

Arthritis education: the integration of patient-reported outcome measures and patient self-management

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Abstract

Objectives

To assess the integration of PROMs and patient education, using the joint-fitness programme, and the effectiveness of this combined approach on disease activity and adherence to therapy.

Methods

This was a double-blind randomised controlled study which included 147 arthritic patients monitored over 18 months. Every patient completed a PROMs questionnaire. By the 6th month of treatment, the patients were randomly allocated to an active group (74 patients) that was able to view former self-reported PROMs scores and discuss the implementation of the joint fitness programme as a tool for psycho-educational interventions. The control group (73 patients) continued their treatment and management based on viewing their recorded PROMs and clinical assessment. The patients were assessed at 3 monthly intervals for another 12 months. The primary outcome was the change in the patients' adherence to their medications, disease activity score (DAS-28) and PROMs domains.

Results

The integration of patient education and PROMs led to a significant greater reduction of disease activity parameters, DAS-28 score, as well as improvement of the patients' adherence to therapy ($p < 0.01$). The improvement of disease activity parameters was associated with the improvement in functional disability and quality of life scores. At the 18-month follow-up, both the self-management and cognitive behavioural therapy intervention demonstrated improvement for disease activity (effect size 1.4 and 1.2, respectively)

Conclusion

The integration of patient education and PROMs succeeded in improving self-perceived health as well as disease activity. The patient education for patients with inflammatory arthritis is feasible in the standard clinical practice.

Key words

PROMs, patient education, joint fitness programme, arthritis

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Introduction

The introduction of the biologic therapy era left health education research in arthritis and musculoskeletal diseases experiencing extraordinary challenges. Whilst educational opportunities for primary prevention of arthritis are limited, a large variety of organised programmes have been developed to help patients deal with their disease. These were planned according to the commonly accepted principles of education, psychology, and psychotherapy; applied consistently by personnel with some kind of training, and were able to produce desirable changes in knowledge, behaviour, as well as health outcome in arthritis patients. In an earlier review, Daltroy and Liang (1) predicted that researchers will increasingly turn to new populations and methods of delivery, as well as development of arthritis-specific applications of theory, especially in areas such as helplessness, cognitive processing, and pain management.

The most common types of educational intervention in the treatment of arthritis are self-management programmes and cognitive-behavioural therapy. Both approaches emphasise learning new skills helpful in managing one's disease (2). Self-management programmes are broadly focused on using information, problem-solving and coping skills for symptom management. Their aim is not only to achieve more than the provision of information to increase knowledge, but also to change health behaviour and health status, teaching patients to identify and solve problems, set goals and plan actions (3). On the other hand, cognitive-behavioural therapy usually emphasises control of pain by understanding the interaction of emotions and cognition with the physical and behavioural aspects of pain (4).

OMERACT (Outcome Measures in Rheumatology) has provided a great stimulus to think about the effects of rheumatic diseases on patients and society, and the impact of their treatment. It all started in 1992, with the development of a core set of outcome measures for rheumatoid arthritis (RA) (5). As biologics have improved the prognosis for RA, the prioritisation of outcomes has shifted. This has reflected on the

way the patients are treated. Given that decreases in quality of life are attributed to the pain, impairment in physical function, sleep disturbances, and fatigue associated with RA, the appropriate management would be selected in view of its ability to improve these factors (6, 7). Over the past years, PROMs has gained importance among regulatory agencies such as the US Food and Drug Administration and the European Medicines Agency. This has brought PROMs assessments into focus, as it became a pivotal asset in the management of patients with RA. Continuous measures of change are generally the most powerful and, therefore, are preferred as primary outcomes in trials and clinical practice (8). Though PROMs is a major advantage for patient management and knowledge transfer, its value in patient education has not been assessed. Earlier reports also noted that studies of educational interventions commonly pay too little attention to statistical power in detecting differences between treatment groups (9).

In this study we assessed the integration of PROMs and patient education, using the joint-fitness programme as a tool for health education in arthritic patients, and the effectiveness of this combined approach to influence disease activity, behaviour and perceived helplessness, health status of persons with arthritis (as determined by improvements in pain, quality of life and physical function) as well as adherence to therapy.

Methods

Study design

A randomised, controlled, repeated measure study was carried out over a period of 18 months.

Subjects

One hundred and forty-seven patients diagnosed to have rheumatoid arthritis according to the ACR criteria (10) were included in this work. Local protocols for approval of the work were followed. All patients who participated in the study signed to agree their data could be used for the purpose of research.

Baseline assessment

Once the diagnosis of rheumatoid ar-

Competing interests: none declared.

thrititis is confirmed and explained to the patient, disease-modifying anti-rheumatic drugs (DMARDs) / biologic therapy was commenced according to approved protocols. The disease activity and DMARDs therapy were monitored regularly every 3 months for a period of 18 months. Prior to assessment in the clinic, each patient completed a copy of the multidimensional PROMs questionnaire (11) whilst sitting in the waiting area. A trained health care staff nurse was available for assistance. The questionnaire includes 11 domains assessing for functional disability, quality of life, visual analogue scale (VAS) for joint pain, global status, fatigue, duration of morning stiffness, review of the systems, falls and cardiovascular risks, self-helplessness (assessed using the modified rheumatology attitudes index [12]) as well as patient self-reported joint pain. The patients were then clinically examined. Tender joint count (28 joints) and swollen joint count (28 joints) were assessed and recorded. In addition to the blood checks to monitor their DMARDs / biologic therapy, each patient had a blood test for inflammatory markers: ESR and CRP.

At 6 months of treatment

By the 6th month of treatment, the patients were randomly allocated to an active group (74 patients) and a control group (73 patients).

Active group (Group I: 74 patients). During their visit to the clinic, the patients were encouraged to discuss their problems, set their own goals related to health areas which they identify as requiring improvement. They were also given the chance to view the scores recorded of their former self-reported outcome measures as well as discuss the changes in their disease activity parameters, co-morbidity risks, functional disability and quality of life. The cognitive domain was addressed through interactive education. The patient together with the treating rheumatologist discussed the best component of the joint-fitness programme to start with. The patients were taught what to anticipate or what was likely to happen, and guided with the skills

needed for self-care and decision making regarding the next step in the joint-fitness programme. The patients were assessed at 3 monthly intervals for another 12 months (unless they sustained a flare-up of their condition, at which time they would be reviewed earlier). Before every assessment in the clinic, every patient completed the multidimensional PROMs questionnaire and the change in the disease activity status was considered in parallel with the appropriate change in the educational targets.

Control group (Group II: 73 patients).

They continued their routine standard management (the patients were managed as per their complaints, outcome measures and examination on the visit day to the rheumatology clinic). The patients were monitored for a 12-month period at 3-monthly intervals. All the patient's disease activity parameters, patient's reported outcome measures, and medications were recorded and discussed verbally with the patient.

Joint-fitness programme

The joint-fitness programme is a patient-based programme that is dedicated to all patients suffering from different types of rheumatic diseases, such as osteoarthritis, rheumatoid arthritis, psoriatic arthritis and lupus. The objectives of the programme were: 1. patients (aimed at better understanding and management of their joint pain and disease in general): a) give patients suffering from inflammatory arthritis/joint pain the strategies and tools necessary to make daily decisions to cope with the disease; b) educate the patient about how to assess the main arthritis outcome measures regularly for their arthritis; c) help the patient identify and manage the impact of arthritis on their personal life; d) show the patient how to keep their muscles and joints fit; 2. health care professionals (aimed at building the doctor-patient relationship): a) review the effects of patient education on pain, disability, joint counts, patient as well as physician global assessments; b) identify the value of patient-reported outcome measures in clinical practice; c) learn how to implement patient-re-

ported outcome measures in the patients' management; d) identify the role of patient education as complementary to the standard medical care.

The programme includes 4 main components: a) educational – joint-learn, b) behavioural – joint-change, c) information – joint act and d) joint-cise (joint-exercise).

a) Joint-learn: Once the patient is diagnosed with arthritis, it's important to educate him/her about the different types of pain relief (medication, acupuncture, complementary medicine and diet). The patients are then informed on things they can do to ease their joint pain.

b) Joint-change: Therapies that interrupt destructive mind-body interactions include: behavioural therapy, lifestyle changes using visual diary charts, and journaling and other coping skills.

These well-studied and effective combinations of talk therapy and behaviour modification help the patient identify – and break – cycles of self-defeating thoughts and actions. Using visual diary charts/tables for activities carried out by the patient throughout the day and its impact on the patient's energy levels helps the patients identify which activities to avoid or how to integrate low energy activities in between activities that consume lots of energy and leave the patient feeling exhausted.

c) Joint-act: This deals with measures the patient can take to help controlling his arthritis and joint pain. While it is true that there is no magic pill that will work immediately, patients can remain ahead of their pain if they stay ahead of their pain and focused on their current disease activity as well as the treatment goals. Patients are taught things to do and others to avoid, to help easing their joint pain.

Joint-cise (Joint-exercise): This includes changes in everyday routines as well as exercises. Active physical exercises vary according to the patient's condition, namely range-of-motion exercises, strengthening exercises and endurance exercises.

Fall prevention: patients are advised to keep moving and how to choose a sensible shoe to wear. They are also taught how to do balance exercises.

Post-treatment questionnaire

At the end of 18 months of management, every patient who participated in the study was asked to complete a questionnaire consisting of 5 items to assess the patients' perspective of the way their disease was monitored and discussed, expectations for improvement and credibility of the intervention both for the educational programme (in the active group) and the standard management protocol (for the control group). These scales were administered using numerical VAS, scale 0–10, where 0 equals “not at all” and 10 corresponds to the maximum of that measure.

Outcome measures

The primary outcome was the change in the patients' adherence to their medications, disease activity score (DAS-28) and PROMs domains: pain score, patient global assessment, functional disability, quality of life and self-helplessness.

As secondary outcome, the rating of the post-treatment questionnaire was recorded and its correlation with medication adherence as well as disease activity parameters in each treatment group was analysed.

Sample size calculation

An expected increase in patient's adherence to treatment was expected to increase from 60 to over 80% (85%, for instance). A sample size calculation revealed a sample of 74 patients in each group enough to elucidate such difference at 0.05 alpha error and 0.90 power of the test. Sample size calculation was performed using the 10th version of STATA programme.

Statistical analysis

Collected measures were introduced to a database for data management and statistical analysis. Categorical variables are expressed in numbers and percentages, *i.e.* frequency tables, while quantitative scaled variables are presented as mean and standard deviation. Alpha error was always set at 0.05. All statistical manipulation and analyses were performed using the 16th version of SPSS.

Table I. Performance of patients towards their illness, by 18 months of therapy, in the active *versus* the control group.

Parameter	Active group	Control group
Adherence to medication	66/74 (89.1%)	47/73 (64.4%)*
Stop medications by the patient because of intolerance	4/74 (5.4%)	14/73 (19.2%)*
Cessation of medication by the physician for systemic side effects	6/74 (8.1%)	6/73 (8.2%)
Number of procedures done in the clinic (over the study period)	30/74 (40.5%)	54/73 (73.9%)*
Number of visits for flare-up of the disease that required early assessment (over the study period)	9/74 (12.1%)	25/73 (34.2%)*

* $p < 0.01$

Table II. Changes in disease parameters from baseline until the 18-month follow-up in both the active and control groups.

	Active			Control		
	At baseline	At 18 months	<i>p</i> -value	At baseline	At 18 months	<i>p</i> -value
PS	9.3 (0.4)	4.6 (0.9)	<0.001*	9.2 (0.5)	5.8 (0.7)	<0.001*
PGA	9.0 (0.5)	4.8 (1.0)	<0.001*	9.1 (0.7)	5.6 (0.7)	<0.001*
FnDis	2.5 (0.2)	0.92 (0.2)	<0.001*	2.6 (0.1)	1.7 (0.2)	<0.001*
QoL	2.4 (0.1)	0.9 (0.3)	<0.001*	2.5 (0.1)	1.4 (0.3)	<0.001*
Helplessness	9.2 (0.3)	4.7 (0.4)	<0.001*	9.1 (0.4)	6.2 (0.2)	<0.001*
DAS28	4.9 (0.6)	3.1 (0.3)	<0.001*	4.9 (0.3)	3.7 (0.3)	<0.001*

Values are mean (SD). PS: pain score; PGA: patient global assessment; FnDis: functional disability; QoL: quality of life; DAS: disease activity score.

Results

Demographic measures

There were no differences among the treatment groups with regard to age, sex, disease duration, socioeconomic status, or other co-morbidities. The mean age in the active group was 53.2±9.6 years, whereas it was 52.8±9.5 years in the control group. Females were 53/74 (71.6%) in group I, whereas they were 54/73 (73.9%) in group II. The mean disease duration in group I was 11.4±9.3 years, whereas it was 11.1±9.5 years in group II. In the active group, 17/74 (23%) were on biologic therapy by the end of year 1 of treatment, whereas 17/73 (23.3%) in the control group were on biologic therapy at the same time.

Outcome measures

There was a significant effect in the active group on subjects' adherence to medications and coping with activities of daily living. Results of the study revealed that 66/74 (89.1%) patients in group I were adherent to their drug therapy in comparison to 47/73 (64.4%) in group II ($p < 0.01$). Table I shows also

that there was a significant reduction of the number of procedures carried out in the clinic as well as the number of visits for flare-ups of the disease that required early assessment in the active group compared to the control group. Analysis of the parameters of disease activity measures over the study period revealed no significant difference at the 3rd and 6th months of treatment, whereas there was a significant difference at the 18th month of therapy between both groups in terms of patient global assessment, pain score, functional disability, quality of life and DAS-28. Table II shows changes in disease parameters from baseline up to the 18-month follow-up in both the active and control groups, whereas Table III shows the mean changes of the measured parameters at 3-month and 18-month follow-up in the active *versus* the control patient group. Both tables reveal that the active group showed significant improvement by the end of the study period in contrast to the control group. Table IV shows the results of the secondary outcome measure. The active group was more adherent to their medication, less

Table III. Mean changes of the measured parameters at 3-month and at 18-month follow-up in the active vs. control patient groups.

	At 3 months			At 18 months		
	Active	Control	<i>p</i> -value	Active	Control	<i>p</i> -value
PS	1.44 (0.9)	1.41 (0.9)	0.788	4.49 (1.3)	3.38 (1.1)	<0.001*
PGA	1.04 (0.8)	1.22 (1.0)	0.060	4.25 (1.1)	3.43 (1.2)	<0.001*
FnDis	0.35 (0.2)	0.36 (0.2)	0.905	1.76 (0.3)	1.22 (0.4)	<0.001*
QoL	0.44 (0.3)	0.46 (0.1)	0.298	1.76 (0.2)	1.31 (0.2)	<0.001*
Helplessness	2.1 (0.4)	2.3 (0.3)	0.361	4.7 (0.4)	3.1 (0.5)	<0.001*
DAS28	0.48 (0.1)	0.49 (0.3)	0.726	1.79 (0.3)	1.21 (0.2)	<0.001*

Values are means (SD). PS: pain score; PGA: patient global assessment; FnDis: functional disability; QoL: quality of life; DAS: disease activity score.

Table IV. Comparison of the patients' answers (mean±SD) to the post-treatment questionnaire.

Question	Active group (n=74)	Control group (n=73)	<i>p</i> -value
Helped understand effect of the treatment on disease activity (0=did not help, 10=helped very much)	8.7 ± 0.7	6.1 ± 0.7	<0.001*
Help to take medication (0=did not help, 10=helped very much)	8.5 ± 0.8	6.3 ± 0.5	<0.001*
Trust in the treating doctor (0=no trust, 10=max trust)	8.4 ± 0.6	6.0 ± 0.6	<0.001*
Concerns about the future (0=no concern, 10=much concerned)	5.1 ± 0.7	7.8 ± 0.8	<0.001*
Coping with daily life and the disease (0= able to cope, 10=unable to cope)	4.6 ± 0.4	7.7 ± 0.6	<0.001*

likely to stop their medication because of intolerance, more able to cope with their activities of daily living, and have less concern about their future. At 18-month follow-up, the joint fitness programme self-management intervention demonstrated improvement compared to controls for disease activity (effect size 1.4), while cognitive-behavioural therapy interventions demonstrated similar improvements in active coping skills (effect size 1.2).

Discussion

The aim of this work was to emphasize testing the intervention based on the best combinations of strategies, PROMs and patient education, with attention to statistical power.

Results of this study revealed significant improvement of the patients' outcomes across all settings and, by integrating the PROMs and medical education in one-on-one discussions, this provided the major opportunity for arthritis patient education. Viewing the PROMs scores before and after treatment in parallel with targeted patient education led to a significant greater

reduction of disease activity parameters, DAS-28 score, as well as improvement of the patients' adherence to anti-rheumatic therapy. Although it is sometimes difficult to draw the line between educational and therapeutic counselling, counselling can be said to be educational when it is primarily informational in content. The decision-counselling model has shown great potential for improving patient education by individual caregivers (13), as it increases the patients' freedom of choice by improving their understanding of the consequences of the action and improve adherence to the action chosen. Thus, increasing patient control in decision making about his treatment leads to increased likelihood that the patient will adhere to the chosen treatment. Earlier reports stated that "the art of counseling is becoming more of a science, and applications in the health field are accelerating rapidly, thus creating a need among health-care providers to become more knowledgeable about health-decision counseling methods" (14).

Education of patients with arthritis

began with an emphasis on conveying knowledge, grew to include behaviour change, compliance, and more general coping and management of disease and then progressed to consider physical and psychosocial health outcomes. Evaluation of programmes is moving away from programme *versus* usual care towards comparison of alternative methods of delivery and matching of method to learner. Results of this study revealed that the joint-fitness programme could significantly improve knowledge, compliance behaviours, and health outcomes. The first generation of researchers in arthritis education tended to be care givers with little formal education in behavioural sciences and evaluation methodology; the programmes they designed were often empirically based. The current generation, nurtured in large part by funds, is better trained in designing programmes grounded in behavioural sciences and educational theory (15).

The statistically significant changes produced by the patient education programme in this study were clinically meaningful and supported the use of this approach in the standard clinical practice. There is substantial agreement among reviewers regarding the effectiveness of patient education methods (16, 17), yet little is known about the extent to which practitioners incorporate those principles correctly into normal clinical practice. Reviews and meta-analyses (18, 19) have shown that patient self-management education programmes can significantly improve knowledge, compliance behaviours, and health outcomes; however, the effectiveness differs between programmes and disease states. Development of new patient education methods will do little good if results are not used. This study supports the suggestion of implementing patient education in standard clinical practice. Being patient-based and involving both self-management and cognitive behavioural approach, the joint fitness programme had a positive impact on the patients' ability to cope with their disease and drug therapy. An earlier study revealed that less than 50% of patients are still following regimens at 6 months regardless of disease

(20), making long-term maintenance of behaviour change an important area for investigation. It should be noted that many patients intend to follow regimens, but have difficulty for various reasons that caregivers might help them overcome in cooperative efforts.

In the long run, collaboration between the rheumatologists and patients will considerably strengthen the effectiveness of education programmes for patients. This is achievable so long as the approach used is planned, has a goal, and is accountable. There is much work still to be done to teach rheumatologists to be better teachers, and patients to be better managers of their diseases. Until they do so, research in new methods is unlikely to achieve its potential for improved practice. Thus, a high priority for research is diffusion and maintenance of patient education skills among practitioners. Although most work has been done with patients with rheumatoid arthritis and osteoarthritis, many of these findings can and should be safely generalised to less studied rheumatic diseases. Finally, it is important to consider the patient first as a person, and to provide education through all avenues, not just the medical care system (2).

In conclusion, using patient education was seen to be successful in improving self-perceived health as well as disease activity and had a significant

impact on the patient's function as well as quality of life. The joint fitness programme included education, behaviour guidance as well as instruction in exercise. Therefore, patient education for patients with inflammatory arthritis is feasible in standard clinical practice.

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