ISRCTN80222865 https://doi.org/10.1186/ISRCTN80222865

Home Administered Pre-surgical Psychological Intervention for Knee Osteoarthritis

Submission date
19/06/2014

Recruitment status
No longer recruiting

Registration date
19/06/2014

Overall study status
Completed

Last Edited
17/06/2019

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Knee replacement surgery reduces pain for many people with osteoarthritis, but a small number of people still have problems after surgery. The success of surgery is partly dependent on patients mood. Having anxiety and low mood are quite common for people who are experiencing pain, and may prevent people gaining full benefit from surgery. Cognitive behavioural therapy (CBT), a `talking treatment, is recommended for treatment of mood problems, including for people with pain. But, so far, no study has examined the effectiveness of CBT before surgery in improving outcomes after knee surgery. This study aims to find out if it is possible to conduct such a study and will look at the suitability of our recruitment, assessment methods and our therapy, and help us to calculate the number of people we will need for a definitive study.

Who can participate?
People, aged over 18 years, with osteoarthritis of the knee who have been referred for knee replacement surgery.

What does the study involve?
If you are willing to take part, you will be asked some questions to find out whether you would be suitable to take part in the study. This will include questions about your mood. If you have scores suggesting you are experiencing some distress or mood disturbance you will be eligible to take part. If you agree to take part you will be asked to complete a consent form and fill in some further questionnaires to check your level of pain, mood, and quality of life. After these assessments you will be randomly allocated into one of the two groups: One group will be invited to attend up to 10 sessions of Cognitive Behavioural Therapy (CBT) during the time they are waiting for knee surgery. The therapy sessions will be offered weekly or twice weekly, on an individual basis, with an experienced clinical psychologist and are designed to reduce anxiety, improve mood, and help you to understand your problems. These sessions can take place either at a hospital clinic, or in your own home, if preferred. This group will also receive their usual care. The other group will not be asked to take part in the therapy sessions but will receive their usual care. Some participants from both groups will be invited to give feedback interviews to assess whether the CBT sessions were helpful and their experience of being involved in our study. These, too, can take place in clinic or in your home, if more convenient. Both groups will be

asked to complete some questionnaires after 4 and 6 months. It will take about 20-25 minutes to complete these each time.

What are the possible benefits and risks of participating?
Taking part in our study means that you may possibly help people with arthritis in the future. The information we get from this study will help us decide whether we should develop this approach further in the hope of further improving surgical outcomes for people with knee OA. We appreciate that taking part will use your time and may therefore be inconvenient. Talking about your problems can occasionally be upsetting, but our researcher is trained to help make you feel as comfortable as possible. The interview and any other aspect of your involvement can stop at any time if you do not wish to continue. However, if during the interview or therapy you disclose something that raises serious concerns about your safety or the safety of others, we may be obliged to break confidentiality and contact your GP.

Where is the study run from?
The study will be run from the following hospitals in the UK;
1. Nottingham University Hospitals NHS Trust, Nottingham
2. Sherwood Forest Hospitals NHS Trust (Kings Mill Hospital in Nottinghamshire)
Participants will need to have been seen at one of these Trusts for their knee osteoarthritis, but the therapy can be delivered at participants homes.

When is the study starting and how long is it expected to run for?
July 2014 to April 2016

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

Who is the main contact?
Dr Roshan das Nair
roshan.nair@nottingham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Roshan das Nair

Contact details
Institute of Work, Health & Organisations
International House
Jubilee Campus
University of Nottingham
Nottingham
United Kingdom
NG8 1BB
-
roshan.dasnair@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16280

Study information

Scientific Title
Home Administered Pre-surgical Psychological Intervention for Knee Osteoarthritis: a single blind feasibility randomised controlled trial

Acronym
HAPPIKNEES

Study objectives
To evaluate the acceptability of a short term psychological intervention based on cognitive behavioural therapy (CBT) in improving outcomes following knee surgery for people with knee osteoarthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/EM/0099; First MREC approval date 11/03/2014

Study design
Randomised; Interventional; Design type: Prevention, Process of Care

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
Topic: Primary Care; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Participants will be randomised to either intervention or treatment as usual (TAU) control group.
1. The intervention group will receive TAU plus up to ten sessions of CBT, tailored to the specific needs of the participant. Interventions will be delivered by a Clinical Psychologist in the participants home or in clinic, once or twice weekly, lasting approximately one hour.
2. Control group participants will receive TAU. They will not receive any therapeutic input from the clinical psychologist.

Participants from both groups will complete the same questionnaires completed at baseline, at four and six months after randomisation. Fifteen participants who had the intervention and 15 from the control group will be invited to take part in a brief semi-structured feedback interview to understand their experience of being in the study. The aim is to conduct these interviews between the first and second follow up assessments. Up to 10 of these interviews will be conducted by trained patient-partners who will be requested to keep a research diary of their experiences, including the challenges of conducting these interviews.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The number of participants identified and recruited will be recorded. The acceptability of the intervention will be determined by the number of participants who received the intervention, and from individual interviews.

Secondary outcome measures
1. Rates of mood problems, recruitment, giving consent, completing treatments and completing outcome questionnaires.
2. The type and amount of missing data found on each questionnaire and whether this missing information could be obtained by telephone follow-up will be determined. These data will also indicate any problems of outcome questionnaires being sent by post and the ease of answering these.
3. The scores from the questionnaires to compute sample-size and power calculations for the future Phase III RCT.
4. The feasibility of using the service-use questionnaire by examining rates of completion, and fidelity of response.
5. Sensitivity analyses will be conducted to look for differences in intervention provision according to location. By recording the dates of recruitment, randomisation, and surgery, we will be able to assess how the intervention fits within the existing patient pathway.
6. Time-sampling, based on minute-by-minute coding of content, and saliency analysis of intervention transcripts to document the content and delivery of the intervention. This will help us develop the final manual for the Phase III RCT.
7. The effectiveness of the participatory research model will be evaluated through an examination of the research diaries, and through an in-depth interview with patient-partners.

Measured using Western Ontario and McMaster Universities Osteoarthritis Index, Intermittent and Constant Osteoarthritis Pain scale, Beck Depression Inventory, Beck Anxiety Inventory, EQ5D, Service-use questionnaire.

Overall study start date
01/07/2014

Completion date
30/04/2016

Eligibility

Key inclusion criteria
1. Adults over 18 years old
2. Listed for, or considered for, total knee replacement surgery
3. Osteoarthritis of the knee
4. Reporting depression or anxiety as assessed by appropriate questionnaires

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50; Description: Patients who are scheduled for total knee replacement surgery

Total final enrolment
51

Key exclusion criteria
1. Other co-morbid psychiatric conditions
2. Be able to speak fluent English

Date of first enrolment
01/07/2014

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Nottingham
Nottingham
United Kingdom
NG8 1BB

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust (UK)

Sponsor details
Queens Medical Centre
Derby Road
Nottingham
England
United Kingdom
NG7 2UH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/01/2016		Yes	No
Results article	results	01/06/2018	17/06/2019	Yes	No
HRA research summary			28/06/2023	No	No