Improving patients' experience and outcome of total joint replacement: the RESTORE programme

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Scientific summary

The RESTORE programme

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Scientific summary

Background

Total hip replacement (THR) and total knee replacement (TKR) are common elective procedures with over 150,000 performed annually in the NHS. For many patients with advanced osteoarthritis, THR and TKR are effective in treating pain and restoring physical function. However, some patients report little functional benefit and long-term pain.

Objectives

Recognising the presence of long-term pain and disability in some patients after joint replacement, the REsearch STudies into the ORthopaedic Experience (RESTORE) programme explored the care and experiences of patients at key times in the pathway from being listed for THR and TKR to the time after surgery when an optimal outcome should be expected. RESTORE consisted of a series of interrelated work packages with systematic reviews, qualitative studies, randomised controlled trials (RCTs), cohort studies and economic evaluations.

Specific objectives were to:

1. Synthesise research in THR and TKR on long-term pain prevalence and assessment methods, and review the impact of comorbidities and pre-surgical factors on long-term patient outcomes.
2. Characterise the patient pathway through THR and TKR and study the experience of trial involvement for health-care professionals and patients.
3. Compare outcome measures over time in patients with hip or knee replacement and assess how well they measure impairment, activity limitation and participation.
4. Evaluate in a RCT the clinical effectiveness and cost-effectiveness of perioperative local anaesthetic infiltration on long-term pain after THR and TKR.
5. Assess relationships between radiographic measures of osteoarthritis severity and patient-reported pain and function. Explore associations between pre-operative patient factors and patient outcomes after THR and TKR.
6. Review the effectiveness of pre-surgical education and exercise.
7. Assess feasibility and acceptability of pain self-management for patients undergoing THR.
8. Review existing evidence on effectiveness of occupational therapy and evaluate the feasibility and acceptability of pre-surgical provision in patients waiting for THR.
9. Update previous reviews of physiotherapy exercise, assess current provision and explore the feasibility of group-based physiotherapy with individualised exercises for patients with TKR.

Methods

To ensure patient and public involvement throughout the programme, work packages were discussed and developed in collaboration with patient representatives and a patient forum.

We appraised existing research using systematic review methods and meta-analysis in accordance with appropriate guidelines.

In a qualitative study, 34 patients receiving THR and TKR were interviewed before surgery, 2–4 weeks and 6 and 12 months after surgery. Interviews elicited patients' experiences of preparing for, undergoing and recovering from surgery. Interviews were audio-recorded, transcribed and analysed using a thematic approach or interpretive phenomenological analysis.

In the Assessing Disability After Partial and Total joint replacement (ADAPT) study, outcome measures were studied prospectively in 263 patients receiving joint replacement. Participants were assessed prior to surgery and at 3 and 12 months. Function was assessed using patient-completed questionnaires, clinician-administered tools and performance tests.

In the Arthroplasty Pain EXperience (APEX) RCTs, 322 patients receiving THR and 316 patients receiving TKR were randomised to receive 60 ml local anaesthetic infiltration (0.25% bupivacaine and 0.3 mg adrenaline) before wound closure or standard anaesthesia. All patients with TKR received a femoral nerve block (FNB). The primary outcome was the Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain score at 12 months. The primary health outcome for economic evaluation was the quality-adjusted life-year measured using the European Quality of Life-5 Dimensions 3-Level version.

The APEX RCTs were also analysed as cohort studies. Radiographic measures of osteoarthritis severity were correlated with pre-operative WOMAC pain and function. Associations between measures of pain over time were explored. Quantitative sensory testing was conducted to assess pre-operative widespread pain sensitisation. Qualitative interviews were conducted with 24 patients and 15 health-care professionals about involvement in the APEX trials and views about analgesics. Data were analysed using thematic methods.

Using systematic review and meta-analysis, we identified RCTs evaluating the effectiveness of pre-surgical education and exercise interventions.

To evaluate the feasibility of conducting a definitive RCT of a pain self-management programme for patients undergoing THR, the Self-managing Pain In aRthritis and ArthropLasty (SPIRAL) study assessed trial procedures and data collection, randomisation, recruitment and attrition rates.

The Pilot Randomised controlled trial Of Occupational therapy For – Total Hip Replacement (PROOF-THR) study evaluated the feasibility of pre-surgical occupational therapy in patients waiting for THR. Primary objectives were to assess patient identification, recruitment and retention, acceptability of allocation, and acceptability of health resource use and outcome measures.

Physiotherapy services were surveyed at 24 high-volume orthopaedic centres in England and Wales. In the Activity orientated REhabilitation following kNee Arthroplasty (ARENA) study, the feasibility of a RCT evaluating a 6-week activity-orientated rehabilitation programme for patients with TKR was assessed. Information was collected on uptake rates, reasons for non-attendance, patient satisfaction and outcomes, acceptability of exercises, outcomes measures and collection of costs.

Results

Prevalence of long-term pain

Studies in representative populations including 25,831 patients suggest that about 7–23% of patients have moderate or severe pain after THR and about 10–34% after TKR.

Outcome measures to assess long-term pain

Systematic review including 1164 research studies in patients with TKR identified extensive variation in pain outcome measures. Few studies attempted to capture the incidence, character and impact of long-term pain. A composite clinician assessment with a single question about pain was widely used but there was an increase in use of patient-reported outcomes over time.

Pre-surgical prediction

In prospective studies, patients with better pre-operative physical function and lower pain generally achieved a better recovery after surgery. Patients with poor physical function before surgery may have greater absolute improvement.

Patients with depression before THR and TKR had poorer long-term pain and functional outcomes. For patients with anxiety or poor general psychological health, there was evidence for a relationship with worse pain and functional outcomes in patients receiving TKR but evidence in THR was equivocal.

Patients with a broad range of body mass index benefited from THR and TKR but those with highest levels may not achieve good levels of function and pain control.

Comorbid conditions

About 64% and 71% of patients receiving THR and TKR, respectively, have comorbidities. In specific clinical conditions, we found little research on patient-reported outcomes. In studies looking at long-term patient outcomes according to diabetic status, research was inconclusive. However, studies show that patients with diabetes, previous heart disease and anaemia are at greater risk of post-surgical adverse events.

Patient experience

In qualitative interviews, patients noted that delays to NHS orthopaedic surgery are common. For patients undergoing joint replacement, changes to the date of surgery have implications for well-being and patients' experiences of time differ from the linear conceptualisation required to plan NHS services.

Undergoing surgery can increase feelings of vulnerability and alter a patient's trust in their own body; the influence of interactions with others on confidence levels and the fears that patients have concerning the potential of causing harm to their new prosthesis. Our research also highlights strategies that patients engage in to limit this. Patients rely extensively on, and value, both informal and formal support networks over the perioperative period and that transformation from a person living with osteoarthritis to a person recovering from a surgical intervention can lead to alterations in the assistance participants received from others. However, when patients are not offered the support of health and social professionals over the perioperative period, for example to aid recovery, negative consequences can ensue including distress and feelings of abandonment. The qualitative research also highlights the complexity of patient expectations for joint replacement surgery and how these expectations can be driven by previous personal experience, knowledge of others' experiences, and information resources provided by the hospital around the perioperative period.

Functional outcomes

In the ADAPT study, a clinically significant improvement occurred in about 90% of patients with THR and 70% of those with TKR. Compared with other outcomes, improvement of walking time was rarely large. Patients with very severe disease at the time of surgery were more likely to have substantial improvements in pain and functional ability. But the destination differs for the two joint sites; those with hip disease can have the similar good destination, irrespective of the starting point, whereas those with knee disease can never 'catch up' (i.e. have as good a final outcome or destination) if they start off with very severe disease at the time of surgery.

As pain and function measures were highly correlated and people with anxiety or depression may assess themselves as being worse off than objective measures suggest, measures of function may need adjustment for pain, psychological status, age and perhaps muscle strength to obtain a satisfactory picture of functional loss. Results suggested that physical function should be measured with a patient-reported outcome measure and a performance test. Range of motion is commonly assessed in clinical practice but correlated poorly with other measures of disease severity.

Perioperative pain management

Systematic review identified 36 RCTs evaluating local anaesthetic infiltration in patients receiving THR and TKR. Few reported long-term follow-up. Local anaesthetic infiltration was effective in reducing short-term pain when compared with no infiltration. Effectiveness was enhanced with the addition of post-closure analgesia. In TKR, there was no evidence of additional benefit if a FNB had already been sited.

In the APEX RCTs, local anaesthetic infiltration was associated with reduced pain 1-year after THR. Findings in patients receiving TKR provided no strong evidence that local anaesthetic infiltration reduced long-term pain additional to that provided by FNB. From the perspective of the NHS and Personal Social Services (PSS), local anaesthetic infiltration is a cost-effective treatment option in primary THR but evidence supporting its use in TKR was weaker.

Trial participation and views about medication

In qualitative interviews, patients and health-care professionals reported that they had weighed up the benefit and cost of involvement. They were interested in involvement in APEX RCTs because they considered the trials important and relevant. Patients expressed their desire to help others by contributing to the furthering of clinical knowledge. Many patients thought that they might benefit physically and psychologically from taking part.

The qualitative study also demonstrated the need for trials to ensure minimal burden. Health-care professionals wanted the trial to have minimal impact on daily clinical practice and patients wanted data collection and participation to be as easy as possible.

Further analysis of the qualitative data showed that the experience of joint replacement can temporarily alter patients' views of the acceptability, necessity and value of pain relief medication. This alteration is related to views about pain from intervention compared with pain from chronic condition, and is influenced by interactions with health-care professionals. However, once initial recovery from surgery has begun, long-standing beliefs about the appropriate use of pain relief medications may take prominence.

Radiographic osteoarthritis severity and pain

In the APEX cohort study, there was no relationship between the degree of radiographic damage and pain or function in patients waiting for THR. In patients waiting for TKR, those with the least severe radiographic damage reported more severe pain and poorer function.

Pain as a predictor of long-term pain

Long-term pain after THR was predominantly associated with pain at rest during the pre-operative and acute postoperative period. In contrast, long-term pain after TKR was predominantly associated with the severity of pain on movement during the pre-operative period.

Pre-operative widespread pain sensitisation and chronic pain

Pre-operative widespread pain sensitivity was not associated with change in pain severity from pre-operative to 12 months post operation in patients with THR and TKR.

Exercise and education interventions before surgery

Systematic review identified 36 interventions targeting optimisation of pre-surgical physical function before THR and TKR. Interventions showed benefit compared with controls for physical function, pain and anxiety. In 27 studies targeting in-hospital recovery, post-surgical anxiety was lower in intervention patients and mobilisation was earlier. In 18 studies, interventions targeting long-term outcomes showed no benefit.

Group-based pain self-management

Of 385 eligible patients with THR, 88 (23%) consented to participate in the SPIRAL study of group-based pain self-management. Common reasons for non-participation were views about the course and transport difficulties. Of the 43 patients randomised to the intervention, 28 attended pre-operative sessions and 11 attended postoperative sessions. Participant satisfaction was high and feedback highlighted that patients enjoyed the group format. Retention of participants in the RCT was acceptable (83%) with high questionnaire return rates except resource-use diaries.

Occupational therapy

In patients receiving THR, systematic review identified seven RCTs of occupational therapy, mainly combined with physiotherapy. There was a suggestion of improved function and reduced pain before surgery but this was not sustained after surgery. In the PROOF-THR study, 44 patients were randomised to pre-operative occupational therapy or usual care. Good recruitment rates, acceptability of randomisation of participants, successful intervention delivery, and reasonable attrition rates suggest a definitive trial would be feasible.

Physiotherapy exercise

Systematic review and meta-analysis identified a few small studies suggesting that physiotherapy exercise can have short-term benefits for patients with TKR. In the UK, physiotherapy is usually provided for patients with THR depending on clinical need. After TKR, group exercises focus on knee-specific strengthening, stretching and functional exercises. In the ARENA study a 6-week group-based activity-orientated rehabilitation programme for patients with TKR was evaluated. Of 124 eligible patients, 46 were randomised (37%). The intervention was generally well received and attendance was good (73%).

Conclusions

The RESTORE programme highlights the importance for patients of support by health and social professionals at different stages of the joint replacement pathway.

Feasibility studies in patients receiving THR and TKR provided information about the acceptability of interventions that might help patients achieve better long-term outcomes. Although participation in pre-operative pain management was low, those who attended provided positive feedback. Research into occupational therapy provision before surgery is feasible, and group-based post-surgical physiotherapy with individualised exercise was well received.

Perioperative care should include appropriate multimodal anaesthesia supported by evidence from adequately powered RCTs. For patients receiving THR, this should include local anaesthetic infiltration but this may not provide additional benefit to FNB in patients receiving TKR. Local anaesthetic infiltration is a cost-effective treatment in primary THR from a NHS and PSS perspective.

While specific intervention components should be evaluated in appropriately powered clinical trials, the best and most acceptable strategies may be complex interventions tailored to THR or TKR. These would include pre-operative assessment to guide treatment of comorbid conditions, psychological problems and pain, with support for exercises to prevent functional deterioration and education to prepare patients for surgery and recovery. Occupational therapy might be provided before hospital admission. Perioperatively, patients would receive multimodal pain management with evidence-based treatments. After hospital discharge, group-based and individualised physiotherapy exercise might be provided.

In conclusion, the RESTORE programme has provided important information to guide the development of new methods to improve long-term recovery after THR and TKR.

Study registration

This trial is registered as ISRCTN52305381.

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