A randomised, controlled study of outcome and cost effectiveness for Rheumatoid Arthritis (RA) patients attending nurse-led rheumatology clinics: a nationwide multi-centre study

Submission date	Recruitment status	Prospectively registered		
13/09/2007	No longer recruiting	☐ Protocol		
Registration date 21/09/2007	Overall study status Completed Condition category	Statistical analysis plan		
		[X] Results		
Last Edited		Individual participant data		
21/12/2011	Musculoskeletal Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ARC Grant Ref: 17632

Study information

Scientific Title

Study objectives

The outcomes from nurse-led clinics will be non-inferior to those obtained by physician led clinics, but at a lower cost.

Please note that as of 07/06/10 this record has been updated to included changes in the number of participants, and sponsor details (Arthritis Research Campaign [ARC] are now known as Arthritis Research UK). Please also note that the end date of this trial has been extended from 30 /06/2010 30/06/2011

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Leeds (West) Research Ethics Committee on the 4th January 2007 (REC ref: 06/Q1205/198).

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied

Rheumatoid arthritis

Interventions

Patients will be randomly assigned to one of two groups:

- 1. A Clinical Nurse Specialist group (Experimental Group [EG])
- 2. A Rheumatologist group (Control Group [CG])

Both the CNS and the Rheumatologist will continue their usual management practice, including making referrals to any members of the multidisciplinary team, changing treatments etc. All interventions undertaken and referrals made by the CNS and the Rheumatologist should be noted on the schedule provided. Any changes to medication and the length of the consultation should also be documented on the schedule.

Total duration for each patient (in both Experimental group and Control group is 1 year - 56 weeks)

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The 28-item Disease Activity Scale (DAS-28) score, undertaken by an independent assessor at recruitment visit, and weeks 0, 13, 26, 39 and 52.

Secondary outcome measures

Secondary measures include both clinical, haematological and questionnaire data:

- 1. C-Reactive Protein (CRP) or Erythrocyte Sedimentation Rate (ESR)
- 2. Pain intensity measured on a 10 cm Visual Analogue Scale (VAS)
- 3. Length of morning stiffness in hours and minutes
- 4. Fatigue measured on a 10 cm VAS

Questionnaires comprise the following:

- 5. Health Assessment Questionnaire (HAQ), completed at recruitment visit, week 26 and week 52
- 6. Hospital Anxiety and Depression Scale (HAD), completed at recruitment visit, week 26 and week 52
- 7. Leeds Satisfaction Questionnaire (LSQ), completed at recruitment visit, week 26 and week 52
- 8. The Arthritis Self Efficacy Scale (ASES), completed at recruitment visit, week 26 and week 52
- 9. Rheumatoid Arthritis Quality of Life questionnaire (RAQoL), completed at recruitment visit, week 26 and week 52
- 10. EuroQoL (EQ-5D) health outcome instrument, completed at recruitment visit, and weeks 0, 13, 26, 39 and 52

Overall study start date

01/09/2007

Completion date

30/06/2011

Eligibility

Key inclusion criteria

- 1. Positive diagnosis of RA as defined by the American Rheumatism Association
- 2. Aged 18 years or above
- 3. Ability to complete questionnaires unaided

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

As of 07/06/10: 164 (at time of registration: 260)

Key exclusion criteria

- 1. Patients unwilling to be randomised to a Clinical Nurse Specialist (CNS) or Rheumatologist group
- 2. Patients suffering from unstabilised concomitant disease
- 3. Patients awaiting surgery
- 4. Patients who have already received care from the practitioners involved in the study

Date of first enrolment

01/09/2007

Date of final enrolment

30/06/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Academic and Clinical Unit for Musculoskeletal Nursing (ACUMeN)

Leeds United Kingdom LS7 4SA

Sponsor information

Organisation

Arthritis Reseach UK (UK)

Sponsor details

Copeman House St Mary's Court St Mary's Gate Chesterfield United Kingdom S41 7TD

Sponsor type

Charity

Website

http://www.arthritisresearchuk.org/

ROR

https://ror.org/02jkpm469

Funder(s)

Funder type

Charity

Funder Name

Arthritis Reseach UK (UK) (Grant Ref: 17632)

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	01/06/2009		Yes	No
Results article	results	01/08/2011		Yes	No