Stratified primary care for adults with musculoskeletal pain: the STarT MSK research programme including RCTs

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Scientific summary

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Scientific summary

Background

Musculoskeletal pain such as back, neck, shoulder, knee and multisite pain is common and costly in terms of burden on individuals, the NHS and society. For some people these musculoskeletal problems are painful but short-lived; however, for others the painful episode fails to resolve or recurs, impacting their ability to work and leading to extensive NHS and societal costs. Most patients with musculoskeletal problems are managed in primary care, where 20% of the registered practice population will consult their general practitioner (GP) annually with a musculoskeletal problem, accounting for one in six GP consultations. There is limited evidence to guide how best to direct the right patient to the right treatment in ways that improve patient outcomes such as pain and disability, and make the best use of health-care resource. The sheer number of patients makes it inappropriate and unsustainable to offer more intensive and expensive treatments to all. Building on a previously successful model of prognostic stratified care for patients in primary care with low back pain, the aims of this programme were to adapt, finalise and test a prognostic stratified primary care model for a much larger group of patients with the five most common musculoskeletal pain presentations.

Objectives

The programme addressed the following objectives:

- on the tool to subgroup patients into prognostic strata –
    - validate and optimise the predictive performance of the Keele STarT MSK (Subgrouping for Targeted Treatment for Musculoskeletal pain) Tool
    - determine the tool risk strata cut-off points based on optimal predictive values and suitability for matched treatment options
    - estimate the proportions of patients at low, medium and high risk of poor outcome and describe their characteristics
    - describe current health-care resource use by all patients and in each risk stratum.
- on the recommended matched treatment options –
    - summarise current best evidence on available treatments for the five most common musculoskeletal pain presentations in primary care
    - explore patients' and GPs' views on the acceptability of prognostic stratified care and the anticipated barriers to and facilitators of its use in clinical practice
    - agree, through expert consensus, the most appropriate matched treatment options that should be recommended for patients in each risk subgroup
    - develop and specify the training and support package to support delivery of stratified primary care.
- on the feasibility of a future main cluster randomised controlled trial (RCT) and of delivery of stratified primary care –
    - estimate participant recruitment and follow-up rates for the main cluster RCT
    - examine evidence of selection bias between trial arms and between participants and non-participants

  - assess GP fidelity to the stratified care intervention (use of the stratification tool and matched treatment options)
  - conduct secondary descriptive analyses of GP decision-making and patient outcomes.

- on the clinical effectiveness and cost-effectiveness of stratified primary care compared with usual care (usual care) –
  - determine the comparative clinical effectiveness of stratified care versus usual primary care for patient outcomes
  - investigate GP fidelity to delivery of stratified care and the impact on clinical decision-making
  - undertake an economic evaluation of stratified care versus usual care
  - conduct a nested qualitative study to understand how stratified care was perceived and operationalised by clinicians and patients.

Methods

A series of studies across four work packages was carried out, involving different research methods:

- work package 1 – a prospective longitudinal cohort study and interviews with patients and clinicians
- work package 2 – an evidence synthesis, qualitative focus groups and interviews, consensus group workshops, and development of an electronic template and training/support package to support GPs to deliver stratified care
- work package 3 – a feasibility and pilot RCT with linked qualitative interviews
- work package 4 – a main cluster RCT including analyses of general practice medical record data, health economic analyses and qualitative interviews.

Results

Work package 1 – the Keele Aches and Pains Study (KAPS)

A total of 1890 patients responded to the invitation and consented to participate (mean age 58 years, 61% female). Subsequently, 1425 participants returned questionnaires at 2 months' follow-up (response rate of 75.8%), and 1452 provided data at 6 months' follow-up (response rate of 78.7%). The amended 10-item Keele STarT MSK Tool has a scale range of 0–12 (0 = lowest risk of poor outcome, 12 = highest risk of poor outcome). The final model fit (R^2) and discrimination (*c*-statistic) in the Keele Aches and Pains Study (KAPS) data set at 6 months' follow-up was 0.422 and 0.839 for physical function, respectively, and 0.430 and 0.822 for pain intensity, respectively; there was also acceptable performance across the five musculoskeletal pain presentations. In the external validation data set, the final model fit (R^2) was 0.224 and discrimination (*c*-statistic) was 0.725 for pain intensity. The cut-off points determined to provide the best combination of sensitivity, specificity, predictive values and likelihood ratios, in combination with suitability for the recommended matched treatments (identified in work package 2), overall and across pain sites, were 0–4 for low risk, 5–8 for medium risk and 9–12 for high risk. The KAPS cohort participants were classified as 25% at low risk, 42% at medium risk and 33% at high risk of poor outcome. There were clear and consistent differences between risk subgroups on key variables, health-care utilisation and associated costs, confirming the discriminative ability of the Keele STarT MSK Tool.

Work package 2 – study to agree matched treatment options and support package for delivery

The evidence synthesis showed that primary care patients with musculoskeletal pain can be managed effectively with non-pharmacological treatments such as self-management advice, exercise therapy and psychosocial interventions, and that pharmacological treatments provide, at best, short-term benefits only. The qualitative focus groups and interviews with patients and clinicians identified four key themes (the acceptability of clinical decision-making guided by stratified care, the impact on the therapeutic

relationship, embedding a prognostic approach within a biomedical model and practical issues in using stratified care). For GPs and patients to see stratified care as useful, it must add to existing knowledge and skills, not undermine GPs' clinical autonomy nor disrupt therapeutic rapport. The need for integration into consultations with minimal disruption was highlighted. In the consensus study, the three Nominal Group Technique workshops with multidisciplinary groups of clinicians led to a total of 17 treatment options being recommended. These were summarised and incorporated into a bespoke electronic health record (EHR) template along with the Keele STarT MSK Tool, in order to make delivery of stratified care as easy as possible for GPs, and a training/support package for GPs was developed, ready for use with GPs participating in the feasibility and pilot trial in the next work package.

Work package 3 – the Treatment for Aches and Pains Study (TAPS) pilot trial

In work package 3's feasibility and pilot RCT, 524 participants (42% of those invited) consented to provide questionnaire outcome data (stratified care n = 231, usual care n = 293). Anonymised EHR data were available for 1281 patients (529 in stratified care practices and 752 in usual care practices). Although follow-up rates over 6 months were high, the length of time taken to recruit participants (28 weeks) was over twice as long as expected (12 weeks). GP fidelity to use of the stratification tool was only 40% of eligible consultations (compared with a target of at least 50%), and both GPs and patients identified the need for several items in the tool to be amended. However, in those with whom the tool was used, over 80% were recorded as having been matched to a recommended treatment option. Key changes were therefore needed prior to the main trial; thus, this feasibility and pilot trial became an external pilot trial (rather than the originally intended internal pilot trial). There was no evidence of selection bias and, therefore, no changes were made to identification or recruitment procedures for the main trial. Given the learning from this pilot trial, amendments were made to the stratification tool (revision of the language used in four of the tool items) and matched treatment options (a total of 14 were recommended).

Work package 4 – the Treatment for Aches and Pains Study (TAPS) main trial

In the main cluster RCT in work package 4, 1211 patients from 24 general practices (12 per arm) participated in self-report data collection (534 in stratified care and 677 in usual care); the participants had a mean age of 60 years and 58.9% were female. Mean pain intensity at the point-of-consultation was 6.73 (6.77 in stratified care, 6.70 in usual care). A total of 1178 (97%) participants provided at least one pain intensity response over the 6 months' follow-up [515 (96%) in stratified care, 663 (98%) in usual care] and 80.9% responded to the follow-up questionnaire at 6 months (77.9% in stratified care, 83.3% in usual care).

The main analysis showed no statistically significant differences in pain intensity over 1–6 months comparing stratified care with usual care, with mean values of 4.4 [standard deviation (SD) 2.3] for stratified care and 4.6 (SD 2.4) for usual care [adjusted mean difference −0.16, 95% confidence interval (CI) −0.65 to 0.34; p = 0.535]. Most sensitivity analyses showed no statistically significant between-arm differences, despite showing consistent slightly favourable results for stratified care. Subgroup analyses showed some between-arm mean differences with a greater difference (although statistically non-significant) in patients at high risk versus those at low risk, and between those with shoulder and knee pain compared with those with neck and back pain. There were no statistically significant differences in secondary clinical outcomes at 6 months, except for a significant improvement in shoulder pain and function and higher satisfaction with care in the stratified care arm compared with the usual care arm.

The health economic evaluation showed that the costs of care were very similar in the two arms of the trial: mean cost of stratified care was £356.36 (SD £864.01) compared with a mean cost of £343.44 (SD £942.92) for usual care. The adjusted incremental cost of stratified care compared with usual care over the 6 months was £6.85 (95% CI −£107.82 to £121.54), with incremental quality-adjusted life-years (QALYs) of 0.0041 (95% CI −0.0013, 0.0094), representing a net QALY gain. Stratified care was associated with a cost-per-QALY gain of £1670. At a willingness-to-pay threshold (λ) of £20,000 per

QALY, the incremental net monetary benefit was £132 and the probability of stratified care being cost-effective was approximately 73%.

The anonymised EHR audit data were available for 2494 patients across all 24 practices and demonstrated several important impacts from stratified care on GP treatment decision-making, including increased provision of written information (58% in the stratified care arm vs. 26% in the usual care arm), physiotherapy referral (63.3% in the stratified care arm vs. 9.9% in the usual care arm), and simple over-the-counter analgesics (16.7% in the stratified care arm vs. 6.3% in the usual care arm). Prescribing of short-term courses of strong opioids increased (20.3% in the stratified care arm vs. 1.0% in the usual care arm), but not long-term opioids. GPs in stratified care practices completed the risk-stratification tool in 29.76% (1056/3548) of possible consultations and reported selecting an appropriate risk-matched treatment option in over three-quarters of patients (77.2% low risk, 77.8% medium risk and 76.7% high risk).

Patient and public involvement

Patient and public involvement and engagement (PPIE) representatives contributed at all stages and to all work packages. In work package 1 they made suggestions on patient-facing materials that improved acceptability and understanding, and gave patient/public perspectives on the draft Keele STarT MSK Tool's face validity. PPIE representative views influenced the presentation of evidence for the work package 2 consensus study, and aided the choice of patient websites and leaflets recommended for GP use (in matched treatment options). In work package 3, PPIE perspectives improved study design and patient-facing materials. PPIE representatives helped the team understand and interpret feasibility/pilot trial findings (quantitative and qualitative), and influenced main trial plans. PPIE input was valuable in wording and ordering the clinician-completed version of the Keele STarT MSK Tool. In work package 4, PPIE input led to improvements in wording and formatting of study documents, and advised on acceptable methods for GPs seeking patient consent. PPIE views were also important in the interpretation of study findings.

Conclusions

The Keele STarT MSK Tool is a valid instrument with which to discriminate between, and predict outcomes of, primary care patients with musculoskeletal pain. However, matching groups of patients to the available treatment options recommended in this programme did not lead to consistently better clinical outcomes than those receiving usual care. Although the randomised trial showed no significant benefit in patient-reported outcomes compared to usual care, some aspects of clinical decision-making improved and there was only a marginal increase in cost.

Implications for health care

The Keele STarT MSK Tool is a valid tool with which to identify patients with different levels of risk of persistent pain. The tool provides additional systematic information about an individual patient's prognosis that can help clinicians to direct patients to the most appropriate treatments. The approach of using one tool for this wide range of patients has the major benefit of simplicity for clinical practice, removing the complexity that would result from multiple, pain site-specific screening tools. The main trial showed that although matching patients to treatment options based on their risk subgroup did not lead to superior patient-reported outcomes for the overall trial comparison, there were important improvements in some aspects of clinical decision-making about treatments. Costs of risk-based stratified care were similar to usual care, with marginal additional benefits. The main trial results are partly explained by a loss in fidelity in terms of the delivery of stratified care by participating GPs, likely

explained by the additional burden of time to deliver stratified care in consultations with patients. The stratified care approach with the EHR template comprising the tool and 14 treatment options may have been too complex to deliver with high fidelity. The challenge remains to improve primary care treatments in ways that lead to better outcomes for patients with musculoskeletal pain.

Implications for research

Stratified care involves matching subgroups of patients to treatments in ways that improve clinical outcomes, reduce unnecessary or harmful treatments and make better use of health-care resource. This programme demonstrated that it is possible to use one brief (10-item) stratification tool to accurately identify the prognosis of patients with musculoskeletal pain using simple self-report information. This required the GP to ask patients questions and record their responses, adding time to consultations. Future research needs to identify ways to use more routinely collected data about patients with musculoskeletal pain so that prognostic subgroup information can be provided to clinicians in more time-efficient ways. The stratified care EHR template in this programme fired only once per patient, so as not to burden GPs, and although this led to important changes in some aspects of clinical decision-making, patients had an average of 4 to 5 musculoskeletal pain-related consultations over 6 months' follow-up. There was no electronic reminder of stratified care during these consultations. Therefore, future research that tests ways to continually 'nudge' clinical decision-making in the right direction is needed. For most patients with musculoskeletal pain, this will require efforts to reduce medication prescriptions and instead support self-management and ensure access to non-pharmacological treatments.

Trial registration

This trial is registered as ISRCTN15366334.

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