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For dental patients assessed as being moderate or high risk for type 2 diabetes, is direct referral or signposting more effective to facilitate contact with a health care professional?

Submission date
31/03/2022

Recruitment status
No longer recruiting

Registration date
30/08/2023

Overall study status
Completed

Last Edited
31/08/2023

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
It has been suggested in recent years by government policy documents such as the Oral Health Improvement Plan that patients could receive general health checks while attending their dental practice for a routine appointment. This study will use risk assessment for type 2 diabetes as an example of a general health check to investigate to compare the effectiveness of two referral strategies (direct referral and signposting) used by primary care dentists for facilitating contact between dental patients assessed as being at moderate or high risk of type 2 diabetes and a healthcare professional. The study will also explore the views and experiences of dental patients and dentists about the use of the risk assessment in a dental setting.

Who can participate?
Patients: Dental patients aged 40 years or older who attend a vocational dental training practice in Scotland can participate. They must be attending their dentist for a routine appointment. Practitioners who work in a vocational dental training practice in Scotland can participate.

What does the study involve?
Eligible dental patients who attend an NHS dental practice for a routine appointment will be invited to take part. If eligible, consenting patients will be asked at this appointment to complete an online risk assessment tool provided by Diabetes UK. Participating dental practices will be randomly allocated to deliver either a direct referral or a signposting intervention to patients with a risk level of "high" or "moderate" to facilitate contact with a healthcare professional. One month later, all participating patients will be asked to complete an online questionnaire which will ask if they made contact with a healthcare professional - this is the main outcome measure of the study. They will also be asked about their experience of being risk assessed in a dental setting, how they felt about being told their risk level and their thoughts about doing risk assessments like this in a dental setting. Participating dentists will also be asked to complete an online questionnaire about their thoughts and experiences about using the risk assessment tool in a dental setting.

What are the possible benefits and risks of participating?
Possible benefits to participants include an increased knowledge of the risk factors of type 2 diabetes. Some patient participants may discover they are at moderate or high risk of developing type 2 diabetes by taking part in this study. This study will encourage these participants to speak to a healthcare professional, which may lead to timely and appropriate clinical investigation and treatment if needed.
Possible risks to participants include a risk that the risk assessment may incorrectly report a patient participant to be at a lower risk of type 2 diabetes when they may be at high risk. There is also a risk that patient participants may feel anxious or concerned about their risk assessment score.
There are no expected risks to practitioner participants.

Where is the study run from?
NHS Education for Scotland is managing the study (UK)

When is the study starting and how long is it expected to run for?
December 2021 to December 2022.

Who is funding the study?
This study is not funded by an external organisation. All costs incurred during the running of the study will be covered by NHS Education for Scotland (UK)

Who is the main contact?
Dr Laura Beaton, laura.beaton@nhs.scot

Contact information

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Public

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Additional identifiers

Integrated Research Application System (IRAS)
306747

Protocol serial number
Dental/VT/01

Study information

Scientific Title
DRAMeRS: Diabetes Risk Assessment and Medical Referral or Signposting. A trial to compare the effectiveness of direct referral or signposting at facilitating contact between dental patients assessed as being at moderate or high risk of developing type 2 diabetes and a healthcare professional

Acronym
DRAMeRS

Study objectives

The aim of the study is to compare the effectiveness of two referral strategies (direct referral and signposting) at facilitating contact between dental patients assessed as being at moderate or high risk of developing type 2 diabetes and a healthcare professional.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/03/2022, East of Scotland Research Ethics Service (Ninewells Hospital & Medical School, Tayside Medical Science Centre (TASC), Residency Block, Level 3, George Pirie Way, Dundee, DD1 9SY, UK; +44 (0)1382 383871; tay.eosres@nhs.scot), ref: 22/ES/0004

Primary study design
Interventional

Study design
Multi-centre two-arm clustered randomized controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Referral strategies for dental patients at risk of type 2 diabetes

Interventions
Practices will be randomised to either directly refer or signpost patients who have been risk assessed as being at moderate or high risk of type 2 diabetes to a healthcare professional. The study will randomise practices on a 1:1 basis.

If directly referred, a letter will be sent from the patient's dentist to their GP practice. If signposted, the patient will receive a leaflet that provides information about type 2 diabetes and encourages them to contact a healthcare professional.

One month following the risk assessment, patients in both arms of the intervention, and those whose risk score was low or intermediate, will receive a follow-up questionnaire. Patients whose score was moderate or high will be asked if they have made contact with a healthcare professional. All participants will be asked about their thoughts and experiences of taking part in the study. Participating practitioners will also be asked to complete an online questionnaire about their thoughts and experiences of taking part in the study.

Intervention Type
Behavioural

Primary outcome(s)
The proportion of dental patients assessed as being at moderate or high risk of type 2 diabetes who make contact with a healthcare professional. This proportion will be measured by follow-up questionnaire sent to participants one month following their assessment.

Key secondary outcome(s)
1. Beliefs of patients regarding the acceptability of the Diabetes UK Risk Assessment tool in a dental setting and their feelings about being told their risk level. Beliefs will be measured by

follow-up questionnaire sent to participants one month following their assessment.
2. Beliefs of patients regarding the acceptability of the Diabetes UK Risk Assessment tool in a dental setting and their feelings about being told their risk level. Beliefs will be measured by follow-up questionnaire sent to participants one month following their assessment.

Completion date
01/12/2022

Eligibility

Key inclusion criteria
Patients:
1. Male or female
2. Aged 40+ years
3. Attending a vocational dental training practice
4. Attending for a routine, non-emergency, appointment

Practitioners:
1. Male or female
2. Adults (18+ years)
3. Dentist in a vocational dental training practice

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 Years

Sex
All

Key exclusion criteria
Patients:
1. Patients who do not meet inclusion criteria.
2. Patients who already have received a diagnosis of type 1 or type 2 diabetes.
3. Patients who are pregnant.

Practitioners:
1. Practitioners who do not meet inclusion criteria.

Date of first enrolment
01/05/2022

Date of final enrolment

30/07/2022

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
TRiaDS, Dental Clinical Effectiveness, NHS Education for Scotland
Dundee Dental Education Centre
Frankland Building
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Sponsor information

Organisation
NHS Education for Scotland

ROR
https://ror.org/011ye7p58

Funder(s)

Funder type
Government

Funder Name
NHS Education for Scotland

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing statement will be provided at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	For patients version 3	08/03/2022	25/04/2022	No	Yes
Participant information sheet	For practitioners version 3	08/03/2022	25/04/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes