INFORMED CONSENT FORM

Study Information

Protocol Title:

CHAT Supportive Interventions (CSI): Randomized Controlled Trial of Six-session Solution Focused Brief Therapy versus Case Management for Youths with Mental Health Distress

Principal Investigator & Contact Details:
Nur Khairunisa Binte Ngaiman, Senior Case Manager, CHAT, Institute of Mental Health. Address: Buangkok Green Medical Park, 10 Buangkok View, Singapore 539747. Telephone: 6389-2000, 6389-6751.

Dr. Tang Yu Zheng, Charmaine, Consultant, CHAT/Department of Psychosis, Institute of Mental Health. Address: Buangkok Green Medical Park, 10 Buangkok View, Singapore 539747. Telephone: 6389-2000, 6389-2835.

Study Sponsor:

The Ngee Ann Kongsi Foundation

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 are between 16- to 30-years-old and may be facing some psychological distress or may be at higher risk for common mental disorders such as anxiety and depression, as based on your assessment with CHAT.

This study is carried out to find out whether a brief, evidence-based treatment offering interim support is more efficacious than existing routine care in preventing worsening of clinical outcomes for clients waiting for their first appointments with specialized mental health services. The study will examine changes in participants' levels of psychological distress, depression symptoms, anxiety symptoms, clinical functioning, perceived self-efficacy and feelings of hopelessness.

This study will recruit 124 participants from CHAT, Institute of Mental Health (IMH), Singapore over a period of 24 months (April 2023 to March 2025). About 124 subjects will be involved in this study.

3. What procedures will be followed in this study

If you take part in this study, you will be randomised to receive either a brief, evidence-based, supportive treatment or existing routine care (i.e. case management). Randomisation means assigning you to one of two groups by chance, like tossing a coin or rolling dice.

If you take part in this study, you are going to receive either a brief, evidence-based, supportive treatment or existing routine care. Each type of intervention will be delivered by trained case managers from IMH, and one intervention is not known to be better than the

other. You will be assured the best care possible and getting your mental health needs met as quickly as possible regardless of which group you are assigned to. Your participation in the study will last for about 18 to 20 weeks.

If you are randomly selected to receive the brief supportive treatment, you will commit to attending 6 weekly sessions of solution-focused therapy. Each session lasts 45 to 60 minutes, and can be held in-person or via teleconferencing. If you are randomly selected to receive existing routine care, you will have frequent phone check-ins from a case manager who will be in charge of getting you connected with a mental health service/provider as soon as possible. The average waiting time for a first appointment is 4-6 weeks, and you will receive routine care for the period until you get your first appointment. If you agree to participate in the study, you will complete self-report questionnaires online before and after the treatment, and be followed up at three months after treatment ends.

Hence, if you are randomly selected to receive the brief supportive treatment, there will be six visits for treatment sessions (in person or via teleconferencing), and four assessments (completed online at your own pace), in the course of the study. If you are randomly selected to receive routine care, there will be up to six phone calls, no in-person or teleconferencing sessions, and four assessments (completed online at your own pace), in the course of the study.

If you agree to take part in this study, the following will happen to you, if you are selected to receive:

<table>
<tr><th></th><th>Brief Supportive Treatment</th><th>Routine Care</th></tr>
<tr><td>Week 0</td><td colspan="2">You will complete an online questionnaire before treatment begins with an individualized survey link, answering questions on your demographic information, psychological distress, depression and anxiety symptoms, level of functioning, perceived self-efficacy and feelings of hopelessness. The questionnaires will take about 30 minutes to complete.</td></tr>
<tr><td rowspan="3">Week 1-6 (up to 8 weeks, if there are reschedule sessions or longer waiting time)</td><td>You will receive six 45-minute-long sessions of solution-focused therapy conducted by trained case managers, in-person or via teleconferencing. You will be required to complete sessions on a weekly basis. You will also have the option to connect with referral to a mental health service/provider after treatment.</td><td rowspan="3">You will receive standard case management with frequent phone-call check-ins from trained case managers, until you receive your first appointment with a mental health service/provider.</td></tr>
<tr><td>As part of the supportive treatment, your clinician will also ask you to rate how you perceive your treatment progress and treatment alliance at the start and end of every session.</td></tr>
<tr><td>Your clinician will seek your consent to audio record your session, which will be used during his or her supervision session to ensure fidelity to the intervention goals and activities.</td></tr>
<tr><td>Week 6-8 (or earlier for the routine care group</td><td colspan="2">You will complete an online questionnaire after treatment ends with an individualized survey link, answering questions on your perceived self-efficacy, feelings of hopelessness and satisfaction</td></tr>
</table>

should you receive your first appointment with a mental health service/provider earlier)	with the treatment/routine care. You will also answer questions on treatment satisfaction. **The questionnaires will take about 15 minutes to complete.**
Week 8-10 (or earlier for the routine care group should you receive your first appointment with a mental health service/provider earlier)	You will complete an online questionnaire after treatment ends with an individualized survey link, answering questions on your psychological distress, depression and anxiety symptoms and level of functioning. You will also answer questions on treatment satisfaction. **The questionnaires will take about 20 minutes to complete.**
Week 18/20 (or earlier for the routine care group should you receive your first appointment with a mental health service/provider earlier)	You will complete an online questionnaire three months after treatment ends with an individualized survey link, answering questions on your treatment history in the past three months, psychological distress, depression and anxiety symptoms, level of functioning, perceived self-efficacy and feelings of hopelessness. **The questionnaires will take about 30 minutes to complete.**

Any individually-identifiable data obtained during the course of this study will be stored and analysed for the purposes of this study and will not be used for future biomedical research.

~~This study will not result in any anticipated or unanticipated incidental findings. "~~Incidental findings" are findings that have potential health or reproductive importance to research participants like your relative and are discovered in the course of conducting the study, but are unrelated to the study's purposes, objectives, or variables. There will not be any incidental findings arising in this research.

Formatted: Indent: Hanging: 0 cm

4. 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 or have an online consultation six times if you are in the group receiving the brief supportive treatment, and have phone call check-ins if you are receiving routine care. You should be prepared to undergo all the procedures that are outlined above.

Should you be randomly selected to receive the brief supportive treatment, you will have to be committed to attend all six intervention sessions, weekly (either through face to face or teleconferencing), to be completed in eight weeks; and be willing to be registered as a client with IMH (so that therapy can be provided, as per IMH protocol).

You will be withdrawn from the study should you receive any concomitant psychological or psychiatric services, or take any psychotropic medications during the period of the study.

5. What Is Not Standard Care or Experimental in This Study

The study is being conducted because the solution-focused brief therapy is not yet proven to be a standard treatment in subjects with psychological distress or subclinical mental health symptoms. We hope that your participation will help us to determine whether a brief solution-focused treatment is equal or superior to existing routine care (case management).

~~Use of blinding (one or more parties unaware of the treatment assignment), and randomization (intervention selection by chance) are only done for research studies.~~

6. Possible Risks and Side Effects

As the brief supportive treatment involves disclosing and problem-solving around problem areas causing distress and impairment to the patient, potential risk may include possible anxiety or emotional discomfort during the intervention. Although the occurrence is rare, this may lead to an increase in symptoms and symptom severity, and might result in destabilisation and hospitalisation. For those receiving routine care, potential risk may also include possible anxiety or emotional discomfort as they talk about their mental health needs during the case management check-ins. It is possible that without an active treatment during this interim period of waiting for specialized services, participants may have an increase in symptoms and symptom severity, and might result in destabilisation and hospitalisation.

To prevent and manage these possible adverse events, case managers providing brief supportive treatment or routine case management will be trained in appropriate therapist assessment and interventions. These include (1) assessment of their difficulties with sensitivity, empathy and care, (2) care will be taken to grade the level of questions, starting from the less sensitive questions first and then gradually increasing to more sensitive questions, paced to the comforts of the participant, (3) the case managers are trained and can assess and manage psychological distress and suicidal risk, (4) the CMs have regular supervision with a senior case manager/psychologist and weekly case discussions with a psychiatrist, and (5) you will be given the freedom to take a break, or postpone, or discontinue the session. Your psychological health is more important than the research. You also have the choice to withdraw from treatment and discontinue the study if it is too uncomfortable for you.

There may be some mental fatigue during the completion of the assessment battery. You will be encouraged to take a break in between or stop the assessment if you feel uncomfortable.

7. Possible Benefits from Participating in the Study

If you are randomly selected to receive the brief supportive treatment, ~~we expect that~~ you may find relief in your levels of psychological distress. ~~as you are receiving an active, evidence-based psychological intervention.~~

If you are randomly selected to receive existing routine care, there are no additional benefits to you but you will receive care-as-usual and be referred to a specialized mental health service before your case is closed.

Your participation in this study can help us evaluate the efficacy of SFBT as a time-limited intervention. Positive results for SFBT can encourage us to develop new models of care, introducing SFBT amongst youth mental health community providers as an evidence-based, low-intensity intervention to improve accessibility to appropriate and quality care. ~~There is no assurance you will benefit from participation in this study. However, your participation in this study may add to the medical knowledge about the use of solution-focused brief therapy and case management.~~

8. Important Information for Women Subjects

There are no known procedures that increase the risk for women subjects.

9. 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 standard case management. ~~The potential benefit of not participating in this study is that you will not be exposed to any known or unknown risks associated with receive solution-focused brief therapy. The potential risk is that you may not benefit from any possible improvement in your psychological distress that could result from solution-focused brief therapy.~~

Formatted: Space Before: 6 pt

10. Costs & Payments if Participating in the Study

If you take part in this study, the following will be performed at no charge to you: brief supportive therapy or standard case management. These costs will be borne by IMH.

~~You will be reimbursed for your time, inconvenience and transportation costs as follows:~~
~~If you complete the study, you will be paid SGD100.~~
~~If you do not complete the study for any reason, you will be paid SGD25 for each visit you complete. The inconvenience and transportation costs are dependent upon the length of your involvement in the study.~~

You will be paid SGD25 for each scheduled visit when you will be required to complete the online assessments, that is, at Week 0, Week 6-8, Week 8-10 and Week 18/20. If you are unable to provide the relevant information via the online assessments for any visit, you will not receive the compensation for that visit.

~~The inconvenience and transportation costs are dependent upon the number of visits you complete (Total 4 visits) as part of your involvement in the study.~~

11. 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 your case manager or a study team member (Research Assistant or the Principal Investigator).

If you withdraw from the study, you will be required to complete an online questionnaire with an individualized survey link, answering questions on your perceived self-efficacy, feelings of hopelessness and satisfaction with the treatment/routine care. 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 Investigator and/or the Sponsor of this study may stop your participation in the study at any time if they decide that it is in your best interests. They may also do this if you do not follow instructions required to complete the study adequately. If you have other medical problems or side effects, the doctor and/or nurse will decide if you may continue in the research study.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you *(or your legally acceptable representative, if relevant*) will be informed in a timely manner by the Principal Investigator or his/her representative.

If you are below the age of 21, we will also require your parent's or legally acceptable representative's consent for you to participate in this study.

12. Compensation for Injury

If you follow the directions of the investigator 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 Institute of Mental Health 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 Institute of Mental Health.

IMH without legal commitment will compensate you for the injuries arising from your participation in the study without you having to prove IMH is at fault. There is 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.

13. Confidentiality of Study and Medical Records

Information 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. You should also not include any of your identifiers in the ~~interview form.~~ questionnaires.

However, the Institute of Mental Health and NHG Domain Specific Review Board, and the 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 Informed Consent Form attached, you are authorizing (i) collection, access to, use, and storage of your "Personal Data", and (ii) disclosure to authorized service providers and relevant third parties.

"Personal Data" means data about you that makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or is likely to have access to. This includes 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.

Your participation in this study will involve the collection of "Personal Data". Information and "Personal Data" collected for this study will be kept confidential.

Data collected and entered into the Case Report Forms are the property of the Institute of Mental Health. 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 Personal Data Protection Notification available at https://www.imh.com.sg/pdp-notification/.

14. Who To Contact if You Have Questions

If you have questions about this research study, you may contact the following:
Nur Khairunisa Binte Ngaiman, Senior Case Manager, CHAT, Institute of Mental Health. Address: Buangkok Green Medical Park, 10 Buangkok View, Singapore 539747. Telephone: 6389-2000, 6389-6751.

Dr. Tang Yu Zheng, Charmaine, Consultant, CHAT/Department of Psychosis, Institute of Mental Health. Address: Buangkok Green Medical Park, 10 Buangkok View, Singapore 539747. Telephone: 6389-2000, 6389-2835.

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 subject, 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 www.research.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.

15. 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 IMH. Your information and contact details will not be released to any parties outside IMH without your permission. When investigators from IMH identify you to be suitable for a particular research study, the investigators or authorised personnel from IMH 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 the following:

Nur Khairunisa Binte Ngaiman, Senior Case Manager, CHAT, Institute of Mental Health. Address: Buangkok Green Medical Park, 10 Buangkok View, Singapore 539747. Telephone: 6389-2000, 6389-6751.

Dr. Tang Yu Zheng, Charmaine, Consultant, CHAT/Department of Psychosis, Institute of Mental Health. Address: Buangkok Green Medical Park, 10 Buangkok View, Singapore 539747. Telephone: 6389-2000, 6389-2835.

CONSENT FORM

Protocol Title:

CHAT Supportive Interventions (CSI): Randomized Controlled Trial of Six-session Solution Focused Brief Therapy versus Case Management for Youths with Mental Health Distress

Principal Investigator & Contact Details:
Nur Khairunisa Binte Ngaiman, Senior Case Manager, CHAT, Institute of Mental Health. Address: Buangkok Green Medical Park, 10 Buangkok View, Singapore 539747. Telephone: 6389-2000, 6389-6751.

Dr. Tang Yu Zheng, Charmaine, Consultant, CHAT/Department of Psychosis, Institute of Mental Health. Address: Buangkok Green Medical Park, 10 Buangkok View, Singapore 539747. Telephone: 6389-2000, 6389-2835.

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 IMH Personal Data Protection Notification.

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 the following methods (you may select more than one):

☐ Phone _____

☐ Mail _____

_____

☐ Email _____

☐ Others _____

☐ No, I do not agree to be contacted for future research.
For this study period only, I agree to be contacted via the following methods (you may select more than one):

☐ Phone _____

☐ Mail _____

_____

☐ Email _____

☐ Others _____

_____	_____	_____
Name of Participant	Signature	Date

_____	_____	_____
Name of Legally Acceptable Representative (if participant is below 21-years-old)	Signature	Date

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

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

The Parties (Investigator, Participant / Legally Authorised Representative & Witness) may execute this Informed Consent Form requiring a party's signature by using electronic signature process (e.g. by DocuSign, E-signature by Adobe Sign etc) and agree that signatures obtained or transmitted through electronic means, including the abovementioned signature process, shall be binding and effective for all purposes as if the signatures were executed in-person.