ADRC Participant Access Request

Access Request Goal

No material listed in survey

Principal Investigator

Name	Meghan Mattos, PhD, RN
Title	Assistant Professor
Institution	University of Virginia
Email	ms2bv@virginia.edu (mailto:ms2bv@virginia.edu)
Phone	(703) 919-6864

No Co-PI listed in survey

Study and Theme Details

Hypothesis

We hypothesize that improvements in sleep outcomes will demonstrate maintenance of cognitive functioning and improved insomnia symptoms

Specific Aims

A1. Examine the efficacy of cognitive behavioral therapy for insomnia via the Internet to maintain cognition in individuals with MCI and insomnia.
A2. Test the efficacy of Internet-delivered CBT-I for older adults to improve sleep and quality of life in persons with mild cognitive impairment (PwMCI).
A3. Investigate PwMCI perceptions of Internet-based treatment by investigating ratings of usability, impact, efficacy, satisfaction, and barriers to use.

This study is not related to Deep South disparities

Funding and IRB Details

Funding source - Not yet funded

IRB Contact - Not yet discussed project with IRB

Subject Sample Size and Profile

Sample size by cognitive ability

Normal Controls	# Unlisted

MCI	# Unlisted

Additional inclusion/exclusion details

Inclusion criteria
• =65 years of age
• MCI based on ADC clinician diagnosis and comprehensive neuropsychological testing
• sleep-onset insomnia and/or sleep maintenance insomnia (>30 minutes for at least 3 nights/week for past three months) and the sleep disturbance must cause significant distress or impairment in social, occupational, or other areas of functioning over past 3 months.
• able to read and speak English
• regular access to the Internet and email
• ability to use a computer

Exclusion criteria
• current psychological treatment for insomnia
• initiation of psychological or psychiatric treatment within past 3 months
• current diagnosis of Huntington’s or Parkinson’s disease
• current treatment for hyperthyroidism
• currently undergoing chemotherapy
• asthma or respiratory concerns with night treatment
• chronic pain treated with opioids at night

- epilepsy
- irregular sleep schedules (e.g., night shift work)
- alcohol or drug abuse within the past year
- other untreated sleep disorders

Racial minorities and other stratifcation

This study does NOT test hypothesis on racial disparities

Requested Resources

Human subject involvement

Study procedures

Participation in this study will be about two years. During the two years, the time commitment will include the following:
• Completion of a 45-minute phone screening and informed consent
• Completion of annual ADC neuropsychological test at baseline, 1 year, and 2 years
• Completion of a 45-60 minute online questionnaire at enrollment, nine weeks after the study intervention (post-assessment), 6 months, 12 months, 18 months, and 24 months. At the same time as the questionnaire, completion of two weeks of daily sleep diaries (10 entries, takes <3 minutes to complete). • Completion of the Internet intervention or education activities: Intervention- during the 1st nine weeks, the intervention or education will take approximately 1 - 2 hours every 1-2 weeks. After the 1st nine weeks, there are no specified time requirements for using the program outside of the assessments. Patient education group content will take approximately 1-2 hours and can be accessed throughout the intervention duration (9 weeks).

Study duration

24 months

Compensation

Participants will receive $50 for completing the post-assessment, another $50 for completing the 6-month assessment, $50 for completing the 12-month follow-up, $75 for completing the 18-month follow-up, and $75 for

completing the 24-month follow-up (total = $300).

Statistical support

Statistician has already been consulted - Sarah Ratcliffe, PhD, University of Virginia