

Interactive exercise therapy at home: a web based solution to improve long-term adherence, self-management and clinical efficacy of a life-style intervention program for patients with Type 2 Diabetes

Published: 01-02-2010

Last updated: 06-05-2024

Primary Objectives: - DirectLifeDirectLifeAre the LiveWorkout® and DirectLife® concept feasible web based training programs for type 2 diabetes patients ?- How do type 2 diabetes patients experience web based training intervention programs ? What...

Ethical review

Approved WMO

Status

Recruiting

Health condition type

Glucose metabolism disorders (incl diabetes mellitus)

Study type

Interventional

Summary

ID

NL-OMON39505

Source

ToetsingOnline

Brief title

Web based interactive exercise therapy for Type 2 Diabetes

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

adult onset diabetes, Diabetes type 2

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Diabetesfonds

Intervention

Keyword: Diabetes type 2, Exercise therapy, life style coaching, Web based

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 Live Workout program.

Secondary outcome

Movement-related everyday activity/energy expenditure and functional capacity

Muscle strength and resistance to fatigue

Glycemic control (HbA1c) and fasting plasma glucose

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.

Study objective

Primary Objectives:

- DirectLifeDirectLifeAre the LiveWorkout® and DirectLife® concept feasible web based training programs for type 2 diabetes patients ?
- How do type 2 diabetes patients experience web based training intervention programs ? What can be recommended for future web based training interventions to increase effectively ?
- What barriers experience patients who are not willing to engage in web based training intervention programs ?

Secondary Objectives:

- Will online exercise training as compared to a usual care program cause an improvement in:
 - Movement-related everyday activity/energy expenditure and functional capacity
 - Muscle strength and resistance to fatigue
 - Glycemic control (HbA1c) and fasting plasma glucose levels
 - Cardiovascular risk profile
 - Is there a difference in adherence between the LiveWorkOut® and DirectLife® group ?
- care improve glycemic control (HbA1c), fasting plasma glucose levels and cardiovascular risk profile?

Study design

A randomized controlled intervention study

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.

Study burden and risks

Since all patients will undergo a symptom limited exercise stress test using ECG-monitoring, the risk for exercise related cardiac ischaemia and/or arrhythmia during the course of the exercise intervention is rather limited. To minimize the risk for a hypoglycemic event, capillary blood glucose following interval endurance training will be measured during the first 2 weeks of the exercise intervention. The exercise intervention is expected to improve glycemic control, blood pressure and workload capacity/physical fitness level. As such, cardiovascular risk profile, general health and well-being is expected to improve in the experimental group. 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).

Contacts

Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

Westzeedijk 361
Rotterdam 3000 CA
NL

Scientific

Erasmus MC, Universitair Medisch Centrum Rotterdam

Westzeedijk 361
Rotterdam 3000 CA
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 maanden-15 years
- Age: 35-75 yrs
- Access to broadband internet including a personal computer with minimally WindowsXP/MacOSX and a USB-connection

4 - Interactive exercise therapy at home: a web based solution to improve long-ter ... 13-05-2025

Exclusion criteria

- Cardio-vascular disease
- Severe orthopaedic impairments
- Renal failure or >grade III retinopathy
- Previous diabetic foot ulcer that limits exercise training
- 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
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	28-04-2010
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO	
Date:	01-02-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	08-05-2012

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-06-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-06-2013
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	NL28342.078.09