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Helping older adults with an overactive bladder protect their brain health by improving sleep

Submission date	Recruitment status	[_] Prospectively registered
10/04/2026	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/04/2026	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
13/04/2026	Urological and Genital Diseases	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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Study information

Scientific Title
A comprehensive intervention study plan for cognitive vulnerability in elderly patients with overactive bladder based on sleep-lymphoid pathway

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/04/2024, Medical Ethics Committee of the Wuxi No.2 People’s Hospital, Jiangnan University Medical Center (No.68 Zhongshan Road, Liangxi District, Wuxi City, Jiangsu Province, Wuxi, 214000, China; +86 15152220089; 9862022074@jiangnan.edu.cn), ref: 2024 Y-26

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control

Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Overactive bladder syndrome

Interventions
Participants will be randomized in a 1:1 ratio to either the control group (standard behavioral management) or the intervention group (standard behavioral management plus a comprehensive mechanism-targeted intervention) using a centralized, computer-generated block randomization scheme stratified by study center, sex, baseline Overactive Bladder Symptom Score (OABSS), and baseline Montreal Cognitive Assessment (MoCA).

Control Group: Standard Behavioral Management
1. Bladder training.
2. Delayed voiding and urgency suppression techniques.
3. Fluid intake and caffeine management.
4. Nocturnal fluid management.
5. Voiding diary–based feedback.
6. Basic pelvic floor and lifestyle education.

Intervention Group: Integrated Mechanism-Targeted Intervention
1. Structured Aerobic Exercise Module
Five sessions per week, 30–40 minutes per session, at moderate intensity, for 24 weeks. Recommended activities include brisk walking, stationary cycling, or elliptical training. Exercise intensity is prescribed at 50%–70% of heart rate reserve (HRR) or a Borg Rating of Perceived Exertion (RPE) of 11–13.
2. Sleep Optimization Module
Standardized management targeting nocturia-related sleep disruption, including fixed sleep–wake schedules, pre-sleep fluid restriction, stimulus control before bedtime, sleep hygiene education, and strategies for managing nocturnal awakenings.
3. Adherence Enhancement Module
Adherence is reinforced through mobile app or paper-based check-ins, biweekly follow-up visits, and wearable device monitoring of step counts and exercise duration, with adherence supervision provided by research nurses.

Intervention Type
Behavioural

Primary outcome(s)
1. Health-related quality of life associated with overactive bladder measured using Overactive Bladder Questionnaire Health-Related Quality of Life (OAB-q HRQoL) total score at Baseline and 24 weeks post-randomization

Key secondary outcome(s))
1. Overactive bladder symptoms, nocturia, and sleep quality measured using composite assessment including: Overactive Bladder Symptom Score (OABSS), Pittsburgh Sleep Quality Index (PSQI) total score, mean number of nocturnal voids per night (bladder diary) at baseline, 24 weeks, and 52 weeks

2. Global cognitive function measured using composite z-score derived from a standardized neuropsychological test battery assessing memory, attention, and executive function at baseline, 24 weeks, and 52 weeks

3. Glymphatic system function measured using diffusion MRI–derived biomarkers, including: Free water (FW) fraction and ALPS (Analysis along the Perivascular Space) index at baseline and 24 weeks

4. Sustained effects of the intervention on clinical and cognitive outcomes measured using maintenance of improvements in OAB-q HRQoL, symptom measures, sleep quality, and cognitive composite scores at 52 weeks post-randomization

5. Mediation effects of sleep and glymphatic function on cognitive outcomes measured using longitudinal mediation analysis evaluating indirect effects of changes in sleep quality (PSQI) and diffusion MRI–derived glymphatic biomarkers (FW and ALPS index) on cognitive composite scores at baseline to 24 weeks, with extension to 52 weeks

6. Incidence of adverse events measured using number and proportion of participants experiencing adverse events, including falls and musculoskeletal injuries, classified by severity and relatedness at baseline to 52 weeks

Completion date
30/04/2026

Eligibility

Key inclusion criteria
1. Age ≥60 years old
2. Idiopathic OAB that meets ICS/ guidelines definitions
3. OAB symptoms persist for ≥3 months
4. OABSS ≥6
5. Nocturia ≥2 times per night
6. PSQI ≥6
7. For people with cognitive fragility but not dementia, MoCA 20 - 27 is recommended
8. Willing to complete the 24-week intervention and follow-up and sign informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 years

Upper age limit
90 years

Sex
All

Total final enrolment
110

Key exclusion criteria
1. Lower urinary tract symptoms (LUTS) clearly caused by neurological disorders
2. Previous diagnosis of dementia or significant functional dependence
3. Significant bladder outlet obstruction or significant residual urine
4. Organic diseases such as acute urinary infections, bladder tumors, and bladder stones
5. Uncontrolled severe depression/anxiety
6. Confirmed moderate-to-severe obstructive sleep apnea that is untreated
7. Recent use of medications that may significantly affect cognition or sleep and cannot be stabilized
8. Contraindications to MRI or inability to complete the exercise intervention

Date of first enrolment
22/04/2024

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
China

Sponsor information

Organisation
Wuxi No.2 People's Hospital

ROR
https://ror.org/0399zkh42

Funder(s)

Funder type

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request