

Study Protocol

Study Title: Wellness Programs for Brain-Injured Individuals

NCT#: 02600637

Date: 4-5-2019

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Behavioral Protocol

Participants will be recruited from Dr. Baldo's large stroke research participant pool at VA Northern California. Individuals in our research pool have current brain MRI scans, have been thoroughly screened for prior medical and psychiatric history, and have already been evaluated on a large neuropsychological battery, which will facilitate the execution of the current proposal in a relatively short timeframe. Participants in our pool sign consent forms that include permission to use their neuropsychological and imaging data for future related studies. If additional research participants are needed, we will recruit patients from our VA Outpatient Neuropsychology and NeuroBehavior Clinics, and the Neurocognitive Rehabilitation Unit in our CLC, with the assistance of our collaborators who run these clinics, VA Staff Neurologist, Dr. D'Esposito and VA Staff Geropsychiatrist, Dr. Hargrave. If needed, patients can also be identified through automated digital searches of VA-CPRS medical records and contacted with IRB-approved letters to eligible participants, as we have done successfully in the past.

Treatment Interventions. Participants will be randomly assigned to either the MBSR or Brain Health control intervention. Although this is a pilot study, inclusion of a control group is highly recommended in order to evaluate all potential procedures for a larger-scale efficacy trial. Randomization will be achieved with freely available software, using covariate adaptive randomization to ensure groups of equal sizes that are balanced for age, education, side of stroke (left vs. right hemisphere), lesion volume, months post-stroke, current cognitive status (based on the Mini-Mental State Examination), and baseline anxiety and depression levels.

Half of the study participants will complete an 8-week Mindfulness-Based Stress Reduction (MBSR) program on our VA campus. The course will be led by a certified MBSR instructor who has received extensive training in mindfulness-based interventions and specifically in MBSR. He has already led multiple groups of brain-injured Veterans through the program on our VA campus. The MBSR group meets once per week for 2½ hours, with a day-long retreat for 7½ hours in the 6th week of the program. Participants are instructed in mindfulness practice in the form of sitting meditation, body awareness and mindful movement, and informal mindfulness practices of daily life (e.g., eating, communicating, working, coping). Between classes, patients enhance their participation by practicing at home with meditation CDs, homework assignments, and readings from the course materials and textbook. Home practice is tracked with pre-made logbooks (used in our prior study) that patients keep for the duration of the study and record the number of hours engaged in practice at home. Logbooks are checked and recorded by study staff each week.

The other half of participants will take part in an active control intervention, a Brain Health program, which is matched for the same number of hours, instructor, schedule, homework, and home practice as the MBSR program. The Brain Health program has been used previously on our VA campus by collaborator Dr. D'Esposito as an active control intervention for cognitive rehabilitation research protocols. It includes background and education about brain-behavior relationships and discusses how brain injuries can disrupt various aspects of cognition, such as memory and attention. We have found that our Brain Health program is the appropriate control intervention because it matches for critical process elements such as clinician interaction, social interaction with the group, and homework activities, without the inclusion of a reflection/mindfulness component, which is hypothesized to be the critical factor for improving functioning.

A battery of standardized psychological and cognitive measures will be administered 1) prior to the intervention (pre-testing) and 2) within one week following the intervention (post-testing). All

pre- and post-testing will be conducted by a licensed neuropsychologist who will be blinded to the participant's intervention condition (MBSR vs. Brain Health/Education). The battery includes the Geriatric Depression Scale, State-Trait Anxiety Inventory, and Repeatable Battery for the Assessment of Neuropsychological Status (RBANS).