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The effects of different community fitness centre based exercise referral interventions in overweight and obese adults

Submission date
20/02/2018

Recruitment status
No longer recruiting

Registration date
06/03/2018

Overall study status
Completed

Last Edited
18/12/2020

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Resistance training is effective at modifying risk factors for metabolic disease. However, 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, delivered through a GP referral scheme, involving resistance training compared with physical activity counselling or a combination of both, upon lean body mass and strength.

Who can participate?
Adults who are overweight or obese, and/or deemed to be at increased risk of type 2 diabetes by their GP, who are not currently taking prescribed medications for any cardiovascular or metabolic conditions

What does the study involve?
Participants enter an exercise referral scheme and are randomly allocated to either a structured exercise program involving resistance training, physical activity counselling, a combination of the two, or a waiting list. Those allocated to the waiting list are randomly allocated to one of the interventions upon completion of the waiting period. At the start of the study and after the interventions (48 weeks) participants have their lean body mass and strength measured.

What are the possible benefits and risks of participating?
Participants benefit from being able to take part in structured exercise interventions or physical activity counselling for 12 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?
London Borough of Bexley (UK)

When is the study starting and how long is it expected to run for?
October 2014 to February 2016

Who is funding the study?
Parkwood Leisure and The London Borough of Bexley (UK)

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

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ParkwoodTrial

Study information

Scientific Title
The effects of structured exercise, physical activity counselling, or a combination of both, upon strength and body composition in overweight and obese adults taking part in an exercise referral scheme

Study objectives
Interventions including structured exercise will result in greater strength and body composition compared with physical activity counselling, or measurement only control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Health Service Research Ethics Committee, London - Queen Square Research Ethics Committee, UK, 01/12/2014, IRAS project ID 172321, REC ref: 15/LO/0540

Study design
Randomised wait-list controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled 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 overweight or obese adults with, or at increased risk of, Type 2 Diabetes. The interventions (I) included three interventions groups described in detail below; a general practitioner (GP) exercise referral scheme of structured exercise (STRUC), physical activity counselling (PAC), or a combination of both (COMB). The comparator (C) was a wait-list control group awaiting entry into the GP exercise referral scheme. Outcomes (O) included body composition and strength.

Participants were randomly assigned to one of four groups including the three intervention groups and one wait-list control group. All interventions were delivered over a period of 12 weeks.

STRUC received one session per week of a structured and supervised GP exercise referral intervention. This intervention was already delivered as part of the care pathway of the local health trust and participants were restricted to these sessions. 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.

PAC received one session per week of physical activity counselling. The sessions were structured around the model proposed by Haase et al. and no access to fitness facilities.

COMB received a combination of physical activity counselling (sessions in weeks 1, 3, 5, 7, 9 & 11) and a structured and supervised GP exercise referral intervention (sessions in weeks 2, 4, 6, 8, 10 & 12).

The CONT group was formed from a wait-list control facilitated by a legitimate 12-week waiting list for entry into the GP exercise referral intervention. CONT participants received the intervention after this period, though only their waiting list period data was included for analysis.

Intervention Type
Other

Primary outcome measure
Measured pre and post (12 weeks) intervention:
1. Body composition, including BF mass (kg), lean mass (kg) and BF percentage (%), measured using bio-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 (12 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 3 min. Following this, the gradient was increased by 1% each minute. Ratings of perceived exertions recorded at 1-min intervals using the OMNI1–10 scale. Oxygen consumption and heart rate continuously monitored via direct gaseous analysis (Fitmate Pro, COSMED, Italy). Predicted VO2max 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 150bpm
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)

Overall study start date
01/10/2014

Completion date
01/02/2016

Eligibility

Key inclusion criteria
1. Overweight and/or obese (BMI 25-35), and/or at increased risk of type 2 diabetes as determined by their General Practitioner (GP)
2. Not currently taking any prescribed medication for cardiovascular or metabolic conditions

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Not classified as overweight or obese
2. Not deemed to be at increased risk of Type 2 diabetes as determined by their General Practitioner (GP)
3. Currently taking prescribed medication for cardiovascular or metabolic conditions

Date of first enrolment
01/01/2015

Date of final enrolment
01/02/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Crook Log Leisure Centre
Brampton Road
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Sponsor information

Organisation
ukactive

Sponsor details
26 28 Bedford Row
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Parkwood Leisure

Funder Name
London Borough of Bexley

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	23/11/2020	Yes	No
HRA research summary			28/06/2023	No	No