

The effect of a structured group education programme combined with continuous glucose monitoring in people with type 2 diabetes on non-insulin therapy

Submission date 02/10/2026	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 02/10/2026	Overall study status Ongoing	☐ Protocol
Last Edited 02/10/2026	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☒ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Public, Principal investigator, Scientific

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Study information

Scientific Title

Structured group education combined with real-time continuous glucose monitoring compared to standard education in adults with type 2 diabetes on non-insulin therapy evaluating glycemic effects and diabetes distress

Acronym

TABLETKA

Study objectives

Ascertain whether the structured education programme Tabletkka provides additive glycaemic and psychological benefits compared to standard education in people with type 2 diabetes on non-insulin therapy when both groups use real-time continuous glucose monitoring.

Ethics approval required

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Ethics approval(s)

Approved 23/09/2025, National Medical Ethics Committee of the Republic of Slovenia (Štefanova ulica 5, Ljubljana, 1000, Slovenia; +386 14786001; gp.mz@gov.si), ref: 0120-464/2025-2711-3

Primary study design

Interventional

Allocation

Non-randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Treatment, Education

Study type(s)**Health condition(s) or problem(s) studied**

Type 2 diabetes

Interventions

Intervention arm 1: Participants receive the Tabletkka programme, comprising 10 contact hours delivered in four interactive meetings (two group workshops and two individual counselling sessions) by registered nurse educators. Participants wear a blinded Syai Tag rtCGM sensor for 14–30 days pre-intervention, followed by two consecutive unblinded sensors (14 days each) during the programme.

Intervention arm 2: Participants receive the Tabletkka programme, comprising 10 contact hours

delivered in four interactive meetings (two group workshops and two individual counselling sessions) by registered nurse educators. Participants wear 2 blinded Syai Tag rtCGM sensors for 14 days each during the programme.

Control arm: Participants receive standard care, consisting of a one-hour group education session on healthy lifestyle. Participants wear two consecutive unblinded Syai Tag rtCGM sensors.

Both arms maintain unchanged glucose-lowering medication throughout the study, with a total follow-up duration of approximately 90 days after the last sensor period.

Intervention Type

Behavioural

Primary outcome(s)

1. Time in tight range measured using TITR, 3.9–7.8 mmol/L at the end of the sensor period (28 days)
2. Time in range measured using TIR, 3.9–10.0 mmol/L at the end of the sensor period (28 days)
3. Diabetes distress measured using PAID-20 questionnaire at baseline and at the final visit (approximately 90 days after the last sensor period)

Key secondary outcome(s)

1. HbA1c measured using blood test at baseline and at the final visit (approximately 90 days after the last sensor period)
2. Body weight measured using kg at baseline and at the final visit.
3. Glycaemic variability (TAR, TBR, GMI, CV, MAGE, MODD) measured using mmol/L; % at the end of the sensor period (28 days)

Completion date

01/10/2028

Eligibility

Key inclusion criteria

1. Adults (≥ 18 years) with newly diagnosed type 2 diabetes or a diagnosis within the previous five years
2. HbA1c $\geq 6.0\%$ (42 mmol/mol)
3. Unchanged non-insulin glucose-lowering therapy for at least three months

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

70 Years

Sex

All

Total final enrolment

100

Key exclusion criteria

1. Current or past insulin therapy
2. Type 1 or other specific diabetes types
3. Conditions limiting participation in education (e.g., cancer, stroke, dialysis dependence)
4. Uncontrolled psychiatric or neurological comorbidity
5. Life expectancy below six months
6. Requiring any change in glucose-lowering therapy during the study

Date of first enrolment

01/10/2025

Date of final enrolment

31/05/2026

Locations

Countries of recruitment

Slovenia

Study participating centre

Department of Endocrinology, Diabetes and Metabolic Diseases, Division of Internal Medicine,
University Medical Centre Ljubljana

Zaloška 7

Ljubljana

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1000

Sponsor information

Organisation

University Medical Centre Ljubljana

Funder(s)

Funder type

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available