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Journal Title: INTERNATIONAL JOURNAL OF AGING & HUMAN DEVELOPMENT

Volume: Volume 97, Number 1

Publisher: SAGE PUBLICATIONS INC | 2022-10-18, Pages 65-80

Type of Work: Article | Post-print: After Peer Review

Publisher DOI: 10.1177/00914150221132163

Permanent URL: https://pid.emory.edu/ark:/25593/w7nrc

Final published version: http://dx.doi.org/10.1177/00914150221132163

HHS Public Access

Author manuscript

Int J Aging Hum Dev. Author manuscript; available in PMC 2023 July 01.

Published in final edited form as:

Int J Aging Hum Dev. 2023 July ; 97(1): 65–80. doi:10.1177/00914150221132163.

Assisted Relaxation Therapy for Insomnia in Older Adults With Mild Cognitive Impairment: A Pilot Study

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Abstract

Insomnia symptoms are prevalent in older adults with mild cognitive impairment (MCI) and can pose treatment challenges. We tested the feasibility, acceptability, and preliminary efficacy of assisted relaxation therapy (ART) to improve insomnia symptoms in community-dwelling older adults with MCI. In this pilot RCT, 25 participants were assigned to intervention or control groups for 2 weeks. The final sample (n = 20) consisted of all Black, primarily female (70%) older adults (mean age 69.10; SD = 7.45) with mean Montreal Cognitive Assessment scores of 21.10 (SD = 2.49). Recruitment was timely; attrition was low (80%). Participants were able to use ART (average use 7.00; SD = 5.07 days). Participants in the ART group improved on Insomnia Severity Index (ISI) (− 7.10; 95% CI [−11.63, −2.55]; p = .004) compared to baseline. There were clinically meaningful mean change scores on ISI for the intervention group compared to the control (− 7.10 vs. − 4.33). Results provide justification for testing ART in a fully powered clinical trial.

Keywords

sleep; insomnia; behavioral intervention; older adults; mild cognitive impairment

Mild cognitive impairment (MCI) is a degenerative condition characterized by a cognitive decline (Petersen et al., 2018). It is estimated that 5 – 37% of older adults have MCI,

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Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

depending on the diagnostic criteria utilized (Sachdev et al., 2015), and people with MCI are at a greater risk for AD or related dementias (Petersen et al., 2018). Insomnia, characterized by difficulty initiating or maintaining sleep, awakening too early, and next day consequences, is the most common sleep disturbance in older adults (Bloom et al., 2009). Insomnia symptoms were reported in up to 40% of older adults in general and can lead to impairment in physical, psychological, and social aspects of life (Stranges et al., 2012). Most notably, older adults with insomnia have an increased risk of developing Alzheimer's disease (AD) and all-cause dementia (Spira et al., 2014). Insomnia symptoms are even more prevalent in people with MCI as almost 60% of people with MCI have insomnia (McKinnon et al., 2014); thus adding the additional risk of AD to an already high-risk population. Therefore, insomnia symptoms in people with MCI are a critical health problem that warrants treatment to preserve cognition and potentially prevent or delay AD.

Several non-pharmacological and pharmacological treatment options exist for insomnia. Non-pharmacologic treatments are preferred over pharmacological agents because they are less likely to be associated with adverse events (Gooneratne et al., 2011). In a mixed methods study (n = 40), 50% of older adult participants had negative beliefs about sleep medication. They did not want to add another medication to their list, felt the medication would not work, wanted to fall asleep naturally, and had fears of grogginess, addiction, and not waking up after taking the sleep medication (McPhillips et al., 2020a). However, in a review of 200 patient records of their first clinician visit for insomnia, 51% were prescribed a sleeping pill and older adults were more likely than younger adults to be offered pharmacological treatment; only 5% of patients were recommended to try cognitive behavioral therapy (Sun et al., 2021). Cognitive behavioral therapy for insomnia (CBT-I) is the most effective treatment for insomnia and includes stimulus control, sleep restriction, relaxation, sleep hygiene, and cognitive restructuring (Geiger-Brown et al., 2015). The core components of CBT-I pose challenges for older adults with MCI. For example, older adults are at a greater fall risk when asked to get out of bed in low-light conditions during stimulus control. In addition, decreased sleep time can lead to daytime sleepiness further impacting cognition during sleep restriction (Baron et al., 2017). Memory impairments also add to the complexity of following CBT-I protocols and contribute to challenges with treating insomnia symptoms.

Taken together, it is critical to develop and test interventions that are accessible, scalable, and cost-effective to improve insomnia in this growing at-risk population. There are very few non-pharmacological therapies for insomnia accessible to older adults with MCI. To address this critical gap in treatment, our objective was to pilot test the feasibility, acceptability, and preliminary efficacy of assisted relaxation therapy (ART) to improve insomnia symptoms in community-dwelling older adults with MCI.

Methods

Design

This study was a pilot randomized controlled trial in community-dwelling older adults with self-reported insomnia symptoms and MCI. Data were collected at baseline and post-

intervention (2 weeks); feasibility and acceptance data were collected throughout the 2-week period.

Setting and Sample

We recruited participants from one urban Program of All-Inclusive Care for Elders (PACE) from October 2019 to February 2020. The study was approved by the Institutional Review Board (IRB) at the University of Pennsylvania and the hospital system IRB. Inclusion criteria were: aged 55 and older; had MCI [Montreal Cognitive Assessment (MoCA) Score between 17 and 25]; had self-reported insomnia symptoms (trouble falling asleep or trouble staying asleep); lived in the community; and spoke English as a primary language.

Data Collection

PACE staff generated a list of eligible participants and asked potential participants: 1) if they were interested in a research study and 2) if they had trouble falling or staying asleep. Participants who said yes were taken to a separate private room and introduced to the research study staff. During the screening, a member of the study team administered the MoCA to ensure eligibility and went over the consent form. Eligible participants were assigned to groups after signing the consent form, by 1:1 simple randomization using consecutive sealed envelopes. A researcher external to the project created the randomization table and placed allocation assignments in sealed, numbered envelopes. Participants were not explicitly told what group they were in.

Data were collected at baseline, throughout the treatment period, and post-intervention. All data collection visits were scheduled when the participant already planned to be at the center and took place in a private room. Visit 1 took about 1 h and began immediately the following consent or at a subsequent scheduled visit, depending on the participant's preference. During the visit, the participant completed study questionnaires and received instructions for using the tablet and completing the sleep diary. All questionnaires were read to participants and responses were entered directly into REDCap by a member of the study team. Participants also received instructions for using the tablet. We called or had in-person meetings at the center 2–3 times, based on the participants' preferences, to discuss technology issues, sleep diary completion, and ART usage. Visit 2 took about 45 min; participants completed the same questionnaires as a baseline in addition to a usability questionnaire regarding the tablet and answered questions related to acceptance. Participants returned the tablets and received a $50 gift card for their time.

Assisted Relaxation Therapy (ART) Intervention

The 2-week ART intervention involved using a wireless-enabled device (i.e., tablet) to implement a breath-based relaxation intervention coupled with a physical anchoring task (tapping). Participants were instructed to place the tablet next to their pillow and tap the tablet screen every time they exhaled while falling asleep in bed. The software was configured to work in a low light mode to avoid light from the tablet disrupting the sleep environment. The anchoring task facilitates redirecting attention to the breathing cycle to identify the point at which exhalation ends and inhalation begins. Participants were asked to focus on their breathing, effectively engaging in thought redirection and disengaging from

anxiety-provoking cognitions. Participants could tap anywhere on the screen. Each tap on the screen was recorded and sent to a central database that contained the participant ID and time stamp; no personal identifiers were stored on the database. The next morning, the research staff could access the database record of tapping to objectively confirm the participant was adherent to the intervention and assess how long it took them to fall asleep while using the intervention the prior night. If the participant was non-adherent, the participant could be contacted by phone or in person at the center to encourage adherence.

ART has several benefits: (1) the breathing cycle occurs every 6–10 s and thus complex, arousal-promoting metacognitive processes are difficult to sustain since participants must return their attention to their breathing cycle frequently; (2) the task is simple enough that it can be taught in 5–10 min; (3) the intervention can be implemented by participants, in their own bed, without the need to get out of bed; (4) tapping allows for real-time adherence monitoring; and (5) tapping can be done universally post-research study participation. For example, participants could continue the intervention after we collected the tablets by tapping their pillow or their bed. The tablets were only used for fidelity monitoring.

We chose a 2-week time frame to determine feasibility and acceptability for a few reasons. First, early-term use (1–3 weeks) of technology predicts long-term use (Mitzner et al., 2019). Furthermore, our preliminary open-label data (n = 14) showed ART improved insomnia symptoms in older adults within 1 to 2 weeks (unpublished). Therefore, we were confident that 2 weeks would be long enough to meet our objectives.

Intervention Group

Study participants in the intervention group received a tablet device which included the ART software, a sleep diary, and sleep hygiene educational content viewable on a pdf document. They were instructed how to use the tablet during the baseline study visit and encouraged to view the installed educational content. They were asked to complete the daily sleep diary and use the ART software when they were going to sleep and if they awoke during the night for 2 weeks. ART usage was tracked using the fidelity component of the software as previously described.

Control Group

Participants in the control group also received a tablet with the sleep hygiene educational content and sleep diary but the ART program was not available to them. Sleep hygiene educational content represents an active control intervention and is recommended as part of the initial treatment of insomnia based on an NIH guide for sleep education (Patlak, 2005). This approach provided staff and technology interaction/attention that was comparable to the intervention arm. It has been used as a placebo comparator for insomnia treatment studies and has low attrition rates (Ritterband et al., 2017). Control group participants were also asked to complete electronic sleep diaries to monitor sleep/wake patterns.

Demographic and Clinical Characteristics—Demographic data included age, sex, and race. Clinical characteristics consisted of chronic medical conditions extracted from the electronic medical record. We used the MoCA to assess cognitive function. The MoCA is

a 10–15-min cognitive screening tool that assesses attention and concentration, executive function, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation (Nasreddine et al., 2005). Scores are summed with a total possible score of 30 points; 26 or above is the threshold for normal. We included participants who scored between 17 and 25 to indicate MCI (Saczynski et al., 2015). The research team was properly trained to administer the MoCA.

Feasibility—Our feasibility outcomes were enrollment and retention rates. Enrollment rates were calculated as the ratio of those who consented to those contacted and retention rates were defined as the ratio of those who completed the study to those who consented. We also examined adverse events and equipment status.

Acceptability—Acceptance outcomes were participant usage rates of ART, ease of use of various software components measured by the System Usability Scale (SUS), and two questions related to credibility. Participant usage rates were calculated as the ratio of nights using ART to the total nights enrolled in the study. The SUS is the most widely used user perception tool for software/devices (Brooke, 1996; Evans et al., 2016). Scores are summed, ranging from 0 to 100, and categorized as follows: > 80.3 is excellent, 68.1 – 80.3 good, 68 okay, 51 – 67.9 poor, and < 51 awful. We asked two credibility questions: (1) How much improvement do you think occurred (range from 0% to 100%)? and (2) How confident would you be in recommending this treatment to a friend who experiences similar problems (1–9; 1 = not at all; 5 = somewhat; 9 = very)?

Preliminary Efficacy—The Insomnia Severity Index (ISI) was our primary outcome for preliminary efficacy. There are seven items that evaluate: (a) the severity of sleep-onset, (b) sleep maintenance, (c) early morning awakening problems, (d) satisfaction with current sleep pattern, (e) interference with daily functioning, (f) noticeability of impairment attributed to the sleep problem, and (g) level of distress caused by the sleep problem (Morin, 1993). The items are rated on a 5-point Likert scale, where 0 indicates no problem and 4 indicates a very severe problem. The scores are summed; the total severity score ranges from 0 to 28. The ISI is a valid and reliable measure of insomnia symptoms (Gagnon et al., 2013; Morin et al., 2011).

Secondary sleep outcomes included Pittsburgh Sleep Quality Index (PSQI) and Epworth Sleepiness Scale (ESS). The PSQI measures seven domains for the prior month: (1) sleep quality; (2) latency; (3) duration; (4) habitual sleep efficiency; (5) use of sleep medications; 6) disturbance; and (7) daytime dysfunction. A global score (0 – 21 points) is obtained by summing the scale domain scores. Higher scores (≥ 5) indicate poorer global sleep quality. The PSQI has been validated in older adults and the global PSQI score was internally consistent in both women and men (α = 0.78 and 0.69, respectively) (Beaudreau et al., 2012; Spira et al., 2012). The ESS measures daytime sleepiness; participants rate the likelihood of falling asleep in eight situations using a 4-point Likert scale ranging from never dozing (0) to a high chance of dozing (3). Scores are summed, with higher scores indicating higher sleepiness, or categorized as not sleepy (< 11) or sleepy (≥ 11). The ESS is internally consistent in older women and men (α = 0.76 and 0.70, respectively) (Beaudreau et al., 2012; Spira et al., 2012).

Statistical Analysis—Descriptive statistics were used to characterize the sample. Continuous variables were presented as mean and standard deviation (SD) and were compared between groups using the 2-sample *t*-tests. Categorical variables were presented as frequencies and percentages and were compared using the χ^2 or a 2-tailed Fisher exact test (when more than 20% of cells had less than five cases).

No a priori power analysis was conducted; a sample size of 20 was chosen to be sufficient to give us enough information to determine feasibility and acceptability based on the team's previous experience with this population. Paired *t*-tests were used to assess within-group differences in sleep outcomes between baseline and postintervention. Changes scores between baseline and intervention were calculated; the difference in changes scores between the two groups was examined using independent *t*-tests. Significance for all analyses was based on $p < .05$. All data were complete and analyzed using STATA v.17.

Results

Descriptive

Our final sample ($n = 20$) was balanced on all demographic and clinical variables and consisted of all Black, primarily female (75%), and older adults (mean age 69.10 ± 7.45) with mean Montreal Cognitive Assessment scores of 21.10 ± 2.49. The most common medical conditions included depression (60%), obesity (60%), anxiety (45%), and Type II diabetes (40%). Only 30% of the sample had a diagnosis of insomnia in their medical record (see Table 1). At baseline, all participants had insomnia symptoms (ISI score 15.35; $SD = 4.26$) and poor sleep quality (PSQI score 12.40; $SD = 3.83$); half had daytime sleepiness (ESS score 10.45; $SD = 4.55$).

Feasibility

Our enrollment rate was 43%; we screened 58 people for eligibility and 25 signed consent. Our retention rate was 80%; five participants dropped out. Three participants were randomized but never started the study because they were no longer interested ($n = 2$) or were unable to be reached ($n = 1$). Two participants started the study but became frustrated with the tablet's usability, such as connecting to the internet and logging into the application. See Figure 1. All tablets were returned and no adverse events occurred.

Acceptability

Intervention (ART) usage ranged from 0 days to 14 days; the average use was 7 days ($SD = 5.07$). The ease of use of the application on the tablet was relatively poor overall; mean SUS scores were 65.00 ($SD = 23.99$). However, we were able to learn from the first half of the participants and make updates to the application for the second half of the participants. The SUS scores were "poor" in the first half of the participants (60.00; $SD = 23.36$) but increased by two categories to "good" (70.56; $SD = 24.81$) ($p = .18$) after we made application updates. Updates included moving our study to the top of the dropdown menu to facilitate participants' logging in; decreasing password requirements to less characters and symbols; allowing the participants to see the password they were typing; allowing the password to be stored; increasing the time for logging participants out to 30 days so that they would not

need to re-enter their password. Furthermore, four of the first five older adults in our study had trouble connecting to their home Wi-Fi or did not have home Wi-Fi (no difference by group). We sent the two participants without Wi-Fi home with a cellular data jetpack, but they still had connectivity issues that we needed to troubleshoot. Therefore, we switched to all cellular data tablets to eliminate any Wi-Fi connection issues.

There were no differences between groups on the two credibility questions. On average, participants thought 60% improvement in their sleep occurred; 70% of participants said at least 50% improvement occurred. Furthermore, 95% of participants were very likely to recommend the therapy to a friend (mean 8.65 ± 0.99); one person was somewhat likely.

Preliminary Efficacy

When examining within-group changes, participants in the intervention group had statistically significant improvements in ISI (−7.10; 95% CI [−11.63, −2.55]; $p = .004$) and PSQI scores (−4.46; 95% CI; [−8.72, −0.19]; $p = .04$) from baseline. Participants in the control group had significantly improved ISI (−4.33; 95% CI; [−8.00, −0.66]; $p = .02$) and nearly significant PSQI scores (−3.00; 95% CI [−6.04, 0.04]; $p = .05$) at posttest. There were no changes in ESS at posttest in either group. Compared with the control group, the ART intervention group showed greater and clinically meaningful improvement in ISI (−7.10 vs. −4.32; $p = .166$). There were no differences between the intervention group and the control group on PSQI or ESS scores. See Table 2.

Discussion

We pilot-tested a 2-week ART intervention for insomnia symptoms in community-dwelling older adults with MCI and evaluated the feasibility, acceptability, and preliminary efficacy. We found that the intervention was feasible and acceptable. Recruitment was timely and attrition was low. We made real-time changes to the application to make it more user-friendly for older adults. Participants in both the intervention and control groups improved on subjective ratings of insomnia; the intervention group showed greater improvement. Participants in the intervention group reported better subjective sleep quality ratings, but there were no statistically significant differences between groups. Neither group improved on daytime sleepiness scores. Our preliminary findings provide promising feasibility and acceptability data and warrant further efficacy testing of the ART intervention in a larger sample of older adults with MCI.

This non-pharmacological intervention to improve insomnia symptoms was both feasible and acceptable. Participants were recruited from a single site; recruitment was timely and efficient. Staff at the facility were cooperative and ensured participants were ready for study visits while on-site. Retention was good; we lost a few participants who consented but never started the study and two that became frustrated with the tablet. Primarily, in the final visit, participants were happy with their self-identified individual improvements and viewed the study as effective in helping their insomnia symptoms.

The mobile device application was challenging for older adults at the beginning of the study. Challenges included difficulty connecting to the internet, and fine motor/dexterity issues

related to typing complex passwords and locating our study from the dropdown menu. We were able to make refinements to the application to increase its usability: moving our study to the top of the dropdown menu for participants to log on easier; decreasing password requirements to less characters and symbols; allowing the participants to see the password they were typing; allowing the password to be stored; increasing the time for logging participants out to 30 days so they did not have to re-enter the password. Furthermore, we found that the older adults in our study did better with cellular data tablets, rather than Wi-Fi-only tablets. The older adults with MCI in our study viewed technology as favorable and could use it, as long as it was designed with the end-user in mind and optimized to meet their needs. Our study points to the importance of selecting mobile device applications with features that are most appropriate for older adults with MCI and monitoring usability throughout the trial (Contreras-Somoza et al., 2021).

ART and sleep hygiene education were both effective at improving subjective insomnia symptoms. Participants in the intervention group improved by over 7 points on the ISI; a 6-point decrease in ISI is considered to be a clinically significant improvement (Yang et al., 2009). ART warrants additional testing for clinical utility in improving insomnia symptoms in older adults with MCI. Prior studies suggest that relaxation therapy and mindful meditation are effective in improving sleep in older adults (Black et al., 2015; Hazlett-Stevens et al., 2019). We hypothesize that one potential mechanism of action of ART is through thought redirection that prohibits arousal promoting metacognitive processes. In other words, people focus on their breathing rather than potential worries and rumination that would otherwise impact their ability to fall asleep. Similar to ART, it has been suggested that mindfulness meditation may attenuate autonomic responses and increase relaxation through control over the autonomic nervous system (Black et al., 2015).

Participants in the intervention group had significant improvements in subjective sleep quality; however, there were no significant differences between groups. Older adults with MCI who were randomized to the control group may have had more insight into their sleep habits and patterns and may have also benefited from the time spent with the research team. Although sleep hygiene principles such as having a set bedtime and wake time are grounded in evidence (Chaput et al., 2020), there is limited evidence supporting the use of sleep hygiene alone to improve insomnia symptoms (Edinger et al., 2021). One explanation is that the etiology for insomnia symptoms may or may not be linked to poor sleep hygiene. That is, sleep hygiene may work for people with poor sleep habits, and work less for people with clinically significant insomnia (Irish et al., 2015). Taken together, sleep hygiene practices should be promoted to improve sleep health in all older adults, but warrant further testing to determine who may benefit the most.

Neither the intervention nor control group improved daytime sleepiness scores. This was not surprising, as only half of our sample reported daytime sleepiness at baseline. These results align with a mixed method study of older adults where only 25% of the sample reported daytime sleepiness despite having nocturnal sleep disruption (McPhillips et al., 2020b). Low reports of daytime sleepiness could be related to limitations in the ESS questionnaire, older adults' ability to sense sleepiness, or age-related health adjustments and adaptation

(McPhillips et al., 2020b). In order to improve the daytime consequences of insomnia symptoms, the intervention may need to be longer than 2 weeks.

Our study provides positive preliminary findings to justify testing ART in a larger sample of older adults with MCI. ART warrants additional testing, and if efficacious, may be more suitable for older adults with MCI compared to traditional CBT-I treatment. For example, ART is simple enough that it can be introduced and taught to someone with MCI in less than 10 min. In addition, participants can easily learn the technique without leaving their own bed, thus decreasing their chance of getting up and falling. Furthermore, we were able to contact participants who were not using the intervention to troubleshoot and promote adherence in real-time. This is an innovative solution to be able to treat insomnia symptoms in people with MCI and addresses the limitations of current treatment options. We were able to troubleshoot technology issues and implement real-time solutions. We found that regular troubleshooting calls or visits were beneficial for the participants and reinforced how to use the technology. While some participants still had problems, many participants left the study with a much better understanding of how to use the technology.

Limitations

Although this pilot shows promising results, the small and homogenous sample limits our ability to make generalizable conclusions. That said, our sample consisted of all Black older adults with MCI, who are often underrepresented in research. Second, we were not fully powered to detect differences between groups, rather we were able to look for clinically meaningful differences. Third, we did not measure time spent with intervention and control groups, and while we would anticipate them to be similar, the differences between groups could confound our results. Lastly, we did not measure if either group made behavioral changes based on the sleep hygiene education. Despite these limitations, our study opens the opportunity for testing a novel way to improve insomnia symptoms in older adults with MCI.

Conclusion

ART is both feasible and acceptable for older adults with MCI. Preliminary results provide justification for testing ART in a fully powered clinical trial with a diverse sample, as it could greatly affect how we treat insomnia in this at-risk group. Future studies should ensure both groups are matched on attention and control, as well as explore the optimal dose of ART therapy for sustained effects.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by the Frank Morgan Jones Fund, University of Pennsylvania School of Nursing Faculty Grant Award and National Institute of Nursing Research (K23NR018487).

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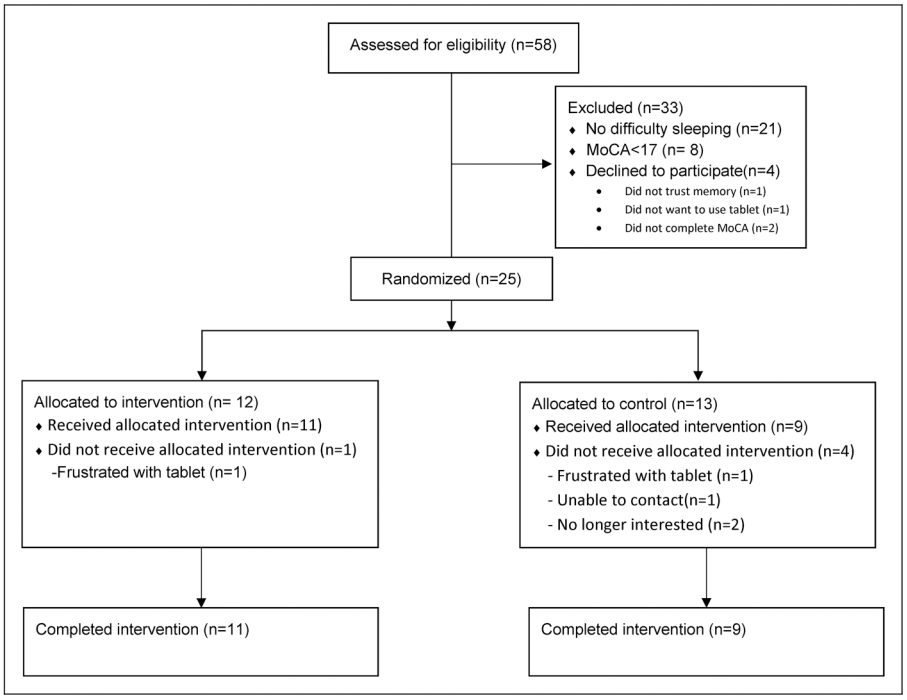

Figure 1.
Consort.

Table 1.

Demographics and Clinical Characteristics.

Variable	Total sample (*n* = 20) *n* (%) or *M* ± *SD*	Intervention group (*n* = 11) *n* (%) or *M* ± *SD*	Control group (*n* = 9) *n* (%) or *M* ± *SD*	*p*-value
Age	69.10 ± 7.45	70.55 ± 7.41	67.33 ± 7.53	0.35
Gender				
Female	14 (70)	8 (72.72)	6 (66.67)	1.00
Male	6 (30)	3 (27.27)	3 (33.33)	
Black or African American	20 (100)			
Montreal Cognitive Assessment	21.10 ± 2.49	21.64 ± 2.29	20.44 ± 2.70	0.30
Depression	12 (60%)	7 (63%)	5 (56%)	1.00
Anxiety	9 (45%)	5 (46%)	4 (44%)	1.00
Obesity	12 (60%)	6 (55%)	6 (67%)	0.67
Type II Diabetes	8 (40%)	5 (46%)	3 (33%)	0.67
Hypertension	9 (45%)	5 (46%)	4 (44%)	1.00
Insomnia	6 (30%)	1 (9%)	5 (56%)	0.05
Obstructive Sleep Apnea	7 (35%)	4 (36%)	3 (33%)	1.00
Insomnia Severity Index	15.35 ± 4.26	14.18 ± 4.12	16.78 ± 4.21	0.18
Pittsburgh Sleep Quality Index	12.40 ± 3.83	11.91 ± 4.83	13.00 ± 2.24	0.54
Epworth Sleepiness Scale	10.45 ± 4.55	10.36 ± 5.32	10.56 ± 3.71	0.93

Table 2.

Within and Between Group Changes.

	Within group						Between groups		
	Intervention			Control					
Sleep outcomes	***MD***	**(95% CI)**	***p***	***MD***	**95% CI**	***p***	***MD***	**95% CI**	***p***
Insomnia Severity Scale	−7.10	(−11.63, −2.55)	<.01	−4.33	(−8.00, −0.66)	.02	−2.76	(−6.77, 1.25)	.166
Pittsburgh Sleep Quality Index	−4.46	(−8.72, −0.19)	.04	−3.00	(−6.04, 0.04)	.05	−0.73	(−4.06, 2.61)	.65
Epworth Sleepiness Scale	−2.81	(−6.93, 1.29)	.17	−1.56	(−5.13, 2.01)	.37	−1.15	(−4.86, 2.56)	.52

Abbreviations: MD = mean difference; CI = confidence interval.