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Study Title: Enhancing Treatment of Hoarding Disorder With Personalized In-Home Sorting and Decluttering Practice

NCT02843308

Scientific background:

Hoarding disorder (HD) is characterized by persistent difficulties parting with possessions, associated distress, and clutter that compromises the intended use of living spaces (American Psychiatric Association, 2022). HD is common, with an estimated overall pooled prevalence of 2.5% of the general population (Postlethwaite et al., 2019). HD causes significant impacts on social, occupational, and other important areas of functioning and health risks include falls and other injuries due to clutter (American Psychiatric Association, 2022). In severe cases, home fires and pest infestation extend health and safety risks to neighbors (Frost et al., 2000). HD is associated with significantly lower quality of life, social isolation, and high rate of co-occurring mental disorders (Frost et al., 2011a; Ong et al., 2015; Saxena et al., 2011; Tolin et al., 2019). Cognitive behavioral therapy (CBT) for hoarding symptoms has shown promise when delivered by a trained therapist in either individual or group settings (Tolin et al., 2015); however, cost and access to a therapist may be barriers for some (Thompson et al., 2017). One alternative is the Buried in Treasures [BIT] Workshop, an evidence-based, highly structured, short-term, skills-based group using CBT principles but led by peers (Frost et al., 2012a) or non-professional facilitators (Frost et al., 2011a). To date, studies have shown BIT can significantly reduce hoarding symptoms when compared to a waitlist control (Frost et al., 2012a) and is as effective as psychologist-led group CBT (Mathews et al., 2016). Despite these promising results, many continue to have impairing symptoms after treatment and high levels of clutter, regardless of modality or type of facilitator (Moulding et al., 2017; Tolin et al., 2015) and under-utilize HD treatments and services (Frost et al., 2012b). Approaches that enhance the clinical effects of these interventions are needed. Based on two studies—one reporting that personalized care and accountability made treatments more acceptable to individuals with hoarding disorder (Rodriguez et al., 2016) and another reporting that greater number of home sessions were associated with better clinical outcomes (Tolin et al., 2015)—we tested the feasibility and effectiveness of adding personalized, in-home uncluttering sessions to the final weeks of BIT with up to 20 hours of supervised in-home uncluttering practices in a small (N = 5) pilot study of BIT+ (Linkovski et al., 2018). Reductions in hoarding symptoms, clutter, and impairment of daily activities were observed. Treatment response rate was comparable to rates in other BIT studies, with continued improvement in clutter level after in-home uncluttering sessions (Linkovski et al., 2018). Although the pilot study of BIT+ was promising, it had limitations including the small sample size and open-label design. To build upon this small pilot, we tested BIT+ in a larger sample using a randomized waitlist-controlled trial design and hypothesized that individuals randomized to BIT+ would have more significant and more substantial benefits on hoarding symptoms than patients randomized to an 18-week long waitlist. After the waitlist, participants were offered BIT+, and the BIT+ completer sample was pooled to allow us sufficient sample size to estimate clinical benefits.

Objectives:

To test BIT+ in a larger sample using a randomized waitlist-controlled trial design; we hypothesize that individuals randomized to BIT+ will have more significant and more substantial benefits on hoarding symptoms than patients randomized to an 18-week long waitlist.

Design:

This randomized waitlist-controlled trial with 1:1 (BIT+ intervention; waitlist control) allocation was conducted at an academic outpatient research setting. Potential participants were recruited via study advertisements posted online and in the local community, radio ads, and by referrals from mental health professionals and local hoarding task forces between October 2016 and June 2019. The study protocol was approved by the Stanford Institutional Review Board (IRB), and participants provided written informed consent. The trial was prospectively registered; clinicaltrials.gov identifier: NCT02843308. Participants were randomized by group, employing random permuted blocks within a 1:1 allocation ratio between intervention and waitlist control groups. The group therapy facilitators could not be blinded to allocation for practical reasons; the independent evaluators who assessed home clutter levels were blinded to allocation. Although several trial designs (with an active comparator) were considered, limited resources prohibited these options. A waitlist-controlled trial design was selected given treatment could be delivered to all participants, while controlling for passage of time and allowing comparison to a prior study of BIT that also employed a waitlist control condition (Frost et al., 2012a).

Methods:

a) Inclusion and Exclusion Criteria

Eligible adults (ages 18–70) had a primary diagnosis of HD according to DSM-5 criteria (American Psychiatric Association, 2013) as assessed via structured clinical interview (SCID) (First et al., 2015), with clinically significant hoarding disorder (Saving Inventory-Revised [SI-R] ≥ 41) (Frost et al., 2012b), clutter that impaired living spaces (Clutter Image Rating [CIR] ≥ 4) (Frost et al., 2008), no or stable psychotropic medication use (defined as medication doses unchanged for >4 weeks prior to assessment or > 8 weeks if fluoxetine). Potential participants were excluded if they lived greater than 30 miles from Stanford University (because the study necessitated home visits), had OCD as a primary diagnosis, a current or history of psychotic disorder or bipolar disorder, a current eating disorder, a current moderate or lifetime severe substance use disorder or were severely depressed (Hamilton Depression Rating Scale >30) (Hamilton, 1960), at risk of suicide (Columbia-Suicide Severity Rating Scale ≥ 4) (Posner et al., 2011) or any other medical or neuropsychiatric condition increased risk of participation or would prevent completion of study procedures. Additionally, we excluded participants who were unwilling to have unclutter volunteers enter their home, were unable to follow study procedures, had clutter levels with the potential for objects falling from overhead (CIR >8 ; approximately above shoulder height or higher), had evidence of animal hoarding or pest infestation, or were at high risk of eviction due to legal proceedings that necessitated a higher level of care. Individuals who had started working with a professional organizer or cognitive behavior therapist for HD within 8 weeks of enrollment were also excluded.

b) Procedures

Participants made 20 study-related visits to the study site: a baseline visit at the study start, 18 weekly visits for the BIT+ intervention, and a close-out visit at the study's completion. The BIT+ intervention consisted of 16 weekly group BIT workshop and 20 h of in-home uncluttering sessions over 18 weeks. The study procedures were identical to the pilot study (Linkovski et al., 2018), with two exceptions based on participant feedback and expert input from LS, RF, and CIR: a) rather than including a one-week break during Week 9 and a two-week break during Weeks 16–17, we continued weekly meeting uninterrupted to improve consistency; b) instead of concentrating the uncluttering at the end of the study with four weeks of twice weekly uncluttering, we slowly titrated up the duration and intensity over the last eight weeks to build up uncluttering stamina. The BIT workshop sessions are 2 hours long and structured based on the book, *Buried in Treasures: Help for Compulsive Acquiring, Saving and Hoarding* (Tolin et al., 2014) and the BIT facilitator's guide (Shuer and Frost, 2016). Each session was led by two trained, non-professional group facilitators and include HD-specific psycho-education, identifying acquisition triggers, tolerating urges to acquire, and developing skills for parting with possessions, following the methods of Frost et al. (2012a). For the uncluttering sessions, pairs of trained non-professional uncluttering volunteers made weekly home visits to each participant's residence for 10 visits of 2 hours each (20 hours of in-home uncluttering sessions over 18 weeks). The content of the sessions closely modeled content that participants learned during the BIT workshop and included the structured exercises detailed in the *Buried in Treasures* workbook (Tolin et al., 2014) and the BIT facilitator's guide (Shuer and Frost, 2016). As described previously (Linkovski et al., 2018), each session included a check-in, facilitated uncluttering time, and a closing in which participants shared their reflections and their objectives for the coming week.

Statistical Plan (including considerations for analysis):

Baseline variables will be assessed using descriptive statistics for the BIT+ and waitlist groups using means and standard deviations for the continuous, and frequencies and percentages for categorical variables.

We will employ standard linear mixed effects modeling (e.g., Bryk and Raudenbush, 2002; Singer and Willett, 2003) to estimate and compare the change from the pre-to post-treatment assessment during the first segment of our study in line with the intention to treat principle. The use of mixed effects modeling was chosen because this approach is better at handling missing data and yields improved power compared to linear regression. Specifically, we used a random intercept model assuming linear change. We will use maximum likelihood estimation with robust standard errors implemented in Mplus Version 8.4 (Muthén & Muthén, 1998–2017). Data points that are missing due to subject attrition will be handled assuming that data are missing at random (MAR; Little and Rubin, 2019) conditional on observed information. In our mixed effects analyses, the change (slope) in the outcome will be modeled as the key dependent variable predicted by the treatment assignment status. In particular, the change in SI-R total from baseline to end of treatment will be assessed. Specifically, will report the number of participants who met and exceeded the response criteria of the SI-R total (SI-R reduction ≥ 14 points).

In all analyses, we will use the nominal significance level ($\alpha = 0.05$). We will not adjust the significance level for multiple testing given that we had one clear primary endpoint. We will analyze several secondary outcomes including subscales of SI-R. We applied the same analytical strategy to analyze the data from the second segment of our study, where the individuals assigned to the waitlist condition

receives BIT+. Additionally, we will compare the first and second segments in terms of the estimated changes under BIT+ treatment.