PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Bilingual prescription medication labels

STUDY INFORMATION

Protocol Title:

The impact of bilingual prescription medication labels on medication adherence and medication management self-efficacy among elderly Singaporeans: A pilot study

Principal Investigator:

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Sponsor:

Population-based, Unified, Learning System for Enhanced and Sustainable Health Centre Grant (PULSES CG)

PURPOSE OF THE RESEARCH STUDY

You are being invited to participate in a research study. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the consent form. You will be given a copy of this document to take home with you.

The purpose of this study is to improve the medication labels provided on medication packets or bottles in Singapore. We would like to understand if provision of medication labels in a preferred language (in addition to English) improves medication taking as well as understanding of medication labels among patients.

You are selected as a potential participant for this study because you are a Singapore citizen or permanent resident aged ≥50 years who has just been given a new oral medication for your chronic disease by your doctor here at Singapore General Hospital. This study will recruit a total of 40 participants from Singapore General Hospital.

STUDY PROCEDURES AND VISIT SCHEDULE

If you agree to take part in this study, you will be first asked to respond to a survey questionnaire in your preferred language. In the survey, you will be asked a series of questions about yourself as well as how you take your medications. Then, you will be randomly assigned (similar to a coin toss) to either Study Group A or Study Group B.

If you are assigned to Study Group A

- Your participation will be for 4 weeks, starting today, followed by bi-weekly phone call interviews.
- Today, your new oral medication will be given to you in Rx Cap™ bottles, which will provide us information on how you take the new medication, such as the number of times the bottle is opened, and the time of opening. Your medication label will be provided in English, the usual practice at Singapore General Hospital.
- Then, you can expect a total of 2 phone calls by our study staff. Each call requires about 30 to 45 mins. The study staff will call you to set up an appointment with you prior to each phone call.
- The timing and purpose of the 2 calls is:
  - End of week 2 – To administer a survey questionnaire. You will then be randomly assigned (similar to a coin toss) to either continue using the English medication label, or to receive a bilingual medication label of your new medication label of your new medication (written in English and your preferred language). The study staff will conduct a home visit to collect information from your Rx Cap™ bottles, You will receive $10 worth of shopping vouchers as a token of appreciation.
  - End of week 4 – To administer a survey questionnaire. The study staff will conduct a home visit to collect information from your Rx Cap™ bottles. You will receive $10 worth of shopping vouchers as a token of appreciation.

If you are assigned to Study Group B

- Your participation will be for 2 weeks, starting today, followed by a phone call interview.
- Today, your new oral medication will be given to you in Rx Cap™ bottles, which will provide us information on how you take the new medication, such as the number of the bottle is opened, and the time of opening. The medication label of your new medication will be either in your preferred language as well as in English or only in English, the usual practice at Singapore General Hospital. The type of label you receive will be randomly assigned (similar to a coin toss).
- Then, you can expect a total of 1 phone call interview by our study staff. Each phone call requires about 30 to 60 mins. The study staff will call you to set up an appointment with you prior to each phone call.
- The timing and purpose of the phone call is:
  - End of week 2 – To administer a survey questionnaire. The study staff will conduct a home visit to collect information from your Rx Cap™ bottle, and administer a survey questionnaire. You will receive $20 worth of shopping vouchers as a token of appreciation.

Throughout this study, private personal information, such as education level and job status, may be collected. You may refuse to answer any question if you feel uncomfortable. Your research data collected during the study may be kept for future research beyond completion of this study. For this purpose, consent for future research will be sought.

YOUR RESPONSIBILITIES IN THIS STUDY

If you agree to participate in this study, you should:

- Follow the advice given to you by the study staff.
- Keep your home visit appointments. If it is necessary for you to miss the appointment, please contact the study staff to reschedule as soon as you know you will miss it.
- To return the Rx Cap™ bottles when your participation ends.

WHAT IS NOT STANDARD CARE OR EXPERIMENTAL IN THIS STUDY

The study is being conducted to determine if provision of medication labels in a preferred language can improve medication taking as well as understanding of medication labels among patients. Such labels, in your preferred language, are not part of your routine care. The survey questionnaire administered and provision of medicine in Rx Cap™ bottles are also for the purpose of research, and are not part of your routine care. At the end of the participation period, the usual English medication labels will be provided to all participants, and the Rx Cap™ bottles will be taken back and your medicine will be provided in the usual SGH Ziploc or pill bottles.

POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES

Possible risks may include a potential breach of confidentiality. However, steps will be taken to ensure protection of your data. Participants may experience tiredness during or after answering the survey questions. If you feel tired, do let the study staff know and you will be allowed to take a short break.

