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Complete List of Authors:	Nøst, Torunn Hatlen; Norwegian University of Science and Technology, Public health and Nursing Steinsbekk, Aslak; Norwegian University of Science and Technology, Department of Public Health and General Practice Bratås, Ola; Norwegian University of Science and Technology, Department of Public Health and Nursing Grønning, Kjersti; Norwegian University of Science and Technology, Department of Public Health and General Practice
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Title page

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

Authors

Torunn Hatlen Nøst [1, 2, *] E-mail: torunn.h.nost@ntnu.no

Aslak Steinsbekk [1] E-mail: aslak.steinsbekk@ntnu.no

Ola Bratås [1, 2] E-mail: ola.bratas@ntnu.no

Kjersti Grønning [1, 2] E-mail: kjersti.gronning@ntnu.no

Affiliation

[1]Department of Public Health and Nursing, Norwegian University of Science and Technology, Trondheim, Norway

[2]Center for Health Promotion Research, Norwegian University of Science and Technology, Trondheim, Norway

[*] **Corresponding author**

Torunn Hatlen Nøst

PhD-candidate, Department of Public Health and Nursing, Norwegian University of Science and Technology

E-mail: Torunn.h.nost@ntnu.no

Tel. + (47) 73 41 25 34

Postal address

NTNU, Faculty of Medicine and Health science

Department of Public Health and Nursing

Postbox 8905, 7491 Trondheim, Norway

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Strengths and limitations of this study

- First RCT to investigate effect of self-management support interventions in this setting
- Broad inclusion criteria
- Valid and reliable outcome measures
- The lack of blinding is a limitation
- The two trial arms received interventions of different lengths

Abstract

Objective: The aim of this study was to investigate the effect on people with chronic pain after three months, of a group-based chronic pain self-management course consisting of educational input and movement exercises, compared to a drop-in low impact outdoor physical activity delivered in an easily accessible service in public primary healthcare.

Methods and design: An open, pragmatic, parallel group randomised controlled trial was conducted. The intervention group was offered a group-based pain self-management course with 2 ½-hour weekly sessions for a period of six weeks. These sessions consisted of educational input, group discussions and movement exercises. The control group was offered a drop-in low impact outdoor group physical activity in one-hour weekly sessions that consisted of walking and simple strength exercises for a period of six weeks. The primary outcome was patient activation measure. Analyses were performed using a two-level linear mixed model.

Results: In total, 121 participants were randomised; 60 participants to the intervention group and 61 to the control group. There was no effect after 3 months of the group-based chronic pain self-management course compared to the control group, on neither primary nor secondary outcomes. Within groups, there were statistically significant minor changes, including a decrease in experienced pain during the previous week for both groups and an increase in experience of global self-rated health for the self-management course group.

Conclusions: In this RCT, there was no support of the self-management course having a better effect after three months than a drop-in low impact outdoor physical activity. Still, the maintained level of patient activation and the decrease in pain perception might indicate that interventions delivered in an easily accessible healthcare service are valuable for people in their efforts to self-manage chronic pain.

Trial registration: ClinicalTrials.gov: NCT02531282. Registered on August 21 2015.

Background

Chronic pain, a long-term condition that affects a substantial portion of the population, challenges societies and healthcare systems in terms of increased healthcare utilisation, medication use and lost work force [1, 2]. Chronic pain also puts a major burden on the affected individuals due to its impact on the social, psychological and physical aspects of life [2, 3].

Chronic pain is a condition that is likely to persist when treatment stops [4], indicating that people in many cases are left to self-manage their pain on an everyday basis [5]. Self-management includes the actions that people take to recognise, treat, manage and engage in behaviours that affect their health [6]. Hence, to be an engaged and activate patient and to function effectively as a self-manager, one must have the necessary knowledge, skills and confidence to make favourable choices about one's health and healthcare [7]. Emphasised within a health promotion and salutogenic approach [8], strengthening people's awareness of and capacity to use own and available resources to self-manage is therefore a central health service task [5, 6]. It is reasonable to believe that increased knowledge enhances the ability to self-manage health-challenges. However, little evidence supports education as a stand-alone intervention to reduce pain intensity or associated disability [9].

Several studies have investigated the effect of self-management support interventions on chronic pain. Common within these interventions is the use of cognitive behavioural therapy (CBT) principles, which have been found to be suitable for teaching chronic pain self-management [10]. Some reviews investigating chronic pain self-management conclude that the investigated interventions have no effect [9, 11], whereas others have found minor effects, such as improvements in self-management skills, pain, symptoms and functioning [12]. Furthermore, physical activity and exercise have increasingly been promoted within chronic pain interventions for their perceived benefits, including improved overall physical and mental health and improved physical functioning [13]. Both aerobic and anaerobic exercise as well as meditation and yoga, have been found to have beneficial effects on chronic pain conditions [14, 15]. Walking has been suggested as an ideal form of activity due to its ease of accessibility and relatively low impact [16].

Due to the need for treatment and support over time, people with chronic pain utilise a variety of different health care services [1]. This ranges from multidisciplinary and pharmacological interventions delivered in specialist healthcare services, to support and guidance on how to

manage everyday life with pain delivered in primary healthcare. Studies on the effects of chronic pain self-management interventions have typically addressed patients with specific diagnoses [17, 18], targeted specific age groups [19], concerned lay-led interventions [20, 21] or investigated interventions delivered in specialist and multidisciplinary healthcare services [22]. However, we have not found studies on self-management support interventions addressing chronic pain and delivered via easily accessible healthcare services.

One such service has become a common feature in most Norwegian municipalities, as they are encouraged to establish Healthy Life Centres (HLCs) as part of their public primary healthcare [23]. These centres focus on health promotion and support people in the management of long-term conditions.

Objective

The aim of this study was to investigate the effect on people with chronic pain after three months, of a group-based chronic pain self-management course consisting of educational input and movement exercises, compared to a drop-in low impact outdoor physical activity delivered in an easily accessible service in public primary healthcare.

Methods

The study was an open, pragmatic, parallel group randomised controlled trial (RCT) conducted from August 2015 through March 2017. The guidelines in the Consolidated Standards of Reporting Trials (CONSORT) statement [24], including its extensions for pragmatic trials [25] and non-pharmacological treatment interventions [26], were used to guide the presentation of the results (see additional file). The protocol for the trial have been published previously [27], but the main features are also accounted for here. There were no changes to the methods after trial commencement.

Setting

The setting for the study was a Healthy Life Centre (HLC) in a main city in Central Norway serving a population of approximately 190,000. The HLCs aim to strengthen participants' capacity to use their own and available resources to make behavioural changes and manage their health [28]. To achieve this, the HLCs' offer non-pharmacological interventions with few barriers for attendance, meaning that people can attend the service with or without referral from others.

The present RCT was situated at a HLC delivering several group-based activities and interventions, (e.g., indoors and outdoors physical activity, healthy diet courses and courses focusing on coping with depression or anhedonia). The HLC had at the time of the RCT 5.5 positions occupied by multidisciplinary health professionals with a bachelor's or master's degree.

Participants

Recruitment for the RCT started in September 2015 and ended in October 2016. Individuals who met the following inclusion criteria were admitted: adults of 18 years or older, self-reported pain for three months or more, able to take part in group-discussions in Norwegian and 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 one 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 in posters and information leaflets distributed to general practitioners, physiotherapists, relevant departments at the hospital, Norwegian Labour and Welfare Administration offices and to other relevant organisations in the municipality. To facilitate self-referrals to 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 (i.e. that they would attend one of two activities delivered in groups at daytime for a period of six weeks) in the informed consent form and orally in relation to the baseline assessment. People 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 randomly allocated to one of two trial arms after completing the baseline assessment. A block randomisation with a ratio of 1:1 was used and those involved in the trial were blinded to the block sizes. Because recruiting men to

self-management interventions is a common challenge [29], stratification for gender was applied to ensure the best balance possible of men in each trial arm.

Immediately after the randomisation informed 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. Blinding of participants and instructors was not possible due to the nature of the interventions. However, the research assistant who conducted the physical ability test at the follow-up appointment was blinded to allocation.

Outcomes were measured at the baseline and at three months after the end of trial activity. At baseline, the self-administrated questionnaire was completed with the first author available for questions. To facilitate the follow-up appointment, the participants received the questionnaire by mail, and the results of a physical test as well as data related to healthcare utilisation and socio-demographic variables, were registered during a follow-up appointment. All data were collected on paper forms, which were scanned and checked by the first author by comparing them to their corresponding data files.

Ethics

The Regional Committee for Medical and Health Research Ethics in South East Norway approved the study (2015/ 1030/ REK sørøst). The participants were informed about the trial both orally and in writing, and a written consent to participate was collected from each participant before enrolment. The trial was registered at the Clinical Trials.gov in August 2015 (number NCT02531282).

Outcome measures

Self-reported socio-demographic variables- such as gender, age, marital status, education, employment status, main reason for pain categorised according to the International Classification of Primary care-2 (ICPC-2), use of pain medication, and whether the individual suffered from more than two chronic conditions- were collected at baseline. At the follow-up appointment, any changes to these baseline assessments were registered. Healthcare utilisation was registered at both baseline and the follow-up as participants' self-report of visits to a general practitioner, physiotherapist, hospitals or rehabilitation centre during the previous three months.

Primary outcome measure

The intervention was expected to strengthen the participants' engagement and increase their knowledge of their own health resources, leading to a higher level of patient activation and engagement. The primary outcome was therefore set to be patient activation assessed with the Patient Activation Measure (PAM) [30]. The PAM has been reported as useful for assessing patient engagement in management of chronic illness, and it is sensitive to changes across several groups and populations [30].

The PAM 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. The responses give 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 [31]. A high score indicates that participants are more activated to adopt and maintain healthy behaviours and self-management of their illness, even under stress [7]. The PAM is translated and validated for use in a Norwegian context [32]. In this trial, the Cronbach's alpha at the baseline was 0.75.

Secondary outcome measures

The short version of the Brief Pain Inventory (BPI) applying a 24-hour recall period was used to assess pain severity and pain interference. The instrument provides 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 function. The instrument has in addition one item asking about percentage of pain relief by analgesics [33]. In the present study, the Cronbach's alpha at the baseline was 0.81 for pain severity, and 0.86 for pain interference.

The participants reported experience of pain during the previous week using a one-item 100 mm Visual Analogue Scale (VAS) [34]. 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 validated and found to be reliable in the assessment of chronic pain [34].

The self-rating instrument- the Hospital Anxiety and Depression Scale (HADS) with 14 items divided into subscales for depression and anxiety [35]- 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), giving a total score from 0 to 21 for both subscales of seven

items each. The instrument is widely used in studies concerning chronic pain and has shown good validity and reliability for patients with musculoskeletal pain [36] and in a Norwegian context [37]. In the present study, at the baseline the Cronbach's alpha was 0.73 for the depression subscale and 0.76 for the anxiety subscale.

The Pain Self-Efficacy Questionnaire (PSEQ) assessed the participants' beliefs concerning their ability to accomplish various activities despite pain using 10 items ranging on a scale from 0 to 6 in terms of how confident they are that they can do an activity at present despite the pain where 6 equals completely confident [38]. The scale has shown good psychometric qualities [38] and was previously used in a Norwegian study [39]. In the present study, the Cronbach's alpha at the baseline was 0.84.

The 13-item Norwegian version of the Sense of Coherence (SOC) scale was used to assess capacity to respond to stressful situations and stay well [40]. The scale measures comprehensibility, manageability and meaningfulness in 13 items, each of them scored on a range from 1 to 7, giving 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 [40]. In the present study, the Cronbach's alpha for the SOC was at the baseline 0.87.

The EuroQoL (EQ-5D-5L) was used to assess health-related quality of life [41]. The instrument has five levels for evaluating each of the following dimensions: mobility, self-care, usual activities, pain/ discomfort and anxiety/ depression. Levels are: 'no problems', 'slight problems', 'moderate problems', 'severe problems' and 'extreme problems' [42]. 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) [41, 42]. The instrument has been validated in similar populations [43] and in a Norwegian context [44]. In the present study, the Cronbach's alpha was at the baseline 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 [45]. The question asked was '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 wellbeing'. The scale's anchoring points were 'worst you have ever been' (0) and 'best you have ever been' (100) [45]. AIOS has been found to be a valid measure of assessing well-being [45] and was previously used in a Norwegian study [17].

To assess global self-rated health, we included the question 'By and large, would you say that your health is:' followed by the options 'poor', 'not so good, 'good', 'very good', and 'excellent'. The question is similar to a question asked in a major population study in Norway [46].

The participants were also asked: 'How often do you exercise on average? (by 'exercise' we mean going for walks, skiing, swimming and working out/ sports)' followed by the options 'never', 'less than once a week', 'once a week', '2-3 times a week', or 'nearly every day'. This question was used in a major population study in Norway [46].

As an objective measure of physical ability, we used the 30-second Chair to Stand Test to measure lower body strength [47]. The test is validated for a wider population [48].

Delivery of trial activities

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

Intervention and control group

Two different teams conducted the intervention and control group activities. The guideline on how to carry out the self-management course, ensuring all groups were offered the same content and material, is available through a previous paper [27]. The low impact physical activity offered the control group followed descriptions of a similar and already existing activity at the HLC. There was no user fee for participation, nor was any financial compensation offered to the participants.

The Self-management course

The self-management course was delivered as 2.5-hour weekly group sessions during the day (12.30 pm- 15.00 pm) for a period of six weeks, for 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 at a multidisciplinary hospital pain clinic.

The HLC staff had developed the course in cooperation with representatives from patient organisations. They used elements from cognitive behavioural therapy (CBT), yielding a focus on thoughts, emotions and actions related to pain. When addressing the participants'

experiences of 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 behaviour. The educational part of the course concerned topics like pain theory, barriers in everyday life due to chronic pain, problem solving, goal setting, and techniques to deal with fatigue, poor sleep, frustrations and isolation. The course aimed to address skills such as setting specific, functional and realistic goals, activity pacing, and structured problem solving. The movement exercises 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 among the participants. Between each session, the participants were encouraged to work on projects such as an action plan and to practice the exercises. The content of the course is outlined in Table 1.

PLEASE INSERT TABLE 1 ABOUT HERE

The control group activity

The low impact physical activity offered to the control group was a weekly one-hour drop-in session during the day (13.00 pm- 14.00 pm) for a period of six weeks, which consisted of walking and simple strength exercises (e.g., squats and push-ups against a tree or a bench). The groups met outdoors on a popular hiking trail. The activity provided an opportunity to meet others with similar health challenges and participation was voluntary, 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 exchange of information among the participants rather than answering questions and giving advice themselves. Hence, there was no educational input presented to the control group.

Sample size

The trial intended to detect clinically important differences between the intervention group and the control group, with a significant difference defined as six points of difference on the primary outcome (PAM) between baseline and 12-month follow-up. We calculated the sample size using a mixed linear model assuming a correlation within participants to be 0.5, with a standard deviation (SD) of 13 [17]. The significance level was set to 5 % and the power to 80 %, generating a necessary number of 55participants for each trial arm. Thus, we aimed to recruit 120 participants, allowing for five dropouts in each trial arm.

Statistics

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

Mean scores on all observed outcomes at the baseline and at the three-month follow-up were calculated independently. Changes in work status, pain medication and healthcare utilisation from the baseline to the follow-up were compared between groups using t tests. The effect of the intervention was assessed using intention to treat (ITT) and per protocol procedures. To take the intra-class correlation between measurements in the same subject into account, the analyses were performed using a two-level linear mixed model [49]. Maximum likelihood estimates allow use of all available data in the presence of dropouts, yielding no need for multiple imputations [49]. Hence, analyses included all available data from all randomly assigned participants.

In the two-level linear mixed-effects model, we compared outcome measures over time for the two trial arms, using participant identification (ID) specified as a random effect and a variable encompassing group allocation and time specified as a fixed effect. The random effect for participant ID aimed to allow participants to start out with different levels of the outcome in question. The variable generated for the fixed effect carried the following three values: 1) 'baseline', 2), 'control three months' and 3) 'intervention three months', acknowledging that differences between groups at baseline were due to chance. Regression assumptions were checked by running the command 'regcheck' in Stata [50], resulting in satisfying 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 the six group sessions in the self-management course. 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 co-authors and a statistician. All analyses were performed using Stata 14 (StataCorp. 2014. Stata Statistical Software: Release 14, College Station, TX: StataCorp LP).

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 as 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 three-month follow-up, 17 people did not respond. They were equally distributed for intervention and control, leaving 52 available cases in each trial arm. Of the remaining participants (n=104), seven participants did not show for the follow-up appointment but returned the questionnaire by mail, leading to missing data on changes in marital status, working status, use of pain medication, healthcare utilisation, and the 30-second Chair to Stand Test as these were data collected during the follow-up appointment.

PLEASE INSERT FIGURE 1 ABOUT HERE

Figure 1. Participants flow through the study

Participants

Most of the participants responded to advertisements in newspapers, social media or email-invitations sent to relevant organisations (68.6 %). Twenty-one participants (17.4 %) approached the study after receiving information at a physiotherapist's office, and two participants (1.7 %) received information at their general practitioner's office. Another 14 people (11.6 %) referred to the HLC by their general practitioner 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 there were men in the sample, and the majority lived with someone else (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.

PLEASE INSERT TABLE 2 ABOUT HERE

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 seven 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, 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 on presenting slides because the participants wanted to use more time to discuss and reflect upon the subjects instead. In some of the groups, there were participants who had difficulty practicing 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 performance of one of the movement exercises. 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 groups, the meeting point for the activity was changed because the participants wanted to end the activity near a café. Some of the participants found it difficult to participate during the winter due to slippery trails, and one adverse event with a participant pulling a leg muscle was reported. A general practitioner was consulted, and the symptoms were gone within a few weeks.

Outcome measures

Observed and estimated scores on all outcomes are presented in Table 3.

Primary outcome

For the primary outcome patient activation, there was no support of the self-management course having a better effect after three months than a drop-in low impact outdoor physical

activity

(-0.5, 95 % Confidence Interval (CI): -4.8 to 3.7, p=0.800). Within groups, there was a slight improvement in patient activation from baseline to three-month follow-up for both groups, however this improvement was not statistically significant for either group.

Secondary outcomes

For the secondary outcomes, only the question in the Brief Pain Inventory (BPI) measuring pain relief by analgesics showed a statistically significant small difference between the groups at the follow-up with an estimated mean of 1.0 (95 % CI: 0.02 to 1.9, p=0.045) in favour of the intervention group. The majority of small statistically insignificant differences between the groups were in favour of the self-management course. Within groups, estimated mean differences in experienced pain from the baseline to the follow-up 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 -6.7 (95 % CI: -11.7 to-1.4, p= 0.013) for the control group. Within the intervention group there was a small but statistically significant improvement in global self-rated health (0.2, 95 % CI: 0.02 to 0.4, p= 0.030). The other within-group changes were mainly in favour of the self-management course.

In terms of working status, there was no statistically significant difference between the groups at the follow-up (p= 0.554), nor were there any significant changes in use of pain medication between the groups (p= 0.544). For health care utilisation, physiotherapy was the most frequently used healthcare service both at baseline and at follow-up. There was no statistically significant change in physiotherapy visits between the groups (p= 0.668) at follow-up. The changes in use of other healthcare services were only minor, and none of them were statistically significant when comparing groups.

PLEASE INSERT TABLE 3 ABOUT HERE

Discussion

There was no effect of the group-based pain self-management course after three months compared to the drop-in low impact physical activity on neither the primary nor the secondary outcomes. The majority of statistically insignificant small differences between the groups were in favour of the self-management course. Within groups, there were minor statistically significant changes from baseline to three months in terms of decrease in experienced pain

during the previous week for both groups and an increase in experience of global self-rated health for the self-management course group. The other statistically insignificant within group changes were mainly in favour of the self-management course.

These results may be due to the intervention simply having very little or no effect. The self-management course presented educational input, used CBT components, facilitated group discussions and introduced exercises for body awareness and relaxation in six weekly sessions. This is similar to interventions in other studies, some of which have found an effect [19, 20, 51] and others which have not [21, 52]. For instance, one study found no effect of a chronic pain self-management course using CBT components [52], whereas another study did find a significant effect in favour of a CBT-based chronic pain self-management course compared to both an exercise-attention control and a waiting list group [19]. Then again, a lay-led chronic pain self-management program of equal length and similar content yielded no effect compared to a usual care control [21]. Even if the evidence for an effect of chronic pain self-management courses of the type provided in our study is conflicting, the tendency is in favour of self-management courses when compared to simpler interventions or usual care.

Another possible reason for not finding a clear difference in effect between the two groups could be because 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 [13]. Walking has been found to be a feasible, acceptable and safe intervention for people with rheumatoid arthritis [53], and it is recommended for people with chronic musculoskeletal pain [16]. In addition, tailored physical activity has been found to be promising for back and upper body pain [54], whereas there is low to moderate evidence for the efficacy of walking on reduction of low back pain [55]. However, in the present study, there were no significant changes over time (i.e. 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 pain experience. This could be either due to the interventions or due to taking part in the trial. There are studies on self-management interventions that have found improvements in pain [19, 51] supporting that such interventions could be the cause. For instance, Nicholas et al. found the pain self-management course group to report significantly less severe usual pain at a one-month follow-up compared to the exercise-attention control group [19], and LeFort et al. found participants in a psychoeducation program for chronic pain self-management to have reduced bodily pain

when compared to a wait-list control group [51]. However, there have also been cases of both intervention and a usual care control group having reported a reduction in pain [21]. As suggested by Mehlsen et al. [21] 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 be an easily accessible service providing interventions to support people in mastering long-term conditions [23]. This is not something that is routinely measured. If it had been, the Patient Activation Measure (PAM) applied in our study could have been used, because it reveals participants' understanding of their role in the care process and how competent they feel in taking on this role [7, 30]. The baseline PAM score in our study was around 63, which was slightly lower than the reported average PAM score of 66 in hospital self-management courses in Central Norway [56] and the baseline score in a study on Norwegian patients with polyarthritis participating in a hospital educational programme (PAM score= 65) [17]. Nevertheless, because positive self-management behaviour at baseline can result in no change in patient activation after interventions, maintaining a relatively high level of the behaviour over time can be seen as a positive result [57]. As such, the maintenance of a high PAM score throughout the study may be viewed as positive.

Strength and limitations

The Norwegian Healthy Life Centres have been in operation for several years, but this is to the best of our knowledge the first randomised controlled trial to investigate the effect of self-management support interventions delivered in this setting. A strength of this study is the broad inclusion criteria that targeted chronic pain in general, which is important because people living with chronic pain have different origins for their pain and experience different impacts of the condition [2, 3]. The study adds knowledge to the field of chronic pain self-management support, given that previous research has largely focused on interventions addressing specific diagnoses and specific age groups, and investigated lay-led interventions or interventions delivered in specialist and multidisciplinary healthcare services. We chose valid and reliable outcome measures found to be responsive to change and to be in accordance with recommendations from the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) [58].

However, some limitations should be noted. Firstly, the lack of blinding is a limitation, but due to the nature of the interventions, blinding was not possible. The pattern of missing values

was examined and the variables were found to be missing at random. Even if we cannot disregard the possibility of bias due to data loss at follow-up, we consider it unlikely that such bias would influence the two groups differentially and thereby confuse the results of the trial.

In the trial, there was no usual care control group. However, by inviting participants this broadly we were able to reach people with chronic pain who considered themselves to be in the targeted group and able to benefit from the interventions. 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 baseline to 12 months. However, this does not influence the conclusions of the study.

Conclusions

In this RCT, there was no support of the self-management course having a better effect after three months than a drop-in low impact outdoor physical activity. Still, the maintained level of patient activation and the decrease in pain perception might indicate that interventions delivered via an easily accessible healthcare service such as the HLC, are valuable for people in their efforts to self-manage chronic pain.

It is still an open question if the interventions can have a long-term effect. This need to be investigated further because chronic pain is a lasting condition with fluctuating symptoms.

Abbreviations

CBT: Cognitive Behavioural Therapy; HLC: Health Life Centre; RCT: Randomised Controlled Trial; CONSORT: Consolidated Standards of Reporting Trials; ICPC-2: International Classification of Primary Care 2. Edition; PAM-13: Patient Activation Measure; BPI: Brief Pain Inventory; VAS: Visual analogue Scale; HADS: Hospital Anxiety and Depression Scale; PSEQ: Pain Self-Efficacy Questionnaire; SOC-13: Sense of Coherence; EQ-5D-5L: EuroQoL 5 dimensions 5 level; AIOS: Arizona Integrative Outcome Scale; SD: Standard Deviation; CI: Confidence interval; IMMPACT: Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials

Declarations

Ethics approval and consent to participate

All informants signed an informed consent form after having received oral and written information to enable them to make an informed choice about participation. The trial has obtained approval from the director for health and social affairs in the municipality, and from the Regional Committee for Medical and Health Research Ethics (REK) (2015/ 1030/ REK sørøst).

Consent for publication

Not applicable.

Availability of data and materials

De-identified datasets are available from the corresponding author on reasonable request.

Competing interest

The authors declare that they have no competing interests.

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Author Contributions

THN, AS, OB, and KG were responsible for the design of the study. THN performed the data collection, analysed the data, and interpreted the results together with AS, OB and KG. THN drafted the manuscript. All authors provided input on the manuscript, and read and approved the final version.

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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. Summarize the whole course. How will you use what you have learned? Information on activities at the HLC and in the municipality.

Table 2. Baseline characteristics of participants

Characteristics	ALL (N= 121)	INTV (n= 60)	CTRL (n= 61)
Female, n (%)	106 (87.6 %)	53 (88.3 %)	53 (86.9 %)
Age years, mean (SD),	52.7 (11.7)	52.1 (11.4)	53.3 (12.1)
(range)	(23- 74)	(27- 71)	(23- 74)
Living with someone, n (%)	86 (71.1 %)	43 (71.7 %)	43 (70.5 %)
Highest level of education, n (%)			
lower secondary school or less	8 (6.6 %)	4 (6.7 %)	4 (6.6 %)
upper secondary school	56 (46.3 %)	28 (46.7 %)	28 (45.9 %)
higher education (college or university)	57 (47.1 %)	28 (46.7 %)	29 (47.5 %)
Main reason for pain, n (%):			
musculoskeletal diseases, ICPC-2 chapter L	93 (76.9 %)	46 (76.7 %)	47 (77.0 %)
neuro system diseases, ICPC-2 chapter N	16 (13.2 %)	10 (16.7 %)	6 (9.8 %)
general and unspecified, ICPC-2 chapter A	12 (9.9 %)	4 (6.7 %)	8 (13.1 %)
Pain duration, n (%)			
7- 11 months	2 (1.7 %)	2 (3.3 %)	0 (0 %)
1- 5 years	24 (19.8 %)	12 (20.0 %)	12 (19.7 %)
6- 9 years	19 (15.7%)	11 (18.3 %)	8 (13.1 %)
10 years or more	76 (62.8 %)	35 (58.3 %)	41 (67.2 %)
More than one chronic condition, n (%)	76 (62.8 %)	32 (53.3 %)	44 (72.1 %)
Work status, n (%)			
working, full or part time	31 (25.6%)	13 (21.7 %)	18 (29.5 %)
disability pension, full or graded	56 (46.3 %)	33 (55 %)	23 (37.7 %)
sick leave, full or graded	20 (16.5 %)	8 (13.3 %)	12 (19.7 %)
retired	14 (11.6%)	6 (10.0 %)	8 (13.1 %)
Pain medication, n (%):			
prescription-only	51 (42.1 %)	23 (38.3 %)	28 (45.9 %)
without prescription	41 (33.9 %)	19 (31.7 %)	22 (36.1 %)
do not use pain medication	29 (24.0 %)	18 (30.0 %)	11 (18.0 %)
Healthcare utilisation, last 3 months:			
visits general practitioner, mean (SD)	1.9 (1.9)	1.6 (1.7)	2.1 (2.0)
visits physiotherapist, mean (SD)	4.8 (6.3)	4.5 (5.9)	5.1 (6.8)
stays rehabilitation centre, mean (SD)	0.07 (0.3)	0.1 (0.3)	0.05 (0.2)
visits hospital outpatient clinic, mean (SD)	0.6 (1.1)	0.5 (0.9)	0.6 (1.3)
admission hospital, mean (SD)	0.1 (0.7)	0.2 (1.0)	0.02 (0.1)
number of days, mean (SD), (range)	0.1 (0.8) (0-8)	0.2 (1.2) (0-8)	0.02 (0.1) (0-1)

INTV: intervention group; CTRL: control group; SD: standard deviation; ICPC- 2: International Classification of Primary Care, Second edition

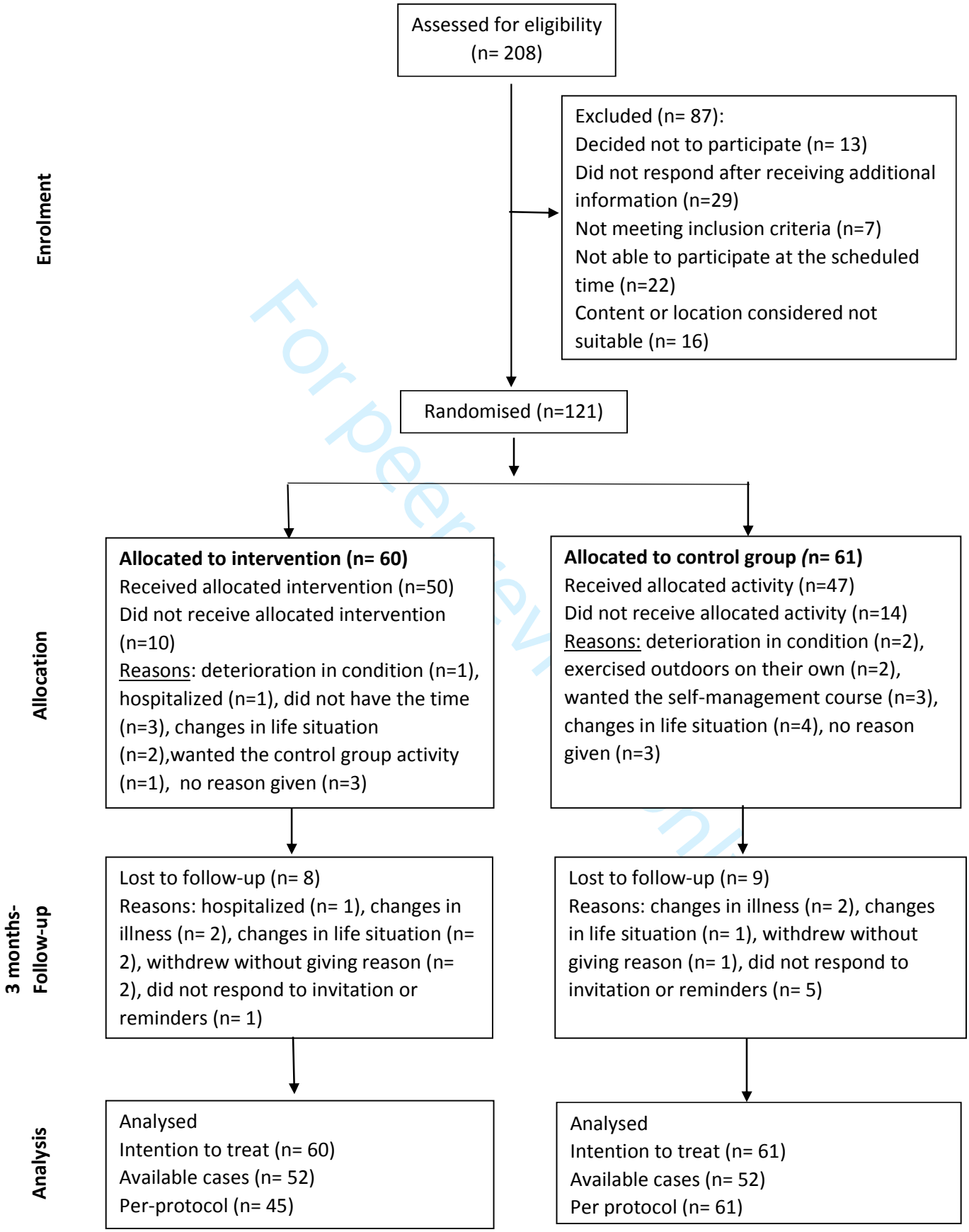
Table 3. Observed mean (SD) at baseline and 3 months, and estimated differences (95 % Confidence interval (CI)) within groups from baseline to 3 months and difference between groups at 3 months

Outcome	Group	Observed		Estimated			
				Within groups Baseline to 3 months		Between groups 3 months	
		Baseline mean(SD)	3 months mean (SD)	Diff (95 % CI)	*p*-value	Diff (95 % CI)	*p*-value
PAM-13 (0-100) ↑	INTV	63.9 (13.2)	64.3 (14.3)	0.4 (-2.8 to 3.5)	0.829	-0.5 (-4.8 to 3.7)	0.800
	CTRL	63.0 (12.9)	64.2 (12.0)	0.9 (-2.2 to 4.0)	0.573		
BPI, severity (0-10) ↓	INTV	18.2 (6.5)	17.1 (7.2)	--1.06 (-2.6 to 0.4)	0.168	- 0.6 (-2.6 to 1.5)	0.597
	CTRL	18.8 (5.6)	18.1 (7.7)	-0.51 (-2.0 to 1.0)	0.516		
BPI, interference (0- 10) ↓	INTV	29.2 (14.0)	28.4 (13.9)	-1.48 (-5.0 to 2.1)	0.417	- 0.3 (-5.1 to 4.5)	0.915
	CTRL	4.7 (1.9)	4.3 (2.5)	-1.22 (-4.8 to 2.4)	0.511		
BPI, pain relief (0- 10) ↑	INTV	3.4 (3.3)	4.0 (3.2)	0.6 (-0.1 to 1.2)	0.112	1.0 (0.02 to 1.9)	0.045
	CTRL	3.5 (2.9)	3.0 (2.8)	-0.4 (-1.1 to 0.3)	0.265		
VAS, Pain last week (0- 100) ↓	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)	0.689
	CTRL	62.8 (15.1)	56.1 (20.6)	-6.7 (-11.7 to -1.4)	0.013		
HADS, depression (0- 21) ↓	INTV	4.4 (3.0)	4.6 (3.4)	0.1 (-0.6 to 0.8)	0.841	0.03 (-0.9 to 1.0)	0.953
	CTRL	5.1 (3.1)	4.9 (3.7)	0.04 (-0.7 to 0.7)	0.901		
HADS, anxiety (0- 21) ↓	INTV	7.8 (3.4)	7.5 (4.2)	-0.5 (-1.2 to 0.2)	0.156	-0.7 (-1.6 to 0.2)	0.143
	CTRL	8.1 (3.6)	8.3 (3.7)	0.2 (-0.5 to 0.9)	0.555		
PSEQ (0-60) ↑	INTV	38.1 (10.5)	38.7 (12.0)	0.7 (-1.8 to 3.2)	0.591	1.7 (-1.7 to 5.1)	0.328
	CTRL	37.5 (10.4)	37.0 (11.7)	-1.0 (-3.5 to 1.5)	0.435		
SOC-13 (13- 91) ↑	INTV	61.4 (12.4)	62.1 (13.4)	0.6 (-1.6 to 2.8)	0.587	0.1 (-3.0 to 3.1)	0.971
	CTRL	61.8 (13.0)	62.8 (12.7)	0.6 (-1.7 to 2.8)	0.621)		
EQ-5D-5L (0- 1) ↑	INTV	0.63 (0.14)	0.61 (0.16)	-0.01 (-0.04 to 0.02)	0.637	-0.04 (-0.1 to 0.01)	0.092
	CTRL	0.61 (0.14)	0.64 (0.18)	0.03 (-0.002 to 0.06)	0.069		
AIOS (0- 100) ↑	INTV	46.3 (21.3)	44.8 (18.9)	-1.0 (-6.5 to 4.5)	0.726	2.3 (-4.8 to 9.4)	0.529
	CTRL	43.4 (18.5)	41.3 (19.5)	-3.3 (-8.8 to 2.3)	0.247		

