# *Pain exposure* physical therapy versus standard therapy for patients with complex regional pain syndrome type 1 (CRPS-1)

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Despite a lacking scientific argumentation, the PEPT approach or Macedonian therapy, is now being adopted on a large scale among physical therapists in The Netherlands for patients with CRPS-1. There are two level C retrospective cohort studies...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Bone and joint injuries |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON32618

**Source**
ToetsingOnline

**Brief title**
PEPTOC trial

### Condition

- Bone and joint injuries
- Musculoskeletal and connective tissue disorders NEC

**Synonym**
sympathetic reflex dystrophy; algo-dystrophy

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud
**Source(s) of monetary or material Support:** 50% ZonMw; 50% afdeling Heelkunde UMC St Radboud

## Intervention

**Keyword:** Complex Regional Pain Syndrome I, Functional recovery, Pain Exposure Physical Therapy, Pharmacological treatment

## Outcome measures

### Primary outcome

1. The Impairment level SumScore (ISS), which consists of three measurement parameters (pain, active range of motion and temperature) and four measurement instruments (VAS, McGill Pain Questionnaire, goniometry of mobility of joints and skin thermometer).

2. The functional disability of the arm, shoulder and hand (as measured by the DASH) or the legs (as measured by the Lower-Limb Task Questionnaire of McNair).

3. The behavior in pain (as determined by the Fear-Avoidance Beliefs Questionnaire (FABQ), a statement list regarding the perception on pain and physical activities).

4. The level of participation as determined by a subscale of the questionnaire SF36, which measures the patient*s point of view regarding health.

A cost-effectiveness analysis from a societal perspective comparing PEPT to usual care in patients with CRPS will be performed. This will be done along-side the clinical trial.

### Secondary outcome

1 At function level, the muscle force measurements as derived from both hands

by a handheld dynamometer and both feet (dorsal- en plantarflexion) by a mycrofet dynamometer.

2 At the level of activity limitations, for the arms the Radboud Skills Questionnaire; a questionnaire regarding two-handed activities of daily living) and for the legs the 10 meter walking test (which measures the time in walking a certain distance) and the timed up-and-go-test (which measures the time from rising from a chair and walking a restricted distance).

# Study description

### Background summary

Complex Regional Pain Syndrome Type 1 (CRPS-1) is a term describing a variety of painful conditions following injury which appears regionally having a distal predominance of abnormal findings, exceeding in both magnitude and duration the expected clinical course of the inciting event, often resulting in impairments of movement-related functions, sensory functions and pain, and showing a variable progression in the course of time. Patients with CRPS in whom a peripheral nerve disorder can be confirmed are classified as type 2 (CRPS-2). CRPS-1 has been a disastrous diagnosis in The Netherlands since decades, resulting in 1988 in the founding of the largest patient platform in the world after the United States with almost 4000 members. This is mainly due to the chronification of currently 20.000 patients with an assumed 8000 new patients per year. Current usual treatment results only in approximately 50% reduction of pain, disabilities and restrictions in participation in patients with CRPS-1 after long follow-up and therefore cannot be qualified as highly effective. It contributes to chronification and subsequent high costs which is an accepted phenomena in CRPS patients. PEPT is expected to result in remarkably better functioning and less pain in patients with CRPS-1. It is focused on full recovery of functioning in a relatively short time. Long-lasting disabilities and participation problems are not to be expected but rather early return to work and social participation. PEPT is therefore a very low-cost approach, which potential success for patients who are motivated to regain functioning and temporarily neglect pain.

### Study objective

Despite a lacking scientific argumentation, the PEPT approach or Macedonian

therapy, is now being adopted on a large scale among physical therapists in The Netherlands for patients with CRPS-1. There are two level C retrospective cohort studies demonstrating a promising and clinical relevant beneficial effect on pain and function after PEPT. In response to the growing demand for scientific argumentation among doctors and physical therapists with respect to the efficacy of PEPT, we conducted a pilot study at the UMC St Radboud Nijmegen. The results of this pilot study were very promising and therefore, we decided to design a large RCT to investigate the treatment effects and costs in CRPS patients treated with PEPT compared to CRPS patients treated with usual therapy according to the Dutch CBO guidelines.

## Study design

Prospective, single-blinded, randomized clinical trial.
After base-line measurements (T0), measurements are performed at three (T1) and six months (T2) after inclusion. Follow-up is at nine months (T3).

## Intervention

Treatment group: In the treatment group medication prescribed for CRPS is tapered to zero. No invasive treatments like sympathetic blocks, and/or operations will be performed. After extensive information about the mechanism of action of PEPT in relation to CRPS, patients receive five sessions of PEPT including homework exercises. The basic of PEPT is a function-oriented exercise therapy. The PEPT physical therapist manipulates restricted joints and intensively trains functional skills irrespective of pain experience during or after the therapy. Patients are stimulated to use an active coping style to achieve a clear functional goal in 5 sessions.
Control group: Usual treatment of CRPS-1 according to the Dutch CBO CRPS guideline 2006 including, analgesics (WHO pain ladder), neuropathic drugs, N-acetylcysteine, calcium channel blocker, ketanserine and DMSO (dimethylsulphoxide). On indication, percutaneous sympathetic blocks or spinal cord stimulation will be performed according to this CBO guideline. In addition, patients receive physical therapy with exercises within pain limits (pain contingent), splints and if necessary, aids for ADL activities.

## Study burden and risks

In a consecutive inhomogeneous series of 87 patients with both acute and chronic CRPS-1, who were all motivated to start with PEPT treatment in our department of physical therapy, 20 patients (23%) stopped during the course of the treatment. Ten patients decided to stop because of a lack of motivation after all and ten other patients stopped when the treatment was interrogated by other (medical) treatments. No single patient ceased because of exacerbation of CRPS-1. Although we expect that in a more homogenous patient group this

percentage will decrease, in this study, 23% will be calculated as drop-out.

# 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

Protocol page 7: Problem definition;Adult patients (age 18-80 years) with CRPS-1 according to the diagnostic criteria list according to Bruehl/IASP for more than three months, but no longer than 2 years. Only patients with CRPS-1 in one extremity are included.

## Exclusion criteria

Patient known or suspected of not being able to comply with this study protocol or indication

of reluctance to participate in the trial.
Previous randomisation in this trial.
Known presence of psychiatric disorder.
Possible other cause of pain disorder (IASP criterium).

# Study design

## Design

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| Study phase: | 3 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-01-2009 |
| Enrollment: | 75 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 29-12-2008 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# 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 | NL24762.091.08 |