Journal of Dentistry 156 (2025) 105643

Contents lists available at ScienceDirect

Journal of Dentistry

journal homepage: www.elsevier.com/locate/jdent

A randomised controlled trial to evaluate the efficacy of a multi-step oral hygiene product intervention to improve oral health in partial denture wearers
Assessing Oral Health Improvement: Complex Intervention for Partial Denture Wearers

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ARTICLE INFO

Key Words:
Gingivitis
Intra-oral scanner
Mgi
Inflammation
Behaviour change

ABSTRACT

Objectives: This study was designed to evaluate the effectiveness of a multi-step oral hygiene intervention among removal partial denture (RPD) wearers.
Methods: A 12-week, single-blind, randomised, 2-armed, parallel-group, controlled trial was conducted with 49 RPD-wearing participants with mild-moderate gingivitis. The intervention group received stannous fluoride toothpaste, sodium fluoride mouth rinse, and an antibacterial denture cleanser foam. They were given detailed instructions on product usage. The control group continued with their usual oral hygiene regimen. Gingival health, denture cleanliness, and oral hygiene indices were assessed at baseline, 6, and 12 weeks.
Results: 48 participants completed the study, (one withdrawal due to concomitant medication). The intervention group reported 12.5 % adverse events, with no events reported in the no-intervention group. Compliance rates were high for toothbrushing (99.4 %), mouth rinse use (99.4 %), and denture cleaning (99.3 %). Significant improvements were observed for the intervention group in bleeding index, modified gingival index, and Turesky Plaque Index at both weeks 6 and 12 ($p < 0.0001$). Denture cleanliness also significantly improved, with lower Partial Denture Cleanliness Index scores at weeks 6 ($p = 0.0039$) and 12 ($p < 0.0001$). Overall, the intervention group showed consistently superior outcomes compared to the control, with significant differences in all plaque and gingivitis measures ($p < 0.0001$).
Conclusion: This study highlighted the efficacy of a multi-step oral hygiene intervention in improving oral health outcomes among RPD-wearers with mild-moderate gingivitis. Findings from this study may inform evidence-based recommendations for optimal oral healthcare in this population, benefiting both patients and oral healthcare professionals.
Clinical Significance Statement: This study demonstrated that a multi-step intervention, including three specific oral hygiene products and education, can significantly improve oral health outcomes for removable partial denture wearers with mild-moderate gingivitis. These findings offer practical insights for enhancing oral hygiene practices and gingival health in this patient population.

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https://doi.org/10.1016/j.jdent.2025.105643
Received 19 December 2024; Received in revised form 17 February 2025; Accepted 18 February 2025
Available online 4 March 2025
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1. Introduction

Oral non-communicable diseases, including tooth loss, are major global public health problems although are not widely recognised as such [1]. The current rates of partial edentulism have been estimated to be between 37 % and 63 % of the adult population internationally [2–5], affecting quality of life, nutrition, social interactions, and general systemic health [6].

Removable partial dentures (RPD)s are considered a non-invasive and cost-effective treatment option indicated for the replacement of missing teeth in partially edentulous individuals, giving predictable long-term success, appropriate aesthetics, increased masticatory efficiency, and improved phonetics when teeth are absent [7,8]. RPDs are also an alternative treatment option where fixed prostheses or dental implants may not be appropriate due to anatomic, systemic, or economic reasons [9]. However, RPDs can present a risk for an individual's remaining teeth, predominantly the abutment teeth, depending on the prosthesis design, health of the supporting periodontal tissues and the individual's oral hygiene level and susceptibility [10].

RPDs accumulate a biofilm, plaque, stain and calculus in a similar manner to the natural dentition [11]. Dental biofilm that accumulates on teeth and denture biofilm that forms on removable prostheses have microbiological differences, leading to distinct clinical implications. Dental biofilm is primarily implicated in gingivitis and subsequent periodontitis [12–15]. Whilst gingivitis is reversible, if left untreated in susceptible individuals, it can progress to the irreversible phase of periodontitis [16], often eventually leading to tooth loss through destruction of the periodontal supporting tissues [2]. Gingivitis can be prevented and resolved through effective plaque control, primarily via mechanical plaque removal [15–17] that can be augmented by chemotherapeutic agents in daily use oral hygiene products [18,19]. Studies have shown clear evidence that RPDs increase dental biofilm and gingivitis in wearers [10,20], likely due to the increased number of plaque retention sites particularly on (or adjacent to) the abutment teeth. Further, denture biofilm, which readily accumulates on the rough surfaces of RPDs, is associated with denture stomatitis and erythema in the denture-bearing area [21]. These differences highlight the need for tailored oral hygiene practices for the natural dentition and removable prostheses to prevent these respective complications.

About 64 % of RPD wearers showed signs of poor oral hygiene in a 10-year follow-up study [22]. Existing literature has demonstrated a lack of knowledge regarding adequate denture hygiene among patients, with several studies identifying inadequate cleaning practices and a decline in adherence to hygiene instructions over time [23–26]. According to Milward et al. [26], 91.8 % of RPD wearers stated they were given education on denture hygiene when provided with their current RPDs; however, 60.2 % were shown to have less than an appropriate level of denture cleanliness. Interventions to improve denture hygiene have ranged from patient education to the use of specialised cleaning products, yet the persistence of poor oral hygiene practices underscores the need to more effective, multi-faceted approaches [6,27–29].

In the light of the need for good oral hygiene practice amongst RPD wearers, this study investigated the effect of a multi-step, oral hygiene intervention. It involved use of products specifically designed to maintain oral health and denture cleanliness, combined with detailed instructions regarding their use, on gingival health measures and denture hygiene in a population of RPD wearers with mild-moderate gingivitis. An intervention group received a stannous fluoride-containing toothpaste, a sodium fluoride-containing mouthrinse, and an antibacterial denture cleanser foam, which were used twice-daily for 12 weeks. They also received detailed instructions to support the use of the product combination. A matched no-intervention group was instructed to continue with their current oral hygiene practice. Both groups were also provided with general oral hygiene advice given in a general dental practice setting. Gingivitis, plaque and other oral health indices (Bleeding Index (BI) [30], Modified Gingival Index (MGI) [31], Calculus (CI) [32], Turesky Plaque Index (TPI) [33], and Oral Debris Index (CI + ODI) [34]) were assessed at baseline, 6 and 12 weeks. Denture cleanliness was assessed by the partial denture cleanliness index (PDCI) which was based on the index of Blair (Blair 1995) at the same time-points. The null hypothesis was that there would be no difference between the two treatment groups in these measures; the primary objective was to determine the change from baseline to 12 weeks for bleeding index between the two treatment groups.

2. Materials and methods

2.1. Study design and conduct

This was a 12-week, single-centre, single-blind (to the examiner performing the dental assessments), randomised, stratified, two-treatment arm, parallel group study in healthy adult volunteers with at least one conventional removable partial denture and generalised, mild-moderate plaque-induced gingivitis (as assessed by MGI) [31]. The study was conducted at a UK dental school in accordance with Good Clinical Practice (GCP) and the Declaration of Helsinki. Ethical approval was given by South Central - Hampshire B REC, 20/SC/0077. The study is registered at clinicaltrials.org; NCT04290624.

Potential participants were recruited from a Dental Clinical Trials Unit database of individuals who had expressed an interest in taking part in clinical trials, from local advertisement and from the regional general dental practitioner (GDP) network. Potential participants were provided with an information sheet and invited to a screening appointment. As the study took place during a period of Covid-19-related restrictions, to ensure the participants' and research team's safety, personal protective equipment and other risk reduction factors and cross infection control measures were instigated in line with NHS England guidance [28].

At the Screening visit (Visit 1), participants provided their written informed consent to participate in the study. Demographics, medical history, dental history and current medications were recorded, and a screening assessment undertaken which included full oral soft tissue (OST) and oral hard tissue (OHT) examinations, the fit of the denture and participant eligibility according to inclusion and exclusion criteria. At screening, the eligible study population inclusion criteria comprised healthy adults who were RPD wearers, aged 18 to 75 with mild to moderate, plaque-induced gingivitis. Participants were required to have at least 4 natural teeth in each arch, with at least 2 scorable abutment teeth and 30 scorable surfaces. Exclusion criteria included pregnancy; breastfeeding; current or recurrent disease or dental pathology that could affect study outcomes; current susceptibility to acid regurgitation; orthodontic appliances, restoration or bridgework that could have interfered with study assessments; recurrent or regular aphthous ulcers; severe gingivitis, (MGI score of 4) [31], cavitated active carious lesions or unstable periodontitis; signs of severe tooth wear; any xerostomia causing condition or medication; frequent use of commercially available denture cleansers, use of denture adhesives in the 28 day period prior to baseline; and requirement of antibiotic prophylaxis for dental procedures. All clinical measurements (baseline and recall) were undertaken by a single examiner to ensure consistency. At Visits 2, 3, and 4, repeatability data were generated for MGI and TPI assessments from replicate examinations on the same subject. 1 repeatability examination for each clinical measure during each clinical session was conducted: at least 1 in the morning and at least 1 in the afternoon on each assessment day. The repeat assessments were conducted with a delay of at least 10 min between the original and repeat measurements, with participants remaining in the same clinical conditions. At the end of the screening visit, participants were instructed to continue to brush using their usual toothpaste and to follow their usual dental/denture cleaning routine until the baseline visit.

Between 1 and 28 days of screening, eligible participants returned to the site for the baseline visit. Participants were asked to abstain from any oral/denture hygiene products for a minimum of 12 h to a maximum of

18 h, and from chewing gum/consuming confectionery containing xylitol, dental prophylaxis or use of any over-the-counter anti-inflammatory products for a minimum of 12 h before each study visit. The 28-day period following screening was chosen to allow stabilisation of oral conditions and to minimise residual effects of prior interventions or medications on baseline measurements in order to ensure that all participants started the study with a consistent and comparable baseline. Participants were asked to abstain from oral/denture hygiene products for 12–18 h prior to each study visit to standardise assessments of plaque accumulation and denture cleanliness. This was implemented to reduce variability in outcomes and improve the reliability of the measurements. In addition, participants were asked to abstain from eating for at least 4 h, and drinking for at least 1 hour prior to each study visit. Participants recorded their medications, and removed their denture for photographs and Partial Denture Cleanliness Index (PDCI) assessment (Table 2). The study dentist undertook a full OST examination and assessments of gingival inflammation (MGI followed by BI) and calculus (CI). Dental plaque was disclosed and TPI and ODI assessments were undertaken. The Oral Hygiene Index (OHI) for each participant was calculated as the sum score of the mean CI and the mean ODI [34]. To determine eligibility for the study, participants needed to present with a mean whole mouth BI ≥ 0.1 to ≤ 1.3, a mean whole mouth MGI ≥ 1.75 to ≤ 2.30 and a mean overall TPI score ≥ 1.5. Participants with mean overall BI, MGI, or TPI scores outside this range were discontinued from the study at this visit. These criteria were to ensure the study population were consistent with the intended condition of having mild-to-moderate plaque-induced gingivitis.

During the Baseline visit, participants completed the first stage of a questionnaire, Table 1 (Q1 to Q11). This questionnaire was based on standard industry practice for consumer product-experience questionnaires, but was developed specifically for this study (and as such was an unvalidated design). It aimed to fulfil an exploratory study objective to understand study participants' confidence regarding their current oral health, motivation and understanding of risks associated with poor oral hygiene, and was revisited at weeks 6 and 12 to identify differences in these measures as a result of study participation.

Evaluable teeth were regarded as those teeth with scorable surfaces for MGI, BI, CI, TPI and ODI, Table 2. To assess clinical examiner reproducibility, a set of participants were selected at random for repeat MGI and TPI assessments (1 participants in 6 examined). These were performed by the examiner at the Baseline, 6- and 12-week visits with a delay of at least 10 min between original and repeat assessments.

A dental prophylaxis was performed for eligible participants by the second study dentist and participants' teeth were disclosed by using a disclosing solution to check for residual plaque to bring the participant to a confirmed score of zero visible plaque (TPI = 0). Participants' dentures were cleaned using the supplied denture cleaning paste and brush to ensure a PDCI score of 0. All clinicians were blinded to treatment throughout the study. Following dental prophylaxis and denture cleansing, participants were stratified based on their denture type (acrylic or cobalt chrome) and baseline mean overall MGI score (low: ≤ 2.0; high >2.0) and then randomised into 1 of the 2 treatment groups. Dispensing was conducted by unblinded study staff in a separate room away from other participants and blinded clinicians.

Participants randomised to the intervention group were asked to use the range of dental/denture products that comprised the intervention (toothpaste, mouthrinse and denture cleanser) and given detailed instructions on their use. They were provided with their assigned study products, a diary, a timer and written instructions on product usage. Participants were asked to brush their natural teeth for 2 timed minutes under supervision with the toothpaste provided and to clean their denture with the supplied denture foam cleanser in accordance with the product usage instructions (Table 3). The participants rinsed their mouths with the mouthrinse for 1 timed minute before re-fitting their denture in their mouth. They continued to use their supplied products twice per day and recorded each use in their study diary. Participants randomised to the no-intervention group continued with their usual dental/denture cleansing regime and recorded each use in their study diary. All randomised participants also recorded any new medications taken or changes to their existing medication in their study diary.

All participants returned to the study site 6 and 12 weeks after randomisation having not performed any oral hygiene since the evening before to allow 12–18 h of no oral hygiene prior to assessment. Eligible subjects were stratified based on denture material type (acrylic or cobalt chrome) and baseline mean overall MGI score (low: ≤ 2.0; high >2.0) to ensure a balance in treatments across the strata, and then randomised into 1 of 2 treatment groups. Allocation concealment was maintained by having the member of the study staff perform randomisation and dispensing in a separate room, away from other participants and blinded clinicians. Throughout the study, staff involved in the dispensing of study products worked in a separate area. The examiner was not permitted in any area where the study product was stored, dispensed, or in use. This ensured that clinical assessors and participants were unaware of the treatment allocation. At each visit study products were collected from participants randomised to the interventional product range and were reviewed for treatment compliance. The diaries of all participants were reviewed to ensure the intervention group had used their assigned products and the no-intervention group had continued with their usual oral hygiene regimen. All participants then completed the short questionnaire (Table 1, Q12 to 18) about their confidence in their oral health as compared to baseline, and ongoing motivation to complete a multi-step oral hygiene intervention. They then removed their denture for assessment using the PDCI. A full OST examination was

Table 1
Oral health questionnaire.

Baseline How confident or not do you feel about		scores
Q1	the cleanliness of your mouth and teeth?	1 to 4*
Q2	the cleanliness of your partial denture?	1 to 4*
Q3	the freshness of your breath?	1 to 4*
Q4	effectively looking after the health of your whole mouth?	1 to 4*
Q5	how your teeth and partial denture looks to others?	1 to 4*
Q6	How motivated are you to stick with your current oral care routine?	1 to 4*
Q7	In the future, how likely are you to continue with your current oral care routine?	1 to 4*
Q8	The risks to my oral health have increased because I have a partial denture	1 to 5**
Q9	I am doing more to care for my mouth (natural teeth and partial) since I experienced losing a tooth	1 to 5**
Q10	Oral cleanliness and hygiene are important	1 to 5**
Q11	I do a good job caring for my mouth (natural teeth and partial)	1 to 5**
*1 = Not at all confident, 2 = Not very confident, 3 = Fairly confident, 4 = Very confident		
**1 = Disagree strongly, 2 = Disagree somewhat, 3 = Neither agree nor disagree, 4 = Agree somewhat, 5 = Agree strongly		
…		
Q12	more or less confident about the cleanliness of your mouth and teeth?	1 to 5***
Q13	more or less confident about the cleanliness of your partial denture?	1 to 5***
Q14	more or less confident about the freshness of your breath?	1 to 5***
Q15	more or less confident you are effectively looking after the health of your whole mouth?	1 to 5***
Q16	more or less confident about how your teeth and partial denture looks to others?	1 to 5***
Q17	more or less motivated to follow a multistage oral care routine?	1 to 5****
Q18	more or less likely to follow a multistage oral care routine?	1 to 5*****
***1 = *A* lot less confident now, 2 = *A* little less confident now, 3 = No difference, 4 = *A* little more confident now, 5 = *A* lot more confident now		
****1 = *A* lot less motivated now, 2 = *A* little less motivated now, 3 = No difference, 4 = *A* little more motivated now, 5 = *A* lot more motivated now		
*****1 = *A* lot less likely now, 2 = *A* little less likely now, 3 = No difference, 4 = *A* little more likely now, 5 = *A* lot more likely now		

Table 2
Indices used in this study.

Score	Description
	The Modified Gingival Index (MGI) [31]
0	Absence of inflammation
1	Mild inflammation: slight change in colour, little change in texture of any portion of the marginal or papillary gingival unit
2	Mild inflammation: criteria as [1] but involving the entire marginal or papillary gingival unit
3	Moderate inflammation: glazing, redness, oedema, and/or hypertrophy of the marginal or papillary gingival unit
4	Severe inflammation: marked redness, oedema and/or hypertrophy of the marginal or papillary gingival unit, spontaneous bleeding, congestion, or ulceration
	Bleeding Index (BI) [30]
0	Absence of bleeding on probing
1	Bleeding observed within 30 s of probing
2	Bleeding observed immediately on probing
	Number of Bleeding Sites (NBS)
	Sum of total bleeding sites
	Turesky Plaque Index (TPI) [33]
0	No plaque
1	Separate flecks of plaque at the cervical margin
2	Thin continuous band of plaque (up to 1 mm) at the cervical margin
3	Band of plaque wider than 1 mm but covering $< 1/3$ of the tooth surface
4	Plaque covering $\geq 1/3$ but $< 2/3$ of the tooth surface
5	Plaque covering $\geq 2/3$ of the tooth surface
	Calculus Index (CI) [34]
0	No calculus present
1	Supragingival calculus covering not more than one-third-of the exposed tooth surface
2	Supragingival calculus covering more that one-third-but not more than two-thirds of the exposed tooth surface or the presence of individual flecks of subgingival calculus around the cervical portion of the tooth or both
3	Supragingival calculus covering more than two-thirds of the exposed tooth surface or a continuous band of subgingival calculus around the cervical portion of the tooth or both
	Oral Debris Index (ODI) [34]
0	No debris or stain present
1	Supragingival calculus covering not more than one-third-of the exposed tooth surface
2	Supragingival calculus covering more that one-third-but not more than two-thirds of the exposed tooth surface or the presence of individual flecks of subgingival calculus around the cervical portion of the tooth or both
3	Supragingival calculus covering more than two-thirds of the exposed tooth surface or a continuous band of subgingival calculus around the cervical portion of the tooth or both
	The Partial Denture Cleanliness Index (PDCI) [34]
0	No visible plaque; no matter adherent to the dental probe on light scraping
1	No visible plaque; matter adherent to the dental probe on light scraping
2	Deposits of plaque just visible on careful examination without need to confirm by scraping
3	Deposits of plaque clearly visible
4	Gross plaque deposits ("velvet appearance")
	The Oral Hygiene Index (OHI) [34]
	The sum score of the CI and the ODI

Table 3
Test products, active ingredients and usage instruction.

Product	Manufacturer	Active ingredients	Usage instruction
Toothpaste	Haleon plc	**Experimental Toothpaste containing** 0.454 % stannous fluoride	1. Wet your supplied toothbrush with running tap water. 2. Apply the supplied toothpaste along the full length of the brush head. 3. Brush all of your teeth with the toothbrush for 2 (two) timed minutes in your usual way. 4. Spit out the toothpaste.
Mouthrinse	Haleon plc	**Experimental Mouth rinse containing** 90 ppm sodium fluoride	1. Pour out 10mls of the supplied mouthrinse. 2. Rinse your mouth with the mouthrinse for 1 timed minute, swishing the rinse vigorously around your mouth. 3. Spit out the mouthrinse. 4. Reinsert your partial denture.
Denture cleanser foam	Haleon plc	**COREGA Purfrisch Reinigungsschaum Denture Foaming Cleanser containing**: sodium lauryl sulphate, cocamidopropyl betaine, sodium PVM/MA copolymer	1. Hold partial denture firmly. 2. Shake bottle. 3. Apply 2 (two) full pumps of foam wash onto partial denture, adjust amount if needed. 4. Brush for 90 s using the supplied denture cleaning brush. 5. Rinse partial denture thoroughly with running water before inserting in the mouth.

undertaken by the study dentist followed by MGI, BI, CI, TPI, ODI assessments. At the 6-week visit participants in the intervention group received another supply of assigned study products and underwent supervised use of the study products per the usage instructions. At the 12-week visit participants in the intervention group returned all study materials and all participants underwent an OHT examination, were given a dental prophylaxis if requested and had their denture cleaned.

In order to aid study compliance, all participants received an SMS (text message) reminder before baseline, 6- and 12-week visits to remind them of the requirement for no oral hygiene on the morning prior to their visit.

2.2. Statistical methods

It was planned to screen a sufficient number of participants to randomize at least 150 participants (maximum 175) to ensure approximately 128 evaluable participants (approximately 64 per treatment group) completed the entire study. Based up on a previous study utilising stannous fluoride toothpaste, with 64 participants per treatment group, the study had at least 80 % power to detect a treatment difference of 0.09 in bleeding index over a period of 12 weeks treatment. The standard deviation planned to be used in the calculation was 0.18. The standard deviation and effect size in this sample size calculation are based on review of GSK Clinical Study 207,014, 2018 (difference=0.09 and standard deviation=0.14) [35], assuming greater variability due to inclusion criteria stipulating that participants can have fewer gradable teeth in this study.

To determine between-group differences at 6 and 12 weeks for whole mouth and abutment teeth clinical scores (BI, NBS, MGI, CI,TPI, ODI, OHI), ANCOVA was conducted. The model included treatment group, gender, denture material type and baseline mean MGI score as factors, with the relevant baseline clinical scores (BI, NBS, MGI, CI, TPI, CI, ODI, OHI, PDCI) as a covariate.

For the Cleaning Perceptions Questionnaire (Table 1: questions 12 to 18), treatment comparison was performed using the Cochran Mantel-Haenszel test. The participant population analysed was the modified

intention-to-treat (mITT) population.

3. Results

This study commenced on 14 October 2020 and ended on 24 February 2022. It was planned to randomise at least 150 participants, however due to the COVID-19 pandemic, participant recruitment proved very difficult, and despite extensive additional recruitment activities, the study was halted before the target participant number was reached. A total of 61 participants were screened, 58 participants were enrolled, and 49 participants allocated to a randomised treatment. A total of 48 randomised participants subsequently completed the study as per protocol as one participant withdrew from the study due to concomitant medication [antibiotic] given for AE [chest infection] in the intervention group (Fig. 1).

Study products were generally well-tolerated. Overall, 3 participants in the intervention group (12.5 %) reported a total of 7 adverse events (AEs). The 7 AEs were (headache [2 events], burnt oral cavity from hot food [2 events], hypercholesterolemia [1 event], COVID-19 [1 event], and lower respiratory tract infection [1 event]). No AEs were reported in the no-intervention group. Most of the AEs were of mild intensity and were resolved at the end of the study. None of the AEs was associated with the intervention products provided and there were no Serious AEs. During the study period, the mean (±SD) participant compliance in the intervention group was 99.4 % (±1.26) for toothbrushing, 99.4 % (±1.23) for mouth rinse use, and 99.3 % (±1.37) for denture cleaning.

Both treatment groups were well-balanced for age, gender and ethnicity (Table 4). The mean age (±SD) of the study population was 60.4 (±9.90) years and the majority were white (81.3 %). Overall, the baseline mean (±SD) MGI score was 2.04 (±0.14) indicating mild to moderate gingival inflammation in the study population, and most participants (60.4 %) fell in the high stratification category (MGI scores of >2.0). Most participants (62.5 %) wore acrylic dentures during the study.

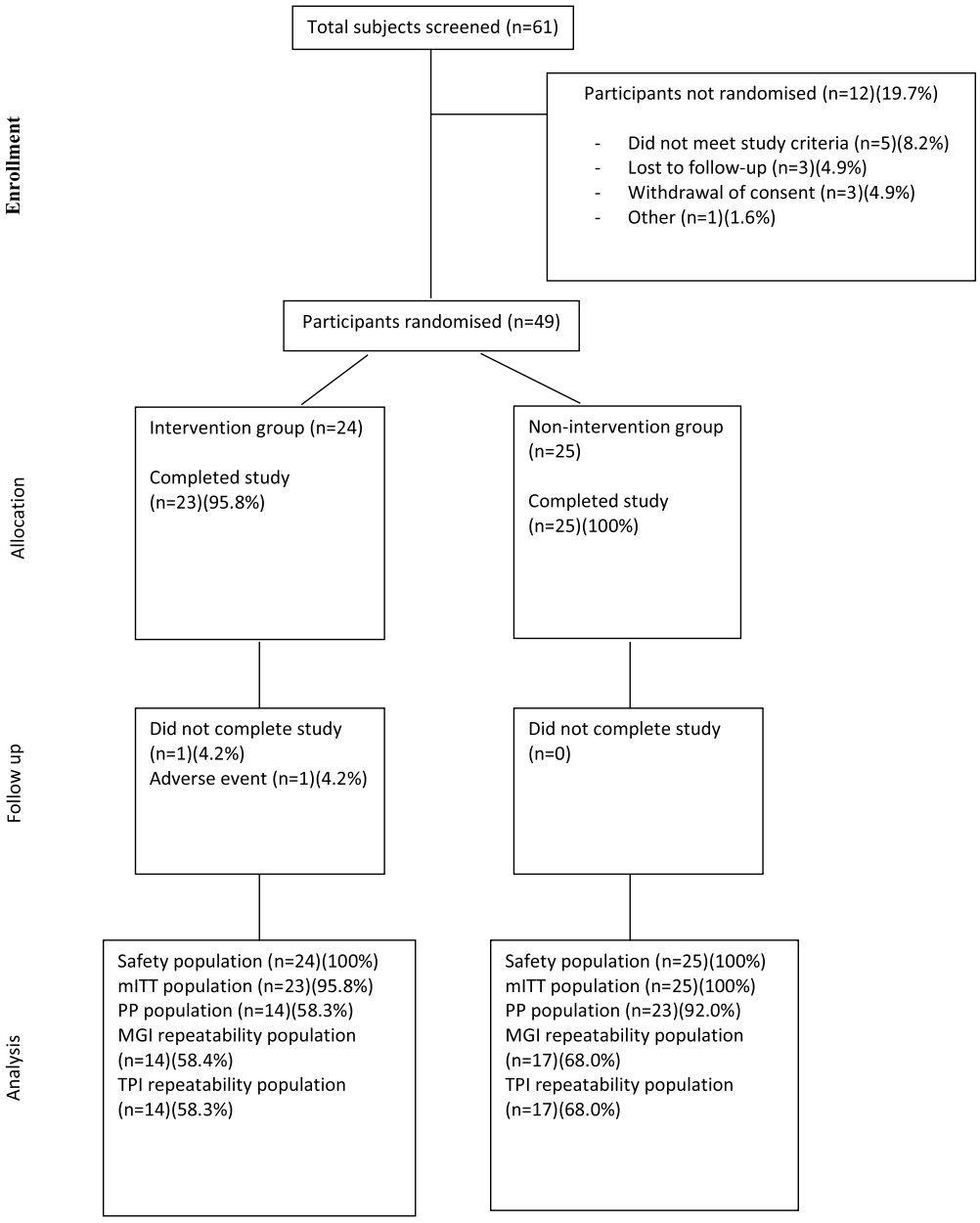

Fig. 1. Consort diagram of patient flow through the study. Abbreviations: MGI = Modified Gingival Index; mITT = modified Intent-to-Treat; n (%) = number (percentage) of participants; PP = Per protocol; TPI = Turesky Plaque Index.

Table 4
Age, gender, ethnicity, stratification and mean clinical scores at baseline (mITT population).

		Intervention ($n = 23$)	No-intervention ($n = 25$)	All ($n = 48$)
Age (SD)		60.2 (9.68)	60.5 (10.30)	60.4 (9.90)
Gender:	Male	52.2 %	44.0 %	47.9 %
	Female	47.8 %	56.0 %	52.1 %
Ethnicity:	white	82.6 %	80.0 %	81.3 %
	Asian	8.7 %	16.0 %	12.6 %
	black	8.7 %	4.0 %	6.3 %
Baseline MGI category at baseline		Low (≤2.0) 39.1 %	Low (≤2.0) 40.0 %	Low (≤2.0) 39.6 %
		High (>2.0) 60.9 %	High (>2.0) 60.0 %	High (>2.0) 60.4 %
Mean Overall Baseline Scores				
BI (±SE)		0.86(±0.046)	0.86(±0.051)	0.86 (±0.034)
NBS (±SE)		84.6(±3.90)	86.9(±5.00)	85.8 (±3.18)
Mean Baseline MGI (SD), (±SE)		2.04 (0.13), (±0.02)	2.04 (0.150), (±0.02)	2.04 (0.14), (±0.02)
TPI (±SE)		3.10(±0.114)	3.11(±0.128)	3.11 (±0.085)
TPI Interproximal (±SE)		3.38(±0.125)	3.36(±0.136)	3.37 (±0.092)
PDCI (±SE)		1.7(±0.21)	1.6(±0.21)	1.7 (±0.15)
CI (±SE)		0.35(±0.055)	0.36(±0.063)	0.35 (±0.041)
ODI (±SE)		0.76(±0.104)	0.74(±0.099)	0.75 (±0.071)
OHI (±SE)		1.11(±0.147)	1.10(±0.154)	1.10 (±0.106)
Mean Baseline Abutment Tooth Scores				
BI (±SE)		0.92(±0.065)	0.96(±0.089)	0.94 (±0.055)
MGI (±SE)		2.16(±0.047)	2.13(±0.077)	2.14 (±0.046)
NBS (±SE)		14.7(±1.53)	13.6(±1.62)	14.2 (±1.11)
TPI (±SE)		3.13(±0.119)	3.16(±0.176)	3.15 (±0.107)
TPI Interproximal (±SE)		3.46(±0.130)	3.44(±0.191)	3.45 (±0.116)
CI (±SE)		0.20(±0.070)	0.24(±0.072)	0.22 (±0.050)
ODI (±SE)		0.69(±0.128)	0.67(±0.113)	0.68 (±0.084)
OHI (±SE)		0.89(±0.184)	0.91(±0.177)	0.90 (±0.126)
Denture material		Acrylic 60.9 %	Acrylic 64.0 %	Acrylic 62.5 %
		Cobalt chrome 39.1 %	Cobalt chrome 36.0 %	Cobalt chrome 37.5 %
The mean (±SD) number of teeth replaced by RPD				3.6 (±2.48)
The mean (±SD) number of abutment teeth				3.20 (±1.35)
The mean (±SD) duration of RPD use				9.06 (±11.89)
The mean (±SD) duration of current RPD use				4.40 (±5.90)

The majority of participants (95.8 %) reported they slept without their RPD in place and most participants (35.4 %) used a Class III (unilateral bounded saddle) type of RPD based on Kennedy Classification or a Class IV (bilateral bounded anterior saddle, 33.3 %). Class II (unilateral free ended saddle), and Class I (bilateral free ended saddle, 8.3 %) were used by 22.9 % and 8.3 % of participants, respectively. Additionally, 75 % of the participants reported that they were completely satisfied, and 25 % of the participants were somewhat satisfied with their RPDs. The main cause of tooth loss leading to the RPD was trauma (45.8 %), followed by caries (31.3 %), unknown (14.6 %), and periodontal disease (8.3 %).

At baseline, 91.7 % of participants reported that they brushed their teeth twice a day, 72.9 % did not use mouth rinse, 8.3 % used mouth rinse twice a day and 14.6 % used it once a day. None of the participants reported denture cleanser usage for their RPDs. For the 5 questions related to aspects of oral health, for all questions the most common response was “fairly confident” ranging from 52.1 % (freshness of breath) to (72.9 % cleanliness of mouth and teeth). For questions relating to motivation and their oral hygiene regimen, 56.3 % participants reported being very motivated to stick with their current oral care routine, 72.9 % reported they were very likely to continue with their current oral care routine and 93.8 % strongly agreed that oral cleanliness and hygiene are important. For the questions relating to ‘the risks to my oral health have increased because I have a RPD’ and ‘I do a good job caring for my mouth’, participants reported as somewhat agreed (37.5 %, 47.9 %) and for questions relating to ‘I am doing more to care for my mouth since I experienced losing a tooth’, 50 % of the participants reported they strongly agreed. Answers were similar in both groups.

Baseline clinical scores are shown in Table 4, and changes in clinical scores from baseline are shown in Table 5.

For the gingivitis and plaque measures, statistically significantly improved BI, NBS, MGI, and TPI whole mouth scores were recorded at Weeks 6 and 12 for the intervention compared as compared to continuing with usual oral care routines (no intervention) ($p < 0.0001$). The primary objective of the study was thereby achieved. Improved denture cleanliness for the intervention group was shown by lower PDCI scores observed at week 6 and 12 ($p = 0.0039$, week 6 and $p < 0.0001$, week 12). For calculus, a lower whole-mouth CI was observed at Week 6 ($p = 0.0367$) for the intervention group than the no-intervention group. The difference in CI between groups at week 12, numerically in favour the intervention group, was not statistically significant ($p = 0.0725$). Further, for the dental cleanliness measures ODI and OHI, the intervention group demonstrated statistically significantly lower values than the no-intervention group (ODI ($p = 0.0006$ and $p = 0.0009$ for Weeks 6 and 12) and OHI ($p = 0.0020$ and $p = 0.0005$ for Weeks 6 and 12)). Due to the clarity of statistical separation observed with the lower-than-expected subject recruitment, it is clear that the original estimate for the treatment differences used in the powering calculation were significantly underestimated.

Table 6 compares the intervention and no-intervention groups after 6 and 12 weeks for BI, NBI, MGI, TPI, CI, ODI and OHI associated with abutment teeth. Following dental prophylaxis, use of the intervention resulted in a significantly greater reduction of BI score, NBS, MGI score, overall and interproximal TPI scores at Weeks 6 and 12, and ODI score and OHI score at Week 6 associated with abutment teeth, as compared to no-intervention. Between-group differences in CI score (at Weeks 6 and 12), ODI score (at Week 12), and OHI score (at Week 12) associated with abutment teeth were not statistically significant; however, numerical differences consistently favoured the intervention group, in line with results observed for the whole dentition.

Comparison of questionnaire responses demonstrated that there was a statistically significant ($p < 0.05$) difference between the intervention and no-intervention groups for questionnaire responses (Table 1) at weeks 6 and 12 (apart from Q12 at week 6).

The majority of the participants in the intervention group felt they were much more confident on their cleaning perception (Q12 to Q16),

Table 5
Changes in clinical scores the intervention and no-intervention groups after 6 and 12 weeks from baseline **(mITT population)**.

Outcome measure	Adjusted mean (SE)		Comparison with no-intervention group				
	No-intervention (n = 25)	Intervention (n = 23)	Adjusted mean difference (SE)	95 % confidence interval	p-value[a]	Proportionate reduction	p-value[b]
BI (week 6)	0.76 (0.031)	0.45 (0.033)	−0.32 (0.045)	(−0.41, −0.23)	<0.0001	41.5	
BI (week 12*)	0.76 (0.034)	0.45 (0.036)	−0.30 (0.050)	(−0.40, −0.20)	<0.0001	40.0	
NBS (week 6)	81.7 (3.26)	53.1 (3.40)	−28.6 (4.73)	(−38.1, −19.1)	<0.0001	35.0	
NBS (week 12*)	80.8 (3.50)	52.9 (3.65)	−27.9 (5.08)	(−38.2, −17.7)	<0.0001	34.6	
MGI (week 6)	1.92 (0.043)	1.52 (0.044)	−0.39 (0.062)	(−0.52, −0.27)	<0.0001	20.6	
MGI (week 12*)	1.86 (0.038)	1.50 (0.039)	−0.36 (0.054)	(−0.47, −0.25)	<0.0001	19.2	
TPI (week 6)	2.97 (0.098)	2.12 (0.102)	−0.85 (0.142)	(−1.14, −0.56)	<0.0001		
TPI (week 12*)	3.02 (0.096)	2.07 (0.100)	−0.95 (0.139)	(−1.23, −0.67)	<0.0001		
TPI Interproximal (week 6)	3.22 (0.104)	2.31 (0.108)	−0.91 (0.151)	(−1.22, −0.61)	<0.0001		
TPI Interproximal (week 12*)	3.29 (0.106)	2.24 (0.111)	−1.05 (0.154)	(−1.36, −0.74)	<0.0001		
PDCI (week 6)	1.7 (0.12)	1.2 (0.12)	−0.5 (0.17)	(−0.9, −0.2)	0.0039		
PDCI (week 12*)	1.9 (0.10)	1.1 (0.11)	−0.8 (0.15)	(−1.1, −0.5)	<0.0001		
CI (week 6)	0.19 (0.034)	0.08 (0.036)	−0.11 (0.050)	(−0.21, −0.01)	0.0367		0.0318
CI (week 12*)	0.18 (0.023)	0.10 (0.024)	−0.08 (0.033)	(−0.14, −0.01)	0.0236		0.0725
ODI (week 6)	0.50 (0.052)	0.22 (0.054)	−0.28 (0.075)	(−0.43, −0.13)	0.0006		0.0024
ODI (week 12*)	0.46 (0.050)	0.20 (0.052)	−0.26 (0.073)	(−0.41, −0.11)	0.0009		0.0053
OHI (week6)	0.69 (0.081)	0.30 (0.085)	−0.39 (0.117)	(−0.62, −0.15)	0.0020		0.0009
OHI (week12*)	0.64 (0.062)	0.30 (0.065)	−0.34 (0.090)	(−0.52, −0.16)	0.0005		0.0173

BI score = the average index value over all tooth sites scored; NBS = the number of sites with a BI value of 1 or 2; MGI score = the average index value over all tooth sites scored; Overall TPI score = the average index value over all tooth sites scored; Interproximal TPI score = the average index value over all interproximal tooth sites (distal and mesial) scored; PDCI score = the highest score of all surfaces of the RPD; CI score = the average index value over all tooth surfaces scored; ODI score = the average index value over all tooth surfaces scored; OHI score was a composite score of the CI and the ODI, calculated as the sum of the mean CI score and the mean ODI score.

[a] Analysed by ANCOVA with treatment group, gender, denture material type (acrylic or cobalt chrome), and baseline mean overall MGI score (low, high) as factors and the baseline score as covariate.

Difference is Intervention Group minus No-intervention Group such that a negative difference favours the Intervention Group.

[b] Proportionate reduction calculated as ([Adjusted Mean of No-intervention Group – Adjusted Mean of Intervention Group]/Adjusted Mean of No-intervention Group)*100. P-value from Van-Elteren test adjusted for denture material type and baseline mean overall MGI score stratification.

Table 6
Changes in clinical scores of the abutment teeth for the intervention and no-intervention groups after 6 and 12 weeks from baseline **(mITT population)**.

