Protocol Number: 2020/ETH01909

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Protocol Version #

5

Protocol Date:

3rd May 2021

Proprietary Notice (if applicable)

Not applicable

Ethics Statement:

The study will be conducted in accordance with the *National Statement on Ethical Conduct in Human Research* (2007), the *CPMP/ICH Note for Guidance on Good Clinical Practice* and consistent with the principles that have their origin in the Declaration of Helsinki. Compliance with these standards provides assurance that the rights, safety and well-being of trial participants are respected.

Contents

Summary

Study title: Interdental Cleaning Comparison Study_Number 2

Protocol version: 5

Objectives:

Primary objective: To undertake an ethical and independent study to determine whether there is any significant difference in the efficacy of interdental brushes (Brand: "Curaprox" vs Oral Irrigation (Brand: "Waterpik" Pic Pocket TM subgingival irrigation tip) in the removal of plaque and the maintenance of periodontal health.

Secondary objectives: To investigate the patient preference and ease of use for the interdental brushes and Oral Irrigation.

Study design: Within-subjects experimental study design

Planned sample size: 40 subjects would be enrolled into the study.

Selection criteria:

1. Disease status/ or disease group for study: Embrasure space of 2 or 3. PSR code<=3.

2. Gender: no restrictions

3. Age range: >18 years

4. At least 24 natural teeth

5. Willingness to provide informed consent and willingness to participate and comply with the study requirements.

Study procedure

Visit 1: Participant enrolment, gain consent; initial full mouth debridement - 2-week break for "Washout"

Visit 2: Clinical parameters would be assessed by clinical examination by two calibrated, blinded examiners (qualified research assistants); dental plaque/stain and supragingival calculus removal; randomised allocation. Participants would use their allocated interproximal aid for 4 weeks.

Visit 3: Clinical parameters will be assessed, and Oral photographs taken. 2-week break for "Washout".

Visit 4: plaque removed only. Participants would receive OHI and use their allocated interproximal aid for 4 weeks.

Visit 5: Clinical parameters will be assessed, Oral photographs taken; Final AirFlow provided. Participants to complete qualitative satisfaction survey.

Statistical considerations

Sample size calculation: 40 subjects would be enrolled into the study. A sample size calculation determined 34 participants were required for an effect size of 0.4 (medium sample size approach), with α=0.05 and β=0.85 (G*Power sample calculation software). An additional 20% is included to allow for dropouts.

Analysis plan: The analysis will be performed using PRISM (Version 8) statistical software, with the level of significance set at $p<0.05$. The difference in clinical parameters between baseline, and between interventions, will be evaluated using a "Paired t-test".

Duration of the Study: up to 2 years

1. BACKGROUND AND INTRODUCTION

1.1. DISEASE/PROPOSED INTERVENTION BACKGROUND

Background Information

Interdental Brushes

There is a significant amount of evidence advocating the use of Interdental Brushes as an effective interdental cleaning aid. A systematic review Slot et al. (2008) highlights the effectiveness of inter-dental brushes as an adjunct to toothbrushing for plaque removal in adult patients. This systematic review also revealed a positive statistical reduction in interdental biofilm when using inter-dental brushes as compared to floss at a control. However, this review also showed that there was no difference in gingival inflammation or bleeding. Interestingly, criteria for selecting adult patients varied throughout the studies reviewed. Health status was not identified in three studies, and health status was reported as "good general health" in six studies. Although all studies included patients, who had inter-dental spaces that could accommodate the use of an inter-dental brush, three studies did not report on the subjects' periodontal status. The diversity in selection of study subjects was quite significant amongst these studies which may well have affected the robustness of the conclusions of the review (Gluch 2012).

However, the sample size of the different trials within this review can be considered large enough to validate statistical and clinically significant differences (Rasines 2009). In a Cochrane review, Poklepovic et al. (2013) reviewed seven studies about inter-dental brushes (total 354 participants analysed). Only one reported objective comparison of toothbrushing with and without inter-dental brush use. The review identified very low-quality evidence that inter-dental brushing in combination with toothbrushing is more beneficial than toothbrushing alone for gingivitis and plaque at the 1-month time frame. Further, there was also low-quality evidence from seven other studies identifying that inter-dental brushing reduces gingivitis when compared with flossing, but these results were only found at 1 month. There was insufficient evidence to determine whether interdental brushing reduced levels of biofilm when compared to flossing. It should be noted here however, that differences were substantial for both the gingivitis and plaque analyses most likely due to methodological and clinical variability between the studies. One included study concerns brushpicks which are not inter-dental brushes but a plastic toothpick with plastic filaments. These two systematic reviews on inter-dental brushes (Slot et al. 2008, Poklepovic et al. 2013) had five shared papers. The differences in their selection for each review was due to alternative inclusion criteria. It is recognized that different studies will provide different outcomes (Bowen 2012).

Schmage et al. (1999) assessed the relationship between the inter-dental space and the position of the teeth. Most of the inter-dental spaces in the anterior teeth are small with embrasure type 1, thus floss is more ideal. Premolars and molars have larger inter-dental spaces with embrasure type 2. They are more accessible with interdental brushes. Further, the primary advantage of inter-dental brushes is their superiority in reaching interdental groves or fissures. These cannot be physically cleaned by any other inter-dental cleaning device. This morphological component had not been used in any of the studies published so far. This makes matching in the random assignment and a true comparison among products difficult; hence, the grouping of all inter-dental brushes into one category (Gluch 2012).

Oral Irrigators

The oral irrigator is an oral hygiene aid that has been developed to assist plaque control and reduce gingival inflammation. Oral irrigators are designed to disturb soft debris and ideally remove biofilm via the mechanical action of a mildly pressurised stream of water. There has been considerable controversy regarding the appropriate use and efficacy of this method of interdental cleaning (van der Weijden & Slot 2011). Husseini et al. (2008) systematically reviewed the literature on the topic of the effect of an oral irrigator in combination with toothbrushing, on controlling plaque, gingival inflammation and pocket probing depth. They determined that there were insufficient studies to perform a meta-analysis. They did

note however, that the oral irrigator, as an adjunct to toothbrushing, does improve gingival health more than regular oral hygiene measures or toothbrushing alone.

There was no evidence suggesting any statically significant biofilm reduction. Further, a 4-week study indicated that oral irrigation in combination with manual toothbrushing was significantly more effective in reducing gingival bleeding scores than the use of dental floss as an interdental cleaning aid (Rosema et al. 2011). The precise mode of action that influences these observations is still unclear. It is thought that oral irrigation does not produce enough water pressure to disrupt and reduce mature biofilm, it may only interrupt newly formed biofilm, thereby interfering with maturation of the microbial biofilm, thereby, influencing gingival inflammation. Another possible effect is the mechanical action of a jet stream of the water and depending on the device, its pulsations, which may reduce the levels of inflammatory mediators in the gingival crevice/pocket, thereby contributing to improved gingival homeostasis and health (Chaves et al.1994, Flemmig et al. 1990, Frascella et al. 2000). Further, it is also possible that any benefit an oral irrigator may have in reducing inter-dental plaque, may be undetectable clinically.

As such, further studies are needed to research the effectiveness of the oral irrigator as an adjunct to regular oral hygiene measures for reducing interdental biofilm and for the long-term maintenance of gingival health (Jin 2009). To date systematic reviews did not specifically evaluate blunt-ended cannulae (WaterPiK Pik Pocket TM subgingival irrigation tip – Water Pik Inc., Fort Collins, CO, USA).

1.2. RATIONALE FOR PERFORMING THE STUDY

There are a number of studies, metanalysis or RCT's which identify further research is required into the efficacy of various interdental cleaning tools.

It is widely accepted teaching practice based upon evidence and recommendations of international associations e.g. the European society of Periodontology that for interdental embrasure types 2 and 3, interdental brushes are now the gold standard for efficient plaque removal and thus reduction in interdental gingival inflammation.

Patient compliance with interdental cleaning has always presented Oral Health clinicians with challenges. Patients have shown more interest in "cleaning devices" which could make the process more effortless.

If our study can determine if a properly calibrated oral irrigation, with standardized correct use of the device, compared to the correct sizing and use of Interdental brushes, can have a significant statistical benefit in plaque/gingival inflammation reduction, this may have a meaningful impact on future patient education.

2. HYPOTHESIS

Null hypothesis: there will be no significant difference in the efficacy of interdental brushes vs oral irrigation in the removal of plaque and the maintenance of periodontal health.

3. STUDY OBJECTIVES

3.1. PRIMARY OBJECTIVES

To undertake an ethical and independent study to determine whether there is any significant difference in the efficacy of interdental brushes vs Oral irrigation in the removal of plaque and the maintenance of periodontal health.

3.2. SECONDARY OBJECTIVES

To investigate the patient preference and ease of use for the interdental brushes and oral irrigation

4. STUDY DESIGN

4.1. DESIGN
Within-subjects experimental study design

4.2. EXPECTED PARTICIPANT NUMBERS
40 subjects would be enrolled into the study. A sample size calculation determined 34 participants were required for an effect size of 0.5, with α=0.05 and β=0.80. An additional 20% is included to allow for dropouts.

4.3. DURATION OF THE STUDY
The study will take approximately 18 months.

May 2021 – Ethics application

June 2021 – December 2021 - Recruitment/Data Collection

January 2022- Data analysis

JFeb-April 2022- Writing up

4.4. PRIMARY ENDPOINT data collection - 9 weeks after initial visit (Visit 1)

4.5. CENTRES
Sydney Dental Hospital - Level 4

5. STUDY PARTICIPANTS

5.1. INCLUSION CRITERIA

1. Disease status/ or disease group for study: Embrasure space of 2 or 3. PSR code<=3.
2. Gender: no restrictions
3. Age range: >18 years
4. At least 24 natural teeth
5. Willingness to provide informed consent and willingness to participate and comply with the study requirements.
6. Women of childbearing potential who are using a reliable contraceptive method(s).
7. Patients from all dietary backgrounds

5.2. EXCLUSION CRITERIA

1. Women lactating, pregnant or of childbearing potential who are not willing to avoid becoming pregnant during the study.
2. Participants with a history of active periodontal disease with a PSR code of 4.
3. Participants with a history of diabetes, tobacco smoking, xerostomia (dry mouth), any form of chronic inflammatory disease.
4. Participants who have taken antibiotics within the past six weeks.

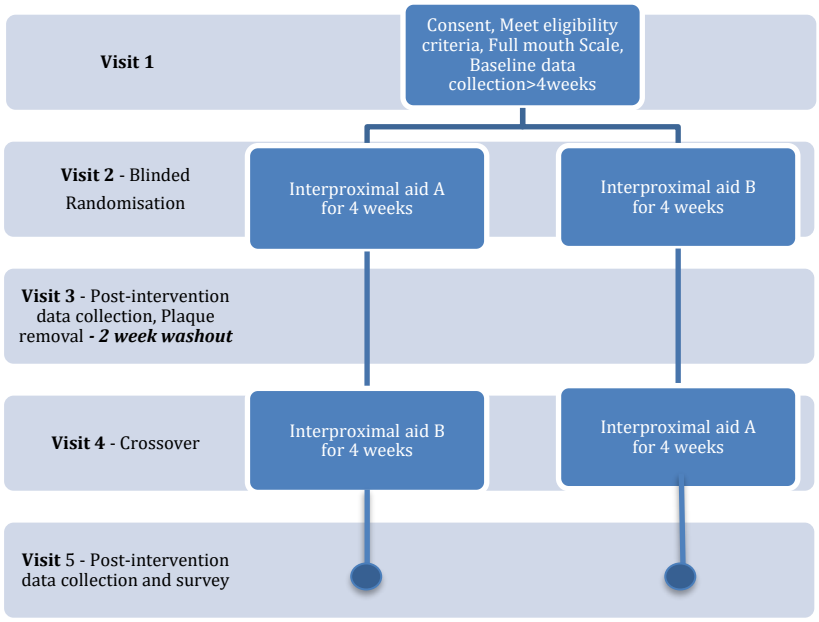
5. Participants currently experiencing psychological illness or other conditions which may interfere with their ability to understand the study requirements or interfere with their motivation to participate in the study, or the evaluation of the study outcome.

6. As the following medication(s) can have interactive effects and may interfere with the participant's ability to meet the study requirements, they cannot be administered during the clinical study (anticoagulants, anti-convulsant, immunosuppressants, tricyclic antidepressants)

7. Participants that have a medical condition which inhibits their ability to safely use the OH tools, e.g. multiple sclerosis, Parkinson's disease.

6. STUDY PROCEDURES

6.1. STUDY FLOW CHART



6.2. INVESTIGATION PLAN

Methodology

Patients attending the clinics at the Sydney Dental Hospital will be invited to participate. BOH, DDS, or Postgraduate Periodontics students providing examinations to patients would assess them for eligibility; provided they met the inclusion and exclusion criteria the patients would then be provided with a Plain Language Statement and Consent form to consider participation. The participants will be given 2 weeks to consider their wish to participate or not and will be asked to call to book in for an appointment to participate in the study should they not wish to consent in writing on the day. A signed consent form will be required prior the participant being admitted into the study.

Visit 1. Is the enrolment visit, study participants would complete their consent form, and will receive a study enrolment number and this will be documented in the participant's medical (or personal) record and on all study documents. Further, they will receive an initial full mouth debridement involving plaque/stain

and gross supra gingival calculus removal using Hand instruments, Ultrasonic instruments and AirFlow (EMS AirFlow) with (PLUS Erythritol powder). There is a 2-week break between Visit 1 and Visit 2.

At **Visit 2,** the following clinical parameters will be assessed:

- Periodontal screening and recording (PSR)
- Modified papilla bleeding index
- Rustogi modified navy plaque index – teeth would be disclosed, and intraoral photos will be taken and assessed later.

Clinical parameters would be assessed by clinical examination by two calibrated, blinded examiners (registered dental practitioners).

Participants will again receive plaque/stain and residual supra gingival calculus removal using Hand instruments, Ultrasonic instruments and AirFlow (EMS AirFlow) with (PLUS Erythritol powder). Project assistants would provide a randomized allocation (using randomized envelopes) to either the interdental brush or water flosser and provide calibrated oral hygiene instructions appropriate to the allocation. Participants would use their allocated interproximal aid for 4 weeks.

Visit 3, clinical parameters will be assessed. Photographs of their teeth and gums taken to accurately record Modified papilla bleeding index and the Rustogi modified navy plaque index. There will be a "washout" period of 2 weeks when the participants will be asked to return to their normal routine for interdental cleaning, they undertook prior to the study commencing.

Visit 4, the Participants would have all plaque removed only with EMS AirFlow. Again, project assistants would provide calibrated oral hygiene instructions appropriate to the 2nd allocation. Participants would use their allocated interproximal aid for 4 weeks.

Visit 5, clinical parameters will be assessed. Photographs of their teeth and gums taken to accurately record Modified papilla bleeding index and the Rustogi modified navy plaque index, Finally, participants will be asked to complete a anonymous satisfaction survey.

Interventions	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
Participant Consent	✓				
Inclusion / Exclusion criteria	✓				
Initial full mouth debridement	✓				
Data collection/examination		✓	✓		✓
Plaque removal (airflow)		✓		✓	✓
Blinded allocation		✓			
OHI		✓		✓	
Patient survey					✓
Adverse Event & Serious Adverse Event Assessment					✓

Note: All study procedures are performed as part of routine dental practice.

6.3. STUDY PROCEDURE RISKS

There is a very small possibility that misuse of oral hygiene tools could cause gingival trauma, however all participants will receive professional, standardised oral hygiene instructions. Any incidences will be reviewed and treated by dental practitioners.

6.4. PARTICIPANT RECRUITMENT AND SCREENING

Participants will be identified via the following means:

1. Review of existing patient lists. Patients will be screened by LHD staff and if they meet the inclusion criteria will be invited to participate and given a PIS.
2. Advertisements (Poster in a clinic foyer - Level 4 SDH).

Patients attending the clinics at the Sydney Dental Hospital will be invited to participate. BOH, DDS, or Postgraduate Periodontics students providing examinations to patients would assess them for eligibility; provided they met the inclusion and exclusion criteria the patients would then be provided with a Plain Language Statement and Consent form to consider participation.

6.5. PARTICIPANT ENROLMENT

Potential participants will be enrolled into the study after the informed consent process has been completed and the participant has been assessed to meet all the inclusion criteria and none of the exclusion criteria. Study participants will receive a study enrolment number, and this will be documented in the participant's medical (or personal) record and on all study documents.

6.6. INFORMATION AND CONSENT

Potential participants would be provided with a Plain Language Statement and Consent form to consider participation following the screening process. The enrolment visit would be scheduled at least 2 weeks after the screening to allow the patients time to consider the Plain Language Statement and ask any questions.

6.7. RANDOMISATION PROCEDURE

The participant will be randomised at Study Visit 1, after the collection of baseline data and professional plaque removal. A project assistant would provide a randomized allocation (using randomized envelopes) to either the interdental brush or oral irrigation device.

6.8. END OF STUDY TREATMENT/WITHDRAWAL PROCEDURE

A participant can leave the research study at any time. When withdrawing from the study, the participant should let the research team know that they wish to withdraw, either in person, by phone or by email. A participant may provide the research team with the reason(s) for leaving the study but is not required to provide their reason.

The final visit is complete with a final plaque removal, and instructions for routine regular care.

6.9. PATIENT WITHDRAWAL

Participants are free to withdraw from the study at any stage.

7. OUTCOMES

7.1. DEFINITION OF OUTCOMES

Periodontal screening and recording (PSR)

Divide the mouth into sextants. Using a periodontal probe, check six sites on each tooth, but the worst finding in the sextant determines the code.

Code definitions (Landry & Jean, 2002)

Code 0 Absence of clinical signs

Code 1 Bleeding on probing

Code 2 Supra and/or subgingival calculus and/or defective margins

Code 3 Periodontal pocket 4mm to 5.5 rnm deep

Code 4 Periodontal pocket 6mm deep

Modified papilla bleeding index

Barnett et al. (1980) modified the PBI index (Muhlemann, 1977) by stipulating that the periodontal probe should be gently placed in the gingival sulcus at the mesial line angle of the tooth surface to be examined and carefully swept forward into the mesial papilla. They timed the appearance of bleeding and graded it as follows:

0 = no bleeding within 30 s of probing;

1 = bleeding between 3 and 30 s of probing;

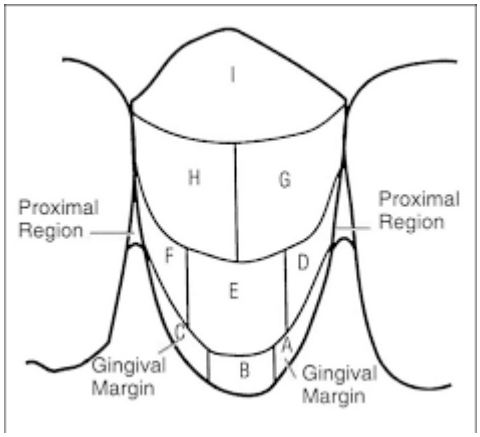
2 = bleeding within 2 s of probing;

3 = bleeding immediately upon probe placement.

The mesial papillae of all teeth present from the second molar to the lateral incisor were assessed. Indices were derived for the maxillary left and mandibular right buccal segments, and the maxillary right and mandibular left lingual segments, and from these a full-mouth index was calculated. This distribution of test sites was utilized since each mesial papilla could only be tested once, i.e. from either the buccal or lingual side. They showed that the modified PBI may be more sensitive than the visual aspects of the GI in assessing changes in gingival health

Rustogi modified navy plaque index

To assess plaque present on teeth, the Modified Navy Plaque Index, developed by Rustogi et al., will be used. Disclosed plaque is scored in each tooth area as present (scored as I) or absent (scored as 0) and recorded for both buccal and lingual surfaces. Tooth area plaque scores are grouped and designated as Whole mouth = Areas A, B, C, D, E, F, G, H and I, Marginal (gumline) = Areas A, B and C only, Approximal = Areas D and F only.



Patient satisfaction

A short survey to determine participant preference and ease of use for the interdental brushes (Brand: Curaprox) and oral irrigation device (Brand: "Waterpik" Pic Pocket TM subgingival irrigation tip) has been designed by the researchers. It consists of nine short questions.

8. STATISTICAL CONSIDERATIONS

8.1. SAMPLE SIZE OR POWER CALCULATION

40 subjects would be enrolled into the study. A sample size calculation determined 34 participants were required for an effect size of 0.4 (medium sample size approach), with α=0.05 and β=0.85 (G*Power sample calculation software). An additional 20% is included to allow for dropouts.

8.2. PROVIDE A DETAILED ANALYSIS PLAN

The analysis will be performed using PRISM (Version 8) statistical software, with the level of significance set at $p<0.05$. The difference in clinical parameters between baseline, and between interventions, will be evaluated using a "Paired t-test".

9. DATA COLLECTION

9.1. PARTICIPANT REGISTRATION

Patients attending the clinics at the Sydney Dental Hospital will be invited to participate. BOH, DDS, or Postgraduate Periodontics students providing examinations to patients would assess them for eligibility; provided they met the inclusion and exclusion criteria the patients would then be provided with a Plain Language Statement and Consent form to consider participation.

At the enrolment visit, study participants would complete their consent form, and will receive a study enrolment number and this will be documented in the participant's medical (or personal) record and on all study documents. They will also have an initial full mouth debridement.

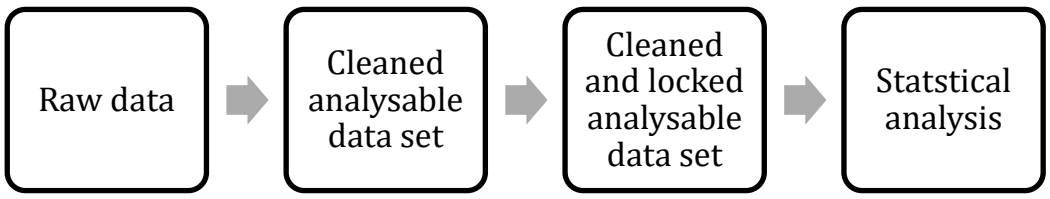
9.2. FORMS AND PROCEDURE FOR COLLECTING DATA

The data will be collected using the standard dental protocols for SDH and adhering to the Dental Board of Australia guidelines for clinical notes. The use of a standardised PSR form will be used and converted to a spread sheet format. This will be undertaken separate to the investigators to ensure the blinding is maintained.

9.3. CASE REPORT FORMS AND SCHEDULE FOR COMPLETION

Participant demographics, clinical outcomes data, and survey responses are entered an excel spreadsheet. Some data will be interpreted by study investigators, and these interpretations will be coded and also entered into the spreadsheet. The data will then be reviewed to be sure that entries make sense and are internally consistent.

9.4. DATA FLOW



10. QUALITY CONTROL AND ASSURANCE

10.1. CONTROL OF DATA CONSISTENCY

Examiners collecting the data will be calibrated and collect data according to the trial protocol.

10.2. AUDITS

Examiners will both examine a small cross-section of participant photographs, to ensure consistency in data.

10.3. PROTOCOL AMENDMENTS

Any proposed amendment to the protocol will seek ethics approval prior to implementation.

11. ETHICS

11.1. INVESTIGATOR AUTHORISATION PROCEDURE

Authorisation required before authorisation is granted to commence recruiting to the study:

- Ethics approval
- Approved versions of the participant information and consent form
- Site approval
- Clinical Trial Notification (CTN)

11.2. PATIENT PROTECTION

The responsible investigator/s will ensure that the study is completed in accordance with the guidelines set out in the *National Statement on Ethical Conduct in Human Research* (2007) (the *National Statement*) and the *CPMP/ICH Note for Guidance on Good Clinical Practice* and any other relevant legislation/guidelines.

All participant data will be de-identified.

12. SAFETY

12.1. ADVERSE EVENT REPORTING

Adverse event (drugs) or an Adverse Drug Reaction are highly unlikely. All materials used are part of routine dental practice and registered with the TGA.

An Adverse Event (Device) is also very unlikely. There is a very low risk that there may be a malfunction of deterioration of the oral irrigator device, in which case a replacement will be offered. There is also a low risk that the participants may cause trauma to the gingiva if either of the tools are used incorrectly; however, they will have been provided with oral hygiene instructions on how to use the tools correctly. If the participant does experience gingival trauma, they should make an appointment to be seen by the researchers at their earliest convenience for advice and treatment.

The CI's commit to adhering to the NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods guidelines.

12.2. SERIOUS ADVERSE EVENT REPORTING

All serious adverse events will be reported immediately to the University, the Health Service and the HREC. The reports will be followed by a detailed written report. Follow-up reports will identify the participant/s by the unique code assigned to participants (rather than by name).

The two interventions are commonly used in routine at-home care, so serious adverse events are highly unlikely. The study is very low risk. Potentially high-risk patients will be screened out during enrolment into the study.

12.3. DATA SAFETY AND MONITORING BOARD (DSMB)

Not applicable - Large multi-centre trials require DSMBs.

12.4. EARLY TERMINATION

In the unlikely case that one or two of the CI's were unable to continue, there is still one CI to continue the project and they can seek amendment to the ethics approval to involve additional researchers.

13. BLINDING AND UNBLINDING

Examiners will be blinded.

Participants will not be blinded as they will be aware of which interproximal cleaning aid they are allocated. They will be randomly allocated by a Project Assistant. The allocations will be kept in spreadsheet separate from the data collection and the Project assistant will blind data after collection, and prior to analysis.

14. CONFIDENTIALITY AND STORAGE AND ARCHIVING OF STUDY

The researchers will have a Research Data Management Plan, and the data storage arrangements in line with the University of Sydney Research Data Management Guidelines. Hard copy files will be scanned, with the electronic copies stored using the University of Sydney OneDrive within Office 365, with access restricted to the researchers. Hard copy files will be destroyed. Study materials will be retained for 5 years after project completion, after which electronic files will be permanently deleted.

15. TRIAL SPONSORSHIP AND FINANCING

The products will be provided free to the University by both companies to support an independent academic study. All other resources are supplied by the University of Sydney

16. INDEMNITY

16.1. COMPENSATION

Reasonable precautions against harms are being taken, using procedures and materials that are already a part of routine dental practice, and devices and materials are approved by the TGA. The risk of harm occurring is extremely low. In the event of harm occurring, the participants will receive professional dental advice and treatment as required, without cost to the participant. No monetary compensation will be provided to participants.

17. REFERENCES

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Van der Weijde, F. & Slot, D. E. (2011) Oral hygiene in the prevention of periodontal diseases: the evidence. Periodontology 2000 55,104–123.

18. APPENDICES

1. Advertisement(s)

2. Participant Information Statement

3. Consent form

4. Questionnaire