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The effect of a behavioural management tool in adults with mild to moderate gum disease

Submission date
15/01/2020

Recruitment status
No longer recruiting

Registration date
30/01/2020

Overall study status
Completed

Last Edited
11/02/2022

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Periodontitis (gum disease) is a common inflammatory disease of the supporting tissues (gums and bone) of the teeth eventually leading to tooth loss if left untreated.
There is evidence that psychological factors such as dental anxiety, oral health beliefs and self-efficacy significantly affect oral-health-related behaviours (e.g. attending dental care, promoting oral hygiene and diet). It is therefore intuitive to think that psychological interventions might be an effective strategy to improve treatment of oral diseases such as periodontitis.
The aim of this study is to compare the effect of a programme specifically developed to promote a behaviour change to a standard oral healthcare communication approach to reduce plaque and improve clinical outcomes, compliance and motivation to oral healthcare in subjects with slight to moderate periodontitis.

Who can participate?
People 35 – 65 years old with at least 20 natural teeth and slight to moderate periodontitis

What does the study involve?
As part of the study, participants will receive the standard treatment for periodontitis, which consists of two visits for the deep cleaning of pockets, and they are randomly (by chance) assigned to either an interactive behavioural management program (Sonicare Connect) or to a standard communication program (control) to be implemented at the time of treatment. In other words, if the patients are assigned to the control group, they receive standard oral hygiene instructions as they would receive in a private practice setting, while patients assigned to the test group are exposed to a programme specifically developed to promote behaviour changes, which included watching a DVD (or reading materials) and engaging with a practitioner trained in motivational interviewing. Periodontal clinical measurements (measurements recorded around teeth and gums) are recorded at baseline and at different follow-up visits and practitioners and participants were asked to fill in questionnaires on their experience.

What are the possible benefits and risks of participating?
The patients benefit from the treatment of periodontitis according to the gold standard of practice in a highly qualified environment and by trained clinicians. Treatment of periodontitis (deep cleaning of pockets) is expected to cause minor discomfort, transient irritation and minor

abrasion of gingival tissue. The two interventions tested in this trial (a standard communication programme and a programme specifically developed to promote a behaviour change) act on the ability of the patient to improve oral hygiene and be motivated and compliant so they are both expected to provide a benefit as part of the treatment of periodontitis.

Where is the study run from?
Eastman Dental Institute, UK

When is the study starting and how long is it expected to run for?
January 2009 to June 2011

Who is funding the study?
Philips Oral Healthcare, Inc (Bothell WA), USA

Who is the main contact?
Prof. Nikolaos Donos
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
DRC-0552

Study information

Scientific Title
The effect of a behavioural management tool in adults with mild to moderate periodontitis. a single-blind, parallel group, randomised controlled trial

Study objectives
Evidence suggests that psychological approaches directed at changing behaviours may successfully improve the effectiveness of oral health education. The aim of this study is to evaluate the effect of a behavioural management program in a controlled clinical trial and to compare it to a standard oral healthcare communication approach to reduce plaque and improve clinical outcomes, compliance and motivation to oral healthcare in subjects with slight to moderate periodontitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/03/2009, The Joint UCL/UCLH Committees on the Ethics of Human Research (Committee A) (ICH Research & Development Directorate Office, 1st Floor, 3 Long Yard, London, WC1N 1EH; +44 (0)207 905 2703; S.Vandayar@ich.ucl.ac.uk), ref: 09/H0714/18

Study design
Randomized single-blind parallel-design trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Periodontal disease

Interventions
The aim is to compare the effect of a behavioral management program (Sonicare Connect) to a standard oral healthcare communication approach (without use of an adjunctive tool) to reduce plaque in subjects with slight to moderate periodontitis

The study consists of 6 visits over a period of approximately 4 months per participant. During Visit 1 (-28 days ±1 day from baseline), patients are screened and, after confirmed eligible, a consent form is signed and their medical and dental history are recorded. All participants receive a powered toothbrush (Sonicare FlexCare, Philips Oral Healthcare, Bothell, WA, USA) with a review of the manufacturer's operating instructions and a standard fluoride-containing dentifrice, and a staff member will instruct participants on how to complete daily oral hygiene habit diaries. At the end of the visit, participants are randomly assigned to either an interactive behavioural management program (Sonicare Connect) or to a standard communication program (control) to be implemented at the time of treatment (visit 3). Randomization is balanced by gender and age (35-60 and 61-65) and smoking status.

Standard non-surgical periodontal therapy consisting of supra and/or subgingival debridement under local anaesthesia (when necessary) using hand and ultrasonic instruments as deemed

appropriate, along with one of the two oral healthcare communication approaches is performed at Visits 3 and 4 (Weeks 1 and 2 after baseline). The two communication approaches (either Sonicare Connect or Standard Communication) are administered by one (not blinded) treatment clinician. Specific training is provided to the clinician to use the Sonicare Connect materials (questionnaire and software) as a platform for dialogue and to act as a guide or a coach rather than a director, as well as to promote self-management of oral healthcare. In the test group, during the waiting room period, patients watch a DVD (or read materials) that prompt them to evaluate their feelings, attitudes and eventually their willingness to change in areas of oral care as well as overall health (i.e., oral hygiene, nicotine consumption and eating habits). The patients then complete a questionnaire and present it to the practitioner during the consultation. The practitioner evaluates the patient's answers and encourages dialogue through the use of motivational interviewing communication techniques, including open questions, affirmations, reflective listening and summarising.

When dealing with control (Standard Communication) patients, the same clinician is asked to follow protocol procedures and apply standard oral healthcare practices, and to instruct them about the protocol's oral hygiene instructions, diary completion and general compliance in the same way that they would normally do in a private practice setting.

Two blinded, previously calibrated dental examiners will perform all the clinical measurements, including full mouth plaque index (PI), gingival index (GI), bleeding on probing (BOP), probing pocket depth (PPD) and clinical attachment level (CAL), which are recorded at Visit 1, 2 (baseline), 5 (week 8 post-non-surgical therapy) and 6 (week 14 post-non-surgical therapy). Moreover, subjects' and practitioner' s questionnaires will be completed at Week 1, Week 2, Week 8 and Week 14.

Intervention Type
Behavioural

Primary outcome(s)
Oral health measured using plaque index 14 weeks after baseline (6 weeks after non-surgical therapy completion)

Key secondary outcome(s))
1. Clinical efficacy of interventions measured using gingival index (GI), plaque index (PI), probing pocket depth (PPD), clinical attachment level (CAL) and bleeding on probing (BOP) at 4 weeks and 8 weeks after baseline
2. Clinical efficacy of interventions communication approach in terms of GI, PPD, CAL and BOP at 14 weeks after baseline
3. Attendance, length of visits and percentage proportional talk time measured using patient records of all visits
4. Subjects' oral healthcare judgement and behavioural parameters documented daily by subjects in brushing diaries from Day -28 through Week 14 post-baseline
5. Subject visit experiences were measured via questionnaires (1-to-5 Disagree-Agree Likert Scale) completed by subjects at Week 1, Week 2, Week 8 and Week 14
6. Questionnaires on practitioner visit experiences (1-to-5 Disagree-Agree Likert Scale) were completed by subjects at Week 1, Week 2, Week 8 and Week 14

Completion date
31/03/2011

Eligibility

Key inclusion criteria
1. 35 - 65 years old
2. Minimum of 20 natural teeth; 35% of all sites with plaque
3. Minimum of 8 sites in at least 2 different quadrants with ≥ 5 mm pocket probing depth (PPD), with 1 – 4mm clinical attachment loss and showing bleeding on probing (BOP) (slight to moderate periodontitis)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Use of antibiotics or anti-inflammatory agents within the previous 2 weeks
2. Need for antibiotic treatment for dental appointments
3. Type I and II uncontrolled diabetes mellitus
4. Pregnant or lactating women
5. Infectious disease including HIV/AIDS
6. Aggressive periodontitis
7. Prior periodontal therapy except for routine dental prophylaxis
8. Current, regular power (electric or battery) toothbrush users

Date of first enrolment
01/10/2009

Date of final enrolment
22/11/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Eastman Dental Institute
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Sponsor information

Organisation
Philips Oral Healthcare

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
Philips Oral Healthcare

Alternative Name(s)
Philips Oral Healthcare, LLC

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/09/2020	11/02/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes