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The effect of a lay-led, group-based self-management program for patients with chronic pain: a randomized controlled trial of the Danish version of the Chronic Pain Self-Management Programme

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Abstract

The Stanford Chronic Pain Self-Management Programme (CPSMP) consists of 6 2½-hour weekly workshops focusing on how to manage pain in daily life. The workshops are facilitated by 2 workshop leaders of whom at least 1 must suffer from a long-term pain condition. The program is highly structured and manualized. Only few controlled trials testing the effect of CPSMP exist. Enrolled in the study were 424 adults from 19 Danish municipalities, (72% women; age: 25-93 years) with pain of any etiology and great variation in pain history (0-50 yrs). Of these, 216 were randomized to a lay-led version of the CPSMP. The primary outcome was pain-related disability. Secondary outcomes were pain, pain catastrophizing, self-efficacy, emotional distress, physical symptoms, and illness worry. Outcomes were measured before randomization, immediately after the CPSMP (response rate: 94%), and at 3-month follow-up (response rate: 92%). National register data on health expenditure were obtained to examine effects on health care use. ClinicalTrials. gov Identifier: NCT01306747. The CPSMP had no effect on the primary outcome pain-related disability or on health expenditure during intervention and follow-up period. Small positive effects on emotional distress and illness worry 3 months after CPSMP were observed. Lay-led CPSMP is not recommended as treatment for chronic pain-related disability. This heterogeneous group of patients with pain did not benefit from the CPSMP except for a small, but clinically insignificant improvement in psychological well-being.

Keywords: Chronic pain, Lay-led, Self-management, Patient education, Chronic Pain Self-Management Programme

1. Introduction

The prevalence of chronic pain has been estimated to be 27% across countries in the European Union.[19] Persons with chronic pain use the health care system about twice as much as persons without pain.[10,18] Psychological treatment of pain has proved efficient in improving quality of life in adults with chronic pain,[9,36] but because specialized treatment is often sparse,[24] simple and low-cost interventions may have relevance. Lay-led, self-management programs have been developed as accessible and affordable interventions for persons suffering from chronic conditions. A Cochrane review examining the effect of lay-led patient education programs for chronic conditions

concluded that evidence suggests significant, but small short-term effects on self-efficacy, self-rated health, symptom management, and exercise.[15] A review examining self-management interventions for chronic musculoskeletal pain found that courses led by health care professionals in a group setting with a duration of <8 weeks and including a psychological component were most effective.[5]

In Denmark, psychological pain treatment is self-funded and not generally available. Therefore, the Danish Committee for Health Education obtained financial support from The Tryg Foundation to implement and evaluate a low-cost intervention with potential for rapid and large-scale dissemination. On this background, a lay-led version of the Chronic Pain Self-Management Programme (CPSMP) was selected for evaluation.

The CPSMP is a patient education program.[20] It emerged from the self-management programs from the Stanford University with the aim to provide participants with tools for managing their health and staying active.[23] The CPSMP is based on the Arthritis Self-Management Program, which has demonstrated efficiency in improving pain, self-efficacy, health behaviors, and health care utilization in patients with arthritis, both with laypersons and health care professionals leading the workshops.[22] The CPSMP was adapted to be more directly applicable to various idiopathic chronic pain conditions.[20]

The teaching methods used in the CPSMP are levelled at increasing participants' self-efficacy, ie, their belief in their ability to implement behavioral changes.[4] The program has a high degree of participant involvement and mutual exchange of experience. The program is not symptom directed; the intention is to optimize pain management and to support rehabilitation and treatment processes.

So far, the CPSMP has been evaluated in a few randomized controlled trials (RCTs). In the first RCT on the CPSMP, 110 participants with idiopathic pain conditions reported significantly less pain, less dependency on others, improved mental health, increased activity, and increased life satisfaction 3 months after a nurse-delivered CPSMP compared with a waitlist control.[20] A pilot study with 45 older adults found small effects on physical role function and pain intensity[12] but no effect was found in the main trial including 256 older patients with chronic pain receiving nurse or psychologist-led CPSMP when compared with patients receiving written material only.[11] However, when adding more treatment time and involving more experienced health care professionals as treatment providers, a more recent study found an effect on pain distress, disability and pain beliefs in 141 older adults[29] and these effects were to some degree maintained one year later.[30]

Previously, we examined the feasibility of a Danish lay-led version of the CPSMP in an uncontrolled study including 87 patients with chronic pain. Our results indicated high rates of patient satisfaction and modest improvements in several pain-related outcomes that were stable at 3-month follow-up.[26]

This RCT examines the effectiveness of the Danish version of lay-led CPSMP.

2. Methods

2.1. Recruitment

Municipal health support centers in 75 Danish municipalities were invited to participate in a study testing the Danish version of the CPSMP. Of these, 22 accepted participation. Each center was required to recruit 16 to 32 participants for the RCT. Three centers enrolled an insufficient number, and their participation was cancelled. Another 3 centers only recruited 15 eligible citizens and received dispensation to enter the RCT. Three centers offered 2 courses yielding 22 courses to be included in the RCT. Participants were recruited from January 2011 to May 2012 at which time the planned number of participants had been included. The follow-up period ended in December 2013. Registry data regarding health expenditure were obtained in January 2015.

Information about the CPSMP and the scientific evaluation was given at information meetings, in local newspapers, and by professionals in health care and social work. After receiving oral and written information and being screened for eligibility by the local coordinator, citizens could sign up for the CPSMP.

The following inclusion criteria were applied:
(1) Pain duration >3 months
(2) Self-rated pain intensity ≥5 on a 10-point Likert scale at the time of enrollment
(3) Age >18 years
(4) Understands, speaks, and reads Danish
(5) Pain should not be caused by conditions presently undergoing significant change where the condition and not pain itself is of primary concern to the participant, eg, curative cancer treatment, pregnancy
(6) No substance abuse, psychiatric, or physical disease preventing participation in weekly sessions

2.2. Sample

Statistical power calculations based on the effect sizes reported in the previous trials of the CPSMP[11,20] and an expected dropout rate of 35% indicated inclusion of 250 in both the intervention and the control arm, which would result in 2 × 163 cases for the analyses. During the inclusion period, it was not possible to implement a sufficient number of CPSMP courses to reach this number. However, the attrition rate was considerably lower than expected both at T2 and T3 follow-ups. The sample size therefore exceeded the planned number of cases for the analysis.

2.3. Randomized controlled trial procedure

At enrollment, eligible citizens completed a baseline questionnaire, signed informed consent, and mailed both to Aarhus University for registration and randomization (T1) 2 to 14 days before the first CPSMP session. After randomization, the local coordinators received a list of participants for each course and informed all enrolled subjects about group allocation. After the last session, the first follow-up questionnaire was mailed to all participants with a postage prepaid envelope (T2). If a response was not received within 2 weeks, a reminder was sent. After 4 weeks, the participants were contacted by phone and asked if they were willing to participate in a short telephone interview about 3 selected outcome measures. Five months after the initial CPSMP session (T3), the same procedure was followed with the second follow-up questionnaire which included program evaluation questions. See **Figure 1** for an overview of participant flow.

2.4. Randomization

The participating municipalities had the flexibility of offering courses with a minimum of 8 and a maximum of 16 citizens. Therefore, the third author (EØ) prepared 32 randomizations with a maximum of 32 citizens. Each of these randomizations consisted of one block randomization of 16 (8 randomized to CPSMP and 8 randomized to control) and 8 block randomizations of 2 (1 randomized to CPSMP and 1 to control). The first block of 16 ensured proper randomization of the minimum number of participants required, the following 8 blocks of 2 allowed the municipality to stop the intake at will and still ensure that the difference between the groups would be no more than one. The 32 randomizations were conducted by means of a computer algorithm that used predefined concealed random numbers. When enrolling in the study, the participants returned the baseline questionnaire and a signed consent form by post. Before this envelope was opened, the study coordinator (first author) applied the next randomization in the list to assign the participant to either treatment or control condition.

The study was approved by the Danish Data Protection Agency and the regional research ethics committee, and it was registered at ClinicalTrials.gov Identifier: NCT01306747. All outcomes are listed in the full study protocol approved by the research ethics committee but the Clinical Trials registration includes only 3 outcomes.

