the two conditions over the course of the study. We did not use a stratification scheme based on site, demographic variables, or medication status. We anticipate that demographic characteristics, such as gender, race, and age will be reflective of the military and veteran population from which we are

Table 2
Inclusion and exclusion criteria for patient 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
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

sampling. These variables will be treated as covariates in our analyses (See Section 2.10). We will examine potential differences in medication use between groups in post-hoc analyses.

2.4. Clinician preparation and training

Assessments are conducted by outcomes assessors that have been blinded to treatment condition. 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 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 patients.

2.5. Behavioral Activation treatment protocol

BATD and other Behavioral Activation protocols originated from behavior analytic models of classical and operant conditioning [25,30,36] and the behavioral component of cognitive therapy for depression [1,15–17]. Behavior analytic theory posits that depression develops when learned behavioral contingencies fail to produce stable, diverse, and reinforcing environmental consequences [13]. 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 naturally 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 et al. [14]. The protocol prescribes 8-sessions of BATD that can be delivered either in-person or by VCT. In the first session, patients 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 patients 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. Patients then collaborate with clinicians to devise lists of activities that exemplify their values. For example, if a patient 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 an hour helping them to complete homework at approximately 6:00 pm 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 patient's day-to-day life. In sessions three through eight, the treatment rationale is continuously reviewed, and patients 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 patient 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 [20] 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). Patients 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 patients randomized to the in-home condition, clinicians identify the best contact information for law enforcement and emergency services nearest each patient'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 intermediate or high risk or if a patient indicates a change in the severity or frequency of suicidal ideation. Individuals advance from low to higher levels of risk based on frequency, intensity, and duration of ideation, as well as presence of intent and/or plan or evaluation of risk factors. For all patients, 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 patient 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' [18] 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 patient 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 patients 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 patient 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. For participants who are determined to be in the "high risk" category on the suicide assessment but are not presently experiencing a crisis, the treatment provider works to establish a safety plan with the participant while coordinating the transfer of the participant out of the study and to appropriate care services. Additional information regarding suicide risk management and assessment procedures used in the present trial are described by Luxton, O'Brien, Pruitt, Johnson, & Kramer (In Press).

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; [8]) 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; [3]), Beck Hopelessness Scale (BHS; [4]), Beck Anxiety Inventory (BAI; [2]), Loneliness Scale (LS; [6]), PTSD Checklist – Military (PCL-M; [38]), Inventory of Attitudes Toward Seeking Mental Health Services (IASMHS;

Attachment 1

Home-based telemental health treatment session checklist.

Treatment Session Checklist

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

Questions to be asked at beginning of session (in-home telehealth condition only)

1. Is anyone else at home today YES NO (circle one)
 - a. If yes, who? _____
2. Do you anticipate any disruptions during our session today? YES NO (circle one)
 - a. If yes, explain: _____
3. Do you feel that your environment is safe and private? YES NO (circle one)
 - a. If yes, explain: _____
4. What number can I reach you at if we get disconnected? _____

Participant

1. Was participant late to the session? YES NO (circle one)
 - a. If yes, how many minutes late? _____
2. Did the participant cancel session early? YES NO (circle one)
 - a. If yes, explain: _____
3. Was the session rescheduled? YES NO (circle one)
 - a. If yes, who was it rescheduled by? _____
4. Did the participant miss the session without giving prior notice? YES NO (circle one)
 - a. If yes, explain: _____
5. Did the participant appear disheveled? N/A YES NO (circle one)
 1. If yes, explain: _____
6. Did participant appear intoxicated? N/A YES NO (circle one)
 1. If yes, explain: _____
7. Did patient show any signs of suicidal ideation? YES NO (circle one)
 1. If yes, explain: _____
8. Did patient exhibit self-harm behavior during session? YES NO (circle one)
 1. If yes, explain: _____
9. Was there a suicide attempt since last session? YES NO (circle one)
 1. If yes, explain: _____
10. Did patient indicate intent to harm to others? YES NO (circle one)
 1. If yes, explain: _____

<p>11. Did participant become upset/distressed during session? YES NO (<i>circle one</i>)</p> <p>1. <i>If yes, explain:</i></p> <p>_____</p>
<p>Safety Protocol</p> <p>1. Was the safety protocol initiated? YES NO (<i>circle one</i>)</p> <p>2. Was it necessary to contact collateral? YES NO (<i>circle one</i>)</p> <p>a. <i>If yes, check all that apply:</i></p> <p><input type="checkbox"/> Able to contact the collateral</p> <p><input type="checkbox"/> Collateral responded to issue</p> <p><input type="checkbox"/> The collateral was helpful</p> <p>3. Was the police non-emergency line or 911 called? YES NO (<i>circle one</i>)</p> <p>a. <i>If yes, check all that apply:</i></p> <p><input type="checkbox"/> The agency initiated an emergency response</p> <p><input type="checkbox"/> The agency chose not to provide an emergency response</p> <p><input type="checkbox"/> The agency was unable to provide an immediately emergency response (e.g., location)</p> <p>4. Was a supervisor notified or consulted? YES NO (<i>circle one</i>)</p> <p>a. <i>If yes,</i></p> <p>i. Name of supervisor: _____</p> <p>ii. Date and time contacted: _____</p>
<p>Environment (in-home telehealth condition only)</p> <p>1. Were there distractions at the patient's location (e.g., pets, children, cell phones)? YES NO (<i>circle one</i>)</p> <p>a. <i>If yes, explain:</i></p> <p>_____</p> <p>b. <i>If yes, was this useful clinical information?</i> YES NO (<i>circle one</i>)</p> <p>2. Was the session interrupted by another person? YES NO (<i>circle one</i>)</p> <p>a. <i>If yes, explain:</i></p> <p>_____</p> <p>b. <i>If yes, was this useful clinical information?</i> YES NO (<i>circle one</i>)</p> <p>3. Any weapons observed during session? YES NO (<i>circle one</i>)</p> <p>a. <i>If yes, explain:</i></p> <p>_____</p> <p>b. <i>If yes, was this useful clinical information?</i> YES NO (<i>circle one</i>)</p> <p>4. Did the participant's room have adequate lighting? YES NO (<i>circle one</i>)</p> <p>a. <i>If yes, explain:</i></p> <p>_____</p>
<p>Technology Issues (in-home telehealth condition only)</p> <p>1. Were there problems <i>initiating</i> the webcam connection? YES NO (<i>circle one</i>)</p> <p>a. <i>If yes, how many minutes until connection made?</i> _____</p> <p>b. <i>Indicate source of problem (check all that apply)</i></p> <p><input type="checkbox"/> Internet Connection (ISP Problem)</p>

[21]), Client Satisfaction Questionnaire (CSQ; [27]), Computer and Audiovisual Technology Questionnaire (Technology Questionnaire; adapted by study authors from [7]), 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

<ul style="list-style-type: none"> <input type="checkbox"/> Software problem <input type="checkbox"/> Hardware problem (PC, webcam, microphone) <input type="checkbox"/> Unable to establish webcam connection <input type="checkbox"/> Unable to follow-up via telephone <input type="checkbox"/> Unable to contact the PSP <p>Describe: _____</p> <p>_____</p>
<p>2. Were there problems <i>maintaining</i> the webcam connection? YES NO (<i>circle one</i>)</p> <p>a. <i>If yes, how many minutes until connection made?</i> _____</p> <p>b. <i>Indicate source of problem (check all that apply)</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Internet Connection (ISP Problem) <input type="checkbox"/> Software problem <input type="checkbox"/> Hardware problem (PC, webcam, microphone) <input type="checkbox"/> Participant purposely terminated contact <input type="checkbox"/> Unable to re-establish webcam connection <input type="checkbox"/> Unable to follow-up via telephone <input type="checkbox"/> Unable to contact the PSP <p>Describe: _____</p> <p>_____</p>
<p>3. Was it necessary to contact participant by phone? YES NO (<i>circle one</i>)</p>
<p>Other Information:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>

data collected from samples with similar demographic profiles). Research on the Loneliness Scale has demonstrated sound psychometric outcomes in a large sample of adults [6], and Mackenzie et al. [21] presented initial validity evidence for the IASMHS with strong psychometrics calculated from a sample of young adult, undergraduate students. Given the frequent movement of military personnel between installations in the United States as well as deployment to overseas locations, the study procedures allow for the three month follow-up assessment to be completed remotely if necessary via a combination of telephone interview (SCID) and mail (self-report questionnaires).

The outcome assessors remain blinded to treatment condition 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 patients 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. If a patient's treatment condition is inadvertently revealed to an outcomes assessor, the assessor documents the occurrence in an assessment disposition note to allow for post-hoc analysis.

2.9. Outcomes

The primary outcome variables (continuous measures) are depressive symptoms measured by the BDI-II and hopelessness measured by the BHS. We are also monitoring patient safety during study participation in order to establish evidence for the safe use of HBTMH. Study clinicians document safety concerns and record any adverse safety events during the course of treatment on the Treatment Session Checklist. Additional analyses will assess treatment group differences in anxiety (BAI) and PTSD (PCL-M) symptoms, patient satisfaction with and attitudes toward 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. Non-inferiority models can be considered “a one-sided test used to determine if a novel intervention is no worse than a standard intervention” ([10], p. 434). 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 [10]. Non-inferiority trials have also been previously used to compare telehealth interventions to conventional in-person care (e.g., [7,23,29]). Our study will test the primary null hypothesis that differences between group outcome measures for patients in the VCT-based BATD condition and those from the in-person BATD condition will be greater than a set threshold or margin (labeled Δ). The null hypothesis will be rejected and thus the VCT treatment considered non-inferior to standard in-person treatment if the confidence interval calculated around the treatment difference falls within the established Δ .

2.10.1. Power analysis

We first determined the non-inferiority margin based on methodology used in similar studies as well as clinical considerations [10,28]. A 0.5 standard deviation change in scores has been used in clinical treatment research as an indicator of clinically significant improvement (e.g., [32,34]). This margin is consistent with clinically significant change in BDI-II total scores and standard deviations of approximately 10 points in both military [39] and civilian [9] 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 [22] approach. Power analyses following a standardized method (variance of 1) based on these parameters (Cohen's *d* of 0.5) yielded a minimum sample size of 49 patients 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. Although we will pool data from the two participating sites for analyses, the sample sizes are adequate to assess any potential differences in demographics and clinical characteristics between the two sites.

2.10.2. Multilevel model

We plan to follow the methodology of previous non-inferiority studies (i.e., [7,22,24]) by using a confidence interval method for evaluating the difference between treatment groups and pairing this approach with an intent-to-treat (ITT) analysis. We will test the primary null hypothesis that differences in outcome measure scores between the two conditions (in-home vs. in-office BATD) at the post assessment time point will be greater than the set clinically relevant threshold or margin using a multilevel (also referred to as *hierarchical* or *random effects*) modeling approach. The primary outcome measure is BDI-II score and secondary analyses will include the BHS. We will include both individual and sessions as units of the analysis with patients nested within sessions. The baseline values for the outcome measures will be accounted for in the model. The null hypothesis will be rejected if the upper limit of the CI calculated around the difference in BDI-II scores between the two groups falls below the established margin,

suggesting that the VCT treatment can be considered non-inferior to standard in-person treatment.

2.10.3. Safety and feasibility

Safety will primarily be evaluated by examining the rates of safety events (e.g., activation of the safety management protocol because of elevated suicide risk, etc.) during the course of treatment. Feasibility will be assessed by examining the frequency and types of technical issues that occur during the course of treatment. Patient drop-out rates, levels of patient treatment satisfaction and attitudes toward treatment will also be compared between the treatment conditions to help evaluate feasibility of HBTMH.

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. Recruitment and assessment phases for the trial are underway and are planned to be completed by the end of 2014. 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 best practices 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, patient 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 patients 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 command 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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Best Practices for Remote Psychological Assessment via Telehealth Technologies

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The use and capabilities of telehealth technologies to conduct psychological assessments remotely are expanding. Clinical practitioners and researchers need to be aware of what influences the psychometric properties of telehealth-based assessments to assure optimal and competent assessments. The purpose of this review is to discuss the specific factors that influence the validity and reliability of remote psychological assessments and to provide best practices recommendations. Specific factors discussed include the lack of physical presence, technological issues, patient and provider acceptance of and comfort with technology, and procedural issues. Psychometric data regarding telehealth-based psychological assessment and limitations to these data, as well as cultural, ethical, and safety considerations are discussed. The information presented is applicable to all mental health professionals who conduct psychological assessment with telehealth technologies.

Keywords: psychological assessment, telehealth, telemental health, video-conferencing, mobile devices

The use of telehealth technologies in psychological practice has steadily increased over the last decade and their use is expected to grow substantially in the years ahead (American Psychological Association, 2010a; Maheu, Pulier, McMenamin, & Posen, 2012). Psychological assessment is an integral component of telemental health (TMH) practice and is necessary for diagnostics, screening, symptom monitoring, and evaluations of treatment progress and outcomes. The use of telehealth technologies to conduct psychological assessments from afar can provide convenience, reduce costs (e.g., travel avoidance), and enable access to assessment services when they are otherwise unavailable.

AQ: 2 There are many technologies available to clinicians who are engaged in TMH practice. These include traditional telephones and video-teleconferencing (VTC) equipment for synchronous (real-time) communication as well as asynchronous (store-and-forward) technologies such as fax or email to send and receive assessment materials. The Internet is also used to administer psychological tests and measures remotely on web pages. Internet-based testing and assessments can make use of

technology-enhancements such as the use of multimedia content (i.e., pictures, videos, sounds, etc.), computer adaptive testing techniques, and automatic scoring and interpretation algorithms (see Barak & Buchanan, 2004). The Internet can also be used for VTC by using personal computers (PCs) and off-the-shelf webcams, which may be an affordable and highly accessible option for home-based TMH (Luxton, 2013a). More recently, smart mobile devices (i.e., smartphones and tablets) have emerged as a way to conduct psychological assessments. Assessment measures can now be in the form of an application or “app” on mobile devices or accessed via Internet connectivity. Traditional interview techniques conducted via VTC using webcams on PCs or mobile devices themselves may be augmented with electronic measures completed on the device with data uploaded to clinicians for review (Luxton, McCann, Bush, Mishkind, & Reger, 2011).

Given the numerous available telehealth technologies and their increasing use, practitioners who use them need to be cognizant of the factors that influence the psychometric properties of psychological assessments when administered via those technologies. Practitioners also need to know whether a given measure or assessment technique is appropriate for use and they need to be familiar with the proper administration procedures in order to assure competent and ethical practice. Our purpose with this article is therefore to review the specific issues that influence the validity and reliability of telehealth-based assessments and to provide best practice recommendations for practitioners. Although we focus primarily on psychological assessment and evaluation during treatment services (i.e., diagnostic and symptom assessment), the principles and procedures that we discuss are pertinent to other remote assessment and testing applications including neuropsychological/cognitive testing, forensic risk assessment, and occupational testing.

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Reliability and Validity Considerations and Recommendations

Remote Physical Presence and Setting

The primary and most obvious difference between telehealth and in-person assessment is the fact that the patient is not in the same room as the clinician. The lack of in-person presence may influence how information is assessed as well as what can be assessed. Nonverbal information is useful for determining the patient's emotional state and, in some cases, risk behaviors. For example, olfactory sensory information can provide clinically relevant information regarding hygiene as well as the use of alcohol or other substances. Body posture, facial expressions, body language (e.g., foot tapping, hand wringing), as well as nonverbal emotional responses such as facial flushing, tearing up, and direction of eye-gaze, also provide important information. The observation of psychomotor and other medical symptoms are also important to observe during psychological assessments. Further, the observation of how an examinee approaches a test or measure may be critical for making an accurate assessment. The lack of physical presence, however, may limit the range of information available or how it can be observed. VTC assessments may be influenced by camera angle, screen size, room characteristics, or other technical factors (e.g., network bandwidth issues) that prohibit the observation of all behaviors. Further, the lack of physical presence in itself may influence a patient's clinical presentation. For example, patients who are socially anxious may underreport symptom severity when they are assessed remotely because the fear-evoking stimulus (i.e., the presence of the assessor) is physically distant (Grady & Melcer, 2005). Also, in the case of home-based assessments, symptoms of panic disorder, agoraphobia, or the hyper-arousal symptom cluster of PTSD may be less salient because the patient is able to avoid situations that may be perceived as threatening, such as driving to a clinic or being around strangers in a busy waiting room.

To help assure the validity and reliability of remote assessment, it is first necessary to make sure that the environmental conditions at the remote location are conducive to the assessment procedures. The location of the room for the assessment session should assure comfort and privacy. The assessment space should be large enough for the patient to feel comfortable in and assessments that involve groups and family interviews will require a space that is large enough to accommodate multiple people and, for some applications, may require a table and other supplies (Kramer, Ayers, Mishkind, & Norem, 2011). In the case of home-based assessment, the presence of roommates, family members, pets, unexpected phone calls, or other distractions may disrupt the assessment process. It is therefore important for the practitioner to work with the patient to plan for and schedule sessions during a time that is free of potential disruptions. These considerations are particularly important for home-based assessments because the practitioner will have less control of the environment than they may have in an office setting.

Given the potential limits of what and how information can be collected during remote assessments, it may be appropriate to modify typical in-person assessment procedures. However, careful review of the instructions or administration manuals for measures and tests should be conducted to assure that procedures or envi-

ronmental conditions for standardized administration are not altered in a way that threatens the reliability and validity of the assessment. In the case of VTC-based assessment, it may be necessary to ask a patient to hold a paper-and-pencil assessment (e.g., self-report measures or therapy homework) up to the video camera for viewing or to use larger handwriting because of small screen size or poor image quality. In addition, it may be helpful to ask the patient to read their responses out loud in scenarios where synchronous video is not used or when the connection quality is inadequate. When nonverbal information is useful but is unavailable or limited, it may also be necessary to ask additional questions to improve the accuracy of the assessment. For example, if administering the Hamilton Rating Scale for Depression (Hamilton, 1967), it may be appropriate to ask the patient to self-report symptoms of psychomotor retardation and agitation with specific follow-up questions such as "Do you have problems sitting still for more than a minute or two" or "Do you move more slowly than your coworkers?".

It is important to note that the procedures for some assessments may not lend themselves to remote administration without physical presence. For example, the Wechsler Adult Intelligence Scale (WAIS-IV; Wechsler, 2008) involves hands-on interaction, such as administration of the Block Design, Matrix Reasoning, and Visual Puzzles subtests from the Perceptual Reasoning Index, which would be inappropriate and impractical to administer via VTC. In some cases, however, it may be feasible to administer assessments remotely, such as cognitive function testing (see Cullum, Weiner, Gehrmann, & Hynan, 2006), whereby an on-site staff member administers the assessment and then shares the results with a remote clinician who scores and interprets them. Also, some assessment instruments, such as the Minnesota Multiphasic Personality Inventory (MMPI)-2 or WAIS-IV, should be physically safeguarded (not made openly available to the public) to assure the validity of future administrations. It is therefore important for the practitioner to consider whether remote administration of assessment materials presents a risk to the integrity of the instrument (e.g., by patients being able to print items at home or share them via the Internet, etc.). Practitioners should also consider whether there is an increased risk for dishonest responses (e.g., responses obtained from the Internet or someone else taking the assessment) because control over the testing environment is reduced (Buchanan, Johnson & Goldberg, 2005; Reips, 2000).

Technology Issues

There are several technical issues associated with the use of telehealth technologies that may influence the quality of telehealth-based assessments. Eye gaze angle is the angle between the eye and the camera and the eye and the center of the display (Tam, Cafazzo, Seto, Salenieks, & Rossos, 2007). A potential problem when using VTC technology is that users often make eye contact with the image of the person on the screen rather than with the camera (Chen, 2002)—a phenomenon that gives the appearance that one person is looking down or away from the other person. Eye contact between a patient and a clinician is important because it provides visual cues to which the participants can respond (Grayson & Monk, 2003; Tam et al., 2007). Eye contact is also a source of clinical information that is useful for determining the presence of psychological states or particular disorders (e.g., autistic disorder).

Interpretation of facial expressions and affect may be difficult when eye contact is misleading, and eye gaze angle may also influence satisfaction with using VTC (Tam et al., 2007). Cameras should be positioned in a way that allows the images of both parties to appear straight-on and centered in their respective monitors so that both appear to speak eye-to-eye with each other (Kramer et al., 2011). Tam et al. (2007) pointed out that improved eye contact can be realized by increasing the horizontal distance of participants from the videoconferencing unit. Sometimes, however, patients may shift position during a session, or the camera may be accidentally be shifted from the optimal angle. It may therefore be necessary to ask the patient to make adjustments. It is also recommended to check-in with the patient to make sure they can see and hear clearly. The “picture in picture” function available on many VTC devices can be used to ensure that the provider is clearly in frame as well.

Network connection quality is another important factor that can influence assessment capabilities and quality. Connection problems can be caused by a variety of factors such as low quality equipment, an overloaded computer (e.g., too many programs running at one time), inadequate bandwidth, and user inexperience with VTC (Hyler, Gangure, & Batchelder, 2005; Jones, Johnston, Reboussin, & McCall, 2001; Luxton, Mishkind, Crumpton, Ayers, & Mysliwiec, 2012). Jones et al. (2001) found that inadequate audio quality can influence the ability to accurately gather information from the patient. For example, the observation of vocal properties (e.g., shakiness, inflection, and tone), as well as whether an individual may be crying, can be an important source of information regarding emotional states, and a low-quality audio connection may inhibit observation of this information. It is also important to consider that technological issues (e.g., bandwidth limitations, signal drop-outs, etc.) may influence how well the patient understands the clinician (not just how well the clinician understands the patient). It is therefore a best practice to test the quality of the connection at the beginning of the assessment session and to check in with the patient from time to time to make sure the connection quality is still adequate. Although there is some guidance available regarding minimum recommended bandwidth requirements for TMH (see *American Telemedicine Association*, 2009), what is or is not adequate in any given application will depend on a variety of factors, including requirements for the type of assessment, environmental conditions, and the technology itself.

Potential distractions caused by use of technology (e.g., web cam, personal computer, microphone, mobile device, etc.) may also introduce threats to the validity and reliability of remote psychological assessments. For example, when conducting a clinical assessment interview over a web cam, the patient may become distracted by inconsistent connections, error messages, or other technical anomalies (Germain, Marchand, Bouchard, Drouin, & Guay, 2009; Yoshino et al., 2001). Furthermore, technical malfunctions during telehealth sessions may become a source of frustration for patients (Luxton, Mishkind, et al., 2012; Luxton, Sirotn, & Mishkind., 2010). Persistent technical malfunctions that occur before or during remote assessment sessions may therefore influence motivation, agreeableness, and adherence to assessment procedures. It is thus important to have a plan to resolve technical malfunctions by expeditiously troubleshooting the problem, re-

scheduling the session, or conducting it with an alternative medium (e.g., over the phone) if necessary.

It is also important to consider potential cognitive and/or sensory deficits that patients may have that could impair their ability to use telehealth technology. Technological aides (e.g., headsets, screen magnification devices, speech to text translation software, etc.) or the involvement of family members or other care givers that can assist may be appropriate. Possible fatigue or physical discomfort caused by technology use (e.g., eye strain when viewing computer monitors) should also be evaluated before and during the assessment process, especially during lengthy assessment sessions.

User Acceptance

Generally, the validity of any psychological assessment is modulated by the degree to which the person being assessed accepts (i.e., is willing to participate in) the context of a given assessment including the setting and manner in which the assessment is conducted (Cronbach, 1970; Elhai, Sweet, Guidotti Breting, & Kaloupek, 2012). An individual's acceptance of a particular type of assessment is a multifaceted construct that depends on an individual's physical and emotional state, motivation, attention, personality, and temperament. Poor acceptance has been cited as a factor that reduces compliance and the motivation to engage in mental health assessments (Rogers, 2001). Inadequate acceptance of TMH by either the patient or practitioner can therefore be expected to have a negative influence on the validity and reliability of psychological assessments.

Several reviews that discuss overall acceptance and satisfaction with TMH provide insight into the factors that may influence acceptance of telehealth-based psychological assessments. For example, Modai et al. (2006) reported that patients and providers are generally satisfied with VTC and that regular use of VTC improves the overall degree of satisfaction with this medium. A review by Richardson, Frueh, Grubaugh, Egede, & Elhai (2009) showed that there are high levels of user satisfaction and acceptance with TMH across diverse clinical populations and services. In particular, the benefits of reduced travel time, wait times, and lost work time, as well as greater sense of personal control over sessions were specifically associated with higher satisfaction among patients (see Hilty, Nesbitt, Kuenneth, Cruz, & Hales, 2007; Simpson, Bell, Knox, & Britton, 2005). These benefits may be especially important when considering the need for multiple visits for some psychological assessments (i.e., initial interview, assessment battery administration, and feedback/treatment planning).

Technological issues may also play an important part in the acceptability of telehealth-based assessments as well as rapport between the patient and practitioner (Glueck, 2013). A review by Backhaus et al. (2012) found that patient acceptability of VTC is generally on par with the acceptability of face-to-face contact, although the most common areas of dissatisfaction were associated with technical difficulties that interrupted sessions. In particular, problems with establishing a connection, connection speed, sound echo/feedback, and inability to transmit written material (e.g., a thought journal or activity log) in a way that allowed both the patient and the therapist to review it together were noted (Cowain, 2001; Folen, James, Earles, & Andrasik, 2001). Hyler, Gangure,

and Batchelder (2005) found that both patients and providers preferred in-person assessment when compared to low-bandwidth VTC assessment, especially when detailed observation of patients was necessary; however, when high-bandwidth VTC was available, this method was preferred over in-person assessments. Also, the loss or distortion of nonverbal behavior and other patient characteristics may also negatively impact a clinician's acceptability of telehealth-based assessments (Grady & Melcer, 2005). Solutions to these technology-based issues are available (e.g., faster Internet speeds, head sets, adjunct technology such as fax/document scanner) but come with financial costs that may limit feasibility. Overall, it is important for practitioners to consider that the factors that may influence the acceptability of telehealth-based psychological assessments may not be consistent across all assessment sessions or settings.

Cultural Considerations

As with in-person psychological assessment and testing, practitioners and researchers who make use of telehealth technologies must attend to a broad range of cultural factors, including the patient's age, technological familiarity, and culture-specific norms to assure valid and reliable assessments. For example, the remote physical presence inherent in TMH may create a barrier that reduces a patient's engagement in the assessment process, especially among members of cultures or groups that emphasize interpersonal connectedness or that rely heavily on nonverbal interactions (Nieves & Stack, 2007; Savin, Glueck, Chardavoyne, Yager, & Novins, 2011). An essential component of this is the provider's ability to make use of whatever nonverbal communication is available. This is a skill that is essential when working with groups where the symptoms of mental illness may be minimized or stigmatized (e.g., Asian and Asian American populations, military populations; Yeung, Hails, Chang, Trinh, & Fava, 2011). Also, patients that are less comfortable or have less experience with technology, such as elderly or severely impoverished populations, may display a more drastic discrepancy between in-person and VTC assessments (Rohland, Saleh, Rohrer, & Romitti, 2000).

When working with specific populations, the provision of TMH services, including psychological assessment, should be tailored to the needs, resources, and technological infrastructure of the local community (Brooks, Spargo, Yellowlees, O'Neill, & Shore, 2013). Preliminary work suggests that the customization of TMH to the needs and features of the group that is being served has the potential to enhance access to psychological services within traditionally underserved populations (Dwight-Johnson et al., 2011). Shore et al. (2008) have also demonstrated that structured assessments provided via VTC were as acceptable as in-person assessments among an American Indian population and that the VTC use did not influence ratings of the perceived usability of the assessment, patient/provider interaction, or overall satisfaction. Also, individual backgrounds may present a strong contextual influence on whether and how technology is used (Brooks, Spargo, Yellowlees, O'Neill, & Shore, 2013). It is therefore important for practitioners to be sensitive to the capabilities and preferences of patients during TMH assessments and also recognize that telehealth-based assessments may not be appropriate for all individuals. The provision of a brief questionnaire or interview survey to evaluate previous experiences and preferences regarding technology may be helpful.

Ethical, Privacy, and Safety Considerations

Attention to general ethical principles, such as those specified in the *Ethical Principles of Psychologists and Code of Conduct* (American Psychological Association, 2010b), is necessary during psychological practice whether it is conducted in-person or remotely. Standard 9, Assessment, specifically addresses standards for psychological assessment and these too apply to all forms and mediums of psychological assessment. There are, however, aspects of telehealth-based assessments that require additional thought in order to assure ethical practice and optimal assessments. For example, it would be inappropriate practice to select, develop, or modify assessment instruments or alter procedures for remote administration without evidence of sufficient scientific validation or the appropriate disclosure of limitations. It is therefore necessary for practitioners to be familiar with what measures or techniques are supported by the scientific literature before using them. Moreover, the assurance of patient confidentiality is an example of ethical practice that may influence the validity and reliability of psychological assessments. If a patient does not feel that their privacy is respected and valued by practitioners, the patient may be less willing to disclose information (Rogers, 2001).

Both physical and electronic safeguards should be used to assure confidentiality during remote psychological assessments. For example, people may speak louder when using telehealth technology than when in-person and electronic speakers may amplify sound significantly. Thus, audio should only be loud enough at each end so that both the patient and practitioner can be easily heard but not so loud that the TMH session can be overheard by people outside the room (Kramer et al., 2011). In the case of home-based TMH assessments, practitioners should assess whether the patient has any extra concerns about their privacy (i.e., whether family members or others may overhear the assessment session).

Practitioners conducting psychological assessments with telehealth technology also need to be cognizant of the applicability of the Health Insurance Portability and Accountability Act, the Health Information Technology for Economic and Clinical Health Act, applicable state law, and local privacy and security requirements. The American Telemedicine Association provides specific practice standards and guidelines regarding this topic (American Telemedicine Association, 2009, 2013). Appropriate disclosure of safeguards and potential risks associated with privacy and electronic data should be addressed during the informed consent process. As pointed out by Maheu and McMenamin (2013) however, the informed consent process or an agreement with patients may not be adequate in all situations, in all states, or in foreign countries. Moreover, the diversity in the types of technologies, network infrastructures, and procedures for their use requires careful review of data security risks and requirements (see Kramer, Mishkind, Luxton, & Shore, 2013; Luxton, Kayl, & Mishkind, 2012). Whether or not a particular technology platform or application meets standards for security and privacy of data can be complicated by complex issues such as whether and how digital data is stored on commercial servers, manufacturer agreements regarding ownership of transmitted data, and other potential technical risks to data security and privacy. Consultation with applicable legal or regulatory offices, information technology system administrators, equipment and software manufacturers, and other experienced experts in the field may be necessary when selecting telehealth

platforms or when uncertainties regarding particular applications exist.

It is also important to consider the safety of the patient during TMH assessment sessions and to have a safety plan in place (Luxton, O'Brien, McCann, & Mishkind, 2012). A principal concern involves what to do if a patient becomes distressed or has a medical emergency during a remote assessment session. Safety plans should include procedures for contacting emergency services in the patient's locale, alternate contact methods in case the synchronous telehealth connection is lost (e.g., backup phone contact), and plans for resolving technical problems (American Telemedicine Association, 2013; Luxton, O'Brien et al., 2012). The identification and involvement of a local collaborator, such as a family member or friend of the patient that can assist with on-site technical problems or provide support to a patient during emergency situations should be considered (American Telemedicine Association, 2013; Gros, Veronee, Strachan, Ruggerio, & Acierno, 2011; Luxton, O'Brien et al., 2012). The use of a collateral person, as well as overall telehealth assessment procedures, risks, and benefits should be addressed during the informed consent process.

Patients with a history of adverse reactions during treatment (e.g., severe panic attacks), or those who are at high risk of harm to self or others (e.g., family members in the case of home-based TMH), may not be appropriate candidates for telehealth services provided to clinically unsupervised settings (Luxton, O'Brien et al., 2012). These issues should also be considered when conducting remote assessments, especially when providing assessment results. As noted by Pope (1992), the form of assessment results and the process of presenting them may influence how patients interpret their meaning. Given these concerns, it is important to consider whether providing assessment results remotely via telehealth technologies is appropriate for any given patient. Prior to engaging in remote assessments, review of the patient's history and potential risks, assessment of available technologies and the patient's familiarity with them, as well as discussion of preferences regarding engaging in remote assessments are recommended. Alternative options (e.g., in-person) may be necessary if patients are not appropriate candidates for telehealth-based services due to safety concerns, clinical contraindications, technological barriers, or personal preferences (Luxton, O'Brien, et al., 2012; Luxton, Sirotnin, & Mishkind, 2010).

Selecting Assessment Measures: Psychometric Considerations

It is important for practitioners to consider that even if an assessment tool has been shown to be valid and reliable in the original paper form or in one particular modality (i.e., in-person interview or computer-based administration) it does not necessarily mean that the measure or tool will be valid or reliable when conducted remotely via telehealth technologies. Moreover, even if there is empirical support for the use of a particular measure in one telehealth technology medium, such as on an Internet web page, it does not necessarily mean that it will be valid or reliable when transferred to another medium, such as a mobile device. The differences in the physical format of these mediums and procedures for use may influence the psychometric properties of measures administered through them. As mentioned previously in this article, it is necessary for practitioners to be familiar with the

available scientific literature regarding a measure or technique's appropriateness for use.

