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Can the use of 3D scans of participant's gum health improve their compliance with their oral hygiene regime?

Submission date
18/05/2021

Recruitment status
No longer recruiting

Registration date
19/05/2021

Overall study status
Completed

Last Edited
23/05/2023

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Gum disease is a prevalent condition which with good oral hygiene at home and regular visits to the dentist can be reversed. However, in most people if gum disease is not treated it progresses to periodontitis which is irreversible and can lead to tooth loss and have a negative impact on quality of life. There is also now evidence to suggest that periodontitis may increase the risk of an increasing number of other diseases such as heart disease, diabetes and Alzheimer's disease. The reason that gum disease is so prevalent is that many people do not have a good oral hygiene regime. They often do not brush their teeth effectively enough or know how they should be brushing even though they have had advice when they have visited the dentist. New techniques that dentists can use to help people improve their oral hygiene regime at home are therefore important. 3D Intraoral scanners can now take very accurate pictures of the teeth and gums and could be used as an aid to help patients understand how to clean their teeth and to motivate them to clean better. The aim of the study is to find out if using 3D intraoral scans along with associated oral hygiene advice and a toothpaste designed for healthy gums can improve overall gum health, more than the use of standard oral hygiene advice given without the aid of the 3D intraoral scans and with the participants' preferred/normal toothpaste and brush routine.

Who can participate?
Healthy adults with early gum disease

What does the study involve?
The study involves completing questionnaires on oral health and four visits to Bristol Dental School. At each study visit, the study dentist will use a marketed intra-oral camera to take three images of participants' mouths, one at the start of the visit, one after the dental plaque has been disclosed using a standard dental disclosing dye and one after the participant has been given oral hygiene advice and asked to brush their teeth. About half of the enrolled participants will be allocated to the control group in which the oral hygiene advice will be that given in standard dental practice and the toothbrush and toothpaste used during brushing will be their own normal preferred toothpaste and toothbrush. The intervention group (about half of those enrolled) will be given oral hygiene advice with the aid of the scans of their mouth and a

marketed gum health toothpaste to use on study days and between study appointments. The intervention group will also receive reminders by text/email about keeping their mouths healthy.

What are the possible benefits and risks of participating?
There are no potential risks involved in taking part in this study. The oral hygiene intervention may provide a benefit and improve oral hygiene. Those in the control group will receive this oral hygiene advice based on their oral scans at the end of the study, so this intervention may benefit this group too.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
November 2020 to April 2022

Who is funding the study?
GSK Consumer Healthcare (UK)

Who is the main contact?
Nikki Hellin
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Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
100221-NXW

Study information

Scientific Title
A study to investigate the impact of behavioral change modification using 3D intra-oral gingival imaging combined with a toothpaste indicated for gingivitis, to deliver an optimized standard of care to improve health

Study objectives
The use of an oral hygiene intervention that comprises a 3D scan of participants gum health, a gingivitis toothpaste and oral hygiene reminders will improve gum health more than the standard of care provided in general dental practice after 6 months

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/04/2021, East of Scotland Research Ethics Service (Tayside Medical Science Centre, George Pirie Way, Dundee, DD1 9SY, UK; +44 (0)1382 383871; Tay.eosres@nhs.scot), ref 21/ES/0036

Study design
Parallel blinded (to the clinician scoring the gingivitis) randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of periodontal disease progression in participants with early gum disease

Interventions
Adults in good general health who give informed consent to take part and have gum disease (a minimum 6 oral sites that exhibit bleeding on probing on the buccal/palatal aspect of teeth, from upper right 6 to upper left 6 and lower right 6 to lower left 6) will be recruited to the study and randomised 50:50 to the test or control arm of the study.

All participants will complete a questionnaire about their current oral hygiene practices once at the start of the study and an oral health quality of life questionnaire twice, at baseline and at their final study visit. After the baseline visit there will be three further visits, at 3 weeks, 3 months and 6 months.

At each study visit (baseline to 6 months) all participants will receive three intra-oral scans: the first at the start of the visit, the second after they have had their dental plaque disclosed with a standard vegetable dye and the third after they have been given oral hygiene instruction and brushed their teeth.

Interventions:
The control group: the oral hygiene delivered between scan 2 and scan 3 will be the standard of care provided in general dental practice and they will brush their teeth with their normal toothpaste and toothbrush.
The intervention group: the oral hygiene delivered between scan 2 and scan 3 will use the images of their gum health as captured by the scan to indicate the areas where they have plaque build-up and need to focus their toothbrushing. This group will also be provided with a marketed anti-gingivitis toothpaste and between study visits will be sent motivational texts reminding them of the need to follow their oral hygiene regime.

Measurements:
In both groups gum health will be monitored at each study visit by bleeding index and clinical plaque score.

Intervention Type
Behavioural

Primary outcome(s)
Gum health measured by bleeding on probing at baseline, 3 weeks, 3 and 6 months

Key secondary outcome(s))
Oral hygiene measured by plaque score at baseline, 3 weeks, 3 and 6 months

Completion date
30/04/2022

Eligibility

Key inclusion criteria
1. Adults 18 years and older
2. Understands and is willing, able and likely to comply with all study procedures and restrictions.
3. Accepts the form of the study and signs a declaration of informed consent.
4. In good health (in the opinion of the investigator/research dentist) without clinical abnormality nor abnormal medical history.
5. A minimum of 10 teeth not including teeth with crowns or bridges from upper right 6 to upper left 6 and lower right 6 to lower left 6
6. At least 6 sites score bleeding on probing (BOP) of 1 on the buccal/palatal aspect of teeth, from upper right 6 to upper left 6 and lower right 6 to lower left 6
7. Use a smart mobile phone or access email via another route

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
85

Key exclusion criteria
1. Adults currently using maxillary or mandibular orthodontic appliances
2. Obvious signs of untreated caries, which in the opinion of the Study Dentist, will affect either the scientific validity of the study
3. Periodontal pocket depth 4 mm
4. Any condition that might affect gingivitis
5. Any participant who in the investigator’s judgement will not comply with the study protocol
6. Any Modified Gingival Index (Lobene, 1986) scores of 4 on upper 6-6 or lower 6-6 teeth, buccal or palatal surfaces
7. Known allergy to the anti-gingivitis toothpaste ingredients

Date of first enrolment
15/06/2021

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Bristol
Bristol Dental School and Hospital
Lower Maudlin Street
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Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Current IPD sharing statement as of 23/05/2023:
Due to the sensitivity of the data involved, these data are published as a controlled dataset at the University of Bristol Research Data Repository data.bris (https://data.bris.ac.uk/data/), at https://doi.org/10.5523/bris.1wjyuvl4r56cy2lde94ojyfo41. The metadata record published openly by the repository at this location clearly states how data can be accessed by bona fide researchers. Requests for access will be considered by the University of Bristol Data Access Committee, which will assess the motives of potential data re-users before deciding to grant access to the data. No authentic request for access will be refused and re-users will not be charged for any part of this process.

Previous IPD sharing statement:
The anonymised participant data (clinical scores and questionnaire) generated during the current study will be shared after the end of the study and after the study has been published. The data 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. Data will not be available until after the study findings have been published, at which point anonymised raw data will be uploaded to the repository with a text 'readme file' that will describe the contents of the study folder. Data was collected with informed consent for future use. Proposals for using the study data will also be subject to prior written consent of the funder GSK Consumer healthcare.

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/02/2023	17/03/2023	Yes	No
Dataset		19/05/2023	23/05/2023	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V2.0	26/03/2021	01/06/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes