# eSupported lifestyle coaching for patients with insulin dependent type 2 diabetes mellitus: a pilot study

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1. to determine the feasibility and acceptability of an e-supported lifestyle coaching program and2. to assess the effects of personalized lifestyle support in patients with insulin dependent type 2 diabetes mellitus immediately after 12 weeks and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

# Summary

### ID

NL-OMON42730

**Source** ToetsingOnline

**Brief title** Lifestyle eCoaching DM2

### Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Nephropathies
- Lifestyle issues

**Synonym** Diabetes mellitus type 2

**Research involving** Human

### **Sponsors and support**

#### Primary sponsor: Leids Universitair Medisch Centrum

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#### Source(s) of monetary or material Support: Ministerie van OC&W

### Intervention

**Keyword:** Chronic Kidney Injury, eCOACHING, Personalized lifestyle intervention, Type 2 diabetes mellitus

#### **Outcome measures**

#### **Primary outcome**

Main study parameter/endpoint

• Feasibility and sustainability of the proposed healthy lifestyle behaviors,

measured with 24-hour recall dietary diary, plus validated self-report on

physical activity and stress management activities (Ornish 1998).

• Attractiveness of the eSupport Lifestyle Intervention, measured via patient

satisfaction and the Technology Acceptance Model (TAM; Szajna 1996) on weeks 4,

12, 50.

#### Secondary outcome

Secondary study parameters/endpoints

- Quality of Life (SF-8)
- Exercise capability (aerobic & resistance tests, see below)
- Fasting plasma glucose, fasting plasma insulin, HbA1C, total cholesterol, HDL

cholesterol and triglyceride levels

- Blood pressure, BMI, waist circumference
- Kidney function: MDRD
- Albuminuria: Albumin/Creatinin Ratio.
- Medication requirements (insulin, metformin, statins, antihypertensives)
- Pancreas, muscle and liver tissue function as reflected by OGTT based
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multi-parameter diagnosis (weeks 0, 12, 50).

• Liver, pancreas, skeletal muscle, kidney and heart ectopic fat accumulation (weeks 0, 12, 50).

• Cardiac function (systolic and diastolic function, pulse wave velocity)

(weeks 0, 12, 50).

a. Heart function:

i. Systolic function: stroke volume, ejection fraction, cardiac output, cardiac index, peak ejection rate.

ii. Diastolic function: early peak filling rate (E), early deceleration peak (E

dec peak), atrial peak filling rate (A), E/A ratio, peak mitral annulus

longitudinal motion (Ea), MR estimate of LV filling pressure (E/Ea)

b. Heart dimensions: End diastolic volume, end-systolic volume, LV mass, LV

mass index, LVMI/EDVI, percentage scar tissue (weeks 0, 12, 50).

c. Aorta and carotid vessel wall imaging: total vessel wall area, average

vessel wall thickness, minimum vessel wall thickness, maximum vessel wall

thickness, vascular distensibility (weeks 0, 12, 50).

d. Body fat distribution: (weeks 0, 12, 50).

i. Adipose tissue distribution, visceral and subcutaneous fat volume

ii. Pancreatic fat content

iii. Epicardial fat volume

iv. 1H-MRS of the heart, skeletal muscle, liver and kidney triglyceride content

These measurements will be conducted at baseline, after 4 weeks, 12 weeks and

at 1 year follow up, with three exceptions: a) the extensive OGTT based

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multi-parameter diagnosis will not be conducted at week 4; b) for patient satisfaction and eSupport attractiveness (TAM) the first measurement is conducted at week 4; c) MR assessment will be performed at baseline, week 12 and at 1 year.

# **Study description**

#### **Background summary**

Our Western lifestyle plays a large role in the onset and progression of diabetes-2 (Lim 2011). Insulin resistance has an important role in creating a vicious circle, where medication needs generally increase over time. Moreover, increasing blood glucose and insulin levels speed up the processes of weight gain, insulin resistance, inflammation, aging and comorbidity (like CVD, kidney failure , cancers, neuropathy and dementia) (Hotamisligl 2010). Hence, reducing insulin dependence and insulin resistance can be seen as an important therapeutic goal. This can be achieved with healthy lifestyle improvements.

Several lifestyle interventions have created improved outcomes in type 2 diabetes patients on insulin therapy, most notably: lower blood sugar and lower medication needs (Jenkins 2008; Esposito 2009). However, these are often highly controlled interventions and the long term sustainability of behaviors is limited. The question is: can we do this on a more \*Do-It-Yourself\* and eSupported basis? This would have two advantages. First, since behavior improvements are implemented within patients\* lives, it improves the chance of sustained health behavior (Simons 2013). Second, it is cheaper. Since 2010 the Health Coach Program has been used to improve lifestyle and metabolic outcomes (including reduced insulin needs for diabetes-2 patients) via eSupport, improved self-management and rapidly improved health behaviors (Simons 2010, Simons 2012). The intervention combines improving health literacy with active behavior change support.

A personalized diagnosis (i.e. pinpointing the exact physiological problem) can help increasing the patients\* understanding of his or her medical condition and the appropriate way to improve it, which is likely to promote adherence to instructions. Several organs can contribute to disruption of (glucose) metabolism in diabetes type 2 (DeFronzo 2009). Functioning of the three main organs, pancreas, muscle tissue and liver, can be assessed by measuring glucose and insulin at 30 min intervals during an oral glucose tolerance test (OGTT) (Abdul-Ghani 2006). Thus, lifestyle improvement can be personalized, depending on organ specific dysfunction, delaying or even reversing diabetes progression (Lim 2011).

Obesity and type 2 diabetes are marked by ectopic fat accumulation in numerous tissues, e.g. liver and heart, which profoundly impacts on tissue function. In fact, a pile of evidence indicates that excess liver fat drives systemic inflammation, insulin resistance and hyperglycemia, and fatty acids in heart muscle are at the root of diabetic cardiomyopathy. Novel imaging techniques can accurately and non-invasively quantify tissue triglyceride content and heart function in vivo.

### Study objective

1. to determine the feasibility and acceptability of an e-supported lifestyle coaching program and

2. to assess the effects of personalized lifestyle support in patients with insulin dependent type 2 diabetes mellitus immediately after 12 weeks and after one year of follow up on:

• Fasting glucose levels, glucose tolerance and medication needs (insulin, metformin)

- Pancreas, muscle and liver function as reflected by OGTT based multi-parameter diagnosis
- Quality of life
- Progression/regression of kidney failure

• Liver, pancreas, skeletal muscle, kidney and heart ectopic fat accumulation, and cardiovascular function

### Study design

Non-randomized, one arm, pilot 12-week intervention study, with additional effect measurement at 1 year of follow up.

#### Intervention

An extensive eSupported lifestyle program is offered, which combines coach sessions with electronic dashboarding and self-management, plus electronic health tips and a digital health quiz game. Intensive coaching is offered for 4 weeks with the purpose of generating self-propelling behaviors and capabilities. The support in weeks 5-12 is more lightweight, with group session at the end of weeks 6, 8 and 12, weekly electronic tips and a digital health game.

As an umbrella overarching the personalized modifications outlined above, the general lifestyle advice follows the guidelines of the Harvard Epidemiology and Nutrition Group for nutrition and physical activity, with specific modifications for diabetics. The guidelines are to increase intake of vegetables and low sugar fruits (each 2,5 servings/day or more), to choose

whole grains instead of refined grains, to limit sugar and other high glycemic load foods, to have one daily serving of nuts and/or legumes, to limit intake of red meat and processed meat, to limit intake of trans and animal fats, and to have no more than 2 (male) or 1 (female) alcoholic beverages/day. Physical exercise guidelines are: at least 60 min/day moderate intensity activity (like walking or gardening) and at least 3x30 min/week intensive activity (Borg level 12-14). Stress management guidelines are: relaxation exercises for >10 min/day.

#### Study burden and risks

Supervision of Diabetes Mellitus Type 2 patients in changing the lifestyle is the most important part of the standard therapy. This study thus is within the scope of the standard clinical care for the treatment of type 2 Diabetes Mellitus. The risk associated with participation is limited to the chance of incidental findings on MRI scan and the risk of lower blood sugars during the diet and exercise intervention. This risk is minimized by strict glycemic control, and where necessary, adaptation of the medication. The benefits of improved glycemic control outweigh the low risk of hypoglycemic events in the long term .

Successful lifestyle change provides health benefits , lower medication requirement. Lifestyle change is difficult to adhere to, so that intensive supervision is needed in order to be successful.

# Contacts

#### Public

Leids Universitair Medisch Centrum

Albinusdreef 2 Leiden 2333ZA NL **Scientific** Leids Universitair Medisch Centrum

Albinusdreef 2 Leiden 2333ZA NL

# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

#### **Inclusion criteria**

Insulin-dependent Type 2 Diabetes Mellitus patients. The goal is to include at least 6 of the 12 patients with kidney damage, with eGFR < 60 ml/min/1,73m2 (CKD-EPI) and/or albumin/creatinin ratio > 2,5 mg/mmol (men) or 3,5 mg/mmol (women).

### **Exclusion criteria**

- Recent (< 3 months) myocardial infarction
- Uncontrolled blood pressure (SBP > 170 mmHg and/or DBP > 100 mmHg, 2 out of 3 measurements)
- Any chronic disease other than type 2 diabetes hampering participation (at the discretion of the investigator)
- Low motivation to participate (score 2 \*weak\* or 1 \*very weak\* on a 5-point scale).
- Alcohol consumption of more than 28 units per week at present or in the past
- Psychiatric disease (as defined by DSM-V)
- Claustrophobia, metal implants or other contraindications for cardiac MRI

# **Study design**

### Design

Study type: Interventional	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

# Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	19-08-2015
Enrollment:	12
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	08-07-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

# **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
ССМО	NL53321.058.15

# **Study results**

Date completed:	26-08-2016
Actual enrolment:	11

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