The impact of a physical reactivation program on type-2 diabetes patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21417

Source
Nationaal Trial Register

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

Health condition

1. Physical activity;

2. Quality of life;

3. Type 2 diabetes;

4. psychological and physical factors.

Fysieke activiteit;
Kwaliteit van leven;
Inspanning;
Type 2 diabetes;
Psychologische en fysische factoren

Sponsors and support

Primary sponsor: POZOB (Praktijk Ondersteuning Zuidoost Brabant), afdeling: Ontwikkeling, Datamanagement & Onderzoek
Source(s) of monetary or material Support: ZonMw

Intervention

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

Rationale:

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.

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 general practice level, 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.

Study population:

The study population will consist of 204 Caucasian, inactive, overweight diabetic patients born between 1931 and 1956. Patients are excluded from participation if they can walk less them 100 meters, suffer from severe malignant hypertension, untreated cardiac ischemia or a life-threatening co-morbidity, if the patient experiences physical or cognitive limitations in performing exercise.

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.

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. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

A physical reactivation program is more effective in improving physical activity behaviour, quality of life, diabetic parameters and psychosocial well being than usual care in type-2 diabetic patients.

Study design

The control group, as well as the intervention group, will be monitored for one year. At baseline, questionnaires will be assessed. This assessment will be repeated three months after inclusion, at the end of the music-accompanied exercise program. Subsequently, the questionnaires are carried out six months and twelve months after inclusion. Data concerning biological parameters will be collected at baseline and twelve months after baseline measurement.

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. The patient is a type-2 diabetes patient;

2. The patient has a Caucasian ethnicity;

3. The patient is diagnosed with diabetes at least one year ago;

4. The patient’s BMI is over 25 kg/m2 and maximal 40 kg/m2;

5. The patient is born between 1931 and 1956.

Exclusion criteria

1. The patient performs exercise more than 2 hours a week;

2. The patient is limited in walking 100 meter;

3. The patient suffers from severe malignant hypertension;

4. The patient suffers from unknown, untreated cardiac ischemia;

5. The patient has physical or cognitive limitations in performing physical exercise;

6. 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:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2008
Enrollment:	204
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-01-2008
Application type:	First submission

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
NTR-new	NL1133

Register	ID
NTR-old	NTR1175
Other	CCMO (ABR-nummer) : 19574
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A