The treatment of co-morbid emotional problems in people with diabetes type 2: Evaluation of a mindfulness-based psychological intervention

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1. To test the effectivity of a mindfulness-based psychological intervention (MBSR) aimed at increasing the emotional well-being and quality of life of patients with type 2 diabetes; 2. To examine which group of patients, with which characteristics...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON33916

Source
ToetsingOnline

Brief title
MBSR intervention in people with diabetes type 2

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes type 2; diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Diabetes Fonds

Source(s) of monetary or material Support: Diabetes Fonds

Intervention

Keyword: emotional well-being, glycaemic control, mindfulness-based intervention, randomized controlled trial (RCT)

Outcome measures

Primary outcome

Emotional well-being, some of which diabetes-related.

Secondary outcome

Quality of life, self-care, health-care consumption, glycemic control and blood

pressure.

Study description

Background summary

A considerable proportion of the patients with type 2 diabetes experience emotional problems, varying from disease-specific worries to general symptoms of anxiety and depression. This emotional well-being is related to other unfavourable outcomes, like reduced quality of life, worse self-care, reduced glycemic control, complications, and mortality. A mindfulness-based psychological intervention may increase the emotional well-being in patients with diabetes, since the intervention has proven to be successful in various other patient populations earlier.

Study objective

1. To test the effectivity of a mindfulness-based psychological intervention (MBSR) aimed at increasing the emotional well-being and quality of life of patients with type 2 diabetes; 2. To examine which group of patients, with which characteristics (like the extent of complications and personality) will benefit most from the intervention; 3. To investigate the effect of the intervention on self-care, health care consumption behaviour, glycemic control, and blood pressure.

Study design

The study is a randomized controlled trial (RCT). For the intervention there are four measurements for the experimental group and seven measurements for the wait-list control group: both groups are measured before the intervention of the experimental group (T1), at week 4 of the intervention (T2), immediately after the intervention (T3), one month after the end of the intervention of the experimental group (T4) and six months after the end of the intervention of the experimental group (T5). In addition, the T5 measurement is the pre-measurement of the control group, who will get another three measurements during and after their intervention.

Intervention

MBSR: the group mindfulness-based intervention will be given in eight weekly sessions (including one booster session) to groups of eight to ten persons. The intervention will be based on a combination of existing protocols. Besides education about the mechanisms of stress, coping, and relaxation, there will be much emphasis on practicing mindfulness (e.i. breathing, moving, and observing and letting-go thoughts with non-judgemental attention) and there will be group discussions about relevant matters concerning the exercises and daily living. Wait-list control group: the wait-list control group will continue to receive regular care (care-as-usual) and will be placed on a wait-list to receive the MBSR intervention six months later. Both interventions will be given by a psychologist.

Study burden and risks

MBSR is a widely applied and investigated intervention, for which no risks are known. Participants join eight sessions of two-and-a-half hours and at several occasions questionnaires (15 - 45 min.) are completed. In addition, no invasive treatments are performed, except two standard venipunctures. Risk is therefore minimal.

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 with type 2 diabetes
Above 18 years of age
Mastery of the Dutch language
Self-reported psychological stress complaints (using a validated questionnaire)

Exclusion criteria

Severe psychopathology (e.g., psychotic history, automutilation, suicidality)
Severe somatic comorbidity (e.g., cancer, heart failure)

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-04-2010
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	06-10-2009
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	04-05-2010
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	23-11-2010
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	16-03-2011
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL25256.008.09