Chronic fatigue in Diabetes type 1: Is it a problem and can fatigue maintaining factors be identified?

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Diabetic complications
Study type	Observational invasive

Summary

ID

NL-OMON36185

Source
ToetsingOnline

Brief title
Chronic fatigue in diabetes type 1

Condition

- Diabetic complications

Synonym
diabetes, diabetes mellitus type 1

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cognitions, diabetes mellitus type 1, fatigue, glucose variability

Outcome measures

Primary outcome

1a) Fatigue severity will be assessed using the fatigue subscale of the Checklist Individual Strength (CIS) a widely used, reliable and well-validated instrument. The fatigue subscale of the CIS consists of 8 items scored on a 7 point Likert scale (8-56). A cut-off score of 35 or higher is an indication for severe fatigue. Chronic fatigue is defined as scoring 35 or higher and indicating that fatigue lasted 6 months or longer.

1b Functional impairments will be assessed with the Sickness Impact Profile (SIP-8). The SIP-8 assesses impairments on eight domains of functioning: mental functioning, sleep/rest, work limitations, homemaking, leisure activities, mobility, social interactions and ambulation. A total score on the SIP-8 higher than 700 is an indication for substantially impaired daily functioning.

1c) Patients will be asked whether they have experienced 36 different symptoms, including fatigue in the past month. If the symptom did occur patients are asked to indicate how troublesome the symptom was on a five point scale from 1 (not at all) to 5 (extremely). The mean will be calculated over how troublesome symptoms were and means will be ranked.

2) - Diabetes self-care behaviours: Diabetic Self-Care Inventory (CIDS) and Diabetic-related distress (Problem areas in diabetes scale (PAID))

-Fatigue related cognitions and behaviours: Self-efficacy concerning fatigue (Self-efficacy Scale (SES-26)), focusing on fatigue (Illness Management

Questionnaire (IMQ)), catastrophising concerning fatigue (JFCS), Physical activity (VLA), somatic attributions concerning fatigue (CAL)

Blood glucose variability: A subgroup of patients (n=100) will be asked to use a continuous blood glucose monitor (CGM) to determine blood glucose levels every few minutes for a period of 5 days. A CGM system consists of a disposable glucose sensor placed just under the skin, and an electronic receiver. Blood glucose variability will be determined by calculating the standard deviation of the blood glucose levels over the 5 days.
Physical activity will be assessed in a subgroup of patients (n=100) with actigraphy using an actometer. An actometer is a motion sensing device. The actometer has the size of a matchbox and is worn around the ankle for 12 consecutive days and nights. It records the number of movements at five-minute intervals. The mean daily physical activity score across twelve days and night will be determined to assess the level of physical activity.

Secondary outcome

The level of fatigue will be assessed in non-responders using a set of three questions (vermoeidheidsvragenlijst, VVV).

Study description

Background summary

It is estimated that about 85.000 people have diabetes mellitus type 1 (DM type 1) in the Netherlands. In clinical practice fatigue is a commonly reported symptom by patients with DM type 1. However, fatigue in DM type 1 has never been studied systematically. Data on fatigue in patients with DM type 2 suggest

that a substantial number of patients report fatigue. Acute elevations of blood glucose can lead to tiredness, and both hypo- and hyperglycemia were associated with fatigue. Suboptimal diabetes self-care behaviours, were also related to fatigue. In clinical practice DM patients can be chronically fatigued although blood glucose levels are stable. This suggests that other variables beside blood glucose play also a role.
It is important to differentiate between acute and chronic fatigue. Chronic fatigue is often defined as being severely fatigued for at least 6 months. Research in patients with other chronic illnesses showed that a substantial proportion of patients are chronically fatigued. This chronic fatigue is associated with more severe disabilities. It is likely that chronic fatigue also occurs often in patients with DM type 1 and will be associated with more impairments in daily functioning.
Research in other chronic illnesses also showed that other factors than the illness itself can perpetuate fatigue. Specifically cognitive and behavioural factors seem to play a crucial role in the perpetuation of chronic fatigue. Examples of these factors are a low self-efficacy with respect to fatigue, catastrophising in response to the fatigue, a disrupted sleep-wake cycle and a reduced level of physical activity. On the basis of these findings cognitive behavioural interventions were developed that demonstrated that by changing fatigue perpetuating cognitions and behaviours, chronic fatigue can be effectively treated. The reduction of fatigue led to a decrease of functional impairments and an improved quality of life.
If chronic fatigue is a clinically relevant problem in DM type 1 it is important to investigate to what extent chronic fatigue in DM type 1 is associated with the aforementioned fatigue perpetuating cognitions and behaviours. If this is the case, this would imply that a cognitive behavioural intervention might be an effective treatment for chronic fatigue in patients with DM type 1.

Study objective

The study has two objectives:
1) Is chronic fatigue a clinically relevant issue in patients with DM type 1? Chronic fatigue will be considered a clinically relevant issue if:
(a): the proportion chronically fatigued DM type 1 patients is at least 25%
(b): it is associated with impaired daily functioning
(c): if chronically fatigued patients rank fatigue as one of the three most troublesome symptoms.

2) Which factors are significantly associated with chronic fatigue in patients with DM type 1? More specifically:
Are diabetic self-care behaviours, glucose variability and fatigue perpetuating cognitions and behaviours significantly associated with fatigue?

Study design

This is an observational study (cohort study).
Three hunderd fifty patients will be randomly selected from the visitors of the outpatient diabetes clinic of the Radboud University Nijmegen Medical Centre. It is expected that two hundred patients will participate in the proposed study (questionnaires). In a subgroup of one hundred patients glucose variability and the level of physical activity will be assessed.

Study burden and risks

Participants have to complete questionnaires. This is without risks. These can be completed online or a paper and pencil version will be send to the participant. It will take about a half hour to complete the questionnaires. If patients participate in the whole study they will wear a continues glucose monitor (CGM) for 5 days. The risks using the CGM are small, utmost there is a risk for a local infection in the area where the needle is placed. Patients will also be asked to were an actometer, a motion sensing device, which will be worn around the ankle for two weeks. There are no risks involved using the actometer.

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 with diabetes mellitus type 1
DM type 1 diagnosed at least one year previously
Being 18 years of age or older.
Being able to read and write and understand Dutch

Exclusion criteria

no additional criteria

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2011
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	28-04-2011
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL35495.091.11