The effect of implementation of a physical reactivation program on physical activity behaviour, quality of life and biological and psychosocial factors on type-2 diabetes patients.

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The aim of this study is to determine whether a physical reactivation program is more effective in improving physical activity, quality of life, diabetes control and psychosocial well being than usual care.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON31123

Source
ToetsingOnline

Brief title
The impact of physical reactivation on type-2 diabetes patients

Condition

- Diabetic complications

Synonym
non insulin-dependent diabetes, type-2 diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Zorgonderzoek Nederland (ZON)
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: physical activity, psychological and physical factors, quality of life, type 2 diabetes

Outcome measures

Primary outcome

The primary outcome is the level of physical activity, assessed with the Short Questionnaire to Assess Health enhancing physical activity (SQUASH).

Secondary outcome

The secondary outcomes are *quality of life*, determined by means of the World Health Organisation Quality Of Life brief questionnaire (WHOQOL-BREF) and *diabetes control*, which is determined by means of several biological factors (such as HbA1c and blood pressure). To determine exercise behaviour determinants, several psychosocial factors (such as depression and self-efficacy) are assessed by means of validated questionnaires.

Study description

Background summary

Type-2 diabetes mellitus is a highly prevalent disease, which is associated with major complications. In order to regulate diabetes accurately, complex care is essential. In diabetes care the adaptation to a healthy lifestyle is an important factor, with a predominant role for physical activity. Despite ongoing diabetes exercise programs, the prevalence of inactivity among diabetics remains high. In order to improve physical activity in diabetic patients a physical reactivation program is implemented in diabetes care, which will be evaluated in this study.

Study objective

The aim of this study is to determine whether a physical reactivation program is more effective in improving physical activity, quality of life, diabetes control and psychosocial well being than usual care.

Study design

By means of a randomisation procedure, performed at the level of general practitioners practice, patients are allocated to the intervention or control group.
Patients allocated to the intervention group will receive regular diabetes care and participate in the physical reactivation program.
Patients allocated to the control group will receive regular diabetes care.

Intervention

The intervention consists of a 12-week music-accompanied physical reactivation program, which is designed to improve the participants* exercise level and self-efficacy. Within this 12-week physical reactivation program the patient is prepared for exercise activities after the 12-week intervention period and is exercise continuation promoted. After the exercise program, two exercise boosts are offered (at 6 and 12 months from baseline), which will be preceded by a telephone call as a reminder of the questionnaire and the upcoming exercise session and to encourage the patient to come to the exercise session.

Study burden and risks

All patients included in this study will receive regular diabetes care. During the one-year follow up patients assigned to the intervention group will additionally participate in a 12-week exercise program and will be stimulated to continue performing exercise. Besides this, all included patients -including the patients allocated to control group- will be asked to fill in the questionnaire 4 times, which will take 25 minutes each time. No additional invasive measurements are necessary, as these assessments are part of regular diabetes care.

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

The patient is a type-2 diabetic patient
The patient has a Caucasian ethnicity
The patient is diagnosed with diabetes at least one year ago
The patient*s BMI is over 25 kg/m2 and maximal 40 kg/ m2
The patient is born between 1931 and 1956

Exclusion criteria

The patient performs exercise more than 2 hours a week
The patient is limited in walking 100 meter
The patient suffers from severe malignant hypertension
The patient suffers from unknown, untreated cardiac ischemia
The patient has physical or cognitive limitations in performing physical exercise
The patient suffers from a life-threatening comorbidity (such as cancer)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	204
Type:	Actual

Ethics review

Approved WMO

Date:	03-01-2008
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL19574.015.07