

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

Submission date 02/05/2008	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 12/06/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 02/09/2014	Condition category Musculoskeletal Diseases	☐ 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
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

Primary study design

Interventional

Study design

Prospective pragmatic assessor-blind multi-centred randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

England

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

Sponsor information

Organisation
King's College London (UK)

ROR
<https://ror.org/0220mzb33>

Funder(s)

Funder type
Research organisation

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

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?
Results article	results	01/02/2015		Yes	No