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Short-term effect of a chronic pain self-management intervention delivered by an easily accessible primary healthcare service: a randomised controlled trial

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ABSTRACT

Objectives To investigate the effects on persons with chronic pain after 3 months of a group-based chronic pain self-management course compared with a drop-in, low-impact outdoor physical group activity on patient activation and a range of secondary outcomes.

Design An open, pragmatic, parallel group randomised controlled trial. Analyses were performed using a two-level linear mixed model.

Setting An easily accessible healthcare service provided by Norwegian public primary healthcare.

Participants A total of 121 participants with self-reported chronic pain for 3 months or more were randomised with 60 participants placed in the intervention group and 61 placed in the control group (mean age 53 years, 88% women, 63% pain for 10 years or more).

Interventions The intervention group was offered a group-based chronic pain self-management course with 2.5-hour weekly sessions for a period of 6 weeks. The sessions consisted of education, movement exercises and emphasised group discussions. The control group was offered a low-impact outdoor group physical activity in 1-hour weekly sessions that consisted of walking and simple strength exercises for a period of 6 weeks.

Main outcomes The primary outcome was patient activation assessed using the Patient Activation Measure. Secondary outcomes measured included assessments of pain, anxiety and depression, pain self-efficacy, sense of coherence, health-related quality of life, well-being and the 30 s chair to stand test.

Results There was no effect after 3 months of the group-based chronic pain self-management course compared with the control group for the primary outcome, patient activation (estimated mean difference: −0.5, 95% CI −4.8 to 3.7, p=0.802).

Conclusions There was no support for the self-management course having a better effect after 3 months than a low-impact outdoor physical activity offered the control group.

Trial registration number NCT02531282; Results.

Strengths and limitations of this study

► This is the first randomised controlled trial (RCT) to investigate the effect of self-management support interventions in a Healthy Life Centre (HLC) setting.
► The RCT had broad inclusion criteria to increase the external validity by allowing all persons with self-reported pain for 3 months or more to participate.
► Outcome measures were chosen among valid and reliable instruments recommended for chronic pain trials and used in trials of chronic pain self-management.
► The lack of blinding for the participants and the professionals delivering the intervention is a limitation, but the research assistant supervising the 30 s chair to stand test was blinded to allocation.
► The different lengths of intervention for the two trial arms is a limitation; however, they reflect the practices of the HLC.

healthcare utilisation, medication use and a reduced workforce.[1 2] Chronic pain also places a considerable burden on the affected individuals due to its impact on the social, psychological and physical aspects of their quality of life.[2 3] The individual burden is also evident in the descriptions of how pain affects daily activities, including the ability to sleep, exercise and perform household chores, and individuals describe being less able or no longer able to maintain relationships with family or friends or to attend social functions.[1 2] The intrusion of the condition into everyday life often requires adjustments to goals, plans and expectations.[4]

Despite the different treatment options offered, chronic pain is perceived as a condition that is not cured but more likely to persist when treatment stops,[5] indicating that in many cases, patients must self-manage pain on an everyday basis.[6] Self-management includes the actions that people take to recognise, treat, manage and engage in behaviours that affect their health.[7] Furthermore, self-management

BACKGROUND

Chronic pain, a long-term condition that affects a substantial portion of the population, presents a challenge for societies and healthcare systems in terms of increased

includes tasks related to the medical management of a condition and maintaining, changing and creating new meaningful behaviours as well as dealing with the emotional consequences of having a chronic condition.[8] Hence, to function effectively as a self-manager, one must have the necessary knowledge, skills and confidence to make favourable choices related to health and healthcare.[9] Required self-management skills are related to problem solving, decision making, resource utilisation, forming a patient–healthcare provider relationship and taking action.[10] Strengthening people's awareness of and capacity to use their own and available resources to self-manage is thus considered a central health service task.[6 7]

Several studies have investigated the effect of self-management support interventions that address chronic pain. Some systematic reviews that summarised chronic pain self-management interventions concluded they have no effect,[11 12] whereas one systematic review concluded there were minor effects, such as improvements in self-management skills, pain, symptoms and functioning.[13] Furthermore, physical activity and exercise have increasingly been promoted for chronic pain interventions due to their perceived benefits, including improved overall physical and mental health and improved physical functioning.[14] Both aerobic and anaerobic exercises as well as meditation and yoga have been found to have beneficial effects on chronic pain conditions.[15 16] Furthermore, walking has been suggested as an ideal form of activity for people with chronic musculoskeletal pain due to its ease of accessibility and relatively low impact.[17]

Self-management programmes are recommended to be community based so that a large number of people can access them.[10] Knowledge related to the effects of chronic pain self-management interventions is increasing; however, most studies that have examined their effects have typically addressed patients with specific diagnoses,[18 19] targeted specific age groups,[20] focused on lay-led interventions[21 22] or investigated interventions delivered by specialists and multidisciplinary healthcare services.[23] Hence, little knowledge exists regarding self-management support interventions that address chronic pain delivered via easily accessible healthcare services.

One such service has become a common feature in most Norwegian municipalities because they are encouraged to establish Healthy Life Centres (HLCs) as part of public primary care.[24] These centres focus on health promotion and support for the management of long-term conditions. The HLCs aim to be easily accessible by allowing self-referrals for their interventions, and in some HLCs, self-management initiatives have been added as a service. At present, no studies have evaluated self-management interventions delivered in this setting.

Objective
The aim of this study was to investigate the effects on persons with chronic pain after 3 months of a group-based chronic pain self-management course compared with a drop-in, low-impact outdoor physical activity delivered through an easily accessible healthcare service on the primary outcome, patient activation and secondary outcomes including assessments of pain, anxiety and depression, pain self-efficacy, sense of coherence, health-related quality of life, well-being and the 30s chair to stand test.

METHODS
An open, pragmatic, parallel group randomised controlled trial (RCT) was conducted from August 2015 to March 2017. The assessments at the 3-month follow-up are reported in this paper. The trial was designed to measure outcomes at 6 and 12 months as well.[25] The guidelines provided in the Consolidated Standards of Reporting Trials,[26] including its extensions for pragmatic trials[27] and non-pharmacological treatment interventions,[28] were used to guide the presentation of the results. The protocol for the trial has been published previously.[25] There were no changes to the methods after trial commencement.

Setting
The setting for the study was an HLC in a large city in Central Norway serving a population of approximately 190 000 inhabitants. The HLC's aim is to strengthen participants' capacity to use their own and available resources to make behavioural changes and to manage their health.[29] To achieve this, the HLCs offer non-pharmacological interventions with few barriers for attendance, meaning that people can access the service with or without a referral. The RCT took place at a HLC that provides several group-based activities and interventions (eg, indoor and outdoor physical activities, healthy diet courses and courses focusing on coping with depression or anhedonia). At the time of the RCT, the HLC had 5.5 positions occupied by multidisciplinary health professionals with a bachelor's or master's degree.

Patient and public involvement
To include the perspective of patients, representatives from patient organisations were included when planning the trial and were also available to the instructors during the delivery of the self-management course. The patient organisations representatives were consulted during the process of developing the research questions and choosing the outcome measures. The participants in the trial assessed the burden of the intervention when they met for follow-up assessments and were asked about their experiences during the intervention. The results of the study will be communicated to participants after publication.

Participants
Recruitment for the RCT began in September 2015 and ended in October 2016. Individuals who met the following inclusion criteria were admitted: adults of 18

years of age or older, self-reported pain for 3 months or more, able to take part in group discussions in Norwegian and a signed agreement to accept randomisation to one of the trial activities after a full explanation of the trial. The exclusion criteria were as follows: inability to participate in low-impact physical activity for at least 1 hour, pain arising from malignant diseases and inability to consent to study participation.

The opportunity for people with chronic pain to participate in the trial was communicated through posters and information leaflets distributed to general practitioners, physiotherapists, relevant departments at the hospital, Norwegian Labour and Welfare Administration offices and other relevant organisations in the municipality. To encourage self-referrals for the trial, advertisements were also placed in local newspapers, websites, social media and email invitations to patient organisations. Those interested in participating were encouraged to contact the first author by either phone or email.

Procedure
Participants received supplementary information about the trial (ie, that they would attend one of two activities delivered in groups during the day for a period of 6 weeks) in the informed consent form and orally in relation to the baseline assessment. Those who met all the inclusion criteria and none of the exclusion criteria were invited to participate in the trial.

Following an individual randomisation procedure from a computer-based internet trial service provided by a third party (Unit for Applied Clinical Research at the Norwegian University of Science and Technology, NTNU), participants were consecutively randomly allocated to one of two trial arms with a ratio of 1:1 after completing the baseline assessment. Because recruiting men for self-management interventions is a common challenge,[30] stratification for gender was applied to ensure an even balance of men. To do so, a block stratification was used, and those involved in the trial were blinded to the block size.

Immediately after randomisation, the first author informed the participants of their allocation by either phone or email. The participants were further informed that there was no possibility of changing their trial activity after allocation. The blinding of participants and instructors was not possible due to the nature of the interventions; however, the research assistant who supervised the physical ability test at the follow-up appointment was blinded to allocation. A new course began when approximately 10 participants were allocated to one of the trial arms or when the preset date for a course was reached.

All outcomes were measured at the baseline and at 3 months after completion of trial activity. At the baseline, the self-administered questionnaire was completed with the first author available for questions. For the follow-up appointment, the participants received the questionnaire by mail, and the result of the physical test as well as data related to healthcare utilisation and sociodemographic variables were registered during follow-up appointments. All data were collected in paper form, which were scanned and checked by the first author by comparing them with their corresponding data files.

Outcome measures
Self-reported sociodemographic variables, such as gender, age, marital status, education, work status, main reason for pain categorised according to the International Classification of Primary Care-2, use of pain medication and whether the individual suffered from more than two chronic conditions, were collected at the baseline assessment. At the follow-up appointment, any changes to these baseline assessments were registered, including changes for work status and medication use. Healthcare utilisation was registered at both the baseline assessment and the follow-up appointments according to the participants' self-reports of visits to general practitioners, physiotherapists, hospitals or rehabilitation centres during the previous 3 months.

Primary outcome measure
Patient activation is considered a key element in the management of one's health and healthcare,[9] it is emphasised in chronic illness models[31] and a typical aim of self-management interventions.[32] Hence, because the intervention was expected to strengthen the participants' engagement in and increase their knowledge of their own health resources, patient activation was perceived to be a suitable primary outcome. Patient activation was assessed using the Patient Activation Measure (PAM).[33] The PAM has been reported as useful for assessing patient engagement in the management of a chronic illness, including chronic pain, and it is sensitive to change across several groups and populations.[33]

The PAM-13 is a unidimensional, Guttman-like measure that contains 13 items representing statements to which the participants indicate their level of agreement on a four-point scale from 'strongly disagree' to 'strongly agree' with an additional 'not applicable' option.[9] The responses provide a raw score from 13 to 52 calibrated to a total score between 0 and 100 using the revised transformation table provided by Insignia Health.[34] A high score indicates that participants are more likely to adopt and to maintain healthy behaviours and self-management of their illness even under stress.[9] The PAM-13 is translated and validated for use in a Norwegian context.[35] Studies have shown that the Norwegian version of the measure is valid and reliable when tested for patient education interventions in a Norwegian hospital (Cronbach's alpha 0.91)[35] and in an RCT of a hospital's outpatient self-management education for patients with polyarthritis (Cronbach's alpha 0.80).[18] In the present study, the Cronbach's alpha at the baseline assessment was 0.75.

