Low volume high-intensity resistance training in type 2 diabetes: effects on glycemic control.

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Primary Objective: (1) To study the efficacy of low volume high-intensity resistance training for improving glycemic control in patients with T2DM. Secondary Objectives: (2) To study the feasibility of low volume high-intensity resistance training...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON41594

Source
ToetsingOnline

Brief title
Low volume high-intensity resistance training in T2DM.

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes, type 2 Diabetes mellitus (T2DM)

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Thuiszorg West-Brabant
Source(s) of monetary or material Support: fit20 Franchise BV,Stichting Thuiszorg West-Brabant

Intervention

Keyword: Blood glucose, Diabetes Mellitus, Resistance training, type 2

Outcome measures

Primary outcome

(1) glycemic control

The absolute change in plasma glycosylated haemoglobin concentration (HbA1c [%]) from baseline to the end of the intervention period between both groups will be assessed as main outcome for glycemic control. In addition fasting plasma glucose (mmol/L) will be assessed.

Secondary outcome

(2) Feasibility

Feasibility will be assessed on the basis of retention, adherence and adverse events. For retention the attrition rate will be established, defined as discontinuation of the intervention or loss to follow-up following randomization or by the end of the intervention period. Adherence will be measured through attendance to the exercise sessions and compliance to the prescribed intensities. All exercise sessions will be monitored by study personnel who note attendance in a log and ensure each participant completes each exercise bout at the individually prescribed intensity and duration.

(3) Risk factors for cardiovascular disease

i. Blood pressure

Both systolic and diastolic blood pressure (mmHg) will be measured.

ii. Plasma lipid values

The total cholesterol, HDL cholesterol and LDL cholesterol levels (mmol/L) will be assessed.

iii. Body composition

Body weight (kg) and height (m) will be assessed and will be used to establish the Body Mass Index (BMI [kg/mm2]). In addition, the waist circumference (cm) will be measured.

(4) Muscle strength

Strength testing involves determination of the maximum weight (kg) that can be lifted 1 time while maintaining proper form (1RM). Testing will be done for 2 exercises that are included in the training program (chest press and leg press). In addition, the maximal voluntary torque (MVT) of the knee extensor muscles will be determined isometrically on a custom-made dynamometer (Faculty of Human Movement Sciences, VU University Amsterdam, Netherlands).

(5) Physical functioning

For physical functioning endurance, walking speed and balance will be assessed. Endurance testing involves determination of the distance walked (m) during the Six-Minute Walk Test (6MWT). Walking speed and balance will be assessed with the 10 meter walk test (10MWT) and the Balance Test, both of which are included in the Short Physical Performance Battery (SPPB), a short performance battery assessing lower extremity function.

(6) Medication use

The patient*s medical files will be used to assess changes in medication use

during the study period.

(7) Well-being

For well-being the quality of life (QoL) and self-management will be assessed.

QoL will be measured with the Medical Outcome Study 36-Item Short-Form Health

Survey' (SF-36). Self-management will be measured with the 'Dutch version of

the Self Sufficiency Maxtrix (SSM-D)'.

Study description

Background summary

The prevalence of type 2 diabetes mellitus (T2DM) is rapidly increasing world-wide and, for example, in The Netherlands over 750.000 registered cases were diagnosed with T2DM in 2011. Despite an overwhelming body of evidence demonstrating the efficacy of regular physical activity to treat or prevent T2DM, there is no consensus on the nature of exercise therapy required to provide adequate health benefits. Aerobic exercise has traditionally been advocated. Recent position statements from the American Diabetes Association (ADA) and the American College of Sports Medicine (ACSM) also recommend the use of resistance training as part of a well-rounded exercise program.
The guidelines for resistance training have largely been based on information regarding healthy individuals and the few randomized controlled trials of resistance training in individuals with T2DM completed at the time that they were published. In line with the aerobic exercise prescriptions, the focus is on high volume and moderate-intensity exercise, which, especially sedentary older patients with T2DM may find difficult to sustain. Moreover, it appears that that the impact of progressive resistance training on muscle mass and muscle strength in both young and older individuals is more pronounced if higher training intensities are used. In older adults without diabetes, high-intensity progressive resistance training programs have been reported to have significant effects on daily energy expenditure, body composition, and insulin sensitivity. To our knowledge, no study has examined the long-term effects and feasibility of low volume high-intensity progressive resistance training in individuals with T2DM. The absence of such data has precluded specific recommendations by the ACSM and ADA with respect to the merits of low

volume high-intensity resistance training for individuals with T2DM.

Study objective

Primary Objective:
(1) To study the efficacy of low volume high-intensity resistance training for improving glycemic control in patients with T2DM.

Secondary Objectives:
(2) To study the feasibility of low volume high-intensity resistance training for improving glycemic control in patients with T2DM.
(3) To study the effect of low volume high-intensity resistance training on risk factors for cardiovascular disease, muscle strength, physical functioning, medication use and well-being in patients with T2DM.

Study design

A 26-week, single-centre, randomized controlled trial.

Intervention

Patients will be randomized to one of two groups, i.e. (1) low volume high-intensity resistance training + usual care, (2) usual care. The intervention consists of 20-30 minute training sessions once per week over a period of 26 weeks.

Study burden and risks

The blood samples for determination of glycemic control will be collected by the patient*s general practitioner (or by the SHL-groep) as part of the standard medical treatment. Additionally, 5ml/a time extra blood will be collected from the same line (required for determination of the plasma lipid values, and during the first visit (intake) for determination of the serum creatinine level). Each visit will take approximately 15 minutes.
All patients will be asked to visit the main office of TWB before and after the intervention period to participate in a physical examination and to fill out questionnaires. The duration of the physical examination, during which measures of blood pressure, body composition, muscle strength (1-RM and MVT), and physical functioning (6MWT, 10MWT and the Balance Test) are determined, will be approximately 1.5 hour. Following the physical examination, all patients receive two questionnaires (SF-36 and SSM-D) to fill out. The duration for completing the questionnaires is approximately half an hour so that the complete procedure has a duration of approximately 2 hours per visit.

Possible medical risks related to the physical fitness tests are considered minimal. To check for contra-indications for high-intensity exercise, a

physician will thoroughly examine all patients before participation according to the guidelines by the ACSM and ADA. TWB is well experienced in providing the training program, and therefore, the occurrence of medical events is considered minimal.
Considering the positive effects of high-intensity resistance training known from preliminary research it can be concluded that the benefits outweigh the burden and minimal risk associated with this study.

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) Diagnosis of T2DM by the American Diabetes Association criteria, i.e. a) HbA1c >=6.5%, or b) fasting plasma glucose >=7.0 mmol/L, or c) 2-h plasma glucose >=11.1 mmol/L.
(2) Baseline HbA1c value of 6.6% to 9.9% (normal range, 4.0% to 6.0%).

(3) Minimum age of 18 years.

Exclusion criteria

(1) Current insulin therapy.
(2) Participation in exercise 2 or more times weekly for 20 minutes or longer per session or in any resistance training during the previous 6 months.
(3) Insufficient mastery of the Dutch language.
(4) Cognitive impairment
(5) Changes during the previous 2 months in oral hypoglycemic, antihypertensive,or lipid-lowering agents or body weight (>=5%).
(6) Serum creatinine level of 200 µmol/L or greater (>=2.26 mg/dL).
(7) Proteinuria greater than 1 g/d.
(8) Blood pressure greater than 160/100 mm Hg.
(9) Restrictions in physical activity because of disease.
(10) Presence of other medical conditions that made participation inadvisable.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	118
Type:	Anticipated

Ethics review

Approved WMO

Date:	12-01-2016

Application type:	First submission
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
CCMO	NL47925.028.15