Effectiveness of Continuous Glucose Monitoring versus Stepped Care with HypoAware, a Web-Based PsychoEducational Intervention, and adding CGM as needed, in Adult Type 1 Diabetes with Impaired Hypoglycemia Awareness: ECSPECT-HYPO trial

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The objective of the study is to evaluate the (cost-)effectiveness of a stepped-care approach starting with HypoAware, compared with CGM in type 1 diabetes patients with an impaired awareness of hypoglycemia.

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

Summary

ID

NL-OMON48870

Source
ToetsingOnline

Brief title
ECSPECT-HYPO trial

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes type 1

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw,Zorgverzekeraars Nederland (ZN)

Intervention

Keyword: Continuous glucose monitoring, Diabetes type 1, Impaired awareness of hypoglycemia, Psychoeducation

Outcome measures

Primary outcome

Frequency of (self-reported) severe hypoglycemia.

Secondary outcome

Quality adjusted life years (QALYs) and societal costs consisting of costs of healthcare consumption, informal care and lost productivity; hypoglycemia awareness (Gold score); frequency of mild hypoglycemia; glycosylated hemoglobin (HbA1c); psychological well-being: fear of hypoglycemia (Hypoglycemia Fear Survey (HFS-II)), diabetes-related distress (PAID); and results from the diagnostic glucose sensor and results from patients wearing a continuous glucose monitoring(CGM device/Freestyle Libre/(insulin pump): time spent in the euglycemic range (interstitial glucose >3.9-<10.0 mmol/L), sensor-derived hypoglycaemic events, nocturnal hypoglycemia, area under curve (AUC) <=3.9 mmol/L and glucose variability, calculated as Mean Of Daily Differences (MODD) and Continuous Overall Net Glycemic Action (CONGA).

The information from the CGM/FSL/insulin pump upload will be gathered as

follows: the physician or researcher will ask the participant*s permission to download an upload from the participant*s CGM/FSL/insulin pump account, in order to transfer the relevant information to a coded research database. In the upload the physician or researcher will erase/cover all personal data and replace it with the participant*s code, before it is sent to the coordinating researcher.

The information from the diabetes diaries, that are kept during the blind sensor week, will be recorded in retrospect in the programme used to upload the blind sensor.

Study description

Background summary

Events of severe hypoglycemia (requiring third party assistance) adversely affect quality of life, and lead to significant morbidity and high societal costs in people with type 1 diabetes mellitus. Both the HypoAware approach, a blended (group and online) psycho-educational intervention based on the evidence-based Blood Glucose Awareness Training (BGAT), and continuous glucose monitoring (CGM) help patients get their blood glucose into the target range for more of the day and prevent hypoglycemic event rates in up to 50% of people with impaired awareness of hypoglycemia. We hypothesize that a stepped-care approach starting with HypoAware, and adding CGM as needed, is more effective in reducing the number of severe hypoglycemic events, in comparison with CGM alone in type 1 diabetes patients with an impaired awareness of hypoglycemia. Additionally, we believe the stepped-care approach will be more cost-effective compared to CGM.

Study objective

The objective of the study is to evaluate the (cost-)effectiveness of a stepped-care approach starting with HypoAware, compared with CGM in type 1 diabetes patients with an impaired awareness of hypoglycemia.

Study design

A two-arm, multicenter cluster randomized controlled trial and economic evaluation.

Intervention

Stepped-care approach, initially with structured diabetes education (step 1, HypoAware), progressing to CGM (step 2) if after 6 months hypoglycemia unawareness has not improved or a severe hypoglycemic event occurs.

This will be compared with CGM.

Study burden and risks

Both HypoAware and CGM are already part of regular clinical care, but there is currently no standard or preferred intervention. There are no known risks associated with following the HypoAware course. The only potential risk associated with (RT-)CGM use is the chance of false hypoglycemic alerts. Although this may be unpleasant for patients, the risk of this evolving into a dangerous situation is minimal and therefore an acceptable risk. Furthermore, if such an event has taken place patients will report this to their diabetes nurse or doctor for further inspection.
Patients in both the Stepped Care and CGM group could benefit from both interventions in preventing severe hypoglycemia and improving their hypoglycemia awareness. Therefore, we believe there is minimal risk in this trial.

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

- 18 years or older
- Type 1 diabetes, treated with either continuous subcutaneous insulin infusion (CSII) or multiple daily insulin injections (MDI)
- Impaired awareness of hypoglycemia, as defined by at least one of the following criteria: Gold criteria (i.e., with a Gold score >=4), or one or more severe hypoglycemic events (defined as events requiring external assistance) the past two years

Exclusion criteria

- Renal insufficiency, with glomerular filtration rate (GFR) < 30 mL/min
- History of myocardial infarction in the last 3 months
- Current untreated proliferative diabetic retinopathy
- Current (treatment for) malignancy
- Current severe psychiatric disorders, in the opinion of the investigator
- Current substance abuse or alcohol abuse (men >21 units/week, women >14 units/week)
- Pregnancy or pregnancy wish
- Current use of FreeStyle Libre, acquired < 3 months prior to screening for problems with hypoglycemia*s
- Any hearing or vision impairment that could hinder perception of the glucose display and alarms, or otherwise incapable of using a (RT-)CGM, in the opinion of the investigator
- Poor command of the Dutch language or any (mental) disorder that precluded full understanding of the purpose and instructions of the study
- No accessibility to a computer

- Any known or suspected allergy to trial-related products

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-08-2018
Enrollment:	124
Type:	Actual

Medical products/devices used

Generic name:	Continuous glucose monitor (CGM)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-04-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	16-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29063
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64474.029.18
OMON	NL-OMON29063