ISRCTN97164929 https://doi.org/10.1186/ISRCTN97164929

The impact of home blood pressure measurement on blood pressure control in the elderly

Submission date 21/09/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 14/10/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/10/2010	**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)
Scientific

Contact name
Dr Christophe Tzourio

Contact details
Inserm U708
Hopital de la Salpetriere
Paris
France
75651
christophe.tzourio@upmc.fr

Additional identifiers

Protocol serial number
2010-A00701-38

Study information

Scientific Title
A longitudinal, cluster randomised, study on the impact of home blood pressure measurement on blood pressure control in the elderly

Study objectives
That self measurement of blood pressure at home by elderly individuals may help to improve blood pressure control

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethics Committee (Comité de Protection des Personnes [CPP] Ile-de-France 7) approved on the 10th of June 1999 for the main cohort and on the 7th of July 2010 for the present study (ref: SC10-004)

Primary study design
Observational

Study design
Observational cluster randomised study

Study type(s)
Prevention

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

Interventions
Patients to the clinic will be randomised by week, those visiting on even weeks will be assigned to:
1. Regular (every 3 months) self-measurement of blood pressure at home with an automatic device
Those visiting on odd weeks will be assigned to:
2. No regular self-measurement
The total duration of the intervention will be one year.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Difference of office mean values of systolic and diastolic blood pressure among hypertensives between both groups at the end of the intervention period (1 year)

Key secondary outcome(s)
1. Difference of home mean values of systolic and diastolic blood pressure among hypertensives between both groups
2. Difference of percentage of participants with hypertension between both groups
3. Difference of use of antihypertensive drugs between both groups

4. Frequency of masked and white coat hypertension and difference between both groups
5. Feasibility
All outcomes will be measured at the end of the intervention period (1 year)

Completion date
01/02/2011

Eligibility

Key inclusion criteria
Volunteers of an ongoing observational cohort study:
1. ≥ 65 year of age
2. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/02/2010

Date of final enrolment
01/02/2011

Locations

Countries of recruitment
France

Study participating centre
Inserm U708
Paris
France
75651

Sponsor information

Organisation
National Institute of Health and Medical Research (Institut National de la Santé et de la Recherche Médicale [INSERM]) (France)

ROR
https://ror.org/02vjkv261

Funder(s)

Funder type
Government

Funder Name
Ministry of Health (France):

Funder Name
National Institute for Prevention and Health Education (Institut National de Prévention et d'Éducation pour la Santé [INPES])

Funder Name
High Authority of Health (Haute Autorité de Santé [HAS])

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration