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Title: Randomised Controlled Trial demonstrating the impact of Behaviour Change intervention provided by dental professionals to improve gingival health

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Short title: Behaviour intervention for gum health

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Key Words: Behaviour change intervention, GPS, gingivitis, bleeding on probing (BOP), oral hygiene, power brush

Conflict of Interest and Funding Statement

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Study registration number: ISRCTN10536130
Abstract

Aims
To determine impact of oral hygiene behaviour change intervention compared to the prevailing standard of oral hygiene advice provided in general dental practice, on bleeding on probing (BOP) in gingivitis patients, over 3-months. The effect of providing power-brushes was also evaluated.

Materials and Methods
NHS dental practices were cluster-randomised to intervention or control (2:1). Dentists at intervention sites received behaviour modification training. Participants were stratified to high (>20% BOP) or low (<20% BOP) presence of gingivitis and a subset assigned a power-brush. BOP and plaque scores were assessed at baseline and 3-months.

Results
A total of 538 participants (369:169; intervention: control) completed the study. BOP reduced in both gingivitis groups with significantly greater reduction in intervention compared to control group (BOP: 38% vs 19%, p=0.0236); Borderline significance favouring the intervention was demonstrated for the low gingivitis group (BOP: 37% vs 15%, p=0.0523). A highly significant reduction in BOP (intervention vs control) was demonstrated for volunteers who swapped from manual to power-brush (44% vs 37%, p=0.0039). Plaque score improved more in control than intervention group (Plaque: 37% vs 44%, p=0.00215).

Conclusions
Behaviour change techniques were readily mastered by the dental professional researchers. The introduction of an oral hygiene behaviour change intervention significantly reduced gingivitis in volunteer patients compared to control at 3 months. Swapping to a power-brush significantly favoured BOP reduction compared to manual brush continuation although plaque reduction did not follow expectation in comparison to BOP scores. Behaviour change techniques should routinely be considered in patient care.

Clinical Significance
Plaque-induced gingivitis is highly prevalent in the UK despite being preventable with good oral hygiene. Its continuum, periodontitis, negative impacts quality of life. This study suggests oral hygiene behavioural interventions (GPS) significantly reduce gingivitis and that GPS introduction will improve oral health and may improve quality of life.
Introduction

A recent study conducted in NHS dental practices by Public Health England (PHE) showed that 52.9% of participants had plaque-induced gingival inflammation even though 84% had attended the dentist at least once in the preceding 12 months [1]. The recommended method for removing dental plaque thereby reducing and/or preventing gingivitis, is twice daily toothbrushing with toothpaste, supplemented by daily use of interdental brushes [2]. However, prevalence figures suggest that ‘home use’ regimens are either not being undertaken regularly and/or are not being carried out effectively. It has been reported previously that most adults do not clean their teeth thoroughly enough to reduce plaque levels to sub-disease thresholds [3]. Whilst gingivitis is reversible with oral hygiene sufficient to disrupt the dental plaque [4], if left untreated it can progress to an irreversible periodontitis characterised by further inflammation, bone loss and eventually tooth loss [5]. As well as impacting mastication, periodontitis has been shown to have psychological impacts such as stress, and results in a negative effect on oral health quality of life[6].

A considerable barrier to care is that plaque related gingivitis is largely painless and therefore not perceived to be significant or worthy of treatment [7]. Patients may be unappreciative that they do not clean their teeth sufficiently well as they are unable to differentiate between oral health and disease. When gingival bleeding is observed it may not be perceived as a problem. Baudet et al [8] reported that 82% of study participants considered gingival bleeding to be ‘benign’. In this study 43% of patients with gingival bleeding had consulted a dentist and been provided with a mouthrinse or toothpaste (55%), or trained in toothbrushing technique (38%), yet for many, gingival bleeding persisted. Similarly, Watt [9] demonstrated that for most people reduction in gingival inflammation condition was not achieved by the prevailing standard of oral hygiene care instruction and demonstration provided by the general dental services, mechanical plaque removal supplemented with oral hygiene products, as this does not result in long-term and improved revised oral hygiene practices or sustained change in plaque reduction.

Whilst changing behaviour is challenging, evidence suggests that interventions based on psychological theories of the behaviour are more successful than non-theory-based interventions, or those that are simply educational in nature [10]. There exists, a large number of behaviour change models with overlapping concepts, precipitating the development of the overarching COM-B model which identifies capacity, opportunity and motivation as factors affecting behaviour [11]. Behaviour change interventions comprise a set of activities aiming to change a specific behaviour by targeting the component(s) in the COM-B model that are deficient [11] and have been successfully used in smoking cessation. Evidence from a recent Cochrane Review confirms increased smoking quit rates
at 6 months or more with the strength of evidence varying for different interventions and their component parts [12].

