Diabetes Risk Assessment and Medical Referral or Signposting (DRAMeRS) Study Protocol

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Study Summary

Study Title	Diabetes Risk Assessment and Medical Referral or Signposting (DRAMeRS)
Study Design	A two-arm clustered randomised controlled trial
Study Participants	Eligible dental patients and dentists working in vocational training practices
Planned Sample Size	140 dental vocational training practices Each participating dentist should recruit 20 patients
Follow-up Duration	One month
Planned Study Period	February – December 2022
Research Aim	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.

1. Background and Rationale

Evidence suggests that dental settings present a potential opportunity to conduct general health checks with patients. Yonel et al. found out that of patients who were regular dental attenders, almost half of them claimed that they had never gone for routine health check at their GP. Furthermore, patients, members of the public, GPs and GDPs were all in favour of screening for non-communicable diseases such as diabetes in dental practices and community pharmacies.[1] In a survey of patients' attitudes towards health screenings in dental settings, 87% of dental patients in South-West England thought that it was imperative that dentists screened patients for medical conditions and nearly 90% also indicated willingness to let a dental team conduct a health screening.[2]

The introduction of general health checks in dental practices was proposed in the 2018 Scottish Oral Health Improvement Plan (OHIP), a strategic framework for improving the oral health of the Scottish population[3], which had a focus on prevention and included a section on general health checks for adults. This suggested that dentistry could utilise its cohort of regular attenders by conducting general health checks for the early detection of chronic diseases. It outlined actions for the Scottish Government, one of which was to "explore the potential for introducing general health checks for adult patients whilst attending for routine dental checks" [5]. This suggests that this research exploring the use of general health checks in dentistry could provide valuable information to inform the implementation of this aspect of the OHIP framework.

Evidence suggests that participation in general health checks can vary considerably. Harte et al. (2018) explored reasons for non-attendance at NHS Heath Checks in England. These checks were available at GP practices, pharmacies and other community settings. The authors found that misunderstanding the purpose of the checks, aversion to preventive medicine, difficulty accessing GP practices, and concerns about pharmacies as an appropriate setting for these checks, all contributed to non-attendance.[4] This suggests that there are numerous potential barriers to introducing general health checks in dentistry; this study will seek to explore this further by investigating the views of patients and dental professionals.

From a range of possible general health checks that could be implemented in dental practices for this study (e.g. blood pressure, heart rate), type 2 diabetes was chosen due to its established links with oral health. Indeed, when considering the links between oral health and general health, the common risk factor approach outlines how diabetes and oral health, specifically periodontal disease and dental caries, share several risk factors, including diet, smoking and stress. [5] There is a clear relationship between type 2 diabetes and periodontitis, with significantly elevated HbA1c levels in periodontal patients[6]. This relationship is considered to be bidirectional, with diabetes increasing the risk for periodontitis and periodontal inflammation negatively impacting glycaemic control, as well as a clear association between the degree of hyperglycaemia and severity of periodontitis.

A systematic review and meta-analysis of the current evidence identified that dental patients could be identified as having undiagnosed type 2 diabetes and non-diabetic hyperglycaemia when a point-of-care, opportunistic screening was used in a dental setting[7]. Furthermore, in research carried out by Lalla et al., more than one third of dental attenders with unrecognised hyperglycaemia were successfully identified in dental settings by using a diabetes risk questionnaire, periodontal screening and a point-of-care HbA1c test. This has suggested that dentists have a significant role in identification of unrecognised diabetes and pre-diabetes.[8]

Diabetes UK is the leading diabetes charity in the UK[9]. Available via their website, they have developed a risk assessment tool that the public can use to determine their risk of developing type 2 diabetes. This tool is based on the Leicester Diabetes Risk Assessment, a validated questionnaire which was designed to be completed by a lay person with the aim of screening and identifying individuals at high risk of impaired glucose regulation and type 2 diabetes mellitus.[10] The assessment tool asks for the following information: gender, age, ethnic background, if you have a close relative with diabetes, waist

measurement, height, weight, and if you have high blood pressure. Your risk level is then calculated. You can either be high, moderate, increased or low risk. Diabetes UK recommends that you should visit your GP for a blood test to check for diabetes if you are moderate or high risk[11]. This tool has been chosen to be the health check used in this study.

There is limited evidence available regarding comparison of signposting or directly referring patients to a healthcare professional. Burns et al. (2021) considered this in relation to interventions that linked families from healthcare services to community-based support. Their study found that the more active the act of linking was, the more successful it was at linking families to support, i.e. referral was more successful than signposting.[12] More evidence is required however, regarding the use of signposting and referral in a dental setting, to another healthcare professional.

Role of Vocational Dental Practitioners

In Scotland, dentists must undertake a 12 month "Vocational Training" (VT) year following completion of their undergraduate training. This VT year involves supervised clinical experience in an approved training practice. There are 140 training practices and these are spread throughout training schemes in 5 regions: North, North-East, East, South-East, and West. Satisfactory completion of the VT year permits dentists to be eligible for an NHS list number which allows a practitioner to become an associate or a principal in the NHS General Dental Service (GDS) or a salaried dentist in the Public Dental Service (PDS). The aim of the VT year is to provide dental graduates with the skills necessary to undertake unsupervised clinical work, as well as enhance their skills and competence with the clinical and non-clinical aspects of dentistry.[13]

During the COVID-19 pandemic the provision of dental services in Scotland was severely disrupted. In March 2020, most routine care ceased, with NHS dental practices closed to patients but providing telephone triage[14]. Dental practices were allowed to re-open in June 2020. They were initially restricted to urgent, non-aerosol generating procedures, but by August were allowed to conduct non-urgent aerosol generating procedures, with restrictions still in place regarding personal protective equipment and the mitigation of aerosol generation[15]. These closures and restrictions have had a significant impact on the numbers of patients that can be treated, leading to backlogs and waiting lists. This also impacted upon VT, resulting in VDPs who had not gained sufficient clinical experience during their 12-month post[16]. As such, a decision was made to extend the 2020-2021 VT year until August 2022, giving the current cohort of VDPs an additional 12 months in which to gain sufficient clinical experience[17].

This additional year was also considered to be an opportunity to provide VDPs with first-hand experience of undertaking a research project. As such, a project team was established with staff from NHS Education for Scotland's Clinical Effectiveness and Vocational Training workstreams, alongside researchers from the University of Aberdeen and a group of VDPs. Twenty-one VDPs volunteered to be involved in the study design process; these VDPs participated in design workshops and have contributed to this protocol and produced supporting resources. They will also be involved in data collection, data analysis and dissemination.

2. Aims and Objectives

2.1. Aim

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.

2.2. Objectives

Primary objective:
To compare the effectiveness of the following referral strategies for facilitating contact between healthcare professionals and patients at risk of type 2 diabetes:

- Direct referral
- Signposting

Secondary objectives:

- to explore the beliefs and experiences of primary care dentists about general health checks and referral in primary care practice.
- to explore the beliefs and experiences of dental patients about general health checks and referral in primary care practice.

3. Method

3.1. Study Design
A two-arm clustered randomised controlled trial.

3.2. Study Setting
This will be a multi-centred study, with patient recruitment and data collection taking place in vocational dental training practices across Scotland. Once recruited, each participating dental practice will receive information and training regarding what is required from their practice before the study can begin, and what they will be expected to do regarding data collection and data storage.

3.3. Sample, Recruitment and Eligibility
All dentists (principal, associate, VDP) working in vocational training practices in Scotland will be contacted via existing vocational training networks inviting them to take part. Eligibility criteria is shown in Table 1.

Table 1: Eligibility criteria for all participant groups

Participant Group	Inclusion	Exclusion
Practices	• vocational training practice • Based in Scotland	• Not a vocational training practice • Outside of Scotland

Practitioners	• Dentist working in a vocational training practice in NHS General Dental Service
	  ○ VDP
	  ○ Principal dentist
	  ○ Associate dentist
	• Private dentists
		• Practitioners in:
		• Public Dental Service
		• Hospital Dental Service

Patients	• Adults $\geq$ 40 years • Attending a vocational training practice for a non-emergency appointment • English speaking	• Adults $<$ 40 years • Patients attending for emergency treatment • Patients who are pregnant • Patients who have been previously diagnosed with diabetes or non-diabetic hyperglycaemia • Patients who do not speak English

Patients will be recruited via communication from their dental practices. Patients will be contacted about the study when they receive their standard appointment reminder message. This can be via email or the patient's preferred method of communication. This recruitment message will contain information about the project and the participant information sheet will also be provided. Patients will be advised that if they wish to take part in the project they should bring their height, weight and waist measurements with them to their next appointment. At the appointment they will be assessed for their eligibility, given the opportunity to ask questions about the study, and asked to consent to their participation.

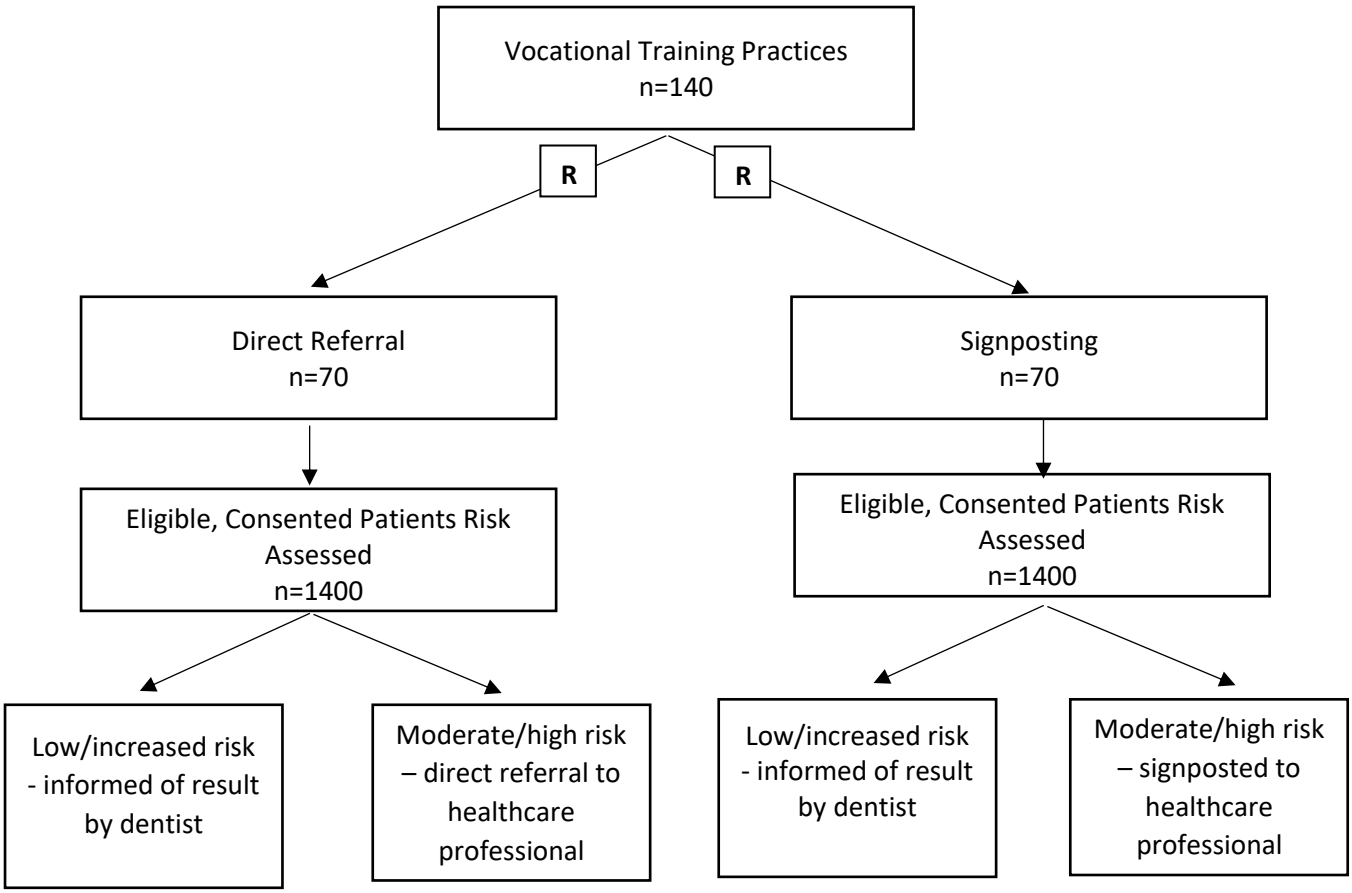
3.4. Randomisation

All eligible NHS dental training practices in Scotland will be invited to take part (n=140). Eligible practices agreeing to take part will be randomised to either signpost or directly refer patients to their GP if their risk assessment score was "moderate" or "high". An automated system will randomise eligible practices on a 1:1 basis. A computer-generated stratification programme, incorporating a random element, will ensure intervention arms are balanced for practice size.

3.5. Intervention groups

There will be 2 intervention groups. Practices in Group 1 will signpost their patients to a healthcare professional. Practices in Group 2 will directly refer their patients to a healthcare professional (see Figure 1).

Figure 1: Trial Design



3.6. Outcomes

Primary: the proportion of patients who make contact with a healthcare professional. Contact may be in person or via the telephone. Healthcare professional may include the patient's GP or pharmacist.

Secondary: beliefs of patients and dentists regarding the acceptability of general health checks in a dental setting and their feelings about being told their risk level.

3.7. Sample size

Our sample size calculation is pragmatic and, therefore, based on the number of sites available to do this study (140 sites). The study will randomise practices on a 1:1 basis, so each arm will have 70 sites. Participating dentists in each site will be asked to recruit 20 patients each. The study will be randomised and analysed at the practice (cluster) level; therefore we implemented a formulae for individually randomised trials using Stata's 16 power command. Assuming 55% of participants will contact a healthcare professional about their risk score if it is elevated, which is supported by evidence coming from a similar and recent study[18], and assuming a standard deviation of 25%, we have 80% power to detect a difference of 12% between arms, equivalent to 67% of participants contacting their healthcare professional in the intervention arm. We assumed no drop-out as the sample size is calculated according to the number of clusters (practices) and we do not expect practices to drop out.

3.8. Data Collection

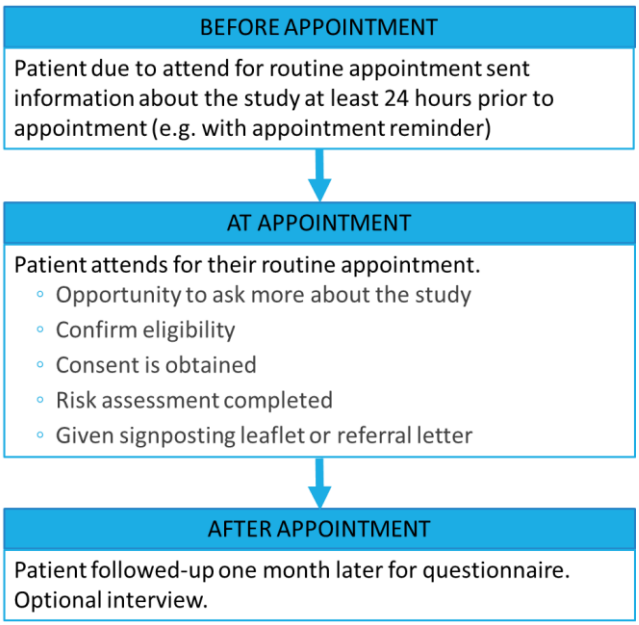
Once a patient has been confirmed as being eligible to participate, and has consented, the dentist will then complete the risk assessment online tool with the patient. The patient will be informed before

attending the appointment what information they will need, and will be asked to take their own measurements (weight, height, waist circumference) before attending. They will be provided with information beforehand about how to take these measurements. Participating dentists will be required to keep a record of the number of patients they conduct the risk assessment with, and the outcome of that assessment, i.e. the patient's risk assessment score, and what action was taken. This information will be stored in the Case Report Form.

Both signposting and referral will involve standardised resources, developed by VDPs. Dentists who signpost patients will be provided with an information leaflet with key information for patients. Dentists who make a direct referral to their patients' GP practice or pharmacist will be provided with a standardised referral letter template. This letter can be customised with patient details and then hand delivered or emailed to the patient's GP practice or pharmacist.

An online self-report survey will be sent to all patients one month following their risk assessment. Paper copies will be available for participants who have not supplied an email address, or who do not have internet access. For patients who were at moderate or high risk, they will be asked if they have contacted a healthcare professional about the outcome of their risk assessment. Due to the impact of COVID-19 restrictions, attendance at a GP practice in person may not be possible; as such, we will consider any verbal contact with GP or other healthcare professional, either in person or via telephone, as "contact" for the purposes of this study. This survey will also measure the secondary outcomes for all patients, i.e. their beliefs and experiences about receiving a general health check. Patients will be asked about their thoughts on the acceptability of general health checks in a dental setting, how they felt about being told their risk score and how they felt about being referred/signposted if they were at moderate or high risk. Demographic information will also be collected. A flow diagram of the patient journey is presented in Figure 2.

Figure 2: Patient Journey



An online survey will be sent to participating dentists, asking about their beliefs and experiences about conducting the risk assessment in their practice, as well as their thoughts on general health checks in dentistry. They will also be asked how they felt about telling their patients their risk score.

In addition, a small sub-group of participants (dentists and patients; n=10 per participant group) will be invited to take part in interviews. This qualitative approach will allow for a deeper understanding of the beliefs and attitudes of participants. Interviews will be conducted online via Microsoft Teams or via telephone, depending on participant preference. All interviews will be audio-recorded using a separate audio-recording device; Microsoft Teams will not be used to record interviews. These interviews will be transcribed by the study administrators for the purposes of data analysis.

3.9. Data Analysis

The quantitative data analysis will be led by the study statistician, Dr Beatriz Goulao. Dr Goulao has agreed access to the NHS Education for Scotland network for data analysis. Restricted access to the data will be provided to Dr Goulao for the purpose of analysis by making the data available on a restricted area of the secure network. All analysis will be carried out on NHS Education for Scotland computers.

A single principal analysis will be conducted post-randomisation following an intention-to-treat framework. The analysis will estimate the difference between the average proportion of patients contacting a healthcare professional between the two randomised groups. We will use a cluster-level analysis with weighted linear regression[19] to estimate the treatment effect of the intervention with 95% confidence intervals. We will adjust the analysis for appropriate covariates.

Qualitative analysis will be led by Dr Laura Beaton. Qualitative data from any free-text boxes in the questionnaire, and the online interviews will be analysed using thematic analysis, whereby data is coded into themes that emerge from commonalities or repeated patterns in the data[20]. This will be undertaken following the six-step process outlined in Braun and Clarke (2006): familiarisation with the data; assigning preliminary codes; searching for patterns in codes; reviewing themes; defining and naming themes; production of final report.

4. Follow-up

There is potential for a longer-term follow-up of participating patients by looking at routinely collected data held by Public Health Scotland (ICD10 database) to determine the diagnostic accuracy of the Diabetes UK Risk Assessment tool when implemented in a dental setting. Participating patients will be asked in the consent form if they agree to be contacted about this follow-up up to 2 years following the study. Not providing consent for this aspect would not preclude patients from taking part in the main study.

5. Data Handling and Storage

5.1. Data Handling and Access

Participating dental practices will be required to identify, recruit and consent patient participants using their patient records. The study team will not have access to patient records. Study paperwork (eligibility checklist, consent form, case report form) will be online with the responses coming directly to the study team. Participating dentists will be responsible for ensuring the appropriate paperwork is completed for each patient. If a paper copy of the consent form is requested by the patient, then these will be stored securely within the dental practice and transferred to the study team on a weekly basis. No personal data collected for the study will be retained by the participating practices.

Participating dentists and dental practices will not be responsible for collecting data from the questionnaires and interviews; this will be the responsibility of the study team. The study team will contact participants about the questionnaire and interview via their preferred method of communication (given in the consent form). Paper copies of the questionnaire may be requested by participants; if so, these will be sent via post. Once completed questionnaires are returned to the study office, the responses will be entered online by a study administrator; the paper copy will be scanned, saved online, and then destroyed.

Members of the study team will have access to personal data only when required. Participating dentists and dental practices will only have access to data from their own practice. When contact is required with participants from the study team in order to contact participants with the link to the questionnaire and recruit for interviews, a limited number of people from the study team (e.g. chief investigator, administrative support) will have controlled access to personal data to allow emails/letters to be sent.

All data collected during the course of the study will be pseudonymised after data collection but before data analysis. Participants will be allocated a participant number by the study team, which will be linked to their name and email address (or other preferred method of communication, e.g. postal address or telephone number); this information will be kept in a password-protected link file and kept separate from the data.

5.2. Data Storage

A. Personal Data

Electronic personal data will be encrypted and all data will be securely stored on NHS Education for Scotland servers and will only be accessed by login and password of the nominated team members, in accordance with the NHS Education for Scotland Corporate Information Security Policy and the Information Governance Policy. If paper copies of documents containing personal data are collected, high-resolution scans will be taken of the documents, the original paper copies destroyed and the scanned documents securely stored on the NHS Education for Scotland servers as outlined above.

B. Research Data

Electronic copies of research data will be securely stored on NHS Education for Scotland servers. If the NHS Education for Scotland information governance regulations change during the study, this policy

will be reviewed and updated as appropriate. If paper copies of documents containing research data are collected, these will be scanned and the paper copies destroyed. The high-resolution scanned documents will be securely stored on NHS Education for Scotland as outlined above. Access to the data will be controlled by the data custodian (Dr Linda Young) or a nominated delegate, and a Data Protection Impact Assessment will be completed before the study commences.
Interviews with participants will be audio and video recorded. These recordings will be destroyed at the end of the study.

5.3. Data Retention

Personal data will be retained for a period of two years following the end of the study, to allow the study team to follow-up patients who have consented to being contacted. If participants have not consented to being contacted, their personal data will be destroyed at the end of the study, once data analysis and write-up is complete. If a patient who has previously consented to being contacted in two years declines to participate in the follow-up study, their personal data will be destroyed.
Research data will be stored for ten years following the end of the study.

6. Ethical Review and Governance

Ethical approval will be sought from an NHS Scotland Research Ethics Committee. Before any sites begin to recruit patients to participate, the Chief Investigator will ensure that appropriate approvals are in place. This work will be conducted in accordance with the UK Policy Framework for Health and Social Care Research and the 2018 edition of the Governance Arrangements for Research Ethics Committees. Any personal or special category data will be stored and managed in accordance with the General Data Protection Regulations (UK GDPR) 2018. A Data Protection Impact Assessment will be undertaken.

Informed consent will be obtained from all participants (patients and practitioners). Before consent is sought, all participants will be given the opportunity to read and ask questions about the participant information sheet. If any relevant new information becomes available during the course of the research then this will be conveyed to participants via their preferred method of communication from the study team.

7. Patient and Public Involvement

An experienced Patient and Public Involvement representative was involved in discussions about the initial development of the research project. Patient-facing resources have been developed with feedback from a small group of dental patients to ensure they are accessible and appropriate. Patient and public involvement will be sought towards the end of the project to help produce a plain English summary of results to be shared with patient participants.

8. Training

All participating practitioners will be required to complete Good Clinical Practice training before undertaking data collection. In addition, they will be asked to complete training provided by Diabetes UK for healthcare professionals and additional training will be offered by a member of the project advisory team regarding communicating with patients about diabetes.

9. Reporting and Dissemination

On completion of the study data will be analysed as outlined above, and a final study report will be prepared. This report will be made available and presented to the NHS Education for Scotland Dental Executive. A summary of findings will be made available to participants, and the VDPs who contributed to the study. The protocol and findings will also be submitted for publication in a peer-reviewed journal and presented at relevant conferences. In addition, other innovative methods of dissemination

will be explored, including online videos. Authorship of reports, papers or presentations will be determined by the criteria developed by the International Committee of Medical Journal Editors[21].

10. Amendments

The Chief Investigator will be responsible for any amendments made to the protocol, and for communicating any substantive changes to the Research Ethics Committee and NHS R&D. Amendments will be noted in the "Amendment History" table below and the protocol version number will be updated accordingly.

Table 2: Amendment History

Version Number	Date	Amendments
Version 1	16/12/2021	
Version 2	05/02/2022	• Changes to the eligibility criteria to include requirement that patient participants must speak English. • Sentence added to the "Ethical Review and Governance" section, to include that participants will be contacted if any relevant new information becomes available during the course of the research. • New subsection added: 3.2 "Study setting" • New section added "Data Handling and Storage". This becomes section 5; subsequent sections renumbered accordingly. • Additional text added to Section 3.9. "Data Analysis" to indicate who will be responsible for analysis of quantitative and qualitative data. • Additional text added to Section 8 "Training" regarding additional training to be offered to participating dentists.
Version 3	08/03/2022	• Additional text added in Section 3.8 "Data Collection" regarding paper copies of questionnaires being available for patients who do not have internet access.
Version 4	23/05/2022	• Text in Section 3.8 "Data Collection" revised to clarify that patient interviews will be audio-recorded using a separate audio-recorder, not using MS Teams.

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