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Solution-focused brief therapy versus case management for youths with mental health distress

Submission date
12/09/2023

Recruitment status
No longer recruiting

Registration date
14/09/2023

Overall study status
Completed

Last Edited
20/01/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims

The demand for mental health services among young persons has increased dramatically in the last decade and during the COVID-19 pandemic, globally and in Singapore. This outpaces the number of available mental health resources in Singapore, leading to longer wait times for a first appointment with a psychiatrist or psychologist among treatment-seeking individuals. Longer wait times are linked to worsening mental health symptoms during the waiting period, poorer treatment prognosis, and reduced treatment engagement even after treatment is accessed. Because symptoms of mood and anxiety disorders are often a transient reaction to life stressors, a significant proportion of individuals with untreated symptoms may remit within 12 months and will not require sustained outpatient treatment. Finally, there may also be a smaller group of individuals who may prefer short-term counselling over psychiatric care (medication) or longer-term psychotherapy. There is an urgent need for more efficient and sustainable mental health delivery models in Singapore that can provide quicker access to effective psychological intervention for as many clients as possible.

Offering interim, low-intensity support to treatment-seekers may help mitigate the adverse effects of waiting for longer-term care, allocate scarce resources to appropriate levels of care, and reduce barriers to engaging in treatment. Solution-Focused Brief Therapy (SFBT) is a brief, manualized, scalable, evidence-based supportive treatment that is focused on identifying and mobilizing a patient's present goals, hopes, and strengths. Interventions based on SFBT have guided effective time-limited clinical services internationally (several exist in Canada, New Zealand, and Australia). At the Institute of Mental Health (IMH), Singapore, an open trial in 2015-2017 found that six-session treatment of SFBT was effective (47% experienced more than 25% distress reduction), well-accepted (93% felt very or mostly satisfied), and feasible (high attendance rate and treatment engagement, where the modal number of sessions attended was full treatment course) among 115 young persons.

The aim of this study is to test the short- and longer-term effectiveness of a six-session SFBT versus treatment-as-usual (TAU) (case management until referral for psychiatric or community counselling/therapy services) in reducing psychological distress among treatment-seeking young people. The study will also investigate if SFBT is better than case management in satisfaction ratings, strengthening clinically relevant proximal outcomes (perceived self-efficacy,

hopelessness), improving clinical functioning, and preventing clinical deterioration (depression and anxiety symptoms) in the short- and longer-term (3-month post-intervention follow-up). Finally, to explore whether SFBT may provide sufficient clinical care for some subset of clients, the study will also report on the number of clients who no longer need to remain on the wait list for psychiatric or community counselling/therapy services after treatment.

Who can participate?
Treatment-seeking young people (aged 16-30 years), of any gender, who either present with an increased risk of developing mental disorders (i.e., with non-specific mental distress, and/or subsyndromal or subthreshold symptoms), or are experiencing a first episode of a mental disorder at the national youth mental health outreach and assessment service (CHAT, Centre of Excellence for Youth Mental Health).

What does the study involve?
All participants will go through four timepoints of assessment: T1 (baseline), T2 (immediate end of treatment or closure of case), T3 (2 weeks after termination), and T4 (3-month post-treatment /case closed follow-up). The window period of assessment is 2 weeks. Participants will spend 6-8 weeks for intervention treatment, and 18-20 weeks for all assessments to be completed. During the CHAT assessment, clinical staging assessment and suicidal risk assessment will be conducted, and results will be known to the PI, research team, and clinical team at baseline. At T1, basic demographics will be collected, including age, sex, sexual orientation, race/ethnicity, level and years of education, psychiatric/psychological treatment prior to study enrolment, employment status, and marital status. At baseline, participants will also self-report on their psychological distress, depression symptoms, anxiety symptoms, and functional impairment. At T2, participants will report on self-efficacy and treatment satisfaction. At T3 and T4, participants will self-report on the same mental health outcomes as the baseline assessment. Participants will complete these English-language self-report questionnaires through an online survey link on Qualtrics, an encrypted and medically compliant online survey platform utilized by IMH. At T2, participants will also complete a post-intervention feedback and satisfaction survey. Each assessment will take about 20-30 minutes to complete.

What are the possible benefits and risks of participating?
Participants in the intervention group may find relief in their levels of psychological distress as they are receiving an active, evidence-based psychological intervention. For participants in the control group there are no additional benefits but they will receive care as usual and be referred to a specialized mental health service before their case is closed. All participants will be compensated for their time through inconvenience fees.
There are no significant risks associated with the study for both groups. Disclosing and problem-solving around problem areas may cause distress to the client, and potential risks may include possible anxiety or emotional discomfort during the intervention. For the control group, potential risks 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 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. However, these will be managed through trained case managers' assessment and interventions, and supervision from the PI/Co-I. Participants also have the choice to withdraw from treatment with no penalty if it is too uncomfortable for them.

