Participant information sheet

Title of Project: The effect of a combined programme of dietary restriction and physical activity on the physical function and body composition of overweight middle aged and older adults with knee OA: Feasibility study

Short title: DRPA

Researchers: Ms Asma Alrushud; Dr Alison Rushton; Dr Carolyn Greig; Dr Simon Jones; Dr Gurjit Bhogal; Mr Fraser Pressdee; Mr Conor Bentley

We would like to invite you to take part in our study. Before you decide, you need to understand why this study is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The main goal of this study is to evaluate the feasibility, acceptability and effectiveness of a combined programme of exercise and diet for overweight middle aged and older adults with knee osteoarthritis (OA). Knee OA is a major public health problem worldwide, as well as the most common chronic 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 with knee OA who is also overweight. Current clinical guidelines and recommendations emphasise the importance of both diet and
exercise on reducing weight and improving function. The effect of the 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.

Why have I been invited?
You have been invited to participate in this study as you have been referred to an outpatient clinic or a physiotherapy department or at the Royal Orthopaedic Hospital (ROH), Birmingham because you have a diagnosis of knee OA and in addition, you are aged 45 years or over and classified as overweight with a body size (body mass index 30 kg.m$^{-2}$ or over).

Do I have to take part?
It is up to you to decide. We will describe the study and go through the information sheet, which we will give to you. We will then ask you to sign a consent form to show you agreed to take part and will give you a copy to keep. You are free to withdraw from the study at any time, without having to give a reason.

What will happen to me if I take part?
- We will organise for you to visit the School of Sport, Exercise and Rehabilitation Sciences (SportExR) at the University of Birmingham for assessment of physical function and to provide a blood sample. We will provide taxi transport or provide you with a parking permit if you prefer to drive. At the end of the assessment session we will provide you with a food diary to record your food intake for 3 days before starting the exercise classes and diet. We will ask you to return this diary by email to the Chief Investigator, Ms Asma AlRushud (asa314@student.bha.ac.uk). Alternatively you can return it to us by post (we will provide you with a stamp-addressed envelope). Also we will give you a simple compliance sheet to use throughout the study in which to indicate whether or not you were able to stick to your diet on that day.
- Approximately one week after this you will receive an education session about knee OA, ideal body weight and the importance of physical activity at the
physiotherapy gym at the ROH and on the same day you will start the first exercise class and will be provided with your diet plan.

- The diet plan will be designed and modified throughout the intervention (if needed) by a qualified clinical dietician (who is a member of the study team) according to your food diary information. We will ask you to follow a caloric restriction diet, in order to reduce you total body weight from 5-10% over 4 months. The prescribed diet will include a variety of foods, and you will be advised that there is some level of flexibility to the diet and there will be opportunities to modify your diet.

- The exercise session will last for 45-60 minutes and consist of some stretching and strengthening exercises which will help you to improve your muscle strength and function. We will ask you to attend one session per week for 4 weeks and you will be encouraged to exercise at home. The classes will be supervised by a physiotherapy technician and a member of the study team will also be present. After 4 weeks, we will ask you to visit SportExR again to repeat the physical assessments and you do not have to provide a blood sample during this visit. You will be provided with a local gym membership to continue your exercise as (1 hour/week) sessions for a further 12 weeks at your local gym.

- A member of the study team will phone you weekly to ask how you are managing with respect to gym attendance and following the diet.

- After completing 12 sessions in your local gym we will ask you to make two more visits to SportExR. The first visit will be to repeat the physical assessments, complete the function and quality of life questionnaire and provide a second blood sample.

- On your next and final visit we will ask you to participate in a discussion group (focus group for approx 1 hour) with other people who have taken part in the study, to give us your feedback. This session will be recorded but we will not record your name or any personal information. The recording device will be password protected and stored by Ms Alrushud. We will listen to the recording afterwards, transcribe the information and then will destroy the recording.
Expenses and payments?
We will cover the costs of your travel to and from SportExR for the physical assessments and focus group (discussion group) meeting.

What will I have to do?

First: We will ask you to complete a food diary and two questionnaires
Food diary: We will give you a special diary so that you can record the things you eat and drink over the course of 3 days (one day of them should be at weekend and two at week days).
Questionnaires: You will be asked to complete two questionnaires; one asks about your quality of life and the other about your condition, including pain, stiffness, and physical functioning. They will take approximately 20 minutes to complete.

Second: We will take some measurements of: your blood pressure, height, body weight, waist circumference (measurement taken around the abdomen at the level of the navel) and your knee joint range of movement. They will take approximately 10 minutes to complete.

Third: We will ask you to do some tests including:
Test of body composition: This is a simple test to measure the proportion of fat and lean tissue in your body. We will ask you to lie down and will place electrodes on your ankle and wrist. A small electrical current is passed through your body (it is so small that you will not feel it) for a few seconds. The test will take approximately 5 minutes.
Test of muscle power: Your leg muscle power will be measured using specialised equipment and will involve simple pushing movements which you will be asked to hold for a few seconds. These tests will take about 10 minutes so you may feel a little tired afterwards but the tests should not cause any pain or discomfort.
Timed up-and-go test: This test will measure your function, ability to walk and balance, we will ask you to rise from a chair walk 3 m to a cone, turn around and walk back to the chair and sit down again. We will ask you do this 3 times and it will take 5 minutes.
Stair climb: This test also measures your functional ability. We will measure the time taken to climb a flight of stairs. This will take 2 or 3 minutes.

A blood test: We will take two small samples of blood from a vein (a total of 10ml/each which is just a bit less than a tablespoon), one at baseline and one at the end of the study. The samples will be used to check your markers of joint function. These markers are what we call 'exploratory' in that we are trying to find out more about them and how they might change with exercise and diet. Therefore we will not feedback those results to you (although of course we will be happy to provide you with the results of your other assessments).

If you haven’t given blood in the last 3 months we will take an extra sample during your first visit (20 ml) for some routine testing just to confirm that it is safe for you to take part of the study. The basic blood testing will help assess the health of your major organs including your liver and kidneys. Any abnormal results will be discussed with you by Dr Gurjit Bhogal, and with your permission, your GP too. Your GP will provide ongoing care if required.

What are the possible disadvantages and risks of taking part?
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 you during the educational session before you start the exercise classes. All the sessions at the ROH will be carried out under the supervision of trained physiotherapy technician. Your diet plan will be designed by a member of the study team who is a clinical dietician and the diet will include a variety of foods, and you will be advised that there is some level of flexibility to the diet and there will be opportunities to modify your diet. Some participants may find the test of lower limb extensor power output uncomfortable; if you find this test painful, we will stop the procedure. Some participants may experience slight discomfort during the blood sampling but the procedure is quick and the sampling will be done by trained member of the study team.

What are the possible benefits of taking part?
Regular exercise has many benefits. It is possible that your participation in this study may result in improved physical function as well as quality of life. This may be further helped by controlling your diet. We cannot guarantee that you will receive all of these benefits but we would be surprised if you did not 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 you directly, the information we get from the study will help to design future studies to improve the management of knee OA.

What if you need further information or there is a problem?
If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions.
If you would like general information about taking part in research then please contact the NHS patient advice and liaison service (PALS) via the NHS choices website http://www.nhs.uk/pages/home.aspx.
If you have a problem and wish to complain formally, you can do this by contacting Dr Sean Jennings, Research Support Group, University of Birmingham (0121 415 8011) Email: s.jennings@bham.ac.uk or the ROH Complaints Department (0121 685 4226), Email: roh-tr.Complaints@nhs.net

Harm: In the event that something does go wrong and you are harmed during the research study, the University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage.

Will my taking part in the study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital/university will have your name and address removed so that you cannot be recognised. Your personal data will be kept by the study team for 12 months after the end of the study to allow patient contact for dissemination of results for contact purposes and will be destroyed after that. Your blood samples will be stored for 6-12 months in SportExR and analysed in the Institute of Inflammation and Ageing,
University of Birmingham. We will ask for your permission to store any leftover material to be used in future Research Ethics Committee approved studies.

**Involvement of the General Practitioner/Family Doctor (GP)**
We will inform your GP about your participation in this study and also to find out if you have had a recent blood test but will do so only with your permission.

**What will happen if I don’t carry on with the study?**
You can withdraw from the study but keep in contact with us to let us know your progress. However, we may still choose (with your permission) to use any data obtained as a result of your participation.

**What will happen to the results of the research study?**
The results of this study will be published in medical journals, reports and textbooks. You will not be identifiable in any report/publication unless you have given your consent.

**Who has reviewed the study?**
This study has been given a favourable ethical opinion for conduct in the NHS by the West Midlands - Solihull Research Ethics Committee.

**Who is organising or sponsoring the research?**
This study is being organised and sponsored by the University of Birmingham.

**Further information and contact details:**
For additional information or different enquires please do not hesitate to contact:
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Thank you