Self-Management in Osteoarthritis of Hip or Knee: A Randomized Clinical Trial in a Primary Healthcare Setting

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ABSTRACT. ***Objective.*** To assess in a primary healthcare setting the efficacy of a self-management program in middle-aged patients with osteoarthritis (OA).

Methods. This was a 2-group randomized controlled trial, with 273 patients aged 40 to 60 years with OA of the hip(s) and/or knee(s). The experimental intervention was compared with care-as-usual. Treatments and followup measurements were performed in a general healthcare setting by general practitioners. Duration of followup was 21 months after start of the intervention. Instruction in self-management techniques was given by physiotherapists. The main outcome measures were pain severity in hips and knees, other significant complaints, and functional limitations.

Results. To begin, 297 patients were randomized: 149 as self-management and 148 controls; before the intervention 24 withdrew for practical reasons (17 self-management, 7 controls). At 3-month followup the intervention group was significantly improved on a visual analog scale (VAS) for knee pain (score 0.67; SD 2.10) and the WOMAC (score 2.46; SD 9.49), while the control group showed stable VAS knee pain (0.01; SD 2.00) and deterioration on WOMAC (–0.53; SD 9.47). At 21-month followup the differences between the groups increased in favor of the intervention group (VAS pain knee: p values from 0.023 at 3 mo to 0.004 at 21 mo; WOMAC: p values from 0.030 to 0.022).

Conclusion. The self-management program positively influenced knee pain and self-reported functional level in this sample of patients with OA. Differences between the study groups increased during followup in favor of the intervention group. (J Rheumatol 2005;32:543–9)

Key Indexing Terms:
OSTEOARTHRITIS — SELF-MANAGEMENT
RANDOMIZED CONTROLLED TRIAL — PRIMARY HEALTHCARE

General practitioners are frequently consulted by patients with osteoarthritis (OA) of the hip or knee. From data collected in a nationwide 3-month study in Dutch general practices, prevalence was estimated to be 14/1000 subjects for OA of the hip and 23/1000 for the knee[1]. Thus, in The Netherlands (total population about 16 million) roughly 775,000 patients of all ages with this chronic joint disorder are currently registered with a general practitioner, of whom about 17% are aged between 40 and 60 years and can be considered relatively young[2]. The average consultation frequency of patients with OA is about 2.8 per year, for a total of over 6 million consultations in general practice each year.

OA is mainly characterized by joint pain, (morning) stiffness, and loss of function[3,4]. Every year about half of all prevalent cases are referred for radiographic examination and a quarter are referred to a physiotherapist for symptomatic treatment, and 15,000 hip and 7000 knee operations are performed as a result of OA. Consequently, the total costs of healthcare for OA are substantial and increasing, as the Dutch population is aging. To reduce the burden of hip and knee OA on the national healthcare budget in the future, it is important to determine the secondary preventive effects of teaching self-management in relatively young patients with OA. This subpopulation is of particular interest because (1) information on the effectiveness of self-management in this group is sparse[5,6]; and (2) from a societal point of view, the gains of self-management may be enormous considering that many OA patients within the specific age group are still active in the labor market and probably will be for several years to come.

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Over 50% of incident OA cases are being treated by a general practitioner alone, usually by means of (pain) pharmacotherapy and referral to physiotherapy. Among general practitioners there is currently no consensus about the optimal treatment of OA in primary care[3], although there is a need for unambiguous, practical self-management programs, from the viewpoint of healthcare professionals as well as patients themselves[7]. Recent international guidelines stress the importance of self-management for OA[8,9].

Several studies show evidence of the efficacy of self-management[10-12] and/or its separate components (exercise[13,14], education[15,16], counselling[17]) in OA of the hip and knee in patients over age 55. One study also indicated a significant reduction of healthcare costs in the long term[11]. Recently, the results of a Dutch trial indicated the efficacy and feasibility of the program developed within the framework of this particular study[4,18,19]. Significant effects were observed on the outcome measures of pain, muscle function, self-efficacy, and knowledge of OA. However, all the studies noted above focused on elderly patients with OA (age > 55 yrs), and although the self-management approach is scientifically well grounded for these older patients, there is a lack of information on the possible secondary preventive effects of self-management in younger OA patients (age < 55 yrs). It is relevant to investigate whether it is possible to beneficially influence prognosis in this younger age group with a method with proven efficacy in the older age group.

We describe the results of a randomized controlled trial on self-management in a primary healthcare setting with middle-aged patients with OA.

MATERIALS AND METHODS

Participants. Participants were recruited from academic registration networks of primary care practices[20,21] and by local advertisements (Figure 1). Two morbidity registration networks in The Netherlands representing about 77 general practitioners collaborated in this study[2,20]. Additionally, letters were sent to 309 other general practices in Limburg, which resulted in 15 more general practitioners willing to refer patients.

The study population consisted of patients with OA 40 to 60 years of age. The following inclusion criteria were used: (1) characteristic radiological appearance; (2) Heberden's nodes; (3) joint disorder of at least 3 months' duration, with no constitutional symptoms and at least 3 of the following: (a) irregular swelling; (b) crepitation; (c) stiffness or limitation of movement; (d) normal erythrocyte sedimentation rate, rheumatoid factor tests, and uric acid; and (e) patient's age over 40 years.

In our study the International Classification of Health Care Problems in Primary Care (ICHPP-2) criteria were administered, because these were used in previous studies in general healthcare settings[22], whereas the American College of Rheumatology (ACR) criteria were recently described not to be validated in general healthcare[23]. In participants that entered the study through advertisements (n = 124), both ACR and ICHPPC criteria were checked, and were found to be in full agreement in this subpopulation.

Patients with rheumatoid arthritis, ankylosing spondylitis, and gout were excluded.

Measurements at baseline. The following baseline characteristics of participants (Table 1) were recorded before the start of the treatment: age, sex, radiological findings for hips and knees, socioeconomic status, and the way of entering the trial (referred by general practitioner or advertisement).

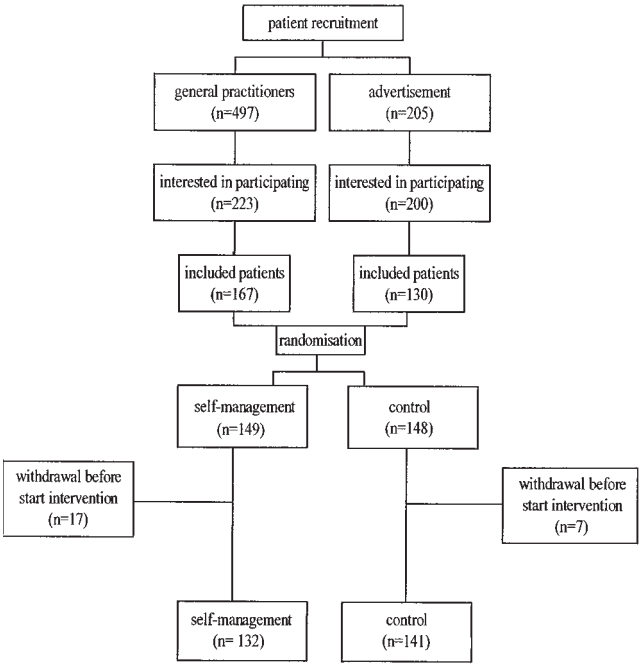

Figure 1. The patient recruitment plan.

Radiographs. A rating score was obtained according to the scoring system proposed by Kellgren[24]. Radiographs of hips and knees were taken at baseline. All radiographs were scored by an independent, experienced radiologist who was blinded for treatment. The Kellgren score in each of the 4 joints (2 knees, 2 hips) ranged from 0 to 5 as given in Table 2.

Socioeconomic status. In this report level of education and job participation are described (Table 1).

Outcome measurements. A patient followup was carried out with measurements at 3 months and 21 months. Primary outcome measures were pain severity and self-reported functional status.

Pain severity. Pain intensity in the hips and knees was measured with visual analog scales (VAS). Since the signs and symptoms of OA vary over time, 3 VAS measurements were recorded: intensity of pain today, intensity of pain last week, and intensity of pain last month. These 3 VAS scores were found to be strongly correlated (Pearson r ranged from 0.806 to 0.956; all significant at p = 0.01). To obtain a reliable and reproducible indication of pain severity, mean VAS scores on these scales were entered in the analyses as a composite score. Anchors of the VAS scales were "no pain at all" and "the worst imaginable pain." Mean scores of pain measures are shown in Table 1.

Functional status questionnaire. The Western Ontario and McMaster Universities OA Index (WOMAC) was developed by Bellamy and colleagues to assess outcome in OA trials[25-27]. This instrument is a 3-dimensional (i.e., pain, stiffness, physical function), disease-specific, self-administered health status questionnaire, available in Likert scale and VAS versions. In this study the Likert version was used.

Patient-specific functional status (PSFS)[28]. Every participant was asked to choose the 2 most salient problems in daily functioning. This is a way of detecting the specific problems of a particular patient. On a VAS the participant scored the importance of the particular activity from his point of view (range from "not important" to "very important"). Next they had to score on a VAS from the difficulty in performing these 2 activities: "How difficult was it last week for you to perform this activity?" ("no difficulty" to "impossible to perform"). All VAS scores were measured on 10 cm lines.

Table 1. Baseline characteristics (total n = 273).

	Self-Management	Control
Patient characteristics, n		
No. of participants	132	141
Age, yrs, mean (SD)	51.0 (5.0)	52.2 (5.1)
Sex, n		
Male	54	56
Female	78	85
BMI	28.0 (4.8)	28.3 (5.2)
Recruitment from		
General practice	69	80
Advertisement	63	61
SES		
Education low	32	38
Education middle	43	39
Education high	24	31
Paying job: yes/no	55/44	55/53
Primary outcome measures, mean (SD)		
WOMAC	32.7 (14.7)	35.7 (17.3)
PSFS	4.9 (2.5)	5.0 (2.6)
VAS knee pain	4.3 (2.4)	3.8 (2.9)
VAS hip pain	3.2 (2.6)	3.5 (2.9)
Secondary outcome measures, mean (SD)		
TSK	36.0 (6.8)	36.7 (7.9)
ASES	3.8 (0.7)	3.7 (0.8)
SF-36		
Health change	45.0 (18.5)	42.3 (19.6)
Physical functioning	61.6 (18.3)	59.1 (21.3)
General health perception	61.0 (17.0)	58.9 (19.2)

BMI: body mass index, SES: socioecomonic status, WOMAC: Western Ontario and McMaster Universities OA INdex, PSFS: patient-specific functional status, TSK: Tampa Scale for Kinesiophobia, ASES: arthritis self-efficacy scale[63], SF-36: Medical Outcome Study Short Form-36.

The following secondary outcome measures were used:

Health related quality of life. General health status was measured with a general health related quality of life questionnaire, the Medical Outcome Study Short Form-36 (SF-36)[29].

Self-efficacy. Self-efficacy was measured with a questionnaire developed by Lorig, *et al*[30] in a Dutch-language version[31]; a total score is the sum of the scores on the 9 items divided by 9.

Pain related fear. The Dutch version of the Tampa Scale for Kinesiophobia (TSK) was used to assess pain related fear. The TSK is a 17-item questionnaire for assessment of fear of (re-)injury due to movement[32] (Miller R, Kori S, Todd D. The Tampa Scale of Kinesiophobia; 1991, unpublished data). Each item provides a 4-point Likert scale with scoring alternatives ranging from "strongly agree" to "strongly disagree." Psychometric properties of the Dutch version of the TSK have been found to be good[33].

Stages of change. Participants were categorized for stages of change using a recently designed questionnaire[35]. During followup these measurements were repeated.

Procedure. The study was approved by the Medical Ethical Committee of Maastricht University and the Maastricht University Hospital. Approval was also received from the Review Committee of the Registration Network of Family Practices (RegistratieNet Huisartspraktijken, RNH)[20].

For the self-management intervention, physiotherapists were recruited from those working in a primary healthcare setting. Prerequisites for physiotherapists participating in the trial were: fulfilment of training for the intervention study (3 sessions of 4 hours each) and having the opportunity to work with groups of 6 to 12 patients (instruction room with facilities for exercise sessions, relaxation, and reception of participants' partners). Several meetings for discussion and description of "care-as-usual" were organized with experienced physiotherapists prior to the start of patient enrollment.

The baseline and outcome measurements were performed by an independent research assistant (with a physiotherapy background) who was blinded to treatment assignment and not involved in the treatment of participants.

Randomization. Upon admission to the study the inclusion and exclusion criteria were checked for each participant. Participants signed an informed consent form and were invited for baseline assessment. A computer generated randomization scheme was prepared and managed by a secretary, who was not involved in patient selection, treatment, or data analysis. A patient was included when he met the inclusion criteria and gave informed consent, and was able to participate in the self-management groups if selected and complete baseline measurements.

Intervention: self-management or care-as-usual. The self-management program was based on earlier studies and publications[4,11,17,19,36,37] and rewritten and redesigned especially for this study (PH and CB). The intervention consisted of 6 sessions of 2 hours each and was led by 2 physiotherapists. These meetings were highly structured; the Appendix offers an overview of the topics per session. Standardized training materials were developed and administered, for example, information sheets and audiovisual material used by physiotherapists during the sessions and booklets for participants, as well as a short handbook on OA and self-management with an overview of all relevant information.

In the self-management program participants were taught how to take initiative in their personal health and functioning. The program included the following: Participants learned to use adequate goal setting in combination with self-incentives as motivators to optimize their level of activity. A rational use of prescribed medication and other treatments was discussed. Self-relaxation training was given for pain control as well as for improvement of overall well being. Problem solving was part of the self-management program for empowering the participant in handling daily hassles. Self-diagnostic skills were taught for monitoring and interpreting changes in one's health status.

Table 2. Radiological criteria for osteoarthritis, in percentages[24].

Score	Description	Criteria	Knee Left, n = 259	Knee Right, n = 259	Hip Left, n = 259	Hip Right, n = 259
0	None	No signs of OA	55.1	49.6	37.0	35.4
1	Doubtful	Doubtful narrowing of joint space and possible osteophytic lipping	20.3	23.0	28.8	30.4
2	Minimal	Definite osteophytes and possible narrowing of joint space	10.5	10.9	17.1	19.8
3	Moderate	Moderate multiple osteophytes, definite narrowing of joint space, and some sclerosis and possible deformity of bone ends	9.8	14.1	11.7	10.1
4	Severe	Large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone ends	4.3	2.3	1.6	3.5
5	Prosthesis	Joint replaced by prosthesis	0	0	3.9	0.8

Participants also received information about community resources and were trained to optimize use of healthcare services. For the intervention applied here the term "self-management" was chosen, because the 6-session intervention resembles the Arthritis Self-Management Programme developed by Lorig, *et al*[30]. It should be noted, however, that the intervention is an example of a cognitive-behavioral intervention, since it includes several techniques such as problem-solving and goal-setting that are typical cognitive-behavioral interventions[37-48].

Care-as-usual was described as that prescribed by a family physician or consulted specialist and that remained unchanged.

Data analysis. All data analyses were done with SPSS statistical software. At baseline, mean scores of patient characteristics and outcome measures of both interventions were compared. The baseline status of the study groups was compared with respect to the distribution of all independent prognostic variables and the baseline values of the outcome variables. Statistical analyses were carried out according to the "intention-to-treat" approach[49]. For each individual the differences between baseline and post-treatment scores of the outcome measures were calculated at 3-month and 21-month followup. These difference scores were calculated so that a positive score represents an improvement (e.g., T4 minus T0 for the SF-36, because a higher score on SF-36 represents improvement, and T0 minus T4 on the VAS for pain, because a lower score represents an improvement) and a negative score represents deterioration. ANOVA was calculated for the mean difference scores of both intervention groups.

RESULTS

Study sample. To begin, 297 patients were randomized: 149 as self-management and 148 controls. Before the start of the intervention 24 participants withdrew for practical reasons (17 self-management and 7 control); some were not able to participate in the intervention schedule and some had disappointment about the result of the randomization. This resulted in 273 participating patients with OA (163 women, 110 men). Participants reported moderate pain intensity in the hips (mean score on VAS 3.36; standard deviation 2.77) and knees (mean VAS 4.06; SD 2.66). An evident level of discomfort and disability (mean score on WOMAC 34; SD 16.13) was noted. Radiological changes were reported in 78.4% (n = 214) of the patients, while examination showed Heberden's nodes in 15.4% (n = 41) and crepitation in the knees in 66.3% (n = 181). Stiffness was reported by 88.6% (n = 242) of participants. In 48.8% (n = 135) of the patients, therapeutic procedures had been performed: e.g., diagnostic arthroscopy (9.2%, n = 25), meniscectomy (19.9%, n = 57), endoprostheses (hip 4.7%, n = 12), osteotomy (1.4%, n = 4), and cartilage remodeling (lavage 3.2%, n = 9, and "patella shaving" 0.4%, n = 1). Table 2 shows the severity of radiological findings assessed with the Kellgren scoring method[24].

Comparability of treatment groups. Mean scores of baseline characteristics (Table 1) were compared between the intervention and control groups (t-test for mean group scores) and showed no relevant differences.

Five participants withdrew during the intervention from the self-management program: 3 were not satisfied by the program, one because of knee pain, and one because of the situation at home.

Data analysis. Results of data analyses are shown in Table 3. Data were analyzed following the intention-to-treat-principle: all participants were analyzed in the intervention group they entered by randomization. Table 3 describes the data set and results as well as the number of missing questionnaires: no imputation method was administered for missing questionnaires. Mean change scores on the primary outcome measures were all in the same direction. At 3-month followup the intervention group was significantly improved on VAS knee pain (score 0.67; SD 2.10) and WOMAC (2.46; SD 9.49), while the control group showed stable VAS knee pain (0.01; SD 2.00) and deterioration on the WOMAC score (–0.53; SD 9.47). At 21-month followup (Table 4) the differences between the intervention and control groups increased in favor of the intervention group (VAS knee pain: p values ranging from 0.023 at 3 months to 0.004 at 21 months; WOMAC p values from 0.030 to 0.022).

DISCUSSION

We examined differences in outcome on pain and daily functioning in a group of patients with OA aged between 40 and 60 years after participation in a self-management intervention or care-as-usual. The effects on knee pain and self-reported daily functioning were better in the self-management group than in the control group. The differences were increasing over time in favor of the self-management intervention.

Participants in this study were recruited in a primary care population, not in specialized clinics, which is particularly interesting since this is a relevant[50] and under-investigated[5,6] circumstance. We believe this is the second report of a randomized controlled trial on self-management in arthritis patients in a primary care setting. The recent study of Solomon, *et al* found no significant clinical benefits at 4 months in patients recruited from primary care practices[6], in contrast to our study. However, Fries, *et al*[50] recently pointed out several methodological flaws in the study of Solomon, *et al* concerning inadequate randomization (on a group level rather than on a patient level, resulting in inadequately balanced groups, and transfer of part of the controls to the intervention arm), insufficient contrast between the 2 trial arms (the control intervention was also an active intervention, using The Arthritis Helpbook), while the period of followup (4 months) was rather short. We claim that in our study these problems do not exist and our study has a longer duration of followup (21 months), which is evidently important in the OA population.

Our self-management program was performed by physiotherapists in a primary healthcare setting. Therefore the conclusion can be drawn that there are possibilities for implementation in general healthcare settings for a broad population. For family doctors and physiotherapists this opens up treatment possibilities for the enormous group of patients with OA.

Further, it is remarkable that a relatively short intervention (6 sessions of 2 hours each in a group format) positive-

Table 3. Primary and secondary outcome measures in intervention (I) and control (C) subjects.

Outcome Measures	Mean Improvement, 3 mo (SD)		n		p	Mean Improvement, 21 mo (SD)		n		p
	Intervention	Control	I	C		Intervention	Control	I	C	
Primary										
VAS pain knee	0.67 (2.10)	0.01 (2.00)	95	107	0.023	0.39 (2.48)	–0.48 (1.95)	96	118	0.004
VAS pain hip	0.22 (1.95)	0.28 (1.83)	96	107	0.830	0.19 (2.19)	–0.17 (2.25)	96	117	0.242
WOMAC	2.46 (9.49)	–0.53 (9.74)	94	103	0.030	2.63 (11.53)	–0.88 (10.28)	94	113	0.022
PSFS	0.13 (1.92)	–0.22 (1.23)	81	81	0.052	0.49 (2.69)	–0.05 (2.47)	105	125	0.026
Secondary										
TSK	2.05 (7.04)	–1.01 (5.91)	85	98	0.002	2.15 (6.16)	–1.68 (6.08)	89	110	0.000
ASES	0.07 (.57)	0.03 (.62)	91	101	0.669	0.09 (.67)	–0.09 (.65)	89	106	0.061
SF-36 subscales										
Health change	3.85 (19.34)	2.00 (22.10)	91	100	0.541	3.85 (26.07)	–1.16 (23.53)	91	108	0.156
Physical functioning	–1.07 (13.31)	–2.60 (14.15)	92	102	0.441	–1.59 (15.64)	–5.80 (15.30)	91	108	0.057
GHP	–1.94 (12.36)	–3.59 (16.44)	89	99	0.442	–0.12 (15.70)	–2.73 (14.57)	87	105	0.234

GHP: general health perception.

Table 4. Mean values (SD) of primary and secondary outcome measures at 21-month followup.

Outcome Measures	Intervention	Control
Primary		
VAS pain knee	3.7 (2.6)	4.2 (2.7)
VAS pain hip	3.0 (2.9)	3.5 (2.7)
WOMAC	30.1 (16.8)	35.1 (17.6)
PSFS	4.4 (2.8)	5.0 (2.8)
Secondary		
TSK	34.1 (6.7)	37.7 (8.0)
ASES	3.9 (0.8)	3.7 (0.9)
SF-36 subscales		
Health change	47.7 (21.6)	41.7 (18.0)
Physical functioning	61.5 (21.3)	55.4 (22.8)
GHP	62.0 (17.8)	58.3 (20.1)

ly influenced pain and self-reported daily functioning, with measurable effects at longterm followup, while in the control group an overall deterioration was observed.

In a previous study on the effects of exercise in OA patients, positive effects of exercise were found at short-term followup. However, in that study these effects were not stable and disappeared over time[52,53]. It then was suggested that further studies were necessary to investigate the effect of interventions in which educational and/or self-management strategies are integrated in order to improve the consolidation of positive effects on pain and daily functioning[52]. Our investigation is an example of such a study, and it confirms the positive influence of a self-management program with education on pain and self-reported daily functioning on longterm followup.

In our study the stages-of-change model was applied[35]. For the purpose of better matching patients with treatment options, several investigators have recently drawn attention to this transtheoretical model of behavioral change[53-60]. This model, first presented by Prochaska, *et al*[61], describes change as a process in which people move from a low to a high level of active participation[61]. They can move through different stages ranging from no intention to change, e.g., with lack of motivation to adopt a self-management program, to optimal active participation with internalization of the new behavior. In our study no differences in outcome were found in subgroup analysis with the stages of change as variable. This is probably because most participants were in the preparation or action stage. Few participants were in the precontemplation and contemplation stages[35], because of the selection procedure of participants. This procedure may cause underrepresentation of people in the precontemplation stage, since the study sample was recruited especially for self-management treatments. It therefore seems unlikely that many participants would be in the precontemplation stage, which would be contradictory to being prepared for participating in a self-management program.

Another relevant aspect of the study concerns its societal impact. In our sample a considerable number of participants were performing paying jobs; improvement of pain and daily functioning in this group evidently has important consequences, because it positively influences opportunities for active social participation and quality of life.

Possible limitations of the study are the following. First, it proved to be difficult to minimize and control the loss to followup. At the end of the study, loss to followup was about 15%. A constraint of the study was caused by incomplete response to questionnaires, as reported in Table 3. Nevertheless, it was shown to be possible, albeit complex, to perform a randomized clinical trial on self-management in a primary healthcare setting and it was possible to draw valid and relevant conclusions.

Second, because of individuals with Kellgren gradings of 0 and 1 in this study (40% of the total group), which is a consequence of diagnosing OA with classification criteria such as the International Classification of Health Care Problems in

Primary Care (ICHPP-2) or ACR, it could be that some participants may not have had OA, and we could be making false conclusions about the influence of self-management on OA. Therefore it is important to note that the effect of the self-management program is primarily on functioning and pain in the person with chronic complaints ascribed to OA, rather than an effect on the process of OA itself.

Third, since it is likely that between the 2 intervention groups there was an unbalanced amount of treatment in favor of the self-management program, the question arises of what caused the observed effect. The study design reflects a pragmatic randomized controlled trial with limitation in explanatory power. Therefore, interpretation of the results with regard to the unbalanced amount of treatment needs caution. The finding, however, that there are differential effects, for example, improvement on knee pain which is not the case in hip pain, suggests that the self-management intervention has a causal effect with regard to improvement.

The self-management intervention administered in a primary healthcare setting showed improvement in pain and self-reported daily functioning in patients with OA, while the control group deteriorated. The differences between the groups increased during followup in favor of the self-management group. These findings are in accord with previous trials on self-management with positive outcome in patients with OA, and therefore broader implementation of this intervention in primary care settings is warranted.

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REFERENCES

Appendix. Content of treatment program

	Session					
Topics per session	1	2	3	4	5	6
Self-help	•					•
What is osteoarthritis?	•					
Moving and exercising	•	•	•	•	•	•
Relaxation		•			•	•
Problem-solving			•		•	•
Communication and emotions			•	•		
Healthcare providers, treatment options, and assistive devices		•		•		
Evaluation					•	
Action plan and feedback	•	•	•	•	•	•

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