


# BMJ Open Efficacy of solution-focused brief therapy versus case management for psychological distress in adolescents and young adults in a community-based youth mental health service in Singapore: protocol for a randomised controlled trial

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## ABSTRACT

**Introduction** There are insufficient scalable, evidence-based treatments to meet increasing mental health needs of young people. Offering interim, brief interventions for young persons with psychological distress can improve access to care and mitigate adverse effects of long waiting times. This study tests the efficacy of solution-focused brief therapy (SFBT), a strength-based, goal-directed intervention, in adolescents and young adults at a community-based youth mental health service in Singapore.

**Methods and analysis** This is a fully powered, randomised, single-centre, two-arm, parallel, superiority, controlled trial. From September 2023 to March 2025, the study will recruit 124 participants (aged 16–30) presenting at a national youth mental health service in Singapore (CHAT, Centre of Excellence for Youth Mental Health) with clinically assessed general psychological distress, subthreshold or prodromal symptoms, or a first episode of a mood disorder. Participants will be excluded if they have high risk of suicide, psychosis, cognitive impairments, or current psychological treatments. Participants will be randomised in a 1:1 ratio to receive six-session, case manager delivered SFBT or treatment as usual (TAU) case management, and be followed up for 3 months post-intervention. Participants receiving SFBT are hypothesised to have greater improvements in self-reported psychological distress, from baseline to 8 weeks, compared with the control group. Secondary outcomes are self-reported depression and anxiety symptoms, and functional impairment. The study will also explore whether SFBT is associated with increased self-efficacy and decreased hopelessness, decreased downstream referrals post-intervention, and sustained clinical gains 3 months post-intervention compared with TAU. Adverse events and clinical deterioration will be recorded and reported.

**Ethics and dissemination** The Institute of Mental Health (IMH) Institutional Research Review Committee

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This will be the first randomised controlled trial to examine the efficacy of six sessions of case manager delivered solution-focused brief therapy (SFBT) compared with routine treatment as usual case management for reducing psychological distress and improving other mental health outcomes (depression and anxiety symptoms, functioning, use of tertiary psychiatric services) among young people in Singapore.
- ⇒ Both the intervention SFBT and TAU case management protocols are manualised, allowing for high treatment compliance.
- ⇒ Multiple clinically relevant assessments will be performed at regular time points to monitor for sustained improvement both during and after the intervention.
- ⇒ The trial has minimal known risks, with appropriate risk management and safety protocols for participants.
- ⇒ The lack of blinding among clinicians and participants is an inevitable limitation in psychotherapy-based trials and there may be a participant response bias.

(reference 822–2022) and the Singapore National Health Group Domain Specific Review Board (DSRB) (reference 2023/00052) have approved the study protocol. Findings will be published in international, peer-reviewed scientific journals. Summaries will be disseminated to study funders, mental healthcare systems administrators, and clinicians.

**Trial registration number** ISRCTN13671612 <https://doi.org/10.1186/ISRCTN13671612>

## INTRODUCTION

The demand for mental health services among young people has increased substantially in the past decade and during the COVID-19 pandemic, globally and in Singapore.<sup>1 2</sup> Mental health disorders were among the top five causes of disease burden in Singapore,<sup>3</sup> the highest proportion being young people aged 18–34 presenting with mood and anxiety disorders.<sup>4</sup> In the 2024 National Youth Mental Health study, one in three young people in Singapore aged between 15 and 35 reported severe symptoms of depression, anxiety or stress.<sup>5</sup> This demand exceeds available resources, leading to longer waiting times for a first appointment with a psychiatrist or psychologist, which reached up to 45 days in public hospitals in 2023.<sup>6</sup> Longer waiting times are associated with worsening mental health symptoms during the waiting period,<sup>7 8</sup> poorer treatment prognosis,<sup>9</sup> and reduced treatment engagement even after treatment is accessed.<sup>10</sup>

Transient symptoms of anxiety and depression in response to stressors often remit spontaneously within 12 months<sup>11</sup> and may not require intensive treatments. Additionally, many young people prefer short-term counselling<sup>12</sup> over medication or longer-term psychotherapy; young people attend an average of less than five psychotherapy appointments.<sup>13</sup> Aligned with Singapore's national mental health strategy to expand the capacity of mental health services,<sup>14</sup> it is imperative to provide interim, time-limited support to distressed individuals that are effective in mitigating adverse effects of waiting for longer-term care,<sup>15 16</sup> reducing barriers to treatment engagement (eg, stigma, costs),<sup>17</sup> and can potentially free up scarce psychiatric services for those who require more intensive treatment.

Solution-focused brief therapy (SFBT)<sup>18 19</sup> is a brief, manualised, evidence-based supportive treatment focused on identifying the client's short-term recovery goals, mobilising their strengths, resilience, hope for recovery and change, and capacities for problem-solving. SFBT asserts that people possess inner resources to solve difficulties they are facing; that one does not need to know what caused a problem to begin solving it; and that the client is an expert in their life and best positioned to address their problems.<sup>19</sup> SFBT can be used with adolescents and adults, regardless of problem type or severity, and can be delivered by certified providers who do not need specialised mental health training. SFBT providers help clients identify a specific, modifiable problem or treatment goal, and create a personalised action plan that draws on their strengths, coping abilities and external resources to take a step towards addressing their identified goals. Time-limited SFBT interventions have been effectively implemented in clinical services internationally, including in the United States,<sup>20</sup> China<sup>21</sup> and the Netherlands.<sup>22</sup> It has been shown to empower clients and improve hopelessness, agency and self-efficacy, and reduce distress in adults on waiting lists.<sup>16 19</sup>

At the Institute of Mental Health (IMH), Singapore, an open trial conducted from 2015 to 2017 with 117 young

people (aged 16–30) seeking treatment found that a six-session treatment of SFBT was feasible (>50% attended at least five sessions), well accepted (99% felt very or mostly satisfied), and effective in improving overall well-being with medium effect size ( $d=0.64$ ).<sup>23</sup> Notably, SFBT was delivered by certified case managers, frontline personnel providing supportive mental health treatment and care coordination in Singapore's mental health system, which allows for scalable early intervention.

We aim to conduct a randomised, two-armed, parallel, superiority trial to investigate whether case manager delivered, six-session SFBT is superior to treatment as usual (TAU) routine case management in reducing psychological distress among adolescents and young adults seeking help in Singapore. We will additionally examine whether SFBT is more efficacious than TAU in reducing secondary outcomes of self-reported depression and anxiety symptoms, and functional impairment. We will also explore any association between SFBT and increased self-efficacy and decreased hopelessness, decreased downstream referrals post-intervention, and sustained clinical gains 3 months post-intervention compared with TAU.

This protocol was written according to the Standard Protocol Items: Recommendations for Interventional Trials and CONSolidated Standards of Reporting Trials.<sup>24</sup>

## METHODS

### Study setting and participant recruitment

Participant recruitment began in September 2023 and will continue until March 2025 from CHAT, Centre of Excellence for Youth Mental Health, a community-based youth mental health outreach and assessment service under IMH in Singapore. CHAT was established to provide free and confidential access for early treatment among young people aged 16–30.<sup>25</sup> CHAT adopts the clinical staging model developed by Patel *et al*<sup>26 27</sup> for assessing severity of mental health syndromes and disorders to facilitate a tiered, stepped-care approach to providing corresponding intervention intensities.<sup>14</sup> Trained case managers will conduct a structured mental health assessment and clinical interview with clients to determine participant eligibility.

### Participant eligibility

Clients are eligible to participate in the trial if they are aged 16–30 and are assessed to have general psychological distress (stage 1a), subsyndromal or subthreshold symptoms (stage 1b), or are experiencing a first episode of a mood disorder (stage 2). All sexes, genders, races or nationalities are eligible. Clients will be excluded from the trial if they have more severe or treatment-resistant mental health disorders (stage 3 or 4); high suicidal risk (determined by the Columbia Suicide Safety Rating Scale)<sup>28</sup> (online supplemental appendix 3); or active positive psychotic symptoms (eg, hallucinations, delusions). Referrals to appropriate treatments and level of psychiatric care will be made according to IMH's protocol. Clients will also

be ineligible if they have significant intellectual disability or cognitive impairments; have active psychotherapy or pharmacotherapy; are younger than 21 years and do not have parental consent to participate in the study; or decline to be registered as a client at IMH if they are randomised to the intervention arm. Only English-speaking and English-literate participants will be invited, as the intervention and certain questionnaires are only available in English; this is unlikely to be limiting as most clients are English literate.

