

Eindhoven Long-term Diabetes Education Study

Gepubliceerd: 22-10-2015 Laatste bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24847

Bron

NTR

Verkorte titel

ELDES

Aandoening

adults with type 2 diabetes mellitus

Ondersteuning

Primaire sponsor: University Medical Center Utrecht

Overige ondersteuning: European Foundation for the Study of Diabetes

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Julius Center for Health Sciences and Primary Care,

Rimke Vos

University Medical Center Utrecht, P.O. Box 85500 (Internal mail no STR 6.313)

Utrecht 3508 GA

The Netherlands

Wetenschappelijk

Julius Center for Health Sciences and Primary Care,

Rimke Vos

University Medical Center Utrecht, P.O. Box 85500 (Internal mail no STR 6.313)

Utrecht 3508 GA

The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adults patients (aged

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	15-01-2014
Aantal proefpersonen:	88
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	22-10-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5405
NTR-old	NTR5530
Ander register	: 13-521

Resultaten

Samenvatting resultaten

NA