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

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

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

Division of Applied Biomedical Research Shepherds House Guy's Campus London England United Kingdom SE1 1UL +44 (0)20 7848 6330 fiona.cook@kcl.ac.uk

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