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

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27656

Bron
NTR

Aandoening

chronic pain

Ondersteuning

Primaire sponsor: Roessingh Research & Developmnt
Overige ondersteuning: Roessingh, centrum voor revalidatie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

•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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Dropped out of rehabilitation program

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2016
Aantal proefpersonen:	142
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-12-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46255
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten