Appendix C

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

STUDY INFORMATION

Protocol Title:

A randomized controlled trial to evaluate the health outcomes of patients with stable chronic disease managed with a healthcare kiosk

Principal Investigator:

Dr Grace Ng

SingHealth Polyclinics – Punggol
681 Punggol Drive
Oasis Terraces #02-01
Singapore 820681
Tel: 6377 8771
Email: grace.ng.b.h@singhealth.com.sg

Study coordinator's contact number:

Sponsor:

Agency for Science, Technology and Research (A*STAR)

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.

A global rise in the prevalence of chronic disease has led to an increase in the demand for primary healthcare services and a shortage of primary care physicians. Addressing these challenges calls for innovations in the healthcare delivery model including greater use of healthcare technology tools. You are being invited to participate in a research study to assess if a healthcare kiosk can be used to manage patients with stable chronic disease. We hope to learn if the kiosk can be as effective as healthcare providers in delivering medical care to stable patients. You have been selected as a potential participant for the study because you have at least one chronic disease condition(s) that is/are well-controlled.

The study will involve 120 subjects recruited from SingHealth Polyclinics – Punggol and will be conducted over a period of 12 months.

STUDY PROCEDURES AND VISIT SCHEDULE

If you agree to take part in this study, you will be randomised to be evaluated by either a healthcare kiosk or a nurse clinician during your subsequent follow-up visits. Randomisation means assigning you to one of 2 groups by chance, like tossing a coin or rolling dice. Randomisation will be done using a random-number generator.

Your personal particulars and medical information will be obtained from the Polyclinic Patient Information System and may be used for purposes of the study only. All demographic data and medical information collected for the study will be anonymised. You will be given a medication prescription that will allow you to refill your chronic medications in 4-monthly intervals for the next 12 months.

During your subsequent visits to the clinic 4 and 8 months later, you will be evaluated by either a nurse clinician or a healthcare kiosk. Your blood pressure, height and weight will be measured.

If you are assigned to be evaluated by the kiosk, a research coordinator will guide you to use the kiosk. The kiosk will determine the status of your chronic condition through a screening questionnaire, physiological measurements (blood pressure, height, weight) and your latest blood test results. You will be classified into well-controlled, sub-optimally controlled, or poorly-controlled groups according to the kiosk decision algorithm and will be advised to either continue on your current medications or be evaluated by a healthcare professional.

If you are assigned to be evaluated by a nurse clinician, your chronic condition will be assessed and managed as per routine clinical practice for patients with stable chronic disease.

At the end of the study, all study participants will be reviewed by a doctor.

All study participants will be asked to complete questionnaires at the start and at the end of the study. The questionnaires will be used to assess your health status, satisfaction, and any adverse events that may have occurred during the course of the study. The questionnaires will take about 15 minutes to complete.

Schedule of visits and procedures:

Visit 1: recruitment

Visit 2 and 3 (Weeks 4 and 8): evaluation by healthcare kiosk or nurse clinician

Final Visit (Week 12): evaluation by doctor

YOUR RESPONSIBILITIES IN THIS STUDY

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

- Keep your study appointments. Please contact the research coordinator if you need to reschedule an appointment.
- Follow the instructions of the research coordinator during your follow-up appointments.
- Answer the study questionnaires to the best of your knowledge.

The above points are applicable to all study participants.

WITHDRAWAL FROM STUDY

You are free to withdraw from the study at any time without prejudice to you or your future medical care. Please inform the research coordinator or Principal Investigator if you decide to withdraw from the study. You will be scheduled for routine clinic visits for your subsequent follow-up care.

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 of this study may stop your participation in the study at any time for one or more of the following reasons*:*

- Your chronic disease condition(s) is/are no longer well-controlled;
- Failure to follow the instructions of the Principal Investigator and/or study staff;
- The study is discontinued;
- Any other unforeseen circumstances.

WHAT IS NOT STANDARD CARE OR EXPERIMENTAL IN THIS STUDY

The healthcare kiosk is not a standard way of care delivery for patients with stable chronic disease. Your participation in the study will help us to determine if the kiosk can deliver equivalent healthcare that is comparable to the existing care delivery method.

POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES

Technical problems that can arise during kiosk usage may cause delays that result in longer visits or the need for rescheduled appointments.

POTENTIAL BENEFITS

You may benefit from shorter waiting times as compared to routine follow-up visits. Your participation in the study will help contribute to the medical knowledge on healthcare kiosks.

ALTERNATIVES

If you choose not to participate in the study, you will continue to receive standard care as for patients with chronic disease.

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 (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.

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.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Your participation in this 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 SingHealth Polyclinics, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties for the purpose of future research studies ("Future Studies").

Where required, such Future Studies will be submitted for review and necessary approval by the relevant institutional review board.

"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 medical conditions, medications, investigations and treatment history.

By signing the Consent Form, you also confirm that you have read, understood and consented to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

Data collected and entered into the *Data Collection Form(s)* are the property of SingHealth Polyclinics. In the event of any publication regarding this study, your identity will remain confidential.

COSTS OF PARTICIPATION

If you take part in this study, the following will be performed at no charge to you: Nurse and kiosk visits

If you take part in this study, you will have to pay for the following: Doctor's visit at the end of study, routine tests and medications.

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

- If you complete the study, you will receive vouchers worth S$20 (for 2 nurse or kiosk visits).
- If you do not complete the study for any reason, you will receive vouchers worth S$10 for each nurse or kiosk visit you complete.

RESEARCH RELATED INJURY AND COMPENSATION

The Polyclinic does not make any provisions to compensate study participants for research related injury. However, compensation may be considered on a case-by-case basis for unexpected injuries due to non-negligent causes.

By signing the Consent Form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

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 Dr Grace Ng at Tel: 6377 8771 or via email at grace.ng.b.h@singhealth.com.sg

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 complaints about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

CONSENT FORM

Details of Research Study

Protocol Title:
A randomized controlled trial to evaluate the health outcomes of patients with stable chronic disease managed with a healthcare kiosk

Principal Investigator:

Dr Grace Ng
SingHealth Polyclinics – Punggol
681 Punggol Drive
Oasis Terraces #02-01
Singapore 820681
Tel: 6377 8771
Email: grace.ng.b.h@singhealth.com.sg

Participant's Particulars

Name: NRIC No.:

Address:

Sex: Female/Male Date of birth _____
dd/mm/yyyy

Race: Chinese/ Malay/ Indian /Others (please specify) _____

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. I also consent to the use of my Personal Data for Future Research.

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

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

I hereby give consent for the above participant to participate in the proposed 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. I also consent to the use of the participant's Personal Data for Future Research.

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

To be filled by translator, if required

The study has been explained to the participant/ legal representative in

_____ by _____.
Language Name of translator

To be filled witness, where applicable

I, the undersigned, certify that:

- 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/participant's legal representative signing this consent form had the study fully explained and clearly understands the nature, risks and benefits of his/ her/ his ward's/ her ward's participation in the study.

_____ _____ _____

Name of Investigator/ Person obtaining consent | Signature | Date