

# Exposure in vivo: procedural fidelity and effectiveness in adults with chronic musculoskeletal pain (CMSP) directly following implementation in a rehabilitation center

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON50836

### Source

ToetsingOnline

### Brief title

Exposure in vivo in chronic pain

### Condition

- Other condition

### Synonym

Musculoskeletal pain; Pain of the posture and locomotor apparatus

### Health condition

chronische pijn

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Centrum Integrale Revalidatie (CIR revalidatie)

**Source(s) of monetary or material Support:** Nationaal Regieorgaan Praktijkgericht Onderzoek SIA (Regieorgaan SIA); onderdeel van NWO, Adelante Zorggroep

## Intervention

**Keyword:** Exposure in vivo, Implementation, Musculoskeletal pain

## Outcome measures

### Primary outcome

Accomplishment of patient\*specific goals and pain-related disability (activities and participation).

### Secondary outcome

Pain and fatigue, illness perception and coping, patients rating of improvement and satisfaction, retention, physical functioning, emotional functioning, symptoms and adverse events, and medical consumption. Procedural fidelity is also a secondary outcome.

## Study description

### Background summary

Various studies have assessed exposure in vivo and, generally, found positive effects. In order to increase the impact of the intervention, an important next step is to investigate the implementation of the protocol in other rehabilitation facilities. Since procedural fidelity is a prerequisite for effectiveness, it is important to ascertain to what extent interventionists, after following the training, deliver the intervention as intended. Moreover, it is of interest to know whether the effectiveness holds directly following implementation in a new setting.

## Study objective

The primary objective is to assess the effectiveness of exposure in vivo directly following implementation in adults with chronic musculoskeletal pain (CMSP). Secondary objectives are to assess procedural fidelity and its progression directly following the implementation \*of exposure in vivo in a rehabilitation center; and to assess whether catastrophizing is a mediator in the potential effectiveness of exposure in vivo in adults with chronic musculoskeletal pain. \*

## Study design

A replicated randomized AB phase single-case experimental design (SCED) with follow-up.

## Intervention

Exposure in vivo treatment: a 12-week module including 16 treatment sessions of one hour each.

## Study burden and risks

Participants will complete 11 daily questions for 14-18 weeks (diary). In addition, audio recordings are made of all treatment sessions.

## Contacts

### Public

Centrum Integrale Revalidatie (CIR revalidatie)

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Zwolle 8025 AX  
NL

### Scientific

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## Trial sites

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- chronic musculoskeletal pain consisting at least three months and diagnosed by a general practitioner or medical specialist;
- aged  $\geq 18$  years; and
- an indication for the exposure in vivo treatment given by an interdisciplinary team including a physiatrist, physical therapist, and psychologist.

### Exclusion criteria

Any of the contra-indications described by Verbunt et al., for instance, an unstable medical, emotional-personal and/or social situation.

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-03-2021

Enrollment: 12  
Type: Anticipated

## Ethics review

Approved WMO  
Date: 29-04-2021  
Application type: First submission  
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

## 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	NL76656.075.21