

# The development and evaluation of an internet-supported intervention program for adolescents with chronic pain: a pilot study

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To develop and evaluate an internet-supported CBT group intervention for adolescents with chronic pain and their parents.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON29939

### Source

ToetsingOnline

### Brief title

An internet-supported intervention for adolescents with chronic pain

### Condition

- Other condition

### Synonym

chronic benign pain, prolonged unexplained pain

### Health condition

langdurige pijn zonder aantoonbare lichamelijke oorzaak

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** adolescent, chronic pain, cognitive-behavioural therapy, internet

## Outcome measures

### Primary outcome

Compliance, activity and participation.

### Secondary outcome

Pain frequency, pain duration, pain medication, quality of life and pain coping.

## Study description

### Background summary

Previous studies show that chronic pain in adolescents is often associated with a decrease in quality of life. Cognitive-behavioural therapy (CBT) seems to be the most effective psychological treatment for recurrent pain. We hypothesize that the use of information and communication technologies (e.g. internet and SMS) increases the effectiveness and cost-effectiveness of CBT in adolescents with chronic pain.

### Study objective

To develop and evaluate an internet-supported CBT group intervention for adolescents with chronic pain and their parents.

### Study design

Prospective study. Pre-stratification by localization of pain.  
(headache: n=8; abdominal pain: n=8; limb and/or back pain: n=16).

### Intervention

The following subjects will be addressed during the CGT-intervention: information and education; physical exercise; ergonomics and time management; relaxation; pain coping; cognitive restructuring and self-efficacy; strain and resilience; stress anticipation and stress management training; problem-solving techniques. The intervention consists of six bi-weekly group sessions followed by two monthly sessions for the adolescents and two parent sessions. Group sessions will be led by a remedial educationalist and a physiotherapist. Information about the group sessions will be made available on internet afterwards. Adolescents will also receive assignments via our homepage. At our internet board they can interact with group members and ask questions at the counsellors.

### **Study burden and risks**

Subjects have to fill in four psychological questionnaires at 3 moments in time. Also, they will be asked to keep a pain diary for two weeks in a row at 3 times. Patient satisfaction will be measured via an interview. Actual physical activity might also be assessed with the actometer, which is an accelerometer worn around the waist, for 2 times 7 days. No risks are involved in this study: the psychological integrity of the subjects will not be violated.

## **Contacts**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)

Adolescents (16-17 years)

### Inclusion criteria

- Age between 12 and 18 years
- Pain duration > 3 months (continuous or recurrent (at least 2 days a week))
- Unexplained headaches, abdominal pain, back pain or limb pain
- Decrease in participation level (hobbies, school): either unable to pursue hobbies more than 5 times during the last 3 months because of pain, or more than 2 school absences
- Referred to medical specialist because of pain complaints
- Completed medical diagnostics
- Availability of hardware/software needed for intervention

### Exclusion criteria

- Severe psychosocial problems in child or parent
  - o (Previously) under psychiatric treatment
  - o Frequent school absence (over 25% in the last 3 months)
  - o Strong medical fixation (consultation of more than 3 specialists within a period of six months on one\*s own or one\*s parents\* initiative)
- Participation in other intervention
- Participation in other study
- Insufficient knowledge of Dutch (parent and/or child)

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

## Recruitment

NL  
Recruitment status: Recruiting  
Start date (anticipated): 01-09-2006  
Enrollment: 32  
Type: Actual

## Ethics review

Approved WMO  
Date: 30-08-2006  
Application type: First submission  
Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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	NL12331.078.06