Energy expenditure and (assessment of) glucose regulation of participants with diabetes mellitus during and after the Camino
SENSOR-D-4

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study a: Sensewear use 1. Total daily energy expenditure (TEE), basal energy expenditure (BEE) and activity-related energy expenditure (AEE) are influenced by (the presence of DM), the degree of prevalent glucose control as measured by continuous...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20112

Bron
NTR

Verkorte titel
SENSOR-D-4

Aandoening

Diabetes Mellitus

Ondersteuning

Primaire sponsor: Diabetes research center, Isala Zwolle
Overige ondersteuning: Sensor materials will be provide by Dexcom

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Study a
TEE, BEE and AEE and the degree of prevalent and chronic glucose control when analyzing DG6

Study b
Time in hypoglycemia, normo- and in hyperglycemia when analyzing DG6 during exercise (with and without using the buddy function)

Study c
Endpoints
A: Time in hypoglycemia, normo- and in hyperglycemia both when analyzing DG6 separately and when comparing both devices; separate analysis of performance during exercise and during resting state
B: MAD and MARD of registered glucose concentrations, taking the capillary measurements as reference value, again both during exercise and during resting state
C: Parkes Error grids (ISO15197:2013) using the capillary measurements as the reference values, during exercise and during resting state
D: Satisfaction with and usability of the devices, especially during exercise

Toelichting onderzoek

Achtergrond van het onderzoek

Study a Energy measurement (with Sensewear)
Physical activity is an important tool to prevent and treat diabetes mellitus T2.
There is a difference in the energy consumption of people with DM and that of people without DM. What is the effect of blood glucose values on energy consumption?
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Study b Buddy function DG6
The Dexcom continuous Glucose Monitor (CGM) DG6 has the possibility to activate a buddy function so that alarm messages can also be sent to another person, that person can also respond to this alarm. Will users of the DG6 better recognize the (early) signs and signals of a hypoglycaemia by adding a buddy? And whether this will result in less time in hypoglycaemia during walking days with buddy function versus walking days without buddy function This could contribute to a better quality of life and safety.

Study c Continuous glucose registration
In people with diabetes mellitus (DM) and in particular with insulin use, regular monitoring of blood glucose levels is of great importance. Usually a glucose meter is used for this purpose (with test strips and a finger prick).

In recent years, the option for continuous glucose registration has also become available ("Continuous Glucose monitoring" = CGM). This continuous glucose regulation is a major step forward, because glucose is measured in the interstitial fluid at a few minutes intervals and the result is displayed in a display. For the purpose of these measurements, a small "probe" is inserted into the subcutaneous tissue, which can remain in place for up to 14 days and passes on a signal to a display. The amount of information that is made available in this way is large.
Dexcom presented the CGM Dexcom G6 in 2018. A "probe" is also inserted into the subcutaneous tissue for this measurement; the lifespan of this registration instrument is 7 days; a glucose measurement is done every minute. The values are automatically sent to a mobile device. The performance and accuracy of the sensor outside of a clinical environment in rest and under sport conditions will be studied.

Doel van het onderzoek

study a: Sensewear use
1. Total daily energy expenditure (TEE), basal energy expenditure (BEE) and activity-related energy expenditure (AEE) are influenced by (the presence of DM), the degree of prevalent glucose control as measured by continuous glucose measurements, and the degree of chronic glucose control as measured by HbA1c.
2. TEE, BEE and AEE are influenced by the presence of microvascular complications, especially autonomic neuropathy
3. The deviations will fluctuate in intensity with different degrees of actual blood glucose concentrations (as assessed by the readings of the DG6)
Whether all these points can be addressed in the proposed study, remains to be seen. Since it is proposed to only study people with diabetes, there will be no non-diabetic control group.

study b: DG6 use and buddy function
Supporting users of the DG6 to recognize (early) forewarnings and signs of hypoglycemia by adding a buddy might add to a higher received QoL and safety :
1. use of the buddy function of the DG6 will result in more confidence of users during exercise
2. Use of the buddy function of the DG6 will result in less time in hypoglycemia on exercise days with the buddy function vs exercise days without the buddy function

study c: assessment of accuracy, reliability and user-friendliness of DG6
Accuracy and reliability of the both devices will be tested, using the same protocol as in earlier studies, with the request to the participants to control their capillary glucose levels at least seven times daily.

To assess accuracy DG6 in 17 subjects with diabetes during a 6 day hike challenge and for one week after the hike tour in Spain. DG6 is used concomitantly during this whole period. During the same time period, capillary measurements will be performed at least 7 times daily, to be used as the reference values.

To assess the (differences in) time in hypo-, normo- ,and hyperglycemia (expressed in minutes per day and episodes per day), using cut-off point as defined by Bolinder et al (ref 8).

In the Bolinder study, sensor-derived glycemic measures comprised: number and duration of hypoglycemic episodes (sensor glucose <3·9 mmol/L in 24 h, by day [0600–2300 h], and night [2300–0600 h]; <3·1 mmol/L in 24 h, and <2·2 mmol/L in 24 h [<70 mg/dL, <55 mg/dL,

Onderzoeksopzet

September 2019

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

Isala Zwolle
Marion Fokkert

038/4242476

Wetenschappelijk

Isala Zwolle
Marion Fokkert

038/4242476

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Subjects with type 1 or type 2 diabetes mellitus, using insulin either by MDI or by CSII
Being fit enough to participate in the Bas van de Goor Foundation “we hike to change diabetes” challenge in September 2019. and willing to spend a week in resting conditions in the week after the challenge.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Those subjects who participate in the hike challenge but abstain from participating

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2019
Aantal proefpersonen:	17
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	01-08-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7922
Ander register	METC Isala Zwolle : 190605– NL70456.075.19

Resultaten