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Evaluation of a care pathway for patients with long-term pain after knee replacement

Submission date
30/08/2016

Recruitment status
No longer recruiting

Registration date
06/09/2016

Overall study status
Completed

Last Edited
12/04/2024

Condition category
Musculoskeletal Diseases

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

Plain English Summary
Background and study aims
Osteoarthritis is a leading cause of pain and disability. Osteoarthritis is when something goes wrong with the repair processes in a joint and this is particularly common in knee joints. Osteoarthritis can lead to changes in a joint including changes in the bone, cartilage, soft tissues and nervous system. Many people with severe knee pain because of osteoarthritis have an operation called total knee replacement. Total knee replacement involves replacing the painful knee joint with an artificial joint. It is a major operation and people often experience some pain in the first three months after surgery. However, around one in five patients report moderate or severe pain after this initial three month recovery period. This is called 'long-term' or 'chronic' pain. Over 75,000 total knee replacements take place every year in the NHS. This means that approximately 15,000 people have long-term pain afterwards. People with long-term pain say that pain stops them from doing things they value, including taking part in work, family and social activities. Pain can also change a person's mood, sometimes leading to anxiety and depression. It is known that many people do not receive or seek care for long-term pain. Improving care and support for people with long-term pain after knee replacement will benefit patients, the NHS and society. Despite efforts to prevent long-term pain, there will always be some people who need care and support after surgery. The aim of this study is to look at new care pathway to see if it is of benefit to patients with long-term pain after knee replacement.

Who can participate?
Adult patients with long-term pain after knee replacement surgery for osteoarthritis.

What does the study involve?
Participants are randomly allocated to receive treatment as usual or the STAR treatment pathway (with twice as many patients receiving the STAR treatment pathway). The STAR pathway involves a clinic appointment at 3 months after knee replacement with a healthcare professional to better understand the possible causes of pain after knee replacement. Patients are then be referred to see relevant health professionals for treatment as needed, such as physiotherapists, orthopaedic (bone) surgeons, GPs, and pain specialists. We may decide that for some people the most appropriate course of action is to regularly monitor their pain, and then begin treatment if the pain worsens. Alternatively, it may be decided that for some patients the most appropriate course of action is to regularly monitor their pain, and then begin treatment if

the pain worsens. A healthcare professional continues to monitor these patients' care over the 12 months of the project, and telephones patients up to 6 times over this period. Participants in both groups are followed up after 6 and 12 months in order to assess pain levels.

What are the possible benefits and risks of participating?
It is not known as to whether participants will benefit, as this study aims to look at whether this care pathway is beneficial. There are no notable risks involved with participating in this study, although filling in the follow up questionnaires will take time.

Where is the study run from?
Southmead Hospital (lead centre) and other hospitals in England and Wales (UK)

When is the study starting and how long is it expected to run for?
November 2015 to August 2020

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

Who is the main contact?
Ms Wendy Bertram
wendy.bertram@nbt.nhs.uk

Study website
http://www.bristol.ac.uk/clinical-sciences/research/musculoskeletal/orthopaedic/research/star/

Contact information

Type(s)
Public

Contact name
Ms Wendy Bertram

Contact details
Musculoskeletal Research Unit
School of Clinical Sciences
University of Bristol
Level 1, Learning & Research Building
Southmead Hospital
Southmead Road
Westbury-On-Trym
Bristol
United Kingdom
BS10 5NB
+44 117 414 7848
wendy.bertram@nbt.nhs.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 31697

Study information

Scientific Title
The STAR trial: Evaluation of a care pathway for patients with long-term pain after knee replacement

Acronym
STAR

Study hypothesis
The primary aim of this study is to evaluate the clinical effectiveness of a new care pathway ('the STAR pathway') compared to usual care for people with long-term pain after knee replacement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West – Central Bristol Research Ethics Committee, 07/07/2016, ref: 16/SW/0154

Study design
Randomized; Interventional; Design type: Treatment, Complex Intervention

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 to request a patient information sheet

Condition

Specialty: Musculoskeletal disorders, Primary sub-specialty: Musculoskeletal pain disorders; UKCRC code/ Disease: Musculoskeletal/ Arthrosis

Interventions

Patients with long-term pain at three months after knee replacement will be randomised with a 2:1 intervention:control randomisation ratio through an online system provided by the Bristol Randomised Trials Collaboration.

Control group: Patients will receive care as usual for the duration of the study.

Intervention group: Patients will be invited to a one hour assessment clinic three months after their knee replacement with an Extended Scope Practitioner to identify potential causes of pain and will then be referred onwards to appropriate existing services. Patients will also receive up to 6 telephone follow-up calls from the Extended Scope Practitioner over the 12 month follow-up period.

Participants in both groups complete follow up questionnaires at six and 12 months post-randomisation. Costs and resource use are also monitored over the 12 month follow-up period.

