RESEARCH PROTOCOL

**Evaluating the Effect of a Psychological Safety Program on Help-Seeking and Well-Being in Primary School Students: A Randomised Controlled Trial**

Prepared by Dr. Kelvin Wong

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# Protocol version history

|  |  |  |
| --- | --- | --- |
| **Protocol number** | **Version number** | **Version date** |
| 1 | 1 | 26/1/2023 |
| 2 | 1 | 17/7/2023 |
| 2 | 2 | 25/7/2023 |
| 2 | 3 | 26/7/2023 |
| 2 | 4 | 8/9/2023 |

# General Information

## Study sponsor

|  |  |
| --- | --- |
| **Name** | CCC Foundation Australia Inc. |
| **Address** | 4 Rylandes Drive  Gladstone Park, VIC, 3043 |
| **Contact** | Jetha Devapura, [jetha@cccfoundation.org.au](mailto:jetha@cccfoundation.org.au) |

## Study sites

|  |  |
| --- | --- |
| **Site name** | **Site address** |
| 10 primary schools (public and private) across Victoria, Australia | TBD |

## Principal investigator

|  |  |  |  |
| --- | --- | --- | --- |
| **Title** | **Name** | **Email** | **Address and phone** |
| Dr. | Kelvin (Shiu Fung) Wong | kelvinwong@swin.edu.au | Swinburne University of Technology  John Street, Hawthorn, VIC, 3122  +61 3 9214 5161 |

## Other study investigators

|  |  |  |  |
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| Ms. | Sheryl Gullia | [s.gullia@latrobe.edu.au](mailto:s.gullia@latrobe.edu.au) | La Trobe University |

## Independent and/or study safety individuals or committees

The following investigator is responsible for notifying HREC of any concerns relating to safety during this study:

|  |  |  |
| --- | --- | --- |
| **Title** | **Name** | **Email** |
| Dr. | Kelvin (Shiu Fung) Wong | kelvinwong@swin.edu.au |

## Funding and resources

Swinburne University of Technology is providing in-kind support through Dr. Kelvin Wong’s involvement and will be responsible for data collection and analysis. The CCC Foundation Australia Inc. will be responsible for the delivery of their intervention (The Let’sTALK Program).

## Insurance

Insurance is provided by the sponsor, CCC Foundation Australia Inc.

# Introduction and Background Information

## Background information

Child and adolescent mental health problems are an important and growing public health concern in Australia (Sawyer et al., 2001). Indeed, 14% of children and adolescents were identified as having mental health problems (e.g., Depressive Disorder), which is associated with increased problems in other life domains and risk for suicidal behaviours (Sawyer et al., 2001). This number has seen a spike during the COVID-19 pandemic, such that 20.2% and 20.4% of Sicouri et al.’s (2023) child and adolescent sample were found to score in the clinical range for anxiety symptoms and depressive symptoms, respectively. Unfortunately, only a quarter of Australian young people with mental health problems access health services within a 12-month period (Reavley et al., 2010). Given this significant gap in help-seeking behaviours, it is crucial to understand and address the barriers to help-seeking in this population.

A recent systematic review identified mental health stigma and poor help-seeking literacy as barriers for young people accessing professional help (Radez et al., 2021). Similarly, Rickwood et al. (2007) outlined that young people are more inclined to seek help for their mental health problems if they have some knowledge about mental health issues and sources of help; feel emotionally competent to express their feelings; and have established and trusted relationships with potential help providers. Given this, Radez et al. (2021) suggested that widespread dissemination of school-based interventions targeting stigma and mental health knowledge is needed to increase help-seeking behaviours in young people. Indeed, adults in community-based roles such as teachers are commonly engaged in behaviour that supported prevention and early intervention for students’ mental health (Mazzer & Rickwood, 2013).

Mazzer, K. R., & Rickwood, D. J. (2013). Community-based roles promoting youth mental health: Comparing the roles of teachers and coaches in promotion, prevention and early intervention. *International Journal of Mental Health Promotion, 15,* 29-42. <https://doi.org/10.1080/14623730.2013.781870>

Radez, J., Reardon, T., Creswell, C., Lawrence, P. J., Evdoka-Burton, G., & Waite, P. (2021). Why do children and adolescents (not) seek and access professional help for their mental health problems? A systematic review of quantitative and qualitative studies. *European Child and Adolescent Psychiatry, 30,* 183-211. <https://doi.org/10.1007/s00787-019-01469-4>

Reavley, N. J., Cvetkovski, S., Jorm, A. F., & Lubman, D. I. (2010). Help-seeking for substance use, anxiety and affective disorders among young people: Results from the 2007 Australian National Survey of Mental Health and Well-being. *Australian and New Zealand Journal of Psychiatry, 44,* 729-735. <https://doi.org/10.3109/00048671003705458>

Rickwood, D. J., Deane, F. P., & Wilson, C. J. (2007). When and how do young people seek professional help for mental health problems? *Medical Journal of Australia, 187,* 35-39. <https://doi.org/10.5694/j.1326-5377.2007.tb01334.x>

Sawyer, M. G., Arney, F. M., Baghurst, P. A., Clark, J. J., Graetz, B. W., Kosky, R. J., Nurcombe, B., Patton, G. C., Prior, M. R., Raphael, B., Rey, J. M., Whaites, L. C., & Zubrick, S. R. (2001). The mental health of young people in Australia: Key findings from the child and adolescent component of the National Survey of Mental Health and Well-being. *Australian and New Zealand Journal of Psychiatry, 35,* 806-814. <https://doi.org/10.1046/j.1440-1614.2001.00964.x>

Sicouri, G., March, S., Pellicano, E., De Young, A. C., Donovan, C. L., Cobham, V. E., Rowe, A., Brett, S., Russell, J. K., Uhlmann, L., & Hudson, J. L. (2023). Mental health symptoms in children and adolescents during COVID-19 in Australia. *Australian and New Zealand Journal of Psychiatry, 57,* 213-229. <https://doi.org/10.1177/00048674221090174>

## Study rationale

The Let’sTALK Program is a school-based intervention targeting mental health literacy and stigma to improve psychological safety. In other words, the goal is to create a positive environment where students feel safe in talking about their mental health problems with peers and trusted adults and to seek help before these escalate into more serious issues. School-based mental health programs such as The Let’sTALK Program have been shown to improve student help-seeking and coping; social and emotional well-being; and psychoeducational effectiveness (O’Connor et al., 2018).

O’Connor, C. A., Dyson, J., Cowdell, F., & Watson, R. (2018). Do universal school-based mental health promotion programmes improve the mental health and emotional wellbeing of young people? A literature review. *Journal of Clinical Nursing, 27,* 412-426. <https://doi.org/10.1111/jocn.14078>

## Study objective

The primary aim of this study is to provide an independent evaluation of a psychological safety program (The Let’sTALK Program). We will collect and analyse data from 10 primary schools to evaluate whether The Let’sTALK Program can increase help-seeking and wellbeing in Victorian primary school children (public and private).

## Type of study

Two-arm randomised controlled trial.

# Study Overview

## Study design

This protocol describes a two-arm randomised controlled trial (Phase II). Ten participating primary schools (public and private) will be randomly assigned to either the intervention group or the control group. In the intervention group, students will complete The Let’sTALK Program over a period of 11 months, focusing on improving communication skills. On the other hand, the control group will be placed on a waitlist for the same duration before being given access to The Let’sTALK Program. To ensure fair measurement, cluster-randomization will be employed within each group to determine which individuals will provide data for the study. Specifically, one classroom, including the students and their teacher, will be randomly selected from Grades 3, 4, 5, and 6 in each school. This rigorous approach allows us to compare the effects of The Let’sTALK Program against the control group, providing valuable insights into its effectiveness in improving communication skills among students.

## Participant flow and measurement timepoints

Participant consent will be provided by signing physical copies and assessment will take place via a secure online questionnaire platform (Qualtrics). Student participants will require their parents/guardians to provide informed consent. After providing informed consent, participants will complete the baseline questionnaires. Subsequent assessment points coincide for participants in both groups after 3 months (end of Term 1, 2024), 6 months (end of Term 2, 2024), 9 months (end of Term 3, 2024), and 11 months (end of Term 4, 2024).

Proposed assessment dates:

Consent forms sent out: 30th January 2024 (first day of Term 1)

Collect signed consent forms: 31st January 2024 to 9th February 2024

Baseline measures: 12th to 16th (up to 23rd) February (2nd week of Term 1)

Term 1, 2024: 18th to 22nd (up to 29th) March (2nd last week of term)

Term 2, 2024: 17th to 21st (up to 28th) June (2nd last week of term)

Term 3, 2024: 6th to 13th (up to 20th) September (2nd last week of term)

Term 4, 2024: 6th to 13th (up to 20th) December (2nd last week of term)

