**STUDY PROTOCOL**

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| --- | --- |
| Title | A randomised controlled trial evaluating the effectiveness of the Engaging Men in Crisis Support training program for Crisis Supporters at Lifeline Australia |
| Trial registration. | 26011 |
| Protocol version | 1.1 |
| Funding | Australian Government Medical Research Future Fund |
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| Role of sponsor | The Centre for Mental Health at the University of Melbourne will host the trial and the Principal Investigator Professor Jane Pirkis will oversee the study design, data collection, management, analysis, and interpretation of data, writing of the report, and the decision to submit the report for publication and will have ultimate authority over these activities. |

Table of Contents

[1. Study Synopsis 7](#_Toc131406150)

[2. Introduction 11](#_Toc131406151)

[2.1. Background 11](#_Toc131406152)

[2.2. Study rationale 15](#_Toc131406153)

[2.3. Objectives 15](#_Toc131406154)

[2.4. Hypotheses 15](#_Toc131406155)

[2.5. Outcomes 15](#_Toc131406156)

[2.5.1. Callers 15](#_Toc131406157)

[2.5.2. Crisis Supporters 16](#_Toc131406158)

[3. Methods 16](#_Toc131406159)

[3.1. Trial Design 16](#_Toc131406160)

[3.1.1. Phase 1: Crisis Supporter training 17](#_Toc131406161)

[3.1.1. Phase 2: Caller data collection 17](#_Toc131406162)

[3.2. Study Setting 20](#_Toc131406163)

[4. Participant selection 20](#_Toc131406164)

[4.1.2. Callers 21](#_Toc131406165)

[4.1.3. Crisis supporters 21](#_Toc131406166)

[4.2. Sample size 22](#_Toc131406167)

[4.2.1. Callers 22](#_Toc131406168)

[4.2.2. Crisis Supporters 22](#_Toc131406169)

[4.3. Recruitment 23](#_Toc131406170)

[4.3.1. Crisis Supporters 23](#_Toc131406171)

[4.3.2. Callers 23](#_Toc131406172)

[4.4. Informed consent procedures 23](#_Toc131406173)

[4.4.1. Callers 23](#_Toc131406174)

[4.4.2. Crisis supporters 25](#_Toc131406175)

[4.4.3. Additional consent provisions for collection and use of participant data and biological specimens 25](#_Toc131406176)

[4.5. Withdrawal 25](#_Toc131406177)

[4.5.1. Callers 25](#_Toc131406178)

[4.5.2. Crisis Supporters 26](#_Toc131406179)

[5. Interventions 26](#_Toc131406180)

[5.1. Explanation for the choice of comparators 26](#_Toc131406181)

[5.1.1. Callers 26](#_Toc131406182)

[5.1.2. Crisis Supporters 26](#_Toc131406183)

[5.2. Intervention description 28](#_Toc131406184)

[5.2.1. Callers 28](#_Toc131406185)

[5.2.2. Crisis Supporters 28](#_Toc131406186)

[5.3. Criteria for discontinuing or modifying allocated interventions 31](#_Toc131406187)

[5.4. Strategies to improve adherence to interventions 32](#_Toc131406188)

[5.4.1. Callers 32](#_Toc131406189)

[5.4.2. Crisis Supporters 32](#_Toc131406190)

[5.5. Relevant concomitant care permitted or prohibited during the trial 32](#_Toc131406191)

[5.6. Provisions for post-trial care 32](#_Toc131406192)

[5.6.1. Callers 32](#_Toc131406193)

[5.6.2. Crisis Supporters 32](#_Toc131406194)

[6. Participant timeline and tasks 32](#_Toc131406195)

[6.1. Callers 32](#_Toc131406196)

[6.2. Crisis Supporters 33](#_Toc131406197)

[6.3. Plans for assessment and collection of outcomes 35](#_Toc131406198)

[6.3.1. Callers 35](#_Toc131406199)

[6.3.2. Crisis Supporters (secondary outcomes/additional data) 36](#_Toc131406200)

[6.3.3. Economic outcomes 40](#_Toc131406201)

[6.4. Plans to promote participant retention and complete follow-up 40](#_Toc131406202)

[7. Assignment of interventions: allocation 40](#_Toc131406203)

[7.1. Sequence generation 40](#_Toc131406204)

[7.2. Concealment mechanism 41](#_Toc131406205)

[7.2.1. Callers 41](#_Toc131406206)

[7.2.2. Crisis Supporters 41](#_Toc131406207)

[7.3. Implementation 41](#_Toc131406208)

[7.4. Assignment of interventions: Blinding 41](#_Toc131406209)

[7.4.1. Who will be blinded 41](#_Toc131406210)

[7.4.2. Procedure for unblinding if needed 42](#_Toc131406211)

[8. Data management 42](#_Toc131406212)

[8.1. Caller data 42](#_Toc131406213)

[8.2. Crisis Supporter data 42](#_Toc131406214)

[8.3. Confidentiality 44](#_Toc131406215)

[8.3.1. Callers 44](#_Toc131406216)

[8.3.2. Crisis supporters 45](#_Toc131406217)

[8.4. Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use 45](#_Toc131406218)

[9. Statistical methods 45](#_Toc131406219)

[9.1. Statistical methods for primary and secondary outcomes 45](#_Toc131406220)

[9.1.1. Callers 45](#_Toc131406221)

[9.1.2. Crisis Supporters 45](#_Toc131406222)

[9.2. Interim analyses 46](#_Toc131406223)

[9.3. Methods for additional analyses (e.g. subgroup analyses) 46](#_Toc131406224)

[9.4. Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data 46](#_Toc131406225)

[9.4.1. Callers 46](#_Toc131406226)

[9.4.2. Crisis Supporters 46](#_Toc131406227)

[9.5. Access to data: Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators 46](#_Toc131406228)

[10. Oversight and monitoring 47](#_Toc131406229)

[10.1. Composition of the coordinating centre and trial steering committee 47](#_Toc131406230)

[10.2. Composition of the data monitoring committee, its role and reporting structure 47](#_Toc131406231)

[11. Adverse event reporting and harms 47](#_Toc131406232)

[11.1. Risks to participants and risk management strategy 47](#_Toc131406233)

[11.1.1. Callers 48](#_Toc131406234)

[11.1.2. Crisis supporters 48](#_Toc131406235)

[11.2. Risk reporting 49](#_Toc131406236)

[11.3. Frequency and plans for auditing trial conduct 49](#_Toc131406237)

[11.4. Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) 49](#_Toc131406238)

[11.5. Declaration of interests 49](#_Toc131406239)

[11.6. Dissemination plans 49](#_Toc131406240)

[11.7. Authorship eligibility guidelines and any intended use of professional writers 50](#_Toc131406241)

[11.8. Plans to give access to the full protocol, participant level-data and statistical code 50](#_Toc131406242)

[12. References 50](#_Toc131406243)

# Study Synopsis

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| **Item** | **Description** |
| **Study Type** | Randomised controlled trial (RCT) |
| **Date of Registration** | To be registered |
| **Study Population** | Lifeline accredited telephone Crisis Supporters  Callers to Lifeline |
| **Sample Size** | N=140 Crisis Supporters  N=3,500 callers (1,400 male callers) |
| **Study Design** | Two-stage, double-randomised RCT with caller participants nested within CSs comparing intervention with care-as-usual + active control. Crisis Supporters (CSs) will either complete the *Engaging Men in Crisis Support* (EMICS) training module (intervention group) or a *Child Safety and Crisis Support* training module (control group). Caller outcome data will then be collected during calls to Lifeline over a period of approx. 18 months. The impact of the EMICS training will be evaluated through comparison of male caller outcome data for callers allocated to CSs in the intervention group compared with the control group. For Crisis Supporters, assessments will take place at pre-training and four weeks post-training. For callers, due to the anonymous nature of support provided by Lifeline, assessment will take place at single time-point (post-call) with no follow up. |
| **Study Rationale** | Men represent approximately 75% of suicide deaths in Australia, but only make up 40% of callers to Lifeline — Australia’s national crisis helpline. Healthcare services often experience challenges engaging men, with evidence suggesting that tailored approaches to care which take into consideration the impacts of socialised masculinity may improve engagement and outcomes. Consequently, an online professional development training package was developed for Lifeline Crisis Supporters adapted to the helpline context, focused on engaging and supporting male callers at Lifeline. This study will evaluate the effectiveness of this intervention on male caller outcomes at Lifeline. |
| **Primary Objective** | **Callers**  Evaluate the effectiveness of the intervention in increasing Lifeline Crisis Supporter ability to support male callers, indicated through lower male caller ratings of feeling distressed, collected post-call. |
| **Secondary Objectives** | **Callers**  Evaluate the effectiveness of the training in increasing Lifeline Crisis Supporter ability to support male callers, indicated through (i) higher male caller ratings of feeling heard, and (ii) lower male caller ratings of suicide risk collected post-call.  **Crisis Supporters**  Evaluate the effectiveness of the training in increasing Lifeline Crisis Supporter self-reported capacity and confidence to engage with and support male callers, indicated by greater increases on these measures in the intervention group compared to the control. |
| **Exploratory Objectives** | **Callers**  Evaluate the impact of the training on male caller outcomes compared with non-male caller outcomes by comparing male caller ratings to non-male caller ratings of feeling distressed, feeling heard, and suicide risk.  Evaluate the cost-effectiveness of the *Engaging Men in Crisis Support* by comparing benefits of the intervention to the cost of intervention development and implementation.  **Crisis Supporters**  Examine the acceptability and feasibility of the *Engaging Men in Crisis Support* training, indicated by qualitive analysis of CS feedback. |
| **Study Endpoints** | **Callers**  ***Primary***  Immediately post-call: Difference between intervention and control groups in male callers’ ratings of feeling distressed..  ***Secondary***  Immediately post-call: Difference between intervention and control in pre-post changes on Lifeline Crisis Supporter ability to support male callers, indicated through higher male caller ratings of feeling heard and lower male caller ratings of suicide risk.  ***Exploratory***  Immediately post-call: Differences between male callers and non-male callers in caller ratings of feeling distressed, heard, and suicide risk.  **Crisis Supporters**  ***Secondary***  Post-intervention: Difference between intervention group and control group in pre-post changes on adapted versions of the Current Clinical Skills and Professional Self-Doubt subscales of the Development of Psychotherapists Common Core Questionnaire (DPCCQ), the Session Management subscale of the Counsellor Activities Self Efficacy Scale (CASES), and bespoke items corresponding to the learning objectives of the training.  ***Exploratory***  Post intervention: (T2): Feasibility and acceptability of the *Engaging Men in Crisis Support* training.  Post intervention: (T2): Cost-effectiveness of the development and implementation of the intervention. |
| **Inclusion Criteria** | **Callers**  Provide opt-in consent.  **Crisis Supporters**  Provide informed consent.  Lifeline Crisis Supporter currently completing paid shifts with a minimum of one four-hour rostered shift per fortnight at a participating Lifeline centre.  Commitment to rostering an additional paid shift on top of their normal crisis support shift in the 4-week training period to complete allocated professional development training. |
| **Exclusion Criteria** | **Callers**  The CS has initiated emergency/000 procedures during the call.  The CS deems the call ‘unwelcome’ (i.e., inappropriate or abusive). These calls will be ended prior to being transferred to the post-call survey in line with Lifeline policy.  The HSs declines to participate.  **Crisis Supporters**  Prior exposure to or completion of the *Engaging Men in Crisis Support* training program.  Previous participation in qualitative research interview/focus group regarding experiences supporting male callers at Lifeline.  Previous completion of specific training in engaging men in mental health care:  *Men in Mind*  *Male-Friendly Counselling: Enhancing Therapy Work with Men*  *Engaging Men in Crisis Support* (e.g., through pilot testing) |
| **Data Sources** | **Callers**  Self-report.  **Crisis Supporters**  Self-report.  Learning management system (LMS).  **Additional**  Learning management system; Lifeline telephony system. |
| **Data Measurement** | **Callers**  Self-report via post-call survey delivered through Lifeline’s interactive voice response (IVR) system.  **Crisis Supporters**  Self-report via online surveys.  Course completion data via LMS.  **Additional**  Call information via Lifeline’s telephony system. |
| **Variables** | **Callers**  Gender.  Caller outcomes measures (distress, feeling heard, and suicide risk).  **Crisis Supporters**  Current Clinical Skills and Professional Self-Doubt subscales of the Development of Psychotherapists Common Core Questionnaire (DPCCQ).  Session Management subscale of the Counsellor Activities Self Efficacy Scale (CASES)  Bespoke items evaluating CS confidence in supporting caller presentations covered by the training.  Bespoke training satisfaction items.  Bespoke free-text items regarding impact of training on subsequent call interactions.  Crisis Supporter learning management system use data (time taken to complete training, repeated visits, and the time spent during each revisit). |
| **Intervention Group** | **Callers**  Receive telephone crisis support (care as usual) from CSs who were assigned the EMICS professional development training module (intervention).  **Crisis Supporters**  Assigned EMICS professional development training module. |
| **Control Group** | **Callers**  Receive telephone crisis support (care as usual) from CSs who were assigned the Child Safety professional development training module (active comparator).  **Crisis Supporters**  Assigned Child Safety professional development training module. |
| **Study Duration** | Approximately 18-months. Trial will end when target caller sample size is reached. |
| **Data Analysis** | Analysis will be undertaken upon conclusion of data collection. |
| **Statistical Methods** | Phase 1 (CS outcomes): Intention to treat, mixed-model repeated measures.  Phase 2 (Caller outcomes): Multilevel mediation modelling. |
| **Funding Provided by** | Australian Government Medical Research Future Fund (APP1199972). |

# Introduction

## Background

Men in Australia account for three quarters of all suicide deaths (Australian Bureau of Statistics [ABS], 2022), with similar trends observed in other high-income countries (World Health Organisation, 2014). Suicide is a significant public health issue in Australia and is the leading cause of death in men under 44 years of age (ABS, 2022), with devastating impacts on individuals, families, and communities. Amid these high suicide rates, researchers have emphasised men’s reluctance to seek help for psychological concerns (Coates et al., 2019; Harris et al., 2015; Yousaf et al., 2015), wherein perceived shame and stigma, a desire for emotional control, limited mental health literacy and poor communication and rapport with health professionals are implicated (Yousaf et al., 2015). Consequently, public awareness campaigns with the aim of increasing men’s uptake of mental health services have risen in popularity, with some level of success; men’s help seeking increased by 8% between 2006-2012 in Australia (Harris et al., 2015). Such increases do not necessarily translate to engagement and positive outcomes for men seeking care. Accordingly, research attention is shifting to exploring the experiences of men who do seek help, in an attempt to understand how mental health services may better engage with men who do seek support (Seidler, Rice, River, et al., 2018; Trail, Wilson, et al., 2022). Research in the psychotherapy context suggests that treatment approaches which are gender-sensitive, tailored and follow a strengths-based style may improve engagement and outcomes of male help-seekers,[[1]](#footnote-2) with an emphasis on collaboration, transparency and action-oriented approaches (Johnson et al., 2012; Seidler, Rice, Oliffe, et al., 2018). This research project aims to adapt and apply such an approach within Australia’s national crisis line, Lifeline, through the development, implementation, and evaluation of a professional development training module for Lifeline telephone Crisis Supporters.

**The role of crisis helplines**

Crisis helplines are a critical component of comprehensive community suicide prevention and intervention (WHO, 2018). The availability, accessibility and anonymity of crisis helplines affords opportunities for immediate identification of suicidality and provision of support, and for referral to appropriate mental health care services for individuals in distress. Helplines aim to provide social and emotional support for those experiencing distress due to stressful life events or challenges with mental ill-health (Woodward & Wyllie, 2016). Most helplines operate on the tenet that distress and suicide risk may be lowered through connection and compassionate, non-judgemental listening (WHO, 2018). This assumption is informed by theories of crisis and coping, which define crisis as a time-limited state of distress during which a person’s capacity to cope is significantly impaired (Caplan, 1964). Helplines are also thought to offer vital social support for individuals often lacking other close interpersonal relationships, which may increase coping capacity. This may be particularly relevant for suicidal individuals, as social support is found to be a protective factor against perceived burdensomeness (McClay et al., 2020); a key factor in the development of suicidal thoughts and behaviours outlined by the Interpersonal Theory of Suicide (Van Orden et al., 2010). Helplines are therefore in a unique position to be able to intervene at the point of crisis and offer support that can reduce feelings of isolation, increase capacity to cope and in turn reduce distress and suicidality.

**Men as callers to helplines**

Systematic reviews highlight the effectiveness of helplines in reducing proximal distress and suicidality (Hoffberg et al., 2020; Hvidt et al., 2016). However, methodological challenges in data collection mean that little is known about their impacts for men specifically. Men are underrepresented in the available research, constituting under 30% of participants across 25 studies of crisis support service users’ expectations and outcomes (Mazzer et al., 2021). While men access crisis helplines less frequently than women in Australia, the proportion of male callers continues to increase in recent years across Australia’s four national helplines, Lifeline, MensLine, SANE, beyond blue, increasing from 28.7% in 2009 to 34.6% in 2013 (Machlin et al., 2014). Currently, approximately 40% of callers to Lifeline, where gender is recorded, are identified as male (Lifeline, personal communication, 2022), indicating a need to ensure services such as Lifeline are well equipped to respond to male distress.

Men’s level of engagement with mental health services such as helplines is influenced by socialised traditional masculine norms, as the prevailing pressures they face to remain emotionally restricted, stoic, and self-reliant reduce the likelihood of both formal and informal help-seeking (Yousaf et al., 2015). For those who do seek help, these same masculine norms continue to act as barriers to engagement and impact the way men present and interact with mental healthcare services, as these factors are at odds with the verbal emotional disclosure often required to engage with care (Rice et al., 2020; Seidler et al., 2016) Men may also be inclined to minimise or not disclose distress and suicidality to publicly embody their masculine ideas. (Cleary, 2017; Johnson et al., 2012) Given these social barriers, cultivating a therapeutic relationship has been suggested as the central component in engaging men in psychotherapy within what is often a ‘short window of opportunity’ (Seidler, Wilson, Trail et al., 2021). Further, research indicates that men who have a negative experience with services are unlikely to re-engage in the future due to a loss of trust and belief they can’t be helped, reinforcing the importance of improving services’ ability to effectively engage men at the first interaction (Seidler et al., 2020).

The unique helpline context creates additional challenges for Crisis Supporters in engaging with male callers. Crisis supporters must respond to a caller’s needs within a time and information limited context, without aid from nonverbal cues such as body language and facial expressions (Hunt et al., 2018a). Similarly, callers have no access to information about their Crisis Supporter which may impact their capacity to form a trusting connection. Further, the helpline interaction provides a single opportunity to connect with and support a caller, as callers can choose to terminate the call at any time, with no option for follow-up. Such considerations indicate that tailored interventions are required for this setting.

Regarding experiences of helpline services, recent survey research suggests that men contact helplines with a diversity of needs including immediate crisis de-escalation, listening and emotional support, and provision of referrals and resources, reiterating the need for Crisis Supporters to tune in to a caller’s needs and respond accordingly, rather than relying on assumptions of male caller preferences (Trail, Wilson, et al., 2022). Other qualitative evidence on men’s help-seeking on helplines suggests that men present as reluctant callers, often referencing another individual as influencing their decision to call, and at times minimise their health concerns to remain in control (Goode et al., 2004; Lopriore et al., 2021). Equipping Crisis Supporters with knowledge to understand how traditional masculine norms interact with men’s experiences of distress and help-seeking will assist them to recognise common male caller presentations and respond to men’s needs more efficiently and effectively.

**Impact of the Crisis Supporter on caller outcomes**

There are strong indications that responder experience has significant impact on caller outcomes, underscoring the need for formally trained Crisis Supporters in specific suicide identification and intervention strategies (Hoffberg et al., 2020). The Lifeline support framework guides Crisis Supporters to focus on the caller’s specific needs at that time rather than tailoring for specific subpopulations of callers or presenting issues. However, there is emerging evidence that Crisis Supporters may naturally defer to assumptions about a caller based on inferred gender, and that this may impact their intervention approach. Crisis supporters may rely on gendered patterns of signs to identify suicide risk in the absence of verbal disclosure, with one study finding Crisis Supporters to be more inclined to implement suicide interventions in male callers due to perceptions around high male suicide risk (Hunt et al., 2018c). Further, Hunt and colleagues (2018c) demonstrated that Crisis Supporters use pattern recognition of emotions and cognitions in calls to make decisions about suicide interventions, and that such patterns might be gendered. For example, Crisis Supporters associated suicidality in men with risk-taking behaviour, compared with withdrawal from friends and family for female callers (Hunt et al., 2018c). This body of work suggests that Crisis Supporters can respond differently depending on caller gender, despite being trained in support frameworks which caution not to do so.

**Potential for gender-sensitised training to improve outcomes**

There is acknowledgement across medical and mental health service research that specific intervention approaches that are tailored towards the needs of men may be required to effectively engage them in services (Nahon & Lander, 2008; Seidler, Rice, River, et al., 2018). Consequently, multiple attempts to establish guidelines for best practice working with men have been made, including common recommendations for practitioners to integrate an understanding of masculinities with mental health treatment and implement a strengths-based and collaborative approach to care (Beel et al., 2020; Mahalik et al., 2012; American Psychological Association, 2018; Seidler et al., 2019). Such approaches strive to shift the onus from men to be ‘better’ help-seekers, onto services to ensure they are able to provide effective and engaging care.

The few existing training programs for practitioners working with men demonstrate potential promise for tailored training to increase practitioners’ knowledge, skills, and confidence to engage with male clients (McCullagh, 2011; Osborne et al., 2018). A recently developed online training program for therapists in engaging men in therapy, *Men in Mind*, shows significant potential in the ability for masculinities focused training to impact clinicians’ competence in working with men (Seidler et al., 2022; Seidler, Wilson, Owen, et al., 2021). *Men in Mind* is an online e-learning program which includes 5 evidence-based modules focused on engaging men in psychotherapy for depression and suicidality. Recent RCT evaluation in over 500 mental health clinicians found that the program was effective at increasing their self-reported competence and confidence in engaging men in care, with these positive outcomes retained at 3-month follow up (Seidler et al., *under review*).

Helpline Crisis Supporters are a key population of care providers for distressed and suicidal men, and therefore also require, and would likely benefit from, access to masculinities-focused training. Development of training for Crisis Supporters requires specific consideration of the helpline context, including working with a predominantly volunteer and layperson workforce, the time-limited and one-off nature of interactions, and challenges in identifying and collecting demographic information such as gender. With the above considerations in mind, our team developed a tailor-made professional development module for Crisis Supporters at Lifeline, designed to build upon their existing care framework and provide Crisis Supporters with additional information and practical skills for engaging with male callers. The training module, titled *Engaging Men in Crisis Support* (EMICS) was developed by Lifeline Australia and the University of Melbourne. It was informed by Seidler et al.’s *Men in Mind* work (Seidler, Wilson, Owen et al., 2021; Seidler et al., 2022), qualitative research undertaken in 2022 with Lifeline Crisis Supporters and male consumers of helplines and lived/living experience consultation.

## Study rationale

With the above considerations in mind, it is evident that there is opportunity to upskill helpline Crisis Supporters in engaging with and supporting male callers. A tailor-made professional development (PD) module was created by Lifeline Australia and the University of Melbourne research team to equip Lifeline Crisis Supporters with the skills, knowledge, and confidence to engage with male callers. The effectiveness of the PD module will be tested in a nested randomised controlled trial (RCT) across centres at Lifeline Australia. The need for RCTs in crisis helpline settings has been previously identified (Hoffberg et al., 2020), but research in these settings has been impeded by methodological challenges in conducting rigorous research. These challenges include measuring outcomes (include post-call follow-up), gaining informed consent, and randomising anonymous callers who may be suicidal (Trail, Baptiste, et al., 2022). This research presents opportunity to test the effectiveness of a novel intervention in this setting through comparison of an enhanced model of care (standard care + additional professional development) with standard care on male caller outcomes. Further, the helpline context provides the unique opportunity to move beyond practitioner self-report measures and evaluate the effectiveness of gender-sensitised training directly on outcomes of help-seeking men, given the access to large numbers of callers. Conduct of this trial will advance both knowledge of best practice for supporting male callers experiencing distress and suicidality, and knowledge regarding conduct of RCTs in helpline settings.

## Objectives

The objective of the trial is to determine the impact of the *Engaging Men in Crisis Support* Professional Development (PD) program on male callers’ outcomes at Lifeline measured via a caller outcome survey.

## Hypotheses

It is hypothesised that male callers who receive care from a Crisis Supporter (CS) who has completed the *Engaging Men in Crisis Support* training will report lower levels of feeling distressed at the end of their call than male callers receiving standard care following a call to Lifeline.

## Outcomes

### Callers

#### Primary outcome

The primary outcome will be the difference between intervention and control groups in male caller’s ratings of distress at the end of their call with Lifeline.

#### Secondary outcomes

Secondary outcomes include the difference between intervention and control group in male caller’s ratings of feeling heard and suicide risk following their call to Lifeline.

#### Exploratory outcomes

Effectiveness of the training on male caller outcomes will also be examined by comparing male caller outcomes with non-male caller outcomes in both the control and intervention group.

### Crisis Supporters

#### Secondary outcomes

Effectiveness of the training will also be demonstrated by mean changes in pre-post scores for the following self-reported measures for the intervention group, relative to the control:

* Clinical Skills and Professional Self-Doubt subscales of the Development of Psychotherapists Common Core Questionnaire (DPCCQ),
* Session Management subscale of the Counsellor Activities Self Efficacy Scale (CASES),
* Confidence to respond to male callers using bespoke items adapted from Seidler and colleagues’ (2022).

#### Exploratory outcomes and additional outcomes

##### Qualitative evaluation

Open-ended survey questions at T2 (post-training) will be analysed thematically to gain insight into training experiences, CS reflections on how learnings are implemented into practice, and to identify areas for future training refinement.

##### Cost analysis

A cost analysis of the *Engaging Men in Crisis Support* intervention will be conducted. These costs included both time costs and material costs of preparatory research, development, design, and implementation of the intervention. We will also estimate the cost per person based on number of males who utilise Lifeline call services.

# Methods

## Trial Design

This study is a two-stage, double-randomized RCT. In Phase 1, CSs will be randomized to the intervention group **(group A: *Engaging Men in Crisis Support* module)** or control group **(group B: *Child Safety and Crisis Support* module)** with a 1:1 allocation with stratification by CS gender (male; female/non-binary). Phase 1 consists of training CSs with their allocated module and obtaining evaluative data via online surveys. Data collection in phase 1 will occur at three time points for CSs: informed consent and eligibility screening, pre-training survey, and post-training survey.

In phase 2, callers will be randomised to receive support from CSs either in the intervention or control group with a 1:1 allocation randomised based on CS availability. For callers, data collection will occur at one time point via a post-call survey (immediately after their Lifeline call) with no follow up.

### Phase 1: Crisis Supporter training

Phase 1 of the trial is summarized in figure 1. After consenting CSs complete the eligibility (T0) survey, eligible CSs will then complete the T1 survey, after which they will be randomised to the intervention group (group A) or the control group (group B). Group A will be provided access to the *Engaging Men in Crisis Support* (EMICS) training: a self-paced e-learning module developed to provide CSs with additional skills in engaging with male callers at Lifeline, expected to take approximately 3-hours. Group B will be provided access to an existing e-learning training, *Child Safety and Crisis Support*: a self-paced e-learning focused on identifying and responding to child safety concerns during interactions with callers, expected to take approximately 2 hours. Both groups will have four weeks to complete their designated training. The T2 survey will then be sent to participants in both groups at the end of this 4-week period.

Participants in group B will also be provided access to the EMICS after the trial is complete.

### Phase 2: Caller data collection

Once CSs have completed their T2 survey they will enter phase 2 of the trial where caller data will be collected after their calls. CSs who do not complete their assigned training intervention will not be included in Phase 2. As shown in Figure 2, callers waiting in Lifeline’s 13 11 14 queue will be notified that they may be provided with the opportunity to complete a brief survey after their interaction with a CS has concluded. Callers will be randomly allocated to CSs in either group A or group B and will complete their call based on CS availability (i.e., minimising caller wait times will take precedence over even allocation to conditions). Callers who wait more than five minutes to speak to a trial CS will be transferred back to Lifeline’s 13 11 14 queue with priority. At the end of their call, the CS will invite eligible callers to participate in a survey delivered through the Interactive Voice Response (IVR) system to provide their anonymous data for the purpose of service evaluation. Callers will be able to decline participation verbally, or by opting-out of the survey by hanging up at any point.

Callers will enter Lifeline’s 13 11 14 queue as per normal. Prior to their call while waiting to be connected to an available CS, they will be informed via a recorded message that they may have the option of completing a short survey after their interaction with a CS has concluded. Callers will provide opt-in consent by remaining on the line at the end of their interaction and completing the evaluation items. Callers will then be presented with the service evaluation questions and will answer using the number keys on their phone or cellular device. Callers can withdraw consent at any time by hanging up the phone. It is conservatively estimated that additional required time for callers in the trial to complete the post-call survey is 2-5 minutes.

Figure 1: Crisis supporter participant flow

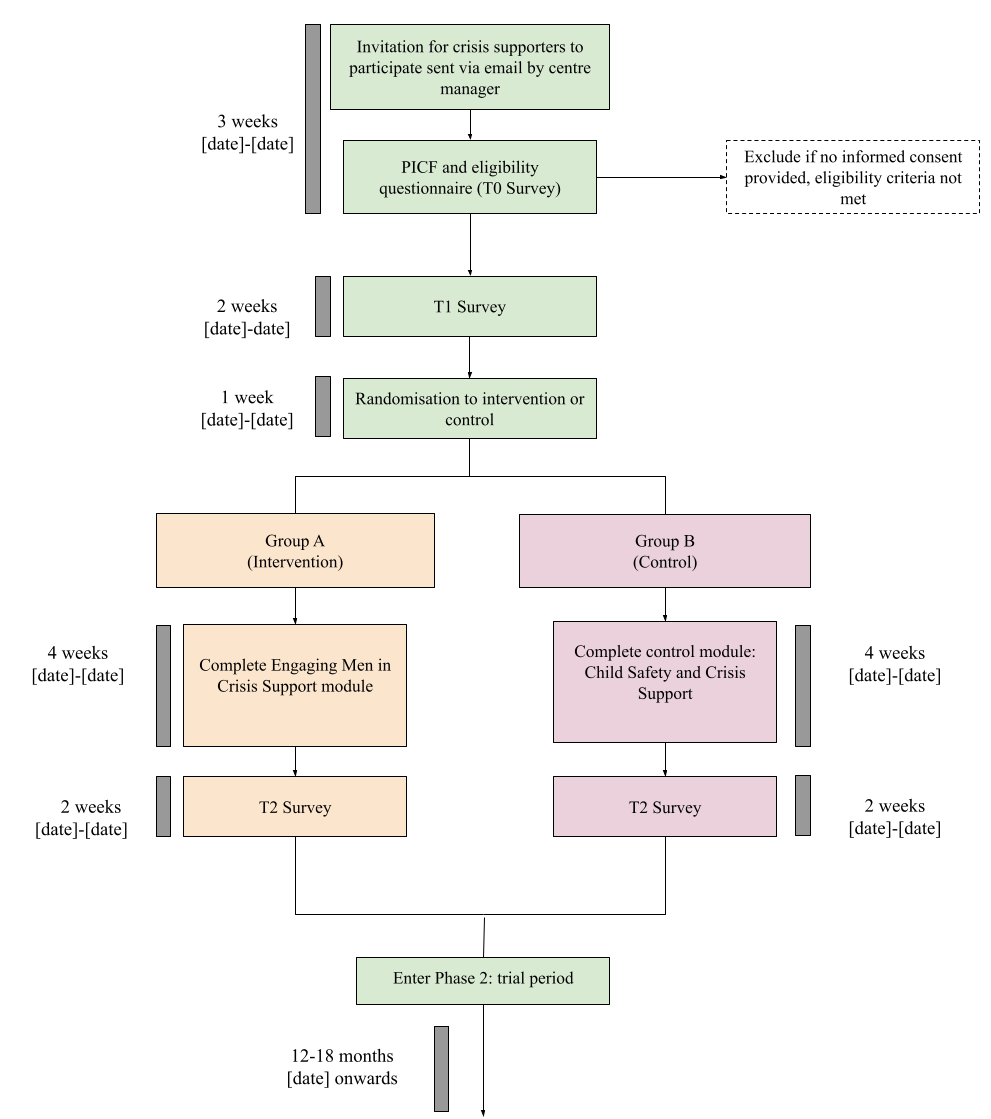
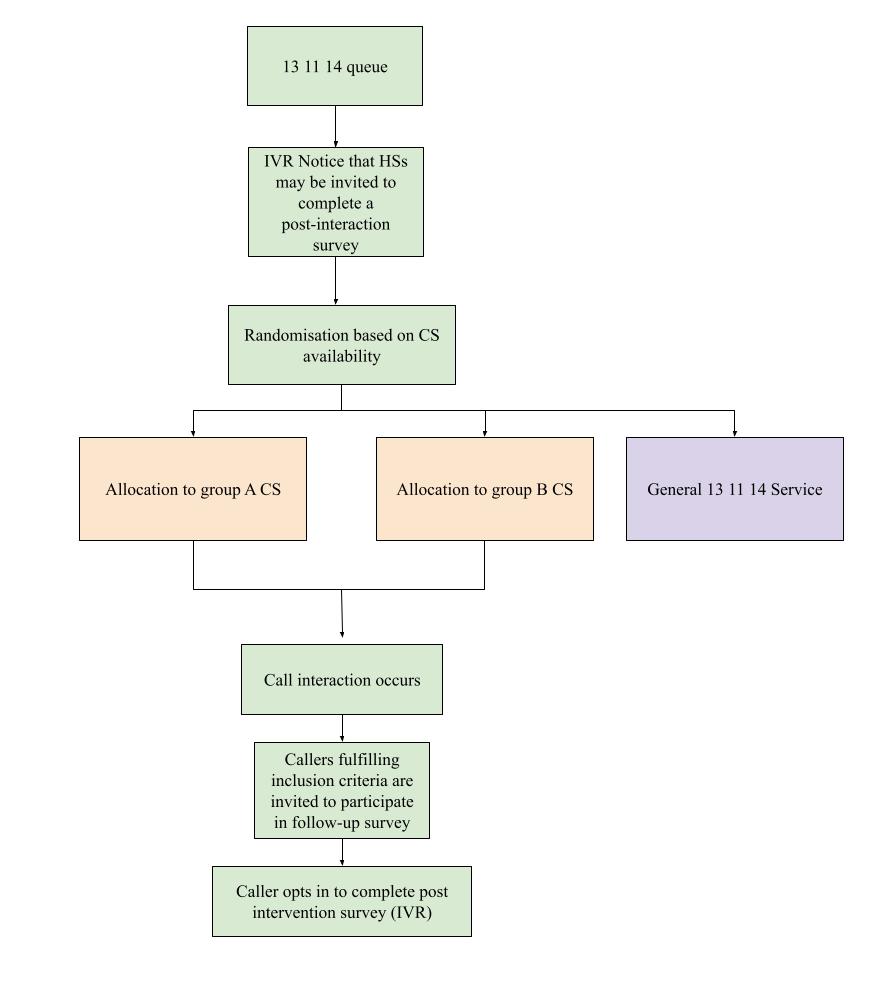
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Figure 2: Caller participant flow



## Study Setting

The study will be conducted at participating Lifeline centres and is coordinated through the Lifeline Research Office at Lifeline Australia.

Lifeline is Australia’s largest telephone helpline, receiving over 1m calls annually (Lifeline Annual report, 2022). Lifeline is a not-for-profit organisation whose telephone line operates out of a national network of 41 centres across the country, offering free and anonymous 24-hour crisis support. Lifeline CSs are trained in a specific model of crisis support, tailored to Lifeline (described below, see section 5.1.2).

The Lifeline Australia national office operates out of NSW and oversees the national operations and functions of Lifeline. As a part of the national office, the Lifeline Research Office coordinates national research activities and related communication with centres.

**Phase 1**

All elements of phase 1 of the trial will be completed remotely. Training evaluation surveys will be administered online via data management subcontractor Logicly. This will allow for participants to access surveys through tailored WebSurvey links with participant data being linked across time points. Participants will complete their allocated modules online through Lifeline’s learning management system (LMS) called Moodle. Data collection will occur in late-2023 and 2024.

**Phase 2**

The trial will be conducted at consenting Lifeline centres across Australia that meet the eligibility criteria outlined below. CSs from these centres will be eligible to participate if they meet the inclusion criteria in 4.1.2. Data will be collected from callers who call 13 11 14, fulfil the eligibility criteria in 4.1.1, and talk to a participating CS.

# Participant selection

#### Eligibility criteria

Lifeline’s 4 largest members, comprising 22 individual centres, will be invited to advertise the study to their CSs. Centres must commit to continuing to provide their CSs with their standard support approaches, including reflexive practice sessions and debriefing with their in-shift supervisor, in the unlikely event that there is distress due to participating in the research study.

### Callers

#### Inclusion criteria

* Provide opt-in consent to the post-call survey by staying on the line after interaction with CS ends.

While the focus of the trial is on male caller outcomes, data from callers of all genders will be collected. This data will be used to compare the effectiveness of the EMICS intervention between gender groups.

#### Exclusion criteria

* The CS has followed the Decision Support Tool protocols to the SUPPORT stage and deems that the HS’s safety is still at immediate risk/experiencing a high level of distress at the end of the call.
* Deemed as ‘unwelcome’ calls by CSs (i.e., inappropriate or abusive). These calls will be ended prior to being transferred to the post-call survey in line with Lifeline policy.

### Crisis supporters

Eligibility will be assessed via a self-report survey at T0. Lifeline’s Service Design & Delivery will confirm that they have completed their assigned training module prior to including them in Phase 2.

#### Inclusion criteria

* Completes paid shifts at a participating Lifeline centre, and normally completes a minimum of 1 four hour shift per fortnight.
* Is able to partake in online study elements including completion of training module and study assessments.
* Phase 2 only: Has completed assigned Phase 1 training module.

#### Exclusion criteria

* Previous completion of *Men in Mind* training program (Seidler, Wilson, Owen, et al., 2021) or the *Male-Friendly Counselling: Enhancing Therapy Work with Men* professional development training.[[2]](#footnote-3)
* Previous participation in qualitative interview or focus group regarding experiences of supporting male callers at Lifeline conducted by The University of Melbourne (conducted in May-April 2022).
* Prior exposure to or completion of the *Engaging Men in Crisis Support* training program.

## Sample size

### Callers

The recruitment target for completed post-survey interviews by male-identifying callers has been set at 1,400 across the intervention and control group. Participants are nested within CSs so possible clustering effects needed to be included in estimating power. The likely intraclass correlation (ICC) due to CSs is uncertain. Accordingly, the effect of values ranging from 0.02 to 0.10 – small to higher than likely – was investigated. This yielded design effects ranging from 1.21 to 2.07 and indicated that effects sizes of between d=0.17 and d=0.22 could be detected with 80% power and an alpha of 0.05. An effect size <d=0.17 was judged to reflect an effect too small to warrant further investment in scaling the training for wider delivery.

If generalized linear modelling is required, achieved power will depend on the method used, distribution and ICC due to CSs. The worst-case scenario would involve dichotomisation of an extreme response distribution. As an example, 80% power to detect a reduction in the active group compared to a response with 80% prevalence in the control group would be obtained for prevalence ranging from 73.2% to 71.7% for ICCs ranging from 0.10 to 0.02 to 0.10. This corresponds to odds ratios ranging from 1.46 to 1.58.

To achieve the target number of male-identifying callers, it is estimated that approx. 35,000 calls will be required to enter the trial. Based on Lifeline’s average call volumes, the estimated time to achieve the recruitment target of male callers is up to 18 months.

Data from non-male identifying callers who enter the trial and complete the post-call survey will also be collected, resulting in an estimated final sample size of ~3,500 callers (based on 40% male callers). This data will be used to compare the effectiveness of the intervention for male callers compared to non-male callers.

### Crisis Supporters

We aim to recruit a minimum of 140 CSs (70 in each condition) into the trial to facilitate adequate power for Phase 1 analyses and to yield the required number of post-call surveys in a timely manner. This sample size is required to staff 16 CSs (8 per condition) on the trial each day. This sample size assumes attrition of 25-33% of participating CSs over the course of the trial, based on Lifeline’s annual turnover rate.

A secondary recruitment period of CSs may occur during the trial period if required to mitigate loss of CSs over the course of the trial and facilitate caller data collection required. This additional recruitment target will be set based on the numbers required to staff 12 CSs on the trial each day. This recruitment will follow the same procedures outlined in section 4.3.2.

## Recruitment

### Callers

Callers will enter Lifeline’s 13 11 14 queue as per normal. Prior to their call while waiting to be connected to an available CS, they will be informed via a recorded message that they may be given the option of completing a short survey after their interaction with a CS has concluded. Callers will provide opt-in consent by remaining on the line at the end of their interaction and completing the evaluation items.

### Crisis Supporters

Preliminary qualitative research for this study involving Lifeline CSs was conducted from January-June 2022 (University of Melbourne HREC approval #22987). For this, an expression of interest to participate in research regarding male callers at Lifeline was circulated to CSs via Centre Managers over email. Interested CSs were able to leave their contact details to be contacted to partake in either the qualitative research, or a future evaluation trial at Lifeline. This list of CSs not involved in the qualitative study has been kept in line with privacy requirements and will be used to recruit CSs for this study. CSs will be eligible if they are employed at one of the members involved in the study. Those not eligible but who have previously expressed interest will be invited to complete the Engaging Men in Crisis Support training following the conclusion of the trial.

Recruitment for CSs will occur via distribution of a study advertisement via centre managers through email. Staff at the Lifeline Research Office will distribute an invitation to 4 of Lifeline’s largest members that explains the purpose of the research project and centre eligibility criteria and ask that their centre managers to pass on an invitation to participate to their CSs via email. This invitation will include a study advertisement explaining the purpose of the trial, the participant inclusion criteria, and tasks required of the CS.

The email from centre managers will also include an invitation to optional information sessions hosted by the Research Manager (Tara Hunt). Information sessions will run for approximately 45 minutes on Teams. Three information sessions will be hosted, each at a different time of day so that CSs from various time zones are able to attend. The sessions will consist of a 20 minute presentation outlining the same details as the participant information sheet, followed by a 20 minute Q&A in which CSs can seek further information on the study.

Interested CSs will be able to follow a link provided on the study flyer which will take them to the T0 survey, containing the study participant information and consent form (PICF) and eligibility screening form (described in section 4.1.1).

Given the estimated length of the trial, some attrition of CSs is expected resulting in reduced ability to collect data from eligible callers. While the target sample size accounts for this, if required a second round of recruitment of CSs into the trial will be conducted at approximately halfway through the trial. Recruitment for this group of CSs will be as described above, and participant flow through the training and assessments will be as described in section 3.1.

## Informed consent procedures

### Callers

#### Consent for intervention

A waiver on consent will be implemented for callers entering the trial to receive intervention. Callers will provide opt-in consent to complete the post-call survey (discussed below).

There is increasing advocacy for the use of pragmatic trials in healthcare which embed research into standard care as seamlessly as possible (Dhamanaskar & Merz, 2020). In this case, interruptions to standard care such as informed consent procedures impact the ability to replicate real life. Further, there is precedent for allowing waivers of consent in emergency settings, where patients are often unable to provide consent and it is necessary to apply interventions very quickly. Systematic review suggests that no prospective informed consent was obtained for 8.8% of high-impact RCTs published between 2014-2018, with 66% of these involving emergency treatments (Dhamanaskar & Merz, 2020). We argue that the crisis helpline context represents an emergency service given a caller’s urgent need of care, and the potential for diminished capacity for consent. Here, implementing informed consent procedures in this setting carries risk in terms of increasing the amount of time between a caller contacting the service and receiving intervention, and as such may be considered unethical. A waiver of consent allows for at-risk populations who are most likely to benefit from the interventions to partake in the research while still ensuring safety (Trail, Baptiste, et al., 2022).

In this case, a waiver on consent meets the conditions required in the National Statement on Ethical Conduct in Human Research (NHMRC, 2018). First, we do not foresee any additional risks for participants due to receiving intervention from either the control or intervention group. All callers in the trial will be allocated to CSs trained in Lifeline’s standard crisis support procedures including having access to emergency intervention procedures as required. The intervention is designed to be an enhancement of the standard care focused on skills related to communicating and engaging with male callers, rather than a replacement of standard care. CSs will implement safety strategies and procedures as required throughout the trial period, as per standard Lifeline policy. It is possible that an approach used by a CS guided by the enhanced training module won’t resonate with a caller, causing disengagement. However, this is true of any interaction at Lifeline, and CSs are trained to adapt to the caller’s needs over the course of a phone interaction. Second, it is impractical to obtain informed consent in a helpline setting due to the time sensitive nature of the interaction and the modality of care. In this setting, obtaining informed consent confers more risk to the caller by increasing the time to access intervention and disrupting the real-world interaction between caller and counsellor. This would also potentially impact engagement due to disruption and therefore decrease the validity of the findings and their applicability to the real-world setting.

Regarding the requirement that there is no known or likely reason for thinking that participants would not have consented if they had been asked, in general callers to Lifeline have no knowledge of the training provided to CSs. Lifeline provides their CSs with various professional development modules to enhance their practice without callers being aware of any changes made to the way the service is delivered.

Conducting a pragmatic trial in a helpline setting has vast potential benefits regarding improving methodological rigor of helpline studies. Further, data collected will provide information of the effectiveness of the implementation of gender-sensitised training for CSs in the helpline setting which has the potential to improve service provision for male callers, a group with high risk of suicidality and low levels of service engagement.

Participants will provide consent for their data to be collected as a part of Lifeline’s quality monitoring activities via the IVR survey at the end of the intervention. Callers to Lifeline are anonymous and no identifying information about a caller will be collected during the trial. Lifeline data masking protocols will be followed when extracting the data, including converting phone numbers to participant identification codes prior to data being extracted from the Lifeline phone system to ensure participant confidentiality is maintained.

#### Consent for data collection

##### Callers

Callers will provide consent to complete the post intervention survey via an opt-in approach. Prior to their call while waiting to be connected to an available CS, they will be informed via a recorded message that they may have the option of completing a short survey after their interaction with a CS has concluded. The implemented message played to callers will inform callers that the survey is short, optional, and confidential. Indicative text for the message is as follows:

*It’s important that we support you in the best way we can while you’re feeling this way, so at times you might be given the opportunity to provide feedback at the end of your call. Please stay on the line after you finish talking to a crisis supporter to answer 4 short questions using your keypad.*

At the conclusion of the call, CSs will verbally invite callers to complete the survey using the following message as a guide:

*“I want to thank you for calling Lifeline today. We really value your feedback to make sure that Lifeline supports you in the best way we can. You are welcome to stay on the line to answer 4 short questions. If you’d like to answer these questions use the buttons on your phone to provide your responses”*

CSs will be encouraged to invite the caller in a way that feels natural and doesn’t break the existing rapport, meaning that some variation in the exact wording of the invitation is expected. Callers will provide opt-in consent by remaining on the line at the end of their interaction and completing the evaluation items.

##### Crisis supporters

Informed consent will be obtained from CS participants before entering the study, in accordance with ethical guidelines. CSs with an interest in partaking in the study will be provided with a link to access the participant information and consent form (PICF) via an online form. The PICF will explain to participants all elements of the study and requirements of participation, including eligibility criteria, time requirements and potential risks and benefits of taking part. CSs will be informed that they can withdraw from the study at any time without consequence, and about what will happen with their data should they withdraw from the study or leave their role at Lifeline during the study period (explained in section 4.5). The PICF will contain the contact information of the study team should any questions or concerns arise. It will also contain contact details of the approving HREC committee should prospective participants wish to contact the committee confidentially about the study. Consent forms will be approved by the HREC prior to being used in the study.

### Additional consent provisions for collection and use of participant data and biological specimens

Not applicable – no biological specimens will be collected.

## Withdrawal

### Callers

Callers may withdraw at any time during the interaction by ending the phone call. Caller data will be kept up until the point where a caller withdraws. As this study will be implementing a waiver of consent (section 4.4.2), callers will not be aware of their involvement in this study outside of the provisions detailed in the IVR consent script. They will therefore not be able to withdraw from this study.

Due to anonymity of calls, callers will not be able to withdraw their data from the study at a later date i.e., once their interaction has ended.

### Crisis Supporters

CSs will be able to contact the research team should they wish to withdraw from the trial without consequence. Should CSs withdraw during phase 1 (training completion), their access to the training program will be removed. Should CSs withdraw following completion of the training (phase 1) but prior to or during collection of caller data (phase 2), data collection for their callers will cease. If CSs withdraw from the study or leave their role as a CS during Phase 2, caller response data collected up until that point will be kept in the trial. This information will be communicated in the in the PICF. Should CSs withdraw from the trial at any point, their survey response data will be deleted.

# Interventions

## Explanation for the choice of comparators

### Callers

Callers in the control group will be allocated to an accredited CS who has been trained in Lifeline’s practice framework, CARE and has completed an online e-learning module called *Child Safety and Crisis Support* (both described below; section 5.1.2).

### Crisis Supporters

The trial will use Lifeline’s standard care combined with a *Child Safety and Crisis Support* e-learning module as a comparator.

All of Lifeline’s 4,500 CSs have received training in Lifeline’s practice framework, CARE. CARE equips CSs to provide short-term emotional support to callers and to increase safety when thoughts of suicide are present and/or other safety concerns are evident. CARE positions Lifeline’s Crisis Support Services to deliver mission-aligned outcomes during any interaction (call, chat, text, and other modalities) to further support the caller, and this may include emergency intervention when needed. Although Lifeline’s Crisis Support Services cannot provide ongoing support or treatment for any condition, they can provide one-off crisis support to attend to the needs of the help-seeker and empower each caller as the expert in their own life.

CARE provides callers with four central elements in any interaction they have with Lifeline: Connection, Attend to needs, Reaffirm and Empower. The Connection element is fundamental to the framework and requires CSs to use micro skills learned and their personal attributes to connect with the caller throughout the interaction. With a real and effective connection between the two human beings in the interaction, the caller is best supported to benefit from the other elements of CARE.

In line with Lifeline’s role as a crisis support and suicide prevention service, CSs must ask about suicide in every crisis interaction, appropriately and in context. Whether or not there is suicidality present, the interaction should continue using the CARE framework. If suicidality is present (whether imminent or not), the CARE Decision Support Tool (DST) must be applied within CARE. The DST provides guidance on steps following a caller’s disclosure of suicidal thoughts including notifying the In-Shift Supervisor and exploring immediate safety in a collaborative way.

The training pathway (Figure 3) is delivered across a minimum of 1 year, including initial training comprising 8 e-Learning topics and 10 face-to-face sessions. Crisis Support students then complete in a minimum of 25-hours of student placement where Crisis Support students participate in observational shifts and coaching sessions. The final stage of training includes an internship consisting of group supervision, ongoing training and support and a final assessment interview. All CSs completing paid shifts at Lifeline are required to have completed the training pathway.

**Figure 3: CS training pathway**

Timeline

Description automatically generated

In order to increase the similarity of tasks for participants in the control and intervention groups, and to improve engagement during the training phase of the trial, CSs in the control group will complete a pre-existing learning module called *Child Safety and Crisis Support*. This module takes approximately two hours to complete and includes content about identifying and responding to child safety concerns during interactions with help-seekers.[[3]](#footnote-4) The *Child Safety and Crisis Support* e-learning module was chosen as a comparator because it is the closest in length of Lifeline’s training materials but does not overlap with the intervention in terms of content. Like the intervention, content is presented in a manner that aligns with CARE. The three learning objectives of the comparator are:

1. Identify potential child safety concerns during an interaction and how these may vary depending on the help-seeker and their circumstances.

2. Respond appropriately as child safety concerns arise during interactions.

3. Collaboratively gather the essential child safety information with help-seeker and provide this information to your ISS (in-shift supervisor).

## Intervention description

### Callers

Callers in the intervention group will be allocated to an accredited CS who has been trained in Lifeline’s practice framework, CARE (described above, section 5.1.2) and has completed the *Engaging Men in Crisis Support* (EMICS) professional development module (described below, section 5.2.2).

### Crisis Supporters

CSs in group A (intervention group) will complete the *Engaging Men in Crisis Support* (EMICS) professional development module designed to upskill CSs in engaging with and responding to male callers.

#### About the intervention

EMICS is online e-learning training package developed specifically for CSs at Lifeline, designed to build upon and fit within Lifeline’s existing CARE framework described above. The training package was developed specifically for this trial through collaboration between Lifeline Australia and The University of Melbourne. The approach to training development and content was informed by Seidler and colleagues’ (2021) *Men in Mind* training program, owned by Movember, which aims to improve therapist competencies in engaging with male clients. Development, creation, and hosting of the EMICS training package was funded through the Australian Government Medical Research Future Fund (APP1199972).

Preparatory qualitative research undertaken in 2022 with Lifeline CSs, Lifeline staff, and male consumers of helplines informed the content areas of the training, identifying key target areas for improved engagement. The goal of the training program is to increase CSs’ ability to engage with male help-seekers through the provision of targeted information about men’s gender socialization and skills to work with masculinities within the context of a Lifeline call. The training package consists of three modules: (1) The gender agenda (2) The role of masculine norms in men’s distress and (3) How to best engage and support male help-seekers (see table 1 for module summary). The training package has been developed with specific considerations of the helpline context in mind. For example, Lifeline is a generalised service, and CSs do not always have information regarding a help-seekers’ gender identity. While the training has a focus on engaging and responding to male help-seekers, there is no requirement for CSs to be able to identify a help-seeker’s gender to use the skills taught. Instead, the training acknowledges and reinstates the diversity of male experiences of distress and help-seeking, while focusing on three kinds of presentations that CSs have identified as common among male help-seekers and challenging to respond to within the current framework.

The training is an interactive e-learning which uses character personas to illustrate interactions between the CS and male help-seekers and provide CSs with opportunity to practice the demonstrated skills (see table 2). The training also includes multiple self-reflection prompts for CSs to reflect on their assumptions and beliefs about male help-seeking. Finally, as part of the intervention, Lifeline has created a ‘quick list’ of services that are tailored towards male help-seekers to their national service finder. The training includes information about how to access this list of male-friendly referral resources for CSs to utilise with male help-seekers.

#### Intervention development

The development of EMICS involved extensive collaboration between researchers, Lifeline practice staff, lived experience consumers and consultants, and learning and user design experts. First, qualitative research was conducted to understand men’s current experiences of helpline services, CS experiences of supporting men, and Lifeline’s organizational considerations when implementing professional development for CSs. In total, interviews and focus groups were completed with 16 male consumers of helplines, 17 Lifeline CSs, 9 Lifeline Supervisors and 4 Lifeline organizational staff members. Data from this research was supplemented by the existing evidence base on engaging men in mental health care services (Englar-Carlson & Kiselica, 2013; Mahalik et al., 2012; Seidler, Rice, Ogrodniczuk, et al., 2018; Seidler, Rice, River, et al., 2018). With this background knowledge and the helpline context in mind, the training content was written by members of the research team and the Lifeline practice team.

The Lifeline Lived Experience Advisory Group (LLEAG) provided input into the development of the training package at various points across the development period Consultation was completed to gain lived experience insight into identification and refinement of content areas for the training, development of the character personas, review of the training content, and user experience testing. Two CSs and two supervisors who participated in the preparatory qualitative research were also engaged in user experience testing of the final training package.

The module is designed as a supplementary training to CARE, rather than an alternative model. As such, all CSs in the trial are trained in CARE and in the implementation of emergency procedures as required.

Table 1. Engaging Men in Crisis Support module summary

|  |  |  |
| --- | --- | --- |
| **Lesson** | **Topics** | **Example** |
| ***Module 1: The Gender agenda*** | * Introduction to the module and qualitative research findings about men’s experiences of crisis helplines. * Practicing self-awareness when supporting male callers. |  |
| ***Module 2: The role of masculine norms in men’s distress*** | * Developing an understanding of gender socialization, common masculine norms and their impact on men’s distress and help-seeking. * Look at some common ways men present at Lifeline. * Introduction of the character personas. |  |
| ***Module 3: How to best engage and support male help-seekers*** | * Building connection with male help-seekers. * How to support male help-seekers who may not directly communicate their feelings. * How to support male help-seekers who present as angry. * How to support male help-seekers who are wanting direction and advice. |  |

Table 2. Engaging Men in Crisis Support character personas

|  |  |  |
| --- | --- | --- |
| Aaron | Ali | Phil |
| * 19-years-old. * History of witnessing and experiencing domestic violence from his father. * Calls Lifeline following an angry outburst at work, experiencing work and relationship difficulties. * Used to illustrate skills in responding to anger on a Lifeline call. | * 40-years-old. * Experiencing a loss of purpose and identity since migrating to Australia from Iraq. * Calls Lifeline wanting advice on how to make life better in Australia. * Used to illustrate skills in supporting male help-seekers who are wanting direction and advice. | * 65-years-old. * Difficulties adjusting to retirement, coupled with recent relationship breakdown. * Prior suicide attempt which caused distrust in mental health services. * Used to illustrate skills in supporting male help-seeker who may not directly communicate their feelings. |

## Criteria for discontinuing or modifying allocated interventions

Should the Research Manager (Tara Hunt) receive complaints during Phase 1 from CSs regarding the intervention, she will communicate these complaints to the steering committee (section 10.1) in addition to following the risk reporting procedure (section 11.2). The steering committee will assess whether the subject of the complaint constitutes a significant risk to other CSs, or to callers participating in the trial. If the complaint constitutes a significant risk, the steering committee will pause the trial and advise participating CSs not to implement any completed training during their shifts at Lifeline until investigations are completed and Phase 1 is re-commenced. If the complaint does not constitute a significant risk but requires significant correction to or clarification of the training content, the training module will be updated according and participating CSs will be emailed to advise them of the correction.

It will not be possible to modify the intervention in Phase 2 as CSs will have already completed the training module. However, the research team will follow the risk reporting and management strategies (sections 11.1 and 11.2). After the trial, any reported risks will be considered when deciding whether to scale the training module for delivery to all CSs working or volunteering at Lifeline. Additionally, if analyses conducted after the trial indicate poorer outcomes for callers in the intervention group compared to callers in the control group, the training module will not be scaled for delivery to all CSs working or volunteering at Lifeline.

## Strategies to improve adherence to interventions

### Callers

There are no strategies to improve adherence to intervention for callers.

### Crisis Supporters

CSs in both groups will be informed at the beginning of the trial that they have ongoing access to the e-learning modules should they wish to revisit the content at any time during the trial period. If a CS has not completed their assigned intervention 2 weeks after being given access, they will be emailed a reminder to liaise with their centre’s workforce management team to schedule an additional paid shift in which to complete the training.

Both groups will have access to standard Lifeline procedures that ensure adherence to the Lifeline CARE framework over the trial period, including ongoing professional development opportunities and reflective practice sessions with their supervisor.

During phase 2, the Project Manager will monitor the average rate at which CSs transfer callers to complete the post-call survey (as a proportion of total calls received). If the call transfer rate falls below 50%, or if it exhibits a consistent downward trend, all participating CSs will be emailed a reminder on the importance of data collection and a refresher on how to appropriately invite and transfer callers to the post-call survey.

## Relevant concomitant care permitted or prohibited during the trial

There are no restrictions on concomitant care in this trial.

## Provisions for post-trial care

### Callers

As calls to Lifeline are anonymous, there will not be opportunity for post-trial care for callers.

### Crisis Supporters

CSs will be provided with normal support and debrief procedures through their Centre and the C-ISS service. They will also be provided with the contact details of the researchers and given access to support resources should they require further support following the conclusion of the trial.

# Participant timeline and tasks

## Callers

Callers will enter Lifeline’s 13 11 14 queue as per normal. Prior to their call while waiting to be connected to an available CS, they will be informed via a recorded message that they may have the option of completing a short survey after their interaction with a CS has concluded. Callers will provide opt-in consent by remaining on the line at the end of their interaction and completing the evaluation items. It is conservatively estimated that additional required time for callers in the trial to complete the post-call survey is 2-5 minutes.

Routing of calls will happen automatically through Lifeline’s telephony system. Once callers have been routed to an available CS, they will complete their crisis interaction as per normal. Callers will then be presented with the service evaluation questions and will answer using the number keys on their phone or cellular device. Callers can withdraw consent at any time by hanging up the phone.

## Crisis Supporters

It is anticipated that the total time commitment for CSs for phase 1 of the study is 4 hours. This includes approximately 3 hours to complete their allocated training package, and an additional maximum of 1 hour to complete informed consent procedures, eligibility screening, and all study assessments (2 x 10-minute survey). This time commitment will be communicated clearly on the PICF. In phase 2 participants will continue to complete their standard rostered shifts. Participants may spend additional time reviewing the training package over the course of the trial if they wish to do so.

CSs will be invited to take part in the trial via an email sent from their centre manager described above. Interested CSs will be directed to follow a link that will take them to the T0 survey. Within this survey they will be able to access the study PICF (with the option to download a copy to keep). Participants who do not provide consent will be thanked and directed out of the webpage. Following provision of informed consent, participants will be asked to complete a brief eligibility screening. Once completed, a message will display thanking them for their interest and stating that their eligibility will be confirmed by the research team. If any consenting CS are deemed ineligible, they will be informed via email by a member of the research team and thanked for their interest in the study.

Following confirmation of eligibility via the T0 survey, participants will be provided access to the T1 survey through an individual link sent via email by Logicly. Participants will have two weeks to complete the T1 survey, with a reminder email sent on days 3 and 5 of that period. At the end of the two-week period, participants will be randomised to group A or group B using the allocation sequence provided to Logicly by the statistician. Logicly will enrol participants in the allocated e-learning module for their condition via Lifeline’s LMS. All of Lifeline’s professional development modules are hosted on this LMS, so CSs will have an existing login and will be familiar with using the system. Participants will be notified once enrolled and advised that they have 4 weeks to complete the training module. Participants will have an additional paid shift scheduled in during this time to complete the module. Following completion of the modules, participants will be sent an email to let them know that the T2 survey will be sent at 4 weeks from their enrolment date in the training. At 4-weeks post enrolment, the T2 survey will be sent to all participants regardless of whether or not they completed the training modules. Participants will have two weeks to complete the T2 survey, with a reminder email sent on days 3 and 5 of that period. At the end of the two-week period the T2 survey will close, and participants will be sent an email to remind them that data from their callers will be collected over the next 12-18 months and provide them with information about how to transfer callers to the post-call survey. It will also contain information about where to seek support during the trial should CSs have any concerns about the trial. Participants will be informed in the PICF that they will be able to revisit the training at any point in the trial.

CS participants will continue to complete their normal Lifeline shifts over the trial period, with the knowledge that caller data will be collected from their calls across this period. The Lifeline Workflow management team will keep track of CS shifts completed and attrition across the trial (e.g., CSs who take leave or resign during the course of trial).

A summary of the study timeline and assessments is presented in table 3.

Table 3. Study SPIRIT diagram

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Time Point** | **Phase 1** | | | **Phase 2** |
|  | **T0** | **T1 (pre training)** | **T2 (post training)** |  |
| **Crisis Supporters** | | | | |
| *Enrolment* | | | | |
| PICF review | X |  |  |  |
| Informed consent | X |  |  |  |
| Eligibility screening | X |  |  |  |
| Randomisation |  | X |  |  |
| *Assessments* | | | | |
| Demographics |  | X |  |  |
| DPCCQ – Current clinical skills (7 items) |  | X | X |  |
| DPCCQ – Professional self-doubt (5 items) |  | X | X |  |
| CASES – Session management (10 items) |  | X | X |  |
| Confidence to respond to male help-seekers (3 items) |  | X | X |  |
| Training experience survey (12 items) |  |  | X (IG) |  |
| Open-ended feedback questions (8 questions) |  |  | X (IG) |  |
| Supplementary data (shift completions) |  |  |  | X |
| **Callers** | | | | |
| Eligibility screening |  |  |  | X |
| Randomisation |  |  |  | X |
| Consent – opt in |  |  |  | X |
| Demographics - gender (1 item) |  |  |  | X |
| Post-call survey (3 items) |  |  |  | X |
| Supplementary data (call length, date, time) |  |  |  | X |

*Note*. IG = intervention group.

## Plans for assessment and collection of outcomes

### Callers

Outcome data will be obtained from participants at the end of their call via a survey integrated into the IVR system. Measures will be Likert scales, where participants can enter their response using the number key on their telephone/cellular device. Indicative text provided to callers about the survey is below:

*It’s important that we support you in the best way we can while you’re feeling this way, so at times you might be given the opportunity to provide feedback at the end of your call. Please stay on the line after you finish talking to a crisis supporter to answer 4 short questions using your keypad.*

At the end of the call, CSs will invite callers to participate in the survey, using the following wording as a guide:

*I want to thank you for calling Lifeline today.*

*We’d like to invite you to stay on the line to answer 4 confidential questions about how you feel. If you’d like to answer these questions, use the buttons on your phone to provide your responses.*

*We really value your feedback to make sure that Lifeline supports you in the best way we can.*

The training modules will include instructions on how to appropriately invite callers to participate in the survey without compromising the quality of the care they receive. These instructions will include answers to anticipated questions from callers such as the type of questions and the confidentiality of their answers.

#### Demographics

Gender identity will be collected via one question: *How do you describe your gender?* (male, female, non-binary, I prefer not to answer). This question will be presented at the beginning of the survey.

#### Caller outcomes

Three self-report items will be used to measure caller outcomes at the end of their call. Items are rated on a 5-point Likert scale of (1) strongly disagree to (5) strongly agree. Callers can also select (0) for non-applicable. The primary outcome is the extent to which a caller feels less distressed after speaking with Lifeline (item 1). The secondary outcomes are the extent to which callers’ feel heard after speaking with Lifeline (item 2), and their self-reported ratings of suicide risk (item 3). The items are presented in the following order:

*1.* *I feel less distressed.*

*2. I feel heard.*

*3. I feel able to stay safe from suicide for now.*

These evaluation items were derived from a recent two-stage Delphi study of crisis line outcome measurement conducted by the University of Canberra and Lifeline Australia, which comprised expert panels of lived experience consumers, Crisis Supporters, and suicide prevention researchers. [[4]](#footnote-5) We have selected the three highest rated outcomes measures in order to support consistent outcome measurement across studies evaluating crisis support services.

### Crisis Supporters (secondary outcomes/additional data)

#### Demographics and background

Demographic information will be collected from all participating CSs: age (in years); gender (man, woman, non-binary/gender-diverse, self-described, don’t know, prefer not to answer); sexual orientation (straight, gay, lesbian, bisexual, pansexual, asexual, queer, not sure, prefer not to have a label, something different – please describe, prefer not to answer); Aboriginal or Torres Strait Islander identification; current employment status (employed full time, employed part time, employed casually, unemployed looking for work, unemployed not looking for work, retired, student, prefer not to answer); profession outside of Lifeline; highest level of education (some high school, trade/certificate/diploma, high school, undergraduate degree, postgraduate degree, prefer not to answer); country of birth; cultural or ethnic background; main language spoken; years of experience as a CS.

#### Eligibility questions

CSs will be asked the following questions to gain data about their role at Lifeline and determine their eligibility for the study: Lifeline centre; current work status; hours per fortnight; plans to continue working at Lifeline.

CSs will also be asked whether they have previously completed the *Men in Mind* training program (Seidler, Wilson, Owen, et al., 2021), the *Male-Friendly Counselling: Enhancing Therapy Work with Men* training program, or EMICS (e.g., through pilot testing), and if they answer yes, they will be excluded from the trial.

#### Training evaluation measures – T1 and T2

**Development of Psychotherapists Common Core Questionnaire (DPCCQ)**

Select subscales from the DPCCQ will be used to assess the effect of the training on CS’s competencies in supporting male callers. The DPCCQ was developed by Orlisnky and Ronnestad (2005) and contains a total of 392 items which assess practitioner’s professional skills. Two subscales of the DPCCQ which are relevant to the current study will be used: the current clinical skills subscale (7 items, α=.87) and the professional self-doubt subscale (5 items, α=.77). Reliability estimates are taken from Seidler and colleagues (2022). Following the approach taken by Seidler and colleagues (2022), minor adjustments will be made to wording to ensure appropriateness for the helpline context and to specify relevance to male callers. ‘Clients’ will be changed to ‘male help-seeker(s)’, and reference to ‘session’ or ‘therapy’ will be adjusted to ‘phone interaction(s)’ to better suit the helpline context. Participants will respond to each item using a 6-point Likert scale from (1) not at all/never to 6 (very much/very often).

***Current clinical skills***

The current clinical skills subscale will be used with amended wording:

Overall, at the present time…

(1) *How effective are you at engaging male help-seekers during an interaction?*

(2) *How ‘natural’ (authentically personal) do you feel while working with male help-seekers?*

(3) *How empathic are you in relating to male help-seekers with whom you have relatively little in common?*

(4) *How effective are you in communicating your understanding and concern to your male help-seekers?*

(5) *How well do you understand what happens moment-by-moment during calls phone interactions with male help-seekers?*

(6) *How much mastery do you have of the techniques and strategies involved in supporting male help-seekers?*

(7) *How much precision, subtlety and finesse have you attained in your work with male help-seekers?*

***Professional self-doubt***

The professional self-doubt subscale will be used with amended wording:

Currently, how often do you feel…

(1) *Lacking in confidence that you might have a beneficial effect on a male help-seeker*?

(2) *Unsure how best to deal effectively with a male help-seeker?*

(3) *In danger of losing control of the interaction with a male help-seeker?*

(4) *Afraid that you are doing more harm than good when supporting a male help-seeker?*

(5) *Demoralised by your inability to find ways to help a male help-seeker?*

**Counsellor Activities Self Efficacy Scale (CASES), Session Management subscale**

The Counsellor Activities Self Efficacy Scale (CASES) was developed by Lent and colleagues (2003) and includes 6 subscales measuring a range of skills related to counsellor self-efficacy. The Session Management subscale from the CASES (10 items; α = .94) will be used to assess the effect of the training on CS’s confidence in guiding interactions with male help-seekers. As with the DPCCQ subscales, minor adjustments will be made to the wording to ensure appropriateness for the helpline context and to specify relevance to male callers. Participants will respond to each item using a 9-point Likert scaled from (1) no confidence to (9) complete confidence.

***Session management***

The session management subscale will be used with amended wording:

Please rate your confidence in your ability to perform the below tasks…

(1) *Help a male help-seeker to understand his thoughts, feelings, and actions.*

(2) *Know what to do or say next after a male help-seeker talks.*

(3) *Help a male help-seeker to talk about his or her concerns at a deep level.*

(4) *Build a clear conceptualization of a male help-seeker and his reason for calling.*

(5) *Help a male help-seeker to explore his thoughts, feelings, and actions.*

(6) *Respond with the best helping skill, depending on what the male help-seeker needs at a given moment.*

(7) *Help a male help-seeker to set realistic goals.*

(8) *Keep phone interactions on track and focused.*

(9) *Remain aware of your intentions (i.e., the purposes of your interventions) during phone interactions.*

(10) *Help the male help-seeker to decide what actions to take regarding his other problems.*

**Confidence to respond to male help-seekers**

Three bespoke items adapted from Seidler and colleagues (2022) have been developed to assess the effect of the training on CSs confidence in supporting male help-seekers with particular characteristics that are covered in the training. Participants will respond to each item using a 5-point Likert scaled from (1) strongly disagree to (5) strongly agree.

(1) *I am confident in my ability to effectively engage and respond to male help-seekers who may have difficulty identifying or expressing their emotion.*

(2) *I am confident in my ability to effectively engage and respond to male help-seekers who become angry or irritable during calls at Lifeline.*

(3) *I am confident in my ability to effectively engage and respond to male help-seekers who are seeking practical solutions or advice.*

#### Training feedback – Intervention group only, T2

**Experience of training**

Select items used in Dong et al.’s (2016) evaluation of a telephone counselling service will be used to assess CSs’ experience of the intervention training module. As with the DPCCQ and CASES subscales, minor adjustments will be made to the wording to ensure appropriateness for the helpline context and to specify relevance to male callers. Participants will respond to each item using a 4-point Likert scaled from (1) strongly disagree to (4) strongly agree.

(1) *I understood the learning objectives.*

(2) *I was able to relate each of the learning objectives to the learning I achieved.*

(3) *I found the course easy to navigate.*

(4) *I will be able to immediately apply what I learned.*

(5) *Overall, I was satisfied with the usefulness of the training.*

(6) *Overall, I was satisfied with the quality of the training.*

(7) *In general, I feel that the Engaging Men in Crisis Support training provided to me equipped me with the necessary skills to answer calls with male help-seekers.*

(8) *In general, I am able to apply what I have learnt from the training into the practice (i.e., answer the real calls).*

Additionally, for CSs in the intervention group, select items adapted from Seidler et al. (2022) will be used to assess the acceptability and feasibility of the training module. As with the DPCCQ and CASES subscales, minor adjustments will be made to the wording to ensure appropriateness for the helpline context and to specify relevance to male callers. Additionally, training module names were substituted with ‘*Engaging Men in Crisis Support*’. Participants will respond to each item using a 7-point Likert scaled from (1) strongly disagree to (7) strongly agree.

(1) *I believe my practice will improve as a result of completing the training.*

(2) *I would recommend the Engaging Men in Crisis Support training to other Crisis Supporters working at Lifeline.*

(3) *After completing the training, I feel more equipped to work with male help-seekers.*

(4) *After completing the training, I am looking forward to working with more male help-seekers.*

Participants will also be asked to respond to the following bespoke questions with free-text responses:

(1) *In your opinion, what was the best thing about the training?*

(2) *In your opinion, what could be improved about the training?*

(3) *How do you think the training will impact your practice as a Crisis Supporter?*

(4) *Do you have anything else you would like to share?*

**Experiences of crisis support after training**

Participants will be asked ‘Since completing the training, have you completed any shifts at Lifeline?' with the option to respond ‘yes’ or ‘no’. Participants who respond ‘yes’ will be asked to respond to the following bespoke questions with free text responses:

(1) *In your own words, tell us about your experience of implementing the skills from the* Engaging Men in Crisis Support *training program into practice.*

(2) *Have you noticed anything different about the needs or outcomes of male callers since completing the training?*

(3) *Is there anything else you’d like to share about your experience implementing the training?*

**Training completion data**

In order to identify which CSs have completed their assigned training, data will be extracted from Moodle activity completion report data by Logicly and stored securely in de-identified format.

**CS shift completion data**

Over the course of the trial, data will also be collected on the number of hours and shifts completed by CSs. This will be communicated by the Lifeline workflow management team to the unblinded Lifeline Research Manager (Tara Hunt).

**Supplementary caller data**

Call date, day of the week and time of day, and length of call is automatically recorded by Lifeline’s telephony system and will be extracted and stored securely with caller outcome data.

### Economic outcomes

A cost-analysis of the Engaging Men in Crisis Support intervention will be conducted. These costs included both time costs and material costs of preparatory research, development, design, and implementation of the intervention. We will also estimate the cost per person based on number of males who have used the Lifeline services.

## Plans to promote participant retention and complete follow-up

CSs will be sent reminders via email to complete all training assessments (T1, T2), with a maximum of two reminder emails sent per assessment.

Involvement in the trial requires CSs to complete their standard Lifeline shifts following completion of the training. Consequently, we do not expect that additional strategies will be required to promote participant retention across the course of the trial. Some attrition of CSs across the length of the trial is expected due to normal turnover of staff at Lifeline.

CSs will be paid their standard rate for their additional rostered training shift. They will also be able to claim the time spent on training as professional development (PD) hours. CSs are required to complete 8 hours of PD per year as part of their accreditation, so participation in this study will function as a means of fulfilling the regular requirements of their employment. Their reimbursement will therefore be proportionate to the time spent on the study.

CSs in the control group will be informed in the PICF that they will be provided access with the EMICS e-learning at the end of the trial period, encouraging participation across the length of the trial.

There are no plans to promote participant retention for callers, and no follow up.

# Assignment of interventions: allocation

## Sequence generation

#### Callers

Callers will enter Lifeline’s 13 11 14 call queue as per normal. Callers will be randomly allocated to CSs participating in the trial in either the control or intervention group based on CS availability to ensure every call is answered as promptly as possible. This is anticipated to result in a randomisation of callers into the control or the intervention group with approximately a 1:1 ratio.

#### Crisis Supporters

CSs will be randomised in a 1:1 ratio to the intervention or control group using an allocation sequence stratified by participant gender. The statistician will generate the randomisation sequence before recruitment.

## Concealment mechanism

### Callers

Callers’ phone numbers will be de-identified through allocation of a unique ID in order to filter by repeated callers. The statistician will access caller data in this anonymised format through Lifeline’s specialised data platform.

### Crisis Supporters

The statistician will transfer the randomisation sequence directly to the data management subcontractor, Logicly, who will allocate participants and provide them with email links to complete the evaluation surveys. Logicly will provide the final data to the researchers in de-identified, blinded format.

## Implementation

Survey data collection will be undertaken by Logicly hosted on a purpose-built web platform. Unique links will be generated for each CS participant, allowing them to be connected across time points. At the end of the trial, Logicly will provide the research team with the survey data in de-identified, blinded format.

Survey data and all supplementary data (LMS analytic data) will then be uploaded to Lifeline’s internal data management platform and linked with the caller dataset for data analysis. Unblinding of the groups will occur after data analysis.

## Assignment of interventions: Blinding

### Who will be blinded

#### Crisis Supporters

CSs will not be able to be blinded as they will be aware of the training content, but they will be asked in the PICF not to disclose information regarding their involvement in the trial and group allocation to callers or other CSs. If CSs have questions about the training content or completing the e-learning this will expose their allocation. They will not be involved in data analysis. If a CS withdraws from the trial the Research Manager (Tara Hunt) will ensure that they are not sent any remaining training surveys or reminders by communicating this with Logicly. They will also communicate this information to the Lifeline Workflow Management team who will monitor the rostering and completion of participant shifts over the course of the trial.

#### Callers

Callers will not have specific knowledge about the trial and so will be blinded to allocation of intervention or control group.

#### Research team

The research team and statistician will be blinded to CS and caller allocation until data analysis is complete. The Lifeline Research Manager (Tara Hunt) will be unblinded as she will facilitate communication with participants during the trial.

### Procedure for unblinding if needed

If a CS withdraws from the trial the unblinded Research Manager will inform Logicly in order to ensure the participant is not sent remaining evaluations or communications.

It will not be possible or necessary to unblind callers of allocation due to the anonymous nature of Lifeline calls.

# Data management

A summary of data management processes for each data type is presented in table 4.

## Caller data

Lifeline Australia will manage call data related to the trial. Call metadata is stored within the Cisco environment (telephony) and in PowerBI (Data and reporting), secured by password protected servers within Lifeline Australia’s infrastructure. Depending on the research time and needs, Lifeline Australia is able to generate custom reports with the required data for extraction and storage. Researchers will be able to access the data in order to complete data analysis via a specialised desktop platform to access Lifeline Australia’s data after signing a Data Access Agreement.

All caller data will be kept in line Lifeline’s privacy policy accessible here <https://www.lifeline.org.au/policies/privacy-policy/>, and may be used for future service evaluations at Lifeline Australia in line with this policy. Callers are informed of this policy while waiting to be connected to a CS, and can access further information by pressing the corresponding number on their keypad. All Phase 2 trial data will be uploaded to Lifeline’s internal data platform in order to complete data analysis with the caller data. This will be accessible by the statistician after signing a Data Access Agreement. At the conclusion of the trial, Lifeline will provide the statistician with encrypted, de-identified version of the Phase 2 data for indefinite storage on the University servers.

## Crisis Supporter data

Data collected from training evaluation surveys will be kept indefinitely on secure, password protected servers in Australia. CS identifying information (contact details) will never be stored with their study data. During the trial, Logicly, the data management subcontractor, will set-up and host the WebSurvey platform to collect the CS response data. Logicly uses Amazon Web Services (AWS) Cloud hosting services where data is stored only in Australia. AWS security policies are implemented and reviewed regularly. The AWS Cloud services have been independently assessed by an Infosec Registered Assessors Program assessor which has certified that applicable controls are in place for operating at the PROTECTED level. AWS is also certified for compliance with ISO/IEC 27001:2013, 27017:2015, and 27018:2014.

Survey data will be collected using an online form developed by Logicly. Logicly will have the details of individual CSs for the purpose of sending out personalised email invitations and reminders but will store this identifying information separately from the survey data. At the end of each of the T1 and T2 survey completions, Logicly will be able to link survey data and provide this to the researchers without any identifying information. CSs’ survey access is via a unique link and locked upon completion of each survey to minimise the risk of inappropriate access.  
  
The Logicly team will work with the University of Melbourne and Lifeline to complete a Data Return Protocol document prior to data being available, to ensure that confidentiality protocols are documented, understood, and adhered to. For example, identifying CS information will not be sent as part of the data return process. Data will be returned to the University of Melbourne and Lifeline via an encrypted, password-protected file transfer system. As part of this project, aggregated data relating to completion statistics may also be available via an administration application hosted by Logicly. Only authorised users will be granted access to access this data.

Crisis Supporter supplementary data (i.e. shift completion data) will be stored securely on Lifeline Australia’s password protected systems data systems.

At the end of the trial, Logicly will provide the statistician (Andrew Mackinnon) with a final encrypted version of the Phase 1 data for indefinite storage on University servers.

Table 4. Summary of data management

|  |  |  |  |
| --- | --- | --- | --- |
| **Data type** | **Details** | **Storage** | **Accessibility** |
| CS contact details | Names, email addresses | Password protected servers at Logicly & The University of Melbourne. Stored separately to all other study data. | * Logicly to facilitate contact, enrolment into training and survey completion * Lifeline Workflow Management Team and participant centre managers to monitor shift completion across trial |
| Demographics and self-report survey items T1, T2 | Demographic questions and responses to DPCCQ and other measures | Stored securely on password protected servers at Logicly against participants study ID. Data will be provided to Lifeline and The University of Melbourne at the conclusion of the study. Kept separately from contact details. | * Logicly * Research team (Lifeline & UoM) |
| System use data | Analytics regarding LMS use including completions, time spent on each module, and revisits during trial period | Extracted from Moodle and stored securely on password protected servers. | Research team (Lifeline & UoM) |
| CS additional data | Record of shift completions over course of trial, number of calls taken during trial | Lifeline | Research team (Lifeline & UoM) |
| Caller self-report data | Gender identity and service evaluation items collected via IVR survey | Lifeline’s CISCO telephony system. Only accessible through this password protected platform. Stored long term at Lifeline for future service evaluation in accordance with Lifeline privacy policies. | Research team (Lifeline & UoM) |
| Caller additional data | Day/date and time of call, length of call | Lifeline’s CISCO telephony system. | Research team (Lifeline & UoM) |

## Confidentiality

### Callers

Lifeline calls are anonymous with no personal or identifying information collected, with the exception of in a situation where emergency procedures are implemented (e.g., calling of emergency services to a callers’ residence/current location). Participants will be given encrypted unique identifiers in place of the phone number that they call from, meaning that research data will be completely de-identified. All data will be handled internally at Lifeline according to their privacy policies. Researchers from the University will be provided access to caller data through Lifeline’s internal password protected server to complete data analysis.

### Crisis supporters

Data collected from CS participants will be stored by Logicly during the trial. Data will be in electronic form and will be stored securely on password-protected servers/computers. At the conclusion of the trial, deidentified data will be provided to the named researchers for data analysis. The research team and Logicly will have participating CSs contact information to provide participants with access to the evaluation surveys. Lifeline’s Workflow Management team and participating centre CEOs will also be aware of a CSs participation in the trial. All evaluation data will be kept in de-identified format separately to participant contact details.

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

NA

# Statistical methods

## Statistical methods for primary and secondary outcomes

### Callers

Prior to data analysis the dataset will be filtered to only include independent callers (i.e., repeat calls from the same number will be removed from the dataset).

The primary analysis of this trial will compare post call caller outcomes for callers assigned to a trained CS to those assigned to CS who received control training. A mixed effects model including trial invention arm (intervention versus control group) and a random intercept for CSs will be included in this model. The primary outcome will be assessed by a planned comparison of the difference between arms of the primary outcome variable (feeling supported by Lifeline). This test will be undertaken with an alpha of .05. Tests of significance will use degrees of freedom adjusted using the Kenward-Roger method based on the observed information matrix. As the outcome are measured with low resolution (5-point scales), generalized linear models may be used in place of linear models if distributional assumptions are untenable even after transformation. Potential models include mixed effect gamma, ordered logistic and logistic (after dichotomisation) models. Analyses of secondary outcomes will use the same methods as for the primary outcome.

Multilevel mediation modelling will seek support for CS training as playing a causal role in outcome differences between callers assigned to the active and control trained CSs.

### Crisis Supporters

Analyses regarding Phase 1 of the trial will be undertaken on an intention-to-treat basis and will include all participants in the intervention arm to which they were randomized (regardless of actual receipt or uptake of the intervention or withdrawal from the study). The model will include factors of trial invention arm (intervention or control group), occasion of measurement (pre- and post-training), and their interaction. The primary outcome will be assessed by a planned comparison of the difference between arms in change of the primary outcome variable (DPCCQ – current clinical skills) from pre- to post-training. This test will be undertaken with an alpha of .05. A pooled unstructured residual variance-covariance matrix will accommodate within-participant dependency. Tests of significance will use degrees of freedom adjusted using the Kenward-Roger method based on the observed information matrix. Where necessary, transformation of the outcome variable will be undertaken to ensure distributional assumptions of the model are met. The robustness of the outcome will be investigated by the exploratory inclusion of covariates adjusting for any CS attributes observed to be imbalanced between intervention arms.

Analyses of secondary outcomes will use the same methods as for the primary outcome. Binary and ordinal outcomes will be analysed using analogous generalized mixed models.

## Interim analyses

No interim analyses are planned.

## Methods for additional analyses (e.g. subgroup analyses)

Additional exploratory analyses will compare outcomes for female callers (excluded from the primary aims of the trial) to those of male callers. Qualitative analysis will be conducted on responses to the “Experience of training” and the “Experiences of crisis support after training” free text questions (section 6.3.2.4) in order to assess the feasibility and acceptability of the training to CSs.

## Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data

### Callers

It is anticipated that a substantial proportion of callers who initially agree to participate in the trial will not complete the post-call survey. Because of the likely substantial attrition and models including only intervention arm and the random effect of CS the status of the analysis and the resultant estimates of effect as ‘intention-to-treat’ will be difficult to establish. Some confidence may be gained by comparison of available call (call length, day, time) and CS attributes between non-completers in each arm. In addition, a tipping point analysis is proposed to give an indication of how great a difference in unobserved outcomes in each intervention group could exist while still yielding a statistically significant effect.

### Crisis Supporters

Mixed-model repeated measures analyses will be used to all include CSs with missing data under the assumption that missingness is at random (MAR). In the event that post-training missingness exceeds 10% a sensitivity analysis will be undertaken using the ‘jump to reference’ approach. This yields an estimate of effectiveness based on the missing not at random model that participants in the active condition who fail to complete the post-training assessment essentially received the control intervention. This is a conservative assumption as participations may have benefitted from partial completion of training. As such it will establish a credible lower bound of the training effect.

## Access to data: Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators

The statistician (Andrew Mackinnon) will be granted access to the final trial dataset for the purposes of carrying out this project, as outlined by the Service Agreement between Lifeline Australia and the University of Melbourne. The statistician has signed a Data Access Agreement, which outlines de-identification requirements, permissions, and conditions of access and use of Lifeline’s data.

# Oversight and monitoring

The Principal Investigator will oversee all aspects of the trial and consult with other investigators associated with the trial at key decision points. The Lifeline Research Manager (Tara Hunt) will oversee recruitment of CS participants and completion of training and study assessments through liaising with the Lifeline Learning and Design team and Logicly.

The Lifeline Project Manager (Satish Shrestha) will be responsible for monitoring data collection over the course of the trial, where a weekly data report will be automatically generated and checked at various intervals to determine the accrued sample size. Once the stopping criterion (caller sample size) is reached, the Project Manager (SS) will alert the Principal Investigator (JP) and associated researchers, and the trial will be stopped. The Project Manager will also liaise with the Workflow Management Team to monitor participant shift completion and attrition of CSs across the trial. If additional recruitment of CSs is required, the Project Manager (SS) will communicate this to the research team to coordinate an additional round of recruitment into the trial.

University of Melbourne researchers and the Lifeline project team will monitor the project through ongoing communications (meetings at least once per month and email communication as required). Recruitment rates/number of completed caller surveys will be communicated by the Project Manager (SS) on a weekly basis. Any reported risks, complaints or concerns communicated to the Lifeline project team during the trial will be logged in a risk register and communicated to the University of Melbourne research team who will report adverse events as required.

## Composition of the coordinating centre and trial steering committee

A steering committee will oversee all aspects of the trial. This committee will be comprised of researchers from the University of Melbourne (Prof. Jane Pirkis, A/Prof Simon Rice, Dr. Zac Seidler) and the Lifeline Research Manager (Tara Hunt).

## Composition of the data monitoring committee, its role and reporting structure

An independent data monitoring committee is not required as no interim analyses are planned, and participant safety (both CSs and callers) will be monitored across the trial by Lifeline’s standard risk and safety procedures. These procedures ensure the safety of participants is monitored independently of the study team. Additionally, the safety management strategy will involve routine internal oversight by the trial steering committee (section 10.1) with regular meetings where any reports from the risk register (described in 11.2) will be reviewed. The steering committee will follow the stopping criteria reported in section 5.3.

# Adverse event reporting and harms

## Risks to participants and risk management strategy

Potential risks to participants and risk management strategies are outlined in the following section.

### Callers

There is risk that the skills or strategies provided in the EMICS module could negatively impact callers to Lifeline. This risk is minimal due to the develop and design process of the training. EMICS has been designed by Lifeline staff as an enhancement to Lifeline’s CARE model, reinforcing Lifeline’s core approaches of connection and help-seeker led care. All CSs will be training in CARE and Lifeline’s emergency intervention procedures and will implement this over the course of the trial as required. Further, the training has been informed by significant consultation with male callers, CSs and Lifeline staff, and the existing evidence-base on engaging men in mental health care. In the event that strategies used do not resonate with a caller or cause disengagement, CSs are encouraged to maintain a caller-led approach meaning that they can adjust their practice based on the response of the caller.

### Crisis supporters

There is risk that CSs may find the content provided in the EMICS training to be distressing due to discussion of sensitive topics including suicide, and presentation of interactions portraying caller anger.

There is a risk of frustration for control participants due to the length of the trial requiring a long wait until they are provided access to the EMICS training.

#### Management strategy:

* The content developed for EMICS reflects realistic interactions that CSs may have with male callers at Lifeline based on consultation with CSs, and therefore would not be unexpected as part of their role. Content warning prompts have been provided in the training prior to sections that may include distressing content. Further, the training includes reminders for CSs to engage with their supervisor as required if they are concerned about anything in the training, and to engage in self-care practices. CSs will have contact information of the research team and of the approving ethics committee in case they have any concerns about training content or conduct of the study. CSs will also be provided with the details of various (non-Lifeline affiliated) support lines.
* CSs will be able to contact the Lifeline project contact during the trial if they have any concerns about their involvement and will be able to withdraw at any time if they wish.
* The time requirements of participation as well as the process of random allocation and the chance that participants may need to wait to gain access to the EMICS training will be clearly articulated in the PICF.
* In order to reduce the risk of frustration or disengagement from control CSs, they will be encouraged to complete the *Child Safety and Crisis Support* module. This will provide control CSs will beneficial information and skills albeit not directly related to the trial aim.
* Control CSs will be given access to the EMICS training after the trial is complete, and they will be informed of this in the PICF and other communications.
* CSs will be able to claim Lifeline professional development hours following completion of the training. As ongoing professional development is a requirement of all Lifeline CSs, this will provide incentive for participants and serve as recognition of their time committed to the study.

## Risk reporting

Lifeline Australia will develop a risk register which involves labelling the risk, what the risk rating is, mitigation and response. The risk register will include the following:

* Complaints from CSs regarding participating in the trial.
* Adverse events as a result of post-interaction survey – In the event that a caller reports an adverse event as a result of the trial (e.g., they are triggered as a result of the post-interaction survey).

In the event that callers have a complaint or experience an adverse event as a result of participating in the trial, they will be directed to follow the Lifeline complaints procedure including reporting via the complaints handling section on the website. Lifeline Australia’s complaints team will forward any complaints regarding the trial to the project team to follow University reporting procedures.

In the event that callers report a complaint or experience an adverse event during the call, the CS will notify the Central In-Shift Supervisor team and the Central In-Shift Supervisor manager will report to project team. The Central In-Shift Supervisor team consists of supervisors who support CS staff while on shift, including by assisting on difficult calls and offering reflective debriefing sessions.

Any concerns or complaints from centre managers, the Central In-Shift Supervisor team or other Lifeline staff will be communicated to the Lifeline PM who will log them in the developed risk register. Any events that constitute a protocol deviation or adverse event requiring reporting to the ethics committee will be communicated to University of Melbourne researchers who will report this.

## Frequency and plans for auditing trial conduct

No specific plans for auditing are apparent. However, the study may be subject to routine auditing by the study sponsor The University of Melbourne and the approving ethics committee (University of Melbourne STEM).

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

Any amendments to the trial protocol will be communicated to the approving ethics committee, trial researchers and the relevant Lifeline staff and reported to the Australian New Zealand Clinical Trial Registry.

## Declaration of interests

The authors declare that they have no competing interests.

## Dissemination plans

A summary of the findings will be provided to Lifeline Australia by the research team for dissemination to staff, CSs, stakeholders, and the general public via the Lifeline website. Findings will also be presented on The Buoy Project website and associated platforms. The findings will also be reported in journal articles and presented at academic conferences.

## Authorship eligibility guidelines and any intended use of professional writers

There is no intended use of professional writers. Authorship eligibility guidelines will be those set out by the National Health and Medical Research Council (NHMRC, 2019).

## Plans to give access to the full protocol, participant level-data and statistical code

The full protocol will be published in a peer reviewed journal. Participant level-data will only be shared under conditions allowed by the Services Agreement between the University of Melbourne and Lifeline and by the Data Access Agreement between the research team members and Lifeline. These conditions include (but are not limited to) the de-identification of data and the provision of prior written consent from Lifeline. Statistical code used for analyses will be included in any relevant publications resulting from the trial.

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1. In this protocol, “help-seeker(s)” refers to individuals seeking support in a variety of contexts (e.g., psychological treatment, general practice, and Lifeline’s SMS and online chat services), while “caller(s)” refers to individuals seeking support via telephone helplines (e.g., Lifeline’s 13 11 14 crisis support line). [↑](#footnote-ref-2)
2. Flyer available at <https://psychology.org.au/aps/media/events/attachments/21160/male-friendly-counselling-2020_1.pdf> [↑](#footnote-ref-3)
3. While this trial only includes callers, all Lifeline training materials (including the intervention and control training modules) refer to “help-seekers” to facilitate accessibility to CSs staffing Lifeline’s SMS and online chat crisis support services. [↑](#footnote-ref-4)
4. Preprint available at: <https://doi.org/10.31234/osf.io/x3guz>. Details about this research project are available here: <https://www.lifeline.org.au/about/our-research/building-a-lifeline-for-the-future-expectations-innovations-outcomes/> [↑](#footnote-ref-5)