



**Effectiveness and cost effectiveness of a novel, group self-management course for adults with chronic musculoskeletal pain: study protocol for a multi-centre, randomised controlled trial (COPERS)**

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**Title**

**Effectiveness and cost effectiveness of a novel, group self-management course for adults with chronic musculoskeletal pain: study protocol for a multi-centre, randomised controlled trial (COPERS)**

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**Key words: RCT, self-management, chronic pain, protocol**

Word count: 4693

## **Abstract**

**Introduction:** Chronic musculoskeletal pain is a common condition that often responds poorly to treatment. Self-management courses have been advocated as a non-drug pain management technique although evidence for their effectiveness is equivocal. We designed and piloted a self-management course based on evidence for effectiveness for specific course components and characteristics.

**Methods/Analysis:** COPERS is a pragmatic randomised controlled trial testing the effectiveness and cost-effectiveness of an intensive, group, cognitive behavioural-based, theoretically informed, manualised self-management course for chronic pain patients against a control of best usual care: a pain education booklet and a relaxation CD. The course lasts 15 hours spread over three days with a two hour follow-up session two weeks later. We aim to recruit 685 participants with chronic musculoskeletal pain from primary, intermediate and secondary care services in two UK regions. The study is powered to show a standardised mean difference of 0.3 in the primary outcome; pain related disability. Secondary outcomes include generic health related quality of life, healthcare utilisation, pain self-efficacy, coping, depression, anxiety and social engagement. Outcomes are measured at six and 12 months post randomisation. Pain self-efficacy is measured at three months to assess whether change mediates clinical effect.

**Ethics/Dissemination:** Ethics approval was given by Cambridgeshire Ethics 11/EE/046. This trial will provide robust data on the effectiveness and cost-effectiveness of an evidence-based, group self-management programme for chronic musculoskeletal pain. The published outcomes will help to inform future policy and practice around such self-management courses, both nationally and internationally. Trial registration: ISRCTN24426731.

### **Key Messages**

- 1) Complex interventions need to be based on evidence and have good theoretical underpinning
- 2) The value of pilot studies cannot be underestimated
- 3) Identifying patients with non-electronically indexed conditions is difficult

## BACKGROUND

Chronic conditions, especially musculoskeletal conditions, impose an increasing burden on health care systems and society[1]. Point estimates of the prevalence of chronic musculoskeletal pain (pain lasting for longer than the normal soft tissue healing time of around 12 weeks[2]) range from 46% to 76%[3]. In 2008 the annual report on public health of the UK Chief Medical Officer identified chronic pain as a major issue which needed addressing[4]. Despite increased understanding of the factors contributing to the development of chronic pain[5], there has been little improvement in how successfully it is treated and managed[6]. Current treatment tends to centre on drug regimens for pain control and depression, physiotherapy and pain management programmes. However, many patients will experience complex care pathways involving multiple referrals to secondary care and often unnecessary and repeated diagnostic tests[7].

Several UK Department of Health reports have recommended self-care for chronic disease as a strategy for improving the long term future of health in the UK[8-10]. Since 2000 the UK has invested in the implementation of lay led (i.e. peer led) self-management training courses; the Expert Patients Programme (EPP) [10]. The available evidence, however, suggests that these courses may not reduce healthcare resource use as expected [11-13] and that there are only modest short term beneficial effects on other outcomes. Very few studies have examined long-term clinical effects [13-15].

In response to the anomaly between continued UK government support of self-management programmes and equivocal evidence of their effectiveness, the COPERS (Coping with persistent Pain, Effectiveness Research into Self-management) study (<http://blizard.qmul.ac.uk/research-generation/329-copers.html>) was commissioned by the National Institute of Health Research (NIHR), as a five year programme grant to identify which components and characteristics of self-management and pain management programmes are most effective and evaluate these components in a trial, in order to inform both the development of a new pain self-management course and the next generation of self-management courses in general. We completed two systematic reviews and a qualitative study that informed the development of the COPERS intervention. One review collated the evidence base