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| --- | --- | --- | --- | --- | --- |
| **Outcomes** | **Baseline (before training)** | **End of Term 1, 2024** | **End of Term 2, 2024** | **End of Term 3, 2024** | **End of Term 4, 2024** |
| **Student participants** | | | | | |
| Strengths and Difficulties Questionnaire | **x** | **x** | **x** | **x** | **x** |
| Stirling Children’s Well-Being Scale | **x** | **x** | **x** | **x** | **x** |
| Psychological Safety Scale | **x** | **x** | **x** | **x** | **x** |
| Let’sTALK survey (developed inhouse) | **x** | **x** | **x** | **x** | **x** |
| Questions measuring help-seeking behaviour (developed inhouse) | **x** | **x** | **x** | **x** | **x** |
| Questions measuring acceptability of the Let’sTALK program (Let’sTALK buddies only; developed inhouse) |  | **x** | **x** | **x** | **x** |
| **Teacher participants** | | | | | |
| People at Work Survey | **x** |  | **x** |  | **x** |
| Strengths and Difficulties Questionnaire (each student) | **x** | **x** | **x** | **x** | **x** |
| Questions measuring students’ help-seeking behaviour (developed inhouse) | **x** | **x** | **x** | **x** | **x** |

Note. Primary outcomes are highlighted.

The questionnaires at each assessment time point is expected to take 1 hour for students (5 hours in total) and 3 hours for teachers (15 hours in total). As part of agreeing to take part in this study, school principals will be aware of the time commitment and Casual Relief Teaching staff will be procured by the CCC Foundation Australia Inc. to help cover any teaching that is interrupted by the study.

Questionnaire references:

Strengths and Difficulties Questionnaire (initially validated in 11-17 year olds but also validated in 8-13 year olds).

Goodman, R. (2001). Psychometric properties of the strengths and difficulties questionnaire. *Journal of the American Academy of Child and Adolescent Psychiatry, 40*, 1337-1345. <https://doi.org/10.1097/00004583-200111000-00015>

Muris, P., Meesters, C., Eijkelenboom, A., & Vincken, M. (2010). The self-report version of the Strengths and Difficulties Questionnaire: Its psychometric properties in 8- to 13-year-old non-clinical children. *British Journal of Clinical Psychology, 43*, 437-448. <https://doi.org/10.1348/0144665042388982>

Stirling Children’s Well-Being Scale (validated in 8-15 year olds).

Liddle, I., & Carter, G. F. A. (2015). Emotional and psychological well-being in children: The development and validation of the Stirling Children’s Well-being Scale. *Educational Psychology in Practice, 31*, 174-185. <https://doi.org/10.1080/02667363.2015.1008409>

Psychological Safety Scale (wording modified to be suitable for 8 year olds).

Roy, D. (2019). Development and validation of a scale for psychological safety in school among high school students in India. *Management and Labour Studies, 44*, 394-416. <https://doi.org/10.1177/0258042X19870330>

People at Work Survey.

Jimmieson, N. L., Bordia, P., Hobman, E. V., & Tucker, M. K. (2010). *The People at Work Project: Development and validation of a psychosocial risk assessment tool* (pp. 1-287). Industry report prepared for Workplace Health and Safety Queensland.

## Study CONSORT diagram

Not applicable

## Study population

The setting for this study is primary schools in Victoria, Australia (10 schools). Participants will be eligible to participate if they are aged 8 years or over and are computer and internet-literate.

## Study hypotheses

* Student participants in the psychological safety intervention, relative to waitlist control, will demonstrate significantly greater improvements in self-reported and teacher reported strengths and difficulties, well-being, and help-seeking behaviour.
* This finding will remain significant even after controlling for school and grade level.
* This intervention effect will be mediated by the students self-reported changes in psychological safety.

## Compliance statement

This study will be conducted in compliance with the protocol outlined herein and the requirements of Swinburne University of Technology HREC approval (SUHREC).

## Investigational product(s)

Not applicable

## Investigational product dispensing and packaging

Not applicable

## Investigational product administration

Not applicable

## Study duration

Please refer to Section 3.2.

# Study Documentation

|  |  |  |  |
| --- | --- | --- | --- |
| **Document** | **Version #** | **Version date** | **Appendix #** |
| Invitation email to principals of Victorian primary schools | 2.0 | 6/9/23 |  |
| Study announcement via school’s internal systems (e.g., COMPASS) | 1.0 | 26/7/23 |  |
| Consent Instruments - Let'sTALK parents\_guardians | 2.0 | 8/9/23 |  |
| Consent Instruments - Let'sTALK teachers | 2.0 | 8/9/23 |  |
| Questionnaire pack for students | 1.0 | 26/7/23 |  |
| Questionnaire pack teachers | 1.0 | 26/7/23 |  |
| Research in Victorian government schools and early childhood settings (RISEC) application form | 2.0 | 10/8/23 |  |
| Collaborative research agreement | 1.0 | 8/8/23 |  |

# Study Procedures

## Selection and recruitment

Principals of Victorian primary schools will be invited to participate in the study via email (see ‘Invitation email to principals of Victorian primary schools’ documents). Schools will be identified using data publicly available from the Victorian Department of Education and Training website.

## Eligibility criteria

Participants will be eligible to participate if they are aged 8 years or over and are computer and internet-literate.

## Screening

Not applicable

## Withdrawal of study participants

Participants can withdraw their consent to participate at any point of the study without consequences.

## Intervention overview

### About The Let’sTALK Program

A group of individuals receive a face-to-face training session at the beginning of the school term on how to use the TALK framework to improve psychological safety in schools. Specifically, a Let’sTALK facilitator guides individuals through the Let’sTALK manual which outlines the application of the framework:

* Topic 1 (T): Tell when someone is in distress and engage in a conversation
  + Introduction – purpose and vision of the Let’sTALK program
  + Psychological safety – the foundation to wellbeing
  + Mindfulness – to be aware of oneself, others, and the tell-tale signs of distress
  + Stigma – to be aware of one’s biases and how it affects open communication
  + Conversation – how to start a conversation with someone in distress, including oneself
* Topic 2 (A): Acknowledge the person and their concerns
  + Vulnerability – how it is a strength and not a weakness
  + Trust – the elements of trust that are critical for open communication
  + Empathy – to step outside one’s experiences to understand others’
  + Gratitude – to make difficult conversations easier for both parties
  + Acknowledge – how a simple statement can validate the other person and build trust
* Topic 3 (L): Listen to help externalise the person’s concerns
  + Listening – why it can be difficult at the best of times
  + The 3 Fs – how facts, feelings, and fears can get to the bottom of a problem
  + Emotional intelligence – how it impacts the quality of conversations
  + Active listening – skills to say less and hear more
* Topic 4 (K): Keep in touch to support and empower the person
  + The three stages of keeping in touch to support someone in distress
  + Referring the person to source appropriate support (i.e., to resources and referral options appropriate for the Victorian education system)
  + Classroom and school-wide activities to embed and sustain a culture of having open conversations
  + Measures to monitor and assess the impact of The Let’sTALK Program on psychological safety and well-being

Up to 30 school staff (Let’sTALK Mentors) are selected to receive an 8-hour training session, and up to 30 students (Let’sTALK Buddies) are selected to receive a 4-hour training session. Mentors and buddies are provided with monthly coaching/mentoring sessions throughout the year by the Let’sTALK facilitator to ensure program fidelity.

### Management and maintenance of The Let’sTALK Program

The Let’sTALK Program is delivered independently of the research team by the CCC Foundation Australia Inc. For enquiries, please contact Jetha Devapura ([jetha@cccfoundation.org.au](mailto:jetha@cccfoundation.org.au)).

## Contraindications

There are no known contraindications for The Let’sTALK Program.

## Subject adherence

Please refer to Section 5.5.1.

## Safety monitoring and reporting

Safety reports will be assessed on the seriousness, causality, and expectedness of the event to the trial treatment(s), intervention(s), investigational medical product(s), investigational medical device(s). The following are known and expected adverse effects, harms, risks or discomforts associated with trial procedures, treatments, or interventions.

1. Known adverse effects:
   1. Nil known adverse effects are expected to occur following The Let’sTALK Program.
2. Known harms, risks or discomforts:
   1. Risks related to questionnaires. It is possible that students and teachers may experience some boredom when completing the questionnaires or discomfort or distress when answering questions about sensitive topics (e.g., school belongingness, loneliness). To mitigate the risk of participants becoming unduly agitated during or after the data collection procedure, we will take the following steps:
      1. Advising parents, students, and teachers in all relevant documentation (e.g., letters of invitation, PICFs) that participation is voluntary, all information provided is confidential, and that participants are free to withdraw from the research project at any time.
      2. All relevant documentation to include contact details of the researchers and support services/procedures:
         1. Emergency services [000], Lifeline [131114], Kids Help Line [1800 55 1800], and Mental Health Line [1800 011 511], and Parent Line [1300 1300 52].
         2. Student safety procedure may differ depending on the site, but should include speaking to their classroom teacher who may refer them to internal school supports (e.g., school counsellor, welfare support) and if requiring escalation, refer them to external allied health support services.
         3. Teacher safety procedure may differ depending on the site, but could include speaking to their manager or the Employee Assistance Program.
      3. Including a disclaimer at the beginning of the questionnaires at each assessment period that students and teachers are free to leave blank any question they do not feel comfortable answering.
      4. Including a note at the beginning of the questionnaires at each assessment period that provides students and teachers with the contact details of the researchers and support services/procedures (see above).
      5. Ensuring that all questionnaires request, rather than force, a response.

|  |  |
| --- | --- |
| **Adverse Event (AE)** | Any untoward occurrence in a clinical trial participant administered the intervention and that does not necessarily have a causal relationship with this intervention.  *Reporting*   * A record of all adverse event reports will be recorded by the research team and reported to SUHREC via the Adverse Event reporting pathway in ERM. |
| **Serious Adverse Event (SAE)** | Any adverse event that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.  *Reporting*   * Any serious adverse events will be reported to SUHREC via the Adverse Event reporting pathway in ERM. |
| **Significant Safety Issue (SSI)** | A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the study.  *Reporting*  Urgent safety measure   * Reports defined as an **urgent safety measure** that adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial will be reported to SUHREC via the Adverse Event reporting pathway in ERM **within 72 hours.** * Reports defined as significant safety issues should be reported to SUHREC via the Adverse Event reporting pathway in ERM **within 15 calendar days** of the research team becoming aware of the issue. |
| **Suspected Unexpected Serious Adverse Reaction (SUSAR)** | An adverse reaction that is both serious and unexpected.  *Reporting*   * All **suspected unexpected serious adverse reactions** occurring in participants will be reported to SUHREC via the Adverse Event reporting pathway in ERM within **15 calendar days** of becoming aware of the case. * All fatal or life threatening Australian **suspected unexpected serious adverse reactions** will be immediately reported to SUHREC via the Adverse Event reporting pathway in ERM, but no later than **7 calendar days** after being made aware of the case, with any follow-up information within a further 8 calendar days. |

## Data management plan

All data will be handled in accordance with the Privacy and Data Protection Act 2014 (Vic), with any health information collected handled in accordance with the Health Records Act 2001 (Vic). Specifically, all data (i.e., all survey responses) will be de-identified to maintain confidentiality and anonymity, as well as password protected and stored securely in the Principal Investigator’s OneDrive for Business within Swinburne University’s IT system. The Qualtrics software will collect, and thus store, participants’ survey responses. Please see the Qualtrics privacy statement for more information: https://www.qualtrics.com/privacy-statement/. Storage of the data collected will adhere to university regulations (https://www.swinburne.edu.au/privacy/). De-identified data will be accessible to and analysed by the research team, and may be stored indefinitely and shared with other researchers on data sharing platforms (e.g., the Open Science Framework) and/or shared with colleagues for research purposes (e.g., meta-analyses).

De-identified data will also be shared with the CCC Foundation Australia Inc. staff involved in the delivery and administration of The Let'sTALK Program. As above, the CCC Foundation Australia Inc. will handle the data in accordance with the Privacy and Data Protection Act 2014 (Vic) and the Health Records Act 2001 (Vic). Data will be stored as encrypted files on password protected computers accessible to only the CCC Foundation Australia Inc. staff involved in the delivery and administration of The Let'sTALK Program.

The signed consent form will be collected by a member of the research team and stored separately to any data collected and only the Principal Investigator will have access.

The anonymous findings of this study will be used to write a report submitted to the Victorian Government. Findings may be submitted for publication in professional publications, academic journals, or conferences. Participants will not be named or identified in any reports or publications arising from this research. If participants want to receive a summary of the findings, they will be able to contact the Principal Investigator via email.

## Analysis plan

Primary outcomes of the study (Section 3.2.) reported by students and teachers will be analysed using a 2-level mixed model repeated measures in SPSS with intervention as covariate at school level and class level as covariate at student level. Missing data will be handled using intention-to-treat.

Using G\*Power (version 3.1.), a sample size of 156 participants was determined to be sufficient for a 90% chance of detecting a small effect (*f* = .10) across 5 measurement timepoints with an intraclass correlation of 0.5, and alpha set at .05 . This study will recruit a total of 190 participants given an expected attrition rate of 17% for longitudinal research in school-aged participants (*n* = 34).

# HREC and Ethical Compliance

Human research ethics (HREC) approval was sought before the commencement of the project.

|  |  |  |  |
| --- | --- | --- | --- |
| **HREC Name** | **Ethics Reference** | **Ethics approval date** | **Ethics expiration date** |
| Swinburne University of Technology HREC (SUHREC) |  |  |  |