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Efficacy of treadmill exercises on arterial blood oxygenation, oxygen consumption and walking distance in healthy elderly people

Submission date	Recruitment status	[_] Prospectively registered
29/04/2016	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
03/05/2016	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
31/05/2016	Other	

Plain English summary of protocol

Background and study aims
Pulmonary (lung) capacity deteriorates gradually with age. However, regular physical exercise can improve lung function even in elderly people, improving their ability to perform daily activities such as walking. We want to study how a program of weekly physical exercise on a treadmill can improve lung function, compared with the standard recommendations on healthy lifestyle and regular exercise.

Who can participate?
Healthy volunteers aged between 60 and 70

What does the study involve?
Participants undergo a 48-week physical exercise program consisting of walking on a treadmill three times a week. Another similar group of participants is encouraged to walk twice a week and receives the standard recommendations for good health.

What are the possible benefits and risks of participating?
The expected benefits are improved lung function compared with people following the standard recommendations. Possible risks are limited to falling from the treadmill.

Where is the study run from?
Dar El Salam General Hospital (Egypt)

When is the study starting and how long is it expected to run for?
March 2006 to September 2013

Who is funding the study?
1. University of Córdoba (Spain)
2. Dar El Salam General Hospital (Egypt)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1/2007

Study information

Scientific Title
Efficacy of treadmill exercises on arterial blood oxygenation, oxygen consumption and walking distance in healthy elderly people: a non-randomized controlled trial

Acronym
HETWAP

Study objectives
Treadmill walking is better than standard recommendations on health for healthy elderly people.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Ethics Committee of Dar El Salam General Hospital in Cairo, 15/01/2007, Number 1/2007
2. Ethics Committee of the Department of Morphological Sciences, School of Medicine, University of Córdoba, 09/10/2008, Number 29102008

Study design
Prospective single-centre non-randomized single-blinded controlled intervention trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Aerobic power

Interventions
Participants were incorporated in an exercise program of moderate intensity (walking on the treadmill) 3 times weekly for 48 weeks; the first 12 weeks were supervised and the remaining 36 weeks of the program were unsupervised. The duration of complete training sessions was of 30 minutes the first three weeks, 40 minutes the next two weeks, 50 minutes the next two weeks, and 60 minutes until the end of the program.

The intervention exercise protocol was applied based on the protocol of Naughton. The exercise program consisted of walking on a treadmill with fixed 0% grade of inclination. The exercise program consists of 3 phases:
1. Warming up phase of 5 minutes on the treadmill
2. Active phase in which the speed of the treadmill is increased to achieve at least 60% and not more than 70% of the maximum heart rate (HR max) according to the protocol of Fletcher and collaborators. The treadmill inclination is fixed at 0% grade during the whole program, so the intensity of the exercise could be increased or decreased only by changing the speed of the treadmill. The active phase of exercise is 20 minutes for the first 3 weeks, 30 minutes for the next two weeks, 40 minutes for the followings two weeks and finally for 50 minutes until the end of the program
3. Cooling down phase for a period of 5 minutes which is achieved by reducing the speed gradually till reaching zero and until the heart rate returned almost to resting level.

A treadmill DKN Run Tech 2.5 with adjustable speed, inclination and timer, and a large LCD screen with 23 training programs and 3 users' profiles was used. The screen displays simultaneously walking time and distance, speed, inclination, burned calories and heart rate. The

treadmill has front and/or side rails to aid in subject stability. Also, a Pulsometer (HR) p610 Accurex Plus was utilized for monitoring of heart rate.

Participants in the control group were encouraged to walk twice a week during 45 minutes through enlightening the benefits of moderate physical activity on health, and received standard recommendations for proper health. A telephone follow-up of the adherence to recommended exercise guidelines was conducted weekly.

Intervention Type
Behavioural

Primary outcome measure
1. Measurement of Oxygen saturation (SaO2). Pulse Oximeter CMS 50DL Finger Pulse Oximeter SaO2 was used to measure SaO2. It was measured one week prior training; pulse oximeter was utilized to measure SaO2 in the right index of each individual. Each individual had to rest for two minutes before the beginning of the measurement. After placing the sensor on the finger, we waited until a reading was displayed on the oximeter, then we waited for another 10-15 seconds to verify a steady signal, this is followed by recording SaO2 and pulse every 10 seconds. Six observations were recorded and their average was used as the individual's SaO2 as in previous studies. These measurements were taken in a specific cardiopulmonary test, regardless of the training sessions.

2. Measurement of Maximum Oxygen consumption (VO2max). A Cardiopulmonary Exercise Test unit (CPET) Zan 800, a gas analyser of O2 and CO2 was used for the measurement of VO2max. Before conducting the test, the humidity collector was cleaned, the connected tube was checked, and the triple V- valve sensor disinfected and the gas analyser calibrated. The heart rate and blood pressure were recorded in the relaxed sitting position for each subject of the group. The mask was fixed with straps and then the triple tube V was connected to the mask. Initially, metabolic parameters such as oxygen consumption, carbon dioxide production and heart rate at rest were measured every three minutes. These measurements were taken in a specific cardiopulmonary test, regardless of the training sessions.

3. Maximal Walking Distance (MWD). This data was obtained from the treadmill DKN Run Tech 2.5. MWD is displayed on the screen. MWD data at baseline was recorded from an exercise test, the same test displayed in the first period of training sessions (warming up phase of 5 minutes on the treadmill, 20 minutes of active phase, and cooling down phase for a period of 5 minutes). At the 12th, 30th and 48th week, MWD was recorded from the training session in the corresponding week.

Secondary outcome measures
Adherence, defined as the completion of the protocol, was measured at the end of the protocol

Overall study start date
12/03/2006

Completion date
25/09/2013

Eligibility

Key inclusion criteria

1. Age between 60 and 70 years
2. Non-smokers or former smokers for more than 5 years
3. Good general health (without neuromuscular, orthopaedic, neurological or cardiopulmonary conditions)

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
Eighty four patients were selected for allocation

Key exclusion criteria
1. Neuromuscular diseases
2. Orthopaedic diseases
3. Neurological diseases
4. Cardio-pulmonary diseases
5. Any chronic deficit that would prevent exercise

Date of first enrolment
15/10/2010

Date of final enrolment
25/01/2011

Locations

Countries of recruitment
Egypt

Study participating centre
Dar El Salam General Hospital
ENT & Ophtalmology Centre
Cairo
Egypt
11611

Sponsor information

Organisation

University of Córdoba (Spain)

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Sponsor type
University/education

ROR
https://ror.org/05yc77b46

Funder(s)

Funder type
University/education

Funder Name
University of Córdoba (Spain)

Funder Name
Dar El Salam General Hospital (Egypt)

Results and Publications

Publication and dissemination plan
Paper submission in progress. Later, we would like to participate in a Geriatric Congress with some poster or communication.

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?
Results article	results	25/05/2016		Yes	No