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

Submission date
09/05/2025

Recruitment status
Recruiting

Registration date
19/05/2025

Overall study status
Ongoing

Last Edited
05/11/2026

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[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 and a blood spot.

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

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Additional identifiers

Integrated Research Application System (IRAS)
346183

Central Portfolio Management System (CPMS)
63817

Protocol serial number
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

Primary study design
Interventional

Study design
Non-randomized study

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

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
Mixed

Lower age limit
40 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 01/06/2026:

1. Patients aged <40 years or >=80 years
2. Diagnosis of type 1 or type 2 diabetes or NDH (pre-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

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Previous 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
England
B1 1TX

Study participating centre
Peninsula Dental Plymouth
20 Research Way, Tamar Science Park

Plymouth
England
PL6 8BT

Study participating centre
Evesham Dental Health Team
16 Broadway Road
Evesham
England
WR11 1BG

Study participating centre
Glossop Dental Centre
27 Kershaw Street
Glossop
England
SK13 8NN

Study participating centre
Hafren House Dental Practice
1 Cressy Road
Alfreton
England
DE55 7BR

Study participating centre
Hertfordshire Centre for Dentistry
9–11 Leyton Road
Harpenden
England
AL5 2HU

Study participating centre
Hitchin Dental
85 Bancroft
Hitchin
England
SG5 1NQ

Study participating centre
John G Plummer and Associates
83 Mary Chapman Close
Norwich
England
NR7 0UD

Study participating centre
Houghton Regis Dental Practice
Bierrum House, 105–111 High Street
Houghton Regis, Dunstable
England
LU5 5BJ

Study participating centre
John G Plummer and Associates – Bradwell
The Old Medical Centre
Beccles Road, Bradwell
Great Yarmouth
England
NR31 8HB

Study participating centre
Luton Dental Centre
1a Peel Street
Luton
England
LU1 2QR

Study participating centre
Morris Dental
20 Union Street
Oldham
England
OL1 1BE

Study participating centre
Nook Street Dental
18 Nook St

Workington
England
CA14 4DX

Study participating centre
Scott Arms Dental Practice
914–916 Walsall Road, Great Barr
Birmingham
England
B42 1TG

Study participating centre
Stoke Park Dental
53 Stoke Park Drive
Ipswich
England
IP2 9TH

Study participating centre
The Grove Practice
6 Beauchamp Hill
Leamington Spa
England
CV32 5NS

Study participating centre
The Maltings Dental Practice
The Maltings, Commercial Road
Grantham
England
NG31 6DE

Study participating centre
Treeline Dental Care Lincoln
361–362 High Street
Lincoln
England
LN5 7RL

Study participating centre
Treeline Dental Sleaford
86a Southgate
Sleaford
England
NG34 7RL

Study participating centre
BUPA Dental Care Dungannon
42 Circular Road
Dungannon
Northern Ireland
BT71 6BE

Study participating centre
BUPA Dental Care Newport
197 Chepstow Road
Newport
Wales
NP19 8GH

Study participating centre
Montrose Dental Care
53 John Street
Montrose
Scotland
DD10 8LZ

Study participating centre
Bells Lane Dental
145 Bells Lane, Druids Heath
Birmingham
England
B14 5QJ

Study participating centre
BJS Dental
109a Front Street
Arnold

Nottingham
England
NG5 7ED

Study participating centre
BUPA Dental Care Tipton
1 Owen Street
Tipton
England
DY4 8HB

Study participating centre
City Dental
364 Dudley Road, Winson Green
Birmingham
England
B18 4HJ

Study participating centre
Green Lane Dental
408 Green Lane
Small Heath
Birmingham
England
B9 5QJ

Study participating centre
Smile Together
Harleigh Road Dental Centre, Marks Drive
Bodmin
England
PL31 1AH

Study participating centre
Woodside Dental Practice
Woodside Health Centre
Barr Street
Glasgow
Scotland
G20 7LR

Study participating centre
mydentist Ankerage Green
Unit 2, Ankerage Green
Worcester
England
WR4 0DZ

Study participating centre
Bhandal Dental Practice
820 Washwood Heath Road
Birmingham
England
B8 2NW

Study participating centre
Doncaster Road Dental Practice Ltd
2 Doncaster Road
Leicester
England
LE4 6JH

Study participating centre
Exeter Dental Education Facility
Veysey Close
Exeter
England
EX2 4SG

Study participating centre
Sheerness Dental Centre
50a High Street
Sheerness
England
ME12 1NL

Study participating centre
Stopsley Village Dental
632 Hitchin Rd
Luton

England
LU2 7UG

Study participating centre
Bupa Dental Care Derry
Units 1 & 2 Timberquay Strand Road
Londonderry
Northern Ireland
BT48 7NR

Study participating centre
Bupa Dental Care Neath
23 Victoria Gardens
Neath
Wales
SA11 3AY

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