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TEAM-KP: Nurse-led Package of Care for Knee Pain

Submission date	Recruitment status	[_] Prospectively registered
27/01/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/02/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/09/2023	Musculoskeletal Diseases	

Plain English summary of protocol
Background and study aims
Osteoarthritis (OA) is a very common condition and the knee is one of the most frequently affected joints. Knee osteoarthritis results in pain, stiffness and disability. Despite being common, people with knee OA often receive no, or only fragmented treatment in primary care. The much-needed advice around exercise, physical activity and weight-loss, or referral to physiotherapy frequently does not occur, and there is no single person who coordinates the care of people with OA. The purpose of this study is to develop and test a nurse-led package of care for people with knee pain due to OA.

Who can participate?
Patients aged 40 years or above with knee pain for longer than three months.

What does the study involve?
Participants will fill in a questionnaire about their musculoskeletal health and how participants feel and an updated questionnaire after 6 months. A sub-group will attend the Academic Rheumatology department at the City Hospital Nottingham, and the David Greenfield lab at the QMC. The study will last up to 6 months in total and require participants to attend the City Hospital Nottingham for approximately ten visits.

What are the possible benefits and risks of participating?
Some people might find answering questions about their health and wellbeing distressing. If you have particular concerns about your health we advise you to discuss them with your doctor. The sub-study may involve exposure to a very small amount of additional radiation from having x-rays taken.

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

When is the study starting and how long is it expected to run for?
December 2018 to March 2022

Who is funding the study?
1. VERSUS ARTHRITIS (UK)
2. NIHR Nottingham Biomedical Research Centre (UK)
3. National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Bonnie Millar
msk-recruitment@nottingham.ac.uk

Study website
http://www.nottinghambrc.nihr.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Bonnie Millar

Contact details
University of Nottingham
Clinical Sciences Building
Nottingham
United Kingdom
NG5 1PB
+44 (0)115 8231754
Bonnie.millar@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
249044

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 39977, IRAS 249044

Study information

Scientific Title
The East-Midlands knee pain multiple randomised controlled trial cohort study: cohort establishment and feasibility cohort-randomised controlled trial

Acronym
TEAM-KP

Study objectives
Knee Osteoarthritis (OA) is a common cause of disability. Community based nurse-led care involving education and holistic assessment has been successfully demonstrated for other common long-term conditions, but has yet to be tested in knee OA. Updated Medical Research Council (MRC) guidance highlights the importance of conducting process evaluation nested in trials. Process evaluation is fundamental to assess fidelity of delivery, explore factors affecting fidelity, and resolve possible challenges in delivering the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/11/2018, NHS HRA East Midlands-Derby REC (NRES Committee – Derby, Health Research Authority, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0)207 104 8109; NRESCommittee.EastMidlands-Derby@nhs.net), ref: 18/EM/0288

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
A package of care will be developed based on current NICE guidelines and on consultation with patients and the public as to the content and delivery of the package of care to ensure it fits well with the local setting and adapt accordingly.

After training the nurses to deliver the package, we will test how well the overall treatment can be delivered to 15-20 patients. Sessions will be videoed in order to review how closely the nurse delivered the content to what was intended. Acceptability of the package will be determined by interviewing the participants (nurses and patients) at this stage.

Having developed the package of care a feasibility study will be conducted to test it. Participants will be required to attend the Academic Rheumatology department at the City Hospital Nottingham. The study will last up to 6 months in total and require participants to attend the City Hospital Nottingham for approximately ten visits. They will be randomly selected to join either treatment group A or treatment group B.

In both groups, a trained research nurse will give them individualised advice and information about their condition; will teach them specific exercises that meet their needs; and will explain to them the lifestyle and other changes they can make to improve their knee pain and osteoarthritis and direct them to the appropriate services as required. Over a 3-month period she /he will see them up to five times. In the last 3 months of the study, while they continue with the exercises, they will also be prescribed painkillers by the study team.

They may require up to ten visits in total. At the first and last visits, they will be required to complete questionnaires, which enquire about health, wellbeing and joint pain. At their first visit they will have x-rays of both knees (if they have not had x-rays within the last 3 years or show significant changes) and blood will be collected from their arms at the first, seventh and last visits. They will also be observed and tested clinically for their ability to walk and perform functional activities they used to do on a daily basis. This will be done through a series of clinical tests.

Further information about the difference between group A and group B has been omitted from the record to ensure blinding of participants to the group they are in.

Intervention Type
Other

Primary outcome measure
Osteoarthritis symptoms measured using the WOMAC score at 26 weeks

Secondary outcome measures
Collected at baseline, week 1, week 13, week 26 visits, and follow-up unless noted otherwise:
1.1. WOMAC (Osteoarthritis symptoms)
1.2. SF-36 V2 (General Health)
1.3. EQ-5D-5L (Quality of life)
1.4. HADS (Anxiety and depression)
1.5. International Physical Activity Questionnaire (IPAQ)
1.6 A service-use questionnaire (SUQ) developed for this study will assess use of NHS or private healthcare, prescription and over-the-counter medicines related to knee pain outside of the study at week 1, week 13, week 26 visits
1.7. Pittsburgh Rehabilitation Participation Scale (PRPS) (week 13 and 26 only)
1.8. Adherence to Exercise Scale for Older Patients (AESOP) (week 13 and 26 only)
2. Clinical and radiological research assessments will include:
2.1. Bilateral tibio-femoral and patellofemoral radiographs (week 1 only)
2.2. Timed Up and Go (TUG) test at week 1, week 13, week 26 visits
2.3. 30-second chair stand test (REF) at week 1, week 13, week 26 visits
2.4. Muscle function testing: isometric strength, isokinetic knee extension, peak power output, fatigue – over 20 knee extensions
2.5. Random cholesterol, HbA1c, and CRP at week 1, week 13, week 26 visits
2.6. Quantitative sensory testing (QST): pain pressure threshold, temporal summation, conditioned pain modulation) at week 1, week 13, week 26 visits

3. Acceptability of the intervention
Qualitative interviews will be conducted after the intervention with participants from both intervention arms, representing those with low- and high-adherence to the advice using AESOP. These will explore participants' overall satisfaction with the intervention and the sequence of treatment, perceptions of nurse-led care and previous treatment experience, level of adherence to the advice, perceptions of managing their knee pain, as well as perceived impact of their knee pain on their daily life before and after the intervention. Participants who withdraw from the intervention will be offered the opportunity to take part in an interview to explore their experiences and reasons for discontinuation. Interviews will be conducted with the study nurses to explore their experience in delivering the intervention, perceived effectiveness of the intervention and barriers to implementation and how these may be overcome. All interviews will be digitally audio-recorded.

4. Trial feasibility outcomes. The feasibility of running a full trial will be assessed by recording the following data throughout:
4.1. Recruitment rates from each recruitment source
4.2. Dropout rates and reasons for drop-out
4.3. Retention rates
4.4. Attendance rates
4.5. Completeness of questionnaire data
4.6. Adherence to exercise using data from participants' exercise diaries (total number of days on which exercises were performed)
4.7. Acceptability of the intervention

Overall study start date
01/08/2018

Completion date
05/07/2021

Eligibility

Key inclusion criteria
1. Knee pain on most days of the previous month
2. Pain rated 4-7 on the pain numeric scale (with 0 being no pain and 10 being as bad as it could be)
3. Knee pain present for longer than 3 months
4. Aged 40 or more years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 2,500; UK Sample Size: 2,500

Key exclusion criteria
1. House-bound or care home resident
2. Dementia
3. Dialysis
4. On home oxygen
5. Serious mental illness
6. Inability to communicate in English
7. Unable to give consent
8. Terminal cancer
9. Known diagnosis of autoimmune rheumatic diseases or psoriasis
10. Knee or hip replacement, or on waiting list for knee or hip replacement
11. Asthma or COPD requiring regular daily oral corticosteroids
12. Unstable angina or heart failure
13. Known peripheral vascular disease
14. Pregnant

Date of first enrolment
01/12/2018

Date of final enrolment
05/07/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
City Hospital
Academic Rheumatology
Clinical Sciences Building
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Queen's Medical Centre
Nottingham University Hospitals NHS Trust
Derby Road
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham

Sponsor details
Research and Innovation
East Atrium
Jubilee Conference Centre
Nottingham
England
United Kingdom
NG8 1DH
+44 (0)1158467906
sponsor@nottingham.ac.uk

Sponsor type
University/education

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

ROR
https://ror.org/01ee9ar58

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

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Nottingham Biomedical Research Centre

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/09/2020	17/09/2021	Yes	No
HRA research summary			28/06/2023	No	No
Results article	Trial feasibility outcomes	23/09/2023	25/09/2023	Yes	No