

# Impact of a device that continuously measures glucose levels and patient education using written information and a consultation with a physician specialising on diabetes on patients with prediabetes identified by point-of-care tests in community pharmacies

<b>Submission date</b> 10/04/2026	<b>Recruitment status</b> Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 10/04/2026	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/04/2026	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific, Principal investigator, Public

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## Additional identifiers

# Study information

## Scientific Title

Impact of continuous glucose monitoring and patient education on patients with prediabetes identified by point-of-care tests in community pharmacies

## Acronym

CGM-Pharm

## Study objectives

1. To investigate the effects of continuous glucose monitoring and patient education on HbA1c% concentrations in patients with prediabetes.
2. To investigate the number of patients with elevated HbA1c levels in point-of-care screening tests in community pharmacies (>5.7%; 5.7-6.4%; ≥6.5%)
3. To investigate the effects of continuous glucose monitoring and patient education on various glucose indices in patients with prediabetes (e.g., time in range, time above range, estimated HbA1c%, mean glucose, continuous overall net glycemic action [CONGA, 1h-, 2h-, 4h-based], standard deviation, coefficient of variability, mean amplitude of glycemic excursions [MAGE], etc).
4. To investigate the successful referral rate to treating physicians in patients with HbA1c levels compatible with diabetes (≥6.5%) when using short-message-service-based reminders
5. To investigate the successful referral rate to treating physicians in patients with HbA1c levels compatible with prediabetes (5.7-6.4%), when using short-message-service-based reminders
6. To semiquantitatively assess the patient experiences with continuous glucose monitoring and the consultation

## Ethics approval required

Ethics approval required

## Ethics approval(s)

1. approved 08/04/2026, Ethics committee of the city of Vienna (Thomas-Klestil-Platz 8/2, TownTown - Eingang: 3, Vienna, 1030, Austria; +43 (0)1 4000-87754; ethikkommission@ma15.wien.gv.at), ref: EK\_25\_251\_0326
2. approved 27/02/2026, Ethics Committee of the Medical University of Vienna (Borschkegasse 8b/E06, Vienna, 1090, Austria; +43 (0)1 4040021470; ethik-kom@meduniwien.ac.at), ref: 2346/2025

## Primary study design

Interventional

## Allocation

Randomized controlled trial

## Masking

Open (masking not used)

## Control

Placebo

## **Assignment**

Parallel

## **Purpose**

Prevention, Screening, Treatment

## **Study type(s)**

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

Prediabetes defined as having an HbA1c of  $\geq 5.7\%$  and  $\leq 6.4\%$

## **Interventions**

Randomization will be conducted with a web-based program available at <https://www.meduniwien.ac.at/randomizer> using permuted blocks of variable size.

A continuous glucose measurement sensor will be applied in the control group after randomization and after 4-6 weeks. Furthermore, patients will receive written information on prediabetes. After 4-9 days of wearing the sensor, a phone consultation with a diabetes specialist will be conducted, in which blood sugar levels and their relationship with food intake will be explained and discussed.

In the control group, patients will receive written information at the beginning of the study, a sensor after 3 months and a phone consultation.

## **Intervention Type**

Mixed

## **Primary outcome(s)**

1. HbA1c% measured using capillary blood samples and point-of-care devices at baseline to 3 months

## **Key secondary outcome(s)**

1. Number of patients at screening with HbA1c  $\geq 5.7\%$  measured using capillary blood samples and point-of-care devices at baseline

2. Number of patients at screening with HbA1c  $\geq 6.5\%$  measured using capillary blood samples and point-of-care devices at baseline

3. Number of patients at screening with HbA1c  $\geq 5.7\%$  and  $\leq 6.4\%$  measured using capillary blood samples and point-of-care devices at baseline

4. Successful referral rate to treating physicians for patients with HbA1c of  $\geq 6.5\%$  using short-message-service-based reminders measured using telephone call or email confirmation at 3 months after study HbA1c quantification

5. Successful referral rate to treating physicians for patients with HbA1c of 5.7-6.4% using short-message-service-based reminders measured using telephone call or email confirmation at 3 months after study HbA1c quantification

6. Successful referral rate to treating physicians for patients with HbA1c of  $\geq 5.7\%$  using short-message-service-based reminders measured using telephone call or email confirmation at 3 months after study HbA1c quantification
7. HbA1c% concentrations after 6 months compared to baseline between interventional group and control group measured using HbA1c% measured using capillary blood samples and point-of-care devices at baseline to 6 months
8. In the control group: HbA1c% concentrations after 6 months (3 months after continuous glucose measurement Phase) vs baseline and vs 3 months measured using capillary blood samples and point-of-care devices at 3 months to 6 months
9. Various glucose indices compared between continuous glucose measurement Phase 1 and continuous glucose measurement Phase 2 in the interventional group (Time in Range, Time in Tight Range, continuous overall net glycemic action (CONGA)- 1h, CONGA-2h, CONGA-4h, mean glucose, median glucose, standard deviation of glucose, coefficient of variation of glucose, mean amplitude of glycemic excursions (MAGE), Mean of Daily Differences (MODD), time below range, time above range) measured using blood sugar concentrations quantified by continuous glucose measurement device at CGM phase 1 (first 10-14 days) and CGM Phase 2 (second 10-14 days), which takes place 4-6 weeks after randomization
10. Various glucose indices within the continuous glucose measurement Phase 1 (in the intervention and control group) comparing the first 50% and the second 50% of the continuous glucose measurement duration (maximum 14 days, minimum to be eligible 7d, e.g. if the sensor is worn for 10 days – 5 vs 5 days) measured using blood sugar concentrations quantified by continuous glucose measurement device at CGM Phase 1 first half vs second half
11. Patient experiences with continuous glucose monitoring and the consultation measured using questionnaire, Likert Scale at 3 months (interventional group); 6 months (control group)

### **Completion date**

13/04/2028

## **Eligibility**

### **Key inclusion criteria**

1.  $\geq 18$  years of age
2. Screening is recommended by the Austrian Diabetes Society:  $>45$  years of age, or  $>35$  years of age with  $\geq 1$  risk factor:
  - 2.1. First-degree relatives with diabetes
  - 2.2. BMI  $\geq 25$  kg/m<sup>2</sup> (or  $\geq 23$  kg/m<sup>2</sup> for people with Asian descent)
  - 2.3. Metabolic syndrome
  - 2.4. Arterial hypertension
  - 2.5. Dyslipidemia
  - 2.6. Steatosis hepatis
  - 2.7. History of gestational diabetes
  - 2.8. Polycystic ovary syndrome

### **For Interventional Trial:**

1. HbA1c% of  $\geq 5.7\%$  and  $\leq 6.4\%$
2. Willingness to participate in the study and comply with the study's requirements:

- 2.1. To wear a continuous glucose monitoring sensor for the projected time (maximum 14 days)
- 2.2. To share quantified glucose concentrations with the study team
- 2.3. To participate in all planned visits within the planned time-frame
- 2.4. To document their food intake during CGM periods (e.g., via taking photos or notes)
- 2.5. To have a smartphone

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

For Screening Part:

1. Prior diagnosis with prediabetes or diabetes
2. Treatment with antidiabetic drugs

For Interventional Trial:

1. Inability to comply with the trial's requirements
2. Skin conditions or prohibiting the use of a glucose monitor (wounds, eczema, dermatitis, infections, sunburns, etc)
3. Allergies or intolerances against the sensor or its materials/constituents, e.g., allergies against acrylic adhesive, isobornyl acrylate (IBOA), polyurethane, epoxy resins, plaster and tapes
4. Pregnancy or breastfeeding
5. Planned magnetic resonance imaging or computed tomography scans during the times when the CGM should be worn
6. Planned treatment with diathermy
7. Pregnancy – females with an ongoing pregnancy with prediabetes must not participate in the trial
8. Intake of methyl dopa or high doses of Vitamin C (>500 mg/day or intravenous Vitamin C)
9. Intake of systemic corticosteroids

**Date of first enrolment**

13/04/2026

**Date of final enrolment**

13/04/2027

# Locations

## Countries of recruitment

Austria

## Study participating centre

**Medical University of Vienna, Department of Clinical Pharmacology**

Währinger Gürtel 18-20

1090

Austria

1090

## Study participating centre

**Apotheke Trillerpark**

Trillergasse 4/16

Vienna

Austria

1210

## Study participating centre

**Mariatroster Apotheke "Zum hl. Ulrich"**

Burggasse 2

Vienna

Austria

1070

## Study participating centre

**Siebenbrunnen Apotheke**

Siebenbrunnengasse 32

Vienna

Austria

1050

## Study participating centre

**Marien-Apotheke**

Schmalzhofgasse 1

1060

Austria

1060

**Study participating centre**  
**Columbus Apotheke**  
Favoritenstraße 73  
Vienna  
Austria  
1100

**Study participating centre**  
**Ludwigs-Apotheke**  
Simmeringer Hauptstraße 128  
1110  
Austria  
1110

**Study participating centre**  
**Apotheke zum Heiligen Joseph**  
Schönbrunner Straße 194-196  
Vienna  
Austria  
1120

**Study participating centre**  
**Apotheke am Lainzer Platz**  
Lainzer Straße 139  
Vienna  
Austria  
1130

**Study participating centre**  
**Apotheke Maria vom Siege**  
Mariahilferstraße 154  
Vienna  
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**Study participating centre**  
**Linden-Apotheke**  
Hernalser Hauptstraße 155

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**Study participating centre**  
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**Study participating centre**  
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Erzherzog-Karl-Straße 84-88  
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**Study participating centre**  
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Schönbrunner Straße 259  
Vienna  
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# Sponsor information

## Organisation

Medical University of Vienna

## ROR

<https://ror.org/05n3x4p02>

# Funder(s)

## Funder type

## Funder Name

Austrian Chamber of Pharmacists

## Funder Name

Roche

## Alternative Name(s)

F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co., Roche Holdings, Inc.

## Funding Body Type

Government organisation

## Funding Body Subtype

For-profit companies (industry)

## Location

Switzerland

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not expected to be made available