

Comparing Digital Therapy, Trazodone, and Daridorexant for Menopause-Related Insomnia Symptoms

NCT07136415

Status	RECRUITING
Phase	Phase 4
Sponsor	Brigham and Women's Hospital
Enrollment	1,000 participants

Key Eligibility Criteria

Inclusion (6)

- Age 40-62 years
- Assigned female sex at birth
- In peri- or early menopause, following the STRAW criteria of self-report of irregular menstrual cycle or within 5 years from the last menstrual period. When menstrual markers are absent or unreliable (e.g., hysterectomy; endometrial ablation), participants must be older than 45 years old and report hot flashes
- Insomnia severity index score ≥ 10 at screening
- Insomnia started or worsened during peri- or early menopause
- ... and 1 more (see full listing online)

Exclusion (12)

- Untreated, previously diagnosed severe sleep apnea (self-report; chart review; clinician assessment)
- Untreated, previously diagnosed moderate-severe restless legs syndrome (self-report; chart review)
- Severe daytime sleepiness (Epworth Sleepiness Scale ≥ 15) at screening
- Sleep schedule issues that would impact effectiveness of the interventions (e.g., night shift workers with ≥ 1 night shift/week; main sleep period outside of 8pm - 11am)
- Regular use of hypnotics ≥ 2 nights/week
- ... and 7 more (see full listing online)

Locations (5 total)

Brigham and Women's Hospital, Boston, Massachusetts, United States
Henry Ford Medical Center, Novi, Michigan, United States
Atrium Health Wake Forest Baptist, Winston-Salem, North Carolina, United States
... and 2 more locations