ISRCTN98753115 https://doi.org/10.1186/ISRCTN98753115

An investigation of the efficacy of a cognitive behavioural treatment for patients with recent onset rheumatoid arthritis

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/07/2018	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Tom Sensky

Contact details
Imperial College School of Medicine
West Middlesex University Hospital
Isleworth
United Kingdom
TW7 6AF
+44 (0)20 8565 2121
abc@123.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RDC00038

Study information

Scientific Title
An investigation of the efficacy of a cognitive behavioural treatment for patients with recent onset rheumatoid arthritis

Study objectives
The present study will aim to investigate the efficacy of a cognitive behavioural intervention for patients with recent onset Rheumatoid Arthritis (RA). Research has clearly demonstrated that cognitive-behavioural treatments are successful in treating patients with RA, but much of the research to date has been with people with a long history of active disease. This is clinically important since earlier intervention might prevent psychologically and/or physical morbidity.

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)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
1. Individual course of cognitive-behavioural therapy
2. Matched waiting list control group

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1. Coping Strategies Questionnaire
2. Percentage of subjects with clinically important depression or anxiety
3. Proportion of subjects with Eryhtrocyte Sedimentation Rate (ESR) of more than 30 mm/hr
4. Proportion of subjects with C-Reactive Protein (CRP) of more than 10 mg/l

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/05/1995

Completion date
30/09/2000

Eligibility

Key inclusion criteria
1. 40 patients recruited from the West Middlesex University Hospital Rheumatology Clinic
2. Age group 18-65
3. Definite or classic Rheumatoid Arthritis with onset of symptoms in the past two years
4. Active but stable on current medication

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
30/05/1995

Date of final enrolment
30/09/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College School of Medicine
Isleworth
United Kingdom
TW7 6AF

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 London (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	initial results	01/01/2001		Yes	No
Results article	long-term efficacy results	01/03/2003		Yes	No
Results article	5-year follow-up results	15/03/2008		Yes	No