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INFORMED CONSENT FORM

1. Study Information

Protocol Title:

AI-CARE: A Novel AI-Driven Mobile Insulin Calculator Integrating Image-Based Carbohydrate Estimation and CGM—A Feasibility Pilot Randomized Controlled Trial

Principal Investigator & Contact Details:

Lian Xia
Advanced Practive Nurse
Tan Tock Seng Hospital
11 Jln Tan Tock Seng
Singapore 308433
822802706

Study Sponsor:

NHG Translational Research Programme Funding

2. Purpose of the Research Study

You are invited to participate in a research study. It is important to us that you first take time to read through and understand the information provided in this sheet. Nevertheless, before you take part in this research study, the study will be explained to you and you will be given the chance to ask questions. After you are properly satisfied that you understand this study, and that you wish to take part in the study, you must sign this informed consent form. You will be given a copy of this consent form to take home with you.

You are invited because you meet the following eligibility criteria:

Inclusion Criteria

You may take part in this study if all of the following apply to you:

- 1) You are an adult aged ≥ 21 years
- 2) You have a diagnosis of Type 1 or Type 2 diabetes
- 3) You are receiving multiple daily insulin injections (MDI)
- 4) You have an HbA1c $\geq 8\%$
- 5) You are willing to wear a continuous glucose monitoring (CGM) sensor for 12 weeks
- 6) You are able to read and understand English

Exclusion Criteria

You will not be eligible to participate in this study if any of the following apply:

- 1) You are pregnant
- 2) You have experienced severe hypoglycaemia or diabetic ketoacidosis within the last 3 months
- 3) You have hypoglycaemia unawareness
- 4) You have significant cognitive impairment that may interfere with the use of the application

The aim of this study is to examine the feasibility, safety, and initial effectiveness of the AI-CARE mobile application in adults with diabetes receiving multiple daily insulin injections. The study will evaluate its impact on blood glucose and patient-reported outcomes in

comparison with usual care, as well as explore participants' experiences and perceptions of using the application.

A total of 48 participants will be recruited from Tan Tock Seng Hospital over a period of two years. Approximately 48 individuals will take part in this study.

3. What procedures will be followed in this study

If you take part in this study, you will be randomised to either the usual care arm or the intervention arm. Participants in the intervention arm will be provided access to the AI-Care mobile application. Randomisation means assigning you to one of 2 groups by chance, like tossing a coin or rolling dice.

AI-CARE is a mobile app designed to help people who use multiple daily insulin injections decide how much insulin to take at mealtimes. The app uses smart technology to suggest insulin doses, but you will always review and confirm the dose yourself before using it. The app can estimate the carbohydrate content of meals by analysing food photos, taking into account common Asian foods. It also uses your personal insulin settings and real-time information from your continuous glucose monitor (CGM) to provide insulin dose suggestions that are tailored to you.

If you choose to take part in this study, you will be asked to attend the clinic for two visits over a period of 12 weeks.

Visit 1 (Week 0)

At your first clinic visit, the following will take place:

- Your eligibility for the study will be confirmed.
- The study will be explained to you in detail, and written informed consent will be obtained.
- You will be randomly assigned to either the usual care group or the intervention group.

Participants in the intervention group will receive access to the AI-CARE mobile application and be provided with 6–8 continuous glucose monitoring (CGM) sensors. They will also receive training on how to use the AI-CARE application.

Participants in the usual care group will be provided with a glucose-monitoring device but will not receive access to the AI-CARE mobile application.

Phone Reviews (Intervention Group Only)

Participants in the intervention group will have two structured phone review sessions:

- Week 1
- Week 2

A study nurse, who will review CGM data with the participant, will conduct these phone reviews.

Visit 2 (Week 12)

All participants from both groups will return to the clinic for their final visit at Week 12.

Participants in the intervention group may also be invited to take part in a focus group discussion to share their experiences of using the AI-CARE mobile application.

If you agree to take part in this study, the following will happen to you:

	Usual Care Arm	Intervention
Visit 1 (Week 0)	<ul style="list-style-type: none">• Eligibility Screening• Randomization	

	<ul style="list-style-type: none"> • Diabetes Education Program • CGM Sensor Application • Structured Self-monitoring of Blood Glucose Training • Data Collection <ul style="list-style-type: none"> ○ Demographic Data ○ Clinical Data (e.g. HbA1c, LDL-M etc.) ○ Anthropometric parameters (e.g. BMI,etc.) • Assess Psychological Data <ul style="list-style-type: none"> ○ Diabetes Treatment Satisfaction Questionnaire (DTSQ) ○ Audit of Diabetes-Dependent Quality of Life (ADDQoL) 	
		<ul style="list-style-type: none"> • Training for AI-Care Mobile Application
Phone Review 1 (Week 1)		<ul style="list-style-type: none"> • Structure phone reviews conducted by nurses. Study Nurse will review CGM data with participants. • Adverse Events Monitoring
Phone Review 2 (Week 2)		
Visit 2 (Week 12)	<ul style="list-style-type: none"> • Data Collection <ul style="list-style-type: none"> ○ Clinical Data (e.g. HbA1c, LDL-M etc.) ○ Anthropometric parameters (e.g. BMI,etc.) • Assess Psychological Data <ul style="list-style-type: none"> ○ Diabetes Treatment Satisfaction Questionnaire (DTSQ) ○ Diabetes Treatment Satisfaction Questionnaire – change version (DTSQc) ○ Audit of Diabetes-Dependent Quality of Life (ADDQoL) 	<ul style="list-style-type: none"> • Interested individuals will be invited to participate in a focus group discussion • Adverse Events Monitoring

Biological materials:

We will take blood twice (“biological materials”) from your arm using a syringe and needle, once during visit 1 and another during visit 2. Each time, we will take approximately 10ml (2 teaspoons) of blood. In total we will take about 20ml (4 teaspoons) over a period of 12 weeks. The blood sample will be tested for HbA1c and LDL-M.

Medical history:

We will collect information (data) from your medical records. The information will include your demographic data such as age, sex, type and duration of diabetes, and current treatments and medications.

Questionnaire:

We will ask you to complete the following questionnaires, Diabetes Treatment Satisfaction Questionnaire (DTSQ) and Diabetes Treatment Satisfaction Questionnaire change (DTSQc), the Audit of Diabetes Dependent Quality of Life (ADDQOL) questionnaire. These patient reported outcomes will assess changes in diabetes treatment satisfaction and quality of life. Participants randomized into the intervention arm will complete an additional mHealth App Usability Questionnaire (MAUQ) to evaluate the application usability.

4. What Happens to the Data and/or Samples Collected for the Research

Any blood or tissue samples obtained during the course of this study will be stored and analysed only for the purposes of this study for a period not exceeding 2 years, and will be destroyed after completion of the study. The blood or tissue samples will not be used for restricted human biomedical research involving human-animal combinations.

Any biological samples and/or information containing your “Personal Data” that is collected for the purposes described in this Informed Consent Form will not be transferred out of Singapore.

5. Incidental Findings

During the course of the study, there is a possibility that we might unintentionally come to know of new information about your health condition from continuous glucose monitoring (CGM) data, clinical assessments, or laboratory results that are conducted as part of the study. These are called “incidental findings”.

“Incidental findings” are findings that have potential health or reproductive importance to research participants like you/your child and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study. These findings may affect your/your child’s current or future life and/or health insurance coverage. Examples of potential incidental findings that may be discovered during the course of this study may include but are not limited to recurrent hypoglycaemia, significant hyperglycaemia, or abnormal laboratory results.

You will be asked to indicate whether you wish to be re-identified and notified in the case of a clinically significant incidental finding that is related to you.

If you agree to be re-identified and notified, your doctor will explain the incidental finding to you and discuss and advise you on the next steps to follow. For this purpose, please inform the Principal Investigator or any of the study contact persons listed in this document whenever there are changes in your contact details. You may wish to do more tests and seek advice to confirm this incidental finding.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

If you do not wish to be re-identified and notified, your decision will be respected. However, in exceptional situations such as discovery of life-threatening incidental findings with available treatment options, you will be contacted to confirm your decision whether to learn more about the incidental findings. In rare situations where the incidental findings have public health implications and as required by the law (e.g. under the Infectious Diseases Act), you will be contacted and informed of the incidental findings.

6. Your Responsibilities in This Study

If you agree to participate in this study, you should follow the advice given to you by the study team. You should be prepared to visit the hospital *2 times* and undergo all the procedures that are outlined above.

7. What Is Not Standard Care or is Experimental in This Study

The study is being conducted because *the AI-Care mobile application* is not yet proven to be a standard *treatment* in participants with diabetes. We hope that your participation will help us to determine whether *AI-Care* is equal or superior to existing *treatment*.

In this study, the *AI-Care* is used is a prototype. A prototype is a first or preliminary version of a device from which other forms are developed.

Use of randomization are only done for research studies.

Although *continuous glucose monitoring and laboratory tests* may be part of standard medical care, in this study these procedure(s) are only being performed for the purposes of the research, and are not part of your routine care.

8. Possible Risks and Side Effects

The potential risks associated with this study are expected to be minimal, as the AI-CARE application functions as a clinical decision support tool and does not replace standard medical care or clinical judgment.

The primary potential risk relates to inaccurate insulin dose recommendations arising from errors in image-based carbohydrate estimation or incorrect input of individual insulin parameters (e.g., insulin-to-carbohydrate ratio or insulin sensitivity factor). Such inaccuracies may lead to inappropriate insulin dosing, which could result in hypoglycaemia or hyperglycaemia. However, participants will be instructed to review all recommendations and retain full responsibility for confirming and administering insulin doses, thereby reducing this risk.

There may also be risks associated with CGM use, including minor skin irritation, discomfort, or allergic reactions at the sensor insertion site. These risks are generally mild and consistent with routine clinical use of CGM devices. In addition, participants may experience a small degree of psychological burden or anxiety related to increased monitoring of glucose levels or the use of new technology.

To minimize risks, several safeguards are in place. The AI-CARE system incorporates safety features such as predefined insulin parameter limits and clinical decision support alerts. Participants will receive structured training on safe app use and insulin dosing principles

Collection of blood:

Obtaining blood can cause pain, bleeding, bruising, or swelling at the site of the needle stick. Fainting sometimes occurs and infection rarely occurs.

Questionnaires:

Some of the questions 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:

As the study involves the collection of personal health information and app usage data. This risk will be mitigated through secure data storage, restricted access to authorized study personnel, and adherence to institutional data protection policies. To protect your confidentiality, only a unique code will be used to identify data that we collected from you.

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.

To further safeguard participant safety, follow-up phone reviews at Week 1 and Week 2 will allow prompt identification of any safety concerns or technical issues. Adverse events,

including hypoglycaemia, will be actively monitored throughout the study. Participants will also be advised to seek medical attention and contact the study team if any concerns arise.

9. Reproductive Risks to You and Your Partner(s)

The effect of *AI-Care* on a baby's development is not known. Therefore, pregnant and breast-feeding women may not take part in this study

10. Possible Benefits from Participating in the Study

There is no known benefit from participation in this study. However, your participation in this study may add to the medical knowledge about the use of this *AI-Care mobile application on managing diabetes treatment*.

11. Alternatives to Participation

If you choose not to take part in this study, you will receive standard care for your condition. In our institution this would be *routine diabetes care*.

12. Costs & Payments if Participating in the Study

If you take part in this study, the following will be performed at no charge to you: continuous glucose monitoring device (6-8). These costs will be borne by *Tan Tock Seng Hospital*.

You will not incur any anticipated expenses as a consequence of participating in this study.

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

- You will receive \$50 for each visit
- *Additionally, \$50 for participation in focus group discussions.*

13. Voluntary Participation

Your participation in this study is voluntary. You may stop participating in this study at any time. Your decision not to take part in this study or to stop your participation will not affect your medical care or any benefits to which you are entitled. If you decide to stop taking part in this study, you should tell the Principal Investigator.

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.

14. Withdrawal From Study

If you withdraw from the study, you will be required to return all un-used glucose-monitoring device. You will be advised to continue treatment for diabetes.

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 and/or the Investigator of this study may stop your participation in the study at any time for one (1) 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.

- Pregnancy
- The study is cancelled.

15. Compensation for Injury

If you follow the directions of the doctors in charge of this study and you are physically injured due to the trial substance or procedure given under the plan for this study, the *Tan Tock Seng Hospital* will pay the medical expenses for the treatment of that injury.

Payment for management of the normally expected consequences of your treatment will not be provided by the *Tan Tock Seng Hospital*.

Tan Tock Seng Hospital without legal commitment will compensate you for the injuries arising from your participation in the study without you having to prove Tan Tock Seng Hospital is at fault. There are however conditions and limitations to the extent of compensation provided. You may wish to discuss this with your Principal Investigator.

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

16. 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. This includes name, national registration identity card (NRIC), nationality, passport information, date of birth, and telephone number, medical conditions, medications, investigations and treatment history.

Information and “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. 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. Your personal data may be disclosed to third parties (e.g. research collaborators) for the purpose of data analysis. In the event of any data sharing with third parties (e.g. research collaborators) whether locally or overseas and publication regarding this study, your identity will remain confidential.

However, NHG Domain Specific Review Board and Ministry of Health will be granted direct access to all your original medical records regardless of where and whom you seek care from, to check study procedures and data, without making any of your information public. These may include data from other hospitals where you may have had medical consultations and/or procedures being carried out and the data is captured under the Next Generation Electronic Medical Records (NGEMR). Such data on NGEMR may be viewed and used if relevant to the study.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by *Tan Tock Seng Hospital* 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 *Tan Tock Seng Hospital* 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 *Tan Tock Seng Hospital*. 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 Personal Data Protection Notification available at www.ttsh.com.sg/patient-guide/page.aspx?id=4468.

17. Who To Contact if You Have Questions

If you have questions about this research study, you may contact the Principal Investigator,

Lian Xia
Advanced Practive Nurse
Tan Tock Seng Hospital
11 Jln Tan Tock Seng
Singapore 308433
822802706

In case of any injuries during the course of this study, you may contact the Principal Investigator,

Lian Xia
Advanced Practive Nurse
Tan Tock Seng Hospital
11 Jln Tan Tock Seng
Singapore 308433
822802706

18. Who Has Reviewed The Study

The study has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval.

If you want an independent opinion to discuss problems and questions, obtain information and offer inputs on your rights as a research participant, you may contact the NHG Domain Specific Review Board Secretariat at 6471-3266. You can also find more information about participating in clinical research, the NHG Domain Specific Review Board and its review processes at ethics.gri.nhg.com.sg.

If you have any complaints or feedback about this research study, you may contact the Principal Investigator or the NHG Domain Specific Review Board Secretariat.

19. Consent to be Contacted for Future Research (Optional)

You are being asked for permission to be contacted in the future for participation in research studies that you may be suitable for. If you agree to be contacted, your information and contact details will be entered and stored in a secured database in Tan Tock Seng Hospital. Your information and contact details will not be released to any parties outside Tan Tock Seng Hospital without your permission. When investigators from Tan Tock Seng Hospital identify you to be suitable for a particular research study, the investigators or authorised personnel from Tan Tock Seng Hospital will contact you to inform you about the research study. Your decision to be contacted for future research studies is completely voluntary and separate from your decision to participate in this study. Your decision will not affect your medical care or any benefits to which you are entitled. You may change your mind at any time by contacting,

Lian Xia

*Advanced Practice Nurse
Tan Tock Seng Hospital
11 Jln Tan Tock Seng
Singapore 308433
822802706*

CONSENT FORM

Protocol Title:

AI-CARE: A Novel AI-Driven Mobile Insulin Calculator Integrating Image-Based Carbohydrate Estimation and CGM—A Feasibility Pilot Randomized Controlled Trial

Principal Investigator & Contact Details:

*Lian Xia
Advanced Practive Nurse
Tan Tock Seng Hospital
11 Jln Tan Tock Seng
Singapore 308433
822802706*

I voluntarily consent to take part in this research study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to my satisfaction. I have also been informed and understood the alternative treatments or procedures available and their possible benefits and risks.

By participating in this research study, I confirm that I have read, understood and consent to the (Institution) Personal Data Protection Notification.

Consent to be Re-Identified and Notified in the Case of an Incidental Finding

☐ Yes, I agree to be re-identified and notified in the case of an incidental finding from this research.

In the event that I cannot be reached, please contact my next of kin

Name of next of kin:

Contact:

☐ No, I do not agree to be re-identified and notified in the case of an incidental finding from this research.

Consent to be Contacted for Future Research

☐ Yes, I agree to be for contacted for future research that I may be eligible for.
I agree to be contacted via:

☐ Phone _____

☐ Mail _____

☐ Email _____

☐ Others _____

☐ No, I do not agree to be contacted for future research.

Name of Participant	Signature	Date
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Witness Statement

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant/ the participant's legally acceptable representative signing this informed consent form has 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/ the participant's legally acceptable representative giving the consent.
- I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Name of Witness	Signature	Date
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1. In accordance with Section 6(d) of the Human Biomedical Research Act and Regulation 25 of the Human Biomedical Research Regulations 2017, appropriate consent must be obtained in the presence of a prescribed witness who is 21 years of age or older, and has mental capacity. The witness must be present during the entire informed consent discussion, and must not be the same person taking the appropriate consent. The witness may be a member of the team carrying out the research.
2. However, if the participant/ the participant's legally acceptable representative is unable to read, and/ or sign and date on the consent form, an impartial witness should be present instead. The impartial witness should not be a member of the study team.

Investigator Statement

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

Name of Investigator / Person administering consent	Signature	Date
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The Parties (Investigator, Participant / Legally Authorised Representative & Witness) may execute this Informed Consent Form requiring a party's signature by using industry standard electronic signature software and delivered electronically by emailed portable document format ("PDF") document (or other mutually agreeable document format) and such electronic version shall be treated as an original. The Parties also agree that such signatures obtained or transmitted through electronic means, shall be binding and effective for all purposes as if the signatures were executed in-person.