Psychological predictors and consequences of nocturnal hypo- and hyperglycemia in adults with type 1 diabetes and their main relative: the DiaN8 study

Published: 19-07-2021
Last updated: 04-07-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON54723

Source
ToetsingOnline

Brief title
DiaN8

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Type 1 diabetes; insulin-dependent diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO Veni,Dexcom

Intervention

Keyword: Diabetes, Glucose, Night, Psychology

Outcome measures

Primary outcome

The main study parameters are the presence of health beliefs and emotions related to nocturnal hypo- and hyperglycemia; behavior with likely hypoglycemic or hyperglycemic impact during the night; nocturnal hypo- and hyperglycemic events; sleep quality; and daytime mood, fatigue, and cognitive functioning.

Secondary outcome

Changes in glucose levels, sleep quality, mood, fatigue, and cognitive functioning from the first ambulatory assessment to an optional second ambulatory assessment three months later.

Study description

Background summary

Optimal glycemic management of type 1 diabetes requires limiting the time spent in hyperglycemia, while avoiding hypoglycemia. Overnight glycemic management is particularly complex. The psychological aspects related to nocturnal hypo- and hyperglycemia are under-researched, as are the consequences of these overnight glucose excursions for sleep and aspects of daytime functioning.

Study objective

The primary objective of the DiaN8 study is to examine which health beliefs and emotions are associated with behavior with likely hypoglycemic or hyperglycemic impact during the night in adults with type 1 diabetes and their main relative

(partner or parent). Secondary objectives are to (a) determine the relation of nighttime glucose levels with sleep and next day mood, fatigue, and cognitive functioning in these groups, and (b) explore the merit of providing tailored change strategy suggestions in case of potentially unhelpful beliefs, emotions, or behaviors.

Study design

This multi-method exploratory observational study with pilot intervention includes: (a) a study visit with an interview, the completion of questionnaires, and a brief training in the use of ambulatory equipment; (b) subsequent real-life ambulatory measurements over seven days (continuous glucose monitor, accelerometer, ecological momentary assessment app, optional sleep wearable); and (c) the provision of written feedback to all participants based on study data, and change strategy suggestions for participants with potentially unhelpful beliefs, emotions or behaviors (followed by a brief follow-up telephone call and an optional second week of ambulatory measurements after three months to evaluate any changes in the main study parameters).

Study burden and risks

In general, participants will not benefit directly from participation. However, the study may expand our knowledge in this area and highlight avenues for intervention. For a subgroup, there is a potential direct benefit as tailored change strategy suggestions are provided based on their study data. Indirect individual benefits include written feedback about the main study parameters (with the option to share data with the diabetes care team) and financial incentive. At the end of the study all participants receive a summary of the most important study results at the group level.
The risks associated with participation can be considered negligible. The burden of participation is limited to an estimated time investment of 2 to 2,5 hours for the baseline study visit, 7 x 30 minutes (divided over five measurements per day) for the ambulatory assessments, and 15 minutes for the follow-up telephone call. For each app invitation, participants are given the option to skip the assessment. Investing further time by implementing change strategy suggestions and participating in a second week of ambulatory assessment is optional. Wearing of the ambulatory devices is of negligible burden and risk. The diagnostic glucose monitoring device is also used in standard care; when following the user instructions, it can usually be inserted and worn without difficulties. As the sensor is inserted in the body, insurance is arranged for participation of the person with type 1 diabetes. The project team requests the Medical Research Ethics Committee Arnhem-Nijmegen to provide dispensation from the statutory obligation to provide insurance for the participating main relative as he/she does not have to wear the diagnostic sensor.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a person must meet all of the following criteria:
- a diagnosis of type 1 diabetes based on the medical record;
- age between 16-64 years;
- diabetes duration >=1 year.
The main relative may participate as well, provided:
- the person with diabetes consents to their participation;
- for a parent: the person with diabetes is living at the parent*s home;
- for a partner: the person with diabetes and the partner are living together.

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:
- inability to speak and read the Dutch language;
- advanced complications (low vision, blindness, kidney disease as evidenced by Modification of Diet in Renal Disease score <45 or macroalbuminuria, symptomatic autonomic neuropathy, amputations, stroke, myocardial infarction or peripheral arterial disease in the previous year or with moderate to severe residual symptom severity);
- other somatic or psychiatric comorbidities or psychosocial problems interfering with the ability to provide informed consent or with study participation;
- pregnancy, breast feeding;
- moderate to severe menopausal symptom severity.

Reasons for postponing participation include:
- recent or planned shift work or time zone travel.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-06-2023
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	19-07-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-08-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-04-2023
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

No registrations found.

In other registers

Register	ID
CCMO	NL72013.091.20