2.5. Treatment condition: the CPSMP

The CPSMP consists of 6 2½-hour weekly workshops focusing on how to manage pain in daily life in groups of 8 to 16 participants who suffer from chronic pain. The CPSMP is a lay-led intervention facilitated by 2 workshop leaders of whom at least 1 of the leaders also suffers from a long-term pain condition. The other leader may suffer from a pain condition, other long-term condition, or be a close relative to a person with a long-term condition. The program is highly structured, and the workshop leaders follow a manual when facilitating the process. Central themes in the course encompass the following: managing feelings such as frustration, anger, and depression; managing fatigue, social
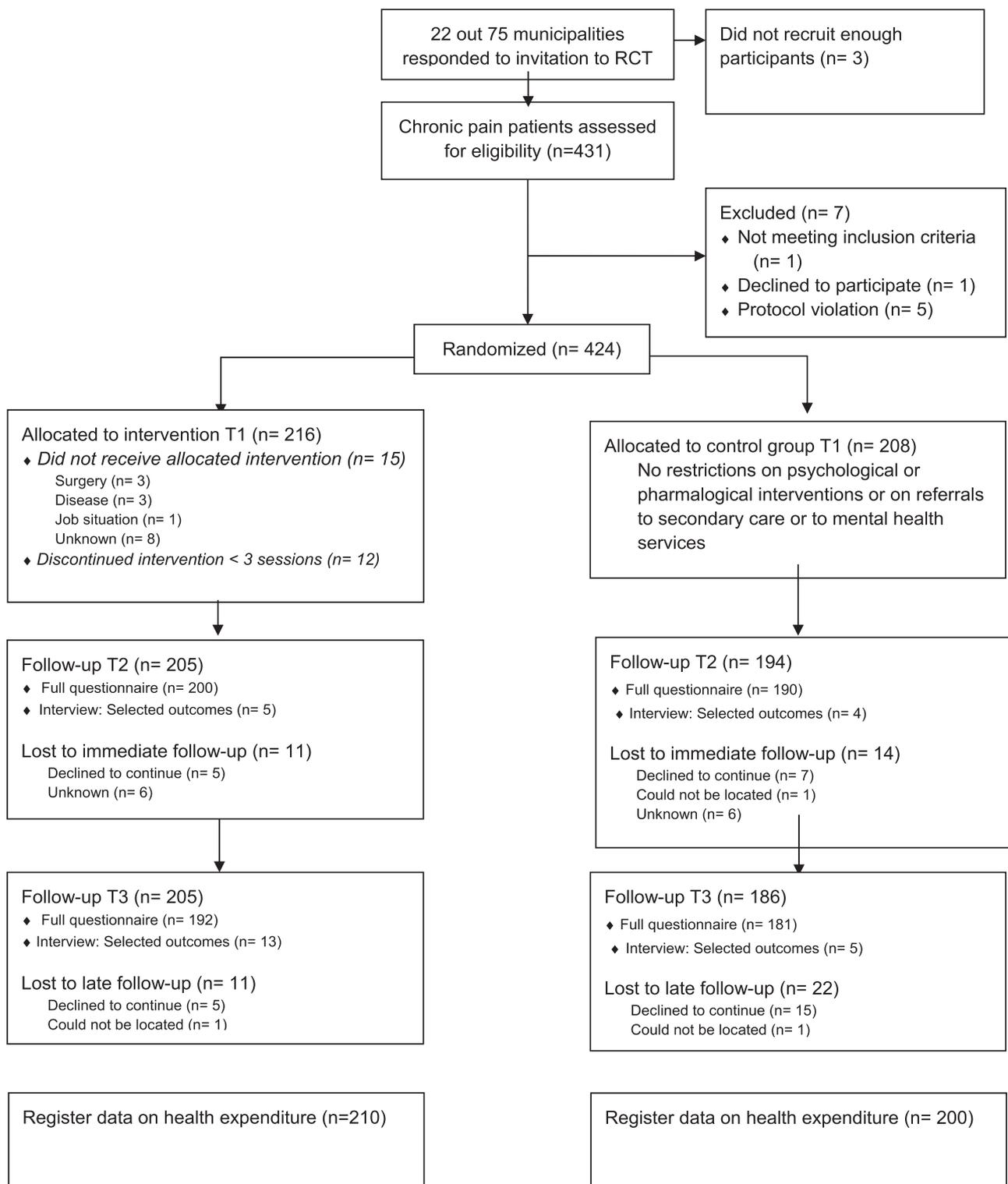
Figure 1. Participant flow-chart. RCT, randomized controlled trial.

isolation and poor sleep quality; improving and maintaining strength, flexibility, and endurance; correct use of medication; effective communication; nutrition; pacing and evaluation of new treatment possibilities. The content of the Danish version of the CPSMP corresponds to the original Canadian version.[20] More specifically, the sessions include lectures and exercises in light physical activity, visualization, relaxation, and communication.

Instructions focus on how participants implement these exercises at home. A major focus is put on implementing *action plans*. *Action plans* involve choosing a goal and determining what activities are needed to achieve it. Afterwards a plan is evaluated. The participants perform *action plans* on a weekly basis, share experiences, and help each other in problem solving related to their pain.

2.6. Ensuring adherence to the CPSMP protocol

The workshop leaders received 4 days of intensive, structured training overseen by master trainers who are certified by the Stanford Patient Education Center to educate workshop leaders. The leaders were evaluated according to the Danish Committee for Health Education's criteria for Stanford self-management program trainers before they were allowed to lead a CPSMP course.[6] The workshop leaders were instructed to follow the manual carefully and to support each other to not improvise or leave out material. During the course, they received supervision 3 times where master trainers monitored their performance while attending the course. After each of these sessions, master trainers gave supervision to the workshop leaders.

2.7. Control condition: treatment as usual

Participants randomized to the control condition were not restricted in terms of access to their usual treatment or new interventions. However, they could not join the CPSMP in their municipality until 5 months after the first session of the course they had signed up for. After this period, they were free to sign up for the CPSMP, but they were not automatically offered participation in the CPSMP.

2.8. Questionnaires

At baseline, questions about sociodemographic parameters, pain duration, and cause of pain were answered. Use of pain medication was measured by 2 self-report items: "Do you take medication for your pain every day" which could be answered *No*, *Yes Over-the-Counter (OTC) drugs*, *Yes prescription drugs*, *Yes several kind of drugs*; and "How often do you take more medication against your pain than planned?" which could be answered *Seldom*, *Several times a week*, *Daily*, *Several times daily*.

2.8.1. Primary outcome

Pain-related disability was the primary outcome. It was measured by the 23-item Modified Roland-Morris Disability Questionnaire, RMDQ.[32,33] A translated Danish version of the 23-item RMDQ has been validated in a sample of 135 patients operated for low-back pain.[2] The RMDQ was developed as a measure of disability related to back pain, but a reworded version of the RMDQ, without reference to the back, has been found to be a reliable and valid measure of pain-related disability for patients with other chronic pain problems as well. The RMDQ includes 23 items where participants answered *Yes* or *No* to statements such as: "I stay at home most of the time because of my pain"; "I only walk short distances because of my pain." Scores range from 0 to 23, with higher scores indicating more severe pain-related disability. Cronbach alpha = 0.789. Test–retest correlation T1-T2: $r = 0.733$.

2.8.2. Secondary outcomes

Pain was measured by a Visual Analogue Scale (VAS) where informants marked "How much pain do you feel right now" from 0 to 100 mm (range 0-100), corresponding to the VAS item from the Short-Form McGill Pain Questionnaire (SF-MPQ).[27] Test–retest correlation T1-T2: $r = 0.523$. Pain measurement by VAS is widely applied in the Danish health care system, but formal validation of a "translated" version is not available. Because of the intuitive nature of the response, validations based on English versions are likely to be applicable also in a Danish context.[16]

Pain catastrophizing. Catastrophizing has broadly been defined as an exaggerated negative orientation toward noxious stimuli. In relation to pain, catastrophizing has consistently been shown to be associated with higher ratings of pain and more distress in reaction to painful stimulation. Pain catastrophizing involves elements of rumination, magnification, and helplessness, which are captured by the Pain Catastrophizing Scale (PCS).[35] A Danish version of the PCS was validated in a sample of 2247 students and 223 patients with pain.[17] This scale consists of 13 items. Participants are asked to reflect on past painful experiences and to indicate the degree to which they experienced each of the 13 thoughts or feelings when experiencing pain on a 5-point scale from 0 (not at all) to 4 (all the time) (range 0-52). Cronbach alpha = 0.913. Test–retest correlation T1-T2: $r = 0.733$.

Pain-related self-efficacy can be considered a personal belief in one's ability to manage pain. This was measured by a 5-item scale inspired by the Arthritis Self-Efficacy Scale (SES).[21] This scale includes 5 items where informants rate on a scale from 1 (very uncertain) to 10 (very certain) their confidence that they can decrease their pain, keep pain from interfering with sleep, keep doing their daily activities, and use other methods than medication to reduce pain (range 5-50). This Danish version has been applied previously in an unpublished evaluation report. Cronbach alpha = 0.832. Test–retest correlation T1-T2: $r = 0.486$.

Illness worry was assessed using the Whiteley-7, which measures the tendency to be bothered by illness worries, eg, "worries that you suffer from a disease you have read or heard about" within the past 4 weeks. Answers are given on a 5-point Likert scale from 1 (not at all) to 5 (extremely) (range 7-35). The Danish version of this scale was validated in a sample of 1785 general practice patients.[7] Cronbach alpha = 0.850. Test–retest correlation T1-T2: $r = 0.685$. We used a cut-off value of 3 of the dichotomized Whiteley-7 Index as an indication of a clinical degree of illness worry.[7]

Emotional distress and physical symptoms were measured by brief subscales of the SCL-90 included in the screening questionnaire for Common Mental Disorders Questionnaire (CMDQ) that was validated in Denmark.[7] The subscales have been validated in various populations, and estimates of sensitivity and specificity have been reported. We used the emotional distress (SCL-8) (range 8-40) and physical symptoms (12 items from the Symptom Checklist Emotional Distress subscale Symptom Checklist Somatization subscale) (range 12-60).[12,13] Participants indicated whether within the past 4 weeks they had been bothered by different symptoms, eg, "headache," "nausea or upset stomach" (physical symptoms), "feeling blue," and "feelings of worthlessness" (emotional distress). Answers were given on a 5-point Likert scale from 1 (not at all) to 5 (extremely). Cronbach alpha = 0.915 and test–retest correlation for emotional distress T1-T2: $r = 0.751$ and Cronbach alpha = 0.772 for physical symptoms and test–retest correlation T1-T2: $r = 0.729$, respectively. A cut-off value of 3 on the emotional distress subscale with dichotomized responses was applied as an indication of clinical distress.[7]

2.8.3. Program evaluation

To evaluate the program, participants at follow-up (T3) were asked to rate: (1) Have you applied any of the skills that you learned from the CPSMP?; (2) Have the skills that you learned from the CPSMP helped you manage your pain?; (3) Would you recommend the CPSMP to other patients with chronic pain? The answers were given on a 5-point Likert scale from 0 (not at all) to 4 (greatly).