In line with the current COVID-19 restrictions, part of the survey questions will be conducted via telephone interview(s). The study staff will then conduct a home visit to complete the remainder of the questionnaire, and collect data from your Rx Cap™ bottle. Each home visit will be limited to 20 minutes to keep you and our study staff safe.

POTENTIAL BENEFITS

There is no assurance you will benefit from this study, but the knowledge to be gained from the study will benefit the public in the future. As Singapore's population is ageing rapidly, the information you provide us may help policymakers and healthcare administrators to improve medication labels for elderly Singaporeans.

COSTS OF PARTICIPATION

Since your visit today to Singapore General Hospital is part of your routine medical care, you will be responsible for the cost of the doctor consultation and any other related costs, including medication costs (which includes the new oral medication we will give to you in Rx Cap™ bottles), that you incur during your hospital visit.

No extra costs will be incurred from participating in this study. The cost of Rx Cap™ bottles and study labels will not be incurred by you as well.

If you complete the study, you will receive a total of $20 worth of shopping vouchers as a token of appreciation. The vouchers will be handed to you during the home visits as per the following schedule:

<u>If you are assigned to Study Group A</u>
End of week 2: $10

End of week 4: $10

If you are assigned to Study Group B
End of week 2: $20

PARTICIPANT'S RIGHTS

Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you will be informed in a timely manner by the Principal Investigator or his/her representative and will be contacted for further consent if required.

By signing and participating in the study, you do not waive any of your legal rights to revoke your consent and withdraw from the study at any time.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation at any time without prejudice to you or effect on your medical care. If you decide to stop taking part in this study, you should tell the Principal Investigator.

You may also be withdrawn from the study if your new oral medication is stopped due to any reason, or if you experience unbearable adverse effects from the new medication, or in the event of death.

However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

Your doctor, the Principal Investigator and/or the Sponsor of this study may stop your participation in the study at any time for one or more of the following reasons:

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- The Principal Investigator decides that continuing your participation could be harmful.
- The study is cancelled.

RESEARCH RELATED INJURY AND COMPENSATION

If you follow the directions of the Principal Investigator of this research study and you are injured due to the research procedure given under the plan for the research study, our institution will provide you with the appropriate medical treatment.

Payment for management of the normally expected consequences of your treatment will not be provided by Singapore General Hospital.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Your participation in the study will involve the collection of Personal Data. Personal Data collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Only your Investigator(s) will have

access to the confidential information being collected.

However, Regulatory Agencies, Institutional Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of your information public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by Singapore General Hospital, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties.

"Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organization has or likely to have access. Examples of personal data include medical conditions, medications, investigations and treatment history.

Research arising in the future, based on this "Personal Data", will be subject to review by the relevant institutional review board.

Data collected and entered into the Data Collection Form(s) are the property of Singapore General Hospital and Duke-NUS Medical School. In the event of any publication regarding this study, your identity will remain confidential.

By participating in this research study, you are confirming that you have read, understood and consent to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

If you have questions about this research study or in the case of any injuries during the course of this study, you may contact the Principal Investigator:

Principal Investigator
Dr Khee Giat Yeng
SGH Outpatient Pharmacy: 6321 4110

Associate Clinical Research Coordinator
Ms Jasmine Owyong
SGH Outpatient Pharmacy：9689 2362

WHO HAS REVIEWED THE STUDY

This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

If you have questions about your rights as a participant, you can call the SingHealth Centralised Institutional Review Board at 6323 7515 during office hours (8:30 am to 5:30pm).

If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

CONSENT FORM
SURVEY OF PATIENTS (BILINGUAL PRESCRIPTION MEDICATION LABELS)

Details of Research Study

Protocol Title:
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I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet.

I have fully discussed and understood the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to ask questions about this study and have received satisfactory answers and information.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected.

By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

Consent for the Use of Data for Future Research

Please indicate your options by indicating a tick (√) on the checkboxes:	**Yes**	**No**
Do you consent for your data to be used for future research?	☐	☐
Note: If you answer "Yes" to the above, please also indicate your consent for the followings: *:*		
Do you agree for the data to be transferred outside of Singapore for future research?	☐	☐

_____	_____	_____
Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The study has been explained to the participant in

_____by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this informed consent form had the study fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative giving the consent.
- I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Witnessed by: _____ _____

Name of witness | Date of signing

_____

Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant or legal representative thumbprint). After the written consent form and any written information to be provided to participant, is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant signing this consent form had the study fully explained and clearly understands the nature, risks and benefits of his/ her participation in the study.

_____	_____	_____
Name of Investigator/ Person obtaining consent	Signature	Date