ISRCTN25539102 https://doi.org/10.1186/ISRCTN25539102

Long term physical activity in rheumatoid arthritis

Submission date
29/12/2010

Recruitment status
No longer recruiting

Registration date
04/03/2011

Overall study status
Completed

Last Edited
14/01/2022

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
christina.opava@ki.se

Study website
http://www.para.n.nu/

Contact information

Type(s)
Scientific

Contact name
Prof Christina Helging Opava

ORCID ID
http://orcid.org/0000-0001-6738-4879

Contact details
Karolinska Institutet
Department of Neurobiology, Care Sciences and Society
Division of Physiotherapy
23100
Huddinge
Sweden
SE 14183
-
christina.opava@ki.se

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
-
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