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

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The intervention will - after succesfull implementation and adoption - lead to a reduction in BMI and body fat and improvements in biomarkers.

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

Samenvatting

ID

NL-OMON28031

Bron
Nationaal Trial Register

Verkorte titel
P4@Work: a lifestlye intervention for workers with Diabetes Mellitus Type 2

Aandoening

Diabetes Mellitus Type 2

Ondersteuning

Primaire sponsor: ZonMw
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- reach and compliance to the intervention
- implementation of the intervention

Toelichting onderzoek

Achtergrond van het onderzoek

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. The focus of this project will be on studying the feasibility of the study.

Doel van het onderzoek

The intervention will - after succesfull implementation and adoption - lead to a reduction in BMI and body fat and improvements in biomarkers.

Onderzoeksopzet

baseline, three months

Onderzoeksproduct en/of interventie

The P4@Work intervention consists of different steps over a period of 13 weeks. Like in the original P4 approach, all participants will start with the 5-point OGTT after their intake by their company doctor. At home participants fill in the digital questionnaires to complete their personalized diagnosis. Based on their subtyping, they receive dietary counseling and/or physical training under supervision of a physiotherapist.The participant visits the company doctor every four weeks for general counseling. The intervention contains 7 consults with a dietician (in week 1, 2, 3 6, 10, 13 and after the program-end in week 15). Physical training under supervision of a physiotherapist is scheduled every week. After the intervention the 5-point OGTT and subtyping is repeated, as well as filling out the digital questionnaires at home.

Contactpersonen

Publiek

TNO
Heleen de Kraker

06-52779105

Wetenschappelijk

TNO

Heleen de Kraker

06-52779105

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) Individuals using insulin medication;
2) dialysis patients;
3) Individuals with planned or recent surgery, psychiatric problems
4) people with possible limiting personal circumstances

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 gestopt

(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	16
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	17-05-2021
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	NL9466
Ander register	Medical Research Ethical Committee Brabant (MREC) : P1943

Resultaten