2.9. Health expenditure

Denmark has a tax-financed health care system in which 98% of the population is registered with a specific primary care physician, who acts as a gatekeeper to secondary health care. For both primary and secondary health care, the majority of services are free of charge. Every contact to the health care system is registered using a unique personal identification number. Using this unique personal identification number, we linked the trial data to data on health expenditure from 3 national patient registries. Health care use related to general and psychiatric hospital inpatients and outpatients is reported to the National Patient Registry[25] and the Danish Psychiatric Central Research Register.[28] Use of primary health care and non–hospital-based specialists, including physiotherapists and psychologists, is reported to the National Health Service Register.[3] Health care utilization is converted to health expenditure via diagnosis related group case-mix codes for all inpatient and outpatient hospital treatments in Danish hospitals and via reimbursed use of primary care.

We had access to data for 12 months before and 5 months after randomization, the latter data corresponding to the period from start of the CPSMP to the T3 follow-up. Health expenditure was calculated as costs in fixed 2011€ and presented as (1) total costs and (2) costs in a) general hospital care (in- and outpatients), b) mental health care (in- and outpatients), c) primary care physician (day care and laboratory samples), d) primary care out-of-hours service, and e) other costs (practicing medical specialist, psychiatrists, psychologists, chiropractor, and physiotherapists).

2.10. Statistical method

To reduce the risk of inflating statistical power in multivariate analyses, missing data in psychometric scales were handled at item level by the procedure described by Schafer and Graham.[34] If more than half of the items on any given scale with sufficient internal reliability (Cronbach alpha >0.70) were completed, missing items were replaced by the mean score of the subject's completed scale items. Imputation of missing item values was not comprehensive; only 2.1% to 5.9% of the participants had more than 10% missing items in the outcome scales and 0.4% to 2.3% had more than 50% missing items on the outcome scales.

In the RCT analysis, we applied an intention-to-treat approach. Changes in pain-related disability, pain symptoms, psychological adaptation to pain, emotional distress, and health-related burden were tested by a series of random effect models. We fitted crude and adjusted random effect models with random intercept and slope to the primary outcome, pain-related disability, as well as to the 6 secondary outcomes. Both crude and adjusted models have 2 primary independent variables; group and time. To allow for different development over time in the 2 groups, an interaction term between group and time was added. We furthermore accounted for a possible cluster effect from patients being in the same treatment group. The adjusted models included the following independent variables; all entered linearly: patient age in years, sex, duration of pain in years, and education (no education, manual or short education, and medium or long education). We tested whether the 2 groups differed regarding changes over time as the main result. Effects sizes were estimated from group differences in slopes of outcomes.

For outcome measures showing statistically significant effects, clinical significance of changes was evaluated by comparison with published cut-off values. For comparison with the published CMDQ cut-off values, CMDQ answers were dichotomized into *Not at all* recoded to zero and all other answers to one. Total subscale scores were calculated as the sum of each recoded subscale item.[7] Percentages exceeding clinical cut-offs before and after intervention were estimated and χ^2 analyses applied to test for group differences.

Health expenditure was calculated separately for each patient and collapsed into the sectors: general hospital care, mental health care, family physician, out-of-office service, and other, and into total costs. In addition, costs were collapsed into 2 periods: a 12-month pretreatment period and a 5-month period covering during and after treatment.

Expenditure was calculated as mean costs per period and presented with 95% adjusted bootstrapped-based confidence intervals. Total health expenditure for the 5-month intervention and follow-up period was compared between the CPSMP and the control group using regression models controlling for baseline costs (costs during the year before randomization). Because of the skewed distribution of costs, this comparison was done using the log-transformed cost in the 5-month intervention and follow-up period as the dependent variable and the log-transformed baseline cost as the independent variable. This led to an estimate of the ratio between median cost in the intervention group and median cost in the control group. All costs were presented as fixed 2011 Euros.

Statistical analyses were done using SPSS version 21; and for the random effect models and the health care cost estimation, STATA version 13 for Windows was used.

3. Results

The sample was heterogeneous. Participants varied considerably in age; the youngest were 25 years old, whereas 16 participants were older than 80 years old. Also, considerable variation in pain history was observed, and most reported more than one cause of their pain. On average, 1.7 causes of pain were reported, and 89 participants reported 3 or more causes of pain. Moreover, participants had several diseases which could be both causes of pain and comorbid conditions they had to manage in addition to their pain condition. On average, participants reported 2 diseases, but 63 participants reported 4 or more diseases.

After completion of the baseline questionnaire, the 424 included participants were randomized to intervention or control condition. No significant differences between the 2 groups were observed at baseline (p: 0.301-0.911) (**Table 1**).

3.1. Adherence and program evaluation

At T2, a total of 193 participants were asked how many sessions they had attended. They had on average attended 4.9 of the 6 sessions. This number includes 20 participants who reported they had dropped out; 15 of these participants dropped out because of illness.

At T3, 55% of the participants reported that they applied skills they had learned from the CPSMP in their daily lives, and 39% reported that these skills had helped them manage their pain (some degree-greatly). A majority of 79% would recommend other patients with chronic pain to attend the course (some degree-greatly).

3.2. Effects of the CPSMP

At T2, immediately after the course, a significantly larger reduction in the primary outcome of disability was observed among CPSMP participants than among the control group ($t = 3.373$, $P = 0.001$). Also distress, somatic symptoms, pain catastrophizing, self-efficacy, and health worry were more reduced in the intervention

Table 1
Participant characteristics.

	Intervention (n = 216)	Control (n = 208)
	Mean (SD)/n (%)	Mean (SD)/n (%)
Age (25–93 y)	54.2 (13.3)	54.8 (12.8)
Women (72%)	156 (72)	148 (71)
Men (28%)	60 (28)	60 (29)
Marital status (%)		
Married (56)	129 (60)	107 (51)
Cohabitating (10)	19 (9)	25 (12)
Divorced (10)	20 (9)	24 (12)
Single (16)	30 (14)	36 (17)
Widowed (6)	12 (6)	12 (6)
Education		
Primary school only	54 (25)	50 (24)
Manual or short education	84 (40)	87 (43)
Medium or long education	74 (35)	68 (33)
Work status		
Under education	1 (0.5)	1 (0.5)
Working	25 (12)	19 (9)
Sick leave	32 (15)	24 (12)
Unemployed	11 (5)	11 (5)
Rehabilitation/sheltered jobs	32 (15)	28 (13.5)
Retirement	97 (46)	107 (52)
Other	14 (6.5)	16 (8)
Pain duration (0–50 y)	9.3 (9.3)	8.4 (7.9)
Daily pain medication (%)		
None (17)	38 (18)	34 (16)
Over the counter (6)	15 (7)	11 (5)
Prescription (35)	75 (35)	74 (36)
Several types (41)	86 (40)	87 (42)

group than in the controls (t: 2.046-2.593, P: 0.010-0.041), but there were no group differences in changes in pain (t = −1.603, P = 0.110).

Table 2 shows the effects of CPSMP at T3. Random effect analyses revealed that there was no statistically significant effect on the primary outcome of pain-related disability or on the secondary outcomes: pain, self-efficacy, pain catastrophizing, or physical symptoms at follow-up (T3). There were small, but significant effects on emotional distress and illness worry (P: 0.0043-0.0079). The mean illness worry score decreased by 12% in the intervention group and increased by 1% in the control group, and the mean emotional distress score decreased 13% in the intervention group and 3% in the control group.

3.3. Clinical significance

To evaluate the clinical significance of changes on the parameters found to differ significantly between the CPSMP participants and controls, we estimated the percentage of participants who scored above the case cut-off in emotional distress and illness worry before and after the CPSMP. χ^2 analyses revealed no significant differences between the percentages of CPSMP participants and the controls scoring above the cut-off on emotional distress and illness worry at either T2 or T3.

3.4. Health expenditure

Data obtained from national patient registries were used to compare the health expenditure for participants in the CPSMP and the control group to test whether the intervention had an effect

on health expenditure. Health expenditure was compared for the 5-month intervention and follow-up period between the CPSMP and the control group using regression models controlling for baseline costs (costs during the year before randomization). Effects were estimated from the ratio between the median cost in the intervention group and the median cost in the control group. As seen in **Table 3**, the ratios did not indicate any differences between CPSMP participants and the controls on health care costs when controlling for baseline costs (P: 0.12-0.88).

4. Discussion

In this RCT of the Danish lay-led CPSMP, we found no effect on our primary outcome of pain-related disability 3 months after the course, nor did we find effects on self-reported pain, catastrophizing, physical symptoms, self-efficacy, or health expenditure.

Small, transient effects in emotional distress, physical symptoms, pain catastrophizing, and illness worry emerged immediately after the course. Unexpectedly, self-efficacy also decreased more in the intervention group than in the control group. Three months later, only small effects on emotional distress and illness worry could still be observed, but these effects are not clinically significant as the percentages of clinically impaired patients on these parameters were the same in the intervention and the control group.

Our results do not differ substantially from the findings of the 2 previous trials of CPMSP led by health care professionals. In the original LeFort (1998) study, posttreatment measures were recorded only once, approximately 3 months after recruitment. The investigators found that participants in the treatment group reported less dependency on others, reduced severity of impact of pain problems, higher levels of self-efficacy and resourcefulness, greater involvement in activities, and had greater life satisfaction than the control group.[20] These positive effects are comparable with our findings immediately after the course ended. In the Ersek (2008) study with older nursing home residents, effects were measured immediately after and 6 and 12 months after the intervention.[11] The intervention was not superior to the control condition in which participants were given a pain management book. Ersek et al found minor decreases in mean disability and pain over time in both groups (statistics not reported), but no group difference in any outcome measures. Nicholas and colleagues (2017) did find diminishing, but still observable effects of self-management cognitive-behavioral intervention at one-year follow-up.[30] Compared to the present CPSMP, their intervention was however intensified by adding more treatment time and applying health care professionals with expertise in pain as treatment providers. Thus a brief, lay-led self-management intervention may not be detailed enough to induce more lasting changes.

Our demonstration of a transient, positive effect of CPSMP on patients with chronic pain that diminishes quickly without any lasting impact on perceived disability and pain appears to be in accordance with the Cochrane review of lay-led patient education programs for chronic conditions. This review only supported the existence of small, short-term effects on self-reported symptoms and function.[15]

4.1. Strengths and limitations

There are 2 major strengths of this study; one is that it was a pragmatic trial. The trial was conducted in municipal health support centers, organized by local health care professionals and not in a specialized university hospital department. This reduces the

Table 2

Changes in symptoms from baseline to follow-up in CPSMP and control group and effects of CPSMP.

	Intervention group	Control group	Time × group			Time × group		
	Observed	Observed	Crude analyses			Adjusted analyses*		
	Mean (SD)	Mean (SD)	$\chi^2(1)$†	P	Cohen's d	$\chi^2(1)$†	P	Cohen's d
Disability (RMDQ)			1.25	0.2366	0.113	1.26	0.26619	0.114
Baseline	14.7 (4.4)	14.8 (3.9)						
T2	13.6 (4.7)	14.8 (4.2)						
T3	13.7 (4.6)	14.2 (4.6)						
Pain (VAS)			0.18	0.6693	0.043	0.17	0.6837	0.042
Baseline	56.1 (16.7)	57.0 (18.0)						
T2	54.3 (15.1)	53.9 (16.0)						
T3	51.7 (19.9)	53.7 (18.4)						
Self-efficacy (SES)			1.92	0.1662	0.140	1.97	0.1602	0.142
Baseline	22.2 (8.8)	24.0 (9.3)						
T2	21.1 (9.3)	23.8 (9.0)						
T3	20.1 (9.6)	23.5 (10.4)						
Pain catastrophizing (PCS)			1.38	0.2399	0.119	1.47	0.2259	0.123
Baseline	25.0 (10.1)	25.2 (10.6)						
T2	22.1 (10.4)	23.7 (10.9)						
T3	21.3 (10.4)	22.4 (11.1)						
Illness worry (Whiteley)			7.05	0.0079	0.271	6.72	0.0095	0.264
Baseline	16.1 (6.1)	15.5 (5.9)						
T2	15.6 (5.7)	16.3 (6.2)						
T3	14.2 (5.2)	15.3 (5.9)						
Emotional distress (SCL-8)			8.17	0.0043	0.292	8.00	0.0047	0.289
Baseline	20.1 (8.2)	20.0 (7.8)						
T2	18.8 (7.8)	20.0 (8.1)						
T3	17.5 (7.4)	19.4 (7.8)						
Physical symptoms (SCL-SOM)			2.32	0.1278	0.155	2.38	0.1229	0.157
Baseline	31.3 (8.0)	30.3 (7.6)						
T2	30.2 (7.3)	30.9 (8.2)						
T3	29.8 (7.6)	30.3 (8.4)						

* Effects are adjusted for patient age in years, sex, duration of pain in years, and education.
† Test of difference between slopes in CPSMP and control group.
CPSMP, Chronic Pain Self-Management Programme; RMDQ, Roland-Morris Disability Questionnaire; VAS, Visual Analogue Scale; SES, Self-Efficacy Scale; PCS, Pain Catastrophizing Scale.

impact that loss of treatment fidelity could have on potential effects when the method is transferred from a rigorously controlled study set-up to real-world application. The intervention proved feasible with satisfactory adherence and high rates of satisfaction.[26]

The other strength is the extent of the RCT. It is much larger than the 3 previously published randomized effect studies of the CPSMP, and our study had adequate statistical power. There was a low attrition rate; we managed to collect follow-up data from 92% of the included participants. Considering the severely impaired population who received no compensation for participation, this is a satisfactory response rate that reduces the risk of selected dropout bias. Furthermore, we conducted a comprehensive feasibility study with 87 patients with chronic pain and adjusted the procedures before the RCT study was launched.[26]

There are, however, also several limitations to this study.

4.1.1. Control group

Patients in our control group improved significantly in disability, pain, and pain catastrophizing over time. We cannot know whether the recorded improvements reflect natural fluctuations in the pain condition or if the improvements are caused by medical interventions, improved pain coping skills, or spontaneous recovery. Possibly, the improvements in our control group were greater than they would have been if the controls had not been included in the study. The control condition was not limited by any restrictions in treatment options. The control participants could have initiated other treatments, which may have blurred the effect of the CPSMP. They were also free to sign up for a CPSMP course 5 months after they were randomized to the control group. When they answered the last questionnaire, some controls ($n = 92$) knew that they were about to start a CPSMP course shortly after, and a few ($n = 16$) had actually started. These persons may have had positive expectations to the course that made them answer more favorably than they would have done otherwise. However, rerunning the analyses without these controls (data not shown) did not alter our results.

4.1.2. Heterogeneous sample

Another potential limitation to this study is the heterogeneous study sample. It has not been examined whether the CPSMP is suitable for all patients with chronic pain. Participants in our study were characterized by considerable variation in age. In the Ersek study where no effect of CPSMP could be observed, only older nursing home residents were included.[11] The mean age in their study was older than 80 compared with a mean age of 40 years in the Lefort study[20] and 54 years in this study. If the CPSMP is better suited for younger adults, the wide age range in our sample may have obscured the effect.

Our participants suffered from very different types of pain and varied considerably in pain history. They reported a mean level of pain corresponding to 57 out of 100 (SD 17.4). In comparison, Danish

Table 3

Health care costs in Euros 12 months before and 5 months after randomization.

	Period before intervention, 12-month period				Treatment + follow-up period, 5-month period				CPSMP effect ratio* controlled for baseline (P)	CI
	Intervention		Control		Intervention		Control			
	Mean, €	CI†	Mean, €	CI†	Mean, €	CI†	Mean, €	CI†		
General hospital care	4257	3372-5701	4186	3398-5239	1847	1346-2643	1782	1353-2359	1.036 (0.88)	0.737-1.455
Mental health care	57	9-218	71	29-165	20	6-48	46	17-109	0.871 (0.82)	0.216-3.520
Family physician	332	300-377	360	319-433	126	113-146	144	126-174	0.933 (0.42)	0.789-1.103
Primary care out-of-hours service	8	4-20	11	7-16	3	1-9	4	2-10	0.536 (0.47)	0.086-3.355
Other	529	440-621	408	342-499	235	188-295	177	144-217	0.920 (0.46)	0.736-1.150
Total	5183	4324-6637	5036	4219-6161	2231	1719-2943	2153	1709-2861	0.820 (0.12)	0.639-1.054

* Ratio: median cost intervention group/median cost control group.
† BCa 95% CI.
CI, confidence interval; CPSMP, Chronic Pain Self-Management Programme.

cancer patients reported a mean pain level of 49 at an audit at an oncological department.[1] The rates of disability and pain in this sample correspond to the Ersek sample, but they are possibly higher than the rates in the LeFort sample, although the measures are not directly comparable. We cannot know whether the CPSMP would be better suited for subgroups of patients with chronic pain. However, the CPSMP was selected for evaluation because of its alleged wide applicability with few restrictions on participant inclusion, and it would be less relevant if it suited only carefully selected groups of patients.

4.1.3. Outcome measures

With the exception of the SES, the applied outcome measures are widely used in pain research and have previously been validated in Danish populations. However, the test–retest correlation of the visual analogue measure of pain and the SES was too low; we therefore cannot reliably interpret change over time in these parameters. Thus, the finding of a transient, negative effect on self-efficacy should be interpreted with caution.

4.1.4. Adherence and application of skills

The majority of the CPSMP participants completed the course. The attendance rate was 80%, which is not unexpectedly low in this disabled and distressed population. We can, however, not be certain whether the participants actually applied the skills that they had learned from the CPSMP. In the program evaluation, half of the participants reported having applied acquired CPSMP skills, and 39% reported that these skills helped them manage pain. In addition to the presented questionnaire data, we conducted in-depth qualitative interviews with 30 participants. From these informants, it was evident that most participants try out some exercises and apply some skills after the CPSMP, but application is highly differentiated and random. Because it has been demonstrated that better outcomes on pain, disability, and distress are dependent on how many self-management strategies a patient applies after an intervention,[31] insufficient application of these strategies may explain the lack of effect on pain-related outcomes in this study.

4.1.5. Novice lay-leaders

Finally, the quality of the lay-leaders' performance could limit the effectiveness of the intervention. Many workshop leaders were novices who received their training immediately before the course. From the qualitative interviews, we learned that some participants were annoyed by the leaders' lack of expertise. They complained that the leaders read directly from the manual and were more focused on the manualized procedures than on the participants. Although the specific leaders may improve with more experience, overgeneralized communication and insensitive adherence to protocol are general limitations to strictly manualized interventions. When conducted by lay-leaders, the risk of keeping focus on the manual rather than on participants is even higher. Possibly, this explains why a recent review found that group-based self-management interventions for chronic musculoskeletal pain by health care professionals are preferable to lay-led programs.[5]

Psychological interventions for patients with chronic pain are generally effective,[9,36] but the CPSMP does not show comparable positive effects. Although the CPSMP may decrease distress and worries slightly, it cannot replace regular psychological pain treatment as it neither reduces the pain-related burden on an individual level, nor reduces health expenditure on a societal level. Lay-led CDSMP may appear attractive in price and in terms of its potential for broad and rapid dissemination, but such advantages are shared by internet-based programs, and at least some internet-based interventions have been shown to have positive effects on disability and pain even with a minimum of clinician support, eg,[8]

5. Conclusion

In conclusion, this study does not support any effect of CPSMP on pain and disability or health expenditure. We found positive effects on emotional distress and illness worry 3 months after the course, but these improvements were small and clinically nonsignificant. On this background, we conclude that this study does not support the CPSMP as a treatment to reduce perceived pain or disability.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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