Several published reviews provide useful information regarding the validity and reliability of remote psychological assessment via various telehealth technologies. For example, Hyler et al. (2005) conducted a review and meta-analysis that included 14 studies that compared telepsychiatry to in-person psychiatric assessments. Five studies used objective assessment measures, two studies used subjective measures (i.e., satisfaction measures), and seven studies used a combination of objective assessment measures and subjective measures. The Brief Psychiatric Rating Scale (Overall & Gorham, 1962) was the most common assessment instrument. The meta-analysis results indicated that objective telepsychiatry assessments were similar to in-person assessments in regard to diagnosis or symptoms assessment. The Telemental Health Standards and Guidelines Working Group (Grady et al., 2011) also conducted a review of published data regarding the psychometric properties of remote telehealth-based psychological assessment. They noted several studies that have examined psychological assessment via clinical interviews or psychiatric interviews based on the Structured Clinical Interview for DSM Disorders (SCID; Spitzer, Williams, Gibbon, & First, 1990). Two studies (Ruskin et al., 1998; Shore, Savin, Orton, Beals, & Manson, 2007) demonstrated high reliability in the administration of the SCID. Comparability between face-to-face and VTC is also demonstrated for the Hamilton Depression Rating Scale for depression (Kobak, 2004; Kobak, Williams, & Engelhardt, 2008). Backhaus and colleagues (2012) conducted a systematic review of the research on psychotherapy using VTC and reported that 69% of the 42 studies that they reviewed used a well-accepted psychometrically validated (in-person) standardized measure for treatment outcomes. Of these, the most common assessment (24% of the 42 studies) was the Beck Depression Inventory (BDI-II; Beck, Steer, & Brown, 1996). Grady et al. also noted that there are not any psychometric data available regarding projective testing over VTC.

Grady et al. also noted evidence that demonstrates the feasibility of remote neuropsychological assessment (Hildebrand, Chow, Williams, Nelson, & Wass, 2004; Saligari et al., 2002) and comparability of scores between remote and in-person assessment (Cullum et al., 2006; Loh, Donaldson, Flicker, Maher, & Goldswain, 2007), as well as some research that has demonstrated differences on test scores (Ball, Tyrrel, & Long, 1999; Loh et al., 2004; Montani et al., 1996). Cognitive assessments that have been examined and validated include the cognitive section of the Cambridge Mental Disorders of the Elderly Examination (Ball & Puffett, 1998), the Mini-Mental State Examination (Grob, Weintrau, Sayles, Raskin, & Ruskin, 2001), the National Adult Reading Test, and the Adult Memory and Information Processing Battery (Tschirch, Walker, & Calvacca, 2006). The development of new norms has been recommended so that the thresholds used for impairment are valid when compared with face-to-face administration (Grady et al., 2011; Kirkwood, Peck, & Bennie, 2000).

Evidence of equivalence as well as differences between Internet-based questionnaire assessments and paper-and-pencil administrations of standardized measures has also been reported in the literature (Barak & English, 2002; Barak, Hen, Boniel-Nissim, & Shapira, 2008; Buchanan, 2002; Naglieri et al., 2004). For example, evaluation of online versions of BDI-II have shown that psychometric properties differ across testing modalities of psycho-

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metrically validated assessments, even when comparisons are made between equivalent samples, and that online BDI-II scores tended to be higher (Glaze & Cox, 1991; Peterson, Johannsson, & Carlsson, 1996; Schulenberg & Yutrzenka, 1999). Also, some evaluations of personality inventories administered online have shown differences in item loadings compared to paper-and-pencil versions (Buchanan, 2001; Buchanan, Johnson, & Goldberg, 2005). These differences may be due to the lessened impact of social desirability, an increase of self-disclosure in online assessment, or as the result of the technology-based presentation itself (Buchanan, 2003).

In sum, the literature base regarding the psychometric properties of telehealth-based assessments is growing; however, there are gaps in the literature that practitioners should consider when selecting particular assessment instruments and mediums. In particular, the vast majority of available measures and assessment tools are based on norms that were established by employing traditional in-person procedures. The reevaluation of these tools with diverse populations, clinical presentations, and telehealth mediums is necessary to assure the validity of assessments conducted via telehealth technologies. It is critical for practitioners to be cognizant of assessment measure limitations and to appropriately disclose and document them in their practice. Keeping up with the scientific literature as well as publications by organizations such as the APA and American Telemedicine Association is recommended.

Discussion

The validity and reliability of psychological assessments conducted via telehealth technology is influenced by factors that are both common to in-person assessment and unique to telehealth-based assessments. Although the psychometric characteristics and standardized procedures of traditional in-person psychological assessments provide useful information about how they may translate to other mediums, practitioners would be remiss to simply assume equivalency between in-person and remote administration of psychological assessments. It is therefore important for practitioners who already use or are considering the use of telehealth technologies to be familiar with these factors and to use appropriate administration techniques when conducting remote psychological assessments. It is feasible to assure reliable and valid remote psychological assessments with appropriate knowledge, preparation, and practice.

The use of telehealth technologies for remote psychological assessment has several benefits for both patients and practitioners. For example, telehealth-based assessments allow practitioners to conveniently monitor symptoms and other health variables between in-person or telehealth treatment sessions. Further, telehealth-based psychological assessment may improve care satisfaction and overall health outcomes by providing services that are specialized for the patient's needs. In particular, telehealth technologies may provide access to clinical specialty assessments (e.g., neuropsychological assessments) that are not available in the patient's locale. Telehealth-based psychological assessment may also increase access to services among patients who speak different languages. For example, a non-English speaking patient could engage in mental health assessment and treatment with a clinician who speaks their native language, regardless of physical location,

which may minimize potential misunderstanding and misdiagnosis of a patient's symptom report (Yeung et al., 2011). This would also be true for the use of American Sign Language and would remove the need for a third-party translator who may unintentionally change the meaning of a communication during the translation process. The use of telehealth technologies also allows patients to connect with providers that are trained in specialized assessments and who also have experience working with particular cultural groups (e.g., military culture, the elderly, specific ethnic groups, etc.).

Current and emerging technologies not only allow remote administration of traditional assessments but may also offer new or improved capabilities and methods of assessment. In particular, the growing field of mobile device apps has created opportunities for self-care assessments and symptom screening that were not possible just a decade ago (Luxton, McCann et al., 2011). Assessment apps on smartphones and tablet PCs can also be useful for measuring the dynamic characteristics of a person. For instance, subjective mood or anxiety levels can be tracked in real-time and data from bio-feedback equipment can be tracked and analyzed remotely. The small size and touch screen features of smartphones and tablet PC devices are factors that may influence the psychometric characteristics of assessments provided on these devices. Preliminary data, however, have suggested that these devices may be a feasible platform for assessments that is comparable to paper-and-pencil and computer-based assessments (Bush, Skopp, Smolenski, Crumpton & Fairall, in press). More research is needed, however, regarding the psychometric properties of psychological assessments administered via mobile devices.

Assessments conducted with computer-simulated virtual reality environments are another emerging capability (Holloway & Reger, 2012; Parsons, Silva, Pair, & Rizzo, 2008; Riva, Wiederhold, & Molinari, 1998). Assessments can be built into the virtual environment so that measures appear virtually while a patient is in the virtual environment or to simulate real-world conditions that are useful for the assessment of particular variables. For example, virtual environments have been tested as a way to create environmental or social cues for assessment of emotional and behavioral responses among patients being treated for addiction or anxiety related behaviors (see Bordnick, Carter, & Traylor, 2011). The application of artificial intelligence technologies to conduct clinical interviews, psychological assessments, and evaluations is also a promising area (Luxton, 2013b). Virtual intelligent agents capable of human-like social interaction can be designed to conduct clinical interviews, analyze results, and provide feedback to patients. These types of systems have already been developed for clinical training and some treatment services (DeAngelis, 2012; Parsons, Kenny, et al., 2008). Artificial intelligence-enabled technologies that use advanced sensing and language processing capabilities are also being developed to assess physiological and psychological variables. These advances in technology have the potential to increase the reliability and validity of psychological assessment, improve clinical care, and reduce costs for both patients and practitioners.

AQ: 5

In conclusion, the use of telehealth technologies provide an opportunity for psychologists and other health care professionals to expand the capabilities of their practice, provide quality services, and meet the health care needs of care seekers. The increased user demand for technology as well as the continued

growth of TMH services will push the need for telehealth-based psychological assessments. The adherence to best practices and competencies for psychological assessment via telehealth technologies is the responsibility of psychologists and others who provide such services. Practitioners must remain familiar with available research and guidelines before engaging in remote assessments. Moreover, practitioners must consider the applicability to specific populations and appropriateness of any assessment measure or technique on a case-by-case basis. Ultimately, the decision to conduct psychological assessments from afar should depend on both the practitioner's and patient's comfort level with the process.

