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Effects of a cardiac rehabilitation program based on continuous high-intensity Nordic Walking training

Submission date
03/06/2022

Recruitment status
No longer recruiting

Registration date
04/07/2022

Overall study status
Completed

Last Edited
29/06/2022

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cardiac patients (with heart and blood vessel diseases) could benefit from rehabilitation based on physical exercise. However, after a normal program, 12 weeks, there is a need to continue exercising but not in the hospital setting because distance, number of patients, etc. An alternative is explored to increase adherence to exercise in the community. Nordic walking is a feasible exercise intervention that should be testes in cardiac patients for a long-time training. Cardiac rehabilitation (CR) phase III has been little investigated for training methods and administration. Our objective was to study the effects of a CR phase III program based on Nordic Walking (NW) after acute coronary syndrome (ACS).

Who can participate?
Any stable cardiac patient that previously followed a cardiac rehabilitation program.

What does the study involve?
A 12-months community high-intensity Nordic WalkingNW training combined with educational strategy through instant messaging.

What are the possible benefits and risks of participating?
Our hypothesis is that Nordic walking improves physical capacity and physical activity levels. The risks are minimal and not greater than those that a person is exposed to by walking or exercising regularly.

Where is the study run from?
Universidad Ramon Llull, Spain

When is the study starting and how long is it expected to run for?
January 2018 to December 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Jordi Vilaró, jordivc@blanquerna.url.edu

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
GIR001

Study information

Scientific Title
Effects of a phase III cardiac rehabilitation program based on continuous high-intensity Nordic Walking training: A randomised controlled trial

Study objectives
Interdisciplinary training that combines high-intensity Nordic Walking endurance training supervised and directed in the community with follow-up educational strategies by sending short text messages is effective in a group of patients with ACS who had completed a three-month inpatient phase II cardiac rehabilitation program.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/02/2018, Clinical Research Ethics Committee of the Hospital Universitari Dr. Josep Trueta de Girona (Avinguda de França, S/N, 17007 Girona, Spain; +34 972940200; no email provided), ref: none provided

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients with stable ischemic heart disease and preserved systolic function

Interventions
The phase III CRP began within a maximum period of 5 days after the end of the phase II and lasted 12 months.

Intervention group:
a) 104 supervised sessions of 75 minutes of NW endurance training supervised and directed in the community, with a frequency of 2 days/week
b) educational strategy to control cardiovascular risk factors through 3 weekly SMS messages and 2-hour monthly group therapy.

Control group:
a) individual proposal of home autonomous physical training of 4 weekly sessions of 60 minutes of aerobic training
b) educational strategy through hospital group therapies identical to that for the EG
c) final cardiological evaluation included an IET.

Intervention Type
Behavioural

Primary outcome(s)
All patients underwent a specific evaluation before (taking the final specific tests and measurements of the phase II CRP) and post-intervention (at 12 months) of each of the following sections:
1. Functional capacity: Incremental exercise test (IET) was performed using the Bruce protocol on an endless treadmill, stopping due to fatigue or symptoms, following the standards defined by the Spanish Society of Cardiology (SEC).
2. Heart rate and blood pressure were measured at baseline, peak condition, and the maximum load in METs.
3. On separate days, the six-minute walk test (6MWT) was performed, following the protocol established by the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR). The maximum distance walked, the baseline and final heart rate, blood pressure, dyspnea and fatigue using the modified Borg Scale were registered.

Key secondary outcome(s))
1. Body composition: body weight and abdominal perimeter were measured. The body composition was carried out using electrical bioimpedance analysis (Bodystat 500, England), following the standards defined by the Spanish Kinanthropometry Group (GREC).
2. Level of daily physical activity: the International Physical Activity Questionnaire (IPAQ) extended version was applied, consisting of 27 questions related to physical activity at work,

home and leisure levels, quantified in minutes/day or minutes/week.
Additionally, were registered cardiological events that required hospital medical treatment and adherence to exercise, which was defined as performing 80% or more of the intervention as it was prescribed.

Completion date
30/12/2021

Eligibility

Key inclusion criteria
Clinically stable patients with a medical diagnosis of non-ST-segment elevation acute coronary syndrome, defined as unstable angina or non-Q acute myocardial infarction, or ST-segment elevation ACS, defined as acute myocardial infarction, who completed the phase II outpatient cardiac rehabilitation program, attending at least 80% of the training sessions and all medical visits.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
80

Key exclusion criteria
Patients who could not follow phase III for working reasons or declined to participate.

Date of first enrolment
01/10/2018

Date of final enrolment
30/10/2021

Locations

Countries of recruitment
Spain

Study participating centre

Hospital Universitari Dr. Josep Trueta de Girona
Avenida de Francia s/n. 17007
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Sponsor information

Organisation
Ramon Llull University

ROR
https://ror.org/04p9k2z50

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			29/06/2022	No	Yes