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Evaluation of uptake and effect on patient-reported outcomes of a clinician and patient co-led chronic musculoskeletal pain self-management programme provided by the UK National Health Service

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Abstract
In the United Kingdom, chronic pain affects approximately 28 million adults, creating significant healthcare and socio-economic costs. The aim was to establish whether a programme designed to use best evidence of content and delivery will be used by patients with significant musculoskeletal pain problems. Of 528 patients recruited, 376 participated in a 7-week-long group-based self-management programme (SMP) co-delivered by clinical and lay tutors. Of these, 308 patients (mean age, 53 years; 69% females, 94% White) completed at least five SMP sessions. Six months after pre-course assessment, participants reported significantly improved patient activation and health status, lower depression and anxiety scores, decreased pain severity and interference, and improved self-management skills. There were no improvements in health state and pain self-efficacy. Uptake rate was 71% and completion 82%. The results should be of value to commissioners of pathways of care for the large numbers of patients attending the English NHS for chronic musculoskeletal pain.

Keywords
Chronic pain, self-management, patient activation, self-efficacy, service evaluation

Introduction
In the United Kingdom, the National Institute for Health and Clinical Excellence provides guidance that recommends combining physical and psychological therapies and providing individually tailored self-management support for people experiencing long-term musculoskeletal pain.¹² Although there is promising evidence that psychological methods and self-management programmes (SMPs) improve self-reported outcomes for adults with various pain conditions, and specifically for chronic musculoskeletal pain³⁻⁸ in research studies, there is limited evidence on which to base decisions about the type and content of SMPs for health services commissioners.⁹ This service evaluation study examines the uptake and effect on patient-reported outcomes of an evidence-based group SMP within usual health services provision of in two health economies in England.

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Background

It is estimated that in the United Kingdom, chronic pain affects just under 28 million people. Musculoskeletal pain accounts for around 15% of all general practitioner (GP) consultations. It is estimated that the total healthcare costs for patients with chronic lower back pain were double those of the matched controls in the United Kingdom (£1074 versus £516; p < 0.05). Of this cost difference, almost 60% was accounted for by General Practice consultations, and 22% by secondary care referrals and the rest by pain relief medications.

Although research to date provides only limited evidence to inform the design of primary care and community services that could be commissioned in the United Kingdom, some studies suggest that SMPs can improve outcomes in people living with chronic conditions including musculoskeletal pain. The US Institute of Medicine defines self-management as ‘the tasks that individuals must undertake to live with one or more chronic conditions. These tasks include having the confidence to deal with medical management, role management and emotional management of their conditions’. Lorig and Holman describe six main self-management skills: problem solving, decision making, resource utilisation, formation of a patient-provider partnership, action planning and self-tailoring. Self-efficacy, described as the confidence that one can carry out behaviours necessary to reach one’s goals, is an important concept underpinning SMPs.

A recent systematic review of SMPs for patients with musculoskeletal pain concluded that SMPs for patients with arthritis have small to moderate long-term effects in improving pain and disability, but there is not enough evidence to draw conclusions about the effectiveness of interventions designed for patients with chronic back pain. A systematic review of effective delivery styles and content of self-management interventions for chronic musculoskeletal pain provided evidence for the clinical effectiveness of group delivered interventions lead by a healthcare professional having more beneficial effects than lay-led programmes (although paying clinicians adds costs). There was mixed evidence for the effectiveness of different intervention components; however programmes with a psychological component produced better outcomes than those without these components.

A randomised controlled trial (RCT) of the effectiveness and cost-utility of a group self-management support intervention for people with chronic musculoskeletal pain showed that in the intervention group at 6 months after completing the programme, self-efficacy, pain acceptance and social integration improved, and the level of anxiety and depression decreased significantly compared to two control conditions of usual care and using an audio relaxation aid. At 12 months after completing the programme, positive changes achieved by patients from the intervention group remained significant for depression and social integration. However, the programme had no effect on pain-related disability at any follow-up point.

Another RCT compared the effectiveness of an outpatient Pain Self-management Programme (PSM) for patients over 65 using cognitive-behavioural therapy (CBT) and exercise with two control conditions. Patients who completed the PSM, compared to other two groups, significantly improved on measures of pain distress, disability, mood, unhelpful pain beliefs and functional reach, and these changes were sustained 1 month after completing the programme.

Aim

The aim of this study was to establish the uptake, retention and outcomes of an evidence-based self-management intervention in the context of National Health Service provision which is open to patients who self-refer themselves to the programme after discussion with their GP or hospital specialist clinician, rather than in the conditions of a clinical trial. We aimed to establish if the programme improves patients’ self-reported activation and confidence to self-manage, their use of self-management skills, their mood and health-related quality of life. Second, we sought to determine the patient characteristics of those who attended and those who most benefited from the programme to inform future health service provision.

Materials and methods

Recruitment

The study protocol was approved by the NHS Research Ethics Committee 07/H1107/143. Patients eligible for inclusion were aged 18 years or older, diagnosed with chronic musculoskeletal pain, and who were physically able to attend a group-based SMP. Patients seen in primary or secondary care settings were recruited for the study between February 2008 and June 2010. Eligible patients were informed by their providers about the programme and received instructions on how to enrol. Patients registered their interest via a dedicated recruitment telephone helpline.

Intervention

The SMP for people living with chronic musculoskeletal pain was delivered as a part of the Co-Creating Health (CCH) programme. CCH is a quality improvement programme commissioned by the Health Foundation which aimed to demonstrate that increased
self-management support leads to improved health and self-management outcomes. The programme was delivered at two National Health Service organisations: Calderdale and Kirklees Primary Care NHS Trusts with Calderdale and Huddersfield NHS Foundation Trust, and North Bristol NHS Trust with Bristol Primary Care NHS Trust.

The SMP was a 21-hour (7-week long, 3-hour per session) group-based SMP co-delivered by a ‘clinical tutor’ (e.g. physiotherapist, clinical psychologist or anaesthetist) and a ‘peer tutor’ (a person living with the condition). Some of the structure, content and theory of the CCH SMP were based on the Stanford University Chronic Disease Self-Management Course,18 which in the United Kingdom is known as the Expert Patients’ Programme (EPP). The SMP contains 27 behaviour change techniques, including those that have a strong evidence base such as goal setting, action planning and problem solving,19 plus weekly pain-specific content. The intervention delivery of the SMP was guided by a manual to ensure consistency of delivery and content, supporting intervention fidelity.20,21

Tutors were trained and accredited to a rigorous set of quality standards with training and course delivery focusing on adherence to the activity times and sequence of activities as set out in the manual.

Measures

Data were collected before attending the SMP (T1) and 6 months after completing the programme (T2).

**Patient Activation Measure.** The Patient Activation Measure (PAM) assesses patient activation,22 which is conceptually similar to self-efficacy. It comprises 13 items assessing patient knowledge, skill and confidence for self-management. Scores range from 0 to 100; higher scores indicate greater activation. An improvement in 4 points on the PAM scale is considered a minimal clinically important difference (MCID).23–25 The PAM is the primary outcome measure and has since been mandated for use in the NHS in England (https://www.england.nhs.uk/ourwork/patient-participation/self-care/patient-activation/pa-faqs/).

**Hospital Anxiety and Depression Scale.** The Hospital Anxiety and Depression Scale (HADS)26 provides separate scores for anxiety and depression ranging from 0 to 21, with higher scores indicating greater anxiety and greater depression. Based on effect size approach, the MCID is 1.40 for the HADS depression score and 1.32 for the HADS anxiety score.27

**EuroQol.** EuroQol is a measure of health-related quality of life.28 It consists of a descriptive measure of health status (EQ 5D index)29 assessing patients’ health state across five dimensions (self-care, mobility, anxiety/depression, usual activities and pain/discomfort), and a visual analogue measure (EQ VAS)30 valuing respondent’s health state with endpoints of best and worst imaginable health state. Improvement by at least 30 points is MCID for EQ VAS,31,32 while for EQ 5D it is a mean change of 0.037 and standard deviation (SD) 0.008.33

**Health Education Impact Questionnaire.** Health Education Impact Questionnaire (heiQ) is a measure of self-management ability.34 The eight scales are positive and active engagement in life, health directed behaviour, skill and acquisition technique, constructive attitudes and approaches, self-monitoring and insight, health services navigation, social integration and support, and emotional well-being. Items are rated on a 4-point Likert scale; higher scores represent higher levels of self-management abilities.

**Brief Pain Inventory and Pain Self-Efficacy Questionnaire.** The Brief Pain Inventory (BPI) includes two subscales: Pain Severity that assesses the pain at its worst, average, least and now, and Pain Interference assessing how much pain affects the person’s daily activities.35 A 2-point reduction in pain from a baseline of 4 was considered clinically meaningful by patients; therefore, a low-end cut-off point level of either 4 or 5 on the 11-point numeric rating scale is considered MCID in patient-based studies.36 The Pain Self-Efficacy Questionnaire (PSEQ) is a 10-item questionnaire assessing how confident patients are in performing a range of activities including household chores, socialising with friends and family, work and hobbies.37 The score change of 8.5 on the PSEQ is considered to be MCID.38

Data analysis

All data analyses were conducted using IBM SPSS Statistics 20. The main analysis was a per-protocol analysis, which included only patients who attended ≥5 SMP sessions (defined as course completers) and who returned 6-month follow-up questionnaires. The level of statistical significance was set at p = 0.05.

Intention-to-treat (ITT) analysis was performed to ensure that the effectiveness of the programme has not been overestimated.39,40 To replace missing data, we used a single imputation method41 replacing missing T2 data with T1 data. Changes in the mean values of the patient outcomes were compared over time using paired T Tests. Liner regression was applied to test whether prognostic factors (T1 scores) and demographic variables predicted changes in primary and secondary outcomes at 6 months. Effect sizes (Cohen’s d) were calculated with boundaries of small (0.2), moderate (0.5) and large (0.8) effect sizes.42 Three categories of change of heiQ scores were
defined: ‘substantial improvement’ (Effective Size (ES) ≥ 0.5), ‘minimal/no change’ (–0.50 < ES < 0.50) and ‘substantial decline’ (ES ≤ –0.5).

Results

Demographic variables

In total, 528 pain patients registered with the recruitment helpline. Of these 152 patients did not attend the SMP, 376 attended at least one session and 308 completed at least five sessions. Some 336 patients completed baseline questionnaires, and 149 patients (44%) completed the primary outcome measure (PAM) at 6-month follow-up.

Patient characteristics are summarised in Table 1. Patients were on average 53 years of age, predominantly White (94%) and female (69.4%). Overall, 74.7% owned their own home and 20% lived alone. Just over a quarter (26%) was in full- or part-time employment. Over a half (51.2%) left education between 16 and 19 years of age, and 21% were educated post 19 years of age.

SMP completers were predominantly White, while there was a higher ratio of patients of other ethnic origin among those who dropped out of the SMP ($\chi^2 = 5.62$ (1); $p < 0.05$). Non-completers also scored significantly lower at baseline (Time 1) on Self-Monitoring and Insight subscale of heiQ (M = 2.82, SD = 0.52) compared to those who completed the SMP (M = 2.97, SD = 0.45; $t = –2.93$ (361), $p = 0.004$, $d = 0.28$). There were no other differences between completers and non-completers.

