Exploring diabetes numeracy and health literacy across Europe - EDUCATE study

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For this study, we will: - Quantify health literacy and numeracy in people with type 1 or type 2 diabetes on intensive insulin therapy (Multiple daily injections of insulin (MDI), or continuous subcutaneous insulin infusion (CSII)) - Examine the...

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

Summary

ID

NL-OMON57080

Source
ToetsingOnline

Brief title
EDUCATE study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: De EDUCATE-study is een aanvulling op een lopend onderzoeksproject getiteld Mobile Artificial Intelligence Solution for Diabetes Adapted Care - MELISSA trial. De EDUCATE-studie is echter gerelateerd aan;maar staat los van de MELISSA-studie. Als zodanig zal aanvullende financiering worden gezocht via

subsidiemogelijkheden om de studie uit te voeren die in dit klinische onderzoeksplan wordt beschreven. Het MELISSA-project;waar deze studie deel van uitmaakt;wordt gefinancierd door het Horizon Europe kaderprogramma voor onderzoek en innovatie van de Europese Unie. Het hele project ontvangt 5;9 miljoen euro gedurende de projectperiode van vier jaar (2022-2026). Daarnaast worden de Zwitserse geassocieerde partners;Debiotech;en de Universiteit van Bern gefinancierd door de Zwitserse overheid met een bijdrage van EUR 1;8 miljoen. De klinische sites die deelnemen aan het onderzoek worden gefinancierd en gebudgetteerd in overeenstemming met de bepalingen in de consortiumsubsidieovereenkomst die door alle partners in het MELISSA-project is ondertekend.

Intervention

Keyword: Cross-sectional study, Diabetes mellitus, Health literacy

Outcome measures

Primary outcome

The main study parameter is health literacy assessed using the health literacy questionnaire (HLQ).

Secondary outcome

Secondary endpoints are numeracy skills assessed by the short version of the diabetes numeracy test (DNT-15), individuals* readiness for usage of digital health services or technology assessed by the Readiness and enablement index for Health technology (RAEADHY), healthy behaviour (dietary pattern assessed through the goFOODTMLite system and Maastricht Food Frequency Questionnaire, and physical activity assessed with the ac-tivPal4TM), and patient reported outcomes (e.g., diabetes treatment satisfaction questionnaire, problem areas in diabetes distress, etc.). Glycaemic outcomes are assessed as haemoglobin A1c and blinded FreeStyle Libre 3 continuous glucose monitoring (CGM) according to inter-national consensus for CGM outcomes for outpatients.

Study description

Background summary

Despite recent advances in diabetes therapy and the availability of innovative diabetes tools, achieving optimal glycaemic remains an ongoing challenge for the majority of people with diabetes, particularly those requiring insulin treatment. Given the complexity of such treatment, the role of health literacy has gained attention as a crucial factor in optimizing diabetes care. Essential skills for diabetes self-management include estimating the carbohydrate content of a meal and adjusting insulin doses. The efforts needed for such self-care are considered complex, time demanding and therefore error-prone. Sparse information exists regarding health literacy skills within the general European diabetes population.

Study objective

For this study, we will:
- Quantify health literacy and numeracy in people with type 1 or type 2 diabetes on intensive insulin therapy (Multiple daily injections of insulin (MDI), or continuous subcutaneous insulin infusion (CSII))
- Examine the relationship between health literacy and numeracy with glycaemic control, health behaviours and patient-reported outcomes.

Study design

This multicentre cross-sectional study will recruit 209 people with type 1 or type 2 on insulin therapy in four outpatient clinics across Europe. Health literacy and numeracy will be assessed with the Health Literacy Questionnaire and the short version of the Diabetes Numeracy Test. Glycaemic control will be assessed through a blinded CGM and standard routine HbA1c measurements. Participants will wear an activPAL4TM to monitor physical activity, and record their dietary pattern using the goFOODTMLite for fourteen consecutive days. Quality of life, diabetes distress, diabetes treatment satisfaction and awareness of hypoglycaemia are also assessed. Multiple linear regression models will be applied to identify factors that are independently associated with health literacy.

Study burden and risks

The study participants will not benefit directly from participating in this cross-sectional study; however, they can gain valuable insights into their numeracy and health literacy skills. Over-all, the risks and burdens associated with this trial can be considered negligible and the burden can be considered minimal. Potentially, some participants may experience skin irritations,

itchiness, or discomfort due to the adhesives of the FreeStyle Libre 3 CGM which are typically self-limiting and short in duration, and with no long-term sequelae.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

To be eligible to participate in this study, a participant must meet all of the following criteria:
- Time from diagnosis of type 1 (inclusief LADA) or 2 diabetes mellitus >=1 year
- Age between 18 to 80 years including both age limits
- On intensive insulin treatment >= 1 year
- Willing and able to use the goFOODTMLite, activPAL4TM and the blinded CGM, and to complete all questionnaires.

- Ability to provide informed consent

Exclusion criteria

- Inability to understand the local language of the country where the study is conducted (at the investigator*s discretion).
- Other subtypes of diabetes than type 1 or type 2 diabetes (e.g., gestational diabetes, MODY)
- Severe cognitive, hearing or visual impairment preventing participants in completing the questionnaires and/or using the trial devices at the investigator*s discretion
- Known hypersensitivity to the CGM sensor band-aid
- Current or recent participation (within the last three months) in clinical trials/research projects (at the investigator*s discretion)
- Unstable cardiovascular disease (major adverse cardiovascular event in the last 6 months), active malignancy (chemotherapy or palliation therapy in the last 6 months), kidney failure (eGFR < 30 mL/min/1.73 m2), and/or dialysis at the investigator*s discretion.
- Severe medical or psychological conditions preventing participants from completing the questionnaires and/or using the trial devices (at the investigator's discretion)
- Current pregnancy or breastfeeding or planning on pregnancy for the duration of the trial

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2024
Enrollment:	53
Type:	Anticipated

Ethics review

Approved WMO Date:	05-11-2024
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL86402.068.24