Web-based intervention based on Acceptance & Commitment Therapy (ACT) and mindfulness for chronic pain patients: A randomized controlled trial

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

Summary

ID

NL-OMON35156

Source
ToetsingOnline

Brief title
Web-based ACT & mindfulness for chronic pain

Condition

- Other condition

Synonym
chronic pain

Health condition

chronische pijn

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Innovatiefonds Zorgverzekaars

Intervention

Keyword: Acceptance & Commitment Therapy, chronic pain, mindfulness, web-based intervention

Outcome measures

Primary outcome

Main study parameter is interference in daily life due to pain, measured with

the MPI-interference subscale.

Secondary outcome

Secundary study are pain disability and pain intensity, psychological

flexibility, mindfulness, values-based living and (positive) mental health.

Study description

Background summary

Chronic pain is highly prevalent in Western countries. Cognitive and behavioral therapies for the treatment of chronic pain have been established, but new factors useful for the treatment of pain have been acknowledged. One of these factors is acceptance. Different laboratory and clinical outcome studies suggested acceptance strategies to be important in restoring functioning and quality of life in the presence of chronic pain. Examples of preventive mechanisms and treatments based on acceptance are Acceptance & Commitment Therapy (ACT) and mindfulness. The University of Twente has developed several effective interventions based on ACT and mindfulness for adults with psychological problems. Now a web-based intervention based on ACT and mindfulness for chronic pain patients has been developed, called *Leven met Pijn online*. The goal of this study is to evaluate the effectiveness of *Leven met Pijn online* in a randomized controlled trial.

Study objective

The primary objective of this study is to evaluate the web-based intervention *Leven met Pijn online* for chronic pain patients in terms of a decrease of interference in daily life due to pain. The secondary objective of this study is to evaluate *Leven met Pijn online* in terms of a decrease in pain disability and pain intensity, and an increase in mental health, satisfaction with life, psychological flexibility, mindfulness and values-based living. Another objective of the study is to evaluate the mediating effects of psychological inflexibility and mindfulness in the effects described in the primary objective.

Study design

A randomized controlled trial will be carried out with three parallel groups:
1) Experimental condition: Web-based intervention *Leven met Pijn online*. Participants are involved from entry/intake until the last measurement for 14 months. There are six measurement points.
2) Minimal intervention condition: Web-based intervention *Expressive writing*. Participants are involved from entry/intake until the last measurement for 14 months. There are six measurement points.
3) Waiting list control condition: Participants will be on a waiting list for six months after randomisation (eight months after entry). They receive an online course of their personal choice after the first follow-up measurement, three months after the end of the intervention for the experimental condition (eight months after entry). Participants are involved in the study for 11 months. There are five measurement points.

As all participants will be randomly assigned to the three groups at one specific moment, there is a waiting time with a maximum of six weeks before people know in what intervention group they are enrolled.

Intervention

The intervention is based on the self-help book *Leven met Pijn* and the web-based intervention *Voluit Leven online* for adults with psychological problems. The intervention is based on ACT and mindfulness. There are 9 modules, which can be worked through in 9-12 weeks. Patients receive exercises on acceptance and mindfulness and explore how they can apply their personal values in daily life. Feedback from a counsellor will be received by e-mail contact on a weekly basis.

Study burden and risks

No risks are expected from participation. Participants can choose for themselves to sign up for study participation. The burden with regard to time

and mental effort are not expected to be too high. Participants are enrolled in the study for 11 or 14 months. There is a waiting time with a maximum duration of six weeks between entry in the study and randomisation over the three groups. If burden of participation is too high, participants can always decide to stop and drop out of the study. Also the questionnaire assessment does not seem to be a very high burden (45 - 60 minutes at T0, T3, T4 and T5; 20 minutes at T1 and T2). If it appears from intake that participants have severe psychiatric problems, they will be advised strictly to see a GP as soon as possible. Participation probably will have benefits such as a decrease in pain interference, pain disability and an increase in mental health, psychological flexibility, mindfulness and values-based living.

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

- Age >= 18 years
- Chronic pain longer > 6 months (self-report)
- Scores on pain intensity (NRS) >= 3, for >= 4 days within a 7-day period (measured during baseline period at screening)

Exclusion criteria

- Severe psychiatric problems
- Extremely low scores on psychological inflexibility (PIPS; >= 2 SD below mean of population of chronic pain patients in a pain rehabilitation centre)
- Enrollment in other cognitive behavioural treatment at entry study
- Having no access to the Internet at home and having no e-mail address
- Not enough time to follow the intervention
- Reading problems (due to insufficient Dutch language skills or illiteracy)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2012
Enrollment:	159
Type:	Actual

Ethics review

Approved WMO Date:	02-01-2012
Application type:	First submission
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21658
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL38622.044.11
OMON	NL-OMON21658