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Activity to reduce obstructive sleep apnoea

Submission date
20/07/2020

Recruitment status
No longer recruiting

Registration date
21/07/2020

Overall study status
Completed

Last Edited
14/08/2020

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Obstructive sleep apnoea (often abbreviated as OSA) is a condition that causes the airway of sufferers to close on multiple occasions during sleep, which temporarily interrupts breathing. OSA is more prevalent in obese individuals and even more prevalent to those who are older. The only effective treatment currently is the use of Continuous Positive Airway Pressure (CPAP), which requires a face mask to be worn during sleep. The adherence to this treatment is poor because the majority of patients find it uncomfortable to wear and socially obtrusive. Exercise has been shown to improve the condition but the feasibility of changing patients' behaviour consistently for exercise to be used as a potential mode of treatment is not well described.

Who can participate?
Adult manual workers aged between 50 and 69 years old with no previous diagnosis or treatment for obstructive sleep apnoea and no history of chest pain during exercise or any kind of heart trouble

What does the study involve?
The study is a 12-week physical activity intervention that requires participants to gradually increase the duration and intensity of their daily physical activity such as walking, daily household tasks (e.g. gardening). Participants are asked to report their total daily amount of physical activity and intensity to an investigator via text message. Levels of physical activity are also monitored by accelerometers at three timepoints for 7 days (during weeks 1, 6, and 12) to validate self-reported physical activity. At the end of the 12-week period, measurements are compared to those taken at the start of the study to assess the effectiveness of the intervention.

What are the possible benefits and risks of participating?
Engaging in physical activity regularly is considered to be a health benefit for everyone and participants in this study will gain these health benefits by increasing the amount of time that they spend being active. The particular benefit to the participants recruited for this study may also have a direct benefit towards the severity of the OSA condition with which they are suffering. An improvement in the severity of the condition due to increased activity levels will reduce the negative results of OSA which are sleepiness, tiredness and deterioration of heart health. The risks of participating in this study relate solely to the participant’s engagement with

exercise. Potential risks of exercise in older adults include possible musculoskeletal injuries and complications secondary to an undiagnosed heart condition. The gradual increase in exercise duration and intensity in this study minimises these risks.

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

When is the study starting and how long is it expected to run for?
March 2017 to December 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr George Balanos
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The implementation of a physical activity intervention in adults with obstructive sleep apnoea over the age of 50 years: a feasibility uncontrolled clinical trial

Acronym
AROSA

Study objectives
Physical activity can improve cardiorespiratory fitness and improve the severity of obstructive sleep apnoea possibly via facilitating upper airway adaption and rostral fluid shift.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/08/2017, University of Birmingham Science, Technology, Engineering and Mathematics Ethical Review Committee (Research Support Group, C Block Dome (room 132), Aston Webb Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT, UK; +44 (0) 121 414 8101; ethics-queries@contacts.bham.ac.uk or s.m.waldron@bham.ac.uk), ref: ERN_16-1326A

Study design
Single-centre non-randomized interventional feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Obstructive sleep apnoea

Interventions
Overnight screening for Obstructive Sleep Apnoea (OSA) indicates eligible participants with an Apnoea Hypopnoea Index (AHI) score greater than 15 who are then invited to take part in the intervention. Prior to the intervention, a screening questionnaire pertaining to the participants' general health is administered and baseline anthropometric measurements are recorded. All participants are invited to complete a questionnaire to measure current daily physical activity levels.

Participants are advised in a face-to-face session with an investigator, as to how to increase the frequency, duration and intensity of their current physical activity (PA) levels over the following 12 weeks. Participants are asked to report their total daily amount of PA and intensity (Rate of Perceived Exertion, RPE) as two numbers to the mobile phone of an investigator via text message. Levels of PA are also monitored by accelerometers at three timepoints for 7 days (during weeks 1, 6, and 12) to validate self-reported PA. Total minimum accelerometer wear time required is 12 hours for seven consecutive days. At the end of the 12-week period, post-intervention measurements including AHI are taken as described earlier and compared to those at baseline to assess the effectiveness of the intervention.

Intervention Type
Behavioural

Primary outcome measure
Feasibility of increasing the duration and intensity of weekly physical activity: participant compliance and adherence to the intervention measured using daily self-reporting via text messaging, objectively confirmed using accelerometry for seven consecutive days during week 6 and week 12

Secondary outcome measures
1. Physical activity measured subjectively using the short form International Physical Activity Questionnaire (IPAQ) at baseline and 12 weeks
2. Physical activity measured objectively using accelerometry at baseline, 6 weeks and 12 weeks
3. The presence and severity of Obstructive Sleep Apnea (OSA) evaluated using the Apnoea /Hypopnoea Index (AHI) using a domiciliary testing device (ApneaLink Air) at baseline and 12 weeks
4. Anthropometric measurements: BMI (kg/m2) and weight and body fat percentage measured using bioelectrical impedance at baseline and 12 weeks

Overall study start date
27/03/2017

Completion date
07/12/2018

Eligibility

Key inclusion criteria
1. Adult manual workers
2. Aged between 50 and 69 years old
3. No previous diagnosis or treatment for obstructive sleep apnoea
4. No history of chest pain during exercise or heart trouble
5. Employed for at least the previous 3 months or longer

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
10 participants for a feasibility study

Total final enrolment
10

Key exclusion criteria
1. Younger than 50 or older than 69 years old
2. Unemployed or employed for less than 3 months
3. Previous diagnosis or treatment for obstructive sleep apnoea
4. History of chest pain during exercise or heart trouble

Date of first enrolment
08/08/2017

Date of final enrolment
04/06/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
School of Sport, Exercise and Rehabilitation Sciences
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Sponsor information

Organisation
University of Birmingham

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Sponsor type
University/education

Website
http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Results of the trial, specifically the potential of physical activity to reduce OSA.

Intention to publish date
01/08/2020

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 George Balanos (g.m.balanos@bham.ac.uk). The data that can be provided will be anonymised participant-level detail of the variables reported in the relevant publication. The data will be made available upon publication of the study (August 2020). Data will be made available for research purposes (such as systematic reviews) and the files containing these data will be shared via encrypted email. Participants have indicated that they consent for their data to be used in future data analysis but this was not explicitly in relation to data sharing.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/08/2020	14/08/2020	Yes	No