Effectiveness and cost-effectiveness of a multimodal rehabilitation programme (MRP) for adolescents with chronic musculoskeletal pain (12-21 years) compared to care as usual (CAU); a Randomized clinical trial

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The primary objective of this study is to evaluate the effectiveness and cost effectiveness of a multimodal rehabilitation program (MRP) in reducing functional disability (measured with the Functional Disability Inventory) for adolescents with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45057

Source
ToetsingOnline

Brief title
2B Active: Outpatient rehabilitation for adolescents with chronic pain

Condition

- Other condition

Synonym
Chronic pain

Health condition

Chronische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Vakgroep Revalidatiegeneeskunde
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting Vooruit;Fonds Nuts Ohra;Adelante

Intervention

Keyword: Adolescents, Chronic pain, Graded Exposure, Multimodal rehabilitation program

Outcome measures

Primary outcome

Primary outcome measure for this study is mean difference in FDI-score between MRP and CAU. The FDI (Functional Disability Inventory) measures functional disability

Secondary outcome

Secondary outcome variables are Quality of life, fear of pain, catastrophizing, depressive symptoms, perceived harmfulness, pain intensity, daily activity, balance and muscle strength. For the economic evaluation, total direct and indirect costs and quality of life are measured and for the process evaluation, protocol adherence, patient centeredness and treatment expectations will be measured

Study description

Background summary

Chronic musculoskeletal pain is a common problem amongst adolescents. Living

with chronic pain not only impacts on the adolescent*s functioning and well-being, but also has negative consequences for the family and society (costs). According to the Fear Avoidance Model, fear of movement and pain catastrophizing play an important role in the occurrence and maintenance of chronic pain complaints. It is hypothesized that a multimodal rehabilitation program, aimed at reducing fear of movement and pain catastrophizing will decrease disability in adolescents with chronic musculoskeletal pain, compared to care as usual.

Study objective

The primary objective of this study is to evaluate the effectiveness and cost effectiveness of a multimodal rehabilitation program (MRP) in reducing functional disability (measured with the Functional Disability Inventory) for adolescents with chronic musculoskeletal pain by comparing to care as usual (CAU). Secondary objectives are to evaluate the effect of MRP on reducing fear of movement, improving quality of life and improving physical fitness, to evaluate MRP in terms of treatment fidelity and patient centeredness and to explore whether parental behaviour affects adolescent treatment outcome (reduced disability).

Study design

A multicentre randomized clinical trial, allocating participants to either MRP or CAU with a ratio of 1:1.

Intervention

The MRP consists of 3 treatment modules. The Graded Exposure (GE) module aims to improve functional ability and reducing pain-related fear by means of exposing adolescents to fear-provoking activities. The combined hypermobility and graded exposure (HMGE) module for patient with hypermobility syndrome and chronic pain starts with physical training before exposure is offered. All adolescents* parents will be offered the parent module, in which parents are assisted to gain insight in how they can provide the right context in which their adolescent can improve. The control condition, CAU consists of the care currently provided in Dutch rehabilitation centres, based on a national consensus report for treatment of adolescents with chronic fatigue and pain.

Study burden and risks

Risks of participating in this trial are considered negligible. Measurements are non-invasive and the burden for the participants consists of 3 extra measurements, next to the two measurements that take place as part of medical care. Measurements consist mainly of a questionnaire, which take approximately 45 minutes each to complete. Measurement of health care utilization consists of

filling in a diary once a month. Completion time is about 5 minutes. For the Maastricht population, the physical fitness measures take 15 minutes to complete and they will be asked to wear the accelerometer for 7 days each measurement moment. This trial is considered a therapeutic trial.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age 12-21 years at the start of the study
* Complaints of chronic non-specific musculoskeletal pain of a duration * 3 months
* Considerable activity limitations / disability according to the expert opinion of the consultant in rehabilitation medicine.

* Fear of movement according to the expert opinion of the consultant in rehabilitation medicine.
* Indication for outpatient multidisciplinary rehabilitation treatment
* Adequate Dutch literacy to complete the assessments (which mainly comprise questionnaires)

Exclusion criteria

* Any suspicion of a medical (orthopaedic, rheumatic or neurological) disease, that can explain the current pain complaints
* Any suspicion of an (underlying) psychiatric disease, for which psychiatric treatment is better suited, according to the expert opinion of the consultant in rehabilitation medicine
* Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-07-2014
Enrollment:	124
Type:	Actual

Ethics review

Approved WMO

Date:	04-06-2014

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-06-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL47323.068.13