Few studies have been conducted to test behaviour change interventions designed to improve oral hygiene practices, and hence these techniques are not recommended in policy guideline papers such as Treatment of Stage I-III Periodontitis [13-14] although an early Cochrane review confirmed tentative evidence that psychological approaches to behaviour management improved oral hygiene measures [15]. Similarly, a systematic review [16] confirmed that evidence supported the use of goal setting, planning and self-monitoring (GPS) for improving oral hygiene behaviours in periodontitis patients. A further systematic review [17] was less specific, reporting a beneficial effect of behaviour change interventions. However, in all three reviews the evidence was weak, being hampered by the variety of interventions from different psychological models evaluated in the individual studies reviewed. To address this variation, re-analysis was undertaken by Newton and Asimakopoulou [18] in which the efficacy of the 16 BCT clusters [19] used as study interventions were assessed. Despite the marked heterogeneity, the evidence continued to indicate that interventions incorporating GPS are effective in improving oral hygiene which supports use in clinical practice. However few RCTs were published in the time between the 2 reviews and the evidence remains limited [18].

The present study is designed to add to the evidence base and enhance volunteer adherence to oral hygiene recommendations to improve oral health by reducing the level of gingivitis. It aims to test an oral hygiene behaviour change intervention administrated by a dental professional, which incorporates GPS and engagement of participants to improve their skills/knowledge/self-belief as compared to the standard oral hygiene advice (OHA) provided in the general dental services, for it’s efficacy to improve oral health. The additional influence of a power brush use on study outcomes was also examined. The study was undertaken in NHS dental practices in the UK.

**Methods**

*Study design and overview*

This study was a cluster randomised, parallel study performed in NHS dental practice in the Dental Foundation Scheme across the UK Southwest and Leeds, Yorkshire and Humber Dental Postgraduate Deaneries over 2 consecutive training placement years. Dental Foundation Trainees (DFTs) in the DF practices recruited study participants and undertook study assessments. The study was approved by the South Central - Hampshire B Research Ethics Committee (REC Ref: 17/SC/0602) and the Health Research Authority, IRAS ID. 235629, and conducted in accordance with Good Clinical Practice.
Randomisation was at the site level (dental practice), participants receiving either (1) Oral Hygiene Advice (OHA) using a GPS approach (intervention) or (2) the standard of care provided in the general dental services based on undergraduate training that the individual learnt at dental school (control). The participants received treatment allocated to the site that they attended. The randomisation schedule by site was generated by the study statistician using SAS software (block site 4) randomization.

The randomisation was undertaken in a 2:1 ratio in favour of the intervention group. Participants were also stratified by presence of high (≥20% BOP) or low (<20% BOP) gingivitis groups. A further sub-set of participants were assigned to receive a power toothbrush. Gingival status was evaluated clinically by using a BOP index recording the binary scores 0 representing no bleeding, and 1 bleeding on probing [20] and plaque score 0 representing no plaque, and 1 plaque present [21] before and 3 months after participants received either intervention or control oral hygiene instruction. Participants completed a questionnaire on their oral health practices and smoking status.

**DFT Training**

All DFTs attended study training for 2 days encompassing Good Clinical Practice, performing clinical research, study documentation, and were calibrated for the assessment of oral health. DFTs based in sites randomised to give the intervention behaviour change intervention also received training by way of an interactive workshop session to provide the tools to deliver the intervention. This included setting attainable goals and to ensure that study volunteers understood and committed to them, tailoring advice to ensure that each study participant had the skill, confidence and a strategy to follow their treatment regimen. In addition, DFTs were provided with a checklist which prompted them to help deliver the intervention and engage their patients with their allocated home oral hygiene regimen. DFTs in this group were asked to rate their confidence in providing oral hygiene instruction before and immediately after this training. Those DFTs at sites that were randomised to deliver control group OHA were given the opportunity to receive the interactive workshop training at the end of the study.

**Recruitment of study participants**

Patients due to attend for regular dental care at dental practices participating in the 2 regional DFT schemes were informed about the study and supplied with a participant information sheet when their appointment was confirmed by the practice. Full written informed consent was obtained from participants who agreed to take part prior to enrolment. Patients were screened against the study inclusion/exclusion criteria. Eligible patients were healthy adults with a minimum of 16 teeth not
including implants, teeth with crowns or bridges or extra-coronal restorations. Patients who did not have a smart phone were ineligible to be recruited to the power toothbrush sub-group, but were not excluded from taking part in the study.

**Intervention Phase**

Eligible participants who had provided informed consent completed a questionnaire about their current oral health practices. Participants were assessed clinically for bleeding on probing (BOP) and plaque score following which they were categorised into either high or low presence of gingivitis. A sub-set of participants across both intervention and control sites and in both gingivitis groups received a powered toothbrush to use during the study. Randomisation to the power toothbrush group was based on enrolment at screening according to a randomisation schedule for each site. Participants who did not receive a powered brush were advised to continue using their current method of toothbrushing, whether that be manual or power brush. If a participant was anticipated to receive a powered brush as per the randomisation schedule but proved ineligible, the powered brush allocation was made to the next enrolled participant. The power toothbrush used in the study (Oral-B Smart 6 6000N Powered Toothbrush, Procter & Gamble, UK) was an oscillating rotating power brush with Bluetooth functionality and a smart phone ‘feed-back’ application to record brushing events (frequency and duration). Participants receiving a powered toothbrush were given full instruction in the use of the toothbrush and application according to manufacturer instructions and asked to download information regarding brushing duration, frequency and missed days on a weekly basis.

**Control group:** These participants were given the standard of OHA provided in the general dental services by the DFT, based on undergraduate training that the individual learnt at dental school. In addition the DFTs received additional refresher training, without behaviour change information, at the study training day. Participants were asked to continue according to the standard of oral care regimen suggested and provided by the general dental services using their normal toothpaste and toothbrush unless they had been randomised to the power toothbrush subgroup. In this case, volunteers were asked to use the power toothbrush in line with the manufacturer’s instructions.

**Intervention group:** Participants in this group were taught about their gum disease, cause and potential consequence as well as their goal of achievable gum health. Participants were provided with instruction and a demonstration by the dentist on cleaning their teeth following which they practiced sufficiently to improve skill and confidence. Oral hygiene goals were discussed and together with a plan for the incorporation of additional tasks such as using their own interdental aids and mouthrinses. Volunteers were allowed to continue with their chosen toothpaste or mouthrinse,
however they were also given advice on efficacious toothpastes and mouthrinses they could purchase and incorporate into their daily oral hygiene regimen, in a manner designed not to feel too onerous and therefore more likely to be maintained. To help participants remember what they had been told about plaque removal they were given a leaflet which confirmed the necessary frequency of brushing and interdental cleaning, and other beneficial oral hygiene practices, together with links to short videos showing how to correctly toothbrush/clean interdentally. In addition, participants identified with high levels of gingivitis and at greater risk of developing periodontitis within the intervention group, received a gum health improvement patient agreement that they were asked to commit to and sign [22], confirming that they would follow the oral health practices as outlined by the DFT. This high-level gingivitis group were also asked to complete a short questionnaire on their oral health habits.

Three month follow up
After approximately 3 months, participants attending both site types returned to their dental practice. Participants were asked to complete the questionnaire on their oral health practices again and the clinical assessments of gingival health and plaque were repeated. Participants in the high gingivitis group were also asked to complete the questionnaire on their attitudes to oral health a second time.

Clinical Measurements
Full mouth BOP scores were used for allocation to risk groups according to the method as described [20]. The presence or absence of bleeding was recorded 30 seconds after probing at four sites of each tooth and participants stratified to low (BOP <20% of total sites) or high (BOP >20% of total sites) [23].

Plaque scores were recorded according to O’Leary et al [21]. Following the application of disclosing solution to all teeth in the mouth and rinsing, the presence or absence of plaque was recorded at four sites on each tooth (mesial, distal, buccal and lingual).

Statistical Methods
An initial sample size was based on the primary outcome measure of a change from baseline to 3 months in BOP. Assuming a change from baseline of 4.5% in the control versus a 9.5% change in the intervention group, SD of 6.2, an intra correlation coefficient of 0.50, power of at least 90% and a two sided type I error of 5%, a total of 2400 participants would be required in a 2:1 randomization (1620 in the intervention vs 780 in the control sites). This was based on 27 sites for the intervention and 13 sites (40 dental practices in total) for the control arm and an average cluster size of 60.
However, recruitment became difficult during the course of the study due to the fixed window of opportunity in the DF placement year, and the sample size was revised using the same assumptions for the SD, type I error, expected difference in BOP and number of sites (40 sites, SD=6.2, difference =5 and the intra class correlation coefficient (ICC) =0.50), resulting in a target sample sizes between 720 to 800 (in a 2:1 ratio in favour of the intervention). This sample size would still have at least 80% power to detect differences between groups.

A subgroup target sample size of up to 500 participants pre-defined by the number of power toothbrushes available were allocated to the intervention group and the control group in a 2:1 ratio (regardless of smoking status), and further allocated in a roughly 1:1 ratio to high or low presence of gingivitis group.

Data were summarized (using summary statistics) by intervention group, cluster, strata and where appropriate, assessment points. In addition, summary statistics were reported separately for powered toothbrush subgroup. The smoking status of each patient was recorded in the patient self-reported oral health questionnaire with results for smoking verses non-smoking analysed.

All analyses were based on an ITT (Intent to Treat) analysis, defined as all patients randomized (within site) to trial intervention. Data was 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 analyses was repeated for each strata and includes covariates for stratification and demographic (and baseline) factors. For responses not Normally distributed, non-parametric tests were conducted.

The secondary outcome of change from baseline to 3 months in plaque score was analysed using models suited to a cluster randomized trials allowing for within and between cluster (subjects within cluster) effects. All other outcomes were summarised descriptively. Treatment effects were adjusted for covariates and stratification variables. Separate effects were presented for the pre-specified subgroups (risk and power brush use).

**Results**

This study set out to recruit 2400 participants, approximately 70 participants per DFT between their period of placement 1st Aug – 31st July. We were unable to start the ethics process until this period had commenced, only being able to arrange DF study training in December and site initiation in January the following year. There were 2 study visits, 3 months apart which limited the recruitment window to only ~ 3-months. Four practices were unable to take part in the first year, and took part
in year 2, when approvals were in place. These DFTs had more time and were able to collect more data.

Between January 2018 and December 2019, 733 participants in 40 UK dental sites were recruited to the study, 504 participants in 28 sites to the intervention and 229 participants in 12 sites to the control arm with an average sample size per site of 18. All dental professionals conducting the study were dentists. No adverse events were reported.

The flow of participants through the study is shown in Figure 1. Participant demographics and baseline characteristics are shown in Table 1. Baseline and demographic characteristics with the exception of gender, were balanced with no statistically significant differences. However, some demographic details were missing.

With regard to smoking status, 53 individuals reported smoking and were evenly distributed across the groups with respect to intervention, risk status and brush type.

### Table 1: Participant demographics and baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Intervention group n=504</th>
<th>Control group n=229</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>47.5 (15.53)</td>
<td>44.2 (15.96)</td>
</tr>
<tr>
<td>Missing</td>
<td>110 (22%)</td>
<td>55 (24%)</td>
</tr>
<tr>
<td><strong>Gender (n,%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>206 (41%)</td>
<td>116 (50.5%)</td>
</tr>
<tr>
<td>Female</td>
<td>278 (55%)</td>
<td>112 (49%)</td>
</tr>
<tr>
<td>Missing</td>
<td>20 (4%)</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td><strong>Ethnicity (n,%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>247 (49%)</td>
<td>105 (46%)</td>
</tr>
<tr>
<td>Asian</td>
<td>4 (0.7%)</td>
<td>9 (4%)</td>
</tr>
<tr>
<td>Black</td>
<td>5 (0.9%)</td>
<td>0</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1 (&lt;1%)</td>
<td>0</td>
</tr>
<tr>
<td>Unknown/missing</td>
<td>247 (49%)</td>
<td>115 (50%)</td>
</tr>
<tr>
<td><strong>Presence of Gingivitis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>250 (49%)</td>
<td>122 (53%)</td>
</tr>
<tr>
<td>High</td>
<td>252 (50%)</td>
<td>107 (47%)</td>
</tr>
<tr>
<td>Missing</td>
<td>2 (1%)</td>
<td>0</td>
</tr>
<tr>
<td><strong>Power Oscillating-Rotating Brush</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>102 (20%)</td>
<td>50 (22%)</td>
</tr>
<tr>
<td>Low Risk</td>
<td>53</td>
<td>27</td>
</tr>
<tr>
<td>High Risk</td>
<td>49</td>
<td>23</td>
</tr>
<tr>
<td>No</td>
<td>397 (79%)</td>
<td>178 (77%)</td>
</tr>
<tr>
<td>Missing / Unknown</td>
<td>5 (1%)</td>
<td>1 (1%)</td>
</tr>
</tbody>
</table>
All participants (100%) completed baseline assessments for the primary outcome and close to 100% completed baseline assessments for secondary outcomes. By 3 months, for the primary outcome there were complete data for 73% and 74% of participants in the intervention and control groups, respectively.

**Primary endpoint analyses: BOP**

BOP scores before and after adjustment for covariates are shown in Table 2. BOP scores in intervention and control groups improved after adjusting for baseline, age, gender, high or low gingivitis groups and whether participants were given a power brush. The improvement in BOP score from baseline was significantly greater in the intervention group than control 38% vs 19% (p=0.0236). Larger reductions in BOP were also observed for the low-risk subgroup as compared to control 37% vs 15% (p=0.0523) although statistical significance was borderline and likely related to a loss in power due to missing data at 3 months (ICC=0.69).

**Table 2: Differences between groups in BOP score (% change from baseline)**

<table>
<thead>
<tr>
<th></th>
<th>Intervention Mean (SE)</th>
<th>Control Mean (SE)</th>
<th>Difference (SE)</th>
<th>95% CI (P-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All [N=538]</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BOP (unadjusted for covariates)</td>
<td>-37.1 (5.35)</td>
<td>16.2 (4.41)</td>
<td>-20.9 (6.93)</td>
<td>-34.9, -6.8 (p=0.0046)</td>
</tr>
<tr>
<td>BOP (adjusted for covariates)</td>
<td>-37.8 (10.60)</td>
<td>-18.6 (10.41)</td>
<td>-19.20 (8.02)</td>
<td>-35.6, -2.8 (p=0.0236)</td>
</tr>
<tr>
<td><strong>High Gingivitis [N=259]</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BOP (unadjusted for covariates)</td>
<td>-33.7 (5.58)</td>
<td>-25.6 (4.13)</td>
<td>-8.2 (6.94)</td>
<td>-22.4, 5.9 (p=0.247)</td>
</tr>
<tr>
<td>BOP (adjusted for covariates)</td>
<td>-30.7 (5.95)</td>
<td>-27.9 (5.24)</td>
<td>-2.8 (8.01)</td>
<td>-19.4, 13.8 (p=0.733)</td>
</tr>
<tr>
<td><strong>Low Gingivitis [N=279]</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BOP (unadjusted for covariates)</td>
<td>-36.4 (6.80)</td>
<td>-11.8 (6.30)</td>
<td>-24.6 (9.22)</td>
<td>-43.4, -5.7 (p=0.012)</td>
</tr>
<tr>
<td>BOP (adjusted for covariates)</td>
<td>-36.6 (8.04)</td>
<td>-15.2 (6.69)</td>
<td>-21.4 (10.52)</td>
<td>-43.01, 0.23 (p=0.0523)</td>
</tr>
</tbody>
</table>

1 Least squares means;
2 Least Squares mean difference based on mixed effects model for Intervention vs Control
3 covariates: age, gender, risk (high, low);
4 covariates: age, gender;
SE: Standard error of the mean; CI: 95% confidence interval for the mean

**Subgroup Analyses for BOP**

Subgroup analysis of power and manual toothbrush use is shown in Table 3. Reductions in BOP were significantly greater in the intervention compared to the control group 47% vs 14% and 34% vs 17%,
respectively (both p<0.05), irrespective of whether participants used a power or manual toothbrush. Significantly larger reductions in BOP in intervention compared to the control group were also observed for the low-risk subgroup with both tooth brushes (manual p<0.05, power p< 0.001) and for the high risk subgroup using the manual toothbrush (p<0.05).

Table 3. Differences between groups in power brush subgroup BOP scores (% change from baseline)

<table>
<thead>
<tr>
<th>Subgroup (overall)</th>
<th>Intervention Mean (SE)</th>
<th>Control Mean (SE)</th>
<th>Difference (SE)</th>
<th>95% CI (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Brush (n=152)</td>
<td>-46.8 (6.15)</td>
<td>-13.8 (10.70)</td>
<td>-33.1 (12.34)</td>
<td>-58.3, -7.9     (p=0.0119)</td>
</tr>
<tr>
<td>No Power Brush (n=575)</td>
<td>-34.1 (5.79)</td>
<td>-16.9 (4.79)</td>
<td>-17.1 (7.51)</td>
<td>-32.3, -1.9    (p=0.0286)</td>
</tr>
<tr>
<td>Power Brush</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Risk (n=76)</td>
<td>-40.1 (8.82)</td>
<td>8.3 (18.20)</td>
<td>-49.0 (20.22)</td>
<td>-90.96, -7.1   (p=0.0241)</td>
</tr>
<tr>
<td>High Risk (n=76)</td>
<td>-48.9 (7.44)</td>
<td>-38.8 (5.06)</td>
<td>-10.1 (9.01)</td>
<td>-28.8, 8.6     (p=0.0823)</td>
</tr>
<tr>
<td>No Power Brush</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Risk (n=281)</td>
<td>-26.9 (9.17)</td>
<td>-6.8 (7.64)</td>
<td>-20.1 (12.01)</td>
<td>-44.5, 4.4     (p&lt;0.001)</td>
</tr>
<tr>
<td>High Risk (n=293)</td>
<td>-41.1 (3.68)</td>
<td>-29.5 (4.33)</td>
<td>-11.6 (5.67)</td>
<td>-23.2, -0.05   (p=0.049)</td>
</tr>
</tbody>
</table>

†Least squares means; ‡Least Squares mean difference based on mixed effects model for Intervention vs Control
SE: Standard error of the mean; CI: 95% confidence interval for the mean

Subgroup analysis of power toothbrush users further sub-divided to existing and new users is shown in Table 4. A highly statistically significant reduction in BOP (intervention vs control) was demonstrated for volunteers who swapped from manual to power brush (44% vs 37%, p=0.0039). Amongst those participants that were already using a power brush and then remained on power brush over the follow up period, a larger reduction in the BOP was observed (Table 4) in the intervention than control group which almost reached statistical significance at the 5% level (p=0.0535).

Table 4. Differences between in power brush subgroup BOP scores (% change from baseline) considering existing/remaining and new power brush users separately

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Intervention</th>
<th>Control</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Brush at baseline and</td>
<td>Median</td>
<td>-46.6%</td>
<td>-32.3%</td>
</tr>
<tr>
<td>remained on Power Brush</td>
<td>Min-Max</td>
<td>-100.0% - 100%</td>
<td>-89.7% - 207.7%</td>
</tr>
<tr>
<td>Manual Brushing at Baseline and</td>
<td>Median</td>
<td>-43.6%</td>
<td>-37.2%</td>
</tr>
<tr>
<td>Switched to Power Brush</td>
<td>Min-Max</td>
<td>-100.0% - 280.0%</td>
<td>-100.0% - 181.5%</td>
</tr>
</tbody>
</table>

†p-value based Wilcoxon Rank Sum test
Secondary endpoint analyses

Summary statistics and secondary end point analysis are shown in Table 5. The median plaque score improvement from baseline was significantly lower (37 vs 44%) in the intervention as compared to the control group (Table 5). There were no statistically significant differences in the change from baseline between the intervention and control groups for any of the other secondary outcomes. However, the frequency of use of additional cleaning aids was higher in those in the intervention group after 3 months although this did not reach significance. Furthermore, it was observed that after 3 months in the intervention group 27% of participants used interdental brushes 5 times a week or more compared to only 18% in the control group. Brushing data downloaded from the app for the power brush use were poorly reported and cannot be meaningfully reported.

Table 5: Summary statistics and Analyses of the differences between groups for Secondary Endpoints

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention</th>
<th>Control</th>
<th>p-value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaque Score (% improvement from baseline)</td>
<td>n</td>
<td>369</td>
<td>169</td>
</tr>
<tr>
<td>Median (min-max)</td>
<td>37.2</td>
<td>44.4</td>
<td>0.00215</td>
</tr>
<tr>
<td></td>
<td>(-85.7 – 138.7)</td>
<td>(-100.0 – 267.7)</td>
<td></td>
</tr>
<tr>
<td>Change in Frequency of toothbrushing (am) (#days)</td>
<td>n</td>
<td>343</td>
<td>165</td>
</tr>
<tr>
<td>Median (min-max)</td>
<td>0 (-6 – 6)</td>
<td>0 (-7 – 6)</td>
<td>0.6239</td>
</tr>
<tr>
<td>Change in Frequency of toothbrushing (pm) (#days)</td>
<td>n</td>
<td>343</td>
<td>165</td>
</tr>
<tr>
<td>Median (min-max)</td>
<td>0 (-7 – 7)</td>
<td>0 (-6 – 7)</td>
<td>0.2237</td>
</tr>
<tr>
<td>Change in Frequency of Mouth wash (#days)</td>
<td>n</td>
<td>303</td>
<td>148</td>
</tr>
<tr>
<td>Median (min-max)</td>
<td>0 (-7 – 7)</td>
<td>0 (-7 – 7)</td>
<td>0.2163</td>
</tr>
<tr>
<td>Change in Frequency additional cleaning aids (#days)</td>
<td>n</td>
<td>308</td>
<td>149</td>
</tr>
<tr>
<td>Median (min-max)</td>
<td>0 (-7 – 7)</td>
<td>0 (-7 – 7)</td>
<td>0.0831</td>
</tr>
</tbody>
</table>

†Wilcoxon Rank Sum test adjusted for covariates (sex, age, risk, power brush)

Periodontal health in the context of the 2017 classification

Participant gingival health was further classified using the new 2017 classification of periodontal disease [24] (Table 6). More participants improved their periodontal status from general gingivitis ($\geq$30%) to localised gingivitis ($\geq$10% - < 30), or from localised gingivitis to health (<10%) in the intervention than in the control group. In the intervention group after 3 months, 24% of individuals who had localised gingivitis improved to health and 4% and 19% of individuals improved from generalised gingivitis to health and localised gingivitis, respectively. In comparison in the control group fewer individuals improved their oral status; after 3 months, 15% of individuals who had localised gingivitis improved to health and <1% and 15% of individuals improved from generalised gingivitis to health and generalised to localised gingivitis respectively.
Table 6. BOP – shift from baseline to month 3 both study groups when assessed using the revised classification of periodontal disease [24]

<table>
<thead>
<tr>
<th></th>
<th>After 3 months</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Healthy† (≤10%)</td>
<td>Localized G. (LG) (10% - &lt; 30%)</td>
</tr>
<tr>
<td>Baseline</td>
<td>Intervention</td>
<td></td>
</tr>
<tr>
<td>Healthy &lt;10%</td>
<td>Healthy &lt;10%</td>
<td>67 (18%)</td>
</tr>
<tr>
<td>Localized G. (10% - &lt; 30%) (LG)</td>
<td>87 (24%)</td>
<td>70 (19%)</td>
</tr>
<tr>
<td>Generalized G (≥30%) (GG)</td>
<td>15 (4%)</td>
<td>70 (19%)</td>
</tr>
<tr>
<td>Total (%)</td>
<td>Intervention</td>
<td>46</td>
</tr>
<tr>
<td>Baseline</td>
<td>Control</td>
<td></td>
</tr>
<tr>
<td>Healthy &lt;10%</td>
<td>Healthy &lt;10%</td>
<td>44 (26%)</td>
</tr>
<tr>
<td>Localized G. (10% - &lt; 30%) (LG)</td>
<td>25 (15%)</td>
<td>42 (25%)</td>
</tr>
<tr>
<td>Generalized G (≥30%) (GG)</td>
<td>1 (&lt;1%)</td>
<td>25 (15%)</td>
</tr>
<tr>
<td>Total (%)</td>
<td>Control</td>
<td>42</td>
</tr>
</tbody>
</table>

†Healthy: <10% BOP for full mouth when undertaking examination ‡LG: Localised gingivitis >10 <30% BOP for full mouth examination §GG:-Generalised gingivitis >30% BOP for full mouth examination

DFT confidence in the delivery of OHA pre and post training in behavioural change techniques.

DFT confidence is shown in Figure 2. Prior to training the majority of DFTs agreed or strongly agreed that their degree had prepared them for giving OHA, and they were confident in giving it. However, less than a third agreed or strongly agreed that they were confident they could give OHA in the time available for their patients. Post training, the vast majority agreed or strongly agreed that they were more confident in giving OHA, were better equipped to give OHA in the time available and would change the way they delivered OHA. However, less than half felt there had been a gap in their knowledge prior to this training.

Discussion

This study demonstrated improvements in gingivitis over a 3-month period in both the intervention and control groups following instruction from an oral healthcare professional. Importantly, bleeding on probing (BOP) reduced significantly more in the group that received the behaviour change modification incorporating GPS with engagement to improve their oral health knowledge and skills, than in the group who received the prevailing standard of oral care provided in the general dental services. This study demonstrated that significant progress in improving patient oral health may be achieved by the dental professional in general dental practice particularly when incorporating GPS with engagement. Furthermore, when the results are summarised in the context of the UK implementation of the new 2017 classification of periodontal diseases [24], more participants in the intervention group improved their gingival status from generalised gingivitis to localised gingivitis, (BOP <30% and >10% of the sites probed in the mouth), and generalised gingivitis to health (<10% of
sites with BOP). Similarly, more individuals at baseline improved from localised gingivitis to health than in the intervention group.

The findings confirm previous studies which show that patients with periodontal diseases, managed in the general dental services who received goals and planning as part of their OHA, showed significantly reduced plaque scores, BOP and pocket depths after 4 months [25] and a significant reduction in BOP, plaque and gingival indices after one year [26]. However, the intervention in both these studies also included feedback and monitoring facilitated by its delivery on multiple occasions. In contrast, the intervention was delivered once in the present study. The intervention sub-groups allocated a power brush also had provision of an App with full video instruction for use. A highly significant reduction in BOP (intervention vs control) was demonstrated for volunteers who swapped from a manual to a power brush, reiterating the value of the behaviour modification. However, the downloaded data received from the App in this study was disappointingly low and could not be analysed meaningfully.

An intervention which included GPS delivered in a single session was also used successfully by Asimakopoulou et al [27], with significantly greater improvements in plaque scores compared to control. However, the GPS was used in combination with an individualised periodontal risk consultation (IPRC), and the IPRC was also administered as an intervention alone with the same outcome. In the present study, all participants in the intervention group also received tailored oral health instruction and were advised of potential consequences of periodontal disease if gingivitis was not reversed [2,28]. Variation of intervention delivered in randomised controlled trials makes statistical comparison difficult, but systematic reviews indicate that interventions based around GPS maybe successful in improving oral hygiene [15,16,18] and the findings of the current study support this.

The intervention in the current study significantly improved the gingivitis scores of all participants including the group with low initial presence of gingivitis (borderline significance). However, there was no significant improvement in the high gingivitis baseline sub-group. This could reflect the fact that some individuals are highly susceptible to periodontal diseases [29] and improving oral hygiene outcomes in this group is challenging [30-32]. A recent systematic review demonstrated that patients who had been treated for their periodontitis complied poorly with subsequent supportive maintenance therapy, but indicated that the psychological reasons behind this are mostly unknown [33].

Smokers were included in this study as it was undertaken in general dental practice to reflect the habits and culture of the UK population. Strong evidence supports systemic and local uptake of components of cigarette smoke which induce microvascular vasoconstriction and fibrosis in the
gingivae, thus masking the clinical signs of BOP [23], despite a significant pathological inflammatory cell infiltrate [34]. The reduced BOP scores in smokers was emphasised at pre study training as part of the management of periodontal diseases together with advice on the substantial systemic and oral health benefits expected from successful smoking cessation. The statistical plan although not stratified or randomised for this variable, planned to analyse results for smokers vs non-smokers in the different groups. However, the numbers of smokers recruited was so low and well balanced between groups, so the effect was deemed negligible in this data set.

There is a strong positive correlation between plaque accumulation and severity of gingivitis, with intensive plaque control able to reverse gingival inflammation to achieve to gingival health [35]. In this study however, although BOP reduction was significantly greater in the intervention group, plaque reduction over 3 months was greater in the control group. Whilst plaque scores recorded at a specific visit may not accurately reflect plaque control over 3 months, this cumulative result was unexpected. Indeed, it would be expected that individuals would have better plaque scores when enrolled in a study and attending a dental professional due to the Hawthorne effect [36] and the triggers for behaviour change. BOP is more objective and reliable for assessing long term adherence to oral hygiene regimes than the plaque scores and it is also suggested that the plaque index whilst dichotomous, was more intricate to score than the bleeding score. This may be reflected in this large group of inexperienced researchers and more training and calibration of plaque data collection may be warranted for future studies of similar design.

No significant differences between intervention and control group were observed for any self-reported oral health care regimens, although increased frequency of interdental brushing in the intervention group compared to control almost reached significance. Significant improvement in frequency of interdental cleaning in groups receiving a behaviour change technique(s) compared to control OHA have been demonstrated in other studies [25,26,37] with daily interdental cleaning being recommended to prevent or reduce gingivitis [2] The increase in frequency of the intervention compared to control group, suggests that this activity was a key factor.

BOP was significantly reduced in the intervention compared to the control group irrespective of whether participants used a power or manual toothbrush, suggesting the behaviour modification change effect is effective. In the experimental group, there was a greater improvement in BOP after 3 months in the low gingivitis power-brush category compared to the non-power-brush group. The data suggests that this is true of the high gingivitis category too, although the sample size was low and greater power would be required to demonstrate significance. The power brush sub-group was included to investigate the value of the power brush compared to the effect of behaviour
modification. In the power brush sub-group BOP improvement in the intervention group compared to control was highly significant for those who switched from a manual to a power brush. For volunteers already using a power brush before study enrolment, the difference reached borderline significance only. This suggest that swapping to a power brush in combination with an effective behavioural intervention can greatly improve oral health outcomes. Studies by Pitcijika et al [38] and Grender et al [39], and a systematic review by Van der Weijden et al [40] support power brushes improving gingival health over a 3 month period compared to manual brushes.

Differences in power brush design complicate comparison of efficacy, however a recent systematic review reported with moderate certainty that a power brush was more effective that a manual toothbrush when a single brushing was assessed [41]. This is supported by a second systematic review and observational study evaluating longer term evidence [38,42]. In addition, an earlier review using a Delphi consensus approach indicated that powered brushes are more effective for plaque removal than manual in the short or long term [43]. Unfortunately, in this study compliance with upload of power-brush App data on brushing time and frequency was not optimal with further analyses of brushing not possible Collectively, these findings suggest that a power brush should be recommended to patients as part of any behavioural change intervention to improve oral health.

Recruitment rates were lower than anticipated, due to the difficulty of recruiting participants for 2 visits over a 3 month period within the fixed window in the DF placement year which also resulted in missing data at 3 months. A multiple imputation analyses was undertaken for sensitivity with results showing the observation statistical and clinical differences to be robust, and the baseline characteristics of patients with missing data between groups similar. Furthermore, recruitment was sufficient to achieve significance with respect to the primary study objective, thus the study has provided robust conclusions and remains the largest RCT to evaluate behaviour change intervention for improving oral hygiene levels to improve gingival health to date. Stratification of participants into high and low presence of gingivitis categories allowed differences between the responses of these subgroups to the intervention to be monitored. The inclusion of a power brush subgroup facilitated analysis of use of power brushes in association with behaviour change interventions.

This was the first occasion that a multicentred RCT has been conducted in Foundation Practice in a primary dental care setting. The study demonstrates that with minimal training oral healthcare professionals can deliver OHA using behaviour change techniques with positive outcome. The cluster design ensured that there was no contamination of the control group and the results yielded a mean percent BOP improvement 4 times greater than the 5% powered for, and are considered clinically significant. Primary care is an ideal setting for an oral hygiene behaviour intervention study,
presenting realistic challenges that the oral health care team encounter daily. The role of homecare by patients is of paramount importance to prevent gingivitis and periodontitis, the EIU economic analysis indicating [44] that eliminating gingivitis using home care prevention techniques delivered by dental professionals, such as toothbrushing, and increasing patient diagnosis rate, can have a positive return on investment. Neglecting to manage gingivitis can significantly increase costs and reduce health life years and therefore the emphasis on self-care and prevention is critical from both an individual and a societal perspective.

Conclusions

The current high periodontal disease prevalence rates indicate that the standard of OHA in the general dental services is not sufficiently effective [1,29,45]. This study unequivocally demonstrates that a behaviour change intervention based on GPS with engagement of participants to improve education/skill and self-belief can be delivered in primary care and is more effective both, statistically and clinically, than the prevailing standard of OHA in the general dental services in bringing about improvements in oral health. Being a largely preventive measure, it may be implemented without undue cost, which is of major importance since the cost of treating periodontal disease is high [46]. The inclusion of GPS in individual patient oral hygiene plans is recommended [47] and this study contributes strongly to the evidence base.
Figure 1: Participant flow through the study
Figure 2. DFT confidence in giving OHA pre and post study training. A; pre training responses to, Q1-I feel my undergraduate training prepared me to deliver OHA in general dental practice, Q2-I am confident in giving OHA in general practice, Q3-I am confident giving OHA in the time slots I am allocated in general practice. B; post training responses Q1-I now feel more confident in OHA, Q2- Before today I felt there was a gap in my OHA knowledge, Q3-I will now be delivering my OHA differently, Q4-I now feel more confident to give OHA in the time slots I am allocated in general practice, Q5-This training has changed my knowledge and behaviour with respect to giving OHA to my patients.
References


