Optimal primary care management of clinical osteoarthritis and joint pain in older people: a mixed-methods programme of systematic reviews, observational and qualitative studies, and randomised controlled trials

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Scientific summary

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Scientific summary

The National Institute for Health Research (NIHR) programme described in this report concerns people with osteoarthritis (OA) and their primary health care.

Osteoarthritis, a common cause of pain and stiffness in the joints in older adults (adults aged \geq 45 years), is:

- a major global cause of disability
- the most frequent cause of restricted physical and social activity in older people in the UK
- the most common long-term condition managed in UK general practice
- estimated to become the dominant preventable cause of chronic disability in the UK by the year 2030.

Osteoarthritis is a long-term condition. Relief of pain and the maintenance of active participation in daily work, domestic and social life are the goals for treatment of most patients, rather than complete cure. Dramatic improvements can be achieved by joint replacement surgery, which is conducted in the minority of patients who develop advanced and severe OA.

The context for the programme

This programme was formulated in 2008–9 on the basis of questions raised by evidence from two sources about OA and its treatment. First was the published research evidence base about OA which is considered below. Second was input from, and work carried out with, members of the research user group (RUG) in the Institute of Primary Care and Health Sciences.

- 1. There was evidence that:
 - i. simple primary care interventions can provide short-term relief of pain and restricted activity in persons with OA. This evidence underpinned core guidance on care for patients with OA from the UK National Institute for Health and Care Excellence (NICE) published in 2008 (National Institute for Health and Clinical Excellence. *Osteoarthritis: The Care and Management of Osteoarthritis in Adults*. Clinical Guideline CG59. London: NICE; 2008)
 - ii. most people with OA have other health conditions (comorbidities) and if effective care is provided for these other conditions, then the pain and disability of OA improves
 - iii. self-management programmes can improve outcomes in patients with long-term conditions, such as irritable bowel syndrome, which, like OA, are managed predominantly in primary care and the community.

2. However, there was also evidence that:

- i. the quality of OA primary care ranks as low compared with other long-term conditions
- ii. there was much variability in the content and quality of primary care offered to patients with OA, and treatments often targeted the diseased joint rather than the person with symptoms
- iii. most persons with OA were not receiving the full range of NICE core treatments for OA, including advice and information
- iv. persons with OA and other long-term conditions want help and support to self-manage their condition
- v. short-term changes in behaviour that benefit persons with OA, such as increased physical activity, are often not maintained in the long term
- vi. comorbidities in persons with long-term painful conditions such as OA are under-recognised in primary care.

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- 3. There was an absence of evidence and information about important aspects of OA care in the community and primary care, including:
 - i. no clear estimate of the potential for population prevention and health-care benefits among older people with joint pain and disability in the UK community. Small effects from simple core treatments applied to large numbers of people with OA could result in substantial population health gains at reasonable cost
 - ii. the best way for general practitioners (GPs) and the primary care team to consult with persons with OA to manage their condition and support self-management. There had been few attempts to involve OA patients in shaping what information they wanted or needed and what to do to manage their condition
 - iii. no formally developed indicators of the quality of primary OA care such as those that existed for other long-term conditions in the UK.
- 4. There was evidence that most OA patients and health-care professionals were pessimistic (or at best stoical) about the long-term course of OA and the likelihood of getting effective care until the condition was bad enough to require an operation. Patients often perceived doctors' views to be negative: 'not much to be done' and 'what else can be expected at your age?'.

The conclusion was that OA care in the UK was suboptimal, despite evidence that primary care and community-based interventions can reduce pain and disability. The research gaps identified included the need for development and evaluation of better information for public health, patients and clinicians, and for new approaches to delivering OA care in practice.

The overall ambition of the programme was to provide an evidence base for optimising the primary care delivered to OA patients by:

- filling gaps in the evidence and information base about optimal primary care for persons with OA
- providing evidence about how to close the gap between established evidence of effective and efficient OA care and the effective and efficient delivery of that care to patients in practice
- providing practical evidence-based outputs and resources for primary care to support self-management by patients with OA.

The programme consisted of four workstreams. These workstreams were developed in parallel during the period of the programme, linked but independent.

The general aims were as follows.

Workstream 1: to develop a model for estimating the potential for effectively delivered primary care OA interventions to improve population health.

Workstream 2: to develop and evaluate new approaches and services for better delivery and monitoring of OA primary care – the Managing Osteoarthritis In ConsultationS (MOSAICS) studies.

Workstream 3: to investigate the long-term effect of targeting patients' adherence to physiotherapy-led exercise and physical activity for OA knee – the Benefits of Effective Exercise for knee Pain (BEEP) trial.

Workstream 4: to investigate the effect of screening for two major comorbidities (depression and anxiety) in patients with OA in primary care – the Primary care Osteoarthritis Screening Trial (POST).

Workstream 1

Objective

To develop a model to estimate cost-effective population prevention of pain and disability by interventions in patients with OA in primary care.

Methods

Meta-analysis and synthesis of published evidence about effectiveness of primary care treatments, combined with secondary analysis of existing longitudinal population-based cohort data, to identify predictors of poor long-term outcome (prognostic factors); and creation of a health economic decision model to estimate cost-effectiveness of different hypothetical strategies for implementing optimal primary care for patients with OA.

Results

A hypothetical model of effectively delivered 'stepped care' for OA, comprising good advice and pain relief for all patients with OA and offering more extensive treatment (including supervised exercise) to those with poor response to initial treatment was likely to be more cost-effective than current primary care. However, long-term cost-effectiveness is still in need of an evidence base.

Practical outputs

Practical outputs include a population impact model that can be updated and adapted with new information on prognosis and treatment of OA in the general population. The lack of published research and evidence about a constructive and effective approach for long-term analgesic use by OA patients was highlighted.

Workstream 2: the MOSAICS studies

Objectives

- To develop and evaluate a linked 'model' GP and practice nurse consultation and optimal general practice-based service provision for patients with OA (the 'MOSAICS model-of-care') as support for self-management and as a means to implement NICE core OA guidance (NICE, 2008).
- To develop and evaluate methods to measure and monitor the quality of primary care for patients with OA.
- To determine the clinical effectiveness and cost-effectiveness of implementing NICE core OA guidance through the MOSAICS model-of-care in general practice.

Methods

A suite of studies, using a mixture of methods, within the framework of a cluster randomised controlled trial (RCT). Outcomes were (1) process [to measure implementation of evidence-based care informed by NICE guidance (NICE, 2008)] and (2) clinical (to measure the impact on patient symptoms and activities of daily life).

Results

The NICE core OA guidance (NICE, 2008) can be successfully implemented and monitored in primary care practice and is well received by patients. However, the impacts on pain and disability for primary care OA patients have not been demonstrated.

Practical outputs

Practical outputs developed, delivered and evaluated in the programme included an OA guidebook developed with patients and health-care professionals, a training programme for a 'model OA consultation' by GPs, a practice nurse-led primary care service for OA and a training programme for practice nurses, an OA quality-of-care monitoring tool for use in routine primary care computerised records, and a general practice-based OA service model that is being disseminated.

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Workstream 3: the BEEP trial

Objective

To determine whether or not early changes in pain and disability in patients with knee OA from physiotherapy-led exercise and physical activity can be better maintained in the long term by enhanced interventions targeting adherence.

Methods

Individual patient three-arm RCT comparing two enhanced exercise interventions led by physiotherapists with usual physiotherapy care (UC) in patients with knee OA (pilot and full trial phases).

Results

Neither of the two experimental enhancements bettered the clinical effectiveness and cost-effectiveness of UC for pain and disability in patients with OA of the knee.

Practical outputs

Renewed support for ensuring that current best practice for physiotherapy-supported physical activity is available to all patients and evidence to support (1) future research identifying the characteristics of patients who respond to exercise interventions and (2) the importance of the therapeutic relationship in improving long-term change in exercise habits.

Workstream 4: the Primary care Osteoarthritis Screening Trial

Objective

To investigate whether or not GP screening for depression and anxiety among older primary care patients presenting with joint pain or OA is acceptable and is clinically effective and cost-effective in improving pain and disability.

Methods

Pragmatic two-arm cluster RCT (pilot and full trial phases).

Results

Systematically screening older patients who present with joint pain and OA in UK general practice is not effective in reducing pain and disability.

Practical outputs

Renewed support for focusing on the OA symptoms (notably joint pain) with which patients present to the GP. One implication of the trial for future research is the need to investigate the usefulness of screening and identifying comorbid joint pain, depression and anxiety in patients being monitored for other long-term conditions.

Conclusions

The programme has provided evidence:

- about the potential for a hypothetical stepped-care model of primary care for patients with joint pain to have a cost-effective impact on population levels of disabling OA
- about ways to implement practical care and support for self-management of OA in UK general practice
- about how to put optimal primary care for OA informed by NICE recommendations into place in the general practice setting
- about ways to monitor and improve the quality of care for patients with OA in UK general practice

- against an additional effect on pain and disability outcomes of adding enhanced interventions to current effective 'usual' physiotherapy-led exercise interventions for patients with knee OA
- against adding screening to current best practice for OA in UK general practice for comorbid depression and anxiety in older patients presenting with musculoskeletal pain.

However, despite workstream 2 providing evidence of successful implementation of optimal evidence-based primary care practice for patients with OA, as supported and endorsed by patients with OA, clinical outcomes (pain and disability) in the study population did not improve as a result. Furthermore, despite successful introduction of a novel screening programme in workstream 4 for two known predictors of poor long-term outcome in older patients with joint pain (depression and anxiety), this also did not lead to subsequent improvement in pain and disability.

