Diabetes by distraction? The effect of Distracted Consumption on glucose fluctuations

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To investigate the effect of distracted consumption on glucose variability in women with GDM and to investigate moderating effects of type of distractor and perceived stress.

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

Summary

ID

NL-OMON56596

Source
ToetsingOnline

Brief title
DisCoVar

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
gestational diabetes mellitus; pregnancy diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Leids Universiteits Fonds

Intervention

Keyword: Distracted Consumption, Gestational Diabetes Mellitus, Glucose variability

Outcome measures

Primary outcome

Glucose profiles in response to meals eaten with and without distraction.

Secondary outcome

• type of distractor

• perceived stress

Study description

Background summary

Gestational diabetes mellitus (GDM) is defined as diabetes diagnosed in the second or third trimester of pregnancy that was not clearly overt diabetes prior to gestation. GDM is associated with adverse outcomes for mother and child. Women with GDM have greater blood glucose fluctuation or glycemic variability (GV), which is a strong predictor of complications for both the child and the mother, during and after delivery. In this study, we propose that not only the amount and contents of food affect GV but eating manners (with or without distraction) may also affect GV in GDM. Nowadays, people pay less and less attention to their meals, often engaging in other activities simultaneously. Since mental capacity is limited, this resulted in less sensory information such as taste. This decreased sensory processing due to distracted consumption may dysregulate the glucose-insulin signalling pathway, resulting in (mild) hyperglycemia and increased GV. In women with GDM post-prandial glucose levels and GV are higher than in people with normal glucose tolerance. This may make women with GDM more susceptible to the dysregulating effects of distracted consumption, which might further exaggerate GV and post-prandial hyperglycemia and increase the risk for negative health outcomes for mother and child.

Study objective

To investigate the effect of distracted consumption on glucose variability in women with GDM and to investigate moderating effects of type of distractor and

perceived stress.

Study design

Observational study. Participants eat a standardized snack at the lab two times, one meal with distraction, completing a computer task, and one meal without distraction. During the meals, glucose levels will be monitored using continuous glucose monitoring (CGM). In the week in between the lab visits, glucose levels will be measured with CGM and distractions during meals and meal content will be measured via a questionnaire filled out via smartphone.

Study burden and risks

This type of paradigm poses no significant risk. Participants monitor their blood glucose levels with a finger stick as part of their regular treatment, for this study they will be asked to do this two additional times. Furthermore, participants will have a snack in the lab during two lab visits (30 min per session). This snack consists of two cereal bars containing a total of 30 g of carbohydrates including 6 g sugar. This particular snack has been carefully chosen by a dietician to provide a slight increase in blood glucose levels. In comparison to the oral glucose tolerance test used for diagnosing GDM, which contains 75 grams of sugar, this snack contains relatively low amounts of sugar and carbohydrates and would fit in a normal diet. Additionally, glucose levels will be monitored using continuous glucose monitoring (CGM), consisting of a sensor inserted under their skin, on the arm, using an automatic inserter. The sensor measures interstitial glucose level. This technique is already implemented in routine care for patients with insulin use, also in pregnancy, furthermore it is painless and does not pose any substantial risks. Finally, participants will fill out some short questions via their smartphone. In summary, the risk associated with participation is assessed as low and the burden as minimal.

Contacts

Public
Universiteit Leiden

Wassenaarseweg 52 100
Leiden 2333AK
NL
Scientific
Universiteit Leiden

Wassenaarseweg 52 100

Leiden 2333AK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Have been diagnosed with gestational diabetes mellitus in the second or third trimester of pregnancy
• Have given their written informed consent
• Above 18 years old
• Fluent in Dutch or English

Exclusion criteria

• Insulin or oral glucose lowering drug use
• Daily smoking
• Multiple pregnancy
• History of medical or surgical interventions that may affect metabolism or glucose management

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-03-2025
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	23-01-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	10-02-2025
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) 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	NL82443.058.22