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Exercise for Obesity in Females for Increasing Fitness: the EXOFFIT study

Submission date
20/07/2021

Recruitment status
No longer recruiting

Registration date
16/11/2021

Overall study status
Completed

Last Edited
15/08/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The prevalence of female obesity has more than doubled in the past 30 years and the incidence of morbid obesity in women is more than twice the incidence recorded in men. Evidence suggests that among adults, women of childbearing age (18-44 years) are the most at risk of developing obesity, with this group demonstrating the highest rate of weight gain. Mounting evidence indicates that excessive weight gained during childbearing years is strongly associated with long term adverse outcomes (including an increased risk of developing cancer, and heart and metabolic issues). In addition, obesity is associated with a greater prevalence of chronic pain and decreased quality of life. Encouragingly, the research indicates that improving fitness, which can be increased with exercise, can largely resolve the health-related risk factors associated with obesity.
Previous research investigating the effectiveness of programmes based on physical activity guidelines have shown that aerobic exercise moderately improves fitness in young women living with obesity. In the general adult population living with obesity, combined (aerobic and resistance) interventions have been shown to be the most promising for improving fitness. However, there is little research investigating other types of interventions (i.e., resistance, combined) in this cohort. Therefore, the overall aim of this study is to evaluate the effectiveness of aerobic exercise, resistance training and combined training for improving fitness, strength and other health outcomes in women living with obesity.

Who can participate?
Women aged 18-50 years with a body mass index (BMI) over 30 kg/m² or a waist circumference over 88 cm who are physically inactive (<150 minutes per week)

What does the study involve?
All participants will be invited to the study site to complete a baseline assessment which consists of the following tests:
1. Body composition: height, weight, waist and hip circumference, fat mass and muscle mass are measured using a measuring tape and a bioelectrical impedance analyser as appropriate.
2. Cardiorespiratory fitness: participants will be instructed to walk on a treadmill until they get tired (about 10-15 minutes).
3. Strength will be measured by performing the following exercises: bench press, leg press and

handgrip squeeze. For the bench press and leg press, participants will be instructed to perform five repetitions at different weights until they reach a weight which they can only perform five reps or fail to perform five reps.
Participants will also be provided with a questionnaire by email or in paper format (as preferred) to complete either before or after their first assessment. This questionnaire will include questions about physical activity levels, sleep, mood, pain and quality of life. All of these outcomes will be measured again after the intervention.
After the first assessment, participants will be randomly allocated to one of the four groups. All programmes will last for 12 weeks and are as follows:
1. Resistance training programme
2. Concurrent (aerobic and resistance training) programme
3. Aerobic exercise programme
4. Control (non-active group)
Participants allocated to one of the exercise programmes will progress the amount and intensity of exercise they do over 12 weeks until they can complete 150 minutes of exercise per week (three 50-minute sessions). Participants allocated to the control group will be asked to maintain their physical activity/exercise levels for 12 weeks. After this period, they will be offered the chance to join one of the exercise groups of their choosing and avail of an individualised and supervised exercise programme for 12 weeks.

What are the possible benefits and risks of participating?
The benefits of being involved in this study include a detailed assessment of fitness, strength and physical functioning and involvement in a structured exercise training programme that will potentially improve fitness and overall health and wellbeing. Exercise does carry a risk of injuries, such as a pulled muscle, muscle soreness or in extreme cases abnormal heart rhythm or cardiac events. However, participants will be closely monitored during testing and throughout the programmes by members of the research team. Should they develop any physical issues /injuries, they will be provided individual advice and rehabilitation by the lead investigator who is a physiotherapist. Given the ongoing COVID-19 pandemic, there is also a minimal risk of COVID-19 transmission associated with exercising indoors. The risk associated with partaking in this study will be no greater than exercising in other indoor settings such as gyms or exercise classes. This study will abide by all public health recommendations at the time. However, in general, to minimise this risk for all involved, stringent procedures will be in place around the use of equipment for exercise and testing procedures and access to the exercise room.

Where is the study run from?
University College Dublin (Ireland)

When is the study starting and how long is it expected to run for?
February 2021 to December 2022

Who is funding the study?
University College Dublin (Ireland)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Comparison of time-matched aerobic, resistance, or combined supervised exercise training in young women living with obesity: a pilot randomised controlled trial. The EXOFFIT Study (Exercise for Obesity in Females to increase Fitness)

Acronym
EXOFFIT

Study objectives
Primary null hypothesis: Post-intervention, there is no difference in outcomes (cardiorespiratory fitness (CRF), strength, body composition, self-reported) between participants randomised to the exercise interventions and the control.

Secondary null hypothesis: Post-intervention, there is no difference in outcomes (CRF, strength, body composition) between participants randomised to the aerobic exercise, resistance training and combined training groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/07/2021, University College Dublin Human Research Ethics Committee - Sciences (Office of Research Ethics, University College Dublin, Belfied, Dublin 4; +353 (01) 7168767; hrec@ucd.ie), ref: LS-21-59-Davis-ODonoghue

Study design
Single-center interventional single-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Obesity in women

Interventions
This four-arm parallel pilot study will be conducted in University College Dublin. Following an initial screening, the participants will be randomised with an allocation ratio of 1:1:1:1 into one of the three time-matched exercise modes or control:
1. Aerobic: progressive aerobic exercise; 150 minutes per week
2. Resistance training: progressive resistance exercise; 150 minutes per week
3. Combined training: progressive combined aerobic/resistance training; 150 minutes per week
4. Control: non-exercise group (participants to maintain baseline physical activity levels)

Participants allocated to one of the exercise programmes will progress the amount and intensity of exercise they do over 12 weeks until they can complete 150 minutes of exercise per week

(three 50-minute sessions). Participants allocated to the control group will be asked to maintain their physical activity/exercise levels for 12 weeks. After this period, they will be offered the chance to join one of the exercise groups of their choosing and avail of an individualised and supervised exercise programme for 12 weeks.

Intervention Type
Behavioural

Primary outcome(s)
Cardiorespiratory fitness is measured using VO_2max at baseline and post-intervention (after 12 weeks)

Key secondary outcome(s))
1. Body composition is measured using BMI, waist circumference, waist-hip ratio, fat mass, body fat percentage, and muscle mass at baseline and post-intervention (after 12 weeks)
2. Strength is measured using 5RM bench press, leg dynamometry, and grip strength at baseline and post-intervention (after 12 weeks)
3. Quality of life is measured using the EuroQol-5D-5L (EQ-5D-5L) questionnaire at baseline and post-intervention (after 12 weeks)
4. Pain is measured using the Brief Pain Inventory at baseline and post-intervention (after 12 weeks)
5. Physical activity is measured using the International Physical Activity Questionnaire (IPAQ) at baseline and post-intervention (after 12 weeks)
6. Sleep is measured using the Pittsburgh Sleep Quality Index at baseline and post-intervention (after 12 weeks)
7. Mood is measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline and post-intervention (after 12 weeks)
8. Trial fidelity and feasibility are measured using the following:
8.1. Recruitment challenges
8.2. Retention rates of all trial arms
8.3. Adherence of participants (% of participants who attended >70% of sessions)
8.4. Incidence of adverse events (an adverse event defined as an event which a participant identifies a problem caused by the exercise programme that required the participant to seek treatment from a health professional and/or prevents participation in the programme)
8.5. Exercise volume/intensity adherence (reps, sets, target heart rate compliance)
8.6. The number of participants needed per group in order to achieve significance in a potential follow-up randomized controlled trial (via a power calculation)
8.7. Acceptability of trial procedures and interventions through a qualitative exploration of subjects experience of each intervention
These will be measured during the study and post-intervention (after 12 weeks) as applicable

Completion date
23/12/2022

Eligibility

Key inclusion criteria
1. Female aged 18-50 years at the time of consent
2. Body Mass Index (BMI) ≥30 kg/m² and /or a waist circumference >88 cm
3. Are currently physically inactive (exercising less than 150 min/week)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
Female

Total final enrolment
67

Key exclusion criteria
1. BMI <30 kg/m² or waist circumference <88 cm
2. Unstable cardiovascular, respiratory, renal or hepatic condition
3. Contraindicated or no clinician (i.e. GP) has advised them against exercising (i.e. chest pain during activity or at rest, severe hypertension, etc)
4. Have undergone weight loss surgery in the past 3 months
5. Are pregnant (or within 6 months post-pregnancy) or lactating
6. Have a significant mental illness or cognitive deficits
7. Are participating in another trial (exercise-based or targeting weight-loss) at the time of consent

Date of first enrolment
30/07/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin
Belfield
Dubin 4
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Sponsor information

Organisation
University College Dublin

ROR
https://ror.org/05m7pjf47

Funder(s)

Funder type
University/education

Funder Name
University College Dublin

Alternative Name(s)
UCD

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan
De-identified participant data are not publicly available as they may contain information that could compromise research participant privacy/consent. However, these data may be made available on reasonable request by contacting the Principal Investigator Dr Gráinne O'Donoghue (grainne.odonoghue@ucd.ie). All data will be anonymised upon entry into a secure database on an encrypted password-protected computer (in a secure office) and on the institution's secure servers, accessed only by the research team. Hard copies of questionnaires and/or other data will be stored in a locked filing cabinet in a locked office which only the research team will have access to.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/04/2024	03/04/2024	Yes	No
Protocol article		21/02/2022	22/04/2024	Yes	No
Other publications	mixed-methods evaluation	14/08/2024	15/08/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes