# eSupported lifestyle coaching for patients with insulin dependent type 2 diabetes mellitus: Leiden regional implementation pilot

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1. To determine the robustness of an e-supported lifestyle coaching program within the first line health care setting of the Leiden region and to explore factors that influence successful integration of the coaching program in the usual care in the...

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| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Glucose metabolism disorders (incl diabetes mellitus) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON45548

**Source**
ToetsingOnline

**Brief title**
Lifestyle eCoaching DMT2 Regional Implementation

### Condition

- Glucose metabolism disorders (incl diabetes mellitus)

**Synonym**
type 2 diabetes; insulin-dependent type 2 diabetes

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Gemeente Leiden

## Intervention

**Keyword:** ecoaching, implementation, Lifestyle, type 2 diabetes

## Outcome measures

### Primary outcome

Primary objective 1: implementation and integration in first line health care setting

* Lessons learned from GP and PA experiences: regarding their preferences and user needs.

* Lessons learned for future implementation in general practice: fit within diabetes *ketenzorg* processes, number of patients approached and number of patients entering the program and number of and reasons for patients leaving the program.

* Lessons regarding user needs and design requirements (infrastructure, architecture, security) for future digital reporting to participating GP*s (General Practitioners) and their PA*s (Physician Assistants) about effects of the intervention and progress achieved, to be used in regular care in order to reach sustainability of behavioral change.

The research team will conduct brief telephone interviews with GP and PA after two weeks (together with the telephone based briefing of patient progress) regarding user needs and design requirements for future digital reporting and regarding implementation barriers and facilitations for implementation of the intervention in regular care.

### Secondary outcome

Secondary objective 2: effect of the intervention

* Impacts on healthy lifestyle behaviors, measured with BRAVO [standardized survey], on Health Related Quality of Life [RAND SF-8 survey] and exercise capability (aerobic & resistance/strength tests). Progress reports of outcomes of the intervention on behaviors and effects will be provided to GP and PA after 2 weeks and at the 10-week out-take coach session.

* Fasting plasma glucose, HbA1C, total cholesterol, HDL cholesterol and triglyceride levels, blood pressure, BMI [as monitored within standard first line diabetes-2 care]

* Medication requirements (insulin, metformin, statins, antihypertensives)

# Study description

**Background summary**

Our Western lifestyle plays a large role in the onset and progression of diabetes mellitus type 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) (Hotamisligil 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 yielded 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. Moreover, the long-term sustainability of behaviors is limited. The question is: can we do this on a more *Do-It-Yourself* and e-Supported 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.

**Study objective**

1. To determine the robustness of an e-supported lifestyle coaching program within the first line health care setting of the Leiden region and to explore factors that influence successful integration of the coaching program in the usual care in the general practice.

2. To assess the effects of lifestyle support in patients with insulin dependent type 2 diabetes mellitus after 10 weeks and after 20 weeks additional follow up on:
* Health behaviours, Health-Related Quality of life, and exercise capability.
* Fasting glucose levels, and medication needs (insulin, metformin) [as monitored by patients].

**Study design**

Non-randomized, one arm lifestyle intervention pilot project, 10 weeks, plus 20 weeks additional follow up.

**Intervention**

eSupported Lifestyle 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 5 weeks with the purpose of generating self-propelling behaviors and capabilities. The support in weeks 6-10 is increasingly aimed at fostering self-management, and includes group sessions at the end of weeks 7 and 10, weekly electronic tips and a digital health game. For the next 20 weeks a light weight support program is offered, with monthly group sessions, plus monitoring of physical activity patterns.
The 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).

**Study burden and risks**

Patients will potentially benefit in terms of reduction of metabolic risk factors for cardiovascular disease and cancer, reduction of medication use, improved quality of life (more energy, better self esteem). Potential harms are cardiovascular complaints during physical exercise.

# 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

* Type 2 diabetes mellitus treated by insulin therapy.

* BMI ><= 28 kg/m2
* Age 30-80 yrs
* Dutch language and basic computer competence (for use of email and web based dashboard)

### 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, and no intentions of moderation.
* Psychiatric disease (as defined by DSM-V)

## Study design

### Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 16 |
| Type: | Anticipated |

## Ethics review

Approved WMO

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| Date: | 18-09-2017 |
| 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 |
| --- | --- |
| CCMO | NL60909.058.17 |