

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

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| <b>Submission date</b><br>30/08/2016   | <b>Recruitment status</b><br>No longer recruiting     | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>06/09/2016 | <b>Overall study status</b><br>Completed              | <input checked="" type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>12/04/2024       | <b>Condition category</b><br>Musculoskeletal Diseases | <input checked="" type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### 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**

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## **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 objectives**

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

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

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

**Completion date**

01/08/2020

## Eligibility

**Key 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  $\leq 14$  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

**Key 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)

**Date of first enrolment**

07/09/2016

**Date of final enrolment**

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? |
|---|-----------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Other publications</a>        | internal pilot results      | 11/04/2019   | 12/04/2019 | Yes            | No              |
| <a href="#">Protocol article</a>          |                             | 21/02/2018   | 31/08/2022 | Yes            | No              |
| <a href="#">Dataset</a>                   |                             | 05/08/2022   | 01/09/2022 | No             | No              |
| <a href="#">Results article</a>           |                             | 27/01/2022   | 01/09/2022 | Yes            | No              |
| <a href="#">Statistical Analysis Plan</a> |                             | 11/06/2019   | 01/09/2022 | No             | No              |
| <a href="#">HRA research summary</a>      | 4-year follow-up results    |              | 26/07/2023 | No             | No              |
| <a href="#">Results article</a>           |                             | 28/01/2022   | 10/10/2023 | Yes            | No              |
| <a href="#">Results article</a>           |                             | 01/06/2023   | 10/10/2023 | Yes            | No              |
| <a href="#">Results article</a>           |                             | 16/12/2023   | 18/12/2023 | Yes            | No              |
| <a href="#">Results article</a>           |                             |              |            |                |                 |
| <a href="#">Results article</a>           | cost-effectiveness analysis | 11/04/2024   | 12/04/2024 | Yes            | No              |