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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
27/05/2025

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.

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

EudraCT/CTIS number
Nil known

IRAS number

346183

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Dental clinic

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/07/2024

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

Age group
Adult

Lower age limit
40 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
Planned Sample Size: 10000; UK Sample Size: 10000

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
England

Scotland

United Kingdom

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
Confident Dental & Implant Clinic
Cotswold House, 37 London Road
Stroud
United Kingdom
GL5 2AJ

Study participating centre
Confident Dental and Implant Clinic – Swindon
Unit 1a
Orbital Retail Park
Thamesdown Drive

Swindon
United Kingdom
SN25 4AN

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
Blaydon Dental Practice
Dunsopp House, Lucy Street
Blaydon-on-Tyne
United Kingdom
NE21 5PU

Study participating centre
Alpha Dental Care Regent Terrace
15 Regent Terrace
Gateshead
United Kingdom
NE8 1LU

Study participating centre
High Street (Dental Surgery)
67 High Street
Newcastle upon Tyne
United Kingdom
NE3 4AA

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

Sponsor information

Organisation
University of Birmingham

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TT
+44 (0)121 414 3344
researchgovernance@contacts.bham.ac.uk

Sponsor type
University/education

Website
https://www.birmingham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Industry

Funder Name
Haleon Plc

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/07/2030

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