Explanations for this absence of impact on clinical outcomes include:

- the possibility that the total pool of patients aged ≥ 45 years with joint pain during the GP consultation in these studies, and considered to have the potential to benefit from these primary care interventions, contains many patients with a good prognosis unaffected by the interventions
- the possibility that the interventions resulted in too little appropriately intensive evidence-based treatment for patients with joint pain who were at moderate or high risk of persistent pain and disability. This includes, in workstream 2, the lack of physiotherapy-led exercise targeted at these groups and, in workstream 4, the lack of active treatments for patients with anxiety and depression targeted at these groups.

But, workstream 1 has provided the basis for modelling of new evidence to investigate alternative strategies, such as stepped care, for resolving these issues. Workstream 2, despite the lack of change in clinical outcomes, has provided evidence of successful implementation of interventions that had been previously evaluated as clinically effective and cost-effective by NICE. This is now the basis for a wider programme of dissemination and evaluation. Workstream 3 patients were selected to have moderate or more severe pain and there was evidence that intensive interventions designed to improve adherence to exercise had been delivered. Usual-care physiotherapy improves pain and disability, but the two novel interventions developed for the BEEP trial did not achieve improved primary clinical outcomes. There was evidence from both the quantitative and qualitative studies that early gains from physiotherapy are not maintained for more than 3 months after the end of physiotherapy treatment. It is likely that community resources and cultural changes, as well as the improvement of therapeutic relationships, are needed to extend the established effectiveness of physiotherapy-led exercise interventions.

Implications for future research and NHS care for patients with osteoarthritis

The conclusions above raise important questions about the need for new conceptual thinking and discussion on OA management in primary care and about the need for further research.

Potential topics for new conceptual thinking and discussion

- 1. NICE core guidance in practice:
 - i. Clarification of the expected benefits of implementing NICE core guidance for patients with OA as a desirable end in itself (e.g. provision of appropriate information and of advice about exercise and pain relief), regardless of whether or not it demonstrably improves clinical outcomes.
 - ii. Critical reflection on whether or not current NICE core guidance, even when implemented in the way that MOSAICS has done, results in big enough shifts in crucial components of patient behaviour to achieve change in clinical outcomes in the short term. An example of this is physical activity when there is evidence from other research that implementation of physiotherapy-guided interventions as

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core treatment could achieve bigger change, so that adding such resource to the MOSAICS package might deliver effects on pain and disability.

- iii. Following on from (ii) above, reviewing the delivery of NICE core guidance for primary care and the capacity of a GP- and nurse-led service alone to improve clinical outcomes without additional resources such as physiotherapy services to provide individualised and supervised exercise interventions.
- 2. Continuing debate and critical enquiry about the role, benefits and costs of systematic screening for anxiety and depression in all people with long-term conditions in primary care.
- 3. The need for new concepts about OA within the research and clinical community:
 - i. regarding achievable goals of long-term care for people with this condition, including whether or not it is appropriate to seek more than small short- to medium-term clinical effect sizes in patients' pain and disability in practice. Maintenance of activity and participation, despite continuing pain, may, for example, be a better long-term measure of effect.
 - ii. regarding a combined approach to the management of OA as a long-term condition (importance of good information, adequate advice and resources for exercise and physical activity and other core interventions, and identification of individuals at high risk of unfavourable future course and targeted interventions for those most likely to benefit).

Recommendations for new research

- 1. Outcomes in long-term conditions.
- Research into new models of long-term care for OA, in the context of other long-term disabling conditions, that focus on the necessary and desirable process and clinical outcomes from patient, clinician and societal perspectives.
- 3. Stratified care for OA patients.
- 4. Research to identify subgroups of patients with OA who may, on the basis of combined evidence from previous cohorts, clinical effectiveness and cost-effectiveness studies, and the successful implementation strategies described in this programme, benefit from specific interventions in primary care. This includes identification of patient subgroups such as (i) those with good prognosis who can be supported to self-manage without additional investigation or treatment and (ii) those who will benefit from specific treatments, such as physiotherapy-led exercise.
- 5. Exercise and physical activity levels in people with long-term conditions:
 - i. research to identify new approaches to improving long-term adherence to exercise and physical activity among patients with OA such as regular monitoring.
- 6. Depression and anxiety in people with OA:
 - i. research into more efficient and effective ways of identifying and treating clinically important levels of anxiety and depression in patients with OA.
 - ii. research into the effects of pain management on psychological outcomes in patients with OA.

Trial registration

The trials in this programme are registered as ISRCTN06984617, ISRCTN93634563 and ISRCTN40721988.

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