NMRR-22-02409-ODX

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OFFICIAL TITLE

A Randomised Controlled Trial to Compare MedBook Portal and Standard Care in Medication Reconciliation at Transitions of Care from Hospital Discharge to Primary Healthcare Settings

PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM

(for adult subjects and interventional studies)

1. **Title of study**:
   A Randomized Controlled Trial to Compare MedBook Portal and Standard Care in Medication Reconciliation at Transitions of Care from Hospital Discharge to Primary Healthcare Settings

2. **Name of investigator and institution:**
   Phang Yen Yen, Pharmaceutical Services Division, Sarawak State Health Department.
   Professor Dr. Kuan Jew Win, Faculty of Medicine and Health Sciences, Universiti Malaysia Sarawak

3. **Name of sponsor**:
   Pharmaceutical Services Division, Sarawak State Health Department.

4. **Introduction:**
   You are invited to participate in a research study because you will be discharged and will be referred to the health clinics for follow up treatment. The details of the research trial are described in this document. It is important that you understand why the research is being done and what it will involve. Please take your time to read through and consider this information carefully before you decide if you are willing to participate. Ask the study staff if anything is unclear or if you like more information. After you are properly satisfied that you understand this study, and that you wish to participate, you must sign this informed consent form.

   Your participation in this study is voluntary. You do not have to be in this study if you do not want to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are otherwise entitled.

   This study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

5. **What is the purpose of the study?**
   The purpose of this study is to examine the effectiveness of an intervention, named as MedBook Portal, in reducing medication discrepancies upon transition of care from hospitals to health clinics. MedBook portal is a webpage that enable sharing of patient medication profile among healthcare facilities under Ministry of Health. MedBook Portal aims to promote medication and patient safety.

   A total of 386 subjects like you from the four public hospitals will be participating in this study. The four hospitals are Sarawak General Hospital, Sibu Hospital, Sarikei Hospital and Miri Hospital. The subjects will be discharged and referred to the ten public primary health clinics, namely, Batu Kawa Health Clinic, Kota Sentosa Health Clinic, Kota Samarahan Health Clinic, Jalan Oya Health Clinic, Lanang Health Clinic, Sibu Jaya Health Clinic, Miri Health Clinic, Tudan Health Clinic, Sarikei Health Clinic and Bintangor Health Clinic.

The whole study will last about 6 months and your participation will be about 1 week to 2 months depending on your appointment date at the health clinic.

6. What kind of study products will I receive?

If you agree to participate in the study, you will be randomly (by chance, like flipping a coin) assigned to one of the treatment groups below. You have equal chance of being assigned to each of the groups.

Group 1:
Your discharge prescription will be uploaded to MedBook Portal which will be accessed by your healthcare providers at the health clinic. MedBook Portal Notice will be attached on your home-based medical card.
After discharge from hospital, you are required to follow at health clinic according to the appointment date. This would be the first follow-up at the health clinic after discharge from hospital. During this appointment, you shall bring over your home-based medical card with the MedBook Portal Notice attached and any documents that are informed by the hospital or health clinic to your doctor and pharmacist. Your doctor will review your case based on your discharge prescription in MedBook Portal, your previous medical record in the home-based medical card and any documents handed over to he or she. Your doctor and pharmacist will conduct medication reconciliation by comparing the discharge prescription in MedBook Portal against the new prescription prepared at the health clinic.

Group 2:
You will be given usual care, in which there is no MedBook Portal and no MedBook Portal Notice provided.
After discharge from hospital, you are required to follow at health clinic according to the appointment date. This would be the first follow-up at the health clinic after discharge from hospital. During this appointment, you shall bring over your home-based medical card and any documents that are informed by the hospital or health clinic to your doctor and pharmacist. Your doctor will review your case based on your previous medical record in the home-based medical card and any documents handed over to he or she.

In order to examine the effectivenss of MedBook Portal, the investigator will compare the percentage of prescription with medication discrepancies between both group using statistical tools.

7. What will happen if I decide to take part?

You will have to attend the first follow-up at health clinic You will be contacted by the investigator via WhatsApp or phone call to remind you on the follow up date at health clinic. Investigator will contact you via the telephone number 082-473200 or 01129060439.

8. What are my responsibilities when taking part in this study?

It is important that you answer all of the questions asked by the study staff honestly and completely. If your condition or circumstances change during the study, you must tell the investigator. You shall bring over your home-based medical card and any documents that are informed by the hospital or health clinic to your doctor and pharmacist during the first appointment at the health clinic after discharge from the hospital. Your participation in this study shall end after the appointment. You will not be paid for participating in this study and you will continue with the follow-up treatment as usual. There will be no additional cost incurred to you to participate in this study.

9. What are the benefits of being in this study?

There may or may not be any benefits to you. Information obtained from this study will help improve the management of other patients with the same condition.

10. What are the potential risks and side effects of being in this study?

Participation in this study will not possess any potential risk, as this study does not involve any invasive procedure. The investigator will inform you in a timely manner about any new findings or changes about the study. Where necessary, you may be asked to reconsent to participate.

11. What are my alternatives if I do not participate in this study?

You do not have to participate in this study to get treatment for your disease or condition. You will be treated according to the usual care as per mentioned in point no.6 (group 2).

12. Can the research or my participation be terminated early?

The sponsor may stop the study or your participation at any time. If the study is stopped early for any reason you will be informed.

13. Will my medical information be kept private?

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and in your medical care, or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary.

Data from the study may be archived for the purpose of analysis, but your identity will not be revealed at any time. You will not be informed of the study findings.

14. Who should I call if I have questions?

If you have any questions about the study, please contact the investigator, Mdm Phang Yen Yen at telephone number 01129060439.

If you have any questions about your rights as a participant in this study, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-3362 8407 / 8205 / 8888.

INFORMED CONSENT FORM

Title of Study: A Randomized Controlled Trial to Compare MedBook Portal and Standard Care in Medication Reconciliation at Transitions of Care from Hospital Discharge to Primary Healthcare Settings

By signing below I confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary and I can at anytime free withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the investigator's instructions related to my participation in the study.
- I understand that study staff, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.
- I agree/disagree* for my family doctor to be informed of my participation in this study. *(*delete which is not applicable)*

Subject:

Signature: I/C number:

Name: Date:

Investigator conducting informed consent:

Signature: I/C number:

Name: Date:

Impartial witness: *(Required if subject is illiterate and contents of patient information sheet is orally communicated to subject)*

Signature: I/C number:

Name: Date: