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Tailored exercise management for people aged 80 years or older with hip/knee osteoarthritis

Submission date
02/12/2021

Recruitment status
No longer recruiting

Registration date
03/12/2021

Overall study status
Completed

Last Edited
29/01/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis happens when the bone and cartilage in a joint breaks down, causing pain and stiffness. This in turn can reduce a person's mobility. Osteoarthritis is becoming more common as the population ages, and the accompanying costs are increasing dramatically. Exercise is recommended for all people with osteoarthritis. However, these recommendations are based on clinical trials including people aged between 60 and 70 years, and these findings cannot necessarily be applied to people aged 80 years or older.
Rapid loss of muscle occurs after 70 years of age, and older people are more likely to have health conditions that contribute to difficulties with daily activities and affect their response to exercise. To improve care for people aged 80 or older with osteoarthritis, it is thought that a tailored exercise intervention targeting both osteoarthritis and other health conditions they have, may be needed.
The aim of this study, funded by the charity Versus Arthritis, is to see if it is possible to conduct a trial to assess a tailored exercise programme for people aged 80 years or older with hip/knee osteoarthritis and other illnesses. The programme has been designed by physiotherapists and patients.

Who can participate?
People aged 80 years or above who have osteoarthritis of the hip or knee and have at least one other illness

What does the study involve?
Three methods of patient identification and recruitment will be used: screening of GP registers, an existing questionnaire study and NHS physiotherapy referrals. Participants will be allocated at random to one of two groups.
One group will receive the TEMPO programme. This will involve four to eight sessions with a physiotherapist over 12 weeks and a home exercise programme. Sessions will include education, a programme of exercises including aerobic, joint movement, muscle strengthening and balance exercises, and a supervised walking programme. This will be tailored to each person’s abilities and other health conditions.
The other group will receive care as recommended by the participant’s GP (known as 'usual care'). This is the treatment that they would otherwise receive. This group will also receive an

information booklet about hip/knee osteoarthritis including exercises.
The researchers will interview some of the patient participants and the physiotherapists who deliver the programme at the end of the study, and ask them what they thought of the study, and how it could be improved.

What are the possible benefits and risks of participating?
The information and exercises from either intervention may help with hip or knee joint pain. It is hoped that the information from this trial will help in the treatment of future patients. Participants are unlikely to be harmed by this treatment. If they attend physiotherapy the researchers will assess them to make sure that the exercises are at the right level for them. However, participants may find that they experience muscle soreness after completing some of the exercises. This is normal and the physiotherapist will give them advice on how to manage this. Sometimes people feel uncomfortable answering certain questions about their health. If there are any questions, from the Researcher, Physiotherapist or in the questionnaire that participants are uncomfortable with then they do not have to answer them.

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

When is the study starting and how long is it expected to run for?
June 2021 to May 2023

Who is funding the study?
Versus Arthritis (UK)

Who is the main contact?
Dr Philippa Nicolson
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Study website
https://www.ndorms.ox.ac.uk/research/tempo

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
303476

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50812, Versus Arthritis grant code 22428, IRAS 303476

Study information

Scientific Title
Tailored Exercise Management for People aged 80 years or older with hip/knee Osteoarthritis (TEMPO): a feasibility randomised trial

Acronym
TEMPO

Study objectives
Osteoarthritis is becoming more common as the population ages, and the accompanying costs are increasing dramatically. Exercise is recommended for all people with osteoarthritis. However, these recommendations are based on clinical trials including people aged between 60 and 70 years, and these findings cannot be generalised to people aged 80 years or older. Rapid loss of muscle occurs after 70 years of age, and older people are more likely to have health conditions that contribute to difficulties with daily activities and impact on their response to exercise. To improve care for people aged 80 years or older with osteoarthritis, it is thought that a tailored exercise intervention targeting both osteoarthritis and other health conditions they have, may be needed.

The aim of this study, funded by Versus Arthritis, is to see if it is possible to conduct a trial to evaluate a tailored exercise programme for people aged 80 years or older with hip/knee osteoarthritis and comorbidities. The programme has been designed by physiotherapists and patients.

Three methods of patient recruitment will be used: screening of GP registers; via an existing questionnaire study and via NHS physiotherapy referrals. Participants will be allocated at random to one of two groups:
1. The TEMPO programme: four to eight sessions with a physiotherapist over 12 weeks and a home exercise programme. Sessions will include education, aerobic, joint movement, muscle strengthening and balance exercises, and a supervised walking programme, tailored to each

person’s abilities and other health conditions.
2. Care as recommended by the participant’s GP (known as 'usual care'). This group will also receive an information booklet about hip/knee osteoarthritis including exercises.

The researchers will interview some of the patient participants and the physiotherapists who deliver the programme at the end of the study, and ask them what they thought of the study, and how it could be improved.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/11/2021, London-Brent Research Ethics Committee (80 London Road, Skipton House, London, SE1 6LH, UK; +44 (0)20 7104 8128, +44 (0)20 7104 8137; brent.rec@hra.nhs.uk), REC ref: 21/LO/0777

Study design
Randomized; Interventional; Design type: Treatment, Psychological & Behavioural, Physical, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Hip and knee osteoarthritis in people aged over 80 years who also have other illnesses

Interventions
TEMPO is a feasibility randomised controlled trial, with an embedded qualitative study, assessing a 12-week tailored exercise intervention versus usual care for adults aged 80 years and over with hip/knee OA and comorbidities. TEMPO will be conducted at three NHS physiotherapy outpatient departments over a 9-month period. Each patient participant will be enrolled in the study for 14 weeks.

Three methods of patient participant identification are being used: screening of GP registers; via the Oxford Pain, Activity and Lifestyle (OPAL) cohort study (an existing questionnaire study over people aged 65 and over from across England), and via NHS physiotherapy referrals.

Identified potential patient participants will be telephoned by TEMPO research staff, who will explain what the study involves, conduct an initial eligibility screen, and if the potential

participant is interested, book them in for an eligibility screen at their local participating NHS physiotherapy outpatient department. The eligibility screen will take approximately 1/2 an hour, and will involve answering questions. If the patient participant is eligible they will complete the informed consent form and proceed to the baseline assessment, which will take approximately 1 hour and will include completing some simple physical tasks and a questionnaire.

Following the baseline assessment patient participants will be randomised by a computer programme to one of two groups: the TEMPO programme or care as recommended by their GP (usual care). Those randomised to the TEMPO intervention will receive four to eight sessions with a physiotherapist over 12 weeks and a home exercise programme. Sessions with the therapist will include education, aerobic, joint movement, muscle strengthening and balance exercises, and a supervised walking programme, tailored to each person's abilities and other health conditions. Sessions 1-4 will be at the local NHS physiotherapy outpatient department. Sessions 5-8 are optional, and can be at the physiotherapy department, or at home via video or telephone consultation. Patient participants randomised to the usual care group will continue to receive care as determined by their GP and a hip or knee OA information and exercise booklet.

All patient participants will be asked to return for a follow-up assessment with a researcher at the NHS physiotherapy outpatient department approximately 14 weeks after their baseline assessment. This assessment will take approximately 1 1/2 hours and will include repeating the simple physical tasks and questionnaires completed at baseline.

When patient participants complete the informed consent form they will be asked if they give their permission to be interviewed by a researcher after their involvement in the study has concluded. This researcher will telephone participants, and if they are willing to be interviewed will arrange a time to complete the interview, either over the telephone or in person. We will not interview all participants. In this interview study we will ask patient-participants about their experiences of treatment and taking part in the study, and any suggestions they have for how we could improve the study. We will also interview the physiotherapists who deliver the TEMPO intervention, to explore their experience of taking part in the study and suggestions for improving the intervention for a definitive trial.

Intervention Type
Behavioural

Primary outcome measure
Patient recruitment to the study and retention in the study is measured using study recruitment screening logs: (number of patients who are screened, eligible consented and randomised) and logs of data collection forms (attrition rate), at screening, baseline and 14-week follow-up

Secondary outcome measures
Patient participant engagement with the study and feasibility of the interventions from patient participant and physiotherapist perspectives:
1. Patient participant engagement is measured by physiotherapy session attendance, home exercise adherence (measured by exercise diaries), treatment/s received by usual care group, attrition rate, qualitative interviews, measured during the intervention period and on completion of the qualitative interviews
2. Intervention fidelity assessed by treatment logs, quality assurance visits and safety reporting forms, measured throughout the intervention period
3. Completion of the expected primary outcome measure for a future definitive trial: self-reported physical function measured using the Nottingham Extended ADL Scale (NEADL),

measured at the end of the study (to estimate the sample size calculation for a definitive trial)
4. Experiences and perceptions of the study design from a patient participant and physiotherapist perspective, assessed by qualitative interviews at the end of the study

Overall study start date
01/06/2021

Completion date
31/05/2023

Eligibility

Key inclusion criteria
Patient participants:
1. Aged 80 years and above
2. Clinical diagnosis of knee or hip OA: knee or hip joint pain lasting 3 months or longer AND knee or hip joint pain on most days of the past month
3. Diagnosis of at least one comorbidity (determined by GP record review and/or self-report)
4. Registered with a primary care practice
5. Willing and able to give informed consent for participation in the study

Qualitative study:
There are no specific exclusion criteria for the qualitative study. If a patient participant has been recruited to the TEMPO study and meets the inclusion criteria they are eligible for the qualitative study.

TEMPO physiotherapist interview participants:
All physiotherapists who deliver the TEMPO intervention (approximately six physiotherapists) will be eligible to participate in the qualitative interviews. Physiotherapists will be selected by local sites to deliver the TEMPO intervention. To be eligible to deliver the TEMPO intervention physiotherapists must be Band 6 or above. There are no additional eligibility criteria for the qualitative interviews.

Participant type(s)
Mixed

Age group
Adult

Lower age limit
80 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Total final enrolment
51

Key exclusion criteria
Patient participants:
1. Has a terminal condition with a life expectancy of fewer than 6 months or under palliative care
2. Any substantial health or social concern that, in the opinion of the patient's GP, would place the patient at increased risk or inability to participate including known inability to provide informed consent
3. Unable to walk 3 m with or without an aid
4. Significant cognitive impairment (Score of 8 or more on the 6-item Cognitive Impairment Test)
5. Unable to follow verbal or written instructions including inability to follow simple safety instructions

TEMPO physiotherapist interview participants:
There are no exclusion criteria for physiotherapists who have delivered the TEMPO intervention taking part in the interview study.

Date of first enrolment
30/05/2022

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Hospitals
Nuffield Orthopaedic Centre
Windmill Rd
Oxford
United Kingdom
OX3 7LD

Study participating centre
Birmingham Community Healthcare
Keynell Covert Surgery
33 Keynell Covert
Kings Norton
Birmingham
United Kingdom
B30 3QT

Study participating centre
Graves Move More Centre
Bochum Parkway
Sheffield
United Kingdom
S8 8JR

Study participating centre
Concord Move More Centre
Shire Green Lane
Sheffield
United Kingdom
S5 6AE

Study participating centre
The O'Hanlon Centre
Peasley Cross Hospital
St Helens
United Kingdom
WA9 3DE

Study participating centre
Whiston Hospital (site)
Whiston Hospital
Warrington Road
Prescot
United Kingdom
L35 5DR

Sponsor information

Organisation
University of Oxford

Sponsor details
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Wellington Square
Joint Research Office
Boundary Brook House
Oxford
England

United Kingdom
OX3 7GB
+44 (0)1865616480
ctrg@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Versus Arthritis

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study protocol will be published in an open-access journal before 31/03/2023. Planned publication of study results in a high-impact peer-reviewed journal prior to 31/05/2025. A lay summary of the study outcomes will be posted to all study participants prior to 31/05/2023.

Intention to publish date
30/08/2025

Individual participant data (IPD) sharing plan

As this is a feasibility study the datasets are not expected to be made available. Participant consent did not include the sharing of data.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	23/09/2021	03/12/2021	No	Yes
Protocol (preprint)		17/10/2022	06/01/2023	No	No
Protocol article	protocol	01/04/2023	04/04/2023	Yes	No
HRA research summary			26/07/2023	No	No