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Long-term effect of physical activity intervention promoting autonomous practice

Submission date
19/11/2015

Recruitment status
No longer recruiting

Registration date
20/11/2015

Overall study status
Completed

Last Edited
29/11/2022

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
Cardiovascular disease (CVD) is a general term used to describe disease of the heart or blood vessels. One of the main causes of CVD is atherosclerosis, a condition where fatty substances, called plaques, build up in the arteries. The plaques can cause hardening and narrowing of the arteries, which leads to reduced flow of blood through the blood vessels. This puts excess strain on the heart which could lead to serious complications, such as heart attack or stroke. Studies have shown that taking part in regular physical activity can help to protect against CVD and even improve the health of people already suffering from it, by strengthening the heart, lowering blood pressure and maintaining a healthy weight. In many cases however, participants of these studies tend to stop exercising regularly when the studies end, as they are no longer attending supervised exercise sessions. Habit formation is a process which is used to make certain behaviours automatic. It is possible that by using this technique, people could be encouraged to maintain the high levels of exercise that they achieve in supervised studies when they are on their own (autonomous training). The aim of this study is to test the effectiveness of actively encouraging people to continue exercising after a supervised training programme has ended.

Who can participate?
Adults suffering from CVD who normally have a low level of physical activity (sedentary).

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in two physical activity sessions every week over a period of 20 weeks. This involves a one hour session of cardio-training (high-intensity exercise designed to increase the heart rate), and a one hour session of Nordic walking (a full-body exercise involving walking with poles to propel yourself forwards). Those in the second group take part in physical activity sessions every week for 10 weeks, and then receive encouragement to continue exercising twice a week, using written material and weekly phone calls for a further 10 weeks. At the start of the study and then again at 5, 7, 9 and 12 months, participants in both groups complete a number of questionnaires in order to test their exercise habits and attitude towards exercise.

What are the possible benefits and risks of participating?
Participants could benefit from improved physical fitness and an overall improvement to their

general health. Risks of taking part in the study are small however the activity sessions may be tiring and could cause temporary discomfort.

Where is the study run from?
Bellvitge's University Hospital (Spain)

When is the study starting and how long is it expected to run for?
May 2012 to February 2014

Who is funding the study?
Malakoff Mederick Group (France)

Who is the main contact?
Mrs Marion Fournier

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Protocol of the “As du Coeur” study: A randomized controlled trial on the maintenance of physical activity for cardiovascular patients

Study objectives
The aim of this trial is to evaluate the effectiveness of an experimental intervention based on habit formation theory on physical activity maintenance.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. "Comité de Protection des Personnes" (National ethical committee for human research), 16/12/2014, ref: 14 073
2. "Agence Nationale de la Sécurité et des Médicaments" (National drug agency), 15/12/2014, ref: 141299B-21

Study design
Multi-centre interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
Cardiovascular patients will be individually randomized in two groups.

Group 1: Participants will have two supervised physical activity sessions per week for 20 weeks. They will receive two supervised sessions over a period of 5 months., including one session of one hour of cardio-training and one session of one hour of nordic walking. Patients will also be recommended to do at least one more session on their own during the week to match with the American College of sports medicine (ACSM) guidelines for cardiac patients.

Group 2: Participants will have the same supervised intervention for the first 10 weeks and one supervised session will be replaced by an encouragement for autonomous practice of physical activity (written material and regular phone call) in the last 10 weeks.

The follow-up involves participants to answer to the International Physical Activity Questionnaire by phone at baseline, 5, 7 and 9 months. Eventually, they will have to participate to the final evaluation at 12 months for physical and psychological measures.

Intervention Type
Behavioural

Primary outcome(s)
Level of physical activity measured using the International Physical activity questionnaire at baseline, 5, 7, 9 and 12 months.

Key secondary outcome(s))
1. Motivation regarding physical activity is measured using the sport motivation scale at baseline, 5 and 12 months
2. Automaticity of physical activity behaviour is measured using Self Report Behavioral Automaticity Index at baseline, 5 and 12 months
3. Quality of life is measured at baseline, 5 and 12 months
4. Physical condition of the patient is measured using the SF-36 questionnaire at baseline, 5 and 12 months
5. Economic evaluation is measured using The Quality adjusted Life Years (QALY) at baseline, 5 and 12 months

Completion date
02/02/2016

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Registered with chronic disease (cardiovascular disease or cardiac deficiency)
3. Considered as sedentary according to the brief physical activity assessment
4. Absence of contraindication to PA stated by a cardiologist
5. Possibility to attend a fitness center for a 60-min session twice a week

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
50

Key exclusion criteria
Contraindication to PA stated by a cardiologist.

Date of first enrolment
10/07/2014

Date of final enrolment
31/01/2015

Locations

Countries of recruitment
France

Study participating centre
Hopital privé gériatrique les sources
10 Camin René Pietruschi
NICE

France
06100

Sponsor information

Organisation
Lamhess

ROR
https://ror.org/03fd87035

Funder(s)

Funder type
Industry

Funder Name
Malakoff Mederick Group

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/05/2018	15/03/2019	Yes	No
Results article	results	06/12/2018	16/08/2019	Yes	No
Protocol article		22/08/2016	29/11/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes