

Doelbewust diabetes.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25321

Source

NTR

Brief title

Beyond Expectations

Health condition

type 2 diabetes

Sponsors and support

Primary sponsor: Linschoten Institute for Psychology

Faculty of Social Sciences, Utrecht University, The Netherlands

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Source(s) of monetary or material Support: The Netherlands Organisation for Health Research and Development (ZonMw)

Intervention

Outcome measures

Primary outcome

Self-management behaviors as assessed through questionnaires (diet, exercise, lifestyle adherence, medication adherence), corroborated by medical outcomes that will be assessed through blood samples (Hba1c, blood glucose levels).

Secondary outcome

Psychological measures, assessed by questionnaires (proactive coping skills, self-efficacy, self-control).

Study description

Background summary

The study aims to test the effectiveness of a behavioral intervention program targeting proactive coping skills in type 2 diabetes patients. The program comprises one individual session and 4 group sessions over a period of 2 months. Using a practical 5-step plan, participants are taught to set concrete goals, recognize conditions and barriers to goal achievement, identify potential difficult situations, formulate necessary actions, and consider how to evaluate their progress. It is expected that the intervention will increase participants' proactive coping skills, which will in turn lead to improved self-care behavior and medical outcomes.

Study objective

It is expected that the intervention will increase participants' proactive coping skills, which will in turn lead to improved self-care behavior and medical outcomes.

Study design

T0 (week 0): Baseline, before intervention;

T1 (week 6): After basis intervention;

T2 (week 36): After booster sessions;

T3 (week 62): 6 month follow-up.

Intervention

All participants are included in a behavioral intervention program targeting proactive coping skills (Beyond Good Intentions). The program comprises one individual session and 4 group sessions over a period of 2 months. Using a practical 5-step plan, participants are taught to set concrete goals, recognize conditions and barriers to goal achievement, identify potential difficult situations, formulate necessary actions, and consider how to evaluate their progress.

After the basis intervention, two different booster session programs are delivered. Participants are randomly assigned to a follow-up program that continues to target small concrete goals, or a follow-up program in which the focus is on large abstract goals.

Proactive coping skills and self-care behavior will be assessed at baseline, after the basis intervention, after the booster sessions, and at follow-up 6 months after the last booster session. Medical outcomes will be assessed at baseline and at follow-up.

Contacts

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Eligibility criteria

Inclusion criteria

1. Recently (< 5 years) diagnosed with type 2 diabetes;
2. Sufficient mastery of Dutch language.

Exclusion criteria

1. Serious physical and psychiatric comorbidities;

2. Currently involved in another diabetes-related self-management program;
3. Insufficient mastery of the Dutch language.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2009
Enrollment:	300
Type:	Actual

Ethics review

Positive opinion	
Date:	16-02-2011
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	NL2637
NTR-old	NTR2765
Other	METC University Utrecht : 07-303
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A