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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

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

Primary study design
Interventional

Study design
Single centre randomised controlled trial

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
9 Years

Upper age limit
18 Years

Sex
All

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)

ROR
https://ror.org/044qwkx83

Funder(s)

Funder type
Research organisation

Funder Name
Robert Bosch Stiftung GmbH (Germany)

Results and Publications

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