Women's Treatment and Early Recovery (MBRP-W)

NCT02977988

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Study Protocol

Study design

This parallel-group RCT was designed to compare retention days in residential treatment among participants randomly assigned to one of two study conditions as adjuncts to their residential SUD treatment: (1) MMWR and (2) Neurobiology of Addiction (NA), with the latter serving as the psychoeducational control condition. Baseline interviews occurred prior to randomization and post-intervention interviews occurred up to 14 days after the last class session of the study intervention. All participants received SUD treatment services as normally provided by the treatment facility without affecting the level of usual care provided to patients. The study site offered no structured mindfulness-based activities or services during the study period. The University of Southern California Institutional Review Board approved this study (UP-14-00391).

Study site standard care

The site for the study was a publicly-funded residential treatment facility for women diagnosed with SUD in Southern California. It had the capacity to provide on-site housing and comprehensive services for up to 110 women and their children. Childcare and children's services were provided on-site along with an array of supportive services for pregnant and parenting women. The site coordinated services for women with multiple vulnerabilities, including those with mental health issues, trauma (physical and/or sexual abuse) in their past or present, and/or health problems such as HIV/AIDS. While women could remain in residential treatment for up to 12 months, the average length of stay was 5.5 months. The program included mental health and SUD diagnosis and treatment, bio-psychosocial assessment, chemical de- pendency education and counseling, individual and group therapy, relapse

prevention, random drug testing, specialized women's groups, trauma education and support, family education and counseling, vocational training, educational support, case management, nutritional education and support, health and wellness activities, and 12-step meetings. Referrals to the following services were made as needed: medical and dental, domestic violence, psychiatric care, GED classes, and Early Head Start. The residential treatment program was situated on a large 4-acre campus that includes residential quarters, space for group therapy and classes, a computer lab, a nursery, and a classroom for the pre-school program that is provided by the local school district.

Participants and procedures

Participants were adult women clinically diagnosed with SUD and admitted to the residential SUD treatment program study site. Upon admission, all patients met one-on-one with the site's intake clinician coordinator who conducted an assessment for substance use disorders, mental health disorders, and suicidality using the DSM-5. At that time, the same clinician also completed a psycho- social assessment using an in-house form to identify important aspects of patient history and patient needs to inform case management and treatment plan. The site psychiatrist and on-site clinician coordinator discussed diagnostic assessment, determined final diagnoses, and made record in the patient chart. The site intake counselor verified study eligibility, and for those women who were eligible, informed clients about our study. The names of clients who assented to be contacted by the study team were provided to the study interviewer. The study interviewer made appointments with prospective participants, conducted the informed consent and HIPAA process, and administered the baseline assessment interview. As part of the site's normal post-admission protocol, patients began receiving services as usual including individual and group therapy, psychoeducation groups and other services. Psychoeducation and therapy groups were scheduled on a six-week cycle.

Inclusion criteria for the research trial were: client at the residential treatment study site, female, adult aged 18 to 65 years, diagnosed with SUD via clinical record, fluent in English, and agreed to participate in the study. Exclusion criteria were: inability to comprehend or sign in- formed consent, cognitive impairment, untreated psychotic disorder or severe chronic mental health condition based on clinical intake LR- DSM-IV or DSM-V diagnostic assessment, older than 65 years of age as this was unusual at the site, reported suicidality during the prior 30 days based on clinical intake assessment, current prisoner, more than 6 months pregnant, and not willing to sign a HIPAA form or be audio recorded during interviews and intervention sessions. Study interventions were held separately two times per week during the same time slot. Study participants joined the first session of their assigned group, which started every six weeks per study site protocol.

To minimize bias across study groups related to participant characteristics and histories, we applied urn randomization as implemented by the Urn Randomization Program (version 1.01) after a group of 10 to 30 women were deemed eligible for randomization. Strata variables were current pregnancy (yes or no) and age (18 to 31 years or 32 to 65 years) to ensure these characteristics were equivalent across groups at baseline because they can affect SUD treatment outcomes. The urn approach is robust against experimental bias in clinical trials because it is a compromise between perfect balance in treatment assignments and complete randomization to eliminate experimental bias.

