

The DiaDDZOB Study: Longitudinal associations between depression, Type D personality and diabetes outcomes in primary care patients with type 2 diabetes

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

Summary

ID

NL-OMON33321

Source

ToetsingOnline

Brief title

DiaDDZOB Study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

type 2 diabetes mellitus; non insulin-dependent diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg

Source(s) of monetary or material Support: Giesje Nefs; de AiO die de gegevens zal analyseren; wordt gefinancierd vanuit eerste geldstroom (Universiteit van Tilburg / CoRPS). De infrastructuur van POZOB wordt gefinancierd door middel van 4e geldstroom gelden (verzekeraars CZ en VGZ).

Intervention

Keyword: Disease-related outcomes, Primary care, Psychosocial and lifestyle factors, Type 2 diabetes mellitus

Outcome measures

Primary outcome

The main study parameters are depressive symptomatology and Type D personality (as assessed by means of validated questionnaires). Other study outcomes include 1) the onset / progression of disease-related outcomes (glycemic control, micro- and macrovascular complications, insulin initiation, mortality); 2) quality of life and health status; 3) health care utilisation. Of further interest is the course of depressive symptoms and the possibly mediating role of lifestyle-related factors (e.g. physical activity, smoking behaviour) in the association between depressive symptomatology / Type D personality and the outcome parameters.

Secondary outcome

Not applicable

Study description

Background summary

Type 2 diabetes mellitus is a chronic and disabling metabolic disease,

affecting a growing number of patients worldwide. Treatment can be complex and burdensome, requiring a substantial degree of self-care responsibility from patients. Psychosocial factors such as depression and/or Type D personality may hamper the patients self-care activities, which in turn increase the risk for the development of diabetes complications. Increasing our understanding of the role these psychosocial factors play in determining both disease-related outcomes and utilisation of health care resources can help us to further improve diabetes care.

Study objective

The aim of the DiaDDZOB project is to examine the associations between psychosocial variables (depression, Type D personality), lifestyle factors (self-care behaviors) and diabetes outcomes (e.g. micro- and macrovascular complications of diabetes). Of further interest is the course of depressive symptomatology and the association between depression / Type D personality and quality of life, insulin initiation and health care consumption.

Study design

The current study is an observational cohort study with a prospective longitudinal design. Assessments will take place on an annual basis, during a three-year period.

Study burden and risks

The DiaDDZOB project aims to improve diabetes care and management through increasing our knowledge about the risk factors for poor prognosis, including the onset / progression of micro- and macrovascular disease. This will be accomplished by systematic recording and evaluation of disease-related, psychosocial and lifestyle parameters, in addition to health care utilisation. Knowledge about psychosocial and lifestyle factors, their interrelationship and their impact on diabetic outcomes may eventually lead to identifying patients at risk as well as provide key factors for intervention. All patients will receive regular diabetes care. The required non-invasive biological measurements are part of the regular programme. Participants are invited three times in three consecutive years to complete a questionnaire, that will take approximately 30 minutes at most. The burden for patients who decide to participate is thus minimal. Patients will not receive any special incentives, compensation or treatment for their participation in the study.

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

The patient has type 2 diabetes mellitus

The main health care provider at time of entry in the study is the primary care nurse practitioner (PO) / general practitioner

The patient is at least 18 years old

The patient has sufficient mastery of the Dutch language

Exclusion criteria

The patient has a condition that causes hyperglycemia other than type 2 diabetes mellitus

The patient is physically and/or mentally incapable of completing a questionnaire, as judged by the PO (e.g. co-morbid dementia, terminal cancer)

The patient does not consent that the general practitioner is notified of deviant scores on the questionnaire

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-01-2010

Enrollment: 10000

Type: Actual

Ethics review

Approved WMO

Date: 07-12-2009

Application type: First submission

Review commission: METC Maxima Medisch Centrum (Veldhoven)

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	NL27239.015.09