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Trials

UPDATE

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Protocol update to a study protocol for the Multimodal Approach to Preventing Suicide in Schools (MAPSS) project: a regionally based randomised trial of an integrated response to suicide risk among secondary school students

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Abstract

Background This update outlines amendments to the MAPSS trial protocol in response to both the COVID-19 pandemic and broader feasibility considerations. While many changes were necessary to navigate pandemic-related disruptions—such as school closures and remote learning—others were made to improve feasibility in the school-based setting, independent of COVID-19. The protocol was updated to align with public health guidelines and general school practices, ensuring feasibility for continued school participation and increased support and flexibility for school communities.

Methods Key adjustments included changes to participant-facing documentation, including implementing digital consent processes, extending timelines for participant recruitment and participation, and enhancing remote engagement strategies. Modifying outcome measures and risk management protocols, including adverse event reporting, ensured both participant safety and data continuity. Lastly, new study measures were added, such as a custom-designed questionnaire to assess study acceptability. Despite the updates, the core trial design, eligibility criteria, and primary outcomes remained unchanged.

Conclusion These protocol amendments reflect the pragmatic challenges of conducting school-based mental health research during a global pandemic and as part of ongoing efforts to enhance feasibility. The adjustments enabled the trial to proceed safely, prioritizing participant engagement and maintaining alignment with public health measures.

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Trial registrations Australian New Zealand Clinical Trial Registry, ACTRN12621000279820, originally registered on 12 March 2021, and currently awaiting update approval. Australian New Zealand Clinical Trial Registry, ACTRN12621000770864, originally registered on 21st June 2021, and updated on 16th February 2025.

Keywords Suicide prevention, Schools, Psychoeducation, Screening, ICBT

Background

Suicide remains the leading cause of death among young Australians, accounting for more than one-third of deaths in those under 25 [1]. The impact of suicide on individuals, families, and communities is profound, with lasting psychological and social consequences [2]. Schools have long been recognized as critical settings for suicide prevention, offering opportunities for universal, selective, and indicated interventions to reach large populations of young people [3]. The Multimodal Approach to Preventing Suicide in Schools (MAPSS) study aims to evaluate the effectiveness, safety, and cost-effectiveness of a multimodal integrated suicide prevention programme combining universal, selective, and indicated approaches delivered in schools across the North-West catchment region of Melbourne.

Due to the COVID-19 pandemic, the implementation of this study faced unprecedented challenges. Melbourne, where the study is located, experienced some of the longest and strictest lockdowns globally [4]. Schools were closed for extended periods, transitioning to remote learning environments and operating under stringent public health guidelines [4]. These disruptions significantly affected the delivery of school-based programmes and research processes.

This update outlines the amendments to the original trial protocol that were implemented to address the operational constraints imposed by the pandemic control measures while ensuring the safety and wellbeing of staff, students, and researchers. These amendments were informed by public health guidance and school policies that were designed to minimize the risk of COVID-19 transmission and aimed to maintain the study's integrity and alignment with its original objectives. Additional amendments were made throughout the trial to enhance participant recruitment and retention and reduce burden on schools—reflecting the study team's learnings from ongoing feasibility and implementation challenges that were emerging.

The sponsor and relevant HRECs reviewed and approved all amendments and changes.

Methods

Recruitment of students

Several strategies were implemented to improve participant-facing documentation and processes, as well as to enhance participant recruitment and ongoing engagement in the study. Many of the existing materials provided to students and parents to inform them about the study (e.g., school assembly announcements, letters to parents, parent and student information evenings, and participant information sheets/plain language statements) were moved online, and a video summarizing the study was created to be distributed alongside the consent forms. This allowed for better engagement when physical school visits were limited due to government-mandated lockdowns, as well as improving consent form accessibility for both parents and students. Additionally, an information flyer overviewing the Component 2 trial (a randomized controlled trial of Reframe IT program, an 8 module online CBT based intervention designed for young people experiencing low mood and suicidal thoughts) and randomization process was created so that school staff could provide students and parents with information about trial participation that they could review later, with an aim to enhance both participant, parent, and school staff understanding of Component 2.

Consent for Component 1 and Component 2

Initially, consent for this study was obtained using paper forms, which did not align with regular school practices, particularly during the COVID-19 pandemic when interpersonal contact was minimized. To address this, the consent process was updated to allow consent completion via an online consent form through either REDCap (Research Electronic Data Capture: [5, 6] or existing school consenting systems such as Compass [7], with a "tick box" provided as an indication for a participant's or parent's signature. This update aligned with government guidance (i.e., limiting in-person contact) during the pandemic and standard procedures for consent collection within school settings.

To further address recruitment challenges and improve access to Component 2, the overall consent process was streamlined by combining the previously separate Participant Information and Consent Forms (PICFs) for Components 1 (Livingworks safeTALK suicide alertness training and study surveys) and 2 (Reframe IT trial) into a single form, with an opt-out provision for Component 2. This change aimed to

significantly reduce participant, parent, school staff, and researcher burden by simplifying logistical processes and ensuring easier access to the intervention. Importantly, the combined PICFs maintained participants' rights to decline or withdraw from Component 2 at any stage. Supporting materials, including revised PICFs, updated flyers, parent messages, and a new explanatory video (see details above), were developed to facilitate this change and enhance communication.

Timeline adaptations

In response to delays in consent form completion, the timeline was extended from 2 to 4 weeks for obtaining consent and confirming participation with parents and students for Component 2. This ensured participants and their guardians had sufficient time to review the materials, consult the study team and school staff as needed, and make an informed decision. It also allowed participants with consent for Component 1 to complete the initial surveys and intervention as planned while waiting to obtain further consent (and subsequently be randomized) for Component 2.

Interventions

Component 1

There was an error regarding the risk management procedures in the original protocol. It was stated: "The REDCap system will automatically flag any participants who score between 1 and 20 on the SIDAS, as 1 is the established cut-off score indicating any level of suicidal ideation in the past month." However, this should have read between 1 and 50, to represent the full-scale SIDAS range, and this procedure was used throughout the study.

Component 2

Government-mandated lockdowns necessitated pausing Component 2, the trial of Reframe IT, throughout 2020 and most of 2021. In 2020, the program could not commence due to remote learning requirements, as Reframe IT was designed for in-person delivery. In 2021, only one student was recruited due to multiple lockdowns and periods of remote learning. With lockdown conditions lifted at the end of 2021, Component 2 was able to recommence in 2022, and the study data collection period was extended to 2024.

Discontinuation and withdrawal

Participant discontinuation criteria

The discontinuation criteria for participants in Component 2 were updated to include a fourth criterion beyond the original three, which accounted for situations where participants did not commence the Reframe IT intervention. Discontinuation of participants from Component 2 will occur where:

1. *Original criterion:* Use of the intervention interferes with appropriate clinical management of risk of harm to self or others (as judged by the school wellbeing staff and/or senior researchers);
2. *Original criterion:* Serious adverse events (SAEs; defined in section "Definitions of adverse events and serious adverse events) occur that could be associated with the Reframe IT intervention;
3. *Original criterion:* The participant or their parent or guardian indicates that they no longer wish to use the Reframe IT intervention;
4. *New criterion:* The participant does not complete any Reframe IT modules.

Outcomes and measures

Additional measures

In mid-2021, a custom-designed 7-item questionnaire was also introduced during the final survey (Time 4) to assess the acceptability of both the suicide risk screening procedures and the overall study questionnaires to participants. The questionnaire included items measuring participants' awareness of the risk management procedures (i.e., that disclosures of suicidal thoughts would be shared with the school wellbeing team and they would be followed up), their acceptability of the follow-up support provided for suicidal thoughts from either the school wellbeing or research teams, and subsequently, their honesty in responding to questions about suicidality. Additional items evaluated whether participants found the overall questionnaires and participating in the MAPSS study upsetting, worthless, boring, too long, interesting, or easy to understand, using a 3-point Likert scale ranging from 1 ("Not at all") to 3 ("A lot"). An open-ended response option was also included to allow participants to provide additional feedback on their experiences of participating in the study. We also added an option for students to indicate if they would be open to being contacted for a follow-up interview about their experience.

At the beginning of 2023, three additional measures were included in each timepoint survey (Times 1–4) to assess aspects of family functioning: (1) the Family Systems APGAR items [8] to evaluate overall family functioning; (2) the Self-Harm and Suicide Disclosure Scale [9] to identify family members to whom individuals disclosed suicidal thoughts or behaviors; and (3) in what circumstances, and the Family Quality Reaction Scale [9] to examine family reactions to such disclosures.

Component 2 information

A form was added for school wellbeing staff to complete at the end of the Component 2 (Reframe IT) trial period (i.e., Time 3), for them to record the number and nature of contact with students participating in the trial. This aimed to facilitate better tracking of the type and length of interventions participants received from the school wellbeing team as part of their "treatment as usual" activities (if applicable), as well as capture additional support provided to participants in the Reframe IT intervention (e.g., general supportive counselling).

Adverse events

Definitions of adverse events and serious adverse events

Serious adverse events (SAE)

The definition of SAEs was revised to ensure participant privacy and streamline SAE reporting requirements. This change eliminated the need for extensive investigations and documentation of suicide attempts reported by participants since the last survey timepoint (e.g., study surveys Times 2–4), without a causal link to the intervention. The revised definition specifies: "Only suicide attempts that occur during the study and are directly linked to the study intervention will be documented as SAEs. To be classified as an SAE, school staff, a healthcare provider, the participant, their close contacts, or their family members must report that the study intervention caused the suicide attempt." Study interventions comprise: (1) the safeTALK program at Time 2 (e.g., universal intervention), (2) the study questionnaires and embedded suicide risk screening measures at each timepoint (e.g., selective intervention), and (3) the Reframe IT program (e.g., targeted intervention) conducted between Time 2 and Time 3.

Research team

Several personnel changes occurred during the trial, and the authorship and author order in this update reflect these changes and the contributions of the core project study team members.

Trial status

Final data collection with students was completed on October 16, 2024, and school staff interviews were completed on December 10, 2024. Data cleaning is currently underway, and analysis will commence shortly.

Abbreviations

APGAR	Adaptability, Partnership, Growth, Affection, and Resolve
COVID-19	Coronavirus disease
HREC	Human Research Ethics Committee
MAPSS	Multimodal Approach to Preventing Suicide in Schools
PICF	Participant Information and Consent Form
SAE	Serious adverse event
SIDAS	Suicidal Ideation Attributes Scale
TAU	Treatment as usual
REDCap	Research Electronic Data Capture

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Role of study sponsor and funders

This is an investigator-initiated research project which has been funded by non-commercial sources. The role of the funder (National Health and Medical Research Council) and Sponsor (Orygen) will not impact on decisions regarding the outcome of this research or how it will be published. Orygen (as Sponsor) has taken an active role in the monitoring of the study as both Orygen and the funder require the studies to be conducted in accordance with local regulatory guidelines and industry best practice. However, the research and its outcomes are independent of both the Sponsor and the funder.

Authors' contributions

J.R., J.P., S.R., S.H., M.S., C.M., and M.H. conceived the study and contributed to the study design. J.R. provided lead oversight to the project and is the chief investigator. M.L. and S.M. conducted project management. S.M., I.B.W., M.L., M.V., B.K., E. Bailey, and S.J.B. conduct implementation procedures, including recruitment of schools and participants. M.J.S. provided methodological oversight. H.P.Y. will conduct statistical analyses. S.R. and E. Brown provided clinical guidance and supervision to research staff. C.M. and Y.Y.L. will conduct the economic evaluation. S.M., I.B.W., M.L., and J.R. prepared the first manuscript. S.M., I.B.W., M.L., and J.R. prepared the revised manuscript. All authors read and approved the final manuscript.

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Data availability

Not applicable.

Declarations

Ethics approval and consent to participate

The study has been granted approval by the University of Melbourne Psychology Health and Applied Sciences Human Ethics Sub-Committee (ID: 1852317) and the Victorian Department of Education and Training (ID: 2019_003951). These committees also reviewed and approved all subsequent amendments to the protocol.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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