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# Effectiveness of a brief multifactorial intervention in adherence to physical exercise prescription of moderate to high cardiovascular risk patients

**Submission date**
21/11/2014

**Recruitment status**
No longer recruiting

**Registration date**
08/04/2015

**Overall study status**
Completed

**Last Edited**
17/12/2020

**Condition category**
Circulatory System

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

## Plain English summary of protocol

Background and study aims
The recommended level of physical activity for adults is at least 150 minutes of moderate-intensity aerobic physical activity throughout the week. The goal of this study is to find out whether a new strategy in the prescription of physical exercise helps more patients to follow this recommendation.

Who can participate?
The study aims to recruit about 616 adult primary care patients with a moderate to high cardiovascular risk.

What does the study involve?
Patients will be randomly allocated to either the control or the intervention group. Patients in the intervention group will be invited to attend a first visit (35 minutes) where his/her nurse /general practitioner will explore their motivation to practice physical exercise and in those patients who are ready, the patient and clinician will agree the amount and type of physical exercise to do. For those patients who are not ready to exercise, the clinician can explore their reasons and trying to motivate the patient to be ready to exercise in the next visits. Four visits for patients from the intervention group are planned in a one-year period.

What are the possible benefits and risks of participating?
The immediate direct benefit to those taking part are improvements in sleep quality, mood and self-esteem; it can also reduce your risk of major illnesses, such as heart disease, stroke, diabetes and cancer by up to 50% and lower your risk of early death by up to 30%. There is no risk if the intensity of the exercise is moderate.

Where is the study run from?
The study has been set up by the University of the Balearic Islands in collaboration with Primary Care and General Direction of Public Health of the Balearic Islands (Spain).

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in January 2015. Participants will be enrolled on the study for a period of 2 years.

Who is funding the study?
Funding has been provided by the Institute of Health Carlos III (Spain).

Who is the main contact?
Professor Antoni Aguiló, aaguilo@uib.es
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# Contact information

### Type(s)
Public

### Contact name
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
PI13/01477

# Study information

### Scientific Title
To evaluate the effectiveness of a brief multifactorial intervention designed to improve the adherence to physical exercise prescription of moderate to high cardiovascular risk patients

### Study objectives
Current hypothesis as of 06/07/2015:
A brief multifactorial intervention based on a motivational interview, the transtheoretical stages of changes of Prochaska and Diclemente, and a individualized prescription of physical exercise (patients will choose from several activities that can be adapted to their day to day living)

improves adherence to the minimum recommended physical activity (150 minute per week) by 7.8% in the absolute percentage in patients with at least two cardiovascular risk factors and with a cardiovascular risk up to 15% measured using the Framingham-Regicor equation.

Previous hypothesis:
A brief multifactorial intervention based on a motivational interview, the transtheoretical stages of changes of Prochaska and Diclemente, and a individualized prescription of physical exercise (patients could choose from 10 activities that can be adapted to their day to day living) improves adherence to the minimum recommended physical activity (150 minute per week) by 8.8% in the absolute percentage in moderate to high cardiovascular risk patients.

On 06/07/2015 the study design was changed from 'Two-arm multicenter cluster randomized clinical trial' to 'Two-arm multicenter randomized clinical trial'.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ballearic Island Ethics Committee, 11/06/2014, 23/41/14PI

## Study design
Two-arm multicenter randomized clinical trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
GP practice

## Study type(s)
Prevention

## Participant information sheet

## Health condition(s) or problem(s) studied
Patient with a cardiovascular risk between 5 and15% in the REGICOR score

## Interventions
Individualized physical exercise and patient-orientated counselling on written prescription referred to formal or informal resources localized in the healthcare centre area

## Intervention Type
Behavioural

## Primary outcome measure
Exercise practice of 150 min/week measured by IPAQ (International Physical Activity Questionnaire) questionnaire at 12 months

### Secondary outcome measures
Exercise practice (METs x min x week) measured by IPAQ (International Physical Activity Questionnaire) questionnaire at 12 months

### Overall study start date
12/06/2014

### Completion date
12/12/2017

## Eligibility

### Key inclusion criteria
Current inclusion criteria as of 06/07/2015:
1. Patients aged 35-75 years
2. Patients with at least two cardiovascular risk factors and with a cardiovascular risk up to 15% measured using the Framingham-Regicor equation

Previous inclusion criteria:
1. Patients aged 18 or above
2. Patients with a cardiovascular risk between 5 and 15% in the REGICOR score

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
616

### Total final enrolment
263

### Key exclusion criteria
1. Institutionalized patient, Barthel below 60, terminal illness, dementia or cognitive impairment
2. Myocardial infarction, bypass or coronary angioplasty in the last 3 months
3. Unstable coronary heart disease or untreated heart failure
4. Living outside the healthcare center area

### Date of first enrolment
01/01/2015

### Date of final enrolment

01/01/2017

# Locations

### Countries of recruitment
Spain

### Study participating centre
**Illes Balears University**
Cra. de Valldemossa, km 7.5. Palma (Illes Balears)
Spain
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# Sponsor information

### Organisation
Universitat de les Illes Balears

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### Sponsor type
Government

### Website
https://www.uib.es/

### ROR
https://ror.org/03e10x626

# Funder(s)

### Funder type
Research organisation

### Funder Name
Institute of Health Carlos III (Instituto de Salud Carlos III) (Spain) PI13_01477

# Results and Publications

## Publication and dissemination plan
We intend to publish one publication, the main results (effectiveness of the intervention)

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary
Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 01/09/2017 | 17/12/2020 | Yes | No |
| Results article | results | 01/03/2021 | 17/12/2020 | Yes | No |