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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27693

Source
Nationaal Trial Register

Brief title
Dia-fit

Health condition

Fatigue, Type 1 diabetes mellitus, vermoeidheid, diabetes mellitus type 1

Sponsors and support

Primary sponsor: Radboud University Medical Center
Source(s) of monetary or material Support: Diabetes Fonds

Intervention

Outcome measures

Primary outcome

Fatigue severity assessed with the subscale fatigue of the Checklist Individual Strength (CIS). Timepoints: baseline, T1 (5 months after start of the intervention), T2 (6 months after the end of the intervention)

Secondary outcome

1. Limitations in daily functioning assessed with the Sickness Impact Profile 8 (SIP8). The SIP8 measures functional disability in eight different domains of functioning. Timepoints: baseline, T1, T2.

2. Diabetes regulation assessed with HbA1c levels and glucose variability. Timepoints: baseline, T1, T2.

Study description

Background summary

Severe fatigue is a common complaint in patients with type 1 diabetes patients which has high impact on daily functioning of patients. Cognitive behavioral factors can maintain the fatigue. Cognitive behaviour therapy which is designed to change dysfunctional thoughts and behaviours could be effective in reducing severe fatigue. Until now there is no evidenced based intervention to treat severe fatigue in type 1 diabetes patients. An intervention was developed for this study consisting of a blended-care CBT of web-based modules and face-to-face sessions with a therapist. The efficacy of CBT directly following treatment will be compared with a waiting list condition in a randomized controlled trial. Furthermore, long term effects of this intervention will be determined.
Patients will be recruited from the diabetes outpatient clinic of the Radboud university medical center in Nijmegen, the Netherlands. When accrual of patients is not sufficient in this center, other hospitals will be approached for participation.

Study objective

Recent research revealed that severe fatigue is a common complaint in patients with type 1 diabetes. This fatigue is often chronic (duration > 6 months) and has a negative impact on the daily functioning of patients. Cognitive behavioural factors can perpetuate the fatigue. Several studies in other chronic conditions have shown that cognitive behaviour therapy (CBT), specifically designed to change fatigue related thoughts and behaviours, is effective in reducing severe fatigue. CBT for fatigue in type 1 diabetes has not been applied so far. Primary objective of this study is to test whether CBT is also effective for severe and chronic fatigue in patients with type 1 diabetes. The CBT will be a combination of face to face sessions with a therapist and interventions delivered by the internet.
Research questions:

1. Does CBT lead to a significant decrease in fatigue in chronically fatigued DM1 patients directly following treatment compared to a waiting list condition?

2. Does CBT for chronically fatigued DM1 patients lead to a significant reduction in the level of disabilities, HbA1c, and glucose variability directly following treatment compared to a

waiting list condition?

3. Are the effects of CBT on the primary and secondary outcome measures sustained at follow-up, six months after the intervention?

4. Do changes in the proposed fatigue maintaining factors mediate the effect of treatment on fatigue severity?

Study design

1. T0 baseline assessment

2. T1 following the intervention; 5 months after start of the intervention

3. T2 follow-up; 6 months after the end of the intervention

Intervention

Patients will receive cognitive behaviour therapy (CBT), offered in a blended-form of web-based modules and face-to-face sessions with a therapist. Based on previous research in fatigued patients with type 1 diabetes a treatment protocol ‘CBT for fatigue in type 1 diabetes patients’ is developed. The protocol consists of five to eight web-based modules aimed at perpetuating factors of fatigue. Five modules will be followed by all patients, three modules are tailored to the patients needs. Baseline assessment determines which of these modules are delivered to the patient. Besides the web-based modules, patients receive five to eight face-to-face sessions with a therapist. The amount of the sessions also depends on patients’ needs. Patients will follow the therapy for a period of 5 months.

Patients assigned to the waiting list conditions also receive CBT after a waiting period of 5 months.

Contacts

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Eligibility criteria

Inclusion criteria

1. Between 18 and 70 years old

2. Being diagnosed with type 1 diabetes at least 1 year ago

3. Able to speak, read and write Dutch

4. Being severely fatigued operationalize as scoring 35 or higher on the subscale fatigue severity of the Checklist Individual Strength (CIS)

5. Fatigued for at least 6 months

Exclusion criteria

1. Moderate to severe renal failure operationalised as having a glomerular filtration rate (GFR) ≤ 45
2. Blindness or severe visual impairment
3. Medical history of congestive heart failure
4. Medical history of a stroke in the past five years
5. Body Mass Index (BMI) ≥ 40
6. Wheelchair-dependent
7. Other concurrent psychiatric or medical co-morbidity that could explain the fatigue

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2014
Enrollment:	120
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	10-12-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40479
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4123
NTR-old	NTR4312
CCMO	NL43178.091.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40479

Study results

Summary results
N/A