Global health (1- 5) ↑	INTV	2.1 (0.89)	2.4 (0.93)	0.2 (0.02 to 0.4)	0.030	0.2 (-0.1 to 0.4)	0.149
	CTRL	2.2 (0.69)	2.2 (0.88)	0.02 (-0.2 to 0.2)	0.845		
Physical activity (1- 5) ↑	INTV	4.0 (0.87)	4.0 (1.06)	0.1 (-0.1 to 0.3)	0.523	0.1 (-0.2 to 0.4)	0.554
	CTRL	4.0 (1.02)	3.9 (0.73)	-0.02 (-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)	0.659	-0.7 (-2.0 to 0.7)	0.347
	CTRL	11.5 (4.0)	12.7 (4.7)	0.9 (-0.1 to 1.9)	0.083		

SD: Standard deviation; CI: Confidence Interval; INTV: Intervention group; CTRL: Control group; PAM-13: Patient Activation Measure; BPI: Brief Pain Inventory; VAS: Visual analogue Scale; HADS: Hospital Anxiety and Depression Scale; PSEQ: Pain Self-Efficacy Questionnaire; SOC-13: Sense of Coherence; EQ-5D-5L: EuroQoL 5 dimensions 5 level; AIOS: Arizona Integrative Outcome Scale.
Estimates presented are from linear mixed effects model (unadjusted) without random slope.
↑ Increase in scores indicates improvement.
↓ Decrease in scores indicates improvement.

The numbers of participants for each outcome at 3 months follow-up varied between 97- 104 due to some missing response



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	4
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9- 10
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6- 9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/ A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5- 6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	16

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	16
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/ A
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12 and Fig.1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Fig.1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	N/ A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Fig.1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Table 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/ A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/ A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	13
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14- 16
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	4
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	18

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Title page

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

Authors

Torunn Hatlen Nøst [1, 2, *] E-mail: torunn.h.nost@ntnu.no

Aslak Steinsbekk [1] E-mail: aslak.steinsbekk@ntnu.no

Ola Bratås [1, 2] E-mail: ola.bratas@ntnu.no

Kjersti Grønning [1, 2] E-mail: kjersti.gronning@ntnu.no

Affiliation

[1]Department of Public Health and Nursing, Norwegian University of Science and Technology, Trondheim, Norway

[2]Center for Health Promotion Research, Norwegian University of Science and Technology, Trondheim, Norway

[*] Corresponding author

Torunn Hatlen Nøst

PhD-candidate, Department of Public Health and Nursing, Norwegian University of Science and Technology

E-mail: Torunn.h.nost@ntnu.no

Tel. + (47) 73 41 25 34

Postal address

NTNU, Faculty of Medicine and Health science

Department of Public Health and Nursing

Postbox 8905, 7491 Trondheim, Norway

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Abstract

Objectives: To investigate the effects on persons with chronic pain after three months of a group-based chronic pain self-management course compared to a drop-in, low-impact outdoor physical group activity.

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 three 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 ½-hour weekly sessions for a period of six 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 one-hour weekly sessions that consisted of walking and simple strength exercises for a period of six weeks.

Main outcomes: The primary outcome was patient activation assessed using the Patient Activation Measure (PAM). 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 30s Chair to Stand Test.

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

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

Trial registration: ClinicalTrials.gov: NCT02531282

Funding: The Research Council of Norway, grant number 238331

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 chronic pain for three 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 assessor of the objective outcome 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

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 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]

Due to the comprehensive impact of chronic pain, treatment options aim to embrace different aspects related to the condition.[5] Thus, the various treatment options range from pharmacological and interventional treatments delivered by specialist caregivers to non-pharmacological treatments, such as exercise, psychological approaches and support and advice regarding how to manage everyday life with pain, typically provided by primary caregivers.[5, 6] 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,[7] indicating that in many cases, patients must self-manage pain on an everyday basis.[8]

Self-management includes the actions that people take to recognise, treat, manage and engage in behaviours that affect their health.[9] Furthermore, self-management 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.[10] 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.[11] Required self-management skills are related to problem solving, decision making, resource utilisation, forming a patient-healthcare provider relationship and taking action.[12] 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.[8, 9] There has therefore been an increase in initiatives to promote patients' engagement by supporting them to take charge of their own health and healthcare outcomes.[13, 14] For chronic pain, this typically include interventions focusing on approaches such as pacing, relaxation, cognitive behavioural strategies and education [15].

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,[16, 17] whereas one systematic

review concluded there were minor effects, such as improvements in self-management skills, pain, symptoms and functioning.[18] 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.[19] Both aerobic and anaerobic exercise as well as meditation and yoga have been found to have beneficial effects on chronic pain conditions.[20, 21] 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.[22]

Due to the need for treatment and support over time, people with chronic pain utilise a variety of different healthcare services and have been found to have a significantly higher use of healthcare services compared to individuals without chronic pain.[23] Furthermore, due to the vast consequences and high prevalence of chronic pain, the condition is considered a public health challenge that calls for effective, safe and sustainable interventions.[3, 6] Self-management programmes are recommended to be community-based so that a large number of people can access them.[12] 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,[24, 25] targeted specific age groups,[26] focused on lay-led interventions[27, 28] or investigated interventions delivered by specialists and multidisciplinary healthcare services.[29] 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.[30] 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 three months of a group-based chronic pain self-management course compared to a drop-in, low-impact outdoor physical activity delivered through an easily accessible healthcare service on the primary outcome, patient activation and a range of secondary outcomes.

Methods

An open, pragmatic, parallel group RCT was conducted from August 2015 through March 2017. The assessments at the three-month follow-up are reported in this paper. The trial was designed to measure outcomes at six and 12 months as well.[31] The guidelines provided in the Consolidated Standards of Reporting Trials (CONSORT),[32] including its extensions for pragmatic trials[33] and non-pharmacological treatment interventions,[34] were used to guide the presentation of the results. The protocol for the trial has been published previously.[31] 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.[35] 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 (e.g. 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 three 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 one 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 (i.e. that they would attend one of two activities delivered in groups during the day for a period of six 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,[36] 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 conducted 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 pre-set date for a course was reached.

All outcomes were measured at the baseline and at three 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 socio-demographic 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 to their corresponding data files.

Ethics

The Regional Committee for Medical and Health Research Ethics in Southeast Norway approved the study (2015/ 1030/ REK sørøst). The participants were informed of the trial both orally and in writing, and written consent to participate was collected from each participant before enrolment. The trial was registered at ClinicalTrials.gov in August 2015 (number NCT02531282).

Outcome measures

Self-reported socio-demographic variables, such as gender, age, marital status, education, work status, main reason for pain categorised according to the International Classification of Primary care-2 (ICPC-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 three months.

Primary outcome measure

The self-management course aimed to increase the participants' knowledge, skills and confidence in managing everyday life with chronic pain.[31] Patient activation is considered a key element in the management of one's health and healthcare,[11] it is emphasised in chronic illness models[37] and a typical aim of self-management interventions.[38] 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).[39] 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.[39]

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.[11] 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.[40] 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.[11] The PAM-13 is translated and validated for use in a Norwegian context.[41] 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)[41] and in a RCT of a hospital's out-patient self-management education for patients with polyarthritis (Cronbach's alpha 0.80).[24] 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), [42, 43] including pain, physical functioning, emotional functioning and coping.[43] In addition, systematic reviews and similar studies on self-management were reviewed for relevant outcome measures. To include the possible influence of the intervention on all relevant domains, a total of seven questionnaires, two single-item questions and one physical test were included as secondary outcomes, which are presented in the following sections.

Having chronic pain was the main inclusion criteria, and pain was accordingly an important domain to measure. The short version of the Brief Pain Inventory (BPI) applying a 24-hour 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.[44] The instrument has been translated to Norwegian (Cronbach's alpha 0.87 for pain severity and 0.92 for the interference scale)[45] and has been used in Norwegian studies of a multidisciplinary pain management programme[46] and among patients with osteoarthritis (Cronbach's alpha >0.80).[47] 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).[48] 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.[48]

Psychological distress is commonly reported among individuals suffering from chronic pain, [2, 49] and the use of the cognitive strategies in the self-management course makes psychological distress an important domain to assess. The self-rating instrument, the Hospital Anxiety and Depression Scale (HADS), with 14 items divided into subscales for depression and anxiety,[50] 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)[51] as well as in a Norwegian large population study (HUNT) (Cronbach's alpha 0.80 for the anxiety subscale and 0.76 for the depression subscale).[52] It was also used for a study on a chronic pain multidisciplinary rehabilitation programme.[53] 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 is a concept related to the confidence people have that they can successfully execute a course of action to accomplish a desired outcome in a given situation,[54] and as such, it is a domain that could be affected by the intervention. The concept was measured using the Pain Self-Efficacy Questionnaire (PSEQ).[55] 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.[55] The scale has shown strong psychometric qualities (Cronbach's alpha 0.92)[55] and was previously used in a Norwegian study.[56] 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.[57] The SOC is often related to salutogenesis, which is an essential component of the activities at the HLC.[30] Thus, this was considered a relevant concept to measure. 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).[57] 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[58] and in a study on multidisciplinary rehabilitation for persons with chronic musculoskeletal pain (Cronbach's alpha 0.83).[59] In the present study, the Cronbach's alpha at the baseline assessment was 0.87.

The self-management course included topics regarding how to manage everyday life with chronic pain, and hence quality of life was a relevant domain to measure. A generic instrument, the EuroQoL (EQ-5D-5L), was used to assess health-related quality of life.[60] 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'.[61] The descriptive core was converted to an index value for health status using the Danish value set, giving a range from 1 (perfect health) to 0 (death).[60, 61] The instrument has been validated in similar populations[62] and in a Norwegian context (Cronbach's alpha 0.69).[63] 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.[64] 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 wellbeing'. The scale's anchoring points were 'worst you have ever been' (0) and 'best you have ever been' (100).[64] AIOS has been found to be a valid measure of assessing well-being[64] and was previously used in a Norwegian study.[24]

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.[65]

Because physical exercise has been found to have beneficial effects on chronic pain,[20, 21] 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.[65]

In addition, an objective measure of physical ability was included using the 30s Chair to Stand Test to measure lower body strength.[66] The test has been validated for a broader population.[67]

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.[31] 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,[12] recommendations found in the literature on chronic pain self-management (e.g.[68-72]) and the guidelines for the HLC[30] in addition to drawing upon 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,[68-70, 72] and introduction of movement exercises.[73]

The course utilised elements from cognitive behavioural therapy (CBT) because this approach has been found to be beneficial for teaching chronic pain self-management[68-70, 72] 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 concluding each session aimed to improve balance, posture and breathing, providing the participants with techniques to increase body awareness and the ability to relax based on psychomotor physiotherapy.[71] 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.

The self-management course was delivered as 2.5-hour weekly group sessions during the day (12.30 pm - 15.00 pm) for a period of six 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.

PLEASE INSERT TABLE 1 ABOUT HERE

The control group activity

Offering an activity to all participants in the trial was recognised as ethical and a good clinical practice.[74] Because physical activity has been found to have beneficial effects on chronic pain conditions,[20-22] 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 one-hour drop-in session during the day (13.00 pm - 14.00 pm) for a period of six weeks, which consisted of walking and simple strength exercises (e.g. 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.[24] 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 standard deviation (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 was a-priori considered statistically significant. No interim analysis was performed.

The mean scores for all observed outcomes at the baseline and at the three-month follow-up assessments were calculated independently. Changes in work status and pain medication (categorical data) were analysed using Pearson Chi-Square 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 (ITT) and per protocol procedures. To take the intra-class correlation between measurements in the same subject into account, the analyses were performed using a two-level linear mixed model.[75] Mixed models allow for the use of all available data in the presence of dropouts, and thus there was no need for multiple imputations.[75] 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 three months' and 3) 'intervention three 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,[76] 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 co-authors and a statistician. All analyses were performed using Stata 14 (StataCorp. 2014. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP).

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 three-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 the data collected during the follow-up appointment.

PLEASE INSERT FIGURE 1 ABOUT HERE

Figure 1. Participants flow through the study

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.

PLEASE INSERT TABLE 2 ABOUT HERE

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 seven 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 practicing 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 three months than a drop-in, low-impact outdoor physical activity (estimated mean difference -0.5, 95 % Confidence Interval (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 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 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 (data not shown). There was no statistical significant differences between the groups for these variables.

PLEASE INSERT TABLE 3 ABOUT HERE

Discussion

There was no effect of the group-based chronic pain self-management course after three months compared to 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 three 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.[24] Hence, a difference between the two groups regarding the primary outcome of six points may be difficult to detect after three months. Valid and reliable outcome measures were chosen in accordance with recommendations from the IMMPACT;[42] 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 six weekly sessions. This is similar to interventions in other studies, some of which have shown an effect[26, 27, 77] and others that have not.[28, 78] For instance, a study on older adults with chronic pain showed no effect of a chronic pain self-management course using CBT components,[78] 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 to both an exercise-attention control and a waiting-list group when expanding the intervention.[26] 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 to a usual care control.[28] 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.[19] Walking has been found to be a feasible, acceptable and safe intervention for people with rheumatoid arthritis,[79] and it is recommended for people with chronic musculoskeletal pain.[22] In addition, tailored physical activity has been found to be promising for back or upper body pain,[80] whereas there is low to moderate evidence for the efficacy of walking related to the reduction of low back pain.[81] However, in the present study, there were no significant changes after three months (i.e. 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, [82] and as the clinical relevance of the item in relation to a non-pharmacological intervention is uncertain, the finding is not further discussed. Nevertheless, there are studies on self-management interventions that have shown improvements in pain,[26, 77] indicating that such interventions could be the cause. For instance, according to Nicholas et al., the pain self-management course group reported significantly less severe usual pain at the one-month follow-up compared to the exercise-attention control group,[26] and LeFort et al. showed that participants in a psychoeducation programme for chronic pain self-management had reduced bodily pain compared to a wait-list control group.[77] However, there have also been cases in which both the intervention and the usual care control group reported a reduction in pain.[28] As suggested by Mehlsen and colleagues,[28] 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.[30] 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.[11, 39] 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.[83] 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 to 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 three months.

Conclusions

During this RCT, there was no support for the self-management course having a better effect after three 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.

Abbreviations

CBT: Cognitive Behavioural Therapy; HLC: Health Life Centre; RCT: Randomised Controlled Trial; CONSORT: Consolidated Standards of Reporting Trials; ICPC-2: International Classification of Primary Care 2. Edition; PAM-13: Patient Activation Measure; BPI: Brief Pain Inventory; VAS: Visual Analogue Scale; HADS: Hospital Anxiety and Depression Scale; PSEQ: Pain Self-Efficacy Questionnaire; SOC-13: Sense of Coherence; EQ-5D-5L: EuroQoL 5 Dimensions 5 Level; AIOS: Arizona Integrative Outcome Scale; SD: Standard Deviation; CI: Confidence Interval; IMMPACT: Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials

Declarations

Ethics approval and consent to participate

All informants signed an informed consent form after having received oral and written information to enable them to make an informed choice regarding participation. Approval for the trial was obtained from the director for health and social affairs in the municipality and

from the Regional Committee for Medical and Health Research Ethics (REK) (2015/ 1030/ REK sørøst).

Consent for publication

Not applicable.

Availability of data and materials

De-identified datasets are available from the corresponding author upon reasonable request.

Competing interest

The authors declare that they have no competing interests.

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Authors' contributions

THN, AS, OB and KG were responsible for the design of the study. THN performed the data collection, analysed the data and interpreted the results along with AS, OB and KG. THN drafted the manuscript. All authors provided input for the manuscript and read and approved the final version.

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Session:	Main topics:

Table 1. Outline of the self-management course

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. Summarize the whole course. How will you use what you have learned? Information on activities at the HLC and in the municipality.

Table 2. Participants' characteristics at baseline.

Characteristics	ALL (N= 121)	INTV (n= 60)	CTRL (n= 61)

Female, n (%)	106 (87.6 %)	53 (88.3 %)	53 (86.9 %)
Age years, mean (SD), (range)	52.7 (11.7) (23- 74)	52.1 (11.4) (27- 71)	53.3 (12.1) (23- 74)
Living with someone, n (%)	86 (71.1 %)	43 (71.7 %)	43 (70.5 %)
Highest level of education, n (%)			
lower secondary school or less	8 (6.6 %)	4 (6.7 %)	4 (6.6 %)
upper secondary school	56 (46.3 %)	28 (46.7 %)	28 (45.9 %)
higher education (college or university)	57 (47.1 %)	28 (46.7 %)	29 (47.5 %)
Main reason for pain, n (%):			
musculoskeletal diseases, ICPC-2 chapter L	93 (76.9 %)	46 (76.7 %)	47 (77.0 %)
neuro system diseases, ICPC-2 chapter N	16 (13.2 %)	10 (16.7 %)	6 (9.8 %)
general and unspecified, ICPC-2 chapter A	12 (9.9 %)	4 (6.7 %)	8 (13.1 %)
Pain duration, n (%)			
7- 11 months	2 (1.7 %)	2 (3.3 %)	0 (0 %)
1- 5 years	24 (19.8 %)	12 (20.0 %)	12 (19.7 %)
6- 9 years	19 (15.7%)	11 (18.3 %)	8 (13.1 %)
≥ 10 years	76 (62.8 %)	35 (58.3 %)	41 (67.2 %)
More than one chronic condition, n (%)	76 (62.8 %)	32 (53.3 %)	44 (72.1 %)
Work status, n (%)			
working, full or part time	31 (25.6%)	13 (21.7 %)	18 (29.5 %)
disability pension, full or graded	56 (46.3 %)	33 (55 %)	23 (37.7 %)
sick leave, full or graded	20 (16.5 %)	8 (13.3 %)	12 (19.7 %)
retired	14 (11.6%)	6 (10.0 %)	8 (13.1 %)
Pain medication, n (%):			
prescription-only	51 (42.1 %)	23 (38.3 %)	28 (45.9 %)
without prescription	41 (33.9 %)	19 (31.7 %)	22 (36.1 %)
do not use pain medication	29 (24.0 %)	18 (30.0 %)	11 (18.0 %)
Healthcare utilization, last 3 months:			
visits general practitioner, mean (SD)	1.9 (1.9)	1.6 (1.7)	2.1 (2.0)
visits physiotherapist, mean (SD)	4.8 (6.3)	4.5 (5.9)	5.1 (6.8)
stays rehabilitation centre, mean (SD)	0.07 (0.3)	0.1 (0.3)	0.05 (0.2)
visits hospital outpatient clinic, mean (SD)	0.6 (1.1)	0.5 (0.9)	0.6 (1.3)
admission hospital, mean (SD)	0.1 (0.7)	0.2 (1.0)	0.02 (0.1)
number of days, mean (SD), (range)	0.1 (0.8) (0-8)	0.2 (1.2) (0-8)	0.02 (0.1) (0-1)

INTV: intervention group; CTRL: control group; ICPC- 2: International Classification of Primary Care, Second edition; SD: standard deviation

912 Table 3. Observed mean (SD) at baseline and 3 months, and estimated differences (95 % Confidence Intervals (CI)) within groups from baseline to 3 months
913 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)	Diff (95 % CI)	*p*-value	Diff (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		

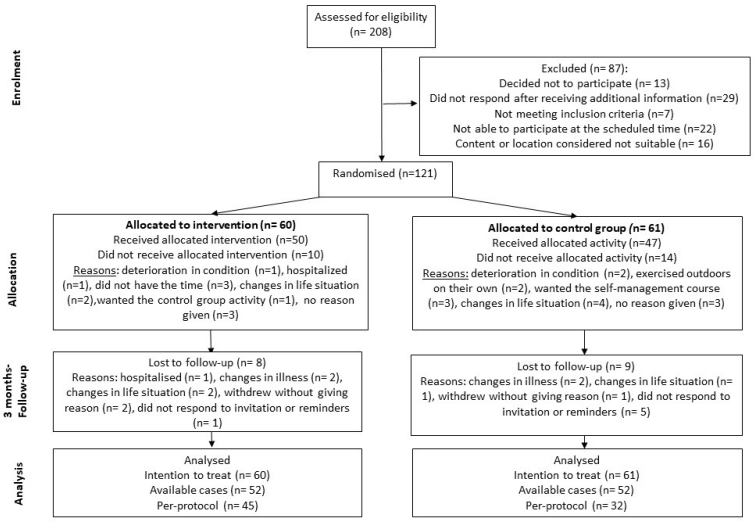
SD: Standard deviation; INTV: Intervention group; CTRL: Control group; PAM-13: Patient Activation Measure; BPI: Brief Pain Inventory; VAS: Visual analogue Scale; HADS: Hospital Anxiety and Depression Scale; PSEQ: Pain Self-Efficacy Questionnaire; SOC-13: Sense of Coherence; EQ-5D-5L: EuroQoL 5 dimensions 5 level; AIOS: Arizona Integrative Outcome Scale.

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

↑ Increase in scores indicates improvement.

↓ Decrease in scores indicates improvement.

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



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Checklist of items for reporting pragmatic trials

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Reported on page NO
Title and abstract	1	How participants were allocated to interventions (eg, “random allocation,” “randomised,” or “randomly assigned”)		1- 2
Introduction				
Background	2	Scientific background and explanation of rationale	Describe the health or health service problem that the intervention is intended to address and other interventions that may commonly be aimed at this problem	4- 5
Methods				
Participants	3	Eligibility criteria for participants; settings and locations where the data were collected	Eligibility criteria should be explicitly framed to show the degree to which they include typical participants and/or, where applicable, typical providers (eg, nurses), institutions (eg, hospitals), communities (or localities eg, towns) and settings of care (eg, different healthcare financing systems)	6- 7
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered	Describe extra resources added to (or resources removed from) usual settings in order to implement intervention. Indicate if efforts were made to standardise the intervention or if the intervention and its delivery were allowed to vary between participants, practitioners, or study sites	12- 13
			Describe the comparator in similar detail to the intervention	13- 14

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Reported on page NO
Objectives	5	Specific objectives and hypotheses		6
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors)	Explain why the chosen outcomes and, when relevant, the length of follow-up are considered important to those who will use the results of the trial	8- 12
Sample size	7	How sample size was determined; explanation of any interim analyses and stopping rules when applicable	If calculated using the smallest difference considered important by the target decision maker audience (the minimally important difference) then report where this difference was obtained	14
Randomisation—sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification)		7
Randomisation—allocation concealment	9	Method used to implement the random allocation sequence (eg, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned		7
Randomisation—implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups		7
Blinding (masking)	11	Whether participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	If blinding was not done, or was not possible, explain why	7
Statistical methods	12	Statistical methods used to compare groups for primary outcomes; methods for additional		14- 15

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Reported on page NO
		analyses, such as subgroup analyses and adjusted analyses		
Results				
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended)—specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome; describe deviations from planned study protocol, together with reasons	The number of participants or units approached to take part in the trial, the number which were eligible, and reasons for non-participation should be reported	Flow chart: Figure 1. 15
Recruitment	14	Dates defining the periods of recruitment and follow-up		6
Baseline data	15	Baseline demographic and clinical characteristics of each group		Table 1. 15- 16
Numbers analysed	16	Number of participants (denominator) in each group included in each analysis and whether analysis was by “intention-to-treat”; state the results in absolute numbers when feasible (eg, 10/20, not 50%)		14- 15
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (eg, 95% CI)		Table 3. Estimates with its precision given as 95% CI used rather than effect sizes.

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Reported on page NO
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating which are prespecified and which are exploratory		Per-protocol analyses were prespecified, page 15
Adverse events	19	All important adverse events or side effects in each intervention group		16- 17
Discussion				
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes		18- 20
Generalisability	21	Generalisability (external validity) of the trial findings	Describe key aspects of the setting which determined the trial results. Discuss possible differences in other settings where clinical traditions, health service organisation, staffing, or resources may vary from those of the trial	18- 20
Overall evidence	22	General interpretation of the results in the context of current evidence		18- 20

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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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Title page

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

Authors

Torunn Hatlen Nøst [1, 2, *] E-mail: torunn.h.nost@ntnu.no

Aslak Steinsbekk [1] E-mail: aslak.steinsbekk@ntnu.no

Ola Bratås [1, 2] E-mail: ola.bratas@ntnu.no

Kjersti Grønning [1, 2] E-mail: kjersti.gronning@ntnu.no

Affiliation

[1]Department of Public Health and Nursing, Norwegian University of Science and Technology, Trondheim, Norway

[2]Center for Health Promotion Research, Norwegian University of Science and Technology, Trondheim, Norway

[*] Corresponding author

Torunn Hatlen Nøst

PhD-candidate, Department of Public Health and Nursing, Norwegian University of Science and Technology

E-mail: Torunn.h.nost@ntnu.no

Tel. + (47) 73 41 25 34

Postal address

NTNU, Faculty of Medicine and Health science

Department of Public Health and Nursing

Postbox 8905, 7491 Trondheim, Norway

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Abstract

Objectives: To investigate the effects on persons with chronic pain after three months of a group-based chronic pain self-management course compared to 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 three 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 ½-hour weekly sessions for a period of six 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 one-hour weekly sessions that consisted of walking and simple strength exercises for a period of six weeks.

Main outcomes: The primary outcome was patient activation assessed using the Patient Activation Measure (PAM). 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 30s Chair to Stand Test.

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

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

Trial registration: ClinicalTrials.gov: NCT02531282

Funding: The Research Council of Norway, grant number 238331

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 three 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 second 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

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 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 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 exercise 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 three months of a group-based chronic pain self-management course compared to 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 RCT was conducted from August 2015 through March 2017. The assessments at the three-month follow-up are reported in this paper. The trial was designed to measure outcomes at six and 12 months as well.[25] The guidelines provided in the Consolidated Standards of Reporting Trials (CONSORT),[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 (e.g., 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 three 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 one 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 (i.e. that they would attend one of two activities delivered in groups during the day for a period of six 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 pre-set date for a course was reached.

All outcomes were measured at the baseline and at three 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 socio-demographic 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 to their corresponding data files.

Ethics

The Regional Committee for Medical and Health Research Ethics in Southeast Norway approved the study (2015/ 1030/ REK sørøst). The participants were informed of the trial both orally and in writing, and written consent to participate was collected from each participant before enrolment. The trial was registered at ClinicalTrials.gov in August 2015 (number NCT02531282).

Outcome measures

Self-reported socio-demographic variables, such as gender, age, marital status, education, work status, main reason for pain categorised according to the International Classification of Primary care-2 (ICPC-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 three 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 a RCT of a hospital's out-patient 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-hour 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 (HADS), 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 (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 wellbeing'. 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 30s 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 upon 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 utilised 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.

The self-management course was delivered as 2.5-hour weekly group sessions during the day (12.30 pm - 15.00 pm) for a period of six 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.

PLEASE INSERT TABLE 1 ABOUT HERE

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 one-hour drop-in session during the day (13.00 pm - 14.00 pm) for a period of six weeks, which consisted of walking and simple strength exercises (e.g., 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 standard deviation (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 was a-priori considered statistically significant. No interim analysis was performed.

The mean scores for all observed outcomes at the baseline and at the three-month follow-up assessments were calculated independently. Changes in work status and pain medication (categorical data) were analysed using Pearson Chi-Square 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 (ITT) and per protocol procedures. To take the intra-class 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 three months' and 3) 'intervention three 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 co-authors and a statistician. All analyses were performed using Stata 14 (StataCorp. 2014. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP).

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 three-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.

PLEASE INSERT FIGURE 1 ABOUT HERE

Figure 1. Participants flow through the study

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.

PLEASE INSERT TABLE 2 ABOUT HERE

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 seven 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 practicing 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 three months than a drop-in, low-impact outdoor physical activity (estimated mean difference -0.5, 95 % Confidence Interval (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 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.

PLEASE INSERT TABLE 3 ABOUT HERE

Discussion

There was no effect of the group-based chronic pain self-management course after three months compared to 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 three 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 three 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 six 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 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 to 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 to 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 three months (i.e. 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., the pain self-management course group reported significantly less severe usual pain at the one-month follow-up compared to the exercise-attention control group,[20] and LeFort et al. showed that

participants in a psychoeducation programme for chronic pain self-management had reduced bodily pain compared to a wait-list control group.[69] 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 to 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 three months.

Conclusions

During this RCT, there was no support for the self-management course having a better effect after three 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.

Abbreviations

CBT: Cognitive Behavioural Therapy; HLC: Health Life Centre; RCT: Randomised Controlled Trial; CONSORT: Consolidated Standards of Reporting Trials; ICPC-2: International Classification of Primary Care 2. Edition; PAM-13: Patient Activation Measure; BPI: Brief Pain Inventory; VAS: Visual Analogue Scale; HADS: Hospital Anxiety and Depression Scale; PSEQ: Pain Self-Efficacy Questionnaire; SOC-13: Sense of Coherence; EQ-5D-5L: EuroQoL 5 Dimensions 5 Level; AIOS: Arizona Integrative Outcome Scale; SD: Standard Deviation; CI: Confidence Interval; IMMPACT: Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials

Declarations

Ethics approval and consent to participate

All informants signed an informed consent form after having received oral and written information to enable them to make an informed choice regarding participation. Approval for the trial was obtained from the director for health and social affairs in the municipality and from the Regional Committee for Medical and Health Research Ethics (REK) (2015/ 1030/ REK sørøst).

Consent for publication

Not applicable.

Availability of data and materials

De-identified datasets are available from the corresponding author upon reasonable request.

Competing interest

The authors declare that they have no competing interests.

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Authors’ contributions

THN, AS, OB and KG were responsible for the design of the study. THN performed the data collection, analysed the data and interpreted the results along with AS, OB and KG. THN drafted the manuscript. All authors provided input for the manuscript and read and approved the final version.

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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. Summarize the whole course. How will you use what you have learned? Information on activities at the HLC and in the municipality.

Table 2. Participants' characteristics at baseline

Characteristics	INTV (n= 60)	CTRL (n= 61)
Female, n (%)	53 (88.3 %)	53 (86.9 %)
Age years, mean (SD), (range)	52.1 (11.4) (27- 71)	53.3 (12.1) (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 utilization, 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)

INTV: intervention group; CTRL: control group; ICPC- 2: International Classification of Primary Care, Second edition; SD: standard deviation

817 Table 3. Observed mean (SD) at baseline and 3 months, and estimated differences (95 % Confidence Intervals (CI)) within groups from baseline to
818 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)	Diff (95 % CI)	*p*-value	Diff (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		

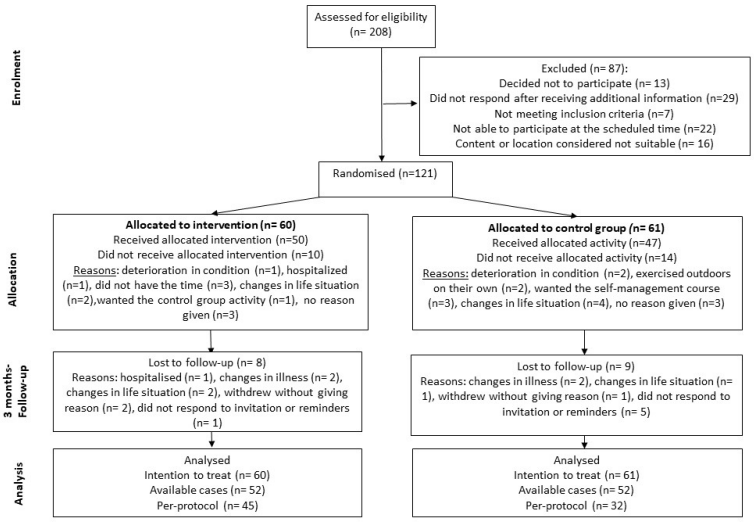
SD: Standard deviation; INTV: Intervention group; CTRL: Control group; PAM-13: Patient Activation Measure; BPI: Brief Pain Inventory; VAS: Visual analogue Scale; HADS: Hospital Anxiety and Depression Scale; PSEQ: Pain Self-Efficacy Questionnaire; SOC-13: Sense of Coherence; EQ-5D-5L: EuroQoL 5 dimensions 5 level; AIOS: Arizona Integrative Outcome Scale.

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

↑ Increase in scores indicates improvement.

↓ Decrease in scores indicates improvement.

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



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Checklist of items for reporting pragmatic trials

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Reported on page NO
Title and abstract	1	How participants were allocated to interventions (eg, “random allocation,” “randomised,” or “randomly assigned”)		1- 2
Introduction				
Background	2	Scientific background and explanation of rationale	Describe the health or health service problem that the intervention is intended to address and other interventions that may commonly be aimed at this problem	4- 5
Methods				
Participants	3	Eligibility criteria for participants; settings and locations where the data were collected	Eligibility criteria should be explicitly framed to show the degree to which they include typical participants and/or, where applicable, typical providers (eg, nurses), institutions (eg, hospitals), communities (or localities eg, towns) and settings of care (eg, different healthcare financing systems)	6- 7
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered	Describe extra resources added to (or resources removed from) usual settings in order to implement intervention. Indicate if efforts were made to standardise the intervention or if the intervention and its delivery were allowed to vary between participants, practitioners, or study sites	12- 13
			Describe the comparator in similar detail to the intervention	13- 14

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Reported on page NO
Objectives	5	Specific objectives and hypotheses		6
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors)	Explain why the chosen outcomes and, when relevant, the length of follow-up are considered important to those who will use the results of the trial	8- 12
Sample size	7	How sample size was determined; explanation of any interim analyses and stopping rules when applicable	If calculated using the smallest difference considered important by the target decision maker audience (the minimally important difference) then report where this difference was obtained	14
Randomisation—sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification)		7
Randomisation—allocation concealment	9	Method used to implement the random allocation sequence (eg, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned		7
Randomisation—implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups		7
Blinding (masking)	11	Whether participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	If blinding was not done, or was not possible, explain why	7
Statistical methods	12	Statistical methods used to compare groups for primary outcomes; methods for additional		14- 15

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Reported on page NO
		analyses, such as subgroup analyses and adjusted analyses		
Results				
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended)—specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome; describe deviations from planned study protocol, together with reasons	The number of participants or units approached to take part in the trial, the number which were eligible, and reasons for non-participation should be reported	Flow chart: Figure 1. 15
Recruitment	14	Dates defining the periods of recruitment and follow-up		6
Baseline data	15	Baseline demographic and clinical characteristics of each group		Table 1. 15- 16
Numbers analysed	16	Number of participants (denominator) in each group included in each analysis and whether analysis was by “intention-to-treat”; state the results in absolute numbers when feasible (eg, 10/20, not 50%)		14- 15
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (eg, 95% CI)		Table 3. Estimates with its precision given as 95% CI used rather than effect sizes.

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Reported on page NO
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating which are prespecified and which are exploratory		Per-protocol analyses were prespecified, page 15
Adverse events	19	All important adverse events or side effects in each intervention group		16- 17
Discussion				
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes		18- 20
Generalisability	21	Generalisability (external validity) of the trial findings	Describe key aspects of the setting which determined the trial results. Discuss possible differences in other settings where clinical traditions, health service organisation, staffing, or resources may vary from those of the trial	18- 20
Overall evidence	22	General interpretation of the results in the context of current evidence		18- 20

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