

# Can recording a patient-specific video of oral hygiene instructions to a person's smartphone help them to follow the instructions correctly at home?

<b>Submission date</b> 02/10/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/10/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/07/2024	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Many people suffer from gum disease which can impact on their daily life. This could be caused by many things such as: not cleaning teeth well, not using the correct brushing technique or not retaining the advice and information given to them by a dentist. This study will compare two different ways a dentist can give oral hygiene information and advice to patients and assess which is the most effective.

The aim of this study is to assess the effectiveness of a patient-specific oral hygiene instructional video, compared to standard spoken oral hygiene instruction (OHI) in terms of plaque and bleeding of gums when probed by the dentist or hygienist, over a 3-month period. In addition to the provision of either video or verbal OHI, the recruited patients will also receive a fluoride toothpaste targeted at improving gum health which they will be requested to use instead of their normal toothpaste over the 3-month period. A manual toothbrush will also be provided for the patients to use over the study period.

The researchers hope that this study will show which method is the most helpful to patients in improving their oral hygiene. They will then be able to pass on this information to dental professionals, giving them additional tools to help their patients succeed in improving their oral health.

### Who can participate?

Adults with their own teeth, recruited from patients attending the Bristol Dental Hospital for routine appointments. The ongoing care of the patient will not be affected by their participation in the study.

### What does the study involve?

The participants will be randomly allocated to one of two groups. To complete the study, the participants will need to attend for two or three visits at the Bristol Dental Hospital, lasting approximately 1.5 hours in total. The first visit starts with screening to check that participants are eligible. Participants will complete two questionnaires regarding their oral hygiene practices

and attitudes to oral health. They will also receive an examination of the gums and mouth. At the second visit, both groups will again receive an examination of the gums and mouth and will be given a manual toothbrush and toothpaste to use for 3 months. One group will be given spoken instructions on how to care for their teeth and gums. The other group will be given the same instructions verbally, but the dental professional will record the instructions as a video on the participant's smartphone so that the participant can watch it again on their phone during the 3-month study period to remind them of the instructions. At the third visit, participant's gums and mouth will be assessed and they will also complete the two questionnaires regarding their oral hygiene practices and attitudes to oral health.

Where is the study run from?  
Bristol Dental School (UK)

When is the study starting and how long is it expected to run for?  
September 2019 to April 2022

Who is funding the study?  
Unilever (Netherlands)

Who is the main contact?  
Professor Nicola West  
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## Contact information

Type(s)  
Scientific

Contact name  
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## Additional identifiers

EudraCT/CTIS number  
Nil known

IRAS number

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

2018-4841

## **Study information**

**Scientific Title**

The use of video technology in demonstrating tailored oral hygiene instructions to modify behaviour and enhance adherence

**Study objectives**

The aim of this study is to assess the effectiveness of a patient specific oral hygiene instructional video, compared to standard verbally-provided oral hygiene instruction (OHI) with regards to patient plaque and bleeding on probing levels, over a 3-month period. In addition to the provision of either video or verbal OHI, the recruited patients will also receive a fluoride toothpaste targeted at improving gum health, which they will be requested to use instead of their normal toothpaste over the 3-month period. A manual toothbrush will also be provided for the patients to use over the study period.

It would be expected from this pilot study that instructional short videos, used as a tailored patient education tool demonstrating effective oral hygiene techniques, would improve patients' adherence to oral health instruction and thus their oral health. The improvement will be demonstrated with decreased plaque and bleeding scores.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 11/04/2019, Health and Social Care in Northern Ireland Research Ethics Committee B (HSC REC B) (Office for Research Ethics Committees Northern Ireland [ORECNI], Customer Care & Performance Directorate, Unit 4, Lissue Industrial Estate West, Rathdown Walk, Moira Road, Lisburn, BT28 2RF; +44 (0)28 95361400; recb@hscni.net), ref: 19/NI/0053

**Study design**

Interventional parallel-arm randomized single-centre study

**Primary study design**

Interventional

**Secondary study design**

Randomised parallel trial

**Study setting(s)**

Hospital

**Study type(s)**

Prevention

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

## **Health condition(s) or problem(s) studied**

Oral health

## **Interventions**

Visit 1 - Screening (approximately 20 minutes)

Participants who provide written informed consent to participate in the study and fulfil the inclusion and exclusion criteria will be entered on the study. Every participant will complete two questionnaires regarding their oral hygiene practices and attitudes to oral health. They will also undergo an oral soft tissue examination.

Visit 2 - Baseline (approximately 40 minutes)

During this appointment, the continuing eligibility of the participant will be confirmed and the oral soft tissue examination will be repeated. Baseline plaque and bleeding on probing scores will be assessed using standard techniques. The participants will then be randomised by study staff to one of 2 treatment groups (Control group - standard verbal oral health instructions (OHI) and a fluoride toothpaste or test group - videoed OHI and a fluoride toothpaste) using a predetermined randomisation schedule. Participants will receive their tailored OHI, either verbally but not recorded (control group) or verbally and video recorded (test) as determined by the randomisation schedule. The videoed OHI instruction will be made using the participant's own smartphone so they can reference the instruction repeatedly over the 3-month period of the study. No copies of the video will be made by the study site. The participants will also be dispensed a standard fluoride toothpaste and a manual toothbrush. Instruction for use will be provided by the study staff to the participants and the participants will be requested to use the dispensed items instead of their usual toothpaste and toothbrush. Where participants normally use an electric toothbrush they will be requested to use the manual toothbrush for the duration of the study. All brushes and toothpaste tubes must be returned to the study site at the end of the study.

Where appropriate, visit 1 and visit 2 can be combined if this is convenient to the participant. If not, an appointment will be made at the participant's convenience for visit 2.

Visit 3 - 3 months after Visit 1 (approximately 30 minutes)

Continuing eligibility of the participant will be confirmed and the plaque and bleeding on probing scores will again be assessed. Participants will complete two final questionnaires regarding their oral hygiene practices and attitudes to oral health. At the end of this visit, their participation in the study will cease.

The primary outcome is the change from baseline to 12 weeks in bleeding on probing and plaque levels. This will be analysed using a mixed effects model suited with random effects for patients. The 95% CI along with the mean difference in mean bleeding probing at 12 weeks for each group will be reported along with unadjusted p-values. This analysis will be performed for the ITT. For each comparison, the 95% confidence intervals and p-values will be derived.

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 to 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.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Bleeding on probing measured using the gingival bleeding index (BOP) at baseline and 12 weeks. BOP scores will be recorded at 4 sites around each eligible tooth at baseline and week 12. The scores will be measured using a 2-point scale, YES (bleeding observed) or NO (no bleeding observed). The proportion of bleeding sites compared to all examined sites will provide the percentage of bleeding per participant.
2. Plaque levels measured using the Modified Tureskey Index at baseline and 12 weeks. Plaque presence will be assessed at 4 sites per tooth of all eligible teeth and scored on a 5-point (0-5) scale. The total score recorded for all teeth is calculated, then divided by the number of tooth surfaces assessed, giving the Turesky score.

## **Secondary outcome measures**

1. Patient perceptions of effectiveness of a viewing video instruction at home as part of their dental care assessed by questionnaire at 3 months after they initially receive the instruction
2. Patient attitudes to oral health assessed by questionnaire at baseline and 3 months

## **Overall study start date**

11/04/2019

## **Completion date**

30/04/2022

# **Eligibility**

## **Key inclusion criteria**

1. Dentate with a minimum of 18 scorable teeth
2. Without removable dental prostheses or fixed or removable orthodontic appliances
3. Average plaque score of  $\geq 2.0$  on the Turesky plaque index and  $>10\%$  bleeding on probing (BOP) of all sites. Patients with  $\geq 50\%$  BOP will be excluded.
4. Willing and able to use a manual toothbrush. Patients currently using a power brush will be requested to use a manual brush for the duration of the study.
5. If assigned to the video OHI group, participants must have a smartphone and be confident in re-playing recorded videos

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

64

**Total final enrolment**

64

**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. Has undergone periodontal surgery within the previous 2 years.
3. Secondary modifying factors in relation to periodontal disease (e.g. immunocompromised individuals and smokers, including e-cigarettes)
4. Any participant who, in the judgement of the investigator, should not participate in the study
5. An employee of the research team or student at each of the study sites
6. Patients who do not have a smart phone or have a smart phone but are unfamiliar with accessing recorded videos on their smartphone will not be included in the subset receiving the videoed oral health instruction

**Date of first enrolment**

11/09/2019

**Date of final enrolment**

31/01/2021

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Bristol Dental Hospital**

Lower Maudlin Street

Bristol

United Kingdom

BS1 2LY

**Sponsor information****Organisation**

University of Bristol

**Sponsor details**

Research and Enterprise Development  
1 Cathedral Square  
Bristol  
Bristol  
England  
United Kingdom  
BS1 5DD  
(0)117 42 83065  
research-governance@bristol.ac.uk

**Sponsor type**

University/education

**ROR**

<https://ror.org/0524sp257>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Unilever

**Alternative Name(s)**

Unilever Global, Unilever PLC, U

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

1. Peer reviewed journal to publish papers from the study
2. Presentation at a dental research conference

**Intention to publish date**

31/10/2022

**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. Proposals will also be subject to the prior written consent of the funder (Unilever).

**IPD sharing plan summary**

Stored in publicly available repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Results article</a>		15/07/2024	29/07/2024	Yes	No