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Effectiveness of a multifactorial intervention, consisting of self-management of antihypertensive medication, self-measurement of blood pressure, hypocaloric and low sodium diet, and physical exercise, in patients with uncontrolled hypertension taking 1 or more antihypertensive drugs: the MEDICHY study

Submission date
23/07/2018

Recruitment status
No longer recruiting

Registration date
08/10/2018

Overall study status
Completed

Last Edited
05/06/2024

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
High blood pressure can lead to an increased risk of heart attack, stroke, kidney damage and damage to the arteries. Mortality due to hypertension is high. There are treatments for hypertension which can reduce this risk; however, incorrect doses, inadequate treatments, not taking medication, smoke, alcohol abuse, excess fat and salt in the diet, sedentary lifestyle and being overweight, hinder the proper control of hypertension. There are many studies that show the benefit of taking care of all aspects related to treatment and healthy living. This study aims to look at the effects of patients self-monitoring their blood pressure, self-managing their antihypertensive medication and following a healthy lifestyle on improvements in the control of high blood pressure.

Who can participate?
Adults between the ages of 35 and 75 years for whom a hypertension treatment strategy with one or more drugs fails to lower office SBP and DBP values to <140 mmHg and/or <90 mmHg, respectively

What does the study involve?
Participants are allocated to one of two groups - the intervention or the control group. Those in the control group continue to with their usual care for high blood pressure. Those in the intervention group will receive the intervention, which consists of the following parts:
Blood pressure measurements: The patient will be asked to record their weekly blood pressure averages 2 times a month during the 6 month study period.

Medication management: Patients will be shown how to adjust their medication for hypertension.
Lifestyle changes: Patients will be asked to follow the DASH diet, which involves reduced fat and salt intake, fewer calories and no alcohol. They will also be asked to perform either moderate exercise for 30 minutes, 5 times a week, or intense exercise for 20 minutes 3 times per week.
a) DASH Diet: We propose a diet that contains less fat, lower salt intake, fewer calories and avoiding alcohol consumption. b) Physical exercise: according to the patient's condition (as a general rule at least, moderate exercise 30 minutes 5 times a week or intense 20 minutes 3 times a week). An educational session will be conducted with a nurse to learn how to use the tensiometer and the step counter that will be delivered to the patients of the "intervention" group, and another session to improve the knowledge related to diet and exercise.
Participants will be asked to complete tests including blood pressure measurements, questionnaires, BMI measurements and blood and urine samples at the start of the study and at the end of the 6 month study period.

What are the possible benefits and risks of participating?
Participating in a study could improve control of blood pressure, regardless of the assigned group. The risks of participating in the study include side effects of medications when receiving higher doses or muscle injuries when performing physical exercise. If the blood pressure reduces a large amount, it can cause dizziness, sweating and paleness.

Where is the study run from?
Balearic Islands Primary Care (Spain)

When is the study starting and how long is it expected to run for?
January 2018 to June 2022

Who is funding the study?
Institute of Health Carlos III (Spain)

Who is the main contact?
Fabián Unda Villafuerte
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI17/02108

Study information

Scientific Title
Effectiveness of self-adjustment medication, self-monitoring, diet, and physical exercise to reduce systolic blood pressure in difficult to control hypertensive patients

Acronym
MEDICHY (Monitoring, Exercise, Diet, Difficult Control. Hypertension)

Study objectives
Current study hypothesis as of 27/03/2019:
In patients that treatment strategy by two or more drugs fails to lower office SBP and DBP values to <140 mmHg and/or <90 mmHg, respectively, an intervention based on self-adjustment of antihypertensive medication, self-monitoring of blood pressure and a lifestyle intervention aimed at increasing physical exercise, caloric restriction and reduction in salt intake reduces systolic blood pressure and is effective.

Previous study hypothesis:
In patients with difficult to control hypertension (defined as hypertension that cannot be controlled by three or more drugs), an intervention based on self-adjustment of antihypertensive medication, self-monitoring of blood pressure and a lifestyle intervention aimed at increasing physical exercise, caloric restriction and reduction in salt intake reduces systolic blood pressure and is effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Balearic Islands Research Ethics Committee (CEI), 18/06/2018, IB 3682/18 PI

Study design
Interventional two-arm parallel multi-centre randomized cluster trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Current interventions as of 27/03/2019:
Participant's GPs will be randomly allocated to either the intervention or control group by the coordinating centre using computer-generated random number tables.
Participants whose GPs are in the intervention group will receive an intervention involving self-monitoring of antihypertensive medication, self-measurement of blood pressure and diet and physical exercise. Patients will receive a blood pressure monitor, which they will be trained to use correctly. Blood pressure will be measured twice a day (morning and afternoon) for the first and third week of each month of the 12 month study duration. Patients will be asked to record their weekly average blood pressure in a table.
The current medication of the patient will be registered. Self-adjustment of medication was completed according to the following algorithm:
Step 1: A dual combination of ACEI or ARA II + CCB or diuretic, unless concomitant conditions or diseases (angina, post-myocardial infarction, heart failure, or heart rate control) are present that require beta-blockers combined with any of the other major drug classes.
Step 2: Add a third drug: ACEI or ARA II + CCB and diuretic.
Step 3: Start the dose increase by diuretic up to 50%, provided there is no hyperuricemia or diabetes. In this case, the first drug to be increased will be ACEI or ARA II
Step 4: The second drug to increase for patients aged over 60 years is CCN; for patients under 60 years, increase the ACEI or ARA II
Step 5: The third drug to increase is the remaining drug (CCB, ACEI or ARA II)
Step 6: In the same order, the 3 drugs will be increased to MRD (if this is adequately tolerated)
Step 7: When the 3 drugs have been increased to optimal doses and control values are not obtained, add spironolactone. In patients aged over 60, the dose increase will be slower, rising first to half of the standard dose, standard dose and double standard dose.
Patients will also be asked to follow the DASH (Dietary Approaches to Stop Hypertension), and will be prescribed moderate or intense aerobic exercise according to the patient's condition. This will generally be moderate exercise for 30 minutes 5 times a week, or intense exercise for 20 minutes 3 times per week. If the agreed exercise is walking or running, a step counter will be provided for patients. An educational session will be conducted with a nurse to learn how to use the tensiometer and step counter, along with another session to improve knowledge related to diet and exercise.
Participants whose GPs are in the control group will receive usual care for hypertension.

Previous interventions:
Participant's GPs will be randomly allocated to either the intervention or control group by the coordinating centre using computer-generated random number tables.
Participants whose GPs are in the intervention group will receive an intervention involving self-monitoring of antihypertensive medication, self-measurement of blood pressure and diet and physical exercise. Patients will receive a blood pressure monitor, which they will be trained to use correctly. Blood pressure will be measured twice a day (morning and afternoon) for the first and third week of each month of the 12 month study duration. Patients will be asked to record their weekly average blood pressure in a table.
The current medication of the patient will be registered. Self-adjustment of medication was completed according to the following algorithm:
Step 1: If between the 3 drugs there is no diuretic, use a thiazide diuretic at a dose equal to 50% of the maximum recommended dose (MRD). If there are no contraindications, remove the non-BCC, ACEI or ARA II
Step 2: If any of the 3 active principles are prescribed at <50% of the MRD, increase it to 50% of the MRD. If there are 2 or 3 drugs at sub-optimal doses, follow the same order as recommended below.
Step 3: Start the dose increase by diuretic up to 50%, provided there is no hyperuricemia or diabetes. In this case, the first drug to be increased will be ACEI or ARA II
Step 4: The second drug to increase for patients aged over 60 years is BCC; for patients under 60 years, increase the IECA or ARA II
Step 5: The third drug to increase is the remaining drug (BCC, ACEI or ARA II)
Step 6: In the same order, the 3 drugs will be increased to MRD (if this is adequately tolerated)
Step 7: When the 3 drugs have been increased to optimal doses and control values are not obtained, add spironolactone. In patients aged over 60, the dose increase will be slower, rising first to half of the standard dose, standard dose and double standard dose.
Patients will also be asked to follow the DASH (Dietary Approaches to Stop Hypertension), and will be prescribed moderate or intense aerobic exercise according to the patient's condition. This will generally be moderate exercise for 30 minutes 5 times a week, or intense exercise for 20 minutes 3 times per week. If the agreed exercise is walking or running, a step counter will be provided for patients. An educational session will be conducted with a nurse to learn how to use the tensiometer and step counter, along with another session to improve knowledge related to diet and exercise.
Participants whose GPs are in the control group will receive usual care for hypertension.

Intervention Type
Mixed

Primary outcome measure
Blood pressure, measured at the baseline 12 months after the start of the intervention, carried out by external personnel who remain blind to the group of the patients. A reduction of at least 5 mmHg in systolic pressure at the end of the study will be considered significant. Blood pressure will be measured while the patient is sitting, using a standardized automated sphygmomanometer (OMROM 7 intelli IT) after a 5-minute period of rest. Two blood pressure readings will be taken 1 to 2 minutes apart and the average will be recorded. The width of the cuff will adapt to the perimeter of the arm and placed on the middle third of the arm. The patient must be seated comfortably and without crossing the legs and with the arm resting on a table and placed at the level of the heart. The patient will be relaxed, with the urinary bladder empty and without having previously smoked or ingested stimulating substances.

Secondary outcome measures

Current secondary outcome measures as of 13/05/2021:
1. Percentage of patients who have reached systolic and diastolic blood pressure levels considered to be under control (< 140/90 mm Hg) after 6 months, assessed as per primary outcome measure
2. Quality of life, assessed using the EuroQol-5D questionnaire at the baseline and after 6 months
3. Proportion of people showing a significant reduction in baseline cardiovascular risk, assessed using the REGICOR risk score at the baseline and after 6 months
4. Adherence to the hypertensive medication, assessed using MPR "Medication Possession Ratio" of the antihypertensive medication registered in the electronic prescription of the patient's medical record, assessed after 6 months
5. Body mass index, assessed by dividing weight in kg by height in metres at the baseline, and after 6 months
6. Physical exercise, assessed using the International Physical Activity Questionnaire (IPAQ) at the baseline and after 6 months
7. Safety of the proposed intervention:
7.1. Percentage of patients with hypertensive crises, assessed by a clinical record review after 6 months
7.2. Number of episodes of hypotension, assessed by a clinical record review after 6 months
7.3. Hypotension requiring visits to the emergency room, assessed by a clinical record review after 6 months
7.4. Adverse effects related to antihypertensive medication, recorded by the GP at each visit and by a clinical record review after 6 months

Previous secondary outcome measures:
1. Percentage of patients who have reached systolic and diastolic blood pressure levels considered to be under control (< 140/90 mm Hg) after 12 months, assessed as per primary outcome measure
2. Quality of life, assessed using the EuroQol-5D questionnaire at the baseline and after 12 months
3. Proportion of people showing a significant reduction in baseline cardiovascular risk, assessed using the REGICOR risk score at the baseline and after 12 months
4. Adherence to the hypertensive medication, assessed using MPR "Medication Possession Ratio" of the antihypertensive medication registered in the electronic prescription of the patient's medical record, assessed after 12 months
(5. Salt intake (grams of sodium in urine), measured using the Kawasaki equation in a fasting urine sample at the baseline and after 6 and 12 months) - outcome measure removed as of 27/03/2019
6. Body mass index , assessed by dividing weight in kg by height in metres at the baseline, and after 6 and 12 months
7. Physical exercise, assessed using the International Physical Activity Questionnaire (IPAQ) at the baseline and after 12 months
8. Safety of the proposed intervention:
8.1. Percentage of patients with hypertensive crises, assessed by a clinical record review after 12 months
8.2. Number of episodes of hypotension, assessed by a clinical record review after 12 months
8.3. Hypotension requiring visits to the emergency room, assessed by a clinical record review after 12 months
8.4. Adverse effects related to antihypertensive medication, recorded by the GP at each visit and by a clinical record review after 12 months

Overall study start date
01/01/2018

Completion date
01/06/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 13/05/2021:
1. Aged 35-75 years old
2. Diagnosed with hypertension
3. Taking 1 or more antihypertensive drugs
4. Systolic and diastolic blood pressure ≥130/80 mmHg in 24-hour ambulatory blood pressure monitoring
5. Written informed consent

Previous inclusion criteria from 27/03/2019 to 13/05/2021:
1. Aged 35-75 years old
2. Diagnosed with hypertension
3. Taking 2 or more antihypertensive drugs
4. Systolic and diastolic blood pressure ≥130/80 mmHg in 24-hour ambulatory blood pressure monitoring
5. Written informed consent

Original inclusion criteria:
1. Aged 35-75 years old
2. Diagnosed with hypertension
3. Taking 3 or more antihypertensive drugs
4. Systolic and diastolic blood pressure ≥130/80 mmHg in 24-hour ambulatory blood pressure monitoring
5. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
350 (175 subjects in the control group and 175 in the intervention group)

Key exclusion criteria
Current exclusion criteria as of 27/03/2019:
1. Pregnancy or breastfeeding
2. Dialysis or with diagnosis of renal failure
3. Myocardial infarction, heart bypass, angioplasty, stroke, peripheral arterial disease, heart

failure, advanced liver disease or atrial fibrillation
4. Institutionalized in a socio-health center indefinitely
5. Severe prognosis that makes it impossible to follow-up during study period
6. Chronic ingestion of corticosteroids
7. Albumin >300 mg/24 hours, glomerular filtration < 45 ml/min1,73 m2

Previous exclusion criteria:
1. Pregnancy or breastfeeding
2. Dialysis or with diagnosis of renal failure
3. Myocardial infarction, heart bypass, angioplasty, stroke, peripheral arterial disease, heart failure, advanced liver disease or atrial fibrillation
4. Institutionalized in a socio-health center indefinitely
5. Severe prognosis that makes it impossible to follow-up during study period
6. Chronic ingestion of NSAIDs or corticosteroids
7. Albumin/creatinine ratio > 1

Date of first enrolment
20/09/2021

Date of final enrolment
01/07/2022

Locations

Countries of recruitment
Spain

Study participating centre
Balearic Islands Primary Care
C/Escuela graduada, 3
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Sponsor information

Organisation
Primary Care Management of Mallorca

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Sponsor type
Government

ROR
https://ror.org/00d9y8h06

Funder(s)

Funder type
Government

Funder Name
Institute of Health Carlos III

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Publication and dissemination plan
Two further publications from this trial are planned:
1. A publication on the effectiveness of the intervention
2. Health economics paper

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Fabian Unda. The dataset will consist of anonymized patient data (ID, allocated group, age, sex, baseline characteristics, primary and secondary outcomes) stored in an SPSS file. All request will be considered if the scientific questions are reasonable.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		24/04/2020	21/11/2023	Yes	No
Results article		21/05/2024	05/06/2024	Yes	No