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Youth prevention study to improve oral health through oral hygiene and nutrition guidance

Submission date 04/08/2026	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 06/10/2026	**Overall study status** Ongoing	
Last Edited 06/10/2026	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Effect of standardised oral hygiene instruction with or without additional nutritional counselling on plaque, gingival inflammation, bleeding and caries experience in adolescents and young adults: a randomised controlled pilot study

Study objectives

The primary objective is to determine whether adding nutritional counselling focused on reducing sugar intake to standardised oral hygiene instruction results in greater improvements in approximal plaque, gingival inflammation and bleeding after interdental brushing than oral hygiene instruction alone over three months. Dental caries experience will also be assessed using the Decayed, Missing, and Filled Teeth (DMFT) index.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/03/2026, Ethics Committee of the City of Vienna (Thomas-Klestil-Platz 8/2, Vienna, 1030, Austria; +43 (0)1 4000 87754; ethikkommission@ma15.wien.gv.at), ref: MA15–EK 25-152-0126

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Adolescent oral health, gingivitis and dental caries prevention

Interventions
Randomisation will be performed before the intervention by drawing lots at the youth centre. After recruitment, participants will be allocated in a 1:1 ratio to one of the two parallel study groups using identical, concealed lots.

Group 1 will receive standardised individual oral hygiene instruction, including toothbrushing technique, interdental cleaning, fluoride advice and plaque disclosure.

Group 2 will receive the same oral hygiene instruction plus nutritional counselling focused on reducing sugar intake.

Clinical assessments will be performed at baseline, after 1 month and after 3 months:

Approximal Plaque Index (API): plaque will be recorded as present or absent at defined approximal sites, and the percentage of plaque-positive sites will be calculated.

Gingival Index (GI): gingival inflammation will be scored from 0 to 3, ranging from healthy gingiva to severe inflammation.
Bleeding on Brushing index (BoB): bleeding within 30 seconds after standardised interdental cleaning will be recorded as present or absent, and the percentage of bleeding sites will be calculated.

DMFT index: caries experience will be assessed visually and non-invasively by recording decayed, missing due to caries and filled permanent teeth. Third molars will be excluded.

Intervention Type
Behavioural

Primary outcome(s)
1. Percentage of plaque-positive approximal sites measured using the Approximal Plaque Index (API) according to Lange at baseline, 1 month and 3 months

2. Severity of gingival inflammation measured using Mean Gingival Index (GI) score according to Löe and Silness on a scale from 0 to 3 at baseline, 1 month and 3 months

3. Dental caries experience measured using the total number of decayed, missing due to caries and filled permanent teeth measured using a visual, non-invasive DMFT assessment based on WHO criteria at baseline, 1 month and 3 months

4. Bleeding after interdental brushing measured using the percentage of assessed interdental sites with bleeding within 30 seconds, measured using the Bleeding on Brushing (BoB) index at baseline, 1 month and 3 months

Key secondary outcome(s)

Completion date
30/12/2027

Eligibility

Key inclusion criteria
1. Adolescents and young adults aged 14–21 years
2. Regular attendance at the participating youth centre
3. Willingness to participate in the study
4. Written informed consent from the participant
5. For participants under 18 years of age, additional written informed consent from a parent or legal guardian

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
14 Years

Upper age limit
21 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Severe acute or chronic medical conditions
2. Ongoing systemic illnesses
3. Treatment requiring regular medical or dental care
4. Current participation in other health studies
5. Inability or unwillingness to provide written informed consent, or absence of parental/legal guardian consent where required

Date of first enrolment
04/09/2026

Date of final enrolment
30/09/2027

Locations

Countries of recruitment
Austria

Sponsor information

Organisation
Medical University of Vienna

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type

Funder Name
Verein für Zahnhygiene e. V.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available