Cognitive behaviour therapy by internet for chronic fatigue in type 1 Diabetes: a randomized controlled trial.

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40479

Source
ToetsingOnline

Brief title
CBT for fatigued diabetes patients

Condition

- Other condition
- Diabetic complications
- Diabetic complications

Synonym
chronic fatigue in patients with type 1 diabetes

Health condition

chronische vermoeidheid bij type 1 diabetes patienten

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Diabetes Fonds

Intervention

Keyword: chronic fatigue, cognitive behaviour therapy, randomised controlled trial, type 1diabetes

Outcome measures

Primary outcome

- Severity of fatigue during the last two weeks (Checklist Individual Strength)

Secondary outcome

- Impairment in eight different areas (Sickness Impact Profile)

- HbA1c and glucose variability during two days

Study description

Background summary

Recent research of our own research group revealed that severe fatigue is a common complaint in patients with type 1 diabetes. This fatigue is accompanied by severe impairment in daily functioning. Perpetuating factors of the fatigue in diabetes patients seem to overlap with the perpetuating factors of chronic fatigue in other patient groups, such as patients with post-cancer fatigue and chronic fatigue syndrome. These factors include fatigue-related dysfunctional thoughts and behaviours. Cognitive behaviour therapy helps patients to change these thoughts and behaviours which has been shown to have a positive effective on fatigue and impairment in above mentioned patientgroups. The intervention might thus also lead to a significant decrease in fatigue severity and impairment in patients with type 1 diabetes. In addition, we expect that a decrease in fatigue should facilitate a better management of the diabetes itself.

Study objective

The main objective of this study is to test whether cognitive behaviour therapy delivered by internet has a significant effect on fatigue in patients with type 1 diabetes en whether this effect is sustained during a follow-up period of six months. Secondary outcome measures are impairment in daily functioning and HbA1c and blood glucose variability as measure for diabetesmanagement.

Study design

We will conduct a randomised controlled trial with a waiting list control group. The executing researcher will be blinded with respect to the condition that patients are allocated to. Assessments are planned before en directly after the intervention or control group condition and at six months follow-up.

Intervention

The intervention (cognitive behaviour therapy) consists of an introduction, six additional sections, and an evaluation:
- The introduction includes goal setting and psychoeducation (2-3 sessions in 3 weeks) and are given on location in Nijmegen.
- The additional sections are arranged for the individual patient by his or her therapist depending on the baseline assessment and will be delivered via internet (maximum of 6 sections in 11 weeks). Potential additional sections are regulation of the sleep-wake pattern, reformulation of dysfunctional fatigue-related thoughts, regulation and gradual increase of physical activity, reformulation of pain-related thoughts, optimalisation of social support, and reduction of diabetes-related stress.
- The evaluation phase (2-4 session in 6 weeks) includes evaluation of the treatment goals and the effects of therapy as well as relapse prevention and is given at location in Nijmegen.

Study burden and risks

The risk of adverse effects is, based on previous research in other patient groups, low. The burden for patients who participate in this research is similar to that of other patients who receive care as usual in our specialised treatment setting (including asessment).

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

- between 18 and 70 years
- being diagnosed with diabetes type 1 at least 1 year ago
- able to speak and read Dutch
- being severely fatigued (operationalised as a score of 35 or higher on the Checklist Individual Strength)
- fatigued for at least 6 months

Exclusion criteria

- current psychiatric or medical co-morbidity that could explain the fatigue
- wheelchair dependent

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	06-02-2014
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	20-06-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-12-2013
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-03-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-09-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-12-2014
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-04-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-05-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-05-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 27693
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL43178.091.13
OMON	NL-OMON27693