

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

Submission date 21/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 25/09/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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
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

Study type(s)

Treatment

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(s)

The EuroQoL 5 dimensions (EQ-5D)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

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

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