ISRCTN23294263 https://doi.org/10.1186/ISRCTN23294263

A trial aiming to improve the effectiveness of physiotherapy-led exercise for knee pain in older adults in primary care - The BEEP pilot study

Submission date
12/05/2010

Recruitment status
No longer recruiting

Registration date
12/05/2010

Overall study status
Completed

Last Edited
26/04/2018

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Knee pain in older adults is a common disabling problem, managed in the UK mostly in primary care (GPs). Approximately 25% of those aged over 55 years are affected at any one time and half will find some daily activities more difficult. Knee pain in older adults is often due to osteoarthritis (OA). Given the ageing population the problem is set to get worse, and the need for effective treatment approaches is clear. Recent national and international guidelines as well as studies show that exercise can help in knee and hip OA. Exercise improves muscle dysfunction and reduces pain and disability without exacerbating joint damage. It can reduce the risk of other chronic conditions and improve the physical status of people with OA. However, there is a lack of evidence around the practical aspects of exercise delivery and maintenance, including what is an appropriate “dose” of exercise and how to support individuals to continue to exercise in the longer-term. Physiotherapists are the largest group of exercise advisor's for musculoskeletal problems in the NHS and are therefore an appropriate group with which to develop and test strategies.
The aim of this initial study is to assess first whether helping people with knee pain to find the right exercise routine and maintaining it over time will produce better results, and secondly whether it is possible to run a larger study.

Who can participate?
Adults over 45 years old with knee pain and referred by their doctor.

What does the study involve?
All participants receive the same advice and information (booklet) and a home exercise programme. They are then allocated to one of three groups:
- Usual care group (Group 1) receive up to 4 face-to face treatment sessions within 12 weeks with the physiotherapist.
- Individually Tailored Exercise group (Group 2) receive between 6 to 8 face-to-face treatment sessions within 12 weeks with the physiotherapist.

- Targeted Exercise Adherence group (Group 3) receive 4 treatment sessions within 12 weeks, plus between 6 to 8 face-to-face treatment sessions within 12 weeks with the physiotherapist

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Keele University Primary Care Musculoskeletal Research Centre, UK

When is the study starting and how long is it expected to run for?
September 2009 to December 2010

Who is funding the study?
National Institute for Health Research (NIHR), UK

Who is the main contact?
Ms Jacqueline Gray
Ms Nadine Foster

Contact information

Type(s)
Scientific

Contact name
Miss Jacqueline Gray

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7371

Study information

Scientific Title
A single centre non-randomised interventional trial of physiotherapy-led exercise versus care as usual for knee pain in older adults in primary care

Acronym
BEEP

Study objectives
Knee pain in older adults is a common disabling problem, managed in the UK mostly in primary care. Approximately 25% of those aged over 55 years are affected at any one time and half will have some restriction of daily activities. Knee pain in older adults is often due to osteoarthritis (OA). Given the ageing population the problem is set to get worse, and the need for effective treatment approaches is clear. Recent national and international clinical guidelines support the overall effectiveness of exercise in knee and hip OA, placing it as a key component of core treatment in primary care. Exercise improves muscle dysfunction and reduces pain and disability without exacerbating joint damage. It can reduce the risk of other chronic conditions and improve the physical status of people with OA. Clinical trials and systematic reviews consistently emphasise the benefit of exercise for this patient group. However, there is a lack of evidence around the practical aspects of exercise delivery and maintenance, including what is an appropriate dose of exercise and how to support individuals to continue to exercise in the longer-term. Physiotherapists are the largest group of exercise advisor's for musculoskeletal problems in the NHS and are therefore an appropriate group with which to develop and test strategies to improve outcomes from exercise with knee pain patients. This study is a pilot study of a clinical trial investigating whether helping people with knee pain to find the right exercise routine and maintaining it over time results in better outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Birmingham East, North and Solihull Research Ethics Committee (REC) approved on the 22nd May 2009 (ref: 09/H1206/77)

Study design
Single centre non-randomised interventional prevention and treatment trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England, Musculoskeletal; Subtopic: Not Assigned, Musculoskeletal (all Subtopics); Disease: Musculoskeletal, All Diseases

Interventions
All patients will receive advice and information (booklet) and a home exercise programme. The usual care group (Group 1) will receive up to 4 face-to face treatment sessions within 12 weeks, with the physiotherapist. Those in the Individually Tailored Exercise group (Group 2) will receive between 6 to 8 face-to-face treatment sessions with the physiotherapist within 12 weeks. Those in the Targeted Exercise Adherence group (Group 3) will receive 4 treatment sessions within 12 weeks, plus between 6 to 8 face-to-face treatment sessions with the physiotherapist within 12 weeks

Follow-up length: 6 months
Study entry: registration and one or more randomisations

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Outcome Measures in Rheumatology Clinical Trials (OMERACT-OARSI) clinical responder criteria, collected at baseline, 3 and 6 months.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/09/2009

Completion date
15/12/2010

Eligibility

Key inclusion criteria
1. Aged 45 years and over, either sex
2. Knee pain or stiffness in one or both knees
3. Primary Care referrals
4. Willing to participate in study
5. Able to give informed consent
6. Has access to a telephone
7. Able to read and write in English

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned sample size: 30; UK sample size: 30

Key exclusion criteria
1. Those with potentially serious pathology, e.g. inflammatory arthritis, malignancy etc
2. Those who have had a total hip or knee replacement to the affected side
3. Those who are already on a waiting list for a total knee or hip replacement
4. Those for whom exercise interventions are contra-indicated
5. Those who have received an exercise programme from a physiotherapist or an injection in the last 3 months

Date of first enrolment
01/09/2009

Date of final enrolment
31/05/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Primary Care Musculoskeletal Research Centre
Keele University
Newcastle
United Kingdom
ST5 5BG

Sponsor information

Organisation
Keele University

Sponsor details
Keele
Newcastle-Under-Lyme
Staffordshire
England
United Kingdom
ST5 5BG

Sponsor type

University/education

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

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Programme Grants for Applied Research (ref: RP-PG-0407-10386)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration