Diabetyping & lifestyle as a medicine

Gepubliceerd: 07-02-2019 Laatst bijgewerkt: 19-03-2025

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29401

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Type 2 diabetes

Ondersteuning

Primaire sponsor: TNO
Overige ondersteuning: TNO

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcomes of this study are process variables related to the organizational and financial feasibility of implementation within primary care: time of primary caregivers, costs of medication and facilities and benefits for patients by lower health care use on the longer term.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Diabetes Mellitus type 2 (T2D) is an enormous and increasing societal and economic burden. Insulin resistance in muscle and liver tissue and beta-cell failure represent the core pathophysiological defects in T2D. The primary symptom is high plasma glucose and medical treatment focuses on lowering glucose. Theoretically, T2D should be reversible, especially when intervened during the early stages of the disease. However, current treatment of T2D focuses on symptom management and not on reversing metabolic dysregulation. “Diabetyping & Lifestyle as Medicine” (DLAM) is a treatment programme for T2D patients developed by TNO. The treatment programme starts with an extensive “360 degree” diagnosis to map the largest bottlenecks (physical- or mental health, lifestyle, medication, financial situation, social environment) for an individual. The 360-degree diagnosis also includes the “diabetyping”, or subtyping of diabetes type 2. This information is used to generate personalized food and exercise interventions. The “profile wheel”, provides an overview of the results from the 360-degree diagnosis, and can support GPA and patient in getting a snapshot overview of the status of the patient and aid GPA and patient in developing a personalized lifestyle action plan.
Objective: The primary objective is to assess the feasibility of implementation of the DLAM-treatment programme for T2D patients in primary care. The secondary objective is to determine to which extend the DLAM-treatment programme contributes to improved health status in people with T2D diabetes.
Study design: This study will be an exploratory implementation study regarding the feasibility of the DLAM-Treatment programme in primary care. The healthcare partnership Stevenshof (collaboration between healthcare centrum Stevenshof and general practice Zaaijer, Zaaijer en Hensing) in Leiden will act as first fieldlab for implementation. In total 18 T2D patients will participate in this study.
Intervention: The intervention of this study is the DLAM-approach for T2D patients. First a “360 degree” diagnosis is done based on health status and questionnaires to map the largest physical- or mental bottlenecks for an individual. The 360-degree diagnosis also includes the “diabetyping”, or subtyping of diabetes type 2 using an Oral Glucose Tolerance Test (OGTT). Furthermore, the “profile wheel” created based on the results can aid GPA and patient in developing a personalized lifestyle action plan. The advice is recorded in goals on which the patient can work during the four months of this pilot. Regular meetings between healthcare providers and patients will be planned and the progress of the action plan will be discussed. Although most consults and medical tests are part of regular care, these might occur more often and in a different order.
Main study parameters/endpoints: The primary outcomes of this study are process variables related to the feasibility of implementation within primary care. Examples are e.g. the extra time it will take for a primary caregiver to execute the DLAM-program, how much extra time is needed as compared to regular care and the expected benefits of the DLAM- treatment for primary care professionals, patients with T2D, health insurers and other stakeholders. Besides, experiences of care professionals and patients with the DLAM-treatment programme will be assessed. This will result in an overview of conditions for implementation of the DLAM-

treatment in daily practice, the bottlenecks and attention points, advantages and disadvantages and suggestions for improvements.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: We do not foresee any health risks. The subjects will be under supervision of several healthcare providers, including their own general practitioner, during the entire duration of the study.

Doel van het onderzoek

TNO aims to implement the DLAM-treatment programme in a primary care setting. This is considered a crucial step in the realisation of lifestyle as medicine and reversing T2D. This study is a pilot to assess the feasibility of implementation of the DLAM-treatment programme in primary care.

Onderzoeksopzet

Extensive diagnosis at week -2 (as part of screening), at week 0 start of the DLAM-treatment programme.
At week 12 and week 24 the extensive diagnosis will be repeated, and two weeks later results will be discussed with the patient.
In between there will be regular consults with the GP's assistant, dietician and physiotherapist (if applicable).
Also group sessions will be organized for all participants in weeks 8, 16 and 27.

Onderzoeksproduct en/of interventie

The intervention of this study is the DLAM-approach for T2D patients, consisting of an extensive “360 degree” diagnosis, an Oral Glucose Tolerance Test (OGTT) that provides insight in the organ function of an individual with type 2 diabetes, and personalized lifestyle recommendations based on these two.
The personalized lifestyle intervention consists of a dietary pattern and/or recommendations for exercise.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patient is newly diagnosed with T2D
- Patient is about to start Metformin
- Patient is about to start with a second oral drug (like SU-derivates)
- Patient is about to start with an injectable drug (Insulin or GLP-1)

Besides that, the patients should meet the following inclusion criteria:
- Aged between 30-80 years
- Have a BMI between 25-35 kg/m-2
- Willing and able to sign the informed consent form
- Able to fill in the 360-degree questionnaire which is in Dutch
- Able to work with computers (e.g. for filling out questionnaires).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Dialysis patients
- Possible limiting personal circumstances (e.g. unemployed, illness in the family, dept restructuring)
- Patients under treatment of a psychiatrist
- Incapacitated patients
- Patients in a palliative phase

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	11-02-2019
Aantal proefpersonen:	16
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
not applicable

Ethische beoordeling

Positief advies

Datum:	07-02-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45788
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7509
CCMO	NL67846.028.18
OMON	NL-OMON45788

Resultaten

Samenvatting resultaten
not applicable