

Development and evaluation of an education programme in rheumatoid arthritis: impact on compliance, function, disease progression and quality of life

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| Submission date 23/01/2004 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 23/01/2004 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 22/02/2008 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
535913

Study information

Scientific Title

Study objectives

Although patient education is assuming an increasingly important role in patient management in many medical disciplines, evaluation of the medium term impact of patient education has not been carried out in rheumatological practice. We wish to know whether a patient education programme will improve compliance with drug, exercise and attendance regimes and the impact of education on disease progression, function and quality of life. We plan a randomised controlled trial of patient education in rheumatoid arthritis based on an ambulant population. We will evaluate the educational benefits of the programme over a four week period and make further outcome assessments for the 12 months following entry into the trial. We hope to show increased compliance with drug regimes and drug monitoring, retention of knowledge and orthodox attitudes to disease management, a reduction in periods of inpatient treatment and unscheduled outpatient attendance. The benefits would accrue primarily to the patients in terms of quality of life and disease progression but would contribute to the cost efficient organisation of the rheumatology department (including number of patient episodes) and in pharmacy costs (currently due, in part, to poor drug compliance and wastage).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Musculoskeletal diseases: Arthritis (rheumatoid)

Interventions

1. Patient education programme
2. Standard care

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Compliance with drug, exercise and attendance regimes and disease progression, function and quality of life. The main outcome variables were the modified Larsen radiological score for the hands and the 36-item short form health survey (SF-36) quality of life questionnaire.

Key secondary outcome(s)

1. Health Assessment Questionnaire (HAQ)
2. Ritchie Articular Index (RAI)
3. Patient Knowledge Questionnaire (PKQ)
4. Compliance Questionnaire (CQ)
5. Plasma viscosity (PV)
6. Pharmaceutical changes and consulting behaviour

Completion date

31/12/1994

Eligibility

Key inclusion criteria

Patients with rheumatoid arthritis.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Unable to speak or read english
2. Previous education programme

Date of first enrolment

01/01/1992

Date of final enrolment

31/12/1994

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
University of Leeds
Leeds
United Kingdom
LS2 9NZ

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | Results | 01/04/1999 | | Yes | No |