

Randomized Controlled Trial of Home-Based Telehealth Versus In-Person Prolonged Exposure for Combat-Related PTSD in Veterans: Preliminary Results

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Objectives: Telehealth technology may reduce the effect of treatment barriers and improve participation in treatment for veterans with posttraumatic stress disorder (PTSD). The present study is an ongoing randomized controlled trial comparing the effectiveness of prolonged exposure (PE) delivered via in person or home-based video telehealth modalities. **Method:** A total of 52 veterans with combat-related PTSD were randomized to receive 8–12 weeks of PE through either home-based telehealth or standard in-person office-based care. **Results:** Participants evinced significant reductions in symptoms of PTSD, depression, and anxiety from pre- to posttreatment across both conditions. Analyses conducted within a noninferiority framework suggested nonsignificant treatment outcome differences in clinician-reported PTSD and self-reported anxiety between the conditions. Results were inconclusive for self-reported PTSD and depression symptoms. Patient satisfaction ratings did not significantly differ between the two groups. **Conclusions:** Results suggest that PE can be delivered via home-based telehealth with outcomes and satisfaction ratings comparable to in-person practices for certain symptoms, however additional research is needed. This modality has the potential to address stigma- and geographic-related barriers to treatment, such as travel time and cost. © 2015 Wiley Periodicals, Inc. *J. Clin. Psychol.* 71:500–512, 2015.

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Symptoms of posttraumatic stress disorder (PTSD) appear to affect more than 20% of veterans of the current Iraq and Afghanistan conflicts (Hoge, Auchterlonie, & Milliken, 2006; Hoge et al., 2004; Milliken, Auchterlonie, & Hoge, 2007). The symptoms of PTSD include the experience of a traumatic event that is followed by episodes of reexperiencing, avoidance, numbing, and arousal. Fortunately, several evidence-based psychotherapies effectively treat PTSD in veterans and military personnel, including prolonged exposure therapy for PTSD (PE) and cognitive processing therapy for PTSD in Veterans and military personnel (Foa, Hembree, & Rothbaum, 2007; Gros, Tuerk, Yoder, & Acierno, 2011; Resick, Monson, & Gutner, 2007). These psychotherapeutic

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interventions are designed to be administered by highly trained providers for 8–16 weekly sessions, guided by a treatment protocol that includes specific session-by-session psychoeducation, skills training, and between-session rehearsal. The primary techniques of these treatments involve exposure therapy, including both situational and imaginal exposures, and cognitive processing restructuring (Gros, Tuerk, et al., 2011).

Despite their effectiveness, available research suggests that veterans with PTSD underuse evidence-based psychotherapeutic services. For example, fewer than 10% of veterans with new PTSD diagnoses attend the minimum number of therapy sessions within a timeframe suggested for evidence-based PTSD treatment (typically at least 8 sessions over less than 15 weeks; Cully et al., 2008). In addition, rates of discontinuation among veterans that initiate evidence-based psychotherapy are high (38%–68%; Garcia, Kelley, Rentz, & Lee, 2011; Gros, Price, Yuen, & Acierno, 2013; Gros, Yoder, Tuerk, Lozano, & Acierno, 2011). These numbers may be due in part to significant barriers to care that may reduce the likelihood that veterans will engage in and/or complete evidence-based psychotherapy (e.g., transportation costs, fear of stigmatization for receiving psychiatric services, and living in rural or provider shortage areas that lack specialty mental health services; Gros, Strachan, et al., 2011; Hoge et al., 2004). Together, these findings suggest that alternative practices should be investigated to address these barriers to treatment and improve participation in, and completion of, evidence-based psychotherapy.

One strategy to mitigate barriers to effectively completing psychotherapy is to incorporate telehealth technologies into treatment delivery (Gros, Morland, et al., 2013; Richardson, Frueh, Grubaugh, Egede, & Elhai, 2009; Yuen, Goetter, Herbert, & Forman, 2012). In general, telehealth involves the use of telecommunications technology (e.g., videoconferencing, telephone, mobile applications, Internet-based applications, store and forward imaging) to provide long-distance clinical services. In particular, videoconferencing technology can be used to provide long-distance, face-to-face communication between patients and providers in real-time. Telehealth services have numerous advantages over in-person practices, including decreased cost (e.g., transportation costs, travel time, missed work) and increased system area coverage (e.g., a given provider can provide services to individuals within a larger geographic area; Dunn, Choi, Almagro, Recla, & Davis, 2000; Trott & Blignault, 1998).

Initial findings generally support telehealth to deliver even complex evidence-based psychotherapies across a wide range of disorders and associated treatment practices, including evidence-based psychotherapy for anxiety disorders (Bouchard et al., 2004; Yuen et al., 2013), mood disorders (Griffiths, Blignault, & Yellowlees, 2006), eating disorders (Mitchell et al., 2008), smoking cessation (Carlson et al., 2012), PTSD (Gros, Yoder, et al., 2011), and acute suicidality (Gros, Veronee, Strachan, Ruggiero, & Acierno, 2011). Although generally supportive, initial telehealth findings for PTSD, in particular exposure-based psychotherapy for PTSD, have been mixed (Gros, Morland, et al., 2013).

To date, more telehealth research has been completed on traumatic stress disorders than any other disorder (Backhaus et al., 2012), due in large part to efforts by the Department of Veteran Affairs (VA) and Department of Defense. Studies have focused on the delivery of individual exposure-based treatment (Germain, Machand, Bouchard, Drouin, & Guay, 2009; Gros, Yoder, et al., 2011; Strachan, Gros, Ruggiero, Lejuez, & Acierno, 2012; Tuerk, Yoder, Ruggiero, Gros, & Acierno, 2010), group cognitive processing therapy (Morland, Hynes, Mackintosh, Resick, & Chard, 2011), and group cognitive behavior therapy (CBT) for anger management (Morland et al., 2010) to participants with PTSD via telehealth.

The aforementioned studies are studies with either (a) nonrandomized group assignment into either telehealth to a remote site or in person at the local clinic (Germain et al., 2009; Gros, Yoder, et al., 2011; Tuerk et al., 2010) or (b) randomized group assignment into either telehealth or in-person condition within the same facilities (Morland et al., 2011; Strachan, Gros, Ruggiero, et al., 2012). Although each of these studies demonstrated pre- to posttreatment symptom reductions in the telehealth conditions, three of the four studies involving exposure-based therapy for PTSD also demonstrated trends toward larger effect sizes in the in-person treatment conditions (Germain et al., 2009; Gros, Yoder, et al., 2011; Tuerk et al., 2010). Although these three studies lacked randomization into treatment conditions, they are in contrast to nonexposure-based

treatment findings that demonstrated similar outcomes across treatment conditions (Morland et al., 2010, 2011).

Therefore, these findings raise the possibility that there may be specific treatment techniques that are unique to exposure therapy for PTSD that are less effective when offered via telehealth compared to in person (e.g., imaginal exposures; Gros, Morland, et al., 2013). For example, imaginal exposures in PTSD treatments are typically challenging for patients, induce high levels of distress initially, and may benefit from a strong therapeutic alliance. In addition, when patients are resistant to situational exposure exercises, it is oftentimes beneficial for therapists to initially accompany the patient in person when completing those exposures (Tuerk et al., 2010). Another potential explanation is that treatment modality preference (in person vs. telehealth) of patients receiving exposure-based treatment for PTSD may influence outcomes. Additional research on exposure-based PTSD treatments incorporating random assignment to treatment modality is needed.

The present article presents preliminary results of one such randomized controlled trial comparing the effectiveness of PE delivered via in person or home-based telehealth modalities. Several potential methodological limitations were addressed to improve upon previous studies (Germain et al., 2009; Gros, Yoder, et al., 2011; Strachan, Gros, Ruggiero, et al., 2012; Tuerk et al., 2010). First, in contrast to previous studies assigning participants to their closest facility and then offering telehealth to that facility, all participants were randomized into treatment conditions. Second, in contrast to providing telehealth at a facility, home-based telehealth technology was used to further reduce the potential barriers to care in the telehealth condition. Third, in contrast to some of the previous effectiveness studies with unstandardized treatments (Gros, Price, Strachan, Yuen, Milanak, & Acierno, 2012; Strachan, Gros, Ruggiero, et al., 2012), a standardized protocol of exposure-based psychotherapy, PE (Foa et al., 2007), was used in the present study.

Fourth, in contrast to previous studies that focused on superiority analyses, the present study involved a noninferiority design that may be particularly well suited for telehealth research (Gros, Morland, et al., 2013). Noninferiority designs are appropriate for clinical trials investigating whether a novel treatment does not produce inferior results compared to another treatment. A noninferiority design was chosen because (a) the same PE protocol was used for both conditions, and (b) we are interested in whether exposure-based PTSD treatment delivered through home-based telehealth is just as effective as when delivered in person.

Based on the previous telehealth research and methodological changes in the present study (i.e., randomization, home-based telehealth, standardized PE, noninferiority design), we hypothesized that roughly equivalent pre- to posttreatment clinical outcomes (e.g., PTSD, depression, anxiety) would be found in the telehealth and in-person treatment conditions. We also hypothesized that the telehealth treatment would be well-tolerated by participants, as demonstrated by ratings of treatment satisfaction in the telehealth and in-person conditions.

Method

Participants

A total of 52 veteran participants completed treatment at the time of the analysis (see Table 1 for demographics). Participants had a mean age of 43.98 (standard deviation [*SD*] = 15.18), ranging from 20 to 75 years of age. The majority of participants were male (98.1%) and mostly White (53.8%) or Black (36.5%), with 9.6% identifying as Hispanic. Theatres included Operations Iraqi Freedom, Enduring Freedom, and New Dawn (57.7%), Vietnam (30.8%), and Persian Gulf (11.5%). Most participants reported seeing a mental health specialist within the past year (88%), although not necessarily for PTSD treatment or psychotherapy, with an average of 5.92 (*SD* = 6.70) visits. Of the participants, 42% had a comorbid diagnosis of major depression and 15% had a comorbid diagnosis of panic disorder, with only one participant in the in-person condition also having agoraphobia. Most participants reported having a computer in their home (90%) and feeling moderately to extremely comfortable with using it (86%). Participants were block

Table 1
Demographics and Baseline Characteristics by Treatment Condition

| | PE via in-person <i>n</i> = 29 % | PE via home-based telehealth <i>n</i> = 23 % |
|--|---|---|
| Female | 3.4% | 0% |
| Race/ethnicity | | |
| Black/African American | 34.5% | 39.1% |
| Hispanic | 6.9% | 13.0% |
| Caucasian | 58.6% | 47.8% |
| Theater | | |
| OEF/OIF/OND | 44.8% | 73.9% |
| Persian Gulf | 20.7% | 0% |
| Vietnam | 34.5% | 26.1% |
| Comorbidity | | |
| Major depressive disorder | 44.8% | 39.1% |
| Panic disorder | 13.8% | 17.4% |
| Visited mental health specialist within past 12 months | 83.3% | 94.4% |
| Computer usage | | |
| Computer in home | 87% | 94.4% |
| Moderately to extremely comfortable | 89.6% | 82.4% |
| | <i>M</i> | <i>M</i> |
| Age | 46.3 (<i>SD</i> = 14.9) | 41.2 (<i>SD</i> = 15.4) |
| Baseline PCL | 61.2 (<i>SD</i> = 10.9) | 62.2 (<i>SD</i> = 13.8) |
| Baseline BDI | 29.6 (<i>SD</i> = 9.9) | 26.9 (<i>SD</i> = 11.8) |
| Baseline BAI | 27.7 (<i>SD</i> = 11.9) | 21.7 (<i>SD</i> = 13.5) |
| No. visits with mental health specialist within past 12 months | 6.05 (<i>SD</i> = 6.2) | 5.75 (<i>SD</i> = 7.4) |

Note. PE = prolonged exposure; M = mean; SD = standard deviation; PCL = Posttraumatic Stress Disorder Checklist; BDI = Beck Depression Inventory; BAI = Beck Anxiety Inventory; OEF/OIF = Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn.

randomized on race (blocks were Black/African American and other) to either the in-person (55.8%; *n* = 29) or telehealth condition (44.2%; *n* = 23).

Participants were recruited primarily through referrals from physicians and other medical staff at a large Southeastern VA medical center (VAMC) and its affiliated community-based outpatient clinics. Recruitment efforts also included screenings of primary care patients, as well as letters of invitation mailed to VA patients who screened positive for PTSD within the past year but had not received PTSD treatment. The opportunity to participate in the treatment study was also advertised via flyers, billboards, health fairs, online advertisements, and media announcements.

Master's-level clinicians delivered in-person intakes and assessments to determine eligibility. Veterans and military personnel meeting the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR; American Psychiatric Association, 2000) criteria for PTSD per the Clinical Administered PTSD Scale (CAPS; Blake et al., 1995) were eligible. Veterans from all theatres were included.

Exclusion criteria included active alcohol or substance dependence within the past 6 months, an active psychotic disorder, and severe suicidal ideation with plan and intent. Alcohol dependence was assessed using the Alcohol Use Disorders Identification Test (AUDIT; Babor, Higgins-Biddle, Saunders, & Monteiro, 2001; score of 21 or higher) and substance dependence was assessed using the Drug Abuse Screening Test (DAST-10; Skinner, 1982). In addition, patients with an active substance dependence diagnosis in their VA medical records or current participation in the VAMC Substance Abuse Treatment Center were excluded. Veterans with an active diagnosis of a psychotic disorder (e.g., schizophrenia) in their VA medical records were excluded, although psychotic symptoms related to their PTSD (e.g. hallucinations during flashbacks) did not preclude participation in this study.

Suicidal ideation was assessed using question number 9 (suicidal thoughts or wishes) on the Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996) and by directly asking the veteran about intent to harm him/herself. To maximize the generalizability of results, the presence of other forms of psychopathology were not a basis for exclusion (e.g., major depressive disorder, anxiety disorders, and substance abuse that did not meet dependence criteria). Participants receiving psychiatric medication were also not excluded, but they were required to be stable on their medication for at least 3 weeks before starting treatment. A longer period of medication stabilization was not enforced to provide veterans with PTSD treatment in a timely manner without a long wait period.

Of 86 potential participants who were screened for the study, 4 did not meet inclusion/exclusion criteria, 8 decided not to participate, and 74 began treatment. The overall dropout rate was 29.7%, with a mean of 3.50 ($SD = 1.93$) sessions completed for those terminating early. There were no significant differences in the rates of dropout between the in-person condition (23.7%) and the telehealth condition (36.1%), $X^2(1) = 3.15, p = 0.21$.

Measures

Participants who consented to the study completed a baseline intake assessment, which included the CAPS (Blake et al., 1995) to determine PTSD diagnosis, the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID; First, Spitzer, Gibbon, & Williams, 1996) modules for major depressive disorder and panic disorder, the AUDIT (Babor et al., 2001), and DAST-10 (Skinner, 1982). Participants also completed the PTSD Checklist-Military (PCL; Weathers, Litz, Herman, Huska, & Keane, 1993), BDI-II (Beck et al., 1996), and Beck Anxiety Inventory (BAI; Beck & Steer, 1990) on a weekly basis, both at baseline and at posttreatment.

In addition, participants completed the Service Delivery Perceptions Questionnaire (Frueh et al., 2007) at posttreatment, which assessed the level of satisfaction with their modality of treatment received (videoconferencing or in person). The Service Delivery Perceptions Questionnaire is an eight-item measure with response options on a 5-point Likert scale. Items cover comfort level of talking to the therapist, quality of the communication, likeliness of using the treatment modality again, likeliness of referring the treatment to a family member or friend, and overall satisfaction level with services received.

Procedures

The local VAMC Research and Development committee as well as the institutional review board at the affiliated university approved all procedures. Participants meeting eligibility requirements were block randomized to either the home-based telehealth or the in-person condition. After intake, participants in both conditions received a binder of PE and assessment materials (e.g., exposure recording forms, PCL, BDI, BAI) to complete throughout their treatment period.

Participants in the home-based telehealth condition had several videoconferencing service options. Eight participants who had access to their own computer or tablet and high-speed Internet connection used encrypted videoconferencing software (e.g., AK Summit) on their home computer or tablet. A total of 12 participants who did not have their own computer and high-speed Internet connection were given a tablet for the duration of the study, which allowed them to use Jabber, Facetime, or Skype on a 3G or 4G wireless network. Two participants were given an analog videophone with a built-in camera and video screen that operated through an analogue telephone line.

Participants in the home-based telehealth condition received assistance from research staff in setting up their software and hardware before their first treatment session. A test call was conducted to teach participants how to use the videoconferencing program and to ensure adequate connectivity. During this time, participants were given basic guidelines for their videoconferencing sessions: select a room with minimal distractions from other people and pets and where others won't overhear them; be alone in the room; wear proper clothing; turn off cell phones or put them on vibrate; refrain from using the computer for other activities (e.g., checking e-mail); and refrain from anxiety-coping behaviors during the session, such as smoking cigarettes or chewing tobacco.

All participants received eight to twelve 90-minute sessions of PE administered by three master's-level therapists, all with experience in conducting exposure-based therapy for PTSD in prior clinical trials. Therapists received weekly supervision from a licensed clinical psychologist who was a certified PE trainer. Each therapist was randomly assigned to provide treatment to participants in both conditions. The main components of PE are available from Foa et al. (2007) and included psychoeducation, situational (in vivo) exposure, and imaginal exposures that involved recounting aloud the most upsetting traumatic memory, followed by processing of the imaginal recounting experience. Participants in the home-based telehealth condition sent their homework forms to their therapist via preaddressed stamped envelopes that were provided when they received their initial PE binder after the intake. After completing the treatment, participants were administered a 1-week posttreatment assessment that comprised a structured clinical interview (CAPS, SCID) and a battery of self-reports (PCL, BDI, BAI). Clinical assessors were blind to participant condition.

The specific number of sessions for each participant was determined on a case-by-case basis, taking the participant's progress into account. Participants were initially told that the therapy comprised 8–12 sessions and that most veterans choose to have about 10 sessions but can go up to 12 if needed. In later sessions, the therapist and participant discussed the participant's Subjective Units of Discomfort Scale scores for exposure exercises as well as their scores on the BDI-II and PCL to mutually agree on how many more sessions were necessary. The mean number of sessions completed was 10.25 ($SD = 1.22$), with 25% of participants receiving the maximum of 12 sessions.

Data Analytic Plan

The present study assessed changes in CAPS, PCL, BAI, and BDI scores from pre- to post-treatment within each treatment modality. First, reductions in outcome variables (CAPS, PCL, BDI, BAI) within each condition (home-based telehealth, in person) were evaluated with paired sample *t*-tests on all participants who completed treatment. Missing data were observed on the outcome measures in the following proportions: CAPS pretreatment: 1.9% ($n = 1$); CAPS posttreatment: 9.6% ($n = 5$); PCL pretreatment: 9.6% ($n = 5$); PCL posttreatment: 17.3% ($n = 9$); BDI pretreatment: 9.6% ($n = 5$); BDI posttreatment: 19.2% ($n = 10$); BAI pretreatment: 11.5% ($n = 7$), BAI posttreatment: 17.3% ($n = 9$). These proportions are consistent with those observed on other clinical trials of combat veterans (Rothbaum et al., 2014).

Cases with missing data did not differ from those with complete data on any of the outcome variables or demographic factors ($ps = 0.12$ – 0.49). There were no significant differences in cases with missing data at posttreatment across the treatment conditions, $p = 0.76$ – 0.99 . Missing data were handled with multiple imputation (MI). MI was used for the repeated measures analyses based on 25 imputed datasets. MIs were informed by all available psychopathology measures at all time points, PTSD diagnostic status at posttreatment, and military theater. Prevalence of PTSD at posttreatment and patient satisfaction scores were compared using chi-squares.

Comparisons between telehealth and in-person conditions at posttreatment were evaluated within a noninferiority framework using the per protocol and intent to treat (ITT) sample (Piaggio et al., 2006). A margin of noninferiority was selected (Δ) to determine the maximum difference in outcomes that would be considered not clinically different. Effect sizes (Hedge's g) were computed for the difference between posttreatment measures between the two conditions such that negative values favored in-person treatment and positive values favored telehealth. Confidence intervals (90% CI) were calculated for each effect size.

Noninferiority was supported if the lower limit of the effect size was greater than Δ . Inconclusive results occurred if the lower limit of the effect size exceeded Δ , but the obtained effect size was less than Δ . Inferiority was supported if the upper limit of the effect size was less than Δ . A recent meta-analysis was used to set the margin of noninferiority at $\Delta = -0.42$ (Powers, Halpern, Ferenschak, Gillihan, & Foa, 2010). This value corresponded to the lower limit of the 95% CI examining the difference between PE and other active treatments across 262 participants with PTSD, which suggests that -0.42 is a reasonable maximum for the difference between active exposure-based interventions.

Table 2
Descriptive Statistics and Effect Sizes for Repeated Measures Comparisons of Pretreatment to Posttreatment

| | Pretreatment | | Posttreatment | | Hedges's <i>g</i> |
|-----------------------|--------------|-----------|---------------|-----------|-------------------|
| | <i>M</i> | <i>SD</i> | <i>M</i> | <i>SD</i> | |
| In person | | | | | |
| CAPS | 68.42 | 14.73 | 38.33 | 22.25 | 1.51 |
| PCL | 61.17 | 10.93 | 42.59 | 18.32 | 1.33 |
| BDI | 29.56 | 9.95 | 16.43 | 12.97 | 1.00 |
| BAI | 27.68 | 11.91 | 16.13 | 14.62 | 1.08 |
| Home-based Telehealth | | | | | |
| CAPS | 65.27 | 11.69 | 35.91 | 17.66 | 1.90 |
| PCL | 62.20 | 13.75 | 43.41 | 18.43 | 1.07 |
| BDI | 26.94 | 11.79 | 19.38 | 15.87 | 0.52 |
| BAI | 21.75 | 13.54 | 13.12 | 14.46 | 0.40 |

Note. *M* = mean; *SD* = standard deviation; CAPS = Clinical Administered PTSD Scale; PCL = Post-traumatic Stress Disorder Checklist; BDI = Beck Depression Inventory; BAI = Beck Anxiety Inventory. *n* = 52. Effect sizes, Hedges's *g*, are repeated measures effects obtained from the comparison of pretreatment to posttreatment scores.

Results

Treatment Outcome

Descriptive statistics for the treatment conditions are presented in Table 2. Posttreatment diagnoses of PTSD were similar for both conditions. For the in-person condition at posttreatment, 40% no longer had a diagnosis of PTSD, 30% had subclinical PTSD symptoms, and 30% continued to meet criteria for PTSD. For the home-based telehealth condition at posttreatment, 46% no longer had a diagnosis of PTSD, 27% had subclinical PTSD symptoms, and 27% continued to meet criteria for PTSD. There were no significant differences among the rates of diagnosis across the conditions, $X^2(2) = 0.62, p = 0.73$.

The groups did not differ at pretreatment on the CAPS, $t(49) = 0.85, p = 0.40$; PCL, $t(51) = -0.32, p = 0.75$; BDI, $t(51) = 0.92, p = 0.36$; and BAI, $t(51) = 1.75, p = 0.08$. Within condition effects of PE were examined with repeated measures *t*-tests. For the in-person condition, CAPS scores, $t(24) = 7.35, p < 0.01$, Hedges's *g* = 1.51; PCL scores, $t(24) = 6.56, p < 0.01$ Hedges's *g* = 1.33; BDI scores, $t(24) = 6.90, p < 0.01$, Hedges's *g* = 1.00; and BAI scores, $t(24) = 4.54, p < 0.01$, Hedges's *g* = 1.08, significantly decreased from pre- to posttreatment with large effect sizes. For the home-based telehealth condition, similar results were observed. CAPS scores, $t(21) = 9.17, p < 0.01$, Hedges's *g* = 1.90; PCL scores, $t(51) = 5.54, p < 0.01$, Hedges's *g* = 1.07; BDI scores, $t(51) = 2.64, p < 0.01$, Hedges's *g* = 0.52; and BAI scores, $t(51) = 3.22, p < 0.01$, Hedges's *g* = 0.40, significantly decreased from pre- to posttreatment with large effect sizes. Taken together, these findings suggest that symptoms (of PTSD, depression, and anxiety) decreased across both treatment conditions.

Effect sizes and 90% CIs were calculated for the difference between the conditions at posttreatment (Figure 1). In calculating the effect size, the mean of the in-person group was subtracted from the mean of the telehealth condition, such that a positive effect size favored the in-person condition and a negative effect favored the home-based telehealth condition. For the CAPS, the ITT effect size ($g = 0.13$; 90% CI [0.32, 0.59]) and per protocol effect size ($g = 0.12$; 90% CI [-0.36, 0.60]) supported noninferiority. For the PCL, the ITT effect size ($g = -0.15$; 90% CI [-0.66, 0.35]) and per protocol effect size ($g = -0.14$; 90% CI [-0.60, 0.32]) were inconclusive. For the BDI, the ITT effect size ($g = -0.19$; 90% CI [-0.64, 0.27]) and per protocol effect size ($g = -0.17$; 90% CI [-0.68, 0.34]) were inconclusive. For the BAI, the ITT effect size ($g = 0.10$; 90% CI [-0.36, 0.55]) and per protocol effect size ($g = 0.12$; 90% CI [-0.42, 0.59]) supported noninferiority.

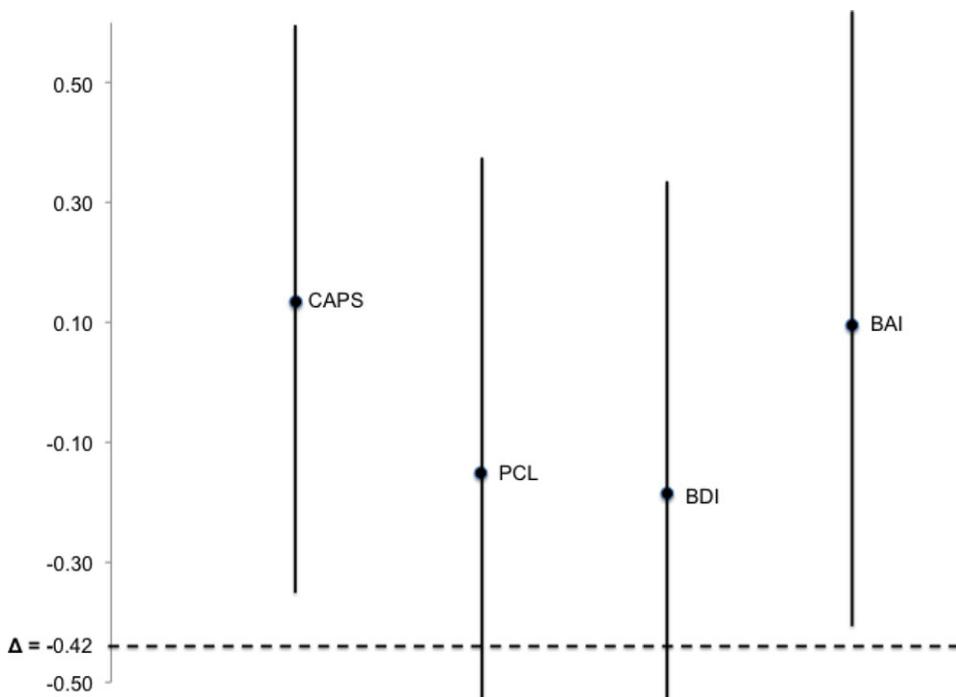


Figure 1. Effect sizes (Hedges's g) and 90% CI for comparison between in-person and home-based telehealth at posttreatment for the ITT sample.

Patient Satisfaction

Satisfaction ratings for participants who completed treatment were high across both conditions. Of the treatment completers, 73% filled out the Service Delivery Perceptions Questionnaire. Overall, participants reported they were satisfied or very satisfied with treatment (in person: 100%; home-based telehealth: 100%). Although none were statistically significant, differences were observed in the satisfaction ratings across the conditions. In the in-person condition, 90.5% reported feeling very comfortable or comfortable when communicating with the therapist, whereas 76.5% in the home-based telehealth condition reported this level of comfort, $\chi^2(3) = 3.98, p = 0.26$. The majority of participants (95.0%) in the in-person condition rated communication with the therapist as excellent or very good, whereas the proportion was 76.9% in the home-based telehealth condition, $\chi^2(3) = 2.77, p = 0.43$.

Last, 85.7% of the participants in the in-person condition reported that they were likely or very likely to use this type of treatment again, compared to 76.9% of the home-based telehealth condition. Of note in response to this question, 14.3% of participants in the in-person condition reported that they are unsure or unlikely to use in-person services again, compared to 23.1% of those in the home-based telehealth condition, $\chi^2(4) = 3.72, p = 0.45$.

Discussion

The present study compared relative symptom decline after PE was delivered in person and via home-based telehealth for veterans with combat-related PTSD. Symptoms of PTSD, depression, and anxiety declined in both treatment modalities. Noninferiority was supported for clinician-rated PTSD (CAPS) and anxiety (BAI), suggesting there were negligible differences between in-person and home-based telehealth conditions. Results were inconclusive for self-reported PTSD symptoms (PCL) and depression (BDI-II), given that their effect sizes were within the noninferiority margin but the lower limits of the confidence intervals exceeded the margin. In

addition, patient satisfaction levels between the two conditions were not significantly different. Together, although these findings are mixed, they provide tentative support for noninferiority for certain symptoms across the two treatment modalities. Completion of this study will provide sufficient power to confirm or disconfirm noninferiority between in-person and telehealth conditions across multiple symptoms.

Although various studies support the notion that psychotherapy delivered through telehealth is comparable to psychotherapy delivered in person for anxiety disorders and depression (for a review, see Gros, Morland, et al., 2013), prior research on the effectiveness of exposure-based treatment for PTSD has been mixed (Germain et al., 2009; Gros, Yoder, et al., 2011; Tuerk et al., 2010; Gros, Yoder, et al., 2011). Based on these findings, it has been hypothesized that exposure therapy, and imaginal exposures in particular, may be less effective when delivered through telehealth compared to in-person delivery (Gros, Morland, et al., 2013). However, in contrast to these predictions, the results of the present study supported noninferiority results for clinician-rated PTSD and self-reported anxiety symptoms. The results for self-reported PTSD and depression symptoms are inconclusive, with either noninferiority or inferiority possible.

Because of several methodological limitations in the previous studies, it is difficult to draw conclusions about the differences between the effectiveness of telehealth versus in-person exposure-based psychotherapy for PTSD. First, the three previously mentioned studies that found greater effect sizes for the telehealth condition (Germain et al., 2009; Gros, Yoder, et al., 2011; Tuerk et al., 2010) used a nonrandomized design, whereby participants who received telehealth were also more likely to live further away from the main clinic. Therefore, factors such as rural residency, income, social isolation, and availability of community resources may have affected treatment outcomes (Gros, Yoder, et al., 2011).

Second, these three studies also used a flexible treatment protocol, whereby the dosage of specific psychotherapy components varied from participant to participant, as did the number of total sessions. For example, in the study by Tuerk and colleagues (2010), the number of sessions was allowed to vary without limits, with sessions ranging from 1 to 21 sessions. Given the limited resources likely available for telehealth technologies, which were nascent and undeveloped at the time these studies were written, the telehealth condition may have received a smaller dose or fewer sessions of psychotherapy as a result.

Third, two of the studies were based on small sample sizes (n of telehealth conditions < 17), suggesting possible influence of outliers and/or non-normality of the distribution of treatment completers. Although a small sample size is also a limitation of the present study ($n = 52$), it is larger than the aforementioned studies, with data collection ongoing. In all three cases, these limitations were specifically targeted and addressed in the present study, suggesting potentially greater confidence in present findings.

This study is one of the first to provide support for home-based telehealth for exposure-based psychotherapy to veterans with PTSD. If home-based telehealth is just as effective as in-person psychotherapy for veterans receiving exposure-based treatment for PTSD, then veterans or other trauma-affected individuals will be able to access treatment while being physically located somewhere other than the therapy office, such as in their own home. This should greatly increase accessibility to exposure-based psychotherapy for PTSD and reduce barriers to treatment such as location, transportation limitations, and concerns about stigmatization.

Future studies should further explore how home-based telehealth technologies can be used to deliver efficacious treatments. Incorporating technology into clinical practice can potentially improve not only the access to treatments but also the quality of the treatments themselves (Price et al., 2013). For example, it is oftentimes beneficial to incorporate family members into treatment, but scheduling or other logistical conflicts may thwart these efforts. Inclusion of family members into treatment may be facilitated by the convenience of home-based telehealth.

Future research should also investigate the utility of mobile technology to conduct real-time treatment wherever and whenever needed. Patients could speak with their therapist through mobile technology when in anxiety-provoking situations or locations in which the therapist would not typically be present, such as the patient's home, at family events, or public places. Patients could engage in situational exposure exercises while being assisted by their therapist through videoconferencing on a mobile device, but without the potential stigma and/or safety

behavior of being accompanied by their provider (e.g., visiting a crowded restaurant). This may be particularly beneficial when patients tackle highly challenging exposures at the top of their fear hierarchy; completing the exposure with the assistance of their therapist via mobile technology may subsequently increase the patients' willingness and motivation to engage in the exposure on their own.

In addition, future research should examine whether effective PTSD services could be provided directly to warzones and disaster-affected areas (assuming life threat is no longer present) for military personnel and civilians who are physically and logistically unable to travel to a traditional office setting for psychotherapy. Privacy would be an important ethical issue to consider in these scenarios; in these settings, there may be a greater challenge for patients to secure a private location in which to speak with a clinician without the fear of being overheard by others.

As the breadth and quality of mobile technologies available to the general public rapidly advances, the mental healthcare field continues to demonstrate strong interest in using these technologies to improve treatment delivery. The present study's preliminary results are intended to inform current practices and provide insight into the potential of home-based telehealth to deliver evidence-based exposure therapy for PTSD as these services grow, rather than informing their existing practice after the full study is completed years later.

Limitations

Several limitations of the study should be acknowledged. First, all intake and posttreatment assessments were completed in person, regardless of treatment condition, suggesting that this requirement may have excluded some potential participants due to transportation limitations.

Second, Internet connection and technical problems were commonly experienced, particularly for participants who lived in rural areas with inconsistent Internet connection quality. The majority of the technical problems that were reported involved lost wireless signals or video or audio quality issues, such as a delay in picture or sound due to poor Internet connection. Therapists anecdotally noted that technical difficulties were most prevalent during the participants' first few sessions as technical problems were worked out. Participants, for example, learned how to properly adjust the volume so that it was at a comfortable level, how to toggle their webcam back on if they accidentally switched it off, how to restart their videoconferencing session if the connection was poor, as well as identifying which room(s) in their house provided the best wireless/cellular connection. If the audio quality remained poor, then the therapist and participant muted their webcams and spoke to each other through the telephone while still using the video feature. Although these technical problems may have temporarily added additional stress or adversely influenced the participant experience, no significant differences were found between conditions at posttreatment.

Third, the analyses were conducted with treatment completers, which could have biased outcomes. Finally, although the sample size was consistent with other noninferiority investigations (Norton & Barrera, 2012), noninferiority trials benefit from larger samples (Piaggio et al., 2006) and missing data were observed at posttreatment. The small sample size and the missing data may have influenced the results, especially for the effect sizes that fell within the noninferiority margin but had lower limits of the confidence intervals exceed the margin. Completion of this study is necessary with larger proportions of completers with complete data to determine if inferiority is supported.

Conclusion

As technology becomes more advanced, there will be increasing opportunities to leverage these methods to improve treatment delivery. Initial findings for delivering exposure-based psychotherapy via telehealth for PTSD have been mixed, suggesting the possibility that these exposure-based components (e.g., imaginal exposure) may be more effectively delivered in person. However, the present study improves upon potential methodological limitations apparent in previous studies (e.g., randomization, standardized protocol) and examines the less explored modality of home-based telehealth for PTSD treatment. These results tentatively suggest no significant differences

between home-based telehealth and in-person practices for certain symptoms, and thus support the expanding use of new technologies and the growth of telehealth as a way to improve access to and delivery of clinical treatments. Additional research is needed to evaluate the feasibility, efficacy, and clinical utility of this modality compared to traditional in-person treatment.

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