

INFORMATION FOR PARTICIPANTS

Interdental Cleaning Comparison Study

Introduction

You are invited to take part in a research study to compare the use of interdental brushes and an oral irrigation device (water flosser) to clean in between your teeth. We wish to investigate using which device will be more effective in removing plaque and reducing signs of inflamed gums. You will be given full oral hygiene instruction and standardised instructions on how to use each implement before you are requested to use them. Your teeth and gums will be checked and cleaned professionally before you use each implement for a period of 4 weeks. The clinical examiners of the study will not know which implement you are using and will check your gum health after using each implement, and at the end of the study. At the end of the study, we will ask you to fill in a brief questionnaire which will only take 5 minutes. We will be seeking your opinion on which device you prefer using and why.

The study is being conducted within this institution by:

- Mr Andrew Terry, Lecturer, School of Dentistry, Faculty of Medicine and Health
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- Dr Melanie Hayes, Senior Lecturer, Faculty of Medicine and Health.
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- Professor Axel Spahr, School of Dentistry, Faculty of Medicine and health
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The study is being undertaken by the University of Sydney and the interdental cleaning aids are being donated free by each company in the interests of pursuing an independent academic, ethics approved study to evaluate the efficacy of their devices. The investigators declare no conflicts of interest. No company will have any commercial, financial or business interests in the study and will not receive any data derived from this study.

Study Procedures

If you agree to participate in this study, you will be asked to sign the Participant Consent Form. You will then be asked to attend for 5 visits. These visits will take place over a 11-week period. Each visit will be approximately 30 – 60 minutes in duration.

Visit 1 – Participant enrolment, study explanation and signing of the consent form to proceed. Receive a full mouth professional cleaning of your teeth and gums to remove any stain/hard deposits above the gumline and dental plaque. We will then make an appointment for you to return in 2 weeks' time.

Visit 2 – We will assess your gum health and plaque levels. Photographs will be taken of your teeth and gums only for record purposes. A research assistant will then randomly assign you either an oral irrigator or interdental brush to clean in between your teeth for the next 4 weeks. They will then provide you individual oral hygiene instructions appropriate to the implement you have been allocated.

Visit 3 – We will again assess your gum health and plaque levels. Photographs will be taken of your teeth and gums only for record purposes. We will then make an appointment for you to return in 2 weeks' time. During these 2 weeks, clean in between your teeth in the same way you did prior to starting this study.

Visit 4 - You will receive a full mouth professional cleaning of your teeth and gums to remove dental plaque only. A research assistant will then provide oral hygiene instructions appropriate to the 2nd implement you have been allocated. You will then be asked to use this implement to clean in between your teeth for the next 4 weeks.

Visit 5 – A final check of your gum health and plaque levels will occur. Photographs will once again be taken of your teeth and gums only for study comparison purposes. Finally, you will then be asked to complete a satisfaction survey so that we can record your thoughts and feelings about both devices. It will take no longer than 5 minutes to complete this written survey. You are invited to keep both devices and use whichever one you prefer, from that point on. You will then be placed back on a regular recall with Sydney Dental Hospital.

In addition, the researchers would like to have access to your medical/dental record to obtain information relevant to this study only.

Risks

All medical procedures - whether for diagnosis or treatment, routine or experimental – involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown and unforeseeable. Despite all precautions, you might develop medical complications from participating in this study.

The risks of participating in this study are very low. Participants receiving a standard tooth cleaning will firstly undergo medical/dental assessments to determine if there are any reasons for exclusion. The risk of a standard dental clean causing harm to healthy individuals is extremely small. A possibility of tooth or gum sensitivity after a standard dental cleaning is very low but if it occurred, the participants would be asked in for immediate consultation. There may be a slight risk of interdental gum bleeding/sensitivity when participants commence regular interdental cleaning. Instructions will be provided to counter this event.

It is important that women participating in this study are not pregnant and do not become pregnant during the study. The reason for this is pregnant women respond

differently to the presence of significant bacterial levels in their mouths and this can affect the outcome of the study results. If at any time you think you may have become pregnant, it is important to let the researchers know immediately.

Benefits

While we intend that this research study furthers medical/dental knowledge and may improve how the recommendations of interdental cleaning are implemented in the future, it may not be of direct benefit to you. You will however receive a free dental check, dental cleaning and will be able to keep both devices you have been given.

Compensation for injuries or complications

If you suffer any dental injuries as a result of this study, you will receive professional dental advice and treatment as required, without any cost.

Costs

Participation in this study will not cost you anything, nor will you be paid.

Voluntary Participation

Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. Whatever your decision, please be assured that it will not affect your medical/dental treatment or your relationship with the staff who are caring for you. You should be aware that data collected up to the time of withdrawal may form part of the research project results. If you do not want them to do this, you must tell the researchers at the time of your withdrawal.

Confidentiality

All the information collected from you for the study will be treated confidentially, and only the researchers named above or listed below will have access to it:

- Ms Sana Ahmad Sindhu – 3rd year Dentistry research student
- Mr Mark Philip Joy Ferrer Suniga – 2nd year Dentistry research student
- Ms Celeste Alana Rhoades – 2nd year Dentistry research student
- Ms Yathu Mahen – 2nd year Dentistry research student
- Mr Fred Zahr – SLHD Dental hygienist

The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in such a presentation.

All data collected will be entered electronically and stored on a research database located on the premises of Sydney Dental Hospital. Only Professor Axel Spahr will have access to this data base. It is hosted and backed up on the Sydney Local Health District (SLHD) servers daily. No personnel other than the researchers will

have access to the research documents. The data will be analysed by the researchers at the Sydney Dental Hospital. All data for use in journal publications and presentations will be de-identified. The files will be retained for 5 years from the day the study is completed. Once this retention expires, the files will be disposed of using the SLHD confidential waste disposal service.

There will no future use of the data for research purposes or sharing or pooling of data with other collaborators. *Waterpik®* are donating oral irrigators for assessment. *Curaprox®* are donating interdental brushes. These companies have no commercial, financial, or business interests in the study and will not receive any data derived from this study.

Further Information

When you have read this information, Mr Andrew Terry, will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact him at Email: a.terry@sydney.edu.au

Ethics Approval and Complaints

The conduct of this study at the Sydney Dental Hospital has been authorized by the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on 02 9515 7899 and quote protocol number 2020/ETH01909

This information sheet is for you to keep