

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	☐ Prospectively registered ☒ Protocol
Registration date 08/04/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/12/2020	Condition category Circulatory System	☐ 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

Mr Alfonso Leiva, aleiva@ibsalut.caib.es

Contact information

Type(s)

Public

Contact name

Mr Aina Riera

Contact details

Departament d'Infermeria i Fisioteràpia

Universitat de les Illes Balears. Cra. de Valldemossa, km 7.5

Palma (Illes Balears)

Spain

07122.

+34 (0) 971 17 30 00

ana.riera@uib.es

Additional identifiers

Protocol serial number

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)

Balearic Island Ethics Committee, 11/06/2014, 23/41/14PI

Primary study design

Interventional

Study design

Two-arm multicenter randomized clinical trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Patient with a cardiovascular risk between 5 and 15% 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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

-

Sponsor information

Organisation

Universitat de les Illes Balears

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

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?
Results article	results	01/03/2021	17/12/2020	Yes	No
Protocol article	protocol	01/09/2017	17/12/2020	Yes	No