

A Randomized Controlled Trial into the effect of a fall prevention program tailored for patients with Rheumatoid Arthritis

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The objective of the study is to evaluate a fall prevention program for persons with RA. The primary parameter is to reduce fall incidence in the participants of the fall prevention program.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON32642

Source

ToetsingOnline

Brief title

Fall prevention in RA

Condition

- Autoimmune disorders
- Joint disorders

Synonym

arthritis, chronic rheumatism, Rheumatoid arthritis

Research involving

Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: Sint Maartenskliniek

Intervention

Keyword: fall prevention, RCT, Rheumatoid Arthritis, training program

Outcome measures

Primary outcome

Prospective fall incidence: registered for a year by means of monthly fall registration cards.

Secondary outcome

- Physical activity: (LAPAQ, pedometer for 1 week)
- Walking skills: obstacle avoidance and recording walking pattern in the laboratory.
- Balance: functional reach and steptest
- Pain: VAS scores on pain in rest and during walking
- Fear of falling and balance confidence: VAS, ABC, SAFFE-NL
- Physical functioning: HAQ
- Quality of life: AIMS2-SF

Study description

Background summary

Falls in general, and falls in persons with Rheumatoid Arthritis (RA) in particular, are an underestimated problem. Retrospective studies show that one out of three persons with RA experience a fall at least once a year. In the healthy elderly population the fall incidence rate is approximately 0.45 falls/person year. Our previous work shows that prospectively measured fall

incidence rate in RA is 0.82 falls/person years, well higher than in healthy elderly. However, patients with RA can not participate in existing programs targeting fall prevention in the health elderly. Therefore, there is a need to develop and evaluate a fall prevention program for persons with RA. Several fall prevention programs have been developed to prevent falls. The Sint Maartenskliniek, developed the "Nijmegen Falls Prevention Program" (NFPP), which was effective in reducing the fall incidents with 46% in healthy elderly. This fall prevention program is already adjusted for persons with osteoporosis. Since persons with RA have a high fall incidence rate and a higher risk for injuries it is important to adjust the program for this target group and evaluate its effectiveness. Developing such an intervention will help RA patients to prevent falls and, in case a fall still might occur, prevent injuries.

Study objective

The objective of the study is to evaluate a fall prevention program for persons with RA. The primary parameter is to reduce fall incidence in the participants of the fall prevention program.

Study design

Randomized single-blind controlled trial (n=100)

Intervention

Fall prevention program: 11 meetings, twice a week. The content of the program is based on the original "NFPP" and the fall prevention program for persons with osteoporosis.

Study burden and risks

Participants have 3 measurements at the Sint Maartenskliniek for approximately 1.5 hours. Furthermore, they get questionnaires to fill in at home, which will take about 0.5 hour. The intervention will be 11 meetings of approximately 2 hours each.

Both the measurements as the fall prevention program do not form a high risk for the participants. These all have been done before in healthy persons as well as in other patient categories, without any adverse effects.

The most important supposed benefit is a reduction in the number of falls in the participants. Hereby decreasing the number of injuries and fear of falling. This will result in a better quality of life and lower medical costs.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- RA according to the ACR criteria
- history of falls in the prior year
- able to walk 10 minutes without the necessary use of an assistive device
- stable disease activity (based on DAS28 score)

Exclusion criteria

- RA of recent onset (<1 year)
- severe neurological disorder
- medical contra-indication for exercise

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Will not start
Start date (anticipated):	01-01-2009
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

CCMO

ID

NL24842.091.08