

Study Protocol Cover Page

Study Title: Mindfulness-Based Stress Reduction to Improve Neuropsychological Functioning in Acquired Brain Injury

Clinical Trials ID: NCT03969563

Document date/IRB approval date: 10/31/2019

Treatment Protocol

We conducted six rounds of each class (see Table 2 for course topics and descriptions). To reduce variability, both courses had the same instructor - a trained and certified MBSR instructor with over 10 years of experience and a Master's degree in Education (emphasis on Curriculum and Instruction) - making her well-qualified to teach both classes. The instructor also received specialized training for teaching MBSR and other educational courses online. Both classes were further matched in terms of the length (2.5 hours/week), schedule (9-week class plus a day-long retreat), class size (7-10 participants), instructor, and amount of homework. All participants were also informed at the beginning of the course that their data would be excluded from the study if they missed more than three classes.

The MBSR class was the standardized program created by the University of Massachusetts, which includes an introductory session, 8 weeks of classes, and a retreat during the sixth week (Kabat-Zinn, 1990b). During the course, participants learned about mindfulness through practices such as body awareness, mindful movement, meditation, and informal mindfulness practices of daily life (e.g., eating, communicating, working, coping). The retreat included a review of class material, meditation and yoga practice, and a group lunch. Our study modified this program slightly by reducing the retreat day to four hours. And, given the population and the course modality, participants completed smaller movement and chair yoga exercises instead of the standard yoga practices. For homework, MBSR participants were assigned practices according to the standard MBSR curriculum, where they followed along to different meditation recordings (provided to them through a web link), engaged in mindful movement, and read from the course manual. The time spent engaging in mindfulness practices were then tracked using online homework logs.

Our active intervention, the Brain Health class, was a modification of an existing VA education class for brain-injured individuals taught on the VA campus. It served as a robust active control because it matched the MBSR intervention in terms of instructor, time interacting with peers and the instructor, movement, schedule, and homework activities. The Brain Health class did not include any meditative/ mindfulness components, which we hypothesized would be the critical factor for how MBSR leads to improved health and cognition (Kabat-Zinn, 1990b).

Specifically, each class consisted of lectures with slides and videos (90 mins) and a group discussion (45 mins), during which time participants learned basic brain anatomy, how brain injuries can affect their cognition, and completed classes on the importance of topics such as sleep, nutrition, and social connection. To match the movement portion of the MBSR class, the Brain Health class also included simple chair exercises, such as stretching and reaching. The Brain Health retreat consisted of a review of class topics, short videos on brain topics, and a group lunch.

Measures

Study Implementation and Satisfaction. We measured study feasibility by examining rates of recruitment (i.e., the percentage of participants who agreed to take part in the study, relative to the total number of people we contacted) and retention (i.e., how many participants completed the program, attendance, homework engagement, and instructor-rated class engagement). Participants were also asked to complete an anonymous nine-item questionnaire created by the authors (see Table 3) to assess course satisfaction. Participants thus used a scale of 1 (very unsatisfied) to 5 (very satisfied) to answer questions such as, *“How satisfied were you with the class?”* and *“How likely are you to continue to study and practice the skills you learned in this class?”*.

Mood, Well-Being, and Health. The Geriatric Depression Scale (Yesavage et al., 1982) was administered to measure subjective symptoms of depression in an older adult population. Participants indicated yes (1) or no (0) to questions such as, *“Do you feel happy most of the time?”* and *“Do you feel your situation is hopeless?”*. The State-Trait Anxiety Inventory (Spielberger et al., 1983) measured current anxiety symptoms. Participants used a 1 (almost never) to 4 (almost always) scale to express how often they *“feel content,”* and *“feel calm.”*