



Cover Letter

04/09/2019

To whomsoever it may concern,

This is to certify that this is the bonafide title of our study- "The Effectiveness of Brushing and Flossing Sequence on Control of Plaque and Gingival Inflammation- A Randomized Controlled Clinical Trial in Klinik Pergigian, MMMC, Melaka." with a NCT number: NCT03989427.

We hereby assure that this was a bonafide study approved by Institutional Ethics and Research Committee of Melaka-Manipal Medical College (MMMC/FOD/AR/B6/E C-2019 (21)). To the best of our knowledge all the information provided in this study is true and is being reported is being reported in compliance with the declaration of Helsinki for clinical trials.

NAME OF RESEARCHERS

Prof. Dr. Rajesh Hosadurga

Prof. Dr. Htoo Htoo Kyaw Soe

Sacha Miriam Augustus

Deevatharshini a/p Jayabalan

Jayahneiswary a/p Ganesan



Participant (Subject) Information sheet & Consent Form

Research title:

The Effectiveness of Brushing and Flossing Sequence on Control Of Plaque and Gingival Inflammation- A Randomized Controlled Clinical Trial In Klinik Pergigian, MMMC, Melaka

Name of Researchers:

Prof. Dr.Rajesh Hosadurga, Prof. Dr. Htoo Htoo Kyaw Soe, Ms. Deevatharshini Jayabalan, Ms.Sacha Miriam Augustus, Ms.Jayahneiswary Ganesan

Brief Introduction to the topic:

Regular oral hygiene is mandatory for dental plaque control. This way, within the available arsenal for controlling supragingival plaque, toothbrush, dental floss, interdental brushes, and end-tufted brushes among others are often used. Toothbrush and toothpaste are the most reliable means of dental plaque control. The reason why the plaque control is most often inadequate is due to limited ability of the toothbrush to reach interdental areas which are more prone for plaque accumulation and inflammation. Various interdental aids such as interdental floss, interdental brush and wooden dental sticks have been used to overcome this problem. According to a systematic review, flossing in addition to tooth brushing is better to reduce gingivitis compared to only tooth brushing. It is possible that the sequence of using toothbrush and dental floss may influence removal of dental plaque and gingival bleeding. Dentifrices produce added benefit to mechanical cleaning.

Purpose of the Study:

To evaluate the efficacy of brushing and flossing sequence on control of plaque and gingival inflammation.

Study Procedures:



1. Intraoral examination of the participants.
2. Subject undergoes oral Prophylaxis
3. Subjects have to abstain from general oral hygiene procedures for 3 days
4. Brushing followed by flossing for 2 weeks with a wash out period for a week, then flossing followed by brushing for 2 weeks with the use of dentifrice
5. Data collection is done after each interval.

Risks

Nil

Benefit of Study:

By participating in this study, the participants can contribute to the data collection which later can be used for oral hygiene care.

Participation in the Study:

Your participation in this study is entirely voluntary. You may refuse to participate in this study or you may stop your participation at any time during this study period.

Queries:

If you have any more clarifications to be made, please contact Miss Deevatharshini at 019-2292995 or email at deejay2995@gmail.com

Confidentiality:

All information will be kept confidential by the researchers and will not be made publicly available unless disclosure is required by law. Data obtained from this study that does not identify you individually may be published or given to the regulatory authorities of some countries. By signing this consent form, you authorize the record review, information storage and data transfer described above.

Signatures:



To be entered into the study, you or a legal representative must sign and date the signature below.

By signing this page, I am confirming that:

1. I have read and understood all the information in this patient information and consent form including any information regarding the risk in this study and I have been provided with time to think about it.
2. All my questions have been answered to my satisfaction.
3. I voluntarily agree to be part of this research study, to follow the study procedures and to provide necessary information to the doctor and other staff members as requested.
4. I may freely choose to stop my participation in this study at any time.
5. I understand that I am not eligible for any monetary benefits by participating in this study.

Participant's Signature & Date

Witness' Signature & Date