Where is the study run from?
Institute of Mental Health (Singapore)

When is the study starting and how long is it expected to run for?
March 2023 to March 2025

Who is funding the study?
Ngee Ann Kongsi Fund (Singapore)

Who is the main contact?
Nur Khairunisa Binte Ngaiman, nur_khairunisa@imh.com.sg

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Study information

Scientific Title
Evaluating the efficacy of a six-session solution-focused brief therapy versus case management for youths with mental health distress: the CHAT Supportive Interventions (CSI) randomized controlled trial

Acronym
CSI RCT

Study objectives
Solution-Focused Brief Therapy will be associated with greater improvements than Treatment As Usual control (case management) in the primary outcome, psychological distress, from baseline to 2 weeks post-termination.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/08/2023, National Healthcare Group, Domain Specific Review Board (Nexus @One-North (South Tower), No. 3 Fusionopolis Link, #03-08, Singapore, 138543, Singapore; +65 (0) 6471 3266; ohrpp@nhg.com.sg), ref: 2023/00052

Primary study design
Interventional

Study design
Single-centre interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mental health distress

Interventions
The study will be conducted at the national youth mental health outreach and assessment service (CHAT, Centre of Excellence for Youth Mental Health).

Solution Focused Brief Therapy (SFBT) is a low-intensity, manualized, and scalable evidence-based supportive treatment that has been found to be effective, acceptable, and feasible among treatment-seeking young persons (age 16-30) who present with either an increased risk of developing mental disorders or are experiencing a first episode of a mental disorder in Singapore. Therapists help patients identify the tools and capacities they already possess to solve a problem at hand, and to take steps, however small, toward a future in which that problem is less influential. SFBT asserts that all people possess inner resources to solve life's challenges; that one does not need to know what caused a problem (e.g., via comprehensive clinical assessment) to begin solving it; and that the client is expert in their life and best-positioned to address their problems (de Shazer, 1985). The purpose of the present study's larger-scale randomized, placebo-controlled trial is to test the short- and longer-term efficacy of a six-session SFBT versus treatment-as-usual (TAU) (case management until referral for psychiatric or community counselling/ therapy services) in reducing psychological distress among treatment-seeking young persons (age 16-30) who are at increased risk of developing mental disorders.

The average number of talk therapy appointments attended by young persons (college students) is 4.3 to 5.0 sessions (Gorman et al., 2020), and less than 40% of adults entering psychotherapy complete more than 3 to 5 sessions (Barrett et al., 2008). Brief, time-limited treatments are thus most acceptable, and feasible among treatment-seekers, and are also less resource-intensive and cost-efficient to provide. For the active intervention, we are providing six 45- to 60-minute sessions of Solution-Focused Brief Therapy (SFBT), in person and/ or via teletherapy, delivered by trained case managers.

The treatment-as-usual (TAU) control condition is routine case management until a referral to and first appointment with psychiatric or community counselling/ therapy services is made. In Singapore's public hospitals, the median waiting time for a new subsidized appointment with a psychiatrist or psychologist was more than 30 days in 2020 (Ministry of Health, 2022); this waiting time is likely to have increased with the advent of COVID-19 and the associated rise in mental health presentations and treatment-seeking. As per routine care, case managers will provide 10- to 45-minute phone check-ins and care coordination with patient every week until referral is made (average 6-8 weeks, length-matched with intervention). The phone contacts focus on five key activities:
1. Assessing the subject's mental state and biopsychosocial needs
2. Co-developing an individualised action plan to address the subject's needs
3. Coordinating resources required to actualise the plan
4. Monitoring the subject's progress towards accomplishing the action plan. It may also involve reassessment and modification of the plan
5. Reviewing with the subject the outcomes of the action plan and the effectiveness of the entire effort before termination

TAU does not include any active therapeutic interventions, such as problem-solving, supportive counselling, or learning of coping skills. We ensure that TAU is consistently provided for all participants in the control arm by training case managers providing TAU with a standardized

case management manual. Case managers providing TAU will also receive ongoing individual supervision with a senior case manager at CHAT to ensure fidelity to the case management goals and activities.

Participants who meet inclusion criteria and provide written informed consent(s) (including parental consent for participants below age 21) to participate in the study will be randomly assigned to either SFBT (intervention) or Case Management (control) according to a 1:1 ratio determined by a computer-generated randomization sequence managed by an off-site biostatistician. Simple randomisation will be used to allocate participants to either the (1) intervention group or (2) TAU control group at random. An independent manager/off-site biostatistician outside of the recruitment team will generate a random number list from a computerised random number generator. The manager will place each random number within individual sealed and opaque envelopes labelled with the participant number sequence. After obtaining written informed consent, a research member will allocate the intervention/TAU group to that participant by opening one envelope.

Assigned case managers will contact the participant for the first session/contact of intervention or treatment-as-usual within five working days of informed consent. For participants in the intervention arm, the case manager (clinician) will bring the case up for clinical review and endorsement by a psychiatrist, as per CHAT protocol. If the participant is uncontactable via phone call within seven working days, the participant will be considered lost to contact and dropped from the study. As per CHAT's protocol, a text message will be sent to the client to check on his/ her wellbeing, following which an email/ text message about case closure, alternative treatment recommendations and resources, as well as an open invitation back to CHAT will be sent before the case is considered closed.

Intervention Type
Behavioural

Primary outcome(s)
Psychological distress measured by the Kessler-10 (K-10) from baseline to 2 weeks post-termination (T3)

Key secondary outcome(s)
1. Depression symptoms measured using Patient Health Questionnaire-9 (PHQ-9) at baseline, 2 weeks post-termination, 3 months post-termination
2. Anxiety symptoms measured using Generalized Anxiety Disorder-7 (GAD-7) at baseline, 2 weeks post-termination, 3 months post-termination
3. Clinical functioning measured using World Health Organization (WHO) Disability Assessment Schedule 2.0 (WHODAS) at baseline, 2 weeks post-termination, 3 months post-termination
4. Hopelessness measured using Beck Hopelessness Scale-4 at baseline, at termination, 3 months post-termination
5. Perceived self-efficacy measured using the General Self-Efficacy Scale (GSE) at baseline, at termination, 3 months post-termination
6. Satisfaction measured using Client Satisfaction Questionnaire (adapted CSQ8) at termination
7. Treatment progress measured using the Outcome Rating Scale (ORS) at the start of each SFBT session
8. Treatment alliance measured using Session Rating Scale (SRS) at the start of each SFBT session

Completion date
01/03/2025

Eligibility

Key inclusion criteria
All study participants must meet the criteria below:
1. 16-30 years old
2. English-speaking and English-literate
3. Non-specific mental distress (Clinical Stage 1a), subsyndromal or subthreshold symptoms (Clinical Stage 1b), or are experiencing a first episode of a full defined syndrome (Clinical Stage 2) based on CHAT assessment

Additional criteria for participants in the intervention arm:
1. Committed to attend all six intervention sessions, weekly (either through face-to-face or teleconferencing), to be completed in 8 weeks
2. Willingness to be registered as a client with the Institute of Mental Health Singapore (so that therapy can be provided, as per IMH protocol)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Lower age limit
16 Years

Upper age limit
30 Years

Sex
All

Key exclusion criteria
All subjects meeting any of the exclusion criteria at baseline will be excluded from participation.
Subjects who:
1. Have high suicidal risk (as determined by Columbia Suicide Safety Rating Scale, during CHAT assessment)
2. Have active and florid psychosis symptoms
3. Have significant cognitive impairments
4. Are participating in other active psychotherapy or psychiatric medication treatment
5. Are below 21 years old and do not have parental consent to participate in the study
6. Decline to be registered as a client at IMH (if they have been randomised to the intervention arm)

Date of first enrolment
19/09/2023

Date of final enrolment

19/09/2024

Locations

Countries of recruitment
Singapore

Study participating centre
Institute of Mental Health Singapore
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Sponsor information

Organisation
Institute of Mental Health

ROR
https://ror.org/04c07bj87

Funder(s)

Funder type
Charity

Funder Name
Ngee Ann Kongsi Fund, Singapore

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Nur Khairunisa Binte Ngaiman, Senior Case Manager, CHAT, Institute of Mental Health. Email: nur_khairunisa@imh.com.sg.

The type of data that will be shared: Patient demographics and quantitative outcome measures.
Dates of availability: The data will be available after the end of the study, March 2025, till 6 years later in March 2031.
Whether consent from participants was required and obtained: After the CHAT Assessment, all eligible participants will be referred by the CHAT assessor to the study research assistant who will contact the participant with a written informed consent to participate in a study that aims to test two different 6-8-week-long psychosocial interventions and requires participants to self-report on some mental health symptoms before and after the intervention. Subsequent data on participants will be de-identified.
Comments on data anonymization: Confidentiality will be protected by anonymizing research data. No participant will be identified in any analysis.
Any ethical or legal restrictions: All individual data from this study resides with the Office of Research, Institute of Mental Health. Data is not available for online access, however, readers who wish to gain access to the data can write to the Clinical Research Committee, Institute of Mental Health. Access can be granted subject to the Institutional Review Board (IRB) and the research collaborative agreement guidelines. This is a requirement mandated for this research study

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		20/12/2024	20/01/2025	Yes	No
Participant information sheet	version 13	31/01/2022	13/09/2023	No	Yes
Statistical Analysis Plan			13/09/2023	No	No