**Help while our children wait: Adapting a brief psychological treatment to bridge waiting times for youth mental health services**

**Ethics protocol for Phase Two**

**Protocol Date: 11/04/2023**

**Version: 3**

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| PROJECT SUMMARY |

**Our request:**

This project comprises two phases: an intervention adaptation phase (phase one) and an intervention testing phase (phase two). We have completed phase one and are now seeking ethical approval for phase two.

**Background:**

In Phase one, we will contextually adapt an evidence-based brief treatment for common mental disorders (depression, anxiety, alcohol use) for use with adolescents (13-19 years old) in WA. The final intervention will target adolescents who have some mental health difficulties but who are at low risk for suicide and whose problems are not severe enough to access WA's Child and Adolescent Mental Health Services.

In Phase Two, we propose a randomized hybrid Type 1 implementation-effectiveness trial of the*Help While You Wait intervention package* which we co-designed with adolescents, parents, and providers in Phase one. The intervention is designed to equip adolescents experiencing mental health difficulties with problem-solving strategies and coping skills to help them manage their mental health while they wait for specialist services. We are now seeking approval for the feasibility test of this intervention.

**Aims**:

*Phase One:* In this phase, our goal is to contextually adapt one such intervention (brief problem-solving treatment) for adolescents in WA and co-develop a strategy to support future implementation of this intervention in the youth mental health treatment system.

*Phase Two*: In this phase, we aim to conduct a formative evaluation of the intervention’s feasibility, applicability, appropriateness, and efficacy, as well as implementation fidelity and cost. We also aim to evaluate the feasibility, applicability, appropriateness, and effectiveness of the training provided to individuals who deliver the intervention.

**Methods**:

*Phase One:* We will first co-adapt an evidence-based intervention for WA adolescents (14-18 years old). We will conduct three online workshops with adolescents (8 per group) who have previously struggled to access mental health services for depression, anxiety. In these workshops we will demonstrate the intervention, and then ask participants for qualitative feedback on how it can be adapted for the WA context and for acceptability. Next, we will explore how we can address barriers to implementing the intervention. We will conduct online qualitative interviews with adolescents, parents, primary care providers, and representatives from the youth mental health service sector to identify their preferences for intervention delivery and recommendations for overcoming barriers to referral, uptake of the intervention, and intervention delivery. We will integrate this information and present it in separate workshops with adolescents and providers for further discussion and inputs.

*Phase Two:* We will conduct a two-arm randomized hybrid Type 1 implementation-effectiveness trial of the adapted intervention. The intervention will be implemented in youth-focused community services. These services will refer adolescents (13-19 years old) to the research program. We will recruit 80 adolescents who will be randomly assigned in a 1:1 ratio to the intervention or a usual care comparison condition. The intervention comprises four sessions of individual counselling delivered by trained non-specialist providers who have completed intervention training and receive weekly supervision. Outcomes will be assessed at baseline, six-week, and 10-weeks post-randomization time points via surveys. Qualitative interviews will also be conducted with interventionists. Primary outcomes will be feasibility and acceptability of study procedures and intervention delivery - assessed from the perspective of adolescent participants and interventionists. Clinical outcomes (psychological distress) will be collected as secondary outcomes. Participants assigned to usual care will be offered the intervention after their final follow up assessment.

**Outcomes**:

*Phase One:* Findings will be used to co-produce an intervention package and implementation strategy for further testing of its feasibility, acceptability, and effectiveness in phase two of the project.

*Phase Two* findings will be used to improve the intervention training, the intervention materials and approach, and the implementation strategies and to inform scale-up and wider implementation of the intervention. Other anticipated outputs include short reports and briefs for providers and policymakers; conference presentations and webinars; and peer-reviewed publications in scientific journals.

**Summary of new request**:

*Phase One* has been fully approved and completed.

In this amendment, we are seeking ethical approval for *Phase Two* only.

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| BACKGROUND |

**A mental health crisis among Western Australian (WA) adolescents**

An increasing number of adolescents in WA are experiencing mental health problems. Since 2013, the rate of mental health difficulties has almost tripled (Thomas et al., 2022), with an estimated 40% of 12–18-year-olds in WA reporting high levels of distress, largely due to common mental health problems like depression and anxiety.This has led to a 50% increase in referrals to the Child and Adolescent Mental Health Services (CAMHS; Mental Health Commission, 2020). Given chronic workforce constraints (Institute for Social Science Research, 2020), specialist CAMH services cannot keep pace with this unprecedented demand. Access to these Tier 3 adolescent mental health services in WA has worsened, with wait times increasing. These system constraints have forced WA’s CAMHS to prioritize adolescents with severe mental health problems who are at risk of suicide. Tier 2 services provided by the non-government sector are available in community settings, but these only offer early intervention services for adolescents with very mild mental health concerns and do not have the capacity or resources to treat adolescents with more significant difficulties. Adolescents with moderately severe mental health problems (that cause them distress and impact on their functioning but who are not at risk of suicide) fall within a therapeutic vacuum between Tier 2 and Tier 3 CAMHS (Emerging Directions, 2021).

These adolescents, referred to as the “missing middle”, are referred by general practitioners or Tier 2 and Tier 3 services to mental health professionals (e.g., Psychologists) in the private sector – the only other therapeutic service available to them. But there are also workforce shortages in this sector (Mental Health Commission, 2020b) with many private providers no longer accepting referrals for new clients. Adolescents generally often wait extended periods of time (6-9 months at minimum, up to 12 months in regional WA) after referral to access these private providers. Additionally, private therapeutic services remain out of reach for adolescents whose families cannot afford the Medicare gap payments and who do not have private health insurance. The longer adolescents wait for therapeutic services, the more their mental health deteriorates and their school and social functioning declines. Untreated mental health problems threaten the chance of adolescents having a healthy and fulfilling life as these problems affect all areas of functioning, tend to get worse, and often last into adulthood (Eyre & Thaper, 2014). Timely access to mental health care is an important indicator of care quality (Butz et al., 2019; Hartveit et al., 2017) and is necessary to protect adolescents’ futures.

**What can be done to reduce these gaps and expediate access to psychological treatments?**

Despite high-level policy commitment to redressing these service gaps (Emerging Directions Report, 2021; MHC Youth Priorities for Action Framework, 2020), little progress is evident (Youth Commissioner Update, 2020). WA cannot rely on conventional solutions (employing more specialists to expand clinical services) given chronic mental health workforce shortages. Instead, WA needs innovative, evidence-based waitlist interventions (WLIs) that bridge the post-referral therapeutic vacuum for adolescents in the “missing middle” that are feasible to implement in a context of workforce shortages.

There is scant evidence globally to guide the selection of WLIs within youth mental health sectors (Clark, 2018; Paton, 2021; Smith, 2018). Prior research has focused on strategies to manage waitlists (such as appointment reminders and prioritization of severe patient presentations), but these strategies have little effect on wait times for services (Vallerand, 2013). Critically, these strategies offer little therapeutic benefit to adolescents who are not prioritized for services because their problems are less severe (Edbrooke-Childs, 2020). This is the case in WA, where treatment through CAMHS is limited to the 20% of treatment-seeking adolescents with complex and severe problems. In the absence of effective systemic interventions, adolescents in the “missing middle” require evidence-based psychological interventions to alleviate their psychological distress and prevent problem escalation (Westin, 2013). However, published research on the feasibility or benefits of psychological WLIs for adolescents is lacking both in Australia and globally.

Efforts to improve access to psychological treatments in the UK and elsewhere recommend offering brief evidence-based psychological treatments to adolescents while they wait for specialist providers as part of a stepped care approach to treatment. In this approach, a brief treatment is provided first by trained non-specialist providers, only ‘stepping up’ to more intensive/specialist services as required. Evidence-based interventions for non-specialist provider (NSP) delivery are available for this age group and include cognitive behavioural treatments as recommended by the World Health Organisation (WHO) and the UK’s National Institute for Health Care Excellence. These are not yet available in WA. We propose contextually adapting one such intervention for use in WA.

**More about the proposed psychological intervention**

The proposed intervention combines two WHO-recommended first-line treatments for common mental disorders: motivational interviewing (MI) and problem-solving therapy (PST). MI is a conversational approach to psychological treatment that facilitates positive change in thinking and behaving by enhancing clients’ motivation and commitment to change (Miller & Rollnick, 2013). PST is a type of cognitive behavioural therapy which is applicable in primary care (Mynor-Wallis, 2005), with meta-analyses demonstrating it is cost-effective in treating common mental health problems like depression, anxiety, and substance use difficulties (Bell et al., 2009; Cuijpers et al., 2007; Malouff et al., 2007). PST is largely based on Lazarus and Folkman’s (1984) coping theory; the approach teaches patients problem-focused coping skills for problems that can be changed, and emotion-focused coping strategies (acceptance and seeking support) for problems that are difficult to change. PST is efficacious for treating depression, anxiety, and emotional disorders more broadly, as well as problem behaviours (including substance use). In other words, the intervention has transdiagnostic relevance. It is a well-established therapeutic approach in developed-world settings and requires limited resources to deliver (Bell et al., 2009; Cuijpers et al., 2007; Malouff et al., 2007). Our proposed intervention combines PST with MI to ensure adolescents are motivated to engage in treatment and apply the PST skills developed through the intervention. There is good evidence that combining MI and PST leads to improved outcomes for patients with depression (Naar & Safren, 2017; Ponser et al., 2016), and patients with comorbid alcohol use disorders and depression (Riper et al., 2014). MI helps build motivation/readiness for treatment and PST provides the skills and coping mechanisms needed to facilitate recovery.

Over the years CIA Myers has developed an intervention package based on MI and PST that we propose to adapt for WA. We have chosen to adapt this treatment package for application in WA because multiple randomised controlled trials have demonstrated this treatment package’s effectiveness for reducing depression, anxiety, and alcohol use severity to below the threshold for clinically significant symptoms. These trials have been conducted with a range of populations and settings outside Australia, including among adolescents, and have demonstrated lasting positive effects (see **Table 1**). As such, we anticipate that the intervention will directly benefit the mental health of WA adolescents who are sitting within the therapeutic vacuum by reducing their psychological distress, mental health symptom severity, and functional impairment.

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| **Table 1** *Summary of evidence in support of the intervention’s effectiveness*  |
| **Study** | **International investigators** | **Population & setting** | **Study design** | **Intervention format** | **Outcomes** | **Other outcomes/notes** |
| Van Hof’t et al., 2011 https://doi.org/10.1186/1471-244X-11-156 | Pim Cuijpers  | 103 individuals with perceived mental health problems  | Pilot test of adapted intervention  | 5 sessions of PST only  | Significant decrease in psychological distress from baseline to post-intervention assessment: (pre: M = 25,79, SE = 7.48, post: M = 20.33, SE = 7.14; post: M = 20.33, SE = 7.14; *t* (72) = 6.87, p < 0.05, d = 0.63). | Adapted and manualised Pim Cuijpers’ PST approach. |
| STRIVE Sorsdahl, Myers, SATPP, 2015 https://doi.org/10.1186/s13011-015-0042-1  | Pim Cuijpers, Vrije Universiteit Amsterdam, The Netherlands.  | 335 patients presenting to ED services in Cape Town, South Africa  | Individually randomised RCT: participants randomised to MI only, MI-PST or treatment as usual (TAU)  | 5 MI-PST sessions versus 1 MI session only  | ASSIST (substance use involvement) scores at three months were significantly lower in the MI-PST group than they were in the MI and control groups (t (332) = −2.08, p = 0.04). For depression, participants in the MI-PST arm reported significantly lower CES-D scores relative to the combined MI and CG arms at follow-up (t (170) = 2.72, p = p > 0.001).  | An economic evaluation demonstrated the cost-effectiveness of the MI-PSt intervention (https://doi.org/10.1186/s12962-018-0109-8). The intervention is being implemented as part of routine practice in 4 EDs in South Africa (Teachable Moments intervention).  |
| Alcohol flagship project (Parry, Myers under review Lancet)  | Paul Shuper, Centre for Addiction and Mental Health, and University of Toronto  | 623 adults receiving HIV treatment in Pretoria, South Africa  | Individual RCT across 6 sites in Tshwane: patients randomised to MI-PST or control  | 4 intervention modules delivered in two face to face counselling sessions  | At 6-month follow up, there was a 35% greater relative drop in the average number of drinks consumed over a 30-day period for the intervention vs. control arm (p<0.05). Over the 6-month follow-up period, participants in the intervention arm reduced their consumption by an estimated total of 50.5 drinks per participant compared to a reduction of 17.7 drinks per control arm participants.  | Qualitative interviews with participants highlighted the benefits and acceptability of the intervention. Participants described how they applied the skills learned in the intervention to manage psychosocial stressors.  |
| Project MIND Myers et al., 2019 protocol paper; outcomes in progress | Christopher Butler, Primary care professor, Oxford University  | 1340 adults with a chronic disease  | Cluster RCT across 24 primary care clinics in South Africa (rural and urban)  | 3 individual sessions and fourth booster session- delivered by chronic disease adherence counsellors | From baseline to 12-month follow up- participants in intervention arm reduced their CES-D (depression screener) scores by 6.5 points more than those in treatment as usual (TAU) (95% CI: -8.3; -4.7; *p*<0.001. From baseline to 12-month follow up, participants in the intervention arm reduced their alcohol use severity (AUDIT) scores by 2 points more than those. | Qualitative interviews with participants and providers highlighted that the intervention was feasible to deliver, acceptable and beneficial to participants. https://doi.org/10.3390/ijerph17072249The Intervention is now being delivered as part of routine practice in rural health districts. |
| PST with pregnant women Spedding, Sorsdahl, Myers et al., 2020.https://doi.org/10.4102/phcfm.v12i1.2378  | Pim Cuijpers  | 38 pregnant women with psychological distress  | Adaptation and feasibility test  | 3 MI-PST sessions  | Significantly decreased depression scores (Cohen’s *d* = 0.61; Hedges’ *g* = 0.60). Reduced impairment to functioning: less disruption to work (Cohen’s *d* = 0.42;), social life (Cohen’s *d* = 0.71) and family and home responsibilities (Cohen’s *d* = 0.43). Perceived Stress Scale scores also significantly reduced (Cohen’s *d* = 0.63).  |  |
| ASPIRE (Myers, PI- outcomes in progress)  | Helen Weiss, LSHTM  | 117 South African adolescents (aged 15-18) randomised to 4 session intervention or first session only  | Adaptation of intervention for adolescents and randomised feasibility trial  | 4 intervention sessions delivered face to face or virtually  | Participant outcomes are preliminary and secondary to feasibility outcomes (stage 2 trial). From baseline to 3 month follow up, greater reduction in ASSIST-Y scores for intervention (14.3 to 4.1) compared to control (13.1 to 6.9, p<0.01). Greater reductions in psychological distress (K-10) for intervention (26.5 to 20.8 compared to control: 25.9-21.5) p<0.03. Greater reductions in GAD-7 scores for intervention (anxiety): 8.9 to 5.6 compared to control: 9.8 to 7.8, p<0.04).  | Findings suggest 4 sessions of MI-PST more effective than 1 session. 98% of participants reported being satisfied with the treatment, 94% found the counselling sessions useful. |

These studies have demonstrated that non-specialist providers (including health counsellors without a formal mental health qualification) can effectively deliver the treatment and that patients are satisfied with the quality of service they receive.

In addition, we have demonstrated that it is feasible for health services to implement this intervention as part of routine practice. The intervention is now being scaled in emergency departments in South Africa as part of the Teachable Moments programme (Van der Westhuizen et al., 2019, 2020). It is also being delivered by community health workers (CHWs) in rural health services in the Western Cape, South Africa, as part of this service’s commitment to integrating mental health services into primary care facilities.

**Cultural and contextual adaptation of the intervention for WA**

While this earlier work shows promise for the feasibility of delivering this evidence-based treatment in WA, contextually adapted treatments are more effective than non-adapted treatments (Benish et al., 2011; Harper et al., 2016). Cultural and contextual adaptation commonly involves systematic modification of interventions and training materials to consider language, culture, and context, with the goal of ensuring that it is compatible with clients’ cultural patterns, meanings, and values (Bernal et al., 2009). To maintain fidelity to the evidence-based treatment, it is generally recommended that the core intervention components are maintained, while other changes can be made to improve “fit” (Bernal et al., 2009). In a review, Chowdhary and colleagues (2014) found that the most common intervention adaptations were made to language, context, and the person delivering the treatment, rather than to core intervention content.

As such *Phase One* of the current study aimed to adapt the proposed intervention for the WA contextwhilst maintaining fidelity to the intervention’s core components (Bernal et al., 2009). In Phase One, we conducted qualitative interviews with 15 adolescents, 14 parents, and 16 providers to understand their experiences and perspectives of wait times for CAMHS, and their preferences for the delivery of the intervention, including the interventionist, delivery setting, and session mode (face-to-face, online), length, and frequency (weekly, fortnightly). The interviews were also an opportunity to understand potential barriers and facilitators to adolescents accessing and engaging with the proposed program.  Next, we conducted a series of co-design workshops with adolescents (6 co-design workshops), parents (two workshops), and providers (two workshops) to iteratively revise the intervention content and materials to improve relevance, fit for WA (in terms of language and metaphor), feasibility, and acceptability, with a focus on changes to improve adolescent’s potential engagement with the program.  However, this adapted intervention had not yet been tested among adolescent populations in WA and therefore the feasibility, acceptability and potential benefits for mental health have not yet been assessed. Phase Two of the study aims to address this gap.

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| AIMS AND OBJECTIVES |

**Overall Aim**

Our research aims to develop and test the feasibility of an innovative solution for bridging the mental health service gaps for WA adolescents in the ‘missing middle’.

**In *Phase One* of this project, we have two objectives:**

*Objective 1:* To adapt an evidence-based transdiagnostic intervention for WA adolescents (14-18 years old) waiting for mental health treatment. During workshops with adolescents (n~ 8/group), we will iteratively co-adapt a 4-session psychological intervention to ensure its relevance and acceptability for adolescents in WA.

*Objective 2:* To Identify barriers and enablers to implementation of the intervention and strategies for overcoming these barriers. Qualitative interviews (n ~ 45) with adolescents, parents, primary care providers, and representatives from the government and nongovernment CAMHS sector will be used to identify preferences for intervention delivery, and barriers to referral, uptake, and delivery. This information will be presented and discussed at intervention design workshops. Findings will be used to produce a coherent intervention package and implementation strategy for feasibility testing during *Phase Two* of the project.

**In Phase Two of the project, we have one main objective:**

*Objective 3:* To evaluate the implementation of the intervention by non-specialist providers (like youth workers, mental health peer support workers) and its preliminary effectiveness for reducing psychological distress of adolescents (13-19 years old) in WA.

To achieve this objective, we propose a randomized pilot Type 1 hybrid effectiveness-implementation trial with 80 adolescents. Through this trial, we will explore the intervention’s preliminary effects on psychological distress (see Figure 1 for trial design). In parallel and using mixed methods, we will explore the acceptability and feasibility of implementing the intervention package from the perspective of adolescents, parents, and interventionists. More specifically we will assess the:

* Feasibility, acceptability, and effectivenessof the training delivered to interventionists for developing therapeutic competencies to deliver the intervention.
* Acceptability, appropriateness, feasibility of implementing the intervention (implementation outcomes) from the perspective of interventionists.
* Acceptability, appropriateness, feasibility of participating in the intervention (implementation outcomes) and efficacy for reducing psychological distress from the perspective of adolescent participants.
* Acceptability, appropriateness, feasibility of participating in the intervention (implementation outcomes) and perceived benefits from the perspective of parents whose children received the intervention.

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| METHODS |

**1. PHASE ONE:**

* 1. **Study Design**

This phase of the study is qualitative in nature. We will use the Ecological Validity Model (EVM; Bernal et al., 1995) as a framework for contextually adapting the intervention. The EVM is widely used to adapt interventions for new settings, populations, and priorities (Perera et al., 2020). It specifies eight dimensions to be considered when adapting interventions to new contexts: language (is the language appropriate), person (the therapist-client relationship), metaphors (symbols and concepts), content (cultural knowledge of the therapist), concepts (treatment concepts consistent with culture), goals (do goals support of positive and adaptive cultural values), methods (cultural enhancement of treatment methods), and context (consideration of economic and social context).

* 1. **Participants**

For this phase of the project, we are recruiting three sets of participants: adolescents, parents, and providers.

* ***Adolescent participants***: To be eligible for study participation, adolescents should be (i) 14-18 years of age, with prior experience of (ii) seeking psychological or other mental health services for depression or anxiety, and (iii) long wait times to access these mental health services, and (iv) not currently at high risk of suicide. We will use the Columbia Suicide Severity Rating Scale – Screen version (Cwik et al., 2020) to assess for risk of suicide. We plan to recruit up to 24 adolescent participants for Objective 1 and up to 15 adolescent participants for Objective 2. Adolescents who participate in Objective 1 activities are eligible to participate in Objective 2 activities should they wish.
* ***Parent participants***: To be eligible for study participation, parents should have prior experience of extended waiting periods to access psychological or other mental health services in WA for one of their adolescent children. We are seeking to recruit up to 15 parents for Objective 2, although the sample size for Objective 2 will depend on saturation of information from the qualitative interviews.
* ***Provider participants***: To be eligible for study participation, providers should be current providers of child and adolescent mental health services in Western Australia. We will seek to recruit a diverse range of participants that represent providers across rural, regional, and metropolitan areas, including both community organizations, and public and private providers. We will seek to recruit approximately 15 providers, although the sample size for Objective 2 will depend on saturation of information from the qualitative interviews.
	1. **Participant recruitment and consent process**

***Adolescent and parent recruitment***: We will distribute digital and print flyers targeting adolescents and parents through a variety of social media channels targeting adolescents and parents in WA (Tiktok, Instagram, Facebook). We will also ask our community partners (Health360, RACGP, WAPHA, Youth Focus, Lifeline, YACWA) to post the flyers on their social media channels. We will also ask our provider networks (private psychologists, GPs) to distribute the flyers in their waiting rooms. See recruitment materials (Appendices 1-3) for examples of these flyers. The flyers contain information about the study, who may be eligible to participate, ethics information and contact information to learn more about the study. Adolescents and parents will be able to use a sign-up link on these flyers to register their interest in study participation (Appendix 4). This sign-up link will request minimal information about the potential participant (first name, whether they are a parent or adolescent, telephone number) so that a researcher or research assistant can contact the potential participant directly. The sign-up sheet will explain to adolescents that parental consent will be required for their participation and will ask them to provide a parent's contact number and email address.

A research assistant will contact parents directly via telephone or a videocall to explain more about study involvement and seek their consent for their child's participation. After this call, parents will receive an email link to an online participant information sheet (Appendix 5) and parental consent form (via Qualtrics; Appendix 6) for their child's participation. Parents can choose not to sign this form. A research assistant will then contact those adolescents whose parents gave consent for their participation and follow a similar process to obtain their assent (Appendices 7 and 8). Only after obtaining parent consent and adolescent assent for participation will we screen adolescents to assess their eligibility for the project. Screening will occur via a Qualtrics survey (Appendix 9). This is because we will assess current risk of harm. Adolescents and parents will be properly informed about the process of assessing eligibility for study participation. Adolescents who are not eligible because they are potentially at risk of harm will be contacted via our study clinicians for further management (see risk mitigation plan attached) and their parents will be informed. Adolescents will only be able to participate if their parent consents to their participation. An email will be sent confirming study enrolment to those adolescents (and their parents) who are eligible for study participation.

Parents approached to provide parental consent for their adolescent child's participation in the study will be offered an opportunity to participate in Objective 2. They will be able to participate in the study even if their child does not assent to being involved. This will be explained to parents when the research assistant contacts them to explain more about the study (during adolescent recruitment for Objective 1). Those parents that are interested in participating in the study will be sent an email link to a participant information sheet and consent form via Qualtrics (Appendices 10 and 11) for electronic completion. Once signed, an email will be sent to parent participants confirming their enrolment in the study.

***Provider recruitment****:* We will recruit service providers and representatives from child and adolescent mental health organizations to participate in in-depth interviews and a workshop (Objective 2). We already have a list of engaged community partners who helped inform and shape our funding proposal. We will contact the CEO of these organizations and clinical managers via email (Appendix 12) to formally request their participation in Objective 2. They will be sent a project flyer, and electronic copies of the participant information sheet and consent form (Appendices 13 and 14) with the email correspondence. In this correspondence, we will ask them to identify the person in their organization whom they think is best suited to participate in the project and to send us their contact details. The researchers will then invite this identified person via email to participate in the project (sharing the above information). CEOs and managers will not be included in this correspondence to avoid coercion/pressure to participate. There will be an opportunity to contact the research team to ask questions about study involvement. Providers will be asked to complete the consent form and indicate their willingness (or not) to continue with the study and to return this consent form via email.

* 1. **Study procedures**

***Objective 1: Adolescent workshops to contextually adapt the intervention***

Following the informed consent process and screening for study eligibility, each participant will be assigned a unique participant ID. A researcher will schedule the workshops with eligible participants. Prior to the workshop, each participant will be asked to complete a brief Qualtrics survey about themselves, their prior difficulties in accessing mental health services, and current levels of psychological distress (using the Kessler-10 screener for psychological distress (Kessler et al., 2003; see Appendix 15 for survey). Data will be used to describe workshop participants and will be linked to the participant through their unique participant ID only. The survey will take no more than 10 minutes to complete.

The workshop will comprise up to 8 adolescents and two facilitators and will occur virtually using Microsoft Teams. At the workshops, the facilitators will present the intervention prototype (each of the original intervention’s counselling sessions) before guiding the participants through a series of focus group discussions (see Appendix 16 for draft discussion guide) about how to adapt the intervention content and materials to better meet the adolescents’ needs and preferences. Facilitators will request feedback on necessary adaptations to improve relevance, fit for WA (in terms of language and metaphor), feasibility, and acceptability. The intervention adaptation workshops will allow for iterative changes to be made to the intervention materials, guided by principles of Human-Centered Design (HCD). A HCD approach brings together intervention developers and end-users to co-create interventions, which will ensure the adapted intervention is context-relevant and tailored to the needs of adolescents (Lyon et al., 2020; Stiles-Shields et al., 2022). After each workshop, the study team will make changes to the intervention prototype before presenting the next iteration of the intervention to a second group of participants. This process will be repeated with a third group of participants. All adaptations to the intervention will be systematically documented using the FRAME approach (Wiltsey Stirman et al., 2019). This will involve mapping when, why, and what modifications were made and contextual factors that influenced the decision.

Each workshop will take three to four hours to complete. Participants will be given breaks after reviewing each counselling session. The workshops will be audio-recorded. A study team member will upload the audio-recording of the workshop to the Curtin R Drive; once uploaded, the study team member will delete the file from the recording device. Workshop participants will receive a $75 Coles/Myer voucher as reimbursement for their time spent participating in the workshop and group discussion.

***Objective 2: Identifying intervention preferences and barriers to implementation***

For Objective 2, we will conduct in-depth interviews with adolescent participants (n=15), parents (n=15) and provider participants (n=15) and workshops to inform further refinements to the intervention and its delivery. Eligibility criteria were described earlier. This objective will be guided by the Consolidated Framework for Implementation Research (CFIR) which we will use to assess barriers to implementation (Damschroder et al., 2009; Piat et al, 2021) from the perspective of adolescents, parents, and providers. CFIR is a meta-theoretical framework that assesses barriers and facilitators to the implementation of a new intervention across 5 domains: the intervention’s characteristics, the external context, the internal context (within the organization), the implementers, and the process of implementation.CFIR will allow us to explore multi-level barriers to implementing the adapted intervention and will help us identify strategies for overcoming these barriers. Interviews with adolescents, parents, and providers will explore these CFIR constructs. Methods for conducting the interviews are described below.

***Objective 2: Interviews***

Adolescent interviews: We will conduct qualitative interviews with 15 adolescents, identified from the adaptation workshops. The interviews will be conducted online using Microsoft Teams, and audio-recorded before being transcribed verbatim. Interview data will be linked to the demographic survey data collected as part of Objective 1 via the participant’s unique study ID number. All interviews will be conducted by a trained interviewer. A semi-structured questionnaire (see Appendix 17 for adolescent interview guide) will guide the interviews. Questions will explore perceptions of (1) the need for psychological treatments for wait-listed adolescents, (2) barriers and facilitators to participating in the proposed intervention, and (3) preferences for the intervention format, structure (duration), delivery, and setting. Interviewers will be trained to instruct participants not to disclose any identifiable data. If any identifiable data is disclosed, it will later be removed or anonymized in the written transcript of the interview. Before beginning an interview, the interviewer will confirm that the participant is in a private location and is able to participate in the interview. We expect interviews to last 45 to 60 minutes. When the interview is complete, a study team member will upload the audio-recording to the Curtin R Drive; once uploaded, the study team member will delete the file from the recording device. Participants will receive a $35 Coles/Myer voucher as reimbursement for their time spent participating in the interview.

Parent interviews: We will conduct qualitative interviews with up to 15 parents. Prior to the interview, each parent participant will be asked to complete a brief Qualtrics survey about themselves, their prior difficulties in accessing mental health services for their child, and the Barriers to Access to Care Evaluation scale (Clements et al., 2012; see Appendix 18 for parent survey). Data will be used to describe participants and will be linked to the interview data through their unique participant ID number only. The survey will take no more than 10 minutes to complete. Once the brief survey has been completed, the interviewer and participant will begin the interview. The qualitative interviews will be conducted online using Microsoft Teams, and audio-recorded before being transcribed verbatim. All interviews will be conducted by a trained interviewer. A semi-structured questionnaire (see Appendix 19 for parent interview guide) will guide the interviews. Questions will explore parents’ perceptions of (1) the need for psychological treatments for wait-listed adolescents, (2) barriers and facilitators to participating in the proposed intervention, and (3) preferences for the intervention format, structure (duration), delivery, and setting. Interviewers will be trained to instruct participants not to disclose any identifiable data. If any identifiable data is disclosed, it will later be removed or anonymized in the written transcript of the interview. Before beginning an interview, the interviewer will confirm that the participant is in a private location and is able to participate in the interview. We expect interviews to last 45 to 60 minutes. When the interview is complete, a study team member will upload the audio-recording to the Curtin R Drive; once uploaded, the study team member will delete the file from the recording device. Participants will receive a $35 Coles/Myer voucher as reimbursement for their time spent participating in the interview.

Provider interviews: We will conduct qualitative interviews with up to 15 providers and key stakeholders in the private and public child and adolescent mental health sector. Prior to the interview, each provider participant will be asked to complete a brief Qualtrics survey about themselves, their training, their occupational role, experience in providing CAMHS, and the Evidence-Based Practice Attitudes Scale (Aarons, 2004; see Appendix 20 for provider survey). Data will be used to describe provider participants and will be linked to the interview data through their unique participant ID number only. The survey will take no more than 10 minutes to complete. Once the brief survey has been completed, the interviewer and participant will begin the interview. The interviews will be conducted online using Microsoft Teams, and audio-recorded before being transcribed verbatim. All interviews will be conducted by a trained interviewer. A semi-structured questionnaire (see Appendix 21 for provider interview guide) will guide the interviews. Questions will explore providers’ perceptions of (1) waiting times for adolescent mental health services, (2) the impact of long wait times on adolescents’ mental wellbeing, (3) strategies that have been implemented to address these wait times and the extent to which these yielded benefits, (4) perceptions of the proposed brief psychological treatment for adolescents waiting to access specialist mental health care, (5) perceived barriers and facilitators to implementing the intervention in usual services, (6) recommendations for the intervention format, structure (duration), delivery, and setting. Interviewers will be trained to instruct participants not to disclose any identifiable data. If any identifiable data is disclosed, it will later be removed or anonymized in the written transcript of the interview. Before beginning an interview, the interviewer will confirm that the participant is in a private location and is able to participate in the interview. We expect interviews to last 45 to 60 minutes. When the interview is complete, a study team member will upload the audio-recording to the Curtin R Drive; once uploaded, the study team member will delete the file from the recording device. Participants will receive a $35 Coles/Myer voucher as reimbursement for their time spent participating in the interview.

We will use the findings from these three sets of interviews to guide a further round of modifications to the intervention content and materials. Modifications will be documented using the FRAMES approach, with the reason for each modification, when it was made, and the nature of the change documented carefully. This next version of the intervention will be presented in a final round of stakeholder workshops with adolescents, parents, and providers.

***Objective 2: Intervention design and implementation strategy workshops***

We will invite interview participants to join either an adolescent, parent, or provider stakeholder workshop. The purpose of these workshops is multi-fold. First, we wish to present the next iteration of the intervention and intervention delivery protocols to obtain further suggestions for refinements prior to feasibility testing. Second, we wish to review the implementation barriers identified through the in-depth interviews and co-design strategies for overcoming these barriers. Third, we wish to build consensus and a roadmap about the steps required for implementation of the proposed intervention in WA’s CAMHS sector. The latter is commonly referred to as building a theory of change (ToC) or logic model for implementation (De Silva et al., 2014). Through these participatory workshops, we will identify steps required to achieve the goal (adoption and implementation of the intervention), activities to achieve each step, underlying assumptions, and indicators of success. We will integrate all findings and feedback into a final iteration of the intervention and intervention delivery protocols that will be tested for feasibility and acceptability in Phase Two of this study for which we will seek additional ethical approval.

Workshops will be conducted online using Microsoft Teams (See Appendix 22). The workshops will have three parts:

* First, the facilitators will briefly present the intervention prototype (each of the original intervention’s counselling sessions). Thereafter, participants will be asked to individually complete a brief 12-item Qualtrics survey on their perceptions of the feasibility, acceptability, and appropriateness of the intervention before sharing with the group their recommendations for how to enhance these aspects of the intervention.
* Second, the facilitators will split the group into two breakout rooms where sub-groups will be asked to play the CFIR card game (Piat et al., 2021). The purpose of this activity is to identify barriers to implementation of the intervention and match these barriers with strategies for overcoming these barriers. Adolescent and parent participants will focus on barriers within three domains: external context, intervention-related barriers, and intervention delivery. Provider participants will also be asked to identify barriers within their organizations (internal context) and the implementation process (the plan). More specifically, the facilitator will present a barrier card to the group and ask the following question: “Is this going to be a challenge/hurdle to implementing the intervention?” The answer will be reached through consensus. The facilitator will prompt for reasons and explanations. If the answer is “Yes” then this barrier will be posted onto an online mural board. We will then use the CFIR-ERIC Matching Tool v.1 (Waltz et al., 2019) to generate the top three expert-endorsed strategies for addressing each identified barrier. The group will be asked to discuss the feasibility and usefulness of these proposed strategies, and to generate alternative strategies for overcoming the barriers. These strategies will be posted on the online mural board and facilitators will take notes and observations of the group process.
* Third, we will bring these elements of the workshop together in a final discussion about the desired impact of the intervention, the short and medium-term steps and outcomes needed to achieve this impact, and indicators for each outcome. During this discussion, the facilitators will use an online mural board to develop a draft ToC map (logic model) that will visually depict the discussion and draft implementation plan (Andersen, 2004). ToC provides a mechanism for building consensus among stakeholders when planning for implementation as well as provide a framework for evaluation (Hernandez & Hodges, 2006).

The workshops will be audio-recorded, and notes will be taken. A study team member will upload the audio-recording of the workshop to the Curtin R Drive; once uploaded, the study team member will delete the file from the recording device. Workshop participants will receive a $50 Coles/Myer voucher as reimbursement for their time spent participating in the 2.5-hour workshop.

**1.5. Data analysis**

A framework analysis approach (Richie & Spencer, 1994) will be used to analyze qualitative data collected during Objective 1 and Objective 2 activities. Data will be analyzed separately for each objective and activity with findings from Objective 1 used to inform Objective 2. The framework method involves five key stages: familiarization, identifying a thematic framework, indexing, charting, mapping, and interpretation. Initial concepts will be identified based on the workshop discussion and interview guides. Concepts will be used to develop a codebook, and two trained independent coders will code each transcript. NVivo will be used to organize the data according to each code. The research team will review the coded transcripts to determine the emerging themes. Final themes will be agreed upon and interrater reliability of coding assessed. For the assessment of inter-rater reliability, we will calculate Cohen’s Kappa and we will strive for a Kappa of at least 0.8. For Objective 2, we will triangulate data from the 3 sets of stakeholders to identify strategies for addressing barriers to implementation and for enhancing the feasibility and acceptability of the proposed intervention.

1. **PHASE TWO**
	1. **Study Design**

This phase of the research is a randomised Type 1 hybrid implementation-effectiveness pilot study adopting a mixed methods approach to evaluating initial outcomes of the *Help While You Wait* program. This hybrid design seeks to simultaneously assess clinical (e.g., psychological distress) and implementation (e.g., acceptability, feasibility, fidelity) outcomes (Curran et al., 2012).

* 1. **Participants**

For this phase of the project, we plan to recruit three sets of participants: interventionists, adolescents, and parents/caregivers of adolescents who received the intervention.

* + 1. *Interventionist Participants*

We plan to train up to 10 interventionists to deliver the intervention, with each interventionist expected to deliver the intervention to up to 5 adolescent participants. To be eligible for study participation, interventionists must:

1. Complete the required training, demonstrate competency to deliver the intervention, and agree to participate in ongoing supervision,
2. Be able to speak English to complete informed consent and study procedures, and deliver the intervention, and
3. Either:
4. have prior experience of working with young people in WA at a youth/ health service, or
5. currently completing or recently completed 4th-year honours-level studies in Psychology at Curtin University, with some experience providing mental health support services.
	* 1. *Adolescent Participants*

We plan to recruit up to 80 adolescents to participate in Phase Two. To be eligible for this phase of the study, adolescents must:

1. Be 13-19 years of age,
2. Have consent from their primary caregiver to participate (adolescents 13-15 only),
3. Screen at risk for psychological distress on the K-10 (Scores ≥20; Kessler et al., 2002) or be seeking mental health services for psychological distress,
4. Be able to speak English to complete informed consent and study procedures, and
5. Not currently be at high risk of suicide (assessed using the Columbia Suicide Severity Rating Scale- Screen version; Cwik et al., 2020).
	* 1. *Parent/Caregiver Participants*

We plan to recruit up to 8 parent/caregivers to participate in qualitative interviews. To be eligible for study participation, caregivers must:

1. Be a caregiver of an adolescent assigned to the intervention, and
2. Be able to speak English to complete informed consent and study procedures
	1. **Participant Recruitment and Consent Procedures**

***2.3.1. Interventionist participants*** *(n~10)* will include a mix of youth workers and case managers from community youth services and students undertaking their 4th year of a Bachelor of Psychology (honours stream) at Curtin University.  We have identified youth centres and headspace mental health services where the intervention will be implemented. At the youth centres, we will train existing case managers working with youth with mental health difficulties to deliver the intervention. These case managers will be identified through the organization managers and sent an email invitation (Appendix 23) to participate in the study. The invitation will include a link to the online Interventionist Expression of Interest Form (Appendix 24), where interested Case Managers will be shown the Interventionist Information Sheet (Appendix 25) and the Implementation Overview (Appendix 26). In the EOI, interested Case Managers will be asked to provide their youth centre affiliation, name, contact email address and phone number, and their CV. EOIs will be reviewed by the research team and Case Managers will be contacted to inform them of the outcome of their EOI.

We will also train students as interventionists who will be embedded in community mental health services serving youth (e.g., headspace clinics). These students will be recruited through an online advertisement (Appendix 27) shared to Curtin University’s online education platform, Blackboard. The advertisement will include a link to the online Interventionist Expression of Interest Form (Appendix 24), where interested students will be shown the Interventionist Information Sheet (Appendix 25) and the Implementation Overview (Appendix 26). In the EOI, interested students will be asked to provide their name, contact email address and phone number, their CV, and a short description of their motivations for participating. EOIs will be assessed by the research team and students will be contacted to inform them of the outcome of their EOI.

Potential interventionists will be contacted by the research team to discuss the role and explain the two components to participation: 1) intervention training and delivery, and 2) evaluation of training and the intervention. From there, potential interventionists will be sent the Participant Consent Form and Pre-Training Survey (Appendix 28). In this form, they will be able to review and download the Interventionist Participant Information Sheet (Appendix 25) and will be asked to provide consent for their participation in each component. Interventionists who select “do not consent” will be prompted to provide a voluntary explanation for their selection. Each interventionist who provides consent will then be able to proceed to a pre-training survey. They will be assigned a unique participant ID#, which will be used to link data collected at various points.

***2.3.2. Adolescent participants*** (*n~*80) will be recruited in three ways: waitlist referral, interventionist-referral, and self-referral. At the community mental health services (headspace clinics), administrative staff will issue an invitation via recruitment flyer (Appendix 29) to all adolescents on waitlists for headspace counselling or who have been referred to other mental health services for which they are waiting who meet eligibility criteria for participation in the pilot study. The invitation will include a summary of the study and a link to the Adolescent Expression of Interest Form (Appendix 30). As interventionists at youth centres are already regularly engaging with adolescents who access their services, they are well-positioned to identify adolescents who may benefit from *Help While You Wait* even if they are not on a waitlist for mental health services. As such, interventionists at these youth centres will identify potentially eligible adolescents, tell them about the study opportunity, and direct them to the Expression of Interest (EOI) survey to sign up if they wish. We will ask our provider networks to distribute the Recruitment Flyer (Appendix 29) to eligible adolescents on their waiting lists. As described above, interested adolescents will be asked to complete the EOI Survey and be contacted per the procedures described above. Adolescents recruited through the flyer will be directed to a headspace clinic or one of our other partners where they will be able to receive the intervention.

Adolescents who access the EOI survey will be shown the Adolescent Information Sheet (Appendix 31) and asked to provide their name, age, postcode, current waitlist status, indicate their service affiliation (i.e., headspace centre, youth centre, self-referral), and provide their own contact details, and, if under 16 years of age, the contact details of their primary caregiver. The research team will review EOIs for participant eligibility before following the below process for obtaining informed consent:

* *If under 16 years of age*

Adolescents under 16 will only be able to participate if their primary caregiver consents to their participation. If the EOI is missing caregiver details, the research team will contact the adolescent to obtain this information. The research team will first contact the adolescent’s primary caregiver using the details provided in the EOI to explain study involvement and seek their consent for their child's participation. After this call, a member of the research team will send the caregiver a link to the Caregiver Information Sheet (Appendix 32) and Consent form (Appendix 33) in which they will be asked if they consent to their child’s participation in the trial and to a qualitative interview. Their response will be recorded electronically, using a ‘Yes, I consent’ or ‘No, I do not consent’ checkbox. Caregivers who select “do not consent” will be prompted to provide a voluntary explanation for their selection. Caregivers will be sent 3 reminders to complete the consent form (after 24 hours, 3 days, and 5 days). No response will be interpreted as non-consent and the adolescent will not be able to participate in the study. The research team will inform adolescents whose caregiver did not provide consent that they will not be able to participate. Once informed consent is obtained from the caregiver, the research team will contact the adolescent to explain the next steps, which are identical to those outlined below for adolescents 16 years or older.

* *If 16 years of age or older*

The research team will contact the adolescent to explain study participation, answer any questions the adolescent has about the study, and evaluate their capacity to consent as a mature minor using the Gillick Competency Assessment (Appendix 34). The adolescent will then be sent a link that will include the Adolescent Participant Information Sheet (Appendix 31) and a baseline survey that will have an embedded electronic consent form that will need to be completed before the adolescent can proceed to the survey questions (Appendix 35). Adolescents who do not consent to participate will be prompted to provide a voluntary explanation for their selection.

The first part of this baseline survey will screen consenting adolescents for eligibility based on their waitlist status, K-10 score and risk of harm. If eligible and at low risk of harm on the screener, the adolescent will be able to proceed to the second part of the survey. If the adolescent is screened at moderate or high risk of harm on the screener, the trial manager (a registered psychologist) will contact the adolescent to conduct a further, detailed risk assessment to determine whether the adolescent is at immediate risk. If the adolescent is not in immediate risk of harm, the *Help While You Wait program* will still be suitablefor the adolescent and the adolescent will be enrolled. If there is an immediate risk, the adolescent will not be enrolled and theprotocol outlined in the Risk Mitigation Plan (described in **section 3; Ethics** and Appendix 48) will be followed. Once enrolled, the adolescent will be assigned a unique participant identification number (ID#) that will be used to link their data across time points.

***2.3.3. Caregiver participants*** (*n* ~ 8) will be recruited via the Caregiver Information Form (Appendix 32) and Consent Form (Appendix 33), within which we will embed an invitation to participate in a Post-Intervention Interview. As part of this consent form, caregivers will be asked to indicate their consent to be contacted in the future for a qualitative interview. Caregivers can choose not to select this checkbox and their choice will have no impact on their adolescent’s participation. We will email caregivers whose children were assigned to receive the intervention and who gave consent to be contacted with an invitation to participate in the Post-Intervention Interview (Appendix 36) , which will include a link to the Caregiver Participant Information Sheet (Appendix 37) and the Caregiver Pre-Interview Survey (Appendix 38) that will have an embedded electronic consent form that will need to be completed before the caregiver participant can proceed to completing the pre-interview questions.

* 1. **Study Procedures**
		1. ***Interventionist training and training evaluation***

All interventionists will be required to complete 4 days of training in the intervention and intervention delivery. Prior to the training, interventionists will be asked to complete the Pre-Training Survey (Appendix 28), which will take no more than 10 minutes to complete. Participants will receive a $15 Prezzee gift voucher for survey completion. Interventionists will then complete the training, which will be facilitated face-to-face by CI Myers and the Trial Manager at Curtin University, Bentley campus. Trainers will present the *Help While You Wait* training package to interventionists, guiding them through four sections: Understanding Mental Health; Counselling Skills and Motivational Interviewing; The *Help While You Wait* Program; Tailoring the Program to Young People; Managing risk; Onward referral. Training will involve group discussions, reflections, and role-play activities to talk through challenging situations and practice learned skills. Interventionists will be provided with a printed training manual to support their learning and intervention delivery. Once training is complete, interventionists’ competencies to deliver the intervention, complete required administrative tasks, and manage risk will be assessed via observation of role-plays. Interventionists who successfully demonstrate competency will be able to proceed with intervention delivery.

Following the training, interventionists will be invited to complete the Post-Training Survey (Appendix 39), which will take no longer than 15 minutes to complete. Participants will receive a $15 Prezzee voucher following survey completion of the survey. Interventionists will also be invited to complete a Post-Training Qualitative Interview (Appendix 40) to further explore their experiences with and perceptions of the training. We aim to interview at least one interventionist from each implementation site (n~6). Interviews will last 45-60 minutes and will be conducted and audio-recorded via Microsoft Teams before being transcribed verbatim. If participants do not want to be video-recorded they will be instructed to turn their cameras off. Transcripts will be de-identified and linked to the participants’ survey data via their participant ID#. Audio-recordings will be deleted following transcription. Each participant will be given a $35 Prezzee voucher after completing the interview.

* + 1. ***Hybrid Type 1 Pilot Trial***
			1. ***Trial procedures***

***Figure 1*** depicts the trial design. Participants will be considered enrolled after completing the baseline survey for which they will receive a $15 gift card. The baseline assessment and all other measures are described in ***Table 2***.



After completing the online baseline assessment, adolescent participants will be randomly allocated to either the intervention or usual care comparison condition in a 1:1 ratio. Participants were randomly allocated in a 1:1 ratio to either the intervention or comparison arm. The randomisation sequence will be prepared by an independent statistician (using a computer program) and allocation will be done by the trial manager. The trial manager will contact adolescent participants after they have completed the baseline survey to inform them of their allocation based on the randomisation sequence. Investigators will be blind to the sequence generation. Participants allocated to the intervention condition will be assigned to an interventionist and appointments will be made for their counselling sessions. These will be spaced at least a week apart from each other. Participants will have six weeks from baseline assessment to complete all four sessions before timing out of the intervention. Participants assigned to the comparison condition will receive usual care offered by the implementation sites. See intervention description below in *2.4.2.2.*

*Follow up assessments*:

Irrespective of study arm, all participants will be asked to complete follow-up assessments at six-weeks (Appendix 41) and 10-weeks post-enrolment (Appendix 42). These will be online assessments. The six-week follow up will assess change in psychological distress, wait list status and perceptions of the intervention acceptability for intervention recipients, and feasibility of study procedures. The survey will take no more than 15 minutes to complete, and adolescents will have one week to complete it. Text and telephone reminders will be sent to adolescents who have not completed the survey within 48 hours. Each participant will be remunerated with a $15 Prezzee voucher for completing the survey.  The 10-week follow up assessment (Appendix 42) will assess maintenance of treatment outcomes and subsequent service utilisation. The survey will take no more than 10 minutes to complete. Participants will have 30 days from their scheduled 10-week appointment to complete the final follow-up assessment before timing out of that appointment. Text and telephonic reminders will be sent to adolescents who have not completed the survey within 48 hours. Each participant will be remunerated with a $15 Prezzee voucher for completing this assessment.

*Post-intervention qualitative interviews with adolescents, parents, and interventionists****:***

To further explore adolescents’ experiences with and perceptions of the intervention, we will conduct qualitative interviews with up to 15 participants who completed at least one intervention session. **Adolescents** assigned to the intervention condition will be contacted within one week of their first follow up assessment and invited to participate in the Post-Intervention Interview (Appendix 43) to explore perceptions of the intervention, barriers, and facilitators to participating in the intervention, and benefits of engaging in the intervention.

We will also invite **parents** of adolescents aged 13-15 to participate in a Post-Intervention Survey (Appendix 38) and Interview (Appendix 44) about their experiences with and perceptions of the intervention. Interviews will last 45-60 minutes and will be conducted and audio-recorded via Microsoft Teams before being transcribed verbatim. Transcripts will be de-identified and linked to the participants’ other data via their ID#. Audio-recordings will be deleted following transcription. Each participant will be remunerated with a $35 Prezzee voucher after completing the interview.

At the end of the trial period, we will also invite **interventionists** to complete a Post-Intervention Survey (Appendix 45) about their perceived acceptability and feasibility of intervention delivery procedures, which will take no longer than 15 minutes to complete. Participants will receive a $15 Prezzee voucher following completion of the survey. Interventionists will also be invited to participate in a Post-Intervention Interview (Appendix 46) about their experiences with and perceptions of the intervention and delivery procedures. Interviews will last 45-60 minutes and will be conducted and audio-recorded via Microsoft Teams before being transcribed verbatim. Transcripts will be de-identified and linked to the participants’ other data via their ID#. Audio-recordings will be deleted following transcription. Each participant will be remunerated with a $35 Prezzee voucher for completing the interview.

**Table 2**describes all the constructs measured in the trial.

|  |
| --- |
| **Table 2.** Measures used and data collected throughout Phase 2 |
| **Intervention training** | **Participants** | **Measures** |
| Pre -training survey | Interventionists | Demographic questions (age, gender, cultural/linguistic identity, residential postcode, role in the project, current profession, time in current profession, mental health-related qualifications); the 15-item Attitudes Toward Adopting Evidence-Based Practice scale (Aarons, 2004), and a 9-item measure of Confidence, Knowledge, and Skill to deliver mental health interventions. |
| Post-training survey | Interventionists | Attitudes Toward Adopting Evidence-Based Practice scale (Aarons, 2004); the 12-item Feasibility, Acceptability, and Appropriateness (Weiner et al., 2017) of the training; a 9-item measure of Confidence, Knowledge, and Skill to deliver mental health interventions; an 18-item Training Evaluation Scale; and three open-ended questions on the training and the intervention. |
| Post-training interview | Interventionists | Experiences and perceptions of the training procedures, the training evaluation and the intervention |
| **Hybrid Type 1 trial** | **Participants** | **Measures** |
| Baseline survey | Adolescent participants | Demographic questions (age, gender, cultural/linguistic identity, residential postcode, schooling, diagnoses, waitlist status); the 2-item Columbia Suicide Severity Scale (screen version); the 10-item Kessler Psychological Distress Scale; the 10-item Perceived Stress Scale; the 8-item Difficulties in Emotion Regulation Scale; and 21 items from the Multidimensional Problem-Solving Therapy Outcome Measure. |
| 6-week and 10-week follow up survey | Adolescent participants | Waitlist status and service use; the 2-item Columbia Suicide Severity Scale (screen version); the 10-item Kessler Psychological Distress Scale; the 10-item Perceived Stress Scale; the 8-item Difficulties in Emotion Regulation Scale; the 15-item Intervention Evaluation Intervention participants only); a 9-item Program Satisfaction measure; and the 24-item Multidimensional Problem-Solving Therapy Outcome Measure. |
| Process measures | Adolescent intervention participants | Session mental health check and session rating forms: relationship with interventionist, relevance/content of the session, helpfulness of approach, and overall satisfaction. |
| Interventionists | Intervention fidelity and competence ratings |
| Post-intervention qualitative interview | Adolescent intervention participants | Experiences of the intervention, with questions seeking to understand perceptions of its usefulness/helpfulness, content, materials, format, structure (duration), delivery, and setting. |
| Post-intervention feedback | Caregiver participants | *Pre-interview survey*: demographic information age, gender, cultural/linguistic identity, family composition and a 9-item Program Satisfaction measure. *Qualitative interview*: Experiences of supporting their adolescent while they completed the program, including benefits, challenges and impacts to themselves and their family. Interviews will also explore caregivers’ perceptions of the intervention, including the content, materials, format, structure (duration), delivery, and setting, and perceptions of their adolescent’s experience with the intervention.  |
| Post-intervention feedback | Interventionists | *Pre-interview survey*: demographic information Attitudes Toward Adopting Evidence-Based Practice scale (Aarons, 2004); the Feasibility, Acceptability, and Appropriateness (Weiner et al., 2017) of the intervention; a 9-item measure of Confidence, Knowledge, and Skill to deliver mental health interventions.*Qualitative interview*: Interventionists’ perceptions of: 1) delivering the intervention, 2) the interventions’ impact on adolescents, 3) the intervention’s impact on the interventionist, 4) barriers to effectively and efficiently delivering the intervention, 5) strategies adopted to support the delivery within the organisation, 6) perceptions of how the intervention was received by adolescents, 7) deviations of fidelity, and 8) recommendations for the intervention format, structure (duration), delivery, and setting. |

* + - 1. *Interventions*

Interventions will be delivered in a face-to-face format at the implementation site from where the participant was recruited or assigned (in the case of self-referral).

* *The Help while you wait program*.

Participants assigned to this condition receive four intervention sessions. The duration of each session is approximately 45-60 minutes (see **Table 3** for session overview). Each session functions iteratively to build readiness to change and adaptive problem-solving and coping skills. All sessions have a motivational component, a psycho-education component, and a problem-solving component. More specifically, participants will be taught steps for addressing problems that are important and can be solved; strategies for dealing with negative and intrusive worries; and steps for coping with problems that are important but cannot be solved. A client workbook, summarizing the content of the counselling sessions and containing worksheets to practice the problem-solving method, guides the intervention sessions. Adolescents will receive a PDF version of the Intervention Workbook and login details to access online intervention materials via the study website ([www.projectlyric.com](http://www.projectlyric.com/)) prior to their first session.

**Table 3:** **Session Overview**

|  |  |
| --- | --- |
| Session 1 | Introduction to programUnderstanding emotionsMental health as a continuum Understanding behavioural activation |
| Session 2 | Exploring valuesUnderstanding types of problems (categorised as green, yellow, or blue)Learning the problem solving technique (PST) for green problems that can be changedPractice using the PST |
| Session 3 | Learning how to manage yellow problems (intrusive thoughts and worries)Making a plan for managing yellow problems |
| Session 4 | Learning how to cope with blue problems (big problems that cannot be changed)Making a plan for blue problemsChecking in on mental healthDiscuss next steps |

At the start of each session, adolescents will complete of the Mental Health Check Survey (Appendix 47) for ongoing monitoring of their mental health. If risk of harm is evident, the interventionist will follow the Risk Management Procedure (**Section 3** of this protocol; Appendix 49) as outlined in the training and the clinical governance procedures of each implementation site. At headspace sites, interventionists will immediately report the increased risk of harm to the headspace Clinical Team Lead and the Trial Manager to discuss and determine appropriate action in accordance with the Risk Mitigation Plan. At the youth centres, interventionists will report the increased risk of harm to the centre manager and trial manager to discuss and determine whether the adolescent continues or exits the study and the additional supports required in accordance with the Risk Mitigation Plan (Appendix 48).

After each session, adolescents will complete the Session Rating Survey (Appendix 50) where they will rate their satisfaction with the following session aspects: relationship with interventionist, relevance/content of the session, helpfulness of approach, and overall satisfaction.   After each session, interventionists will complete a Session Record Form (Appendix 51) that records details about the session (e.g., session number, date, time started and finished, content covered/not covered, deviations from procedure), the adolescent (e.g., their unique ID#, any identified risks, main topics/issues discussed), and any other important notes.  Participants will not be restricted from accessing specialist mental health services or self-help (e.g., online resources) during their participation in the intervention.

* *Comparison arm: Usual Care*

Participants assigned to this arm will receive the usual care and support provided by their implementation site. This generally involves ongoing monitoring and case management while they wait for their appointment with a mental health provider. Participants assigned to this comparison condition will not be restricted from accessing specialist mental health services or self-help (e.g., online resources) during their study participation. At the end of their last follow up appointment and study involvement, we will offer participants assigned to this arm an opportunity to receive the *Help while you wait* intervention.

* + - 1. *Interventionist supervision and fidelity assurance*

Following training and continuing throughout the implementation of the intervention, interventionists will receive regular face-to-face and virtual supervision and debriefing provided by a registered psychologist in group and individual format. We have used this model of supervision successfully in our previous work (Jacobs et al., 2020). Supervision notes and feedback will be recorded using the Supervision Record Form (Appendix 52).

To assess and monitor treatment-specific and counsellor competency, we will audio-record all intervention sessions with consent from participants. We will randomly select one session from the total number of completed sessions of 15 participants to review. For treatment-specific competencies (often referred to as fidelity), an intervention delivery checklist will be used to assess whether the objectives of the intervention session were addressed adequately. Further, the Enhancing Assessment of Common Therapeutic Factors tool (Kohrt et al., 2015) will be used to measure core therapeutic competencies and skills thought to be required for an interventionist to adequately deliver any evidence-based intervention.

* 1. **Data analysis**

We will adopt a triangulation approach to data analysis, examining both qualitative and quantitative data from multiple informants and in multiple formats to examine the feasibility, acceptability, appropriateness, and efficacy of the training and the intervention. To evaluate the training, we will generate descriptive statistics to describe the sample of interventionists. We will then examine pre- and post-training data, comparing mean scores on the feasibility, acceptability, and appropriateness of the training, as well as interventionists’ perceived confidence, knowledge, and skill to deliver the intervention, and attitudes toward evidence-based practice. These comparisons will be descriptive in nature, as our sample will not be large enough to reliably conduct null-hypothesis significance testing. We will then combine interventionists’ responses to the quantitative and qualitative training evaluation questions to describe their experiences with and perceptions of the training. Qualitative data analysis will use procedures described in Phase one.

To evaluate the *implementation and clinical outcomes* of the intervention, we will generate descriptive statistics to describe the sample of adolescent participants, disaggregated by group (intervention vs comparison). Implementation outcomes (feasibility, acceptability, and fidelity) will be presented descriptively and participant flow through the trial will be presented in a standard CONSORT diagram. Descriptive statistics will be reported for all other relevant outcomes at each time-point by trial arm. Adjusted means differences will be calculated for secondary clinical outcomes (psychological distress, perceived stress, emotion regulation, problem-solving confidence) comparing intervention and control groups using linear regression models, adjusting for the baseline score of the given outcome. We will then use conventional content analysis to examine adolescent, caregiver and interventionists’ qualitative responses to open-ended questions and interview transcripts to gain further insight into their experiences with and perceptions of the intervention, as well as their feedback on the intervention’s delivery, format, and presentation.  We will then triangulate within and across methodology, method, and group (Campbell et al., 2020) to generate a comprehensive overview of the intervention’s feasibility, applicability, acceptability, and efficacy.

## 3. ETHICAL CONSIDERATIONS

**3.1. Informed Consent for Adolescents** (Phase Two)

For the informed consent of adolescent participants, we have stated that for adolescents aged 13 to 15, we will require consent from the primary caregiver and assent from the adolescent for their participation in the trial (Phase Two). For adolescents aged 16 and 17 we are requesting approval to use mature minor assessment during consent procedures. Our implementation partners use this as standard practice. For a 16 or 17 year old to be considered a mature minor they must be “sufficiently mature and intelligent to make health care decisions on their own behalf” and able to “fully comprehend the nature, consequences, and risk of the proposed action” (Department of Health WA, 2020). During the initial study call, the research team will assess referred adolescents who are 16-17 years old for mature minor status in alignment with the Department of Health’s *Guidelines for Protecting Children 2020.* For adolescents aged 16 and 17 who are deemed not competent to consent as a mature minor, primary caregiver consent will be required and sought. For those adolescents aged 18 and above, they are legally considered adults and will provide consent for themselves to participate in the trial.

**3.2. Potential risks to participants**

We foresee only minimal risk to participants for this study. We foresee the following risks: (1) as with all studies, there is a risk of improper disclosure of confidential information; and (2) mental discomfort or harm associated with study participation, and risk of coercion for interventionists. Each of these risks is discussed below.

***3.2.1. The risk of improper disclosure of information***.

As with all studies, there is a small risk of inadvertent breach of confidentiality. However, the probability of improper disclosure by staff is low because of the measures we will use in the proposed study. To minimise this risk, participants will be assigned a unique study identifier. This will be used to link their consent, screener (for adolescent participants), qualitative interview, and workshop discussion transcripts together in phase one. The interviews and focus group discussions will not collect personal identifying information. In the group discussions as part of the workshops, participants will be reminded to keep the content of the discussions confidential (not to share information about other participants). In Phase two, this identifier will be used to link their responses to all surveys and interviews (if applicable).

The personal information on the consent and contact information forms will be stored separately from participants' data (qualitative transcripts) in password protected folders on Curtin's secure R Drive. All project staff (research assistants, future students) and interventionists will receive intensive training in participant confidentiality procedures and sanctions if confidentiality is broken. The importance of confidentiality and case examples of confidentiality will be discussed during staff meetings, interventionist training and clinical supervision. The exception to these regulations includes threats of imminent harm to self or others. All staff will be trained in how to manage issues of harm to self or others that a participant might raise during data collection. All interventionists will be trained in how to manage issues of adolescent participant harm to self or others that a participant might raise during the intervention sessions. Participants will be informed of the need to breach confidentiality in such situations, and the informed consent/assent forms note these exceptions to confidentiality. All the proposed research and project staff will complete Curtin's Research integrity training and an online training course on Good clinical practice.

***3.2.2. The risk of psychological harm.***

***Phase One:***

It is unlikely, but there is a potential risk that some participants could experience psychological distress when reflecting on the intervention materials and discussing their intervention preferences in *Phase One*. Importantly, we are not asking participants to reflect on or share information about their psychological difficulties or past challenges in accessing support. Importantly we will screen adolescents to ensure their suitability and eligibility for the study. Adolescents will only be eligible if they are at low risk of suicide. Some have argued that these screening questions may be distressing; however, research suggests the contrary (e.g., Hasking et al., 2015). Instead of being distressing, research suggests that participants experience involvement in the design of mental health interventions positively, as they feel they are contributing positively to mental health services research. Research also suggests that at-risk groups can experience improved well-being after answering questions about sensitive topics, including risk of suicide (Hasking et al., 2015; Hasking et al., 2019; Idrees et al, 2021; Jorm, 2007; Robinson et al., 2011). Hence, we do not anticipate that adolescent participants will experience negative effects from study participation. Potential psychological discomfort that may arise from the eligibility screening or questions covered in the interviews or focus group discussion will be minimized by using experienced and well-trained interviewers and workshop facilitators and the option of referral to mental health services in the unlikely event of a participant being distressed. All members of our project team with direct participant contact are clinically trained and therefore well-placed to assess risk of distress and potential for harm. To minimise discomfort, participants will be informed at the beginning of the screening, interviews, and group discussions that they can refuse to answer any questions. They will be given an information letter at the start of the study which outlines the nature/type of questions asked. Participants will be advised that there is a minor risk that some people might experience discomfort. Participants will be advised in this information letter that they are under no obligation to complete the study activities, and that they can take a break or at any time without penalty. Participants will be provided with a list of resources/support services (e.g., Lifeline) that they can contact if they want psychological support. This list of resources will be provided at the end of the screening process to adolescents regardless of whether they are eligible for study participation. Screening will assess for risk of harm using standardised self-report assessments. Staff involved in discussions and interviews will be trained on how to identify distressed participants who may be at risk of harm. Dr. Preece, a registered psychologist, will be responsible for contacting these identified participants to assess their risk of suicide using established protocols to identify and manage these risks (see attached). In the highly unlikely event that an adolescent participant experiences a psychiatric emergency, Prof. Chen, a child and adolescent psychiatrist, will be available to assist Dr. Preece in risk mitigation to ensure that the participant receives appropriate services.

***Phase Two*:**

As with any psychological intervention, there is potential for participants to experience psychological distress when reflecting on their mental health. We have established robust risk management procedures to minimise and mitigate the risk of lasting impacts. All potential adolescent participants will be screened for suicide risk prior to enrolment to ensure their suitability and eligibility for the study. Adolescents will complete the Columbia Suicide Severity Scale- Screen version (Cwik et al., 2020) and, if identified as moderate-high risk, will be contacted for further assessment by the Caitlin Munro, who is a registered psychologist skilled in assessment and management of suicide risk. If adolescents are deemed at high risk, they will be supported to access services in accordance with the Risk Mitigation Plan. Adolescents will only be eligible if they are not at high risk of suicide. This process ensures that our participants are well enough to meaningfully engage in the study and minimises the risk of harm to adolescents in suicidal distress. Some have argued that risk screening questions may be distressing; however, research demonstrates that there is minimal risk (e.g., Hasking et al., 2015). In the highly unlikely event that an adolescent participant experiences a psychiatric emergency, Prof. Chen, a youth psychiatrist and Assoc. Professor Furlong will be available to assist Caitlin Munro in risk mitigation to ensure that the participant receives appropriate emergency psychiatric services.

The nature of this research necessitates questions about adolescents’ mental health, including experiences of personal problems, distress, stress, emotion regulation, and suicidality. As such, adolescents may experience psychological discomfort when completing research activities, including surveys, interviews, and the intervention itself. To minimise the impact of this potential discomfort, several strategies are in place:

* All interventionists will be trained to deliver the intervention in accordance with the Research Protocol and Risk Management Procedure
* All interventionists and members of the research team will be trained to assess and manage distress and risk of suicide
* All members of the research team will be trained to conduct all research activities in accordance with the Research Protocol and Risk Mitigation Plan
* All qualitative interviews will be conducted by trained and experienced interviewers
* All participants will be fully informed of what is involved in their participation, including the questions they will be asked, the activities they will be asked to complete, and the potential risks to participating in this project, with this information provided to them verbally and via the Participant Information Sheets
* All participants will be informed that their participation is voluntary, they can withdraw at any time, and they can choose to not to participate in any aspect of the research
* All participants will receive a comprehensive Resource Sheet at the EOI, Baseline, and (if enrolled) subsequent surveys including supports that they can access outside of the research project. This Resource Sheet will be downloadable within the surveys and accessible on the study website
* Participants receiving the intervention will receive weekly monitoring so that risk of harm can readily and quickly be detected.
* All participants in the trial will benefit from the intervention being implemented in usual care settings that have established clinical safety and governance procedures to protect adolescent participants from risk of harm and ensure rapid referral for psychiatric emergencies.

The risk of harm from completing the intervention sessions is also minimal, as the intervention has been built upon established therapeutic methods and has been implemented and evaluated in various forms and settings with positive outcomes (Myers et al., 2019; Sorsdahl et al., 2015; Spedding et al., 2020). The program also has clear boundaries in its scope, offering psychoeducation and problem-solving skills with limited exploration of personal experiences (i.e., we do not ask them to discuss their difficulties in detail) or adverse experiences. The scope of the intervention will be clearly defined with adolescent participants so they understand the limits of the intervention and have clear expectations of what they will receive and the potential benefits. Interventionists will be trained to keep the intervention within its intended scope and to respond appropriately to adolescent participants’ disclosure of information that may require follow-up. All interventionists will receive comprehensive training that includes risk identification and management protocols at an appropriate level for the interventionist role. We will assess risk of harm at the start of each session to ensure participant safety (Appendix 47). If risk of harm is evident, the interventionist will follow the Risk Management Procedure (Appendix 49) and the clinical governance procedures of each implementation site. At headspace sites, interventionists will immediately report the increased risk of harm to the headspace Clinical Team Lead and the Trial Manager to discuss and determine appropriate action in accordance with the Risk Mitigation Plan. At the youth centres, interventionists will report the increased risk of harm to the centre manager and trial manager to discuss and determine whether the adolescent continues or exits the study and the additional supports required in accordance with the Risk Mitigation Plan.  All interventionists will have access to fortnightly supervision as well as incidental supervision should the need arise. Supervision will be delivered by qualified psychologists who have been trained to provide clinical supervision.

Participants always retain the right to withdraw from the research and/or the program at any stage for any reason. In the unlikely event that harm occurs, the Trial Manager and Clinical Supervisor will collaborate to offer support and resolution. All necessary actions to reduce the risk of harm to others will be implemented. Any participants who feel that they have experienced harm or are at risk of harm due to the intervention can contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au to discuss concerns and lodge a complaint.

Instead of being distressing, research suggests that participants’ involvement in research of mental health interventions is often a positive experience, as they feel they are contributing to the improvement of mental health services. Research also suggests that at-risk groups can experience improved well-being after answering questions about sensitive topics, including suicide (Hasking et al., 2015; Hasking et al., 2019; Idrees et al, 2021; Jorm, 2007; Robinson et al., 2011). In Phase One, we did not have any incidents of psychological distress or adverse events, hence, we do not anticipate that adolescent participants will experience negative effects from the research activities.

***3.2.3. Risk of coercion for Interventionists*** (Phase Two)

Interventionists are participating in Phase two as both an implementer and a research participant. Therefore, interventionists hold dual roles. This could impact on interventionists’ participation in this project if they feel pressure to complete research activities. To reduce the potential for perceived or inadvertent coercion, a member of the research team not involved in the training, fidelity checking or supervision of interventionists will conduct the research activities involving the interventionists (i.e., surveys and qualitative interviews). All research data collected from Interventionists will be linked with an identifiable ID# but the data itself will be deidentified for analysis. Interventionists’ training will include a comprehensive explanation of their role within this project, clearly identifying what is considered within their role as an interventionist and what is considered within their role as a study participant. In all communications about research activities, it will be clearly stated that interventionists’ participation in these activities is completely voluntary. Furthermore, research activities will be remunerated with gift cards to further distinguish between interventionist activities and participant activities. Interventionists will be encouraged to discuss their dual role in supervision, and should any issues arise, they will be managed in accordance with principles for ethical practice to minimise any negative consequences to the interventionist, adolescent participants, and the research.

**4. PARTNERSHIPS AND COMMUNITY INVOLVEMENT**

In developing this project, we have consulted broadly with the CAMHS sector to ensure the project is aligned with the sector’s priorities. The following organisations have agreed to be part of a broad stakeholder advisory group: WA RACP and WAPHA (representing primary care providers); Youth Focus, Health360, and Lifeline representing nongovernmental organisations offering Tier 2 services; WAAMH, the peak body for the NGO mental health sector; YACWA, the peak body of the youth NGO sector; WA Child and Adolescent Health Service (Perth Children Hospital’s Crisis Connect Service and Community CAMHS representing publicly-funded Tier 3 services) who will provide program information to adolescents in the “missing middle”); South Metro Health Service (Fiona Stanley Hospital), who will provide program information to adolescents who present at ED and do not require acute services. The Mental Health Commission is also aware and supportive of the project- a representative will participate in our advisory group. For consumers and community stakeholders, we have formed a youth advisory group who have already provided input into our recruitment processes and questions.

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| **List of Appendices for Phase Two** |
| **Appendix\_##** | **Document Title** | **Document Type** |
| Apppendix\_23 | Interventionist Invitation – Case Managers | Recruitment |
| Apppendix\_24 | Interventionist Expression of Interest | Survey |
| Apppendix\_25 | Interventionist Information Sheet | Document |
| Apppendix\_26 | Pilot Implementation Overview | Document |
| Apppendix\_27 | Interventionist Flyer – Students  | Recruitment |
| Apppendix\_28 | Pre-Training Survey – Interventionists | Survey |
| Apppendix\_29 | Recruitment Flyer – Adolescents | Recruitment |
| Apppendix\_30 | Adolescent Expression of Interest | Survey |
| Apppendix\_31 | Adolescent Information Sheet | Document |
| Apppendix\_32 | Caregiver Information Sheet for Child | Document |
| Apppendix\_33 | Caregiver Consent Form | Survey |
| Apppendix\_34 | Gillick Competence Assessment | Document |
| Apppendix\_35 | Baseline & Screening Survey – Adolescents  | Survey |
| Apppendix\_36 | Caregiver Invitation | Recruitment |
| Apppendix\_37 | Caregiver Information Sheet for Self | Document |
| Apppendix\_38 | Pre-Interview Survey – Caregivers  | Survey |
| Apppendix\_39 | Post-Training Survey – Interventionists  | Survey |
| Apppendix\_40 | Post-Training Interview – Interventionists  | Interview Guide |
| Apppendix\_41 | 6-week Follow-Up Survey – Adolescents | Survey |
| Apppendix\_42 | 10-week Follow-Up Survey – Adolescents  | Survey |
| Apppendix\_43 | Post-Intervention Interview – Adolescents  | Interview Guide |
| Apppendix\_44 | Post-Intervention Interview – Caregivers  | Interview Guide |
| Apppendix\_45 | Post-Intervention Survey – Interventionists  | Survey |
| Apppendix\_46 | Post-Intervention Interview – Interventionists  | Interview Guide |
| Apppendix\_47 | Mental Health Check  | Survey |
| Apppendix\_48 | Project Risk Mitigation Plan | Document |
| Apppendix\_49 | Risk Management Procedure – Interventionists | Document |
| Apppendix\_50 | Session Rating Form | Survey |
| Apppendix\_51 | Session Record Form | Document |
| Apppendix\_52 | Supervision Record Form | Document |

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