ISRCTN93634563 https://doi.org/10.1186/ISRCTN93634563

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

Submission date
29/09/2011

Recruitment status
No longer recruiting

Registration date
29/09/2011

Overall study status
Completed

Last Edited
11/12/2018

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Primary Care Sciences
Keele University
Newcastle-Under-Lyme
United Kingdom
ST5 5BG
-
s.j.tooth@cphc.keele.ac.uk

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 consulters willing to particpate 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?
Protocol article	protocol	27/07/2014		Yes	No
Results article	results for nested study on ICECAP-A outcome measures	03/03/2016		Yes	No
Results article	results	01/05/2017		Yes	No

Results article	results	01/02/2018	Yes	No
Results article	results	17/02/2018	Yes	No
Results article	results	01/07/2018	Yes	No