



Home-based telehealth to deliver evidence-based psychotherapy in veterans with PTSD[☆]

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ABSTRACT

Although medical service delivery via home-based telehealth technology (HBT) is gaining wider acceptance in managing chronic illnesses such as diabetes or chronic obstructive pulmonary disease, few studies have tested HBT applications of psychotherapy. Clinicians, administrators, and researchers question whether delivering psychotherapeutic services to patients in their homes via video-conferencing technology compromises patient safety, potency of treatment, or data security. Despite these concerns, HBT service delivery may increase access to evidence-based psychotherapies for veterans with posttraumatic stress disorder (PTSD), who may be less willing or less able to receive weekly treatment at a VA medical center or outpatient clinic due to symptom severity or other similar barriers to care. Indeed, although combat-exposed service members endorse high rates of psychiatric disorders, few appear to initiate mental health services or receive an adequate dose of treatment. Thus, using HBT technologies to administer evidence-based therapies remains uncharted territory in both the clinical and research arenas. This manuscript describes an ongoing four year randomized controlled trial comparing in-person Prolonged Exposure (PE) – a specialized evidence-based psychotherapy for PTSD – and PE delivered via HBT, with a particular focus on the selection, application, and strengths/weaknesses of HBT procedures. © 2011 Elsevier Inc. All rights reserved.

1. Introduction

Military personnel deployed to the war zone are at heightened risk of trauma exposure and development of subsequent posttraumatic stress disorder (PTSD), a debilitating psychiatric

illness with significant mental and physical health morbidity [1–4]. Despite impressive scientific and organizational support for exposure psychotherapies [5–8], veterans with PTSD underutilize these interventions. A recent study [9] suggested that less than 10% of veterans with new PTSD diagnoses received minimally adequate care (e.g., defined as at least 9 psychotherapy sessions in less than 15 weeks). Further, in the largest clinical trial of exposure therapy to date, nearly 40% of patients terminated treatment participation prior to completion [10]. Barriers to care (e.g., fear of stigmatization for receiving psychiatric services, living in rural or physician shortage areas that lack specialty mental health services, etc.) may reduce the likelihood that veterans will engage in evidence-based exposure therapies (e.g., Prolonged Exposure therapy [11]) that typically require 9 to 12 weekly, 90-minute sessions to complete.

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Home-based telehealth (HBT) may enhance enrollment and retention of veterans with PTSD in exposure therapy by extending service delivery to veterans in their own homes. Although HBT is routinely used by primary care providers to improve the management of chronic health conditions, mental health clinicians have traditionally been reluctant to use HBT when treating PTSD patients, citing concerns about patient safety, confidentiality, diluting the potency of imaginal exposure exercises, and/or compromising the therapeutic alliance [12]. To our knowledge, only one randomized controlled clinical trial (RCT) has tested HBT service delivery against in-person service delivery for veterans with PTSD symptoms, with only preliminary findings to date [13,14]. As such, methodologically rigorous studies (i.e., inclusion of a comparison or control condition, random assignment) that evaluate the feasibility, efficacy, safety, and clinical utility of HBT psychotherapeutic service delivery modalities are needed.

2. The current study

The proposed study involves a randomized controlled design powered for non-inferiority analyses to compare Prolonged Exposure (PE) [11] delivered via HBT (PE-HBT) and in-person (PE-IP). We will recruit 226 male and female veterans with PTSD in the catchment area of a large Veterans Affairs Medical Center (VAMC) in the Southeastern United States and randomize them to either the PE-HBT or PE-IP condition. All participants will receive 9 to 12 sessions of PE and be assessed at baseline, mid-treatment, one-week post-treatment, and at 3- and 6-month follow-up across clinical, process, and economic outcome variables. The design and method of the current study are consistent with recommendations suggested for the implementation of non-inferiority trials [15]. Specifically, we will test an innovative application (i.e., service delivery of PE via HBT video-conferencing technology) of an already established reference intervention for PTSD against the conventional application (i.e., in-person, office-based delivery of PE). We hypothesize that although the conditions will produce comparable clinical outcomes, barriers to care, such as lack of transportation, residence over 20 miles away from the VA facility and/or community-based outpatient clinic (CBOC), and stigma of receiving care at mental health facility, will moderate treatment and process outcomes across condition. Below we describe the basic method of the study, highlighting several innovations including: 1) the selection of HBT technology used in the study; 2) coordinating with VA information technology (IT) staff to establish the HBT capacity without overburdening the VA network; and 3) strategies used to troubleshoot the potential safety concerns that may arise when delivering PE via HBT.

3. Method

3.1. Participants

Participants will be 226 male and female veterans and military personnel, age 21 and over, with PTSD as assessed by the Clinician Administered PTSD Scale (CAPS) [16], who are enrolled in a program of VA healthcare. This may include active duty and reserve personnel who are enrolled in VA services via the TRICARE agreement which allows Department of

Defense (DoD) beneficiaries to receive treatment in VA medical facilities in some circumstances. Veterans with PTSD related to civilian and/or military traumas will be included. Veterans with active alcohol and/or substance dependence (as assessed by the Structured Clinical Interview for the DSM-IV [SCID-IV] [17] alcohol and substance dependence modules), those who are actively psychotic, and those who endorse severe suicidal ideation with plan and intent will be excluded from participation. To maximize generalizability of results, presence of other forms of psychopathology will not be a basis for exclusion. Further, veterans receiving psychopharmacological treatment for PTSD and/or associated symptoms or non-PTSD focused psychotherapy will not be excluded from participation; however, those who report recent changes in psychiatric medication use (i.e., changes in type or dose of medication) will be required to delay the first treatment session for a stabilization of three weeks. To minimize potential confounds to results, we will collect information about patient involvement in concurrent mental health treatments at the baseline, mid- and post-treatment assessments, and will co-vary these data in the final analyses.

3.2. Recruitment plan

Our prior experience conducting non-inferiority treatment outcome research in military health facilities has informed several key strategies designed to maximize recruitment and enrollment of eligible participants [18]. Our research team has established collaborative relationships with mental health teams at the core VAMC and the affiliated CBOCs. We will employ four primary recruitment paths: 1) VAMC PTSD clinic receives automated referrals derived from mandatory screening of all primary care patients. Each veteran referred to the clinic is offered an opportunity to participate in clinical research; 2) letters of invitation mailed to VAMC patients screening positive over the past year but not attending PTSD clinics for treatment identified from the VHA Decision Support System (DSS); and, 3) VA provider referral independent of PTSD screens, from VA physicians, other clinic staff such as nurses, or patients themselves in response to recruitment flyers displayed in prominent locations in the study clinics.

3.3. Strategies to maximize retention

Strategies described here are consistent with recommendations for maximizing participant retention in treatment outcome studies with trauma populations [18] and are informed by our previous experiences conducting clinical trials with veterans with PTSD [13,14]. First, all veterans who enroll in the study will attend a pre-treatment orientation session that provides general information and expectations and requirements regarding participation in this VA-sponsored treatment outcome research project. In our previous clinical trials, we have found that informing participants about routine procedures and expectations (i.e., completion of self-report measures every other session), and about important milestones associated with progression through the study (i.e., completion of post-treatment assessment and 6-month assessment) increases consistency of session attendance and the likelihood that patients will complete post-treatment assessments. Second, consistent with data that suggest family support is

associated with higher session attendance and completion rates, with the participant's permission, we meet with and answer questions from family members and significant others regarding the research project and the treatment itself. In addition, participants are given the opportunity to authorize family members or significant others as a secondary point of contact for the duration of the study. Third, we request participant permission to notify other providers (e.g., case manager, primary care physician, psychiatrist) when the participant has completed or missed an important study milestone (e.g., first therapy session, post-treatment assessment). In this way, study participation maintains the continuum of care found in good clinical practice. Fourth, to the best of our ability, we will schedule post-treatment and follow-up assessments so that they coincide with the participant's other medical appointments at the VAMC. Fifth, we will provide compensation to participants for attending the post-treatment assessments. Finally, we have designated one study representative to serve as the patient liaison. The patient liaison is primarily responsible for monitoring patient attendance across the duration of the study. Specific job related duties include: scheduling all therapy and follow-up assessment appointments, making reminder phone calls, and alerting the investigative team when patients have gone "missing in action" or appear to be at risk of dropping out of the study. We have found that having a familiar face monitor attendance across the entire duration of the study reduces risk of attrition during transition periods (i.e., enrollment to first treatment session, last session to post-treatment assessment, post-treatment assessment to 3-month follow-up, 3-month follow-up to 6-month follow-up).

3.4. Procedures

To determine eligibility, the CAPS and SCID will be administered to all referrals by a trained, masters-level clinician. All interviews will be audiotaped to calculate inter-rater reliability on a randomly selected 20%. Consented participants will be randomized to PE-IP or PE-HBT using a block randomization procedure. Participants randomized to the HBT condition will be provided with in-home video-conferencing technology, or they may choose to use their existing internet connection and computer. All participants will receive 9 to 12, 90-minute sessions of PE administered by masters-level therapists and will be assessed across primary outcome variables at baseline, one-week post-treatment, and at 3- and 6-month follow-up. Number of sessions required for each patient will be determined by therapist and patient agreement on treatment progress and termination.

Therapists completed a four-day training program with Dr. Edna Foa (lead developer of PE and co-investigator in present study) as well as a three-day refresher course provided by designated PE trainers within Dr. Foa's team. Further, clinicians were required to shadow a senior level clinician throughout a complete course of PE before administering the treatment independently. Therapists will meet weekly with the principal investigator (Dr. Ron Acierno) for supervision throughout the duration of the study. Consistent with the guidelines for the PE dissemination initiative, all sessions will be recorded and 20% will be monitored by an independent rater to ensure treatment fidelity.

3.5. Intervention

All participants will receive 9 to 12 sessions of manualized PE [11]. PE is based on emotional processing theory which suggests that traumatic events are incompletely and inaccurately encoded in memory as fear networks. Gradual exposure to corrective information via the confrontation of traumatic stimuli within a safe and therapeutic environment results in a competing and antithetical memory structure that inhibits the conditioned fear response. PE relies on two primary therapeutic tools: in vivo exposure and imaginal exposure. During in vivo exposure, the patient confronts feared, but safe, stimuli that cue trauma-related distress. Common examples of in vivo exposure exercises used in the treatment of war veterans may include driving alone at night, visiting a war memorial, or watching a movie in a dark theater alone. During imaginal exposure, patients "revisit" the traumatic event, providing a detailed verbal account that includes sensory information, thoughts, feelings, and reactions experienced during the traumatic event. PE includes the following components: 1) education about common reactions to trauma and presentation of the treatment rationale (sessions 1 and 2), 2) repeated in vivo exposure to traumatic stimuli (in vivo exercises are assigned as homework during sessions 2 through 11), 3) repeated, prolonged, imaginal exposure to traumatic memories (implemented during sessions 3 through 12), and 4) relapse prevention strategies and further treatment planning (session 12). Prior to beginning treatment, all participants will be provided with a digital audio recorder and a PE workbook that includes homework and supplemental forms required to complete the treatment. All sessions are audio recorded and patients will be instructed to listen to the session audio-recording (of the entire session) and imaginal exposure audio-recording (of the imaginal exposure) for between session homework.

3.6. Treatment conditions: home-based telehealth (HBT) versus in-person (IP) service delivery

Veterans randomized to PE-HBT will receive 9 to 12, 90-minute sessions of PE delivered via their choice of two video-conferencing modalities: (a) encrypted internet-based televideo software to their home computer, or (b) an analog "plug-and-use" videophone with built-in camera and video screen that operates using plain old telephone service (POTS line). The videophone looks like a standard telephone with the exception of having a 4-inch LCD color screen with real-time motion display. Both formats (i.e., encryption software, videophone) offer two-way videoconferencing capability and thus offer enhanced functionality over currently used telehealth audio and monitoring devices. Given significant advances in consumer-driven video-conferencing technology over the past 3 years, it is unlikely that the analog videophones will be used in future HBT clinical trials. Indeed, the VA is moving towards providing patients who receive HBT with televideo devices that look and function like laptop computers. Further, in our HBT clinical trial experience we have found that most patients – even older Vietnam veterans – have access to computers with videoconferencing capability and prefer this modality to the videophone. Additionally, fewer younger veterans have landline telephones, relying instead on cell phones. All operations are in compliance with the Health Insurance Portability and

Accountability Act (HIPAA) privacy requirements and protect personal health information.

Telehealth technology used in the current study was funded by our VA Health Services Research and Development (HSR&D) grant support (VA Merit Award: Prolonged Exposure (PE) for PTSD: Telemedicine vs. In Person). Patients who choose option (a) are provided with the software, a camera, and a microphone for use in the study. Patients who choose option (b) are provided a videophone for use in the study. All equipment is inventoried and patients sign a release acknowledging that they have received the equipment and that they will return it after completing the study.

Use of un-standardized equipment may introduce confounds to the results and we have taken precautions to improve interpretation of the data. Research staff records information about the type of network connection (e.g., cable, wireless, dial-up), computer hardware, and miscellaneous equipment (e.g., camera, microphone, etc.) used by each participant in the study. Further, the therapist records and describes technical problems that occur (e.g., loss of sound, loss of video, connection interrupted) during each telehealth session using a standardized form. We will co-vary this information (e.g., average number of technical disruptions per session, type of network connection) in the final analyses to determine if equipment and connection quality are associated with clinical and process outcomes.

Participants in the HBT condition will receive instruction in using the technology prior to starting treatment. If necessary, project staff or VAMC IT staff will be available to visit participants in their homes to help set up the equipment. However, preliminary investigations suggest that even computer “neophytes” navigate the technology easily [19]. Nonetheless, we will track the type and amount of assistance required across sessions in order to describe difficulties with in-home use and derive cost estimates.

3.7. Assessment of clinical, quality of life, and process outcomes

Participants will be assessed across clinical, quality of life, and process outcomes at baseline, mid-treatment (every other session), one-week post treatment, and three and six month follow-ups by blind raters.

3.7.1. Clinical descriptive and outcome measures

The following measures have been widely used in the clinical evaluation of adults with PTSD, and will be used in the present study: clinical interviews (CAPS [16] and SCID-IV [17] administered at baseline, post-treatment, and at 3- and 6-month follow-up) and self-report measures (PTSD Checklist-Military [PCL-M] [20], Beck Depression Inventory 2nd edition [BDI-II] [21]). Veterans who endorse non-military traumas as their index trauma during the CAPs are provided the non-military version of the PTSD Checklist (i.e., PCL) to complete at baseline, mid-treatment, post-treatment, and 3- and 6-month follow-up assessments. Participants must be enrolled in a program of VA healthcare to participate in the study. Veterans' SF-12 Health Survey (SF-12) [22,23], and Index of Functional Impairment (IFI) (administered at baseline, post-treatment, and at 3- and 6-month follow-up). Each of these measures has received thorough investigation and support for their psychometric properties in the literature.

3.7.2. Process outcome measures

Several measures are included to assess process variables associated with treatment (e.g., treatment satisfaction, adherence, credibility): Treatment Expectancy Scale [24] (baseline assessment), Charleston Psychiatric Outpatient Satisfaction Scale (CPOSS) (session 5 and post-treatment assessment) [25], and the Service Delivery Perceptions Questionnaire (baseline and session 5 assessment) [19]. Indices of treatment adherence also will be recorded, such as homework completion, session attendance, and study attrition.

3.7.3. Economic outcomes

To determine the relative cost-effectiveness of service delivery via HBT, capital costs of HBT technology will be estimated for both the central center and the HBT sites (homes). Further, incremental HBT-related variable costs per treatment session will be estimated for therapist and IT support staff time using the DSS National Dataset which provides estimates of hourly salaries and benefits for about 80 classes of employees. Staff training costs will also be estimated using the DSS National Data and included in sensitivity analyses. It is important to calculate costs and benefits with and without training costs since they are important initially but are likely to become nominal if the intervention is implemented on a wide scale basis. Finally, transportation costs will be estimated for those veterans who meet the criteria for travel reimbursement from the VA based on distance from the centroid of the zipcode of the veteran's residence to the VAMC or CBOC at prevailing mileage reimbursement rates. This is a potentially important cost off-set for the proposed HBT intervention. Finally, incremental benefits of the proposed intervention relative to the comparator will be measured in two ways. First, differences between the two conditions in reduced PTSD symptoms (severity) as measured by the CAPS scale. Second, differences in symptom reduced days and finally, monetary value based on an accepted value of individual willingness to pay for an additional symptom-reduced day [26].

3.7.4. Covariables

Participants will also complete the Deployment Risk and Resiliency Inventory (DRRI) and the Combat Exposure Scale (CES) at baseline [27]. The DRRI is collection of self-report measures assessing 14 key deployment-related risk and resilience factors with demonstrated implications for veterans' long-term health. The CES is a 7-item self-report measure that assesses the frequency and severity of combat-related events. Based on previous research on the factors that predispose trauma-exposed individuals to PTSD [28], we hypothesize that certain pre-deployment factors (e.g., childhood family environment), deployment factors (e.g., frequency and severity of combat exposure) and post-deployment stressors (e.g., perceived social support) measured by the DRRI will moderate the relation between warzone trauma exposure and the development of mental health symptoms.

3.8. Power

We posit that a maximum clinically unimportant difference in response proportion (Δ , the non-inferiority effect size) is 0.15 between PE-HBT and PE-IP groups (upper limit of one-sided 90% confidence interval must not be greater than

$\Delta = 0.15$ for HBT to be declared noninferior). We further assume that the response proportion for the standard in-person mode of delivery is 0.75. The primary response variable for sample size calculation is the proportion (%) of patients who respond to treatment, defined as having at least a 1.5 standard deviation pre- to post-treatment improvement on the PCL, and maintained over follow-ups. For detecting a non-inferiority effect size of $\Delta = .15$ between PE-HBT and PE-IP, power is 85%, with one-sided $\alpha = 0.10$, $P_{In Person} = 0.75$, and $N = 226$ (assuming 20% dropout rate, with 90 completers per condition).

3.9. Data analyses

Treatment response, defined as a pre- to post-treatment improvement of at least 1.5 standard deviations, will be evaluated at the end of the active treatment phase and at each of the follow-up time points. To reflect the fact that, in a non-inferiority assessment, use of the intent-to-treat (ITT) sample will often increase the risk of falsely claiming noninferiority [29] we will consider equally the ITT and the per protocol samples. To investigate potential limits on generalizability, we will compare characteristics between the PE-HBT and PE-IP conditions of the premature exits/protocol non-adherent with those who were completers/protocol adherent, using an independent sample *t*-test or Wilcoxon rank sum test for continuous variables and a chi-square test for categorical variables.

To test the hypothesis that PE-HBT and PE-IP groups are similar in clinical outcomes, two approaches will be taken to compare outcomes for active and follow-up phases for dichotomous variables. The first approach will estimate the unadjusted proportion of responders (% responders) at the end of the active intervention course and at the end of the 6 month follow-up phase. With a one-sided non-inferiority confidence interval approach, the upper limit of the one-sided 90% confidence limit for the difference in % responders (unadjusted and adjusted) for the PE-HBT and the PE-IP groups must be 0.15 (Δ) or less to accept the hypothesis of a non-inferior novel treatment. The second approach will estimate % responders adjusted for putative confounding variables based on a multivariable modeling approach, and then will apply the methods described above (one-sided confidence intervals) to evaluate non-inferiority of the two interventions. Adjustment covariables include age, race, gender, baseline level of the variable of interest, initial disease severity, and use of psychiatric medication.

The analyses for continuous clinical outcome measures (clinical rating scales) will use the same basic non-inferiority confidence interval approach as described above for the dichotomous outcome variables. A general linear model (GLM) approach will be used to model the adjusted relationship between intervention modality and the continuous clinical outcomes at the immediate post intervention time point. For the GLM model, each continuous clinical outcome serves separately as the dependent variable, with intervention (PE-HBT and PE-IP) as the primary independent variable and additional covariates added to adjust for the effect of the putative confounding variables. The non-inferiority analyses for the dichotomous outcome and the continuous clinical outcomes

will be repeated for the 3- and 6-month naturalistic follow-up time points.

Mixed effects models (MEM) analyses (or equivalently, random regression models or hierarchical linear models) will be used on the weekly PCL data to compare the longitudinal trajectories of PTSD symptom severity for the PE-HBT and PE-IP conditions from pre-treatment to follow-up. Longitudinal methods for continuous, binary (e.g. response status) and categorical or ordinal outcomes [30–32] will be used as appropriate for a given clinical outcome variable. The possible effect modification (interaction) of the covariables on the relation between intervention status (delivery mode) and post-intervention clinical outcomes will be evaluated through inclusion of treatment by covariate interaction terms in the model. For the naturalistic follow-up period, we will carry out post hoc subgroup analyses considering participants' intervening events (e.g., grouped by amount/type of additional treatment). Where appropriate, we will include these events as covariables in the regression models. We will estimate the relapse proportions and differences in proportions for PE-HBT and PE-IP using confidence intervals (CIs) and non-inferiority analyses as described above. We will estimate the adjusted proportion of relapsers (and corresponding CIs) for the PE-HBT and PE-IP groups using a multivariable logistic regression approach (as described above). All analyses for the naturalistic follow-up period will be considered exploratory.

Process outcome variables include CPOSS total score, treatment credibility, Service Delivery Perceptions, treatment adherence (percent of returned, completed homework assignment forms; project therapist's subjective ratings of the completeness of and adherence to homework assignments (inclusive of reading assignments) for each session), session attendance/attrition (percent of missed sessions, and dropout status). The process outcomes will be analyzed using the unadjusted and adjusted (via GLM and MEM modeling for continuous outcomes, and logistic regression for dichotomous outcomes) noninferiority approaches as described above for clinical outcomes. In further exploratory analyses, we will repeat the multivariable methods to explore predictors of treatment satisfaction and treatment attrition.

Analyses to evaluate the cost-effectiveness of PE-HBT versus PE-IP will consist of both descriptive statistics and net benefit regression analysis. First, simple tabulations of treatment effect and cost-effectiveness data will be provided. For the proposed intervention and the comparator, means and standard deviations of effect size in symptom-reduced days will be provided as well as means and standard deviations of total costs and severity (measured by CAPS). We will then use regression analysis to estimate the effect of the proposed intervention (relative to the comparator) on extra effect and extra cost via ordinary least squares regression analysis estimation, and then estimate a model of net benefit. Cost-effectiveness (based on symptom reduced days and reduced severity) and cost-benefit ratios will be calculated varying values for training costs, discount rates and willingness to pay, to provide a range for VA managers and policy makers to examine when making decisions about recommendations regarding the proposed telehealth intervention.

To evaluate whether the effect of mode of treatment delivery (PE-HBT vs. PE-IP) on clinical and process outcomes

differs by race and sex, non-inferiority analyses (90% one-sided CI) will be repeated within race and sex strata to describe African-American versus Caucasian and male versus female participants' outcomes at immediate post-treatment and 6-month follow-up time points. GLM (for single end of study outcomes) and MEM (for longitudinal data), and logistic regression analyses (for the dichotomous outcomes, e.g., responder/nonresponder), as described above, will be used to evaluate whether the relations between intervention and outcomes (clinical and process) are different for African Americans and Caucasians or for males and females through inclusion of race/sex by treatment interaction terms in the multivariable models. Because sample sizes within strata are small, particularly for sex, these are exploratory analyses.

4. Discussion

To the extent that findings from the current study indicate that HBT service delivery is effective, safe, and feasible, HBT may enhance access to care for veterans who would otherwise go underserved. For some veterans with PTSD (e.g., those who lack consistent transportation, those who live in rural or physician shortage areas, those with impaired physical mobility due to ambulatory or physical health conditions, etc.), HBT may offer the only viable avenue to evidence-based care. For others, HBT may offer the flexibility and convenience necessary to maintain consistent attendance to therapy appointments (i.e., by eliminating travel time to and from the medical facility and thereby reducing the total amount of time needed to take off from work or childcare responsibilities due to travel). Despite these possible advantages, specific considerations should be made prior to implementing HBT in a particular facility. These include considerations of safety, informed consent and technology access, billing, practice privileges and licensure, and data protection and HIPAA compliance.

4.1. Special safety considerations for HBT condition

Providers are often concerned about whether a treatment that involves prolonged and repeated exposure to upsetting memories can be safely delivered to patients at heightened risk of suicide via HBT. However, a recent case report suggested that when managing suicidal patients remotely, many of the same principles of in-office management of at-risk patients apply (e.g., consult with professional colleagues, act consistently with facility-level guidelines for management of at-risk patients). Further, for severely depressed, suicidal patients, HBT may confer some advantages over in-person. For example, suicidal patients may lack motivation to travel to their mental health treatment center for their appointment. However, with HBT, the effort required to connect to the therapist who is standing by for their session is dramatically reduced, and thus at-risk patients may be more likely to attend session. Additionally, HBT therapists may have access to the patient's loved ones/family members who may be home at the time of the crisis. These individuals can help ensure the patient's safety.

4.2. Informed consent and technology access

While seemingly obvious that a patient is consenting to the process of telehealth by virtue of the steps one must take to engage in such treatment, consent also must entail the consideration of alternative approaches to receiving psychological care. Specifically, whenever possible, in-person treatment should be offered as an alternative to patients receiving telehealth, at least in the near future until this format is generally accepted, and more importantly, reliably demonstrated as equally effective with respect to treatment outcomes.

With respect to technology access, there appear to be a myriad of options, and in this case, more is better. At a most basic level, the provider will need a basic internet connection and webcam with microphone. The patient will require an internet connection, either DSL, Cable, or cellular broadband. In addition, a video monitor and audio device is necessary. These can range from a standard desktop or laptop, to a tablet with front facing camera, to a smart phone. The range of options is growing daily, and the important point to be considered is that the patient very likely has the required equipment in their possession, or can acquire it for relatively less expense than long distance travel and extended time off from work that in-person treatment would require.

4.3. Billing, practice privileges and licensure, and HIPAA requirements

Most coding standards and reimbursement rates are based on resource utilization. When telehealth is used according to the 'hub and spoke' model, where providers sitting in a central facility export services via telehealth to satellite facilities, two offices, an extremely large bandwidth channel, and remote office staff are required. Hence, hub and spoke services generally are billed at higher rates relative to standard in-person services. By contrast, HBT involves one therapist, one office, and one standard internet bandwidth channel. As such, billing is routinely the same as in-person services because the resources required are the same.

More controversial is the topic of licensure and privilege. The federal government has published national standards outlining many of these parameters, but these are being refined and are guidelines at this point. Typically, the medical records must reside where the patient is receiving services, whereas the privileging process and maintenance is based on the standards of the site from which the provider practices. Licensure currently does not restrict interstate practice of psychology and psychiatry; however, in the absence of interstate agreements, cross state telehealth is prohibited in many states. The exception to this rule is when the provider and patient are both in federal facilities, such as the VA or DoD facilities. However, while this exception clearly includes the hub and spoke (main facility to satellite facility) model of telehealth, it leaves unaddressed the issue of HBT, where treatment originates from a central federal facility (e.g., VAMC), but is received across state lines in the patient's home. It is very likely that legislative action is needed wherein telehealth services originating from federal facilities are protected across state (and across national) lines if they are

being delivered to US citizens, legal residents, or active duty personnel.

4.4. Data protection and HIPAA compliance

There are two general approaches to maintaining patient confidentiality over video-conferencing: third party server recording of all transmitted data versus real time transfer, without recording, of patient data. Vendors of telehealth devices typically bundle the device and the server storage, and assure HIPAA compliance and data integrity. By contrast, providers may not want to engage the services of a third party provider, and may not want session audio and video data to be recorded. In this case, confidentiality, data security, and HIPAA compliance are maintained by high level encryption software, such as that specifically engineered for HBT by “AK Summit” software and others. Using these products, patients are given an encryption program and key that allows them to communicate with their provider who runs a similar program and key. Any intercepted data are encrypted and hence not interpretable.

For the current study, patients randomized to PE-HBT will receive 12, 90-minute sessions of PE delivered via standard desk or laptop computer running AKT4002 software. This software allows users to teleconference with their providers in real time, using federal government tested and approved encryption. Importantly, this software meets federal government standards for encryption, is already Federal Information Processing Standard (FIPS) 140-2 certified (18 months federal government testing) and can be installed on Federal government and VA computers immediately.

5. Conclusions

Overall, the issues and problems confronting telehealth in general and HBT in particular are relatively easily resolved, as demonstrated by recent research in the area [13,14,33]. Several issues do remain, not the least of which is interstate and international licensing standards. These may require new legislation to resolve, which is not unprecedented in health care emerging technologies. Ultimately, this technology will most certainly become widespread because patients appear to like it, want it, and more importantly, need it. We recommend that researchers considering HBT should engage in the following steps: 1) identify an IT representative; 2) identify the technology requirements of the facility; 3) ensure that the system requirements of the selected device are compatible with technology at your facility; 4) ensure that your device and HBT procedures are HIPAA compliant; 5) ensure that all providers are credentialed to provide telehealth services, including completion of the telehealth curriculum offered via the VA Employee Education System (Telehealth Foundations, Telehealth Clinical Applications, and Concepts of Health Informatics); 6) develop a safety plan for providers should a patient become suicidal over HBT.

The lack of research testing HBT delivery of evidence-based psychotherapy against in-person delivery using RCT methodology limits dissemination of HBT and therefore precludes wider acceptance among community providers. The current study is an RCT that will directly compare HBT and in-person PE for PTSD to examine effectiveness, acceptability,

and financial costs. As the practice of HBT becomes more common and widely accepted, patients will experience improved access to evidence-based services.

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