# The impact of self-quarantining on diabetes self-management and distress during the coronavirus outbreak

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The current study aims to assess the impact of self-quarantine on glycemic control. In addition, this study describes diabetes self-management, well-being and distress in Dutch patients with type 1 and type 2 diabetes, during a nationwide period of...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Diabetic complications |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON49865

**Source**
ToetsingOnline

**Brief title**
COVID-19 glycemic control study

### Condition

- Diabetic complications

**Synonym**
diabetes, diabetes mellitus

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Diabetes self-management, Distress, Glycemic control, Self-quarantine

## Outcome measures

### Primary outcome

To determine the effect of a period of nationwide self-quarantine on glycemic control, assessed by HbA1c, in patients with type 1 and type 2 diabetes

### Secondary outcome

- To determine the effect of a period of nationwide self-quarantine on glucose variability assessed by the standard deviation (SD) of glucose values (glucose variability) in patients with type 1 and type 2 diabetes

- To assess the association between (diabetes) distress and glycemic control during a period of nationwide self-quarantine. (Diabetes) distress will be measured by *Perceived Stress Scale*(PSS) and *Problem Areas in Diabetes* (PAID).

- To assess the association between well-being and glycemic control during a period of nationwide self-quarantine. Well-being will be measured by the WHO-5.

- To assess the association between between diabetes self-management and glycemic control during a period of nationwide self-quarantine. Self-management behaviour will be measured by the *Summary of Diabetes Self-Care Activities* (SDSCA) and *Diabetes Self-Management Questionnaire-rev.* (DSMQ-R)

- To determine differences HbA1c, glucose variability, well-being, distress and self-management between patients with type 1 and type 2 diabetes

# Study description

### Background summary

The last few months have been characterized by the viral outbreak of COVID-19 and the measures and precautions that came along with this pandemic. In all affected countries these strategies required major adaptations of behavioral patterns, social activities and employment of the population.
Such sudden and major disruptions from every-day-life are known to influence both mental and physical health. Recent studies describing the psychological impact of quarantine, showed that experiencing quarantine is related to a wide range of stress and mood related symptoms, such as depression, anxiety, irritability, poor concentration, insomnia and post-traumatic stress disorder (PTSD). Longer periods of quarantine have been associated with increased chances of developing PTSD. In addition, several studies suggest that such symptoms might even last long after ending quarantine.
Recent studies and global media suggest that individuals with diabetes mellitus (DM) are more likely to be infected and are at a higher risk for complications and death from COVID-19. People with diabetes and their relatives may therefore experience increased feelings of stress, fear and anxiety regarding the risk of being infected with COVID-19. And additionally, may put even greater emphasis on the importance of self-quarantine.
Emotional distress as well as changes in daily structures and behaviors are known to influence diabetes self-management and glucose regulation. Maintaining glycemic control during self-quarantine can therefore be challenging. Alterations in physical activity, diet and daily patterns may result in an imbalance between blood glucose values and the amount of insulin injected or other drugs prescribed, resulting in glycemic dysregulation

### Study objective

The current study aims to assess the impact of self-quarantine on glycemic control. In addition, this study describes diabetes self-management, well-being and distress in Dutch patients with type 1 and type 2 diabetes, during a nationwide period of self-quarantine.
It is hypothesized that experiencing this period of nationwide quarantine influences glycemic control and that patients reporting severe distress or low well-being experience more problems in regard to diabetes self-management and maintaining glycemic control than those without psychological distress or low well-being.

### Study design

This is an observational cross-sectional study.
Patiënts will perform an HbA1c fingerprik, fill out a questionnaire about

stress, general well-being and self-management and data of the continuous or FreeStyle Libre sensor over the last 3 months (only if they have a sensor) will be collected, once.

### Study burden and risks

The burden of participation exists out of the fingerprick measurement of the HbA1c. Participation in this study will cost the patient circa 60 minutes of their time. The HbA1c fingerprick measurement can result in a short-lasting period of discomfort. However, many patients with diabetes peform such fingerprick measurements regularly to measure their blood glucose values. The risk of participation is low. Potentially filling out the questionnaires on distress and well-being may result in an increased focus on these feelings.

## 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

- Type 1 or type 2 diabetes mellitus
- 18 years or older
- Ability to perform fingerprick HbA1c self-measurement
- Sufficient Dutch language comprehension
- Ability to fill out online questionnaire

### Exclusion criteria

- Pregnancy
- Newly diagnosed malignancy, with the exclusion of non-melanoma skin cancer, in the previous 6 months
- Chemotherapy or immunotherapy for malignancy
- Admission to hospital or rehabilitation center

## Study design

### Design

**Study type:** Observational invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Other |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 02-05-2020 |
| Enrollment: | 318 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 29-04-2020 |

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| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |
| Approved WMO Date: | 07-05-2020 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

# 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 | NL73778.058.20 |

# Study results

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| Date completed: | 01-03-2021 |
| Actual enrolment: | 492 |