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A 12-month randomized controlled trial of patient education on radiographic changes and quality of life in early rheumatoid arthritis

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Abstract

Objective. In rheumatoid arthritis, education programmes successfully impart knowledge but, notwithstanding issues of empowerment, this knowledge has to be translated into behavioural change to have a chance of improving disease outcome. Arguably, behavioural change must also occur early if outcomes are to be improved. For these reasons, we planned a study of patient education in early disease, with radiological damage and quality of life as the main outcome variables.

Methods. We performed a randomized controlled trial in people with rheumatoid arthritis of <5 yr duration. The main intervention was a 4 week education programme, each weekly session lasting 2 h. Assessments were made at entry, at 4 weeks and at 12 months. The main outcome variables were the modified Larsen radiological score for the hands and the SF-36 quality of life questionnaire. Secondary outcome variables were the Health Assessment Questionnaire (HAQ), Ritchie Articular Index (RAI), Patient Knowledge Questionnaire (PKQ), Compliance Questionnaire (CQ), plasma viscosity (PV), pharmaceutical changes and consulting behaviour.

Results. The patient numbers were 34 (10 male, 24 female) for the control group and 43 (16 male, 27 female) for the education group. The groups were matched for age (56.5 yr for control, 55 yr for education), disease duration (3.5 yr *vs* 3.0 yr) and duration of second-line drug therapy (14 months *vs* 12 months). We found no significant difference between the groups for Larsen scores at 12 months, although scores for the education group were lower (39.5 *vs* 43.0, $P = 0.13$). The 'social functioning' and 'general health perception' subscales of the SF-36 showed a significant improvement in the education group, but no significant differences between groups were seen. No significant differences were found for the HAQ, RAI, PV and CQ, but the education group had more disease-specific knowledge than the control group at 12 months (PKQ scores: 17 *vs* 21, $P = 0.0002$). No differences were found for out-patient visits and in-patient admissions, but the education group had slightly more changes in second-line drugs during the study (0.43 changes/person in the control group, 0.51 changes/person in the education group).

Conclusions. We found no significant difference between the groups in our primary outcome measures, but a trend in favour of the education group was found in radiological progression. Further studies of this kind, using larger patient numbers, are required since the difference may result from improved self-care, better compliance with joint protection strategies and, possibly, improved drug compliance.

KEY WORDS: Rheumatoid arthritis, Patient education, Quality of life.

Patient education programmes are now a well-established part of the treatment of rheumatic diseases, particularly rheumatoid arthritis [1]. A number of well-conducted randomized trials have demonstrated benefit in terms of knowledge, pain and disability [2]. However, imparting knowledge is not the same as changing behaviour, and if patient education programmes are to be of true benefit to the person, a 'positive' behavioural change must occur. In this context, a 'positive' behavioural change would be, for instance, increased compliance with drug therapy or the use of joint protection techniques during hand function. Lorig *et al.* [3, 4] have

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demonstrated increased use of favourable behaviours, but have ascribed these changes to increased 'self-efficacy' rather than increments in knowledge.

As a result of behavioural change, it might be possible, given an early intervention, to demonstrate retardation of joint damage and a better functional outcome. At the same time, knowledge of disease, drug and non-drug therapies and self-management techniques would promote more participation and control in disease management, and may provide the basis for a better perceived quality of life. Since neither of these two issues have been adequately addressed previously, the aims of this study were to record, in early rheumatoid arthritis, the effect of an education programme on radiological damage and quality of life.

Methods

All subjects were recruited from routine out-patient clinic appointments. People with a diagnosis of rheumatoid arthritis (using the 1987 ARA criteria [5]) of <5 yr duration who were able to read and speak English were eligible. None of the subjects had previously participated in a group patient education programme. After giving verbal and written information, subjects were asked to sign a consent form and were then randomized to an experimental or a control group. Randomization codes were taken from a table of random numbers and were concealed in consecutive, numbered, sealed envelopes. If a patient decided to leave the study immediately after randomization, then that number and code were discarded. Control subjects were advised that they would be eligible for patient education classes after the 12-month study if such classes were found to be of benefit.

Education programme

This comprised a standard recommended format [1]. The education classes took place over 4 weeks in four afternoon sessions lasting 2 h. Subjects were encouraged to bring a partner, although this happened infrequently. For people who were still working or who preferred to come with a partner, evening sessions were arranged. The format of the sessions was a talk from a non-medical health professional using overhead projection, a discussion period and the distribution of supporting literature. The content of the sessions included the pathophysiology of rheumatoid arthritis, drug treatments, local treatments, mechanisms and control of pain, stress, exercise and rest, joint protection, task allocation, splinting and assistive equipment.

Assessment intervals

The Larsen scores and the SF-36 were taken at entry and 12 months. Other assessments were made at entry, immediately after the education programme (or 4 weeks if the patient was in the control group) and 12 months after entry. Subjects were seen at special clinic appointments so that these encounters were not included in the final totals for clinic visits over the year.

Outcome measures

The primary outcome measure was the scoring of hand and wrist radiographs using the Larsen scoring system [6]. The films were masked for name and date, shuffled and read independently by two observers (PSH, PFE); the mean of the two scores was used in the study. On each hand, proximal interphalangeal joints 2–5, metacarpophalangeal joints 1–5 and the wrist were assessed. Each joint was given a score from 0 to 5 so that, with the wrist score multiplied by 5, the maximum score for both hands was 140. The agreement between and within the observers was determined by scoring a subset of 25 of these films on two occasions, 1 week apart. The median difference between the observers for the first reading of these films was -2 (range -18 to $+18$) units. The median difference between the first and second scores for both observers was -2 (range -19 to $+17$) units.

Secondary outcome measures included the self-administered SF-36 quality of life instrument completed at entry and 12 months (eight separate subscales with scores ranging from 0 to 100, with improvement as scores increase [7]), the Patient Knowledge Questionnaire (PKQ; scores range from 0 to 28 [8]), the Health Assessment Questionnaire adapted for a British population (HAQ; scores range from 0 to 3.00 in parallel with increasing disability [9]) and a Compliance Questionnaire (CQ; range 0–4 with higher scores indicating better compliance [10]). Clinical assessment comprised the Ritchie Articular Index administered by an observer blind to treatment group (RAI; range 0–75 [11]). Laboratory assessment was by measuring the plasma viscosity (PV). In addition, we kept a record of admission and clinic attendance (both scheduled and unscheduled), drug [disease-modifying antirheumatic drug (DMARD)] consumption and drug changes.

Statistics

No assumptions were made about the normality of the data so that all comparisons were made with non-parametric statistics. We compared the final scores between groups by the Mann–Whitney U-test (or χ^2 test for categorical data) and within-group comparisons were made with the Wilcoxon matched pairs signed-ranks test.

Results

Seventy-nine subjects were randomized. There were no drop-outs immediately after randomization, but one patient died (myocardial infarction) during the study and one patient had a cerebrovascular accident resulting in a hemiplegia, leaving 77 subjects. The randomization procedure used resulted in unequal groups with 34 subjects in the control group and 43 in the education group. We found the groups to be well matched in terms of demographic and baseline details (Table 1).

In the education group, four people did not complete all the group sessions, but they were included in the

TABLE 1. Baseline variables. Median (range) unless otherwise stated. None of the statistical comparisons showed a significant difference

	Control	Education
n	34	43
M/F	10/24	16/27
Age (yr)	56.5 (28–78)	55 (23–71)
Duration of disease (yr)	3.5 (0–5)	3 (0–5)
Rheumatoid factor positive *n* (%)	24 (71)	35 (81)
Initial Larsen score	36 (4–96)	37 (7–87)
Number (%) erosive initially	32 (94)	40 (93)
Initial Larsen score	36 (4–96)	37 (7–87)
Initial plasma viscosity	1.75 (1.44–2.03)	1.69 (1.46–2.03)
Education: leaving school before age 17 yr *n* (%)	31 (91)	38 (88)
NSAID use *n* (%)	26 (76)	25 (58)
Steroid use *n* (%)	2 (6)	3 (7)
DMARD use *n* (%)	33 (97)	39 (91)
Duration of most recent DMARD (months)	14 (1–60)	12 (1–70)
Number of previous DMARDs	1 (0–3)	1 (0–6)

analysis by intention to treat. Three people attended the education classes with their partners.

Table 1 indicates that the median duration of DMARD use before entering the trial was similar between groups. However, 21% of control group subjects and 36% of education group subjects (χ^2, not significant) had been taking their latest DMARD for <6 months. The majority of patients in both groups (16/34 control, 24/43 education) were taking sulphasalazine, with methotrexate the second most frequent drug (7/34 control, 7/43 education). An equal percentage of patients in both groups were taking prednisolone (6% control, 7% education). Slightly more subjects in the education group changed DMARD because of inefficacy or intolerance at 1 month: 6 (17%) in the control group and 9 (21%) in the education group. At 12 months, a further 8 (23%) changes had been made in the control group and 9 (21%) changes in the education group.

The main and secondary outcome variables (except the SF-36) are compared in Table 2. As expected, disease-specific patient knowledge increased significantly in the education group and was largely maintained at 12 months. Both groups experienced modest reductions in PV and RAI, and minimal increases were found in the HAQ scores. Most of the participants in this study had a high drug compliance score (CQ) and this did not change during the study in either group.

There was no significant difference between groups in radiological progression at 12 months (final Larsen scores: control median 43, education median 39.5, $P = 0.13$), although a trend in favour of less radiological progression in the education group was seen (Fig. 1). However, since the initial and mean PV scores were higher (although not significantly so) in the control group, we performed forward stepwise multiple linear regression with the difference in Larsen scores as the dependent variable and mean PV, rheumatoid factor, group, initial HAQ, duration of disease and gender as independent variables. The only variables in the final equation (with a P value of <0.05) were mean PV and group. The full equation was: difference in Larsen scores $= [-53.67 \pm 24.75] - [6.10 \pm 2.86 \times$ group $(1 =$ control, $2 =$ education$)] + [47.14 \pm 13.77 \times \mathrm{PV}]$. $R^2 = 0.29$ (partial contribution to R^2: mean PV, 0.2; group, 0.06).

The SF-36 quality of life scores are given in Table 3.

TABLE 2. Initial and final scores for Larsen scores and secondary outcome variables (median and range)

	Control				Experimental				Between groups[b]
	Initial	4 weeks	Final	P[a]	Initial	4 weeks	Final	P[a]	P
Larsen	36		43	0.001	37		39.5	0.03	ns
	4–96		5–101		7–87		1–92		
HAQ	0.875	0.750	1.00	ns	0.875	0.875	0.875	ns	ns
	0.25–2.00	0–2.125	0–2.75		0–2.00	0–2.625	0–2.125		
PKQ	16	17	17	0.02	16	22	21	0.001	0.0002
	5–24	3–27	5–27		5–26	11–28	10–27		
CQ	4	4	4	ns	4	3.5	4	ns	ns
	2–4	2–4	2–4		1–4	1–4	1–4		
PV	1.75	1.74	1.69	0.05	1.69	1.66	1.69	ns	ns
	1.44–2.03	1.50–1.92	1.50–2.16		1.46–2.03	1.44–2.00	1.43–2.03		
RAI	10	7.5	6.5	ns	11	8	7	0.003	ns
	0–23	0–20	0–20		0–47	0–31	0–20		

HAQ, Health Assessment Questionnaire; PKQ, Patient Knowledge Questionnaire; CQ, Compliance Questionnaire; PV, plasma viscosity, RAI, Ritchie Articular Index.

[a]Final compared to initial (Wilcoxon matched pairs signed-ranks test).

[b]Mann–Whitney *U*-test.

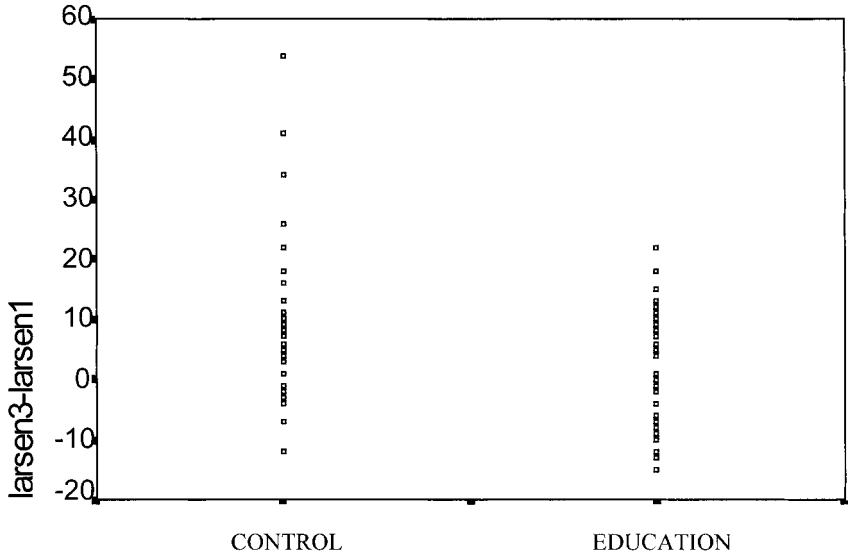

FIG. 1. Scattergram of difference in Larsen scores (final – initial score) between control and education groups.

TABLE 3. SF-36 scores (median and range)

	Control			Education		
	Entry	1 yr	P^a	Entry	1 yr	P^a
Physical functioning	45 (15–90)	42.5 (5–95)	ns	50 (0–90)	45 (0–95)	ns
Social functioning	75 (32.5–100)	75 (27.5–100)	ns	75 (12.5–100)	82.5 (12.5–100)	0.05
Role—physical	25 (0–100)	25 (0–100)	ns	25 (0–100)	0 (0–100)	ns
Role—emotional	100 (0–100)	100 (0–100)	ns	67 (0–100)	100 (0–100)	ns
Mental health	76 (24–96)	80 (16–100	ns	68 (28–92)	76 (32–100)	ns
Vitality	45 (10–85)	45 (0–90)	ns	50 (10–75)	45 (10–100)	ns
Bodily pain	44.4 (0–100)	44.4 (0–88.9)	ns	44.4 (0–88.9)	44.4 (11.1–100)	ns
General health perception	59.5 (15–90)	56 (10–87)	ns	53.5 (13–82)	57 (20–92)	0.01

[a]Within-group comparison of entry and 12 months (Wilcoxon matched pairs signed-ranks test). None of the between-group differences were significant.

Significant subscale differences within the control group were not seen, but within the education group significant improvements were seen in the 'social functioning' and 'general health perception' subscales. At 12 months, none of the contrasts between the control and education groups were significant.

Appointments and admissions did not differ between the groups. The majority of routine out-patient visits were made to the rheumatology clinic—a few people were seen by the rheumatology nurse practitioner, physiotherapist and occupational therapist. The median number of visits per person per year was four for the control group and five for the education group (not significant). Extra out-patient visits were also recorded. In the control group, three people had one extra appointment and one person had two extra visits; in the education group, three people had one extra visit each. There were a few planned admissions, four people having one admission in each group. Two people had unplanned admissions in the control group: one person had one admission and one person three admissions. In the education group, there were two single unplanned admissions.

Discussion

Whereas previous studies on the effects of patient education have concentrated on demonstrating an increase in knowledge and the translation of that knowledge into changed health behaviours [12], as well as reductions in pain and disability [2], we have concentrated our effort on demonstrating a retardation of disease progression. Although the median difference in scores between the groups exceeded the intra-observer error for both assessors, the observed difference was small and may not be of clinical relevance. However, a trend in favour of the education group is apparent in the figure and the multiple linear regression would support the influence of treatment group on the change in Larsen scores. We would suggest, therefore, that larger studies of this kind are required to investigate the possibility of a type I error. Of interest, the effect size of education in this study is comparable to treatment with gold salts or methotrexate in other studies [13, 14], although larger between-drug differences have been shown [15].

What factors may have confounded this result? Our groups were well matched for age, gender, initial disease

duration, use of prednisolone, seropositivity and initial Larsen score. More of the education group had been on their latest disease-modifying drug for <6 months and it is possible that these patients subsequently responded clinically, thus reducing radiological progression. However, the factor with the greatest influence on radiological progression, the initial PV, was higher (albeit not significantly) in the control group at entry. It is likely that some of the greater deterioration seen in the control group was a function of this discrepancy. Indeed, the multiple regression model would support this, but it also indicates that group membership was a significant, if less influential, predictor of radiological progression, allowing for differences in PV.

It is possible that better compliance with taking DMARDs may have contributed to the difference in radiological scores. Although the measure of compliance used indicated that the subjects largely complied with administered therapy, the measure is based on positive responses to only four simple questions. The data of Pullar *et al.* [16] have shown that, even when people indicate that they are taking drugs as prescribed, actual compliance is poor. If we assume that compliance at entry was less than ideal in our study population, then the observed treatment effect may in part result from a relative improvement in compliance with DMARD therapy in the education group. Recent data from Leeds, completed but not yet published, using labelled D-penicillamine to monitor compliance in patients participating in education, will examine this possibility.

Lorig *et al.* [3] have argued that the beneficial effects of patient education are mediated by improved self-efficacy (defined as the expectation of a person that she/he can perform a given behaviour successfully). Although people cannot participate in their own care without knowledge, this knowledge must be translated into improved health behaviours if it is to be of benefit to the individual. The translation of knowledge into improved behaviours is made possible by cognitive changes which result in more positive attitudes to control over illness. Our group education programme was not specifically designed to effect these cognitive changes, but emphasis was repeatedly made on coping strategies and appropriate self-care behaviours, and these features, together with group interactions (a positive feature of the group sessions reported by several participants), are likely to have resulted in improved self-efficacy.

The relationship between perceived self-efficacy and quality of life has not been formally examined in arthritis, but in other conditions, notably asthma, a positive correlation has been described between a disease-specific measure of self-efficacy and subscales of the SF-36, notably 'physical functioning', 'role limitation—emotion', 'role limitation—physical', 'mental health' and 'health perception' [17]. Similarly, we would expect that the quality of life measure we used reflected the greater confidence and feeling of control appropriate to the people who experienced the group education programme, particularly with regard to the 'social functioning', 'mental health' and 'role limitation—emotional' subscales. However, none of these items were significantly different between the groups at 12 months, possibly reflecting the 'one-off' nature of the education programme. Perhaps an initial programme should be supported by interim reinforcement sessions to maintain any benefits that might have accrued. In this context, it is appropriate to note that a study involving 150 patients with rheumatoid arthritis found no significant improvement in quality of life in a group given an education booklet, although there was a trend in favour of the education group [18].

We were unable to demonstrate any differences in the consumption of hospital health services. In fact, the numbers of unscheduled appointments and hospital admissions were low in both groups, and it is likely that this study was also underpowered to detect differences in these outcome measures. Prior to entry to this study, most of our patient population would have seen members of the rheumatology team for at least one consultation so our control group was not entirely naive about their disease and its management (supported by baseline PKQ results). This may have produced some blurring of the treatment effect, especially in the use of the available hospital services.

In summary, we found no significant difference between the groups in our primary outcome measures, but a trend in favour of the education group was found in radiological progression. Further studies of this kind are required, using larger patient numbers, to examine the possibility that patient education can retard radiological progression by influencing patient self-care, compliance with joint protection strategies and drug compliance.

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