Outcome measure	Adjusted mean (SE)		Comparison with no-intervention group				
	No-intervention (n = 25)	Intervention (n = 23)	Adjusted mean difference (SE)	95 % confidence interval	p-value[a]	Proportionate reduction	p-value[b]
BI (week 6)	0.75 (0.046)	0.48 (0.048)	−0.27 (0.067)	(−0.41, −0.14)	0.0002	36.3	
BI (week 12*)	0.78 (0.046)	0.49 (0.048)	−0.29 (0.066)	(−0.42, −0.16)	<0.0001	37.2	
NBS (week 6)	12.0 (0.77)	8.6 (0.80)	−3.4 (1.11)	(−5.6, −1.1)	0.0040	28.2	
NBS (week 12*)	12.6 (0.66)	8.8 (0.68)	−3.9 (0.95)	(−5.8, −1.9)	0.0002	30.6	
MGI (week 6)	2.04 (0.067)	1.56 (0.070)	−0.48 (0.097)	(−0.68, −0.29)	<0.0001	23.7	
MGI (week 12*)	1.88 (0.061)	1.56 (0.063)	−0.33 (0.088)	(−0.50, −0.15)	0.0006	17.3	
TPI (week 6)	2.90 (0.117)	2.21 (0.122)	−0.69 (0.170)	(−1.03, −0.35)	0.0002		
TPI (week 12*)	2.93 (0.121)	2.17 (0.126)	−0.76 (0.175)	(−1.12, −0.41)	<0.0001		
TPI Interproximal (week 6)	3.18 (0.120)	2.41 (0.125)	−0.77 (0.174)	(−1.12, −0.42)	<0.0001		
TPI Interproximal (week 12*)	3.23 (0.136)	2.41 (0.142)	−0.82 (0.197)	(−1.21, −0.42)	0.0002		
CI (week 6)	0.07 (0.038)	0.02 (0.039)	−0.05 (0.055)	(−0.16, 0.06)	0.3801		0.4934
CI (week 12*)	0.09 (0.035)	0.01 (0.037)	−0.07 (0.051)	(−0.18, 0.03)	0.1497		0.1588
ODI (week 6)	0.46 (0.070)	0.23 (0.073)	−0.24 (0.101)	(−0.44, −0.03)	0.0246		0.0365
ODI (week 12*)	0.46 (0.071)	0.20 (0.074)	−0.26 (0.102)	(−0.47, −0.06)	0.0137		0.2486
OHI (week6)	0.53 (0.088)	0.25 (0.092)	−0.28 (0.128)	(−0.54, −0.02)	0.0324		0.0284
OHI (week12*)	0.55 (0.095)	0.21 (0.099)	−0.33 (0.138)	(−0.61, −0.05)	0.0205		0.3058

BI score = the average index value over all tooth sites scored; NBS = the number of sites with a BI value of 1 or 2; MGI score = the average index value over all tooth sites scored; Overall TPI score = the average index value over all tooth sites scored; Interproximal TPI score = the average index value over all interproximal tooth sites (distal and mesial) scored; PDCI score = the highest score of all surfaces of the RPD; CI score = the average index value over all tooth surfaces scored; ODI score = the average index value over all tooth surfaces scored; OHI score was a composite score of the CI and the ODI, calculated as the sum of the mean CI score and the mean ODI score.

[a] Analysed by ANCOVA with treatment group, gender, denture material type (acrylic or cobalt chrome), and baseline mean overall MGI score (low, high) as factors and the baseline score as covariate.

Difference is Intervention Group minus No-intervention Group such that a negative difference favours the Intervention Group.

[b] Proportionate reduction calculated as ([Adjusted Mean of No-intervention Group – Adjusted Mean of Intervention Group]/Adjusted Mean of No-intervention Group)*100. P-value from Van-Elteren test adjusted for denture material type and baseline mean overall MGI score stratification.

Table 7
Summary of general oral care confidence questionnaire result.

	Intervention (SD)	No-intervention (SD)	mean difference	95 % confidence intervals[a]	p-value[a]
Weeks 6	4.14 (±0.725)	3.46 (±0.665)	0.68	0.28, 1.09	0.0014
Weeks 12	4.40 (±0.703)	3.66 (±0.722)	0.74	0.33, 1.16	0.0008

[a] *t*-test (mean difference, 95 % confidence interval and p-value).

more motivated and more likely to follow a multistage oral care routine (Q17) after the study. The mean (±SD) general oral care confidence (Q12 to Q16) reported for the intervention and no-intervention groups is summarised in Table 7, showing statistically significant differences between groups at week 6 and 12. Individuals in the intervention group felt more confident about the cleanliness of their mouths, their dentures, freshness of their breath, appearance of their denture and were more confident to look after the health of their mouth.

Repeatability (other efficacy result): A weighted Kappa coefficient (κ), along with the 95 % confidence interval was calculated to assess the intra-examiner repeatability. Fleiss-Cohen weighted kappa was calculated for the repeatability analysis. Excellent intra-examiner repeatability was observed for MGI ($\kappa = 0.9235$) and TPI ($\kappa = 0.9662$) in the repeatability analysis.

3.1. Discussion

Poor oral hygiene is a common complication associated with RPD use [22], and the resulting increased plaque and gingivitis can lead to denture stomatitis and/or further tooth loss. In this study, a multi-step intervention with a range of dental and denture products specifically designed for RPD wearers with detailed product usage instructions, was tested and evaluated for its efficacy in maintaining oral health, compared to participants' existing oral hygiene measures.

This intervention was able to improve gum health and cleanliness of RPDs. Due to the greater than expected treatment effect, there were statistically significant differences between the two groups favouring the multi-step intervention for gingival health overall, and that associated specifically with abutment teeth, in BI, NBS, MGI, TPI at Week 6 and Week 12 in spite of the low participant numbers. Further, the intervention group were significantly more confident about the cleanliness of their mouth and teeth, and were more motivated and likely to maintain good OH.

The rationale for the multi-step product treatment, comprising a 0.454 % stannous fluoride toothpaste indicated for gingivitis, a 90 ppm F sodium fluoride mouth rinse indicated for cavity protection and a denture cleanser foam containing high-cleaning surfactant system, was to address several long-term oral health issues in RPD wearers. Control of dental plaque and gingivitis, and thereby risk of periodontitis, was a critical consideration. In conjunction with mechanical plaque control, oral hygiene products with chemotherapeutic agents can be a safe and effective delivery system for antimicrobial agents with the potential to inhibit plaque growth, reduce gingivitis and improve oral health beyond tooth brushing alone [19]. Stannous fluoride is an effective, broad-spectrum antibacterial agent [36], and has a long history of use as an antiplaque and antigingivitis agent when formulated at 0.454 % in a toothpaste [37–39]. The antiplaque/antigingivitis benefits of the present stannous fluoride toothpaste formulation have been previously clinically tested in a non-denture wearing population [40,41].

Control of caries, another important oral disease linked to poor plaque control, can also be addressed by both the stannous fluoride toothpaste and the sodium fluoride mouthrinse [42,43]. The addition of mouthrinse was undertaken to overcome the loss of fluoride that normally occurs when individuals rinse with water after toothbrushing with toothpaste. Salivary fluoride concentration drops markedly as a result, but may be re-introduced by use of a fluoride mouthrinse to increase caries protection [43]. However, no caries, or caries risk, assessment was made in this short-term study.

An intervention to improve cleanliness of the denture, to reduce plaque retention and possible impact on stomatitis, gingival health and even caries, was also included. Plaque readily forms around dentures and contains pathogenic microbes including, *Candida albicans*, which is linked with denture stomatitis [44,45]. Specifically formulated denture cleaning agents with low abrasivity have been shown to enhance the cleaning capabilities of normal manual cleaning methods [26,46], without detrimental wear to the denture surface. The low-abrasive antibacterial denture cleanser foam used in this clinical study has previously been demonstrated to clean denture surfaces effectively [47–49].

The most important limitation of this study was the low number of participants, due to restrictions and public perceptions related to COVID-19. This situation was a significant factor in reducing participants' confidence in enrolling in a study based at a primary healthcare setting, particularly as the eligibility requirements tended to drive recruitment towards a more elderly participant population. Attempts to meet the recruitment target included increasing recruitment time, extending the study end date, increasing advertising, extending to the community network and using social media, but with limited effect. Study recruitment was consequently severely impacted, with only about a third of the intended number of subjects randomised. However, the study was able to demonstrate clear statistical differences, despite not achieving the intended number of subjects, because the observed treatment effects were substantially superior to those anticipated. In the sample powering calculations prior to study commencement, a difference between treatment groups in BI at 12 weeks of 0.09 was used: in the event, this difference was 0.3. The standard deviation of the treatment effects was close to that anticipated in the sample powering calculations. This situation means the power of the study was considerably greater than anticipated, so was not, as it turned out, underpowered. That is, the greater-than-anticipated treatment difference balanced out the low participant numbers, meaning that the findings of the study were not meaningfully compromised and should therefore be considered at face value.

The reasons behind the apparently elevated treatment effects against plaque and gingivitis need to be considered in terms of the key elements of the study design: the multi-step product treatment procedure and the accompanying oral hygiene instruction provided to the intervention group only, which is likely to have given extra motivation to this group to maintain their gingival health and denture cleanliness.

This study design utilised a no-intervention group as a control: these participants were asked to continue with their current oral hygiene regimen. This approach can be considered both a weakness and a strength of the study. Participants in the no-intervention group may well have realised they were in a 'control' group. In contrast, those in the intervention group may well have realised they were in a 'treatment' group. This in itself may have affected behaviour in the study, modulating any product effects on study measures [50]. Furthermore, the range of products and procedures being used by the no-intervention group may have increased the heterogeneity of the results in this group, decreasing precision. However, the strength of this experimental design is that it directly addresses, in a controlled study, the consequence of individuals changing from their current oral hygiene regimen to a specified Test regimen, when their current regimen is leaving them with ongoing mild-moderate gingivitis.

Hence the strong treatment effects on plaque and gingivitis were likely due to a combination of product and motivational benefits. That is, the product benefits were boosted by intervention group participants being more motivated in their oral hygiene practice because they were using a novel three-product range twice a day, and received instruction in their use. This enhanced motivation likely meant that they used their products more diligently than the no-intervention group, thereby

boosting their therapeutic/cleansing effects. This conclusion was supported by the results from the questionnaire, which showed that participants in the Test group were more confident and more motivated in their oral hygiene.

Regular denture hygiene education and practice, for RPD wearers, is an important component of overall good oral health and for prevention of periodontal issues, dental caries, and denture stomatitis. Improper denture care negatively impacts denture clinical longevity [44,45]. However, due to a lack of conclusive systematic review evidence to base appropriate oral hygiene recommendations for RPD wearers, professional recommendations and denture wearer habits are diverse, with no consensus on the most appropriate denture cleaning methods [51]. There are number of recent recommendations suggesting how to optimally care for and maintain dentures [52,53]. These recommendations include: brush dentures daily using a toothbrush or denture brush along with a non-abrasive cleaner, soak dentures daily using a denture cleanser, take out dentures at night and visit a dentist regularly. However, there is a lack of information on the care of the remaining dentition and oral soft tissues and the amount of advice relating to the whole patient care is inconsistent. This advice does not clearly indicate what kind of home intervention needs to take place in order to improve oral hygiene efficacy and gingival health of RPD wearers. Dental diseases are easily prevented with better oral hygiene [54] and evidence suggests that even periodontal conditions in periodontitis patients can be improved solely with oral hygiene [55–58]. Furthermore, evidence-based, theoretically framed complex interventions are proven as an effective method of influencing oral hygiene outcomes [59,60].

This clinical study was designed to compare a multi-step intervention using a range of dental and denture products specifically designed for removal partial denture wearers, with accompanying oral hygiene education, to continuing with current oral hygiene habits. It demonstrated the effectiveness of this intervention for improving oral health over 12 weeks among RPD wearers. The oral health of those in the intervention group was significantly better than those who continued with their usual oral hygiene regime, the control group of the study.

3.2. Conclusion

This clinical study has the potential to inform new evidence-based recommendations for optimal oral health of partial denture wearers, both for the public, patients, oral healthcare professionals and stakeholders.

Funding Statement

This study was carried out by the Clinical Trials Unit at Bristol Dental Hospital. This study was Supported by Haleon, UK. JEC, GRB, ES, MA are employees of Haleon and Haleon contributed to the design of the study and the manuscript. NW and JS contributed to the design of the study. The study was carried out, analysed and prepared for publication by JS and NW.

CRediT authorship contribution statement

Joon Seong: Writing – review & editing, Writing – original draft, Methodology, Investigation, Data curation. **Creeth JE:** Writing – review & editing, Resources, Funding acquisition, Data curation, Conceptualization. **Burnett GR:** Writing – review & editing, Resources, Funding acquisition, Data curation, Conceptualization. **Sanchez E:** Writing – review & editing, Formal analysis, Data curation. **Araga M:** Writing – review & editing, Formal analysis, Data curation. **Nicola West:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Conceptualization.

Declaration of competing interest

Nicola West reports financial support was provided by Haleon plc. Jonathan Creeth, Gary Burnett, Mako Arafa and Edwin Sanchez report a relationship with Haleon plc that includes: employment. Joon Seong declares that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

from the Clinical Trials Unit at Bristol Dental Hospital contributed to the work presented in this manuscript.

clinicaltrials.org: NCT04290624NTC.

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