Interventions

Moment-by-Moment in Women's recovery (MMWR)

This intervention was delivered twice weekly for 80 min each for a total of 12 group sessions (6 weeks) during residential treatment. MMWR was guided by an instructional manual with

standardized lesson plans. An experienced teacher trained in both MBSR and MMWR facilitated all sessions along with an on-site masters-level clinician with experience in SUDs who co-facilitated the intervention. Each class session had a central theme divided into five segments in the following general order: (1) welcome, review of group culture, brief homework practice check-in, objectives, and brief mindfulness meditation or practice; (2) didactic psychoeducational presentation and discussion of lesson content; 3) experiential meditation and mindfulness practices related to the session's theme; (4) practice of sitting or walking meditation, body scan, and/or standing stretching; and (5) selected reading related to session topic, assignments for the next class, and closing meditation. Trainees were expected to learn skills to approach experiences and stressors using mindfulness principles. Students learned about the role of automatic reactivity to stressors and its relation to addiction and relapse; the connections between stress, triggers, and relapse; and how to use mindfulness practices to respond best to related thoughts, emotions, body sensations (including those related to stress in a residential treatment setting that could lead to treatment dropout), and triggers while still avoiding relapse. As with MBSR, trainees learned and practiced self-regulation strategies using four foundational mindfulness practices. Teachers instructed on the use of formal (audio- guided sitting meditation, sitting meditation without audio, loving kindness meditation, walking meditation, body scan, and mindful stretching) and informal practices (stop light technique, triangle of awareness, mindfulness of breath, mindfulness of emotions, mind- fulness of thoughts, mindfulness of body sensations, and mindfulness of cravings). Throughout the course, students were encouraged to bring mindful awareness into their daily activities by using informal practices and to engage in formal meditation practices as homework in accordance with practice assignments and guided meditation audio recordings. Participants received a MMWR Participant Workbook at the beginning of the course organized by session, containing key concepts and practices introduced in each session, and homework and practice assignments for each session. Participants were asked to bring their Workbook to each session so that they

could report on the previous week's assignment and the current session's homework and practice assignments could be explained by the facilitator and reviewed as women followed along. Some assignments asked participants for specific reflections and written responses. Participants received a MP3 player with meditation audios for each session to guide participants through practices introduced in each session.

Neurobiology of addiction (NA) psychoeducation attention control

This intervention was delivered twice weekly for 80 min each for a total of 12 group sessions (6 weeks) during residential treatment. NA was guided by an instructional manual with standardized lesson plans (Amaro et al., 2016; unpublished facilitator's manual). The curriculum was previously developed by H.A. over 3 years with input and review from focus groups of women and providers in SUD treatment, and subsequently reviewed by three experts in NA. A masters-level educator with a background and training in the NA facilitated all sessions and an on-site masters-level clinician with experience in SUDs and training in NA co-facilitated the intervention. Participants received didactic education on the structure and function of the brain and the neurobiology of addiction. Although educational and centered on knowledge acquisition, the program has no proven efficacy in altering substance use behavior. It included didactic psychoeducational presentation using PowerPoint, video recordings, exercises, games, and group discussions to reinforce the session content and respond to questions. Sessions did not address behavior change strategies, stress reduction, mindfulness, or relapse-related content. Films, videos, exercises, activities, and discussions were used to explain content and promote participant engagement. Topics included: (1) definition of addiction and why it is a brain disease; (2) brain structures and functions and those related to addiction; (3) effects of various types of substances on the brain; (4) rewarding effects of substances and how these effects lead to addiction; (5) definitions and brain functions related to craving and withdrawal; and (6) the roles of treatment in recovery. Participants were expected to gain knowledge pertaining to

basic brain structure and function and the effects of drugs on both. The intervention was equivalent to MMWR in time, teacher attention, expectancy of benefit, and group support. Participants received a NA Participant Workbook organized by session that included session specific information covered in each session such as selected PowerPoint slides and were asked to bring these to class to help them identify questions they had from the previous session. Participants received MP3 players with audio clips of key sections of videos introduced in class.