

## APPENDIX 1

### PATIENT INFORMATION SHEET

Please read the following information carefully, do not hesitate to discuss any questions you may have with your Doctor, Dr. Liuk Ing Wei.

#### **Study Title**

Electromyographic determination of treatment outcome in occlusal splint therapy for temporomandibular disorders.

#### **Introduction**

Many types of pain can happen on the face. Some pain on the face may not be caused by the tooth. One of the ways to stop this kind of pain is by using a splint. A splint is a plastic appliance that you can wear inside the mouth to sleep. In this study, an electric recorder will be used to test how effective the splint is in lessening the pain.

#### **What is the purpose of this study?**

To use the electric recorder to test how effective the splint is in lessening the pain of the face that is not caused by the tooth.

#### **What are the procedures to be followed?**

The following steps will be carried out:

1. Your mouth and face will be examined.
2. A mould of your teeth will be taken to make the splint.
3. Your chewing ability will be tested with the electric recorder, before wearing the splint.
4. Your chewing ability will be tested again with the electric recorder, after wearing the splint.
5. You can go back and wear the splint to sleep for 6 weeks.
6. You can take pain killer whenever necessary to control the pain in the joint.
7. Your mouth and face will be examined for any improvement after 6 weeks.
8. The same test with the electric recorder will be carried out again to test your chewing ability.

#### **Who should not enter the study?**

1. Patients who had received treatment before for this pain.
2. Patients who are wearing false teeth or braces.

#### **What will be the benefits of the study:**

##### **a. to you as a subject?**

To help you find the best way to lessen the pain.

##### **b. to the investigator?**

To study whether the electric recorder is able to test how effective the splint is in lessening the pain.

#### **What are the possible drawbacks?**

There are no drawbacks.

#### **Can I refuse to take part in the study?**

Yes, if you do not wish to take part in this study you may stop at any time during the procedure. However the doctors on duty shall continue to provide you the usual treatment.

#### **Who should I contact if I have additional questions during the course of the study?**

Doctor's name: Dr. Liuk Ing Wei

Tel: 012-2051976 (Office)

03-86568606 (Home)

Supervisor: Prof. Dr. Siar Chong Huat

Tel: 03-79674859 (Office)

012-3553313 (Mobile)

**Ethics Approval: DF OP0304/0016(P)**

**APPENDIX 2**

**CONSENT BY PATIENT FOR CLINICAL RESEARCH** *FACULTY OF DENTISTRY, UNIVERSITY OF MALAYA, KUALA LUMPUR*

I, ..... Identity card no .....  
*(Name of patient)*  
of  
.....  
*(Address)*

hereby agree to take part in the clinical research ( clinical study ) specified below :  
**Title of study : Electromyographic determination of treatment outcome in occlusal splint therapy for temporomandibular disorders**

the nature and purpose of which has been explained to me by Dr.....  
*(Name & designation of doctor)*  
and interpreted by ..... to the best of his/her ability in .....  
*(Name & designation of interpreter )*  
language/dialect.

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 free will to participate in the clinical research specified above.

I understand that I can withdraw from this clinical research at any time without assigning any reason whatsoever and in such a situation shall not be denied the benefits of usual treatment by the attending doctors.

Date ..... Signature or thumbprint .....  
*(Patient)*

**IN THE PRESENCE OF**

Name .....

Identity card no ..... Signature .....  
*(Witness for signature of patient)*

Designation .....

I confirm that I have explained to the patient the nature and purpose of the above mentioned clinical research.

Date ..... Signature .....  
*(Attending doctor)*

**CONSENT BY PATIENT  
FOR  
CLINICAL RESEARCH**

R.N.  
Name  
Sex  
Age  
Unit

### APPENDIX 3

#### CONSENT BY RESPONSIBLE RELATIVE FOR CLINICAL RESEARCH FACULTY OF DENTISTRY, UNIVERSITY OF MALAYA, KUALA LUMPUR

I, ..... Identity card no .....  
(Name)  
of  
.....  
(Address)

hereby agree that my relative ..... I.C.no .....to  
participate in the clinical research ( clinical study ) specified below :  
**Title of study : Electromyographic determination of treatment outcome in occlusal splint therapy for temporomandibular disorders**

the nature and purpose of which has been explained to me by Dr.....  
(Name & designation of doctor)  
and interpreted by ..... to the best of his/her ability in .....  
(Name & designation of interpreter)  
language/dialect.

