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Effects of accumulated exercise on risk factors for heart disease

Submission date 04/01/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/10/2012	**Overall study status** Completed	
Last Edited 12/10/2017	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Overweight and obese people have a higher risk of getting cardiovascular (heart) disease (CVD). However, regular moderate physical activity reduces the risk of CVD. This study had two aims. Firstly, it looked at whether or not overweight people can reduce their risk of CVD (particularly the flexibility of their arteries; arterial stiffness) by including 30 minutes of brisk walking in three ten minute sessions on five days per week for six months. Secondly the study looked at the level of telephone contact needed by these individuals to help them maintain their increased activity.

Who can participate?
Overweight/obese people, aged 30-55, who were inactive (less than 30 minutes of moderate activity per day over the last six months).

What does the study involve?
Before starting the study, everyone taking part in the study had their height and weight measured. They also had the width of their waist, hips and upper arm measured. The researchers also measured the participants percentage body fat. Participants were randomly allocated into one of three groups. In the walking weekly group, participants were asked to include 30 minutes of walking into their normal routine on five days per week. They were told that the walking could be carried out in three bouts of ten minutes. They were contacted by telephone once per month to check that they were doing their exercise and to provide support. In the walking monthly group, participants were asked to include 30 minutes of walking into their normal day on five days per week, and were contacted by telephone once every week. This allowed the researcher to see if the more frequent telephone calls had an effect on the people's adherence to the extra walking. In the dummy group, participants were asked to do some stretching and relaxation exercises every day. These exercises would have no effect on their CVD risk. They were contacted by telephone once per month to check that they were doing their exercises. At the beginning of the study, in the middle of the study (3 months in), at the end of the 6 month study and again 4 months after the study had ended, all participants were asked to write down what they had eaten over a given four days. These food diaries were used to check that the people on the study had not changed their diet over the course of the study. If the participants had changed their diet, then the researcher wouldn't know if any changes to their CVD risk were due to the increased walking or due to the changes in their diet. Everyone taking part in the

study was asked to keep their normal eating habits. At the beginning of the study, the end of the study and four months after the study ended the following measurements were taken. The participant's fitness levels were measured by a treadmill walking test. A fasting blood sample was also taken and blood pressure was measured using an automated machine. The flexibility and stretchiness of the artery wall in the arm (arterial stiffness) was also measured.

What are the possible benefits and risks of participating?
There were no risks to the people taking part in the study and although the study may not have brought about any direct benefits to the participants, the results can be used by the researcher to determine the benefits of exercise carried out in short 10-minute bouts.

Where is the study run from?
University of Ulster (UK)

When is study starting and how long is it expected to run for?
September 2008 to September 2009

Who is funding the study?
Department for Employment and Learning (UK)

Who is the main contact?
Dr Alison Gallagher

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effects of accumulated walking on cardiovascular disease risk factors in overweight and obese subjects

Study objectives
The aim of the proposed study is two-fold. Firstly, it will investigate whether or not obese /overweight individuals can reduce their risk of cardiovascular disease (CVD) by incorporating 30 minutes of walking in shorts bouts into their daily routine. This risk will be measured using traditional measures such as fitness levels, blood lipids and insulin resistance but it will also include pulse wave velocity which is a novel non-invasive measurement of arterial stiffness. Secondly it will look at the level of contact required by the individuals from a support worker in order to sustain this level of exercise and be successful in modifying their daily routine to include 30 minutes of moderate exercise and will be based upon the Stages of Change model developed by Prochaska and Diclemente (1983).

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Ulster Research Ethics Committee, 14/04/2008, ref: REC/07/0176

Study design
Randomised controlled single-centre intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

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

Interventions
Control group:
The control group will be shown some stretching and relaxation exercises to do on a daily basis, the researcher will contact this group monthly either by telephone or text to check that they are doing their exercises. We anticipate that the actual stretching exercises will not alter the subject's activity levels, and monthly contact is included as an attempt to control for any 'attention effects' that might occur between the control and ER1.

Exercise Routine 1 (ER1) group:
The ER1 group, will be asked to incorporate 30 minutes of walking into their normal routine each day. They will be advised that this walking can be undertaken in three bouts of ten minutes each. This group they will be contacted by the researcher monthly to check that they are doing their exercise and also to provide support.

Exercise Routine 2 (ER2) group:
The ER2 group will be asked to incorporate 30 minutes of walking into their day, five days a week (as for ER1). However they will be contacted more regularly than the ER1 group (i.e. weekly rather than monthly). This will allow us to examine the usefulness of more regular contact on adherence and effect of intervention. As for ER1, contact will be by the researcher by text message or telephone to check that they are doing the exercises and to provide encouragement.

Intervention Type
Behavioural

Primary outcome measure
Arterial stiffness: measured using Pulse Wave Velocity (PWV) as an indirect measure. All PWV recordings will be on the same (left) arm for subjects, between the brachial and radial pulse sites of the arterial tree (identified by manual palpation). Pulse wave traces are calculated using the Labview program (Version 7.0).

Secondary outcome measures
1. Anthropometry: height, weight (used to calculate body mass index) and waist/hip circumferences will be recorded using standardised methods (Jones et al. 1986). Mid-upper arm circumference will also be measured. In addition percentage body fat will be measured using bioelectrical impedance.
2. Physical fitness: evaluated using a sub maximal treadmill-walking test, which will involve walking for 3 minutes at four progressive workloads (12 minutes total). Expired air analysis and heart rate will be used to predict maximal oxygen uptake and blood lactate will also be measured through a pin prick. Grip strength and flexibility will also be measured using standardised methods.
3. Blood profiles: the role of abnormal lipids, inflammatory markers and homocysteine in the genesis of cardiovascular disease is well recognised. Thus fasting blood samples (30 ml) will be analysed for blood glucose, insulin (used to calculate homeostatic model assessment [HOMA]), lipids (total cholesterol, high density lipoprotein [HDL] cholesterol, low density lipoprotein [LDL] cholesterol and triglycerides), C-reactive protein (CRP - as a marker of inflammation), plasma homocysteine and related B vitamins and other novel CVD risk factors (including cholecystokinin [CCK], glucagon-like peptide-1 [GLP-1], ghrelin [activated form], leptin, and adiponectin).
4. Blood pressure: measured at each sampling time point using an automated BP machine and taking the average of two measurements

Overall study start date
01/03/2008

Completion date
01/04/2009

Eligibility

Key inclusion criteria
1. Sedentary (self reported of less than 30 mins/day, moderate intensity activity during past 6 months) but otherwise apparently healthy non-smokers
2. Male or female, aged 30 - 55 years
3. Body mass index (BMI) 27 - 35 kg/m^2 (i.e. overweight/obese)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
90 subjects

Key exclusion criteria
1. Hypertension (blood pressure [BP] greater than 140/90 mmHg)
2. Documented ischaemic heart disease or heart failure, peripheral vascular disease or cerebral vascular disease, diabetes mellitus, chronic renal disease or lung disease (including asthma or chronic obstructive pulmonary disease)
3. Current recent (less than 6 months) or planned pregnancy
4. Any injury or orthopaedic condition precluding walking for exercise

Date of first enrolment
01/03/2008

Date of final enrolment
01/04/2009

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
University of Ulster
Coleraine
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BT52 1SA

Sponsor information

Organisation
Department for Employment and Learning (UK)

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Sponsor type
Government

Website
http://www.delni.gov.uk/

ROR
https://ror.org/05w9mt194

Funder(s)

Funder type
Government

Funder Name
Department for Employment and Learning, Northern Ireland

Alternative Name(s)
Department for Employment and Learning, DEL, NI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration