

# Motivational techniques to improve oral hygiene for patients in general dental practice

<b>Submission date</b> 08/02/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/02/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/10/2022	<b>Condition category</b> Oral Health	<input checked="" type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The aim of this study is to look at different ways a dentist can give information and advice to patients, to find out which methods are most helpful to patients in improving their oral hygiene. This information will be passed on to dental professionals, giving them additional tools to help their patients succeed in improving their oral health.

### Who can participate?

Healthy volunteers aged 18 or over attending a general dental practice for a check-up or review appointment with a dental professional

### What does the study involve?

Participants are required to attend two review appointments. These appointments are referred to as Visit 1 and Visit 2 for the study and are 3 months apart. Participants undergo a short clinical exam as part of Visit 1 that lasts about 10 minutes. The dentist begins by examining the health of the participant's gums by placing a dental instrument used by all dentists around the gum. The dentist records whether the gums around any of the teeth are bleeding, and gives the participant an overall score known as a bleeding score. This test is routinely carried out by dentists. Next, the dentist applies some Vaseline to the lips and uses a small brush to paint a solution onto the teeth which highlights pink and blue areas in the mouth. This shows the dentist where plaque is present and allows them to determine plaque scores. The bleeding score and plaque index together can be used to determine whether participants are high risk or low risk for oral disease. Participants are randomly allocated by the dentist to receive 1 of 8 possible oral hygiene advice programs, with each program tailored to either low or high risk of oral disease. The participants are asked to complete a questionnaire relating to their current oral hygiene routine and also record if the participant is a smoker. If participants are allocated to the enhanced oral hygiene treatment group, they may be asked to complete additional questionnaires relating to their current attitudes relating to oral health and are also asked to sign a Gum Health Improvement Patient Agreement. This agreement is between the patient and the dentist to help improve the participant's current oral health as a combined effort. Depending on which program participants are allocated to, they may also receive a power toothbrush to use which includes the downloading of an app onto a smartphone which monitors their use of the power brush. If participants are allocated to a power toothbrush, they receive

full manufacturer's instructions for use. The power brush provided is commercially available and the app works via Bluetooth with a smartphone. Participants are asked to share their toothbrushing activity with the study team directly from the app via email. Participants are asked to return to the dental practice 3 months after their initial visit where the dentist reassesses bleeding and plaque scores, and invites participants to give feedback via a questionnaire on the advice they were given and whether the participants thought it led to an improvement in their oral health.

What are the possible benefits and risks of participating?

Where patients are allocated a power toothbrush and asked to use a smartphone app, the patients need to feel confident they are able to use this. Before allocation to the power brush, all patients are asked if they have access to a power brush and are confident in the use of apps. The clinical exam is undertaken by a qualified foundation year dentist or a hygienist who has received additional training in the clinical scores that are to be recorded and the motivational behavioural intervention to be delivered to the test group patients. The conditions are scored as they would be in a standard clinical exam. All data collected is anonymised, participants being allocated a study number on enrolment, and only anonymised data will be published. The study adds some time to the appointments of patients and the patient is required to attend again in three months' time for a second visit, but this is explained to the patient when they are approached to take part and they can decline participation if they do not have time to spare without this affecting their care in any way.

Where is the study run from?

Bristol Dental School & Hospital (UK)

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

September 2017 to August 2018

Who is funding the study?

Procter and Gamble (USA)

Who is the main contact?

Prof. Nicola West

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Nicola West

**ORCID ID**

<https://orcid.org/0000-0002-9127-5530>

**Contact details**

School of Oral & Dental Science  
Bristol Dental School & Hospital  
Lower Maudlin Street

Bristol  
United Kingdom  
BS1 2LY

## **Additional identifiers**

**Integrated Research Application System (IRAS)**  
235629

**Protocol serial number**  
2855, IRAS 235629

## **Study information**

### **Scientific Title**

Behavioural motivation to enhance adherence to oral hygiene recommendations for patients in general dental practice

### **Study objectives**

This project will assess whether behavioural motivation to enhance adherence to oral hygiene is more effective in improving oral hygiene in patients at high or low risk of oral disease compared to standard oral health instruction where patients are provided with simple instruction alone. A further aim of this study is to assess if the young foundation dentists and hygienists have found the motivational oral hygiene advice training of benefit to them thus providing them with additional tools to help their patients succeed in maintaining oral health.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

South Central - Hampshire B Research Ethics Committee, 12/12/2017, IRAS: 235629

### **Study design**

Cluster randomised 8-treatment parallel study

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

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

Improving oral hygiene with different interventions

### **Interventions**

There will be a total of 8 treatment groups. These will be comprised of a 'Test' group and a 'Control' group, each stratified to low and high risk relating to oral disease. There will be a further subset of these groups that will receive a power toothbrush. The treatments will be allocated through a cluster randomised design in a 2:1 ratio (in favour of the test group). Since randomization will occur at the site (cluster) level, patients treated by different DFT/hygienist

within each site will all be allocated to either experimental or control intervention at the site (cluster) level. All patients will be stratified as to either high or low risk relating to oral disease. The level of risk will be determined by bleeding on probing scores as part of the clinical examination.

Participants will be enrolled onto the study and allocated a unique identification number. The allocated number will be sequential.

To complete this study, participants will be required to attend two appointments with their dentist. These appointments will be referred to as Visit 1 and Visit 2 for the study and will be 3 months apart. Following Visit 2, the study will be completed for each participant. The participants will remain under the care of their dentist and normal routine and treatment appointments will continue as planned.

Test group:

Low risk: patients will receive:

- Patient self reported Oral Health Questionnaire - Visit 1 and 2
- Oral Health Information Sheet - Visit 1 only
- Access to oral health instructional videos relating to patients current oral hygiene regimen (Appendix 3)

OR

- Patient self reported Oral Health Questionnaire - Visit 1 and 2
- Oral Health Information Sheet - Visit 1 only
- Provision of a power toothbrush with review of manufacturers instructions for use including smartphone App and access to power brushing instructional video - Visit 1 only

High risk: patients will receive:

- Patient self reported Oral Health Questionnaire - Visit 1 and 2
- Oral Health Information Sheet - Visit 1 only,
- Gum Health Improvement Patient Agreement - Visit 1 only
- Access to oral health instructional videos dependent on patients current oral hygiene regimen
- Patient attitude questionnaire - Visit 1 and 2

OR

- Patient self reported Oral Health Questionnaire - Visit 1 and 2
- Oral Health Information Sheet - Visit 1 only
- Gum Health Improvement Patient Agreement - Visit 1 only
- Patient attitude questionnaire - Visit 1 and 2
- Provision of a power toothbrush with review of manufacturers instructions for use including smartphone App and access to power brushing instructional video

Control group:

Low risk: patients will receive:

- Patient self reported Oral Health Questionnaire - Visit 1 and 2
- Individualised oral hygiene advice related to risk of oral disease as learnt in dental school and currently practiced - Visit 1 only

OR

- Patient self reported Oral Health Questionnaire - Visit 1 and 2
- Individualised oral hygiene advice related to risk of oral disease as learnt in dental school and currently practiced - Visit 1 only
- The provision of a powered toothbrush and manufacturers instructions

High risk: patients will receive:

- Patient self reported Oral Health Questionnaire - Visit 1 and 2

- Individualised oral hygiene advice related to risk of oral disease as learnt in dental school and currently practiced - Visit 1 only

OR

- Patient self reported Oral Health Questionnaire - Visit 1 and 2
- Individualised oral hygiene advice related to risk of oral disease as learnt in practice and currently practiced - Visit 1 only
- The provision of a powered toothbrush and manufacturers instructions

The primary outcome is the change from baseline to 3 months in bleeding probing expressed as a percent. This will be analysed using a mixed effects model suited to a cluster randomized design with random effects for sites and effects for subjects within sites (i.e. clusters). The 95% CI along with the mean difference in mean bleeding probing will be reported along with unadjusted p-values. The analyses will be repeated for each strata and will also include covariates for stratification and demographic (and baseline) factors. For the subgroup of subjects given a power brush, a separate analysis will be undertaken to compare effects within this group with the appropriate covariates. The primary outcome will also be summarized (using summary statistics) by intervention group, cluster, strata and where appropriate assessment points. In addition, for the subgroup, summary statistics will be reported separately.

