ISRCTN13024854 https://doi.org/10.1186/ISRCTN13024854

The effects of different community fitness centre based interventions in sedentary adults

Submission date
20/02/2018

Recruitment status
No longer recruiting

Registration date
05/03/2018

Overall study status
Completed

Last Edited
15/02/2019

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Loss of lean body mass and strength are key public health concerns. Aerobic physical activity as currently prescribed in guidelines is relatively ineffective for improving these outcomes. Resistance training however is known to improve both. There is relatively little research examining community-based resistance training interventions for public health. The aim of this study is to examine the effects of community fitness centre based exercise interventions involving resistance training using either a structured or unstructured approach, or physical activity counselling, upon lean body mass and strength.

Who can participate?
Sedentary adults (not meeting physical activity recommendations) currently not taking any medication for cardiovascular (heart) disease

What does the study involve?
Participants are offered one of two pathways. Those choosing the fitness centre pathway are randomly allocated to one of two interventions: a structured exercise programme or free /unstructured exercise. Those choosing a non-fitness centre pathway are randomly allocated to either physical activity counselling (PAC), or to just participate in the measurement sessions. At the start of the study and after the interventions (48 weeks) participants have their lean body mass and strength assessed.

What are the possible benefits and risks of participating?
Participants benefit from being able to take part in either community fitness centre interventions or physical activity counselling for 48 weeks, which may result in improvements in lean body mass and strength. The potential risks include injury or other complications as a result of the exercise program.

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

When is the study starting and how long is it expected to run for?
January 2013 to April 2015

Who is funding the study?
University of Greenwich (UK) and ukactive (UK)

Who is the main contact?
1. Dr Steven Mann
2. Dr James Steele

Contact information

Type(s)
Public

Contact name
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CommunityFitnessCentreStudy

Study information

Scientific Title

The effects of 48 week structured exercise, unstructured exercise, physical activity counselling, or measurement only control on strength and body composition in sedentary adults

Study objectives
A structured exercise intervention will result in greater strength and body composition improvements compared with either unstructured exercise, physical activity counselling, or measurement only control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Greenwich, 10/07/2012, ref: UREC/11/12.5.6.11

Study design
Semi-randomised trial

Primary study design
Interventional

Secondary study design
Semi-randomised trial

Study setting(s)
Community

Study type(s)
Other

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
Physical activity and exercise

Interventions
The population (P) was sedentary adults. The interventions (I) included two fitness centre interventions and a physical activity counselling intervention both described below, and the comparator (C) was a measurement only control group. Outcomes (O) included body composition and strength.

A semi-randomised trial design was utilised. Participants were initially offered one of two pathways. Those choosing the fitness centre pathway were randomised to one of two interventions; a structured exercise programme (STRUC), or free/unstructured exercise (FREE). Those choosing a non-fitness centre pathway were randomised to either physical activity counselling (PAC), or to a measurement only control condition (CONT) including two health checks. Interventions were delivered over 48 weeks with measures at 0 (baseline) and 48 weeks.

STRUC had access to all fitness centre facilities and received an individualised and structured RT programme. This programme was based on guidelines published by the American College of

Sports Medicine (ACSM). RT loads were based upon calculations of one-repetition maximum (1RM) derived from baseline data (see below). As the studies were conducted in ecologically valid community settings there was some flexibility in the exercises utilised based on participant preferences and any orthopaedic issues/injuries. However, all participants at a minimum followed a full body routine consisting of an upper body multi-joint push (e.g. chest press, overhead press, or dip), upper body multi-joint pull (e.g. pulldown, or seated row), and lower body multi-joint push (e.g. leg press). Exercise professionals met STRUC participants once a month to discuss their progress.

FREE participants had access to all fitness centre facilities but received no structured programme. Exercise professionals met with FREE participants once each month to discuss progress.

PAC participants met exercise professionals once each month for counselling sessions structured around the model proposed by Haase et al. and delivered within the fitness centre location. PAC participants did not however have access to any fitness centre exercise facilities.

CONT participants acted as the comparator group, did not receive an intervention, and did not have access to any fitness centre exercise facilities. Whilst CONT did not receive an exercise intervention, they did receive two free health screens (pre and post measurement) over the duration of the study. Exercise professionals were instructed to have no contact with CONT participants other than to arrange data collection at 0 and 48 weeks.

Intervention Type
Behavioural

Primary outcome measure
Measured pre and post (48 weeks) intervention:
1. Body composition, including BF mass (kg), LBM (kg) and BF percentage (%), measured using bioelectrical-impedance (Bodystat 1500, Bodystat, Isle of Man, UK). Guidelines from the National Institute of Health Research Southampton Biomedical Research Centre were followed for body compositions assessment (http://www.uhs.nhs.uk/Media/Southampton-Clinical-Research /Procedures/BRCProcedures/Procedure-for-bioimpedance-with-Bodystat-1500.pdf).
2. Predicted 1RM for chest press, pull down and leg press obtained by gauging the maximal weight that could be lifted successfully for between 5 and 15 repetitions, and inputting these data into the Brzycki equation (i.e. weight/(1.0278-(0.0278 x No. Repetitions)). These results were collapsed into a single strength measure (the mean of the predicted 1RM for each exercise).