Primary outcome

Per-protocol analysis showed that patients’ activation significantly improved 6 months after completing the SMP (M = 56.6, SD = 15.6) compared to baseline level (M = 51.3, SD = 12.7; $t = 4.75$ (148), $p < 0.001$, $d = –0.43$; Table 2). The improvement reached the level of MCID. Baseline PAM score ($\beta = .44$, $t(124) = 5.05$, $p < 0.001$) and living situation ($\beta = 0.24$, $t(120) = 2.8$, $p < 0.006$) significantly predicted activation at 6 months. Baseline PAM score explained 20% of variance of 6 months’ PAM scores, while living situation only predicted 4%. ITT analysis produced similar results (Table 2). Some 50.3% of patients showed a meaningful improvement (i.e. ≥ 4 points) in patient activation scores. None of the prognostic and demographic factors predicted patient activation over time.

Secondary outcomes

Per-protocol analysis showed that patients’ health state (EQ-VAS) did not change 6 months after completing the SMP (Table 2). The difference between baseline and 6-month scores did not reach the level of MCID. However, patients’ health status (EQ 5D index) significantly improved 6 months after completing the SMP (M = 0.39, SD = 0.34) compared to baseline (M = 0.30, SD = 0.33, $t = –2.64$ (128), $p < 0.008$, $d = –0.26$; Table 2). The change in score reached the level of MCID. ITT analysis produced similar results for both EQ-VAS and EQ 5D Index (Table 2). Baseline health-related quality-of-life score ($\beta = 0.47$, $t(127) = 6.5$, $p < 0.0001$) and employment status ($\beta = –0.39$, $t(113) = 4.1$, $p < 0.0001$) were significant predictors of health status score at 6 months, meaning participants who were not employed and with lower EQ 5D Index score at baseline showed less improvement at 6 months. Baseline health status explained a 20% of variance in follow-up score, while employment status explained 10%.

Per-protocol analysis showed that depression decreased significantly 6 months after completing the SMP (M = 7.61, SD = 3.78) compared to baseline
(M = 8.74, SD = 4.05, t = 2.89 (105), p = 0.005, d = –0.27; Table 2), reaching the level of MCID.26 Both baseline anxiety (β = 0.26, t(63) = 2.1, p < 0.03) and depression (β = –0.28, t(63) = –2.1, p < 0.03) were significant predictors of depression level at 6 months. This is unsurprising as at baseline anxiety and depression are strongly correlated (r = 0.76; p < 0.001). Baseline anxiety explained 35% of variance in depression scores at 6 months, while baseline depression score accounted for 8% of variance. Of the demographic variables, only living situation was a weak but significant predictor of depression scores at 6 months (β = –0.25, t(84) = 2.3, p < 0.02) and accounted for 4% variance.

Anxiety decreased significantly 6 months post SMP (M = 9.14, SD = 4.57) compared to baseline (M = 10.33, SD = 4.33, t = 3.06 (105), p = 0.003, d = 0.27), reaching the level of MCID.26 ITT analysis produced similar results (Table 2). Baseline anxiety (β = 0.68, t(63) = 6.3, p < 0.0001) and depression (β = –0.24, t(63) = –2.1, p < 0.03) were significant predictors of anxiety level at 6 months. Baseline anxiety score explained 20% of variance of anxiety score at 6-month follow-up, while baseline depression score accounted for 10%. None of the demographic variables predicted anxiety level 6 months post intervention.

Per-protocol analysis showed that patients’ self-management skills in two out of eight heiQ domains significantly improved 6 months after attending the SMP. Self-Monitoring and Insight improved significantly 6 months after completing SMP (baseline M = 2.99, SD = 0.50; follow-up M = 3.11, SD = 0.48; t = 2.17 (106), p = 0.032, d = 0.24), as well as Skills and Technique Acquisition (baseline M = 2.51, SD = 0.68; follow-up M = 2.84, SD = 0.49; t = 4.95 (105), p < 0.001, d = 0.68). Effect sizes ranged from 0.50 for Skills and Technique Acquisition to 0.00 for Health Directed Behaviour, Constructive Attitude Shift, Social Integration and Support and Health Service Navigation (Table 2).

