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Efforts to overcome orthostatic hypotension in schizophrenia patients

Submission date	Recruitment status	[_] Prospectively registered
11/10/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/10/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/10/2025	Circulatory System	[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Orthostatic hypotension (OH) is a common adverse effect of antipsychotic medication that increases the risk of falls and injury among psychiatric patients. Due to limited options for pharmacological adjustment, non-pharmacological interventions are needed. This study aims to evaluate the effectiveness of leg exercise and water consumption interventions in preventing or reducing the incidence of orthostatic hypotension among schizophrenia patients on antipsychotic therapy.

Who can participate?
Participants diagnosed with schizophrenia and identified as experiencing OH in several psychiatric hospitals in Indonesia.

What does the study involve?
Quasi-experimental study with four groups:
- Group A: Control (no intervention)
- Group B: Leg Exercise + Water
- Group C: Leg Exercise only
- Group D: Water only

Each group consisted of 45 participants.
Leg Exercise: Performed in a supine position using a 3 kg foot band. Included hip, knee, and ankle flexions held for 25 seconds each, performed alternately on the right and left leg.
Water Consumption: Adequate fluid intake monitored over 24 hours using labeled water bottles with volume indicators.
Outcome Measurement
Blood pressure was measured in a supine position after 5 minutes of rest and during standing at minutes 1, 3, 5, and 10. Measured daily from Day 1 to Day 5.
Data Analysis was used to assess within-group and between-group differences.

Study Timeline
- Day 0: Screening and group allocation
- Days 1–5: Intervention and daily evaluation
- Day 5: Final assessment

What are the possible benefits and risks of participating?
The benefit of this intervention is to help address recurrent orthostatic hypotension through leg exercises and hydration according to protocol. There are no known downsides or negative effects from this intervention.

Where is the study run from?
Binawan University, Indonesia.

When is the study starting and how long is it expected to run for?
June 2023 to April 2024

Who is funding the study?
Investigator-initiated and funded

Who is the main contact?
Mrs Sari Binawan, sari@binawan.ac.id

Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effectiveness of leg exercise and hydration interventions on orthostatic hypotension among schizophrenia patients in mental hospital

Study objectives
Leg exercise and water consumption are effective in reducing the incidence of orthostatic hypotension

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/06/2023, Health Research Ethics Committee of Institute of Research and Community Service University of Catholic Atmajaya (Jalan Jenderal Sudirman 51, Jakarta, 12930, Indonesia; +62-21-5703306; lppm@atmajaya.ac.id), ref: 0006P/III/PPPE.PM.10.05/06/2023

Study design
Quasi-experimental design with four groups

Primary study design
Interventional

Study type(s)
Treatment, Safety

Health condition(s) or problem(s) studied
Patient with schizophrenia with experiment orthostatic hypotension

Interventions
Orthostatic hypotension is defined as a significant drop in blood pressure upon standing, specifically a decrease in systolic blood pressure of at least 20 mmHg or diastolic blood pressure of at least 10 mmHg within three minutes of standing.

A quasi-experimental study with four groups was conducted in a psychiatric hospital. A total of 180 patients diagnosed with schizophrenia were enrolled and assigned into four equal groups (n = 45): control, leg exercise, water consumption, and combined intervention. Interventions were conducted over five consecutive days. Blood pressure was measured at supine and at 1, 3, 5, and 10 minutes after standing.

Intervention Procedures
Group A (Control): No intervention, follow the routine activities and management nursing care in the wards.

Group B (Leg exercise + water consumption)
Participants received a combination of leg exercise and water consumption interventions:
Water Consumption: Each participant was provided with a water bottle labeled with their name and water volume indicators. Water intake was monitored over 24 hours to ensure adequate hydration. Once adequate hydration was confirmed, the participant proceeded to the leg exercise intervention.
Leg Exercise: The exercise was conducted in a supine position using 3 kg ankle weights (1.5 kg per foot). The exercise protocol involved sequential lower limb movements: hip flexion to 60 degrees, knee flexion to 90 degrees, and ankle dorsiflexion to 90 degrees. Each movement was held for 25 seconds and performed alternately on the right and left legs, completing 10 repetitions per leg.
Before starting the exercise, participants were instructed to lie in a supine position for 5 minutes, and their blood pressure was measured and recorded in that position. Immediately after completing the exercises, participants were instructed to stand up, and their blood pressure was measured at minutes 1, 3, 5, and 10.

Group C (Leg exercise only): Participants received a leg exercise intervention only.
Before starting the exercise, participants were instructed to lie in a supine position for 5 minutes, and their blood pressure was measured and recorded in that position. The exercise was conducted in the supine position using a 3 kg per pair foot band. The exercise protocol included: hip flexion to a 60-degree angle, knee flexion to a 90-degree angle, ankle flexion to a 90-degree angle, done simultaneously and held for 25 seconds. The exercise is performed alternately on the right and left legs. Immediately after completing 10 repetitions in each leg, the participant stood up, and their blood pressure was measured at minutes 1, 3, 5, and 10.

Group D (Water consumption only): Each participant was provided with a labeled water bottle indicating their name and volume markers. Water intake was monitored over 24 hours to ensure adequate hydration, and the results were then documented using a standardized form. Once adequate hydration was confirmed, participants were instructed to lie in a supine position for five minutes. Blood pressure was then measured and recorded in the supine position. Afterwards, participants were instructed to stand up, and their blood pressure was measured at 1, 3, 5, and 10 minutes post-standing.

Inferential statistics were applied to test the effectiveness of the interventions. A repeated measures analysis of variance (RM-ANOVA) was used to evaluate changes in systolic and diastolic blood pressure over five days within and between the intervention and control groups. This approach allowed the detection of time effects, group effects, and interaction effects (time-group). When a significant difference was found, post hoc tests, Bonferroni, were performed to determine which groups differed significantly from one another.

The research was a quasi-experimental (non-randomized) clinical study. Several wards were designated as representatives of the intervention groups. For example, Ward A was for the control group; Wards B and C were for the combination intervention group; Wards D and E were for the leg exercise intervention group; and Wards E and F were for the water consumption group.

Intervention Type
Behavioural

Primary outcome(s)
Orthostatic hypotension: blood pressure was measured using a sphymomanometer at 1, 3, 5, and 10 minutes post-standing, daily from day 1 to day 5

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
06/04/2024

Eligibility

Key inclusion criteria
1. Diagnosed with schizophrenia
2. Undergoing antipsychotic treatment
3. Identified as having orthostatic hypotension based on blood pressure measurements
4. In a calm, non-aggressive state

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
59 years

Sex
All

Total final enrolment
198

Key exclusion criteria
1. Haemoglobin levels <10 g/d l
2. Estimated glomerular filtration rate (e gfr) <30%
3) New York Heart Association (NYHA) class iii or iv heart failure
4. Undergoing dialysis
5. Violent behavior
6. Recent lower limb orthopedics surgery

Date of first enrolment
01/11/2023

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
Indonesia

Study participating centre
Marzoeki Mahdi Hospital
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Study participating centre
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Sponsor information

Organisation
Binawan University

Funder(s)

Funder type
Other

Funder Name
Investigator initiatived and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (https://repository.binawan.ac.id/)

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes