# Continuous glucose monitoring during diets that differ in glycemic load

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To assess the ability of the CGM device to monitor differences in glucose concentrations during two diets, that differ in glycemic load (GL).

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON43100

**Source**
ToetsingOnline

**Brief title**
GLOW
Glucose LOWering

### Condition

- Other condition

**Synonym**
Glucose metabolism, risk factor for type 2 diabetes mellitus

**Health condition**

Metabolisme

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Unilever
**Source(s) of monetary or material Support:** Unilever R&D;Vlaardingen

## Intervention

**Keyword:** Continuous Glucose Monitoring, Glycemic load, Human intervention study

## Outcome measures

### Primary outcome

The difference in 2-hour postprandial glucose concentrations between the low GL and the high GL diets, as measured with the CGM device. For this, the positive incremental area under the curve during two hours (+iAUC0-2h) after the three main meals (breakfast, lunch, dinner) for each of the three days of each dietary period will be calculated.

### Secondary outcome

Differences in glucose concentrations between the low and the high GL diets as quantified by the total area under the curve (tAUC) for the full 3 days and also for daytime [07:00-22:00] and night-time [22:01-06:59]; the difference in glucose variability between the low and the high GL diets; and the agreement between venous plasma glucose concentrations and CGM values.

# Study description

### Background summary

Larger increases in blood glucose during the postprandial state may contribute to the risk for developing chronic disease. Historically, glucose was measured in blood collected by finger sticks but recently Continuous Glucose Monitoring (CGM) devices have been developed for diabetes patients. These devices measure glucose in the interstitial fluid for several days and report glucose

concentrations that mirror those in capillary blood. A CGM device that has become available very recently is smaller, easier to wear, collect data for longer periods and does not require frequent calibration against fingersticks anymore. That should make this device ideal for use in healthy subjects during dietary interventions.

## Study objective

To assess the ability of the CGM device to monitor differences in glucose concentrations during two diets, that differ in glycemic load (GL).

## Study design

Single-blind (those collecting and analysing data), randomized, cross-over study comparing two diets varying in glycemic load. Subjects will consume both diets for three days separated by a washout/recovery of 2* days.

## Intervention

Subjects will receive a low and a high glycemic load diet in random order. Contrast in the intakes of available carbohydrates and glycemic index of those diets will be maximised within the limits of what can still be considered a normal diet by using off the shelf food and beverage products.

## Study burden and risks

Before the start of the study subjects will be screened to determine eligibility during one 20 min visit. At screening, body weight, and height will be measured and a blood sample (2 mL) will be drawn via venapunction. Subjects will be asked to fill in a medical and general questionnaire, including information on physical activity. The study starts with an instruction meeting (30 min) and the application of the CGM sensor (30 min). Subjects will receive food items differing in glycemic load and will be instructed to substitute these products into their habitual diets during two periods of three days. They will be asked to wear an activity tracker during those two periods. The subjects will also participate in two postprandial tests immediately after the two dietary interventions. After arriving at the university in a fasted state, an intravenous cannula will be inserted into their antecubital vein. Before and after consumption of a meal consisting of 200 grams white rice, eighteen blood samples (nine samples of 2 ml for plasma glucose and nine samples of 4 ml EDTA samples for plasma insulin) will be drawn during a five hour period. Subjects will be asked to keep a study-diary during both dietary interventions of three days each, registering intake of food and beverages, as well as any signs of illness, medication used, and any deviations from the protocol. Blood sampling might cause some bruising or hematoma. In very rare cases the adhesive of the CGM may cause allergic reactions. Total time investment for the subjects will

be approximately 12 hours.

## 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

- Apparently healthy men and post-menopausal women (post-menopausal for at least one year)
- BMI >= 25.0 and <= 35.0 kg/m2
- Age: 50-70 yrs
- Signed informed consent

### Exclusion criteria

- Having a medical conditions which might affect the study measurements.
- Reported use of over-the-counter or prescribed medication or food supplements, which may interfere with study measurements.
- Use of oral antibiotics 40 days or less prior to the start of the study
- Reported participation in another nutritional or biomedical study 3 months before the screening or during the study
- Reported participation in night shift work 2 weeks prior to screening or during the study.
- Reported intense sporting activities > 2h/w.
- Reported alcohol consumption > 10 units/week (female) or > 14 units/week (male)
- Reported use of any nicotine containing products in the 6 months preceding the study and willing to abstain from use of nicotine containing products during the study.
- Reported dietary habits: medically prescribed diet, slimming diet, vegetarian.
- Reported weight loss/gain (> 3 kg) in the last 2 months before the study.
- Blood donation in the past 3 months
- Known allergy or intolerance to food products.

## Study design

### Design

**Study type:** Interventional

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| Masking: | Single blinded (masking used) |
| Control: | Uncontrolled |
| Primary purpose: | Prevention |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 16-02-2017 |
| Enrollment: | 23 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 21-12-2016 |

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| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

# 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 |
|---|---|
| ClinicalTrials.gov | NCT02926118 |
| CCMO | NL58974.068.16 |