# Physical Activity in Rheumatoid Arthritis: a randomised controlled multi-centre study

Submission date [ ] Prospectively registered Recruitment status 21/12/2006 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 28/12/2006 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 25/09/2019 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

N/A

# Study information

#### Scientific Title

Physical Activity in Rheumatoid Arthritis: a randomised controlled multi-centre study

#### Acronym

PARA study

#### **Study objectives**

- 1. A one-year support program for healthy physical activity will:
- a. increase/maintain physical activity levels
- b. improve health-related quality of life and functioning
- c. be cost-effective
- 2. Improvements will sustain one year after end of intervention.
- 3. Clusters of characteristics (demographic, disease-related, cognitive-behavioural and body functions) can be distinguished and related to health-related quality of life and physical activity behavior respectively.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Regional Research Ethics committee, Karolinska Institutet (ref: d.nr. 00-010).

#### Study design

Single blind randomised controlled trial with intervention group and control group.

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Other

#### Study type(s)

Treatment

#### Participant information sheet

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

Rheumatoid arthritis according to American College of Rheumatology criteria

#### Interventions

All participants in both groups had access to, but were not specifically encouraged to participate in, 'ordinary physical therapy treatment' including patient education, treatment with physical modalities, and organised exercise a maximum of twice per week. This was the treatment generally offered to patients with RA, which seldom resulted in regular physical activity in daily life.

Those randomised to intervention furthermore underwent a one-year program aiming at implementing healthy physical activity (moderately intensive, 30 minutes/day, more than four days/week). They were individually coached by a physical therapist and were informed about the benefits of physical activity. Their thoughts about their body function and their possibilities for physical activity were discussed. Goal setting for their physical activity behaviours were formulated and documented according to a structured manual based on the principles of graded activity training.

Perceived obstacles to a successful implementation were discussed and problem-solving strategies to help overcome present and future barriers were discussed and documented. Continuous telephone support was given after one week and then once monthly by the physical therapist. Tests of body functions were performed every third month as part of the intervention and oral and written feedback given about the test results. Activity logs were used two weeks prior to each test occasion to support adherence. Goals related to physical activity behaviour were systematically evaluated and adjusted whenever required.

#### **Intervention Type**

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

The EuroQoL 5 dimensions (EQ-5D)

#### Secondary outcome measures

- 1. The Grippit for maximum grip strength
- 2. The Timed Stands Test for lower extremity function

# Overall study start date

01/01/2000

#### Completion date

31/12/2006

# **Eligibility**

#### Key inclusion criteria

- 1. Rheumatoid arthritis according to American College of Rheumatology criteria
- 2. Less than two years since diagnosis
- 3. Ability to undergo body function testing and answer questionnaires

#### Participant type(s)

Patient

#### Age group

Not Specified

#### Sex

Not Specified

### Target number of participants

91 per group (beta=0.2, alfa=0.05)

#### Key exclusion criteria

Not applicable

#### Date of first enrolment

01/01/2000

#### Date of final enrolment

31/12/2006

# Locations

#### Countries of recruitment

Sweden

# Study participating centre Department Of NSV

Huddinge Sweden SE-14183

# Sponsor information

#### Organisation

Karolinska Institutet (Sweden)

#### Sponsor details

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Stockholm Sweden SE-17177 +46 (0)852 480 000 admin@ki.se

#### Sponsor type

Hospital/treatment centre

#### Website

http://ki.se/ki/jsp/polopoly.jsp?d=130&l=sv

#### **ROR**

https://ror.org/056d84691

# Funder(s)

#### Funder type

Research council

#### **Funder Name**

The Swedish Research Council (Sweden)

#### **Funder Name**

The Vårdal Foundation (Sweden)

#### **Funder Name**

The Swedish Rheumatism Association (Sweden)

#### **Funder Name**

The Västerbotten County Council Research Fund (Sweden)

#### **Funder Name**

The Stockholm County Council (EXPO) (Sweden)

#### **Funder Name**

The Health Care Science Postgraduate School at Karolinska Institutet (Sweden)

# **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	sub-study results	01/12/2018	25/09/2019	Yes	No