Effect of Behavioral Sleep Intervention on Lower Urinary Tract Symptoms in Older Women

NCT05604222

Status	RECRUITING
Phase	Phase 4
Sponsor	Shachi Tyagi
Enrollment	120 participants

Key Eligibility Criteria

Inclusion (4)

- ambulatory women aged 60+ years
- urgency incontinence or urge-predominant mixed incontinence (able to differentiate between stress symptoms-cough, laugh, exercise-and leakage following the sudden onset of a strong urge to void that is difficult to defer during questioning on telephone screening) occurring at least five times weekly for e 3 months despite treatment for reversible causes
- nocturia e2 each night
- subjects with current or previous use of anticholinergic medications will be considered for the study if willing to go through a washout period of at least 4 weeks of duration

Exclusion (12)

- contraindication to any of the drugs used (e.g., mirabegron, prophylactic antibiotics)
- cognitive impairment (MOCA score \<24 or inability to accurately complete a voiding diary, perform a 24-hour pad test, reliably take daily medication, or comply with fMRI testing)
- prior treatment with intradetrusor onabotulinum toxin or sacral neuromodulation.
- spinal cord injury; history of pelvic irradiation, advanced uterine or bladder cancer; multiple sclerosis
- urethral obstruction; urinary retention \[PVR \>200 ml\]

... and 7 more (see full listing online)

Locations (1 total)

University of Pittsburgh, Pittsburgh, Pennsylvania, United States