Diabetying & lifestyle as medicine programme for people with diabetes type II in primary care
* an implementation pilot

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Primary objectiveThe primary objective is to assess the organizational and financial feasibility of implementation of the DLAM-treatment programme for T2D patients in primary care. This includes an observational cost-benefit analysis, informing...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON45788

Source
ToetsingOnline

Brief title
Diabetyping & lifestyle as a medicine

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
sugar; glucose metabolism disorder

Research involving
Human

Sponsors and support

Primary sponsor: TNO

Source(s) of monetary or material Support: TNO;de verzekeraar Zorg & Zekerheid en de KNMP

Intervention

Keyword: diabetes type 2, implementation, lifestyle intervention, primary care

Outcome measures

Primary outcome

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. Relevant questions are:

- How much extra time will it take for a primary care caregiver to execute the DLAM-programme?

- How much extra time and costs are involved as compared to regular care (e.g. time of care professionals, facilities for extra blood analysis)?

- Do the benefits offset the extra time and costs of the DLAM-treatment programme identified by primary care professionals, patients with T2D and health insurers?

Besides, experiences of care professionals and patients will be assessed, including:

- Conditions for implementation of the DLAM-treatment in daily practice

- Bottlenecks and attention points

- Advantages, disadvantages and suggestions for improvements

Secondary outcome

The secondary outcomes are related to (change in) health status of participants which will mainly be evaluated in a qualitative fashion. First, changes in diabetes related markers such as HbA1c, glucose and insulin will be evaluated. Several indices can be derived from an OGGT and can indicate organ-specific effects of a distorted glucose tolerance. With these indices several subtypes of diabetes can be distinguished. Three different indices are used in the stratification of T2D patients:

- Disposition Index (DI): a measure for beta-cell function and insulin production capacity.
- Hepatic fasting (HG) index: a measure for the insulin resistance in the liver.
- Muscle insulin resistance index: a measure for the insulin resistance in the muscles.

Besides that, BMI, weight, hip circumference, waist circumference and medication use will be evaluated. Physical aspects will be assessed during the 360-degree diagnosis at baseline and after the intervention. Examples are subjective health, mood, stress, diabetes related worries and pain.

Study description

Background summary

T2D is usually diagnosed in primary care by the general practitioner (GP) or general practitioner assistant (GPA). When T2D is diagnosed the first advice is to try to change lifestyle for three months mainly by increasing exercise and eating healthier (Nederlandse Diabetes Federatie, 2015). However, primary care professionals do not have the knowledge and time to give sufficient support, and most patients fail. After the first three months, most T2D patients start

with medication which only effects consequences of T2D and not the cause.

A new approach with personalised lifestyle interventions that target metabolic, physical and social aspects, as well as behaviour is necessary. Sustainable lifestyle and behaviour changes are challenging (Venkat Narayan, 2016). This requires a careful and versatile approach in which science, clinical practice and the needs of T2D patients assemble (Van Ommen et al., 2018). *Diabetyping & Lifestyle as Medicine* (DLAM) is a treatment programme for T2D patients that is developed by TNO. Aim of the programme is to reverse and, if possible, cure T2D using lifestyle. The treatment programme consists of a combination of proven-effective interventions in healthcare and the living environment of patients. The 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 consist of an Oral Glucose Tolerance Test (OGTT), based on which it can be determined which organs are insulin resistant and to what extent the pancreas can still produce insulin. This information is used to generate personalized dietary and exercise interventions. TNO used the OGTT, diabetes subtyping and similar lifestyle advices before in the P4 Hillegom pilot. The research protocol was approved by the METC Brabant (NL48742.028.14).

The *profile wheel* developed by TNO can support GPA and patient in getting a good overview of the patient and where most room for improvement is based on the results from the complete 360-degree diagnosis, and can aid GPA and patient in developing a personalized lifestyle action plan. The *profile wheel* is an interactive, visual representation of the core components which are; body (e.g. glucose, cholesterol, blood pressure and weight), Think & feel (e.g. experienced health, stress, problems with T2D), behaviour (mainly lifestyle) and environment (financial-, relational-, or housing problems). The advice is recorded in goals on which the patient can work.

