

## **PATIENT INFORMATION SHEET**

Please read the following information carefully. Do not hesitate to discuss any questions you may have with your child's doctor.

### **STUDY TITLE**

THE EFFECTIVENESS OF T-SHAPED TOOTHBRUSH ON PLAQUE REMOVAL AND MAINTAINING GINGIVAL HEALTH IN CHILDREN.

### **INTRODUCTION**

Toothbrushing is a mechanical action or method that most people used for tooth cleaning. This method is widely accepted and efficient in maintaining adequate oral hygiene. Children, majority show poor compliance toward brushing due to their ability to use the toothbrush varies greatly not only according to their age, but also to their dexterity, motivation and ability to follow instructions.

Before agreeing to participate in this research study, it is important that you read and understand this form. If your child participate, you will receive a copy of this form to keep for your records.

Your child is invited to take part voluntarily in a research study of effectiveness of a toothbrush. Your child's participation in this study is expected to last up to maximum of three months. Up to 100 patients will be participating in this study.

### **WHAT IS THE PURPOSE OF THIS STUDY?**

The main objectives of this study are to evaluate the effectiveness of T-shaped toothbrush in plaque removal and maintaining healthy gingivae when compared to a conventional manual toothbrush. T-shaped toothbrush is a new toothbrush with innovative T-shaped brush head, which is modelled after the shaver. This toothbrush was invented by Jack Liew Hon Seong (Malaysia) in 2009 after he discovered the tooth decay often occurs at the rear of the teeth that difficult to reach when brush the teeth.

So, the purpose of this study are to determine if, during the 3-months period, brushing with T-shaped toothbrush twice a day when compared to brushing with conventional manual toothbrush twice a day will results in: 1) better plaque score (level of food debris on the tooth surfaces) and, 2) improved gingival health (appearance of the gums).

### **WHAT ARE THE PROCEDURES TO BE FOLLOWED?**

At first visit, if you agree for your child to participate in this study, he/she will have a detailed oral examination. In addition, your child will be interviewed regarding their understanding, knowledge, attitude and practice of about toothbrushing. Your child will be given instructions and demonstration on how to use the toothbrush. Your child will be asked to use the toothbrush for three months duration, twice daily using the provided toothbrush and toothpaste. A detailed oral examination will be done again at the end of 2 weeks, 1 month and 3 months.

Your child will be randomly divided into two treatment groups. One group will use the T-shaped toothbrush and another group will use the conventional manual toothbrush.

### **WHO SHOULD NOT ENTER THE STUDY?**

The doctor in charge of this study or a member of the study staff will discuss with you the requirements for participation in this study. It is important that you are completely truthful with the doctor and staff about your child health history. Your child should not participate in this study if they do not meet all requirements.

Some of the requirements to be in this study are:

- Your child must have normal motor and cognitive development
- Your child must be 8 to 10 years old

Your child cannot participate in this study if:

- Your child has a Medical history
- Your child has history of receiving antibiotic and / or antiseptic therapy in the past 1 month.
- The dentist finds that:
  - Your child have an acute intraoral lesion
  - Your child has an interproximal caries or restorations.
  - Your child has 3 or more extracted teeth in one quadrant.

**WHAT WILL BE THE BENEFITS OF THE STUDY:**

***(a) To your child as a subject?***

Study toothbrush and study procedures will be provided at no cost to your child. Your child may receive information about their oral health from any oral examination and measurements to be done in this study. We hope that the outcome and information regarding this research will be beneficial to future patients/children.

***(b) To the investigator?***

We hope the outcome and information regarding this research will benefit oral health professional in advising children to maintain a good oral hygiene.

**WHAT ARE THE POSSIBLE DRAWBACKS?**

There are no drawbacks by participating this study. However some discomfort may be experienced due to the unfamiliarity of using a new type of toothbrush, but most children should be able to overcome this problem in a short time.

**CAN I REFUSE TO TAKE PART IN THE STUDY?**

Your child's taking part in this study is entirely voluntary. Your child may refuse to take part in the study or your child may stop participation in the study at anytime, without a penalty or loss of benefits to which your child are otherwise entitled. Your child's participation also may be stopped by the study doctor for valid reason without your consent.

**WHO SHALL I CONTACT IF I HAVE ADDITIONAL QUESTIONS DURING THE COURSE OF THE STUDY?**

If you have any question about this study or your child's rights, please contact;

Main and other investigators:

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CONSENT BY PATIENT'S PARENT FOR CLINICAL RESEARCH

*FACULTY OF DENTISTRY, UM, K.L.*

I, ..... Identity Card No. ..... of

*(Name of patient's parent)*

..... hereby agree

*(Address)*

to allow my daughter/son named ..... Identity Card No.

*(Name of Patient)*

..... to participate in the clinical research (clinical examination and questionnaire) specified below:

**Title of Study: THE EFFECTIVENESS OF T-SHAPED TOOTHBRUSH FOR PLAQUE REMOVAL AND GINGIVAL HEALTH IN CHILDREN.**

I have been told about the nature of the clinical research in terms of methodology, possible adverse effects and complications (as per the patient information sheet). After knowing and understanding all the possible advantages and disadvantages of this clinical research, I voluntarily consent of my own child to participate in the clinical research specified above.

I understand that my child can withdraw from this clinical research at any time.

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.....

**Date**

**Signature of Parents**