Trials

STUDY PROTOCOL

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Promoting mental health among at-risk adolescents in Malaysia (MyHeRo): study protocol for a cluster randomised controlled trial to evaluate the effectiveness and cost-effectiveness of a school-based intervention compared with study skills condition for adolescents identified as at risk for anxiety and depression

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Abstract

Background In Malaysia, adolescent anxiety and depression are increasing faster than ever, and rates of suicidal behaviour are rising especially among those living in deprived communities. However, Malaysia's mental health system is currently constrained by limited workforce capacity, affecting the delivery of effective interventions. The overall aim of this trial is to use a school-based intervention to promote mental health among at-risk adolescents from low-income communities in Malaysia. Our primary aim is to evaluate the effectiveness and cost-effectiveness of a school-based intervention ("Super Skills for Life"; SSL) in reducing anxiety and depression, and in improving mental wellbeing in adolescents aged 12–14 years. We also aim to determine the characteristics of adolescents who benefit from SSL, compared to those who do not, as well as to identify contextual factors related to the successful implementation of SSL in Malaysian schools.

Methods The design will be a two-arm, cluster randomised controlled trial comparing school-based intervention (Super Skills for Life; SSL) to study skills control condition (Study Skills Programme; SSP) using a 1:1 allocation ratio. Classrooms will be the cluster unit for randomisation. Three stratification factors will be used for randomisation: school size, classes/forms and school location (urban vs rural). The study will recruit adolescents in at least 20 secondary schools in economically deprived, rural and urban regions in Malaysia. These adolescents will be invited to complete a screening questionnaire (i.e. Depression Anxiety and Stress Scale-21; DASS-21). Based on power calculation, 428

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adolescents (214 per arm) who experience moderate to severe levels of anxiety and depression on the DASS-21 will be invited to participate in the trial. Classes will be randomly allocated to SSL or SSP, with eligible adolescents from each class receiving the allocated intervention. Assessment will be conducted at screening, at pre- (i.e. baseline) and post-intervention (i.e. 2 months), and at two follow-ups (i.e. 6 and 12 months post-intervention). The primary outcomes will be a reduction in anxiety and depressive symptoms, and an improvement in mental wellbeing at 12 months post-intervention.

Discussion Findings of this trial will determine if delivering a group school-based intervention by school staff for adolescents at risk of anxiety and depression is effective and cost-effective. The findings will advance understanding of the role of school staff in the delivery of a school-based intervention and will generate new knowledge on the role of socio-cultural and other contextual factors in predicting intervention uptake and treatment outcome.

Trial registration ClinicalTrials.gov NCT07138664. Registered on August 16, 2025.

Keywords Anxiety, Depression, Mental health problems, Lifestyles, Cognitive behaviour therapy, Prevention, Adolescents, Super Skills for Life, Schools, At risk, Cost-effectiveness

Introduction

Background and rationale {6a}

Mental health problems (MHP) such as anxiety and depression account for 13% of the global burden of disease and affect approximately 20% of adolescents worldwide [1]. The onset of anxiety and depression typically occurs before 14 years of age, and these MHP are associated with poor school performance, alcohol and drug misuse, and suicidal behaviour [1]. If left untreated, adolescent MHP could lead to social exclusion, economic deprivation, risks for poor health, and other adverse life outcomes [1]. In low- and middle-income countries (LMICs) such as in Malaysia, adolescents with MHP have limited or no access to effective interventions, stigma hinders help-seeking, and there is a lack of government investment in mental healthcare.

School-based interventions can reduce barriers to accessing treatment such as cost and can circumvent stigma. Targeted school-based interventions are effective in reducing adolescent's MHP and psychosocial impairments, and in improving self-esteem and mental wellbeing [1]. However, almost all trials of targeted school-based interventions have been conducted in high-income countries, and there are methodological limitations such as limited long-term follow-up, small sample size, and lack of process evaluation. Thus, there is a need to conduct school-based targeted prevention studies in LMIC such as Malaysia, with improved methodological rigor.

Why Malaysia?

Even before the COVID-19 outbreak, between 20 and 40% of the adolescents in Malaysia had anxiety and depression, and 10% had attempted suicide, exceeding Southeast Asian and global comparators [2]. Adolescent mental health has been described as "the hidden epidemic" [3] in Malaysian society as anxiety and depression are increasing faster than ever, and rates of suicide are rising. Adolescents from low-income families and socially marginalised groups have the highest prevalence of anxiety and depression [2] which is often linked to rapid societal changes, including urbanisation.

Malaysia's mental health system faces workforce constraints that limit its capacity to deliver effective interventions addressing rising rates of anxiety, depression, and suicide. In its 2021 national budget, less than 2% of the country's total budget was allocated to address mental health problems, violence prevention, and substance abuse [4]. It is, therefore, not surprising that there are high levels of unmet mental health needs, with between 0.41 and 0.61 mental health workers per 100,000 residents [5]. Furthermore, stigma is a major barrier to help-seeking; the Malaysian word for mental illness is "gila" (crazy or madness) which has a very negative connotation, and suicide as well as attempted suicide have only been decriminalised in May 2023.

What should mental health promotion programmes target?

In mental health promotion, adolescents are taught skills to improve positive behaviours which protect mental health. Most programmes use cognitive behaviour therapy-based (CBT) interventions targeting either anxiety or depression. There is strong evidence that lifestyle factors (e.g. physical activities, healthy diet, and sleep) benefit mental health [6], but programmes that integrate healthy lifestyle habits within CBT-based interventions are currently lacking. Such a siloed approach fails to recognise the common risk factors and opportunities for a more integrated and resource-efficient approach. Indeed, recent World Health Organisation policy documents (e.g. *Motion for your mind and Global Strategy on Diet, Physical Activity, and Health*) have advocated such integration [7]. Furthermore, little is known about moderators and

mediators of intervention and implementation outcomes in school-based interventions targeting mental health conditions such as anxiety and/or depression in LMIC such as Malaysia [8–10]. Understanding these factors would maximise the effectiveness of interventions and intervention uptake in schools.

Aims and objectives {7}

The aims of this study are to:

(a) Evaluate the effectiveness and cost-effectiveness of a school-based psychosocial intervention ("Super Skills for Life"; SSL [11]) in reducing anxiety and depression, and in improving mental wellbeing in adolescents aged 12–14 years, in comparison to adolescents who received a control intervention (Study Skills Programme; SSP [12]).
(b) Determine the characteristics of adolescents who benefit from SSL, compared to those who do not.
(c) Identify contextual factors related to the successful implementation of SSL in Malaysian schools.

Primary objective

To determine the effectiveness of SSL in reducing anxiety and depression, and in improving mental wellbeing in adolescents 12 months after receiving SSL, compared to SSP.

Hypothesis

Adolescents in the SSL group will show significant reductions in anxiety and depression, and improvements in mental wellbeing at 12 months, compared to those in the SSP group.

Secondary objectives

(a) To investigate the effectiveness of SSL in reducing psychosocial impairments, suicidal behaviour, and in improving self-esteem, executive function, and social skills.
(b) To examine the impact of SSL on adolescent's educational performance.
(c) To examine the impact of SSL on adolescent's lifestyle habits.
(d) To explore the moderators and mediators of the primary outcomes.
(e) To assess the cost-effectiveness of SSL in reducing anxiety and depression, health-related quality of life, and cost–utility.
(f) To identify processes that influence SSL implementation such as social validity (e.g. uptake, acceptability, feasibility) and factors affecting its delivery (e.g. facilitator's characteristics and the school environment).
(g) To evaluate the role of implementation variability in moderating the impact of SSL on outcomes for adolescents.
(h) To determine factors associated with the sustainability of the intervention in schools.

To address these objectives, our research will consist of four stages (Fig. 1).

This protocol follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [13] (see Supplementary file: SPIRIT checklist).

Trial design {8}

The trial design will use a cluster randomised controlled trial with two arms comparing SSL to SSP using a 1:1 allocation ratio. Classrooms will be the cluster unit for randomisation. This design has been selected to prevent potential imbalances in group allocation arising from school-related effects. The randomisation procedure will be conducted by an independent statistician.

