

Diabetes in the context of daily life: a study exploring goal-conflict management in young adults with type 1 diabetes

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The study has the following aims: 1. To get insight in goal-conflict i.e. the personal goals of young adults with type 1 diabetes mellitus and the extent to which their goals conflict with diabetes self-management tasks 2. To get insight in...

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

Summary

ID

NL-OMON48767

Source

ToetsingOnline

Brief title

Diabetes in the context of daily life

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

diabetes mellitus

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Glycemic control, Goal-conflict, Goal-conflict management, Self-management, Well-being

Outcome measures

Primary outcome

The primary study parameters are goal-conflict, adherence to self-management recommendations and subjective well-being.

Secondary outcome

The secondary endpoint is glycemic control.

Study description

Background summary

Type 1 diabetes, which is a chronic and as yet incurable condition, requires an intensive and challenging self-management regimen. This includes daily treatment with insulin, frequent blood glucose tests, close monitoring of food intake and regular exercise. Adherence to diabetes self-management recommendations is very important in order to minimize serious long-term diabetes complications. Studies have shown, however, that adherence to these recommendations is difficult, especially for young adults. Young adulthood is a period of growing independence and exploration and many young adults report difficulty fitting diabetes management in their daily lives. We propose that this problem is partly the result of a conflict between patients' diabetes self-management tasks and personally meaningful goals in other life domains, but this has not been studied yet.

Study objective

The study has the following aims:

1. To get insight in goal-conflict i.e. the personal goals of young adults with type 1 diabetes mellitus and the extent to which their goals conflict with diabetes self-management tasks
2. To get insight in individual differences in goal conflict.
3. To investigate the impact of goal-conflict i.e. the associations between

goal conflicts, diabetes related functioning (adherence to diabetes self-management recommendations, glycemic control) and subjective-well-being.
4. To get insight in the goal conflict management strategies of young adults with type 1 diabetes

Study design

Cross-sectional observational study. The study which will be carried out in two substudies. Study 1, which addresses study aims 1,2,3, employs a quantitative design. The study has one-time assessment by means of a questionnaire. Study 2 (aim 4) has a qualitative design and consists of a semi-structured interview and a 4 day diary (the first dairy will be filled in during the interview).

Study burden and risks

Study 1: study participants will receive a link to a one-time online questionnaire. The expected time to fill in questionnaire is 30 minutes. Study 2: involves a 45 minutes semi-structured interview (about goal-conflict and strategies to deal with goal-conflict) and a 4-day diary. The diary (of which the first day is filled in during the interview) has to be filled in once a day (15 minutes/day). The risk of study participation is negligible, no invasive procedures are performed and neither the questionnaire nor the interview/diary is expected to cause any discomfort. Given the nature of the study, no SAE*s are to be expected.*

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

Inclusion criteria:

- Age 18-25 years
- being diagnosed with type 1 diabetes
- - being able to understand the Dutch language
- given written informed consent

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 30-05-2018

Enrollment: 138

Type:

Actual

Ethics review

Approved WMO

Date:

09-05-2018

Application type:

First submission

Review commission:

METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:

15-05-2019

Application type:

Amendment

Review commission:

METC Universitair Medisch Centrum Groningen (Groningen)

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

NL65805.042.18