Effectivity and efficiency of an Internet-based cognitive behavioural intervention for chronic pain patients

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

Summary

ID

NL-OMON32411

Source
ToetsingOnline

Brief title
Internet intervention

Condition

- Other condition

Synonym
aspecific pain, chronic pain

Health condition

chronische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic pain, Cognitive behavioural treatment, Internet intervention, Psychoeducation

Outcome measures

Primary outcome

Catastrophizing (as measured with Pain Catastrophizing Scale)

Secondary outcome

- Pain coping (as measured with Pain Coping and Cognition Scale (PCCL))

- Internal pain control (as measured with Pain Coping and Cognition Scale

(PCCL))

- External pain control (as measured with Pain Coping and Cognition Scale

(PCCL))

- Overall health status (as measured with Rand-36)

- Pain(VAS)

- Limitations because of pain (VAS)

- Fatigue (VAS)

- Medication

- Work status

- Opinion of the intervention

Study description

Background summary

The medical treatment of chronic pain often fails to be effective. Catastrophizing, coping strategies and locus of control are important factors in the development and maintainance of chronic pain. Cognitive behavioural group interventions aimed at these factors are effective in the treatment of chronic pain patients. Despite this effectivity, these group interventions have certain disadvantages, such as a the burden for the patients and it being time consuming for the course facilitators. Internet-based cognitive behavioural interventions appear to be an excellent alternative. International studies have reported Internet-based interventions to be effective in various patient groups and to be more costeffective compared to face-to-face treatment. Until now no studies have been published about Internet-based interventions for chronic pain patients in the Netherland.

Study objective

Aim of this study is to evaluate if a cognitive behavioural intervention voor patient with chronic pain on the Internet is at least as effective with respect to catastrophizing, locus of control, pain coping, quality of life and medical costs compared to a cognitive behavioural groupintervention (care-as-usual). Also the cost effectiveness of the Internet intervention compared to care-as-usual (group intervention) will be studied.

Study design

Randomized clinical trial

Intervention

Participant will be allocated at random to either a cognitive behavioural Internet intervention of a cognitive behavioural group intervention. Both interventions have a duration of 8 week (intervention of 7 weeks, last module in week 15).

Study burden and risks

The extra burden of participating in the study is limited. Participants are asked to fill in some questionnaires at 4 point during the study. Questionnaires used are: biographical variables, Visual Analoge Scales for pain, limitations and fatigue, questions regardig medication use and workstatus, questions regarding the opinion of the intervention (at T1, T2 and T3). Pain Catastrophizing Scale, Pain Coping and Cognition Scale (PCCL) en Rand-36.
The risks of participation in the study are minimal. Considering the type of study/ intervention, no adverse effects are expected. Participant can benefit

from participation in the study. They will receive an intervention aimed at better coping with the pain (with expected effects on catastrophizing and locus of control).

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

Chronic pain
Minimal age of 18 years
Able to change, learn and train
Motivated for a cognitive behavioural approach
Have the disposal of a computer with internet connection and an emailadress

Exclusion criteria

Major psychopathology (SCL-90>224)
Limited Intelligence level (highest education < primary education)
Strong somatic fixation

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-10-2008
Enrollment:	84
Type:	Actual

Ethics review

Approved WMO

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	NL20047.042.07