Three stratification factors will be used for randomisation: school size, classes/forms, and school urbanicity. Our initial design was to include the state as a stratification variable; however, this was changed due to recruitment and screening pace across the three states. Adolescents, aged 12 to 14 years, studying in Form 1 and Form 2 (i.e. the first two years of secondary school) will be invited to participate in screening. Adolescents who experience moderate to severe levels of anxiety and/or depression are eligible to participate in the trial.

Assessment will be conducted at five assessment points: screening, baseline (pre-intervention), and at 2 months, as well as at 6 and 12 months post-intervention. Except for the screening which will be conducted by the study research assistants, the trial outcome assessments will be conducted by trained independent assessors.

Process evaluation will also be examined by conducting qualitative interviews to explore adolescent's experiences of taking part in the intervention and school staff's (i.e. SSL facilitators) experiences of delivering the intervention. SSL facilitators will be interviewed to identify factors that affect the delivery of SSL (e.g. school environment, social validity of SSL).

Methods: participants, interventions, and outcomes

Study setting {9}

All data collection will take place in Malaysia, a culturally diverse country in Southeast Asia with an estimated population of 33 million, with 42% of its population being younger than age 25. The study is planned to be conducted in 20 secondary schools in rural and urban areas of predominantly economically deprived regions in the Malaysian states of Sarawak,

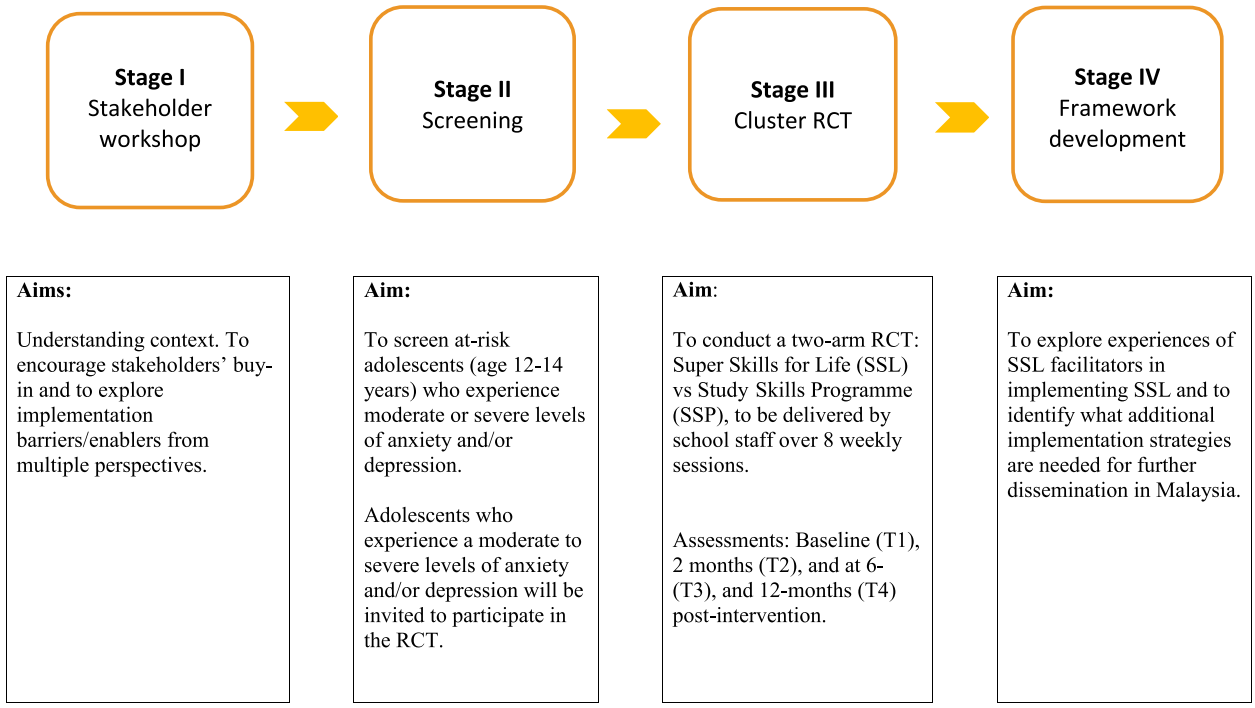

Fig. 1 The study design

Sabah, and Selangor. These states are chosen because adolescents in these areas have been reported to have a high prevalence of anxiety and depression [2] and they represent different regions in Malaysia.

Eligibility criteria {10}

Inclusion criteria

(1) Adolescent (aged 12–14) who are in the first two years (Form 1 and Form 2, equivalent to year 7 and 8 in the UK school system, respectively) in lower secondary schools. We have chosen this age range because it is a period of rapid behavioural, cognitive, and neural development, during which time mental health promotion programmes may have a maximal impact [14]. Adolescence is the peak age of onset of anxiety and depressive disorders [1] and is the stage at which lifestyle habits are developed [6]. In Malaysian schools, this age group has been reported to have the highest rate of mental health problems and suicidal attempts [2]. Furthermore, having recently transitioned from primary to secondary school, adolescents in this age group are exposed to new social and structural environments, especially those who live in remote areas as they move for the first time away from their parents to live in a boarding school.

(2) Adolescents score moderate to severe levels of anxiety and/or depression on the Depression Anxiety and Stress Scale-21 (DASS-21) based on the original cut-off norms (DASS-21 Anxiety scale ≥ 10 and/or DASS-21 Depression scale ≥ 14) as proposed by the authors of DASS-21 [15]. DASS-21 is a reliable and widely used scale in adolescent research in Malaysia, including the National Adolescent Survey that involved more than 30,000 adolescents [2].

(3) Adolescent's parent/carer provides written consent.

Exclusion criteria

(1) Being diagnosed with neurodevelopmental disorders.
(2) Being diagnosed with intellectual disability.

Who will take informed consent? {26a}

When the inclusion and exclusion criteria for eligibility to participate in the screening and the trial are met, the study Research Assistant will obtain written consent from the parents/carers and assent from the adolescents under the supervision of the project's co-investigator at the respective site. The adolescents and their parents/carers will receive information about the study and will be given sufficient time to consider participation. Informed written consent from the parent and informed assent from the adolescent will be obtained prior to inclusion in the study.

To ensure that stigmatisation of the adolescents taking part in this research does not occur, participants were invited to participate in a programme which has been reported to enhance adolescents' emotional well-being and social skills. Participants will furthermore be informed that in this programme, they will be taught specific strategies including: identifying activities to increase self-esteem, using coping skills (e.g. relaxation), and various social skills (e.g. communication skills).

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Not applicable. No biological samples will be collected.

Interventions

Explanation for the choice of comparators {6b}

We have chosen this active control condition (i.e. Study Skills Programme [12]) because we want all adolescents to benefit from participating in our research. The high rates of MHP among adolescents in Malaysia have been found to be associated with school-related factors (e.g. exam stress, pressure to do well academically) [2]; thus, it is possible that SSP would help to alleviate anxiety and depressive symptoms. Furthermore, the adolescents with moderate-to-severe symptoms of depression or anxiety in Kenya have shown some positive effects of SSP in their MHP [12]. Active compared to passive control conditions also provide a more rigorous standard of comparison [12].

Intervention description {11a}

Super Skills for Life (SSL)

SSL [11] is a manualised psychosocial intervention for the prevention and early intervention of anxiety and depression and for promoting healthy lifestyles, which is based on the principles of cognitive behavioural therapy. SSL focuses on the following: (1) promoting healthy lifestyles; (2) building emotional resilience through stress management; (3) encouraging peer learning and building peer networks; and (4) promoting self-confidence and social skills. These key elements are organized over 8 weekly sessions in a group format (45 minutes per session) that address the following topics: Healthy lifestyle; Enhancing self-esteem; Feelings and thoughts; Thoughts-Feelings-Behaviour; Managing stress; Relationship and social skills; Problem-solving steps; and Hopeful future.

SSL materials include the following: (a) Facilitator Manual, gives step-by-step instructions on how to implement each session of SSL. (b) Adolescent Workbook, contains main messages of each session, exercises, activities, role plays, and homework.

The SSL material have been translated into several languages (including in Bahasa Malaysia) and adapted to different cultures. The intervention has already been adapted to a Malaysian sociocultural milieu and implemented in Malaysian adolescents [16].

Control condition Study Skills Programme (SSP) [12] will be used as a control condition. SSP is a modified version of the Study Skills control intervention, developed by Osborn and colleagues [12]. In order to make it comparable to the SSL, the SSP was expanded from the original 4 to 8 sessions. SSP will be implemented in a group format (45 minutes per session) in 8 weekly sessions, covering: note-taking skills, effective study strategies, reading techniques, concept mapping, and time management.

Intervention facilitators The facilitators will be staff members (e.g. teachers, school counsellors) of the participating schools who will be randomly assigned to facilitate either the SSL or the SSP groups (and given appropriate training, see below) to minimize differences in competence and leadership style. They will be blind to the study design and hypotheses.

Criteria for discontinuing or modifying allocated interventions {11b}

The study is not expected to cause any harm or severe worsening of mental health problems. Thus, there will be no criteria for discontinuing the allocated intervention or modifying the allocated intervention. However, the Independent Data Monitoring and Ethics Committee will advise the Trial Steering Committee on whether there are any ethical or safety reasons why the trial should not continue. The Trial Steering Committee will consider the advice of the Independent Data Monitoring and Ethics Committee and make a final decision on whether these recommendations should be implemented.

Furthermore, all participants (adolescents or their parents) may withdraw their consent at any timepoint without giving any reasons. If they withdraw, their data may still be used in de-identified form as part of an aggregated data set.

Strategies to improve adherence to interventions {11c}

Facilitator training

All facilitators will participate in a mandatory 20-hour in-person training and supervision to ensure quality control and adherence code.

SSL facilitators The workshop will cover topics related to anxiety and depression, and their risk factors, and principles of prevention. At the end of this training, facilitators will roleplay the delivery of SSL with research staff members, during which they are required to adequately deliver 80% of key components for each session before

implementing the SSL in the school. For the first group of adolescents that the facilitators will deliver the SSL to, they will be accompanied by our research staff member who will offer support to adhere to the study protocol as needed. Following the successful completion of this first training step, facilitators will independently deliver the SSL to the at-risk adolescents.

SSP facilitators The workshop will cover topics related to study skills such as note-taking, effective study strategies, reading techniques, concept mapping, and time management skills.

Both the SSL and SSP workshops will also cover organisation and ethical issues in running a group intervention with adolescents, as well as group leadership and group process skills.

Fidelity monitoring

To ensure that the facilitators adhere to the intervention sessions, an independent assessor will observe the sessions across participating schools. The assessor will use a structured observation scale to assess fidelity to the intervention protocol. Any significant deviations identified during these observations will be communicated to the project lead and/or the study site Co-Investigator, who will, in turn, provide targeted feedback to the relevant facilitators to support consistent delivery of the intervention.

In addition, while the weekly check-ins with the trial manager are intended to support logistical aspects of the trial, fidelity-related issues which will be flagged by the independent assessors will also be discussed during these check-ins as needed.

Relevant concomitant care permitted or prohibited during the trial {11d}

Throughout the trial, the participants are allowed to seek medical or other forms of care as needed. At the 12-month follow-up, the adolescents will be asked whether they have used additional services, and this will be controlled for in the analysis.

Provisions for post-trial care {30}

No post-trial care will be provided as a part of this study. However, our research team will maintain contact with the teacher in charge of this research in each respective school in the event that any post-trial care is needed. Furthermore, at the end of the study, each participant will be given a debrief form which includes contact details of organisations that offer mental health support to adolescents. The debrief form also has researchers' contact information if the participants have any questions about their participation.

Outcomes {12}

Screening measures

Adolescent's severity of anxiety and depressive symptoms will be assessed using the Depression Anxiety and Stress Scale-21 (DASS-21) [15]. The DASS-21 consists of 21 items which are divided equally across the anxiety, depressive, and stress subscales, i.e. with each subscale containing seven items. Participants are asked to indicate how much each item applies to them over the past week on a 4-point Likert Scale (range from 0 [did not apply to me at all] to 3 [applied to me very much or most of the time]). The total severity score of each subscale will be calculated by summing all the 7 items. Based on the cut-off norms recommended by the authors of the DASS [15], adolescents who either endorse moderate to severe depressive (raw score $\geq$ 14 on the depression subscale) or anxiety symptoms (raw score $\geq$ 10 on the anxiety subscale) will qualify for the trial. DASS-21 is a reliable and widely used scale (open access) in adolescent research in Malaysia [2]. A cross-country study [17] with a sample of Malaysian adolescents revealed adequate reliability indexes, with Cronbach's alpha values from 0.74 (Anxiety scale) to 0.82 (Depression scale). A recent study using the Malay version of the DASS-21 showed Cronbach's alpha values of 0.95, 0.85, and 0.87, respectively, for Depression, Anxiety, and Stress domains [18].

Additional measures

In addition to the screening measure (DASS-21), the participants will complete a set of questionnaires:

Socio-demographic information A bespoke sociodemographic questionnaire will be used to collect participant socio-demographic information at screening such as age, year group, ethnicity, gender, and number of people living in the household. Other information collected during Stage II will include the school size, number of classes, and school location (i.e. rural or urban areas).

Teenage Executive Functioning Inventory (TEXI) will be used to measure working memory and inhibition [19]. It contains 20 items which can be rated on a 5-point Likert scale ranging from 1 ("definitely not true") to 5 ("definitely true").

Lifestyle habits (physical activity levels, quality sleep and sleep hygiene, and dietary choice) will be measured using a modified version of the Lifestyle and Habits Questionnaire (LHQ-B) [20]. It contains 16 items, and adolescents are asked about how frequently they perform each behaviour in the past 30 days, on a 5-point scale from "never" to "always".

The Educational Stress Scale for Adolescents [21] will be used to measure adolescent's perceived academic stress. Its

16 statements can be rated on a five-point Likert scale ranging from "strongly disagree" to "strongly agree". This scale has five factors: "Pressure from study", "Workload", "Worry about grades", "Self-expectation stress", and 'Despondency'.

School Connectedness Scale [22] will be used to assess adolescents' feelings about their school and teachers. Its 5 items can be rated on a five-point response format ranging from 0 (Strongly disagree) to 4 (Strongly agree). Higher scores indicate a higher level of school connectedness. The scale showed adequate psychometric properties in Malaysian adolescents (composite reliability index = 0.89) [23].

A modified version of The Mental Health Knowledge Schedule (MAKS) [24, 25] will be used to measure adolescents' knowledge of mental health problems. Following Goodfellow and colleagues [25], only two factors will be used in the present study. The first factor is related to knowledge of treatment efficacy and consists of two items (i.e. medication and psychotherapy). The second factor will be used to measure adolescents' ability to identify mental health problems and consists of three items (schizophrenia, depression, bipolar disorder). Items are measured on a 5-point scale (1 = "strongly disagree" to 5 = "strongly agree"). The Malay version of MAKS has been reported to show a satisfactory Cronbach's alpha score of 0.62 [26].

The General Help Seeking Questionnaire (GHSQ) [27] will be used to measure intended help-seeking from both formal (teacher; mental health professional) and informal (i.e. friend; parent; other family member/relative) services. It contains 10 items which can be rated from 1 (extremely unlikely to seek help) to 7 (extremely likely). The Malay GHSQ has been reported to have a satisfactory internal reliability, with Cronbach's Alpha of 0.85 [28].

Trial measures

Primary outcome

The two primary outcomes are as follows: (1) reduction in anxiety and depressive symptoms, and (2) improvement in mental wellbeing at 12 months post-intervention, chosen for their clinical relevance and public health importance.

Anxiety and depression are highly prevalent among adolescents and contribute significantly to functional impairment and reduced quality of life. Symptom reduction is therefore a key indicator of intervention efficacy and aligns with clinical priorities to address the most immediate aspects of mental ill-health. Mental wellbeing reflects positive functioning, life satisfaction, and resilience, offering a complementary perspective to symptom reduction. This aligns with the dual continuum model of mental health, which recognises wellbeing as distinct from the absence of mental illness.

Assessment at 12 months post-intervention enables evaluation of the sustained impact of the program, determining whether benefits are maintained over time and integrated into participants' daily lives.

Anxiety and depression as measured by the Revised Children's Anxiety and Depression Scale (RCADS) [30], and mental wellbeing as measured by the Short Warwick-Edinburgh Mental Well-being Scale (WEMWBS) [29], will be administered at baseline, and 2 months as well as at 6 and 12 months post-intervention.

The Revised Children's Anxiety and Depression Scale [30] will be used to identify symptoms of anxiety and depressive disorder in adolescents. It contains 6 items for measuring anxiety and 5 items for depression symptoms, which are to be rated on a 4-point Likert Scale from 0 ("never") to 3 ("always"). Although a validation study is lacking for Malaysian adolescents, results from studies in ASEAN countries and in countries [31] with a similar cultural background have shown satisfactory reliability levels (Cronbach's alpha > 0.71).

A Short Warwick-Edinburgh Mental Well-being Scale [29] will be used to measure mental wellbeing. All its 7 items are worded positively and cover feeling and functioning aspects of mental wellbeing. The items can be rated on a 5-point scale from 1 (none of the time) to 5 (all of the time). The Malay version of the WEMWBS showed adequate psychometric properties in Malaysian young adults (Cronbach's alpha = 0.91) [32].

Secondary outcomes will be the change from baseline scores (total scores or means) of the following assessments in the following domains

(a) Psychological domains

Cognitive Emotion Regulation Questionnaire (CERQ) [33] will be used to measure emotion regulation strategies. It consists of 18 items, which can be rated on a 5-point Likert scale ranging from 1 (almost never) to 5 (almost always) in response to how often each of the 9 emotion regulation strategies is used: refocus on planning, putting into perspective, acceptance, positive refocusing, positive reappraisal, self-blame, other blame, rumination, and catastrophising. The CERQ showed adequate reliability in Malaysian adolescents with problematic drug use (Cronbach's alpha = 0.84) [34].

The Paykel Suicide Scale (PSS) [35] will be used to measure suicidal behaviour. The scale consists of 5 items, with a dichotomous response system, i.e. Yes or No. Although the instrument has not been validated for Malaysian adolescents, adequate reliability indexes

are found for the PSS in other countries (Cronbach's alpha > 0.80) [36, 37].

The Social Skills Questionnaire [38] will be used to assess the participant's social skills. The original scale has been adapted to the Malaysian context, which consists of 13 items that can be rated on a 3-point Likert scale ranging from not true (0) to mostly true (2).

(b) Educational domains

Information about the participant's academic grade and school attendance will be obtained from the school.

(c) Mental skills

Teenage Executive Functioning Inventory (TEXI) [19] will be used to measure working memory and inhibition. It contains 20 items which can be rated on a 5-point Likert scale ranging from 1 ("definitely not true") to 5 ("definitely true"). The instrument showed adequate reliability levels in adolescents (Cronbach's alpha 0.85–0.86 for the scales).

Executive function will also be measured using milliseconds in an experimental task to measure attention control and working memory [39].

(d) Lifestyle habits

Lifestyle habits (physical activity levels, quality sleep and sleep hygiene, and dietary choice) will be measured using a modified version of the Lifestyle and Habits Questionnaire (LHQ-B) [20]. It contains 16 items which ask adolescents about how frequently they perform each behaviour in the past 30 days on a 5-point scale from "never" to "always". The LHQ-B showed adequate reliability in Malaysian adolescents with problematic drug use (Cronbach's alpha = 0.87) [34].

Moderators of primary outcome

Potential moderators of the primary outcome at 12 months will be measured at pre-intervention as we are interested in determining the role of confounding factors in the relationship between the SSL delivery and changes in the primary outcomes. For further description of moderation effects, see Baron and Kenny [40].

(a) *Adolescent level*: adolescent gender, age, lifestyle habits, self-esteem, and academic stress.

Rosenberg Self-Esteem Scale (RSES) [41] will be used to measure global self-worth. Three out of 10 items will be used in the present study, which can be rated on a 4-point Likert scale format ranging from 4 (strongly agree) to 1 (strongly disagree). The RSES showed satisfactory reliability in adolescents from Malaysia (Cronbach's alpha = 0.74) [42].

The Educational Stress Scale for Adolescents (ESSA) [21] will be used to measure adolescents' perceived academic stress. Its 16 statements can be rated on a five-point Likert scale ranging from "strongly disagree" to "strongly agree". This scale has five factors: "Pressure from study", "Workload", "Worry about grades", "Self-expectation stress", and "Despondency". This scale does not have a validated version for Malaysian adolescents. However, the instrument has shown adequate reliability indexes in adolescents from Asian countries (Cronbach's alpha > 0.80) [43, 44].

A modified version of the *Lifestyle and Habits Questionnaire* (LHQ-B) [20] will be used to measure lifestyle habits (physical activity levels, quality sleep and sleep hygiene, and dietary choice). It contains 16 items, and adolescents are asked about how frequently they perform each behaviour in the past 30 days, on a 5-point scale from "never" to "always".

(b) *School level*: school size, school climate, and location.

School Connectedness Scale [22] will be used to assess adolescents' feelings about their school and teachers. Its 5 items can be rated on a five-point response format ranging from 0 (Strongly disagree) to 4 (Strongly agree). Higher scores indicate a higher level of school connectedness. The scale showed adequate psychometric properties in Malaysian adolescents (composite reliability index = 0.89) [45].

(c) *Facilitator level*: The SSL facilitators will be asked to complete a set of questionnaires to measure their self-efficacy, and confidence level and attitudes towards evidence-based intervention.

- *Evidence-based Practice Attitude Scale for Teachers* (S-EBPAS) [46] will be used to measure facilitators' attitudes toward the adoption of evidence-based practices (EBPs). It contains 13 items that covers four attitude domains: Appeal (i.e. the intuitive appeal of the new practices); Openness (i.e. being open to new practices); Fit (i.e. teacher's perception as to whether EBP fit with their teaching philosophy and their student's need); and Burden (i.e. the degree to which a teacher perceives the EBP to add burden). The S-EBPAS has showed satisfactory reliability in a sample of geographically diverse mental health providers (Cronbach's alpha =.79) [47].

- *Self-Efficacy Scale*, designed specifically for this project, will be used to measure facilitator's perceptions in their overall ability to deliver SSL in their school.

- *Confidence level in delivering SSL* (e.g. of questions: "How confident are you in facilitating the SSL to a group of adolescents in your school?" "How much do you know about SSL, in terms of its principles, rationale, and content?" "How confident were you in your ability to lead/

support/make decisions about the SSL program?"). The facilitators will be asked to rate on a 5-point Likert scale ranging from "not at all confident" (0) to "extremely confident" (4) their level of confidence in their skills, knowledge, experience, ability to overcome existing obstacles such as limited time, space.

Health economic outcomes

Costs and cost-effectiveness will be assessed at baseline and at 12 months. For this purpose, adolescents and their parents will be asked to complete the Child Health Utility and the Self-reported European Quality of Life Five Dimension, respectively. The parent will also be interviewed using the Client Service Receipt Inventory.

(a) Questionnaire for adolescents

The Child Health Utility (CHU9D) [48] will be used to measure health-related quality of life. It consists of 9 domains (worry, sadness, pain, tiredness, annoyance, school, sleep, daily routine, and activities), and within each dimension, there are five different levels with increasing levels of severity

(b) Questionnaire/interview for parent

Self-reported European Quality of Life Five Dimension (EQ-5D-3L) [49] will be used to measure parents' quality of life, cost-utility of healthcare interventions, and computation of quality-adjusted life years. It consists of two components: a health descriptive component and a visual analog scale (VAS). The descriptive component evaluates five items related to health which include mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each item can be rated on a 5-point scale, ranging from no problems to extreme problems. The VAS is a straight line ranging from 0 (the worst imaginable health) to 100 (the best imaginable health) on which people can define their current health status. The EQ-5D has been extensively applied in the Malaysian population, with adequate reliability levels [50, 51].

The parent will be interviewed using the Client Service Receipt Inventory [52] to collect information on cost-related data by estimating associated costs across healthcare, social care, and community settings. It contains five main sections: background information, household and carer support, healthcare service and resource utilisation, community support, and education and employment. The parent will further be asked about the adolescent's frequency and cost of using mental and physical health and social services. Some of the items will be adapted to be in line with the Malaysian health care system.

Implementation outcomes

Data to measure implementation outcomes (i.e. intervention reach, uptake, acceptability) will be collected by interviewing SSL facilitators. All interviews will be audio-recorded and transcribed verbatim.

Participant timeline {13}

Assessments will be administered at screening, baseline (i.e. pre-intervention; T1), 2 months (i.e. post-intervention; T2), and at 6 months (T3) and 12 months (T4) post-intervention (see Table 1). We will use mixed methods (questionnaire, interview, experimental task) to evaluate the primary and secondary outcomes, as well as health economic and implementation outcomes, as detailed above. Outcome assessments will be conducted by trained independent assessors.

Sample size {14}

Our target sample size is 428 adolescents, aged 12–14 years, who experience moderate to severe levels of anxiety and/or depression on the DASS-21 [15] during Stage II (screening stage).

For a priori sample size calculation, the main analysis will focus on longitudinal structural equation modeling (SEM) to assess the point-specific levels and trajectory of change of the primary outcomes, according to the study groups. The following parameters were considered for a priori sample size analysis:

(1) The four measurement points: Pre-intervention, post-intervention (at 2 months), and follow-ups at 6 and 12 months
(2) Four moderators (exogenous covariates in the context of MLGC): Gender, state of origin, school size, and urbanicity
(3) Two latent (endogenous) variables from each primary outcome: a latent intercept and a latent slope for the growth process
(4) Statistical power parameters: $\alpha = 0.05$ and $1-\beta = 0.80$
(5) Model fit: Root Mean Square Error of Approximation (RMSEA) ≤ 0.05. As a result, a minimum sample of 329 participants is required for the study. All calculations were performed using the semPower package in the R software [53].

For sensitivity analysis, another a priori sample size was conducted under a generalized linear model approach. The following parameters were considered: (1) a binary variable (individuals with reliable reduction in symptoms vs. those who do not); (2) medium effect

Table 1 Participant timeline. The schedule of enrolment, intervention, and assessment

Timepoint	Screening Spring 2025 - Summer 2025	Allocation*	Informants	T1 (baseline/pre-intervention)	T2 (2-months post-intervention)	T3 (6-months post-intervention)	T4 (12-months post-intervention)
ENROLMENT							
School consent	x						
Parent consent (for screening)	x						
Screening	x						
ALLOCATION							
Class randomization		x					
INTERVENTIONS							
Super Skills for Life				●———	———●		
Study Skills programme (control condition)				●———	———●		
ASSESSMENTS							
Screening Questionnaire							
Depression, Anxiety, Stress Scale (DASS-21)	x		A				
Additional measures during the screening stage							
School connectedness (SC)	x						
Educational Stress Scale for Adolescents (EES)	x						
Lifestyle and Habits Scale (LS)	x						
Teenage Executive Functioning Inventory (TEXI)	x						
Mental Health Literacy items	x						
Primary Outcomes							
Revised Children's Anxiety and Depression Scale (RCADS) for Adolescents			A	x	x	x	x
Short Warwick-Edinburgh Mental Wellbeing Scale			A	x	x	x	x
Secondary Outcomes							
Rosenberg Self-Esteem Scale (RSES)			A	x	x	x	x
School connectedness (SC)			A	x		x	
Educational Stress Scale for Adolescents (EES)			A	x	x	x	x
Paykel Suicide Scale (PSS)			A	x	x	x	x
Lifestyle and Habits Scale (LS)			A	x	x	x	x
Executive Functioning - Teenage Executive Functioning Inventory (TEXI) - Milliseconds experimental task			A A	x x	 x	x x	x x
Cognitive Emotional Regulation Questionnaire (CERQ)			A	x	x	x	x
Social Skills Questionnaire (M-SSQ)			A	x	x	x	x
Health Economics Outcomes							
Child Health Utility			A	x			x
European Quality of Life Five Dimension (Questionnaire)			P	x			x
Client Service Receipt Inventory (Interview: Adolescent's frequency and cost of using mental and physical health and social services)			P	x			x
Implementation Outcomes							
Interview: School characteristics, school culture and climate			T	x			
Interview: Intervention uptake/reach and adoption			T	x			x
Questionnaire: School Evidence-based Practice Attitude Scale; Confidence level in delivering			F	x			
SSL; Self Efficacy Scale			F	x			
Fidelity (after each session) - Questionnaire			F	x	x		
Interview: Satisfaction and acceptability of SSL			A, F		x		
Other measures							
Mental health literacy				P F	x x		
Monitoring of serious adverse events				SC	x	x	x

T1 = 1 week before the intervention; T2 = 2 months post-intervention; T3, T4 = 6- and 12-months post-intervention, respectively

A Adolescents, *F* SSL facilitator, *T* Teacher, *P* Parent, *SC* School counsellors

*The maximum interval between screening and randomisation is 30 days

size, OR = 1.5; 2) covariates (e.g. sex, age, state of provenance, size of school, urbanicity), explaining at least $R^2 = 0.10$; 3) $1-\beta = 0.80$, and $\alpha = 0.05$. The sample size needed is 342 participants. Assuming we have up to a 25% drop-out rate, 428 adolescents will be recruited. The analysis was conducted using the G*Power software, version 3.9.1.7 [54].

Recruitment {15}

School recruitment

A list of secondary schools in the Malaysian states of Sarawak, Sabah, and Selangor will be obtained from the online portal of the Ministry of Education to identify eligible schools based on the region (i.e. economically deprived area), school type (government or government-aided secondary schools with Forms 1–2 (i.e. first two years of secondary schools), school size (mid-size school with a maximum of six Form 1 and six Form 2 classes), and school location (i.e. rural and urban areas). Based on these criteria, a new list of secondary schools will be generated.

Following permission from the Malaysian Ministry of Education and the Department of Education in the three participating states (i.e. Sarawak, Sabah, Selangor), schools will be contacted and invited to participate in the proposed study via email or post, and follow-ups will be done via telephone whereby more details about the study will be discussed with the headteachers.

School principals who agree that their schools will participate in the project will nominate a teacher to lead the organisational aspects of the project within the school, including the participant recruitment. Information about the eligible classes (e.g. number of students, class time—i.e. whether it is a morning or afternoon class) will be provided by the schools. Participating schools will be offered payments of no more than £100 to thank them for the time they invest in the study.

Participant recruitment

After the schools agree to participate in the study, parents and adolescents will be informed about the study which will involve screening the adolescents who are at risk of developing anxiety and/or depression. Study information about the screening will be distributed by the school staff to parents/carers of all eligible adolescents. Parents/carers will need to provide written consent for their children to participate in the study.

Adolescents who experience moderate to severe anxiety and/or depression and who fulfil the above-stated inclusion and exclusion criteria for the trial will be invited to participate in the intervention study. Information about the related intervention programme (SSL or SSP) together with a parental consent form will be distributed to the parents.

Assignment of interventions: allocation

Sequence generation {16a}

Block randomisation procedures will be followed, considering units of randomisation (classes from schools) for each state independently, to achieve balanced arm assignment across states. After the screening assessment stage, the classes in each school from the same state will be randomised to the intervention (SSL) or control condition (SSP) in a 1:1 ratio stratified based on three stratification variables: school location (i.e. rural or urban areas), number of classes in the school, and class/form (i.e. Form 1 or Form 2).

A statistician, independent from the Trial Steering Committee and the research team, will conduct randomisation via a computer-generated algorithm. More concretely, the stratified function from the splitstackshape R package (also calling for the sampling package) will be used to select a sample of classes which at-risk students will be allocated to the SSL condition, according to the aforementioned stratification variables. The rest of the classes will be assigned to the SSP condition. Randomisation will be done after screening in the participating schools is completed at each state. The result of this randomisation will be passed to the research team in each study site who will then inform the teachers who have been designated to lead this project within their respective school.

Randomisation occurs at the class level to avoid contamination between students in the same class and to align with the practical delivery of the program (e.g. by teacher or classroom).

Knowing the number of eligible (at-risk) students in each class before randomisation is important for feasibility and implementation planning. If a class has only one or two eligible students, it may not be practical to deliver the program to that class alone, given facilitator and teacher workload constraints. Therefore, screening establishes who is eligible, and randomisation determines which group (SSL or SSP) the class is assigned to. When a class has too few eligible students, those students are grouped with others from the same year level who were assigned to the same condition (SSL or SSP), ensuring that program delivery remains feasible while maintaining the integrity of the randomisation process.

Concealment mechanism {16b}

Randomisation will be done by a statistician, who is blind to screening procedures and participant personal data, after screening in the participating schools is completed. Based on this randomisation, the class will either receive SSL or SSP. Participants in each class, and their parents,

will be made aware of their randomisation arm via their class teacher.

Implementation {16c}

A statistician who is not involved in the screening process will generate the allocation sequence and assign classes to either the SSL or SSP. Trained independent assessors who will be conducting the outcomes assessments will be masked to classes' condition assignment.

Assignment of interventions: blinding

Who will be blinded {17a}

The participants and the intervention facilitators cannot be blinded about the intervention condition as they will be informed about intervention allocation. Outcome assessments for the trial will be conducted by trained independent assessors who will be blind to the intervention arm. Assessors will be graduates in psychology, social work, or counselling who had training in youth mental health. The participants will be asked not to reveal their trial arm during the assessment. The study statistician will be blind to the class trial arm until the end of the primary outcome analyses.

Procedure for unblinding if needed {17b}

None of the independent assessors who conduct the outcome assessments will be unmasked. Unmasking of the assessors will only occur if they no longer conduct the outcome assessments.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Screening assessment will be conducted by the research assistants at each study site. All questionnaires will be administered using Qualtrics. Adolescents will be provided with a Qualtrics link, and they will complete the questionnaires online in a designated room in their school. A research assistant will be present to provide assistance if necessary and to ensure independent responding.

Trial outcome assessments will be conducted by trained independent assessors at four different timepoints: immediately prior to the start of the intervention (i.e. baseline), immediately following completion of the 8 programme sessions (i.e. post-intervention at 2 months), and at two follow-ups (i.e. 6 and 12 months post-intervention). Independent assessors will collect all questionnaire data using Qualtrics and conduct the interview to assess process evaluation and implementation outcomes.

The adolescents will complete the questionnaires online on Qualtrics in a designated room in their school, with trained independent assessors present to provide assistance if necessary and to ensure independent responding. To ensure data quality, we will use Qualtrics' built-in features to promote data accuracy, including response validation and forced-response settings on key items to minimise missing or invalid data. Furthermore, the independent assessors will monitor response data to identify any patterns suggestive of poor data quality (e.g. unusually fast completions).

Plans to promote participant retention and complete follow-up {18b}

We will maintain engagement with the participants between assessments by sending newsletters and a dedicated website link about any updates regarding the project to participants.

Data management {19}

The data will be collected and stored in accordance with the study data management plan and UK data protection laws. The Qualtrics platform will be used to collect questionnaire data from participants via online surveys. A unique identity code will be given to each school and participant.

A linking document with ID will be stored on a secure University of Roehampton's cloud drive (OneDrive) which provides secure, encrypted password-protected servers with daily backup. Personal data will be securely stored by local researchers in a restricted-access office, with access limited to authorized research team members.

Audio recordings of qualitative interviews will be transferred from the recording device to the University of Roehampton OneDrive until analysis is complete, and then permanently destroyed.

Study statistician will have access to the pseudonymized trial data file on University of Roehampton's cloud drive (SharePoint on OneDrive). These data files will not reveal the name of the class arm.

Confidentiality {27}

All primary data collected in this project will be stored on a secure University of Roehampton's cloud drive (OneDrive), with access restricted to research team members. All research data will be pseudonymized using unique identification numbers and stored without any identifying information such as names, email addresses, and phone numbers. All research data will be retained for 10 years from completion of the study, and this consent form will be retained for six years from completion of the study. Consent forms will be securely stored by local researchers in a restricted-access office, with access limited to authorized research team members.

Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable because no biological specimens will be collected.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Primary and secondary clinical outcomes Statistical analyses will use multi-level regression models controlling for the variables involved in sample stratification (i.e. class/form, school size and location). Robust standard errors will be estimated. The assessment point will be used as the multi-level factor. Analyses will be conducted using the software R and Stata. All analyses will use an intention-to-treat approach. The statistician, qualitative data analyst, and health economist will be blinded to intervention allocation.

Quantitative data We will complete the CONSORT flow diagram and present outcome measures at all assessment points by arms. Outcome trajectory will be conducted using a multi-group latent growth curve analysis to identify overall outcome trends of study group participants across the measurement points. We will model the course of the quantitative outcomes across assessment points with latent processes comprising two interrelated constructs: intercept (outcome score at each measurement point) and slope (score trends across measurement points). The measurement invariance tradition will be followed to detect potential group-specific differences in latent intercept and slope levels; constrained models are estimated, and their fit will be compared. A better fit of a more constrained model compared to the unconstrained one (i.e. growth model with freely estimated parameters) would be indicative of differences between groups. Different estimates for goodness of fit of each model will be used: the χ2-based test, the root mean squared error of approximation (RMSEA; with RMSEA < 0.08 to uphold adequate fit), the comparative fit index (CFI) and the Tucker-Lewis index (TLI; CFI and TLI $\geq$ 0.95 are indicative of good fit); and the standardized root mean squared residual (SRMR; with SRMR < 0.08 to endorse good fit). Incremental RMSEA, CFI, and SRMR will be used for measurement invariance comparison. The study group will be considered as a multigroup factor. Four covariates will be included: Gender, state of origin, school size, and urbanicity. Weighted Least Square Mean and Variance estimator will be used for parameter estimation (note that the covariates will not follow a normal distribution). Bootstrapping procedures will be used to estimate robust standard error of estimated parameters. The R^2 will be used as a model effect size estimate.

As a sensitivity analysis, binary logistic regression will be used to study the features of participants who meaningfully reduce their symptom levels (on the basis of the reliable change index) [55], between the baseline and 8-week post-intervention, and from the baseline to the 12-month follow-up. A logistic regression will be performed for each primary outcome. As a predictor, the membership in the intervention group and latent means of the intercept and slope variables derived from the secondary outcomes will be used. Moreover, the covariates included will be those related to stratification variables: sex, age, state of provenance, size of school, urbanicity. The odds ratio (OR) will be used as a loading estimate, and the adjusted Cox and Snell R^2 will be used as a model effect size estimate.

Economic outcomes Costs and cost-effectiveness will be assessed using data collected at baseline and at 12 months. We will take a broad perspective by including costs related to mental and physical health care services in both formal and informal sectors such as traditional and faith healers. Resource use and other economic impacts will be assessed using an adapted version of the Client Service Receipt Inventory [52, 56]. For the secondary economic analysis (i.e. Quality Adjusted Life Years; QALYs), we will use the Child Health Utility 9D [48] and the European Quality of Life Five Dimension (parent self-report) [49]. The SSL sessions will be costed based on the facilitator's on-costs and will include indirect costs such as supervision on-costs. Data on costs will be combined with QALYs to estimate the cost-per-QALY associated with the intervention that will inform the cost-effectiveness analysis. Incremental cost-effectiveness ratios (ICERs) comparing both interventions will be calculated over measurement points. The net benefit regression method will be used to examine the cost-effectiveness of the SSL, under the ordinary least-squares estimation method. Analyses will be adjusted for baseline outcome scores, baseline costs, age, sex, and location.

Qualitative data Interviews will be audio-recorded, transcribed verbatim, and analyzed using thematic analysis. We will adopt a critical realist perspective [57] which will enable us to draw conclusions about the intervention whilst at the same time accounting for contextual and cultural factors.

Interim analyses {21b}

One interim analysis, to be conducted when one-third of the participants have completed the 6-month follow-up in the trial. The aim of this analysis is to evaluate the safety outcomes for the Independent Data Monitoring and

Ethics Committee. Primary and secondary effectiveness outcomes will not be evaluated in the interim analyses.

Methods for additional analyses (e.g. subgroup analyses) {20b}

Subgroup (sensitivity) analyses for the primary and secondary outcomes will be performed at baseline data to determine potential covariates such as gender, ethnicity, under traditional fixed-effects, and mixed-effects models.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Patterns of randomness will be explored regarding missing data. Missing values will be estimated using multiple imputation procedures under the random forest algorithm, when the missingness rate is below 10% per variable. Sensitivity analyses will be conducted to examine diversions in the distribution of imputed data in comparison to the real data distribution.

Plans to give access to the full protocol, participant-level data and statistical code {31c}

We will make de-identified data available five years after the project completion, with some restrictions because of the study's ethics approval. Interested individuals can make reasonable requests by contacting the corresponding author.

Process evaluation: aims

The overall aim of the process evaluation is to understand how the SSL intervention is implemented across diverse school settings, and to identify factors influencing variation in its outcomes across schools and participants. These insights will inform the interpretation of the main trial's findings regarding effectiveness and cost-effectiveness.

The process evaluation will be guided by the UK Medical Research Council (MRC) framework for complex interventions [58], which outlines three key components: Implementation, mechanisms of impact, and context. Additionally, two established implementation science frameworks will be used, namely, the Consolidated Framework for Implementation Research (CFIR) [59] and the RE-AIM framework [60], which will be used to evaluate implementation outcomes, including reach, effectiveness, adoption, implementation, and maintenance.

Participants

Four stakeholder groups will be involved in the process evaluation:

- Adolescents (12–14 years old)
- School senior management (e.g. principals)
- SSL facilitators (teachers delivering the intervention)
- Independent assessors

Data sources and instruments

Four types of data will be collected and triangulated: school data, self-report questionnaires, structured observations, and qualitative interviews.

(1) School-level data: Contextual information (e.g. school size, location, type) will be extracted from the Malaysian Ministry of Education's public database.
(2) Self-report questionnaires: SSL facilitators will complete an online survey post-training via Qualtrics, comprising:

- Demographics and Practice-Related Items, including conceptualisations of mental health, current practices, perceived needs, and service gaps.
- Evidence-based Practice Attitude Scale for Teachers (S-EBPAS) [46]: An adaptation of the EBPAS [47] designed for educators. This 13-item scale assesses four domains: intuitive appeal, openness to new practices, perceived fit, and perceived burden.
- Self-Efficacy Scale: Adapted from Bandura [61], this scale measures facilitators' confidence in delivering SSL content, overcoming constraints (e.g. limited time/space), and engaging students. Responses use a 5-point Likert scale (0 = not at all confident; 4 = extremely confident).

(3) Structured observations: Independent assessors who will be trained in the SSL protocol will observe selected SSL sessions using a structured checklist and field notes. Observations will assess fidelity, delivery quality, facilitator style, group dynamics, and student engagement.
(4) Qualitative interviews:

- SSL facilitators will be interviewed about their experience delivering SSL, including motivations, challenges, perceived effectiveness, and institutional support.
- Adolescents will be asked about their experiences with SSL, perceived benefits, and barriers to participation.

Data analysis

Quantitative and qualitative data will be analysed independently and subsequently integrated through triangulation, following these steps:

(a) Findings will be organised into meta-themes aligned with the evaluation objectives, identifying patterns of agreement or divergence.
(b) A convergence coding matrix will be developed to assess the level and nature of convergence (e.g. agreement, partial agreement, silence, or dissonance) across datasets.
(c) Through an iterative synthesis process, overarching meta-themes will be generated by integrating qualitative insights with quantitative patterns.
(d) To ensure rigour, all interpretations will be reviewed by multiple researchers. Discrepancies will be resolved through discussion and, where necessary, re-examination of data.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

The University of Roehampton (UoR) is the sponsor that will be supporting the successful delivery of this project. The sponsor had no role in the study design including the delivery of the trial, writing of this article, and the decision to submit it for publication. The UoR has a well-established management risk and sponsorship procedure and is in compliance with the Research Governance Framework. The study will also be conducted in accordance with local Research Governance requirements in Malaysia. To achieve the project objectives, we will operate an efficient management at task level which requires continuous project progress and external risk monitoring. We have set up the following main committees:

The Project Management Group, including all investigators, will oversee all aspects of the project in their respective study site and report to the Principal Investigator (PI). To ensure all activities are well coordinated, the PI and all the Co-Investigators (Co-Is) will have regular online meetings, and among local co-investigators in Malaysia and the project's PI, there will be 2 face-to-face meetings per year throughout the project lifecycle.

Independent Trial Steering Committee (TSC) will meet twice a year to monitor the project's progress towards achieving its goals; to advise the investigators on both scientific and management issues; and to make sure that there are no significant deviations from the study protocol. This committee is made up of an independent chair and 7 other members representing teachers, parents, researchers.

The TSC Chair is an academic psychologist whose research focuses on the etiology of concurrent and longitudinal associations between sleep disturbances and various psychological and behavioural difficulties. An independent statistician, with expertise in clinical trials of cognitive behavioural therapy (CBT) for children and adolescents, also serves on the committee.

Youth Advisory Group (YAG): Each of the three Malaysian states study sites (Sarawak, Sabah, and Selangor) established a Youth Advisory Group comprising up to five members aged 12–18 years, including individuals with lived experience. These groups have been actively involved in all stages of the project, including the study design.

Public and service users involvement and engagement

We have worked closely with representatives of public and service users (PSU) from the conception of this research. We will continue to work closely with our PSU group to ensure that the needs of the beneficiaries of the research (i.e. adolescents) are central to the study (see Fig. 1).

Composition of the data monitoring committee, its role and reporting structure {21a}

Independent Data Monitoring and Ethics Committee (IDMC) has been set up for this trial and comprises four independent members (including a chair), with expertise in clinical trials, statistical methods, health economic evaluations, and a clinical psychologist with experience in delivering psychological interventions within schools.

The IDMC will advise the Trial Steering Committee on whether there are any ethical or safety reasons why the trial should not continue. This committee will meet once a year and will have access to unblinded data and will consider the need for any interim analysis.

Adverse events and harms {22}

Adverse events and harms will be monitored throughout the study by the counsellors in each school. In the event that any participant experiences a serious adverse event and harm such as elevated suicidal risk during the study, the Co-I will notify the PI who in turn will notify the sponsor institution's (University of Roehampton) institutional review board within the same 24-hour period of the research team becoming aware of the incident, as well as the Independent Data Monitoring and Ethics Committee.

Additionally, the emergency protocol for participant risk scenarios (i.e. No risk, Low-risk, Medium risk, High-risk), which was developed by Venturo-Conerly and colleagues [62, 63] will be adapted for the present study. This emergency protocol suggests talking with the adolescents in a sensitive and natural way and to balance confidentiality and the need to inform the adolescent's teachers. If the harm is considered to be at high risk, the adolescent's parent will need to be notified.

Frequency and plans for auditing trial conduct {23}

The project is closely monitored by the project's PI. To ensure adherence to the study protocol, all Co-Is, research assistants, independent assessors, and intervention facilitators in the project must commit to following detailed instructions in all stages of the study. Given the robustness of the study protocol to ensure participant safety and data integrity, and the low risk of adverse events, it is considered not necessary to conduct auditing trial visit.

Although no formal auditing trial visit is planned for this low-risk study, procedures will be implemented to ensure the integrity and quality of self-reported data collected from the adolescent participants. Surveys are administered via Qualtrics, which includes built-in features to promote data accuracy: Response validation and forced-response settings will be used on key items to minimize missing or invalid data. Furthermore, during data collection, the independent assessors will conduct routine checks for unusually fast completion times.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

All changes to the protocol will be submitted for approval by the Institutional Review Board, Malaysian Ministry of Education, and the Department of Education in each participating state, and must be approved before being implemented. The changes will be updated on the trial's registration.

Dissemination plans {31a}

The findings of this study will be widely disseminated to relevant stakeholders and become a key reference programme for mental health promotion. To maximise the impact of our dissemination activities, we will take the following steps: (a) Stakeholder analysis (i.e. WHO are our relevant stakeholders?), (b) Defining messages and contents (WHAT content and messages should be disseminated?), (c) Defining dissemination channels (HOW should the messages be disseminated?). Input from our User Involvement and Youth Advisory groups will be central to address these questions.

We will communicate the trial findings using lay language to participating schools for publication in school newsletters and/or school websites. Participants and parents will also be provided with these findings via email and/or WhatsApp group. We will also disseminate findings from this research to policy makers, such as the Malaysian Ministry of Education, Department of Education, Ministry of Health,Ministry of Youth and Sports in the participating states (Sarawak, Sabah, Selangor), and to various relevant stakeholders such as the Parent Action Group for Education Malaysia, and those working in the youth mental health services and school services.

Results of the study will also be widely disseminated to reach academic audiences by publishing them in scientific journals with open access. We will also share the findings through a wide range of channels, including conference presentations, study website, social media (e.g. Facebook, LinkedIn, and X).

Discussion

This trial seeks to determine the effectiveness and cost-effectiveness of the school-based psychosocial intervention (SSL) as delivered by school staff in improving the mental health and wellbeing of at-risk adolescents in secondary schools in the Malaysian states of Sarawak, Sabah, and Selangor. This study will also identify contextual factors related to the successful implementation of SSL in Malaysian schools.

The innovation potential of this project is far-reaching:

(a) We aim to train at least 20 school staff to deliver the SSL. These SSL facilitators will train their peers, disseminate intervention materials, and help build sustainable local capacity for school-based health services. To the best of our knowledge, this project will be the first large randomized-controlled trials using school-based approaches to promote mental health of adolescents from low-income households in Malaysia or in other LMICs.

(b) While targeted prevention studies of anxiety or depression in schools exist, they remain limited in number and quality and have not systematically focused on both effectiveness and implementation processes. Our project is amongst the first of its size to focus on both effectiveness and implementation and has the potential to significantly shape the knowledge base in this new area of inquiry.

(c) Given the complexity of the school context and differences in support systems among ethnic groups in Malaysia, implementation processes may vary across Malaysia, offering us an opportunity to examine the effect of school factors on effectiveness and implementation outcomes. This will require the use of multi-level analytic methods, which have been underutilized in school-based mental health promotion research but are needed to advance theories that explain multi-level effects.

(d) We will use multiple data-gathering methods and participatory approaches, including involving ado-

lescents in planning and dissemination activities. Combining these approaches means that adolescent's voices will be heard, and their experiences reflected in research, which will create new knowledge of immediate value.

(e) This project will advance understanding of the role of school staff in the delivery of a school-based intervention.

(f) We will generate new knowledge on the role of socio-cultural and other contextual factors in predicting intervention uptake and treatment outcome.

If found to be effective, cost-effective, and acceptable, this trial can inform future implementation and scale-up of mental health services in schools in Malaysia and other low-resource settings. Within the Malaysian context, our trial could contribute to the government target of reducing adolescent mental health problems below 15% by 2025 [64]. Furthermore, using a school-based programme that is culturally appropriate will help to mitigate inequalities in access to mental health services and help to overcome stigma. Training school staff to facilitate SSL will help to reduce the treatment gap and deliver economic benefits to the health system. In the longer term, these changes should bring benefits to the economy through reduced healthcare costs.

Trial status

School recruitment began in Spring 2024, and recruitment of participants for screening is expected to start in spring 2025.

The trial is expected to begin in Summer 2025 and is expected to continue through winter of 2025. The follow-up assessments are expected to take place in the summer-winter period of 2026.

Trial registration: ClinicalTrials.gov Identifier: NCT07138664, first posted on August 16, 2025.

Protocol version: August 16, 2025.

Abbreviations

SSL	Super Skills for Life
SSP	Study Skills programme
MHP	Mental health problems
LMICs	Low- and middle-income countries
CBT	Cognitive behaviour therapy
RCADS	Revised Children's Anxiety and Depression Scale
TEXI	Teenage Executive Functioning Inventory
LHQ-B	Lifestyle and Habits Questionnaire
ESSA	Educational Stress Scale for Adolescents
SCS	School Connectedness Scale
DASS-21	Depression and Anxiety Stress Scale-21
WEMWS	Short Warwick-Edinburgh Mental Well-being Scale
RSES	Rosenberg Self-Esteem Scale
CERQ	Cognitive Emotion Regulation Questionnaire
PSS	The Paykel Suicide Scale
M-SSQ	Social Skills Questionnaire
S-EBPAS	Evidence-based Practice Attitude Scale for Teachers
EBPs	Evidence-based practices
SFS	Self-Efficacy Scale
CHU9D	The Child Health Utility
EQ-5D-3L	Self-reported European Quality of Life Five Dimension
VAS	Visual analog scale
CSRI	Client Service Receipt Inventory
PSU	Public and service users

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-025-09368-7.

Supplementary Material 1.

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Authors' contributions {25b}

CAE is the project PI and led the design of the study and the application for funding. CAE oversees all aspects of the project. SZ translated and adapted the questionnaires (from English to Bahasa Malaysia), as well as the manuals and workbooks for the Super Skills for Life and Study Skills programme. CAE led the group that back translated the questionnaires using the recommended translation procedure. CHT and JLAC double-checked the final version of the adapted questionnaires for their content and ease of language understanding. ADT is responsible for creating statistical plans and statistical analyses, including health economic evaluation. All investigators in Malaysia are responsible for the study coordination and participant recruitment. All authors contributed towards the writing of the manuscript and read and approved the final manuscript.

Funding {4}

This project is funded by the Kavli Trust. The funder has not contributed to the study design, data collection, management, analysis, and interpretation of data; or the decision to submit reports for publication. The views expressed are those of the authors and not necessarily those of the Kavli Trust.

Data availability {29}

Anonymized data arising from this study will be available five years after the project completion upon reasonable request from the corresponding author.

Declarations

Ethics approval and consent to participate {24}

The study (Screening and Trial) has been approved by the (1) University of Roehampton Research Ethics Committee (Reference: PSYC 23/483), (2) Sunway University Research Ethics Committee (Reference: SUREC 2023/093), (3) Malaysian Ministry of Education (Reference: KPM.600–3/2/3-eras [19064], and KPM.600–3/2/3-eras [21819]).

Written consent will be obtained from parents/carers for the screening and the trial. Written parental consent will also be obtained for qualitative interviews.

Consent for publication {32}

Participants will be informed about the findings of the present study, which will be submitted for publication and presented at academic conferences. The participants will be informed that the information they provide will be treated in confidence by the researcher and that their identity will be protected in the publication of any findings. Participant consent will be collected with regard to data collection, publication of data, and audio/video recording.

Competing interests {28}

CAE is a co-developer of the SSL. CAE and none of the co-authors make any financial gain from the intervention used in this study.

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