The impact of the P4 approach, preventive, predictive, personalized and participatory, in prediabetic and newly diagnosed type 2 diabetics in Hillegom.

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

Summary

ID

NL-OMON42117

Source
ToetsingOnline

Brief title
P4 approach in diabetes type 2 and prediabetics.

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Diabetic complications

Synonym
Diabetes type 2; glucose disturbed

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: Ministerie van Volksgezondheid;Welzijn en Sport

Intervention

Keyword: Improved diagnosis, personalized treatment, prevention, Type 2 diabetics

Outcome measures

Primary outcome

A diversity of parameters related to glucose metabolism will be measured before and after the three month intervention period. Primary study parameters will be HbA1c, fasting plasma glucose (FPG), 2h glucose after oral glucose tolerance test (OGTT).

Secondary outcome

In addition, diabetes medication, quality of life (QoL) and lifestyle questionnaires, lipid profile, blood pressure, body weight (BW), waist circumference (WC), body mass index (BMI), body fat%, and indices for beta cell function, hepatic insulin resistance and muscle insulin resistance during OGTT will be determined as secondary study parameters.
Finally, the number of participants that reach normoglycemia (fasting blood glucose level of less than 6.1 mmol/L) will be determined as derivative of the fasting blood glucose for each subject at the end of the study (wk 13) as well as after two years of follow-up.

Study description

Background summary

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. Prediabetics develop these symptoms. The primary symptom is high plasma glucose and medical treatment focuses on lowering glucose by reducing glucose synthesis or increasing insulin excretion. Remarkably, the real problem (specific organ dysfunction) is hardly addressed except by lifestyle changes restoring the energy balance (*eat less and exercise more*). Increasing evidence of distinct subgroups within the T2D population and prediabetes population exists, which may require tailored treatment approaches instead of a *one-size fits all* treatment. The P4 approach provides an innovative method to predict (P1) which organ failure must be treated, to prevent (P2) further deterioration and stimulate improvement, to personalize (P3) diagnosis and tailor treatment, and to enhance participation (P4) of patients. The complete program resulting from the integration of these four terms is called the *P4 approach*.

Study objective

The main objective is to assess the impact of the P4 approach on established markers of glucose metabolism. Secondary objectives are changes in physical characteristics, questionnaires and the indices for beta cell function, hepatic insulin resistance and muscle insulin resistance as calculated from the OGTT response in the different P4 intervention groups.

Study design

Proof-of -principle exploratory study assessing the impact of the P4 approach in prediabetics and diabetes type 2 patients. The study is an open, non-randomized study.

As control, historical data from the GPs Information System from newly diagnosed diabetes patients and prediabetics in the last five years will be used.

Intervention

Prediabetics and newly diagnosed type 2 diabetics are presented the choice of participating in the P4 program. After investigation of the status of the different organs involved in diabetes, subjects are divided into three subgroups. Each subgroup receives a personalized lifestyle advice. The lifestyle advice may comprise different interventions, varying in severity of the diet ((very) low calorie diet) and type of physical activity (strength training, endurance training) or a combination of both.

Study burden and risks

We do not foresee any health risk. The subjects in the intervention group receive personalized treatment, provided by health care insurances as well. The intervention will be under supervision of their own general practitioner.
The Modifast diet may result in formation of gall stones. The short period (one week) and the regular control by professionals will result in frequent investigation of adverse events. Patients with low beta-cell function will not undergo one week VLCD, but only LCD (less strict).
During the intervention period of three months subjects visit the physiotherapist for their exercise activities (three times per week) and the dietician every 2-4 weeks. The possible occurrence of injuries will be prevented bu the guidance of physiotherapists.
At the beginning of the intervention and after three months an OGTT test will be performed. Physical performance and different anthropometric measures will be determined.

After the intervention period the subjects will return to usual care via the general practitioner. Dietary support will be available via three additional consults with the dietician. In addition, subjects will be given the choice of participating in an exercise program consisting of weekly visits with an exercise coach of the Hillegom community during three months.
After 6, 12 and 24 months follow-up measurements will consist of the above mentioned parameters for glucose metabolism with the exception of the OGTT, in addition to lifestyle questionnaires.
The beneficial effects of the study may be deteriorate when the intervention is stopped and subjects do not comply to the treatment anymore.
The (pre)diabetic study population is chosen because of the increase in prevalence of diabetes type 2. The type of intervention, personalized lifestyle intervention, may be most appropriate in this group of patients.

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

1. Healthy as assessed by the
- health and lifestyle questionnaire, (P9607 F02; in Dutch)
- physical examination
- results of the pre-study laboratory tests
2. Age 30-80 years
3. Stable BMI 25-35 kg/m2
4. Diagnosis diabetes type 2 based upon:
Fasting glucose >6.9 mmol/l on two different days or one measurement of non-fasting glucose >11.0 mmol/l in combination with symptoms of hyperglycemia or preidabetes (fasting glucose between 6.1-6.9 mmol/L)
5. Duration of diabetes maximally 1 year
6. Informed consent signed;
7. Willing to comply with the study procedures during the study;
8. Appropriate veins for blood sampling/ cannula insertion according to the general practitioner assistant (GPA);
9. Voluntary participation
10. Physically able to perform training activities
11. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years.

Exclusion criteria

1. Use of insulin, corticosteroids (systemic), or beta-blockers in past month
2. Diabetes occurring after several attacks of pancreatitis known as pancreatic diabetes
3. Slow onset type 1

4. Use of oral diabetes medication in past year
5. (Having a history of a) medical condition that might significantly affect the study outcome as judged by the medical investigator and health and life style questionnaire. This includes diabetes type 1, gastrointestinal dysfunction, diseases related to inflammation or allergy, or a psychiatric disorder.
6. Hypertension: systolic blood pressure >160 mmHg, diastolic blood pressure >90 mmHg
7. Kidney problems based upon proteinuria and creatinine >150 mmol/l
8. Physical activity higher than according to the Diabetes guidelines(1 hour a day)
9. Alcohol consumption > 21 (women) - 28 (men) units/week
10. Reported unexplained weight loss or gain of > 2 kg in the month prior to the pre-study screening
11. Recent blood donation (<1 month prior to the start of the study)
12. Not willing to give up blood donation during the study
13. Personnel of TNO and their partner
14. Not having a general practitioner
15. Not willing to accept information-transfer concerning participation in the study, or information regarding his health, like laboratory results, findings at anamnesis or physical examination and eventual adverse events to and from his general practitioner.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	14-07-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	11-08-2014
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-09-2014
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	15-04-2015
Application type:	Amendment
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
ClinicalTrials.gov	NCT02196350
CCMO	NL48742.028.14