

# Cover Letter

08/01/2020

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**

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#### **4.4 Variables and Research Tools**

#### **4.5 Statistical Analysis**

### **CHAPTER 5: RESULTS**

#### **5.1 Descriptive Statistic/Sociodemographic Profiles**

#### **5.2 Table/ Graphs**

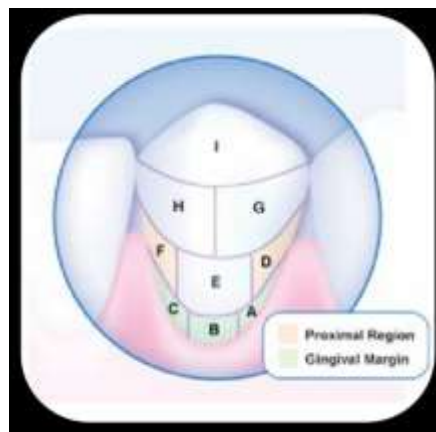
#### **5.3 Inferential Statistic answering the objectives**

## Operational Definitions

### 1. Rustogi Modified Navy Plaque Index(RMNPI):

This index divides buccal and lingual surfaces into nine areas(A to I) that are scored for the presence (score=1) or absence (score=0) of plaque.

Whole mouth=Areas A,B,C,D,E,F,G,H and I; Marginal areas A,B and C; Interdental D and F



Presence of plaque: Score 1

Absence of plaque: Score 0

Buccal surface- 9 areas (A to I)

Lingual surface- 9 areas (A to I)

Interdental - D and F

RMNPI Score=  $(\text{Sum of all "1" marks}) / (\text{Total number of sites score})$

### 2. BPI-Bleeding point index (bleeding point index, BPI; Lenox et al,

**1973)**

Bleeding on probing is recorded and provides evaluation of gingival inflammation around each tooth in patient's mouth.

Evaluates level of oral hygiene performance

A periodontal probe is inserted 1 mm into the sulcus at the buccal, lingual, mesial and distal surfaces

After 20–30s scores will be recorded

0 – No bleeding

1 – Bleeding present

Percentage of BPI =  $(\text{Number of bleeding surface}) / (\text{total number of dental surfaces}) \times 100$

The percentage of the number of bleeding surfaces will be calculated by:

$$\frac{\text{Number of bleeding surface}}{\text{total number of dental surfaces}} \times 100$$

### **List of abbreviation**

FB-Flossing and brushing

BF-Brushing and flossing

BPI-Bleeding point Index

RMNPI-Rustogi modified navy plaque index

DJ- Deevatharshini Jayabalan

SA- Sacha Augustus

JG- Jayahneiswary Ganesan

DHE-Dental Health Education

MMMC- Melaka-Manipal Medical College.

## **Statistical Analysis Plan**

### **Participant Flow Overview**

Protocol Enrolment: 30

Total Started in Participant Flow: 30

Total arms :2

Arm1: Brushing first flossing later (BF)

Arm2: Flossing first Brushing later (FB)

Number of participants per arm :15 each

### **Variables and Research Tools-**

**Independent variables:** age , sex, ethnicity, Academic year , Treatment order

**Dependent variables are :** BPI scores and RMNPI scores.

**Research tools:** We will be using Microsoft Excel for data entry and SPSS version 18 for data analysis. We will calculate change score (Post – Pre) for outcome variables like BPI and RMNPI scores. Descriptive statistics such as mean and standard deviation were calculated the outcome variables

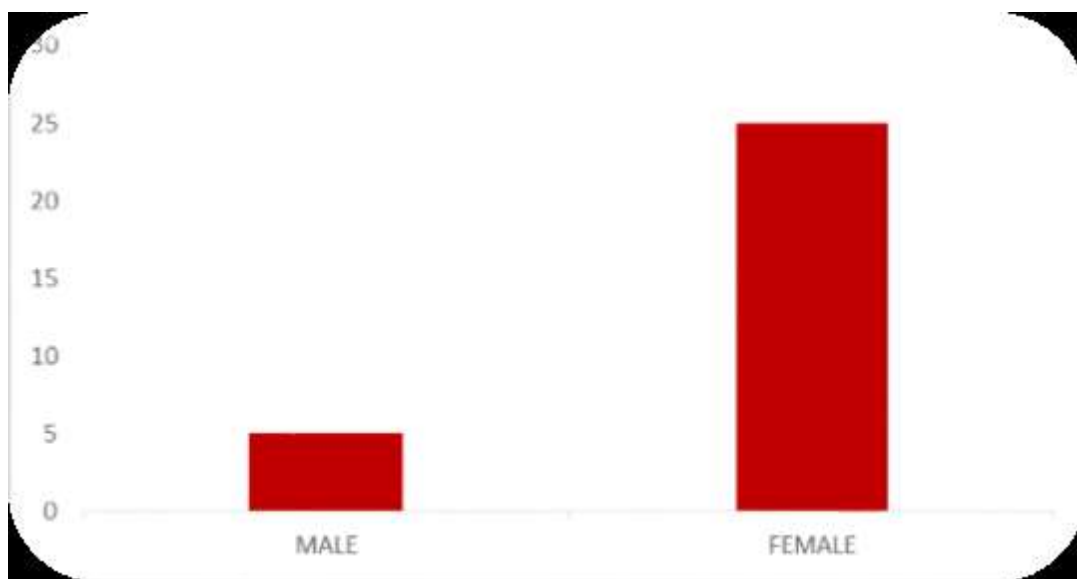
### **Baseline characteristics of the population;**

1. **Age-** continuous data in years
2. **Sex:** Male or female in percentage
3. **Ethicity-** Malay, Chinese, Indians and others in percentage
4. **Academic Year-** Number of participants' year wise.
5. Study specific measurements- change score of BPI and RMNPI index.

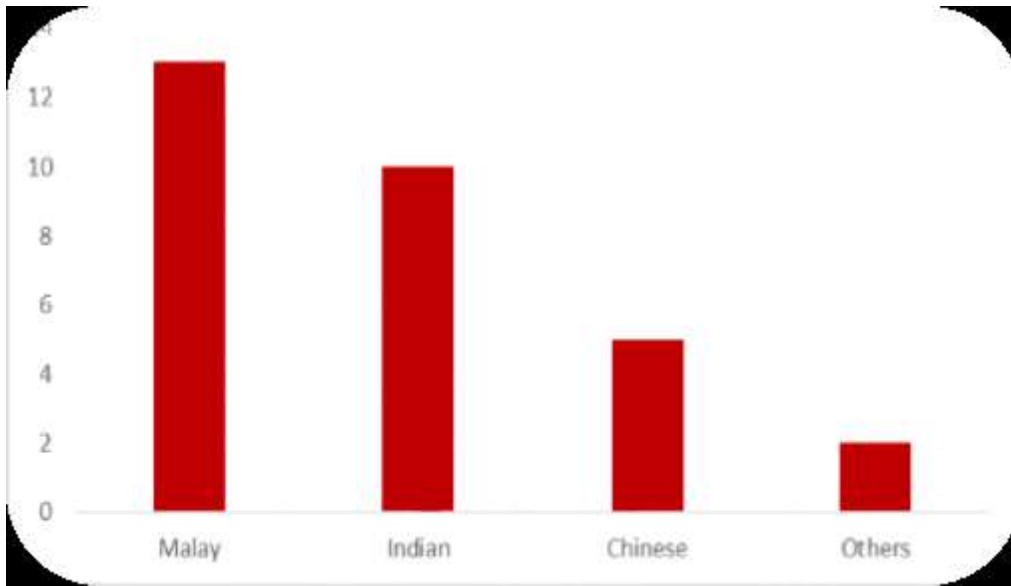
**Inferential statistics:** ANOVA

## Results

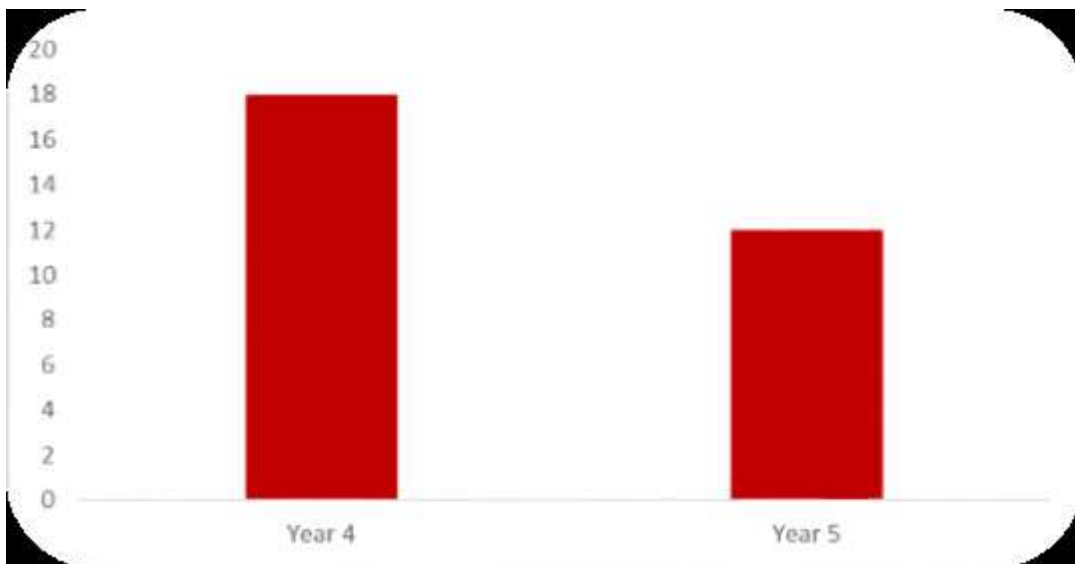
### Sociodemographic Profile



**Fig1 : Gender**



**Fig2: Ethnicity**



**Fig3: Academic Year**

**Table 1:** Descriptive data

<b>Intervention</b>	<b>Mean Difference (SE)</b>
Brush-Floss	-0.015(0.015)
Floss-Brush	

**Three-way mixed ANOVA**

To determine the effect of "Intervention" on "BPI score " is said to be moderated by "order (BF-FB or FB-BF)" and "academic year" combined.

Table 2.1: Interaction between intervention, academic year and order of intervention on BPI score

<b>Interaction</b>	<b>P value</b>
Intervention*Academic year*Order of intervention	0.061
Intervention*Academic year	0.064
Intervention*Order of intervention	0.127
Academic year*Order of intervention	0.938

Table 2.2: BPI change score (Post – Pre) between two Brushing Flossing and Flossing Brushing

	Mean (SE)	Mean difference (95% CI)	P value
Brushing Flossing	0.396 (0.410)	1.424 (0.221, 2.628)	0.022
Flossing Brushing	-1.028 (0.392)		



There was no significant three-way interaction between intervention, academic year and order of intervention. Therefore, we assessed if there was two-way interaction. There were no significant two-way interaction between intervention and order of intervention, academic year and order of intervention, and intervention and academic year.

There was significant difference of BOP between brushing flossing and flossing brushing (P=0.022). Mean change score (Post – Pre) of BOP in brushing flossing was 0.396 while it was -1.028 in flossing brushing.

**Plaque score (RMNPI)**

Table 3.1: Interaction between intervention, academic year and order of intervention on plaque score (RMNPI)

<b>Interaction</b>	<b>P value</b>
Intervention*Academic year*Order of intervention	0.282
Intervention*Academic year	0.050
Intervention*Order of intervention	0.497
Academic year*Order of intervention	0.184

Table 3.2: Plaque (RMNPI) change score (Post – Pre) between two Brushing Flossing and Flossing Brushing

	Mean (SE)	Mean difference (95% CI)	P value
Brushing Flossing	0.042 (1.043)	-0.058 (-3.335, 3.219)	0.971
Flossing Brushing	0.101 (1.427)		

There was no significant three-way interaction between intervention, academic year and order of intervention. Therefore, we assessed if there was two-way interaction. There were no significant two-way interaction between intervention and order of intervention, academic year and order of intervention, and intervention and academic year.

There was no significant difference of plaque score (change from baseline) between brushing flossing and flossing brushing (P=0.971).