

Is metabole regulation of diabetes type 2 patients starting with insuline therapy improved by self-management training? An investigation into decreasing psychological barriers and exploration of etnical barriers.

Published: 20-03-2007

Last updated: 08-05-2024

The objectives of the present study are twofold:1 screening patients with diabetes type 2 for psychological risk factors and2 studying the effect of a self-management training on metabolic regulation in patients starting with insuline therapy

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

Summary

ID

NL-OMON30627

Source

ToetsingOnline

Brief title

Self management of diabetes type 2 patients

Condition

- Diabetic complications

Synonym

diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: diabetes type 2, group therapy, intercultural medicine, self-management

Outcome measures

Primary outcome

Primary outcome is HbA1c level. Secundaire medical outcome measures are systolic blood pressure and cholesterol levels.

Secondary outcome

Secondary outcome is the effect of the training on self-efficacy and self-management behavior. Furthermore, possible ethnic differences in the effectiveness of the intervention are explored.

Study description

Background summary

The prevalence of diabetes type 2 is estimated to be 5,1%, and increasing. Life style and increasing life expectancy can explain this increase. The risk of a cardiovasculair indident is about twice to four times higher and 70 to 80% of the patients die from such an incident. Furthermore, depression is prevalent in about 10 to 15 % of the patients, together with eating disorders and other psychological problems. Severe complications occur in diabetic patients, such as amputations, blindness and renal failure. The incidence of these complations can be reduced by about 50% when metabolic regulation is good and when cardiovasculair risk factors are decreased. Succesful treatment of diabetes is largely dependent on the patient himself. Only 7% of the patients are capable of adequate self-management and in 25% of the patients metabolic regulation is inadequate.

Meta-analysis showed that psychological interventions can improve metabolic regulation and reduce psychological problems. The effect size was large enough to decrease the risk of microvascular complications. Few studies have addressed patients with poor psychological functioning. Furthermore, psychological problems may form a barrier to successful treatment of diabetes. Little research is carried out into the relation of ethnicity and self-management.

Study objective

The objectives of the present study are twofold:

- 1 screening patients with diabetes type 2 for psychological risk factors and
- 2 studying the effect of a self-management training on metabolic regulation in patients starting with insulin therapy

Study design

The study is a randomised controlled study, comparing the effect of the self-management training to a waitinglist control group receiving standard medical care.

Intervention

The intervention consists of 10 weekly sessions of 2 hours in groups of 8 to 10 patients. Ingredients of the training are cognitive restructuring and behavioral techniques. Individual goals will be formulated for each patient, to improve self-management of each patient. Attention will be paid to eating and exercising, controlling glucose levels and self-care.

Study burden and risks

The burden for the participants is the time that the intervention takes. Whenever psychological stress is too much increased by the intervention, individual counseling will be provided.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

patients starting with insuline therapy

sufficient understanding of Dutch language

elevated scores on the SCL-90, but below the psychiatric range

Exclusion criteria

diagnosed psychiatric disorders

insufficient understanding of Dutch

no elevated scores on SCL-90

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-08-2007

Enrollment: 100

Type: Actual

Ethics review

Approved WMO

Date: 20-03-2007

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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

CCMO

ID

NL14800.078.07