

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
Registration date 02/01/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 29/05/2026	Condition category Circulatory System	☐ Individual participant data ☒ Record updated in last year

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

Active

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 the 4-item Morisky Medication Adherence Scale (MMAS-4), maintaining the original validated wording, structure, and standardized scoring method at baseline, 6 months and 12 months

Previous 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

31/08/2027

Eligibility

Key inclusion criteria

Current key inclusion criteria as of 29/05/2026:

1. Age ≥ 60 years
2. Diagnosis of arterial hypertension
3. Prescribed antihypertensive medication
4. Non-adherence according to the MMAS-4 standardized scoring method
5. At least one primary care visit in the previous year
6. Written informed consent

Previous 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

0

Key exclusion criteria

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

Date of first enrolment

09/02/2026

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