ERIC (Emotion Regulation and Impulse Control): A Sustainable Program for Vulnerable Young People with AOD and Mental Health Issues.

Alcohol and Other Drugs Early Intervention Innovation Fund

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Abbreviations

AOD	Alcohol and other drugs
EBP	Evidence-based Practice
CICADA	Care and Intervention for Children and Adolescents affected by Drugs and Alcohol
ERIC	Emotion Regulation Impulse Control Intervention
FYRST	Follow on Youth Recovery and Support Team
LHD	Local Health District
HNE	Hunter New England
MERIT	Magistrates Early Referral into Treatment
NGO	Non-Government Organisation
NSW	New South Wales
SCHN	Sydney Children's Hospital Network
YDACS	Youth Drug and Alcohol Clinical Services

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Executive Summary

The NSW Health ERIC project conducted over the past 3.5 years offers rare insights into the mental health and substance use characteristics of vulnerable young service users, alongside many unique perceptions of the practitioners who are assigned the complex role of intervening to improve their social and emotional outcomes. The investigators of the ERIC study sought to address one of the most significant challenges facing the youth AOD sector - meaningfully improving outcomes of vulnerable young people with multiple and complex needs. Meeting this challenge is a necessity for all youth services in the coming 'COVID normal' period, to address the interrelated mental health and substance use comorbidities in vulnerable young people and to arrest their trajectories of social disadvantage and harm.

The primary purpose of this study was to implement ERIC, a novel skills based intervention co-designed with vulnerable young people. ERIC has been associated with improved social and emotional outcomes in vulnerable young people seeking treatment in youth AOD services across Victoria and NSW's Hunter New England region, when delivered alongside standard care. The investigators of this ERIC project examined an extended exposure to ERIC over a 3 month period to determine whether vulnerable young people showed improvement in meaningful markers of social and emotional wellbeing – e.g. school engagement, having prosocial peers, psychological wellbeing, symptoms of anxiety and depression and substance use. In this study, we sought to implement ERIC across eight AOD services (including NGO, LHD and LHN) with 100 vulnerable young people and 57 participating practitioners. The chief investigators implemented a research design that examined both young people and the practitioners and services they were accessing, to determine whether ERIC was adopted and implemented with young people and whether ERIC impacted their social and emotional wellbeing.

The ERIC project was met with several implementation challenges – the primary one being service and practitioner barriers that prevented ERIC from being delivered to young people with consistency and at a sufficient exposure ('dose'), to maximise outcomes. In spite of the limited exposure to ERIC, the study found mild improvements in young people's social engagement, engagement in extracurricular activities, and psychological wellbeing. However, no changes to school or vocational engagement or engagement with prosocial peers was determined. The investigators also found that young people reported mild improvements in their ability to regulate their emotions alongside moderate reductions in symptoms of depression, anxiety and stress and small reductions in their harmful use of cannabis and methamphetamine. These modest changes were observed in spite of the acute vulnerability of

participating young people (e.g. co-occurring mental health and substance use difficulties, histories of trauma and ongoing social disadvantage) and the limited exposure that many had to the ERIC skills.

In addition to improving the social and emotional wellbeing of vulnerable young people the chief investigators sought to explore the feasibility of implementing ERIC across the NSW youth AOD sector. In attempting to answer this question interviews about the barriers and facilitators contributing to the uptake to ERIC and other evidence based interventions were conducted with practitioners and managers across the participating services. Interviews revealed that services who adopted models of care which preferentially focused on *'building the therapeutic relationship'* rather than creating change through skill development, reported significant difficulties in integrating ERIC. Interestingly, many practitioners (largely in case management roles) also shared the belief that the delivery of evidence based skills interventions was outside of their 'role' as a support for the young person. Some practitioners adopted ERIC seamlessly into their practice, regardless of the clients presenting issues or complexity of needs. Others reported a resistance to adopting a new intervention in their practice, attributing the complexity or vulnerability of the client group as a barrier to their adoption of ERIC.

Finally, the ERIC study highlighted the significant barriers that exist in undertaking clinical research in real world settings with this population of vulnerable young people. Despite the willingness of young people to participate in the research, the lack of research capability at many of the NGO services in addition to the arduous ethics procedures required for participation in hospital sites meant that many young people were unable to be represented in this research study.

Chapter 1: Background

Context

Young people seeking treatment from Alcohol and Other Drug (AOD) services have significant mental health issues alongside their substance use concerns[1] which, if left untreated, pose an ongoing risk to their social and emotional wellbeing [4-6]. These young people are arguably one of the most vulnerable groups in society, due to their concurrent and interrelated mental health and substance use comorbidities, which present alongside significant histories of social disadvantage and trauma. However, in spite of the known morbidity and mortality associated with comorbid mental health and substance use issues[7], evidence-based interventions for vulnerable young people have traditionally focused on discrete problems such as drugs used (e.g. methamphetamine) or mental health disorders (e.g. depression) and encounter multiple implementation barriers because they are not developed in partnership with young people or youth practitioners and are inconsistent with the complex needs of vulnerable young people in AOD services.

The Emotion Regulation and Impulse Control (ERIC) intervention addresses these limitations and provides a program for young people with multiple and complex needs. ERIC was developed from the 'ground up' incorporating consumer and worker input alongside the identification of existing evidence-based strategies. ERIC specifically teaches young people how to regulate their emotions and manage impulsivity, two areas of social and emotional development that are impacted by childhood trauma and required to transition successfully through adolescence. ERIC skills have an empirical basis in helping young people to regulate their emotions, control impulsive responding and reduce psychological distress[6].

Vulnerable Young People with Multiple and Complex Needs

The target audience for the project was vulnerable young people with multiple and context needs. Young people seeking treatment from AOD services have significant mental health and substance use concerns[1] and more than often have histories of social disadvantage and trauma, including high rates of abuse, neglect, child protection involvement, family conflict, involvement in child protection services, early exposure to alcohol and other substances, low educational attainment and literacy and disconnection from prosocial protective factors such as schooling, family and community [4,8]. Early experiences of adversity disrupts the social and emotional development of these individuals which may impair the development of self-regulation mechanisms[9]. For example, the capacity to modulate emotions

and manage impulses leads to ongoing emotion dysregulation, impulsive behaviours and interpersonal difficulties during the adolescent developmental period, which is already characterised by increased negative affect and emotional lability[10,11]. This arguably contributes to continued trajectories of social and emotional disadvantage through adolescence to young adulthood, manifesting in disengagement from school or work, association with peers who engage in antisocial behaviour, involvement with the criminal justice system, self-harm behaviour, repeated risk taking, high levels of aggression, and continued contact with police and youth justice [10,12,13]. Indeed, baseline data from 867 young people (mean age 20.18 years) receiving treatment across primary mental health and AOD services in Victoria and New South Wales across several studies undertaken by the chief investigators supports this assertion. Participating services included youth primary mental health, youth community AOD (Government and non-Government), youth tertiary AOD, youth community health centres and youth justice departments. Findings showed that one-fifth of all young people had been involved in the criminal justice system, two-thirds had experienced homelessness (38.7%) and nearly two-thirds had engaged self-harm across their lifetime (62.3%). Moreover, 29 percent of all young people were not engaged in either work or study at the time of the survey. Taken together, the characteristics of young people engaged in these services paint a concerning picture of the complex interplay between early developmental trauma resulting in disruptions in social and emotional development, mental health, and developmental difficulties, all of which contribute to ongoing cycles of disadvantage[14].

The Novel Features of ERIC

ERIC is a modular cognitive and behavioural skills-based program that targets Emotion Regulation and Impulse Control, two transdiagnostic processes that underlie symptoms of the most common mental health and substance use disorders present in young people as indicated in a recent study conducted by the chief investigators. Both of these processes are developmentally impacted by trauma[15], and as such, skill building in these areas are essential for healthy social and emotional development[15,16]. Without these skills, vulnerable young people are more vulnerable to continue along a trajectory to developing more severe substance dependence, mental ill health and significant social problems[17,18]. ERIC is novel because unlike other evidence-based treatments for youth, it is transdiagnostic, does not require intensive group attendance, and in line with recommendations on youth participation, has been co-designed with young AOD service users[19].

ERIC's transdiagnostic approach focuses on underlying factors shared across disorders rather than diagnostic categories[20]. In a systematic review of 67 studies conducted by the Chief Investigators, changes in emotion regulation skills after psychological treatments were associated with reduced symptoms of psychopathology across five classes of mental health disorders: depression, anxiety, borderline personality disorder, substance use disorders and eating disorders[21]. These mental health issues were among the most common mental health co-morbidities found in the sample of young AOD service users by the chief investigators. In another study conducted in 2018 by the chief investigators[6], clinically significant symptoms of these five disorders were found to occur in over 75% of a cohort of 306 young people seeking treatment at youth AOD services in Victoria. The above research supports emotion regulation skill development as an important underlying mechanism and treatment target for young people with co-existing mental health and substance use disorders.

ERIC also aligns with the NSW Health Drug and Alcohol Psychosocial Interventions Professional Practice Guidelines[22] and has been adapted from the extensive evidenced-based Cognitive Behaviour Therapy (CBT) and Dialectical Behaviour Therapy (DBT) based treatments for anxiety, depression, disordered eating, borderline personality disorder, deliberate self-harm, and substance use disorders. ERIC was developed through a three-year participatory research program in partnership with Victoria's YSAS and Hunter New England LHD[23]. ERIC promotes sustained practice, coaching and intentional emotion regulation skill building and was designed to be delivered as an adjunct to existing service models across sectors that work with vulnerable young people. ERIC was developed to overcome known barriers to the implementation of evidenced based interventions and was designed in a modular fashion to aid integration with the diverse psychosocial interventions commonly delivered by these sectors (e.g., life skills training, restorative justice, anger management, offending behaviour programs, case management, youth outreach support, AOD and primary mental health). The modular framework permits practitioners to deliver the intervention flexibly in accordance with the emotion regulation needs of their specific clients[24]. Furthermore, ERIC's sensitivity to the challenges of adolescents and the stages of social and emotional development, aligns closely with a recent Substance Use and Young People Framework proposed by the NSW Ministry of Health[25].

ERIC's Evidence Base to Date

In an initial ERIC acceptability pilot[26], a case series (*n* = 10) was conducted with young people receiving treatment in a residential AOD setting, with complex needs and comorbid mental health issues, demonstrated clinically significant changes in: (1) deficits in awareness

and understanding of emotional experience; (2) use of effective strategies to control emotions; (3) avoidance of emotions (i.e. use of drugs, alcohol to cope) and; (4) ability to engage in goal directed behaviour when distressed. ERIC subsequently underwent a series of acceptability pilot studies conducted in Victoria, NSW and QLD[32]. During 2015 - 2016, ERIC pilots were conducted in: (1) a residential AOD service in Victoria; (2) a drop-in AOD service in Queensland with predominantly ATSI clients; (3) 14 regional youth AOD services in Victoria and; (4) across the Drug and Alcohol Clinical Services of Hunter New England Health Service in NSW. Pilot data ($n = 79$; Mean age 19.3 years) in a single arm trial of ERIC delivered by Youth AOD practitioners showed statistically significant decreases in anxiety and stress and increases in emotional regulation skills in young people. Moderation analysis revealed that the change over time in emotion dysregulation moderated the change over time in symptoms of distress, depression, anxiety and stress, providing preliminary evidence for the role of emotion regulation as a key treatment target in this population[27]. Qualitative outcomes of these studies have indicated ERIC is: developmentally appropriate, applicable across the spectrum of AOD use; appropriate for different literacy levels; culturally relevant for young people from culturally diverse backgrounds and Aboriginal and Torres Strait Islander backgrounds; and acceptable to LGBTIQ+ young people and young offenders. While the evidence base for ERIC is building in relation to mental health symptoms and emotion regulation skills, an important question of whether exposure to emotion regulation interventions has an impact on broader social and emotional wellbeing, such as engagement in prosocial behaviour and improvement in quality of life, is yet to be undertaken. This extension to the evidence base for ERIC was the focus of the current project, along with important aims regarding feasibility and implementation.

Known Challenges in Treating Young People

Current Approaches Do Not Account for Client Complexity

Despite growing recognition of the multiple and complex needs of the young people accessing AOD treatments, few evidence-based interventions that address social and emotional wellbeing in young people with substance use and mental health difficulties have been implemented across the youth AOD sector. Some barriers to widespread adoption of these interventions include intervention characteristics, such as session-by-session manuals that are not developmentally appropriate, or protocols that focus on one mental health issue rather than multiple comorbid mental health and substance use issues associated with histories of childhood trauma [28-30]. These forms of interventions are an imperfect fit for youth AOD settings because they fail to address the complex patterns of mental health comorbidity

and interrelated psychosocial difficulties and complex trauma that are often that are present in young AOD service users[29].

Implementation and Workforce Barriers

Evidence-based interventions that *do* account for the complex interplay of difficulties in vulnerable young people through targeting core underlying construct (i.e. emotion regulation in DBT[31]) require significant practitioner training and involve service adoption of complex therapeutic practices, processes and behaviours and thus face significant implementation challenges. For example, the DBT model entails a comprehensive program that structures the treatment environment across multiple modalities to enhance the client's capabilities (skills training group), improve motivation (individual therapy), aid generalisation of new skills (telephone skills coaching), and supervise DBT therapists (consultation team model)[32]. Thus while DBT represents an effective treatment for co-occurring mental health and substance use difficulties[33-35], its format represents a feasibility challenge for many services and young people presenting to AOD settings. DBT implementation is often not feasible for young service users with chaotic presentations, sporadic attendance and difficulties adhering to a structured group program. In addition, treatments such as DBT present significant workforce challenges in that they require costly resource in both training and implementation (i.e. require staff to be highly qualified with many DBT studies requiring masters or doctoral-level training[36]) and have a strong theoretical and practical understanding of the treatment and attendance at regular case supervision. These requirements are often inconsistent with AOD service models and funding structures characterised by comparatively brief episodes of care, delivered by staff who often do not have professional backgrounds and/or competencies in the delivery of structured evidence-based interventions[37,38].

Frameworks of care that underpin treatment approaches at many youth AOD services also present notable implementation challenges. For example, trauma-informed care is a service level approach that is sensitive to the way in which clients' presentation and service needs can be understood in the context of their trauma history[39]. While this framework provides a set of core principles to inform treatment delivery (i.e. safety, trust, choice, collaboration, empowerment and culture[40]), it does not provide guidance on how to implement specific psychological skills to address the sequalae of trauma related emotional and behavioural challenges that young clients may experience.

In summary, young people accessing AOD services present with complex mental health and substance use concerns and more than often have histories of sexual, emotional

and physical trauma and/or neglect[4,6]. Early childhood trauma results in emotion dysregulation, impulsive behaviours and interpersonal difficulties[41,42]. While our current approaches to young people have a strong evidence base, challenges to their implementation mean that widespread adoption, implementation fidelity, and sustainability of evidence-based practices remains a rarity in front line youth services[43,44]. Although the gap between evidence and routine practice is not unique to youth services, the added acute vulnerability of the population of young people seeking treatment in youth AOD and mental health services makes this gap particularly deleterious. ERIC is an innovative program that teaches emotion regulation and impulse control skills. Skill development in these areas aims to address social and emotion issues, substance use and mental health difficulties that interfere with major protective factors such as engagement in school and prosocial behaviours. ERIC acknowledges known implementation barriers which exist for practitioners and services and provides flexible and modular resources that emphasize clinical freedom and can be integrated into a broader care-planning model (i.e. Trauma-informed Care) or delivered alongside existing evidence-based treatments (i.e. CBT, MI or ACT). Unlike most evidence-based treatments that follow a linear and prescribed format, ERIC has been developed as a modular resource and can be used as stand-alone materials. ERIC has been designed to be delivered by practitioners without extensive clinical training and it does not rely on large amounts of assumed knowledge from previous sessions. ERIC also addresses young people's needs in a manner that incorporates developmental considerations specific to this cohort.

Project Overview

The purpose of the current project was twofold: 1) to determine the impact of ERIC on social and emotional outcomes, mental health and AOD use for vulnerable young people with multiple and complex needs and; 2) to determine the practicality and feasibility of implementing ERIC across a diverse range of youth AOD services and to inform the policy and workforce training requirements needed to implement ERIC to scale across the NSW Health youth sector, to ultimately improve outcomes for vulnerable young people. The study was a comprehensive multi-site feasibility and implementation single arm trial utilising mixed-methods data and had aims relating to each of the two areas of examination.

The project aims relating to the social and emotional outcomes for young people were to examine:

1. Changes in **prosocial behaviours** in young people following exposure to ERIC; Prosocial behaviours were measured by:

a. Quality of life (physical wellbeing, psychological wellbeing, autonomy and parents, peers and social support, school environment).

b. Engagement in school, treatment, work, extracurricular activities and presence of prosocial peers.

2. Changes in **emotion regulation, mental health and substance use** outcomes in young people following exposure to ERIC; Emotion regulation, mental health and AOD outcomes were measured by:

a. Difficulties with emotion regulation.

b. Anxiety, depression and stress symptoms.

c. Harmful substance use.

The project aims relating to the **practicality** and **feasibility** of implementing ERIC to inform the design of an **implementation model** for delivery of ERIC to scale across NSW Health were measured by:

1. Quantitative examination practitioners' knowledge, attitudes and behaviours towards evidence-based practice.

2. Practitioner engagement and attrition in delivery of ERIC.

3. An economic estimation of training and implementation costs.

4. Qualitative data via semi structured interviews to examine practitioner experience of engagement with ERIC and key facilitators and barriers to implementation.

Chapter 2: Project Governance and Methodology

The project was funded as part of AOD Early Intervention Innovation Fund and aligned with priority focus areas for NSW:

a) Vulnerable young people
b) Delivering accessible, evidence-based and coordinated care for young people with multiple and complex needs.

A comprehensive multi-site feasibility and implementation single arm design was chosen in consultation with NSW Health during the grant review process, utilising both quantitative and qualitative data. The project methodology was necessarily complex to address the aims. The study examined social and emotional outcomes of a sample of young people who have multiple and complex needs. It evaluated a workforce development and implementation model and examined policy implications for the broader NSW youth AOD context. The project was ambitious in that it was conducted across diverse hospital and community youth AOD services and recruited partners from both LHD and NGO services in metropolitan Sydney and Newcastle and regional NSW in the Hunter. Chapter two outlines the project governance structure and project methodology.

Project Governance and Phases

This project was funded by the NSW Ministry of Health through a competitive translational research grant awarded in 2017 through the AOD Early Intervention Innovation Fund. It was undertaken through a combined research practice partnership between Deakin University and Hunter New England Local Health District with a team of investigators with experience in clinical and translational research. The project was governed by an Expert Advisory Group (EAG) which was composed of the chief and associate investigators from academic institutions (Deakin University and University of Newcastle), senior clinical leaders from each participating NGO, LHD and Speciality Health Network and the project manager. A project team and the project manager reported into the EAG and consisted of the designated research assistants and officers across the sites.

This project occurred across three phases to account for delays in ethics approval at hospital sites. Phase 1 included all NGO sites and commenced in January 2018, governed through Deakin University Human Research Ethics Committee. Phase 2 commenced at HNE LHD in February 2019 and Phase 3 at SCHN, Sydney LHD and St Vincent's in October

2019. Phase 2 and 3 sites were governed by Hunter New England Health Hospital Human Research Ethics Committees governed the research at each of the hospital sites. Figure 1 provides a schematic representation of the ethical governance of the study, which occurred in collaboration with numerous ethics committees and boards.
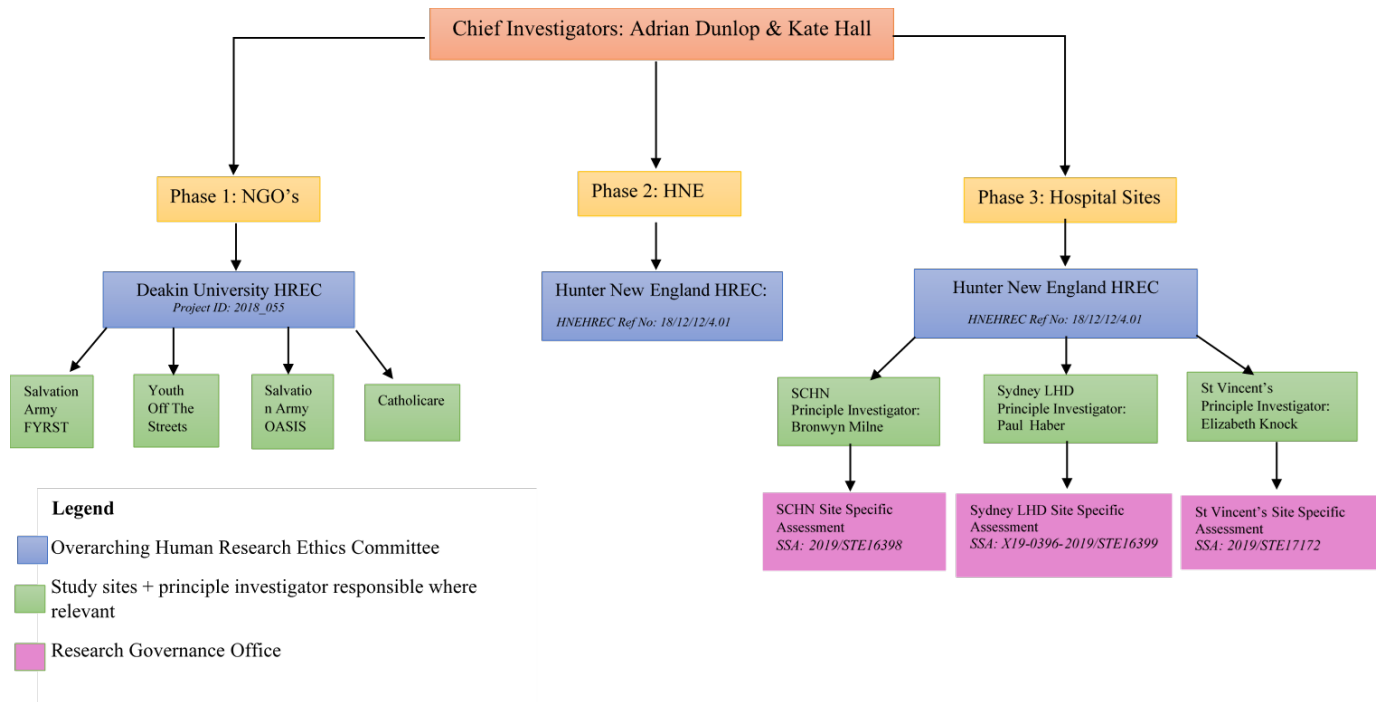
Figure 1. Research Ethics Governance structure of the ERIC project

Chief and Associate Investigators

The research team was led by Chief Investigators Conjoint Professor Adrian Dunlop (HNE LHD) and Dr Kate Hall (Deakin University) who both have extensive experience in driving and implementing clinical research. Associate investigators included: Professor Amanda Baker (University of Newcastle), Associate Professor Petra Staiger (Deakin University), Dr Angela Simpson, Dr Natasha Perry (HNE LHD), Dr Richard Moulding (Deakin University), Dr Arvind Kendurkar (HNE LHD) and Dr George Youssef (biostatistician, Deakin University). All team members have expertise in both research and clinical practice and were ideally placed to provide a "real world" implementation trial within busy youth service systems. The research team had the primary purpose of providing oversight of the research protocol and research deliverables with investigators from research sites providing site specific direction to ensure the research deliverables were met. ERIC developer Dr Kate Hall facilitated the ERIC training workshops.

Research Team

A research team was led by project manager Dr Elise Sloan and included a team of research assistants based at Deakin University, HNE LHD and SCHN. The project manager and research team were responsible for recruitment, data collection and analysis. Chief investigator meetings were held on a regular basis whereby project updates were provided and issues with implementation at each site were discussed.

Participating Services and Project Partners

A broad range of services across the NSW AOD sector were recruited to the project. Services were recruited during the grant process through written invitation and partnered in the study with endorsement from senior management, who delegated a project lead practitioner or manager. Services included a mix of NGO's (i.e. Salvation Army FYRST, Salvation Army Oasis, Youth Off The Streets and Catholicare) and local health district or networks (i.e. Hunter New England LHD, Sydney LHD and Sydney Children's Hospitals Network), which ensured that the NSW AOD sector was broadly represented. Senior staff at each participating organisation were identified and involved in the Expert Advisory Group during their active phase of the project. Regular stakeholder meetings and weekly communication with both senior staff and practitioners at participating sites occurred throughout the recruitment and implementation phases of the project. Table 1 provides detailed information of each service involved in the project.

Table 1

Participating Organisations and Services

Organisation	Lead Practitioner or Manager	Service Name	Description
Youth Off The Streets	Ms Eisa Madani: Program Manager.	Dunlea Alcohol and other Drug Youth Service.	For young people (13-19 years) with varied levels of substance use and motivation. Includes information and assessment, harm minimisation groups, referral, and case management. Can also provide one-to-one counselling.
Catholic Care		Holyoake Family AOD Program.	Offers group education, therapy and support programs for families impacted by substance dependence.
Salvation Army	Mr Dimitri Poulos: Therapeutic Programs Manager.	Oasis Youth Support Network.	Therapeutic services for young people aged 16–25-years experiencing disadvantage or homelessness. Services include: counselling, therapeutic groups and education programs.
Salvation Army FYRST	Ms Michelle Smith: Coordinator.	Youthlink – FYRST.	A specialist youth service for young people aged 12-15-years-old, providing: intensive case management, vocational training, support for rehabilitation and detox, crisis intervention and vocational training for young people across Greater Western Sydney.
		Youthlink - headfirst.	Specialised AOD and mental health counselling services to young people aged between 12-25 years old. Co-located at headspace services.
Hunter New England	Melinda Benson: Clinical Coordinator.	Youth Drug and Alcohol Clinical Services.	Youth specific drug and alcohol service for young people aged 12-18 years offering assessment, counselling, treatment and case management.
		Stimulant Treatment Program.	Assessment and counselling for individuals over 16-years of age concerned with stimulant use.
		Cannabis Clinic.	Assessment and counselling for individuals over 16-years of age concerned about their cannabis use.
		MERIT Program.	Drug diversion scheme through NSW Courts that provides case management, counselling, detox and rehabilitation for individuals over the age of 18 with AOD issues who are eligible for bail.
		Community Drug and Alcohol Services.	Psychosocial counselling for individuals over the age of 18 at community health services throughout the HNE Region.
Sydney Children's Health Network	Dr Bronwyn Milne: Paediatrician and Addiction Medicine Specialist.	CICADA Adolescent Drug and Alcohol Service.	Adolescent Specific Drug and Alcohol Service for individuals aged 10-18-years in a tertiary paediatric hospital. CICADA provides assessment, medical consultation, psychology and family intervention for adolescents with substance use.
Sydney LHD	Professor Paul Haber: Clinical Director, Drug Health Services, Sydney LHD.	Drug and Alcohol Services: Consultant and Liaison at Royal Prince Alfred.	Specialist AOD services operating in hospital settings to provide consultation advice regarding the management of AOD related issues for referred patients, and liaison and enhancing the capacity of generalist health providers to address AOD issues in their routine clinical work.
		Drug and Alcohol Services: Community Youth.	Drug and Alcohol Counselling for young people aged 12-15 years.
St Vincent's Hospital	Dr Elizabeth Knock: Senior Psychologist.	The Burton Street Centre – Youth Alcohol and Drug Services.	Counselling service for young people aged 16-25 who have difficulties with alcohol or other drugs with a focus on methamphetamine and other stimulants. Services include individual counselling, assessment and referral, medical services.

Project Design

The project design and methodology was registered in June 2018 through the Open Science Framework[45]. This registration is available in Appendix A. The study was a comprehensive multi-site feasibility and implementation single arm trial utilising mixed-methods. Further information on the project design and methodology are provided below according to each study aim. The study protocol specific for HNE is also provided in Appendix B for further reading.

Project Aim One: Social and Emotional Outcomes of Young People

Project aim one relating to changes in primary (quality of life, prosocial behaviours) and secondary outcomes (emotion regulation, mental health and substance use) were examined through a multi-level design compromising repeated measures data (two time points of self-report data by young people; a maximum of 12 time points of practitioner recorded data). The two timepoints of self-report data was collected from young people at baseline (T1) and immediately following a three-month active intervention period (T2). Data pertaining to both primary and secondary outcomes was also collected by practitioners at each contact that they had with the young person throughout the three-month intervention period. This was for a maximum of 12 data collection points assuming that a young person has contact with a practitioner weekly for three months. The study procedure pertaining to this aim is presented schematically in Figure 2 and in more detail in the text below.

Step 1: Recruitment of Young People and Completion of Baseline Assessment (Time 1)

Young people were recruited to the study by their treating practitioner who was provided with a number of resources to assist them with this process. The young person was eligible to participate if they were aged between 16-25 years and had the capacity to provide written informed consent. Young people were excluded from participating if they were experiencing an acute crisis presentation (e.g. intoxication or withdrawal episode, severe depressive episode requiring hospitalisation, active suicidality, intellectual disability i.e. unable to provide informed consent). The inclusion/exclusion criteria differed slightly between sites based on the ethical committee that gave study approval for each site. An example of the participant information sheet provided to participants at HNE is provided in Appendix C.

Once young people had consented to participate they were invited to completed a baseline assessment in person or over the phone with a member of the research team. A comprehensive list of measures is outlined in Table 2.

A number of strategies were put in place to enhance recruitment of young people across all services:

- Young people were contacted via multiple modalities to complete the baseline assessment (i.e. SMS and phone).
- Flexibility for the young person to complete the assessment over the phone when it suited them (including after hours).
- Appropriate reimbursement ($30 grocery voucher) provided to young people upon completion of the assessment.

Additional Research Support Provided at NGO Sites

NGO organisations had minimal experience in conducting clinical research projects and therefore required additional support in the recruitment of both practitioners and young people as well as adherence to the research protocol. Consequently, a number of steps were put in place to reduce the research burden on practitioners to support the participation of these organisations. For example, practitioners from the NGO sector were not required to obtain informed consent from young people. The research protocol for these sites was developed so that practitioners had minimal involvement in recruitment. Practitioners were required to identify eligible young people and pass their contact details to the research team who would then contact the young person to: 1) assess their eligibility; 2) obtain informed consent; 3) complete the baseline assessment.

Step 2: Intervention Delivery

Participating young people received ERIC as an adjunct to their existing treatment provided by their practitioner over a period of three months. At each session practitioners collect data pertaining to the young person's psychosocial functioning, engagement in prosocial behaviours and drug and alcohol use. An example of the measure used to collect this data is available in Appendix D. Table 2 provides details on the measures administered. At mid treatment (6 weeks into the intervention), telephone contact from a researcher occurred with an invitation for the young person to update their primary contact details.

Step 3: Follow-Up (Time 2)

Immediately after the three-month intervention period, young people completed a follow-up assessment over the phone or in person with a researcher (see Table 2) and received a $30 grocery voucher as compensation. A number of retention strategies were implemented across all sites to reduce the risk of participant attrition for young people. These included:

i. Phone call or SMS with young person at midpoint (halfway through intervention period) to update contact details and check in with intervention progress.

ii. Ongoing contact with practitioners to document client engagement.

iii. Attempted contact with young person through multiple modalities for follow-up (i.e. emails, text message, phone call).

iv. Flexibility to complete follow up assessments while young person was in session with their practitioner.

v. Appropriate reimbursement for completion of follow-up ($30 grocery voucher).
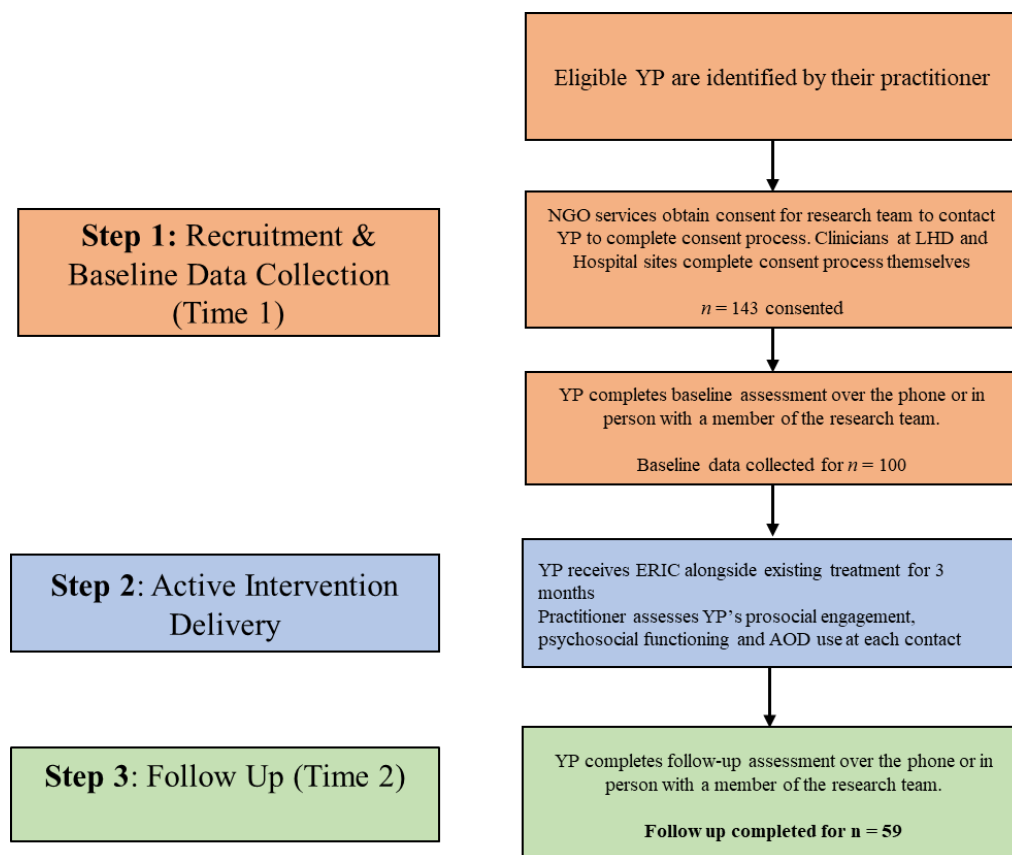
Figure 2. Schematic representation of procedure for study aim 1.

