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Education and eXercise Training in early Rheumatoid Arthritis (EXTRA) study

Submission date	Recruitment status	[X] Prospectively registered
02/05/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/06/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/09/2014	Musculoskeletal Diseases	

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
PRF/07/03

Study information

Scientific Title
Rehabilitation of upper limb sensorimotor dysfunction in patients with early rheumatoid arthritis: an assessor blind, pragmatic randomised controlled trial

Acronym
EXTRA study

Study objectives
Main research question:
Do people with early rheumatoid arthritis (RA) who receive an upper limb, home exercise programme supplemented with supervised group exercise and educational sessions have less upper limb disability than those receiving usual care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kings College Hospital Research Ethics Committee, 27/08/2008, ref: 08/H0808/118

Study design
Prospective pragmatic assessor-blind multi-centred randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Rheumatoid arthritis

Interventions
12-week home exercise programme supplemented with four group exercise and educational sessions versus usual medical care.

In the randomised controlled trial (RCT) all participants will be followed up 3 months and 9 months after initial assessment (the duration of the intervention is 3 months therefore final follow up will be 6 months after cessation of the intervention). Study duration is 9 months in total.

Approximately fifteen participants (purposive sample based on DASH score, gender etc.) who complete the intervention arm of the study, will be invited to attend for a 30 minute qualitative interview to explore the motivations and barriers to exercise adherence, experiences of the RCT, etc.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Disability of Arm, Shoulder and Hand Questionnaire (DASH), re-measured at each assessment.

Secondary outcome measures
1. Upper limb muscle strength
2. Joint position sense
3. Function and quality of life measures

All outcome measures are re-measured at each assessment.

Overall study start date
30/09/2008

Completion date
30/09/2012

Eligibility

Key inclusion criteria
1. RA of less than 5 years duration
2. Over 18 years of age, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
130

Key exclusion criteria
1. Unstable disease
2. Surgery or physiotherapy to upper limb within the previous 6 months
3. Unable to give informed consent

Date of first enrolment
30/09/2008

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Division of Applied Biomedical Research
London
United Kingdom
SE1 1UL

Sponsor information

Organisation
King's College London (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.kcl.ac.uk/schools/biohealth/research/applied/

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research organisation

Funder Name
Physiotherapy Research Foundation (UK) (ref: PRF/07/03)

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	01/02/2015		Yes	No