Secondary outcomes will be analysed using models suited to a cluster randomized trials allowing for within and between cluster (subjects within cluster) effects. The intraclass correlation coefficient will be reported along with estimates of treatment effects and 95% CIs. All other outcomes will be summarized descriptively along with demographic and where appropriate clinical characteristics (by group and site within group). Treatment effects will be adjusted for covariates and stratification variables. Separate effects will be presented for pre-specified subgroups.

## **Intervention Type**

Other

## **Primary outcome(s)**

Bleeding on probing, measured using scores for each eligible tooth recorded during the oral examination at baseline (Visit 1) and 3 months (Visit 2)

## **Key secondary outcome(s)**

1. Plaque scores obtained for each eligible tooth recorded during the oral examination at baseline (Visit 1) and 3 months (Visit 2)
2. Patient self-reported attitudes relating to improving oral hygiene, measured using a questionnaire in the test/high risk group at baseline (Visit 1) and 3 months (Visit 2)
3. Patient self-reported oral hygiene regimens, measured using a questionnaire at baseline (Visit 1) and 3 months (Visit 2)
4. DFTs' and hygienists' oral health knowledge and behaviour, measured using a questionnaire pre and post training and after the study has completed

## **Completion date**

30/09/2019

## **Eligibility**

### **Key inclusion criteria**

1. Healthy volunteers of either gender who are attending a general dental practice for a check up or review appointment with a dental professional
2. Aged 18 or over
3. Understand and are willing, able and likely to comply with all study procedures and restrictions
4. Accept the form of the study and sign a declaration of informed consent
5. Have a minimum of 16 teeth not including implants or teeth with crowns or bridges excluding teeth with extra-coronal restorations

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

733

**Key exclusion criteria**

1. Persons incapable of responding to the questions
2. An employee of the general dental practice, and/or a family relative of the employee
3. Patients without a smartphone will not be eligible to receive a powered brush

**Date of first enrolment**

05/02/2019

**Date of final enrolment**

30/04/2019

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

United Kingdom

England

**Study participating centre**

Glen Lea Dental Suite

20 York Road

Whetherby

United Kingdom  
LS22 6SL

**Study participating centre**

**A2 Dental Studio**  
3 Effingham Square  
Rotherham  
United Kingdom  
S65 1AP

**Study participating centre**

**MyDentist**  
133 Hessle High Road  
Hull  
United Kingdom  
HU4 6SB

**Study participating centre**

**Azure Dental**  
121 Bawtry Road  
Sheffield  
United Kingdom  
S9 1UF

**Study participating centre**

**Worthley House Dental**  
70 The Village  
Haxby  
York  
United Kingdom  
YO32 2HX

**Study participating centre**

**Genix Dental**  
Britannia Building  
St George Square  
Huddersfield  
United Kingdom  
HD1 1LG

**Study participating centre**  
**Swabys Dental Practice**  
10-11 Walkergate  
United Kingdom  
H17 9BZ

**Study participating centre**  
**Horbury Dental Care**  
Vincent House  
Queen Street  
Horbury  
Wakefield  
United Kingdom  
WF4 6LP

**Study participating centre**  
**Kimberworth Park Dental Practice**  
248 Kimberworth Park Road  
Rotherham  
United Kingdom  
S61 3JN

**Study participating centre**  
**Wheata Plave Dental Clinic**  
570 Wordsworth Avenue  
Sheffield  
United Kingdom  
S5 9JH

**Study participating centre**  
**Eclipse Dental Care**  
27 Branch Road  
Batley  
United Kingdom  
WF17 5SB

**Study participating centre**  
**Eccleshill Dental Surgery**  
9 Institute Road  
Eccleshill Village

Bradford  
United Kingdom  
BD2 2HY

**Study participating centre**  
**Archway Dental Practice**  
15 High Street  
Stokesley  
United Kingdom  
TS9 5AD

**Study participating centre**  
**R Dental**  
460 Idle Road  
Bradford  
United Kingdom  
BD2 2AR

**Study participating centre**  
**Royd House Dental Surgery**  
Doncaster Road  
Rotherham  
United Kingdom  
S65 1DY

**Study participating centre**  
**Dental 22**  
Chapelgate  
Retford  
United Kingdom  
DN22 6PL

**Study participating centre**  
**Royd House Dental Practice**  
99 East Street  
Huddersfield  
United Kingdom  
HD3 3NF

**Study participating centre**

**LWT Dental Care**  
719 Ecclesall Road  
Sheffield  
United Kingdom  
S11 8TG

**Study participating centre**

**Penn Hill Dental Practice**  
1 Penn Hill  
Yeovi  
United Kingdom  
BA20 1SF

**Study participating centre**

**Portishead Dental Practice**  
52 Nore Road  
Portishead  
United Kingdom  
BS20 6JY

**Study participating centre**

**Moor Dental Care**  
7 West Street  
Ashburton  
United Kingdom  
TQ13 7DT

**Study participating centre**

**North Petherton Dental Practice**  
46 Fore Street  
North Petherton  
United Kingdom  
TA6 6PZ

**Study participating centre**

**Riverside Dental Practice**  
Butts Path  
Braunton  
United Kingdom  
EX33 2EU

**Study participating centre**

**Dunedin Clinic**

Silverdown Office Park

Exeter

United Kingdom

EX5 2UX

**Study participating centre**

**Chulmleigh Dental Practice Ltd,**

South Molton Street

Chumleigh

United Kingdom

EX18 7BW

**Study participating centre**

**Matford Dental Clinic**

1A The Venture Centre

Yeoford Way

Marsh Barton Business Centre

Exeter

United Kingdom

EX2 8LB

**Study participating centre**

**Browns Dental Practice**

Cedar Rise

Fore Street

Ivybridge

United Kingdom

PL21 9AE

**Study participating centre**

**Mount Wise Dental Practice**

15A Cumberland Street

Devonport

Plymouth

United Kingdom

PL1 4DX

**Study participating centre**

**Truro Dental Health**

46 Lemon Street

Truro

United Kingdom

TR1 2NS

**Study participating centre**

**Chipping Manor Dental Practice**

10 Long Street

Wotton Under Edge

United Kingdom

GL12 7ER

**Study participating centre**

**Wessex House Dental Practice**

Westbury

Sherborne

United Kingdom

DT9 3EH

**Study participating centre**

**Church Street Dental Practice**

7A Church Street

Wincanton

United Kingdom

BA9 9AA

**Study participating centre**

**Oldland Common Dental Practice**

206 High Street

Oldland Common

Bristol

United Kingdom

BS30 9QW

**Study participating centre**

**Apple Dental Practice**

97 High Street

Winterbourne

Bristol  
United Kingdom  
BS36 1RD

**Study participating centre**  
**The Promenade Dental Practice**  
12 Gloucester Road  
Bishopson  
Bristol  
United Kingdom  
BS7 8AE

**Study participating centre**  
**Quedgeley House Dental Practice**  
39-42 Space Park  
Olympus Way  
Quedgeley  
United Kingdom  
GL2 4AL

**Study participating centre**  
**Oasis Dental Care**  
1A Madeira Road  
Poole  
United Kingdom  
BH14 9ET

**Study participating centre**  
**Wylve Valley Dentistry**  
1 Station Road  
Warminster  
United Kingdom  
BA12 9BR

**Study participating centre**  
**Dental Centre Bournemouth**  
11 The Triangle  
Bournemouth  
United Kingdom  
BH2 5RY

**Study participating centre**  
**Savernake Forest Dental Practice**  
Salisbury Road  
Marlborough  
United Kingdom  
SN8 4FD

**Study participating centre**  
**Springfield Dental Clinic**  
2 Springfield Road  
Guiseley  
United Kingdom  
LS20 8AL

## **Sponsor information**

**Organisation**  
University of Bristol

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

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
Procter and Gamble

**Alternative Name(s)**  
Procter & Gamble, PandG, The Procter & Gamble Company, P and G, Procter & Gamble Company, P&G

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
For-profit companies (industry)

## Location

United States of America

# Results and Publications

## Individual participant data (IPD) sharing plan

The anonymised participant data (clinical scores and questionnaire) 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 (P&G).

## IPD sharing plan summary

Stored in publicly available repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		24/10/2021	02/11/2021	Yes	No
<a href="#">Dataset</a>		07/12/2021	19/10/2022	No	No
<a href="#">Protocol file</a>	version 2.0	10/12/2017	25/10/2022	No	No