The effectivity of Graded Exposure in vivo versus standardized physiotherapy in Complex Regional Pain Syndrome type I (CRPS-I) patients with pain related fear: a randomized clinical trail

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The objective of the proposed project is to compare the effectivity of GEXP in vivo with that of standardized physiotherapy in CRPS-I patients with pain related fear.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35167

Source
ToetsingOnline

Brief title
GEXP in vivo vs. physiotherapy in CRPS-I

Condition

- Other condition

Synonym
reflex sympathetic dystrophy, Suedeck dystrophy

Health condition

pijnsyndroom

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Complex regional pain syndrome type I Physiotherapy, Graded exposure in vivo, Pain-related fear

Outcome measures

Primary outcome

1. Functional disability measured with:

1.1. Radboud Skills Questionnaire (RASQ; Oerlemans, Cup et al., 2000), for

upper limbs.

1.2. Walking Ability Questionnaire (WAQ; Perez et al., 2002), for lower

limbs.

Secondary outcome

2. Physical activity in daily life, measured with the accelerometer Actiwatch

(Cambridge Neurotechnology Ltd., Cambridge, UK) for upper and lower limbs.

3. Body function and structure:

3.1. Pain, measured with:

a) Neuropathic Pain Scale (NPS; Galer & Jensen, 1999).

b) McGill Pain Questionnaire Dutch version (MPQ-DLV; Melzack, 1975; van der

Kloot, Oostendorp, van der Meij, & van den Heuvel, 1995).

3.2. Sensory symptom allodynia, measured with Von Frey hairs (Rommel et al.,

1999).

3.3. Vasomotor symptoms: temperature differences (IR thermometry), coloured area's scored from a digital picture.

3.4. Sudomotor symptoms: edema, measured as difference in volume.

3.5. Motor symptom flexibility (goniometry).

4. Fear of movement measured with:

4.1. Tampa Scale for Kinesiophobia (TSK; Goubert et al., 2004; Vlaeyen, Kole-Snijders, Boeren, & van Eek, 1995).

4.2. Photograph series of daily activities (PHODA) for upper limbs (PHODA-UE; Dubbers & Vikström, 2003) and for lower limbs (PHODA-LE; Jelinek, Germes, & Leyckes, 2003).

5. Fear of pain measured with the Angst Pain Anxiety Symptoms Scale (PASS-20; McCracken & Dhingra, 2002).

6. Catastrophizing, measured with the Pain Catastrophizing Scale (PCS; Sullivan, Bishop, & Pivik, 1995).

7. Coping with pain measured with the Pijn Coping en Cognitie Lijst (PCCL; Stomp-van den Berg et al., 2001).

8. Emotional distress: Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983).

9. Participation, measured with the IPA (IPA; Cardol, de Haan, van den Bos, de Jong, & de Groot, 1999).

10. Emotional involvement measured with the potential emotional involvement subscale of the Inventarisatielijst Sociale Betrokkenheid (ISB; Van Dam Baggen & Kraaimaat, 1992).

Study description

Background summary

Research on the treatment of CRPS-I, as described in the Dutch evidence based treatment guidelines (Richtlijn Complex Regionaal Pijn Syndroom type I, 2006), mainly showed improvement at the level of coping with pain. Only little improvement in functional restoration was found. Research in other pain populations such al neck- and back-pain patients has shown that pain related fear contributes to the development of functional disability. GEXP in vivo which aims on systematically reducing fear of movement, shows promising results in CRPS-I patients (de Jong et al., 2005).

Study objective

The objective of the proposed project is to compare the effectivity of GEXP in vivo with that of standardized physiotherapy in CRPS-I patients with pain related fear.

Study design

The study concerns a single blinded, single center, randomized clinical trial. The treatment will be preceded by two pre-measures. After treatment there will be one post-measurement, 6 and 12 month follow-up measurements.

Intervention

The two interventions that will be compared are GEXP in vivo (de Jong et al., 2005) and standardized physiotherapy according to the protocol of Oerlemans, Oostendorp, de Boo en Goris (1999). The GEXP in vivo comprises 17 sessions of one hour, the physiotherapy treatment of 34 sessions of 30 minutes. Both treatments will be given over a period of 17 weeks.

Study burden and risks

The burden of the study is that patients have to fill questionnaires on five occasions (ca. 1,5 hours per occasion) and that physiological measures will be taken on four of these occasions (ca. 1 hour per occasion).
Furthermore, patients will be asked to complete a dairy with 15 short questions during the intervention and during 7 days around all occasions of measurement (ca. 5 min. per day).
In addition patients are required to wear three accelerometers for periods of 7 days on four occasions. The accelerometers are very small and light and will not be much of a hinder.
On four occasions of each two weeks patients will be asked to keep a diary in

which they keep track of disease related expense. This will only take a couple of minutes per week. Patients will also be asked to keep track of the number of home exercise they completed and how much time they spent on them. This will only take 2-3 minutes per day.
A benefit of participation in the study is that patients can be treated more effectively in future.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Diagnosis CRPS-I according to IASP criteria.
2. Pain related (PHODA-LE-score >= 35 and PHODA-UE-score >= 32)
3. Age between 18 and 65.

4. Rehabilitation treatment has been indicated.

Exclusion criteria

1. Pregnancy.
2. Insufficient fluency in Dutch.
3. Generalized pain syndrome.
4. Dystonia.
5. Psychopathology
6. Involvement in a claim regarding the disease.
7. Symptoms on both upper or both lower extremities.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2008
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO

Date:	14-04-2008
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-07-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-02-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-06-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-10-2010
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
ClinicalTrials.gov	NCT00625976
CCMO	NL20067.068.08