



## A non-inferiority trial of Prolonged Exposure for posttraumatic stress disorder: In person versus home-based telehealth



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### ARTICLE INFO

#### Article history:

Received 4 July 2016

Received in revised form

15 November 2016

Accepted 19 November 2016

Available online 22 November 2016

#### Keywords:

PTSD

Prolonged exposure

Telehealth

Non-inferiority

RCT

### ABSTRACT

This is the first randomized controlled trial to evaluate non-inferiority of Prolonged Exposure (PE) delivered via home-based telehealth (HBT) compared to standard in-person (IP) PE. One-hundred thirty two Veterans recruited from a Southeastern Veterans Affairs Medical Center and affiliated University who met criteria for posttraumatic stress disorder (PTSD) were randomized to receive PE via HBT or PE via IP. Results indicated that PE-HBT was non-inferior to PE-IP in terms of reducing PTSD scores at post-treatment, 3 and 6 month follow-up. However, non-inferiority hypotheses for depression were only supported at 6 month follow-up. HBT has great potential to reduce patient burden associated with receiving treatment in terms of travel time, travel cost, lost work, and stigma without sacrificing efficacy. These findings indicate that telehealth treatment delivered directly into patients' homes may dramatically increase the reach of this evidence-based therapy for PTSD without diminishing effectiveness.

Published by Elsevier Ltd.

### 1. A non-inferiority trial of Prolonged Exposure for post-traumatic stress disorder: in person versus home-based telehealth

Veterans are at high risk for repeated exposure to potentially traumatic events and subsequent risk of a broad range of mental health problems, including posttraumatic stress disorder (PTSD; Cohen et al., 2010; Fulton et al., 2015; Hoge et al., 2004; Hoge, Auchterlonie, & Milliken, 2006; Keane & Wolfe, 1990; Ramchand, Rudavsky, Grant, Tanielian, & Jaycox, 2015). Estimates of PTSD in veterans across eras range from 5 to 30% (Fulton et al., 2015; Hoge et al., 2004, 2006; Iversen et al., 2005; Kang, Natelson, Mahan, Lee, & Murphy, 2003; Kulka et al., 1990; Ramchand et al., 2010; Seal, Bertenthal, Miner, Sen, & Marmar, 2007). Fortunately, screening veterans for mental health problems is now routine (Wright, Huffman, Adler, & Castro, 2002), and those in need of help are

more likely than ever to be identified. Moreover, mental health improves, and service use and costs are decreased when evidence based treatments such as Prolonged Exposure (PE; Foa et al., 2005, 1999; Foa, Rothbaum, Riggs, & Murdock, 1991) are offered and completed (Tuerk et al., 2013). Nonetheless, even though over 40% of those screening positive indicate that they want care for PTSD symptoms, and despite existence of effective and cost-reducing treatments, only 25% of those screening positive actually receive these services (Hoge et al., 2006). Stigma and logistics-based barriers likely play a role in low treatment utilization (Hoge et al., 2004; Kim, Thomas, Wilk, Castro, & Hoge, 2010). Thus, effective evidence based treatments for combat-related PTSD such as PE must be delivered by methods that address relevant barriers to care for military personnel and Veterans in order to optimize opportunities for broad dissemination.

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### 1.1. Barriers to seeking treatment and a potential solution: home-based telehealth

Veterans experience stigma associated with psychiatric conditions (Iversen et al., 2005). Among both active duty and veteran personnel who have experienced military culture, “succumbing” to PTSD may be perceived as a failure, a weakness, or as evidence of an innate deficiency of strength or leadership capability (Friedman, 2004). An attitude of “wanting to solve my own problems” has also been cited as a factor that prevents treatment seeking in earlier studies (Kulka et al., 1990). More obvious, logistical barriers to attending consecutive multiple weekly appointments also play a large role in preventing access to evidence-based PTSD care. Barriers range from difficulty accessing care due to parking issues in urban areas, travel time to and from appointments, and lost work time to difficulties in scheduling and location (Hoge et al., 2004). Such logistical problems are amplified for those commuting from rural areas (Beachler, Holloman, & Herman, 2003; Hogan, 2003).

Given these barriers, an alternative medium for service delivery is needed that addresses both stigma and logistical factors impeding access to care. “Hub and spoke” telehealth-delivered care was initially proposed as one such solution, with an expert or provider at centralized clinic delivering care to patients at satellite clinics. Indeed, such telehealth formats often come at a lower patient-side cost and with easier access for both patients and providers (Bose, McLaren, Riley, & Mohammedali, 2001; Elford et al., 2000; Morland et al., 2010) and are effective means of service delivery (Bolton & Dorstyn, 2015). Several Department of Veterans Affairs (VA) and Department of Defense studies demonstrate that hub and spoke telehealth can be implemented within the existing system infrastructure (Shore, Goranson, & Lu, 2014; Tuerk, Yoder, Ruggiero, Gros, & Acierno, 2010; Williams, Tuerk, & Acierno, 2015), is cost effective (Fortney, Maciejewski, Warren, & Burgess, 2005; Glueckauf, 2002; Jerome & Zaylor, 2000; Perednia & Allen, 1995), and is clinically effective (Morland, Hynes, Mackintosh, Resick, & Chard, 2011). However, as patients must travel to satellite clinics, stigma and logistic barriers are still present in hub and spoke telehealth models. By contrast, home-based telehealth (HBT)-delivered psychotherapy may address these barriers to a higher degree, and initial work by our group demonstrates encouraging results (Acierno et al., 2016; Egede et al., 2015).

### 1.2. The present study

As noted earlier, HBT delivery of PE for PTSD may be one way to address stigma and logistical barriers to care that confront veterans. However, few studies have evaluated comparability (non-inferiority, specifically) of traditional, office based treatments with telehealth-delivered treatments (Bolton & Dorstyn, 2015), particularly with complex diagnoses such as PTSD and rigorous psychotherapies such as PE. The distinction between psychotherapy delivered through standard telehealth, which almost always follows the hub and spoke model of care and psychotherapy delivered through HBT is an important one. HBT amplifies all advantages with respect to travel time, cost, and stigma, potentially obtained through standard telehealth, but lacks supportive infrastructure found in both traditional in-person care and satellite office-based telehealth care. Thus, the current study was designed to determine if HBT delivery of evidence based PE for PTSD, “is as good as” traditional in-person (IP) PE, in terms of standard measures of PTSD and major depression (MD), the latter of which was included as an outcome in keeping with existing treatment outcome research on PTSD (Foa et al., 1999; 2005).

## 2. Methods

### 2.1. Design

The current study used a between groups repeated measures randomized controlled design powered for non-inferiority conclusions. Participants were randomly assigned (1:1) to either HBT or office based IP delivery of the identical PE treatment (PE-HBT vs. PE-IP). Repeated assessments were conducted by blind interviewers at pre-treatment, post-treatment, 3-month follow-up, and 6-month follow-up. A non-inferiority approach was chosen for clinical outcome variables measuring PTSD and MD based on hypotheses derived from prior research on PTSD and satellite clinic based telehealth (Acierno et al., 2016; Tuerk et al., 2010). Specifically, we predicted that the mean treatment outcome difference scores of PE-IP minus PE-HBT would be within *a priori* defined confidence intervals (i.e., 90% one sided) demonstrating that PE-HBT is “as good as” PE-IP.

### 2.2. Participants and recruitment

Participants were recruited from the Ralph H. Johnson Veterans Affairs Medical Center (VA) and the Medical University of South Carolina via provider referral to the VA PTSD clinic (see Fig. 1 for CONSORT diagram). Data were collected November 2010 through April 2015. The Clinician Administered PTSD Scale (Blake et al., 1995) was used to determine PTSD eligibility and required that the criterion A event (i.e., the traumatic event) be combat-related. Individuals who were actively psychotic, acutely suicidal, or met criteria for current substance dependence, as determined by the Structured Clinical Interview for DSM-IV (SCID-IV; First, Spitzer, Gibbon, & Williams, 1996) were excluded from participation. To enhance generalizability of study findings, (a) veterans from each of the major conflicts comprising the majority of those served by the VA were included (i.e., OIF/OEF/OND, Persian Gulf, & Vietnam), and (b) participants receiving psychotropic medication or case management services for PTSD, mental health treatment for other psychiatric disorders, or those who met criteria for substance abuse were not excluded from participation. However, participants were asked to maintain their medication dosages at current levels and, in instances where medications were newly prescribed, required to wait four weeks for stabilization, at which point baseline measures were re-collected and study initiation commenced. Participant descriptions and demographics from the relatively larger Intent to Treat (ITT) sample (N = 132) are given in Table 1. Participants were predominantly male (n = 127), Black (n = 44) or White (n = 80), and married (n = 73). Just under half were employed (n = 55), and the average service connection rating, referring to compensated disability for injury suffered while in the military, was 53.5%.

### 2.3. Measures

#### 2.3.1. Clinician-administered PTSD scale (CAPS)-IV

The CAPS is a clinician-rated scale designed to diagnose current and lifetime PTSD (Blake et al., 1995). The CAPS has adequate internal consistency, inter-rater reliability, and test-retest reliability (Orsillo, Batten, & Hammond, 2001). In addition, the CAPS has adequate convergent validity with alternative measures of PTSD and adequate discriminant validity with respect to measures of depression and anxiety (Weathers & Litz, 1994). Finally, the diagnosis established by the CAPS compares well to alternative structured interviews (Weathers, Ruscio, & Keane, 1999), including the SCID (First et al., 1996). For this study, the CAPS was used to define inclusion criteria (i.e., PTSD diagnosis), not treatment response.

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