A randomised controlled trial of an online aftercare proram in pain rehabilitation

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27656

Source
NTR

Health condition

chronic pain

Sponsors and support

Primary sponsor: Roessingh Research & Developmnt
Source(s) of monetary or material Support: Roessingh, centrum voor revalidatie

Intervention

Outcome measures

Primary outcome

Main study outcome is pain interference measured by the Multidimensional Pain Inventory – subscale pain interference (MPI – interference) (Kerns et al., 1985; Lousberg et al., 1999).

Secondary outcome

Pain Intensity measured by the Multidimensional Pain Inventory – subscale pain intensity (MPI – intensity) (Kerns et al., 1985; Lousberg et al., 1999).

Psychological distress meadured by Hospital Anxiety Depression Scale (HADS) (Zigmond & Snaith, 1983).

Psychological flexibility measured by
Psychological inflexibility in Pain Scale (PIPS) (Wicksell et al, 2010; Trompetter et al., 2014).

Study description

Background summary

Rationale:
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.

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.

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.

Study population:
The study population exists of chronic pain patients that have received an inpatient or outpatient treatment at the Pain Department of the RCR.

Intervention (if applicable):
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.

Main study parameters/endpoints:
Main study outcome is pain interference measured at 3 month follow-up. Secondary study parameters are pain intensity, psychological distress and psychological flexibility at 3 months follow-up.

Study objective

The online aftercare program with support of a human coach is not superior to the online aftercare program without support of a human coach.

Study design

Study parameters are measured at the end of the rehabilitation program (T1) and at 3 month follow-up after the end of the rehabilitation treatment (T2). This is one month after the end of the aftercare program.

Intervention

The intervention consists of NaDien, CoCo and a contact module in the experimental condition.

NaDien: This program is based on Acceptance & Commitment Therapy. The website and mobile application aim at sustaining valued actions. Participants register their life values, describe committed actions and register the frequency of them. They can obtain a graph of their committed actions. Exercises learned during treatment are sampled in a library. In addition participants compose a scheme of motivational and reminder text messages that are sent to them at later moments.
CoCo: The physical training program consists of films and instructions of physical exercises that can be adapted individually. At the end of the rehabilitation program each participant composes his own training scheme together with a physiotherapist.

Contact module: This 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 sends an e-mail once a week on a predetermined day. The task of this professional is to encourage participants to adhere to the aftercare program, to coach in maintaining behaviour changes learned in treatment, to discuss possible barriers in maintaining behaviour change and to resume changed behaviours after a possible relapse in unhelpful behaviour.

Contacts

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Eligibility criteria

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

Dropped out of rehabilitation program

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2016
Enrollment:	142
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-12-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46255
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5463
NTR-old	NTR5607
CCMO	NL55824.044.15
OMON	NL-OMON46255

Study results