

# The correlation between the quality of life using the World Health Organization Quality of Life Assessment questionnaire (WHOQOL-BREF) and Glycated Haemoglobin (HbA1c) in patients with diabetes

<b>Submission date</b> 24/05/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/06/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 31/12/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Patients with diabetes have a lower quality of life compared with individuals without diabetes in the same age group, and the quality of life in diabetes patients continues to deteriorate with disease progression and complications. Diabetes imposes a considerable economic burden on the society as a whole, and on individual patients and their families. Reduced quality of life in diabetes patients through disability, diabetes complications and loss of productivity may negatively influence economic progress. Better quality of life may also improve adherence to diabetes therapy and also may lead to better glucose control and fewer complications. This study will examine the correlation between glucose control and the WHOQOL-BREF quality of life score and also the relationship between the quality of life score and the Hba1C value.

### Who can participate?

Patients aged 18 to 80 with diabetes type 1 or type 2

### What does the study involve?

Quality of life is evaluated using the WHOQOL-BREF questionnaire form. Glucose control is measured using HbA1c value in the medical notes and type of diabetes treatment is measured using outpatient data and medical notes.

### What are the possible benefits and risks of participating?

The aim of this study is to measure and improve quality of life for diabetes patients in the diabetes outpatient clinic. It is a survey using a questionnaire and there will be no risks for the participants.

### Where is the study run from?

Melk General Hospital (Austria)

When is the study starting and how long is it expected to run for?  
February 2018 to February 2020

Who is funding the study?  
Melk General Hospital (Austria)

Who is the main contact?  
Dr Nawras Altaie

## Contact information

**Type(s)**  
Public

**Contact name**  
Dr Nawras Al-taie

**Contact details**  
Landeskrankenhaus Melk Krankenhausstraße 11  
Melk  
Austria  
3390 Melk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
GS1-EK-4/493-2017

## Study information

### Scientific Title

The correlation between the quality of life using the World Health Organization Quality of Life Assessment questionnaire (WHOQOL- BREF) and Glycated Haemoglobin (HbA1c) in patients with diabetes

### Study objectives

This study will examine the correlation between glycemic control and WHOQOL-BREF scale score and also the relationship between the quality of life score and the HbA1C value. This study will examine the internal consistency, responsiveness and the reliability of the WHOQOL-BREF scale and its four domains (Physical health, Physical health, Social relationships and Environment) for patients living with diabetes in Austria.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics board for the government of Lower Austria region, 21/08/2017, ref: GS1-EK-4/493-2017

**Study design**

Observational cross-sectional study

**Primary study design**

Observational

**Secondary study design**

Cross sectional study

**Study setting(s)**

Hospital

**Study type(s)**

Quality of life

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

Diabetes mellitus type 1 and type 2

**Interventions**

The data is collected over 6-12 months. Quality of life is assessed using the WHOQOL-BREF questionnaire.

The latest HbA1c is documented for each patient in their WHOQOL-BREF questionnaire form. Patients will be further subdivided into different groups according to their diabetes therapy (the patient should be on this therapy for at least 6 months).

**Intervention Type**

Other

**Primary outcome measure**

1. Quality of life, measured using the German version of WHO-BREF at 2 years
2. Glycemic control, measured using HbA1c value in the medical notes at 2 years

**Secondary outcome measures**

Type of diabetes treatment, measured using outpatient data and medical notes at 2 years

**Overall study start date**

01/02/2018

**Completion date**

01/02/2020

# Eligibility

## Key inclusion criteria

Current inclusion criteria as of 24/08/2018:

1. Patients with diabetes both type 1 and type 2
2. Age range between 18 and 80 years old

Previous exclusion criteria:

1. Patients with diabetes both type 1 and type 2
2. Age range between 18 and 65 years old

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

250

## Total final enrolment

223

## Key exclusion criteria

Current exclusion criteria as of 24/08/2018:

1. Gestational diabetes
2. Patients younger than 18 and older than 80

Previous exclusion criteria:

1. Gestational diabetes
2. Patients younger than 18 and older than 65

## Date of first enrolment

01/03/2018

## Date of final enrolment

01/03/2019

# Locations

## Countries of recruitment

Austria

**Study participating centre**  
**Melk General Hospital**  
Melk  
Austria  
3390

## **Sponsor information**

**Organisation**  
Landeskrankenhaus Melk

**Sponsor details**  
Krankenhausstraße 11  
Melk  
Austria  
3390

**Sponsor type**  
Hospital/treatment centre

## **Funder(s)**

**Funder type**  
Hospital/treatment centre

**Funder Name**  
Melk General Hospital

## **Results and Publications**

### **Publication and dissemination plan**

Planned to be published in a peer-reviewed journal related to diabetes and with a high impact factor. The trialists also plan to present this study at national and international meetings to increase awareness about quality of life in diabetic patients.

**Intention to publish date**  
01/02/2021

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Nawras Al-Taie.

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	16/12/2019	31/12/2019	Yes	No
<a href="#">Results article</a>	results	01/09/2011	31/12/2019	Yes	No