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Title: A Randomized Controlled Trial of Home-Based Tele-behavioral Health Care for U.S. Military Personnel and Veterans with Depression.

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Presentation Format: Oral presentation

Word Limit: 500

Background: Home-based tele-behavioral health (HBTBH) care has the potential to provide US military Service members with increased access to care, convenience, and privacy. While the Veteran's Health Administration (VHA) has already sanctioned HBTBH services, home-based care is not presently a standard of care in the Military Health System (MHS). The safety, feasibility, and effectiveness of HBTBH needs to be evaluated in the military setting before it can be considered for adoption across the MHS. This presentation will report the results of the first randomized controlled trial of a tele-behavioral health treatment delivered via videoconferencing technology (VCT) directly to the homes of U.S. Service members.

Methods: Participants meeting DSM-IV criteria for depression were recruited from outpatient behavioral health programs at a large regional military treatment facility and VHA medical center. Following informed consent, participants (n=121) were randomized to receive Behavioral Activation Treatment for Depression either in-person or in-home via a laptop and webcam. Both groups received the same manualized treatment protocol which included eight weekly one-hour sessions. Clinical assessments occurred at baseline, 4-week midpoint, 8-week treatment completion, and 3-month follow-up time points. Depression, hopelessness, anxiety symptoms, treatment seeking attitudes, treatment satisfaction, and occurrence of any events involving initiation of a safety protocol were assessed.

Results: For participants in the in-person condition, Beck Hopelessness Scale (BHS) scores decreased by an average of 6.20 points (95% CI = -7.74, -4.67) and Beck Depression Inventory (BDI-II) scores decreased by an average of 17.64 points (95% CI = -20.90, -14.38) at post treatment assessment. Among in-home participants, BHS scores decreased by an average of 3.90 points (95% CI = -5.11, -2.70) and BDI-II scores decreased by an average of 13.39 points (95% CI = -16.17, -10.60) at post treatment. A linear mixed effects regression model was used to test whether the upper bound of a 90% confidence interval exceeded the non-inferiority margin of 0.50 at the post treatment assessment period. The confidence interval exceeded the margin for both the BHS and BDI-II scores, indicating that we could not reject the null hypotheses of inferiority beyond the defined margin. Using a two-tailed 95% confidence interval, the in-home condition demonstrated inferiority to the in-person condition on the BHS, but the interval for the inferiority of BDI-II included zero. Patient safety was maintained effectively in both groups throughout the trial and favorable attitudes toward- and satisfaction with- the treatment did not differ between the two treatment groups.

Conclusions: This study represents the first RCT of home-based tele-behavioral health care conducted in the US military setting. Based on the data, delivering psychotherapy for depression in both a face-to-face and in-home medium reduced depression and hopelessness scores. However, the comparison of these modalities did not support the non-inferiority of HBTBH compared to standard in-person services. The observed results regarding overall safety and treatment satisfaction support home-based tele-behavioral healthcare as a potentially viable option for meeting the health care needs of U.S. military and VHA health care beneficiaries that don't have access to- or are unwilling to seek out- traditional services.

Additional Clinical Benefits of Home-Based Telemental Health Treatments

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Home-based telemental health (HBTMH) has several important benefits for both patients and clinical practitioners including improved access to services, convenience, flexibility, and potential cost savings. HBTMH also has the potential to offer additional clinical benefits that are not realized with traditional in-office alternatives. Through a review of the empirical literature, this article presents and evaluates evidence of the clinical benefits and limitations of HBTMH. Particular topics include treatment attendance and satisfaction, social support, access to contextual information, patient and practitioner safety, and concerns about privacy and stigma. By making use of commonly available communication technologies, HBTMH affords opportunities to bridge gaps in care to meet current and future mental health care needs.

Keywords: telemental health, home-based, telehealth, telemedicine, telecommunications

Home-based telemental health (HBTMH) is the delivery of mental health services directly to a patient's home via the use of telecommunications technology. Current technologies used to facilitate HBTMH include, but are not limited to, synchronous modalities such as telephone and Internet-based video teleconferencing (VTC) and asynchronous (store-and-forward) technologies such as e-mail and text messaging (Hilty et al., 2013; Hilty et al., 2006). Informational Internet sites or Web-based interactive pro-

grams can also be used in HBTMH (Rizzo et al., 2011). Mobile devices such as smartphones and tablets have also recently emerged as a method to provide care via synchronous video or mental health "apps" (Luxton, McCann, Bush, Mishkind, & Reger, 2011).

Treatments delivered via HBTMH have been used to address diverse mental health conditions including bipolar disorder, substance abuse, depression, obsessive-compulsive disorder, post-traumatic stress disorder (PTSD), schizophrenia, and panic disorder (Bensink, Hailey, & Wootton, 2006; Brand & McKay, 2012; DelliFraine & Dansky, 2008). Treatments for depression and anxiety delivered via video-based HBTMH have garnered the most extensive study (e.g., Choi, Hegel, Marinucci, Sirrianni, & Bruce, 2013; Gros et al., 2011; Strachan et al., 2012) and have primarily examined the application of cognitive-behavioral therapies (CBT), including those with exposure-based components such as prolonged exposure (e.g., Strachan et al., 2012) and exposure and response prevention (e.g., Brand & McKay, 2012). Generally, clinical outcomes studies suggest that HBTMH is both a feasible and effective treatment option and that both in-home and in-person treatments demonstrate comparable effects with regard to both the magnitude and the direction of change over the course of specific cognitive-behavioral treatment protocols (Gros, Yoder, Tuerk, Lozano, & Acierno, 2011; Gros et al., 2012; Rabinowitz, Brennan, Chumbler, Kobb, & Yellowlees, 2008; Strachan et al., 2012). The maintenance of clinical gains for periods ranging from 3 months to 2 years have also been reported among individuals with serious mental illness diagnoses as well as home-bound older adults with depression (Choi et al., 2012; D'Souza, 2002). There is also evidence that telemental health, including HBTMH, can help prevent inpatient rehospitalization, reduce the number of days spent in psychiatric hospitals, and improve overall treatment satisfaction

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and compliance (D'Souza, 2002; Godleski, Darkins, & Peters, 2012).

In sum, evidence is accumulating to suggest that the degree of clinical effectiveness of HBTMH treatments is comparable with the same treatments delivered in conventional in-office settings. There are also unique aspects of HBTMH that may provide additional clinical benefits and enhancements that are not realized in traditional in-office care settings. Our goal with this article is to highlight and review the evidence of the additional benefits that have been given less attention in the literature. Although we recognize that self-directed mental health services accessed via the Internet at home are a form of home-based treatment, our review is focused on clinical HBTMH treatments that are provided directly to the patient, in real time, by trained mental health professionals (e.g., psychologists, psychiatrists, social workers, psychiatric nurses, etc.). Our focus is primarily on telepractice with mental health populations; however, some of the benefits that we review also pertain to behavioral medicine applications such as pain management, sleep disorder treatment and diet/exercise counseling. Our aim is to provide information that is useful to practitioners and researchers who have an interest in HBTMH.

Treatment Attendance and Satisfaction

One of the principal benefits of HBTMH is its potential to improve treatment attendance and satisfaction which can lead to more positive treatment outcomes. The benefits of reduced travel, less time off work, shorter appointment wait-times, and greater personal control are frequently cited as advantages of telehealth-based care over in-person care (Hilty, Nesbitt, Kuenneth, Cruz, & Hales, 2007; Simpson, Bell, Knox, & Britton, 2005). These benefits are especially salient with HBTMH because of the cost-avoidance benefit of not having to travel to a clinic or arrange for childcare, for example.

Another benefit of providing a HBTMH option to patients is that it may communicate that the practical concerns the patient has about seeking treatment (e.g., cost, travel time, time off work, etc.) are valid. This idea is supported by research that has shown that the validation of patient concerns is associated with adherence to pain management treatment (Linton, Boersma, Vangronsveld, & Fruzzetti, 2012). This patient-centered validation of the patient's needs on the part of the practitioner may have important implications for a patient's willingness to seek and complete treatment. This is consistent with a study that showed that switching to HBTMH increased both medication compliance and appointment attendance among adolescent patients who were noncompliant with in-person services (Hommel, Hente, Herzer, Ingerski, & Denson, 2013).

HBTMH may also be a preferred option for some patients with anxiety conditions (e.g., social anxiety, panic disorder with agoraphobia, specific phobia) who are contemplating seeking care but who are concerned about confronting anxiety provoking stimuli (e.g., crowds, driving, etc.). Patients who are less able to tolerate anxiety may be less likely to seek or adhere to conventional in-office care. A HBTMH option creates an opportunity to discuss treatment rationale and provide evidenced-based treatments to individuals who find it too distressing to attend treatment in-person, at least initially. It is important to note that although HBTMH provides an option for patients who may not otherwise attend treatment in an office or other clinical setting; it may fail to

provide the benefit of naturalistic behavioral activation and exposure that would occur if the patient was to attend treatment in person. The comfort and conveniences of staying at home may inadvertently minimize a patient's contact with beneficial processes such as attending to personal hygiene, leaving the house, engaging in social interactions, and self-exposure to anxiety provoking stimuli that are often required for in-person care. It is thus important for practitioners to consider and work with patients to find opportunities to engage in therapeutic and exposure-based behaviors during the time between treatment sessions.

Published data regarding satisfaction specific to HBTMH is limited at this time; however, the broader TMH literature does provide evidence of patient satisfaction with treatments provided via VTC that is comparable with in-person treatment (Richardson et al., 2009). Low-quality VTC software, however, can have negative effects on satisfaction due to the disruption that low bandwidth connections can have on the continuity of VTC image quality and fluidness of the interaction (Hylar, Gangure, & Batchelder, 2005). Moreover, a perceived lack of technical savvy and insufficient experience with computer equipment has been cited by potential HBTMH patients as a reason why they choose to avoid remote care, suggesting that fear about the technological aspects of home-based care may be an important barrier to the acceptance of this treatment modality (Shore, Savin, Novins, & Manson, 2006; Starling & Foley, 2006). There is evidence, however, that with minimal training HBTMH patients can learn to use telehealth equipment and software effectively in relatively short amounts of time (Bischoff et al., 2004; Gabrielian et al., 2013; Shore et al., 2006). Cooperative problem solving of technical issues during treatment may also have several therapeutic benefits. For example, collaborative set-up or troubleshooting of equipment may facilitate initial and sustained rapport, facilitate collaborative problem solving, and build self-confidence.

Practitioners of behavioral health care also report overall positive attitudes and levels of satisfaction with the use of TMH, especially in terms of its ability to improve access to care. This is especially true among those who have had direct experience using TMH in their practice (Simms, Gibson, & O'Donnell, 2011). Indeed, a practitioner's regular use of VCT and their ratings of user satisfaction are positively correlated (Modai et al., 2006) which suggests that satisfaction increases as experience is gained.

Social Support and Connectedness

Social support is a key factor in the development, severity, and recovery from psychopathology (e.g., Cohen & Wills, 1985; Sarason & Sarason, 1982). Similarly, the interpersonal connection and empathic support present in psychotherapeutic interventions is a meaningful component of mental health treatment (Roehrl & Strouse, 2008) and adaptive interpersonal functioning (Haber, Cohen, Lucas, & Baltes, 2007; Holt-Lunstad, Smith, & Layton, 2010). Telehealth can facilitate social connections and support that may not otherwise be feasible. For example, telehealth procedures have been used to promote relationship building via remote contact with socially isolated caregivers of individuals suffering with dementia who often must sacrifice their own social support to provide care for others (Wright, Bennet, & Gramling, 1998). In this example, telehealth allowed these caregivers to achieve meaningful social interactions without disrupting their caregiving re-

sponsibilities. Additionally, Blank, Chang, Fox, Lawson, and Modlinski (1996) have reported that among patients at risk for treatment drop-out, individuals who received a telephone call between sessions were more likely to attend their next session.

HBTMH also allows for more contact between patients and practitioners in cases where treatment frequency is affected by logistical factors such as travel time and cost. Treatments that require a significant amount of between session homework (e.g., activity monitoring, exposure exercises, symptom tracking, etc.) would benefit from the closer treatment intervals that HBTMH can provide. HBTMH may also allow practitioners to more effectively monitor symptoms, assess risk, and intervene before a patient worsens or a crisis develops. For example, weekly contact via HBTMH with a patient that is at high risk for suicide and who lives several hours away from their treatment practitioner's office could provide an opportunity to detect early stage increases in suicidal ideation that may not be possible with less frequent in-person (e.g., monthly) contact. Moreover, frequent contact that fosters a caring social connection between practitioner and patient may in itself help to protect against suicidal behavior. This idea is consistent with "caring letters," the suicide prevention intervention that involves the maintenance of a caring connection through brief messages of care between treatment practitioners and patients following treatment or hospital discharge (Luxton, June & Comtois, 2013; Motto, 1976). Although the routine patient contact made through HBTMH services is not the same in form or intent as the "caring letters" intervention, HBTMH may nonetheless provide the same sort of regular, empathetic contact by a care practitioner that may be especially important for high-risk patients who are geographically isolated or who lack supportive social connections.

Access to Contextual Information

Another potential benefit of HBTMH is the ability to observe, when clinically appropriate and with the consent of the patient, information in real-time about the patient's living environment. The capability to view the patient's home environment with VTC technology can provide a short-cut to valuable information for the practitioner. For example, if a provider discovers that a patient's pet is present during a session, that information can be used to spark a discussion about how much the pet means to the patient and what that relationship provides to them. This also provides the practitioner with information about the patient's activity level and an opportunity to plan for meaningful and important caretaking behavior. Alternatively, when treating a patient with insomnia the practitioner could, with permission, "tour" the patient's sleeping environment. The practitioner could then identify factors (e.g., presence of bright alarm clocks, lack of window-coverings, or other environmental characteristics) that could be addressed as part of treatment (Henry, Rosenthal, Dedrick, & Taylor, 2013). Similarly, for a patient seeking treatment for substance abuse or dependence, the practitioner and patient could work collaboratively, in real time, to remove or dispose of drug related paraphernalia or other relapse triggers in the patient's environment (Benavides-Vaello, Strode, & Sheeran, 2013).

The capability to view a patient's environment and personal effects in their home, when clinically relevant, may also contribute to rapport and connectedness in a manner akin to the joining process that occurs when a therapist physically conducts treatment

with a family in their own home, wherein the practitioner gains experiential insight into the day-to-day routines, context, and contingencies operating in the family system (Reiter, 2000). For example, a patient may have a dedicated room for a hobby, sports team, or another personal interest, and those interests or activities can be brought into the therapeutic context to build a stronger and more personalized therapeutic relationship. However, practitioners should consider the clinical implications of taking an active role in assessing a patient's home environment versus educating and encouraging the patient to assess their own environment. Practitioners must also be sensitive to the privacy needs of patients and consider them based on a given patient's clinical presentation and needs.

As has been noted elsewhere (Luxton, Pruitt, & Osenbach, 2014; Wagnild, Leenknecht, & Zauher, 2006), some clinically relevant data (e.g., olfactory impressions of a client with a history of alcohol dependence, view of the client's entire body with which to gauge psychomotor agitation) may go unobserved when using telehealth technologies. Conducting treatment remotely, whether to a supervised clinic or the home, requires practitioners to ply their craft in a flexible manner that suits the context. This is true not only in terms of clinical data gathering but also with regard to the adjustments that must be made to how treatment is conducted. For example, the practitioner may need to account for others that may be in the patient's environment, make sure that the on-screen image of the practitioner can be seen and heard clearly, and discuss with the patient how to manage potential disruptions to session that occur in the patient's home. It is important to note that these potential problems are manageable, and that as VTC technology continues to improve (e.g., easily accessible smartphone and tablet platforms, the ability to share materials between sites, integration with the electronic medical record, etc.) it is likely that the impact of these potential disruptions will be reduced (Brooks, Turvey, & Augusterfer, 2013).

Patient and Practitioner Safety

HBTMH can also help to improve the safety of patients which may lead to improved treatment adherence and outcomes. For example, an elderly patient with reduced mobility and difficulty driving may be better served with care delivered to their home, rather than having to navigate the risks of attending an in-person session. Similarly, patients living in locations with harsh winter environments may benefit from avoiding long trips on treacherous roads.

A primary safety concern associated with HBTMH centers around the management of situations when a patient is in crisis or threatens harm to self or others at the end of a session or just before the patient unexpectedly ends the session. A decreased sense of control, unfamiliarity with safety procedures, and liability concerns are all factors that may influence practitioners' confidence in providing HBTMH services (Luxton, Sirotnin, & Mishkind, 2010). However, there have not been any published studies that we are aware of to suggest that HBTMH is less safe than in-office care. The available literature indicates that patient safety during TMH, including HBTMH, can be effectively managed with appropriate training and safety planning (Gros et al., 2011; Luxton, Sirotnin, Mishkind, 2010). Moreover, recently published guidelines (e.g., American Psychological Association [APA], 2013; American

Telemedicine Association [ATA], 2013), a practice recommendations review (Luxton, O'Brien, McCann, & Mishkind, 2012), and a TMH guidebook (Kramer, Ayers, Mishkind, & Norem, 2011) all discuss and provide guidance regarding safety management and are available to TMH practitioners.

Safety planning during HBTMH may have some clinical benefits that have not been previously discussed in the literature. In particular, the process of working collaboratively with patients to establish a safety plan may in itself have a therapeutic benefit. Additionally, the identification of another person at the patient's location who can assist during emergencies or with technical issues during HBTMH sessions is a TMH practice recommendation (ATA, 2013; Luxton et al., 2012). If the support provided by this person matches the patient's needs in a moment of crisis, their involvement is likely to increase feelings of social connectedness (Callaghan & Morrissey, 2008), help to establish therapeutic alliance by showing concern for the patient's well being, and provide the patient with a sense of control. This idea is consistent with clinical interventions that emphasize collaborative treatment planning approaches such as Collaborative Assessment and Management of Suicidality (CAMS; Jobes, 2006). Collaborative safety planning may also provide the patient with increased confidence that there is a plan to resolve emergencies and therefore contribute to improved comfort in and acceptance of the HBTMH process.

Home-based TMH may also provide, in some cases, safety benefits for practitioners. Consider that nonfatal, job-related violent crime perpetrated against mental health professionals by patients occur at a rate of 68.2 per 1,000, approximately four times greater than the rate for non-psychiatrist physicians and approximately three times greater than the rate for nurses (Anderson & West, 2011; Friedman, 2006). Thus, patients with a history of violence toward treatment practitioners or who are at an elevated risk for violence may be appropriate candidates for remote services because the potential for physical harm to treatment staff is minimized by the physical distance between the patient and practitioner (Luxton et al., 2012). In any situation, the evaluation of the entire range of safety risks, including risks for the patient, family members, and staff members (if considering in-office care) should be considered when determining the most appropriate treatment services option.

Improved Privacy and Concerns About Stigma Associated With Care Seeking

One of the most significant benefits of HBTMH is that it may help to overcome concerns about privacy and stigma associated with seeking care in person (Olden, Cukor, Rizzo, Rothbaum, & Difede, 2010). Concerns about privacy may be an issue when clinic areas or waiting rooms are highly visible to others. Patients who forgo seeking treatment due to these concerns may be willing to participate in care when it is provided in the privacy of their own home.

Although HBTMH may offer improved privacy in some areas, additional privacy-related concerns may arise related to the use of technology and the lack of physical presence inherent HBTMH services. In particular, concerns about the security of data transmission (e.g., over the Internet) and data storage may influence both patients' and practitioners' willingness to engage in TMH services. The use of VTC in the home also presents some addi-

tional privacy concerns because it is possible to view the private home environment of the patient, and family members or roommates may walk in on or overhear session content. Further, patients may have concerns about whether there may be someone else in the practitioner's office that may be able to hear the conversation.

It is therefore important that practitioners communicate to patients that privacy and data security are taken seriously and that there are procedures in place to maximize privacy and data security. The steps taken by the provider as well as those required of the patient should be addressed during the informed consent process before commencing treatment (APA, 2013; Luxton et al., 2014). For example, discussion of data encryption and risks, recommendation for securing the treatment environment (e.g., closing doors and windows), and negotiating with family members in the house about dedicating time and space for treatment sessions are recommended. These steps may, in some cases, be clinically beneficial. For instance, these activities may help to facilitate communication of needs between a patient and their partner or provide a patient with a sense of control and support in achieving their goals. It is important to note that HBTMH may also burden the patient with assuring that they have a private space that can be secured during appointment times. Care practitioners thus need to be cognizant of this issue when practicing HBTMH and to work with their patients to achieve optimal therapeutic conditions.

Conclusions

HBTMH is an option to improve access to mental health services by bringing care into the convenience and comfort of a patient's home. Advancements in both the sophistication and omnipresence of Internet connectivity, Webcams, videoconferencing software, and smart mobile devices have made HBTMH more feasible now than ever before. A growing literature base suggests that treatments provided via HBTMH may be as effective and acceptable as in-person services with the potential to offer some unique and important clinical benefits. These benefits include enhanced social support, safety, understanding of patient's home context, and privacy. HBTMH is also in line with larger health care goals, including field-wide progress toward integrated care and a patient-centered medical home model (PCMH; Stange et al., 2010). These aspects of home-based care are the driving force behind initial efforts to implement large scale HBTMH programs in both public (e.g., VA) and private health care systems. HBTMH is a critical component of integrated care because it enables primary care and mental health services to be efficiently and conveniently integrated without requiring patients to attend two or more clinics for services. Moreover, because telehealth allows for shorter follow-up or assessment sessions, integrated HBTMH care can provide an economic benefit to both patients and health care systems.

There is still much work that remains to be done before HBTMH sees wide-spread implementation. As noted by Brooks, Turvey, and Augusterfer (2013), three of the biggest issues facing the practice of TMH, and by extension HBTMH, are (a) the provision of clinical services via this modality may not be eligible for medical reimbursement; (b) it is unknown how remote services affect and are affected by laws regulating the practice of mental health professionals across state lines (e.g., issues associated with

mandatory reporting, duty to warn, etc.); and (c) changes need to be made to liability standards to make this mode of treatment delivery a feasible practice. Although further discussion of these specific topics is beyond the scope of this article, the issues associated with liability highlight the challenges facing the adoption of new health care models into standard practices. It is essential to support and increase the access practitioners have to HBTMH training given the liability, safety, and practical nuances of HBTMH. We recommend that practitioners become familiar with published practice guidelines by professional organizations such as the American Psychological Association (APA, 2013) and the American Telemedicine Association (ATA, 2013). We also recommend that practitioners seek training that is available through several organizations such as the American Psychological Association and the American Telemedicine Association.

Additional research is also needed to move HBTMH practice forward. Limitations of the existing clinical effectiveness literature center around concerns about the methodology used, including small samples, statistically underpowered comparisons, and lack of random assignment to treatment conditions (Hylar, Gangure, & Batchelder, 2005; Richardson et al., 2009). Other limitations that have been noted include a lack of diverse study samples (i.e., clinical presentations, socioeconomic diversity, various cultural aspects), failure to compare HBTMH with face-to-face comparators using gold-standard treatments, and failure to use conservative, gold-standard measures of clinical outcomes, and treatment compliance (Aoki, Dunn, Johnson-Throop, & Turley, 2003; Hilty et al., 2004; Roine, Ohinmaa, & Hailey, 2001). To address these issues, the field must move away from small studies that are underpowered to detect between group differences, fail to randomly assign participants to treatment groups, or include homogeneous samples that hamper generalization of findings. More rigorous, randomized controlled trials with adequately large and diverse samples are needed in order to provide meaningful conclusions that apply to broad populations of potential HBTMH consumers. Further, HBTMH should be investigated using treatments that have been empirically validated and make use of gold-standard outcome measures.

Just as it is important to understand who may benefit from HBTMH, understanding who is less likely to benefit from it is equally important—a concept that harkens back to the guiding question posed by Paul (1967): “What treatment, by whom, is most effective for this individual, with that specific problem, and under which set of circumstances?” (p. 111). In the case of HBTMH, practitioners must remain cognizant of whether the modality is the best option for any given patient based on that patient’s needs. Particular attention must also be paid to both patient and practitioner preferences for—and acceptance of—HBTMH in order to make this modality a viable treatment option with maximum benefit.

In conclusion, HBTMH services are highly relevant because they have the potential to help meet the current and future demands on the national (U.S.) health care system. The implementation of HBTMH may yield improved mental health care access to the nearly 80 million Americans who reside in areas without a sufficient number of mental health care practitioners to meet the needs of those communities (U.S. Health and Human Services Health Resources and Services Administration, 2013). Even in urban environments, where mental health professionals are in greater

numbers, cost, transportation, and time constraints often prevent people from seeking mental health services (Novotney, 2011). Telehealth may function as a balancing factor in the misdistribution of mental health practitioners by providing clinical care at a distance in both rural and urban settings. Barriers that currently prevent individuals from seeking treatment may be greatly reduced by the use of HBTMH services and may offer additional clinical benefits that improve treatment outcomes, health promotion, and overall well-being.

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