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# Rheumates@work

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| **Submission date**<br>20/03/2013 | **Recruitment status**<br>No longer recruiting | ☐ Prospectively registered |
| | | ☐ Protocol |
| **Registration date**<br>29/04/2013 | **Overall study status**<br>Completed | ☐ Statistical analysis plan |
| | | ☒ Results |
| **Last Edited**<br>15/09/2016 | **Condition category**<br>Musculoskeletal Diseases | ☐ Individual participant data |

**Plain English summary of protocol**

Background and study aims
Juvenile Idiopathic Arthritis (JIA) is a chronic disease in which periods of active inflammation alternate with periods of inactive disease in an unpredictable way. Although impairments are most pronounced in children with disease activity, deficits like fatigue, low aerobic and anaerobic exercise capacity and decreased physical activity levels remain long after disease control is obtained. Exercise and physical activity is an important form of enhancing and retaining health and vitality and concerns every human being including children with JIA. For the present JIA patients are prone to sedentary lifestyles and are at risk of becoming social outcasts. 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. Internet is used increasingly for interventions. Internet-based physical activity interventions can reach large number of people at relatively low costs. To increase physical activity levels in children with JIA, an internet-based program has been developed.
An initial study showed that it improved physical activity and exercise capacity in children with JIA.
The aim of this larger study is to explore the feasibility and benefits of an internet based training programme including a physical, educational and cognitive training programme on activity levels for children with JIA.

Who can participate?
All patients with JIA, aged 8 up to 13 years are eligible. The patients must be in remission, have an excellent comprehension of the Dutch language and they must have a computer with an internet connection. Physical activity level and pattern and exercise capacity of selected children are determined. Children with sedentary physical activity levels and/or an exercise capacity < p5 for age and gender are selected for the study.

What does the study involve?
Participants are randomly allocated to one of two groups: an intervention group (cognitive and physical internet based training program for 14 weeks combined with 4 group sessions) or a waiting list control group (standard care). During a 14 weeks period small texts have to be read and assignments have to be performed weekly which are internet based. Time expenditure is 2 hours every week. During this period the children and their parents have to visit the clinic 3-4 times 2 hours to join a group meeting with their peers. At the start (t=0) and after finishing the

intervention (t=1/14 weeks) and 3 months later (t=2) and one year after t=1 (t=3) the patients undergo aerobic physical testing and they have to fill in questionnaires. Testing is combined with regular visits to the children's rheumatologist if necessary and/ or possible.

What are the possible benefits and risks of participating?
The participants of the pilot study reported the program to be meaningful and enjoyed participation. No blood or urine samples are taken. There is evidence that physical activity and exercise have no adverse effects on disease activity.

Where is the study run from?
Lead center:
University Medical Center Groningen, University of Groningen, 2 departments:
1. Pediatric Rheumatology, Beatrix Children's Hospital
2. Center for Rehabilitation
Participating centers:
1. University of Utrecht, University Medical Center Utrecht, Utrecht, the Netherlands, 2 departments:
a. Children's Rheumatology/immunology Wilhelmina's Children Hospital
b. Child Development and Exercise Center Wilhelmina's Children Hospital
2. Reade Location Jan van Breemenstraat Amsterdam

When is the study starting and how long is it expected to run for?
The study started in December 2010. Recruitment and inclusion of participants took place until October 2012. Final tests are expected to be completed by March 2014.

Who is funding the study?
The Dutch Arthritis Foundation and Nutsohra (Netherlands)

Who is the main contact?
Dr Wineke Armbrust
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**Study website**
http://www.reumaatjesatwork.nl/

# Contact information

**Type(s)**
Scientific

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

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

### Study objectives
The aim of this multicenter study is to explore the feasibility and benefits of an internet based training program including a physical, educational and cognitive training programme on activity levels for children with juvenile idiopathic arthritis

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Medical Ethical Committee of the University Center of Groningen, 16/11/2011, ref: METc2010/283

### Study design
Waiting list randomized controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Quality of life

### Participant information sheet
Not available in web format, please contact Kinderreumatologie@umcg.nl to request a patient information sheet

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

Juvenile idiopathic arthritis

## Interventions

The intervention is an internet based education, physical activity and cognitive behavioral training program implemented over 14 weeks. During the intervention the child receives the normal standard treatment for juvenile idiopathic arthritis (JIA).
Recruitment of JIA patients takes place by their own pediatrician and or physiotherapist by spreading information flyers. When the child and his/her parents give permission and agree to participate they are invited for the test panel.
1-2 weeks before the program starts baseline testing is conducted:
1. A regular visit to the children's rheumatologist. In which disease activity is measured according to the core set criteria
2. Bruce test
3. Wearing an accelerometer for one week
4. Fill in a 7-day activity diary
5. Questionnaires
5.1 CASE (Self efficacy scale for children with arthritis)
5.2 PedsQL (Quality of life)
5.3 PedsQL multidimensional fatigue questionnaire
5.4 Exercise barriers
5.5 CBSK (subscale: self-worth)
5.6 Stages of change

Inclusion in the study of those patients who fulfil one or both of the following two criteria:
1. Exercise capacity on the Bruce test below the 5th percentile for gender and age
2. Children with a sedentary PA level defined as not meeting the Dutch health standards for physical activity in 4 or more of the measured 7 days.

The patients will be randomly and blindly assigned to an intervention or a waiting-list control group. The randomisation procedure is done by SPSS and it is centralized in Groningen. The randomisation is performed for each centre. The controls can participate in the internet-based program at a later stage. The children who don't fulfil the two criteria are not included in the study but are offered the opportunity to participate in Rheumates@work. The program 'Rheumates@work' starts with a group session. Group sessions are repeated three times, meaning that patients come together four times over the 14 week period. The group sessions contain three elements: education, group process (peer support) and a fun activity. Every session deals with a different theme.
- Session 1: Knowledge about JIA and setting goals
- Session 2: Exercise barriers and benefits
- Session 3: Support from parents, friends and school
- Session 4: 'Keep going'

After the first group session the internet based educational, cognitive and physical training program 'Rheumates@ Work' will start. The program lasts 14 weeks. Every week the children will work on a specific theme. For example: what is JIA, how to achieve goals, energy and pacing etc. Every week's theme consists of some theory and an assignment which has to be worked on before Friday of that specific week. There is a break until Sunday. The child will receive a reminder by e-mail when he/she has not returned the assignment. A loop has been built into the program to verify whether the child has read the theory or not. During the whole week the child can ask questions by mail.
The intervention lasts 14 weeks. Every weeks deals with a different theme:
- week 0 = start and introduction of Buddy, the animated figure who is leading the child through

the program
- week 1 = JIA; What is JIA and what is wrong with the immune system? The child is educated with animations about the immune system. How it works in normal situations and in the case of an auto-immune disease
- week 2 = How to tackle disease-related participation problems. The schedule 'problematic situation, thoughts, feelings and action' is introduced. The child learns to cope with set-backs
- week 3 = Energy and condition. The child learns to cope with fatigue and learns to manage his or her energy level during the day and the week
- week 4 = To be active in a healthy way. The child learns to manage activities and to be and stay active in times of active disease and in times of remission
- week 5 = Pain. How to differentiate between JIA pain and pain any child can experience, such as muscle pain
- week 6 = Setting goals. The child looks at his or her own goal that was set in the first group session and is helped to formulate 2 SMART (specific, measurable, acceptable, realistic and timebound) goals
- week 7 = Increasing motivation by rewarding yourself. The child learns that when you achieve a goal it is good to reward yourself
- week 8 = Taking responsibility, barriers and benefits. The child learns about the barriers and benefits that one meets when a person wants to change activity-related behavior. The child is made aware of the benefits of being active
- week 9 = Activities and chatting. Every child has to fill in an activity diary for one day. All the children will then join a chat session led by the staff to discuss their experiences
- week 10 = Doing things together and asking for help. Being active together with friends is more fun. The child learns what he or she can do with friends. And the child is encouraged to ask for help when something is hard to do because of the JIA
- week 11 = Talking about the JIA. The children learn that being open about the JIA gives them benefits
- week 12 = Setbacks. The child learns that JIA is a disease that can fluctuate. They learn to adjust their goals when the arthritis becomes active again
- week 13 = Motivation. The child learns that it is important to hold on. One can hold on by developing motivation and the child is made aware that motivation is like a reward: when you reach your goals it gives you something worthwhile
- week 14 = The last week gives a summary of all that the children have learned

Controls will follow the program after 6 months on the waiting list.

### Intervention Type
Behavioural

### Primary outcome measure
The main outcome measures are the Physical Activity Level (PAL) and Physical Activity Pattern (PAP). The amount of physical activity can be expressed as PAL. The basis for PAL was formulated in 1985 by the FAO/WHO/UNU expert committee on energy requirements. Energy needs are expressed as multiples of Basal Metabolic Rates (BMR) and PAL is defined as Total Energy Expenditure (TEE) divided by BMR. BMR for boys and girls of a given age and weight are predicted with the mathematical equation derived by Schofield. In terms of age and sex, Schofield's equations coincided with measured BMR in boys and girls 7- 16 years old in The Netherlands, the UK and the USA. PAL and PAP are measured with a 7-day activity diary. A 7-day activity diary provides a close estimate of PAL as validated by the doubly labelled water method. Reliability is high from the age of 10 years and onwards. 7-day diaries measure frequency, duration and intensity of daily activities and are therefore suitable instruments to describe PAP.

PAL and PAP are also measured with an accelerometer. Accelerometers objectively monitor physical activity levels for weeks at a time. Data can be expressed as Activity Counts, Active Energy Expenditure (AEE), METs (metabolic equivalents), and also as time spent within various levels of activity (cut points - for sedentary, light, moderate and vigorous activity levels). It is evident that no single motion sensor will provide an accurate estimate of energy expenditure across all activities. The combined use of an accelerometer plus questionnaire or diary is advocated. PAL and PAP are measured at baseline, after completion, at 3 months and at 1 year follow-up.

**Secondary outcome measures**
1. JIA disease activity is determined at maximal one month before the intervention, at the end, 3 months after and finally one year after completion of the internet based program. Disease activity is defined according to a validated set of criteria called JIA core set criteria and they consist of:
1.1 Functional ability measurement by the Childhood Health Assessment Questionnaire (CHAQ38)73-75. The CHAQ38 consist of two components: disability and discomfort. Disability is assessed using 38 questions in 9 domains covering major aspects of daily living: dressing, grooming, arising, eating, walking, hygiene, reach grip, activities and extra-curriculum activities. Each question is rated on a 4 point scale (no difficulty, some difficulty, and much difficulty, unable to do). The disability index is calculated as the mean of the 9 domains and yields a score between 0 (no disability)-3(most severe disability). Discomfort is measured by a 100-mm visual analogue scale (VAS) anchored at either end by 'no pain' and 'severe pain'. A similar 100-mm VAS assesses overall disease severity and disease impact
1.2 Number of active joints (pain/swelling) is assessed by the children's rheumatologist.
1.3 Assessment of joint mobility is performed by the children's rheumatologist.
1.4 Physician's global assessment of disease activity on a 100mm VAS
1.5 ESR and CRP
2. Disease flare is scored according to the known criteria
3. Quality of life is measured by PedsQL (Pediatric Quality of Life Inventory) (Children's Hospital and Health Center, San Diego, California), a modular instrument for measuring health-related quality of life (HRQOL) in children and adolescents ages 2 to 18. The PedsQL 4.0 Generic Core Scales consist of 23 items applicable for healthy school and community populations, as well as pediatric populations with acute and chronic health conditions. The questionnaire consists of 4 subscales; physical, emotional, social and school functioning. Cronbach's alpha 0.88
4. Fatique is measured by the PedsQL multidimensional Fatigue Scale. This 18 item scale was designed to measure fatigue in pediatric patients and compromises the General Fatigue scale (6 items), Sleep/rest fatigue scale (6 items) and cognitive fatigue scale (6 items). Cronbach's alpha resp 0.95, 0.93 and 0.88
5. Exercise Barriers are measured by the Exercise Barriers Self-efficacy scale for children. It is a self-report instrument intended to assess exercise barriers self efficacy or the degree one believes he or she possesses the ability to overcome social, personal and environmental barriers to participating in exercise. The scale contains 10 items. Cronbach's alpha 0,79
6. Stages of change is a one item scale which measures motivation for behavioral change. A 100-mm VAS assesses the motivation to change whereas 0 means not willing to change and 100 mm reflects that the person is already changing
7. Self efficacy is measured by the CASE (Children's Arthritis Self-Efficacy Scale) and consists of 11 items. The questionnaire includes 3 subscales; a symptom sub-scale, an emotion sub-scale and an activity subscale. Cronbach's alpha resp 0,90, 0,87 and 0,8581
8. Self-worth is measured by the CBSK (Competentie Belevings Schaal voor Kinderen). 1 out of the available 6 dimensions is measured: Global self-worth. This item consists of 6 questions
9. Aerobic exercise capacity is measured by means of a Bruce test. The Bruce treadmill protocol

is suitable for children as young as age 4 years and maximal endurance time may be used as the sole criterion of aerobic exercise capacity. The treadmill is programmed for increases in grade and speed every 3 minutes as outlined by Bruce et al. Normal values for children are available for a Dutch population. The duration of the test is between 6 to 15 minutes
10. Quality of life by proxy is also measured with the PedsQL (Pediatric Quality of Life Inventory). The PedsQL 4.0 Generic Core Scales by proxy consist of 23 items applicable for healthy school and community populations, as well as pediatric populations with acute and chronic health conditions. Cronbach's alpha 0.90
11. Other study parameters or confounders will be:
11.1 JIA type
11.2 Gender
11.3 Age
11.4 Type of school
11.5 Used medication
11.6 Family composition
11.7 Socio-economic status
11.8 Sport and leisure activity of the parents
11.9 Sport and leisure activity of the child
11.10 School absenteeism

### Overall study start date
17/12/2010

### Completion date
01/03/2014

## Eligibility

### Key inclusion criteria
Diagnosis: all subtypes of JIA according to the ILAR classification without active arthritis
1. Ages 8 up to13 years old
2. Command of Dutch language (patient and at least one of the parents)
3. Have internet connection and computer at home

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
8 Years

### Upper age limit
13 Years

### Sex
Both

### Target number of participants

120

### Key exclusion criteria

1. Active arthritis; visual analogue scale scored by the children's rheumatologist >20 mm on a 1-100 scale
2. Other diagnosis influencing exercise capacity
3. Co-morbidity influencing physical or psychological development
4. No command of Dutch language
5. No free access to internet
6. No computer at home
7. Participating in a cognitive behavioral program aimed at physical activity

### Date of first enrolment

17/12/2010

### Date of final enrolment

01/10/2012

## Locations

### Countries of recruitment

Netherlands

### Study participating centre

**SecretaryX 4.206**
Groningen
Netherlands
9700 RB

## Sponsor information

### Organisation

University Medical Center Groningen (Netherlands)

### Sponsor details

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### Sponsor type

Hospital/treatment centre

**ROR**
https://ror.org/03cv38k47

# Funder(s)

**Funder type**
Charity

**Funder Name**
Reumafonds

**Alternative Name(s)**

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
Netherlands

**Funder Name**
Fonds NutsOhra

**Alternative Name(s)**
NutsOhra Foundation, NutsOhra Fund, Stichting Nuts Ohra

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
Netherlands

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 23/07/2015 | | Yes | No |