# Enhancing the medium and long-term benefits of a structured rehabilitation (Beweegkuur+) program in long-standing type 2 diabetes patients with multiple disabling co-morbidities.

Published: 03-08-2010
Last updated: 04-05-2024

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...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Glucose metabolism disorders (incl diabetes mellitus) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON38219

**Source**
ToetsingOnline

**Brief title**
Beweegkuur+

### Condition

- Glucose metabolism disorders (incl diabetes mellitus)

**Synonym**
adult onset diabetes, Diabetes type 2

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** ZonMw;NISB Nederlands Instituut voor Sport en Beweging

## Intervention

**Keyword:** Co-morbidity, Diet, Exercise, Type 2 diabetes

## Outcome measures

### Primary outcome

The primary outcome measure evaluates the clinical efficacy of the intervention

on the standard diabetes outcome parameter for glycemic control (HbA1c)

### Secondary outcome

The secondary diabetes related outcome measures evaluate the overall effect on

health:

-risk profile for cardiovascular disease (lipid profile, blood pressure)

-body composition (BMI, waist circumference, regional fat distribution)

-cardiorespiratory fitness (VO2peak)

-functional capacity and muscle strength

-health-related quality of life (SF-36)

-level of depressive symptoms using the Centre for Epidemiologic Studies

Depression Scale (CES-D)

-Diabetes symptom distress (using the revised version of the Type 2 Diabetes

Symptom Checklist

# Study description

## Background summary

Physical exercise training is an important tool for improving blood glucose homeostasis in type 2 diabetic patients. A combined resistance and endurance type exercise training program can be applied effectively to improve functional capacity, body composition and metabolic control in type 2 diabetes patients. However, in obese long-standing type 2 diabetes patients with multiple co-morbidities, the impact of structured exercise on health has not been assessed. Because of the high cardiovascular risk profile and functional disabilities in these patients, therapeutic exercise programs have hardly been evaluated in this type 2 diabetes subpopulation.

## Study objective

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.

## Study design

a multi-center clinical trial

## Intervention

In addition to the protocolised diabetes care, 60 type 2 diabetes patients 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. There are 3 possible test and training locations:
1) location Erasmus MC, department of Rehabilitation Medicine and Physical Therapy,
2) Medical Center Haaglanden, location Antoniushove, department of Sports Medicine
3) Zorgsaam Zeeuws-Vlaanderen, location de Honte, department of Physical Therapy
At all 3 locations a physician will be available within 5 minutes in case of complications.
At the end of each exercise session participants will be asked and motivated to walk or cycle at least 30 min a day on the remaining days of the week.On top of the supervised exercise sessions and ususal care the intervention group will

consult a dietician on a montly basis during the first 6 months to guide and support patients in following an energy restricted diet (-600 kcal/day) aimed at a weight reduction of 5-10% over 6 months.
In addition to the protocolised diabetes care, 30 type 2 diabetes patients not participating 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 complete the questionnaires and will be interviewed preferably during an appointment in one of the participating hospitals and when this is not possible by telephone.

Patients willing and not willing to participate will be asked to fill out a short questionnaire to assess their motivational status and reasons for (not) participating.
All diabetes health care workers working in a hospital setting, that showed interest or agreed to recruit patients for this study, will be asked to fill in a validated questionnaire that assesses barriers and facilitators for implementation.

As an extension of the original research proposal, all diabetes health care workers working in a hospital setting, that showed interest or agreed to recruit patients for this study, will be asked to fill in a validated questionnaire that assesses barriers and facilitators for implementation. The latter questionnaire has been developed by the Centre for Quality of Care Research (WOK) (61) and assessing the perceived barriers and difficulties for the Beweegkuur+ life-style intervention from the perspective of the health care provider. Furthermore, patients that have been approached by their health care provider, but have decided not to participate will be asked to fill out a questionnaire on the perceived barriers to participate in this trial. The latter information will be essential for a successful implemention of well-structured exercise and dietary interventions in a hospital setting in the near future

**Study burden and risks**

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

Fasting blood samples will be obtained to measure Hb, Ht, CRP, HbA1c, plasma glucose, HDL-C, LDL-C, T-Chol, Triglycerides and FFA, during fasting conditions. 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.

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.

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 and blood pressure 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.

Muscle strength testing will be used to measure muscle strength of the upper arm and leg muscles. 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.

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.

Patients willing and not willing to participate will be asked to fill out a short questionnaire to assess their motivational status and reasons for (not) participating.

## Contacts

**Public**
Academisch Medisch Centrum

postbus 2040
3000 CA Rotterdam
NL
**Scientific**
Academisch Medisch Centrum

postbus 2040
3000 CA Rotterdam
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

•Type 2 diabetes > 3 months
•Signs of 2 or more diabetes-related 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 including (partial) foot amputations ie Lisfranc or Chopart amputations, lower leg amputations.)
•Stable diabetic foot problems and diabetic ulcers (not prohibiting participation in the training program or exercise test procedures)
•HbA1c: >7.0%
•Age: 30-80 yrs
•BMI > 27kg/m2
•Sedentary behaviour (i.e. <30 min/day moderately active assessed by activity monitoring)
•Agreement to volunteer for the study by giving a written informed consent

## Exclusion criteria

•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)
•Severe orthopaedic impairments that would prohibit participation in the training program (eg severe diabetes ulcers of the foot, in case of amputations: inadequate prosthesis/footwear)
•Cerebro-vascular disease (CVA) or other neurological diseases or deficits that would prohibit participation in the training program (eg spasticity).

# Study design

## Design

**Study type:** Interventional

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Prevention |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 18-10-2010 |
| Enrollment: | 90 |
| Type: | Actual |

# Ethics review

| | |
|---|---|
| Approved WMO Date: | 03-08-2010 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 16-01-2012 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 17-12-2012 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 | NL31793.078.10 |