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

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
22/02/2008

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/01/1992

Completion date
31/12/1994

Eligibility

Key inclusion criteria
Patients with rheumatoid arthritis.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
77

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
England

United Kingdom

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

Sponsor information

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

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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