

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	☐ Prospectively registered
		☐ Protocol
Registration date 12/05/2010	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 26/04/2018	Condition category Musculoskeletal Diseases	☐ 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

Primary Care Musculoskeletal Research Centre

Keele University

Newcastle

United Kingdom

ST5 5BG

Additional identifiers

Protocol serial number

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 advisors 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)

Primary study design

Interventional

Study design

Single centre non-randomised interventional prevention and treatment trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Primary Care Musculoskeletal Research Centre

Keele University

Newcastle

United Kingdom

ST5 5BG

Sponsor information

Organisation

Keele University

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration