

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

Submission date 01/01/2026	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 02/01/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 19/08/2026	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

Current study objectives as of 19/08/2026:

The primary objective is to evaluate whether a nurse-led multidimensional educational and behavioural intervention improves adherence to antihypertensive treatment at 6 months, compared with usual care, among adults aged 60 years or older with hypertension in primary care. Adherence will also be assessed at 12 months to determine whether any intervention effect observed at 6 months is maintained over time.

Secondary objectives are to evaluate the effects of the intervention on 24-hour ambulatory blood pressure, health-related quality of life, cardiovascular-related emergency department visits and hospital admissions, symptoms of anxiety and depression, adherence to the Mediterranean diet and physical activity; to examine reasons and patterns of non-adherence, medication burden, anthropometric and selected laboratory variables; to explore sociodemographic and clinical factors associated with adherence to antihypertensive treatment; to assess the association between symptoms of anxiety and depression and adherence to antihypertensive treatment; to assess concordance between adherence measured using the MMAS-4 and adherence estimated from electronic prescription dispensing records; and to explore whether intervention effectiveness differs by sex.

Previous 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

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Health services research, Prevention, Treatment

Study type(s)**Health condition(s) or problem(s) studied**

Arterial hypertension

Interventions

Current interventions as of 19/08/2026:

Randomisation was performed at the primary care centre level (cluster randomisation). The 14 participating primary care centres were centrally allocated in a 1:1 ratio to either the intervention group or the usual-care control group, with seven centres per group. Two nurses participate at each centre, and all participants recruited within the same centre receive the allocation assigned to that centre.

The allocation sequence was generated centrally using a computer-generated random sequence by an independent researcher who was not involved in participant recruitment or intervention delivery. Because of the nature of the intervention, participating nurses and patients

are not blinded to group allocation. Both groups undergo the same standardised outcome assessments. For the prespecified statistical analysis, the study groups will be coded as A and B, and the analysts will remain blinded to group identity until completion of the primary analysis.

The intervention is a nurse-led multidimensional educational and behavioural programme delivered in primary care. Before study initiation, nurses delivering the intervention attended a standardised 6-hour face-to-face training session conducted over one morning. Training covered medication adherence, motivational interviewing, antihypertensive pharmacotherapy, the Mediterranean diet, healthy lifestyles, physical activity, intervention materials and standardised study procedures.

The intervention comprises:

Individualised education on hypertension, cardiovascular risk and antihypertensive treatment. A structured motivational interview to identify barriers to adherence to antihypertensive treatment and agree on individualised adherence-support strategies.

Review of the antihypertensive treatment regimen, medication-taking routines, dosage schedules and practical barriers.

Individualised Mediterranean-diet and physical-activity counselling supported by standardised educational materials and weekly exercise programmes. Each participant allocated to the intervention group receives an elastic resistance band. Recommendations are tailored according to the participant's clinical characteristics, comorbidities and previous level of physical activity. Two telephone reinforcement contacts planned during the 12-month follow-up period.

Physiotherapy support and pre-existing physical-activity promotion programmes are available at all seven intervention centres. All face-to-face intervention sessions are conducted at the participating primary care centres; home visits are not part of the intervention. The structured medication-adherence component focuses specifically on antihypertensive treatment.

Participants in the control group receive usual care and do not receive the structured multidimensional intervention. Both study groups are followed for 12 months.

Previous 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)

Current primary outcome(s) as of 19/08/2026:

Adherence to antihypertensive treatment measured using the 4-item Morisky Medication Adherence Scale (MMAS-4), maintaining the licensed wording, structure and standardised scoring method at baseline, 6 months (primary endpoint) and 12 months (assessment of maintenance of the intervention effect)

Previous primary outcome(s) as of 29/05/2026:

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)

Current key secondary outcome(s) as of 19/08/2026:

1. Ambulatory blood pressure measured using 24-hour ambulatory blood pressure monitoring with the Microlife WatchBP O3 AFIB (BP3SZ1-1), recording mean systolic and diastolic blood pressure for the overall 24-hour period and for the daytime and night-time periods at Baseline, 6 months and 12 months
2. Health-related quality of life measured using the EQ-5D-3L descriptive system and EQ Visual Analogue Scale (EQ-VAS) at baseline, 6 months and 12 months
3. Symptoms of anxiety and depression measured using the Goldberg Anxiety and Depression Scale (GADS) 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. Adherence to antihypertensive treatment estimated from dispensing records measured using electronic prescription dispensing records, comparing the number of antihypertensive tablets dispensed with the number prescribed during the preceding 180 days, at baseline, 6 months and 12 months
7. Maintenance of the intervention effect on adherence to antihypertensive treatment measured using the 4-item Morisky Medication Adherence Scale (MMAS-4), maintaining the licensed wording, structure and standardised scoring method, at 12 months
8. Adherence to the Mediterranean diet measured using the Mediterranean Diet Adherence Screener (MEDAS) at baseline, 6 months and 12 months
9. Physical activity measured using the International Physical Activity Questionnaire (IPAQ) at baseline, 6 months and 12 months
10. Reasons and patterns of non-adherence to antihypertensive treatment measured using the self-reported EFNA questionnaire at baseline, 6 months and 12 months
11. Anthropometric measurements measured using weight, height, body mass index and waist circumference at baseline, 6 months and 12 months
12. Selected laboratory variables measured using laboratory test results obtained from electronic health records, including haematocrit or haemoglobin, glucose, glycated

haemoglobin, total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, triglycerides, potassium, sodium, uric acid, creatinine, estimated glomerular filtration rate, calcium, urinary albumin-to-creatinine ratio and microalbuminuria at baseline, 6 months and 12 months

13. Medication burden measured using the total number of prescribed medications recorded in the electronic health record at baseline, 6 months and 12 months

14. Concordance between adherence measures measured using agreement between adherence assessed using the 4-item Morisky Medication Adherence Scale (MMAS-4) and adherence estimated from electronic prescription dispensing records at baseline, 6 months and 12 months

Previous 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

Current key exclusion criteria as of 19/08/2026:

1. Institutionalised patients
2. Life expectancy of less than 12 months
3. Cognitive or physical conditions preventing participation or completion of the study procedures

Previous 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