

Self management of arthritis in primary care: randomised controlled trial

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Abstract

Objective To evaluate clinical effectiveness of a self management programme for arthritis in patients in primary care with osteoarthritis.

Design Randomised controlled trial.

Setting 74 general practices in the United Kingdom.

Participants 812 patients aged 50 and over with osteoarthritis of hips or knees (or both) and pain or disability (or both).

Intervention Participants were randomised to six sessions of self management of arthritis and an education booklet (intervention group) or the education booklet alone (control group).

Main outcome measures Primary outcome was quality of life, as assessed by the short form health survey (SF-36). Several other physical and psychosocial secondary outcomes were assessed. Data were collected at baseline, four months, and 12 months.

Results Response rates were 80% and 76% at four and 12 months. The two groups showed significant differences at 12 months on the anxiety subscore of the hospital anxiety and depression scale (mean difference -0.62 , 95% confidence interval -1.08 to -0.16), arthritis self efficacy scale for pain (0.98, 0.07 to 1.89), and self efficacy for other aspects of management (1.58, 0.25 to 2.90). Results were similar for intention to treat and per protocol analyses. No significant difference was seen in number of visits to the general practitioner at 12 months.

Conclusions The self management of arthritis programme reduced anxiety and improved participants' perceived self efficacy to manage symptoms, but it had no significant effect on pain, physical functioning, or contact with primary care.

Trial registration Current Controlled Trials ISRCTN79115352.

Introduction

Patient centred programmes for self management of arthritis, tested in the United States on volunteers from the community with osteoarthritis and rheumatoid arthritis, had beneficial effects on pain, depression, exercise taken, communication with doctors, and participants' perception of their capacity to manage the disease (arthritis self efficacy).¹ Similar results were

found in studies on volunteers in the UK.² A review commissioned by the Department of Health suggested that self management can improve knowledge, performance of self management behaviours, self efficacy, and aspects of health status compared with standard care, but the studies had small sample sizes and short follow-up, and they used non-validated outcome measures.³

A recent small US randomised controlled trial of participants from primary care with osteoarthritis, rheumatoid arthritis, or fibromyalgia recruited to programmes for self management of arthritis showed no difference in any outcomes measured at four months.⁴ The UK government is promoting the expert patient programme in primary care settings, a generic self management programme for people with a variety of chronic diseases (www.expertpatients.nhs.uk/), developed from the arthritis self management programme. We hypothesised that for primary care patients with osteoarthritis, participation in an arthritis self management programme and receipt of an educational booklet would improve their overall function compared with receipt of the booklet alone.

Methods

Practices

People with osteoarthritis were recruited from UK general practices in areas where the voluntary organisation Arthritis Care provided the "challenging arthritis" intervention. This is a programme for self management of arthritis developed from the original US model based on social cognitive theory, in which self efficacy plays an important part (see box A on bmj.com).⁵ General practices were identified from the Medical Research Council's research framework or local primary care research networks.

Recruitment

We recruited participants between December 2000 and February 2003. Twelve month follow-up for all participants ended in March 2004.

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Figures A and B, figure legends, and boxes 1 and 2 are on bmj.com



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Participants

Patients were eligible if aged 50 or more, clinically diagnosed with osteoarthritis of the hips or knees (or both) for at least a year, and if they had had associated pain or functional disability (or both) during the past month. We excluded people who had been recommended surgery for arthritis or who had poor mobility, poor understanding of English, associated neurological signs, or cognitive impairment.

General practitioners identified potential participants from practice attendees over a six week period. Practices' computerised records were also searched for relevant osteoarthritis clinical terms (Read codes) and prescriptions for regular non-steroidal anti-inflammatory drugs or analgesics. We examined all clinical records to establish the duration of the diagnosis of osteoarthritis. Patients who met all eligibility criteria and agreed to participate were randomised to one of two groups.

Randomisation

We used an independent centralised computerised system to randomise the participants (see *bmj.com*). The intervention group received an education booklet and an invitation to participate in a local challenging arthritis course. The booklet was designed for the study and incorporated information available to the public from Arthritis Care and the Arthritis Research Campaign.

The control group received only the education booklet, reflecting standard primary care. Leaflets have substantially less impact than the self management programme on the outcomes measured.⁶

Outcomes were assessed through questionnaires completed by the participants at entry to the trial before randomisation and at four and 12 months (box B on *bmj.com*). All measures were validated in primary care populations. Non-responders were sent a reminder questionnaire. At 12 months, non-responders were telephoned and given the option of completing only the primary outcome measure (the short form health survey, SF-36).

Statistical methods and analysis

From our sample size calculation, based on the primary outcome measure (SF-36), we needed 1000 participants (see *bmj.com*). We used descriptive statistics to outline the characteristics of the trial

participants. To adjust for baseline scores, we used analysis of covariance to compare outcome between the two groups. Assumptions required for this method were found to be valid for all outcomes. Primary comparisons assessed the effect of the intervention at 12 months. Analysis was based on intention to treat. We used imputation techniques to assess the impact of missing data (see *bmj.com*).

For the multiple imputation analysis we split participants into those who attended four or more sessions (judged to have received a clinically significant "dose") and those who attended fewer than four. We also undertook a per protocol analysis of patients who had attended four or more sessions and for whom full sets of data were available.

Results

We approached 2891 people from 74 UK general practices and recruited 812 participants (see *bmj.com*). Questionnaire response rates were 95% at baseline, 80% at four months, and 76% at 12 months, with no significant differences in response rates between groups. We found no significant differences in patient characteristics at baseline between the intervention and control groups. The mean age of participants was 68 years and two thirds (66%; 510/812) were women. Most participants were white and owned their homes rather than renting. In the intervention group more than half (56%; 219/392) attended four or more sessions, 9% (37/392) attended only one or two sessions, and 29% (115/392) attended none.

At baseline we found no significant differences between the groups in outcome variables. In the intention to treat analysis with imputation of missing values we found no significant differences in the primary outcome (SF-36 physical and mental health scores), but in the intervention group we found a trend towards improvement on the mental health scale (table; figs A and B on *bmj.com*). With respect to the secondary outcomes, we found no significant differences for the three components of the WOMAC osteoarthritis index, although the intervention group showed a consistently favourable trend, which was greater at 12 months than at four months.

In the intervention group the anxiety subscore of the hospital anxiety and depression scale (HADS) was

Outcomes of a randomised controlled trial of self management of arthritis

Outcome measure	Adjusted difference in means (95% CI)			
	4 months		12 months	
	Intention to treat analysis	Per protocol analysis	Intention to treat analysis	Per protocol analysis
Short form 36				
Mental health	0.11 (-1.18 to 1.40)	0.82 (-0.94 to 2.57)	1.35 (-0.03 to 2.74)	1.56 (-0.28 to 3.39)
Physical health	0.22 (-1.50 to 1.94)	-0.37 (-2.02 to 1.28)	0.33 (-1.31 to 1.98)	0.24 (-1.63 to 2.11)
WOMAC osteoarthritis index				
Pain	-0.15 (-0.57 to 0.28)	-0.30 (-0.79 to 0.19)	-0.33 (-0.78 to 0.13)	-0.47 (-1.05 to 0.10)
Stiffness	-0.05 (-0.28 to 0.17)	-0.12 (-0.36 to 0.11)	-0.17 (-0.43 to 0.09)	-0.13 (-0.40 to 0.14)
Physical function	-1.22 (-2.59 to 0.16)	-0.80 (-2.24 to 0.63)	-1.17 (-2.84 to 0.50)	-0.95 (-2.63 to 0.74)
Hospital anxiety and depression scale				
Anxiety	-0.36 (-0.76 to 0.05)	-0.68 (-1.15 to -0.20)*	-0.62 (-1.08 to -0.16)*	-0.72 (-1.24 to -0.21)*
Depression	-0.40 (-0.76 to -0.03)*	-0.57 (-0.96 to -0.18)*	-0.41 (-0.82 to 0.01)	-0.33 (-0.76 to 0.10)
Arthritis self efficacy scale				
Pain	1.63 (0.83 to 2.43)*	2.55 (1.56 to 3.56)*	0.98 (0.07 to 1.89)*	1.43 (0.37 to 2.48)*
Other	1.83 (0.74 to 2.92)*	2.81 (1.74 to 3.87)*	1.58 (0.25 to 2.90)*	1.54 (0.48 to 2.60)*

*Statistically significant.

significantly reduced at 12 months (adjusted difference in means -0.62 , 95% confidence interval -1.08 to -0.16). We also found a significant reduction in the depression subscore at four months (-0.40 (-0.76 to -0.03), but this was lost by 12 months. We found a significant difference between groups for the pain subscore of the arthritis self efficacy (ASE) scale after four and 12 months (1.63 , 0.83 to 2.43 ; 0.98 , 0.07 to 1.89) and for the “other” subscore (1.83 , 0.74 to 2.92 ; 1.58 , 0.25 to 2.90).

The two groups did not differ significantly in rates of consultation with a general practitioner at 12 months before the study or at 12 months’ follow-up. The results of the intention to treat analysis and the per protocol analysis (those patients who completed four or more sessions of the intervention and for whom we had complete data) were similar (table).

Discussion

Our trial adds to the literature on self management of osteoarthritis because of its relatively large size,⁷ and because participants were recruited from primary care rather than from outpatient clinics or via advertisements. The intervention had an impact on the psychological wellbeing of participants. It reduced anxiety, as measured by the hospital anxiety and depression scale, and it increased self efficacy—participants were more confident about managing pain and other arthritis related symptoms as a result.

Other outcomes, in particular the mental health subscale of the SF-36, showed a favourable trend in the intervention group, but this was not statistically significant. These findings indicate that the intervention improves the participants’ ability to manage their symptoms and leads to a sustained reduction in anxiety, but that it does not substantially affect physical functioning or levels of pain experienced. The intervention did not reduce the number of consultations with a general practitioner; this may be because the intervention encouraged participants to seek advice from their general practitioner. Reductions in consultation rates might arise after the 12 month follow-up, as a result of greater self efficacy.

Comparison with other studies

We used established and validated clinical measures that have been used in other studies of osteoarthritis. Many studies have used other outcome measures, including health behaviours and health status, which are usually self reported, not always validated, and have indicated an increase in desirable patient behaviours, such as taking more exercise, after the intervention.⁷ It is not clear whether these changes have positive and long term effects on patient behaviour and morbidity. Moreover, only a few studies report improved quality of life.⁸ This raises questions about which outcomes are most meaningful and what are appropriate effect sizes.

Previous studies of self management programmes for arthritis were heterogeneous in terms of the intervention, underlying theory, and methods.^{7,9} A systematic review of education programmes for self management of chronic disease found small to moderate effects for selected outcomes (such as diabetes and asthma). For arthritis there was a trend towards reduced pain and disability, but the effects were not

statistically significant.⁹ Psychological outcomes were not examined. Some evidence exists that treating depression in patients with osteoarthritis may help reduce the amount of pain and improve functional status and quality of life.¹⁰

Strengths and limitations

Although we did not recruit the initial target of 1000 participants, our attrition rate (24% by 12 months) was lower than anticipated. Our data showed that we had overestimated the sample size needed. The trial would probably have identified clinically meaningful differences in primary outcomes if they existed.

We recruited participants who had been diagnosed with osteoarthritis by their general practitioner rather than applying formal assessment criteria, which are not used in routine general practice. The sociodemographic data for our participants in terms of housing status was similar to 2001 UK census data, apart from a slight predominance of white participants (99.5%) compared with the national average of 96% for this age group.

Almost 30% of the intervention group did not attend any “challenging arthritis” sessions. Telephone interviews with a subgroup of non-attenders indicated the main reason was timing of the local group or difficulties with access. Results of the intention to treat and per protocol analyses suggest that poor attendance did not affect the final results.

Our trial showed small positive changes across all outcome measures, but these were statistically significant only for mental health outcomes and arthritis self management behaviours. Patients who volunteered for previous studies may have been more severely affected than those recruited from primary care for this trial. The hospital anxiety and depression scale showed higher mean baseline values in a group of UK volunteers studied¹¹ than in the primary care patients in our trial. Despite this, our intervention group still showed a significant improvement in anxiety.

Policy implications

The UK government has been promoting the large scale provision of the expert patient programme through referral from primary care before a formal evaluation has been completed.¹² Our trial indicates that the intervention can lead to benefits in perceived psychological wellbeing, anxiety, and self efficacy for participants with osteoarthritis; however, although these psychological benefits were statistically significant, the effects were small and their clinical relevance for the population tested as a whole is unclear. Larger effects may be more likely in volunteers with high levels of motivation and morbidity.

Importantly, it was often difficult to recruit patients to a self management programme, which suggests that patients may not perceive a need for such programmes.

Conclusions

Our study adds to the literature on self management programmes for arthritis. Little doubt exists that such techniques provide some benefit for patients with chronic conditions, but the best way to provide the intervention is unclear, and insufficient evidence exists

What is already known on this topic

Self management programmes for arthritis tested on US and UK volunteers indicate benefits to pain, depression, exercise taken, communication with doctors, and participants' perception of their ability to manage the disease

The government is promoting the widespread provision of a generic self management programme for chronic disease through primary care

What this study adds

Participants recruited from UK primary care to a randomised controlled trial of self management for arthritis reported reduced symptoms of anxiety and improved self efficacy in managing symptoms

The intervention had no significant effect on pain, physical functioning, or primary care contacts at 12 months' follow-up

These modest benefits do not justify a policy of active recruitment in primary care

to justify a policy of active recruitment of patients from primary care settings.

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A bloody day at the accident and emergency department

It was an unusually quiet night duty. I started at midnight on a cold winter night. My colleague handed me two cases to follow up—one was an asthmatic patient, who was discharged after two hours, and the other was a patient with renal colic, who became better with analgesia. Five hours passed without any patient knocking at the door. I thought it might be the cold that made people prefer to stay at home rather than coming to hospital.

At 7 10 am, we heard a loud explosion. No one knew what it was. Shortly afterwards, about 80 schoolgirls were brought to casualty with severe injuries. Blood was everywhere, and their clean white school uniforms had turned crimson. They were crying, their innocent faces deeply shocked. Everyone was shocked: we were used to seeing casualties and lethal injuries, but not 80 schoolgirls at once. All this was because a terrorist had blown himself up at the entrance to a high school when the students were about to start their classes.

We did not have enough beds for all of them. A red emergency state was declared, and within minutes many doctors and nurses were at the scene. We had to put two girls into each bed. We ran out of suturing materials and had to open the store. Many children were taken to theatre to repair their major injuries, some with minor injuries were managed in the

accident and emergency department, and, sadly, some died. It was a bloody morning I had that day.

When everything finished at the end of the day, I went home shocked at what I had seen. What made me feel sick was that I couldn't find any answer to the question of why a person would blow himself up to kill innocent schoolgirls. This is an everyday story in Iraq, my beloved country. This experience has given me more determination to help the innocent people, hoping that some day there will be an end to this death toll.

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