

# Long term physical activity in rheumatoid arthritis

<b>Submission date</b> 29/12/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/03/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/01/2022	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Rheumatoid arthritis is a long-term condition that causes pain, swelling and stiffness in the joints. People with rheumatoid arthritis have an increased risk of disability and premature death. A health-enhancing physical activity (HEPA) programme could help to reduce this risk. The aim of this study is to test a two-year HEPA programme in patients with rheumatoid arthritis.

### Who can participate?

Patients aged 18 - 74 with rheumatoid arthritis

### What does the study involve?

Participants take part in at least two 45-minute exercise sessions, including strength training and aerobic exercise, and are encouraged to perform additional moderate-intensity physical activity for at least 30 minutes on most of the other days of the week for one year. They also take part in regular support group meetings for one hour every other week. General health perception, pain, fatigue, muscle function and any cardiovascular events (e.g., heart attack) are measured at the start of the study and after one and two years.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

Karolinska Institutet (Sweden)

### When is the study starting and how long is it expected to run for?

January 2011 to January 2022

### Who is funding the study?

1. Swedish Research Council (Sweden)
2. Combine Sweden (Sweden)
3. Swedish Rheumatism Association (Sweden)
4. National Postgraduate School of Health Care Sciences (Sweden)

Who is the main contact?  
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## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
2010/1232-31/1

## Study information

**Scientific Title**  
Long term Physical Activity in Rheumatoid Arthritis - health perception, cardiovascular risk and underlying mechanisms related to inflammation, fatigue and pain

**Acronym**  
PARA 2010

**Study objectives**  
Current study hypothesis as of 13/01/2022:  
The overall aim of the present study is to investigate the implementation of a 2-year health-enhancing physical activity programme (HEPA), including strength training, among patients with rheumatoid arthritis (RA) and its outcome as regards general health perception, pain, fatigue, muscle function and cardiovascular events as well as relations between HEPA and mechanisms underlying low muscle performance, reduced muscle mass, systemic and local inflammation, pathophysiological pain mechanisms and cardiovascular function.

### Previous study hypothesis:

The overall aim of the present study is to investigate the implementation of a 2-year health-enhancing physical activity programme (HEPA), including strength training, among patients with rheumatoid arthritis (RA) and its outcome as regards general health perception, pain, fatigue, muscle function and cardiovascular events as well as relations between HEPA and mechanisms underlying low muscle performance, reduced muscle mass, systemic and local inflammation, and pathophysiological pain mechanisms.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 01/09/2009, Stockholm Regional Research Ethics Committee, ref: 2010/1232-31/1

Added 14/01/2022:

Approved 01/09/2010, Stockholm Regional Research Ethics Committee, ref: 2010/1232-31/1

Approved 27/07/2011, Stockholm Regional Research Ethics Committee, ref: 2011/1241-32

Approved 26/04/2012, Stockholm Regional Research Ethics Committee, ref: 2012/769-32

### Study design

Prospective cohort multi-centre trial

### Primary study design

Interventional

### Study type(s)

Quality of life

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

Rheumatology and physical therapy

### Interventions

Each intervention participant will take part in at least two 45-minute exercise sessions, including strength training and aerobic exercise, and encouraged to perform additional moderate-intensity physical activity at least 30 minutes on most of the other days of the week for one year. They will also take part in regular support group meetings one hour every other week, which will be designed to increase their knowledge and strengthen their self-efficacy for adopting and maintaining HEPA.

During the subsequent year, the participants will take increased responsibility for their own HEPA as well as for the support group meetings.

### Intervention Type

Behavioural

### Primary outcome(s)

General Health Perception Visual Analogue Scale (VAS), assessed at baseline and after one and two years respectively

### Key secondary outcome(s)

Each outcome will be assessed at baseline and after one and two years respectively:

1. Pain
2. Fatigue
3. Fear avoidance beliefs
4. Exercise self-efficacy
5. Muscle function
6. Aerobic capacity
7. Systemic and local inflammatory activity
8. Pain sensitivity
9. Cardiovascular events

**Completion date**

14/01/2015

## **Eligibility**

**Key inclusion criteria**

1. Rheumatoid arthritis according to American College of Rheumatology 1987 criteria
2. Aged between 18 - 74 years, either sex
3. Disease duration over one year
4. Independence in daily living
5. Recommended levels of health enhancing physical activity (HEPA) not currently reached

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

249

**Key exclusion criteria**

1. Problems with speaking and understanding Swedish
2. Other major diseases preventing HEPA

**Date of first enrolment**

15/01/2011

**Date of final enrolment**

09/10/2012

## Locations

### Countries of recruitment

Sweden

### Study participating centre

Karolinska Institutet

Huddinge

Sweden

SE 14183

## Sponsor information

### Organisation

Karolinska Institute

### ROR

<https://ror.org/056d84691>

## Funder(s)

### Funder type

Research council

### Funder Name

Swedish Research Council (Sweden)

### Alternative Name(s)

Swedish Research Council, VR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

Sweden

**Funder Name**

Combine Sweden (Sweden)

**Funder Name**

Reumatikerförbundet

**Alternative Name(s)**

Swedish Rheumatism Association, Svenska Reumatikerförbundet

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Associations and societies (private and public)

**Location**

Sweden

**Funder Name**

National Postgraduate School of Health Care Sciences (Sweden)

**Funder Name**

Forskningsrådet om Hälsa, Arbetsliv och Välfärd

**Alternative Name(s)**

Swedish Research Council for Health, Working Life and Welfare, Forskningsrådet om Hälsa, Arbetsliv och Välfärd, FORTE

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Sweden

## Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as the June 2017 ICMJE statement was not valid at the time of data collection, and most of the results have been published already.

## IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Pain substudy #I	15/03/2018		Yes	No
<a href="#">Results article</a>	Pain substudy #II	26/11/2018		Yes	No
<a href="#">Results article</a>	Cardiovascular substudy #I	13/12/2017	12/01/2022	Yes	No
<a href="#">Results article</a>	Cardiovascular substudy #II	25/05/2018	12/01/2022	Yes	No
<a href="#">Results article</a>	Cardiovascular substudy #III	15/12/2021	12/01/2022	Yes	No
<a href="#">Results article</a>	Experiences of PA participation	20/06/2014	12/01/2022	Yes	No
<a href="#">Results article</a>	PA intervention, 1 year	27/11/2014	12/01/2022	Yes	No
<a href="#">Results article</a>	PA intervention, 2 years	01/05/2018	12/01/2022	Yes	No
<a href="#">Results article</a>	Perceptions of PA maintenance	07/12/2020	12/01/2022	Yes	No
<a href="#">Protocol article</a>	Study protocol	01/06/2012		Yes	No
<a href="#">Other publications</a>	Selection procedure	01/05/2014	12/01/2022	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes