Cover Page Protocol and SAP

Official Title of the study: A 14 Week Study of Mindfulness Effects on Attentional Control in Older Adults (The MACS Study: Mindfulness and Attentional Control in Seniors)

NCT number: NCT02714426

Date of the document: IRB version: 03-30-2016

1. Background:

The proposed study is an intensive micro-longitudinal 14-week investigation exploring week to week changes in attentional and emotional control in older adults who do and do not receive 8-weeks of mindfulness education and training. The study focuses narrowly on attentional and emotional control. The study compares changes in attentional and emotional control between one group of participants who receive fourteen weeks of weekly testing plus eight weeks of mindfulness training and education, and another that receives that receives the same fourteen weeks of testing plus eight weeks of active control 'brain health' educational sessions. The development of this study was guided by several key concepts:

Mindfulness meditation, with its primary focus on attention to the present moment,[1] is one possible avenue for attentional improvement in young and middle-aged adults. A small but steadily growing body of literature suggests that meditation may have similar effects on attentional control in late life, a period of normative decline [2,3] It has been shown that mindfulness meditative practice, such as a standardized mindfulness based stress reduction program (MBSR; Kabat-Zinn, 2003),[1] increases the efficiency of attention networks.[4,5,6] so applying mindfulness inspired interventions would seem to offer one route to cognitive remediation in older adults.

Additionally, to date, the majority of studies that have related mindfulness meditation practice to attentional control have been based on retrospective self-reported mindfulness or cross-sectional measurement in experienced meditators.[7,8,9] More recent experimental studies have ventured only to determine that meditation naïve individuals can experience attentional improvement with mindfulness intervention,[10,11,12] (rather than why) using pre-post mindfulness training designs. The time course of the association of mindfulness training with attention has yet to be studied, leaving a gap in the field's collective knowledge of when and how these improvements manifest.

Finally, although emotion regulation is thought to improve through mindfulness,[13] the time course of its development and its potential influence on attentional control have thus far been unclear. Therefore, emotion-related data is important to collect with respect to the time course of attentional change.

2. Specific Aims:

The proposed micro-longitudinal research study will consider the relationship between mindfulness meditation practice and attentional control in older age, with a focus on the temporal dynamics of attentional and emotional change produced during 8-weeks of mindfulness sessions. This study, by examining the week-to-week trajectory of gains in an older adult sample undergoing training in mindfulness, will expand our understanding of possible dose-response relationships, as well as possible mediators of those gains, areas for which minimal data exist.

3. Research Plan / Study Description:

Initial Telephone Contact:
Prior to in-person contact with the study, potential participants will first be contacted via telephone.
Exclusion criteria are:

- Under 65 years of age
- Lack of time and willingness to commit to the completion of this 14-week study
- Less than an 8th grade education
- Having been told by a healthcare provider that they
    - Have ever had a major stroke or mini-stroke
    - Have ever had a traumatic brain injury (e.g. moderate to severe brain injury)Have ever had another significant brain abnormality
    - Have a neurodegenerative disorder (Parkinson's disease, Huntington's disease, dementia of any type, etc.)
- Current or past history of major psychiatric disturbance including schizophrenia, or active psychosis, current major depressive episode, current alcohol or substance abuse or history thereof within the past six months, or EVER HOSPITALIZED for any of the above conditions
- Radiation treatment for cancer above the neck
- Extreme difficulty reading ordinary print in a newspaper, or have stopped reading due to poor eyesight.
- Extreme difficulty hearing, or being completely unable to hear, ordinary speech in low-noise conditions, even with hearing aid
- Currently participating in cognitive training or brain training
- Having participated in any cognitive or brain training study within the last 6 months
- Any prior training in (e.g. multi-day course) in mindfulness meditation, or current practice of any form of meditation.
- History of receiving cognitive or neuropsychological testing within the last 6 months

To avoid collecting personal health information, participants will not be asked to report on their status regarding these exclusion criteria individually. Instead, they will be asked to endorse their eligibility based on all the criteria in the single block. This ensures that investigators do not know, and cannot record, which specific exclusion criteria, if any, disqualifies the individual.

If individuals are eligible to take part in the study, they will be scheduled for an intake consent and baseline assessment session.

Consent, Baseline Assessment/Pretest, and Post-test Assessment:
Consent procedures are described below. Baseline assessments will include a demographics questionnaire, a self-administered health comorbidity scale, a global health-related quality of life survey, measures of self-reported everyday function, a measure of global cognition, and a measure of reading literacy (Appendix B). Participants will also complete emotion, mood, and mindfulness questionnaires, and will complete computerized and paper-and-pencil cognitive testing. Following this initial visit, participants will be randomly assigned to either the active control brain health group or the mindfulness group.

At the Post-test visit, all participants will complete a subset of the same emotion, mood, and mindfulness questionnaires, and cognitive testing measures that were completed at the Consent and Baseline/Pre-test visit. It should be noted that the inclusion of the global cognition measure and mood questionnaires is NOT for clinical case determination/diagnosis or screening. Rather, these measures are being used as brief, well validated measures of individual differences in mood and global cognition, to characterize the sample in manuscripts.

Weeks 1-14
The total anticipated sample has the goal of enrolling 48 individuals who fully complete all study activities. To distribute workload, the study will be conducted in three to four replicates, each enrolling twelve (12) to sixteen (16) participants. For all participants, their personal study participation is 14-16 weeks long (including pre- and post-testing, and includes 1 hour of attentional and emotional control assessment challenges each week for 14 weeks. Participants will also spend an additional 2 hours each week with the study in weeks 4-11 to participate in 8 weekly group sessions (mindfulness or active control 'brain health' education).

Mindfulness Procedure
In the mindfulness program, participants will participate in 8 weekly group sessions, each lasting approximately 2 hours in duration, along with a half day Mindfulness Retreat at the end of the training period. Specific course material will adhere strictly to a manualized protocol by Stahl and Goldstein (2000).[14] A detailed schedule of training session content is outlined in Appendix E. Each session will include 1) a psychoeducational component, 2) formal exercises in the form of guided practice, and 3) thoughtful exploration of ideas and questions. Formal mindfulness practices will follow 21 guided pre-recorded meditative MP3 tracks from the authors for use in class

and at home, promoting both fidelity to the protocol and uniformity across replicates. Activities in the protocol include mindful breathing, eating, walking, and various other practices well documented in the literature to promote mindfulness. Participants will also be asked to practice on their own time and to take note of the amount of practice they complete outside of class.

Active Control Procedure

An active control comparison group will be included in this study. This group will take the form of a health enhancement 'brain health' education program. Topics to be presented and discussed in this group will include healthy sleep, healthy eating, exercise, aging and mental health, dementia risk factors, cognitively stimulating activities, overall safety and health management in older age, and social engagement in late life. Like in the mindfulness program, participants randomized to this active control group will participate in 8 weekly group sessions, each lasting approximately 2 hours in duration. Every effort will be made to keep this group equivalent to the mindfulness group in terms of length of session, participant interaction with each other and with study staff, and other factors like time of day.

Data analysis:

Jacqueline Maye, with the assistance of Dr. Michael Marsiske, will conduct analyses once data have been collected. Multivariate latent change models (e.g. curve of factors or factors of curves) and dual change score models will be used to examine overall trajectory of global attentional change as well as lead-lag relations between affective and cognitive changes across 14 weeks.

4. Possible Discomforts and Risks:

To the best of our knowledge, the physical, psychological, and social risks associated with this study are less than minimal. However, some participants may experience some frustration or worry about their performance during the attention tasks. Participants will be encouraged to simply try their best during these tasks. During the testing session, participants will be asked frequently about their level of comfort; if they become uncomfortable, they will be offered as many breaks as they want.

In addition, some participants may feel uncomfortable completing required activities in front of others in the group. Participants are reminded that their participation is voluntary, that they will be randomly assigned to an experimental group, and selecting to opt out of participating will not affect their medical care or residential status at The Village (if applicable) in any way.

There is, as with all research studies, a slight risk that information about participants could be revealed inappropriately or accidentally (e.g., if there is a forced break-in into our locked offices and locked file cabinets). Although we consider such risk to be less than minimal, depending on the nature of the information, such a release could upset or embarrass participants.

5. Possible Benefits:

There is no guaranteed direct benefit to participants. Repeated re-testing over 14 weeks has been shown in many studies to result in practice-related improvement. Therefore, many participants may be expected to experience improved cognitive scores. In addition, given that mindfulness meditation therapies have been effective at improving mood and coping, some participants may experience mood benefits that would include decreased symptoms of depression, apathy, anxiety, and perceived stress**.**

6. Conflict of Interest:

No financial or ethical conflicts of interest exist or are anticipated by any investigator.