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A combined programme of dietary restriction and physical activity in people with osteoarthritis of the knee

Submission date
06/01/2017

Recruitment status
No longer recruiting

Registration date
12/01/2017

Overall study status
Completed

Last Edited
21/02/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and aims
Knee osteoarthritis (OA) is a major public health problem worldwide, as well as the most common long-term illness among older adults. Knee OA may result in pain, discomfort and stiffness which may in turn restrict activities of daily living and have a negative effect on quality of life. This is more likely to happen in someone who is also overweight or obese. Current clinical guidelines and recommendations to help manage knee OA emphasise the importance of both diet and exercise on reducing weight and improving function. The effect of combined diet and exercise in overweight older adults with knee OA has been evaluated in the United States but no UK studies have been published to date. The main aim of this study is to evaluate the feasibility of a combined programmed of exercise and diet for older adults with obesity and knee OA.

Who can participate?
Obese patients aged 45-90 years, who have been referred to an outpatient clinic and physiotherapy department at the Royal Orthopaedic Hospital, Birmingham with knee OA

What does the study involve?
All participants receive an initial education session about knee OA, advice about physical activity, healthy diet and ideal weight. They then follow a diet alongside usual physiotherapy care for 4 months. They are asked to attend three assessment sessions to complete a questionnaire, undertake some physical tests and provide a small sample of blood. Also, they are asked to attend a group discussion at the end of the study to give their feedback and report their experience of participating in the study.

What are the possible benefits and risks of participating?
Regular exercise has many benefits. It is possible that the participation in this study may result in improved physical function as well as quality of life. This may be further helped by controlling diet. We cannot guarantee that participants will receive all of these benefits but we would be surprised if they didn't receive any. However the main purpose of the study is to find out whether the delivery of a combined diet and exercise programme is acceptable to older adults with knee OA. So although this study may not benefit participants directly, the information we

get from the study will help us design future studies to improve the management of knee OA. We have taken every step in the design of this study to minimise any possible disadvantages and risks. Safety considerations for exercise will be explained to participants during the educational session before starting the exercise classes. All the sessions will be carried under a supervision of trained physiotherapist and the diet plans will be designed by a member of the study team who is a clinical dietician.

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

Who is funding the study?
University of Birmingham (UK)

Who is the main contact?
1. Ms Asma Alrushud (scientific)
2. Dr Carolyn Greig (public)

Contact information

Type(s)
Scientific

Contact name
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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ERN_16-1432

Study information

Scientific Title
The effect of a combined programme of dietary restriction and physical activity on the physical function and body composition of obese middle aged and older adults with knee OA (DRPA): Feasibility study

Acronym
DRPA

Study objectives
A combined intervention programme of dietary restriction plus usual care for older adults with knee OA is feasible, acceptable and effective. Also, it is hypothesized that all outcome measures including body weight, waist circumference, knee joint inflammation and pain will be reduced and physical function and quality of life will be improved.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. West Midlands - Solihull Research Ethics Committee, 12/05/2017, ref: 17/WM/0122
2. HRA approved protocol number ERN_16-1432; RG_17-024, Version 6.0 01/03/2018

Study design
Single-centre feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
Current interventions as of 06/06/2018:
Participants will be recruited via the ROH outpatient clinic and physiotherapy department. Potential participants will be identified by a ROH clinician or senior physiotherapists according to the eligibility criteria. Eligible participants will be provided with a copy of the participant information sheet and a response slip, which will include a telephone number and email address to contact the study team directly and a stamped addressed envelope for those who prefer to respond by post.

After consenting to participate, participants will be invited to attend the Sport, Exercise and Rehabilitation School (SportExR), University of Birmingham where the study procedures will be explained in further detail, participants will be given the opportunity to ask questions, informed consent will be obtained and baseline data collected. Participants will be asked to complete a 3-day food diary (week day and week end) and to return it by post to a member of the study team (using the stamped addressed envelope provided to them), and a date will be scheduled to begin the exercise classes at ROH. The first class will be preceded by an educational session about knee OA, during which participants will be given the opportunity to ask any further questions. The study will be run in the physiotherapy gym under the supervision of a physiotherapist for one month.

Participants will receive a physiotherapy usual care programme for knee OA (stretching and strengthening exercise) for 60min/week. Participants will continue to exercise in their local gyms for 3 months. The study team will assist participants with application for a free (or discounted, funded by the study) gym pass via the Birmingham Be Active scheme. Participants will follow dietary restriction throughout the 4 months of the intervention and we aim for a decrease of 300-500 kcal.day-1 or 500-1000 kcal.day-1 as appropriate to initial BMI. The diet will be planned and modified (if needed) by a qualified clinical dietician. All outcome measures will be recorded 3 times except the biomarkers of joint remodelling and body composition only at baseline and 16 weeks. Finally, feasibility questionnaire and focus groups will be organised.

Participants focus group and feasibility questionnaire for ROH physio staff will be completed at the final assessment point (week 16).

Previous interventions:
Participants will be recruited via the ROH outpatient clinic after being identified by a ROH clinician according to the eligibility criteria. Eligible participants will be provided with a copy of the participant information sheet and a response slip, which will include a telephone number and email address to contact the study team directly and a stamped addressed envelope for those who prefer to respond by post.

After consenting to participate, participants will be invited to attend the Sport, Exercise and Rehabilitation School (SportExR), University of Birmingham where the study procedures will be explained in further detail, participants will be given the opportunity to ask questions, informed consent will be obtained and baseline data collected. Participants will be asked to complete a 3-day food diary (week day and week end) and to return it by post to a member of the study team (using the stamped addressed envelope provided to them), and a date will be scheduled to begin the exercise classes at ROH. The first class will be preceded by an educational session about knee OA, during which participants will be given the opportunity to ask any further

questions. The study will be run in the physiotherapy gym under the supervision of a physiotherapist for one month.

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Participants focus group and feasibility questionnaire for ROH physio staff will be completed at the final assessment point (week 16).

Intervention Type
Other

Primary outcome measure
Feasibility assessed via focus group (participants) and questionnaire (ROH physio staff) at week 16.

Secondary outcome measures
1. Body weight, waist circumference and body mass index (BMI) are measured using standard anthropomorphic techniques at baseline, 4 and 16 weeks
2. Musculoskeletal function is measured at baseline, 4 and 16 weeks:
2.1. Knee range of motion is measured by goniometry
2.2. Lower limb muscle power is measured by Nottingham Power Rig
3. Physical performance is measured using a stair climb and timed up and go test at baseline, 4 and 16 weeks
4. Pain intensity is measured using WOMAC pain subscale at baseline, 4 and 16 weeks
5. Quality of life is assessed using the SF-36 questionnaire at baseline, 4 and 16 weeks
6. Body composition is measured by body impedance analysis; BIA at baseline and 16 weeks
7. Markers of joint remodelling are assessed by Blood samples analysis at baseline and 16 weeks

Overall study start date
01/09/2016

Completion date
30/11/2018

Eligibility

Key inclusion criteria
Current inclusion criteria as of 06/06/2018:
1. Older adults (men and women aged 45-90 years)
2. Obese according to BMI ≥30 kg/m²
3. Not participating in regular exercise more than twice a week
4. Diagnosed with knee OA with or without radiographic evidence

Previous inclusion criteria:
1. Older adults (men and women aged ≥55 years)
2. Obese according to BMI ≥30Kg/m²
3. Not participating in regular exercise more than twice a week
4. Diagnosed with knee OA with or without radiographic evidence

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
30

Total final enrolment
35

Key exclusion criteria
Current exclusion criteria as of 06/06/2018:
1. Significant co-morbid disease that would pose a safety threat or impair ability to participate such as coronary artery disease, severe hypertension, peripheral vascular disease, stroke, congestive heart failure, chronic obstructive pulmonary disease, insulin-dependent diabetes, psychiatric disease, renal disease, liver disease, active cancer other than skin cancer, advanced osteoporosis and anaemia
2. Previous acute knee injury (moderate-severe) which may restrict the participant
3. Neuromuscular impairments that preclude participating in physical activity, visual, hearing, or moderate/ severe cognitive impairments
4. Unwillingness to modify diet or physical activity patterns or inability to comply with the intervention because of inability to access a gym, food allergies or reactions to the meal replacement
5. Resting systolic blood pressure greater than 200 mmHg and resting diastolic blood pressure greater than 100 mmHg

Previous exclusion criteria:
1. Significant co-morbid disease that would pose a safety threat or impair ability to participate such as coronary artery disease, severe hypertension, peripheral vascular disease, stroke, congestive heart failure, chronic obstructive pulmonary disease, insulin-dependent diabetes, psychiatric disease, renal disease, liver disease, active cancer other than skin cancer, advanced osteoporosis and anaemia
2. Previous acute knee injury (moderate-severe) which may restrict the participant
3. Neuromuscular impairments that preclude participating in physical activity, visual, hearing, or moderate/ severe cognitive impairments
4. Unwillingness to modify diet or physical activity patterns or inability to comply with the intervention because of inability to access a gym, food allergies or reactions to the meal replacement

Date of first enrolment

02/10/2017

Date of final enrolment
20/07/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal Orthopaedic Hospital
Royal Orthopaedic Hospital NHS Foundation Trust
Bristol Road South
Northfield
Birmingham
United Kingdom
B31 2AP

Study participating centre
University of Birmingham
School of Sport, Exercise and Rehabilitation Sciences
University of Birmingham Edgbaston Birmingham
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United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham

Sponsor details
Edgbaston
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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
University/education

Funder Name
University of Birmingham

Results and Publications

Publication and dissemination plan
Results of this trial will be submitted for publication in peer reviewed journals and the full study report can be accessed 6 months after completing the trial.

Intention to publish date
01/03/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr. Carolyn Greig (c.a.greig@bham.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1.3	09/01/2017	12/01/2017	No	Yes
Participant information sheet	version v5	10/01/2018	06/06/2018	No	Yes
Protocol article	protocol	14/12/2018	06/11/2019	Yes	No
Results article	results	01/12/2020	30/01/2020	Yes	No
Other publications	systematic review and mixed method data synthesis	08/06/2017	21/02/2023	Yes	No
HRA research summary			26/07/2023	No	No