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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

Submission date
10/04/2026

Recruitment status
Recruiting

Registration date
10/04/2026

Overall study status
Ongoing

Last Edited
11/05/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 ≥5.7% and ≤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 ≥5.7% measured using capillary blood samples and point-of-care devices at baseline

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

3. Number of patients at screening with HbA1c ≥5.7% and ≤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 ≥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 ≥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. ≥18 years of age
2. Screening is recommended by the Austrian Diabetes Society: >45 years of age, or >35 years of age with ≥1 risk factor:
2.1. First-degree relatives with diabetes
2.2. BMI ≥25 kg/m² (or ≥23 kg/m² 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 ≥5.7% and ≤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 methyldopa 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
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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
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1070

Study participating centre
Siebenbrunnen Apotheke
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Study participating centre
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1060

Study participating centre
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
Medical University of Vienna

ROR
https://ror.org/05n3x4p02

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Funder type

Funder Name
Austrian Chamber of Pharmacists

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Roche

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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.5	14/04/2026	11/05/2026	No	No