

## **Trial Design**

This study is a randomized controlled trial that tests the efficacy of brief behavioral sleep therapy (BBT-I) in comparison to a self-monitoring and attention control (SMAC) group in treating insomnia in older adults. University of Florida's Institutional Review Board (UF IRB-02) approved the protocol, and all subjects signed informed consent forms prior to participating. This trial protocol is registered on [clinicaltrials.gov](https://clinicaltrials.gov) (NCT: 02967185). Data collection began in 2005 and the last follow-up was conducted in 2010. SMAC participants were offered the treatment following completion of their follow up assessments. Participants received the treatment and parking on the UF campus at no charge.

## **Participant Recruitment, Screening, and Randomization**

Based on a priori power analysis, a sample size of 62 was determined to allow for adequate statistical power for detecting significant effects on primary and secondary outcomes. Sixty-two older adults with insomnia (65 years or older) were recruited from Gainesville and surrounding areas through newspaper (including the Senior Times-a publication targeting seniors in Gainesville/Ocala, FL) and other community advertisements for treatment of late life insomnia.

Participant screening occurred in three stages. First, the preliminary telephone screening was conducted. This consisted of a 20 minute, structured interview to address inclusion and exclusion criteria (excepting BDI-II, GDS, & MMSE which were assessed in the second stage), rule-out other sleep disorders, and establish a probable diagnosis of insomnia. Interested and eligible individuals were then scheduled for the second screening stage. The second stage consisted of an in-depth clinical interview conducted at the first neuropsychological assessment. At this time additional criteria were used to rule out psychiatric causes of insomnia (e.g., clinical

interview, GDS, and BDI-II), general medical factors in insomnia, and severe cognitive impairment (MMSE). High scores on the GDS and BDI-II did not result in automatic disqualification. Instead, high scores prompted additional probing about depression and/or anxiety symptoms, and individuals meeting DSM-IV criteria for an anxiety disorder were excluded. Appropriate referrals were for excluded individuals. The third and last stage of the screening process confirmed the presence of insomnia and ruled out other sleep disorders. Baseline sleep diaries were used to confirm the validity of the sleep complaint. The sleep diary data needed to demonstrate sleep onset or wake time during the night >30 minutes at least six times during the two weeks. Ambulatory monitoring of blood oxygen saturation and respiration (Medcare Diagnostics) was conducted in each participants' home for one night during the two-week baseline period to rule out sleep apnea. Periodic limb movement disorder was ruled out using actigraphy, ambulatory monitoring, baseline sleep diaries, and clinical interview.

Advanced doctoral students in UF's APA-accredited doctoral programs in clinical and counseling psychology conducted all screening interviews using structured and semi-structured instruments. The senior author (CSM) supervised all screening interviews and confirmed final insomnia diagnoses. Simple randomization using computer-generated random numbers was conducted by the study's project coordinator to assign participants to either BBT-I or SMAC.

### **Treatment Contents and Fidelity**

Participants in BBT-I each received a manualized, four-week brief behavioral treatment program for insomnia that was individually administered over four weekly, one-hour sessions by three doctoral trainees in UF's American Psychological Association (APA) accredited counseling psychology program. They were trained and supervised by the senior author (CSM), a licensed clinical psychologist board certified in behavioral sleep medicine by the American

Board of Sleep Medicine. BBT-I included four established behavioral sleep techniques (i.e., sleep hygiene, stimulus control, sleep restriction, relaxation) shown to be effective for treating late life insomnia (Morin et al., 2006). Participants were each given a treatment workbook containing written instructions of each technique and associated home practice assignments and daily compliance logs. To ensure that treatment was delivered as intended, the treatment integrity procedures recommended by Lichstein and associates (1994) were followed (Lichstein, Riedel, & Grieve, 1994). To ensure adequate comprehension of treatment, participants were asked about their experience with home practice of techniques and procedural modifications were adopted as necessary.

## References

- Lichstein, K. L., Riedel, B. W., & Grieve, R. (1994). Fair Tests of Clinical-Trials - a Treatment Implementation Model. *Advances in Behaviour Research and Therapy*, *16*(1), 1-29.  
doi:Doi 10.1016/0146-6402(94)90001-9
- Morin, C. M., Bootzin, R. R., Buysse, D. J., Edinger, J. D., Espie, C. A., & Lichstein, K. L. (2006). Psychological and behavioral treatment of insomnia:update of the recent evidence (1998-2004). *Sleep*, *29*(11), 1398-1414.