

# Does Self-Management Education Benefit All Populations with Arthritis? A Randomized Controlled Trial in a Primary Care Physician Network

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**ABSTRACT. Objective.** Studies have suggested that the Arthritis Self-Management Program (ASMP) course is effective at reducing arthritis pain and health care costs in volunteer participants. There have been no reports of trials of the ASMP in the context of primary care physicians' practices, where the potential for spreading the program may be greatest. We conducted a randomized controlled trial of the ASMP course in a large primary care physician network.

**Methods.** Patients with osteoarthritis, rheumatoid arthritis, or fibromyalgia were recruited for the study. Subjects in the intervention practices received the 6 week course and those in the control practices received only the ASMP book, without course. Disability, pain, self-efficacy, mental health, and satisfaction were measured using validated instruments at baseline and at 4 months.

**Results.** One hundred thirteen patients were recruited for the ASMP course (intervention) and completed baseline and 4 month followup questionnaires. Eighty-four percent completed at least 4 of 6 classes. Seventy-four patients received the ASMP manual (controls) and completed both questionnaires. Patients in the intervention and control groups had similar baseline pain ( $p = 0.94$ ), self-efficacy to control pain ( $p = 0.90$ ), mental health ( $p = 0.10$ ), and vitality scores ( $p = 0.21$ ), but those in the intervention arm had slightly less disability ( $p = 0.04$ ). At 4 months, there was no significant improvement from baseline in any endpoint and no difference between patients in the intervention and control groups (all  $p > 0.2$ ). Patient satisfaction with arthritis care and outcomes was no different for intervention and control patients (all  $p > 0.3$ ). All types of health care resource use were similar at baseline and followup for both intervention and control groups (all  $p > 0.2$ ).

**Conclusion.** While the ASMP course has been found to be effective in other patient groups, there were no significant clinical benefits noted at 4 months in patients recruited from primary care practices. (J Rheumatol 2002;29:362-8)

## Key Indexing Terms:

ARTHRITIS

FUNCTIONAL STATUS

SELF-MANAGEMENT

SELF-EFFICACY

PAIN

EFFECTIVENESS

Self-management programs have been developed for a number of chronic medical conditions, such as asthma, diabetes, hypertension, and arthritis<sup>1-8</sup>; the goals of such programs include giving the patient tools for assessing the activity of

disease, helping the patient to determine the appropriate level of treatment, and alerting the patient when to seek medical attention<sup>9</sup>. Following these principles, Lorig and colleagues developed the Arthritis Self-Management Program (ASMP)<sup>7,10</sup>, a 6 session course led by a trained facilitator based on a structured syllabus<sup>7</sup>.

Several controlled studies have shown that participation in the ASMP is associated with a decrease in both a patient's level of pain and their use of health care resources<sup>7,11</sup>. All these factors have contributed to the US Centers for Disease Control, the Arthritis Foundation, and the American College of Rheumatology (ACR) recommending that persons with arthritis consider participating in the ASMP<sup>12-15</sup>, and promotion of the course through local chapters of the Arthritis Foundation.

We examined the effectiveness of the ASMP for patients treated by primary care physicians participating in a large integrated delivery system. We compared the ASMP classes (intervention) to use of just the ASMP "manual" (control)<sup>16</sup> with respect to their effects at followup on patients' levels of pain, function, self-efficacy, mental health, and vitality.

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## MATERIALS AND METHODS

**Study sites and patient recruitment.** The study took place in a physician network (the “network”) in Massachusetts. The network is linked by common insurance contracts, and includes roughly 1000 primary care physicians, about 1100 community specialists, and a group of affiliated acute care hospitals. The network is organized into physician and physician-hospital organizations by geographical site; quality improvement programs, such as the ASMP, are carried out through the site-specific physician organizations. Twelve sites agreed to participate in this trial. Eligible patients included all persons with primary care physicians in the participating network who could be identified using claims data as having osteoarthritis (OA) or rheumatoid arthritis (RA). To target patients with these diagnoses for participation in the trial we required potential subjects to be members of insurance plans that provided to the network administrative claims data containing diagnosis codes (714.0 for RA and 715.1–715.9 for OA). We searched the claims records of all eligible patients during the year prior to the study to determine the number of potential subjects from each site. We then randomly selected 6 sites for participation in the intervention group and 6 for the control group. To ensure roughly equal numbers of eligible patients, sites were randomized as a block into either the intervention or control arm. One intervention site dropped out of the network several months after the trial had begun, and we elected to replace it with a large control site.

With the consent of the primary care physicians, we sent letters to patients who were from intervention sites inviting them to participate in the ASMP course. The patients could choose not to be contacted further or ask to be enrolled. If there was no response, we called patients to determine their interest in the course. We enrolled patients into courses over the study year until we achieved our goal enrollment. Patients in the control sites were also contacted initially by letter. Those who expressed an interest or did not refuse further contact were then telephoned. A research assistant explained the study, and patients who agreed to participate were sent a baseline questionnaire and the ASMP manual<sup>16</sup>.

**Arthritis self-management program course and manual.** The ASMP course has been described in detail<sup>10</sup> and consists of 6 weekly sessions, each about 2 hours in duration, led by a trained facilitator. The meetings are interactive discussions that each focus on a different topic from *The Arthritis Helpbook*, including basic explanations of RA, OA and fibromyalgia, development of a self-management plan, exercising, managing pain and fatigue, and working with your health care resources<sup>16</sup>. Each participant received a free copy of *The Arthritis Helpbook* and was asked to read sections prior to a given class. The same facilitator participated in all classes in this trial, sometimes with a co-leader. The courses were taught at a variety of locations (hospital conference rooms, physician office buildings, senior citizen centers) based on availability and ease of transportation and parking for participants. Transportation was provided for several classes and parking was always reimbursed. Participants paid no fees to take the class. Meeting times were consistent for each session of a given course, but we alternated courses times between late morning, early afternoon, and early evening to allow as many people as possible to attend.

Patients in the control group were sent a copy of *The Arthritis Helpbook* and asked to read it; however, they were not offered the course including interactive sessions.

**Patient questionnaires.** All patients expressing an interest in participating were sent a baseline questionnaire prior to starting the ASMP course or reading the manual. Patients in the intervention group that filled in the baseline questionnaire and attended at least one class were sent a followup questionnaire 4 months after their initial survey was received. In the control group, every patient that sent in a baseline questionnaire also was sent a 4 month followup questionnaire. Items from the questionnaire formed the basis for the study’s primary endpoints, including pain, disability, self-efficacy for pain control, mental health, and vitality.

Each of these outcomes was assessed using validated instruments and all had excellent reliability in our study population (all Cronbach alpha > 0.90). Disability information was collected using the Modified Health Assessment Questionnaire developed and validated by Pincus and colleagues<sup>17</sup>. This 8

item scale asks patients to determine whether they are able to perform specific activities that require upper and lower extremity disability (0 = “without any difficulty” and 3 = “unable to do”). A one item numeric response scale was used to survey for pain with 1 = “no pain” and 10 = “pain as bad as it gets”<sup>18</sup>. We examined patients’ confidence in their ability to control pain and arthritis symptoms using the self-efficacy scale developed by Lorig and colleagues, where 1 = “very uncertain” and 10 = “very certain”<sup>19</sup>. Mental health and vitality were assessed using these subscales from the Medical Outcomes Study Short Form-36<sup>20,21</sup>. Standard scoring algorithms were applied to the mental health and vitality indices so that 0 = the lowest (worst) mental health or vitality and 100 = the highest (best)<sup>22</sup>.

Secondary endpoints consisted of patient satisfaction with arthritis care, patient satisfaction with arthritis treatment outcomes, patient satisfaction with the ASMP course (intervention) or manual (controls), and self-reported resource use. We used validated indices of patient satisfaction with arthritis care and outcomes (1 = “very satisfied” and 4 = “very dissatisfied”) that were highly reliable (both Cronbach alpha > 0.90)<sup>23</sup>. Six questions about the patient’s satisfaction with the course or manual were included on the followup questionnaire (Cronbach alpha = 0.94). Finally, patients were asked to report how many times in the past 4 months they had seen a health care provider in general and for arthritis, how many times they had visited an emergency department in general and for arthritis, and how many times they had stayed overnight in a hospital for any cause and for arthritis. Patients also provided lists of prescription and nonprescription medications at baseline and followup.

Sociodemographic variables collected on the baseline questionnaire included age, sex, race, marital status, and annual household income. Other information about the patient’s arthritis included diagnosis (RA, OA, or other arthritis), duration of arthritis, and primary arthritis doctor. The names of all primary arthritis doctors were cross-indexed against the ACR 1998 Membership Directory to determine whether patients had seen a rheumatologist<sup>24</sup>. Additionally, patients reported their comorbid medical illnesses using a validated self-report instrument<sup>25</sup>.

All aspects of this study were approved by our institutional review board, including questionnaires, recruitment material, and intervention methods.

**Analysis.** We first compared baseline characteristics of patients from control and intervention groups using Student t tests or chi-square tests. Next, the primary and secondary outcomes were assessed at baseline and followup. Values were compared at baseline and followup for each group assignment and then intervention versus control using Student t tests. We considered performing adjusted multivariable analyses controlling for baseline patient characteristics and sites; however, the null results for all primary endpoints obviated such analyses. To determine whether subgroups of patients improved in pain or disability, we calculated a change score and examined whether baseline patient characteristics were associated with improvement for intervention patients versus controls. P values were calculated using Student t tests.

For the secondary endpoints, resource use and satisfaction, we conducted similar unadjusted comparisons of control and intervention patients. We found some differences between satisfaction at followup and thus created multivariable models adjusting for age, sex, and where appropriate, baseline satisfaction. All analyses were conducted using SAS statistical software<sup>26</sup>.

We examined what size difference in endpoints between intervention and control patients could be detected based on the effective sample size, assuming an alpha of 0.05 and a power of 0.80.

## RESULTS

Based on the assignment of sites, 1692 patients were invited to participate in the ASMP course (intervention) and 921 patients were invited to receive the ASMP manual (controls). The recruitment rate (patients agreeing to participate whether they actually did or not) for the intervention arm was 12.2% and for the controls 12.9%. Patients who were successfully recruited did not differ in age or sex from those who refused

(both  $p > 0.2$ ). Of those patients who agreed to participate, 43% did not complete either the baseline or 4 month followup questionnaires. This group of noncompleters was similar to those who completed the study with respect to age and sex (both  $p > 0.8$ ).

Patients in the intervention arm who completed baseline and 4 month questionnaires were compared to those in the control arm (Table 1). Patients in the intervention arm were slightly older and fewer were college educated (both  $p < 0.05$ ). As well, they were more likely to have lower annual household incomes and less likely to have paid employment (both  $p < 0.05$ ). Fewer patients in the intervention arm had RA ( $p = 0.006$ ) and there was a trend toward less being seen by a rheumatologist for their arthritis care ( $p = 0.08$ ). The 2 groups did not differ significantly in sex, race, marital status, duration of arthritis, or number of comorbid illnesses ( $p$  values  $> 0.05$ ).

While there were some differences noted in baseline patient characteristics between the intervention and control groups, pain, disability, self-efficacy for pain, mental health, and vitality scores were all similar at the start of the study (all  $p$  values  $> 0.05$ ) (Figure 1). At the 4 month followup, the intervention and control groups still had similar scores for all primary endpoints. Additionally, none of the followup scores for any of the primary endpoints differed significantly from baseline scores in the intervention or control groups. These results were tested in adjusted models controlling for baseline age, sex, household income, primary arthritis diagnosis, and

whether or not the patient was treated by a rheumatologist; no significant differences between intervention and control groups were seen in these multivariable models.

We next examined whether there were any patient subgroups that experienced improvement in pain or disability from the intervention (Table 2). Characteristics that were analyzed included age, sex, education level, annual income, diagnosis, baseline self-efficacy, baseline pain, and baseline disability. None of these patient features identified a group that experienced significantly more improvement in intervention versus control groups.

We assessed the secondary endpoints patient satisfaction and health care resource use. There were no significant differences in satisfaction with arthritis treatment or outcomes between patients in the intervention and control groups (Table 3). In analyses adjusting for age and sex, patients in the intervention groups were more likely to agree with recommending the ASMP course than control patients were to recommend the ASMP manual ( $p = 0.008$ ). We found no differences in baseline or followup physician visits, visits for arthritis, hospitalizations or emergency department visits for arthritis, and medication use (all  $p > 0.05$ ) (Table 4).

Finally, we calculated the size of the effect for which we had 80% statistical power to detect differences between intervention and control groups for the primary endpoints. Based on the standard deviations observed, we had sufficient power to detect a difference  $\geq 9\%$ .

Table 1. Baseline patient characteristics.

Characteristics	Intervention, n = 104	Control, n = 74
Age, yrs mean $\pm$ SD	68 $\pm$ 10*	61 $\pm$ 12
Sex, % female	69	74
Race, % white	96	93
Marital status, % married	63	53
Educational level, % college graduate	29	46
Annual household income, column %		
< \$20,000	28	16
\$20,000–39,999	27	22
\$40,000–59,999	14	23
$\geq$ \$60,000	7*	16
Employment status, column %		
Student	4	1
Retired	52*	34
Disabled or unemployed (variable)	4*	11
Housework	12	12
Paid employment	20*	37
Primary diagnosis, column %		
OA	61	49
RA	23*	42
Other	17	16
Duration of arthritis, mean $\pm$ SD	12 $\pm$ 12	11 $\pm$ 12
Rheumatologist treats arthritis, % yes	39	53
Comorbid conditions, mean $\pm$ SD	3.4 $\pm$ 2.1	3.3 $\pm$ 1.6

\* P values (chi-square or Student t tests)  $\leq 0.05$ . See text for description of variables.

## DISCUSSION

We describe a randomized controlled trial comparing the Arthritis Self-Management Program course to the ASMP manual in patients diagnosed with OA, RA, or fibromyalgia seen primarily by primary care physicians. Patients were well balanced between intervention and control groups with respect to baseline pain, disability, self-efficacy, mental health, and vitality. Four months after the baseline questionnaire, patients in the intervention group showed no significant benefits with respect to these primary endpoints and did not differ from controls. Satisfaction levels for the intervention group for their arthritis care were not significantly different from the control group. However, intervention patients were more likely to recommend the ASMP course than the controls were to recommend the manual. Resource use was not different between the 2 groups.

These results are in contrast to previous findings suggesting a benefit from the ASMP course. Lorig and colleagues developed and tested this program in volunteers recruited passively through print and radio public announcements<sup>7</sup>. Their original controlled trials and followup studies showed a significant and clinically meaningful benefit in pain reduction, but not function. This change appeared to be mediated by an improvement in self-efficacy<sup>7,27,28</sup>. Additionally, their work suggested a reduction in resource use that translated into very favorable cost-effectiveness ratios for the program<sup>29,30</sup>.

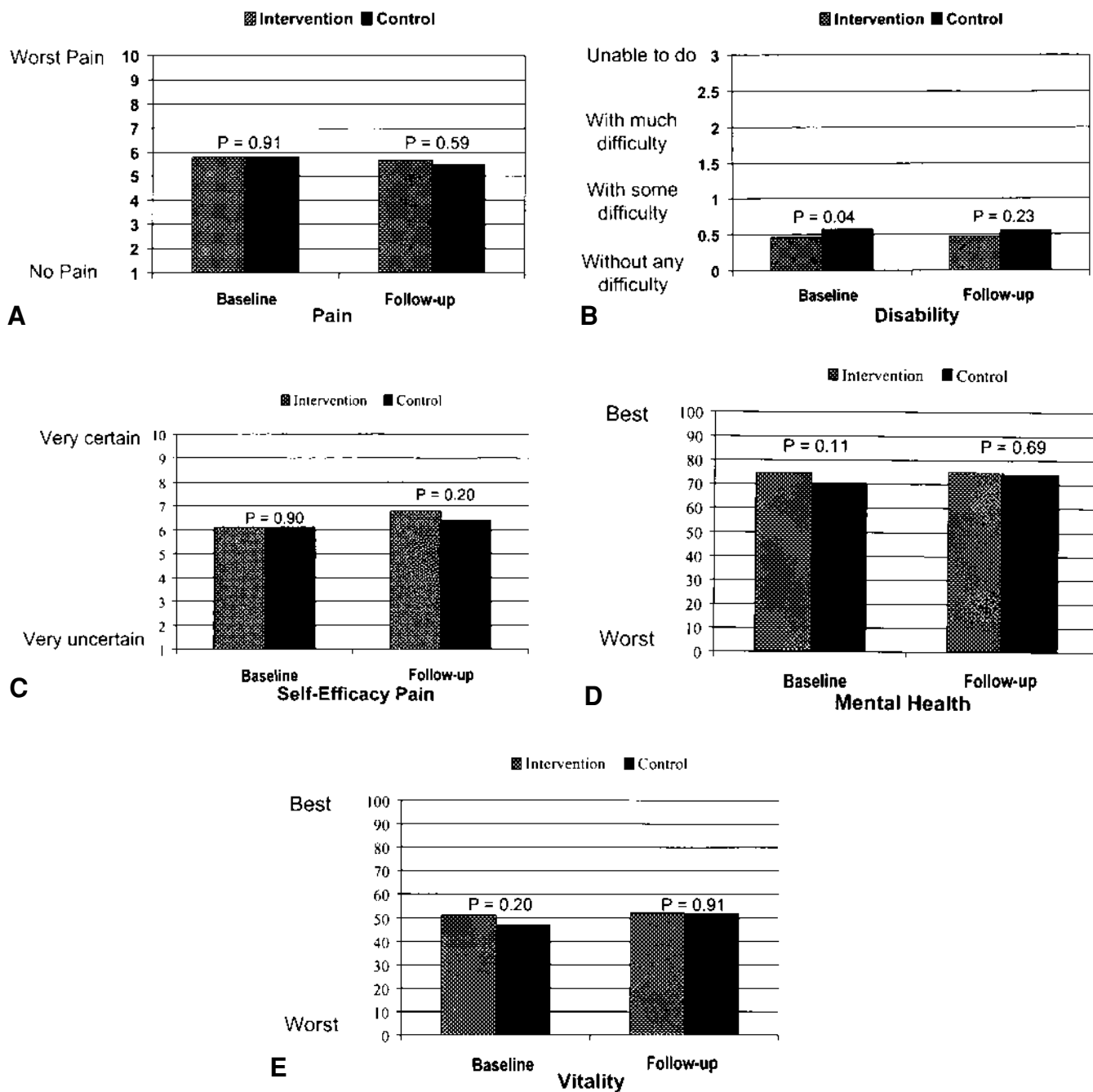


Figure 1. Baseline and 4 month followup in pain, disability, self-efficacy, mental health, and vitality. Pain was measured using a numeric response scale<sup>18</sup>. Disability was measured using the Modified Health Assessment Questionnaire<sup>17</sup>. Self-efficacy for pain was measured using a scale developed by Lorig, *et al*<sup>19</sup>. Mental health and vitality were measured using the appropriate subscales of the SF-36<sup>20</sup>.

Comparable results have been found from the ASMP course when tested in other countries using similar patients<sup>31</sup>.

The contrasting results of this study may be the result of differences in the study population. While we also recruited volunteers, subjects in this study were more actively recruited through letters and telephone followup, which may have meant that the population studied was less motivated to adhere to suggestions made in the ASMP course. Viewed through

Prochaska's transtheoretical stages of change model, patients in this trial of the ASMP may have been "pre-contemplators" (they may not have been as ready to change their lifestyle to improve); while in more successful trials, subjects may have been "contemplators" or already in the "preparation" or "action" stages<sup>32</sup>. It is also possible that the ASMP course was taught in a less effective manner by the instructors participating in this trial. However, the training for facilitators is stan-

*Table 2.* Patient improvement by baseline patient characteristics. All percentages are based on calculations for the given column. High baseline self-efficacy refers to  $\geq 6$ , the median, on a scale of 1 to 10. Low baseline pain refers to  $< 6$ , the median, on a scale of 1 to 10. Low baseline disability refers to  $< 0.5$ , the median, on a scale of 0 to 3. P values were calculated from chi-square tests to examine the differences between intervention and control groups. No p values  $< 0.05$ .

Predictor	Improvement in Pain		Improvement in Disability	
	Intervention Patients, n (%)	Control Patients, n (%)	Intervention Patients, n (%)	Control Patients, n (%)
<b>Age</b>				
< 65 yrs	9 (39)	16 (46)	9 (31)	14 (37)
$\geq 65$ yrs	19 (32)	4 (17)	24 (36)	10 (33)
<b>Sex</b>				
Female	23 (38)	23 (36)	22 (32)	18 (36)
Male	8 (30)	5 (29)	12 (36)	6 (33)
<b>Education</b>				
< College graduate	19 (32)	7 (24)	23 (32)	12 (34)
College graduate	13 (46)	13 (43)	12 (38)	12 (36)
<b>Annual income</b>				
< \$40,000	25 (36)	10 (31)	25 (31)	15 (38)
$\geq$ \$40,000	7 (37)	10 (37)	10 (43)	9 (31)
<b>Diagnosis</b>				
OA	21 (38)	10 (36)	19 (31)	15 (45)
RA	6 (29)	7 (26)	10 (38)	10 (34)
Other	5 (31)	5 (50)	8 (44)	2 (18)
<b>Baseline self-efficacy</b>				
High	19 (41)	11 (31)	18 (35)	15 (38)
Low	9 (38)	11 (29)	17 (35)	9 (33)
<b>Baseline pain</b>				
Low	8 (23)	6 (23)	9 (26)	9 (35)
High	24 (45)	14 (42)	21 (40)	12 (34)
<b>Baseline disability</b>				
Low	19 (44)	9 (38)	12 (22)	8 (28)
High	13 (30)	11 (31)	23 (47)	16 (41)

*Table 3.* Satisfaction with arthritis care and Arthritis Self-Management Program. Satisfaction was measured using a scale developed by Solomon and colleagues, where 1 = “very satisfied” and 4 = “very dissatisfied”<sup>23</sup>. Agreement with statements was measured with a 5 point Likert scale, where 1 = “strongly agree” and 5 = “strongly disagree.” P values represent differences between intervention and control groups and were calculated from linear models adjusting for age and sex. For satisfaction models, baseline satisfaction was also included as a covariate.

	Intervention		Control	
	Baseline	Follow up	Baseline	Follow up
<b>Satisfaction with</b>				
Physician communication				
about arthritis	1.5	1.5	1.4	1.3
Treatment outcomes for arthritis	2.4	2.3	2.2	2.0
<b>Agreement with</b>				
ASMP course (intervention) or manual (control)				
helped me manage my arthritis	NA	2.2	NA	2.4
Would recommend course (intervention) or manual (control)	NA	1.5*	NA	1.8

\* p  $< 0.05$ . NA: not available

*Table 4.* Health care resource use at baseline and 4 months. All figures represent the average number of the specific resource being examined. P values were calculated from Student t tests to examine the differences between intervention and control groups.

Resource Use (in prior 4 months)	Intervention		Control	
	Baseline	Followup	Baseline	Followup
Physician visits	2.7	2.5	3.6	2.6
Physician visits for arthritis	1.0	0.9	1.5	0.9
ED visits	0.1	0.1	0.3	0.06
ED visits for arthritis	0.02	0.03	0.01	0.0
Hospitalizations	0.0	0.2	0.1	0.07
Medications	4.6	4.5	4.7	4.5
Medications for arthritis	1.8	1.7	1.7	1.8

No p values < 0.05. ED: emergency department.

standardized, the course follows a carefully outlined syllabus, and the primary course facilitator in this study has extensive experience leading the course and teaching other facilitators. While this trial's primary facilitator does not have arthritis, a factor that some believe may contribute to a facilitator's effectiveness, prior data suggest no significant difference between lay-taught and professionally-taught courses<sup>33</sup>.

One possible limitation of our study was the method of patient recruitment, which was associated with low enrollment and high dropout rates. After one intervention site dropped out of the physician network, we substituted a large control site because of concerns about recruiting enough patients into the ASMP course. This created an imbalance in the total eligible populations for intervention and control groups; however, we are not aware that this created any systematic bias in the patients eligible for intervention or control groups. Additionally, the recruitment rate was low and the dropout rate substantial. We examined what data were available on the nonrecruited patients, and they did not differ from those that filled in baseline surveys with respect to age or sex. Similarly, patients who only completed a baseline survey and not a followup were not different from those who completed both. Based on our calculations of the effect size detectable within the study sample, we should have been able to detect a relatively small difference between intervention and control groups, if one existed; however, no differences were detected.

These findings suggest that the ASMP, when administered through an integrated network of primary care and specialist physicians, may not be as effective as traditional programs with more passive recruitment. This is particularly important since self-management programs have been developed for a number of chronic conditions, such as diabetes, hypertension, and asthma, that are increasingly the focus of quality improvement in organized delivery systems. One might imagine that organized health care systems present an ideal environment in which to recruit and run such self-management programs. However, the results of this trial suggest that the effects of a self-management program, such as the ASMP, may not easily

transfer to such a model of care. More controlled trials of self-management efforts should be conducted in a variety of practice settings to determine how best to deploy such programs.

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