Study Protocol Plan

Study Title: Mindfulness Training in Healthy Older Veterans

NCT#: NCT02816723

Date: 3/6/2016

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Participants will be recruited at VA Northern California, using the PIs existing participant database, posted fliers, and CPRS searches.

Participants will be randomly assigned to either the MBSR or Brain Health control intervention. Randomization will be achieved with freely available software, using covariate adaptive randomization to ensure groups of equal sizes that are balanced for age, education, 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. 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 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 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.

Treatment fidelity will be assessed by videotaping the course instructor during both the MBSR and Brain Health classes. Two independent individuals with extensive familiarity with the classes will rate the instructor on a scale from 1-5, with higher numbers indicating better adherence to the course manuals. Since the same instructor teaches both the MBSR and Brain Health class (in order to avoid the variability associated with different instructors), it is possible that there could be cross-contamination across classes (e.g., discussion of meditation in the Brain Health class). To monitor this, our fidelity check will also include review of class videotape for any possible cross-contamination, as judged by the independent raters. Also, our instructor is very aware of this potential issue and is very conscious of avoiding cross-contamination, for example, by redirecting discussion if a student in the Brain Health class mentions topics covered in the MBSR class, such as meditation. As a further check of cross-contamination, we will query participants with a short post-intervention questionnaire about their prior knowledge of class topics and how much they learned during the class about topics such as mindfulness (which should only be endorsed by participants in the MBSR class) and brain anatomy (which should only be endorsed by participants in the Brain Health class).

A battery of standardized psychological and cognitive measures will be administered 1) within two weeks prior to the intervention (pre-testing) and 2) within two weeks 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 and State-Trait Anxiety Inventory as primary outcome measures, and the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) as a secondary outcome measure. The RBANS was developed for the purpose of testing examinees at different time points with multiple, matched versions of the battery that test a wide range of cognitive functions. The RBANS battery includes 12 subtests and yields a total scaled score for overall performance.

All study staff involved in testing are licensed psychologists and will be vigilant in monitoring for acute suicidality. A verbal indication of suicidal intent or ideation during screening will be immediately evaluated and will trigger the VA Northern California Suicide Prevention Protocol which includes: 1) evaluation of imminent risk by a licensed psychologist; 2) if imminent risk, patient is immediately brought to suicide team provider in Mental Health; 3) patient's mental health or primary care physician is notified; and 4) written notification of a serious adverse event to the VA Institutional Review Board and Safety Monitoring Board within 24 hours. A determination of whether it is appropriate for the patient to continue in the research study will be made by clinical study staff in conjunction with the patient's medical providers.