Project Aim Two: Feasibility and Practicality of Implementation

Project aim two pertaining to the practicality and feasibility of ERIC to inform an implementation model for delivery to scale were examined through a mixed-methods approach.

Step 1: Recruitment, Baseline Assessment and Training

Eligible practitioners were identified by managers at each site and invited to attend the ERIC training and participate in the study. Practitioners were eligible if they met the following requirements: (a) have a minimum of 5 young people (16-25 years) on their caseload who require support and; (b) work in a role that provides clinical services in the form of treatment, case management, counselling or outreach. Practitioners who registered to be involved in the study were required to:

- Complete a baseline assessment consisting which consisted of demographics, questions, education and workforce and attitudes towards EBP. An overview of these measures is provided in Table 2.
- Attend a two-day training workshop which provided an overview of the research requirements and the ERIC intervention. Learning methods employed in the workshop included didactic, role-plays, case discussion and small group activities.

Step 2: Implementation of ERIC

Practitioners delivered ERIC as an adjunct to their existing treatment with young people on their caseload who signed up to the study. Practitioners were provided with a suite of ERIC resources and materials including: the manual for the intervention (Appendix E); access to a series of written and digital resources including training videos on the ERIC website; A4 double sided skills worksheets outlining all skill building exercises; wallet cards with skills prompts; a USB containing all printable worksheets; ERIC pads which recorded social and emotional outcomes and A5 abbreviated and simplified 'easy to read' versions of all worksheets and; fortnightly coaching emails embedding an ERIC skill with an accompanying 'how to' video. Practitioners are also provided with fortnightly coaching emails that include coaching videos and further information to assist with implementation. All practitioners were also offered a one-on-one coaching session to troubleshoot any difficulties in adherence or implementation.

Step 3: Follow-Up

Practitioners completed a follow up questionnaire (see Table 2). Qualitative semi-structured interviews were also undertaken with managers from each participating site alongside a subset of practitioners. Questions in the semi-structured interview aimed to

explore practitioner experience and engagement with ERIC in addition to key facilitators and barriers to implementation. Quantitative analysis was used to provide economic estimation of training and implementation costs and practitioner engagement.

Study Measures

A comprehensive list of measures is outlined in Table 2 and in Appendix B in the HNE Study Protocol.

Table 2

Outcome Measures for Young People and Practitioners.

Outcome Measures	Descriptions	Baseline	Intervention	Follow-up
Young People				
Demographic and Lifestyle Factors	Basic demographics, cultural background, accommodation, family dynamics, criminal history, exposure to child protection domestic violence, engagement in education or work, pro-social and anti-social peers, physical health, treatment history, mental health.	x		
Depression, Anxiety and Stress Scale (DASS-21) [46]	The DASS-21 is a 21-item self-report questionnaire used to assesses symptoms of depression, anxiety and stress which are rated on a four-point Likert scale ranging from 0 (*did not apply to me at all*) to 3 (*applied to me very much, or most of the time*).	x		x
Difficulties in Emotion Regulation Scale (DERS-SF) [47]	The short form of the DERS is an 18-item measure that assesses individuals' typical levels of emotional dysregulation across five separate domains: 1) non-acceptance of negative emotions; 2) inability to engage in goal directed behaviours when experiencing negative emotions; 3) difficulties controlling impulsive behaviours when experiencing negative emotions; 4) limited access to emotion regulations strategies perceived as effective and; 5) lack of emotional clarity.	x		x
NIDA modified Alcohol, Smoking and Substance Involvement Screen Test (ASSIST) [48]	The NIDA modified ASSIST was adapted from the Alcohol, Smoking and Substance Involvement Screen Test developed by the World Health Organisation. This measure generates a substance involvement score that indicates the severity and complexity of substance use.	x		x
KIDSCREEN-27[49]	A self-report measure of quality of life across five domains: 1) physical well-being; 2) psychological well-being; 3) autonomy and parent relation; 4) social support and; 5) peers, and school.	x		x
Social and Occupational Functioning Assessment Scale (SOFAS)[50]	The SOFAS is a one-item rating of consumer functioning scored 0-100 and is intended to assess social and occupational functioning independently of the severity of psychological symptoms.		x	
Practitioner Recorded Engagement in Prosocial Behaviors	Structured questions, administered by practitioner, assessing engagement in prosocial behaviours over the past two weeks including the number of days engaged in school, work, and extracurricular activities; the number of nights with stable accommodation, days 'hanging' out with friends; rating of social, physical and mental health on a scale of 0 (not at all) to 5 (very much so), and service utilisation (Centrelink, AOD, housing, DOCS, GP).		x	
Practitioner Recorded Alcohol and Substance Use	Alcohol and substance use measured by how many days consuming alcohol/substances over past two weeks and amount of alcohol/substances consumed on typical occasion.		x	

Practitioners				
Demographic and Work-Related Factors	Gender, age, country of birth, Aboriginal or Torres Strait Islander descent, job title, sector, type of workplace, number of years in sector, highest level of training or qualification, training or qualification in specialist AOD work, client contact hours and interventions typically used.	x	25	
Evidence-based Practice Profile Questionnaire (EBPPQ)[51]	The EBPPQ is a 74-item self-report measure comprising 5 domains of EBP (Relevance, Terminology, Confidence, Practice and Sympathy). Only the Relevance (i.e., the value, emphasis or importance placed on EBP) and Sympathy (i.e., the compatibility of EBP with professional work) were included.	x		x
Evidence-based Practice Attitudes Scale Questionnaire (EBPAS)[52]	The EBPAS is a 15-item self-report measure that assesses willingness to adopt EBP based upon its appeal, requirements from external sources, general openness to innovation and perceptions of divergence between EBP and current practices.	x		x
Semi-Structured Interview	Acceptability of ERIC and participation in research component of study.			x

Chapter 3: Study Outcomes Relating to Young People

Young people seeking treatment from AOD services have significant mental health and substance use concerns[1] which, if left untreated, pose an ongoing risk to their social and emotional wellbeing. ERIC promotes healthy social and emotional development in young people by building **E**motion **R**egulation and **I**mpulse **C**ontrol skills to help manage emotions, urges and decision making in order to navigate the immense social and emotional demands of young adulthood. The development of healthy social and emotional wellbeing is protective against ongoing trajectories of mental ill health, substance use and social disadvantage. Quality of life and engagement in prosocial behaviours are standard ways of measuring social and emotional wellbeing.

The following chapter addresses the study findings relating to outcomes for young people who received ERIC. The project aims relating to the social and emotional outcomes for young people were to examine:

1. Changes in **prosocial behaviours** in young people following exposure to ERIC;
   Prosocial behaviours were measured by:
   a. Quality of life (physical wellbeing, psychological wellbeing, autonomy and parents, peers and social support, school environment).
   b. Engagement in school, treatment, work, extracurricular activities and presence of prosocial peers.
2. Changes in **emotion regulation, mental health and substance use** outcomes in young people following exposure to ERIC;
   Emotion regulation, mental health and AOD outcomes were measured by:
   a. Difficulties with emotion regulation.
   b. Anxiety, depression and stress symptoms.
   c. Harmful substance use.

Participant Characteristics

It is becoming increasingly acknowledged within the clinical research literature that young people seeking treatment from youth AOD services often present with significant mental health alongside their substance use concerns and have histories of significant disadvantage and trauma[4,8]. As this section illustrates, the sample of young people recruited

into this study were highly representative of the sub-population of young people characterised as having multiple and complex needs, as evidenced by their sociodemographic, mental health and substance use characteristics.

Sociodemographic Characteristics of Young People in the Current Study

A total of 100 young people were recruited into the study. The sample had an average age of 19.6 years, just over half were male (55%) and most were Australian-born (85%). More than one-fifth (21%) of young people identified as Lesbian, Gay, Bisexual, Transgender/gender diverse, Intersex and Queer (LGBTIQ+) and 15 percent identified as Aboriginal or Torres Strait Islander. The majority of young people reported that they had been involved in the criminal justice system (53%), almost half had experienced homelessness (48%) and almost one-third had experienced family violence across their lifetime (32%). According to ratings made by their treating practitioners, the literacy and numeracy levels of most young people in the sample was rated to be in the "ok" or "good/excellent" range; however, 5 percent and 6 percent of young people were rated as having literacy and numeracy levels in the "poor/cannot manage" range respectively. Forty one percent of the sample had completed Grade 10, 15 percent had completed Grade 12 and 20% had engaged in higher education. Relevant sociodemographic characteristics of the sample are presented in Table 3.

Key Findings

- 21% of young people identified as LGBTIQ+.
- 53% of young people had been involved in the criminal justice system and 48% of young people had experienced homelessness in their lifetime.
- 41% of the sample had completed Year 10.

Table 3

Sociodemographic Characteristics of Young People (N = 100)

	n	%
Gender		
Male	55	55%
Female	43	43%
Other	2	2%
Australian-born	85	85%
Identifies as Aboriginal or Torres Strait Islander	15	15%
Identifies as LGBTIQ+	21	21%
Educational Attainment		
Has not completed Grade 10 [a]	24	24%
Has completed Grade 10	41	41%
Has completed Grade 12	15	15%
Higher Education[b]	20	20%
Child Protection Services Involvement	18	18%
Criminal Justice System Involvement	53	53%
Experienced Family Violence	32	32%
Experienced Homelessness	48	48%
Practitioner-rated Literacy (n = 69) [c]		
Cannot Manage / Poor	5	5%
OK	26	28%
Good / Excellent	38	41%
Practitioner-rated Numeracy (n = 63) [c]		
Cannot Manage / Poor	6	7%
OK	23	25%
Good / Excellent	34	37%
	M	*SD*
Age	19.58	2.89

Note. LGBTIQ+ = lesbian, gay, bisexual, transgender/gender diverse, intersex, queer, asexual, different [non-straight] identity; a: includes the portion of participants that were still in Grade 10; b: any study completed after high school, including certificate, diploma, apprenticeship or university; c: percentages displayed are derived from the entire sample of practitioners for whom a case file audit was completed (N = 92) to acknowledge missing data. Practitioner-rated literacy and numeracy were measured on 5-point Likert scale (0="Cannot Manage"; 1="Poor"; 2="OK"; 3="Good; 4="Excellent"). Items 0-1 and 3-4 were combined.

Mental Health Characteristics of Young People

Mental Health Diagnoses.

As expected, 77 percent of young people had been diagnosed with a comorbid mental health disorder across their lifetime. As per Figure 3, most young people had been diagnosed with a mood (58%) or anxiety/obsessive compulsive (OCD) disorder (56%), whereas only 3 percent had been diagnosed with an eating disorder.
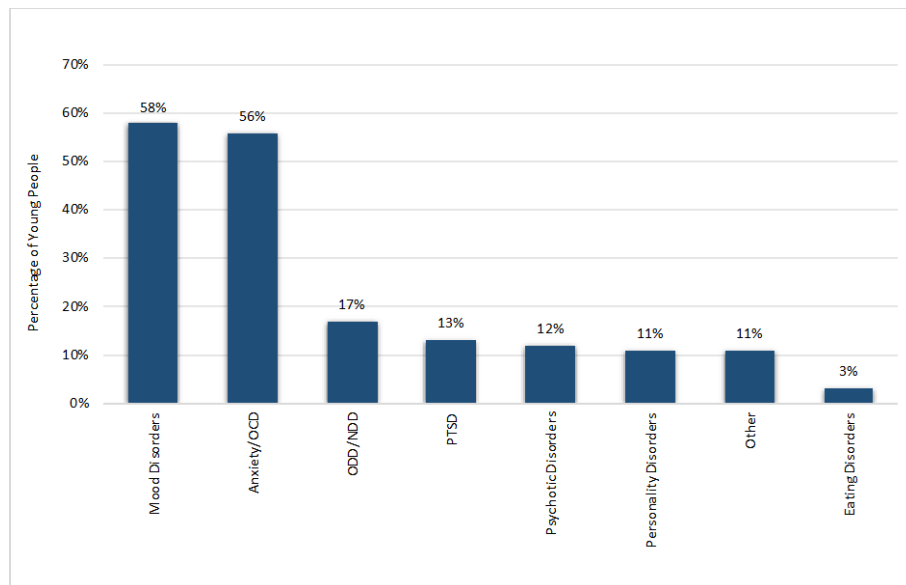
Figure 3. The percentage of young people that had been diagnosed with or treated for a specific mental health disorder (N = 100).

Key Finding

- Mental health comorbidity was the norm in the sample of young people.
- Over half of young people had been diagnosed with mood and anxiety/OCD disorders, more than nine times the population prevalence for depression and four times the population prevalence for anxiety[3].
- 12% were diagnosed with psychotic disorders, more than 26 times the population prevalence of psychotic illnesses[3].

Mental Health Disorder Complexity.

The vulnerable young people in the present sample had complex needs, with the majority having been diagnosed with at least two mental health disorders (61%), or with three or more diagnoses (32%). Only 17 percent of young people in the sample had been diagnosed with one mental health disorder, and 22% had no mental health diagnosis (Figure 4).
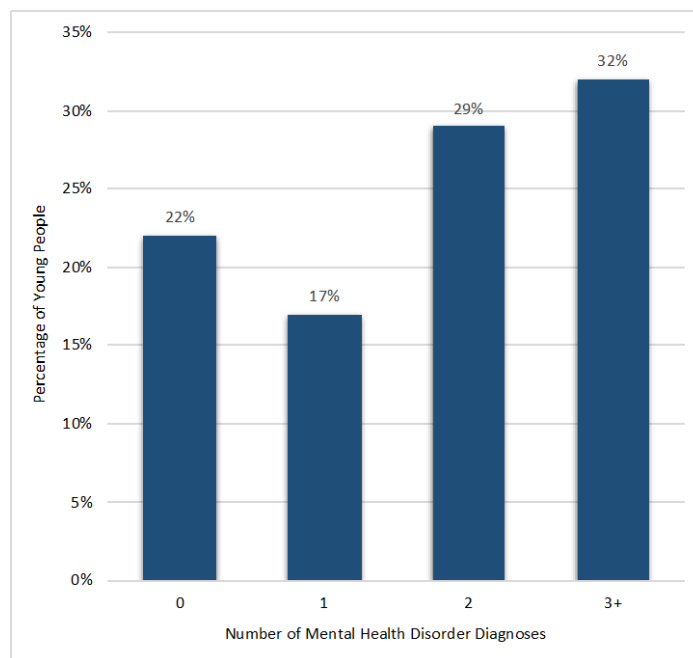
Figure 4. The percentage of young people diagnosed with 0, 1, 2 or 3+ mental health disorders.

Key Finding

61% of young people had two or more mental health diagnoses, indicating multiple and complex mental health issues alongside their AOD use.

Self-harm and Suicidality.

