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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
-
Stockholm
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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