Eligible participants will be referred to the study's research coordinator who will obtain written informed consent (online supplemental appendix 1). Parental consent will be taken for clients younger than 21, which is the age of consent in Singapore. Participants will be informed that if they are randomised to the intervention arm, they will be required to attend six intervention sessions, and register as a client in IMH.

### Sample size calculation

For a fully powered, two-arm randomised trial (statistical power 0.80, type 1 error rate 0.05), we estimate needing 47 participants per arm to reject the null hypothesis with a moderate effect size of 0.50 on the primary outcome (psychological distress) for the intervention group, and assuming an effect size of 0.15 response for the control group based on the rate of spontaneous remission of symptoms. Accounting for a 30% attrition rate based on the pilot data,<sup>23</sup> 62 participants will be prospectively recruited per arm, resulting in a total of 124 participants. This recruitment target is feasible given that CHAT assessed 930 individuals in 2022.<sup>29</sup> Reasons for attrition will be analysed and retention strategies (eg, simplifying procedures to reduce participant burden) will be implemented to minimise high attrition.

### Intervention assignment and blinding

Participants will be assigned to either SFBT (intervention) or case management (TAU) in a 1:1 ratio determined by a computer-generated simple randomisation sequence managed by an off-site statistician. The statistician will place each random number within individual sealed, opaque envelopes labelled with a participant number sequence. After obtaining consent, a research coordinator will assign the participant to the respective arm by opening one envelope. The research coordinator will then assign a case manager to participants based on the final arm allocation. The case manager will contact the participants within five working days of receiving informed consent. Participants in the intervention arm will have their case reviewed by a psychiatrist after contact by the case manager. The principal investigator, research coordinators, clinical supervisors, case managers and participants will be aware of the intervention being received. The statistician conducting data analysis will be blinded to the treatment arm allocation.

### Interventions

Participants in the intervention arm will receive six weekly sessions of SFBT, each lasting 45–60 min, delivered

virtually or in person by six IMH case managers certified as solution-focused practitioners by the International Alliance of Solution-Focused Teaching Institutes (IASTI). Certification is based on completing intensive didactic and experiential training, self-study, individual supervision from a Master level certified SFBT therapist, and meeting competency benchmarks on an oral examination. Case managers will deliver a manualised version of SFBT that includes problem description, co-construction of therapy goals, exploration of clients' preferred outcomes, and identification of previous solutions and resources in solution building. SFBT will be personalised according to process evaluation measures that assess treatment engagement and experience. The Outcome Rating Scale (ORS)<sup>30,31</sup> will be administered at the start of sessions and assesses four areas of life functioning: individual well-being, interpersonal well-being, social role, and overall well-being. The Session Rating Scale (SRS),<sup>32,33</sup> a measure of therapeutic alliance, will be administered at the end of each session to identify and address problems in real time. As part of the intervention protocol, measures will be interpreted in-session with the participant to collaboratively assess treatment progress. After completing six sessions, if participants demonstrate a treatment response in decreasing psychological distress, they will terminate care and receive a summary of their strengths, goals and subsequent steps. Those who continue to experience high psychological distress or deterioration in psychological symptoms (as determined by clinicians and verified by measures) at the end of the 6-week intervention will be referred to psychiatric or community counselling services. Throughout the study, case managers delivering SFBT will receive monthly group clinical supervision with a Master level certified SFBT therapist to ensure intervention compliance and discuss treatment goals and strategies.

The TAU group will receive routine case management, comprising weekly 10 to 45 minute-long phone calls. The goal is to provide care coordination and referrals to appropriate psychiatric or community therapy services. Case management will continue until contact with psychiatric services is established, which averages 10 weeks.<sup>29</sup> Case managers will focus on five key activities: (1) assessing the participant's mental state and biopsychosocial needs; (2) co-developing individualised action plans; (3) coordinating resources to actualise the plan; (4) monitoring the participant's progress; (5) reviewing the outcomes and the overall effectiveness of the effort before termination. TAU differs from SFBT by focusing on assessing present mental health symptoms and maintaining clients in the help-seeking process, rather than guiding clients in future and recovery oriented, goal-directed problem solving. TAU does not include active therapeutic strategies, such as problem solving, supportive counselling, or learning and reinforcement of skills for coping with psychological distress or behavioural change. Instead, TAU uses generic attending skills as opposed to specific responding and questioning techniques. Case managers



providing TAU will be trained with a standardised case management manual developed by CHAT based on the strength-based case management model.<sup>30</sup> They will receive ongoing individual supervision with a senior case manager at CHAT to ensure treatment compliance.

