# Introducing diabetes checks in dental settings: a study to explore whether dental settings can be used to identify new cases of prediabetes and diabetes

<b>Submission date</b> 09/05/2025	Recruitment status Recruiting	<ul><li>Prospectively registered</li></ul>
		☐ Protocol
Registration date	Overall study status	Statistical analysis plan
19/05/2025	Ongoing	Results
Last Edited	Condition category	Individual participant data
18/09/2025	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

## Plain English summary of protocol

Background and study aims

This study aims to evaluate the diabetes risk assessment process in dental settings. One of the reasons to risk assess for a medical condition (type 2 diabetes) in dental settings is that many people see their dentist regularly when they feel healthy. But many people only see their GP when they have a health problem or feel unwell. This may allow dental teams to pick up problems early. Furthermore, patients with periodontitis (severe gum disease) are more likely to have other chronic inflammatory diseases, including type 2 diabetes. So, this may be another reason why dental teams could be used to identify those at risk of diabetes. Although for this study, all dental patients, regardless of their gum health status, will be welcome to participate. If risk-assessing patients for type 2 diabetes in a dental setting is practical and both patients and dental teams think it is a good idea, then it may lead to earlier diagnosis for patients. This, in turn, may mean they can access care sooner. Early identification benefits patients' health and well-being and may also save the NHS money. If this research shows that knowing the patients' gum health status can provide an additional benefit in the screening process, members of the dental team may be best placed to provide this type of risk assessment.

## Who can participate?

Patients who are attending for their routine appointment with their dental care professional, are between 40 and 80 years old and are able to give consent to assist in this research. It is also important that patients have not been told by a healthcare professional that they already have diabetes (and have not been tested in the prior 12 months), sickle cell, or sickle cell trait.

## What does the study involve?

Patients will be asked to complete a risk questionnaire and will have a finger-prick blood sample collected. Patients will also be asked if they are willing to provide a small saliva sample.

What are the possible benefits and risks of participating?

Benefits: Participating in the study will provide insight into participants' diabetes risk. By

supporting the research, they will be helping to advance research into screening for type 2 diabetes in a dental setting. It is hoped that this may lead to early detection of type 2 diabetes and implementation of screening procedures in dental settings.

Risks: There are minimal risks to taking part in this research, although before participating, patients may wish to consider whether they are likely to feel anxious depending on the result of the risk assessment. Some participants may find that being told they may be at risk of diabetes will cause them a degree of stress or anxiety. If this is the case, they may decide you do not want to participate in the study.

Where is the study run from?

The study is run from up to 50 high street dental practices across the UK. It is sponsored by the University of Birmingham, UK.

When is the study starting and how long is it expected to run for? July 2024 to July 2029

Who is funding the study? Haleon Plc

Who is the main contact?

Zehra Yonel, Clinical Lecturer and honorary Specialist Registrar in Restorative Dentistry, University of Birmingham, School of Dentistry, z.yonel@bham.ac.uk

## **Contact information**

## Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Zehra Yonel

### **ORCID ID**

https://orcid.org/0000-0002-5477-8315

### Contact details

Clinical Lecturer and honorary Specialist Registrar in Restorative Dentistry, University of Birmingham, School of Dentistry, 5 Mill Pool Way Birmingham United Kingdom B5 7EG +44 (0)1214665128 z.yonel@bham.ac.uk

## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

## ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

CPMS 63817, Grant Code 14583

## Study information

### Scientific Title

INtroducing Diabetes Checks in A denTal sEtting-2

## Acronym

**INDICATE-2** 

## **Study objectives**

Null hypothesis: Dental settings will not successfully identify new cases of (previously undiagnosed) prediabetes/diabetes

### Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 05/12/2024, Surrey Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048 088; surrey.rec@hra.nhs.uk), ref: 24/LO/0830

### Study design

Non-randomized study

### Primary study design

Interventional

### Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Diabetes

### Interventions

Eligible patients will be identified by the dental practice teams, who will invite those eligible to read the patient information sheet (PIS) about the study and ask any questions they may have. Where practices can email patients in advance of their appointment, they may opt to send eligible participants electronic copies of the PIS and consent form in advance. Where practices do not routinely contact patients in advance of their appointment, the practice receptionist may elect to inform eligible patients on arrival to the practice that the practice is involved in a research study and ask if they are happy to be emailed the PIS. This type of "opportunistic" recruitment would be more aligned with real-world practice if this intervention were to be

adopted into routine practice beyond this study. Information posters have been generated that the practices can display in their waiting rooms to highlight the study to patients who may be interested.

Those participants who consent to undergo the Risk Assessment process will be invited to complete an electronic risk questionnaire. This will consist of a single electronic survey on the encrypted REDCap platform and will include the questions from the Diabetes Risk Assessment in Dentistry Score (DDS) and the Leicester Risk Assessment score (LRA). All participants, regardless of their score on the questionnaire, will be offered the Point Of Care Test finger-prick blood HbA1c. This will allow the research team to assess the performance of both these Risk Assessment tools in this prospective cohort and validate them both on a UK dental population. Any participant who scores ≥42mmol/mol will be informed that they are potentially at increased risk of Type 2 Diabetes Mellitus and that they would benefit from a formal test and follow-up with their GP.

The participant will also be provided with the results from the RA process in the form of a standardised letter and where they provide consent, a standardised letter will be sent to their GP informing them of the study and the patient's POCT result. If a participant withholds consent for the dental team to contact the GP, the participant will be given an additional copy of the letter intended for their GP, such that they can present it to their GP later should they subsequently change their mind.

In the event the dental practice does not receive return correspondence from the patient's primary care medical team (GP), further attempts will be made to acquire this information. This information is important for the patient's clinical oral health team to know. Following the initial letter informing the GP of the risk-assessment process and requesting results from any formal diagnostics. If no response is received within 3 months, this will be logged in REDCap. At 3 months, REDCap will then autogenerate an email to the GP practice email address from the dental care team's email address explaining they did not receive follow-up correspondence to their initial letter and requesting the information once again. If there is still no response to the email, one further letter will be sent to the GP practice at 6 months post-risk assessment from the study chief investigator. Patient participants will also be asked to consent to have diabetes data collected directly via NHS Digital, where this is possible, to minimise the burden on GPs.

Having completed the RA process, all participants will be contacted for a follow-up survey 1 week post-risk assessment process to understand their views on the process. This follow-up will be via an electronic survey sent to the email address they provide to the research team.

For those participants considered high-risk, there will also be a survey sent at 6 weeks post-risk assessment. The follow-up survey will consist of questions relating to: if and how they acted on the information provided by the dental team following the RA process. Also, pertaining to what action was taken by their GP if they sought an appointment with their GP practice following the RA in the dental setting.

As per the consent form. For those participants considered high-risk, a letter will be sent to their GMP informing their doctor that the patient had an HbA1c test within the dental practice, and given that it has revealed a score ≥42mmol/mol, they are potentially at risk. This is to keep the GP informed and up-to-date. Given that HbA1c (glycaemic levels) will impact the patient's oral health, in particular periodontitis risk, the participants' dental teams need to be aware of any formal tests for diabetes, the results and any subsequent medications. A request will be made for the GP to share that information (diabetes status, test result and medications/ interventions) with the dental team to aid their onward management of the patient. The research team will

also record this information to ensure the validity of the testing process. Where a response isn't received follow-up will be sent to GPs. The final request for information will be sent at 6 months post-risk assessment. Only 1 response is required from the GP in that initial 6-month period.

## Intervention Type

Other

### Phase

**Not Specified** 

## Primary outcome(s)

Prediabetes/non-diabetic hyperglycaemia (NDH)/diabetes risk is measured using a validated risk assessment questionnaire (LRA/DDS) and Siemens DCA VANTAGE HbA1c point of care test at baseline. Then followed up with referral to GP for definitive testing up to 6 months from baseline.

## Key secondary outcome(s))

There are no secondary outcome measures

### Completion date

31/07/2029

## Eligibility

## Key inclusion criteria

- 1. To read and understand the PIS and consent form sufficiently well to provide informed consent and to participate in the study
- 2. To be competent to provide informed consent
- 3. Patients aged >=40 and <=80 years
- 4. Have not had a diabetes check in the past 12 months

## Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

40 years

## Upper age limit

80 years

### Sex

All

## Key exclusion criteria

- 1. Patients aged <40 years or >=80 years
- 2. Diagnosis of type 1 or type 2 diabetes
- 3. Diagnosis of sickle cell or sickle cell trait
- 4. Unable to provide informed consent
- 5. Pregnant
- 6. They have knowingly been tested for diabetes in the past 12 months

## Date of first enrolment

16/12/2024

## Date of final enrolment

01/01/2028

## Locations

## Countries of recruitment

United Kingdom

England

Northern Ireland

Scotland

Wales

## Study participating centre Birmingham Dental Specialists

9 Waterfront Walk Birmingham United Kingdom B1 1TX

## Study participating centre The Belvedere Dental Practice Ltd

25 Station Road Workington United Kingdom CA14 2UX

Study participating centre Breeze Dental

180 Chester Road

Sunderland United Kingdom SR4 7EY

## Study participating centre Darrell House Dental Practice

85 West Street Dunstable United Kingdom LU6 1SE

## Study participating centre Chong Kwan Dental Care

6a High St Dunfermline United Kingdom KY12 7AR

## Study participating centre Claregate Dental Practice

65 Pendeford Avenue Wolverhampton United Kingdom WV6 9EH

## Study participating centre Darnall Dental Clinic

652–654 Staniforth Road Sheffield United Kingdom S9 4LP

## Study participating centre Peninsula Dental Plymouth

20 Research Way, Tamar Science Park Plymouth United Kingdom PL6 8BT

## Study participating centre Evesham Dental Health Team

16 Broadway Road Evesham United Kingdom WR11 1BG

## Study participating centre Glossop Dental Centre

27 Kershaw Street Glossop United Kingdom SK13 8NN

## Study participating centre Hafren House Dental Practice

1 Cressy Road Alfreton United Kingdom DE55 7BR

## Study participating centre Hertfordshire Centre for Dentistry

9–11 Leyton Road Harpenden United Kingdom AL5 2HU

## Study participating centre High Street Dental Clinic

38 High Street Staveley, Chesterfield United Kingdom S43 3UX

## Study participating centre Hitchin Dental

85 Bancroft Hitchin United Kingdom SG5 1NQ

## Study participating centre John G Plummer and Associates

83 Mary Chapman Close Norwich United Kingdom NR7 0UD

## Study participating centre Houghton Regis Dental Practice

Bierrum House, 105–111 High Street Houghton Regis, Dunstable United Kingdom LU5 5BJ

## Study participating centre John G Plummer and Associates – Bradwell

The Old Medical Centre Beccles Road, Bradwell Great Yarmouth United Kingdom NR31 8HB

## Study participating centre Luton Dental Centre

1a Peel Street Luton United Kingdom LU1 2QR

## Study participating centre Morris Dental

20 Union Street Oldham United Kingdom OL1 1BE

## Study participating centre

### **Nook Street Dental**

18 Nook St Workington United Kingdom CA14 4DX

## Study participating centre Alpha Dental Care Regent Terrace

15 Regent Terrace Gateshead United Kingdom NE8 1LU

## Study participating centre Scott Arms Dental Practice

914–916 Walsall Road, Great Barr Birmingham United Kingdom B42 1TG

## Study participating centre Stoke Park Dental

53 Stoke Park Drive Ipswich United Kingdom IP2 9TH

## Study participating centre The Grove Practice

6 Beauchamp Hill Leamington Spa United Kingdom CV32 5NS

## Study participating centre Shirebrook Dental Clinic

17 Patchwork Row Shirebrook, Mansfield United Kingdom NG20 8AJ

## Study participating centre The Maltings Dental Practice

The Maltings, Commercial Road Grantham United Kingdom NG31 6DE

## Study participating centre Treeline Dental Bolsover

29 Market Place Bolsover, Chesterfield United Kingdom S44 6PN

## Study participating centre Treeline Dental Care Lincoln

361–362 High Street Lincoln United Kingdom LN5 7RL

## Study participating centre Treeline Dental Keyworth

361/362 High Street Lincolnshire United Kingdom NG12 5AA

## Study participating centre Treeline Dental Lincoln

44 High Pavement Nottingham United Kingdom NG1 1HW

## Study participating centre Treeline Dental Sleaford

86a Southgate Sleaford United Kingdom NG34 7RL

## Study participating centre Peninsula Dental Truro

Treliske Truro United Kingdom TR1 3HD

## Study participating centre UCLAN Dental Clinic

University of Central Lancashire Preston United Kingdom PR1 2HE

## Study participating centre University of Suffolk Dental CIC Waterfront Building, 19–21 Neptune Quay Ipswich United Kingdom

Study participating centre

**BUPA Dental Care Bangor Springhill** 

Unit 4a Killeen Ave Bangor United Kingdom BT19 1NB

IP4 1QJ

Study participating centre BUPA Dental Care Dungannon

42 Circular Road Dungannon United Kingdom BT71 6BE

## Study participating centre

## **BUPA Dental Care Newport**

197 Chepstow Road Newport United Kingdom NP19 8GH

## Study participating centre BUPA Dental Care Pentwyn

Pentwyn Drive Pentwyn United Kingdom CF23 7EY

## Study participating centre Montrose Dental Care

53 John Street Montrose United Kingdom DD10 8LZ

## Sponsor information

## Organisation

University of Birmingham

### **ROR**

https://ror.org/03angcq70

## Funder(s)

## Funder type

Industry

## **Funder Name**

Haleon Plc

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from the study CI, Zehra Yonel, z.yonel@bham.ac.uk.

Anonymised data only. The data will be available 24 months after study completion and will be available to access for up to 5 years by people outside the original research group. In order to access data, a data access request form will need to be completed, outlining a brief overview of the intended use of the data and completion of all other elements of that form. The form will be made available on request to the study CI. Any future analyses will need to acknowledge the CI of the current project and the original research team. Depending on intended use and project needs (as outlined on the data access form), it is likely only the specific data requested will be shared rather than the entire dataset. There is likely to be an administrative cost required to prepare and provide access to the data requested.

## IPD sharing plan summary

Available on request

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes