

# Clinical trial on the efficacy of an intervention package to improve adherence to treatment for systolic blood pressure (BP) reduction in primary care patients with poorly controlled or uncontrolled BP

<b>Submission date</b> 17/06/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/07/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/01/2015	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Miss Lucia Moreno

**Contact details**  
Gerencia de Atención Primaria  
C/ Reina Esclaramunda nº 9  
Palma de Mallorca  
Spain  
07003  
-  
lmoreno@ibsalut.caib.es

## Additional identifiers

**Protocol serial number**  
PS09/01456

# Study information

## Scientific Title

A randomised controlled trial on the efficacy of a multifactorial intervention to improve adherence to treatment for systolic blood pressure (BP) reduction in primary care patients with poorly controlled or uncontrolled BP

## Study objectives

Background:

Lowering blood pressure (BP) with antihypertensive drugs has an important risk reduction effect on cardiovascular events, mainly stroke and total mortality. However lack of adherence to antihypertensive medication reduces its effectiveness and increases the risk for adverse effects to the medication. Improvement of patient adherence to the treatment could be similar in relative risk reduction than the development of a new drug.

Hypotheses:

1. In primary care patients with poorly- or un-controlled BP and low adherence to treatment, a 9-month multifactorial intervention with the aim of improving communication between medical staff and patient and thus facilitating the taking of medication will result in decreased systolic blood pressure (SBP) at 12 months compared with patients in the control group
2. The estimated direct cost at 12 months resulting from the use of health services associated with hypertension in the intervention group will be at least 10% lower than the control group
3. The number needed to treat (NNT) will be 10 - 15

Please note that as of 16/01/2013, the following changes were made to the record:

1. The public title was previously "Clinical trial on the efficacy of an intervention package to improve adherence to treatment for systolic blood pressure (BP) reduction in primary care patients with poorly controlled or uncontrolled BP and low adherence to treatment"
2. The scientific title was previously "A randomised controlled trial on the efficacy of a multifactorial intervention to improve adherence to treatment for systolic blood pressure (BP) reduction in primary care patients with poorly controlled or uncontrolled BP and low adherence to treatment"

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The Ethical Committee on Human Research of Balearic Islands approved on the 26th May 2010

## Study design

Cluster randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

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

Non-optimally controlled hypertension

## **Interventions**

Patients in the intervention group will attend of 3 sessions consisting of a 30 minute semi-structured motivational interview and a 15-minute health education programme combined with simplifying dosing regimens, family and/or social support, blood pressure self-monitoring and use of medication reminders.

Patients in the control group will receive treatment as usual.

The duration of the intervention will be 6 months. The total duration of follow-up will be 12 months.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

Change in systolic BP at 12 months

## **Key secondary outcome(s)**

1. Change in diastolic BP
2. Proportion of participants with adequate BP control at 12 months
3. Total direct cost

## **Completion date**

15/12/2012

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 16/01/2013:

1. Patients between 18 and 80 years of age
2. Non controlled BP according to European Societies of Hypertension and Cardiology (ESH/ESC) guidelines (i.e. BP less than 140/90 mmHg or less than 130/80 mmHg in diabetic or renal failure patients)

Previous inclusion criteria until 16/01/2013:

1. Patients between 18 and 80 years of age
2. Non controlled BP according to European Societies of Hypertension and Cardiology (ESH/ESC) guidelines (i.e. BP less than 140/90 mmHg or less than 130/80 mmHg in diabetic or renal failure patients)
3. Adherence below 80% to AHT by Hayness-Sacket Test

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Non-essential hypertensive patients
2. Haemodialysis patients
3. Institutionalised patients

**Date of first enrolment**

15/10/2010

**Date of final enrolment**

15/12/2012

**Locations****Countries of recruitment**

Spain

**Study participating centre**

Gerencia de Atención Primaria

Palma de Mallorca

Spain

07003

**Sponsor information****Organisation**

Health Service of the Balearic Islands (Servei de Salut de les Illes Balears [IB-salut]) (Spain)

**ROR**

<https://ror.org/00d9y8h06>

**Funder(s)****Funder type**

Government

## Funder Name

Health Research Fund (Fondo de Investigaciones Sanitarias [FIS]) (Spain)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	27/09/2010		Yes	No
<a href="#">Other publications</a>	resultst	05/12/2014		Yes	No