

Effects of online self-management support for type 2 diabetes with and without coaching: A randomized controlled trial, nested in an observational cohort study in primary diabetes care

No registrations found.

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

Summary

ID

NL-OMON20746

Source

Nationaal Trial Register

Brief title

N/A

Health condition

Type 2 diabetes mellitus (T2DM)

Sponsors and support

Primary sponsor: VU University medical center

Source(s) of monetary or material Support: Stichting Zorg Binnen Bereik

Intervention

Outcome measures

Primary outcome

Our ambition is to improve the self-care activities measured with the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire.

Secondary outcome

Symptoms of diabetes-distress will be assessed using the Problem Areas In Diabetes care (PAID) survey, 5-item version. The five items (WHO-Five) questionnaire covers positive mood, vitality and general interests. Health-related Quality of Life (HRQoL) is tested by using the EQ-5D questionnaire.

Study description

Background summary

Background

Every year the number of people with T2DM in the Netherlands increases. However the number of care providers is not growing accordingly. To keep health care available and affordable, a shift in patient treatment is necessary. A web-based self-management program has the potential of supporting T2DM patients with managing their diabetes and reducing the workload for the care provider. This study aims to test the effectiveness of online coaching within a web-based self-management program.

Research design and methods

The effects of a web-based self-management program including coaching will be tested with a nested randomized controlled trial within a healthcare group of the region Drenthe in the Netherlands. For one year 220 T2DM patients will be randomized in to an intervention group (n=110) or a control group (n=110). The intervention group will receive the online self-management program including online coaching. The control group will receive only the online self-management program. Participants will be followed for one year and will have a follow-up measurements at 3,6 and 12 months.

Discussion

The intervention being tested is set to support T2DM patients with their disease self-management and is expected to have beneficial effects on self-care activities, well being and clinical outcome measures. When proven effective this self-management support program could be offered to other health care groups and their T2DM patients in the Netherlands.

Study objective

We aim to test the hypotheses that offering additional online adaptive coaching to a web-based self-management program will be more effective than a web-based self-management program without coaching in terms of self-management behaviour without being at the expense of diabetes distress, quality of life, satisfaction with care and metabolic outcomes. We hypothesize that the self-management behaviour and biomedical outcomes will be significantly better in the group with online adaptive coaching versus those who don't receive additional adaptive coaching.

Study design

Participants will be followed for one year and will have follow-up measurements at 3, 6 and 12 months.

Intervention

110 randomized patients receive additional online coaching who provide feedback on the behaviour goals, action plans and evaluation of the executed health behaviours. The coaches serve as facilitator, and focus on process and are instructed to let the patient think for themselves.

Contacts

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Eligibility criteria

Inclusion criteria

The sample consists of people with type 2 diabetes mellitus (T2DM) who are treated in primary health care in the Drenthe region of the Netherlands. The available sample pool consists of approximately 18.500 T2DM patients.

Inclusion criteria are A diagnosis of type 2 diabetes mellitus, as registered in the primary care system under the diagnosis T90.2, and where the GP is defined as the main care giver; and aged ≥18 years.

Exclusion criteria

Exclusion criteria for the RCT are: Mental retardation or psychiatric treatment for schizophrenia, organic mental disorder or bipolar disorder currently or in the past. Insufficient knowledge of the Dutch language to understand the requirements of the study and/ or the questions posed in the questionnaires. Life expectancy <1 year due to malignancies or other terminal illnesses. Cognitive impairment, including dementia, which interferes with trial participation. Any condition that the Investigator and/or coordinating Investigator feel would interfere with trial participation or evaluation of results.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2013
Enrollment:	220
Type:	Anticipated

Ethics review

Positive opinion

Date: 08-07-2013

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	NL3902
NTR-old	NTR4064
Other	Wetenschapscommissie : WC2012-056.
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A