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Staying active with physiotherapy in patients with osteoarthritis

Submission date
21/01/2022

Recruitment status
No longer recruiting

Registration date
15/02/2022

Overall study status
Completed

Last Edited
17/11/2023

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is the leading cause of disability and pain in people who are 45 years of age or more. In the UK, about one-third of people 45 years of age or more (about 9 million people), have had treatment for it. Knee and hip OA are the most common types of OA. In the UK about 4 million people have knee OA and 2.5 million have hip OA. Increasing activity levels is one of the best ways to help people with OA to reduce their pain and gain as much function as possible. However, people with OA are generally less active than those without pain. Physiotherapists (physios) are the main professionals who help people with OA to be more active. Physiotherapy treatment is most effective at helping people with OA to reduce their pain and symptoms for about 3 months.
However, symptoms often return around 6 months after physio treatment starts. This is usually because people with OA can have difficulty following the physio's suggestions and often stop doing their activities after they are discharged from care. People go through several psychological 'stages' when they are changing their levels of activity. The most important stages that will happen when people are becoming more active are adoption (which happens during physio treatment) and maintenance (which would carry on after discharge). Importantly, the things that make people with lower-limb OA more active during adoption and maintenance are different. Therefore, the physio treatment needs to use different psychological techniques depending on which stage the person is in. This is the first theoretical psychological physiotherapy treatment that aims to help people with osteoarthritis be active as possible during physiotherapy treatment and after discharge. It uses techniques that aim to get people as active as possible during the 'adoption' and 'maintenance' psychological phases. Before conducting a large study, the researchers need to see what people with osteoarthritis and physiotherapists think of the psychological treatment. Therefore, they are testing how acceptable the psychological physiotherapy treatment is to people with OA and physiotherapists and how easy it is to deliver in practice

Who can participate?
Patients aged 45 years of age or over with lower-limb OA who have been referred to the Royal Orthopaedic Hospital (ROH), Birmingham

What does the study involve?
The study involves two key components: the physiotherapy treatment and outcome assessment
The psychological physiotherapy treatments main aim is to create a motivational treatment environment to support the person with lower-limb OA to be as active as possible. The treatment also uses specific techniques to help the person with their chosen activity.
People with lower-limb OA will attend one-to-one sessions (about six based on a previous study and current trust parameters) with ROH physiotherapists. Treatment sessions will be conducted in person or via phone or 'Attend Anywhere', a secure virtual platform used by the NHS. The trust's standard physiotherapy sessions are 40 minutes for the first appointment and 20 minutes for a follow-up. People with lower-limb OA will receive two paper-based workbooks. People with lower-limb OA who attend sessions in person will be given hard copies of the workbooks while those who attend remotely will receive them by email. The first workbook encourages the person with lower-limb OA to identify appropriate activity goals. The book includes a weekly activity planner and each person with lower-limb OA will be given a pedometer to keep as thanks for participating.
The person with lower-limb OA will complete outcome assessment at three timepoints: just before their physiotherapy appointment, and then 3 and 6 months later. They will have a virtual outcome appointment scheduled at each timepoint with an outcome assessor which should last less than 30 minutes. The outcomes include several forms to fill in and an accelerometer which records how active the person with lower-limb osteoarthritis is. These will be posted to people with lower-limb OA home addresses one week before their scheduled outcome assessment appointment. People with lower-limb OA will be asked to fill in their forms before their outcome appointment but will be able to ask any questions during the outcome appointment. People with lower-limb OA will be asked to wear the accelerometer for 7 days apart from when they are asleep or in water. During the outcome assessment appointment, the outcome assessor will ask if there have been any flare-ups as the result of their activity and ask people with lower-limb OA to do two simple tasks including standing up and sitting down as many times as possible in 5 seconds and walking in a figure of 8. The outcome assessor may ask if the person with lower-limb OA would like to attend an interview at the 3-month session to give their opinion of the physiotherapy treatment.

What are the possible benefits and risks of participating?
This is a low-risk study that poses a similar risk to standardised physiotherapy and as such adverse events are not expected. There may be some minor, short-lived increase in symptoms from physiotherapy due to people with lower-limb OA increasing their activity level. However, the overall benefits of increased activity levels include greater function and reduced symptoms. Each person with lower-limb OA will be given a pedometer to keep as thanks for participating

Where is the study run from?
Royal Orthopaedic Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2020 to November 2023

Who is funding the study?
1. Musculoskeletal Association of Chartered Physiotherapists (UK)
2. University of Birmingham (UK)

Who is the main contact?
Matthew Willett
m.j.willett.1@bham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Matthew Willett

ORCID ID
http://orcid.org/0000-0001-5107-1771

Contact details
School of Sport, Exercise and Rehabilitation Sciences
College of Life and Environmental Sciences
University of Birmingham
Edgbaston
-Birmingham
United Kingdom
B15 2TT
+44 (0)121 415 8591
m.j.willett.1@bham.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
303710

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 51080, IRAS 303710

Study information

Scientific Title
STaying Active with Physiotherapy in patients with Lower-limb Osteoarthritis (STAPLO): Feasibility Trial

Acronym
STAPLO

Study objectives
As this study is a feasibility study, it does not have a hypothesis. It aims to work out whether a new psychological physiotherapy treatment is acceptable to patients and physiotherapists and if the study can be delivered in an NHS setting. If it is found to be acceptable and ok to deliver, a

randomised controlled trial (RCT) may be run next. This would compare the psychological physio treatment to other groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/11/2021, London - Riverside Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6P, UK; +44 (0)207 104 8184; riverside.rec@hra.nhs.uk), REC ref: 21/PR/1490

Study design
Non-randomized; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Physical, Rehabilitation

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
The study uses a single group of up to 35 patients with lower-limb OA. They will complete written and some functional outcome measures before treatment and 3 and 6 months later. The researchers are aiming to recruit about 35 people so they have enough information to measure whether the key objectives have been met. After they have completed treatment, about 10 participants will be offered the chance to discuss their opinions of the treatment with a member of the research team. The physiotherapists who delivered the psychological treatment, and the ROH research team will also give their opinions of how the study worked in an NHS setting.

Study setting
People with lower-limb OA who have been referred to the Royal Orthopaedic Hospital (ROH), Birmingham will be able to participate in the study. People with lower-limb OA will have the choice of having their treatment sessions in the ROH physiotherapy clinics or remotely via telephone or ‘Attend Anywhere’, a secure virtual platform used by the NHS. As part of the treatment, ongoing activity will be done by people with lower-limb OA in their own home or the community.

Recruitment of participants

People with lower-limb OA will be identified from the physiotherapy waiting lists at the ROH by a member of the clinical care team. They will be sent a Participant Information Sheet (PIS), two study consent forms (one to return and one to keep), and a stamped, addressed envelope.

As standard practice, each person referred for physiotherapy is contacted by the ROH to arrange their appointment. If the person has been sent a PIS their appointment to arrange physiotherapy treatment will be conducted by a member of the clinical care team. At the appointment, the person will be asked if they have reviewed the PIS and if they are interested in participating in the study. If the person reports being interested, the member of the clinical care team will confirm eligibility, outline the study, answer any questions, and go through the consent form with the person.

Consent will be taken by the member of the clinical care team during the phone call and witnessed by another ROH member of staff. The member of the clinical care team will ask each participant to confirm their name prior to reading through each item on the form and gain consent in real-time. Once consent has been established, the member of the clinical care team will sign and date the form and the other member of staff will countersign the form to confirm that consent was established. A copy of the consent form will be posted to the person with lower-limb OA for their records.

The appointment with the member of the clinical care team will be held a minimum of 1 week after the PIS and consent forms have been sent out so the person has had the opportunity to review all documents and consult family and friends about the study.

During the meeting, the member of the clinical care team will state that people are free to withdraw from the trial at any time and that this will not impact their current or future healthcare. Once consent has been obtained, the trial staff will schedule an initial physiotherapy session and an online assessment appointment (phone or Zoom/Skype depending on the persons' preference) with a trained blinded outcome assessor. The baseline outcome assessment will be scheduled just before the physiotherapy session.

Methods of data collection

Outcomes during the trial

The person with lower-limb OA will complete outcome assessment at three timepoints: just before their physiotherapy appointment, and then three months and six months later. They will have a virtual outcome appointment scheduled at each timepoint with an outcome assessor which should last less than 30 minutes. The outcomes include several forms to fill in and an accelerometer that records how active the person with lower-limb osteoarthritis is. These will be posted to people with lower-limb OA home addresses one week prior to their scheduled outcome assessment appointment. People with lower-limb OA will be asked to fill in their forms before their outcome appointment but will be able to ask any questions during the outcome appointment.

People with lower-limb OA will be asked to wear the accelerometer for 7 days apart from when they are asleep or in water. Simple instructions and a belt to help secure the accelerometer will be included. A stamped, addressed envelope will also be included for the return of accelerometers and forms to the research team at the Royal Orthopaedic Hospital.

During the outcome assessment appointment, the outcome assessor will ask if there have been any flare-ups as the result of their activity and ask people with lower-limb OA to do two simple tasks including standing up and sitting down as many times as possible in 5 seconds and walking in a figure of 8. The outcome assessor may ask if the person with lower-limb OA would like to attend an interview at the 3-month session.

People with lower-limb OA will be reminded to return their outcomes at each virtual assessment. If outcomes are not returned within 2 weeks of their assessment appointment, the person with lower-limb OA will be contacted via text/telephone by the research team and asked

to send them back when they are able.
All patient documents were designed with a person with lower-limb OA with extensive experience in public involvement and a lifetime's work in effective communication.

Intervention

The psychological physiotherapy treatments main aim is to create a motivational treatment environment to support the person with lower-limb OA to be as active as possible. The treatment also uses specific techniques to help the person with their chosen activity. These techniques were identified in a previous qualitative study (IRAS 247904).
People with lower-limb OA will attend one-to-one sessions (approximately six based on our previous study and current trust parameters) with ROH physiotherapists. Treatment sessions will be conducted in person or via phone or 'Attend Anywhere', a secure virtual platform used by the NHS. The ROH trust's standard physiotherapy sessions are 40 minutes for the first appointment and 20 minutes for a follow-up.
People with lower-limb OA will receive two paper-based workbooks. People with lower-limb OA who attend sessions in person will be given hard copies of the workbooks while those who attend remotely will receive them via email. The first workbook encourages the person with lower-limb OA to identify appropriate activity goals. The book includes a weekly activity planner and each person with lower-limb OA will be given a pedometer (YAMAX) to keep as thanks for participating.
People with lower-limb OA will be given the second workbook in session 4. This workbook focuses on helping people with lower-limb OA to find changes that need to be made to their home or social environment to help them maintain their activity after they have finished physiotherapy.
The trial workbooks will be supported by the Hip or Knee Versus Arthritis booklet which provides general information on OA and support services.

Physiotherapist training

The physiotherapists will be trained in how to deliver the psychological treatment. The main aim of the training is to help physiotherapists understand how the treatment environment can affect the person with lower-limb OA's confidence and motivation to participate in their chosen activity. The training will involve presentations and practice delivering the psychological techniques and creating a motivational treatment environment.
The physiotherapists will receive printed and electronic material including a treatment handbook and some research articles.
Training will be provided by two members of the research team; Professor Joan Duda (JD), the creator of the training programme who possesses a PhD in psychology, and Matthew Willett (MW), whose PhD has focused on the development of the psychological treatment. Training will include two in-person group sessions of three hours and a follow-up 2-hour 'top-up' session.

Data collection and analysis

The main way to determine if the psychological physio treatment is acceptable and can be delivered in the NHS, is to gain the opinions of the people involved in the study. Therefore, most of the data will be qualitative.

Interviews with participants

After they have finished physiotherapy treatment about 8-10 people with lower-limb OA will be asked if they would like to attend an interview so they can give their opinions of the treatment. This sample size should allow us to gain opinions from participants of different gender and age. Participants will be approached by a member of the clinical care team at their 3-month assessment appointment and offered the choice of having their interviews conducted visually (Skype/Zoom) or by telephone. The interviews should last about 30-45 minutes each.

Focus groups with treating physiotherapists and research staff
The physiotherapists who delivered the treatment and ROH study research staff team will be invited to attend focus groups to give their opinions of the treatment and how well the study worked. The physiotherapists will also be asked about their opinions of the training they received. The physiotherapists and ROH research staff will be approached by the site lead researcher. It is anticipated that the physiotherapist focus group will last 90 minutes and the research staff focus group will about 1 hour.

Data analysis
As this is a feasibility trial, the main mathematical analysis will outline the sample and recruitment. A diagram will outline the number of people with lower-limb OA who were identified, recruited, commenced and finished treatment. Where possible, reasons for dropout during the treatment will be reported. The number of non-completed outcomes will be reported as a percentage.
To assess how well the treatment was delivered, some treatment sessions will be recorded on a Dictaphone. The file will be anonymised and then emailed securely to Matthew Willett who will organise for the intervention words to be typed out. These will be reviewed by Matthew Willett one other member of the research team to assess if the treatment was delivered as planned.

Qualitative data analysis
The interviews and focus groups will be done by Matthew Willett who will record them on a Dictaphone. The files will be anonymised and then the recorded words will be typed out (transcribed). The transcripts will be returned to participants for checking to ensure the typed-out words are accurate. Interview and focus group transcripts will be analysed by Matthew Willett and one other researcher to identify common themes that participants thought about the treatment.

Success criteria to see if a randomised controlled trial (RCT) is appropriate
Once data analysis is complete, it will be decided if the objectives have been met. If the overall study is found to be acceptable and able to be run, further discussion with public involvement will be used to see the study needs to be changed before attempting an RCT.

Anticipated study timelines
In preparation for the trial, a review of the ROH physiotherapy waiting lists were undertaken. Approximately 65 patients are referred to the trust each week and it is thought that about three per week would be people with lower-limb OA. Based on previous studies at the ROH, approximately one in three of those approached consent to participate. Therefore, recruitment of 35 participants would take 9 months. Training of the physiotherapists will take place as recruitment begins. Participant interviews will and the physiotherapy focus group should run within the study timeline. Including a 6-month follow up and approximately 2 months of data analysis and study write up suggests the study will take 17-18 months to complete.

Intervention Type
Other

Primary outcome measure
The feasibility of conducting an RCT using the behaviour change intervention, established through descriptive statistics and qualitative analysis of participants' and physiotherapists' perceptions of the intervention and trial-related queries. Descriptive statistics will be inputted iteratively and analysed at the end of the trial. Interviews with people with lower-limb osteoarthritis will occur after they have been discharged from care (approximately 4 months

post-baseline). Focus groups of physiotherapist and research staff will take place at the end of the trial (approximately 15 months from the trial commencing).

Secondary outcome measures
As part of the trial, outcomes that are intended for use in the RCT will be collected (to test the feasibility of outcome assessment):
1. Physical activity measured using an actigraph 9 accelerometer at baseline, 3 and 6 months
2. Physical activity measured using the Short-Form (7-questions) International Physical Activity Questionnaire at baseline, 3 and 6 months
3. Adherence to physical activity/exercise recommendations measured using Section B of The Exercise Adherence Rating Scale (6 Items) at baseline, 3 and 6 months
4. Pain measured using the 11-point Numerical Pain Rating Scale at baseline, 3 and 6 months
5. Function measured using the self-report Short form Hip Disability and Osteoarthritis Outcome Score (SF-HOOS)/Short-From Knee Injury and Osteoarthritis Outcome Score (SF-KOOS) at baseline, 3 and 6 months
6. Function measured using the 5 times sit-stand test and the figure of 8 walking test at baseline, 3 and 6 months
7. Bothersomeness measured using the Bothersomeness Index: 5-point Likert scale at baseline, 3 and 6 months
8. Quality of life measured using the EuroQol 5-domain instrument (EQ-5D) at baseline, 3 and 6 months
9. Self-efficacy for physical activity/exercise measured using the Self-Efficacy for Exercise Scale 9-items at baseline, 3 and 6 months
10. Motivation regulations to participate in physical activity/exercise measured using the Behavioural Regulation in Exercise Questionnaire-3 24-Items at baseline, 3 and 6 months
11. Psychological needs satisfaction measured using a modified version of the Psychological Need Satisfaction in Exercise Scale at baseline, 3 and 6 months
12. Social psychological environment/ perceptions of autonomy support measured using the Health Care Climate Questionnaire 15-items at 3 months post baseline

Overall study start date
01/11/2020

Completion date
30/11/2023

Eligibility

Key inclusion criteria
1. Diagnosis of unilateral or bilateral lower-limb osteoarthritis (OA) based on the NICE guidelines
2. Males or females ≥45 years of age
3. Morning joint-related stiffness lasting ≤30 minutes or no morning joint-related stiffness
4. Activity-related joint pain

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
Planned Sample Size: 45; UK Sample Size: 45

Total final enrolment
46

Key exclusion criteria
1. A further joint-related pathology that could affect the biomechanics of the hip or knee e.g. rheumatoid arthritis or lumbar nerve root lesion
2. Previously had or awaiting knee or hip joint replacement
3. Wheelchair dependent
4. Unwilling/unable to give informed consent for treatment
5. Unable to communicate fluently in English
6. Diagnosed with a psychiatric illness (e.g. schizophrenia)
7. Diagnosed with an upper motor neurone lesion e.g. multiple sclerosis
8. Unwilling/unable to attend physiotherapy sessions

Date of first enrolment
14/03/2022

Date of final enrolment
20/12/2022

Locations

Countries of recruitment
United Kingdom

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

Sponsor information

Organisation
University of Birmingham

Sponsor details

Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 (0)121 415 8011
researchgovernance@contacts.bham.ac.uk

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
Musculoskeletal Association of Chartered Physiotherapists (MACP)

Funder Name
University of Birmingham

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Trial protocol to be submitted for publication in March 2022. Trial results are planned for publication in a high-impact peer-reviewed journal around 1 year after the trial end date.

Intention to publish date
30/08/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		31/03/2023	03/04/2023	Yes	No
HRA research summary			28/06/2023	No	No