### Adverse event monitoring and attrition

Our trial has minimal known risks. Potential harms for both the SFBT and control groups include emotional discomfort during the intervention, which could rarely lead to increased symptom severity. To prevent and manage this risk, case managers will be trained in appropriate therapeutic interventions, suicide risk assessment and safety planning, and will receive regular supervision from a senior psychologist and psychiatrist. In cases of high suicidal risk, participants will be assessed by a psychiatrist who will follow IMH protocols for safety planning and appropriate referrals for care. All adverse events will be recorded and reported to the principal investigator, and to the Domain Specific Review Board (DSRB) within seven calendar days, and within 24 hours if they involve deaths and high suicide risk. In the case of significant clinical deterioration or adverse events (eg, self-harm, suicide or homicide), an interim analysis will be performed, and results will be presented to the principal investigator to determine the appropriateness of premature study termination. All participants will continue to receive TAU and modifications to the protocol will be submitted to the DSRB.

If participants are uncontactable, they will be considered to have dropped out. Follow-up text messages will be sent to monitor participants' well-being, providing alternative treatment recommendations and resources, as well as an open invitation to continue receiving services at CHAT. Participants may be asked to withdraw from the study if adverse events occur (eg, high suicidal risk), or if they receive concomitant psychological or psychiatric services during the intervention period. Participants who drop out or withdraw from the study will be replaced if the recruitment numbers are not reached. Should any participants be physically harmed during the study, IMH will cover the medical expenses for injury treatment.

### Outcomes and measures

All measures have been validated for use in non-Western and other Asian countries with culturally diverse populations, and are valid for use with adolescent and young adult populations.

#### Primary outcome

Psychological distress will be measured using the Kessler-10 (K-10),<sup>34</sup> a 10-item screening scale for general psychological distress that has been validated in culturally diverse settings.<sup>35 36</sup> Participants rate their experience of distress in the past 2 weeks, including fatigue, hopelessness, depression and worthlessness, on a five-point scale (1=none of the time to 5=all of the time). A higher summed score indicates greater severity. To determine

treatment response in the intervention arm, a K-10 score of  $\leq 19$  will be considered a negative screen for psychological distress based on the measure's recommended scoring.<sup>34 37</sup>

#### Secondary outcomes

Depressive symptoms will be measured by the Patient Health Questionnaire-9 (PHQ-9),<sup>38</sup> a validated<sup>39</sup> nine-item scale based on the Diagnostic and Statistical Manual for Mental Disorders, fifth edition (DSM-5)<sup>40</sup> criteria for Major Depressive Disorder. Participants will rate the frequency of depressive symptoms experienced over the past 2 weeks on a four-point scale (0=not at all to 3=nearly every day). Higher summed scores indicate greater symptom severity.

Anxiety symptoms will be measured using the Generalised Anxiety Disorder-7 (GAD-7),<sup>41</sup> a seven-item scale based on DSM-5<sup>40</sup> criteria for Generalised Anxiety Disorder, which has been validated in non-Western settings.<sup>42</sup> Participants will rate the frequency of symptoms experienced over 2 weeks on a four-point scale (0=not at all to 3=nearly every day). Higher summed scores indicate greater symptom severity.

Functional impairment will be measured by the 12-item self-administered version of the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0),<sup>43</sup> which has been validated in community samples.<sup>44</sup> This scale assesses clinical functioning over the past 30 days across the following domains: cognition, mobility, self-care, interpersonal interactions, life activities, and participation in society. Participants will rate items on a five-point scale of difficulty (0=no difficulty to 4=extreme difficulty/cannot do). Higher summed scores indicate greater functional impairment.

#### Clinically relevant proximal outcomes

Perceived self-efficacy will be measured using the 10-item General Self-Efficacy Scale,<sup>45</sup> which has been validated in Asian countries.<sup>46</sup> Respondents will rate their agreement with items, assessing the belief that one can perform novel or difficult tasks or cope with adversity, on a four-point scale (1=not at all true to 4=exactly true). Higher summed scores indicate higher levels of perceived self-efficacy.

