'Glycemic control for people with diabetes after three months of information about nutrition and feedback about physical activity behaviour'

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

Summary

ID

NL-OMON40754

Source
ToetsingOnline

Brief title
Live healthy with diabetes

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes type 2, diabetic

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

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

Intervention

Keyword: diabetes, digital health care, e-health, sensor technology

Outcome measures

Primary outcome

The primary outcome is HbA1c.

Secondary outcome

o VAS perceived health

o Mood (PAM; pick a mood)

o Motivational questionairre (measured in four determinants: intention,

attitude, self-efficacy and social norm)

o Physical activity (measurend by an activity tracker and by the1-item

questionnaire)

o BMI

o Waist and hip circumference (cm)

o Compliance (use of the digital healh program);

* - Number of login times care giver

- Number of login times participant

- Percentage *activities completed' within the digital

program*

- Number of e-consults conducted between the care giver and

participant

* - Use of the activity tracker (percentage use relative to the complete

studie)

Study description

Background summary

For people with diabetes optimal glycemic control is of big improtance in order to prevent different complications and comorbidiy. A healthy lifestyle, which means sufficient physical activity and a balanced diet has been proven to be effective for decreasing the risk for complications. However, self-mangament and long term behaviour change towards a healthy lifestyle are hard to reach for people with chronic disease. Digital health care (e-health) and real-time feedback on physical activity behaviour are mentioned lately as a possible solution to improve lifestyle and physical activity behaviour for diverse populations.

Study objective

The primary aim of the present research is to determine if a digital health program, with information about nutrition/physical activity/diabetes and feedback on physical activity behaviour by an activity tracker leads to improvement of glycemic control.

Study design

A randomized clinical trial, with one intervention group and one control group.

Intervention

The intervention group receives during 12 weeks in additon to the regular care a digital health program. Central in the program are a web application and an activity tracker. Using the internet application the subject set their own goals with regard to physical activity, the receive feedback with regard to their own physcial activity behaviour (feedback from the activity tracker) and they receive information about diabetes, lifestyle and nutrition. Through the web application the subjects have contact with their care giver.

Study burden and risks

The e-health intervention does not bring any risks with it. A possible risk for hypoglycemia for patients that use insulin is low, becasue only patients with an HbA1c of >= 58 mmol/mol are included. Furthermore, the subjects receive the regular advizes for hypoglycemia.

The measurements are non-invasive. In total there will be three real life consults with the health care provider. In these consults, the body weight, hip and waist circumference are measured. Other secondary outcome measures are digitally completed within the e-health program at baseline, week 6, 12 and 24. The HbA1c is obtained by the care giver in week 0,12, 24 en week 48 for the intervention group and in week 0, 12, 24, 36 en 60 for the control group.

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

- people with type 2 diabetes
- Moste recent HbA1c-value >= 58 mmol/mol (7.5%)
- Age >=18 years
- Access to a computer and the internet

- Some experience with the use of a computer and the internet

Exclusion criteria

- Pregancy
- More than 3 hours of intensive sports per week
- Severe comorbidity
- Cognitive or mental problems

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-04-2015
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO Date:	23-12-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-07-2015
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-11-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL49925.042.14