University of BRISTOL

PROTOCOL

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

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Project proposal

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

Introduction

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 (General Dental Council UK, 2012). Poor oral heath in patients is commonly reflected in dental plaque induced diseases, such as periodontal (gum) disease and dental caries (tooth decay). The accumulation of dental plaque and change in the dental microflora can lead to gingival inflammation, which in turn may progress to chronic periodontal disease and the eventual loss of affected teeth (Holt et al., 2000).

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 practicing effective dental hygiene, including correct toothbrushing 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 intervention (Philippot et al., 2005) and were found to be more effective than verbal oral hygiene instructions (Renz et al., 2007). Kreuter (2000) concluded that patient specific tailoring of treatment related to individual goals, may be more effective in reaching the health goals than the generalised "targeting approach" and suggested defining the term tailoring as: "*any combination of information or change strategies intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and have been derived from an individual assessment*". Thus, patient specific oral hygiene instructions (OHI) could be more effective than generic standardised OHI, particularly in the control of periodontal disease.

Oral health educators have important and valuable role within dental practices to promote good oral health care and work with patients to prevent disease 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.

Non-invasive diagnostic aids have appeared in recent years. These devices rely on the principles of transillumination, laser and differential quantitative measurement of fluorescence or electrical impedance. 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 of all areas of tissue inflammation by utilising combination of blue light absorption by soft tissue and selective chromatic amplification.

The purpose of the study is 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.

This study will be Sponsored by the University of Bristol and funded by Acteon UK. The study will be undertaken by the Clinical Trials Unit within the University of Bristol Dental School.

Aims

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.

Primary Objectives

- To compare patient plaque levels and gingival health following the provision of enhanced OHI with a detailed pictorial report for the patient vs. the use of standard verbal OHI instructions alone over a 4-week period.

Secondary Objectives

- Patient perceptions of effectiveness of a having a pictorial report of their oral health as part of their dental care
- Patient attitudes to oral health measured at baseline and 4 weeks
- Participants' understanding of gingival health vs gingival disease
- Assessment of the accuracy of the intra-oral camera's ability to assess plaque levels compared to the clinician using traditional techniques using dye

Study Design

The study will be a parallel, randomised (1:1 ratio) 2 treatment, single centre study. The study sites will be the University of Bristol Dental School and Hospital including the South Bristol Community Hospital outreach centre, and the general dental practice Redland Park Dental Surgery. The study will be conducted by the Clinical Trials Unit team members who are part of Bristol Dental School.

At Visit 1, following provision of informed consent and confirmation of eligibility to take part in the study, participants will be provided with a questionnaire to complete regarding gum (gingival) health and then shown standard pictures of teeth and gingivae. 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.

The participants will undergo an oral hard and soft tissue examination.

An intra-oral diagnostic camera will then be used by the clinician to take an intra-oral scan including images and a video of the patient's mouth. The images and video captured will be downloaded and a pictorial report prepared of their oral health. The camera software has the ability to detect plaque on the teeth and this will also be used to assess the levels of plaque present on the participant's teeth.

The study dentist will carry out a gum health examination (Modified Gingival Index, MGI) for the participant and will then measure the amount of plaque present using a traditional technique involving placing dye (food colouring) onto the surface of the teeth which highlights plaque (O'Leary et al 1972).

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.

The images captured will be downloaded and form a pictorial report of the health of the patient's mouth which will be provided to the patient. For those participants allocated to receive the pictorial report + verbal OHI (test group), the images and video captured will be explained to the patient so they can understand their current oral health. Participants assigned to receive standard verbal OHI alone will not be shown or have a review of the images collected by the intra-oral camera or be provided with a pictorial report of their current oral hygiene at Visit 1, however they will receive this at the end of the study.

For all participants, oral hygiene instruction will then be provided by a single dental clinician. This will be a different clinician from the clinician performing the dental assessments and scans of the mouth. For participants assigned to receive the pictorial report + verbal OHI (test group), they will be provided with oral hygiene instruction, a leaflet on oral health and a mouth mirror to use at home.

Participants will also receive questionnaires on their current oral hygiene practices and attitudes to oral health.

An appointment will be made for the patient to return to the study site in 4 weeks and they will be assessed for plaque levels and gingival health and a further scan of their mouth taken. For those participants assigned to receive the pictorial + verbal OHI, a pictorial report will be generated and reviewed alongside their initial report with the patient and advice provided for ongoing oral health maintenance.

For those participants who were assigned to receive standard verbal OHI alone, following the completion of study assessments at Visit 2, the dental clinician will then review the 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.

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 30minutes)

- 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.

All assessments and the provision of oral hygiene instruction will be provided by a single dental clinician.

Study Recruitment

The study will recruit approximately 20 healthy dentate female and male participants aged 18 or over. The Clinical Trials Unit has a database of previous study participants who have expressed an interest in taking part in more studies. These contacts will be approached to take part.

Inclusion Criteria

- Be aged 18 years and over, of either gender and in good health.
- Participants should be dentate with a minimum of 18 scorable teeth, with at least 4 teeth in the upper anterior sextant.
- Participants should be without removable dental prostheses or fixed or removable orthodontic appliances
- Be willing and competent (verbally and cognitively) to give written informed consent and complete a medical history form.
- Be willing and physically able to carry out all study procedures.
- Have an MGI score of ≥1 on at least one of the 2 identified teeth for assessment.

Exclusion Criteria

- 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
- Participants with secondary modifying factors in relation to periodontal disease (e.g. immunocompromised individuals and smokers, including vaping nicotine with e-cigarettes).
- Any participant who, in the judgement of the investigator, should not participate in the study.
- An employee of the research team at the study site.

Study dental assessments

The intra-oral camera will record images of the teeth and gums of the patient which will be downloaded to form a pictorial report tailored to the patient. The intra-oral camera also detects and measures plaque levels present on the surface of teeth. This function will be used to assess the plaque levels present on the upper 3-3) prior to any dye being placed on the participants teeth.

The baseline and 4-week plaque and gingival health assessments will be performed by a single dental clinician. Teeth in the upper 3-3 area will be scanned using the intra-oral camera. The teeth for gingival health and plaque assessment within the study will be 2 suitable teeth within the upper 3-3 region as determined by the study clinician. The same 2 teeth will be assessed by the clinician at Visit 1 and Visit 2 for plaque and gingival health.

Plaque scores will be recorded at Visit 1 and 2 following the method established by O'Leary et al (1972). Plaque will be scored using a 2-point code (buccal and lingual/palatal) where NO (0) = no plaque and YES (1) = presence of plaque.

Gingival health will be assessed using the Modified Gingival Index (MGI) (Lobene, 1986) and the gingival bleeding index (BOP) as described by Ainamo & Bay (1975). The MGI index is a non-invasive visual evaluation of gingival health. Each site (2 per tooth) will be classified as healthy or exhibiting gingivitis. If the site exhibits gingivitis the MGI index will be used to assess the degree of gingival inflammation at 2 sites (buccal and lingual/palatal) of each suitable scorable teeth and scored on a 5-point scale. Gum health will also be assessed by recording bleeding on probing. A periodontal probe with a 0.5 mm diameter tip is inserted into the gingival crevice and swept from distal to mesial, around the tooth at an angle of approximately 60° while in contact with the sulcular epithelium. For each tooth assessed, a binary recording of either YES (bleeding observed) or NO (no bleeding observed) for bleeding will be made at 4 sites per tooth. The proportion of bleeding sites compared to all examined sites will provide the percentage of bleeding per participant.

Items provided to patient

The items to be supplied to the participants are detailed below:

- Pictorial record and report of their current oral health - at Visit 1 and Visit 2
- Patient Information Leaflet on Oral Health – at Visit 1
- Participant own use intra-oral mirror - at Visit 1

For participants assigned to receive standard verbal OHI alone, then they will be provided with all items following completion of all study assessments at Visit 2.

Outcomes

Primary Objectives

- To evaluate patient gingival health and plaque levels prior and following the provision of a pictorial report and tailored OHI over a 4-week.

Gingival health changes from Visit 1 (baseline) to Visit 2 (week 4) will be measured using a 5-point MGI scale (Lobene, 1986) and bleeding on probing will be measured using a 2 point scale, 'YES(1)' or 'NO (0)'. Changes from Visit 1 (baseline) to Visit 2 (week 4) in plaque scores will be measured using the O'Leary et al (1972) 2 point scale, 'YES(1)' or 'NO (0)'.

Secondary Objectives

- Patient perceptions of effectiveness of a having a pictorial report of their oral health as part of their dental care at Visit 1 and Visit 2
- Patient attitudes to oral health measured at Visit 1 and Visit 2
- Participants understanding of oral health vs oral disease at Visit 1 and Visit 2
- Assessment of the accuracy of the intra-oral camera's ability to assess plaque levels compared to the clinician using traditional techniques using dye

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.

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 (using SAS version 9.4).

Statistical Methods

Populations for Analysis

The intent to treat (ITT) population will be defined as all participants randomized to study intervention. Patient data will be analysed according the treatment randomized.

Sample Size

This is a pilot study, therefore the sample size of 20 subjects will be for the purposes of estimation rather than hypothesis testing. Hence, a sample size of 10 per group (20 in total) will ensure that the 95% CI for the mean difference in the change from baseline (at week 4) plaque scores lie to within about 0.16 units of any observed difference. For example, if the observed difference was in fact 0.69, the true (population) difference would lie somewhere between 0.607 and 0.772 with 95% confidence (a measure of uncertainty).

Statistical Analyses

Descriptive statistics (number of subjects, mean, standard deviation, median, minimum and maximum for continuous variables, and frequency and percentage for categorical variables) will be provided for demographic and baseline data.

A mixed effects model with random effects for participants and fixed effect for treatment. The 95% CI along with the mean difference (of change from baseline) in mean plaque levels at 4 weeks for each group will be reported. Adjustment for covariates (e.g. gender, age) will be included in the model.

The primary outcome will also be summarized (using summary statistics) by intervention group, and where appropriate assessment points. Where appropriate and data permitting covariates (e.g. age, gender) will be included in the model. For each secondary outcome, similar analyses will be performed as the primary outcome using a generalized linear model with an appropriate link function depending on the nature of the outcome. Appropriate 95% confidence intervals and p-values will be generated.

Expected outcomes

It would be expected from this pilot study that the provision of a pictorial report of the participants oral health with tailored oral health instruction used as a "tailored" patient education tool demonstrating effective oral hygiene techniques, would improve participants' oral health. The improvement will be demonstrated with decreased plaque and MGI scores. It is also expected that the intra-oral camera will have a similar accuracy in measuring participants plaque scores compared to traditional method using dye to highlight plaque.

Safety measures related to Covid-19

In response to the current coronavirus pandemic, a number of measures have put in place to protect the participants and the study staff from risk of Covid-19 infection. The study will operate to current Public Health England and the Chief Dental Officer England guidelines relating to the use of PPE, social distancing and patient flow through the surgery, disinfection and Covid-19 symptom checks. Before any study activities, all study staff will be trained in the new guidelines and any subsequent updates.

For the participants, prior to their initial appointment (Visit 1, screening), they will be sent a letter from the study team by either email or post to outline the social distancing and safety measures employed at the study site. The letter will provide details as to what the participant can expect when they attend the study site and what processes they will need to follow from when they arrive to when they leave the study site. By sending the information in advance, the participants will have time to ask any questions they may have about what they will be required to do in advance of the appointment.

The study staff will also contact participants approximately 24-48 hours prior to each of their scheduled appointments (Visits 1-4 inclusive) to assess the participants current Covid status. This screening will be performed by telephone using a checklist and the responses will be charted, following the answers will be risk assessed prior to confirmation of the appointment. This is to ensure the risk of transmission of Covid-19 is minimised for both the participants and study team.

Reporting adverse events and serious adverse events

AEs will be reported from the time a signed and dated informed consent form is obtained until the participant completes the last study-related procedure. Those occurrences meeting the definition of SAEs will be reported using the UH Bristol Serious Adverse Event Form, including SAEs spontaneously reported to the Investigator within 30 days after the participant has completed the study (including post study follow-up). UH Bristol, on behalf of the Sponsor, will evaluate any safety information that is spontaneously reported by a Principal Investigator (PI) beyond the time frame specified in the protocol.

All AEs, regardless of seriousness, severity, or presumed relationship to study treatments, will be recorded in the source document and the CRF, together with any measures taken. The PI will record in the CRF their opinion concerning the relationship of the adverse event to study therapy. UH Bristol, on behalf of the Sponsor, assumes responsibility for appropriate reporting of adverse events to the regulatory authorities.

Reporting Adverse events

AEs will be recorded in the AE section of the CRF.

Reporting serious adverse events

All SAEs will be reported to the UH Bristol contact (0117 3420233) by investigational staff within 24 hours of their knowledge of the event. All SAEs that have not resolved by the end of the study, or that have not resolved upon discontinuation of the participant's participation in the study, will be followed until any of the following occurs:

- the event resolves
- the event stabilizes
- the event returns to baseline, if a baseline value is available
- the event can be attributed to agents other than the study drug or to factors unrelated to study conduct
- when it becomes unlikely that any additional information can be obtained (participant or health care practitioner refusal to provide additional information, lost to follow-up after demonstration of due diligence with follow-up efforts)

The death of a participant is considered an SAE, as is any event requiring hospitalization (or prolongation of hospitalization) that occurs during the course of a participant's participation. Exceptions to this are hospitalizations for:

- social reasons in absence of an adverse event
- the in-clinic protocol procedures
- surgery or procedure planned before entry into the study (must be documented in the CRF)

Follow-up of adverse events and serious adverse events

After the initial report, the investigator will be required to proactively follow up with each participant and provide further information on the participant's condition. All AEs/SAEs will be followed until resolution, until the condition stabilizes, until the event is otherwise explained, or until the participant is lost to follow-up. The investigator may be required to obtain additional laboratory tests or investigations, and/or provide the University of Bristol with additional documentation, including autopsy reports.

Ethical and Regulatory Aspects

Local Regulations/Declaration of Helsinki

The Principal Investigator will ensure that this study is conducted in full conformance with the laws and regulations of the country in which the research is conducted and the Declaration of Helsinki.

Informed Consent

It is the responsibility of the investigator, or designee, to obtain written (signed and dated by the participant) informed consent from each individual in this study. Major/substantial amendments to the protocol that affect the scope of the study at the participant level will be reflected in the consent form and active participants re-consented.

Independent Ethics Committee

This study has been reviewed and given a favourable opinion by an independent UK NHS Research Ethics Committee. Any amendments will be reviewed by the Sponsor prior to submission for approval by the NHS Research Ethics Committee.

Study Data

Each participant will be assigned and identified by a unique Screening Number. Any reference made to an individual participant within the study must be done using the unique Screening Number.

All participant data recorded as part of the protocol will be recorded in participant specific case report forms (CRF). Scans recorded of the participants mouth will saved on University computers which are password protected. These scans will not be used outside of the study protocol.

For each participant who has given informed consent and has been screened, a CRF must be completed and signed by the Principal Investigator (or authorized designee) to certify that the data are complete and correct.

In order to protect the privacy of subjects, no Personally Identifiable Information (PII) (including the subject's name or initials or birth date) is to be recorded in the CRF or as part of the query text.

Adverse events and concomitant medications terms (if applicable) will be recorded in the CRF.

All data recoded will be archived securely for a period of 15 years following the end of the study.

Monitoring of the Study

The University of Bristol has a policy for monitoring 10% of studies. Monitoring of studies is conducted in accordance with UH Bristol monitoring policy in relation to the service level agreement with the University of Bristol.

Insurance

The University of Bristol has arranged Public Liability insurance to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from management or design of the research by the University, and the policy provides policy provides an indemnity their employees for their potential liability for harm to participants during the conduct of the research.

In addition, Professor Nicola West and Miss Jessica Naylor hold honorary appointments with University Hospitals Bristol NHS Foundation Trust giving them the protection of the NHS indemnity scheme.

Conflict of Interest and publication

The investigators have no conflict of interest with regards to this study. Data from this study will be published in a peer reviewed journal.

Reimbursement

As a thank you for taking part in the study, all participants will be provided with an electric toothbrush at the end of the study. No financial alternatives will be provided.

References

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Appendix 1: Patient Questionnaires for Visit 1

Patient Oral Health Questionnaire- Visit 1 – Part A

If you have trouble completing this questionnaire, please ask a member of staff to assist you.

1. What is your date of birth ☐☐/☐☐/☐☐☐☐
   D D M M Y Y Y Y
2. How old are you? ☐
3. I identify my gender as…
   - Man ☐
   - Woman ☐
   - Prefer not to disclose ☐
4. How many times per day do you regularly brush your teeth? *(Please tick one box only)*
   - Less than once a day ☐
   - Once a day ☐
   - Twice a day ☐
   - More than twice a day ☐
5. When do you normally brush your teeth? (*Please tick all that apply*)
   - In the morning ☐
   - In the evening ☐
   - During the day ☐
6. Did you usually brush your teeth *(Please tick one box only)*
   - Before breakfast ☐
   - Neither before or after breakfast ☐
   - After breakfast ☐
   - Both before and after breakfast ☐
7. Which kind of toothbrush did you use the most often? *(Please tick one box only)*

Manual

☐

Power (Electric)

☐

8. Are you right-handed or left-handed? *(Please tick one box only)*

Right-handed ☐

Left handed ☐

Both ☐

9. Do you currently use a toothpaste?

YES ☐

NO ☐

If yes, which toothpaste do you currently use? _____

10. Do your gums bleed when you brush your teeth?

YES ☐

NO ☐

11. Do you think you have bad breath?

YES ☐

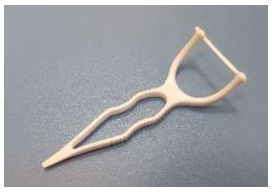
NO ☐

12. Do you use any of the following additional teeth cleaning aids? *(examples are shown below, please tick the box next to any you have used or if you use none of these, tick none)*

Dental Floss

☐

Flossettes



☐

Single tufted brush

☐

Interdental brushses (e.g TePe)

☐

Air flosser (e.g Phillips Airfloss Plus)

☐

Water flosser (e.g Waterpik)

☐

None

☐

13. If you have indicated you have used an additional cleaning aids, how often do you use them?

Daily ☐

Weekly ☐

Occasionally ☐

14. Are you currently concerned about your oral health?

YES ☐

NO ☐

15. If yes, what are your concerns?

Condition of teeth ☐

Function of teeth ☐

Appearance ☐

Breath ☐

Sensitivity ☐

Other/Not sure ☐

None ☐

16. How would you rate your current oral health?

Excellent ☐

Very good ☐

Good ☐

Fair ☐

Poor ☐

Not sure ☐

17. Are you motivated in maintaining oral health?

Very motivated ☐

Fairly motivated ☐

Neither motivated or not motivated ☐

Not motivated ☐

Not sure ☐

Patient Oral Health Attitudes Questionnaire- Visit 1 – Part B

On a scale of 1 to 10, with 1 as 'Not at all' and 10 as 'extremely so' please rank the following statements accordingly:

1. Do you think bleeding gums and gum disease is a serious health concern

1	2	3	4	5	6	7	8	9	10
Not at all									Extremely so

2. If my bleeding gums are left untreated the likelihood that I will develop gum disease in the future is high

1	2	3	4	5	6	7	8	9	10
Not at all									Extremely so

3. Following my Oral Health plan over the next 4 weeks will improve the health of my mouth and reduce my risk of developing gum disease

1	2	3	4	5	6	7	8	9	10
Not at all									Extremely so

4. I know I can follow my Oral Health plan over the next 4 weeks

1	2	3	4	5	6	7	8	9	10
Not at all									Extremely so

5. Following my Oral Health plan will be difficult to do.

1	2	3	4	5	6	7	8	9	10
Not at all									Extremely so

6. My gum disease concerns me

1	2	3	4	5	6	7	8	9	10
Not at all									Extremely so

Appendix 2: Patient Questionnaires for Visit 2

Patient Oral Health Questionnaire - Visit 2 – Part A

If you have trouble completing this questionnaire, please ask a member of staff to assist you.

1. How many times per day do you now regularly brush your teeth? *(Please tick one box only)*

- Less than once a day ☐
- Once a day ☐
- Twice a day ☐
- More than twice a day ☐

2. When do you now normally brush your teeth? (*Please tick all that apply*)

- In the morning ☐
- In the evening ☐
- During the day ☐

3. Do you usually brush your teeth *(Please tick one box only)*

- Before breakfast ☐
- Neither before or after breakfast ☐
- After breakfast ☐
- Both before and after breakfast ☐

4. Do your gums bleed now when you brush your teeth?

- YES ☐
- NO ☐

5. Do you think you have bad breath now?

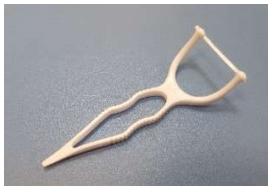
- YES ☐
- NO ☐

6. Do you use any of the following additional teeth cleaning aids now ? *(examples are shown below, please tick the box next to any you have used or if you use none of these, tick none)*

Dental Floss

☐

Flossettes



☐

Single tufted brush

☐

Interdental brushses (e.g TePe)

☐

Air flosser (e.g Phillips Airfloss Plus)

Water flosser (e.g Waterpik)

None

☐ ☐ ☐

7. If you have indicated you have used an additional cleaning aid, how often did you use them?

Daily ☐

Weekly ☐

Occasionally ☐

8. Are you currently concerned about your oral health?

YES ☐

NO ☐

9. Has your diet changed since you started the study with us?

Yes ☐ No ☐ Not sure ☐

How?.....

10. Was the pictorial report of your oral health provided in this study useful for you?

Very useful ☐

Fairly useful ☐

Neither useful or not useful ☐

Not useful ☐

Not sure ☐

11. How often did you refer o your pictorial report provided in this study?

Daily ☐

Weekly ☐

Didn't refer to it ☐

12. Are you currently concerned about your oral health?

YES ☐

NO ☐

14. If yes, what are your concerns?

Condition of teeth ☐

Function of teeth ☐

Appearance ☐

Breath ☐

Sensitivity ☐

Other/Not sure ☐

None ☐

15. How would you rate your current oral health now?

Excellent ☐

Very good ☐

Good ☐

Fair ☐

Poor ☐

Not sure ☐

16. Are you motivated in maintaining oral health now?

Very motivated ☐

Fairly motivated ☐

Neither motivated or not motivated ☐

Not motivated ☐

Not sure ☐

17. Has your motivation to maintain your oral health changed since you started the study with us?

Yes ☐ No ☐ Not sure ☐

How?.....

Patient Oral Health Attitudes Questionnaire- Visit 2 – Part B

On a scale of 1 to 10, with 1 as 'Not at all' and 10 as 'extremely so' please rank the following statements accordingly:

7. Do you think bleeding gums and gum disease is a serious health concern

1	2	3	4	5	6	7	8	9	10
Not at all									Extremely so

8. If my bleeding gums are left untreated the likelihood that I will develop gum disease in the future is high

1	2	3	4	5	6	7	8	9	10
Not at all									Extremely so

9. Following my Oral Health plan over the last 4 weeks has improved the health of my mouth and reduce my risk of developing gum disease

1	2	3	4	5	6	7	8	9	10
Not at all									Extremely so

10. I know I can continue to follow my Oral Health plan in the future

1	2	3	4	5	6	7	8	9	10
Not at all									Extremely so

11. Following my Oral Health plan will be difficult to maintain.

1	2	3	4	5	6	7	8	9	10
Not at all									Extremely so

12. My gum disease concerns me

1	2	3	4	5	6	7	8	9	10
Not at all									Extremely so

Appendix 3: Standard Images of oral health and oral disease

Do the images below, in your opinion, show oral health or oral disease?
Indicate which image you think represents your current oral health
Please 'tick' the box which represents your answer for each image

	IMAGE 1	IMAGE 2	IMAGE 3
Health			
Disease			
Do not know			
Represents my current oral health			

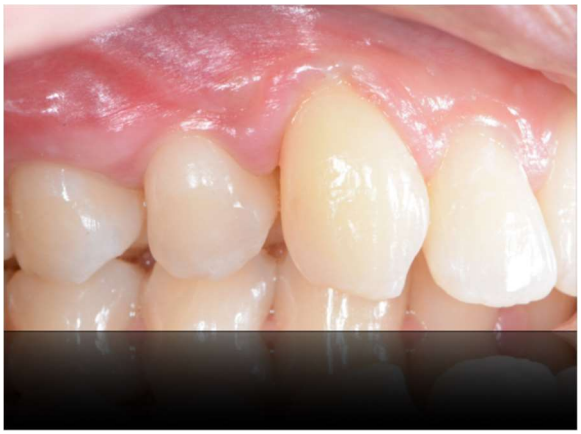


IMAGE 1

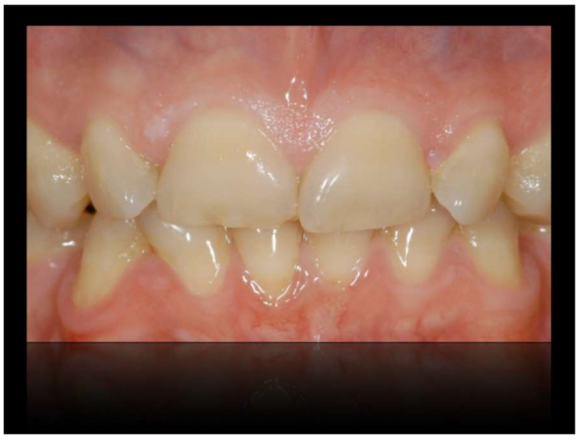


IMAGE 2

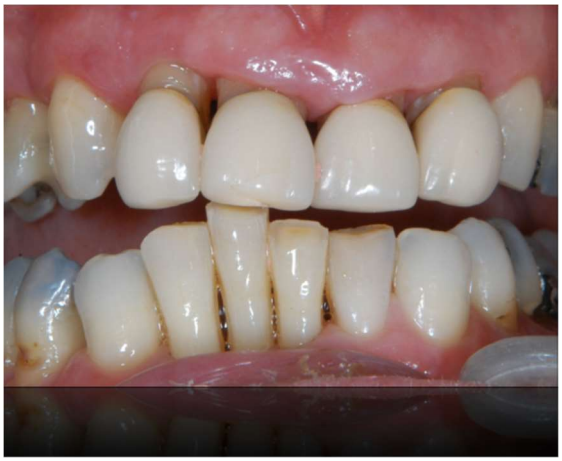


IMAGE 3

Appendix 4 – Clinical Assessments

Plaque Scores

Plaque scores will be recorded at Visit 1 and 2 following the method established by O'Leary et al (1972). Plaque will be scored using binary code as follows:

'NO' plaque = 0

'YES' plaque present = 1.

Gingival Health

Gingival health will be assessed using the Modified Gingival Index (Lobene, 1986) which is a non-invasive visual evaluation of gingival health. Each site (2 per tooth) will be classified as healthy or exhibiting gingivitis. If the site exhibits gingivitis the MGI index will be used to assess the degree of inflammation at 2 sites (buccal and lingual/palatal) of all scorable teeth and scored on a 5-point scale as follows:

0 = normal (absence of inflammation)

1 = mild inflammation (slight change in colour, little change in texture) of any portion of the gingival unit

2 = mild inflammation of the entire gingival unit

3 = moderate inflammation (moderate glazing, redness, oedema, and/or hypertrophy) of the gingival unit

4 = severe inflammation (marked redness and oedema/hypertrophy, spontaneous bleeding, or ulceration) of the gingival unit.

Bleeding on probing is assessed using the gingival bleeding index (BOP) as described by Ainamo & Bay (1975) and will also assess gingival health. A periodontal probe with a 0.5 mm diameter tip is inserted into the gingival crevice and swept from distal to mesial, around the tooth at an angle of approximately 60° while in contact with the sulcular epithelium. For each tooth assessed, a binary recording of either YES (bleeding observed) or NO (no bleeding observed) for bleeding will be made at 4 sites per tooth. The proportion of bleeding sites compared to all examined sites will provide the percentage of bleeding per participant.

Appendix 5: Oral Health Assessment using an Intra-oral camera (Soprocare Acteon® (PERIO mode and DAYLIGHT mode))

The pictorial record of participant plaque and gingival condition will be assessed/obtained using Soprocare Acteon® (PERIO mode and DAYLIGHT mode).

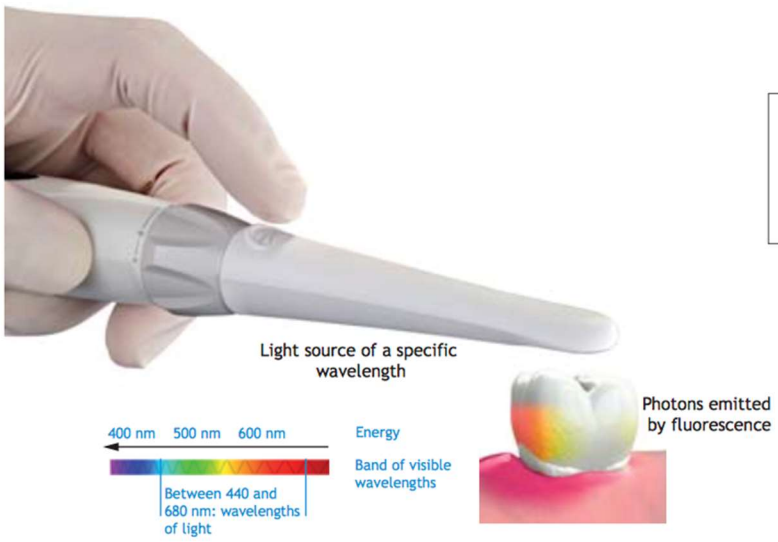


Figure 1: Operating principle of the SOPROCARE in PERIO mode

The PERIO mode also uses the phenomenon of fluorescence but this time combined with selective chromatic amplification.

When this mode is in use, the tooth is illuminated with both blue LEDs (for fluorescence) and white LEDs (to maintain the relief) in order to recover the fluorescence emitted in return by pigments present in dental plaque.

To highlight gingival inflammations, SOPROCARE uses the settings of selective chromatic amplification to enhance this pathology.

Example of a pictorial Patient Report