Hopelessness will be measured by the Beck Hopelessness Scale-4,<sup>47 48</sup> a four-item validated scale abbreviated from the original 20-item Beck Hopelessness Scale, which has been validated in East Asian populations.<sup>49</sup> Participants will report their agreement with items assessing the affective, cognitive and motivational components of hopelessness on a four-point scale (0=not at all true to 3=often true). Higher summed scores indicate greater hopelessness.

#### Treatment satisfaction

Treatment satisfaction will be assessed using the Client Satisfaction Questionnaire,<sup>50</sup> which has been validated in therapy settings,<sup>51</sup> adapted to our interventions. It includes five items assessing service satisfaction on

**Table 1** Assessment schedule

Measure	Baseline (T1; week 0)	Post-intervention (T2; week 6–8)	2 weeks post-intervention (T3; week 8–10)	3 months post-intervention (T4; week 18–20)
Demographics	x			
Primary outcome				
Psychological distress: Kessler-10	x		x	x
Secondary outcomes				
Depression symptoms: Patient Health Questionnaire-9	x		x	x
Anxiety symptoms: Generalised Anxiety Disorder-7	x		x	x
Functional impairment: WHO Disability Assessment Schedule 2.0	x		x	x
Proximal outcomes				
Hopelessness: Beck Hopelessness Scale-4	x	x		
Perceived self-efficacy: General Self-Efficacy Scale	x	x		
Treatment satisfaction				
Satisfaction: adapted Client Satisfaction Questionnaire		x		

a four-point scale, and three open-ended questions regarding what participants found to be the most helpful, and their recommendations for improving the treatment services they received. Higher summed scores indicate greater satisfaction.

### Assessment procedures

After treatment allocation, all participants in both arms will undergo four time points of assessment: baseline (T1), post-intervention (T2), 2 weeks post-intervention (T3), and 3 months post-intervention (T4). The window period of assessment is up to 2 weeks. For participants in the intervention arm, the T2 assessment is conducted when six SFBT sessions are completed, up to 8 weeks from T1 assessment. If a SFBT participant voluntarily withdraws from the study during the intervention period at any time, the participant will be invited to complete the T2 assessment and continue TAU with CHAT. The number of non-responders in the SFBT arm will be noted and will not be included in the 3-month post-intervention assessment, as this will allow us to assess if sustained clinical gains are due to SFBT and not the follow-up treatment. For the TAU group, T2 assessment is completed when a participant has been successfully referred to downstream services (eg, counselling, therapy or psychiatric services) or at 8 weeks from T1 assessment, whichever comes first.

**Table 1** summarises the assessment schedule. Primary and secondary outcomes will be assessed at T1, T3 and T4. Outcomes will be measured 2 weeks post-intervention to prevent overlap with the intervention period as scales assess for symptoms experienced in the past 2 weeks. Clinically relevant proximal outcomes of hopelessness and self-efficacy will be measured at T1 and T2. Treatment satisfaction will be measured at T2. To monitor treatment engagement in both arms, case managers will record how sessions were delivered (whether in-person or remotely; via video or phone call), the frequency and duration of each session of intervention or phone contact, and each participant's attendance.

### Data management

Participants will complete English-language self-report questionnaires through an online survey on Qualtrics, an encrypted and medically compliant platform. Each assessment will take approximately 20 minutes to complete. Participants will be compensated SGD\$25 for each assessment.

To ensure the confidentiality of the participants, all data collected (online supplemental appendix 2) will be deidentified and coded. Hardcopy data will be stored in locked cabinets, while electronic records will be maintained in encrypted and password-protected databases.

that do not contain identifying information. Identifiers will be stored in file systems separate from data files and be password protected. Project data will only be accessed by the project investigators, research coordinators, statisticians and the clinical team. Study data will be available for 6 years from the end of the study, until March 2031. All data from this study will reside with the IMH Office of Research, and will not be available for online access unless permission is granted by the IMH Institutional Review Board (IRB).

### Statistical analysis

To test whether SFBT is efficacious in improving psychological distress (primary outcome), depressive and anxiety symptoms, and functional impairment (secondary outcomes) from baseline (T1) to 2 weeks post-intervention (T3) and whether gains are sustained at 3 months post-intervention (T4), a two (intervention: SFBT, TAU case management) by three (assessment time: T1, T3, T4) factorial analysis of variance (ANOVA) for repeated measures will be conducted. This will examine the statistical significance for the main effect of intervention and time, and the interaction between them. For binary outcomes (K-10 cut-off score of  $\leq 19$ ), a logistic generalised estimating equations analysis will be used for detecting the intervention effect. Significant main effects will be probed with multiple two-way comparison tests (ie, T1 vs T3, T1 vs T4, and T3 vs T4). To explore whether SFBT is associated with greater improvements than TAU in self-efficacy and hopelessness (proximal outcomes) and reductions in downstream referral rates from baseline to post-intervention (T2), ANOVA for repeated measures will be conducted for T1 versus T2. For all analyses, covariates will include clinical stage, age, sex, race, employment, marital status, educational level, and history of psychiatric treatment. Effect sizes (Cohen's *d*) for each outcome will be calculated to indicate the magnitude of change in treatment outcomes for each treatment group from T1 to T3, T1 to T4, and T3 to T4. Established thresholds will be applied for interpreting the effect sizes, with Cohen's *d* of 0.2 denoting a small effect, 0.5 a medium effect, 0.8 and above a large effect.<sup>52</sup> Participants in each group will be analysed according to intention-to-treat principles. Missing data will be analysed using the last observation carried forward, a common method to handle missing data in intervention clinical trials most likely due to drop-outs or treatment disengagement, as it maintains sample size and allows for an intention-to-treat analysis. Sensitivity analyses will be conducted with multiple imputations for missing data.<sup>53</sup> All statistical analyses will be performed in SPSS version 29 (IBM Corp, 2022).

### Data monitoring

Our trial has a short duration, a modest sample size and minimal known risks. A formal data monitoring committee is not required by the IRB. Analysis will only be completed at the end of the intervention trial and after follow-up data has been collected. In the case of

significant clinical deterioration or improvement, an interim analysis will be performed and results will be presented to the PI to determine the appropriateness of premature termination. To ensure data quality and the feasibility of the study, study team members will randomly audit 10% of available data semi-annually. This audit will inform any necessary changes in procedures. Discrepancies in data will be corrected and deviations from the protocol will be reported to the PI and the IRB.

### Ethics and dissemination

The Clinical Research Committee (IMH) (reference 822-2022, 4 January 2023) and DSRB of the National Health Group in Singapore (reference 2023/00052, 24 August 2023) have provided ethical approval of the study. Research findings will be published in peer-reviewed scientific journals and disseminated to the community of mental healthcare system administrators and clinicians.

### Data sharing statement

The data supporting the findings of this study is not publicly available due to privacy and ethical restrictions. However, deidentified data may be accessible from the last author, Dr Charmaine Tang, on reasonable request and with the approval of the IRB. Researchers wishing to access the data will be required to sign a data-sharing agreement to ensure compliance with privacy and ethical guidelines.

### STRENGTHS AND LIMITATIONS

This randomised controlled trial will be the first to examine the efficacy of case manager delivered, six-session SFBT compared with routine case management for psychological distress and other mental health outcomes among young people in Singapore. The lack of blinding among clinicians and participants is an inevitable limitation in psychotherapy-based trials and there may be a participant response and social desirability bias. In addition, while it is not feasible and pragmatic to implement structured fidelity measurement due to resource constraints, we enhance intervention fidelity by manualising the content and delivery of SFBT and TAU using systematic clinical note documentation, and providing robust clinical supervision, monitoring and auditing to ensure the case manager's compliance with these treatment modalities.

If this study can demonstrate SFBT's efficacy for psychologically distressed young people seeking mental health treatment, it will encourage increasing capacity of low-intensity treatments that can be delivered by front-line mental health case managers in Singapore, thus improving access to evidence-based psychological interventions in the community.

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**Contributors** CYSF, NKBN, YPL, EA, JAV, CT were involved in the design of the clinical aspects of the study. NKBN, DSD, YCC, YPL, CT contributed to the study operations. CYSF, EA, JAV, CT contributed to the biostatistical design, planning and data analysis plan. CYSF and TH drafted the paper with input from all authors. All authors reviewed and approved the final manuscript. CT is the guarantor.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and was approved by The Clinical Research Committee (IMH) (reference 822-2022, 4 January 2023) and the Domain Specific Review Board (DSRB) of the National Health Group in Singapore (reference 2023/00052, 24 August 2023). Participants gave informed consent to participate in the study before taking part.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data are available upon reasonable request. Recruitment and data collection commenced in September 2023 and will continue until March 2025.

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