ISRCTN10536130 https://doi.org/10.1186/ISRCTN10536130

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

Submission date
08/02/2018

Recruitment status
No longer recruiting

Registration date
26/02/2018

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
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
http://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

EudraCT/CTIS number

IRAS number
235629

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
25/09/2017

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
There are 780 in the control group vs 1620 in the experimental group. The number of clusters (sites) for the experimental group are 27 and for the control group are 13 (40 sites in a 2:1 ratio). The cluster (site) size (number of subjects) in the experimental group is approximately n=60 per site and the number of subjects per site in the control group is n=60 . A total of at least 40 practices (sites) are needed

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
England

United Kingdom

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
Eclispe 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
Wylye 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

Sponsor details

Senate House
Tyndall Ave
Bristol
England
United Kingdom
BS8 1TH

Sponsor type
University/education

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&G

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
It is planned that the study will be written up and published in a high-impact peer reviewed journal. This will be approximately a year following data analysis following the end of the study.

Intention to publish date
30/11/2021

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?
Results article		24/10/2021	02/11/2021	Yes	No
Dataset		07/12/2021	19/10/2022	No	No
Protocol file	version 2.0	10/12/2017	25/10/2022	No	No