

# 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
<b>Registration date</b> 29/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/07/2013	<b>Condition category</b> 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**  
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

### **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?
<a href="#">Results article</a>	results	01/01/2013		Yes	No