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Studying how different oral health care methods affect the daily life and performance of endurance athletes in Finland

Submission date	Recruitment status	[_] Prospectively registered
18/01/2026	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/01/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
26/01/2026	Oral Health	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to provide valuable insights into the impact of enhanced traditional oral health care on the oral health and performance of endurance athletes. By systematically evaluating the effectiveness of standard oral care methods in a controlled setting, the study seeks to contribute to the understanding of how oral health influences athletic performance and to promote better oral hygiene practices among athletes.

Who can participate?
Endurance athletes aged 18-45 years who are systematically healthy and actively competing

What does the study involve?
This two-phase crossover study is a medical research study focused on health and treatment methods, but it does not involve testing or using any pharmaceutical drugs or medications. This study will assess the effectiveness of traditional oral healthcare methods in improving oral health and, subsequently, athletic performance in endurance athletes. The study will span over 12 weeks, during which participants will undergo a control period with traditional oral health care routines, and an intervention period where enhanced, modern oral care routines are implemented.

What are the possible benefits and risks of participating?
Participants will receive an assessment of their oral health status, personalized oral hygiene guidance, and information about their own oral health. In addition, they will receive information on how basic and enhanced oral care change during the study and whether these changes have an impact on performance.
The enhanced oral care routines are expected to be safe, with the main risks being those commonly associated with standard oral hygiene practices, such as mild gum irritation from brushing or flossing. The study team will also monitor any study-related unexpected events.
If a condition potentially requiring acute care is identified in the teeth or mouth, the participant

is advised to contact the acute oral health service in their community in accordance with local guidelines. If needed, the investigator will have the possibility to consult a dentist according to the study site guidelines.

Where is the study run from?
Metropolia University of Applied Sciences and Helsinki University, Finnish Institute of High Performance Sport KIHU and the UKK Institute for Health Promotion Research (Finland)

When is the study starting and how long is it expected to run for?
February 2025 to December 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Study information

Scientific Title
Oral health in endurance athletes in Finland - the impact of enhanced traditional and modern oral health self-care on an athlete’s daily life and performance

Study objectives
1. Primary Objective:
1.1. To evaluate whether systematic and enhanced traditional oral health care can significantly improve oral health outcomes in endurance athletes.

2. Secondary Objectives:
2.1. To assess athletes’ self-perception of their oral health and its impact on performance.
2.2. To explore the correlation between improved oral health and specific athletic performance metrics, such as resting heart rate and heart rate variability.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/01/2025, HUS Regional Medical Research Ethics Committee (HUS Alueellinen Lääketieteellinen Tutkimuseettinen Toimikunta) (Biomedicum 2, Tukholmankatu 8,, Helsinki, 00290, Finland; +358403594618; eettinen.toimikunta@hus.fi), ref: HUS/8142/2024

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Health services research, Prevention, Screening, Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Oral health in endurance athletes

Interventions

Phase 1: Initial Assessment and Standard Oral Care / Weeks 0 - 6:
Week 0: Baseline assessment, including oral health evaluation (Visible Plaque Index [VPI], Bleeding on Probing [BOP], and Periodontal Pocket Depth [PPD]). The study participants will complete a modified Oral Health Impact Profile (OHIP-14) questionnaire. Participants will receive instructions on the best possible traditional oral health care and professional cleaning.
Weeks 1-6: Participants will maintain daily oral health care using traditional methods such as electric toothbrushing and interdental cleaning. Participants also monitor their physical performance (heart rate monitoring) and answer a questionnaire on perceived recovery three times during the period. The questionnaire can be in electronic or paper format.
Week 6: Mid-point reassessment of oral health using the same metrics as at Week 0.

Phase 2: Enhanced Oral Care for 6 weeks:
Weeks 6-12: Participants will be re-instructed on the best possible traditional oral health care, also instructed to a home-use antibacterial oral health therapy device for improved oral health. Participants will also self-monitor their physical performances.
Week 12: Final assessment and evaluation of oral health, along with a comparison of performance measures across the two phases.

This study is an exploratory, indicative study. The sample size will consist of 36 participants, with each athlete serving as their own control during the crossover phases. The sample size for this study was calculated based on data from a randomized trial of dual-light antibacterial photodynamic therapy (aPDT) for periodontal disease. Early interim results of that study have recently been published (Pakarinen et al. 2022). The study focused on assessing changes in oral hygiene levels three months after the initiation of regular aPDT treatment in participants with periodontal disease. Based on the data, the required sample size was calculated using the Sample Size Calculator (ClinCalc LLC), setting an alpha error level of 5% and a type II error level of 20% (80% power). Based on this, a sample size of 16 participants per group was concluded. Given the possibility of drop-out, which has been in the order of 10% in previous studies, the study group ended up recruiting 36 participants for this pilot study. The target size will allow for a statistically significant comparison between the two phases of the study.

The OHIP-14 measure, which has been validated in English, will be used. So far, this measure has not been validated in the Finnish language, but it has been widely used in Finnish studies, and the risk of the measure not working is considered low.

Recruitment process:
A survey, as part of a separate research, will be sent to Finnish sports federations during the winter of 2024-2025 to be distributed to the federations' goal-oriented athletes. At the end of the survey, an additional question will be asked about a possible interest in participating in this clinical trial. Individuals interested in learning more about the study are invited to contact the lead investigator for this study, who will then conduct a preliminary screening of the potential subject's suitability (exclusion and inclusion criteria) for the study. For potentially suitable persons more detailed information about the study is given.

The stages of recruitment:
Step 1: In winter 2024-2025, as part of a separate survey, a questionnaire will be sent to Finland's largest sports federations and clubs, such as the Finnish Sports Confederation, the Finnish Institute of Top Sports (KIHU), the Finnish Skiing Association, the Finnish Swimming Association, the Orienteering Association, the UKK Institute and the Finnish Triathlon Association to reach out to endurance athletes. At the end of the questionnaire, an additional question will be asked about possible interest in participating in this clinical trial.
Step 2: Those interested in participating in the study will be invited to contact the principal

investigator of this study, who will conduct a preliminary screening of the suitability (exclusion and inclusion criteria) of potential subjects for the study. Potentially suitable subjects will be given more detailed information about the study.
Step 3: If the study team does not receive enough participants by the deadline, the recruitment of participants will be based on the snowball method, whereby an athlete already participating in the study recommends the study to another athlete.
The investigator is therefore not the primary recruiter, even if the investigator is an athlete and a representative of a particular endurance sport.

Oral health assessments:
Participants will undergo oral health evaluations at three key points: baseline (Week 0), mid-point (Week 6), and final assessment (Week 12). The assessments will include:
Visible Plaque Index (VPI): Assessment of six index teeth measured at four sites per tooth. VPI will be reported as the percentage of sites with plaque.
Bleeding on Probing (BOP): Full-mouth assessment with six sites per tooth. BOP will be reported as the percentage of sites with bleeding.
Periodontal Pocket Depth (PPD): Measurement of pocket depth from the base of the pocket to the gingival margin, recorded if more than 3.5 mm.

Athlete Performance Monitoring:
Athletes will track their daily resting heart rate and heart rate variability throughout the study. These metrics will be used to assess whether improvements in oral health correlate with enhancements in physical performance. Athletes in the study will use their own sports equipment to monitor heart rate variability.

Surveys and Diaries:
Participants will complete a survey regarding their perception of oral health and its impact on performance: a modified questionnaire OHIP-14 (Annex 1). Additionally, they will maintain a diary to record their daily use of aPDT device (Annex 4) and any relevant observations or changes.

APDT device instructions:
The antibacterial photodynamic therapy device is meant to be used at home together with regular oral self-care procedures, toothbrushing, and interdental cleaning. The device shall be used within its intended purpose of prevention of oral disease according to the manufacturer's instructions. Study protocol section study phases explain the required frequency for the device use. All participants will be individually shown a demo device on how to use the device, and also how to fill in the device follow-up diary.

Data analysis:
Statistical analysis will be conducted using software tools such as SPSS or R. The primary endpoint will be the comparison of VPI between the two study phases. Secondary endpoints will include BOP, PPD, and self-assessed oral hygiene scores.
The Wilcoxon signed-rank test is used to compare changes within a group over time. The chi-square test is used to evaluate categorical data. The limit of statistical significance is set at $p < 0.05$.

Intervention Type
Procedure/Surgery

Primary outcome(s)

1. Amount of visible dental plaque measured using Visible Plaque Index (VPI) at three measurements every 6 weeks

2. Gingival inflammation measured using bleeding on probing (BOP) at three measurements every six weeks

Key secondary outcome(s)
1. Depth of probing pocket measured using probing pocket depth (PPD) at three measurements every 6 weeks

2. Level of physiological stress and recovery measured using heart rate variability(HRV) at once a day for 12 weeks

3. Level of overall physiological stress, recovery status, and cardiovascular fitness measured using daily resting heart rate (RHR) at once a day during 12 weeks

4. Level of oral health–related quality of life measured using Oral Health Impact Profile (OHIP-14) at before and after survey

Completion date
30/12/2026

Eligibility

Key inclusion criteria
1. Male or female endurance athletes aged 18-45 years.
2. Competitively active and systematically healthy.
3. Willingness to participate in the study and adherence to the protocol.
4. Ability to provide informed consent.
5. Possession of a sports or activity bracelet, sports watch, or similar device that allows self-monitoring and reporting of heart rate values.

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Pregnant or lactating women.
2. Active use of any nicotine products.
3. Medicated diabetes mellitus (DM).
4. Active oral thrush or other severe oral infections that require acute care in oral healthcare.
5. Participation in other oral health-related studies within the last 6 months.
6. Previous use of aPDT device within the last 6 months prior to recruitment.
7. Previous acquaintances of the Site Principal Investigator.

Date of first enrolment
28/02/2025

Date of final enrolment
30/03/2026

Locations

Countries of recruitment
Finland

Sponsor information

Organisation
Helsinki Metropolia University of Applied Sciences

ROR
https://ror.org/03hdaef25

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