ISRCTN13397152 https://doi.org/10.1186/ISRCTN13397152

Impact of a multidisciplinary family-integrated educational model on treatment adherence, self-care behaviours and blood pressure control in elderly chinese patients with hypertension

Submission date
25/03/2026

Recruitment status
No longer recruiting

Registration date
27/03/2026

Overall study status
Completed

Last Edited
26/03/2026

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Qianqian Liu

Contact details
No. 55, Ninghai Middle Road, Hai'an High-tech Zone
Nantong
China
226600
+86 18934506226
liuqq_liu2505@126.com

Additional identifiers

Nantong Social and People's Livelihood Science and Technology Plan-Guidance Project
MSZ2023107

Study information

Scientific Title

The impact of a multidisciplinary family-integrated educational model on treatment adherence, self-care behaviours and blood pressure control in elderly chinese patients with hypertension: a randomised controlled trial

Study objectives
To evaluate the impact of the manager–urger–self-manager–teacher (MUST) educational model on treatment adherence, self-care behaviours and blood pressure (BP) control in elderly Chinese patients with hypertension.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/03/2024, Ethics Committee of Hai'an Traditional Chinese Medicine Hospital (No. 55, Ninghai Middle Road, Hai'an High-tech Zone, Nantong, 226600, China; +86 0531-81819880; haszyykjk@163.com), ref: HLYLL2024018

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Sequential

Purpose
Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Treatment adherence, self-care behaviours and blood pressure control in elderly chinese patients with hypertension

Interventions
Participants will be randomised to an experimental and a control group at a 1:1 ratio using a computer-generated randomisation sequence created by an independent statistician using SAS 9.4 software (IBM, Armonk, NY, USA). The sequence will stratify by hypertension grade (Grade 1 vs Grades 2 and 3) to ensure balanced disease severity across groups. Allocation concealment will be achieved through the use of sequentially numbered, opaque, sealed envelopes containing group assignments.

Control group
Patients in the control group will receive routine post-discharge care, comprising structured

telephone follow-ups and home visits.
This included (1) psychological counselling with basic education and success stories; (2) dietary guidance (limit sodium to ≤6 g/day, reduce animal fat, increase vegetable/protein intake); (3) training on strict medication regimen compliance; (4) lifestyle advice on exercise, smoking cessation, alcohol consumption of ≤50 g/day and stress management; and (5) 20-minute phone calls (biweekly) and 60-minute home visits (monthly) for 6 months.

Intervention group
The experimental group underwent a 6-month multidisciplinary MUST enhancement programme. Team composition and roles will be as follows: the manager (physician) will develop personalised treatment plans and supervised collaboration; the urger (family caregiver) will monitor compliance, co-learn with the patient and reported BP fluctuations; the self-manager (patient) will collaborate to master disease knowledge and enhance self-care; and the educator (nurse) will serve as an advanced practice leader, co-directing care planning, independently monitoring clinical data, evaluating treatment efficacy and dynamically adjusting educational strategies using behavioural change theories (e.g. motivational interviewing, self-efficacy frameworks).

Specifically, nurses will translate physician treatment targets (e.g., BP <140/90 mmHg) into individualized, actionable patient behaviours—such as specific timing for medication intake, sodium reduction strategies tailored to dietary preferences, and simplify home BP monitoring routines—thereby bridging the gap between clinical protocols and patients' daily lives. This study is specifically focus on the nurse-led educational components of the model, with physicians serving in a supervisory capacity to support nurse-led intervention delivery. Delivery methods will combine 10-minute bi-weekly WeChat video sessions (12 total) featuring simple language and interactive Q&As with monthly 60-minute in-person workshops (6 total) using simplified PowerPoint presentations (on patient-selected topics), peer experience sharing and practical BP measurement demonstrations.

Intervention Type
Mixed

Primary outcome(s)
1. Medication adherence measured using the 8-item Morisky Medication Adherence Scale (MMAS-8) at baseline, post-intervention (6 months)

2. Multidimensional compliance measured using the Therapeutic Adherence Scale for Hypertensive Patients (TASHP) at baseline, post-intervention (6 months)

3. Self-care behaviours measured using the Hypertension Patients Self-Management Behavior Rating Scale (HPSMBRS) at baseline, post-intervention (6 months)

4. Blood pressure (mmHg) measured using home monitoring with a calibrated Omron HEM-7120 devices at three daily measurements (morning, afternoon and evening). Data were recorded by family members in a standardised logbook and submitting weekly averages via WeChat screenshots to maintain blinding.

Key secondary outcome(s)

Completion date
26/09/2024

Eligibility

Key inclusion criteria
1. Exhibited stabilised BP (<140/90 mmHg for ≥1 month) while on a consistent antihypertensive medication regimen, defined as no changes in drug class, dosage or frequency during the 4 weeks preceding enrolment and throughout the 6-month intervention period.
2. Adequate family support was defined as having at least one literate adult family member available for ≥75% of sessions.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
186

Key exclusion criteria
1. Secondary hypertension
2. Sefractory hypertension
3. Severe hepatic or renal dysfunction
4. Malignancy
5. Cognitive impairment (i.e. a mini-mental state examination [s mmse] score of <24) and living alone or being illiterate.

Date of first enrolment
06/01/2021

Date of final enrolment
30/12/2023

Locations

Countries of recruitment
China

Sponsor information

Organisation
Hainan Provincial Hospital of Traditional Chinese Medicine

ROR
https://ror.org/04xar0g84

Funder(s)

Funder type

Funder Name
Nantong Municipal Science and Technology Bureau

Alternative Name(s)
, Nantong City Science and Technology Bureau

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available