Better post-operative prediction and management of chronic pain in adults after total knee replacement: the multidisciplinary STAR research programme including RCT

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Scientific summary

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Background

Chronic pain after total knee replacement places considerable burden on individuals, society and the NHS. With nearly 100,000 patients receiving knee replacements in the NHS annually, around 20,000 patients will have chronic post-surgical pain. Pre-operative prediction of who will have chronic pain after knee replacement is of limited value, referral for assessment and care is inconsistent and varies widely, and people do not necessarily receive or seek care. This programme aimed to address these issues and provide evidence on improvements to patient care and service delivery.

Objectives

The programme aimed to improve outcomes for patients with chronic pain ≥ 3 months after total knee replacement. Specific programme objectives were as follows:

1. synthesise evidence on the effectiveness of interventions for preventing chronic pain after knee replacement and the treatment of chronic pain after diverse surgeries, and identify post-surgical predictors of chronic pain after knee replacement
2. characterise the long-term trajectory of chronic pain, including pain characteristics and resource use up to 5 years after total knee replacement
3. finalise an assessment process and a care pathway for patients with chronic pain after total knee replacement
4. evaluate the clinical effectiveness and cost-effectiveness of a new care pathway for patients with chronic pain after total knee replacement
5. identify reasons for non-use of services
6. make evidence-based suggestions about the best-practice care for patients with chronic pain after total knee replacement and evaluate the implementation of these.

Methods

To meet the objectives, we conducted six work packages.

Work package 1: systematic reviews and analysis of national databases

Systematic reviews of the following were carried out: post-surgical predictors of chronic pain after total knee replacement; the effectiveness of pre-, peri- and post-operative interventions for chronic pain after total knee replacement; and the effectiveness of interventions for chronic pain after diverse surgeries.

In addition, we undertook an analysis of data from the National Joint Registry (NJR) linked to Hospital Episode Statistics (HES) and Patient Reported Outcome Measures (PROMs) databases to identify post-operative predictors of chronic pain.

Work package 2: long-term follow-up and analysis of databases

Using the annual follow-up of the Clinical Outcomes in Arthroplasty Study (COASt) cohort of patients with total knee replacement, we were able to collect pain and resource use data for 5 years after surgery. We also analysed the Clinical Practice Research Datalink (CPRD), linked to the Hospital Episode Statistics (HES) and Patient Reported Outcome Measures (PROMs) database, to characterise the natural history of chronic pain after total knee replacement, including resource use.

Work package 3: finalisation of an assessment protocol and care pathway

Consensus questionnaires completed by and meetings with health-care professionals were used to refine our previously developed intervention. We also tested intervention delivery and acceptability with 10 patients and evaluated the views of 10 health-care professional stakeholders on future implementation using a questionnaire based on the Normalisation Measure Development (NoMAD) instrument.

Work package 4: randomised controlled trial

The multicentre Support and Treatment After joint Replacement (STAR) randomised controlled trial was carried out with 363 participants to evaluate the clinical effectiveness and cost-effectiveness of a new care pathway for patients with chronic pain after total knee replacement. The primary follow-up time point was 12 months post randomisation and the coprimary outcomes were the Brief Pain Inventory (BPI) severity and interference scales (scored 0–10), with the minimal clinically important difference pre-specified as 1 point on either scale. Two embedded qualitative studies with 56 patients explored trial processes and acceptability of the intervention.

Work package 5: qualitative study

We undertook a qualitative interview study with 34 people with chronic pain after total knee replacement who made little or no use of formal health-care services and explored reasons for non-use of services.

Work package 6: implementation and dissemination

Interviews, based on the NoMAD instrument, were carried out with 14 health-care professionals who implemented the intervention within the trial. An online meeting, short animated film and survey were all used to communicate findings to key stakeholders and engage health-care professionals in maximising the embedding of the intervention in practice. A range of dissemination activities to engage health-care professionals, researchers, policy-makers, patients and the public were undertaken.

Patient and public involvement

Patient and public involvement was integral to the programme's design and remained at its core during the programme. We worked with an existing patient forum and developed a complementary group focusing exclusively on chronic pain after total knee replacement. Contributions of this group included the design of study materials and processes, research management and dissemination strategies.

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This report

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