

Rheumates@work: an interactive internet program to promote physical activity in children with juvenile idiopathic arthritis

Published: 16-11-2010

Last updated: 04-05-2024

To improve physical activity levels and physical activity patterns in children with JIA by means of cognitive behavioural training based on the social cognitive theory and the health promotion model, delivered by internet and supported by group...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON36385

Source

ToetsingOnline

Brief title

Rheumates@work

Condition

- Autoimmune disorders
- Joint disorders

Synonym

Juvenile Rheumatoid Arthritis, Rheuma of childhood

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Reumafonds en Nuts/Orha

Intervention

Keyword: cognitive behavioural training, juvenile idiopathic arthritis, physical activity, self efficacy

Outcome measures

Primary outcome

The main outcome measures are the Physical Activity Level (PAL) and Physical Activity Pattern (PAP)

Secondary outcome

Secondary outcome parameters are: JIA disease activity, quality of life, exercise Barriers, stages of change, self efficacy, self-worth, fatigue, aerobic exercise capacity and quality of life by proxy

Study description

Background summary

Juvenile Idiopathic Arthritis (JIA) is a chronic disease in which periods of active inflammation alternate periods of inactive disease in an unpredictable way. In children with JIA there is some evidence of an increased risk of premature atherosclerosis and osteoporosis. Although impairments are most pronounced in children with active disease, deficits like fatigue, low aerobic and anaerobic exercise capacity and decreased physical activity levels remain long after disease control is obtained. For the present JIA patients are prone to sedentary lifestyles and are at risk of becoming social outcasts. In the past physical activity was thought to be harmful for children with JIA. There is evidence that exercise testing and exercise programmes are safe, feasible and acceptable in children with JIA. Adolescents with JIA who are more fit feel better. Physical activity, exercise and fitness have beneficial effects in healthy children and adolescents on growth and development. For children with JIA the same benefits are recognised. The importance of exercise

in managing JIA is recognised and not any longer disputed. Usual care (oral advises given by the children*s rheumatologist combined with brief counselling by a physiotherapist) has not been effective to induce a positive change in exercise capacity in children with JIA. Exercise and physical activity can be seen as a type of behaviour. Therefore we expect that cognitive behavioural therapy (CBT) could be a successful approach to improve exercise and physical activity levels in children with JIA. A literature search on the content and efficacy of psychological interventions for improving exercise behaviour in children with JIA showed that no such intervention for children with JIA exists. There is increasing evidence that cognitive behavioural therapy is effective in managing chronic pain and to enhance quality of life in adults with rheumatoid arthritis. Bandura's Social Cognitive Therapy en The Health Promotion Model designed by Pender focuses on improving self-efficacy. They can be used to develop a Cognitive Behavioural Programme to improve physical activity in JIA patients.

The use of internet technology has provided new opportunities for treatment and for promoting various health behaviours such as physical activity. Besides supplying information internet is used increasingly for interventions.

Internet-based physical activity interventions can reach large number of people at relatively low costs. Patients with JIA are scattered over a large geographical area and therefore internet based programmes are attractive to reach them.

A recent pilot study studying the effects of Rheumates@work showed that children with low activity levels and low exercise capacity improved significantly. Children as well as parents enjoyed the program and the group sessions.

Study objective

To improve physical activity levels and physical activity patterns in children with JIA by means of cognitive behavioural training based on the social cognitive theory and the health promotion model, delivered by internet and supported by group sessions.

Study design

This study is a randomized controlled trial, which comprises an intervention group and a waiting list control group. The internet-based intervention will last 14 weeks.

Inclusion is based on the diagnosis, age and disease activity. Selection of the definite study group is based on the exercise capacity an activity level. The selected group will be randomised in an intervention and a control group.

Children who are not selected for the study are offered to participate in Rheumates@work at a later stage.

Intervention

The intervention is an internet based program lasting 14 weeks, combined with 4 group sessions. It comprises education, physical activity and a cognitive behavioural training. During the intervention the child will receive standard care for the JIA.

Study burden and risks

Physical activity and exercise are safe for children with JIA and therefore there are no risks in participating.

During the study questionnaires are taken which is not performed in standard treatment. This takes 4 times 1, 5 hours within one year; at the start of the intervention, 14 weeks later at the end of the intervention, 3 months later and 9 months later. Disease activity and exercise testing are routinely taken in the standard care. Exercise testing will normally be performed 1-2 times a year. In this study it will be done 4 times within one year. During the intervention the children have to invest 2 hours on a weekly basis. We expect that the patients will benefit directly from participating in the program.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

-All subtypes of JIA according to the ILAR classification without active arthritis, aged 8 up to 12 years

Exclusion criteria

Active disease; visual analogue scale scored by the children*s rheumatologist >20mm on a 1-100 scale
-Other diagnosis influencing the exercise capacity
-Co-morbidity influencing physical or psychological development

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	19-01-2011
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date: 16-11-2010

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 25-08-2011

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	ID
CCMO	NL34044.042.10