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Comparison of a peer facilitated support group to cognitive behavior therapy: Study protocol for a randomized controlled trial for hoarding disorder

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ABSTRACT

Although individual and group cognitive-behavioral therapy (CBT) is the standard treatment approach for hoarding disorder (HD), it requires trained mental health professionals with specialization in HD. There is a need to offer additional options and services due to the limited number of professionals with advanced training, combined with the high prevalence rate of individuals with HD. A structured support group led by trained facilitators or lay professionals using a facilitator's manual and participant workbook (Buried in Treasures or BiT), addresses this need and increases accessibility. Prior studies of BiT groups have shown decreased hoarding symptoms. Only one retrospective study compared BiT and CBT outcomes in a naturalistic setting and showed no difference. Thus, a well-powered randomized controlled trial is needed to directly compare these forms of treatment. This paper presents a non-inferiority controlled trial protocol that compares group CBT to group BiT. Three hundred participants with HD, 18 years or older, are being recruited for a 16-week treatment study. Participants are randomly assigned to either the CBT or BiT group. The primary outcome is reduction in hoarding symptom severity. Secondary outcomes include reduction in other indices of hoarding symptomology, including functional impairment, physical clutter, cognition, and changes in neuropsychological functioning.

1. Introduction

In 2013, Hoarding Disorder (HD) was formally recognized as a distinct mental illness in the DSM-5[1]. HD is defined as persistent difficulty and/or distress in discarding possessions, resulting in accumulation that prevents the use of living spaces and impairment in social, occupational, or other areas of functioning. Although under-recognized, HD has a profound impact on individuals' functioning and quality of life. At 2–5% [2,3], HD has a lifetime prevalence rate that is comparable to or higher than those of more commonly known disorders (1% for Autism, 2% for Obsessive Compulsive Disorder, 4% for Bipolar) [4,5]. Rates increase substantially over age 55, to 6.2% [6–9]. However, despite these rates, research and consequently our understanding of HD lags behind other disorders.

The standard of care for treatment of HD is individual or group cognitive-behavioral therapy (CBT) [10], performed by licensed mental health providers, using a HD-specific CBT treatment manual and facilitators' guide [11,12]. However, due to the limited number of providers who specialize in the treatment of HD, increased access to care for this underserved population is needed. One strategy is to disseminate evidence-based HD treatments that can be delivered by non-mental health professionals in group settings. Hence, a self-help workbook called Buried in Treasures (BiT) [13], and an associated peer facilitators' guide [14], were developed for people with HD that can be delivered by lay or peer professionals in group settings. A recent study suggests that group CBT and group BiT have similar improvement rates in hoarding symptoms [15]. Though these initial results are promising, there have only been two studies conducted using the BiT protocol [15,16], and the existing CBT studies vary in structure (e.g., home visit and session length variation), and type of comparison group [10]. There is a need to directly compare group CBT and BiT in a randomized trial of a large cohort of participants, using a protocol that would be feasible and sustainable in community settings (i.e., real-world conditions).

Moreover, individuals with HD often express distress regarding memory loss, difficulties with attention, and other executive dysfunctions. In a

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recent study, participants with HD showed impairment in some neurocognitive domains (e.g. categorization and verbal learning) but improvement in others (e.g., abstract reasoning) [17]. Given the association of specific cognitive impairments with HD and patient perceived cognitive dysfunction, there is a need to further evaluate neurocognitive functioning in treatment outcome—both whether neurocognitive functioning predicts treatment outcome, and whether participation in treatment is associated with improvement in specific aspects of cognitive functioning.

This study's objective is to compare the efficacy of manualized BiT and CBT group treatment for HD using a randomized controlled non-inferiority trial design. We hypothesize that CBT and BiT are equally effective in improving symptoms of HD. In addition, this study will examine predictors of treatment outcome across both conditions, and examine the relationship and impact of cognitive function and other individual characteristics on treatment outcome. This paper provides a detailed methodological description of this randomized clinical trial, which can serve as a model for other investigators designing HD treatment trials.

2. Methodology

2.1. Overview

This trial compares the current standard of care for group treatment of HD (CBT) to an innovative and promising community-based group treatment (BiT). After screening and pre-treatment assessments confirm the diagnosis of HD, 300 participants will be stratified by gender and geographic location and randomized to either CBT or BiT. Participants in both treatment arms receive one 2-h session of group therapy weekly with CBT participants receiving 16 sessions and BiT participants 15 sessions. The study was approved by the Institutional Review Board of the University of California, San Francisco.

2.2. Collaborative partners and project team organization

The project is a partnership between the Mental Health Association of San Francisco (MHASF) and the University of California, San Francisco (UCSF). The Principal Investigator (PI) of the Project, a psychiatrist at UCSF, directs the overall operations and scientific conduct of the project. The partnership operations have two arms: 1) patient advocacy; and 2) research. The patient advocacy arm, led by the MHASF team, is primarily responsible for recruiting and screening participants, securing group treatment sites, training BiT group leaders and leading BiT groups. The MHASF team includes members of the administrative staff with expertise in hoarding related programs, including those who oversee the annual hoarding related conference held by MHASF. In addition, the team includes a research coordinator, peer-facilitators who are trained to deliver BiT and are individuals from the community with lived hoarding experience, and supervisors for the peer facilitators who are community clinicians and/or individuals with lived hoarding experience and prior group facilitation experience. Lastly, a consultant who is the developer of the BiT facilitators' manual provides consultation on BiT implementation. The research arm is led by the UCSF team with a primary responsibility for clinical and neuropsychological assessments, training and supervising CBT group leaders, conducting CBT groups, data management, and analyses. The UCSF team consist of a psychiatrist (the PI) with clinical and research expertise in HD, a biostatistician with expertise in clinical trials design, a neuropsychologist with expertise in neurocognitive assessment of individuals with HD, a research coordinator, and postdoctoral psychology fellows who are trained to deliver CBT following the HD-specific CBT manual. Thus, the collaborative relationship between the investigators at UCSF and those at MHASF complements each other's unique specialties and strengths.

2.3. Recruitment

Individuals with HD are being recruited through media advertisements (radio, internet), advertisements on the MHASF website and on hoarders.org, emails sent to treatment providers, the MHASF listserv and the International Obsessive Compulsive Disorder Foundation (IOCDF) local support group chapter's listserv. Peer facilitators speak at organizations and at outreach events as “peers” who share their lived experience with our target population. Flyers are distributed at coffee shops, laundromats, libraries, and community centers. Furthermore, announcements are made at ongoing drop-in support groups for HD conducted by the MHASF, and at the annual conference on Hoarding and Cluttering, which is attended by individuals with HD, their family members, treatment providers, and other key stakeholders. The study has also been registered with clinicaltrials.gov (NCT02040805).

2.4. Eligibility criteria

2.4.1. Screening and inclusion criteria

Individuals are screened if they are 18 years of age or older, reside in the greater Bay Area community, are identified by mental health professionals as having hoarding behaviors, and are interested in treatment for hoarding. Interested people contact MHASF staff (i.e., peer facilitators or recruitment coordinator) by telephone or in person. They then conduct an initial screening to ensure that potential participants have primary hoarding behaviors (difficulty discarding, excessive acquiring) rather than difficulties primarily arising from problems with organization or physical or mental health limitations (such as depression) that lead to passive clutter rather than specific difficulties with discarding objects. They explain the nature of the study, including randomization, monetary compensation, and group treatment information to potential participants. At that time, verbal consent to participate is obtained.

Individuals who meet the self-reported hoarding problems and treatment criteria complete three screening questionnaires: the Savings Inventory-Revised (SI-R), the UCLA Hoarding Symptom Scale (UHSS), and the Clutter Image Rating Scale (CI-R) (see descriptions below). These measures are commonly used to assess HD related behaviors and cognitions. Individuals who meet the cutoff scores for clinically significant hoarding on two of the three measures (SI-R≥42, UHSS≥20, CI-R≥12) are then contacted by UCSF staff for the final screening in-person interview with UCSF staff to confirm a diagnosis of HD using the Structured Instrument for Hoarding Disorder (SIHD) [18]. As has been done in previous studies [17,19], the screening criteria were chosen to rule out participants who live in a hoarding environment (e.g., family members who hoard), but who would not themselves meet the criteria for HD.

2.4.2. Exclusion criteria

Individuals with dementia are excluded due to an associated high rate of collecting or hoarding behaviors that differ phenotypically and etiologically from HD. Individuals with current or past psychiatric comorbidities or symptoms are not excluded unless they are disruptive and cannot be redirected during in-person UCSF evaluations or during group treatment. Individuals who have participated in either CBT for hoarding (group or individual) or in group BiT in the past year are excluded from participation. We chose this time frame for exclusion based on prior treatment because we anticipated, from clinical experience, that the gains received from HD specific prior treatment would be stable after a year, and that individuals who met the severity criteria for entry into the study at the time of assessment would stand to benefit. Individuals who receive (d) non-CBT forms of treatment for HD or CBT treatments for non-hoarding disorders are not excluded from the study. This includes participation in support groups such as Clutterers Anonymous or the receipt of individual therapy for other problems (e.g., PTSD, depression). Similarly, medication treatment for HD is not an exclusion criterion.