ITT analysis produced similar results for all but one heiQ subscales (Table 2). While per-protocol analysis showed no significant improvement in Social Integration and Support Subscale, ITT analysis provided a contradictory result showing significant improvement (baseline M = 2.58, SD = 0.71; follow-up M = 2.74, SD = 0.62; t = 4.10 (362), p < 0.001, d = 0.22). As shown in Table 3, 35% of patients showed substantial improvement in Skills and Technique Acquisition and around a quarter in Positive and Active Engagement, Emotional Well-Being and Self-Monitoring and Insight. Fewer patients (around 20%) substantially improved in relation to Health Directed Behaviour, Constructive Attitude Shift, Social Integration and Support, and Health Service Navigation. None of the prognostic or demographic factors predicted heiQ subscale scores at 6 months post intervention.

### Condition specific outcomes

Per-protocol analysis showed that Pain Self-Efficacy level significantly decreased 6 months post SMP
(M = 43.51, SD = 14.90) compared to pre-course level (M = 46.55, SD = 13.81; t = 2.78 (146), p = 0.006, d = –0.21), reaching the level of MCID. ITT analysis produced similar results (Table 2). Baseline Pain Self-Efficacy level was a significant predictor of the 6-month follow-up score (β = 0.76, t(94) = 5.6, p < 0.0001), with baseline score accounting for 30% variance at follow-up. None of the demographic variables was a predictor of Pain Self-Efficacy level 6 months post intervention.

Per-protocol analysis showed no improvement on BPI subscales (Table 2). However, ITT analysis showed small but significant improvement in Pain Severity subscale (baseline M = 7.61, SD = 1.87; follow-up M = 7.44, SD = 2.03; t = 1.98 (350), p = 0.048, d = –0.09) and larger improvement in Pain Interference score (baseline M = 6.31, SD = 1.81; follow-up M = 6.84, SD = 2.04; t = 4.10 (360), p < 0.001, d = 0.29; Table 2). None of the prognostic or demographic factors predicted changes in follow-up BPI subscales.

Discussion

Results of the study showed that attending SMP for patients with long-term musculoskeletal conditions was associated with improved patient activation and health status, decreased depression and anxiety, and significant improvements in two self-management skills: Self-Monitoring and Insight and Skills and Technique Acquisition. No changes were observed in patient’s health state, and unexpectedly, Pain Self-Efficacy decreased after the programme. Per-protocol analysis showed no changes in Pain Severity and Pain Interference scores; however, ITT analysis showed moderate but significant improvements in both areas.

The study showed the programme was feasible to be offered to a large number of eligible patients and had good levels of attendance. Those who dropped out were more likely to be of non-White ethnicity, suggesting the course recruitment and retention could be improved by tailoring the recruitment strategy to patients of different ethnicities. Referrers and call centre staff could be trained to use motivational interview techniques to enhance patients’ positive attitudes to self-management techniques in general, and the use of self-monitoring materials given out before the course. Analyses by demographic and prognostic factors were largely not significant and do not permit us to make recommendations to target and support particular patient groups.

We compared our results to the review of 18 trials of chronic disease SMPs, the majority of which were for arthritis, and the Cochrane review of lay-led SMPs for a range of conditions. Attending at least five sessions of the SMP programme resulted in significant improvements in patient activation with half gaining a 4-point or more improvement. In studies reviewed by Nolte and Osborne, the effect size reported for a conceptually related self-efficacy measure were small to medium with median size effects of 0.30, with only one study reporting an effect size of 0.75. In relation to these results, we can conclude that the SMP programme evaluated in this study was associated with medium effect size improvements in participants’ activation. The systematic review of trials assessing lay-led SMPs for people with chronic conditions (including pain) included 10 studies that assessed self-efficacy to manage pain. All these studies reported size effects smaller than in our study (ranging from –0.21 to –0.35); however, these were RCTs, while being more robust in design, with selected and more homogeneous patient groups, with less validity to a health service context.

In this study, while health state (EQ-VAS) did not change, health status (EQ 5D) improved. This outcome was not included in the studies reviewed by Nolte and Osborne, but measures of physical function were assessed in four studies, and effects were very small or negligible. Foster et al.’s review included six
studies that assessed quality of life using EQ 5D. In these studies, size effects on this measure were significantly smaller compared to those found in our study.

In this study, the improvement in depression scores was small; however, the effect size was larger compared to the median effect size from 10 trials (0.12). The scores for anxiety also improved (d = –0.27), but anxiety was not included in the studies reviewed above.

In our study, there were no improvements in Pain Severity, but we noticed significant improvement in Pain Interference (as measured by BPI). However, the effect sizes were very small which is consistent with the results from studies included in the reviews. Surprisingly, in our study, Pain Self-Efficacy decreased 6 months after completing the SMP programme. These findings are not consistent with results of three studies included in the review by Foster et al. that specifically assessed pain-related self-efficacy. All three studies noted small but significant improvements.

Improvements in self-management skills (as measured by heiQ) were greatest for Skills and Technique Acquisition and Self-Monitoring. Improvement on these two subscales were comparable to those reported in the same measure by the national self-management evaluation in Australia. However, in regard to all remaining heiQ subscales, the proportion of patients in the Australian survey making a substantial improvement was greater. However, not all SMP programme attenders in the Australian study were pain patients, and intake of patients may differ in chronicity and severity of pain, so results are not directly comparable.

Adherence to the intervention may explain some of the variation in results achieved in different studies. For example, a study by Nicholas et al. of 567 participants showed that patients who better adhere to self-management support strategies taught during a 3-week cognitive-behavioural SMP for chronic musculoskeletal pain showed more significant reductions in pain, disability and depressive symptoms compared to participants with poor adherence. In studies of CBT for pain, homework adherence has rarely been reported, and little is known about patient engagement beyond rates of session attendance and study drop-out. Research is needed on ways to enhance patients’ active participation in SMPs, as well as to develop measures that adequately capture such engagement.

Commissioners of services must address issues of equity and access to services and aim to reduce health inequalities. The majority of participants were female and middle aged, in line with other studies reported in a systematic review of self-management group interventions. The patients were mainly White, and fewer of those from ethnic minorities completed the programme, which may suggest that further development of culturally sensitive delivery may be beneficial. Education and house ownership variables show a wide range but also a median level, suggesting the programme may have attracted more of those who are educated and have higher incomes. Further co-production of recruitment methods and content with potential participants from a wide spectrum of a locality is recommended.

Limitations of the study

First of all, the sample in the described study was self-selected, thus the results need to be interpreted with caution. It is possible that patients who volunteered to participate in the SMP were highly motivated and interested in improving their quality of life. Comparison of completers and non-completers showed that patients who attended less than five SMP sessions scored significantly lower on the Self-Monitoring and Insight subscale of heiQ at baseline. This may suggest that patients who volunteered to attend the SMP, those who completed it were already more engaged in managing their condition than those who dropped out early on. Second, the study design did not use a comparison group, so we cannot conclude with full certainty that observed improvements were solely the result of attending the SMP. Data were not achieved from all patients at each time point, leading to the possible response bias of those responding having better outcomes than non-responders.

Implications and conclusion

The study provides an evaluation of the implementation of an evidence-based group SMP in the context of the English NHS. Over the 29-month recruitment period, 528 patients were recruited, 376 entered the programme and 308 completed at least five sessions. Comments by patients and clinicians (reported elsewhere) suggest this high level of acceptance and retention was achieved in part by the conversations between clinicians and patients about the appropriateness of the programme for their needs. We recommend that future studies include data on healthcare use, which could be used by commissioners in a business case for investment, since it is plausible that better self-management facilitate more appropriate healthcare use and may reduce costs of unnecessary investigations and ineffective interventions. The study provides data on outcomes that are readily collected in routine practice. Services in the United Kingdom are mandated to use the primary outcome measure used here and commissioners will have valuable data on which to compare the improvements achieved from this type of programme in their local health services.
These results give support to the case for investment in supported SMPs for long-term pain, and for referral by clinicians such as GPs, musculo-skeletal and chronic pain management services.

Conflict of interest
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