

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

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<b>Registration date</b> 19/05/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/09/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

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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)

346183

**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  $\geq 42$ mmol/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  $\geq 42$ mmol/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  $\geq 40$  and  $\leq 80$  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  
IP4 1QJ

**Study participating centre**

**BUPA Dental Care Bangor Springhill**

Unit 4a Killeen Ave  
Bangor  
United Kingdom  
BT19 1NB

**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