



## INFORMATION SHEET

Study Title:	Effectiveness of a Structured Group-Based Intervention “Know Your Medicine – Take It For Health” (KYM-TIFH) in Improving Medication Adherence among Malay Patients with Underlying Type 2 Diabetes Mellitus in the Sarawak State of Malaysia: A Randomized Controlled Trial ( <b>MedAdh-RCT</b> )
Protocol No.:	NCT03228706 / NMRR-17-925-35875
Sponsor:	Pharmaceutical Service Division, Sarawak State Health Department
Investigator Name:	Ting Chuo Yew/Abu Hassan Alshaari Abd Jabar/Loo Shing Chyi
Investigator Contact No.	016-8605496 / 016-8783133 / 010-3666933

### Respondent’s Information:

Name:	
Telephone No.:	
Address:	
Identity Card Number:	

### Introduction

You have been invited to take part in a research study to examine the effectiveness of a group based intervention in improving medication adherence among Malay patients with underlying Type 2 Diabetes Mellitus in Sarawak State of Malaysia.

The outcome of this study will be used to evaluate the effectiveness of the existing group based intervention under the “Know Your Medicine” campaign in improving medication adherence with an aim to apply the intervention to larger population particularly Malay patients with underlying Type 2 Diabetes Mellitus.

This information sheet gives you a detailed description of this study and will help you to decide if you would like to participate. Please read this sheet thoroughly and ask any questions that may occur to you. Participation in this research is voluntary.

This study has been registered with National Medical Research Register (NMRR) and approved by the Medical Research and Ethics Committee (MREC) of Malaysia. Notably, any change relevant to the consent will be informed through phone call. Besides, any future research will also need to be registered with NMRR and approved by MREC.

**Q1: What is the study about?**

This is an experimental study, which aims to examine the effectiveness of a group based intervention in improving medication adherence among Malay patients with underlying Type 2 Diabetes Mellitus in Sarawak State of Malaysia. The study is being conducted in both Health Clinic Petra Jaya and Health Clinic Kota Samarahan which provide healthcare services to most Malay patients in Sarawak State of Malaysia. Approximately 442 respondents from both Health Clinics will be participating in this study. Your profile details will be taken with strict confidentiality.

**Q2: What will happen when you agree to participate?**

*Before the program:*

If you agree to take part in this study, the researcher will obtain written consent from you. After that, you will be invited to attend a program which will be held at Health Clinic Kota Samarahan during 17-21 July 2017 and Health Clinic Petra Jaya during 24-28 July 2017. You may choose the date that you prefer to attend and you are acquired to present on the date that you had chosen. However, any change of your preference before the program must be informed to the investigators.

As this is an experimental study, you should be aware that you could be assigned to either intervention group or controlled group. Only participants who are assigned to intervention group will have to attend a program that last for 3 hours, while participants who are assigned to controlled group will only have to answer questionnaires related to this study which would last for 1 hour. However, both researchers and participants would not be aware of the actual participants who will be assigned to intervention group or controlled group before the program because the random assignment will be carried out by third party.

*During the program:*

On the day of the program, you will need to register yourself at outpatient pharmacy department of the health clinic Petra Jaya or Kota Samarahan. After registration, you will be informed about the actual location of the program that you will attend. One of the location will be the venue for intervention group while the other one for controlled group. Participants assigned to intervention group will attend the KYM-TIFH program which will take approximately 2.5 hours. Following the program, you will be asked to spend approximately 20 minutes to complete a questionnaire. On the other hand, participants assigned to controlled group will be asked to spend approximately 30 minutes to answer questionnaires related to this study.

*After the program:*

After one (1), three (3), six (6) and twelve (12) months of the program, participants from both groups will be interviewed for approximately 5 minutes through phone call about your medication adherence behaviour.

**Q3: Are there any risks?**

Since there is no clinical intervention or invasive procedure involved for this study, thus no risks on your health would arise.



**Q4: Are there any benefits?**

The outcome of this study will be used to evaluate the effectiveness of the existing group based intervention in improving medication adherence with an aim to apply the intervention to larger population particularly Malay patients with underlying Type 2 Diabetes Mellitus. However, the results of this study will not be informed to you individually as it only aimed to be translated into practical implications.

**Q5: What if you do not want to take part, and when can you leave the study?**

Your participation in this study is voluntary and it is entirely your decision. You can choose to leave the study at any time. Having agreed to participate and having signed the inform consent form, if you change your mind, your choice will be respected. However, you should inform the researcher about the reason behind your decision to withdraw.

**Q6: What is the cost of the study?**

You do not need to pay and will not be paid for taking part in this study.

**Q7: Will the information and your identity remain confidential?**

You will be given an identification code to maintain confidentiality of your data. All the results of this study will be treated in complete confidence to the extent permitted by law. All the data are restricted to the principal investigators and solely used for research purposes. The findings of analysis will be reviewed by the study investigators of the Pharmaceutical Service Division, Sarawak State Health Department. The confidentiality of your identification and information will always be protected. Your identification and information will not be used for other purpose or by other parties without your consent.

**Q8: How will my personal data be used?**

None of your personal data will be recorded for the purpose of this study.

**Q9: What if you have more questions or do not understand something?**

If during the course of this study, you or your relatives have any questions about the study please contact our principal investigator.

Mr Ting Chuo Yew

at 0168605496 or [tc.yew@moh.gov.my](mailto:tc.yew@moh.gov.my)



## INFORMED CONSENT FORM

### PARTICIPANT COPY

#### STUDY TITLE

Effectiveness of a Structured Group-Based Intervention “Know Your Medicine – Take It For Health” (KYM-TIFH) in Improving Medication Adherence among Malay Patients with Underlying Type 2 Diabetes Mellitus in the Sarawak State of Malaysia: A Cluster Randomized Controlled Trial (**MedAdh-RCT**) (**Protocol Number:** )

#### CERTIFICATION BY INVESTIGATOR

I, being the researcher, confirm that I have fully explained the nature, purpose and reasonably foreseeable risks of taking part in this study to the participants or legal representative. He/she has read and kept a copy of the Information Sheet and signed the Informed Consent Form. He/she has freely agreed to participate in the study.

\_\_\_\_\_  
Name of Investigator

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date

#### CONSENT BY PARTICIPANT

I have read and understood the Information Sheet about this research and have been given the chance to ask any questions. I understand and accept the answers that have been given.

I confirm that I have been given enough time to think about and have freely agreed to take part in this research and know that I can at any time, ask for more information from the pharmacist and doctor, and cease to participate in the research without affecting my health status in any way.

I also understand that should I decide to stop taking part in this study, I do not need to give any reason why. In this case I must report the details to the pharmacist.

Finally, I agree to participate in the research and to closely follow the instructions I am given. I have received a copy of the Information Sheet and Informed Consent Form.

\_\_\_\_\_  
Name of Study Participant

\_\_\_\_\_  
Signature of Study Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Identification Card Number

#### IF REQUIRED IMPARTIAL WITNESS

\_\_\_\_\_  
Name of Witness

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date

\_\_\_\_\_  
Identification Card Number of Witness



## INFORMED CONSENT FORM

FACILITY COPY

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Signature of Study Participant

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Name of Witness

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Signature of Witness

\_\_\_\_\_  
Date

\_\_\_\_\_  
Identification Card Number of Witness