Secondary outcome measures
The secondary outcomes were chosen to cover the domains recommended for chronic pain interventions

by the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT),[36] [37] including pain, physical functioning, emotional functioning and coping.[37]

The short version of the Brief Pain Inventory (BPI) applying a 24 hours recall period was used to assess pain severity and pain interference. The instrument includes four questions related to severity and seven questions regarding interference, all items rated on 0–10 scales with 10 being pain as bad as one can imagine or pain that completely interferes with normal functions. The instrument has an additional item that asks about the percentage of pain relief by analgesics.[38] The instrument has been translated to Norwegian (Cronbach's alpha 0.87 for pain severity and 0.92 for the interference scale)[39] and has been used in Norwegian studies of a multidisciplinary pain management programme[40] and among patients with osteoarthritis (Cronbach's alpha >0.80).[41] In the present study, the Cronbach's alpha at the baseline assessment was 0.81 for pain severity and 0.86 for pain interference.

In addition, the participants reported experienced pain during the previous week using a one-item, 100 mm visual analogue scale (VAS).[42] The participants were asked to draw a vertical mark on the 100 mm line indicating their average pain during the previous week. The scale's anchoring points were no pain (0) and intolerable pain (100). The VAS scale has been found to be reliable for the assessment of chronic pain.[42]

The Hospital Anxiety and Depression Scale, with 14 items divided into subscales for depression and anxiety,[43] was applied to assess psychological distress. Each item is rated from 'not experiencing a symptom' (0) to 'experiencing a symptom nearly all the time' (3), yielding a total score from 0 to 21 for both subscales of seven items each. The instrument is widely used in studies on chronic pain and has shown good validity and reliability for patients with musculoskeletal pain (Cronbach's alpha for the anxiety subscale 0.83 and for the depression subscale 0.84)[44] as well as in a Norwegian large population study (The Nord-Trøndelag Health Study (HUNT) (Cronbach's alpha 0.80 for the anxiety subscale and 0.76 for the depression subscale).[45] It was also used for a study on a chronic pain multidisciplinary rehabilitation programme.[46] In the present study, the Cronbach's alpha at the baseline assessment was 0.73 for the depression subscale and 0.76 for the anxiety subscale.

Self-efficacy was measured using the Pain Self-Efficacy Questionnaire (PSEQ).[47] The PSEQ assesses participants' beliefs regarding their ability to accomplish various activities despite pain using 10 items, each asking responders to rate their agreement using a scale from 0 to 6 in terms of how confident they are that they can perform an activity at present despite the pain, where 6 equals completely confident.[47] The scale has shown strong psychometric qualities (Cronbach's alpha 0.92)[47] and was previously used in a Norwegian study.[48] In the present study, the Cronbach's alpha at the baseline assessment was 0.84.

The 13-item Norwegian version of the Sense Of Coherence (SOC) scale was used to assess the capacity to respond to stressful situations and remain healthy.[49] The SOC measures comprehensibility, manageability and meaningfulness through 13 items, each scored using a range from 1 to 7, yielding a total score of 13–91. A higher score indicates a stronger sense of coherence. The SOC scale has been found to be a reliable, valid and cross-culturally applicable instrument (Cronbach's alpha in 127 studies 0.70–0.92).[49] The Norwegian version of the SOC-13 has among others been used in a study that investigated life satisfaction for people with long-term musculoskeletal pain[50] and in a study on multidisciplinary rehabilitation for persons with chronic musculoskeletal pain (Cronbach's alpha 0.83).[51] In the present study, the Cronbach's alpha at the baseline assessment was 0.87.

The EuroQoL (EQ-5D-5L) was used to assess health-related quality of life.[52] The instrument has five levels to evaluate each of the following dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The levels are: 'no problems', 'slight problems', 'moderate problems', 'severe problems' and 'extreme problems'.[53] The descriptive score was converted to an index value for health status using the Danish value set, giving a range from 1 (perfect health) to 0 (death).[52] [53] The instrument has been validated in similar populations[54] and in a Norwegian context (Cronbach's alpha 0.69).[55] In the present study, the Cronbach's alpha at the baseline assessment was 0.55.

The Arizona Integrative Outcomes Scale (AIOS) was used to measure an overall experience of well-being using a one-item, 100 mm long visual analogue scale.[56] Participants were requested to: 'Reflect on your sense of well-being during the last month. Take into account your physical, mental, emotional, social and spiritual condition and mark the line for your summarised overall sense of well-being'. The scale's anchoring points were 'worst you have ever been' (0) and 'best you have ever been' (100).[56] AIOS has been found to be a valid measure of assessing well-being[56] and was previously used in a Norwegian study.[18]

To assess global self-rated health, participants were asked: 'By and large, would you say that your health is: poor, not so good, good, very good or excellent'? The question is similar to a question asked during a major population study in Norway.[57]

Because physical exercise has been found to have beneficial effects on chronic pain,[15] [16] the participants were asked: 'How often do you on average exercise? (by exercise, we mean going for walks, skiing, swimming and working out/sports): never, less than once a week, once a week, 2–3 times a week or nearly every day'. This question was used for a major population study in Norway.[57]

In addition, a measure of physical ability was included using the 30 s chair to stand test to measure lower body strength.[58] The test has been validated for a broader population.[59]

Delivery of trial activities

To evaluate the delivery of the trial activities, the instructors completed evaluation forms after each group session to report their own experiences with the delivery and group dynamics as well as whether there were any changes in relation to the guidelines and if any adverse events occurred. Attendance was recorded at each session for both trial activities.

Intervention and control group

Two different teams conducted the intervention and control group activities. The guidelines for carrying out the self-management course, ensuring all groups were offered the same content and material, are available in the published protocol.[25] The low-impact physical activity offered to the control group followed descriptions of a similar activity currently offered at the HLC. There was no user fee for participation, and financial compensation was not offered to the participants.

The self-management course

The HLC staff had considered persistent pain to be a common challenge among users and therefore decided to initiate a chronic pain self-management course. Thus, in cooperation with a representative from a patient organisation, the HLC staff developed an intervention based on the characteristics of self-management courses,[10] recommendations found in the literature on chronic pain self-management[60–64] and the guidelines for the HLC[24] in addition to drawing on their own experiences related to behavioural changes and self-management of chronic conditions. This resulted in a chronic pain self-management course that included education emphasising cognitive and behavioural strategies[60–62 64] and introduction of movement exercises.[65]

The course used elements from cognitive–behavioural therapy (CBT) by creating a focus on thoughts, emotions and actions related to pain. When discussing the participants' experiences with pain in everyday life, the instructors focused on activating events, beliefs or presumptions related to the events as well as consequences in terms of feelings, physical symptoms and behaviours. The course included topics such as pain theory, barriers in everyday life due to chronic pain, problem solving, goal setting and techniques to deal with fatigue, poor sleep, frustration and isolation. The course aimed to teach skills such as setting specific, functional and realistic goals, activity pacing and structured problem solving. The movement exercises based on psychomotor physiotherapy[63] concluding each session, aimed to improve balance, posture and breathing, providing the participants with techniques to increase body awareness and the ability to relax. In addition, the instructors facilitated group discussions and sharing of experiences among participants. Between each session, the participants were encouraged to work on projects, such as an action plan, and to practice the movement exercises. The content of the course is outlined in table 1.

Table 1 Outline of the self-management course

Session:	Main topics
1	What is pain? Understanding the difference between acute and chronic pain. Elements from CBT in relation to pain. My everyday life and the everyday circle. Movement exercises; focusing on the jaw.
2	My challenges. What stops me in achieving what I want? Focus on problem solving. The thoughts' influence on everyday life. Elements from CBT. Movement exercises; focusing on easing of tension.
3	How to cope better in everyday life? Acceptance, self-efficacy and sorting. Self-confidence, self-esteem and self-image. Movement exercises; focusing on easing of tension using stretch and release, or hold and release.
4	Goal setting. How to make an action plan. Set smart goals for yourself. Movement exercises; focusing on different techniques for stretch and release.
5	'I can- I have a choice!'. How to make good choices. How to manage pain more appropriate. Movement exercises.
6	The way ahead. Summarise the whole course. How will you use what you have learnt? Information on activities at the HLC and in the municipality.

The self-management course was delivered as 2.5-hour weekly group sessions during the day (12:30–15:00) for a period of 6 weeks and a total of 15 hours. The self-management course was facilitated by two HLC physiotherapists experienced in working with behaviour changes, coping and chronic pain. One of the physiotherapists was educated in psychomotor physiotherapy and had extensive experience from a multidisciplinary hospital pain clinic.

The control group activity

Offering an activity to all participants in the trial was recognised as ethical and a good clinical practice.[66] Because physical activity has been found to have beneficial effects on chronic pain conditions,[15–17] the control group was offered a group-based physical activity that was already available as an activity at the HLC. The low-impact physical activity was a weekly 1 hour drop-in session during the day (13:00–14:00) for a period of 6 weeks, which consisted of walking and simple strength exercises (eg, squats and push-ups against a tree or a bench). The activity was adjusted to the participants' physical abilities to make it both easily accessible and rewarding. The

groups met outdoors on a popular hiking trail. The activity provided an opportunity to meet others with similar health challenges. Participation was voluntary, which is in line with the drop-in policy for this type of activity at the HLC. Two dedicated instructors familiar with physical exercise led the activity. The instructors encouraged the exchange of information among the participants rather than answering questions and giving advice themselves. Hence, there was no education for the control group.

Sample size

The findings of an RCT that investigated the effect of an educational programme on patients with polyarthritis where the PAM was one of the secondary outcomes were used to calculate the sample size.[18] The aim was to identify clinically important differences between the intervention group and the control group with a significant difference defined as six points of difference for the primary outcome (PAM-13) between the baseline and the 12-month follow-up assessments. The sample size was calculated using a mixed linear model assuming a correlation within participants to be 0.5 with a SD of 13. The significance level was set to 5% and the power to 80%, generating a necessary number of 55 participants for each trial arm. Thus, the aim was to recruit 120 participants, allowing for five dropouts for each trial arm.

Statistics

Descriptive statistics were used to describe the characteristics of the participants at the baseline assessment. Distributions of all outcome measures were examined with graphical displays and descriptive statistics and found to be approximately normally distributed. Patterns of missing values were investigated and determined to be missing at random. The confidence level was set to 95%, and a p value of ≤0.05 a priori considered statistically significant. No interim analysis was performed.

The mean scores for all observed outcomes at the baseline and at the 3-month follow-up assessments were calculated independently. Changes in work status and pain medication (categorical data) were analysed using Pearson χ^2 test or Fisher's exact test. Frequency of healthcare utilisation at the follow-up was analysed with t-tests. The effect of the intervention was assessed using an intention-to-treat and per-protocol procedures. To take the intraclass correlation between measurements in the same subject into account, the analyses were performed using a two-level linear mixed model.[67] Mixed models allow for the use of all available data in the presence of dropouts, and thus there was no need for multiple imputations.[67] Hence, the analyses included all available data from all randomly assigned participants.

