Improving the self-management of chronic pain: COping with persistent Pain, Effectiveness Research in Self-management (COPERS)

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Scientific summary

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Introduction

Chronic pain (pain persisting beyond 3 months) is a common and increasing problem – one estimate suggests that 7.8 million people in the UK suffer moderate to severe pain lasting for > 6 months. Musculoskeletal disorders are costly to the UK, accounting for around 10% of the secondary health-care budget (around £5.16B in 2011) and resulting in around 21 million primary care consultations per year. In common with other health services worldwide, attempts to optimise patients' own management of their condition (so called 'self-management') have been one of the UK Department of Health's key responses to the increasing burden of long-term conditions among the population. However, despite better understanding of the causes of chronic musculoskeletal pain, the best way to promote self-management among those with chronic musculoskeletal pain is unclear.

Original aims and objectives of the programme

Our overall aim was to develop a method to improve the quality of life and clinical and social outcomes, and reduce the health-care resource use of people living with chronic, non-malignant pain, specifically via a self-management programme derived from a modified, condition-specific version of the Expert Patients Programme. Following an extensive examination of the research evidence we departed from basing the programme on the Expert Patients Programme to develop what we hoped might be a more effective intervention.

The objectives were to develop a new self-management programme and evaluate its clinical effectiveness and cost-effectiveness.

The report is divided into two parts: the first part describes the development work and the feasibility testing of the new intervention; the second part describes a large randomised controlled trial (RCT) including a cost-effectiveness study.

Part I: development

Identifying effective components and characteristics of self-management programmes for chronic musculoskeletal pain and who is likely to respond such programmes

We conducted a systematic review of RCTs of self-management courses for chronic musculoskeletal pain to identify the most successful course content and the optimal delivery characteristics. We searched 10 databases for RCTs comparing self-management with usual care or a waiting list control for papers published between January 1994 and April 2009, including MEDLINE, EMBASE, PsycINFO and The Cochrane Library. Outcomes of interest included global health, pain intensity, functional capability, quality of life, self-efficacy, anxiety, depression and social function. Interventions were categorised according to the presence of psychological, mind–body therapy, physical, lifestyle and educational components; group or individual delivery; tutor; setting; and duration. Data were extracted and meta-analysed (random-effects models) as standardised mean differences (SMDs) when possible. We compared subgroups of studies with and without particular features to explore their potential influence.

We included 46 RCTs in the original review ($n = 8539$), covering a wide variety of chronic musculoskeletal conditions. In summary, the findings suggested that these interventions resulted in small beneficial effects across most outcomes in the short and medium term but that these positive effects were reduced in the longer term. Self-efficacy showed small improvements in the short, medium and longer term. There was most evidence to support group-delivered courses and health-care professional-delivered courses or mixed professional-/lay-delivered courses. Results were inconclusive for course setting and duration. Most interventions included a psychological component and there was little evidence in favour of those that did not. There appeared to be evidence in favour of interventions with a physical activity component, inconclusive positive evidence for educational and mind–body therapy components and no evidence that interventions that included a lifestyle component were superior to those that did not or that interventions with many different components were superior to those that had fewer components. These subgroup analyses involved multiple testing and so our findings should be viewed as exploratory and tentative. Using the same searches we reviewed the evidence for predictors, moderators and mediators of patient outcomes. We also conducted a meta-regression of the studies looking for evidence of moderators. We defined 'predictors' of treatment outcome as baseline variables that affect outcome but do not interact with treatment. 'Moderators' are variables measured at baseline that interact with treatment to change outcomes. 'Mediators' are variables measured during treatment that impact on outcome, with or without interaction with treatment. There was evidence that self-efficacy and depression at baseline predict outcome and evidence that pain catastrophising and physical activity can mediate outcome from self-management. There was no clear evidence on moderators.

Exploring experiences of self-management courses for chronic musculoskeletal pain

We conducted a qualitative study to understand how the different components and characteristics of self-management courses are perceived by people with chronic musculoskeletal pain, tutors and experts, with the aim of exploring the reasons why they might be associated with different outcomes and to inform the new intervention. We interviewed 16 previous self-management course participants, including four who had completed less than half a course, and conducted two focus groups, one with experts in self-management and the other with course tutors.

We observed differences between patients whose lives revolved around their pain and patients who had managed to achieve and sustain positive change in their lives. When asked what would be an important outcome from a self-management course, although patients always mentioned a reduction in their pain, other important outcomes related to personal confidence in their ability around functional, emotional and social activities. Barriers to course uptake were explored. Good facilitation and the social aspects of group courses appeared to be important for successful course delivery.

Selecting outcome measures for evaluating self-management programmes for patients with painful musculoskeletal conditions

We reviewed relevant consensus statements and the literature to develop a preferred list of patient-centred outcome measures for evaluating self-management programmes for patients with chronic painful musculoskeletal conditions. Outcome domains were informed by the findings of the first two projects (the systematic review and the qualitative project). We reviewed papers published between 2004 (i.e. subsequent to the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials consensus statement) and 2009 (when we conducted the work) that had reported or reviewed clinimetric data on outcome measures in three domains: pain and disability, depression and fear avoidance. For our two other domains of interest, self-efficacy and social support, we carried out a systematic literature search and reviewed the clinimetrics of the measures. The most validated and reliable measures were presented to a panel of eight people and consensus was sought on the most appropriate instruments. Data from our pilot study also informed our final choice of outcome measures for the main trial.

Development and feasibility testing of the new intervention

Based on evidence from our previous work we designed and manualised a psychologically orientated group course based on principles of cognitive–behavioural therapy with elements covering acceptance, education about chronic pain, distraction, relaxation, visualisation, posture, social time, encouragement to buddy up and an introduction to new hobbies and activities. We called the new course COPERS (Coping with persistent Pain, Effectiveness Research into Self-management) after our study. The COPERS course was underpinned by social learning theory and the theory of planned behaviour/reasoned action. Twenty-four individual course components (sessions) were delivered over 3 days with a single 2-hour follow-up session 2 weeks later. Teaching and learning modalities were varied and included a digital versatile disk featuring a medical expert addressing frequently asked questions, group discussion, role play and exercises. The course, for groups of up to 14 participants, was designed to be highly interactive and included experiential learning. Courses were facilitated by two trained facilitators – a lay individual with previous experience of facilitation of chronic pain and a health professional with experience of treating chronic pain (general practitioner, psychologist, physiotherapist, chiropractor or osteopath). We designed a 2-day training programme for potential facilitators.

To test the feasibility of the intervention and inform a future definitive trial we planned a pilot RCT of 100 participants randomised to the COPERS intervention or usual general practice care plus a patient advice leaflet on a 3 : 1 basis, favouring the active intervention. In addition, we planned a non-randomised arm in which we delivered a version of the course translated into Sylheti to a cohort of Bangladeshi patients not fluent in English. We used a mixed-methods approach with qualitative feedback from course participants, facilitators and observers, and quantitative information obtained from self-report questionnaires and activity data.

Systematically identifying eligible participants from general practice medical records proved difficult and spurred us to develop better search strategies for the main trial. Very uneven initial randomisation allocation led us to abandon the randomised design and offer everyone the intervention. A total of 167 (32%) of 526 potential participants expressed an interest in participating, 70 (42%) of whom were recruited to the English-speaking courses and 40 (24%) of whom were recruited to the Sylheti-speaking course. We ran nine COPERS courses, six in English and three in Sylheti. Forty-two people attended an English-speaking course and 26 attended a Sylheti-speaking course. Nine facilitators were trained and seven facilitated a course. A facilitator focus group was convened and 13 interviews were conducted with participants, which indicated that the COPERS course was regarded as beneficial by most participants. The influence of the group experience was important. Key recommended changes included:

- better facilitator training
- audio recording of each course to check quality and ‘treatment drift’
- shortening the outcome questionnaire
- adopting the pain-related disability subscale of the Chronic Pain Grade (CPG) as the primary outcome
- providing a more credible control
- conducting the trial in English only.

Part II: the main trial

Trial aims

To establish the clinical effectiveness and cost-effectiveness (expressed as the cost–utility) of the COPERS self-management intervention for patients with chronic musculoskeletal pain added to usual care plus a relaxation CD.

Methods

We conducted a pragmatic, multicentre, individual patient RCT. Participants aged > 18 years with at least a 3-month history of musculoskeletal pain were recruited from primary care or physiotherapy services in east London and the Midlands. Patients were randomised to the intervention or the control (allocation ratio 1.33 : 1) using varied permuted blocks and strict allocation concealment.

We collected follow-up data at 12 weeks (self-efficacy only) and 6 and 12 months. Our primary outcome was pain-related disability (CPG subscale) at 12 months. We also measured NHS resource use and costs (Secondary Uses Service data and general practice records), health utility [European Quality of Life-5 Dimensions (EQ-5D)], anxiety and depression [Hospital Anxiety and Depression Scale (HADS)], pain acceptance (Chronic Pain Acceptance Questionnaire), social engagement and integration in populations exposed to self-management interventions (Health Education Impact Questionnaire social integration subscale), self-efficacy (Pain Self-Efficacy Questionnaire) and pain intensity (CPG subscale) and calculated defined daily doses (DDDs) of prescribed analgesics and weak and strong opioids.

To determine the fidelity with which the intervention was delivered we audio-recorded each COPERS course and two researchers systematically assessed facilitator adherence to the course content and competence in delivering the course material.

We sought to randomise 685 participants (391 intervention participants and 294 control participants) to detect a SMD of 0.3 in CPG disability between the intervention group and the control group, with 80% power at the 5% significance level. All main analyses followed intention-to-treat principles and accounted for clustering by course in the intervention arm. We used multiple imputation for missing, or incomplete, primary outcome data.

The EQ-5D scores were used to estimate the total quality-adjusted life-years (QALYs) for each participant over the 12 months of follow-up. Missing data for costs and QALYs were imputed. We calculated the incremental cost-effectiveness ratio (ICER) and examined the probability of the intervention being cost-effective.

Results

We identified 5878 potentially eligible primary care patients in our electronic searches. These patients were invited by post to participate and 531 (9%) joined the study. Including patients from secondary care we recruited 703 participants in total, with a mean age of 60 years. In total, 81% were white, 67% were female, 23% were in employment, 85% had pain for at least 3 years and 23% were on strong opioids. Symptoms of depression and anxiety were common, with baseline mean HADS scores of 7.4 [standard deviation (SD) 4.1] and 9.2 (SD 4.6), respectively.

We delivered 31 COPERS courses, 14 in London and 17 in the Midlands. Intervention integrity was assessed as high, particularly for adherence. Overall, 282 (70%) intervention participants achieved our predefined adherence criterion (≥ 17 sessions attended) and we considered 95 (24%) to be non-adherent (attending ≤ 8 sessions), including 67 (17%) who did not attend any sessions.

At 12 months there was no significant difference between treatment groups in CPG disability [difference –1.0 intervention vs. control, 95% confidence interval (CI) –4.9 to 3.0]. However, self-efficacy, anxiety, depression, pain acceptance and social integration were significantly better in the intervention group at 6 months. At 12 months' follow-up the differences favouring the intervention were sustained for depression (–0.7, 95% CI –1.2 to –0.2) and social integration (0.8, 95% CI 0.4 to 1.2), with the results for self-efficacy (1.4, 95% CI –0.2 to 3.1) and anxiety (–0.4, 95% CI –0.9 to 0.1) tending to favour the intervention.

Intervention patients received considerably more analgesics than control patients in the 12 months after randomisation (mean difference in DDD 98, 95% CI 17 to 178). There was no evidence of any difference in the prescription of strong opioids between study arms (mean difference in DDD –1, 95% CI –12 to 11) nor in the proportions of those receiving strong opioids at 12 months.

Post hoc moderator analysis showed that the improvement in depressive symptoms seen in the intervention arm at 12 months was concentrated in those who were depressed at baseline (SMD –0.50, 95% CI –0.74 to –0.25), with those who were not depressed at baseline experiencing no overall change in depression (*p*-value for interaction = 0.004).

The total cost of the course per participant across the two centres was £145.24, including the cost of facilitator training. Total costs were higher in the intervention group than in the control group (£2955 vs. £2767). The difference in mean costs was £188 (95% CI –£125 to £501). Total QALYs were higher in the intervention group (0.4475) than in the control group (0.4150). The difference in mean QALYs was 0.0325, which is equivalent to approximately 12 quality-adjusted days (95% CI –0.0074 to 0.0724). The ICER point estimate was £5786 per QALY. The COPERS intervention had a high probability (87%) of being cost-effective compared with usual care at the National Institute for Health and Care Excellence threshold of £30,000 per QALY.

All reported results proved robust in extensive sensitivity analyses and with different analytical approaches.

Conclusions

The COPERS intervention had marked psychological effects that were concentrated in those who were depressed at baseline, but did not appear to affect health-care resource use or disability. We are not in a position to say with certainty what the active elements of the intervention were but it seems likely that these were the psychologically orientated components and the effect of being in a group of peers. In the absence of more effective group self-management interventions, the COPERS intervention could be used as a substitute for less well-evidenced (and more expensive) pain self-management programmes. However, effective interventions to improve harder outcomes in chronic pain patients, such as disability, are still required.

Trial registration

This trial is registered as ISRCTN22714229.

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