Study Protocol

HbA1c Screening in Dental Care for Patients With Advanced Periodontitis

Acronym: DENT-PC

Protocol version	1.0
Protocol date	16 April 2025
Study type	Observational feasibility study
Study setting	Public dental clinics in Skane, Sweden, in collaboration with primary healthcare
Principal investigators	Susanna Calling, MD, PhD; Peter Nymberg, RN, PhD; Nils Oscarson, DDS, PhD
Ethics approval	Swedish Ethical Review Authority, Dnr 2025-01744-01
Planned enrolment	Approximately 450-600 participants

1. Background and rationale

Periodontitis, particularly in advanced stages, is associated with prediabetes, type 2 diabetes and cardiovascular disease. The relationship between periodontitis and diabetes is bidirectional: diabetes increases the risk and severity of periodontitis, while periodontal inflammation may contribute to insulin resistance and impaired glucose regulation. Patients with advanced periodontitis may therefore represent a clinically identifiable group at risk of undetected elevated blood glucose.

Previous studies suggest that diabetes screening in dental settings can be effective, but feasible care pathways between dental care and primary care are not yet established in Swedish routine practice. A previous Swedish referral-based screening model was limited by loss to follow-up after referral to primary care. This study evaluates whether HbA1c testing performed directly during routine dental care, followed by standardized referral when needed, is feasible and can support earlier detection and preventive follow-up.

2. Objectives

The primary objective is to evaluate whether HbA1c screening in patients with advanced periodontitis can identify individuals with elevated blood glucose and facilitate appropriate referral to primary healthcare.

Specific objectives are to:

1. determine the prevalence of previously undetected elevated HbA1c levels in patients with advanced periodontitis;

2. assess the feasibility and costs of HbA1c testing in dental clinics;

3. evaluate referral and follow-up in primary care for patients with elevated HbA1c.

3. Study design

This is a cross-sectional, observational feasibility study conducted in public dental clinics in Skane, Sweden, in collaboration with primary healthcare providers. The study is embedded in routine dental visits. There is no randomization and no investigational medicinal product. The intervention consists of point-of-care HbA1c testing at the dental clinic and standardized referral to primary care when HbA1c is elevated.

4. Study setting

Participants will be recruited opportunistically during ordinary dental check-ups at public dental clinics in Skane. Two clinics started recruitment in autumn 2025, and an additional clinic may be added during the recruitment period. Primary healthcare centers in Skane will provide follow-up according to routine clinical guidelines after referral.

5. Study population

The study population consists of adult dental care patients with advanced periodontitis and no previous diagnosis of diabetes mellitus.

6. Eligibility criteria

Inclusion criteria

- Age 18 years or older.
- Advanced periodontitis, defined as stage 3-4 periodontitis or grade B/C periodontitis according to clinical and radiographic assessment during routine dental care.
- Ability to understand study information and provide informed consent.

Exclusion criteria

- Previously diagnosed diabetes mellitus.
- Inability to provide informed consent, for example due to severe mental disorder or markedly impaired health status as judged by the clinical staff.

7. Periodontitis case definition

Periodontitis will be assessed during ordinary dental examination by trained dentists or dental hygienists. Probing depth, clinical attachment loss and bleeding on probing are measured using a periodontal probe, together with radiographic assessment. Patients are eligible if they meet criteria for periodontitis stage III or IV, or grade B or C. Stage III/IV includes at least two non-adjacent teeth with clinical attachment loss of 5 mm or more, radiographic bone loss extending to the middle third of the root or beyond, or loss of at least four teeth due to periodontitis. Grade B/C is defined using the radiographic bone loss/age ratio on at least two non-adjacent teeth.

8. Recruitment and consent

Eligible patients will be informed about the study by a dentist or dental hygienist during the dental visit and will receive written participant information. Patients will be given the opportunity to ask questions. Written informed consent will be obtained before HbA1c testing. All patients asked to participate will be recorded in a screening log. For patients declining participation, only sex and age will be recorded for feasibility assessment.

9. Study procedures

1. Routine oral examination and confirmation of periodontitis eligibility.

2. Update of the dental health declaration, including tobacco status, self-reported general and oral health, medication, allergies, cardiovascular disease, diabetes and healthcare contacts.

3. Written informed consent.

4. Capillary blood sampling at the dental clinic.

5. HbA1c analysis using a validated point-of-care instrument (HemoCue).

6. Provision of test result and written information to the participant.

7. Referral to primary care for participants with HbA1c 42 mmol/mol or higher.

8. Follow-up of the referral process and primary care assessment through medical records and regional registers.

10. Referral pathway

Participants with HbA1c below 42 mmol/mol will receive their result and no study-specific referral will be made. Participants with HbA1c 42 mmol/mol or higher will receive standardized information and a referral to their listed primary healthcare center in Skane for further diagnostic assessment and management according to routine clinical guidelines. The referral and subsequent follow-up will be documented for feasibility evaluation.

11. Outcomes

Primary feasibility outcomes

- Number and proportion of eligible patients who are asked to participate.
- Participation rate and reasons for non-participation when available.
- Proportion of participants with successful HbA1c testing at the dental clinic.
- Proportion of participants with HbA1c 42 mmol/mol or higher.
- Proportion of participants referred to primary care.
- Proportion of referred participants with documented primary care follow-up within six months.
- Dropout and missing data.
- Time and costs related to study-specific procedures.

Secondary outcomes

- Prevalence of elevated HbA1c in patients with advanced periodontitis.
- Primary care follow-up: contact type and date, laboratory results, blood pressure, heart rate, weight, height, clinical assessment, diagnosis, medication, preventive advice and planned follow-up.
- Descriptive comparison of elevated HbA1c prevalence with Swedish population data and previous literature.

12. Sample size

As the primary aim is feasibility, no formal power calculation is required. Before study start, the planned sample size was estimated from clinic size and expected prevalence of advanced periodontitis. Each dental clinic has approximately 4,000 listed patients, and around 10% are expected to have stage 3-4 periodontitis. Assuming that approximately 50% will not be included because of patient refusal or practical constraints, about 200 participants may be included per clinic and year. With two to three clinics, the planned enrolment is approximately 450-600 participants.

13. Data collection and management

Study data will be collected using screening logs, patient data logs, health declarations, HbA1c test results, referral documentation, regional registers and medical records. Study-specific data include eligibility, consent,

periodontitis classification, listed primary healthcare center, HbA1c value, patient information provided, referral status, time used for study procedures and follow-up outcomes.

Personal data and consent forms will be stored securely and separately from analysis data. Data will be pseudonymized before analysis. Paper documents will be stored in locked facilities at the dental clinics. Electronic study data will be stored securely according to Region Skane and Lund University procedures, including access control and two-factor authentication when transferred to the approved research platform.

14. Statistical analysis

Descriptive statistics will be used to summarize baseline characteristics, inclusion rate, participation rate, HbA1c results, referral outcomes, primary care follow-up and costs. Categorical variables will be presented as numbers and percentages. Continuous variables will be presented using mean and standard deviation or median and interquartile range, as appropriate. The prevalence of elevated HbA1c will be compared descriptively with Swedish population data and previous literature. The content of primary care follow-up will be described. No hypothesis testing is required for the primary feasibility aim, but exploratory comparisons may be performed if appropriate.

Statistical Analysis Plan

This is a feasibility study, and the analyses will primarily be descriptive. All analyses will be performed using standard statistical software, such as SPSS or R. A detailed statistical analysis plan will be finalized before database lock.

The study population will be described using means and standard deviations, medians and interquartile ranges, or frequencies and percentages, as appropriate. Baseline characteristics will include age, sex, tobacco use, self-rated general and oral health, medication, comorbidity, periodontal classification and listed primary care centre.

The primary feasibility outcomes will include the number and proportion of eligible patients invited, the proportion consenting to participation, successful HbA1c sampling, time required for study procedures, proportion with HbA1c ≥42 mmol/mol, proportion referred to primary care, and proportion with documented primary care follow-up within six months. Dropout and reasons for non-participation or incomplete follow-up will be described when available.

The prevalence of elevated HbA1c will be calculated with 95% confidence intervals. Results will be presented overall and, where feasible, stratified by sex, age group, tobacco use and periodontal severity. The prevalence of elevated HbA1c, prediabetes and diabetes will be compared descriptively with Swedish population data and previous studies.

For participants referred to primary care, follow-up data will be summarized descriptively, including type and date of healthcare contact, repeated blood test results, clinical assessment, diagnosis, lifestyle advice, medication and planned follow-up. No formal hypothesis testing is planned for the primary feasibility outcomes, but exploratory comparisons between groups may be performed using chi-square tests, t-tests, Mann–Whitney U tests or regression models when appropriate.

Costs will be calculated per participant using a standardized micro-costing approach, including staff time, material, documentation, blood sampling and analysis. Patient-related costs will be estimated from the additional time required for study-specific procedures.

As the primary aim is feasibility, no formal power calculation is required. The planned sample size of approximately 450–600 participants is considered sufficient to estimate recruitment, referral and follow-up rates with acceptable precision and to inform the design of a future larger implementation or cluster-randomized study.

15. Cost analysis

Costs will be calculated per participant using a standardized model that includes dental staff time, administrative time, materials, blood sampling and HbA1c analysis. Patient-related costs will be limited to extra time required for study-specific procedures, since the study is performed during an ordinary dental visit. Additional costs for staff training, devices and consumables will be allocated to participating patients and reported as cost per participant.

16. Monitoring and quality assurance

Given the low-risk, non-pharmacological nature of the study, monitoring will follow a proportionate, risk-based approach. Monitoring will include central data review and targeted oversight of recruitment, consent, HbA1c testing, referral procedures and data quality. A monitoring plan will be developed in collaboration with Clinical Studies Sweden Forum South. Dental staff have received study-specific training, including HbA1c sampling procedures, use of the HemoCue instrument, documentation and referral routines.

17. Safety considerations

The study involves capillary blood sampling and is considered low risk. Potential risks are minor discomfort, bruising or anxiety related to test results. Participants will receive standardized information about their HbA1c result. Participants with elevated HbA1c will be referred to primary care for further assessment; the study itself does not establish a diabetes diagnosis or initiate treatment.

18. Ethical considerations

The study has ethical approval from the Swedish Ethical Review Authority (Dnr 2025-01744-01). All participants will provide written informed consent before any study-specific procedure. The study will be conducted in accordance with the Declaration of Helsinki, applicable Swedish regulations and data protection requirements. Participants may withdraw from the study at any time without consequences for their dental or medical care.

19. Timeline

- 2025: Ethical approval, planning, staff training and preparation of study documents.
- 2026-2027: Recruitment and data collection in dental clinics.
- 2027-2028: Follow-up, data analysis, cost analysis, manuscript preparation and dissemination of results.

20. Dissemination and implementation

Results will be disseminated through scientific publications, presentations to dental care and primary care stakeholders, and discussions with clinical managers in Public Dental Care Skane and Primary Care Skane. If feasible, the model may be developed into a larger cluster-randomized study and may inform regional implementation of standardized HbA1c screening and referral routines for patients with advanced periodontitis.

21. References

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