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3 for components and characteristics of pain and self-management courses and the other collated the  
4 evidence for predictors, mediators and moderators of outcomes in these programmes[16, 17]. In a  
5 qualitative study we explored the views and experiences of participants and tutors from self-  
6 management courses about expectations, course content, recruitment, tutoring and attendance[18].  
7  
8 The findings from this work suggested that group delivered courses led by health care professionals  
9 and/or lay people were most likely to be effective. We also found that courses lasting for a shorter  
10 time appeared to be as effective as longer courses and that the setting in which courses were delivered  
11 (i.e. in health care settings or the community) appeared to make little difference to any beneficial  
12 effects. Evidence also suggested participants particularly enjoyed the relaxation elements of courses  
13 but were averse to exercise being included.  
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17 Our systematic reviews found evidence to support psychological approaches; therefore we based our  
18 course around concepts from cognitive behavioural therapy and acceptance and commitment therapy  
19 [19, 20]. Some elements of the COPERS intervention are similar to the EPP, such as the inclusion of  
20 relaxation, goal setting and action planning, and improving consultations with health care  
21 professionals. We also included sessions related to improving posture and social activities, for  
22 example art and massage. Self-efficacy has been reported as an important mediator for success in  
23 these types of ‘treatment’ approaches[21]. Since healthcare professionals and lay tutors have both  
24 been reported as effective facilitators for self-management programmes we used both[22, 23]. There  
25 is mixed evidence for the optimal duration of self-management courses and ‘dose’ per week. Short  
26 weekly sessions over six weeks or more are the usual model, but attendance can be poor[14].  
27  
28 However, evidence from mental health research shows that brief/intensive interventions can be  
29 effective and are often preferred[24, 25]. The COPERS course is delivered as a three-day intensive  
30 course on consecutive days, the rationale being to address the high attrition often reported anecdotally  
31 in other programmes[14].  
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35 The protocol has been designed as a result of a feasibility study which enabled us to modify our  
36 approach to recruitment, the intervention and to test a variety of outcome measures. Recruitment was  
37 problematic in the feasibility study as there is no specific electronic diagnostic code for chronic pain.  
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3 We have since piloted a search strategy based on repeat prescriptions, 'Read' codes and frequency of  
4 visits, which identifies many of our target population. To optimise recruitment, we decided to also use  
5 face to face consultations and self-referral via adverts in surgeries and clinics. We found that filling  
6 courses within a set time period was difficult especially when, by chance, the majority of participants  
7 were randomised to the control. We have accommodated this by using randomly varied permuted  
8 block randomisation and phasing the recruitment of patients to specific time periods between school  
9 holidays.  
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18 We convened a focus group consisting of two experts in outcome measures, two general practitioners  
19 (GPs), two psychologists and two patients with chronic pain. This focus group selected the most  
20 appropriate measures to test in the pilot trial. In addition to piloting quantitative data collection, we  
21 evaluated the intervention thoroughly during the pilot using feedback from observers, participants and  
22 facilitators. The pilot study indicated that the COPERS self-management course was viable and well  
23 received by participants, with good attendance (85% full attendance). We found the quality of  
24 facilitation was a key determinant for the success of a course, and invested more time and resources  
25 into facilitator training and recruitment for the main trial. Additionally we found that the group nature  
26 of the course was valued highly by participants, therefore we allowed for more socialising during the  
27 intervention.  
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### 39 **Aims of the study**

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42 The aim of this study is to establish the effectiveness and cost-effectiveness of the new self-  
43 management (COPERS) course for those with chronic musculoskeletal pain, when compared with  
44 usual care plus a CD recording of simple relaxation exercises (also received by the intervention arm  
45 via the self-management course).  
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### 52 **Trial Purpose**

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55 This trial will provide the data needed by NHS purchasers to decide whether or not to fund  
56 programmes of this nature.  
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## METHODS/DESIGN

### Trial design

A multi-centre pragmatic randomised controlled trial (RCT) conducted in the UK with unbalanced randomisation (1.33: 1) (intervention:control) to accommodate for the effects of clustering. The unbalanced randomisation may also improve recruitment; if participants are told that they are more likely to receive the active treatment then they may be more likely to join the study.

### Trial setting

The trial is based in north east London, and in the Coventry and Warwickshire region. Participants are recruited from primary and secondary care settings, such as general practices, musculoskeletal physiotherapy units and pain clinics. The population of these two localities, taken together, is broadly representative of the UK as a whole.

### Target population:

#### *Inclusion criteria:*

- people aged 18 or over with chronic musculoskeletal pain of more than three months[2]. This includes pain from osteoarthritis and fibromyalgia or chronic widespread pain.

#### *Exclusion criteria:*

- inability to give informed consent,
- not fluent in English,
- chronic pain arising from active malignant disease,
- pain from inflammatory arthritis, such as rheumatoid arthritis, ,
- serious active co-morbidity or terminal illness,
- serious mental health or substance abuse issues which render the individual unable to attend the course.

### Participant recruitment

Participants are recruited from primary and secondary care using three methods.

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3 Our main method of recruitment will be bulk mail outs from targeted searches of secondary care  
4 clinic and general practice electronic records. Electronic records are searched by identified key liaison  
5 staff in the practices and clinics. These personnel use a generic search strategy developed and tested  
6 by the study team. The search strategy has a tiered approach focussing on demographic data (patient  
7 registered at the practice, alive and >18 years old), repeat prescriptions for analgesics, tricyclic  
8 antidepressants and anxiolytics, followed by clinical symptoms (e.g. low back pain, back pain,  
9 osteoarthritis, fibromyalgia) and attendance in the previous three month period. During pilot testing  
10 these searches identified 5-7% of general practitioners as possibly eligible and roughly identified our  
11 target population in general practices.

12  
13 The list of potential participants identified via the electronic search is screened by clinicians at the  
14 practice or clinic to check suitability based on the eligibility criteria. Eligible patients are invited to  
15 join the study by letter from their GP or secondary care clinic. They are asked to complete an  
16 expression of interest form to send to the study team or to contact the study team directly. Clinicians  
17 working in participating practices are also able to invite patients consulting with chronic pain to  
18 participate by handing them an information pack. Lastly, advertisements and invitation packs will be  
19 placed in general practice and clinic waiting rooms to attract interested patients, who can contact the  
20 study team directly for further information.

### 21 **Recruitment and informed consent**

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23 People expressing an interest in the study, who are eligible and available to participate, are sent a  
24 baseline questionnaire, a trial consent form to complete and a freepost envelope to return the  
25 questionnaire and trial consent form to the study team. All participants are telephoned and asked  
26 whether they need more information, and the consent form is discussed before a member of the study  
27 team counter signs the consent form indicating informed consent. A summary of participant flow  
28 through the study is shown in Figure 1.

### 29 **Intervention group**

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31 The intervention is a group based, facilitated learning course supporting patients to manage their  
32 chronic pain better. It is a complex intervention using psychological approaches which have been  
33 shown to promote behaviour change of proven benefit in low back pain [26-28]. The course also  
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3 includes pain education, attention control, relaxation and visualisation techniques, social interaction  
4 and the opportunity to try a new activity unrelated to pain (Table 1). Teaching and learning methods  
5 include facilitated learning through group discussion, sharing narratives and experiences to foster  
6 social interaction, problem solving, an educational DVD, role play, practising attention and distraction  
7 techniques and ‘good’ posture. We hypothesise that these group delivered courses with plenty of  
8 breaks for social interaction will build confidence to manage chronic pain better i.e. improve self-  
9 efficacy, improve social integration and, where necessary, help re-activate participants to re-engage  
10 into social activities [29, 30]. The intervention consists of a short course run in one week over 3 days  
11 (typically Monday Wednesday and Friday) during school hours (10.00am – 2.45pm), with a two hour  
12 follow-up session two weeks later. The total course comprises 24 individual ‘components’ spread  
13 over 15-16 hours. A detailed training manual for facilitators was developed, tested and refined in the  
14 pilot study. The manual provides the aims and theoretical basis for each component.

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27 In the absence of any evidence favouring a particular setting for such group self-management courses,  
28 courses are held in local medical or community venues that are accessible to participants (e.g. with  
29 disabled parking and near to public transport).

### 30 31 32 33 34 **Recruitment of facilitators for the intervention**

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36 Each course is led by two facilitators, a healthcare professional (a professionally registered  
37 physiotherapist, osteopath, chiropractor, occupational health practitioner or psychologist) and a lay  
38 person with experience of both living with chronic pain and of tutoring or facilitating small groups.  
39 Health care professional facilitators are recruited via press releases about the study in professional  
40 magazines. Lay facilitators are recruited via local contacts with community interest companies  
41 delivering self-management type programmes (typically the Expert Patient Programme,  
42 <http://www.expertpatients.co.uk>).

### 43 44 45 46 47 48 49 **Training facilitators**

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52 Facilitators attend a two-day training course that covers the course content, how to facilitate, dealing  
53 with difficult situations and what to do if an adverse event occurs. During the courses the trainee  
54 facilitators are required to demonstrate actively that they are: good listeners, empathic, flexible, able  
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3 to encourage equal participation and laughter, able to manage difficult people, and able to introduce,  
4 lead and summarise sessions whilst putting the course content into a chronic pain context. We also  
5 assess their understanding of the course via a written assessment at the end of the training.  
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9 Only facilitators who are assessed as competent (i.e. demonstrate the skills required during role plays  
10 and provide written answers that illustrate an understanding of the key concepts) will deliver the  
11 intervention. They are to be paired with trained and experienced facilitators from the pilot study for  
12 their first course to ensure consistency of delivery and promote confidence in the newly trained  
13 facilitators.  
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### 20 21 **Control Group**

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23 In our pilot study we found that a usual care control arm was insufficient to encourage participation in  
24 the trial. Our interviews and pilot studies suggested that participants particularly enjoyed the  
25 relaxation part of the courses, whilst our systematic review found little evidence that the relaxation  
26 component of pain management courses had much observable beneficial effect. In this trial we  
27 include a 'relaxation pack' as the control intervention to make participation more appealing. This  
28 includes a simple audio CD of three breathing and relaxation sequences, instructions and the rationale  
29 behind them. The CD is also used and distributed on the COPERS course. After randomisation,  
30 participants in the control group receive the relaxation pack and are asked to practise relaxation at  
31 least once a day every day for three weeks (the same duration as the intervention) and as often as they  
32 like thereafter.  
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43 In an attempt to ensure that all study participants receive best usual care, all participants are also all  
44 given a copy of a booklet called the 'The Pain Toolkit'[31] which is published by the UK Department  
45 of Health and freely distributed to UK GPs to give to any patient with chronic pain.  
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### 50 51 **Hypothesis**

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53 We hypothesised that the benefits of the intervention will be: improved function, greater self-  
54 confidence, better coping skills, increased social engagement and more appropriate health care  
55 resource use (Table 2). Our outcome measures reflect these domains.  
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## Outcomes

For the main trial we selected a group of measures based on both the published literature regarding their validity and reliability and the extent of their use in other studies, and on the focus group and pilot study.

## Primary Outcome

Our primary outcome is pain related disability (we are not aiming to change pain severity in the short term as current understanding of the mechanism of chronic pain suggests it is unlikely to improve rapidly)[32]. To measure function we chose a well validated tool, the Chronic Pain Grade (CPG)[33]. The CPG is made up of two constructs - pain intensity and pain related disability. Each construct has been validated separately, they are scored independently and can be combined to produce the Chronic Pain Grade [34]. Our primary outcome is pain related disability. This measure has three questions about pain related function, and the responder rates their circumstance on a scale from 0 to 10. The pain related disability score is the mean of the three questions.

Since there is a paucity of evidence on the long-term effectiveness of these types of interventions [14], we will measure outcomes by patient-completed postal questionnaire at baseline (before randomisation) and at six and 12 months after randomisation. There will be one postal reminder for each follow-up data collection point, after which non-responders will be contacted by phone to obtain the primary outcome and quality of life measures. To encourage completion and return of questionnaires we will send participants a £5 'high street shop' voucher redeemable in multiple stores on a non-conditional basis along with their six month and 12 month questionnaires. This expression of appreciation has been shown to improve questionnaire return rates. A Cochrane review has found that 'the odds of response were more than doubled when a monetary incentive was used (odds ratio 2.02; 95% confidence interval 1.79 to 2.27) and almost doubled when incentives were not conditional on response (1.71; 1.29 to 2.26) [35].

## Secondary outcomes

Table 2 shows our secondary outcomes.

### Criteria for Withdrawal

All participants are free to withdraw from the study at any time without having to give any explanation.

### Sample size

The sample size calculation was based on detecting a standardised mean difference of 0.3 in pain related disability between intervention and control groups, with a power of 80% at the 5% significance level. This effect size is commensurate with the largest change seen in a recent systematic review of expert patient programmes[14], and also with the sort of change effected by interventions for other chronic pain syndromes, such as low back pain, on any continuous outcome measure[36]. A simple sample size calculation indicates that we would require data on 350 subjects. We inflated the sample size because of the possibility of a ‘clustering’ effect in the group intervention arm and chose the ratio between intervention and control participants to increase statistical efficiency [37]. Using an intra-cluster correlation coefficient (ICC) of 0.1, and assuming on average nine individuals providing data from each group results in 480 individuals needed with 275 in the intervention group and 205 in control the control group (1.33:1 intervention:control). Allowing, conservatively, for a 30% loss to follow-up (from an average of 13 individuals recruited per group) we sought to randomise 685 participants (391 intervention participants and 294 controls).

Previous research and electronic record searches from the pilot study indicated that around 5% of adults on GP registers consult with chronic musculoskeletal pain. Of these, based on our pilot study, we estimate that 10% may be interested in participating in the trial and around half of these will be recruited into the trial.

We estimated that around 80% of the population are adults over 18 years ([www.statistics.gov.uk](http://www.statistics.gov.uk) 2010). This means that to recruit our 685 participants we need a population base of around 342,000 (342,000 registered patients of whom approximately 80% are adults (274,000). Five percent of these may have chronic pain (13,700) and of these we estimate that around 10% may express interest in the

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3 study (1,370). Half of these may be recruited and enrolled (685). Using an average total GP list size of  
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5 7,000, this equates to around 49 practices. We estimate that we will recruit between 12 and 14 patients  
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7 per practice.

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10 This may be an overestimate of the number of practices needed as it does not account for participants  
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12 recruited from pain or musculoskeletal physiotherapy clinics or from face-to-face invitations and  
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14 advertisements within general practices. After signing up to the study, general practices are given a  
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16 choice of recruitment phases corresponding to blocks of pre-booked course dates. Recruitment will be  
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18 split roughly equally between each of our study sites.

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21 We are aiming to book participants onto courses within 12 weeks of randomisation. The minimum  
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23 course size is nine due to the cost implications of running more courses. If a course is undersubscribed  
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25 (< 9) at the outset, it is either cancelled and those registered offered alternative dates for other courses,  
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27 or those from other courses will be transferred onto the more imminent courses where possible.

### 30 31 **Randomisation**

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33 The randomisation plan was developed by the Pragmatic Clinical Trials Unit (PCTU) at Queen Mary,  
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35 University of London (<http://blizard.qmul.ac.uk/pragmatic-clinical-trials-unit.html>). Randomisation  
36  
37 was stratified by centre (the Midlands or London). To ensure that allocation provides sufficient  
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39 participants for each course, but cannot be predicted by researchers, we used randomly varied  
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41 permuted blocks of size seven and 14 with an allocation ratio of 1.33:1 (intervention: control). Those  
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43 returning completed questionnaires were telephoned by the study team. People who were able and  
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45 willing to participate and gave valid informed consent were randomised over the phone. During the  
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47 phone call researchers entered the participant's trial identification number and recruiting centre into a  
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49 central randomisation service, ensuring allocation concealment, and participants received immediate  
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51 notification of their allocation. Participants are then informed and either immediately booked on a  
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53 course or sent a relaxation pack.

### 54 55 56 57 **Blinding and protection from bias**

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3 All baseline data are collected by self-completed questionnaire prior to randomisation. After  
4 allocation, however, it is impossible to blind researchers and patients to allocation due to the nature of  
5 the intervention and the unequal randomisation. In compliance with our research ethics committee  
6 requirements, GPs are informed of their patient's enrolment into the trial, but not to their allocation.  
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8 Although participants are free to divulge this information to their primary care team, we feel this  
9 information in itself should have little impact on their care. Outcome data is by patient completed  
10 postal questionnaire. For non-responders, primary outcome data and the Euroqol instrument are  
11 collected over the phone by research personnel blind to treatment allocation who use a set script  
12 asking participants not to divulge their allocation prior to asking participants for their data.  
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### 23 **Data management**

24 All data are managed in line with PCTU standard operating procedures and subject to review by audit  
25 and the Data Monitoring and Ethics Committee (DMEC). All electronic participant data are stored in  
26 encrypted and/ or password protected files in a secure environment. A database has been designed to  
27 manage the data input to ensure consistency of practice and coding, with a built in audit trail enabling  
28 us to track all entries and changes. Regular audit and double-checking of all primary outcomes will be  
29 conducted to ensure accuracy of data input, and a further random 10% of all data entry will be double-  
30 checked.  
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### 40 **Adverse event reporting**

41 These are reported via the facilitators. Minor adverse incidents (e.g. a participant being tearful and  
42 distressed during a session) are logged and fed back to the study team by the end of the course.  
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44 Serious adverse events related to the study (e.g. extreme distress or expressing suicidal thoughts) are  
45 reported immediately to the study principal investigator in accordance with good clinical practice  
46 guidelines and, where necessary, reported to the Data Monitoring and Ethics Committee (DMEC) and  
47 the study sponsor.  
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### 55 **Statistical analysis**

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3 We will use Stata[37], R[38] and MLwiN[39] as appropriate to analyse the data. Descriptive statistics  
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5 will be used to summarise the characteristics of participants in each arm of the trial. Outcomes at  
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7 follow-up will be analysed as dependent variables in mixed effects regression models. The model will  
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9 include as covariates: baseline outcome measure, allocation (intervention or control), age, gender,  
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11 study centre (London or the Midlands) as fixed effects, and the intervention group as  
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13 a random effect. Where participants withdraw we will compare the characteristics of those  
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15 withdrawing against those who remain in the study.  
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20 Our primary analysis is an available case analysis following intention-to-treat principles  
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22 ([http://www.consort-statement.org/consort-statement/further-explanations/box6\\_intention-to-treat-](http://www.consort-statement.org/consort-statement/further-explanations/box6_intention-to-treat-analysis/)  
23  
24 [analysis/](http://www.consort-statement.org/consort-statement/further-explanations/box6_intention-to-treat-analysis/)). We will use mixed effects models appropriate for each outcome (linear, logistic, Poisson)  
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26 with intervention arm, age and gender and baseline level of outcome as fixed effects and group as a  
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28 random effect. The random effect will only be present in the intervention arm. We will examine  
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30 patterns of ‘missingness’ and conduct a secondary analysis using multiple imputation and assuming  
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32 variables are missing at random. We will also conduct a complier-average causal effect (CACE)  
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34 analysis to estimate the effect of the intervention on compliers[40]. We define ‘compliers’ as those  
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36 who attend more than half of the course (i.e. those present for at least 12 of the 24 course  
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38 components). We are also interested in the dose of the intervention participants receive, and define  
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40 ‘full’ exposure to the intervention as being present at 17 to 24 individual course sessions, moderate  
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42 exposure as being present at nine to 16 components, and non-exposure as being present at eight or  
43  
44 fewer components. We will report effect estimates with confidence intervals. For selected outcomes  
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46 we will estimate the proportions who improve over the threshold of 30% from baseline, a figure  
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48 commonly used in relation to back pain and from this we will estimate numbers needed to treat and  
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50 relative risks for improvement [36].  
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53 If the analysis shows an effect of the intervention on our primary outcome (pain related disability), we  
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55 will conduct an exploratory analysis to explore whether any of the following are moderators of the  
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57 effect: baseline duration of chronic pain, severity of pain related disability and pain self-efficacy. We  
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3 will also conduct a mediator analyses to determine whether the level of exposure to the intervention or  
4 a positive change in self-efficacy from baseline to 12 weeks post randomisation mediates the effects at  
5 six or 12 months.  
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### 9 10 **Health economic analysis**

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12 At 12 months post randomisation we will conduct a cost utility analysis using EQ-5D data to measure  
13 Quality Adjusted Life years (QALYs) from an NHS perspective. The costs will cover primary care  
14 services, prescribed medication, investigations, intermediate care referrals, and secondary care (using  
15 Secondary User Services (SUS) data). Primary care services include consultations with GPs and  
16 practice nurses both scheduled and unscheduled. Intermediate care referrals data will be collected on  
17 physiotherapy, mental health services (including Improved Access to Psychological Therapies (IAPT)  
18 referrals), podiatry, community nursing, community rehabilitation, and other unscheduled primary or  
19 community care (out-of-hours-services and walk-in-centres). Secondary user services (SUS) will  
20 include Accident and Emergency visits, outpatient appointments and inpatient episodes. The SUS data  
21 will have ICD 10 and OPCS codes which will provide information about disease and billing data.  
22 Information derived from the Office for National Statistics (ONS) death reports will be the filter for  
23 attrition by death, as the cause of death is included in this information. A secondary analysis will  
24 include broader societal costs such as the patients' out of pocket treatments for their pain such as  
25 complementary therapies, mobility devices, private investigations and private hospital admissions.  
26 The data will be collected from three main sources: primary care utilisation from GP electronic  
27 records at 12 months follow up, SUS data from the local strategic health bodies at 15 months (since  
28 there is a three month 'lag' in the availability of SUS data) and patient reported cost and utility data  
29 from the six and 12 month questionnaires. Data on the costs of training sessions will be collected from  
30 trial records. Primary and intermediate care unit costs will be derived from UK published sources[41].  
31 The unit costs for medications will be obtained from the Prescription Cost Analysis database for  
32 2010[42]. The unit costs for secondary care will be based on health resource groups[43].  
33 If appropriate we will use multiple imputation to guard against any bias that may result from missing  
34 EQ-5D or cost data. The imputation model will impute missing data based on age, gender, study  
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3 centre (London or the Midlands), EQ-5D and cost. The imputation model for the intervention arm will  
4  
5 also account for clustering by group in the intervention arm (by including the intervention group as a  
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7 random effect).

8  
9 Our primary economic analysis is a cost-utility analysis over 12 months, examining the cost per  
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11 QALY gained for all participants who were assessed for EQ-5D prior to randomisation and had SUS  
12  
13 data extracts. Descriptive statistics will be used to summarise the costs and QALYs.

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17 We will use a mixed effects regression model to adjust estimates for costs and QALYs for the  
18  
19 following covariates: baseline outcome measure, allocation (intervention or control), age, gender,  
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21 study centre (London or the Midlands) as fixed effects and the intervention group as a random effect.  
22  
23 The Incremental Cost Effectiveness Ratio (ICER) will be calculated using the QALYs for each patient  
24  
25 as a utility measurement along with the costs to the NHS incurred by each patient, where:

$$26 \text{ ICER} = \frac{27 \text{ (Cost of intervention - Cost of control)}}{28 \text{ (Utility of intervention - Utility of control)}} 29$$

30  
31 The spread of incremental cost-effectiveness ratio across the four quadrants of cost effectiveness will  
32  
33 be plotted and we will use bootstrapping to estimate the confidence intervals of our estimates. We  
34  
35 also plan to assess the cost-utility of the intervention using willingness to pay thresholds ranging  
36  
37 between £0 and £40,000[44] and to run two sensitivity analyses:

- 38 1. Excluding high cost individuals (top 5%).
- 39 2. Including costs from the societal perspective (out of pocket treatments for pain).

#### 40 41 42 **Quality control and fidelity of intervention delivery**

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44 The first day of each course is observed, and where we have first time facilitators, or facilitators who  
45  
46 lack confidence, these courses are observed in their entirety to check the fidelity of the intervention.

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48 In addition every course is audio recorded. A random selection of audio-taped sessions will be chosen  
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50 for evaluation of fidelity. The evaluators will use a checklist to record adherence to structure and  
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52 content and facilitator competence. Feedback to facilitators will be provided where necessary, so they  
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54 can modify and improve their performance.  
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## CONCLUSION

This definitive trial will provide robust data on the effectiveness and cost-effectiveness of an optimised package of care designed to improve self-management of chronic pain. This will help to serve to inform future policy and practice for running self-management courses both nationally and internationally.

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## Figure Legends

### Figure 1 Flow diagram of the study

**Table 1 Outline of course and theoretical models**

Day	Sessions	Module aims	Theory
1	1: Introduction 2: Pain education DVD 3: Acceptance: the uninvited guest	Understanding pain and acceptance	Acceptance and Commitment Therapy[19, 45]
	Lunch break		
	Taster activity (e.g. art)	Distract from pain perception with physical activity	Attention and distraction
	4: Pain, when is it bearable and when is it not?	Pain is not just physiological, it is a psychological, emotional and social phenomenon	Biopsychosocial model of medicine[46]
	5: The pain cycle	Recognising the pain cycle and signposting ways out	Fear avoidance and catastrophising[47]
	6: Movement and posture 7: Breathing and relaxation (CD track 1)	Reduce muscle tension to ease pain and become aware of physical weakness and strengthen areas	Physical therapy principles and Alexander technique, biofeedback
2	8: Reflections from day one	Improve social bonding, group cohesion and community social support	Social cognitive theory[30, 48], Social Learning Theory[29]
	9: Identifying problems, goal setting and action planning 10: Barriers to change - Unhelpful thinking	Recognising errors in thinking in order to promote a constructive/rational view of a situation	Cognitive therapy[20, 49], theories of reasoned action and planned behaviour [50-52], Rational emotive therapy[53]
	Lunch break		
	Taster activity (e.g., art)	Distract from pain perception with physical activity	Attention and distraction
	Session 11: Barriers to change - reframing negatives to positives	Recognising errors in thinking in order to promote a constructive/rational view of a situation	Cognitive therapy[20, 49] and theories of reasoned action and planned behaviour [50-52]
	12: Attention control and distraction	Distract from pain perception using visualisation	Attention control[54]
	13: Identifying things that make pain more manageable	Reminders to apply techniques as coping strategies	Embedding learning
	14: Movement and balance	Reduce muscle tension to ease pain, become aware of	Physical therapy principles and

	15: Breathing, relaxation and visualisation (CD track 2)	physical weakness and strengthen areas. Distraction from pain perception using visualisation	Attention management[54]
3	16: Reflections from day two	Improve social bonding, group cohesion and community social support	Social cognitive theory[30, 48]
	17: Communication with health professionals 18: Listening skills	Promote constructive healthcare consultations and effective communication	Theories of reasoned action and planned behaviour [50-52] and Social cognitive theory[30, 48]
	19: Anger, irritability and frustration	Recognising errors in thinking in order to promote a constructive/rational view of a situation	Cognitive therapy[20, 49], theories of reasoned action and planned behaviour [50-52]
	Lunch break		
	Taster activity (e.g. art)	Distract from pain perception with physical activity	Attention management
	20: Movement and stretch 21: Breathing, relaxation and mindfulness (CD track 3)	Reduce muscle tension to ease pain, become aware of physical weakness and strengthen areas. Distraction from pain perception using mindfulness	Physical therapy principles and Attention management[54]
	22: Summing up	Reminders to apply techniques as coping strategies	Embedding learning
Follow up	23: Reflections & narratives	Improve social bonding, group cohesion and community social support	Social cognitive theory[30, 48]
	24: Managing setbacks	Reminders to apply techniques as coping strategies	Embedding learning

**Table 2 Outcome measures and other data collection**

Domain	Measures	Follow up (months)*
Pain duration	Numerical scale	0
Pain intensity	Chronic Pain Grade (pain intensity subscale)[33]	0, 6, 12
Pain disability	Chronic Pain Grade (pain disability subscale)[33]	0, 6, 12
Quality of Life	EQ-5D (health utility)[55]	0, 6, 12

1	Self-efficacy	Pain Self-Efficacy Questionnaire[56]	0, 3, 6, 12
2	Mood	Hospital Anxiety and Depression Scale[57]	0, 6, 12
3	Coping	Chronic Pain Acceptance Questionnaire[58]	0, 6, 12
4	Social activity	HEIQ (Social integration subscale)[59]	0, 6, 12
5	General Health	Census global health question[60]	0, 6, 12
6	Demographics	Age, NHS Number, sex, ethnicity, educational background, employment status, language fluency, living arrangements (alone or with others)	0
7	Economic analysis	Healthcare resource use: primary care consultations, secondary care consultations, hospital admissions, surgeries, imaging, tests and prescriptions from general practice electronic records	0 to 12
8	Co-morbidities	From general practice electronic records according to the Cumulative Illness rating Scale[7]	12

\*post randomisation

### Trial Status

We anticipate our results will be complete and submitted for peer review publication in January 2014.

### Competing interests

No authors have any competing interests to declare

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### Ethical approval and trial registration

Cambridgeshire Ethics Committee provided favourable ethical review for this study Ref: 11/EE/046.

The ISCTRN is 24426731

### Contributorship

MU, DC and ST conceived the original idea for the study. ST, MU, DC, KH, TP and AR were integral to the design of the intervention and the trial and SE, SB, MU were specifically responsible for the statistical components of the trial and the statistical analysis protocol. DC wrote the first draft of the protocol. KH, ST, MU, KH, AR, TP and SE contributed to each successive draft of the manuscript and all authors approved the final version. MU and ST are joint PIs for the study, DC is

the trial manager and KH the senior researcher, SB and SE are the trial statisticians and AR and TP are on the trial management board and have provided substantial input into the intervention design.

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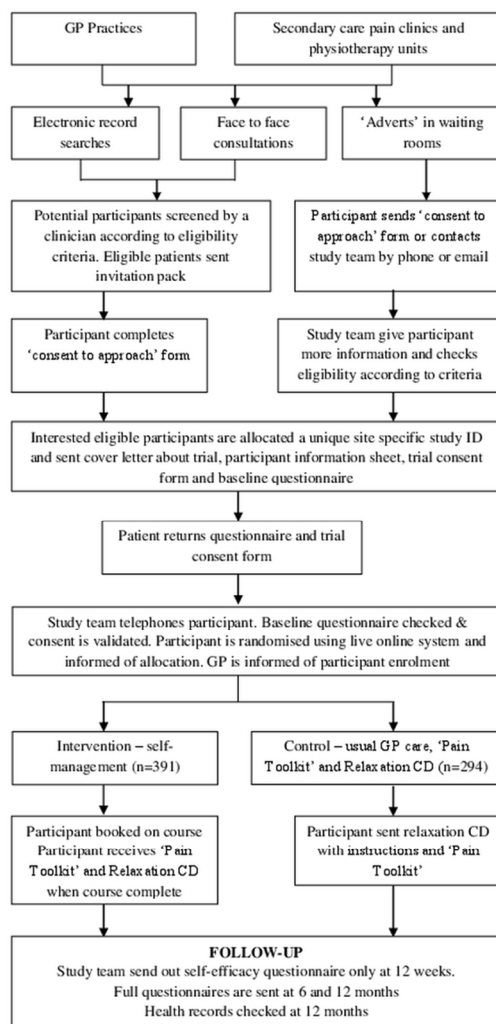
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Figure 1 Flow diagram of the study



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