Intervention Type

Other

Primary outcome measure

Pain intensity and pain interference are assessed using the Brief Pain Inventory at baseline and 12 months after randomisation.

Secondary outcome measures

1. Pain and physical functioning are measured using the Brief Pain Inventory (at baseline and 6 months) and Oxford Knee Score (OKS) at baseline, 6 and 12 months
2. Pain description is assessed using PainDETECT and Douleur Neuropathique 4 (DN-4) at baseline, 6 and 12 months
3. Emotional aspects of pain are measured using the Hospital Anxiety and Depression Scale (HADs), Pain Catastrophizing Scale (PCS), and Possible Solutions to Pain Questionnaire (PaSol) at baseline, 6 and 12 months
4. Use of pain medications is measured using Resource use questions at baseline, 6 and 12 months
5. Improvement and satisfaction with pain relief is measured using the Self-Administered Patient Satisfaction Scale (single-item question on comparison of pain to pre-operative pain) at baseline, 6 and 12 months
6. Temporal aspects of pain are measured using Single-item questions on pain frequency during past 24 hours and 4 weeks, at baseline, 6 and 12 months
7. Capability is measured using the ICECAP-A at baseline, 6 and 12 months
8. Health-related quality of life is measured using EQ-5D-5L and Short Form-12 (SF-12) at baseline, 6 and 12 months
9. Pain elsewhere is assessed using a body diagram to assess chronic widespread pain at baseline, 6 and 12 months
10. Resource use is measured as use of health services including primary, secondary and tertiary care; use of personal social services; additional costs (travel, lost income, home modifications) using follow-up trial questionnaires at 12 months. Resource use data including inpatient stays and outpatient visits for all patients will be obtained from hospital electronic systems. If this is

not possible, they will be extracted from hospital records and recorded on standardised proformas.

Overall study start date
04/11/2015

Overall study end date
01/08/2020

Eligibility

Participant inclusion criteria
1. Patients aged 18 years and over
2. Patients who received a primary total knee replacement for osteoarthritis at a participating NHS Trust
3. Patients who have pain in their operated knee at 2-3 months after surgery, defined as a score of ≤14 on the 7 pain items of the Oxford Knee Score

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 380; UK Sample Size: 380

Total final enrolment
363

Participant exclusion criteria
1. Lack of capacity to provide informed consent to participate
2. Previously participating in the STAR trial for contralateral knee
3. Taking part in another research study that interferes unacceptability with STAR (or vice versa)

Recruitment start date
07/09/2016

Recruitment end date
31/05/2019

Locations

Countries of recruitment

England

United Kingdom

Wales

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Royal Devon and Exeter Hospital
Knee Unit
Princess Elizabeth Orthopaedic Centre
Barrack Road
Exeter
United Kingdom
EX3 5DW

Study participating centre
University Hospital Llandough
Penlan Road
Penarth
Cardiff
United Kingdom
CF64 2XX

Study participating centre
King's Mill Hospital
Mansfield Road
Sutton-in-Ashfield
United Kingdom
NG17 4JL

Study participating centre
Wrightington Hospital
Hall Lane

Appley Bridge
Wigan
United Kingdom
WN6 9EP

Study participating centre
Robert Jones & Agnes Hunt Orthopaedic Hospital
Gobowen
Oswestry
United Kingdom
SY10 7AG

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester General Hospital
Leicester
United Kingdom
LE1 5WW

Study participating centre
Royal Orthopaedic Hospital
The Woodlands, Bristol Rd S
Birmingham
United Kingdom
B31 2AP

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Research and Innovation
3rd Floor, Learning and Research Building
Southmead Hospital
Southmead Road
Westbury-On-Trym
Bristol
England
United Kingdom
BS10 5NB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/036x6gt55

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
All manuscripts resulting from the trial will be published open access in line with NIHR guidance. Publications will include a final report, as well as presentations at scientific meetings and publication of findings in scientific literature.
The trial protocol will be published in 2017 and the main trial results paper in 2020.
In addition, all participants in the trial will be sent a summary of the final results written in plain English.

Intention to publish date
01/08/2021

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	internal pilot results	11/04/2019	12/04/2019	Yes	No
Protocol article		21/02/2018	31/08/2022	Yes	No
Dataset		05/08/2022	01/09/2022	No	No
Results article		27/01/2022	01/09/2022	Yes	No
Statistical Analysis Plan		11/06/2019	01/09/2022	No	No
HRA research summary			26/07/2023	No	No
Results article		28/01/2022	10/10/2023	Yes	No
Results article		01/06/2023	10/10/2023	Yes	No
Results article	4-year follow-up results	16/12/2023	18/12/2023	Yes	No
Results article	cost-effectiveness analysis	11/04/2024	12/04/2024	Yes	No