

Effect of lifestyle changes on metabolic health and PCSK9 levels in people with prediabetes

Submission date 21/04/2026	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 23/04/2026	Overall study status Completed	☐ Protocol
Last Edited 23/04/2026	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, Scientific, Principal investigator

Contact name
Mr Yunus Saglar

Contact details
Ankara City Hospital
Ankara
Türkiye
06800
+90 5334518933
yunussglr@gmail.com

Additional identifiers

Study information

Scientific Title
Lifestyle intervention improves metabolic parameters but does not modify PCSK9 levels in prediabetes: a prospective cohort study

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 27/12/2023, Clinical Research Ethics Committee No. 2 (Ankara City Hospital, Ankara, 06800, Türkiye; +90 312 552 60 00; ankara.sehirhastanesi@saglik.gov.tr), ref: E2-23-5663

Primary study design

Interventional

Allocation

N/A: single arm study

Masking

Open (masking not used)

Control

Uncontrolled

Assignment

Single

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Prediabetes, insulin resistance, metabolic dysregulation

Interventions

Lifestyle intervention consisting of individualized medical nutrition therapy and a structured exercise program.

Dietary intervention included personalized caloric planning based on age, sex, and body mass index, with a Mediterranean-style diet emphasizing whole grains, fruits, vegetables, legumes, and healthy fats. Participants were advised to limit saturated fat intake (<10% of total energy), avoid refined carbohydrates, and increase dietary fiber intake.

Exercise intervention consisted of at least 150 minutes per week of moderate-intensity aerobic physical activity (3–6 METs), such as brisk walking. The program was progressive and individualized, including warm-up, active, and cool-down phases.

Participants were followed for 3 months with regular monitoring and reinforcement of adherence through clinic visits and telephone contact.

Intervention Type

Behavioural

Primary outcome(s)

1. Serum PCSK9 levels measured using enzyme-linked immunosorbent assay (ELISA), expressed in ng/mL at baseline and at 3 months following completion of lifestyle intervention

Key secondary outcome(s)

1. Anthropometric measurements (body weight, BMI, waist circumference, body fat percentage) measured using standardized clinical methods at baseline and at 3 months following completion of lifestyle intervention
2. Biochemical parameters (fasting plasma glucose, HbA1c, lipid profile) measured using automated laboratory analyzers; at baseline and at 3 months following completion of lifestyle intervention
3. Insulin resistance indices (HOMA-IR, TyG index) measured using standard formulas at baseline and at 3 months following completion of lifestyle intervention

Completion date

07/11/2024

Eligibility**Key inclusion criteria**

1. Adults aged 18–65 years
2. Confirmed diagnosis of prediabetes based on ADA criteria (HbA1c 5.7–6.4%)
3. Ability and willingness to comply with lifestyle intervention and follow-up assessments
4. Provision of written informed consent

Healthy volunteers allowed

Yes

Age group

Mixed

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

Total final enrolment

132

Key exclusion criteria

1. Diagnosis of type 2 diabetes mellitus
2. Use of lipid-lowering medications (including statins or PCSK9 inhibitors)
3. Chronic liver or kidney disease
4. Active infection or inflammatory disease
5. Malignancy
6. Pregnancy or lactation

Date of first enrolment

27/12/2023

Date of final enrolment

07/11/2024

Locations

Countries of recruitment

Türkiye

Sponsor information

Organisation

Ankara City Hospital

Funder(s)

Funder type

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

Individual participant data underlying the results reported in this study (including de-identified demographic, clinical, and laboratory data) will be available from the corresponding author upon reasonable request, following publication. Data will be shared with researchers who provide a methodologically sound proposal, in accordance with institutional policies and applicable data protection regulations.

IPD sharing plan summary

Available on request