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.

After a successful first pilot in 2018/2019, an effectivity study will be executed in 2020. Aim is to prove the added value of the treatment programme as compared to regular care. On the longer term, the aim is to implement the DLAM-treatment programme on a larger scale, with the ultimate goal to change the T2D treatment from care to cure.

Study objective

Primary objective

The primary objective is to assess the organizational and financial feasibility of implementation of the DLAM-treatment programme for T2D patients in primary care. This includes an observational cost-benefit analysis, informing primary care healthcare providers, and assessing experiences and identifying bottlenecks from both care giver and patient perspective.
As a part of this, we will determine:
1. the organizational and financial possibilities for integrating the DAM-treatment programme in primary care.
2. how costs and benefits change for health insurers, healthcare providers in primary care and diabetes patients as a result of the DLAM-treatment programme.

Secondary objectives:
The secondary objective is to determine to which extend the DLAM-treatment programme contributes to improved health status in people with T2D diabetes, based on improvements in OGTT response profiles, body weight and use of medication which will be assessed descriptively.

Study design

This study will be designed as an exploratory implementation study regarding the feasibility of the DLAM-Treatment programme in primary care. The healthcare partnership Stevenshof (collaboration between healthcare center Stevenshof and general practice Zaaijer, Zaaijer en Hensing) in Leiden will act as first fieldlab for implementation.
The study has two phases, as the initial high time investment from the involved GPA*s limits the number of participants that can start at once. Besides that, a two-phase approach allows for elimination of possible start-up issues in the treatment programme and implementation thereof during the first phase.
T2D patients at healthcare partnership Stevenshof that are on the verge of a change in their treatment will be asked to participate in this study by their GPA.
Based on the 360-degree diagnosis (questionnaires, health data, OGTT) and a consult with the GPA in which the profile wheel is used, these participants will receive personalised lifestyle advise. During this study (six months), the participants will have regular consults with their GPA, dietitian and optionally physiotherapist. Besides that, group consults will be organised for all participants. The GPA, dietitian, GP and pharmacist will be present during these group consults. After 3 and 6 months the 360 diagnosis and OGTT will be repeated.

Study design cost-benefit analysis
We have chosen an observational study design through process evaluation and estimates. For the process evaluation we analyse monitor-data and information from observations and semi-structured interviews with professionals, patients and the purchasers of the main health insurer in the region. The estimations will be based on existing evidence on elements (Chen et al, 2015), effectivity (Israel, 2018) and the costs and benefits (Business Case, TNO: Zeist, 2017) of

the DLAM-treatment programme. We have chosen this design because of the limited number of participants, making a quantitative cost-effectiveness analysis impossible. The proposed design is in line with the usual methods for economic evaluation of health and social care programmes, as has been worked out in various manuals (for instance Drummond et.al, 2005; Larsen & De Boer, 2011).
In this study the following seven steps are followed:
1. Problem analysis: outline of the problems or bottlenecks for which the intervention is being deployed; in this case health and lifestyle problems owing to T2D.
2. Definition situation intervention: an interpretation of design, purpose and effectiveness of the DLAM-treatment programme based on the results of previous or adjacent research findings.
3. Definition zero alternative: In this step a description is made of the most likely situation if the DLAM-treatment programme is not applied. It is a description of costs and benefits in euros of regular care for diabetes patients based on Dutch health standards (NHG standaard diabetes; NDF Standard of Care Diabetes) and available data of diabetes care within Stevenshof.
4. Determine time horizon: In this step we analyse within which time (years) effects can be realized. For the DLAM-treatment programme, costs must first be incurred before any benefits arise. In addition, there will be benefits in the longer term because the patients* lifestyle is expected to change. The chosen time horizon is crucial: if it is too near, important benefits are not included in the analysis. If the time horizon is far away, the benefits become more uncertain.
5. Determine costs: We collect information about the costs of the DLAM-treatment programme from primary health care professionals within Stevenshof and the provider of the OGTT. These costs will relate to time spent by professionals and analysts, medication used, and facilities needed. We compare an overview of the costs of the DLAM-treatment programme witch the costs of the zero alternative.
6. Determine benefits: a draft of possible benefits of the DLAM-treatment programme in euros is compiled with the available business case of TNO. Then we test these possible benefits against Stevenhof*s practice setting based on available monitoring data and interviews witch professionals and patients. We compare an overview of the benefits of the DLAM-treatment programme with that of the zero alternative.
7. Overview of costs and benefits: The costs and benefits of the DLAM-treatment programme are brought together in an overview. A distinction is made between the return of investment for the parties involved: the patients, the healthcare providers and the health insurers. If necessary, we conduct sensitivity analysis to clarify the consequences of certain assumptions by working out bandwiths of costs and benefits of the DLAM-treatment programme.

