Remission of type 2 diabetes in shift workers through a personalized lifestyle intervention.

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

Summary

ID

NL-OMON48433

Source
ToetsingOnline

Brief title
Remission of T2D among shift workers.

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: ZonMw.

Intervention

Keyword: Diabetes Type 2, Implementation, Lifestyle Intervention, Shift work

Outcome measures

Primary outcome

The first aim of this study is the feasibility of implementation of the DOP-lifestyle program within occupational healthcare services. Regarding this goal, mainly qualitative outcome measures will be used. These outcome measures will be obtained from evaluations of several topics from the DOP-lifestyle program (profile wheel, lifestyle advice, group consults, et cetera) by professionals and participants.

Secondary outcome

The secondary goal of this study is to get a sense of the effect of the program on physical and mental health of participants. Before- and after results from the 360-degree diagnosis questionnaires, clinical markers and indices will be evaluated. These will be summarized using descriptive statistics and these outcome measures will be shared in a report and scientific paper.

Study description

Background summary

BACKGROUND
In the Netherlands, 1.2 million people are diagnosed with diabetes (5.0% of the Dutch population). This number increases by 1200 every week. Type 2 diabetes (T2D) is by far (90%) the most prevalent type. Of the total workforce, 2.0% has diabetes.

Diabetes has profound consequences for society and patients. On societal level healthcare costs are rising while patients cope with diabetes-related

consequences such as cardiovascular problems, eye, kidney and nerve diseases but also depression. Additionally, workers with diabetes are at higher risk for sickness absence and reduced productivity.

In addition to an unhealthy lifestyle shift work increases the risk of (the onset) of T2D. This could be explained by three mechanisms:
1. Rotating shifts, including evening and night shift, disturbs the circadian rhythm which influences the metabolic system;
2. Sleep deprivation (also an effect of rotating shifts) negatively affects glucose response;
3. Shiftwork is related to an unhealthy lifestyle, e.g. unhealthy eating, lack of exercise, stress. About 14% of the Dutch workforce is engaged in shift work and this percentage is increasing rapidly.

Despite the risks of shift work very few general lifestyle interventions and no personalized lifestyle interventions have been tailored to shift workers or this type of work setting.

LIFESTYLE INTERVENTIONS
Over the past 20 years, a large number of the developed T2D interventions focused on lifestyle instead of pharmacotherapy, targeting the metabolic dysregulation rather than the symptoms. Already in 2002, the Diabetes Prevention Program demonstrated that both medication (metformin) and healthy lifestyle effectively reduced T2D biomarkers. However, lifestyle changes proved to be more efficient compared to medication.
TNO developed a personalized intervention program, including the subtyping of T2D, which aims to reverse and, if possible, cure T2D using lifestyle. The treatment program consists of a combination of proven-effective interventions in healthcare and the living environment of patients. The program 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 T2D. This consists 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 advice before in the P4 Hillegom pilot. The research protocol was approved by the METC Brabant (NL48742.028.14).

Results of the 360-degree diagnosis will be presented in a so-called *profile wheel*. This wheel aims to support the occupational physician and the patient in getting a good overview of the patient regarding his or her lifestyle. 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), behavior (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 this treatment program in an occupational health setting. This is considered a crucial step in treatment of T2D among shift workers. This study is a pilot to assess the feasibility of implementation of the program in occupational healthcare services.

Study objective

The primary objective is to addapt the lifestyle program to shift workers, taking their specific preferences, their response to behavioral change techniques and work demands into account. The feasibility of implementation in occupational healthcare services will also be assessed. This includes the assessment of user-experiences (both caregivers and shift workers with T2D) and the identification of bottlenecks.

The secondary objective is to determine to which extend the lifestyle program contributes to improved health status in shift workers with T2D, based on improvements in OGTT response profiles, body weight and use of medication.

Study design

This study will be designed as an exploratory implementation study regarding the feasibility of the lifestyle program in an occupational healthcare services setting. The work context at Tata Steel in IJmuiden will act as the first field lab for implementation. The study has two phases, this allows for the elimination of possible start-up issues in the lifestyle program and implementation thereof during the first phase. In this first phase, the lifestyle program will be modified to suit the specific work settings at Tata Steel and its shift workers with T2D. This phase will result in a small-scale pilot including six participating shift workers with T2D who will test the lifestyle program. Participants will be recruited by the occupational health physician.

Based on the 360-degree diagnosis (questionnaires, health data, OGTT) and a consult with the occupational health physician in which the profile wheel is discussed, the participants will receive personalized lifestyle advice. During the 13-week intervention period, participants will be adviced and supported by their occupational health physician, a dietician and, depending on the T2D subtype, a physiotherapist. Together with these healthcare providers, the participant turns the advice into an action plan including goals. After 13 weeks, results of a second OGTT and the questionnaires will reveal insight into the progression.

Intervention

The intervention lasts a total of 13 weeks and consists of 2 parts 1) 360-degree diagnosis, and 2) personalized lifestyle interventions.
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 subtyping of diabetes type 2. This consist of an Oral Glucose Tolerance Test (OGTT) that provides insight into the organ function of an individual with type 2 diabetes. Based on the OGTT six T2D subtypes can be distinguished.

Furthermore, results of the 360-degree diagnosis are displayed in a "profile wheel". This profile wheel supports the occupational health physician and the participant 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. In close cooperation with the involved dietician, these four dietary patterns will be adjusted to the specific work context (physical demands and working in shifts) at Tata Steel. The dietician will support and coach all participants in adhering to their selected dietary pattern.

Based on their diabetes subtype participants may also be recommended to increase their physical activity. The possible training programs include strength training, endurance training or a combination of these two. A physiotherapist will provide the participant with a fitting exercise plan, based on their condition and capabilities. The physiotherapist will support and coach the participant in compliance with the training program.

Using the profile wheel, the advice is further concretized and recorded in goals on which the participant can work during the pilot phase.

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 consults. All medical activities, including blood sampling, will only be performed by professionals. There are no expected risks (nor benefits) related to consuming the standardized glucose solution. A potential risk is a nausea after consumption of the glucose solution. Benefits include that participants can get more insight into their individual health status and their behavior. Additionally, participants are provided with more personalized lifestyle advice and professional support in adhering to this advice; this can help participants 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

In order to be eligible to participate in this study, a participant must meet all of the following criteria:
* The participant has diagnosed type 2 diabetes;
* The participant has a BMI between 25-35 kg/m2;
* The participant is able and willing to fill out the informed consent form;
* The participant masters the Dutch language sufficiently to fill in digital questionnaires;
* The participant has digital (computer) skills enabling him to complete the questionnaires.

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:
* Dialysis patient;
* Possible limiting personal circumstances (e.g. illness in the family, financial problems, etc.);
* Under treatment of a psychiatrist;
* No insulin resistance and no low- or moderate beta-cell function based on glucose and insulin response following an Oral Glucose Tolerance Test;
* Use of insulin;
* Planned or recent surgery.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2019
Enrollment:	22
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-11-2019
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

No registrations found.

In other registers

Register	ID
CCMO	NL70758.028.19