Bewegingstherapie via het internet voor patienten met type 2 diabetes.

No registrations found.

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

Summary

ID

NL-OMON23270

Source
NTR

Brief title
Web based interactive exercise therapy for Type 2 Diabetes

Health condition

Diabetes type 2

Sponsors and support

Primary sponsor: Erasmus Medical Center
Department of Rehabilitation Medicine
Source(s) of monetary or material Support: Wetenschappelijk College Fysiotherapie (WCF)

Intervention

Outcome measures

Primary outcome

Adherence to the exercise program as measured by percentage of dropouts as well as an increase in total weekly energy expenditure. The feasibility of the LiveWorkout and Direct Live program.

Secondary outcome

1. Movement-related everyday activity/energy expenditure and functional capacity Muscle strength and resistance to fatigue;

2. Glycemic control (HbA1c) and fasting plasma glucose;

3. Cardiovascular risk profile.

Study description

Background summary

Physical exercise training is an important tool for improving glucose homeostasis in type 2 diabetic patients. A combined strength- and endurance training program appears to improve functional capacity, body composition and metabolic control in type 2 diabetes patients. However, long-term adherence to such programs is generally poor. Therefore, alternative strategies are warranted to reduce attrition rate.

Objective: (1) Does online supervised exercise therapy using the LiveWorkout concept result in better adherence to therapeutic bouts of exercise in type 2 diabetes patients as compared to Direct Life online lifestyle coaching. Are the LiveWorkout and Direct Life concepts feasible e-coaching programs? (2) Will online exercise training as compared to an online lifestyle coaching program cause an improvement in: movement-related everyday activity/energy expenditure and functional capacity, muscle strength and resistance to fatigue. (3) Does online exercise training as compared to usual care improve glycemic control (HbA1c), fasting plasma glucose levels and cardiovascular risk profile?
Patients will be randomized to follow either a supervised progressive interval endurance and resistance type of training at the ErasmusMC (13 weeks) combined with an interactive web based (LiveWorkout®) resistance training at home (26 weeks), or to take part in a webbased activity monitor based lifestyle coaching program (26 weeks). Both programs are aimed at increasing daily physical activity levels. All patients will be seen 3 times (in total approximately 3.5 hrs) before and after the intervention. Measurements that will be done during those visits are: questionnaires (PAR-Q, SF-36, specifically designed LiveWorkout users questionnaire), body composition, blood pressure, spiroergometry, muscle strength (upper arm and leg), Sit to Stand-test, fasting blood sample (3x7 ml). Patients will be asked to wear a small accelerometry-based Activity Monitor for 7 days and register movement related activities (7 days) as well as dietary intake (3 days).

Study objective

Regular exercise has been recommended for diabetes patients for many years, and has been

identified along with diet and insulin as one of the three components of good therapy. From a physiological perspective, structured exercise interventions have at least equal therapeutic strength as currently applied pharmaceutical solutions aimed to improve glycemic control and cardiovascular risk profile. Despite this growing body of evidence showing the health benefits of exercise in type 2 diabetes, recently published surveys show that the majority of patients with diabetes do not engage in regular physical activity. This study investigates the feasibility of an online interactive exercise therapy to improve movement-related everyday activity/energy expenditure and functional capacity, muscle strength and resistance to fatigue.

Study design

All patients will be seen 3 times (in total approximately 3.5 hrs) before and after the intervention. Measurements that will be done during those visits are: questionnaires (PAR-Q, SF-36, specifically designed LiveWorkout users questionnaire), body composition, blood pressure, spiroergometry, muscle strength (upper arm and leg), Sit to Stand-test, fasting blood sample (3x7 ml). Patients will be asked to wear a small accelerometry-based Activity Monitor for 7 days and register movement related activities (7 days) as well as dietary intake (3 days).

Intervention

Patients will be randomized to follow either a supervised progressive interval endurance and resistance type of training at the ErasmusMC (13 weeks) combined with an interactive web based (LiveWorkout®) resistance training at home (26 weeks), or to take part in a webbased activity monitor based lifestyle coaching program (26 weeks). Both programs are aimed at increasing daily physical activity levels.

Contacts

Public
P.O. box 2040
D. Visser
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7031679
Scientific
P.O. box 2040
D. Visser
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7031679

Eligibility criteria

Inclusion criteria

1. Type 2 diabetes <15 years;

2. HbA1c: 7.0- 10.0%;

3. Age: 35-75 yrs;

4. BMI: 27-40 kg/m2;

5. Access to broadband internet including a personal computer with USB-interface.

Exclusion criteria

1. Cardio-vascular disease;

2. Severe orthopaedic impairments;

3. Renal failure or >grade III retinopathy or previous diabetic foot ulcer;

4. Cerebro-vascular disease (CVA), neurological diseases or deficits.

Study design

Design

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

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-03-2010
Enrollment:	48
Type:	Anticipated

Ethics review

Positive opinion Date:	25-02-2010
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	NL2108
NTR-old	NTR2225
Other	MEC Erasmus MC : MEC-2009-230
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A