

# Educational material on cardiovascular disease in rheumtoid arthritis (RA)

<b>Submission date</b> 29/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/07/2013	<b>Condition category</b> Musculoskeletal Diseases	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
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 arthritis 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)

**Study design**

Randomised interventional process of care trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Diagnostic

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**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 measure**

Knowledge of heart disease at 6 months

### **Secondary outcome measures**

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

### **Overall study start date**

04/01/2007

### **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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

Planned Sample Size: 180

### **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**

England

United Kingdom

**Study participating centre**

**Rheumatology Department**

Dudley

United Kingdom

DY1 2HQ

## Sponsor information

**Organisation**

Dudley Group of Hospitals NHS Foundation Trust (UK)

**Sponsor details**

Department of Rheumatology

Dudley

England

United Kingdom

DY1 2HQ

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.dgoh.nhs.uk/home/>

**ROR**

<https://ror.org/014hmqv77>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Arthritis Research Campaign (ARC) (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?
<a href="#">Results article</a>	results	01/01/2013		Yes	No