

Beyond expectations: the effectiveness of a theory driven intervention to achieve and sustain optimal self-management in patients with type-2 diabetes

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The present study examines an extended version of this intervention that aims to address more challenging self-management goals once patients have mastered the skills necessary to achieve relatively small improvements in their self-management. The...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON31669

Source

ToetsingOnline

Brief title

Beyond expectations

Condition

- Diabetic complications

Synonym

Diabetes, Diabetes Mellitus type 2, Non insulin dependent diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Utrecht

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Behavioral discipline and activities, intervention, self-care, Type 2 Diabetes Mellitus

Outcome measures

Primary outcome

Primary outcome is self-management behavior (including diet, physical activity, medication adherence and smoking), corroborated by medical measures (BMI, blood pressure, Hba1c and lipid profiles).

Secondary outcome

Mediators include self-regulatory competence, self-efficacy, outcome satisfaction and emotional outcomes. Moderators include sociodemographic characteristics, self-control, the tendency to be goal oriented and outcome expectations

Study description

Background summary

There is a call for effective interventions which can support patients with type-2 diabetes in improving their self-management. The present study builds forth on the success of a previous theory driven intervention proven effective in helping patients recently diagnosed with type-2 diabetes to achieve and maintain small changes in self-management behaviors using a proactive 5-step plan.

Study objective

The present study examines an extended version of this intervention that aims

to address more challenging self-management goals once patients have mastered the skills necessary to achieve relatively small improvements in their self-management. The effectiveness of this more challenging goal-setting strategy will be compared with one that continues to focus on small goals which are achievable in the short term.

Study design

A prospective randomized controlled design will be employed to compare the effectiveness of two conditions, (2x150) over 18 months (including 6 month follow-up). Conditions include the experimental condition (the original course plus ambitious extension) and a control condition (including the original course plus extension focusing on small, short-term goals).

Intervention

All patients will receive the original intervention which uses a 5-step plan, based on self-regulation theory and proactive coping, to help them translate their intentions into concrete goals and plans. The original program will be extended to 12 months and include 4 additional sessions focusing on either small, realistic goals (control condition) or more challenging goals geared to achieving an optimal diabetes management (experimental condition).

Study burden and risks

All patients will receive the original self-management course which has been proven effective. Patients will fill out 4 questionnaires and about 10ml of blood will be taken at the beginning and end of the study

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

certified diagnosis of type-2 diabetes within the last 5 years

sufficient mastery of the dutch language

Exclusion criteria

serious physical and psychiatric comorbidities

insufficient mastery dutch language

simultaneous participation in another self-management education program

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 10-02-2009
Enrollment: 300
Type: Actual

Ethics review

Approved WMO
Date: 04-03-2008
Application type: First submission
Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL20285.041.07