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Educational material on cardiovascular disease in rheumtoid arthritis (RA)

Submission date	Recruitment status	[ ] Prospectively registered
29/04/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/07/2013	Musculoskeletal Diseases	

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
4566

Study information

Scientific Title
Development and evaluation of educational material to address the cardiovascular aspects of rheumatoid disease

Study objectives

This study compares a cognitive behavioural educational course addressing cardiovascular risk factors in patients with rheumatoid arthrits against a standard education leaflet using knowledge of heart disease, lifestyle behaviours and clinical results as outcome measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dudley Local Research Ethics Committee approved on the 12th December 2006 (ref: 06/Q2702 /81)

Primary study design
Interventional

Study design
Randomised interventional process of care trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
The intervention is an 8-week cognitive behavioural education course about cardiovascular disease in rheumatoid arthritis which is compared against a leaflet about CVD in RA. Follow up for both groups is 6 months in total.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Knowledge of heart disease at 6 months

Key secondary outcome(s)
Measured at baseline, 2 months and 6 months:
1. Self efficacy questionnaires for stopping smoking
2. Exercise
3. Healthy eating and achieving a normal weight
4. Smoking status
5. Diet diary
6. International Physical Activity Questionnaire
7. Weight
8. Blood pressure
9. Lipid profile
10. Disease activity score in 28 joints
11. EuroQol

Completion date
01/11/2009

Eligibility

Key inclusion criteria
1. Diagnosis of rheumatoid arthritis
2. Aged over 18 years, either sex
3. Any ethnicity
4. The ability to read, understand and write English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Severe mental illness
2. Terminal physical illness

Date of first enrolment
04/01/2007

Date of final enrolment
01/11/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Rheumatology Department
Dudley
United Kingdom
DY1 2HQ

Sponsor information

Organisation
Dudley Group of Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/014hmqv77

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (ARC) (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	01/01/2013		Yes	No