Secondary outcome measures
Measured pre and post (48 weeks) intervention:
1. Maximal aerobic capacity (VO2max) predicted using the Modified Balke Protocol. Participants walked on a treadmill at between 3.6 and 5.6kph, depending on ability, for 3min. Following this, the gradient was increased by 1% each minute. Ratings of perceived exertions were recorded at 1min intervals using the OMNI1–10 scale. Oxygen consumption and heart rate were continuously monitored via direct gaseous analysis (Fitmate Pro, COSMED, Italy). Predicted VO2max was automatically extrapolated using the relationship with heart rate. The test was terminated when participants indicated perceived exertion above six (hard) and/or their heart rate reached 150 bpm.
2. Mean arterial pressure (MAP), which describes the average arterial pressure during a single cardiac cycle, incorporating both systolic and diastolic phases, but weighted towards the

diastolic. Systolic (SBP) and diastolic (DBP) blood pressures (mmHg) were measured using a commercially available blood pressure monitor (Omron Healthcare, Japan). Three readings were collected and the mean value reported. MAP was estimated via the calculation MAP=DBP+0.33 (SBP–DBP).
3. Total cholesterol (TC: the sum of low-density lipoprotein (LDL) and high-density lipoprotein (HDL) cholesterol) measured via finger-prick blood analysis (Cholestech LDX, Alere, UK)

Overall study start date
01/01/2013

Completion date
01/04/2015

Eligibility

Key inclusion criteria
1. Sedentary, defined as currently not meeting the physical activity recommendations of the UK Chief Medical Officer
2. Taking no medication that might impact cardiovascular risk

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
2080

Key exclusion criteria
1. Not classified as sedentary
2. Currently taking medication that might impact cardiovascular disease risk

Date of first enrolment
01/08/2013

Date of final enrolment
01/12/2013

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Topnotch Health Club
Unit 2
Phoenix Square
Wyncolls Rd
Colchester
United Kingdom
CO4 9AS

Study participating centre
ESPH
116 Lordship Lane
London
United Kingdom
SE22 8HD

Study participating centre
DC Leisure – Malden Centre
Blagdon Road
New Malden
United Kingdom
KT3 4TA

Study participating centre
DC Leisure - Harbourne
Lordswood Road
Harborne
Birmingham
United Kingdom
B17 9QS

Study participating centre
The Shrewsbury Club
Sundorne Road
Shrewsbury
United Kingdom
SY1 4RG

Study participating centre

Life Leisure: Avondale
Heathbank Road
Cheadle Heath
Stockport
United Kingdom
SK3 0UP

Study participating centre
Eze Fitness Redditch
17 Alcester Street
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United Kingdom
B98 8AE

Study participating centre
Airdrie Leisure Centre
Motherwell Street
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ML6 7HU

Study participating centre
The Essex Golf & Country Club
Earls Colne
Colchester
United Kingdom
CO6 2NS

Study participating centre
Chartham Park
Felcourt Road
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East Grinstead
United Kingdom
RH19 2JT

Study participating centre
Adam Nicholas Eze Fitness
E Service Road
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Derby

United Kingdom
DE21 7BB

Study participating centre
Richie Sundaram / Jermaine Ward
15 Thomas More Square
London
United Kingdom
E1W 1YW

Study participating centre
White Horse Leisure and Tennis Centre
Audlett Drive
Abingdon
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OX14 3PJ

Study participating centre
All Seasons Leisure Centre
United Kingdom
PR7 1EX

Study participating centre
Ravenscraig Regional Sports Facility
O'Donnell Way
Motherwell
United Kingdom
ML1 2TZ

Study participating centre
Leith Victoria Leisure Centre
Junction Place
Edinburgh
United Kingdom
EH6 5JA

Study participating centre
Nizels Golf & Country Club
Nizels Lane

Hildenborough
United Kingdom
TN11 8NU

Study participating centre
Pent Valley Leisure Centre
Tile Kiln Lane
Cheriton
Folkestone
United Kingdom
CT19 4PB

Study participating centre
Fitness First
179a Tottenham Court Road
London
United Kingdom
W1T 7PA

Study participating centre
Eze Fitness Scarborough
Dunslow Road
Eastfield Business Park
Scarborough
United Kingdom
YO11 3UT

Study participating centre
Pontefract Squash and Leisure Club
Stuart Road
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United Kingdom
WF8 4PQ

Study participating centre
Fitness First
Aspects Leisure Park
Kingswood
Bristol
United Kingdom
BS15 9LA

Study participating centre
DC Leisure
Penns Place
Petersfield
United Kingdom
GU31 4EX

Study participating centre
St James Leisure Centre
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Sponsor information

Organisation
University of Greenwich

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University of Greenwich
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University/education

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ukactive

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Sponsor type
Industry

Organisation
University of Greenwich

Sponsor details

Sponsor type
Not defined

Website
http://www2.gre.ac.uk/

ROR
https://ror.org/00bmj0a71

Funder(s)

Funder type
University/education

Funder Name
University of Greenwich

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
ukactive

Results and Publications

Publication and dissemination plan
Planned publication in BMC Public Health.

Intention to publish date
23/05/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Steven Mann or Dr James Steele.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/03/2018		Yes	No