In the two-level linear mixed-effects model, outcome measures over time for the two trial arms were compared using participant identification (ID) specified as a random effect. The effect of intervention and time was specified as fixed with the following three values: (1) 'baseline', (2) 'control 3 months' and (3) 'intervention 3 months',

acknowledging that differences between groups at the baseline were due to chance. The random effect for participant ID aimed to allow participants to begin at different levels of the outcome in question. Regression assumptions were checked by running the command 'regcheck' in Stata,[68] resulting in satisfactory values for assumptions of homoscedasticity, normally distributed residuals and influential cases.

Per-protocol analyses included participants who had been present at a minimum of three out of six group sessions. The per-protocol analyses provided only minor changes in the estimates and did not change any conclusions about the interventions. They are thus not further reported.

The first author performed the analyses, which were overseen and discussed with the coauthors and a statistician. All analyses were performed using Stata V.14.

RESULTS

Of the 208 people who responded to the trial announcement, 87 declined to participate after receiving additional information or did not meet the inclusion criteria, leaving 121 participants suitable for inclusion. The number of eligible participants and their flow through the study is displayed in the flow chart in figure 1.

At the 3-month follow-up, 17 people did not respond. They were equally distributed for intervention and control, leaving 52 available cases for each trial arm. Of the remaining participants (n=104), seven participants did not attend the follow-up appointment but returned the questionnaire by mail, leading to missing data regarding changes in marital status, work status, use of pain medication, healthcare utilisation and the 30s chair to stand Test, as these categories comprised data collected during the follow-up appointment.

Participants

Most participants responded to advertisements in newspapers, social media or email invitations sent to relevant organisations (68.6%). Twenty-one participants (17.4%) responded after receiving information at a physiotherapist's office, and two participants (1.7%) received information at their general practitioners' offices. Another 14 (11.6 %) participants referred to the HLC by their general practitioners for other reasons were considered by the HLC staff to potentially benefit from participation in the trial and were thus referred to and included in the trial after meeting the inclusion criteria.

The participants' mean age was 53 years (SD 11.7, range 23–74 years) (table 2). There were more women (88%) than men in the sample, and the majority lived with someone (71%). Many of the participants had experienced pain for 10 years or more (63%), and more than half (63%) reported more than one chronic condition. Musculoskeletal diseases were the most commonly reported causes of chronic pain (77%). The baseline characteristics of the participants are shown in table 2.
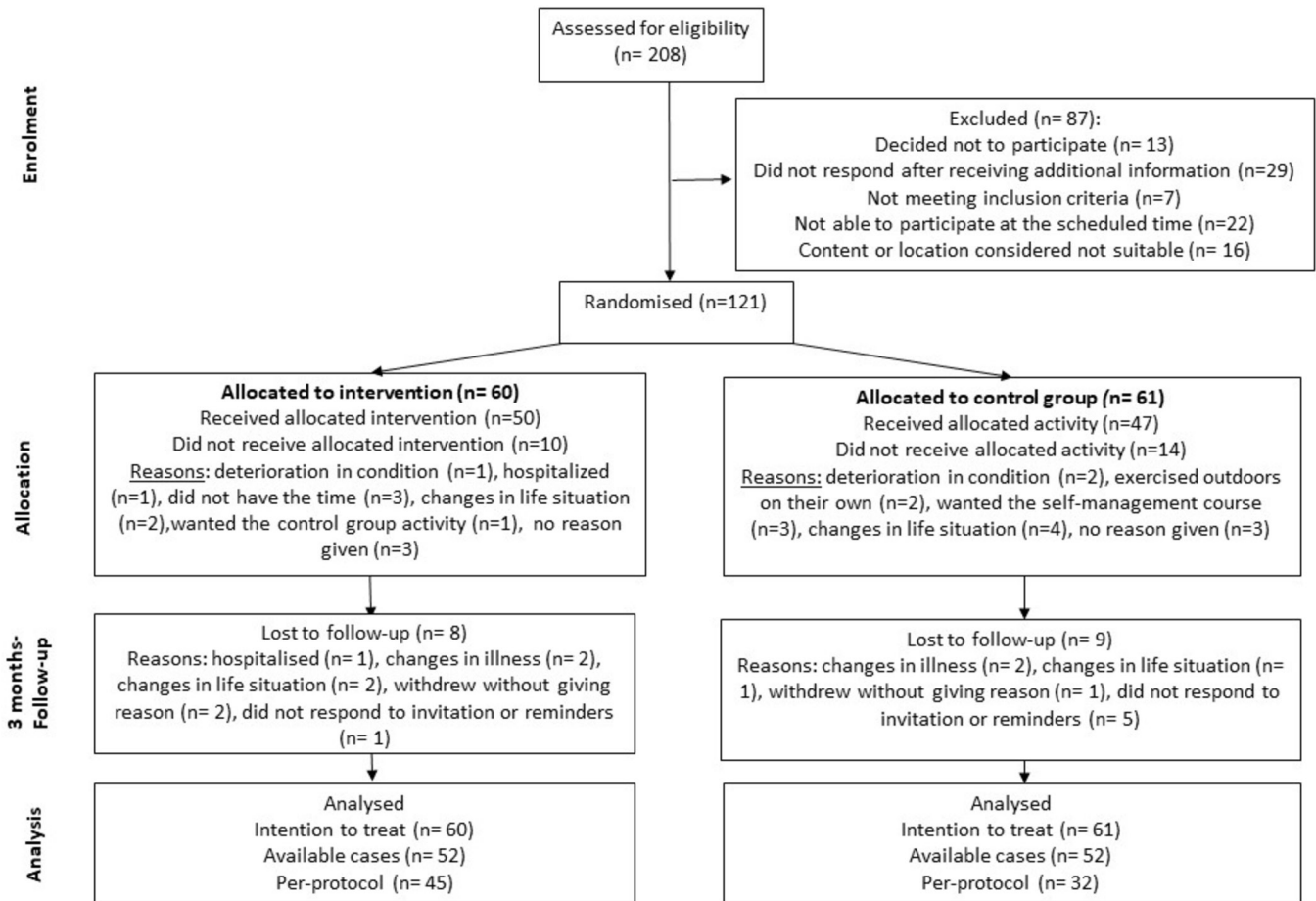
Figure 1 Participants flow through the study.

Delivery of trial activities

Overall, there were six self-management course groups and six physical activity groups. The number of participants allocated to each group varied between 7 and 13 (median 10). Ten participants did not attend the self-management course, and 14 participants chose not to participate in the control group activity. For the self-management course groups, the average overall attendance was 67.1% (range for the different groups: 50.0%–79.6%), and for the physical activity groups, the average overall attendance was 44.4% (range for the different groups: 21.2%–73.3%).

The instructors of the self-management course reported that the participants were engaged and active by taking part in discussions and sharing experiences. The instructors reported that in some sessions, they spent less time presenting slides because the participants preferred using more time to discuss and to reflect on the subjects. In some groups, there were participants who had difficulty practising some of the movement exercises. Two adverse events were reported during the self-management courses: one participant had an anxiety attack and one participant reported benign paroxysmal positional vertigo after performing a movement exercise. The symptoms were gone within a short time; however, the benign paroxysmal positional vertigo led to hospital admission.

The instructors for the low-impact outdoor physical activity described participants as interacting with each other and taking part in the suggested exercises. After three group sessions, the meeting place for the activity was changed because the participants preferred to end the activity near a café. Some participants found it difficult to participate during the winter due to slippery trails, and one adverse event during which a participant pulled a leg muscle was reported. A general practitioner was consulted, and the symptoms were gone within a few weeks.

Outcome measures

The observed and estimated scores for all outcomes are presented in table 3.

Primary outcome

For the primary outcome, patient activation, there was no support for the self-management course having a better effect after 3 months than a drop-in, low-impact outdoor physical activity (estimated mean difference −0.5, 95% CI −4.8 to 3.7, p=0.802).

Secondary outcomes

For the secondary outcomes, only the question in the BPI measuring pain relief by analgesics showed a statistically

Characteristics	INTV (n=60)	CTRL (n=61)
Female, n (%)	53 (88.3 %)	53 (86.9 %)
Age years, mean (SD)	52.1 (11.4)	53.3 (12.1)
(range)	(27–71)	(23–74)
Living with someone, n (%)	43 (71.7)	43 (70.5)
Highest level of education, n (%)		
Lower secondary school or less	4 (6.7)	4 (6.6)
Upper secondary school	28 (46.7)	28 (45.9)
Higher education (college or university)	28 (46.7)	29 (47.5)
Main reason for pain, n (%)		
Musculoskeletal diseases, ICPC-2 chapter L	46 (76.7)	47 (77.0)
Neuro system diseases, ICPC-2 chapter N	10 (16.7)	6 (9.8)
General and unspecified, ICPC-2 chapter A	4 (6.7)	8 (13.1)
Pain duration, n (%)		
7–11 months	2 (3.3)	0 (0)
1–5 years	12 (20.0)	12 (19.7)
6–9 years	11 (18.3)	8 (13.1)
≥10 years	35 (58.3)	41 (67.2)
More than one chronic condition, n (%)	32 (53.3)	44 (72.1)
Work status, n (%)		
Working, full or part time	13 (21.7)	18 (29.5)
Disability pension, full or graded	33 (55)	23 (37.7)
Sick leave, full or graded	8 (13.3)	12 (19.7)
Retired	6 (10.0 %)	8 (13.1 %)
Pain medication, n (%)		
Prescription only	23 (38.3)	28 (45.9)
Without prescription	19 (31.7)	22 (36.1)
Do not use pain medication	18 (30.0)	11 (18.0)
Healthcare utilisation, last 3 months		
Visits general practitioner, mean (SD)	1.6 (1.7)	2.1 (2.0)
Visits physiotherapist, mean (SD)	4.5 (5.9)	5.1 (6.8)
Stays rehabilitation centre, mean (SD)	0.1 (0.3)	0.05 (0.2)
Visits hospital outpatient clinic, mean (SD)	0.5 (0.9)	0.6 (1.3)
Admission hospital, mean (SD)	0.2 (1.0)	0.02 (0.1)
Number of days, mean (SD) (range)	0.2 (1.2) (0–8)	0.02 (0.1) (0–1)

Table 2 Participants' characteristics at baseline

CTRL, control group; ICPC-2, International Classification of Primary Care, Second Edition; INTV, intervention group.

significant small difference between the groups with an estimated mean difference of 1.0 (95% CI 0.01 to 1.9, p=0.047). Within groups, estimated mean change from baseline to follow-up in experienced pain during the previous week showed statistically significant changes for both groups, with a reduction in pain of −7.9 (95% CI −13.1 to −2.7, p=0.003) for the intervention group and −6.6 (95% CI −11.8 to −1.4, p=0.014) for the control group. Within the intervention group, there was a small but statistically significant improvement in global self-rated health (estimated mean change 0.2, 95% CI 0.01 to 0.4, p=0.032).

For most of the participants, there was no change in work status (83.5% unchanged), pain medication (75.3% unchanged) or frequency of healthcare utilisation from baseline to follow-up. There was no statistical significant differences between the groups for these variables.

DISCUSSION

There was no effect of the group-based chronic pain self-management course after 3 months compared with the drop-in, low-impact physical activity on either the primary or the secondary outcomes.

This study contributes knowledge to the field of easily accessible chronic pain self-management support given that previous research has largely focused on interventions that address specific diagnoses or specific age groups and has investigated lay-led interventions or interventions delivered by specialist and multidisciplinary healthcare services. However, the study only included data collected 3 months after the completion of the intervention, and thus short-term effects can only be discussed. The lack of blinding is a limitation of the study, but due to the nature of the interventions, blinding was not possible. Furthermore, even if the possibility of bias due to data loss at follow-up cannot be disregarded, it is unlikely that such bias would influence the two groups differentially and thereby affect the results of the study. It should be noted that the two trial arms received interventions of different lengths, and the power calculation for the trial was conducted with regard to the primary outcome from the baseline to 12 months based on a study in which the comparator did not receive an intervention activity.[18] Hence, a difference between the two groups regarding the primary outcome of six points may be difficult to detect after 3 months. Valid and reliable outcome measures were chosen in accordance with recommendations from the IMMPACT[36]; however, although a wide range of outcomes was chosen to encompass domains the intervention could affect, other measures may have been more sensitive to changes caused by the intervention.

The self-management course included education applying cognitive and behavioural strategies, group discussions and exercises for body awareness and relaxation during 6 weekly sessions. This is similar to interventions in other studies, some of which have shown an effect[20 21 69] and others that have not.[22 70] For instance, a

Table 3 Observed mean (SD) at baseline and 3 months, and estimated differences (95% CIs) within groups from baseline to 3 months and difference between groups at 3 months

| | | Observed | | Estimated | | | |
| | | | | Within groups Baseline to 3 months | | Between groups 3 months | |
	Group	Baseline mean (SD)	3 months mean (SD)	Difference (95% CI)	P value	Difference (95% CI)	P value
PAM-13	INTV	63.9 (13.2)	64.3 (14.3)	0.4 (−2.9 to 3.6)	0.829	−0.5 (−4.8 to 3.7)	0.802
(0–100)↑	CTRL	63.0 (12.9)	64.2 (12.0)	0.9 (−2.3 to 4.0)	0.576		
BPI, severity	INTV	18.2 (6.5)	17.1 (7.2)	−1.1 (−2.6 to 0.5)	0.171	−0.6 (−2.6 to 1.5)	0.599
(0–10)↓	CTRL	18.8 (5.6)	18.1 (7.7)	−0.5 (−2.1 to 1.0)	0.520		
BPI, interference	INTV	29.2 (14.0)	28.4 (13.9)	−1.5 (−5.1 to 2.1)	0.419	−0.3 (−5.1 to 4.6)	0.913
(0–10)↓	CTRL	32.6 (13.1)	30.1 (17.5)	−1.2 (−4.9 to 2.4)	0.516		
BPI, pain relief	INTV	3.4 (3.3)	4.0 (3.2)	0.6 (−0.1 to 1.2)	0.115	1.0 (0.01 to 1.9)	0.047
(0–10)↑	CTRL	3.5 (2.9)	3.0 (2.8)	−0.4 (−1.1 to 0.3)	0.268		
VAS, Pain last week	INTV	62.7 (18.2)	54.8 (20.2)	−7.9 (−13.1 to −2.7)	0.003	−1.4 (−8.0 to 5.3)	0.691
(0–100)↓	CTRL	62.8 (15.1)	56.1 (20.6)	−6.6 (−11.8 to −1.4)	0.014		
HADS, depression	INTV	4.4 (3.0)	4.6 (3.4)	0.1 (−0.6 to 0.8)	0.844	0.03 (−0.9 to 1.0)	0.955
(0–21)↓	CTRL	5.1 (3.1)	4.9 (3.7)	0.04 (−0.7 to 0.7)	0.902		
HADS, anxiety	INTV	7.8 (3.4)	7.5 (4.2)	−0.5 (−1.2 to 0.2)	0.159	−0.7 (−1.6 to 0.2)	0.147
(0–21)↓	CTRL	8.1 (3.6)	8.3 (3.7)	0.2 (−0.5 to 0.8)	0.558		
PSEQ	INTV	38.1 (10.5)	38.7 (12.0)	0.7 (−1.9 to 3.2)	0.594	1.7 (−1.7 to 5.1)	0.332
(0–60)↑	CTRL	37.5 (10.4)	37.0 (11.7)	−1.0 (−3.5 to 1.5)	0.439		
SOC-13	INTV	61.4 (12.4)	62.1 (13.4)	0.6 (−1.6 to 2.8)	0.590	0.1 (−3.0 to 3.1)	0.972
(13- 91)↑	CTRL	61.8 (13.0)	62.8 (12.7)	0.6 (−1.7 to 2.8)	0.623		
EQ-5D-5L	INTV	0.63 (0.14)	0.61 (0.16)	−0.01 (−0.04 to 0.02)	0.641	−0.04 (−0.1 to 0.01)	0.095
(0–1)↑	CTRL	0.61 (0.14)	0.64 (0.18)	0.02 (−0.003 to 0.06)	0.071		
AIOS	INTV	46.3 (21.3)	44.8 (18.9)	−1.0 (−6.6 to 4.6)	0.729	2.3 (−4.9 to 9.4)	0.531
(0–100)↑	CTRL	43.4 (18.5)	41.3 (19.5)	−3.3 (−8.8 to 2.3)	0.251		
Global health	INTV	2.1 (0.89)	2.4 (0.93)	0.2 (0.01 to 0.4)	0.032	0.2 (−0.1 to 0.4)	0.153
(1- 5)↑	CTRL	2.2 (0.69)	2.2 (0.88)	0.02 (−0.2 to 0.2)	0.846		
Physical activity	INTV	4.0 (0.87)	4.0 (1.06)	0.1 (−0.1 to 0.3)	0.527	0.1 (−0.2 to 0.4)	0.557
(1- 5)↑	CTRL	4.0 (1.02)	3.9 (0.73)	−0.01 (−0.2 to 0.2)	0.875		
30 s chair to stand	INTV	12.5 (4.1)	12.6 (5.6)	0.2 (−0.8 to 1.2)	0.660	−0.7 (−2.0 to 0.7)	0.353
↑	CTRL	11.5 (4.0)	12.7 (4.7)	0.9 (−0.1 to 1.9)	0.086		

Estimates presented are from linear mixed effects model (unadjusted) without random slope.

The numbers of participants for each outcome at 3 months varied between 97 and 104 due to some missing responses

↑Increase in scores indicates improvement.

↓Decrease in scores indicates improvement.

AIOS, Arizona Integrative Outcome Scale; BPI, Brief Pain Inventory; CTRL, control group; EQ-5D-5L, EuroQoL 5 dimensions 5 level; HADS, Hospital Anxiety and Depression Scale; INTV, intervention group; PAM-13, Patient Activation Measure; PSEQ, Pain Self-Efficacy Questionnaire; SOC-13, Sense of Coherence; VAS, visual analogue scale.

study on older adults with chronic pain showed no effect of a chronic pain self-management course using CBT components,[70] whereas another study conducted in a similar population did show a significant effect in favour of a CBT-based chronic pain self-management course compared with both an exercise-attention control and a waiting-list group when expanding the intervention.[20] A lay-led chronic pain self-management programme of equal length and similar content to the intervention in the present study showed no effect compared with a usual care control.[22] Evidence of an effect of chronic pain self-management courses similar to the type provided in this study is thus conflicting.

The present study included broad inclusion criteria that targeted chronic pain in general, which is important because those living with chronic pain have different

origins of pain and experience different impacts of the condition.[2 3] By inviting a broad range of participants, those with chronic pain who considered themselves to be in the targeted group and able to benefit from the interventions could be reached. Accordingly, a strength of this study is the broad inclusion criteria that targeted chronic pain in general. Even though this reflects the persons targeted by the HLC, thus increasing the external validity of the study, the broad inclusion might also be a reason for not finding an effect, as there are ranges of conditions that can be the cause of chronic pain, which in turn may require different management strategies. It might thus be that all self-management strategies the participants potentially may benefit from are difficult to target specifically in a generic self-management course.

During the RCT, there was no usual care control group. Consequently, a possible reason for not finding a clear difference in the effect between the two groups could be that the control group activity had an effect equal to that of the self-management course. Physical activity and exercise are relevant chronic pain interventions that are believed to improve quality of life and functioning.[14] Walking has been found to be a feasible, acceptable and safe intervention for people with rheumatoid arthritis,[71] and it is recommended for people with chronic musculoskeletal pain.[17] In addition, tailored physical activity has been found to be promising for back or upper body pain,[72] whereas there is low to moderate evidence for the efficacy of walking related to the reduction of low back pain.[73] However, in the present study, there were no significant changes after 3 months (ie, within group changes) to support a clear effect of the drop-in, low-impact physical activity.

Nevertheless, there were improvements in experienced pain during the previous week within both groups, indicating an effect on experiencing pain. This could either be due to the interventions or due to taking part in the trial. The question in the BPI that measured pain relief by analgesics showed a statistical significant difference between the groups; however, this BPI item is described as not useful in some studies,[74] and the clinical relevance of the item in relation to a non-pharmacological intervention is uncertain. Nevertheless, there are studies on self-management interventions that have shown improvements in pain,[20 69] indicating that such interventions could be the cause. For instance, according to Nicholas et al[20], the pain self-management course group reported significantly less severe usual pain at the 1-month follow-up compared with the exercise-attention control group, and LeFort et al[69] showed that participants in a psychoeducation programme for chronic pain self-management had reduced bodily pain compared with a wait-list control group. However, there have also been cases in which both the intervention and the usual care control group reported a reduction in pain.[22] As suggested by Mehlsen and colleagues,[22] improvement in pain might thus be due to natural fluctuations in symptoms or in the condition itself. Hence, to separate the effect of interventions and

the effect of time, an additional observation group would be needed.

The HLCs aim to offer easily accessible services, providing interventions to support people in managing long-term conditions.[24] This is not something that is routinely measured. If it had been, the PAM applied in this study could have been used because it reveals participants' understanding of their roles in the care process and how competent they feel in assuming the roles.[9 33] The baseline PAM score in this study was around 63, which is in the higher range. Because positive self-management behaviours at the baseline can result in no change in patient activation after interventions, maintaining a relatively high level of the behaviours over time can be viewed as a positive result.[75] This study indicates that self-management interventions delivered via easily accessible healthcare services may be a safe contribution to patients' efforts to self-manage chronic pain because there were few reported adverse events related to participation. However, no effect of the self-management course was found on any of the chosen outcomes when compared with the low-impact physical activity. This might be due to the intervention simply having very little or no effect; however, it may also be related to the time span from the intervention to the follow-up assessment. Increasing one's ability to self-manage chronic pain will most likely take time, and it might therefore be unrealistic to expect an effect after 3 months.

CONCLUSIONS

During this RCT, there was no support for the self-management course having a better effect after 3 months than drop-in, low-impact outdoor physical activity sessions offered the control group. It is still unclear whether the interventions can have long-term effects. This should be investigated further because the changing of perceptions towards pain most likely take time.

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