

Multi-center Trial to Improve Nocturia and Sleep in Older Adults

NCT06110091

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|-------------------|---------------------------|
| Status | RECRUITING |
| Phase | Not Applicable |
| Sponsor | Atlanta VA Medical Center |
| Enrollment | 192 participants |

Key Eligibility Criteria

Inclusion (4)

- Age \geq 60 years
- Average of \geq 2 episodes per night of nocturia on the International Consultation on Incontinence Questionnaire-Overactive Bladder Module (ICIQ-OAB) questionnaire
- Insomnia Severity Index \geq 7
- Able to attend weekly study visits

Exclusion (16)

- Prior cognitive behavioral therapy for insomnia
 - Presence of bipolar disorder
 - Significant cognitive impairment as measured by a score $<$ 20 on the Mini-Mental State Exam
 - Sleep disturbance better explained by another sleep disorder such as restless legs syndrome, narcolepsy, insufficient sleep syndrome, or circadian rhythm sleep-wake disorders
 - Untreated sleep-disordered breathing (respiratory event index \geq 15 plus • Epworth Sleepiness Scale \geq 10 or respiratory event index \geq 30. Note that participants with treated sleep-disordered breathing will not be excluded)
- ... and 11 more (see full listing online)

Locations (2 total)

VA Greater Los Angeles Healthcare System, Los Angeles, California, United States
Atlanta VAHCS, Atlanta, Georgia, United States