UNIVERSITI MALAYA
PUSAT PERGIGIAN

PARTICIPANT INFORMATION SHEET

Please read the following information carefully. We will be glad to assist you with any questions you may have throughout this study.

Study Title

Cross-Cultural Adaptation of a Betel Quid Cessation Program and Evaluation of Its Effectiveness in A Malaysian High-Risk Community

Introduction

Betel quid chewing is known as one of the most common causes of oral cancers in Malaysia (OHD, 2018) and more than 50% of the patients present at the later stage of the disease which is at Stage III and IV. Besides oral cancer, chewing betel quid too can result in many other diseases such as submucous fibrosis, periodontal disease, malnutrition, gastric ulcer, hypertension, coronary artery spasm, poor quality of blood, difficulty of breathing, placental damage, preterm birth and many more.

Betel quid chewing habit was also recognised by the World Health Organisation (WHO, 2010) to be a habit that binds the chewers with a dependency syndrome. Hence, spontaneous withdrawal or cessation of the habit might not be possible or achievable by just a few brief advises. Thus, a cessation program is highly required. Through a cessation program, participants (chewers) will be given adequate knowledge and awareness and be guided how to quit this behaviour gradually and successfully.

Till to date, there is no cessation program developed or adapted for the betel quid chewers in Malaysia. Thus, it is timely for Malaysia to adapt a cessation program for the high-risk groups in Malaysia to help them change their behaviour and achieve a healthier life.

What is the purpose of this study?

This is an experimental research study. The aim of this study is to cross-culturally adapt a betel quid cessation program for a Malaysian high-risk community and to evaluate the effectiveness of the adapted program using a combination of self- reported outcomes and salivary biomarkers measurements.

What are the procedures to be followed?

1) You will be required to complete a set of questionnaires. You will be guided by an interviewer to complete it. The questionnaire will comprise of:
   a) Demographic details
   b) Composition of betel quid chewed, current chewing behaviour and chewing history
   c) Reason(s) for betel quid chewing
   d) Betel quid dependency level
   e) Readiness to quit chewing habit
   f) Self-perceived barriers to quit chewing habit

2) You will be required to join 2-5 sessions within 21 days based on your allotted appointment schedules and followed up after 3 months.

3) You will be required to provide a sample of your saliva at the end of few sessions for chemical testing. Around 1-2mL of your saliva sample will be collected in a 20 mL, conical shape tubes via passive drool method which will later be stored in an insulated cooler box.

4) No intra-oral clinical examination will be carried out in this study.

Who should not enter the study?

1) Non-Malaysian citizen
2) Those who cannot read or write in Malay or Bajau
3) Participants below 18 years old
4) Participants who are not willing to quit betel quid chewing habit during the time of study
5) Women who are pregnant or nursing at the time of study
6) Individuals with psychiatric illness or special social situations that would limit their compliance with study requirements

A total of 92 participants are needed for this study. The study will be conducted within the month of April until December 2023 but participants are only required to attend the session based on appointment dates given.

What will be the benefits of the study?

(a) To participant?

You will be able to increase your knowledge and awareness towards betel quid chewing habit and be able to cease the habit. By an early cessation, the negative effects of betel quid chewing on health can be prevented and participants can lead a healthier life. A monetary token of RM20-RM50 will be given to participants that comply and attend to all study visits.

(b) To the investigator

The investigators will be able to introduce a cessation program that will benefit the high-risk communities in Malaysia. This cessation program can later be utilised by the stakeholders in the Ministry of Health (MOH), Malaysia to cater for other high-risk populations in Malaysia.

(c) **What are the possible risks / complications / adverse effects that may happen?**

There is no risk or drawback associated in participating with this study.

Complaints on unethical conduct can be forwarded to Faculty of Dentistry Medical Ethics Committee (FDMEC), UM at 03-79676460 or via email to ethics_dental@um.edu.my.

Can I refuse to take part in the study?
Your participation is totally voluntary. You can choose to refuse to participate in this study and your refusal will be treated with respect. It will not affect any medical or dental services that you are entitled in the public hospitals or clinics.

Who will have access to my research data, and will it be kept confidentially?
Only principal investigator and co-investigators will have access to participant's research data.
All research data will be kept in the researchers' laptop and their cloud account. Extra measures will be taken to keep the hardcopy data safe and confidential in the researcher's locker in the Department's room.

What will happen to the results of the research study?
Research findings would be disseminated through academic papers, conference presentations or other means. Extra care would be taken to anonymize any identifiable information prior to dissemination. Study findings will be shared with participants upon request.

Who shall I contact if I have additional questions/complications during the course of the study?

(1) Investigator's Name: Dr. Mary Melissa A/P Sarimuthu
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CONSENT BY PARTICIPANT FOR RESEARCH
FACULTY OF DENTISTRY, UM, K.L.

I, …… Identity Card No ……
(Name of participant)

of ……
(Address)
hereby agree to take part in the research specified below:

Title of Study:

Cross-Cultural Adaptation of a Betel Quid Cessation Program and Evaluation of Its Effectiveness in A Malaysian High-Risk Community

The nature and purpose of the research has been explained to me by ……
(*Name & designation of doctor*)
and interpreted (when necessary) by ……..... to the best of his/her ability
(*Name & designation*)
in …… (*specify language*). After knowing and understanding all the possible advantages and disadvantages of this research, I voluntarily consent of my own free will to participate.

I understand that I can withdraw from this research at any time without assigning my reason whatsoever.

Signature …… Date ……
(*Participant*)

IN THE PRESENCE OF

Name ……,

I/C No. ……., Position ……...

Signature …… Date .....
(Witness for signature of participant)

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

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

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