Promoting a healthy lifestyle among low educated shift workers with T2D: a personalized physiological and behavioral approach

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27741

Source
Nationaal Trial Register

Brief title
DOP

Health condition

Type 2 diabetes

Sponsors and support

Primary sponsor: ZonMw
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Feasability of the intervention operationalized by the RE-AIM framework including items on

Reach, Effectiveness, Adoption, Implementation, Maintenance

Secondary outcome

HbA1C, FPG, BMI

Study description

Background summary

In 2017, 1.2 million people in the Netherlands have diabetes, in about 90% of the cases type 2. This number increases by 1200 every week. Among the working population data indicates that about 2% has diabetes. This prevalence differs by socioeconomic position (SEP). In 2015 an estimated 2,6% of low SEP workers had diabetes compared to 1,4% of the intermediate and high educated workers combined. Diabetes is associated with cardiovascular, eye, kidney and nerve diseases as well as depression which leads to higher sickness absence and reduced productivity. All in all diabetes does not only cause human suffering but also has profound financial consequences for individuals, companies and society. The latter could ultimately lead to increasing socioeconomic health inequalities.
An important factor increasing the risk of the onset of type 2 diabetes (T2D) is shiftwork on which low SEP workers often depend given the financial compensation. Through a disturbed circadian rhythm and sleep deprivation the metabolic system is dysregulated as is the glucose response. Shiftwork is also related to an unhealthy lifestyle. By 2016, 14% of the Dutch workforce is engaged in shiftwork and this percentage is on the rise. Given these numbers, there is a high need for effective (preventive) T2D interventions.
Over the past 20 years, T2D interventions focused on lifestyle instead of pharmacotherapy, targeting the metabolic dysregulation instead of the symptoms. Already in 2002, positive effects of lifestyle interventions were found. Not all participants benefit equally from the current ‘one-size-fits all’ interventions. Recent insights showed various T2D subtypes based on specific organ dysfunction. Lifestyle interventions tailoring these subtypes could increase the effectiveness for all participants. In a previous study called P4@Hillegom such a personalized lifestyle intervention was developed and offered by health care professionals. Based on the Oral Glucose Tolerance Test individuals were divided into one of six subtypes. Additionally, individuals were appointed to a 13 week personalized lifestyle intervention, that matched their subtype, focusing on either nutritional advice, an exercise program or a combination. Preliminary results of 60 participants showed strong significant improvements (10%) in fasting plasma glucose level over time, an indication of glucose efficiency regulation of the body.
Despite the high prevalence of T2D in low SEP workers and the negative influence of shiftwork, T2D lifestyle interventions targeting low SEP (shift)workers are lacking. Therefore we aim to adapt the P4@Hillegom approach to this specific population. The content of the lifestyle intervention (the diet and the exercise program) will be adapted to work demands and working condition of the target group. Behavioral Change Techniques used will be adjusted to fit low SEP workers. The intervention will be developed in close collaboration with

Tata Steel and Zorg van de Zaak (ZvdZ), and the target group.

Study objective

By adapting the intervention to the workplace of shiftworkers with type 2 diabetes, we expect more people to benefit from the approach and for diabetes-related outcomes and quality of life to improve.

Study design

To gain insight in the effectiveness of the intervention, participants will complete a questionnaire and an assessment of various biomarkers based on the OGTT before and after the 13-week intervention period. The questionnaire will assess health behavior, general health, mental well-being and individual characteristics at baseline and at 13 weeks follow-up.

To get insight into the reach, adoption, implementation and maintenance elements of the framework, interviews and focus groups will be organized. To assess the extent to which the intervention was implemented and carried out as designed, telephone semi-structured interviews will be conducted with the company doctor, physiotherapist and dietician at the end of both the first pilot (T1) and the second pilot (T2). In addition, telephone semi-structured interviews will be conducted with six participants from the first pilot (T1) and six participants from the second pilot (T2). The purpose of the interviews is to gain insight in factors that may facilitate or hinder a successful implementation. During the interviews, notes are taken which will be reflected into a report afterwards. These reports provide input for the implementation or adaptions to the protocol. A total of 18 interviews will be conducted.

Qualitative data on adoption and maintenance are collected in two focus group meetings. In a meeting with company doctors, facilitators and barriers with regard to adoption in the existing care services will be identified. The goal is to eventually make the intervention part of regular services. Therefore, in the same meeting, the conditions for sustainable maintenance will also be discussed. The results from the focus group will be described in a report and the protocol will be supplemented with conditions for implementation. This meeting will be organized after the second pilot.

Intervention

The personalized lifestyle program consists of 2 components, 1) a personalized diagnosis and 2) a personalized lifestyle advice.

(1) The personalized diagnosis is based on the Oral Glucose Tolerance Test (OGTT) which is considered an accurate test in determining the cause of T2DM. Based on the test, different indices will be calculated for stratification purposes. First the Disposition index 1 will be calculated, which is a measure for beta-cell function. This index will be used to stratify participants into the moderate- or low beta-cell function subgroups. Then, the hepatic fasting (HF) index and the muscle insuline resistance index will be calculated within both subgroups.

Based on these indices, the two subgroups are distinguished into the following causes of T2DM : 1. have no organ insulin resistance, 2. liver insulin resistance, 3. muscle insulin resistance, and 4. liver and muscle insulin resistance. This subtyping procedure ultimately results in eight subgroups.

(2) Personalized lifestyle advice. Based on their subtypes participants will receive a personalized lifestyle program which includes a dietary intervention, see table 1. Dietary interventions include a Mediterranean diet, a (very) low caloric diet or a low carbohydrate diet. A Mediterranean diet is rich in vegetables, fruits, unsaturated fat and fibers, and increases insulin sensitivity of muscles. A low caloric diet can help to increase the insulin sensitivity of the liver and improves insulin production. Limiting sugar and starchy foods (low carbohydrate diet) can help reduce fluctuations and increase insulin sensitivity in muscles. During the 13-weeks course of the intervention participants visit their dietician 6 times. Participants also received an advice on physical activity. Again, this advice depended on the T2DM subtype (Table 1). Possible exercise programs included strength training, endurance training or a combination of both. A physiotherapist guided the participants during the course of the intervention. The participant visited the physiotherapist three times a week.

Contacts

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Eligibility criteria

Inclusion criteria

1) diagnosed with T2DM by a physician; 2) a BMI between 25 and 35 kg/m2; 3) sufficient mastery of the Dutch language; 4) digital skills to fill out two online questionnaires; 5) signed a written informed consent.

Exclusion criteria

Individuals using insulin medication will be excluded because of possible disbalances in insulin levels and negative side-effects. Also, dialysis patients, individuals with planned or recent surgery, psychiatric problems, or people with possible limiting personal circumstances (e.g. illness in the family) will be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2020
Enrollment:	22
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	23-03-2021
Application type:	First submission

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
NTR-new	NL9373
Other	METC Brabant : P1943

Study results