

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 27/02/2014	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 physician appointments (parental report)
5. Pain medication (physicians 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

Germany

45711

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