

A digital health program combined with an activity tracker to improve lifestyle behavior.

No registrations found.

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

Summary

ID

NL-OMON28551

Source

NTR

Health condition

HbA1c, diabetes type 2, lifestyle behavior, activity monitoring, feedback.

Leefstijl, zelfmeting van beweging, feedback.

Sponsors and support

Primary sponsor: Hanze University of Applied Sciences, research group Healthy ageing, Allied health care and Nursing.

Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

HbA1c.

Secondary outcome

1 - A digital health program combined with an activity tracker to improve lifestyle ... 13-05-2025

Mood (Pick A Mood; PAM)

Motivational questionnaire (measured in four determinants: intention, attitude, self-efficacy and social norm)

Physical activity (measured by the Fitbit, and by the 1-item questionnaire)

BMI

Waist and hip circumference (cm)

Compliance use of the digital health program

Use of the Fitbit Zip

□

Study description

Study objective

The alternative hypothesis: there will be a significant difference in HbA1c after receiving a digital health program with information about nutrition and feedback about physical activity behavior, relative to the control group which receives care as usual.

De 0-hypothese luidt dat er geen verschil is in HbA1c na het ontvangen van enerzijds drie maanden een digitaal gezondheidsprogramma met informatie over leefstijl en feedback op het beweeggedrag plus care as usual en anderzijds care as usual alleen.

De alternatieve hypothese luidt dat het ontvangen van drie maanden care as usual plus een digitaal gezondheidsprogramma met informatie over leefstijl en feedback op het beweeggedrag zorgt voor een significante daling in HbA1c ten opzichte van de care as usual alleen.

Study design

T0 (week 0)

T 1 (week 12)

T 2 (week 24)

Intervention

A digital health program combined with an activity tracker (Fitbit Zip). Participants receive weekly information about physical activity, nutrition and diabetes. They gain insight in their physical activity behavior through the digital program, and receive stimulating feedback messages.

Contacts

Public

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Eligibility criteria

Inclusion criteria

- People with type 2 diabetes
- Most recent HbA1c-value $\geq$ 58 mmols/mol (7.5%)
- Age $\geq$ 18 jaar
- Access to a PC and the internet

- some experience with the use of a computer and the internet.

Exclusion criteria

- Pregnancy
- Already exercising more than 3 hours per week
- Severe co-morbidity
- Cognitive or mental problems

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	24-04-2015
Enrollment:	96
Type:	Anticipated

Ethics review

Positive opinion	
Date:	30-04-2015
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	NL5083
NTR-old	NTR5215
CCMO	NL

Study results