# Depressive symptoms, sleep quality and cognitive functioning in outpatients with type 2 diabetes

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The aim of this study is to investigate the prevalence of impaired cognitive functioning in outpatients with DMT2. Second, we will investigate the relationship between impaired cognitive functions and sociodemographic factors, clinical features and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Diabetic complications
Study type	Observational non invasive

# Summary

## ID

NL-OMON41784

**Source** ToetsingOnline

#### **Brief title**

Depressive symptoms, sleep quality and cognitive functioning in diabetics

## Condition

• Diabetic complications

**Synonym** Diabetes mellitus, sugar diabetes

**Research involving** Human

## **Sponsors and support**

Primary sponsor: Universiteit van Tilburg Source(s) of monetary or material Support: Ministerie van OC&W

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## Intervention

Keyword: cognition, depression, diabetes, sleep

### **Outcome measures**

#### **Primary outcome**

- Cognitive functioning will be measured in three domains; memory,

information-processing speed and attention & executive functioning

o Memory

- \* Rey cft
- \* 15 woordentest
- \* Digit span WAIS-IV-NL
- o Information-processing speed
- \* TMT-A
- \* Stroop part 1 & 2
- o Attention & executive functioning
- \* TMT-B
- \* Stroop part 3
- \* Letter fluency
- \* Modified Wisconsin cart sorting task
- Depressive symptoms will be measured the PHQ-9 questionnaire.
- Sleep quality will be measured with the Pittsburgh sleep quality index.

#### Secondary outcome

The following factors will be measured and analysed:

HbA1c, Blood pressure, Cholesterol, Any macrovascular event, Diabetes duration,

History of hypertension, Hypoglycemic events, Stroke or cardiovascular disease.

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The following factors will be measured because they might intervene with the

study parameters:

Medication use, Smoking and alcohol consumption habits, BMI, Head trauma.

# **Study description**

#### **Background summary**

Diabetes mellitus has become a point of major concern around the world. It is estimated that the total number of persons with diabetes will increase to 366 million in 2030. Diabetes type 2 accounts for 90-95% of the cases. It is associated with a variety of secondary complications. Diabetes type 2 can damage multiple organs including the eyes, kidneys, heart and brain. This article focuses on brain related complications in diabetes. Research indicates that cognitive impairment and depression are among the most common brain related complications in DM. DM patients are 1.5 times more likely to experience cognitive decline, with research showing that 25.8% of persons with DM had cognitive impairment. These impairments are consistently found in the domains of memory, information-processing speed, and attention and executive functioning. DMT2 is also associated with a high prevalence of depression. At least 10-30 of DM patients suffer from elevated depressive symptoms and approximately 10% from a major depressive disorder. The guestion arises if depression and cognitive impairment share the same aetiologies in DMT2: both conditions may have shared risk factors. Research indicates a few underlying mechanisms for the occurrence of depression in persons with DMT2 and possible underlying mechanisms for the relationship between cognitive impairment and depression. An example is, DMT2 is associated with a decreased insulin production or receptor resistance to insulin in its target tissues. The central insulin receptors are mainly localised in the hippocampus, olfactory bulbs and hypothalamus. As a part of the limbic system,

the hippocampus takes part in neuroendocrine responses to emotional stressors. Under these stressors, the release of acetylcholine in the hippocampus increases. At the same time the plasma glucose will elevate. As mentioned before, a high level of glucose can result in accumulation of advanced glycation end-products, which has a toxic effect on neurons in the brain. Emotional stressors like depression, activate the amygdala as a part of the limbic area. Amygdala activation leads to elevated cortisol levels, which is known as a stress hormone. A high level of cortisol can result in insulin resistance of the tissue, a decrease in glucose uptake by muscles and plasma glucose will be elevated. Which can lead to more AGE\*s and impaired cognitive functioning. Besides this example research indicates more possible underlying mechanisms. Based on above-mentioned facts, we might assume that there are some underlying mechanisms or interactions between cognitive functioning and depression in persons with DMT2. Research on the relation between cognitive impairment and depression in patients with DMT2 has been conducted several times, but findings differ. Previous studies were mainly conducted in primary care units and had important methodological limitations. The prevalence rates of depression and cognitive impairments were at the lower end of the range of differences between persons with DMT2 and control group. This indicates that the research group may not have been an accurate reflection of the diabetic population. This also accounts for the HbA1c of the participants, participants had mainly well controlled diabetes in earlier studies. In contrast to primary care, patients in an out-patient clinic report more depressive symptoms and have higher comorbidity rates. Based on above-mentioned mechanisms we assume that there is a negative relationship between depressive symptoms and cognitive functioning in DMT2 patients.

#### **Study objective**

The aim of this study is to investigate the prevalence of impaired cognitive functioning in outpatients with DMT2. Second, we will investigate the relationship between impaired cognitive functions and sociodemographic factors, clinical features and depressive symptoms.

The following hypotheses will be investigated:

- There is a negative relationship between depressive symptoms and cognitive functioning
- There is a negative relationship between sleep quality and cognitive functioning
- The relationship between cognitive functioning and HbA1c is explained by depressive symptoms and/or sleep quality
- There is a negative relationship between sleep quality and depressive symptoms
- The relationship between subjective cognitive functioning and depressive symptoms is stronger than the relationship between objective cognitive functioning and depressive symptoms

The aim of this research is to increase the knowledge about the comorbidity of diabetes type 2. Research about cognitieve functioning in outpatients with diabetes type 2 is rare. Findings can give more insight in the identification of psychosocial or cognitive problems in patients with diabetes. Additional diagnostics or treatment can be handed and the quality of healthcare will be improved. Research findings will be shared within the profession.

#### Study design

The nurses of the department of diabetes will make a list of eligable patients.

The researcher will approach these patients with a introduction letter and an informed consent form. If patients want to participate they receive an information letter which two questionnaires; PHQ-9 and the PSQI. Additional, participants attend the hospital for one day in which a neuropsychological examination will be conducted. Clinical characteristics will be obtained from medical records (HbA1c, blood pressure, cholesterol, any macrovascular event, BMI).

The examination starts with a standardized interview in which additional medical data are collected. A neuropsychological test battery will be administered, which will adress the domains memory, information-processing speed and attention and executive functioning. The following tests will be administered:

- Rey cft
- 15 woordentest
- digit span WAIS-IV-NL
- TMT A/B
- Stroop 1/2/3
- M-WCST
- LFT
- NLV

Thereafter a structured interview about subjective cognition will take place. The appointment will take about 1.5 hour to complete.

#### Study burden and risks

The risk of this study is negligible. Patients can experience fatigue during the neuropsychological assessment but this is not harmfull for their health. If scores from assessment indicate problems, patients are only approximated when they have given permission on their informed consent form. The obtained findings of this study are important for the profession and quality of healthcare. Due to the low risk, this research is justified.

# 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**

Inclusion criteria for this study are patients with diabetes type 2 between 55 and 80 years of age. Participants need to have a minimal diabetes duration of one year, need to be functionally independent and capable of understanding the Dutch language. Since comorbidity is a part of the diabetic condition, participants with diabetes-related conditions will be included.

## **Exclusion criteria**

Exclusion criteria are a history of alcohol or substance abuse and all other psychiatric or neurological disorders.

# Study design

## Design

Study type:Observational non invasiveMasking:Open (masking not used)Control:Uncontrolled

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Primary purpose:

Diagnostic

# Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-02-2015
Enrollment:	50
Type:	Anticipated

# **Ethics review**

Approved WMO	
Date:	25-02-2015
Application type:	First submission
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 CCMO ID NL52242.028.15