Intervention

The intervention of this study is the DLAM-approach for T2D patients. First the *360 degree* diagnosis is performed based on health markers and questionnaires

to map the largest physical and/or mental bottlenecks for an individual. The 360-degree diagnosis also includes the *diabetyping*, or subtyping of diabetes type 2. This consist of an Oral Glucose Tolerance Test (OGTT) that provides insight in the organ function of an individual with type 2 diabetes. Based on the OGTT six T2D subtypes can be distinguished (see figure below). Furthermore, the *profile wheel* that provides an overview of the 360-degrees diagnosis results can aid GPA and patient in developing a personalized lifestyle action plan. Which dietary intervention is recommended to a T2D patient is personalized based on their diabetes subtype. The possible dietary interventions include a Mediterranean diet, a low carbohydrate diet, a low calorie diet or intermittent fasting. All four dietary pattern plans have been developed in close collaboration with the dietician at Stevenshof. The dietician will support and coach all patients in adhering to their selected dietary pattern.
Based on their diabetes subtype patients may also be recommended to increase their physical activity. If this is the case, a physiotherapist will provide the patient with a fitting exercise plan, based on their condition and capabilities.
Using the *profile wheel* tool, the advice is further concretized and recorded in goals on which the patient can work during the four months of this pilot. Regular meetings between the relevant healthcare providers and the patients will be planned and progress of the action plan will be discussed. Although most of the consults and medical tests are part of regular care, these might occur more often and in a different order.

Study burden and risks

The risks associated with participation can be considered negligible and the burden can be considered minimal. There are no expected risks related to the extra consults. All medical actions, including blood collection, will only be performed by primary care professionals. There are no expected risks (nor benefits) related to consuming the standardized glucose solution. A potential risk is nausea after consumption of the glucose solution, bruises from the blood withdrawal, and a small risk for hypo due to insulin overshoot in response to the glucose solution. This latter risk is limited and can be sufficiently dealt with by the presence of health care professionals during the OGTT. They will monitor the participants sufficiently to enable a safe execution of the OGTT. Participants will be asked how they feel and their behaviour will be monitored (sweating, alertness).
Other potential risks are concern amongst participants due to increased insight in their health status from the 360-degree diagnosis. However, the results from the 360-degree diagnosis will be explained by the GPA, which can also comfort the patients.
Besides the risks accompanied with regular diabetes care, blood collection and performing an OGTT, no other risks or negative side effects are known or expected for the study tools.
With respect to treatment the participating GPs remain medical responsible of

their own participating patients.

Benefits include that participants can get more insight in their individual health status and their behaviour. Additionally, participants are provided with more personalized lifestyle advice and professional support in adhering to this advice; this can help patients improve their health status and potentially reverse their T2D.

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

The participants will be recruited from the T2D patient population of healthcare partnership Stevenshof. Four GPA*s work for healthcare partnership Stevenshof. Each GPA will select two T2D patients in each of the two study phases. These patients should meet one of the

following requirements:
- 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
- Have a BMI between 25-35
- 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 in digital questionnaires)

Exclusion criteria

A candidate who meets any of the following criteria will be excluded from participation in this study:
- 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

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	16
Type:	Anticipated

Ethics review

Approved WMO Date:	08-01-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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: 29401
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL67846.028.18
OMON	NL-OMON29401

Study results

Summary results
Trial never started