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# Effectiveness and cost-analysis of a three-week multimodal inpatient pain treatment for children and adolescents suffering from chronic pain

**Submission date**
17/02/2010

**Recruitment status**
No longer recruiting

**Registration date**
28/05/2010

**Overall study status**
Completed

**Last Edited**
27/02/2014

**Condition category**
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## 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
Effectiveness and cost-analysis of a three-week multimodal inpatient pain treatment for children and adolescents suffering from chronic pain: a single centre randomised controlled trial

### Acronym
WiKo-study

### Study objectives
The present study is a cost-effectiveness study. The first aim is to investigate the short- and long-term effectiveness of a three-week multimodal inpatient pain program for children and adolescents with chronic pain. The second aim of the study is to analyse the costs determined by chronic pain before and after the inpatient pain program.

As of 01/02/2012, the anticipated end date of trial has been updated from 30/11/2011 to 24/02/2012.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics Committee of Witten/Herdecke University approved on the 30th September 2009

### Study design
Single centre randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (German only)

### Health condition(s) or problem(s) studied
Chronic pain disorder

### Interventions

All participants receive multimodal inpatient pain treatment (e.g. cognitive behavioural therapy, physiotherapy, music therapy).

Participants will be randomly allocated to one of two groups differing in time intervals between first contact and hospitalisation (admission within 1 - 5 days versus admission within 3 - 4 weeks).

The total duration of the treatments are three weeks. The total duration of follow-ups for all arms are 12 months. The timepoints are as follows:
1. First contact (randomisation)
2. 3 - 4 weeks after randomisation
3. 6 - 7 weeks after randomisation
4. 6 months after randomisation
5. 12 months after randomisation

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Composite endpoint:
1. Mean pain intensity in the last 7 days/4 weeks (adolescents on a Numerical Rating Scale [NRS], with 0 = no pain to 10 = maximal pain; children on a faces pain scale, with 0 = no pain to 10 = maximal pain)
2. Pain related disability (Pediatric Pain Disability Index [P-PDI]): disability in daily activities due to pain on 12 items, rated on a 5-point scale (1 = never to 5 = always)]
3. School absence due to pain: school absence was assessed via parental report as the number of days the child missed school within the preceding 4 weeks

### Secondary outcome measures
1. Pain related coping (PPCI-R: self report questionnaire)
2. Childs and parents pain related anxiety (FSBK-K, PCS-P: self report questionnaires)
3. Parents pain related behaviour (ISEV: self report questionnaire)
4. Number of physican appointments (parental report)
5. Pain medication (physicans report by pain medical history)

Outcomes are measured at timepoints 1- 5, mentioned in the interventions section.

### Overall study start date
02/11/2009

### Completion date
24/02/2012

## Eligibility

### Key inclusion criteria
1. Chronic pain patients fulfilling criteria for multimodal inpatient pain treatment
2. Age at enrolment between 9 and 18 years, either sex
3. Appropriate comprehension of German

**Participant type(s)**
Patient

**Age group**
Child

**Lower age limit**
9 Years

**Upper age limit**
18 Years

**Sex**
Both

**Target number of participants**
120

**Key exclusion criteria**
1. Previous treatment at the Vodafone Foundation for Children's Pain Therapy and Paediatric Palliative Care
2. Chronic regional pain syndrome (CRPS)
3. Malignant disease

**Date of first enrolment**
02/11/2009

**Date of final enrolment**
24/02/2012

# Locations

**Countries of recruitment**
Germany

**Study participating centre**
**Children's Hospital Datteln**
Datteln
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# Sponsor information

**Organisation**

Vodafone Foundation Institute (Germany)

### Sponsor details
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### Sponsor type
Research organisation

### ROR
https://ror.org/044qwkx83

## Funder(s)

### Funder type
Research organisation

### Funder Name
Robert Bosch Stiftung GmbH (Germany)

## 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 | 01/12/2013 | | Yes | No |
| Results article | results | 01/01/2014 | | Yes | No |