

Eindhoven Long-term Diabetes Education Study

No registrations found.

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

Summary

ID

NL-OMON24847

Source

NTR

Brief title

ELDES

Health condition

adults with type 2 diabetes mellitus

Sponsors and support

Primary sponsor: University Medical Center Utrecht

Source(s) of monetary or material Support: European Foundation for the Study of Diabetes

Intervention

Outcome measures

Primary outcome

Change in BMI (difference of 0.77 kg/m² is considered clinical relevant) between baseline and follow-up (2 years after the start of the course).

Patient randomized to the control group will receive usual care according to the NHG

guideline.

Secondary outcome

Change between baseline and 2 years follow-up of:

1. Clinical measures: systolic blood pressure, HbA1c, lipid profile (total cholesterol, LDL, HDL, triglycerides);
2. Quality of Life;
3. Diabetes self-management behavior (level of physical activity, dietary intake, medication adherence);
4. Proactive coping;
5. Cost-effectiveness of the intervention (total health care resources use during the whole study period)

Study description

Study objective

The theory based 12 weeks self-management program 'Beyond Good Intentions' (BGI) is one of the very few programs that improved cardiovascular risk factors at 9 months follow-up and is cost-effective. Originally it was designed for patients with screen-detected type 2 diabetes, but the program is now implemented on a larger national scale. If long-term effectiveness and a higher cost-effectiveness ratio could be proven, the program will be reimbursed by health insurance companies and implementation across Europe could be encouraged.

Study design

Clinical measures over the complete study period will be extracted from the electronic medical record of the general practitioner. For the primary outcome (BMI) an average of 6 measurement over the 2 years study course is expected.

Questionnaires on diabetes self-management, health related quality of life, and proactive coping will be filled in at baseline and 2 years follow-up

Intervention

This study elaborates on the existing self-management course "Beyond Good Intentions". The course lasts 12

weeks and consists of two 30-minutes individual sessions and four 2.5-h group sessions. In addition, one booster-session is given 52 weeks after the second individual session.

Contacts

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Eligibility criteria

Inclusion criteria

Adults patients (aged

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1. High self-management capability or low capability on the domains "Anxiety" or "Depression" (of the SeMaS questionnaire)
2. Insufficient cognitive functioning;
3. Insufficient understanding of the Dutch language to follow instructions and to complete questionnaires.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-01-2014
Enrollment:	88
Type:	Anticipated

Ethics review

Positive opinion	
Date:	22-10-2015
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

NTR-new

NTR-old

Other

ID

NL5405

NTR5530

: 13-521

Study results

Summary results

NA