Beweegkuur +.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20347

Bron
NTR

Aandoening

diabetes mellitus type 2

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center Rotterdam
Overige ondersteuning: -ZonMw
-NISB Nederlands Instituut voor Sport en Beweging

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure evaluates the clinical efficacy of the intervention on the standard diabetes outcome
parameter for glycemic control (HbA1c).

Toelichting onderzoek

Achtergrond van het onderzoek

Because of the high cardiovascular risk profile and functional disabilities of obese long-standing type 2 diabetes patients, therapeutic exercise programs have hardly been evaluated in this subpopulation. The current research proposal aims to investigate the medium and long-term health benefits of a combined supervised
exercise and dietary intervention versus a dietary intervention (=usual care) in obese long-standing type 2 diabetes patients. It is hypothesized that supervised exercise training combined with dietary measures will improve muscle strength cardiorespiratory fitness and body composition. The latter will improve both physical and mental health status, resulting in improved metabolic control through a durable increase in total weekly energy expenditure.

Intervention group:

In addition to the protocolised diabetes care offered at the Diabetes Plein at Erasmus University Medical Centre (usual
care), 40 type 2 diabetes patients randomized for the exercise and dietary intervention will be invited for an intake with a sport and exercise/rehabilitation physician and a physical therapist. Subsequently they will be asked to adhere to 26 weeks of once a week progressive resistant type of exercise, supplemented by short bouts of high intensity interval endurance training. Subjects can choose from 4 possible training locations.

Control group:

The 40 patients randomized to the control group will have 3-monthly motivational interviews with a lifestyle coach/nurse practitioner in addition to the protocolised diabetes care offered at the Diabetes Plein (usual care) or their general practitioner. During these interviews patients will get practical advices on how to increase physical exercise level, based on the results from the baseline physical activity monitoring and personal exercise diaries. Furthermore, they will consult a dietician on a monthly basis during the first 6 months to guide and support patients in an energy intake restriction diet (-600 kcal/day) aimed at a weight reduction of 5-10% over 6 months.

Testing procedures before and 26 and 52 weeks following the start of the exercise intervention:

1. Before final inclusion all patients will undergo a symptom limited cycle ergometry test with

12 lead ECG monitoring. In case silent myocardial ischaemia is suspected [58], patients will be referred to a cardiologist to assess myocardial perfusion with a stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging;

2. Furthermore, at the beginning and 26 and 52 weeks following the exercise intervention, left ventricular diastolic function will be monitored using echocardiography;

3. Fasting blood samples will be obtained to measure HbA1c, plasma glucose, plasma insulin, HDL-C, LDL-C, T-Chol, Triglycerides and FFA, both during fasting conditions;

4. Subjects will be asked to fill out a 3-day dietary record both before as well as 26 and 52 weeks following the start of the training program to estimate energy consumption and meal composition. The latter information will be used to provide the patient with a tailor made online advice on a healthier diet as recommended by the Dutch Diabetes Federation;

5. Accelerometry based activity monitors (Actigraph) will be worn by the patients during 7 days to assess daily energy
expenditure and both In addition and personal exercise diaries, will be used to estimate leisure-time physical activity;

6. Peak whole-body oxygen uptake capacity (VO2peak) and maximal workload capacity (Wmax) will be measured during
an incremental exhaustive exercise test until volitional exhaustion, performed on a cycle ergometer using a ramp
protocol. Gas exchange measurements will be performed continuously. During exercise testing a 12-lead electrocardiogram will be monitored and recorded. Because the exercise test will be executed in a hospital setting with ECG monitoring and direct supervision of a physician, the risk of cardiac ischemia/arritmia is small. If a hypoglycemic event occurs, there will carbohydrate solutions or, in case of loss of consciousness, Glucagon (Glycagen, 1 mg dissolved in 1 ml) are available;

7. Isokinetic strength testing will be used to measure muscle strength and resistance to fatigue of the upper arm and leg muscles;

8. To test improvements in functional capacity a standardized Sit-to-Stand as well as a steep ramp test on a cycle ergometer will be performed;

9. Resting blood pressure will be measured twice during 15 min supine position using an automatic blood pressure measuring device. Simultaneously a continuous heart rate monitor will be used to measure heart rate variability as a
validated measure for autonomic dysregulation;

10. Dual Energy X-ray Absorptiometry (DEXA) will be used to monitor regional changes in body composition (trunk vs legs) and fat percentage;

11. Health related quality of life will be measured using the Short-Form 36 questionnaire health survey.

Levels of depressive symptoms will be measured using the 20-item Centre for Epidemiologic Studies Depression Scale
(CES-D score ≥ 16). To measure diabetes symptom distress, we will use the revised version of the Type 2 Diabetes Symptom Checklist.

Doel van het onderzoek

Because of the high cardiovascular risk profile and functional disabilities of obese long-standing type 2 diabetes patients, therapeutic exercise programs have hardly been evaluated in this subpopulation. The current research proposal aims to investigate the medium and long-term health benefits of a combined supervised
exercise and dietary intervention versus a dietary intervention (=usual care) in obese long-standing type 2 diabetes patients. It is hypothesized that supervised exercise training combined with dietary measures will improve muscle strength cardiorespiratory fitness and body composition. The latter will improve both physical and mental health status, resulting in improved metabolic control through a durable increase in total weekly energy expenditure.

Onderzoeksopzet

Testing procedures will take placebefore and 26 and 52 weeks following the start of the exercise intervention.

Onderzoeksproduct en/of interventie

In case of an abnormal stress-ECG during a symptom-limited exercise test, more extensive cardiovascular screening (stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging) left ventricular diastolic function using echocardiography will take place by a cardiologist. Patients will be randomized to follow either a 26 weeks combined supervised exercise and dietary intervention program or to take part in a dietary intervention program aimed at decreasing daily energy intake with 600 kcal/day. Before and after 26 and 52 weeks, blood samples (HbA1c, plasma glucose, plasma insulin, HDL-C, LDL-C, TChol, Triglycerides and FFA, both during fasting conditions) and questionnaires will be collected to assess changes in glycemic control, lipid profile, health-related quality of life (Short-Form 36 questionnaire health survey), diabetes burden (revised version of the Type 2 Diabetes Symptom Checklist) and depression scores (20-item Centre for Epidemiologic Studies Depression Scale), respectively. Accelerometry based activity monitors (Actigraph) and personal exercise diaries, will be used to assess changes in daily physical activity levels. Changes in regional body composition, functional capacity, muscle strength and cardiorespiratory fitness will be assessed using respectively DEXA-scan and skinfold measurements, functional tests (Sit-to-Stand, 6 minute walking test), isokinetic testing and cycle-ergometry protocol.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Type 2 diabetes > 5 years;

2. Signs of 3 or more diabetes¨Crelated co-morbidities (history of sensori-motor or autonomic neuropathy,retinopathy (gr II or higher), micro-albuminuria, coronary artery disease, transient ischaemic attack, intermittent claudication/peripheral artery disease);

3. HbA1c: 7.0- 10.0%;

4. Age: 45-75 yrs;

5. BMI > 27kg/m2;

6. Sedentary behaviour (i.e. <30 min/day moderately active assessed by activity monitoring);

7. Agreement to volunteer for the study by giving a written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Cardio-vascular disease, recent (< 3 m) decompensatio cordis, recent (3 m) unstabile angina pectoris, recent
(< 3 m) myocardial infarction, significant cardiac ischaemia during SPECT myocardial perfusion imaging, heartfailure (EF<40% or NYHA class 3 or 4);

2. Severe orthopaedic impairments that would prohibit participation in the training program (eg diabetes ulcers of the foot, amputations);

3. Cerebro-vascular disease (CVA) or other neurological diseases or deficits that would prohibit participation in
the training program (eg spasticity).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	10-08-2010
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-08-2010
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	NL2357
NTR-old	NTR2464
Ander register	METC Erasmus MC : MEC-2010-154
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A