

# Rehabilitation of Patients with Rheumatoid Arthritis (RA): Changes in Muscle, Functional and Biochemical Parameters

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|--|---|--|
| <b>Submission date</b><br>23/01/2004   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>23/01/2004 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>26/11/2009       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
|  |   | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

PCD/A1/87

## Study information

## Scientific Title

### Study objectives

Rheumatoid arthritis is an extremely debilitating condition that attacks and destroys synovial joints. Atrophy of muscles acting across damaged joints is a common clinical feature of RA and contributes to disability. Although physiotherapy is frequently requested to improve strength and function, its efficacy is uncertain. Moreover, recent research has suggested reperfusion-injury following exercise of RA joints may be one of the mechanisms of joint destruction. The objectives of the research were:

1. To compare the differences in lower and upper limb sensorimotor function, functional performance and patient-reported disability between healthy subjects and patients with rheumatoid arthritis (RA).
2. To investigate the effect of a brief, clinically applicable course of exercise rehabilitation on these variables and establish whether rehabilitation exacerbates disease activity. Separate knee and elbow trials were conducted.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Primary study design

Interventional

### Study design

Randomised controlled trial

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Arthritis (rheumatoid)

### Interventions

The intervention consisted of 10 exercise sessions (twice a week for 5 weeks) at a hospital outpatient department. Exercises were tailored to address each individual patient's disabilities.

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome(s)

1. Knee Study: Isometric quadriceps strength
2. Elbow Study: Elbow flexor strength

### Key secondary outcome(s)

1. Knee Study:
  - 1.1. Voluntary quadriceps activation
  - 1.2. Knee joint position sense
  - 1.3. 4 common activities of daily living
  - 1.4. Health Assessment Questionnaire (HAQ)
  - 1.5. Disease Repercussion Profile
  - 1.6. Clinical measures of disease activity in RA
  - 1.7. Serum concentrations of IL-1, IL-6, TNF-alpha

2. Elbow Study:
  - 2.1. Voluntary flexor activation
  - 2.2. Elbow joint position sense
  - 2.3. HAQ
  - 2.4. Arthritis Impact Measurement Scale-2
  - 2.5. Clinical measures of disease activity

**Completion date**

01/07/1999

## Eligibility

**Key inclusion criteria**

Patients with knee and elbow rheumatoid arthritis.

1. Knee study: 133 participants were recruited to the cross-sectional study, 108 RA patients and 25 healthy participants. 93 patients were recruited to the rehabilitation trial.
2. Elbow study: 21 participants were recruited to the cross-sectional study, 12 patients with RA and 9 healthy participants. These 12 patients participated in the rehabilitation study.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

All

**Key exclusion criteria**

Does not match inclusion criteria

**Date of first enrolment**

01/04/1996

**Date of final enrolment**

01/07/1999

## Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

Physiotherapy Division

London

United Kingdom

SE22 8PT

## Sponsor information

### Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

## Funder(s)

### Funder type

Government

### Funder Name

NHS Physical and Complex Disabilities National Research and Development Programme (UK)

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/02/2002   |            | Yes            | No              |