



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:

Exploring the feasibility of digital intervention games as a diagnostic and management tool for delirium at SGH inpatient wards.

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.

Singapore General Hospital

Principal Investigator:

Fan Peijin Esther Monica

Nursing Research and Transformation

Tel: 6576 2590

Institution Mainline: 6222 3322

PURPOSE OF THE RESEARCH STUDY

The purpose of this study is to explore the usability and acceptability of a digital game to aid in the delirium screening and management of at-risk delirium hospitalized patients.

You were selected as a possible participant in this study because you are aged 65 and above, currently admitted in a medical ward and capable of using a tablet.

This study targets to recruit 50 participants from Singapore General Hospital.

STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY

The study involves the following:

Study device:

A game deployed via a tablet. This game has demonstrated potential for cognitive training. You will be taught how to play the game by a study team member. Following that, you will be expected to play the game once a day (each session lasts 12 minutes) and be followed up for five days or till you are discharged from the hospital.

You will also be offered optional games to play. These games are aimed at improving memory and reduce cognitive decline.

Deidentified game play data will be recorded for further analysis.

Medical history:

We will collect information (data) from your medical records. The information will include any diagnosis of any cognitive impairment or delirium.

Questionnaire:

We will ask you to complete questionnaires that include information about your demographics, daily assessments of your cognitive ability and survey questions for feedback on the game.

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 the use of the game is not yet proven to be a standard diagnostic tool or management in patients with delirium. We hope that your participation will help us to determine whether the use of this game is equal or superior to existing screening tools.

In this study, the use of the game is being performed for the purposes of the research, and are not part of your routine care.

POSSIBLE RISKS, DISCOMFORTS OR INCONVENIENCES

Questionnaires/ surveys/ interviews:

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:

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.

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. However, your participation may add to the medical knowledge about the use of this intervention.

ALTERNATIVE IF YOU DO NOT PARTICIPATE IN THE STUDY

There is no alternative to the study procedures. You can choose not to take part in this study. The study procedures will not be carried out.

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.

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

- If you complete the study, you will receive a \$50 voucher.

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 the questionnaires 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 a participant like you 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 cause you to feel anxious and may affect your 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 having delirium. You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you.

If you agree to be re-identified and notified, your study doctor/ a qualified healthcare professional will explain the incidental finding to you and discuss and advise you on the next steps to follow. 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.

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,

- You will not continue to play the game.
- You will not be asked to complete any further questionnaires.

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.
- If you are transferred to another ward that is not part of this study.
- You require treatment not allowed in the study.
- 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 (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. 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 8126 3660 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.

Restricted, Sensitive (Normal)

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:

Exploring the feasibility of digital intervention games as a diagnostic and management tool for delirium at SGH inpatient wards.

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 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.

(iv) 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/ Signature Date
Person obtaining consent