Rationale, design, and implementation of a clinical trial of a mindfulness-based relapse prevention protocol for the treatment of women with comorbid post traumatic stress disorder and substance use disorder

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ABSTRACT

Comorbid post-traumatic stress disorder (PTSD) and substance use disorders (SUD) commonly co-occur and is associated with a more complex clinical presentation with poorer clinical outcomes when compared with either disorder alone, and untreated PTSD can predict relapse to substance abuse. A number of integrated treatment approaches addressing symptoms of both PTSD and SUD concurrently demonstrate that both disorders can safely and effectively be treated concurrently. However, attrition and SUD relapse rates remain high and there is need to further develop new treatment approaches. Innovative approaches such as mindfulness meditation (MM) successfully used in the treatment of SUD may offer additional benefits for individuals with SUD complicated with PTSD. Specifically, Mindfulness-based Relapse Prevention (MBRP) integrates coping skills from cognitive-behavioral relapse prevention therapy with MM practices, raising awareness of substance use triggers and re-active behavioral patterns, and teaching skillful coping responses. Here we present the design and methods for the “Mindfulness Meditation for the Treatment of Women with comorbid PTSD and SUD” study, a Stage 1b behavioral development study that modifies MBRP treatment to address both PTSD and SUD in a community setting. This study is divided into three parts: revising the existing evidence-based manual, piloting the intervention, and testing the new manual in a randomized controlled pilot trial in women with comorbid PTSD and SUD enrolled in a community-based SUD treatment program.

1. Introduction

Post-traumatic stress disorder (PTSD), a chronic condition that develops following an extremely distressing traumatic event, is characterized by a set of symptoms resulting in significant functional impairment [1]. PTSD can often co-occur with substance use disorders (SUD), which are associated with poorer clinical outcomes than PTSD or SUD alone [2–7]. Women are twice as likely to be diagnosed with PTSD as compared to men, [8–10] so women-only community groups provide an emotionally safe and supportive environment that allows women to address sensitive issues such as domestic violence and victimization [11–15].

A number of integrated treatment approaches addressing symptoms of both PTSD and SUD concurrently have been explored in the past decade, including integrated treatments using exposure techniques for PTSD and cognitive behavioral therapy (CBT) for SUD that have shown promise in improving both PTSD and SUD [16,17].

As both PTSD and SUD have been conceptualized as disorders of emotional dysregulation [18], disrupted emotional regulation and intolerance to negative internal and external experiences may be an important mediating factor between trauma exposure and subsequent SUDs. Researchers have found that distress tolerance was inversely associated with PTSD symptom severity in a group of trauma exposed cocaine dependent adults [19]. Another study in male veterans with comorbid PTSD and SUD showed a similar relationship between distress tolerance and PTSD symptom severity, particularly the intrusive thoughts and hyperarousal symptoms [20]. Mindfulness meditation (MM), a self-directed practice of intentionally attending to present-moment experiences (physical sensations, perceptions, affective states, thoughts and imagery) [21–23], has been shown to lead to better emotional processing and thus, improved emotion and self-regulation skills [24–26]. MM may provide a way for individuals with PTSD and...
SUD to experience a greater sense of control in relation to cravings triggered by trauma-related intrusive thoughts, memories and sensations. Individuals able to modulate these internal experiences may be less emotionally reactive and less prone to relapse related to escape/avoidance of distressing symptoms. Experiencing repeated exposure to PTSD and SUD triggers through MM without the associated emotional or behavioral reactivity, individuals practicing MM may habituate to these experiences resulting in diminished trauma symptoms and craving.

Mindfulness-Based Relapse Prevention (MBRP) integrates coping skills from cognitive-behavioral relapse prevention therapy with MM practices, raising awareness of substance use triggers and reactive behavioral patterns, and teaching skillful coping responses [27]. Although MM interventions have shown promise in reducing symptoms of PTSD, there are no studies investigating MM in patients with comorbid PTSD and SUD, particularly in women who represent a high percentage of patients being treated in community programs.

This study attempts to fill the gap in research by investigating an adapted MBRP treatment to address both PTSD and SUD in a community-based treatment setting. A description of this behavioral therapy development study is presented, including the process of adapting an existing intervention, design and methodology of the pilot intervention, outcome measures used, data analysis, and safety precautions.

2. Methods and study design

2.1. Study overview

This study is a behavioral development 8 week, Stage 1b, single site study that seeks to modify an existing evidence-based treatment targeting SUD, MBRP, to address both PTSD and SUD in a community-based treatment setting. The primary purpose of the study intervention is to evaluate the feasibility and preliminary efficacy of an adapted MBRP in combination with treatment as usual (TAU) as compared to TAU alone for women with comorbid PTSD and SUD in a community-based SUD treatment program. The execution of the project consists of training/certifying the community therapists in the MBRP intervention, piloting the intervention in 2 patient groups, revising the manual to address PTSD symptoms, and testing the revised manual in a randomized controlled pilot trial that compares MBRP/TAU to TAU alone in 80 women enrolled in intensive community SUD treatment.

The majority of the modifications for the manual occur before (based on theoretical rationale, previous research) and after the pilot groups. The revision is an ongoing process and based on observations of the pilot sessions, interviews with therapists and participants, and discussions with the developer of the manual. Once the randomized control trial (RCT) is started the adaptations that have been made are incorporated, however, further adaptations can be made based on participant responses, attrition and/or adverse events. In this phase of the study, the RCT is not to test the effectiveness of the intervention but rather to assess the feasibility, safety and preliminary efficacy of the intervention. If successful, the behavioral development grant is followed by a larger randomized effectiveness trial.

Process assessments include measures of manual adherence, therapist competence, therapeutic/patient alliance and therapist/patient acceptability and satisfaction. Comprehensive evaluation on measures of MM, PTSD symptom severity, and substance use outcomes are done at baseline, periodically at 8 weekly visits throughout the intervention, post treatment, and at the 3 and 6 months post-treatment visits. Changes in emotion regulation and components of MM (attention, awareness to present moment and acceptance) will be explored to determine the intervention impact on PTSD symptoms, craving and substance use. If promising, results from this pilot study will provide effect size estimation for a larger Stage II randomized clinical trial. This pilot project will also test the feasibility of training and fidelity monitoring procedures for community therapists and assess acceptability, knowledge and adherence/competence.

A brief overview of the study protocol is shown in Fig. 1. In short, a small randomized pilot study will mimic the study design of the primary protocol in 3–6 women per group. Careful monitoring of participants during this phase will help address questions concerning the best match of trauma related components with the MBRP techniques. Weekly monitoring of PTSD, emotion regulation, craving and substance use will provide information concerning the timing, impact and duration of the intervention effects. After the final pilot group session, participants are invited to attend a focus group to provide feedback regarding interest, acceptability, benefits/usefulness, duration and timing of intervention in the treatment program and ability/willingness to practice meditation outside of the sessions. Specific adaptations to the revised manual are based on observations of the taped MBRP sessions, qualitative data from the focus groups and feedback from the community therapists. Recruitment, attrition, participant feedback, home practice completion, helping alliance questionnaire are part of the feasibility. The therapists’ acceptance, ease of delivery and belief that participants benefit from the intervention are another component. An innovative aspect to this intervention is that it is conducted in a front line community program and if successful, dissemination and adoption become less of a challenge.

Following completion of the pilot therapy and manual adaptation phase of the study, a randomized control phase will be implemented. In this phase of the study, the active intervention group receives MBRP...
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