

Long term physical activity in rheumatoid arthritis

Submission date 29/12/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/03/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/01/2022	Condition category 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?
Prof Christina Helging Opava
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Study website

<http://www.para.nu/>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

15/01/2011

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

450 for intervention, 900 matched controls

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

Sponsor details

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Stockholm

Sweden

SE 171 77

Sponsor type

University/education

Website

<https://www.ki.se/en>

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, FORTE

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Results and Publications

Publication and dissemination plan

The researchers hope to be able to publish results from the sub-study on systemic and local inflammation during 2022

Intention to publish date

31/12/2022

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?
Protocol article	Study protocol	01/06/2012		Yes	No
Results article	Pain substudy #I	15/03/2018		Yes	No
Results article	Pain substudy #II	26/11/2018		Yes	No

Other publications	Selection procedure	01/05/2014	12/01/2022	Yes	No
Results article	Cardiovascular substudy #I	13/12/2017	12/01/2022	Yes	No
Results article	Cardiovascular substudy #II	25/05/2018	12/01/2022	Yes	No
Results article	Cardiovascular substudy #III	15/12/2021	12/01/2022	Yes	No
Results article	Experiences of PA participation	20/06/2014	12/01/2022	Yes	No
Results article	PA intervention, 1 year	27/11/2014	12/01/2022	Yes	No
Results article	PA intervention, 2 years	01/05/2018	12/01/2022	Yes	No
Results article	Perceptions of PA maintenance	07/12/2020	12/01/2022	Yes	No