A randomized controlled trial of an online aftercare program in pain rehabilitation and a qualitative study of the experiences of users and their opinions on support by a health care professional.

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

Summary

ID

NL-OMON46255

Source
ToetsingOnline

Brief title
Online aftercare in chronic pain rehabiltation

Condition

- Other condition

Synonym
chronic pain, non-acute pain

Health condition

chronische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: Roessingh;centrum voor revalidatie

Intervention

Keyword: Acceptance & Commitment Therapy, Pain interference, Physical condition training, telemedicine

Outcome measures

Primary outcome

Main study outcome is pain interference measured at 3 month follow-up.

Secondary outcome

Secondary study parameters are pain intensity, psychological distress and

psychological flexibility at 3 months follow-up..

Outcomes of the qualitative part are user experiences and the opinions of

participants concerning support by a health care professional.

Study description

Background summary

Many chronic pain patients find it difficult to retain behavior changes after multidisciplinary pain rehabilitation program. They experience barriers in living according to their personal values and to realize a balanced daily activity schedule in the presence of pain or negative thoughts. An aftercare program that prevent relapses is needed but not routinely offered due to limited therapist time and a lack of (financial) resources. A relapse prevention program based on e-health might overcome these barriers. Thus far, it is unknown whether patients can use the program on their own or whether a minimum of professional support is needed.

Study objective

The first objective is to evaluate if the online aftercare program is more effective when it is supported by e-mail contact with a health care professional compared to no support in decreasing interference of pain complaints with daily life.
The secondary aim is to assess the clinical benefits of the online program on the outcomes pain intensity, psychological distress and the process variable psychological flexibility.
The third objective is to qualitatively evaluate the experiences of a subsample of 20 participants while using the program and to assess their opinions concerning support of a health care professional.

Study design

The design is a randomised controlled superiority study with two conditions. In the experimental condition patients get access to the online aftercare program and to a contact module that enables them to exchange e-mails with a healthcare professional. In the control condition patients only get access to the online aftercare program.
In addition, a qualitative study will be done with a subsample of 20 participants from both the experimental and control condition.

Intervention

The intervention consists of a psychosocial module, a physical module and a contact module in the experimental condition. The psychosocial module based on Acceptance & Commitment Therapy. The website and mobile application aim at sustaining valued actions. The physical training program consists of films and instructions of physical exercises that can be adapted individually. The contact module offers the opportunity to exchange e-mails in a safe environment. Participants are free to send as much e-mails as they want, the healthcare professional reacts once a week.

Study burden and risks

Participants who receive the online aftercare program can gain direct benefit from participation in this study, as the program is expected to prevent relapse. No risks are expected from participation in this study. Questionnaires used in the study are non-invasive and they are part of the standard measurement procedures of Roessingh Rehabilitation Centre. Additionally, no drugs or physical procedures are involved in the protocol.
Telephone interviews in the qualitative part take 30 minutes at the most.

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

* Patients aged between 18 and 65 years old
* Primary complaint is chronic musculoskeletal pain
* Having finished a pain rehabilitation treatment at RCR
* Being able to use an online program
* Disposal of a smartphone, I-pad or PC
* Permission to use data for scientific purposes

Exclusion criteria

There are no exclusion criteria for including participants into the study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-07-2016
Enrollment:	142
Type:	Actual

Ethics review

Approved WMO Date:	09-02-2016
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	01-08-2017
Application type:	Amendment
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: 27656
Source: NTR
Title:

In other registers

Register	ID
Other	23539
CCMO	NL55824.044.15
OMON	NL-OMON27656