SingHealth

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

You are being invited to participate in a research study. Your participation in this study is entirely voluntary. 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. Your questions will be answered clearly and to your satisfaction. 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.

STUDY INFORMATION

Protocol Title:
Evaluation of a structured nurse-led patient education and tele-monitoring to review asthma patients with suboptimal control: A pilot study

This research study is recruiting at the following SingHealth institution(s). Please note that the word "SingHealth" refers to the institution where you are recruited into the study.

☐ **SingHealth Polyclinics – Bedok**
Principal Investigator:
Ms. Roslinda Bte Sadon
Department of Nursing
Tel: 63507600
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☐ **SingHealth Polyclinics – Outram**
Principal Investigator:
Ms. Tham Kwee Lian
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☐ **SingHealth Polyclinics – Pasir Ris**
Principal Investigator:
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PURPOSE OF THE RESEARCH STUDY

The purpose of this study is to investigate a structured nurse-led patient education and tele-monitoring via video follow-up for asthma patients with suboptimal control (inadequate control or asthma exacerbation). Currently in Singhealth Polyclinics, the routine standard of care for asthmatic patients with inadequate control without asthma exacerbation is doctor's consultation during their visit only. Patient education or intervention by nurses is not mandatory, and is based on ad-hoc referral by the doctor. We hope to find out whether a structured nurse-led patient education followed by a video follow-up will help to improve asthma control. For patients with asthma exacerbation, there is structured nurse-led patient education, but the

video follow-up is not mandatory. We hope to find out whether a video follow-up will help improve asthma control.

You were selected as a possible participant in this study as your asthma control is inadequate or you had an asthma exacerbation. We hope to improve patients' asthma control by providing asthma education and video follow-up via Zoom.

This study targets to recruit 120 participants from SingHealth Polyclinics at Bedok, Outram and Pasir Ris.

STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY

The study will involve the use of randomization; assigning you to one of two groups by chance, like tossing a coin or rolling dice. For participants with inadequate control and no asthma exacerbation, if you agree to take part in this study, you will be randomised to either control group or intervention group. In the control group, the participants will receive the current standard of care, which is doctor's consultation. In the intervention group, the participants will receive the current standard of care (doctor's consultation) plus asthma intervention, which is a nurse-led structured patient education plus a follow-up 3-5 days later. The follow-up is a 10-15 minutes video follow-up by a registered nurse to assess and give further advice on asthma management based on your current asthma condition. For participants with asthma exacerbation, you will receive the asthma intervention as described above. The asthma intervention is a nurse-led structured patient education plus a follow-up 3-5 days later. The follow-up is a 10-15 minutes video follow-up by a registered nurse to assess and give further advice on asthma management based on your current asthma condition.

The study involves the following:

Questionnaire:
We will ask you to complete questionnaires on your demographics and about your asthma control on the recruitment day. At the 2 to 4-week period when you come for your next follow-up appointment, you need to complete questionnaires on your asthma control. We will contact you via phone if your appointment does not fall within the 2 to 4-week period, or if you are unable to come for your appointment. At 3-month, we will contact you via phone to ask on your asthma control and the questions will include your feedback on the asthma education.

Medical history:
Your medical records will be accessed only after you have been recruited into the study, and it will be done during study enrolment to collect demographic data. Subsequently, your medical records will be accessed during the video follow-up session, and when you come for asthma review in the polyclinic as part of routine clinical care. Your current list of medications, Written Asthma Action Plan (WAAP), previous outpatient consultation notes and hospitalization notes (if applicable) will be extracted from your medical record.

Interview with audio recording:
You may be invited for a face-to-face interview, and the interview can coincide with your doctor visit. The interview will be audio recorded and takes about 30-60 minutes. You can still participate in the study if you do not wish to be interviewed.

Data deposition into scientific database:
We will deposit data collected in this study, including the data we collect about you to public and/or controlled-accessed scientific databases. It will not include your name or other data that directly identifies you. This will enable other researchers, whether locally or overseas, to use the data to investigate other important research questions.

Your participation in the study will last for a period of 3 months. You will be followed up at the 2 to 4-week, and 3-month during the study period. The data will be obtained via telephone or in person.

If you agree to participate in this study, you should follow the advice and directions given to you by the study team.

WHAT IS NOT STANDARD CARE OR IS EXPERIMENTAL IN THIS STUDY

The study is being conducted because a structured nurse-led patient education and tele-monitoring via video follow-up to review patient is not yet proven to be a standard or main-stream service in managing asthmatic patients with inadequate control. We hope that your participation will help us to determine whether a structured nurse-led patient education plus video follow-up is equal or superior to existing standard care.

In patients with inadequate asthma control but no exacerbation, this structured education and video follow-up is not part of standard medical care. The study will involve the use of randomization, with selection to have a structured nurse-led patient education and video follow-up by chance.

For patients with asthma exacerbation, the education is part of standard care, but the video follow-up is an available option for patient to choose as part of the standard care. Also, patients are followed-up by telephone instead of Zoom.

POSSIBLE RISKS, DISCOMFORTS OR INCONVENIENCES

Questionnaires/ surveys/ interviews:

Some of the questions in the survey or interview might make you feel uncomfortable or upset. You may refuse to answer any of the questions and/or take a break at any time during the study.

Personal privacy and confidentiality:

This study uses information that may affect your privacy. To protect your confidentiality, only a unique code will be used to identify data that we collected from you.

Your email and mobile number will be obtained after signing the consent form, and will be required to arrange the video follow-up. Your personal identifiers and contact details will not be in the survey or interview data collected.

As there will be a link between the code and your identifiable information, there is still a possibility of data breach. A data breach is when someone sees or uses data without permission. If there is a data breach, someone could see or use the data we have about you.

Even without your name, there is a chance someone could figure out who you are. They could misuse your data. We believe the chance of this is very small, but it is not zero.

POTENTIAL BENEFITS

There is no assurance you will benefit from this study. If you are in the intervention group, you may benefit from the nursing education and nursing tele-monitoring. Your participation will help us understand the usefulness of the nursing education and tele-monitoring.

ALTERNATIVE IF YOU DO NOT PARTICIPATE IN THE STUDY

If you choose not to take part in this study, the alternative is to have what is considered standard care for your condition. In our institution, this would be polyclinic doctors and nurses providing asthma related clinical management. You may discuss the possible risks and benefits of the alternatives with your doctor and/or nurse.

COSTS & PAYMENTS IF PARTICIPATING IN THIS STUDY

There is no cost to you for participating in this research study.

The cost of your usual medical care (procedures, medications and doctor visits) will continue to be billed to you. For patients with asthma exacerbation, the asthma counselling is standard medical care. Hence, the cost will continue to be billed to you. The video follow-up will be provided at no charge to you. For patients with no asthma exacerbation, the counselling and video follow-up will be provided for free.

You will be reimbursed for your time, inconvenience and transportation costs as follows:

- If you complete the study, you will receive a $10 voucher on study enrolment and another $10 voucher on study completion (complete both second and third data collection). You will need to collect the voucher at the Polyclinic.
- For participants who received the intervention only: If you participate in a face-to-face interview, you will receive $10 voucher for the interview.
- If you do not complete the study for any reason, you will receive $10 voucher on study enrolment and completion of baseline data.

INCIDENTAL FINDINGS

There will not be any incidental findings arising in this research. “Incidental findings” are findings that have potential health or reproductive importance to research participants like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study.

PARTICIPANT’S RIGHTS

Your participation in this study is entirely voluntary. You have a right to ask questions, which the study team will do their best to answer 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 (or your legal representative, if relevant) will be

informed in a timely manner by the Principal Investigator or his/her representative and will be contacted for further consent if required.

WITHDRAWAL FROM STUDY

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

If you withdraw from the study, there will be no consequence, and standard care will be continued for your condition.

However, any research information or data obtained before your withdrawal of consent will be retained and may continue to be used. This is to allow a complete and comprehensive evaluation of the research study.

Your study doctor, the Principal Investigator 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 to your health or safety.
- 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 structured patient education and video follow-up 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 (i.e. consequences of your treatment which are not caused by your participation in the research study) will not be provided.

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 this study will involve the collection of Personal Data. “Personal Data” means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. Examples of personal data include name, national registration identity card (NRIC), nationality, passport information, date of birth, and telephone number.

Personal Data collected for this study will be kept confidential and stored in Singapore. Your study records and medical records (if applicable), to the extent required by the applicable laws and regulations, will not be made publicly available. To protect your identity, your Personal Data will be labelled with a unique code. The code will be used in place of your name and other information that directly and easily identifies you. The study team will keep a separate

file that links your code to your Personal Data. This will be kept in a safe place with restricted access. In the event of any data sharing with third parties (e.g. funding agencies, research collaborators) whether locally or overseas and publication regarding this study, your identity will remain confidential.

However, the monitor(s), the auditor(s), the Institutional Review Board, and the regulatory authority(ies) will be granted direct access to your original medical records (if applicable) and study records to verify 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 SingHealth, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties as mentioned above. To the fullest extent permitted by applicable law, under no circumstances will SingHealth and/or its affiliates be liable for any direct, indirect, incidental, special or consequential loss or damages arising out of any data breach event.

All data collected in this study are the property of SingHealth Polyclinics. The data will be used for the purpose of this research study only.

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 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 81263660 during office hours (8:30 am to 5:30pm).

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 your study doctor, the Principal Investigator listed under STUDY INFORMATION section, at the beginning of this document.

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

CONSENT FORM FOR RESEARCH STUDY

Protocol Title:
Evaluation of a structured nurse-led patient education and tele-monitoring to review asthma patients with suboptimal control: A pilot study

Declaration by Research Participant

(i) I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

(ii) I understand the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to discuss and ask questions about this study and am satisfied with the information provided to me.

(iii) I understand that the de-identified data collected about me in this study may be deposited in open-access or access-controlled scientific database for potential use by other researchers, whether locally or overseas, to answer other important research questions, to advance medical research.

(iv) 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.

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

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

To be completed by parent / legal guardian / legal representative, where applicable

I hereby give consent for _____ (Name of Participant) to participate in the research study. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

_____	_____	_____
Name of participant's parent/ legal guardian/ legal representative	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The study has been explained to the participant/ legal representative 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 to him/her in a language understood by him/ her and clearly understands the nature, risks and benefits of the participant's 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 reasonable 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's or legal representative's 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 the 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/ participant's legal representative signing this consent form had the study fully explained to him/her and clearly understands the nature, risks and benefits of the participant's participation in the study.

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