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Does the provision of a personalised oral health report including pictures aid patients in improving their gum health over a four week period?

Submission date
18/11/2019

Recruitment status
No longer recruiting

Registration date
20/11/2019

Overall study status
Completed

Last Edited
25/10/2022

Condition category
Oral Health

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
According to the General Dental Council in the UK, it is the responsibility of the dental care team to provide patients with comprehensive and accurate preventative education and instruction in a manner which encourages their self-care and motivation. Poor oral heath in patients is commonly reflected in dental plaque-induced diseases, such as gum (periodontal) disease and tooth decay (dental caries). The accumulation of dental plaque can lead to inflammation of the gum (gingival) tissue, which in turn may progress to irreversible periodontal disease and the eventual loss of affected teeth.

Plaque removal from teeth is a skill that can be accomplished only when a patient understands the goals of plaque removal and has been appropriately educated in practising effective dental hygiene, including correct tooth brushing technique and the use of interdental cleaning tools. In recent years, cognitive behavioural techniques, such as the formation of goals, actions and written coping plans have been integrated with dental hygiene and were found to be more effective than verbal oral hygiene instructions.

Oral health educators have an important and valuable role within dental practices to promote good oral health care and work with patients to prevent diseases such as gingivitis (reversible gum disease) and periodontitis (irreversible gum disease). Oral hygiene instructions (OHI) given by an oral health educator make a patient more aware of periodontal disease and consequently improve gingival health.

Intraoral cameras (which record images and video inside the mouth) are non-invasive diagnostic aids which have appeared in recent years. However, their limited field of investigation and constraints on their use make them difficult to integrate into the daily dental practice. A new camera has been developed and is intended for clinical practice in general dentistry, directed

towards preventive concepts, prophylactic care and overall patient management. The intraoral diagnostic camera (Soprocare Acteon® (PERIO mode and DAYLIGHT mode) improves visibility and can be used to show patients areas of tissue inflammation in the mouth.

The purpose of the study is to use this camera alongside the delivery of verbal oral hygiene advice to inform both the dental professional and patient about the condition of the oral tissues being examined. The camera can be used live because it does not emit ultraviolet or ionising radiation, the PERIO mode informing practitioners about the presence of dental plaque while simultaneously enabling them to distinguish healthy from diseased gingival tissues.

The aim of this study is to estimate the effectiveness of the provision of patient-specific oral hygiene instruction (OHI) with the use of a pictorial report following consultation with a dentist compared to standard verbally provided oral hygiene instruction with regards to patient plaque levels and improved gingival health, over a four-week period.

Who can participate?
The study will recruit approximately 20 healthy dentate female and male participants aged 18 or over.

What does the study involve?
A single dental clinician will carry out baseline and 4 week plaque and gingival health assessments and deliver OHI to all participants. The on-going dental care of the patient will not be affected by their participation in the study. To complete the study, the participants will need to attend for two visits at the study site, lasting approximately 1 hours 10 minutes, in total.

Visit 1 (approximately 40 minutes)
Participants who provide written informed consent to participate in the study will be assessed whether they fulfil the inclusion and exclusion criteria. Participants who are suitable to take part in the study will have an oral hard and soft tissue examination and will complete a questionnaire regarding gum (gingival) health. They will then shown standard pictures of teeth and gingivae (gum). They will be asked to indicate whether they think the pictures demonstrate oral health or oral disease and which they think represents their current oral health. Participants then will have an intra-oral scan of their mouth taken with the diagnostic camera, and the images captured will be downloaded and a pictorial report prepared of their oral health. The camera will also assess the levels of plaque present on the patients teeth. The report will be recorded containing the participants study ID number only. Only teeth in the upper 3-3 region will be recorded. The study dentist will then examine the participants gingival (gum) health by carrying out a standard gum health examination and then will measure the amount of plaque present using a traditional technique involving dye (food colouring) which is placed onto the surface of the teeth which highlights plaque. The teeth for assessment throughout the study will be 2 suitable teeth as determined by the study dentist in the upper 3-3 region of the mouth.

The participant will then be randomised by study staff to one of 2 treatment groups (Control group - standard verbal oral health instructions (verbal OHI) or Test group – pictorial report + verbal oral health instructions (picture + verbal OHI) using a predetermined randomisation schedule. Participants will then be asked to complete questionnaires on their current oral hygiene practices and attitudes to oral health.

Participants will then receive OHI according to the study group they are allocated to. Only participants enrolled into the picture + verbal (test) group, as determined by the randomisation schedule, will be shown images and video captured during the scan of their mouth which will be explained to them by the study dentist. Participants enrolled into the control group will receive

verbal OHI only by the study dentist. Following the delivery of OHI, all participants will complete a second questionnaire on their attitudes to their oral health.

Participants receiving picture + verbal OHI (test group) will receive a copy of their pictorial report to take away with them along with an oral health leaflet and mouth mirror for use at home. Copies of the pictorial report will be kept at the study site. An appointment will be made for the patient to return to the study site in 4 weeks.

Visit 2 – 4 weeks after Visit 1 (approximately 30 minutes)
During this appointment, the continuing eligibility of the participant will be confirmed and an oral soft tissue examination will be carried out. Participants will complete a questionnaire regarding their oral hygiene practices and attitudes to oral health.
All participants will have another intra-oral scan of their mouth taken with the diagnostic camera, and the images and video captured will be downloaded and a pictorial report prepared of their oral health, then the gingival health and plaque assessments will be repeated.

Participants assigned to receive the picture + verbal OHI will receive their pictorial report which will be reviewed alongside their initial report by the study dentist, who will give advice for ongoing oral health maintenance.

For those participants who were assigned to receive standard OHI alone, following the completion of study assessments at Visit 2, the dental clinician will then review the video and images of their mouth captured at both Visit 1 and Visit 2 and provide the patient with a copy of their pictorial report from both visits to take away with them. These participants will also be provided with a mouth mirror and an information leaflet regarding the importance of maintaining good oral health along with advice for their individual ongoing oral health maintenance. Following this, participants will be asked to complete a second questionnaire on their attitudes to oral health.
At the end of this visit, their participation in the study will cease.

What are the possible benefits and risks of participating?
Research participants will receive a pictorial report of their oral health status and tailored Oral Health Instructions which will enhance the maintenance of good oral hygiene. In one group, this will be given at visit 1 whilst the other group will receive the pictorial report at the end of visit 2.

There are no potential risks to the participants as the dental assessments made as part of the study (plaque score and gingival health assessment) are all standard techniques, routinely carried out as part of usual dental care. All assessments will be carried out by a dentally qualified clinician.

Where is the study run from?
University of Bristol Dental Clinical Trials Unit, UK

When is the study starting and how long is it expected to run for?
December 2019 to December 2020

Who is funding the study?
Acteon UK

Who is the main contact?
Professor Nicola West
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
265051

Protocol serial number
2019-3848

Study information

Scientific Title
A proof of principle study to evaluate the provision of a pictorial report following dental oral hygiene instruction to aid participants improving their gum health over a 4-week period

Study objectives
The aim of this study is to estimate the effectiveness of the provision of patient-specific oral hygiene instruction (OHI) with the use of a pictorial report following consultation with a dentist compared to standard verbally provided oral hygiene instruction with regards to patient plaque levels and improved gingival health, over a four-week period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/11/2019, South East Scotland REC 01 (NHS Lothian, Waverley Gate, 2 - 4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)131 465 5473; Sandra.Wyllie@nhslothian.scot.nhs.uk), ref: 19/SS/0114

Study design
Interventional randomized parallel trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Oral hygiene

Interventions
Randomisation
Approximately 20 participants will be recruited to the study, with 10 participants assigned to each of the two possible treatment groups. Randomization will be at the patient level and executed through the Bristol Dental Clinical Trials Unit, according to a predetermined randomization schedule.

Participants will be randomised by study staff to one of 2 treatment groups (Control group - standard verbal oral health instructions (verbal OHI) or Test group – pictorial report + verbal oral health instructions (picture + verbal OHI) using a predetermined randomisation schedule.

A unique screening number will identify each subject screened for study participation. Screening numbers will be assigned in ascending numerical order as each subject signs their consent form. Subjects who meet all inclusion and exclusion criteria will be randomised according to the randomisation schedule. Randomisation numbers will be assigned in ascending numerical order as each subject is determined to be fully eligible. The randomisation schedule will be generated via a computer-generated system.

For each patient recruited to the study, they will be required to attend 2 study visits with the research team. The appointments are as outlined below:

Visit 1: (Approximately 40 minutes)
• Consent
• Oral hard and soft tissue examination
• Eligibility
• Patient assessment of standard mouth images with dentist to look at the appearance of healthy vs non- healthy mouths (See Appendix 3)
• Intra-oral scan of patient's mouth and assessment of plaque – download report for patient to take away (Appendix 5)
• Plaque and gingival health assessments (See Appendix 4)
• Randomisation
• Completion of questionnaire with regards to current oral health/hygiene practices (Part A) and patients' attitudes to oral health (Part B) (See Appendix 1 – Parts a and b)
• Provision of OHI instruction by dentist – depending on randomisation either standard verbal OHI or enhanced OHI (pictorial + verbal OHI) with a detailed pictorial report for the patient
• Provision of OH leaflet and mouth mirror for participants use at home – for those participants assigned to the pictorial + verbal OHI group only.

Visit 2: 4 weeks (approx.) following Visit 1: (approximately 30 minutes)
• Confirm Eligibility
• Oral hard and soft tissue examination
• Completion of questionnaire with regards to current oral health/hygiene practices (Part A) and attitudes to oral health (Part B). (See Appendix 2)
• Final intra-oral scan – download patient report
• Final plaque scores and gingival health assessments
• Provision of pictorial oral health report for patient to take away.
• For participants assigned to the standard verbal OHI alone, review of patient pictorial report obtained at Visit 1 and Visit 2 and provision of tailored OHI advice and a copy of their pictorial report, provision of mouth mirror and leaflet on oral health.

Intervention Type
Mixed

Primary outcome(s)
At baseline and 4 weeks:
1. Plaque levels measured using the O'Leary et al (1972) 2 point scale, 'YES(1)' or 'NO (0)'
2. Gingival health measured using a 5-point MGI scale
3. Bleeding on probing will be measured using a 2 point scale, 'YES(1)' or 'NO (0)'

Key secondary outcome(s))
At baseline and 4 weeks:
1. Patient perceptions of the effectiveness of a having a pictorial report of their oral health as part of their dental care measured using questionnaire
2. Patient attitudes to oral health measured at baseline and 4 weeks measured by questionnaire
3. Participants' understanding of gingival health vs gingival disease measured by questionnaire
4. Assessment of the accuracy of the intra-oral camera's ability to assess plaque levels by comparison to traditional techniques (using dye)

Completion date
09/12/2020

Eligibility

Key inclusion criteria
1. Aged 18 years and over, of either gender and in good health
2. Dentate with a minimum of 18 scorable teeth, with at least 4 teeth in the upper anterior sextant.
3. Without removable dental prostheses or fixed or removable orthodontic appliances
4. Willing and competent (verbally and cognitively) to give written informed consent and complete a medical history form
5. Willing and physically able to carry out all study procedures
6. MGI score of ≥1 on at least one of the 2 identified teeth for assessment

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
22

Key exclusion criteria
1. Medical condition and/or regular use of any medication which might affect the outcome of the study, as determined by the study dentist, principally a course of anti-inflammatory, antimicrobial or statin drugs
2. Secondary modifying factors in relation to periodontal disease (e.g. immunocompromised individuals and smokers, including vaping nicotine with e-cigarettes)
3. In the judgement of the investigator, should not participate in the study
4. An employee of the research team at the study site

Date of first enrolment
11/12/2019

Date of final enrolment
04/11/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Bristol Clinical Trials Unit
Bristol Dental School and Hospital
Lower Maudlin Street
Bristol
United Kingdom
BS1 2LY

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Industry

Funder Name
Acteon

Results and Publications

Individual participant data (IPD) sharing plan
The anonymised participant data (clinical scores and questionnaire data) generated during the current study will be shared once the data has been published and will be stored in the publicly available University of Bristol Research Data Repository (https://data.bris.ac.uk/data/) with a DOI maintained for a minimum of 20 years. Data will be made available as restricted access to bonafide researchers who provide a methodologically sound proposal and evidence of ethical approval (if required), subject to the agreement of the University of Bristol Data Access Committee for analysis to achieve aims in the approved proposal

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/01/2022	24/02/2022	Yes	No
Dataset		09/03/2022	19/10/2022	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 3.0	13/07/2020	25/10/2022	No	No