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 free will to participate in the clinical research specified above.

I understand that I can withdraw from this clinical research at any time without assigning any reason whatsoever and in such a situation shall not be denied the benefits of usual treatment by the attending doctors.

Date ..... Relationship to patient .....  
Signature or thumbprint .....

**IN THE PRESENCE OF**

Name .....,  
Identity card no ..... Signature .....  
(Witness for signature of patient)  
Designation .....

I confirm that I have explained to the patient the nature and purpose of the above mentioned clinical research.

Date ..... Signature .....  
(Attending doctor)

**CONSENT BY PATIENT  
FOR  
CLINICAL RESEARCH**

R.N.  
Name  
Sex  
Age  
Unit

## APPENDIX 4

### Patient Examination Form

Name : \_\_\_\_\_ Date: \_\_\_\_\_ Subject No.: \_\_\_\_\_

Registration No. : \_\_\_\_\_ Identity Card No. : \_\_\_\_\_

Telephone No. (Office) : \_\_\_\_\_  
(Home) : \_\_\_\_\_  
(Mobile) : \_\_\_\_\_

Address : \_\_\_\_\_  
\_\_\_\_\_

Email Address: \_\_\_\_\_

Date of Birth : \_\_-\_\_-19\_\_ Age: \_\_\_\_

Gender : Male / Female

Race : Malay / Chinese / Indian / Others: \_\_\_\_\_

Religion : Muslim / Christian / Buddhist / Hindu / Others: \_\_\_\_\_

Marital Status: Single / Married / Divorced / Widowed No. of Children: \_\_\_\_

Education Level: Standard 6 / Form 3 / Form 5 / Diploma / Degree and higher

Occupation: \_\_\_\_\_ (Professional/ Skilful/ Semi-skilful/ Unskilful/ Student)

Comment of negative for Study /Job /Family /Friendship/ Environment/ Others: \_\_\_\_\_  
\_\_\_\_\_ such as stressful, busy, tiring, noisy, boring, hard living, conflict and others:  
\_\_\_\_\_

Level of income per month (RM): 0-1,000  
1,001-2,000  
2,001-3,000  
3,001-5,000  
>5000

No of dependent: \_\_\_\_

**APPENDIX 4, continued**

**A) Complain and History:**

1. Complaint:

\_\_\_\_\_

2. Date of pain onset: \_\_/\_\_\_\_ duration up to today: \_\_\_\_months / years

3. Persistency of pain: on & off / persistent

4. Time of having pain: waking /morning /afternoon / evening /night / whole day

5. Frequency of pain episodes: \_\_\_\_\_time(s)/ \_\_\_\_\_month /year

6. Severity of Pain

a) At rest

Right											Right										
Muscle						Joint					Muscle						Joint				
0	1	2	3	4	5	6	7	8	9	10*	0	1	2	3	4	5	6	7	8	9	10

b) During function: eating /talking / wide opening/ others: \_\_\_\_\_

Right											Right										
Muscle						Joint					Muscle						Joint				
0	1	2	3	4	5	6	7	8	9	10*	0	1	2	3	4	5	6	7	8	9	10

\* Scale of pain: 0-no pain, 10-pain as bad as could be

7. Pain relieving factor:

\_\_\_\_\_

8. Pain contributing factor:

\_\_\_\_\_

9. History of injury of masticatory system:

\_\_\_\_\_

10. History of rheumatoid arthritis/ osteoarthritis/ systemic lupus erythematosus/ other

medical condition:

\_\_\_\_\_