

# Benefits of Effective Exercise for knee Pain - The BEEP main trial

<b>Submission date</b> 29/09/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/09/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/12/2018	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## 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 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. It is the continuation of a smaller study done with a smaller number of participants.

### 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. The usual care group (Group 1) receive up to 4 face-to face treatment sessions within 12 weeks with the physiotherapist. The Individually Tailored Exercise group (Group 2) receive between 6 to 8 face-to-face treatment sessions within 12 weeks with the physiotherapist. The 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?

October 2010 to May 2015

Who is funding the study?

National Institute for Health Research (NIHR), UK

Who is the main contact?

Ms Stephanie Tooth

Ms Nadine Foster

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Stephanie Tooth

### Contact details

Arthritis Research UK Primary Care Centre

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

9270

## Study information

### Scientific Title

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

### Acronym

BEEP

## **Study objectives**

This is a randomised controlled trial investigating whether helping people with knee pain to find the right exercise routine and maintaining it over time results in better outcomes.

The main aim of the study is to determine the clinical cost-effectiveness of the two physiotherapy-led exercise interventions to improve individual tailoring of adherence to exercise in known osteoarthritis (OA) patients in primary care, in comparison to usual physiotherapy care with nested qualitative interviews.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

First MREC, 09/06/2010, ref:10/H1017/45

## **Study design**

Randomised interventional treatment trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

GP practice

## **Study type(s)**

Treatment

## **Participant information sheet**

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

## **Health condition(s) or problem(s) studied**

Musculoskeletal, All Diseases

## **Interventions**

Individually Tailored Exercise

Patients will receive between 6-8 face-to-face treatment sessions with a physiotherapist within 12 weeks

Targeted Exercise Adherence Group

Patients will receive 4 treatment sessions within 12 weeks, plus between 4 to 6 additional contacts with the physiotherapist from week 12 to month 6

Usual Care

Patients will receive up to 4 face-to-face treatment sessions within 12 weeks with a physiotherapist

Follow Up Length: 36 month(s); Study Entry : Registration and One or More Randomisations

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Pain and Function from the WOMAC (Western Ontario and McMaster Universities) Index of Osteoarthritis

WOMAC is collected at baseline, 3, 6, 9, 18 and 36 months

## **Secondary outcome measures**

1. 7-day accelerometry; Timepoint(s): Collected at baseline, 3, 6, 9, 18 and 36 months
2. Anxiety (GAD-7); Timepoint(s): Collected at baseline, 3, 6, 9, 18 and 36 months
3. Body Mass Index; Timepoint(s): Collected at baseline, 3, 6, 9, 18 and 36 months
4. Cost-effectiveness; Timepoint(s): Collected at 3, 6, 9, 18 and 36 months
5. Depression (PHG-8); Timepoint(s): Collected at baseline, 3, 6, 9, 18 and 36 months
6. Exercise adherence; Timepoint(s): Collected at 3, 6, 9, 18 and 36 months
7. Healthcare utilisation (self report & Med Rec Review); Timepoint(s): Collected at 6, 18 and 36 months
8. ICE CAP-A capabilities; Timepoint(s): Collected at baseline, 6 and 18 months
9. Illness Perceptions (IPQ); Timepoint(s): Collected at baseline, 3 and 6 months
10. Medication usage; Timepoint(s): Collected at baseline, 3, 6, 9, 18 months
11. OMERACT-OARSI; Timepoint(s): Collected at baseline, 3, 6, 9, 18 and 36 months
12. Overall health status (EQ-SD); Timepoint(s): Collected at baseline, 3, 6, 9, 18 and 36 months
13. Patient's Global Assessment of Change; Timepoint(s): Collected at 3, 6, 9, 18 and 36 months
14. Physical activity levels (self report PASE); Timepoint(s): Collected at baseline, 3, 6, 9, 18 and 36 months
15. Self-efficacy for exercise (SEE); Timepoint(s): Collected at baseline, 3 and 6 months

## **Overall study start date**

27/10/2010

## **Completion date**

30/04/2015

## **Eligibility**

### **Key inclusion criteria**

1. Aged 45 years and over
2. Knee pain or stiffness in one or both knees
3. Primary care consultants willing to participate in the study
4. Able to give informed consent
5. Has access to telephone
6. Able to read and write in English
7. Target Gender: Male & Female

### **Participant type(s)**

Patient

### **Age group**

Adult

**Sex**

Both

**Target number of participants**

Planned Sample Size: 7713; UK Sample Size: 7713; Description: 7213 postal and 500 trial (500 screened from 7713 responding to survey).

**Key exclusion criteria**

1. Those with potentially serious pathology
2. Those on a waiting list to have a hip or knee replacement to affected side
3. Those who have already had a hip or knee replacement to affected side
4. When the knee problem is caused by a recent sports injury, fall or accident
5. Those for whom exercise interventions are contra-indicated
6. Those who have had an exercise programme from a physiotherapist, or an injection in the last 3 months
7. Those living in a nursing home

**Date of first enrolment**

19/11/2010

**Date of final enrolment**

28/02/2015

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Arthritis Research UK Primary Care Centre**

Keele University

Newcastle-Under-Lyme

United Kingdom

ST5 5BG

## **Sponsor information**

**Organisation**

Keele University (UK)

**Sponsor details**

Keele  
Newcastle-Under-Lyme  
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

NIHR - Programme for Applied Research (UK)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

31/12/2016

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	27/07/2014		Yes	No
<a href="#">Results article</a>	results for nested study on ICECAP-A outcome measures	03/03/2016		Yes	No
<a href="#">Results article</a>	results	01/05/2017		Yes	No

<a href="#">Results article</a> results	01/02/2018	Yes	No
<a href="#">Results article</a> results	17/02/2018	Yes	No
<a href="#">Results article</a> results	01/07/2018	Yes	No