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Nurse-led intervention to improve medication adherence in older adults with hypertension in primary care

Submission date 01/01/2026	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 02/01/2026	**Overall study status** Ongoing	
Last Edited 05/01/2026	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Public, Scientific

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Additional identifiers

Ethics committee reference number
PI_2023/92

Study information

Scientific Title
Efficacy of the implementation of a nurse-led adherence protocol in older patients with hypertension in primary care centres

Acronym
NURSE-ADHERE-HTN

Study objectives
The primary objective is to evaluate whether a nurse-led mixed educational and behavioural intervention improves medication adherence compared with usual care in adults aged 60 years and older with hypertension in primary care.

Secondary objectives are to assess the effect of the intervention on blood pressure control, health-related quality of life, and use of healthcare services (emergency department visits and hospital admissions) at 6 and 12 months; to explore sociodemographic and clinical factors associated with medication adherence, including sex-specific differences; to screen for symptoms of anxiety and depression using the Goldberg Anxiety and Depression Scale; and to evaluate whether the effectiveness of the nurse-led intervention on medication adherence, health-related quality of life, and cardiovascular morbidity outcomes (emergency department visits and hospital admissions) at 6 and 12 months differs by sex/gender (effect modification analysis).

An additional secondary objective is to explore the association between symptoms of anxiety and depression and medication adherence.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/08/2023, Navarra Clinical Research Ethics Committee (CEIm) (Irunlarrea Street, 3, Pamplona, 31008, Spain; +34 (0)848 42 24 95; ceicnavarra@navarra.es), ref: PI_2023/92

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Historical

Assignment
Parallel

Purpose
Diagnostic, Health services research, Prevention, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Hypertension

Interventions
Randomisation will be performed at the level of the nursing professional (cluster randomisation). Within each participating primary care centre, nurses will be randomly allocated in a 1:1 ratio to either the intervention group or the control group (usual care). All eligible patients under the care of each nurse will be assigned to the same study arm as their nurse.

The randomisation sequence will be generated centrally using a computer-generated random allocation sequence. Due to the nature of the intervention, blinding of nurses and patients is not feasible; however, outcome assessment will be performed using standardised instruments and routinely collected clinical data.

A nurse-led mixed educational and behavioural intervention delivered in primary care, consisting of:
1. Training of nursing professionals in medication adherence and motivational interviewing
2. Structured motivational interview with patients
3. Systematic medication review
4. Lifestyle counselling (diet, physical activity, smoking, alcohol)
5. Reinforcement through telephone calls and home visits

Duration of patient follow-up: 12 months

Intervention Type
Mixed

Primary outcome(s)
1. Medication adherence measured using Morisky–Green questionnaire at baseline, 6 months and 12 months

Key secondary outcome(s))
1. Blood pressure control measured using office blood pressure measurement at baseline, 6 months and 12 months

2. Health-related quality of life measured using EuroQol-5D at baseline, 6 months and 12 months

3. Symptoms of anxiety and depression measured using Goldberg Anxiety and Depression Scale at baseline, 6 months and 12 months

4. Cardiovascular-related emergency department visits measured using electronic health records at baseline, 6 months and 12 months

5. Cardiovascular-related hospital admissions measured using electronic health records at baseline, 6 months and 12 months

6. Medication adherence measured using pharmacy refill data (electronic prescription records) at baseline, 6 months and 12 months

These outcomes (blood pressure control, health-related quality of life, cardiovascular-related emergency department visits and hospital admissions, and medication adherence based on

pharmacy refill data) will also be analysed to evaluate whether the effectiveness of the intervention differs by sex/gender (effect modification analysis).

Completion date
30/12/2026

Eligibility

Key inclusion criteria
1. Age ≥60 years
2. Diagnosis of arterial hypertension
3. Prescribed antihypertensive medication
4. Non-adherence (Morisky–Green score ≥1)
5. At least one primary care visit in the previous year
6. Written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 years

Upper age limit
120 years

Sex
All

Total final enrolment
320

Key exclusion criteria
1. Institutionalised patients
2. Life expectancy <12 months
3. Cognitive or physical conditions preventing participation

Date of first enrolment
23/08/2023

Date of final enrolment
23/08/2026

Locations

Countries of recruitment
Spain

Sponsor information

Organisation
Department of Health of the Government of Navarra (Spain)

Funder(s)

Funder type

Funder Name
Department of Health of the Government of Navarra (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available