The Effect of a Behavioural Management Tool in Adults with Mild to Moderate Periodontitis. A Single-blind, Randomised Controlled Trial.

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Concise title: Changing behaviour in periodontitis treatment

Abstract

Objective To compare a behavioural management program to a standard communication approach (control) to reduce plaque, improve clinical outcomes and patient's compliance with oral self-care.

Background Since psychological factors affect oral-health-related behaviours, approaches directed at changing behaviours and improving compliance might improve the effect of oral health education.

Materials and Methods This was a randomised, single-blind, parallel-design trial involving 71 patients with mild to moderate periodontitis. During a run-in period, all participants began using a power toothbrush. Two sessions of non-surgical periodontal therapy were performed post baseline, along with one of the two oral healthcare communication approaches. Plaque and bleeding scores, probing pocket depth (PPD) and clinical attachment level (CAL) were recorded at the screening visit, baseline visit and at 8- and 14- weeks post baseline. Patients were asked to fill in oral self-care diaries. Experience questionnaires were administered to both clinicians and patients to assess subjective experience of the clinician-patient interactions during the visits.

Results In both groups a significant reduction in plaque and bleeding scores was observed from baseline to 8 weeks after baseline, which then remained stable at week 14, but no differences between the groups were noted. An improvement in CAL and PPD was recorded at week 8 post baseline in the test group. No inter-group differences in the clinician's and subject's experience questionnaires were observed.

Conclusion Both approaches significantly promoted periodontal health. However, changing lifestyle requires repeated communication/engagement over time and a behavioural management program based upon 2 visits did not provide additional benefit compared to a standard approach.

Keywords behavioural management, periodontitis, oral health, dental hygiene

Introduction

Periodontal diseases (gingivitis and periodontitis) are inflammatory diseases of microbial origin, caused by the accumulation of plaque/biofilm around and below the gingival margin [1]. It is therefore indubitable that plaque control represents a requirement in order to successfully prevent and treat periodontitis. Dental professionals treating patients affected by periodontal disease are constantly faced with the challenge of encouraging motivation for consistent and effective patient self-care. There is evidence that psychological factors such as dental anxiety, sense of coherence, locus of control, oral health beliefs and self-efficacy significantly affect oral-health-related behaviours (e.g. attending dental care, promoting oral hygiene and diet) [2]. It is therefore intuitive to think that psychological interventions might be an effective strategy to facilitate treatment of oral diseases such as periodontitis.

Evidence suggests that psychological approaches directed at changing behaviours may successfully improve the effectiveness of oral health education. For instance, it has been shown that an individually tailored oral health educational programme (ITOHEP) based on social cognitive strategies and motivational interviewing has a more positive impact on oral hygiene behaviour (gingivitis and plaque control, as well as self-reported frequency of daily inter-dental cleaning) compared with a standard oral hygiene educational programme [3,4]. Moreover, the incremental costs per "successful-NSPT" case associated with ITOHEP was considered as low and strengthened the suggestion that an ITOHEP integrated into non-surgical periodontal treatment is preferable to a standardized education programme [5]. Motivational interviewing (MI) is another approach for discussing behaviour change that fosters a collaborative doctor-patient relationship with the aim to promote better outcomes for patients [6]. Few studies suggested that MI might improve patients' interdental cleaning self-efficacy and might help the clinician in guiding patient communication in a desired direction and reduce expressions of resistance [7,8]. However, when MI was used only in single interventions it did not lead to additional benefits [9,10], thus reinforcing the idea that behavioural changes require repeated communication/engagement over time.

In a systematic review, Newton et al. [11] concluded that interventions based on the use of goal-setting, self-monitoring and planning seem to be effective in improving oral health-related behaviours. They also showed that the perception of the benefits of a behavioural change and the seriousness of the disease are positively related to the adherence to oral hygiene

instructions in adult patients. Another systematic review showed less strong results, with a small significant reduction in plaque presence when psychological interventions were compared with traditional oral health education [12]. Therefore, the authors concluded that psychological interventions should not be routinely applied in patients with poor oral health, but they might be used if benefits, risks, cost-effectiveness and ethical aspects are accounted for. Recently, Carra et al.[13] highlighted that, although oral hygiene in patients with periodontal disease may be improved by a therapeutic patient education based on behavioural interventions, cognitive constructs and motivational interviewing, there is insufficient evidence to assess their clinical efficacy and support one approach over the other.

Both manual and electric toothbrushes have demonstrated to be effective in removing supra-gingival plaque and reducing signs of gingival inflammation. According to a systematic review of the literature, powered toothbrushes show superiority to manual brushes in reducing supragingival plaque and gingivitis [14], although the clinical relevance of the results might not be so obvious and the heterogeneity between studies make them difficult to compare. Although the use of interactive devices to promote oral hygiene such as electronic support systems for power toothbrushes and timers is currently promoted, at present, evidence of a long-term successful change in behaviour is not available [15].

Sonicare Connect is an interactive behavioural management program that was designed to enhance communication between practitioners and patients, engage patients, facilitate a patient-centered approach and make dental visits less stressful both for the clinicians and the patients. It was developed by Philips Oral Healthcare (POHC) based upon the principles of motivational interviewing. It aims of having an impact on treatment outcomes by facilitating the improvement of oral self-care through the application of techniques to enhance clinician empathy, patient choices and engagement, therefore increasing patients' motivation to adopt and maintain self-care routines.

The aim of this study was to evaluate the effect of a behavioural management program in a randomised controlled clinical trial and to compare it to a standard oral healthcare communication approach to reduce plaque, improve clinical outcomes and patient's compliance with oral self-care in subjects with slight to moderate periodontitis.

Materials and Methods

This was a randomised, single-blind, parallel-design trial conducted in 71 otherwise systemically healthy patients with mild to moderate periodontitis. The study was conducted in full accordance with the ethical principles of the Declaration of Helsinki (version, 2008) and ICH Good Clinical Practice, and was independently reviewed and approved by the relevant local Ethics Committee (National Research Ethic Service of the NHS, REC reference 09/H0714/18). The study was registered via http://isrctn.org/ (registration number ISRCTN29412903). Informed consent was obtained from all individual participants included in the study. CONSORT statement for reporting randomised trials was adopted (http://www.consort-statement.org) for manuscript preparation. The study consisted in 6 visits over a period of 20 weeks.

The **primary objective** of the study was to compare the effect of a behavioural management program (Sonicare Connect, Philips Oral Healthcare, Bothell, WA, USA) (Test) to a standard oral healthcare communication approach (Control) to reduce plaque index 14 weeks after baseline (6 weeks after non-surgical therapy completion). The **secondary objectives** were to: 1) evaluate the clinical efficacy of Sonicare Connect compared to a standard oral healthcare communication approach in terms of gingival index (GI), plaque index (PI), probing pocket depth (PPD), clinical attachment level (CAL) and bleeding on probing (BOP) at 8 weeks after baseline; 2) evaluate the clinical efficacy of Sonicare Connect compared to a standard oral healthcare communication approach in terms of GI, PPD, CAL and BOP at 14 weeks after baseline; 3) assess the effects of Sonicare Connect on subject's attendance, length of visits and percentage proportional talk time compared to a standard oral healthcare communication approach; 4) assess the effects of Sonicare Connect compared to a standard oral healthcare communication approach in terms of subjects' oral healthcare judgement and behavioural parameters; 5) assess the effects of Sonicare Connect compared to a standard oral healthcare communication approach on the practitioner's oral healthcare judgement; 6) assess the clinical efficacy of a powered toothbrush to reduce PI, GI, PPD, CAL, BOP following 4 weeks of product use in patients with slight to moderate periodontitis (day 0 to -28).

Inclusion/exclusion criteria and study design

Subjects were enrolled if they fulfilled the following criteria: i) 35-65 years old; ii) minimum of 20 natural teeth; ≥35% of all sites with plaque [16]; iii) 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) [17]. Main exclusion criteria included: i) use of antibiotics or anti-inflammatory agents within the previous 2 weeks; ii) need for antibiotic treatment for dental appointments; iii) type I and II uncontrolled diabetes mellitus; iv) pregnant or lactating women, v) infectious disease including HIV/AIDS; vi) aggressive periodontitis; vii) prior periodontal therapy except for routine dental prophylaxis; viii) current, regular power (electric or battery) toothbrush users.

The study design is illustrated in Figure 1.

During Visit 1 (-28 days ±1 day from baseline), patients were screened and, after confirmed eligible, a consent form was signed and their medical and dental history were recorded. All participants received 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 instructed participants on how to complete daily oral hygiene habit diaries. At the end of the visit, participants were randomly assigned to either an interactive behavioural management program (Sonicare Connect, test group) or to a standard communication program (control group) to be implemented at the time of treatment (visit 3 and 4). No oral hygiene instructions other than manufacturer instructions on operation of the power toothbrush were provided at Visit 1. Randomisation was balanced by gender and age (35-60 and 61-65) and smoking status. Participants of both groups were allowed to use interdental cleaning aids throughout the study, such as dental floss, interdental brushes, dental sticks, rubber tip stimulators and irrigation devices. Two blinded, previously calibrated dental examiners performed all the clinical measurements, including full mouth plaque index (PI) [16], gingival index (GI) [18,19], bleeding on probing (BOP), probing pocket depth (PPD) and clinical attachment level (CAL), which were recorded at Visit 1, 2 (baseline), 5 (week 8 post non-surgical therapy) and 6 (week 14 post non-surgical therapy).

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 was performed at Visits 3 and 4 (Weeks 1 and 2 after baseline). The two communication approaches (either Sonicare Connect or Standard Communication) were administered by one (not blinded) treatment clinician. The risk for crossover effect from the use of one communication approach to the other between subjects was assessed and was minimised by scheduling test and control patients on different days of the week and ongoing quality assurance measures as outlined in Supporting Material (Appendix 1). The treatment practitioner was also responsible for collecting and reviewing patients' diaries, addressing completion errors, reviewing adverse events and concomitant medications, checking compliance, and they also filled in the practitioner treatment program experience questionnaire. A dental nurse recorded consultation length and percentage of proportional talk time and checked the completion of the participant treatment program experience questionnaire.

Oral healthcare communication approaches

As previously mentioned, the same clinician administered both communication approaches. When dealing with control (Standard Communication) patients, the clinician was 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. A specific training was 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 directing or instructing, as well as to promote self-management of oral healthcare (more details can be found in Supplementary material). In the test group, during the waiting room period, patients watched a DVD (or read materials) that prompted 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 completed a questionnaire and presented it to the practitioner during the consultation. The practitioner evaluated the patient's answers and encouraged dialog through use of motivational interviewing communication techniques, including open questions, affirmations, reflective listening and summarising. Communication tools to engage the patient in conversation included values ruler, that is to say asking the patient on a scale of 1 – 10 how they felt about

particular aspects related to their oral hygiene routine. The clinician encouraged the patient to set small realistic goals and to use the diaries to monitor their progress.

Consultation parameters

Beginning at Week 1 and at each study visit thereafter the following were recorded*: i) subject attendance*- percentage of appointments attended by the patient; *ii) total length of each consultation visit* – measured in minutes: seconds from the time that a subject is first engaged by the assigned practitioner until the end of engagement*; iii) percentage proportional talk time* – per consultation visit, total talk time between the subject and the assigned practitioner (minutes : seconds) divided by the total visit length. Comparisons between groups were evaluated and correlations with clinical outcomes were assessed.

Judgement and behavioural parameters

Subject Self-Management of Oral Hygiene Habits (i.e. brushing duration, frequency and interdental cleaning frequency) were documented daily by subjects in brushing diaries from Day -28 through Week 14 post baseline. *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 (Supporting Material, Appendix 2). 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 (Supporting Material, Appendix 3). Changes from Week 1 to the subsequent follow-ups were evaluated within group and between groups for all aforementioned parameters.

Statistical analysis and sample size calculation

All recorded variables were summarized by descriptive statistics. Normal distribution of the outcome variables was assessed with the Kolmogorov Smirnov test and by checking frequency distribution (histograms). The primary efficacy variable was the change from baseline (Visit 2) to 14 weeks in plaque score. The primary analysis was carried out on an intent-to-treat (ITT) basis, including all randomized subjects with a baseline and an endpoint evaluation. The null hypothesis of no difference between the treatment groups was rejected only if the primary endpoint reached significance at the 0.05 alpha level (two-sided test). A

linear mixed effects model was applied by using SAS 9.1.3. Comparisons between the treatment groups was performed using the appropriate F-Test.

Changes in clinical parameters from Day -28 to Day 0 and from baseline (Day 0) to Weeks 8 and 14 within treatment groups were analyzed by using a paired t-test. Consultation Parameters, Subject Judgment and Behavioural Parameters, Practitioner Judgment Parameters, self-reported compliance parameters were also investigated as follows: changes from baseline were analyzed using paired t-test and between-group comparisons were performed by applying a linear mixed effects model.

By assuming a two-sided $\alpha = 0.05$ level, a parallel design, 20% dropout rate and also by adopting a standard deviation of the primary outcome of 19% (based on a pilot 2-month study), a sample size of 36 subjects per treatment group including drop-outs (30 subjects per group to complete) was calculated in order to detect with 80% power a treatment difference of 14% of plaque containing surfaces index between groups after 14 weeks post baseline (12 weeks post completion of treatment).
An intention-to-treat analysis was applied.

Results

Seventy-three subjects were screened, with 71 randomised to treatment. Sixty-four subjects completed the study, 33 out of the 37 assigned to the test group and 31 out of the 34 assigned to the control group. Following enrolment (visit 1), seven patients decided not to continue participation in the study or were withdrawn because they no longer met inclusion/exclusion criteria, therefore they did not receive the intervention and their data could not be considered for analysis. Table 1 shows the demographics of the participants, which were similar in both groups.
No adverse events occurred during the study.

Clinical parameters

Changes in PI at the different time points are presented in Figure 2. Both groups showed a significant reduction in PI in the 28-day period from screening to baseline ($p<0.001$) following implementation of standardized home oral hygiene with powered toothbrushing. (Figure 2).

The least square mean (LS mean) change in PI from baseline to week 8 was 15.6% (SE 4.86%) for the test group and 13.3% (SE 5.18%) for the control group. The treatment difference (mean 2.4%, SE 2.73%) was not statistically significant (p=0.3929). The change from baseline to week 14 was 7.6% (SE 4.08%) for the test group and 3.4% (SE 4.32%) for the control group. The treatment difference (mean 4.3%, SE 3.14%) was not statistically significant (p=0.1781).

In both groups, the mean GI was 0.7 at screening, then it significantly reduced to 0.6 (SE 0.06) in the control group (p=0.0168) at baseline, while the reduction was not significant in the test group (0.7, SE 0.05) (p=0.5552). In both groups, GI significantly reduced from baseline to week 8 and remained stable at 14 weeks (Table 2). The LS mean change from baseline to week 8 was 0.4 (SE 0.05) for both groups. The treatment difference (mean 0.0, SE 0.03) was not statistically significant (p=0.2235). Likewise, the change from baseline to week 14 in overall GI was 0.4 (SE 0.04) for both groups, with no statistically significant differences observed (mean 0.0, SE 0.04, p=0.4116).

The BOP, that at baseline was 40% (SD 18%) and 50% (SD 21%) in the control and test group, respectively, significantly decreased in both groups from baseline to 8 weeks, and remained stable at 14 weeks (Table 2). The LS mean change from baseline to week 8 was 0.3% (SE 0.01%) for Sonicare Connect and 0.2% (SE 0.01%) for Standard Communication. The treatment difference (mean 0.0%, SE 0.02%) was not statistically significant (p=0.0563). The LS mean change from baseline to week 14 was 0.2% (SE 0.03%) for the test and 0.2% (SE 0.04%) for the control group. No differences were observed between the two treatment groups (mean 0.0%, SE 0.02%, p=0.3156).

Data on PPD at all time points is presented in Table 2. While the test group presented with a statistically significant increase in PPD (of 0.1 mm, SE 0.03 mm, p=0.0316) from screening to baseline, the PPD then decreased significantly at week 8 (by 0.7 mm, SE 0.03 mm; p<0.0001) and remained stable at week 14. In the control group, no differences in terms of PPD were detected from screening to baseline, while the LS mean change from baseline to week 8 was 0.5 mm (SE 0.04 mm). The treatment difference between test and control group at 8 weeks (mean 0.1 mm, SE 0.05 mm) was statistically significant (p=0.0119), indicating that the test intervention reduced PPD significantly more than the control intervention at this time point.

At 14 weeks both groups maintained a reduced PPD (2.8 mm, SD 0.5 mm and 2.8 mm, SD 0.45 mm in the control and test group, respectively) with no statistical difference observed between treatments (Table 2). The LS mean change from Baseline to week 14 was 0.6 mm (SE 0.05 mm) for the test and 0.5 mm (SE 0.05 mm) for the control participants. The treatment difference (mean 0.1 mm, SE 0.07 mm) was not statistically significant (p=0.2553).

Regarding CAL, the LS mean change from baseline to Week 8 was 0.3 mm (SE 0.08 mm) for the test and 0.1 mm (SE 0.08 mm) for the control group. The treatment difference (mean 0.2 mm, SE 0.06 mm) was statistically significant (p=0.0010), indicating that the test group had a CAL gain significantly more pronounced than the control group at week 8. Both groups experienced a statistically significant gain in attachment level from baseline to week 14, with a LS mean change of 0.2 mm, SE 0.07 mm and of 0.3 mm, SE 0.06 mm in the control and test group, respectively. The treatment difference at this time point (mean 0.1 mm, SD 0.09 mm) was not statistically significant (p=0.4442).

Consultation parameters

Subject talk time (minutes : seconds) was significantly higher for the test subjects at all visits. Conversely, the practitioner talk time tended to be higher in the control group, with a significant difference in comparison to the test group at week 2 and 8 (4.4 vs 3.1 and 6.0 vs. 4.8, respectively, and p = 0.002).

Judgement and behavioural parameters

Compliance in the reported brushing frequency (twice a day) between the two treatment groups was not statistically significantly different, as per subject reported brushing diaries. The number of participants that reported brushing 2 minutes per episode increased in both groups along the study, with the test participants fully complying at week 14, compared to the control group, where 5 participants were not fulfilling the requirement at the end of the study (p = 0.019). No difference in the frequency of interdental cleanings was observed between the two groups at all times.

The summary of subject responses to the experience questionnaire are presented in Table 3. The majority of the participants in both groups strongly agreed the treatment helped them

understand what was happening with their teeth and gingivae, they felt involved and the treatment will help them progress in looking after their teeth and gums. There was no treatment difference with respect to the Top 2 Box ("strongly agree" and "somewhat agree"). However, the participants assigned to the test group at all visits tended to more strongly agree that during the treatment they made good progress in promoting good oral hygiene (Table 3).

Likewise, the practitioner judgement was similar for the two groups. When interviewed about subjects' responsiveness to think about improving oral hygiene, the practitioner replied that they "somewhat agreed" for the majority of the patients at all visits. However, when dealing with patients assigned to the test group, the practitioner tended to answer more frequently that they "strongly agreed" with the aforementioned sentence (for 8 vs. 2 patients at week 1, for 13 vs. 2 patients at week 2, for 15 vs. 5 patients at week 8 and for 16 vs. 6 patients at week 14).

When asked if patients were motivated to improve oral hygiene during the treatment, the practitioner "somewhat agreed" for the majority of the patients of both groups at all visits. Nevertheless, when dealing with the test group the practitioner tended to reply more frequently that they "strongly agreed" with the aforementioned sentence (for 7 vs. 2 patients at week 1, for 12 vs. 2 patients at week 2, for 16 vs. 5 patients at week 8 and for 16 vs. 6 patients at week 14).

The results of the Sonicare Connect questionnaire are presented in Table 4. Overall the questionnaire showed that most patients found it easy to fit in the visits, they were comfortable to come and see the dentist and they thought they were getting on well with looking after their teeth and gums during the study. The majority of the participants of the test group found the information and advice on plaque and on healthy eating and drinking helpful. Conversely, the information and advice on tobacco use were found very unhelpful or unhelpful by the 22.9% and 17.1% of the participants, respectively. 63.9% of the patients also thought they were unhappy about their teeth and gums.

Discussion

This study compared a behavioural management program (Sonicare Connect) to a standard oral healthcare communication approach (control) to enhance patient motivation in performing self-care oral hygiene procedures. Both approaches, when combined with non-surgical debridement, were able to significantly improve periodontal status in these periodontitis patients, as suggested by the significant reduction in plaque and bleeding scores, the reduction in PPD and CAL gain. It has been well demonstrated that non-surgical periodontal therapy significantly reduces PPD, with a magnitude of PPD reduction that is positively related to the magnitude of initial PPD [20-23]. In particular, a mean PPD reduction from baseline to 8 weeks of 0.7 mm and 0.5 mm was observed in the test and control groups, respectively. The reduction in PPD reflected in a mean gain in attachment level of 0.3 and 0.1 mm in the test and in the control group, respectively. The clinical improvements observed in the present study are in line with previous findings from studies where an individualised approach to behaviour change delivered by a dental hygienist trained in psychological methods was able to improve not only the oral hygiene behaviour, but also the plaque scores and the probing pocket depth [4,24,25]. It is however difficult to compare this trial with previously published studies, as the range of interventional approaches adopted is very heterogeneous, from cognitive behavioural approaches [3,24,25] to motivational interviewing [10,26], with different measurements of patient's adherence applied.

Sonicare Connect was designed to enhance communication between practitioners and patients, engage patients and facilitate a patient-centered approach based upon the principles of motivational interviewing[6]. In other words, we aimed at increasing patient's engagement to promote a behaviour change by acting as a guide or coach rather than directing or instructing the patients on what to do. This patient engagement could have facilitated goal setting, but the short duration of study did not allow for proper planning and monitoring. In the context of today's taxonomy model, our approach could be considered within the "feedback and monitoring", "self-belief" and "identity" taxonomy clusters [27].

A recent meta-review reported that there is insufficient evidence to demonstrate the superiority of any specific behavioural intervention over another or over standard interventions on periodontal parameters. Approximately half of the existing systematic reviews demonstrated a positive effect of behavioural interventions on parameters of plaque and gingivitis, while only 21.43% showed a beneficial effect on probing pocket depth [28]. This inconclusive evidence may be the result of too few studies meeting the inclusion criteria of

the reviews or, as reported in the meta-review, due to high levels of heterogeneity in study design, in particular in the type of intervention. This variability is not surprising, as behaviour approaches are often based upon communication styles and approaches such as goal setting, which are not procedures but "a way of being with the patient" [6]. To date, guidelines on standardized protocols or frameworks on the type of psychological interventions, number of sessions and reinforcements that should be followed in periodontitis patients in order to ensure long-term compliance are missing [13].

In the current project, the toothbrush device was standardised between the groups at the screening visit to minimise potential bias as a result of toothbrush type. At this time, all patients were provided with a powered toothbrush and a standard fluoride-containing dentifrice, with only review of the instructions of device function. Previous studies have suggested that power toothbrushes associated or not with debridement interventions are able to significantly impact on PI, GI and BOP, especially in the short term [14,29-31]. Our outcomes are in line with those results, as a significant reduction in PI and BOP was observed in both groups from enrolment (when the toothbrush was provided) to baseline. Although the standardisation of the type of toothbrush made the study design more robust, it might have partially masked the effect of the behavioural management program on plaque and bleeding scores at the subsequent follow-ups.

Oral hygiene instructions were individualised to each patient during the non-surgical therapy (visit 3), which took place following the baseline visit. These instructions were provided either using the Sonicare Connect guiding approach or standardised instruction were given. When looking at the brushing diaries, the Sonicare Connect did not promote a better compliance in terms of reported brushing frequency and interdental cleaning, but a better compliance to the 2-minutes brushing was observed at 14 weeks. It should be noted that these results are based on patients' self-assessment, which has obvious limitations and needs to be interpreted with caution. Future studies should benefit from more standardized outcomes to assess motivation and behaviour change, along with standardized means to assess those outcomes. Overall, participants of both groups reported a positive experience at all visits and they felt involved and more aware of what was happening with their teeth and gums (Table 3). Whilst the experience questionnaire did not return significant differences between the groups, at all visits a higher number of participants assigned to the behavioural management program

tended to strongly agree that during the treatment they made good progresses in promoting good oral hygiene. Remarkably, when answering the question "**During the treatment, I made good progress in promoting good oral hygiene habits",** the large difference in the percentage of participants that strongly agreed between test and control group (three times higher) suggests that the test intervention was more supportive in terms of self-efficacy and in promoting patients' autonomy in oral hygiene. Likewise, the practitioner's responses to the experience questionnaire showed a non-statistically significant trend for a higher agreement towards patients' responsiveness and motivation to improve oral hygiene reported when dealing with patients from the test group (Table 4).

It is worth highlighting that the same practitioner delivered both communication approaches and that the study took place in a well-established university research facility, where a research team with years of experience dealt with the participants and this can possibly limit the external validity of our results. Although the practitioner received specific training and quality control was in place to minimize the risk for crossover effect, there is the risk that the standard of communication adopted was anyway higher than it would have been in an average private practice setting or with two separate clinicians. Such interventions require a paradigm shift or behaviour change from the clinician, so it may also come into question whether or not a clinician can return to the traditional directive approach after training in patient engaging approaches of communication.

It is not possible to anticipate what would be the long-term effect of the behavioural management program (Sonicare Connect), as the present study had a follow-up of 14 weeks, which might be considered a short period to be able to demonstrate a sustained behaviour change. It should be noted that, despite plaque score significantly improved in both groups from screening to baseline and a further non-significant improvement was observed at 8 weeks, neither of the two groups managed to reach a satisfactory plaque score at the end of the study (48.6% in the control and 44.7% in the test group at 14 weeks). This might have influenced the response to the causal therapy and indicates some limitations in the approaches employed. Nevertheless, some of the clinical parameters (PPD and CAL) showed significant differences at 8 weeks, which levelled off at week 14, but longer follow-ups might be helpful to assess the long-term effect of this approach in terms of improved clinical

outcomes, judgement and behavioural parameters. In a large trial assessing the effect of an individualised approach to behaviour change delivered by a dental hygienist in association with non-surgical debridement, the approach induced significant improvements in both clinical periodontal parameters and self-reported behaviour at 1 year of follow-up [3,4,25].
Besides the short follow-up, a potential limitation of this study is the limited number of visits during which the two different approaches took place. Psychological theory and previous studies incorporating principles of motivational interviewing and individualised care suggest that behaviour change is challenging and requires time, as it is based upon building rapport with the patient and exploring goals together [32,33]. The results of this study support the notion that behaviour change is not likely to be maximised based upon only two or three patient-clinician interactions. Another potential limitation of the study is that we did not take into account the level of education of the participants. It has been reported that education level is correlated with oral health status [34]. However, the aim of the study was to engage the patient based on the communication style and not on the level of education. Hence, despite potential differences in education level, this tailored approach should have allowed all participants to adequately engage in the conversation to embrace self-care.

It is worth to mention that one of the challenges associated with researches dealing with patient-centered outcomes is that, being the patient aware of the intervention received, the outcome assessor (the patient in this case) could measure differently the outcome as compared to the other group because, for example, the patient perceived that had received a more “sophisticated” treatment/care. This potential bias in the measurement of the outcome (as per Cochrane Risk of Bias Tool for randomized clinical trials, RoB 2) was overcome by making efforts to present the two interventions in a neutral manner at the time of consent. As such, clinicians put particular efforts not to refer to “test” and “control” group, as “test” could have possibly implied a more sophisticated treatment and they never implied that one treatment was better or newer than the other.

A behavioural management program requires trained personnel and possibly a higher communication time with the patient during the appointments, with possible extra costs to be considered. Considering the often limited health resources available, cost-effectiveness considerations should always be taken into account when two different treatment strategies

are compared. Jonsson et al. [5] compared costs and consequences of an individually tailored oral health educational programme based on cognitive behavioural strategies integrated into a non-surgical periodontal treatment with a standard treatment programme. In that study, costs referred to both treatment costs and costs contributed by the patients, while outcomes were expressed as the proportion of individuals that reached the pre-set criteria for treatment success after non-surgical treatment ("successful-NSPT"). Remarkably, more patients assigned to the tailored programme reached the successful-NSPT with a low incremental cost. Therefore, they concluded that a tailored cognitive behavioural strategy integrated into non-surgical periodontal treatment is preferable to a standardised education programme. In our study, the cost component was not considered. However, in the future it would be important to compare the treatment costs and outcomes associated with the two different approaches, so to assess the overall cost-effectiveness of Sonicare Connect.

Compliance with Ethical Standards

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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Conflict of interest

Beside the fact that Phillips funded the study, the authors declare that they do not have any conflict of interest.

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Table legend

Table 1 Demographics of the participants of the test (Sonicare Connect) and control (Standard Communication) groups. Standard deviation is reported in brackets, when applicable

Table 2 Periodontal clinical parameters at the different visits. GI, gingival index; PPD, probing pocket depth; CAL, clinical attachment level; BOP, bleeding on probing. Data are reported as mean (Standard Deviation; 95% confidence interval). * indicates a statistically significant differences compared to screening; # indicates a statistically significant difference compared to baseline; ψ indicates a statistically significant difference between test and control group ($p < 0.05$). As previously indicated, 37 Test and 34 Control patients were enrolled at the screening visit, while 2 Control patients dropped out at baseline and 1 at week 2 (so did not attend visit 5). Amongst the Test patients, 2 dropped out at week 2 (so did not attend visit 5) and 2 at week 8 (so did not attend visit 6).

Table 3 Summary of subject responses to the experience questionnaire. Data as reported as number of patients and percentage (in brackets).

Table 4 Summary of subject responses to the Sonicare questionnaire (test group). Data as reported as number of patients and percentage (in brackets).

Figure legend

Figure 1 Flowchart of the study. The main procedures performed at each study visit are reported. The two treatment approaches (test or control) were implemented at the time of treatment (visit 3 and 4).

Figure 2 Plaque Index recorded in the two groups at the different study visits. Data are presented as mean and standard deviation.

Supporting material

Appendix 1: Sonicare Connect Communication approach, practitioner training

Appendix 2: Subject Treatment Program Experience Questionnaire

Appendix 3: Practitioner Treatment Program Experience Questionnaire

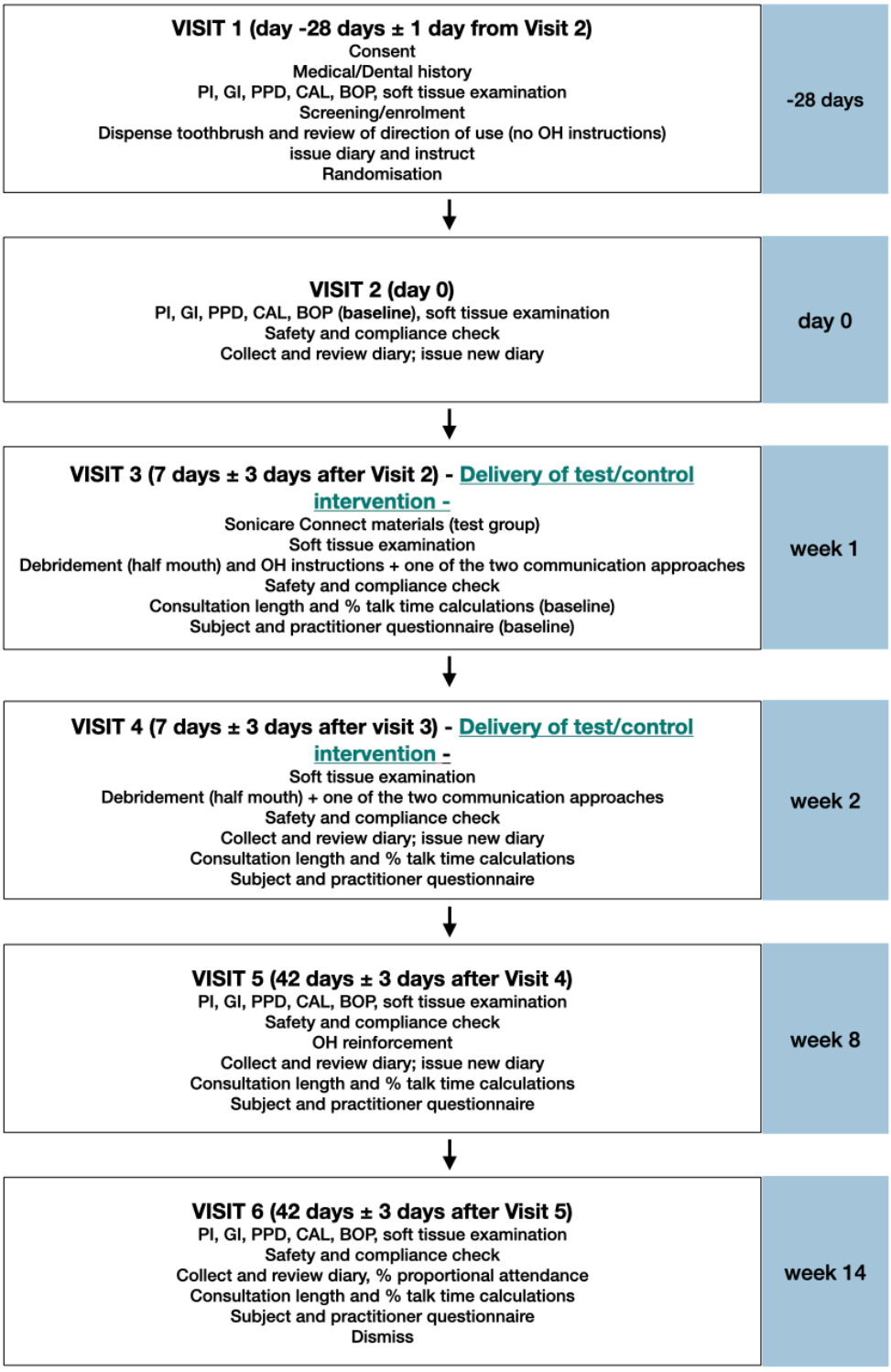
VISIT 1 (day -28 days ± 1 day from Visit 2)
Consent
Medical/Dental history
PI, GI, PPD, CAL, BOP, soft tissue examination
Screening/enrolment
Dispense toothbrush and review of direction of use (no OH instructions)
issue diary and instruct
Randomisation
-28 days
VISIT 2 (day 0)
PI, GI, PPD, CAL, BOP (baseline), soft tissue examination
Safety and compliance check
Collect and review diary; issue new diary
day 0
VISIT 3 (7 days ± 3 days after Visit 2) - Delivery of test/control intervention -
Sonicare Connect materials (test group)
Soft tissue examination
Debridement (half mouth) and OH instructions + one of the two communication approaches
Safety and compliance check
Consultation length and % talk time calculations (baseline)
Subject and practitioner questionnaire (baseline)
week 1
VISIT 4 (7 days ± 3 days after visit 3) - Delivery of test/control intervention -
Soft tissue examination
Debridement (half mouth) + one of the two communication approaches
Safety and compliance check
Collect and review diary; issue new diary
Consultation length and % talk time calculations
Subject and practitioner questionnaire
week 2
VISIT 5 (42 days ± 3 days after Visit 4)
PI, GI, PPD, CAL, BOP, soft tissue examination
Safety and compliance check
OH reinforcement
Collect and review diary; issue new diary
Consultation length and % talk time calculations
Subject and practitioner questionnaire
week 8
VISIT 6 (42 days ± 3 days after Visit 5)
PI, GI, PPD, CAL, BOP, soft tissue examination
Safety and compliance check
Collect and review diary, % proportional attendance
Consultation length and % talk time calculations
Subject and practitioner questionnaire
Dismiss
week 14

Figure 1

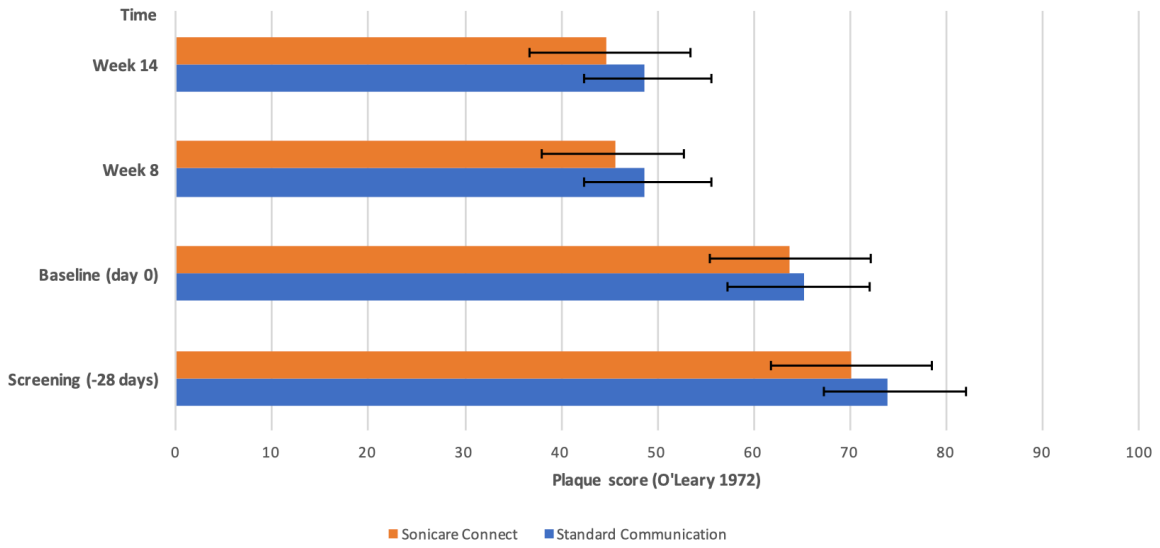

Figure 2

	Standard Communication	Sonicare Connect
Age (years)	47.5 (8.0)	46.4 (7.6)
Gender		
Male	11 (32.4%)	11 (29.7%)
Female	23 (67.6%)	26 (70.3%)
Race		
Asian	6 (17.6%0	8 (21.6%)
Black	3 (8.8%)	5 (13.5%)
White	23 (67.6%)	17 (45.9%)
Mixed	2 (5.9%)	6 (16.2%)
Other	0	1 (2.7%)
Tobacco use	2	
Smokers	6 (17.6%)	5 (13.5%)

Table 1

	Parameter	**Visit 1 (Screening; -28 days from Visit 2)**	**Visit 2 (Baseline; day 0)**	**Visit 5 (Week 8)**	**Visit 6 (Week 14)**
Control group	GI	0.7 (0.37; 0.6 to 0.8)	0.6 (0.34; 0.5 to 0.8)*	0.3 (0.21; 0.3 to 0.4)#	0.3 (0.19; 0.2 to 0.4) #
Test group		0.7 (0.30; 0.6 to 0.8)	0.7 (0.31; 0.6 to 0.8)	0.3 (0.12; 0.3 to 0.3) #	0.3 (0.15; 0.2 to 0.3) #
Control group	PPD (mm)	3.4 (0.64; 3.1 to 3.6)	3.3 (0.63; 3.1 to 3.5)	2.8 (0.46; 2.6 to 3.0) #	2.8 (0.50; 2.6 to 3.0) #

Test group		3.4 (0.66; 3.2 to 3.6)	3.4 (0.68; 3.2 to 3.7) *	2.7 (0.40; 2.6 to 2.9) #ψ	2.8 (0.45; 2.6 to 2.9) #
Control group	CAL (mm)	3.8 (0.78; 3.5 to 4.1)	3.8 (0.75; 3.5 to 4.1)	3.6 (0.77; 3.3 to 3.9)	3.6 (0.76; 3.3 to 3.8) #
Test group		3.8 (0.80; 3.6 to 4.1)	3.9 (0.80; 3.7 to 4.2) *	3.5 (0.65; 3.2 to 3.7) #ψ	3.6 (0.78; 3.3 to 3.9) #
Control group	BOP (%)	0.5 (0.19; 0.4 to 0.6)	0.4 (0.18; 0.4 to 0.5)*	0.2 (0.12; 0.2 to 0.3) #	0.2 (0.13; 0.2 to 0.3) #
Test group		0.5 (0.21; 0.5 to 0.6)	0.5 (0.21; 0.4 to 0.6)*	0.2 (0.10; 0.2 to 0.2) #	0.2 (0.11; 0.2 to 0.3) #

Table 2

VISIT	TREATMENT	Strongly Agree	Somewhat Agree	Neither Agree or Disagree	Somewhat Disagree	Strongly Disagree	Top 2 Box	Bottom 2 Box	P=value
This treatment helped me to understand what is happening to my teeth and gums									
Week 1	Standard Communication Sonicare Connect	30 (93.8%) 35 (94.6%)	0 1 (2.7%)	0 0	0 0	2 (6.3%) 1 (2.7%)	30 (93.8%) 36 (97.3%)	2 (6.3%) 1 (2.7%)	0.5932
Week 2	Standard Communication Sonicare Connect	29 (90.6%) 35 (94.6%)	1 (3.1%) 1 (2.7%)	1 (3.1%) 0	0 0	1 (3.1%) 1 (2.7%)	30 (93.8%) 36 (97.3%)	1 (3.1%) 1 (2.7%)	0.5932
Week 8	Standard Communication Sonicare Connect	26 (83.9%) 31 (91.2%)	1 (3.2%) 0	0 1 (2.9%)	0 0	4 (12.9%) 2 (5.9%)	27 (87.1%) 31 (91.2%)	4 (12.9%) 2 (5.9%)	0.7006
Week 14	Standard Communication Sonicare Connect	28 (96.6%) 31 (93.9%)	1 (3.4%) 0	0 0	0 0	0 2 (6.1%)	29 (100%) 31 (93.9%)	0 2 (6.1%)	0.4939
During this treatment, I felt involved while talking about my teeth and gums									
Week 1	Standard Communication Sonicare Connect	28 (87.5%) 34 (91.9%)	2 (6.3%) 2 (5.4%)	0 0	0 0	2 (6.3%) 1 (2.7%)	30 (93.8%) 36 (97.3%)	2 (6.3%) 1 (2.7%)	0.5932
Week 2	Standard Communication Sonicare Connect	28 (87.5%) 34 (91.9%)	2 (6.3%) 2 (5.4%)	1 (3.1%) 0	0 0	1 (3.1%) 1 (2.7%)	30 (93.8%) 36 (97.3%)	1 (3.1%) 1 (2.7%)	0.5932
Week 8	Standard Communication Sonicare Connect	25 (80.6%) 30 (88.2%)	2 (6.5%) 1 (2.9%)	0 0	0 0	4 (12.9%) 3 (8.8%)	27 (87.1%) 31 (91.2%)	4 (12.9%) 3 (8.8%)	0.7006
Week 14	Standard Communication Sonicare Connect	28 (96.6%) 30 (93.9%)	1 (3.4%) 1 (3%)	0 0	0 0	0 2 (6.1%)	29 (100%) 31 (93.9%)	0 2 (6.1%)	0.4939
This treatment will help me progress in looking after my teeth and gums									
Week 1	Standard Communication Sonicare Connect	29 (90.6%) 34 (91.9%)	1 (3.1%) 2 (5.4%)	0 0	0 0	2 (6.3%) 1 (2.7%)	30 (93.8%) 36 (97.3%)	2 (6.3%) 1 (2.7%)	0.5932
Week 2	Standard Communication Sonicare Connect	30 (91.9%) 34 (91.9%)	0 2 (5.4%)	1 (3.1%) 0	0 0	1 (3.1%) 1 (2.7%)	30 (93.8%) 36 (97.3%)	1 (3.1%) 1 (2.7%)	0.5932
Week 8	Standard Communication Sonicare Connect	26 (83.9% 31 (91.2%)	1 (3.2%) 0	0 0	0 0	4 (12.9%) 3 (8.8%)	27 (87.1%) 31 (91.2%)	4 (12.9%) 3 (8.8%)	0.7006
Week 14	Standard Communication Sonicare Connect	28 (96.6%) 31 (93.9%)	1 (3.4%) 0	0 0	0 0	0 2 (6.1%)	29 (100%) 31 (93.9%)	0 2 (6.1%)	0.4939
During the treatment, I made good progress in promoting good oral hygiene habits									
Week 1	Standard Communication Sonicare Connect	2 (6.3%) 6 (16.2%)	16 (50%) 23 (62.2%)	13 (40.5%) 8 (21.6%)	1 (3.1%) 0	0 0	18 (56.3%) 29 (78.4%)	1 (3.1%) 0	0.0702

Week 2	Standard Communication Sonicare Connect	2 (6.3%) 10 (27%)	22 (68.8%) 21 (56.8%)	7 (21.9%) 6 (16.2%)	1 (3.1%) 0	0 0	24 (75%) 31 (83.8%)	1 (3.2%) 0	0.3875
Week 8	Standard Communication Sonicare Connect	5 (16.1%) 15 (44.1%)	16 (51.6%) 15 (44.1%)	9 (29%) 4 (11.8%)	0 0	1 (3.2%) 0	21 (67.7% 30 (88.2%)	1 (3.2%) 0	0.0692
Week 14	Standard Communication Sonicare Connect	5 (17.2%) 16 (48.5%)	19 (65.5%) 13 (39.4%)	4 (13.8%) 4 (12.1%)	1 (3.4%) 0	0 0	24 (82.8%) 29 (87.9%)	1 (3.4%) 0	0.7221

Table 3

		RESPONSE			
Question ID	**Parameter**	**1**	**2**	**3**	**4**
P1.1	How easy was it for you to fit this visit in today?	0	13 (36.1%)	18 (50.0%)	5 (13.9%)
P1.2	How comfortable are you about coming to see us?	1 (2.8%)	6 (16.7%)	23 (63.9%)	6 (16.7%)
P2.1	How happy are you with your teeth and gums?	6 (16.7%)	23 (63.9%)	7 (19.4%)	0
P2.2	How are you getting on with looking after your teeth and gums?	3 (8.3%)	8 (22.2%)	22 (61.1%)	3 (8.3%)
P3.1	How helpful would you find information and advice on plaque?	1 (2.8%)	0	21 (58.3%)	14 (38.9%)
P3.2	How helpful would you find information and advice on tobacco use?	8 (22.9%)	6 (17.1%)	16 (45.7%)	5 (14.3%)
P3.3	How helpful would you find information and advice on healthy eating and drinking?	0	2 (5.6%)	22 (61.1%)	12 (33.3%)
Response values					
Question ID	**1**	**2**	**3**	**4**	

P1.1	Very difficult	Difficult	Easy	Very easy
P1.2	Very uncomfortable	Uncomfortable	Comfortable	Very uncomfortable
P2.1	Very unhappy	Unhappy	Happy	Very happy
P2.2	Very badly	Badly	Well	Very well
P3.1/P3.2/P3.3	Very unhelpful	Unhelpful	Helpful	Very helpful

Table 4