According to their treating practitioners, 40 percent of young people had engaged in self-harm across their lifetime and 28 percent had attempted suicide (Figure 5).
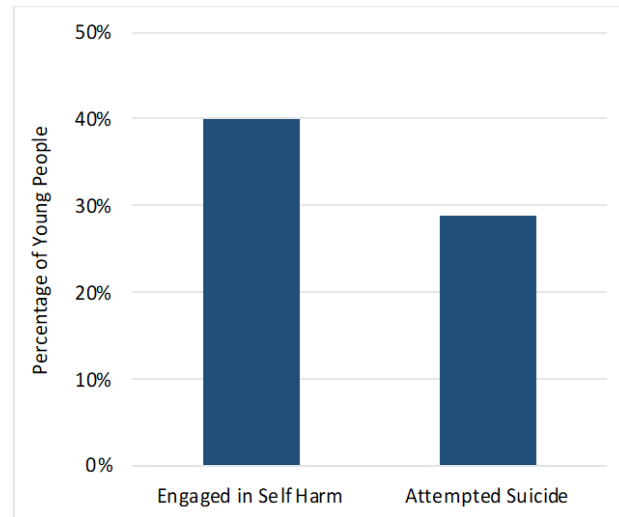
Figure 5. The percentage of young people who had engaged in self-harm or attempted suicide across their lifetime.

Key Finding

The sample of young people had historical risk factors that were significant, including 28% of young people had attempted suicide and 40% had engaged in self-harm.

Substance Use Characteristics of Young People

Harmful Drug Use.

Young people started using alcohol and other drugs at a young age. On average, young people were 13.8 years-old ($SD = 2.8$) when they first used alcohol and 14.2 years-old ($SD = 2.4$) when they first used other drugs. Further, 83 percent of young people had used tobacco in the past six-months. The overwhelming majority of young people harmfully used alcohol or other drugs (91%). As shown in Figure 6, most young people used cannabis harmfully (74%), followed by stimulants (38%) and alcohol (36%).
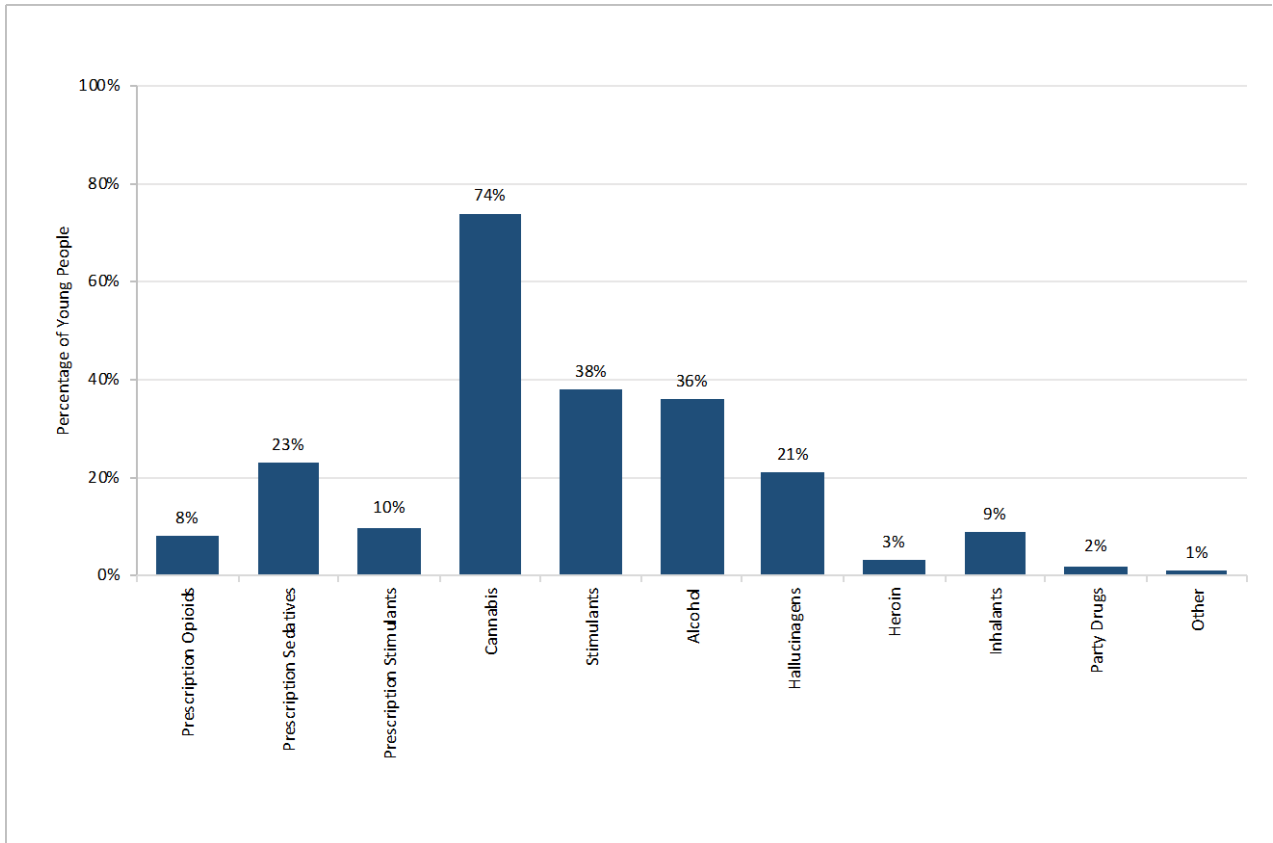
Figure 6. The percentage of young people who engaged in harmful drug use across different drug categories.

Key Findings

- 83% of young people had used tobacco in the past six-months.
- 91% of young people reported *harmful* use of drugs or alcohol.
- Most young people used cannabis (74%), stimulants (38%) and alcohol (36%) harmfully.

Polysubstance Use.

Use of multiple substances was common, with almost half of all young people reportedly having engaged in use of drugs from at least two different drug categories in the last three months (49%), whereas 39 percent reported only using one drug category (see Figure 7).
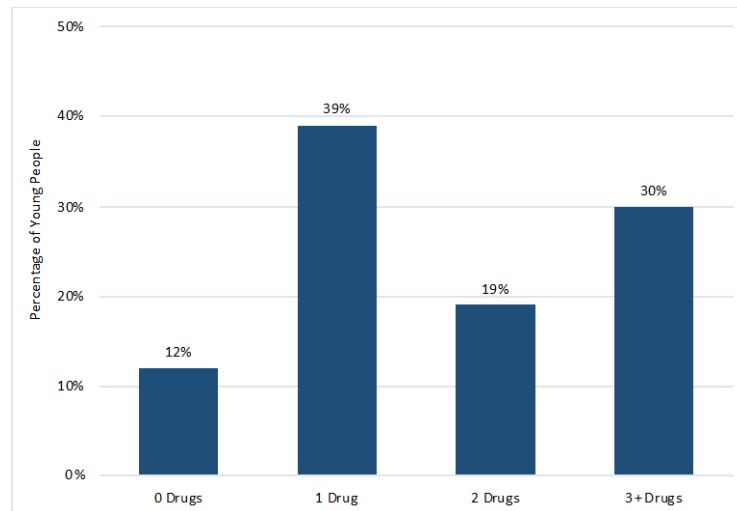
Figure 7. The percentage of young people who had used 0, 1, 2 or 3 or more different drug categories in the last three-months. Please note, polysubstance use does not include tobacco use.

Key Finding

Consistent with the picture of vulnerable young people with multiple and complex needs, almost half of all young people in the sample used multiple substances (49%).

Key Recommendations

1. The essential competencies of the AOD workforce need to include LGBTIQ+ sensitive practice; the ability to reduce symptoms of high prevalence disorders, such as depression and anxiety and; risk management skills, including the management and reduction of suicidal ideation and self-harm.
2. Tobacco-use interventions and strategies needs to be prioritised, alongside harm reduction strategies and relapse prevention for illicit substance use, particularly cannabis use.
3. Given the high proportion of young people engaged in the criminal justice system, there is a critical need to develop systems of care that coordinate across Youth AOD and criminal justice.

Improvement in Prosocial Behaviours Reported by the Young Person

Prosocial behaviours are critical protective factors against mental ill-health and AOD use and therefore, were a primary outcome for this study. Despite the short-term nature of the intervention (i.e., three-months) and the relatively low number of treatment sessions that young people were able to receive in this time period, young people reported significant improvements to their prosocial behaviours (Figure 8). Specifically, young people reported a significant increase in their social life rating from baseline to follow-up, and the size of this increase was in the small range ($dz = .32$)[a] according to Cohen's guidelines[53]. Similarly, young people reported a significant increase in the number of hours they engaged in hobbies and extracurricular activities from baseline to follow-up, and the size of this increase was in the small range ($dz = .35$). Young people reported no significant changes to their engagement with prosocial peers, engagement with antisocial peers or their engagement in education and work.
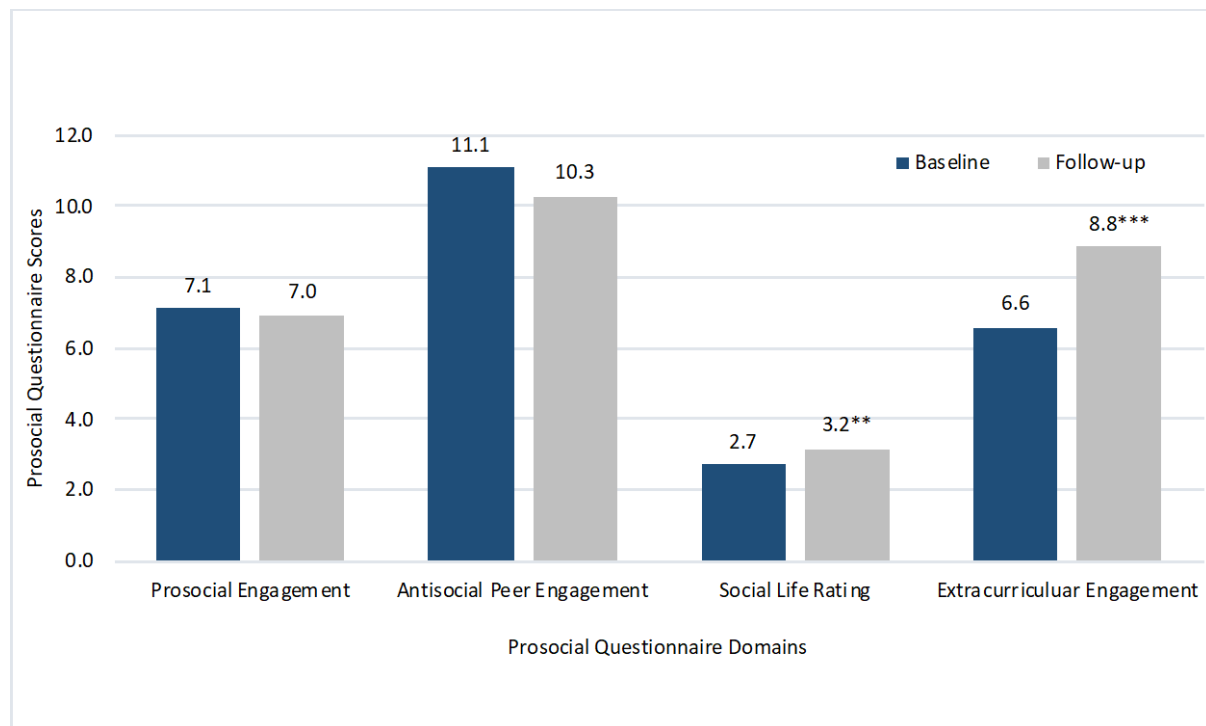
Figure 8. Prosocial outcomes at baseline and follow-up. *Note.* * $p < .05$; ** $p < 0.01$; *** $p < .001$

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[a] An effect size is a common way to measure the magnitude of change in scores between two timepoints. We used Cohen's *dz* which quantifies the magnitude of change in participant mean scores from baseline to follow-up in standard deviation units. According to Cohen's guidelines, *dz* values of 0.20, 0.50 and 0.80 correspond to small, moderate and large effects. For example, a *dz* value of 0.32 equates to a 0.32 standard deviation increase in young people's social life rating from baseline to follow-up and corresponds to a small effect.

Improvement in Prosocial Behaviours Reported by the Practitioner

At the end of each treatment session, the treating practitioner completed a SOFAS, and a brief questionnaire on the young peoples' social, physical, mental health and AOD use. Practitioners reported a significant improvement to young peoples' SOFAS score and mental health over time, suggesting that for every one standard deviation increase in number of treatment sessions that a young person attended, their SOFAS score increased by .11 standard deviations ($p < .001$, $\beta = .11$). No other significant changes were reported.

Key Findings

- Young people reported significant, albeit it small, improvements to their social life and extracurricular engagement from baseline to follow-up.
- For every treatment session that a young person attended, practitioner ratings of their social and occupational functioning (SOFAS) significantly increased.

- Young people reported no significant changes to their engagement with prosocial peers or their engagement in education and work – two highly protective prosocial outcomes.

Improvement in Quality of Life Reported by the Young Person

As shown in Figure 9, young people reported significant improvements to their psychological wellbeing from baseline to follow-up and, the size of this improvement was in the small range (*dz* = .35). Young people reported no significant change to their physical wellbeing, social support, parental autonomy and their school environment.
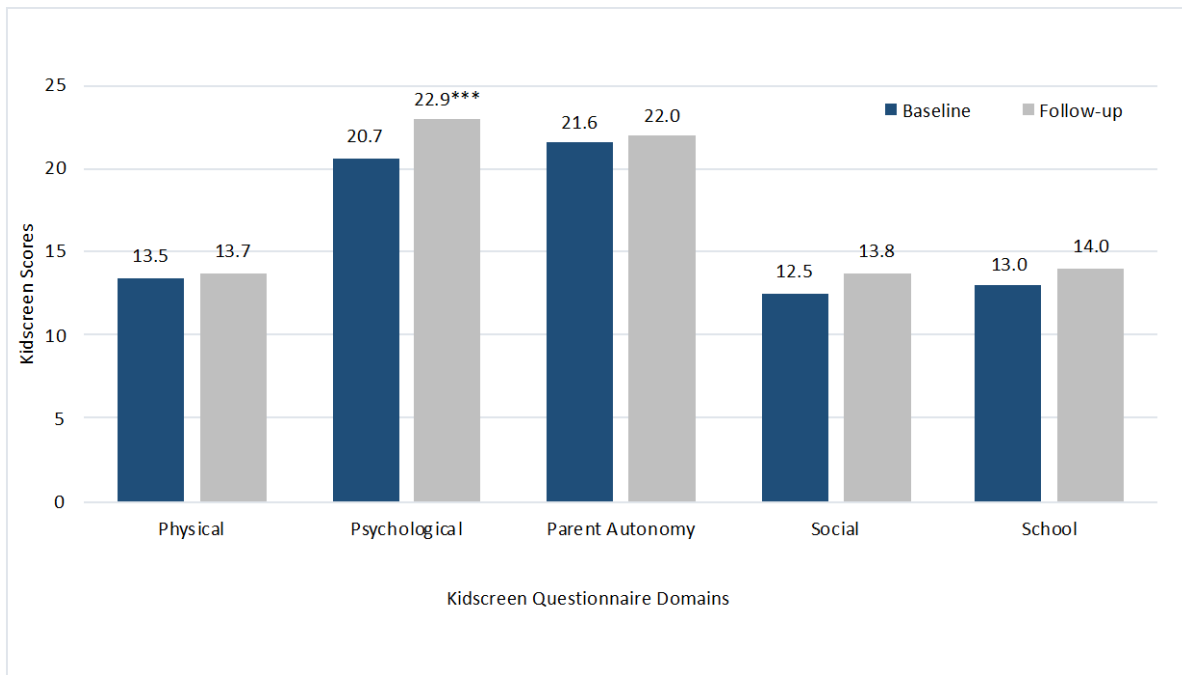
Figure 9. Kidscreen questionnaire scores at baseline and follow-up. *Note.* * *p* < .05; ** *p* < 0.01; *** *p* < .001.

Key Finding

- Young people reported significant, albeit small, improvements to their psychological wellbeing from baseline to follow-up.
- Young people reported no significant change to their physical wellbeing, social support, or their school environment.

Improvement in Emotion Regulation and Mental Health

As shown in Figure 10, young people reported a significant reduction in their emotion regulation difficulties from baseline to follow-up as measured by the DERS and the size of this reduction was in the small range ($dz = -.30$). Similarly, young people reported significant reductions to their symptoms of depression, anxiety and stress from baseline to follow-up as measured by the DASS-21 and, the size of these reductions were in the moderate range ($dz = -.62, -.59$ and $-.65$ respectively).
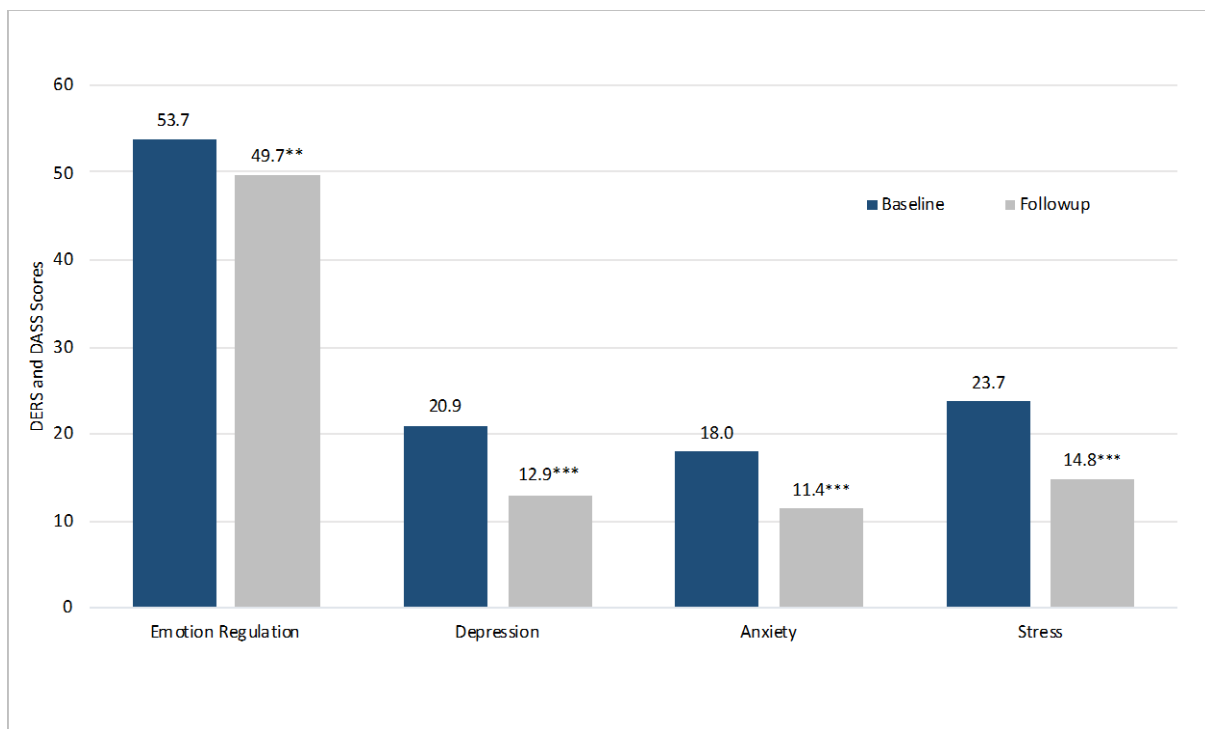
Figure 10. Emotion Regulation and Depression, Anxiety and Stress at baseline and follow-up. *Note.* $* p < .05; ** p < 0.01; *** p < .001$

Key Findings

- Young people reported significant reductions, of moderate magnitude, to their symptoms of depression, anxiety and stress.

- Young people reported significant, albeit small, reductions in emotion regulation difficulties.

Improvements in Alcohol and Drug Use

As per Figure 11, young people reported significant reductions to their harmful cannabis and methamphetamine use from baseline to follow-up, both of which were in the small range (dz = -.36 and -.23). No other significant changes to harmful drug use were found.
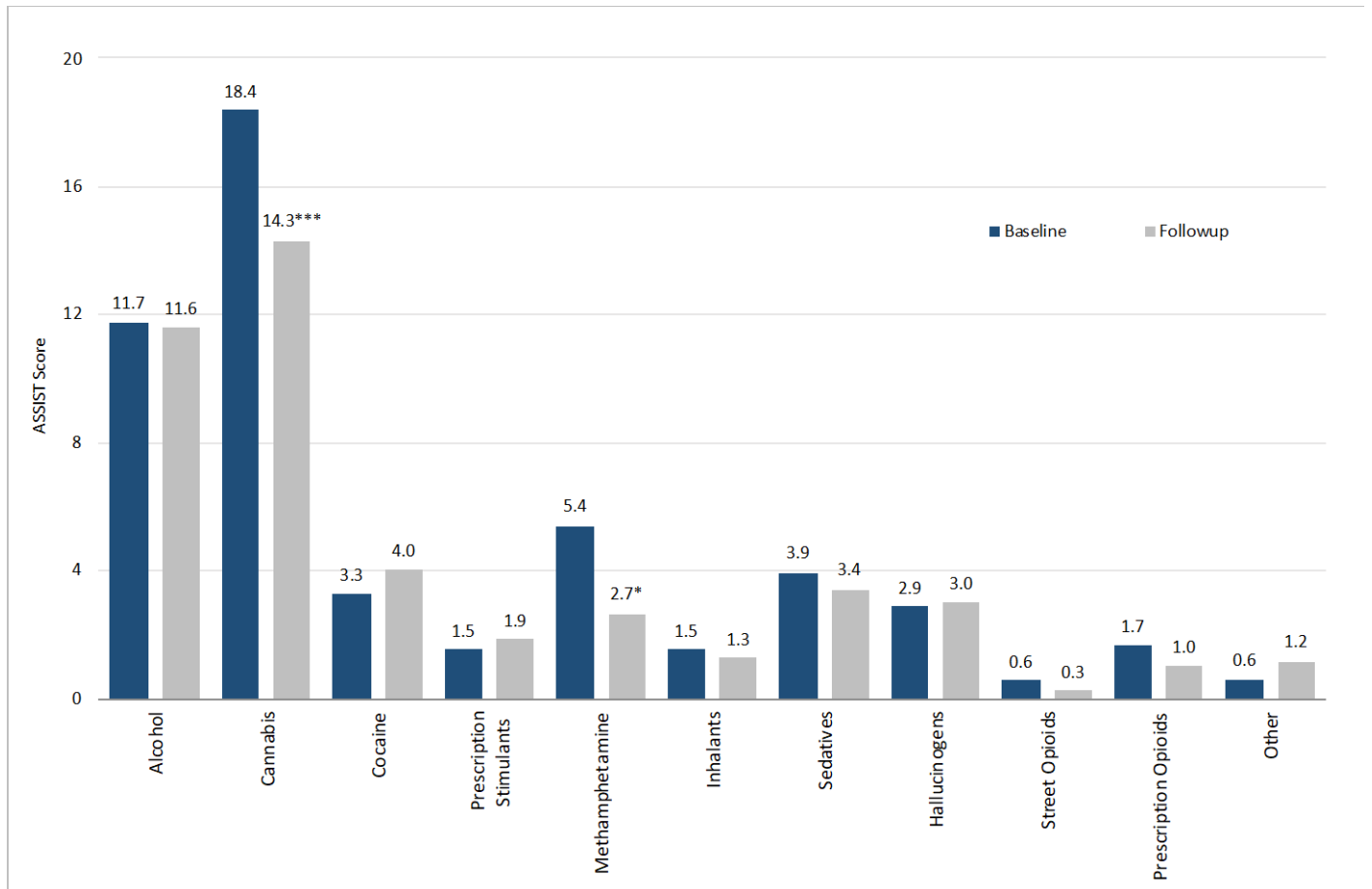
Figure 11. Harmful substance use at baseline and follow-up as measured by the ASSIST.

Note. * $p < .05$; ** $p < 0.01$; *** $p < .001$

Key Finding

Young people reported significant reductions, albeit small, to their cannabis and methamphetamine use.

Chapter 4: Study Outcomes Relating to Practicality, Feasibility and Implementation

Evidence-based treatments for young people often encounter a range of implementation barriers, which result in poor uptake and ultimately, contribute to the growing evidence gap in youth AOD treatment[8]. To examine the facilitators and barriers to implementation, the present study undertook a comprehensive, mixed-methods approach. These findings relate to the outcomes regarding the extent to which it is practical and feasible to implement ERIC across a diverse range of youth AoD services and recommendations regarding the implementation of ERIC to scale. The following chapter addresses the study findings that inform the workforce development and policy recommendations for an effective implementation model.

The project aims relating to whether ERIC is **practical and feasible** for delivery across NSW LHD and NGO youth AOD services were to quantitatively examine:

1. Practitioners' knowledge, attitudes and behaviours towards evidence-based practice
2. Practitioner engagement and attrition in delivery of ERIC.
3. An economic estimation of training and implementation costs.

The project aims relating to informing the design of **an implementation model** for delivery of ERIC to scale across NSW Health were to qualitatively examine:

1. Practitioner experience of engagement with ERIC and key facilitators and barriers to implementation.

This chapter also provides an overview of the characteristics of the practitioners that were involved in the study.

Demographic Characteristics of Practitioners

A total of 57 practitioners were recruited into the study. Practitioners were predominantly female (81%), had an average age of 40.2 years and were primarily Australian-born (77%). Practitioners had a high level of educational attainment, with 62 percent attaining an undergraduate degree and 33 percent a post-graduate degree. Practitioners had a diverse range of job titles, with psychologist being the most common

(19%) and, had a wide range of experience, with 45.6 percent having eight or more years' experience, whereas 17.5 percent reported less than one-year experience. On average, practitioners engaged in 3.67 hours of client-contact per day and reported using a range of therapeutic modalities, the most common of which included motivational interviewing (MI), relapse prevention, CBT, acceptance and commitment therapies (ACT) and mindfulness strategies.

Table 4

Characteristics of Practitioners Involved in ERIC (N = 57)

	n	%
Gender		
Female	46	81%
Male	11	19%
Australian-Born	44	77%
Identifies as Aboriginal or Torres Strait Islander	1	2%
Educational Attainment		
Graduate	35	61%
Post-Graduate	19	33%
Other	3	5%
Job Title		
Psychologist	11	19%
Counsellor	10	18%
Social worker	9	16%
Youth worker	1	2%
Nurse	8	14%
Paediatrician	5	9%
AOD Case Manager	7	12%
Other	6	11%
Time in Sector		
Less than 1 year	10	18%
1-3 years	11	19%
4-7 years	10	18%
8+ years	26	46%
	Mean	*SD*
Age	40.21	11.94
Client contact hours per day	3.67	1.67

Knowledge, Attitudes and Behaviours towards Evidence-Based Practice

An important factor underpinning the adoption and implementation of novel, evidence-based treatments relates to the knowledge, attitudes and behaviours of practitioners towards EBP. As such, practitioners completed two questionnaires at both baseline and follow-up to examine their initial knowledge, attitude and behaviours towards EBP and subsequently determine if these changed over the course of the project (see Table 4 for description of these measures). The findings showed that practitioner knowledge, attitudes and behaviours towards EBP were predominantly positive at both baseline and follow-up, with practitioners scoring between 69 percent and 84 percent of the maximum possible score for each questionnaire. Furthermore, practitioner attitudes, knowledge and behaviours towards EBP did not significantly change between baseline and follow-up (see Figure 12).
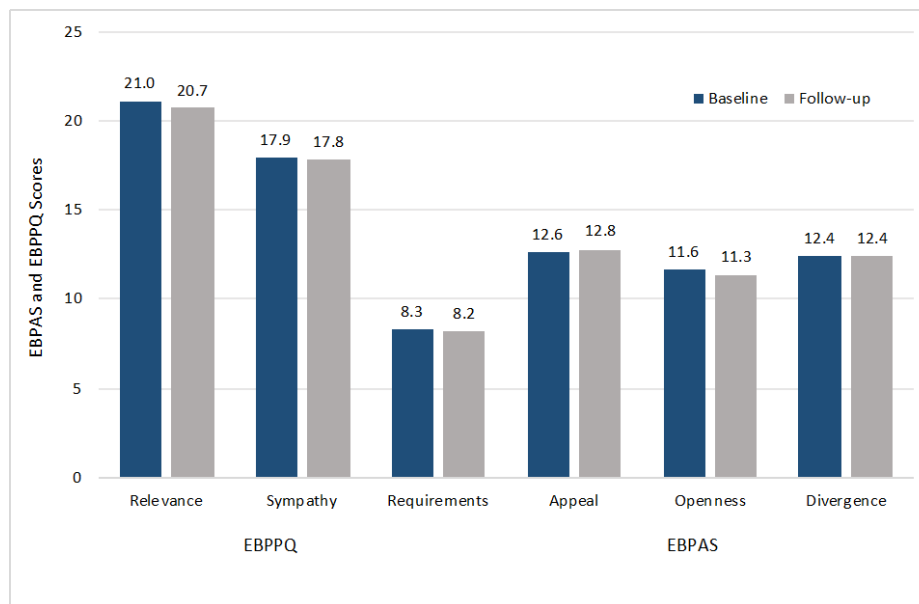
Figure 12. Evidence-based Practice Profile Questionnaire (EBPPQ; Relevance and Sympathy items) and Evidence-based Practice Attitudes Scale (Requirements, Appeal, Openness, Divergence items) at baseline and follow-up. Higher means for divergence indicates less divergence from research-based interventions.

> **Key Finding**
>
> Practitioner knowledge, attitudes and behaviours towards EBP were predominantly positive at baseline and follow-up and did not change over time. Consequently, barriers pertaining to implementation of ERIC are unlikely to be attitudinal.

Practitioner Engagement

Practitioner engagement was explored quantitatively by examining the percentage of practitioners who signed up to the study and completed the baseline interview compared with the percentage who went on to deliver the intervention to young people. Intervention delivery was said to occur if the practitioner recorded that they had delivered an ERIC exercise. As shown in Table 5, the vast majority of practitioners who signed up to participate in the study went on to complete the baseline interview (92%); however, only 44 percent continued to deliver the ERIC intervention to young people.

Table 5

Practitioner Engagement Across the ERIC Project

	Provided Informed Consent	Completed Baseline Interview		Delivered ERIC Intervention	
Service	N	*n*	%	*n*	%
Hunter New England	29	27	93%	13	45%
Catholicare	1	1	100%	1	100%
Salvation Army FYRST	10	10	100%	5	50%
Salvation Army Oasis	5	3	60%	2	40%
Sydney Children's Hospital	6	6	100%	2	33%
St Vincent's Hospital	3	3	100%	1	33%
Sydney Local Health District	3	3	100%	1	33%
Youth Off The Streets	5	4	80%	2	40%
Total	62	57	92%	27	44%

Key Finding

Of the 62 practitioners that signed up for the project, less than half (44%) continued to deliver the intervention to a young person. Barriers to engagement will be discussed in the qualitative results.

Economic Estimation of Training and Implementation Costs

Table 7 details an economic estimation of training and implementation based on the number of practitioners who participated in the study. To calculate the cost of practitioner time in workshop, the average award wage for the NGO health sector and the average hospital award grade were used. To estimate the cost of the time that practitioners spent reviewing the training materials, we assumed based on practitioner feedback that 10% of this time was done "on company time", with the remainder being completed during "personal time". The training delivery was fixed at $400 per person, which included the ERIC licence and organisation-wide access to resources and materials. The per person cost for NGO services was estimated at $1280, which was marginally less than the per person total cost per HNE / LHD services of $1366. These training and implementation costs are significantly less than other evidence-based treatments such as CBT and DBT which are estimated to cost $4700 and $14985 respectively per practitioner[54].

Table 7

Economic Estimation of Training and Implementation Costs

Component	NGO (*n* = 18) ($)	HNE / Sydney LHD (*n* = 39) ($)	Combined (N = 57) ($)
Workshop Training			
Training Delivery	7,200	15,600	22,800
Practitioner time in workshop	10,512	29,016	39,528
Practitioner time reviewing material	5,329	8,649	13,978
Total cost	23,041	53,265	76,306
Total Cost per person	1,280	1,366	1,339

> **Key Finding**
>
> ERIC training costs are less than other intervention packages however, this training model is not sufficient for implementation. It is likely that the ERIC resources and manuals alongside a train-the-trainer model is the most cost-efficient way of implementing ERIC to scale.

Qualitative Analysis of Facilitators and Barriers to Implementation through Semi-Structured Interviews

Qualitative data collected from 27 practitioners and managers was analysed using thematic analysis[55] to identify the key barriers and facilitators to the implementation of ERIC and more broadly, psychological interventions to vulnerable young people. Facilitators and barriers were examined at differing levels and informed by the Consolidated Framework for Implementation Research (CFIR[56]) which is a leading implementation framework recommended for use in the context of AOD research[57]. This framework categorises implementation factors according to five domains: (1) intervention characteristics, (2) outer setting, (3) inner setting, (4) characteristics of the individuals involved, and (5) the implementation process. Facilitators and barriers to implementation were identified in three of the five domains: characteristics of individuals, intervention characteristics and inner setting. An additional barrier related to the implementation of the research is also discussed; however, this does not form one of the five CFIR domains.

Facilitators to Implementation

Facilitations to the implementation of ERIC were identified in two of the five CFIR domains. Characteristics of Individuals refers to the attitudes, actions and behaviours of individuals within an organisation which influence implementation. For the current study, this related directly to participating practitioners. Intervention Characteristics refers to key attributes of the intervention which may influence the success of implementation.

Characteristics of Individuals – Practitioners

Intervention experience and confidence

Practitioners who had past experience in delivering psychological interventions (i.e. structured interventions that target cognitions, emotions or behaviours contributing to social, emotional and behavioural difficulties, such as cognitive and behavioural interventions for mood or substance use issues) or were working within a counselling framework (as opposed to case management) generally found it easier to implement ERIC into their practice.

- These practitioners acknowledged that ERIC *"aligned with the way* [they] *practiced"* and often noted that they were already delivering emotion regulation-based concepts just *"not in the* [ERIC] *format"*. Practitioners working within counselling frameworks described experience in delivering a range of evidence-based treatments from cognitive and behavioural underpinnings including Dialectical-Behavioural Therapy, Motivational Interviewing, Cognitive-Behavioural Therapy, and Acceptance and Commitment Therapy.

- Practitioner experience of psychological interventions also appeared to be relevant to perceived barriers about delivering ERIC due to client complexity. Numerous practitioners working in counselling roles who had prior experience in integrating psychological treatments noted few difficulties in delivering ERIC to young people with significant complexity. This was highlighted by one counsellor who stated: *"I have very complex patients, most of the kids live in out of home care, are in constant crisis, are using substances, have psychosis, have changing living arrangements constantly, don't know where they're going to sleep tonight, and I deliver it with them, I think they like the structure of it and the idea of it and something they can come back to, I think that's when it should be delivered".* Another practitioner with experience in the delivery of EBP noted that ERIC actually facilitated *"breaking down what the current crisis may be".*

Research experience and confidence

Practitioners who had experience participating in research projects were more confident and skilled in being able to manage the demands of the research (i.e. screening and consent process). This was particularly evident in relation to increased confidence in being able to manage the dual role of recruiting their clients to a research study and completing the research requirements (i.e. delivery of consent, facilitation of baseline interview) alongside their existing role as the young person's treating practitioner.

> **Key Finding**
>
> Practitioners who had experience and comfort in delivering cognitive and behavioural interventions (i.e. goal and agenda setting with a young person in order to facilitate emotional and behavioural change), or who had worked from a counselling framework (as opposed to case management model) outlined fewer barriers in their implementation of ERIC.

Intervention Characteristics

Modularity facilitates integration of ERIC into existing treatment

There was an overwhelming consensus from practitioners across all services that the format of ERIC made it easy to integrate into existing clinical models of care.

- Practitioners noted that the ERIC techniques were *"so simple and easy to slip into sessions"* and that they were *"easy to explain and easy to understand"*.

ERIC addressed barriers of existing psychological treatments

Practitioners across services acknowledged that while they had been trained in numerous evidence-based treatment approaches (i.e. CBT, DBT, ACT, MI) these were rarely suitable for their clients given their length and format. One counsellor highlighted that *"ERIC helped us have a goal for what we can do for at least the 7-minutes that we had"* noting that they *"wanted to do some DBT but he never really gave us much back and forth time in our appointments"* while the manager of one service noted that that "*DBT in its entirety is not a possible option. Working with something as tangible as ERIC is such a relatable way of framing it for young people that I think it fitted really well to what we were doing, and it would certainly be incorporated into our next model of care"*.

ERIC design and packaging

Practitioners responded favourably to the various formats that ERIC was presented in (i.e. small worksheets, large worksheets, wallet cards) and identified that the wallet cards were their favourite component. Practitioners also noted that the packaging of ERIC appealed to their clients and helped with engagement. One practitioner noted that their client was *"curious about it because it wasn't just black and white cheap paper, it was interesting and had pictures on it"*.

Barriers to Implementation

Barriers to implementation were identified in two of the five CFIR domains- Characteristics of Individuals and Inner Setting[58]. Characteristics of Individuals refers to the attitudes, actions and behaviours of individuals within an organisation which influence implementation. In the context of the current study, this related specifically to individual characteristics of participating practitioners. The Inner setting refers to the structural, political and cultural context in which implementation occurs. Barriers to implementation related specifically to the research process are also discussed, however these do not form part of the CFIR framework.

Individual Characteristics – Practitioners

Characteristics of practitioners that were identified as barriers to implementation included both attitudinal barriers about psychological skills-based interventions in general and perceptions of client characteristics. These included: (1) beliefs that the delivery of skills-based interventions were not part of their *role* as a support to a young person; (2) concern that the delivery of skills based interventions in general would impair the therapeutic relationship, (3) resistance to the adoption of novel approaches and; (4) perceptions of client complexity as a barrier to the delivery of psychological skills based interventions.

Practitioners role in the provision of psychological treatments

There was a commonly held belief by AOD practitioners who were in a case management role that the delivery of cognitive and behavioural skills-based interventions, such as ERIC, was outside of their *"role"* as a key support for the young person. This was highlighted by a case manager who stated *"We're not psychologists or counsellors, our role is a case worker, so we help coordinate clients, make referrals to other services if they need support with different areas that we can't address, we set some case work goals, they can be simple things around drug and alcohol use, I guess looks like counselling, but we don't go*

into any therapeutic techniques necessarily". This was further supported by a manager at one service noting that their key priority was addressing the young person's basic needs: *"financially we need to make sure the young people are going to have food, access to food and things like that, you know"*. The belief that the delivery of ERIC was outside of their 'role' was associated with reluctance by many case managers to integrate ERIC skills into their work with a young person.

- One case manager noted that they *"only ever stayed on the surface (accommodation, help getting a job) with the young person"* and that they *"never really got down to dealing with the core issue..."* noting that they "*tried to go there but they pushed back and I thought ok you are not ready, so I kind of let it go"*.
- Another case manager noted experiencing "*hesitation in the moment"* when attempting to explain an ERIC skill to a young person, noting that they were concerned that their delivery of the concept or skill would be *"lost"* in translation to a young person because it is *"not something that they normally do"*.

Resistance to adoption of novel approaches

Practitioners also described a "*resistance"* to adopting new techniques or ways of practicing. This theme was most frequently endorsed by practitioners who were working in case management roles whereby the adoption of a novel approach, such as incorporating ERIC skills into their work with young people was perceived to be outside of their usual role. For example, one case manager noted that they were *"set in my ways"* while another stated that they had *"their own ways of working"*. This was reinforced by a manger of one NGO service who noted that *"some practitioners get set in their ways. They have been using the same old techniques for years and they don't like to go out of their comfort zone"*.

Disruption to the therapeutic alliance

Many practitioners also expressed concern that the integration of skills-based interventions would impair or disrupt the therapeutic relationship that they had built with a client. This barrier was more commonly endorsed by practitioners in case management roles. It appeared that these practitioners held a preferential position of *"building the therapeutic relationship"* rather than creating change through skill development or focusing on measurable outcomes with young people. This was highlighted by a manager who noted that the relationship with a practitioner was essential in serving a "*gentle entry point"* for young people to access other areas of the service. These practitioners reported discomfort with using

session time for skill building rather than debriefing/supportive counselling, with one practitioner noting that it *"felt like an intrusion to kind of give our sessions an agenda"*.

Practitioner perception of client complexity as a barrier

Practitioners frequently cited the 'complexity' of their clients as a barrier to being able to deliver ERIC. Complexity included both mental health (i.e. self-harm, suicide risk), substance use (i.e. withdrawal, intoxication) and psychosocial factors (i.e. homelessness). Interestingly, this perception regarding the suitability of evidence-based treatments for complex clients was mainly endorsed by practitioners across the NGO sectors, despite comparisons between NGO and LHD service users indicating that for some of these factors (i.e. involvement in criminal justice system, number of mental health diagnoses, number of suicide attempts in lifetime), LHD service users presented with greater client complexity. For example, one practitioner noted that when their client is in crisis they need to "*do safety and nurturing and not too much work",* while another case manager stated that they just *"don't think it would be appropriate to try and deliver that yet* [when client presents with significant drug use] *... there's got to be some sort of calm in their life".* A manager from one of the NGO services expressed a similar belief, noting that *"One of the main reasons why we didn't do the program with a bunch of them was they were in crisis and we didn't think it was kind of appropriate for a client who was hard to get a hold of and very volatile at the time".*

Key Recommendations

1. Practitioners in the youth AOD sector require training and competencies in addressing and managing the multiple and complex needs of young people presenting to their services, including reducing symptoms of co-morbid mental health issues and targeting the promotion of social and emotional activities.

2. Practitioners in case management roles require workforce training and development and minimum competencies in directive counselling skills, goal setting and outcome monitoring and delivering skills-based interventions.

3. Workforce development strategies to increase skills and confidence in integrating skills building with case co-ordination e.g. be informed by the ERIC Case Model would be an important core competency. Consensus definitions and best practice pillars are developed and integrated in all youth service models for case management roles.

4. Adoption of the National Quality Framework for Drug and Alcohol Treatment Services[2] across Youth AOD services to ensure a quality benchmark for the delivery of best practice treatment whilst monitoring service coordination, implementation and practice.

5. Implementation of sector wide best practice standards through adoption of National Quality Framework that incorporate psychological skills building and social and emotional wellbeing models of care for young people with multiple and complex needs.

6. Core competencies in practitioners working within the Youth AOD sector are required to address symptoms of comorbid mental health issues, social and emotional wellbeing domains and training in trauma informed practice, including emotion regulation skill development.

7. Competency in the integration and adoption of evidenced based interventions for common mental health issues such as anxiety and mood disorders.

8. Case coordination strategies that incorporate maximising educational attainment while also addressing social and emotional development.

9. Reviewing the minimum qualification or standards requirements for clinicians working in case management roles to increase clinical competency in the delivery of evidence-based treatments that address comorbidity and complexity.

10. Continued training in trauma informed practice and delivery of evidenced based interventions for high prevalence mental health symptoms.

Inner Setting

The inner setting included characteristics within service settings that influenced the adoption of ERIC. These barriers included: (1) low attendance and high rates of disengagement by young people; (2) client age range at each service; (3) the organisational values and culture; (4) team involvement; and (5) administrative requirements.

Low attendance and disengagement

Sporadic engagement and low attendance of young people accessing the service were reported as barriers to implementing ERIC across all services and endorsed by practitioners in both counselling and case management roles.

- Consistency in attendance was recognised as a consequence of client complexity by many practitioners. For example, one practitioner noted that their service had "*always had issues with consistency around attendance... someone might be arrested, hospitalised…We have patches of engagement and then we won't see anyone for ages and then all of a sudden they'll reappear*".

- Long waitlists to access services was also noted as a precursor to disengagement and thus, a barrier to delivering ERIC. For example, one practitioner noted that their waitlist was "*incredibly long* [3-4 months], *so by the time they booked an appointment* [with the young person], *they weren't interested, they had quit* [drugs and alcohol] *themselves, or their circumstances would change*".

- Low attendance also resulted in practitioners prioritising existing treatment in the small window of time that they had with clients. For example, one case manager noted that "*Even though they agree to regular appointments sometimes they often miss sessions, so we just continued with our case plans and treatment based on their goals*".

Client age range

Practitioners from LHD services noted that the limited number of clients within the included age range for the study (16-25 years) as being a barrier to participating in the research trial. This was particularly relevant for the adult funded services that participated through HNE where there just "*wasn't a lot of young people coming through*" and for SCHN where the average age of clients was 14-16 years of age.

Organisation values and culture

Organisational values and culture refer to the shared norms, values, assumptions and behavioural expectations that characterise and guide behaviours within a service. Values and culture within a service often shape beliefs and perceptions of clinical processes (e.g. which therapeutic technique or approach is effective) and by signalling to practitioners how they should prioritise tasks and approach their work[59]. Each participating service in the study adopted slightly different models of care which appeared to impact the implementation of ERIC within their service. For example, many of the NGO services described adopting *"trauma-informed model of care"* which centred on *"engagement"* and the development of a *"trusting therapeutic relationship"*. This was highlighted by a manager of an NGO organisation who noted that the focus is on *"relationship building"* and *"through that relationship* [young people] *can be referred to other parts of the service... so if they want counselling and stuff like that, it's a gentle entry"*. The model of care within these services did not explicitly include the delivery of skills-based interventions, psychological interventions or EBP. Indeed, many practitioners who were in an organisation where the focus was purely on engagement and relationship building noted difficulties in being able to introduce a skills-based treatment into their session. This was highlighted by one practitioner who stated that they *"didn't feel comfortable using up* [their] *time that* [they] *needed to kind of talk to me about things and debrief... I guess it felt like an intrusion to kind of give our sessions an agenda"*. Difficulty in integrating ERIC into sessions was commonly cited by practitioners who worked within a model of care whereby the primary therapeutic focus was on building and maintaining trust with the young person.

In contrast, services that adopted models of care which were also informed by the utilisation of existing evidence-based approaches (i.e. ACT, DBT, CBT, Motivational Interviewing) described far less difficulty in integrating ERIC into their sessions. These practitioners recognised the similarities between ERIC and their current practice and noted that it integrated *"seamlessly"* into it.

Management and team work

 This barrier refers to the commitment and involvement of managers in the implementation of a new treatment within a service as well as the interaction between members of a clinical team to support implementation[59]. There were differing levels of support from managers involved in the study. Generally, however, practitioners who noted difficulties in implementing ERIC also described a lack of "*top down support*" and

endorsement of the project from both management and within their team. For example, one practitioner noted that *"It would have been nicer to have everyone on board…we didn't really prioritise it, I saw the value in it but I didn't feel like my other colleagues saw it the same way or put the same priority on it"* Another service experienced similar difficulties with the manager noting difficulties in *"trying to balance the research project against what we're doing on a daily basis in terms of offering a service"*… they noted that *"it was really clear cut that we need to, you know, focus on service delivery, and I don't think they were able to participate or have the students participate at that point of the study"*.

The importance of team culture in achieving *"clinician buy in"* was also acknowledged, with one manager of a service noting that the geographic spread of services meant the "*practitioners weren't together that were providing ERIC to young people so you don't have the contact of chit chat which was difficult…so that made it a bit tricky getting clinician buy-in"*.

Administrative requirements

Administrative requirements of the service were cited by many practitioners within LHD sectors as a barrier to implementation. The large burden of paperwork, the lack of time dedicated for learning the resource and the clinical re-design which was occurring simultaneously at one service were all cited as factors making the integration of ERIC into routine practice difficult. This was highlighted by the manager of one service which was going through a clinical redesign: *"This (clinical re-design) entailed a total change of practice for a lot of services and we were still guided by an enormous amount of paperwork* [and electronic records]*. I think that was quite daunting for a lot of people at the same time. We had to think, we're doing this research and we're doing redesign. And everyone was getting audited and you know, so that made for another layer of stress and I think probably for some ERIC was the thing that they dropped"*.

Key Recommendations

1. Models of care in NGO Youth AOD services need to increase scope so that skill building through delivery of evidence-based interventions for mental health comorbidities can occur alongside standard care such as case management and client engagement.

2. Adoption of the National Quality Framework for Drug and Alcohol Treatment Services[2] across Youth AOD services to ensure a quality benchmark for the delivery of best practice treatment.

3. Monitoring service coordination and practice through outcome monitoring. Treatment outcomes, including the use of EBP are documented and reported through local governance structures

4. Conduct preparatory work with services prior to investment and commencement of research. Include exploration of staff profiles/roles, existing model of care, experiences in adoption of evidence-based treatments and potential implementation challenges.

5. Introduction of ERIC (or other new evidence-based treatments) to health service managers with endorsement from the ministry of health and other lead agencies prior to attempted roll-out. Top down support and endorsement from management must to occur to ensure integration of evidence-based approaches into practice.

6. Implementation of evidence-based interventions such as ERIC need to be a standing agenda item in regular team meetings and tabled at Executive Meetings.

7. Identify a champion of ERIC within each site who has experience in delivering evidence-based strategies. Support this champion to offer coaching and support to other team members.

Research Barriers

Research barriers refer specifically to barriers in adhering to and adopting the research requirements of the project, that is, obtaining research ethics, recruitment, screening, informed consent. These included difficulties in adhering to the research requirements due to the complexity of clients, administrative requirements of the service and concern for the therapeutic relationship.

Research capability of services

The majority of NGO services who took part in the study had minimal experience in conducting clinical research projects. A number of steps were put in place to reduce the research burden on practitioners to support the participation of these organisations (i.e.

minimal involvement in recruitment, removal of practitioner requirement to obtain informed consent). Despite these amendments, these services still reported significant difficulty in adhering to the research requirements of the study.

Research ethics approval process

The ethics approval process required to conduct the study across multiple sites was identified by the CI's, research team and key stakeholders as a significant barrier. As illustrated in Figure 1, different sites were governed by different ethical bodies. Time delays and concerns raised by the ethics board over the inclusion of young people in research (16-18-years-old) resulted in both delays to recruitment and the exclusion of the voice and experience of young people to this study. For example, the ethics approval process for HNE and then site-specific assessment/research government for Sydney LHD, St Vincent's and SCHN took over nine-months to obtain. Furthermore, HNE HREC's concern over the capacity for young people to consent to their participation in research meant that parental consent was initially required for young people aged 16-17-years old. Practitioners across all services at HNE identified this as a significant barrier, noting that young people in this age range often have histories of family conflict and relationship break down or do not have an ongoing relationship with their parents. Following an amendment to the ethics committee, the requirement for consent was removed; however, this process resulted in an additional six-month delay to recruitment and the exclusion of a number of eligible young people who despite consenting to treatment and meeting all other inclusion criteria, were unable to participate due to this consent barrier.

Client complexity

Practitioners across numerous sites reported that the complexity of presentation and the frequent situational crisis that are disclosed during sessions made it difficult to screen and obtain informed consent from the young person. This was acknowledged by one practitioner who noted that the "*consent process is not at the forefront of my mind when I'm working with highly vulnerable and distressed clients…*". Another practitioner reported similar difficulties noting that *"when young people come in distressed it's hard to recruit them to research"*. This perception was in contrast to the research team collecting baseline data and obtaining informed consent, who determined that young people were open to involvement in the study, in spite of the ongoing crises in their lives and they appreciated the opportunity to be involved in meaningful activities that had the potential to help other young people.

Administrative requirements to participate in research

Practitioners from LHD sectors noted that there were already extensive assessment and reporting requirements to be completed prior to commencing treatment with a young person, making the additional paperwork required for the research project (i.e. informed consent documentation, screening log) difficult. This was highlighted by one practitioner who raised concerns over the "*time that went into going through the whole consent process*", noting that *"it takes us so long to get our initial assessment done for someone coming in for an initial appointment... so, adding more information on top of that isn't appropriate in the first session".*

Therapeutic relationship

Practitioners also raised concern that the screening and consent process required for participation in the research study would impair the therapeutic relationship that they had developed with their client. For example, one practitioner noted that it *"wasn't the most comfortable thing to get them to sign into something and also you want to make sure that it's therapeutic and it doesn't cause them any stress or anything like that and they're fully informed of what they're signing up for and things like that".* Another practitioner reflected that they felt like a "*sales person*" when trying to get young people to sign up to the research study. This was in contrast to the team of trained clinical RA's who successfully engaged young people via phone interviews, delivered plain language statements and obtained informed consent prior to collecting baseline data.

Key Recommendations

1. Assessment of research readiness and trial preparation should be conducted and facilitated by the NSW Ministry of Health in order to identify systemic barriers and address these prior to embarking on clinical research partnerships with trial naive sites.

- Learnings from the current project could be included in this preparation and may include: Good Clinical Practice training for all practitioners who will engage in research, examination of electronic medical records/research data collection methods to minimise dual entry and facilitate high quality data collection, integration of research processes (i.e. informed consent) into initial intake, and meaningful and collaborative service and research partner relationships.

2. practitioners working in clinical trials and collecting data. This could include: Good Clinical Practice training for all practitioners who will engage in research, examination of electronic medical records/research data collection methods to minimise dual entry and facilitate high quality data collection, integration of research processes (i.e. informed consent) into initial intake.

3. Representation from young service users, their significant others and/or clinicians from the youth AOD sector should occur as standard practice on hospital and university ethics committees to advise on issues such as consent processes. Research ethics committees are predominantly capable in traditional research design, such as RCT, that

Chapter 4: Summary and Recommendations

This ambitious project was funded by the NSW Ministry of Health under the AOD Early Intervention Innovation Fund and aimed to address one of the known challenges in supporting vulnerable young people with multiple and complex needs - improving access to evidence based treatments. ERIC, a novel skills-based intervention, was trialled across eight AOD sites with 100 young people and 57 practitioners over a three-year period whereby the chief investigators sought to:

1. Explore whether ERIC improves the social and emotional wellbeing of vulnerable young people with multiple and complex needs
2. Explore the feasibility of implementing ERIC across a diverse range of youth AOD services with an aim to inform any policy and workforce training requirements that would be needed in order to implement ERIC to scale across NSW Health sector.

Outcomes Observed in Vulnerable Young People

Young people demonstrated improvements in their social life, engagement in extracurricular activities, and overall psychological wellbeing following three months of ERIC as an adjunct to their existing treatment. These outcomes are predictive of social and emotional wellbeing and are protective against later substance use and mental health difficulties[60]. It should be noted that there was no improvement found in young people's prosocial or antisocial peer engagement, education and work, physical wellbeing, social support or school environment. Young people also reported improvements in their ability to regulate their emotions, symptoms of depression, anxiety and stress and in their harmful use of cannabis and methamphetamine. Importantly, these changes occurred despite the acute vulnerability of this sample of young people and at times, their limited exposure to the ERIC skills due to their sporadic attendance or as a consequence of practitioner barriers to ERIC's implementation.

Feasibility and Practicality of Implementing ERIC

ERIC has been designed in a modular fashion to aid integration with existing psychosocial interventions commonly delivered by the AOD sector (e.g. life skills, anger management, case management, youth outreach). Furthermore, its modular framework permits practitioners to deliver the intervention flexibility in accordance with the needs of their specific client. Despite these factors there were still significant challenges faced by the youth AOD sector in the implementation of ERIC and evidence-based treatments more

broadly. It was clear from the experiences shared by practitioners that many did not feel competent or believed that it was not part of their role to provide skills-based interventions such as ERIC to vulnerable young people. This was found in spite of the fact that ERIC has been designed to be delivered by practitioners *without* prior training or expertise in evidence-based treatments. Those who did feel competent had prior experience in the use of cognitive and behavioural skills-based interventions and in the participation in clinical research. More broadly, many AOD services (namely NGO's) did not adopt a clear model of care outside of engagement and relationship building, and this was identified as a significant barrier to the integration of ERIC within these services. Conversely, services that had a clear model of care informed by the utilisation of existing evidence-based approaches reported fewer difficulties in implementation. Finally, despite the willingness of young people to participate in the research study, the lack of research capability at many of the NGO services in addition to the ethics approval process required for participation meant that many were unable to be involved.

Recommendations

The comprehensive findings of this study relate to both improving outcomes for vulnerable young people and the workforce development needs of practitioners who have the complex and challenging task of making a difference in vulnerable young people's lives. The qualitative interviews of a sample of practitioners informed a series of recommendations pertaining to the feasibility of implementing ERIC across NSW Health and other barriers and facilitators to evidence-based practice. The following recommendations are also informed by the in-depth examination of the interrelated and co-morbid mental health and substance use characteristics of the sample of vulnerable young people included in the study. Recommendations specific to the implementation of research to practice are also relevant to the current findings and included in this summary.

Recommendations Relating to Implementation of ERIC

The following recommendations are informed by the implementation checklist found in the Clinical Care Standards for Alcohol and Other Drug Treatment. These recommendations relate specifically to the implementation of ERIC across NSW.

Table 8.

Recommendations for Implementation of ERIC Across NSW

Domain/Outcome	Actions
Training & Accessibility	- Train the trainer model is utilised for ERIC training, including identification and training of champions - ERIC intervention package, clinical tools and client worksheets are circulated and made widely available online through access to the ERIC website at each AOD treatment service.
Commitment	- Clear support for the introduction of ERIC is required by management prior to any roll out – this needs to include detailing of barriers found in the current study (i.e. poor acceptance of an evidence based paradigm by some staff, reluctance by some staff to change behaviour). - ERIC should be explicitly included within the model of care adopted at a service (i.e. within a trauma informed model of care) and ERIC skills and processes are adapted and integrated into existing education and workforce development initiatives. - Service outcomes include ERIC and these are measured and aligned to standards

	• Quality improvement initiatives are aligned to improving adherence to evidence-based practice (including ERIC).
Communication	• Introduction of ERIC to a service with endorsement from the ministry of health and other lead agencies • New employees are introduced to ERIC as part of their orientation and provided with a manual and linked in with a champion • Current employees are introduced to ERIC through regular communication channels and staff forums • The use of ERIC is discussed in clinical practice and review meetings as a benchmark for practice • Specific clinical supervision needs to occur to support ERIC implementation • ERIC reporting and outcomes are incorporated into Electronic Medical Records
Workforce Development	• Practitioners receive training in the use of ERIC through a train the trainer model. • Services adapt and integrate ERIC skills and processes into existing education and workforce development initiatives. • Performance reviews include the use of ERIC and identify any areas of practice improvement.
Local engagement and ownership	• Services identify a champion of ERIC who has experience in delivering evidence-based strategies. This champion should offer coaching and support to other team members, which is particularly important given that prior experience in the delivery of interventions was a key facilitator to the implementation of ERIC
Local implementation and monitoring	• Treatment outcomes, including the use of EBP are documented and reported through local governance structures

Workforce Recommendations

Competency in addressing multiple and complex needs of young service users

Young people who participated in this study were acutely vulnerable and were representative of service users with complex needs. In addition to polysubstance use, most young people had two or more comorbid mental health disorders, had high levels of involvement in the criminal justice system (53%), experienced significant rates of homelessness (48%) and family violence (32%) and, more than one-fifth (21%) identified as LGBTIQ+. Given these findings, it is recommended that:

- Practitioners in the youth AOD sector develop competencies in assessing and addressing client complexity, including reducing symptoms of co-morbid mental health issues and targeting the promotion of social and emotional wellbeing.
- Practitioners working within the youth AOD sector meet core competencies in addressing symptoms of trauma and delivering trauma-informed care which should include emotion regulation skill development.
- Practitioners in the youth AOD sector develop competency in risk-management, including interventions for reducing self-harm and suicidal ideation.
- Immersive therapeutic programs that involve residential therapeutic options be made available for young people with multiple and complex needs.
- Skills-based interventions that address symptoms of high prevalence disorders such as depression and anxiety need to be disseminated across the youth AOD sector as standard practice.
- The development and coordination of systems of care between Youth AOD, criminal justice, education and vocational services and homelessness support services be prioritised. Active reintegration in formal training and learning opportunities is a specific need.
- Competency in addressing the unique vulnerabilities and associated high prevalence of mental health comorbidities of minority groups, such as LGBTIQ+ populations must be met.

A substantial portion of young people in this study smoked tobacco (83%), almost half engaged in harmful polysubstance use (49%) and most used cannabis harmfully (74%). Given these findings, it is recommended that:

- Tobacco interventions and strategies needs to be prioritised, alongside harm reduction strategies and relapse prevention for illicit substance use, particularly harmful cannabis use.

Competency in the delivery of evidence-based interventions

Despite ERIC being designed to be delivered by practitioners who have no prior training in evidence-based practice, practitioners, particularly case managers, experienced significant difficulty integrating and delivering skills-based and evidence-based interventions to young people. It is therefore recommended that:

- The minimum qualification or standards requirements for practitioners working in case management roles should be revised to increase clinical competency in the delivery of evidence-based treatments that address comorbidity and complexity.

- Sector wide best-practice standards should be implemented through the adoption of the *National Quality Framework* that incorporates skill building in the areas of social and emotional wellbeing for young people with multiple and complex needs.

- Workforce development strategies are needed to increase skills and confidence in integrating skill-building with case co-ordination. Consensus definitions and best practice pillars need to be developed and integrated in all youth service models for case management roles.

- Best practice pillars for case management be defined and include competence in assessment and treatment of comorbid mental health presentations, trauma informed practice, counselling skills and the delivery of evidence-based interventions.

Service Recommendations

The models of care in the participating services appeared to evolve over time, were upheld by practitioner beliefs and team culture, and were unique to each service, even if governed by the same organisation. Models of care were observed to influence practitioner attitudes and were an important factor in the successful implementation of ERIC. Models of care that were informed by the utilisation of existing evidenced-based approaches appeared to *facilitate* the implementation of ERIC, whereas models of care that did not explicitly include the delivery of skills-based or evidence-based interventions, preferentially focused on client engagement over client goals and outcomes (i.e. case management models) *impeded* its implementation. It is recommended that:

- Youth AOD services adopt the *National Quality Framework for Drug and Alcohol Treatment Services[2]* to ensure a quality benchmark for the delivery of best practice treatment while monitoring service coordination, implementation and practice.

- Models of care in NGO youth AOD services increase in scope so that skill building through the delivery of evidence-based interventions for mental health comorbidities can occur alongside standard care such as case management and client engagement.

- Adherence to the implementation and delivery of evidence-based practice and principles be monitored and, evaluation and outcome monitoring be adopted by services. Measures of implementation fidelity and workforce performance monitoring

and continuing professional develop occurs to ensure adequate adherence and competency in the delivery of interventions focused on impacting client outcomes.

- ▪ ERIC should be explicitly included within the model of care adopted at a service and ERIC skills and processes are adapted and integrated into existing education and workforce development initiatives.

Research to Practice Recommendations

This study experienced many of the common challenges that occur when trying to implement clinical research, however uniquely to this project, nearly all participating services had not run research projects before and were research and evaluation naïve. Therefore, much of the initial project phase included preparation for research trial readiness and engagement in meaningful research and service collaborative partnerships. Of relevance to the barriers to conducting research in community based clinical settings is the ambivalence in much of the sector toward evidence-based practice. Though not the primary focus of the current project, in the spirit of supporting innovation, NSW Health may wish to consider the degree to which it prioritises an evidence-based paradigm for youth AOD services. Given the dearth of evidence-based treatments for young people with multiple and complex needs, it can be argued this policy and funding area is worth investing. As outlined comprehensively in the findings and methodology the current study encountered unique challenges in the implementation of this research project into clinical practice. Given these challenges, it is recommended that:

- • Assessment of research readiness and trial preparation should be conducted and facilitated by the NSW Ministry of Health in order to identify systemic barriers and address these prior to embarking on clinical research partnerships with trial naive sites.
- ▪ Services who have not participated in research and who do not collect comprehensive psychosocial or AOD and mental health information from clients at intake should receive formal preparation prior to investment and commencement of research to facilitate practitioners' capability in the measurement of outcomes, principles of evaluation and working in clinical trials and collecting data. Learnings from the current project could be included in this approach: Good Clinical Practice training for all practitioners who will engage in research, examination of electronic medical records/research data collection methods to minimise dual entry and facilitate high quality data collection, integration of research processes (i.e. informed consent) into

initial intake, and meaningful and collaborative service and research partner relationships.

- University ethics committees include representation from young service users, their significant others and/or clinicians from the Youth AOD sector as standard practice to advice on issues such as consent processes. Research ethics committees are predominantly capable in traditional research design, but less so with hard to reach populations, such as vulnerable and complex young people in the AOD sector.

Appendix A: Open Science Framework

Study Information

    1.   Title

           1.1.   Provide the working title of your study. It may be the same title that you submit for publication of your final manuscript, but it is not a requirement.

ERIC (Emotion Regulation and Impulse Control): a sustainable program for vulnerable young people with Alcohol and Other Drug (AOD) and mental health issues

    2.   Authorship

Kate Hall
Elise Sloan
Petra Staiger
Richard Moulding
George Youssef
Angela Simpson

    3.   Research Questions

           3.1.   Please list each research question included in this study.

1. To determine whether young people seeking support from Youth AOD services show improvements in prosocial behaviors (e.g. engagement in school, treatment, work, extracurricular activities and presence of prosocial peers) and quality of life following exposure to a three month emotion regulation intervention (ERIC).

2. To determine whether young people seeking support from Youth AOD services show improvements in emotion regulation and impulse control, depression, anxiety, stress and substance use following exposure to a three month emotion regulation intervention (ERIC).

3. To examine the feasibility and acceptability of an emotion regulation intervention (ERIC) across youth AOD services in NSW

    4.   Hypotheses

           4.1.   For each of the research questions listed in the previous section, provide one or multiple specific and testable hypotheses. Please state if the hypotheses are directional or non-directional. If directional, state the direction. A predicted effect is also appropriate here.

1. It is predicted that young people who receive the emotion regulation intervention (ERIC) will show improvement from baseline (T1) to end of active intervention period (T2) across the following primary outcomes variables:

    a. Self reported quality of life (KIDSCREEN-27; physical wellbeing, psychological wellbeing, autonomy and parents, peers and social support and school environment)

2. It is predicted that young people who receive the emotion regulation intervention will demonstrate significant improvement from T1 to T2 on the following secondary outcomes:
   a. Self-reported anxiety, depression and stress (DASS-21)
   b. Self-reported emotion regulation and impulse control skills (DERS-18)
   c. Self-reported AOD Use (measured by the NIDA ASSIST)

3. It is predicted that young people who receive the emotion regulation intervention (ERIC) will show improvement over the three month active intervention period in the following outcomes as assessed on each contact with the young person (max 12 assessments based on weekly contact during the duration of the intervention period) :

Primary Outcomes:
   a. Practitioner recorded engagement in prosocial behaviors (number of hours engaged in school, work, treatment)
   b. Social and emotional functioning (SOFAS) as assessed by clinician rated scale

Secondary Outcomes:
   c. Practitioner recorded frequency of engagement in drug and alcohol use
   d. Practitioner recorded social, physical and mental health

Sampling Plan

In this section we will ask you to describe how you plan to collect samples, as well as the number of samples you plan to collect and your rationale for this decision. Please keep in mind that the data described in this section should be the actual data used for analysis, so if you are using a subset of a larger dataset, please describe the subset that will actually be used in your study.

5. Existing data

    5.1. Preregistration is designed to make clear the distinction between confirmatory tests, specified prior to seeing the data, and exploratory analyses conducted after observing the data. Therefore, creating a research plan in which existing data will be used presents unique challenges. Please select the description that best describes your situation. Please do not hesitate to contact us if you have questions about how to answer this question (prereg@cos.io).

        5.1.1. Registration prior to creation of data: As of the date of submission of this research plan for preregistration, the data have not yet been collected, created, or realized.

        The data for this study has not been collected yet.

        5.1.2. Registration prior to any human observation of the data: As of the date of submission, the data exist but have not yet

been quantified, constructed, observed, or reported by anyone - including individuals that are not associated with the proposed study. Examples include museum specimens that have not been measured and data that have been collected by non-human collectors and are inaccessible.

> 5.1.3. Registration prior to accessing the data: As of the date of submission, the data exist, but have not been accessed by you or your collaborators. Commonly, this includes data that has been collected by another researcher or institution.

> 5.1.4. Registration prior to analysis of the data: As of the date of submission, the data exist and you have accessed it, though no analysis has been conducted related to the research plan (including calculation of summary statistics). A common situation for this scenario when a large dataset exists that is used for many different studies over time, or when a data set is randomly split into a sample for exploratory analyses, and the other section of data is reserved for later confirmatory data analysis.

> 5.1.5. Registration following analysis of the data: As of the date of submission, you have accessed and analyzed some of the data relevant to the research plan. This includes preliminary analysis of variables, calculation of descriptive statistics, and observation of data distributions. Studies that fall into this category are ineligible for the Pre-Reg Challenge. Please contact us (prereg@cos.io) and we will be happy to help you.

6. Explanation of existing data

> 6.1. If you indicate that you will be using some data that already exist in this study, please describe the steps you have taken to assure that you are unaware of any patterns or summary statistics in the data. This may include an explanation of how access to the data has been limited, who has observed the data, or how you have avoided observing any analysis of the specific data you will use in your study. The purpose of this question is to assure that the line between confirmatory and exploratory analysis is clear.

> No data that exists will be used in this study

7. Data collection procedures.

Please describe the process by which you will collect your data. If you are using human subjects, this should include the population from which you obtain subjects, recruitment efforts, payment for participation, how subjects will be selected for eligibility from the initial pool (e.g. inclusion and exclusion rules), and your study timeline. For studies that don't include human subjects, include information about how you will collect samples, duration of data gathering efforts, source or location of samples, or batch numbers you will use.

Sixty practitioners will be recruited into the project and undergo a baseline assessment and training in the intervention. These practitioners will then administer the intervention to their own clients. Practitioners will be eligible to participate if they have at least five young people on their caseload. As such, it is expected that the sample of young people will comprise

approximately 300. Put another way, the sample will comprise of multiple time points of data, nested within 300 young people, who are in turn nested within 60 Practitioners administering the intervention. Additionally, 10 Managers will be recruited to provide specific qualitative data regarding their experience about how practitioners in their service responded to the training and intervention delivery.

Details of each of the participant groups is presented below.

Young People

- This study will recruit approximately 300 young people (14-25 years) who are seeking support from services within NGOs or LHDs
- Young people are eligible to participate in the study if they (a) have the capacity to provide informed consent; (b) are aged 14-25 years and (c) are seeking support or assistance from a NGO or LHD service. Young people will not be eligible to participate in the project if they are exhibiting any signs of acute stress, psychosis or suicidality.
- For young people who are eligible, their practitioner will explain the project to them and invite them to participate.
- Young people who complete the study will receive a small token of appreciation ($40) for their time.

Data collection

- Research Question 1 & 2 will be addressed through the following data collection methods
  a) Self report questionnaire administered at T1 and T2 to assess both primary and secondary outcomes.
  b) Practitioner recorded information collected at each contact with the young person throughout the three month active intervention period (maximum of 12 data collection points assuming young person has contact with practitioner weekly for three months) to assess both primary and secondary outcomes.
- Research Question 3 will be addressed through qualitative interviews (one on one or a focus group discussion) with a subset of young people (n= 10-15) at the conclusion of the study period to obtain feedback regarding their experiences and engagement in ERIC.

Practitioners

- This study will recruit approximately 60 practitioners, who work with young adults in either Non-Government Organisations (NGOs) or Local Health Districts (LHDs).
- Practitioners are eligible for the ERIC training and implementation if they meet the following requirements; (a) have a minimum of 5 young people (14-25 years), on their caseload who require support, (b) work in a role that provides clinical services in the form of treatment, case management, counselling or outreach.
- Mangers within these services will identify eligible practitioners who will then be invited to attend training in the ERIC intervention
- Practitioners who complete the ERIC training and implement the intervention in their service will receive a $400 reimbursement toward professional development..

Research Question 3 will be addressed through the following:
- a) Qualitative interviews (one-on-one interview or a focus group discussion) with a subset of practitioners (n= 10-15) at the conclusion of the study period. The purpose of this will be to determine the feasibility and acceptability of delivering ERIC at a service level
- b) Self report questionnaire at T1 and T2 that examines self-efficacy in their work and their attitudes towards evidence based practice

Managers

- This study will recruit approximately 10 managers/team leaders of participating Non-Government Organisations (NGOs) or Local Health Districts (LHDs).
- Research Question 3 will be addressed through qualitative interviews (one on one or a focus group discussion) with these participants at the conclusion of the study period. The purpose of this will be to determine the feasibility and acceptability of delivering ERIC at a service level.

8. Sample size

    8.1.   Describe the sample size of your study. How many units will be analyzed in the study? This could be the number of people, birds, classrooms, plots, interactions, or countries included. If the units are not individuals, then describe the size requirements for each unit. If you are using a clustered or multilevel design, how many units are you collecting at each level of the analysis?

This project is multilevel, comprising repeated measures data (2 time points of self-report data by young People; a maximum of 12 time points of practitioner recorded data), nested within 300 young people, who are clustered within 60 practitioners administering the intervention. The two time-points of self-report data collected from young people will be obtained at Baseline (T1) and immediately following the three month active intervention period (T2). Data will be collected from young people at a maximum of 12 time points. Specifically, practitioners will record information from the young person at each contact that they have with them throughout the three month intervention period.

Managers

10 practitioners will also be recruited into the study and they will complete one qualitative assessment.

9. Sample size rationale

    9.1.   This could include a power analysis or an arbitrary constraint such as time, money, or personnel.

This project is funded to recruit 60 practitioners into the study who will be taught how to administer the intervention to their clients. Given that practitioners will be required to have at least five Young People on their caseload, it is anticipated the sample size of young people in the project will be approximately 300 participants. The primary hypotheses are focused on estimating change from T1 to T2 in a single arm design. Consequently, the anticipated sample size is sufficiently powered to detect even a small change over time. Specifically, an anticipated 20% dropout (i.e., due to the difficulty retaining this sample) results in an expected sample at the final assessment of 240 young people. A sample of n=70 will provide

82% power to detect small differences (i.e., Cohen's d_z = .35) in the variables of interest from baseline to the end of the intervention period (alpha = .05). To account for clustering of young people within practitioners, the proposed sample allows for a design effect of 3.4 (i.e., based on average cluster size of 5 young people per practitioner and an estimated intra-cluster correlation of .6). When taken together, 70x3.4 = 238 participants are required for the project.

10. Stopping rule

    10.1. If your data collection procedures do not give you full control over your exact sample size, specify how you will decide when to terminate your data collection.

Data collection will be terminated when the stated number of young people are recruited.

Variables

In this section you can describe all variables (both manipulated and measured variables) that will later be used in your confirmatory analysis plan. In your analysis plan, you will have the opportunity to describe how each variable will be used. If you have variables that you are measuring for exploratory analyses, you are not required to list them, though you are permitted to do so.

11. Manipulated variables

    11.1. Describe all variables you plan to manipulate and the levels or treatment arms of each variable. For observational studies and meta-analyses, simply state that this is not applicable.

The manipulated variable includes the exposure of the ERIC condition to young people

12. Measured variables

    12.1. Describe each variable that you will measure. This will include outcome measures, as well as any predictors or covariates that you will measure. You do not need to include any variables that you plan on collecting if they are not going to be included in the confirmatory analyses of this study.

Young people

Survey completed by young people – baseline and follow up:

- Basic demographics
- Cultural background
- Accommodation
- Criminal history
- Exposure to child protection
- Domestic violence
- Prosocial Peers
- Anti Social Peers
- Physical Well-Being (KIDSCREEN)
- Psychological Well-Being (KIDSCREEN)

- Autonomy and Parents (KIDSCREEN)
- Peers and Social Support (KIDSCREEN)
- School Environment (KIDSCREEN)
- Depression (DASS-21)
- Anxiety (DASS-21)
- Stress (DASS-21)
- Emotion Regulation and Impulse Control (DERS)
- Substance use: NIDA-Modified ASSIST

Fortnightly survey:
- Social and occupational functioning: SOFAS
- Housing
- School
- Work
- Service utilization
- Extracurricular activities
- Social health
- Physical health
- Mental health
- Substance Use

Practitioners

Survey completed by practitioners – baseline and follow up:
- Basic demographics
- Workplace information (job title, type of workplace)
- Number of years in the AOD sector, number of years in sector,
- Training and Qualifications (highest level of training or qualification, training or qualification in specialist AOD work)
- Average Client contact hours,
- Interventions typically used
- Occupational Self Efficacy
- Attitudes towards evidence based practice

13.   Indices
13.1.   If any measurements are going to be combined into an index (or even a mean), what measures will you use and how will they be combined? Include either a formula or a precise description of your method. If you are using a more complicated statistical method to combine measures (e.g. a factor analysis), you can note that here but describe the exact method in the analysis plan section.

Young People

- Mental health will be calculated using the three subscales within the DASS-21; anxiety, stress and depression (Antony, Bieling, Cox, Enns, & Swinson, 1998).
- The Kidscreen will be calculated based on the scoring instructions to obtain the subscales including; physical well-being, psychological well-being, autonomy and parent relation, social support and peers, and school (Ravens-Sieberer et al., 2007).
- Emotion regulation will be calculated based on the scoring instructions to obtain the subscales including: awareness, clarity, goals, impulse, nonacceptance, and strategies. A total score is the sum of these subscales [60]
- Substance Use will be calculated according to the NIDA Modified ASSIST V2.0 which produces an overall Substance Involvement (SI) score for each of the substances assessed. Using this score, the young persons risk level will be identified.

Practitioners

Occupational Self Efficacy will be calculated by summing the total score for the measure Rigotti, Schyns & Mohr (2008)

Evidence Based Practice Attitudes will be calculated by summing a total score for the measure.

Design Plan

In this section, you will be asked to describe the overall design of your study. Remember that this research plan is designed to register a single study, so if you have multiple experimental designs, please complete a separate preregistration.

14. Study type

Observational Study - Data is collected from study subjects that are not randomly assigned to a treatment. This includes surveys, natural experiments, and regression discontinuity designs.

15. Blinding

    15.1. Blinding describes who is aware of the experimental manipulations within a study. Mark all that apply.

        15.1.1. No blinding is involved in this study.

16. Study design

    16.1. Describe your study design. Examples include two-group, factorial, randomized block, and repeated measures. Is it a between (unpaired), within-subject (paired), or mixed design? Describe any counterbalancing required. Typical study designs for observation studies include cohort, cross sectional, and case-control studies.

The study design will be a comprehensive multi-site feasibility and implementation single arm trial utilising mixed methods. Quantitative outcome data will be collected within subjects over time. A process evaluation will also occur with a feasibility component which will involve qualitative methods.

17. Randomization

> 17.1.   If you are doing a randomized study, how will you randomize, and at what level?

N/A

Analysis Plan

You may describe one or more confirmatory analysis in this preregistration. Please remember that all analyses specified below must be reported in the final article, and any additional analyses must be noted as exploratory or hypothesis generating.

A confirmatory analysis plan must state up front which variables are predictors (independent) and which are the outcomes (dependent), otherwise it is an exploratory analysis. You are allowed to describe any exploratory work here, but a clear confirmatory analysis is required.

18.   Statistical models
> 18.1.   What statistical model will you use to test each hypothesis? Please include the type of model (e.g. ANOVA, multiple regression, SEM, etc) and the specification of the model (this includes each variable that will be included as predictors, outcomes, or covariates). Please specify any interactions that will be tested and remember that any test not included here must be noted as an exploratory test in your final article.

The primary and secondary hypotheses will be examined using a three-level mixed effects regression. This approach allows us to account for attrition using a maximum likelihood based approach. Specifically, separate models will be estimated for each of the dependent variables outlined in the primary and secondary hypotheses. Specifically, we will be estimating a separate model for each of the subscales for each of the included measures: KIDSCREEN (5 models), DASS (3 models), DERS (5 models), NIDA modified ASSIST (1 model), Prosocial behaviours: SOFAS (1 model), School (1 model), Work (1 model), Extracurricular activities (1 model), Service utilization (1 model). This equates to 19 separate analyses.

We will estimate a random intercept to account for nesting of timepoints within participants, and a random intercept to account for participants nested within practitioners. The independent variable will be Time-point which will be used to estimate the change from baseline to follow-up. For the self-report data, only two timepoints of data will be used. However, for the practitioner data, multiple timepoints will be used. The mixed effects model used will be based on the distribution of the outcome variable (e.g., linear, logistic, negative binomial)

Research Question 3: It is predicted that ERIC is a feasible intervention to implement in the NSW Health setting

This will be assessed using quantitative and qualitative data collected from practitioners and stakeholders at the conclusion of the project that will examine the extent to which implementing the intervention within the NSW health setting is feasible.

1. Transformations
   a. If you plan on transforming, centering, recoding the data, or will require a coding scheme for categorical variables, please describe that process.

No transformations are planned for the analysis. In the event of low frequency responding or highly skewed data (e.g., substance use), data may be collapsed to ensure that the models can be estimated without error. A robust variance estimator and bootstrapping may also be used to account for skew and/or outliers. In any case, we will report all results from untransformed data before presenting results based on changes to variables.

2. Follow-up analyses
   a. If not specified previously, will you be conducting any confirmatory analyses to follow up on effects in your statistical model, such as subgroup analyses, pairwise or complex contrasts, or follow-up tests from interactions. Remember that any analyses not specified in this research plan must be noted as exploratory.

3. Inference criteria
   a. What criteria will you use to make inferences? Please describe the information you will use (e.g. p-values, Bayes factors, specific model fit indices), as well as cut-off criterion, where appropriate. Will you be using one or two tailed tests for each of your analyses? If you are comparing multiple conditions or testing multiple hypotheses, will you account for this?

We will use p is less than .05 criteria for determining if the analyses suggests that the results are unusual given the null hypothesis. Two tailed tests will be used. Given the nature of the project as a feasibility study, and anticipated highly correlated effects observed (given the nature of the variables measured), we will not adjust for multiple comparisons in analysis.

4. Data exclusion
   a. How will you determine what data or samples, if any, to exclude from your analyses? How will outliers be handled?
Extreme outliers (i.e., >4 SD) will be windsorised to reduce the influence of these observations on the overall effects of interest.

5. Missing data
   a. How will you deal with incomplete or missing data?

We will use a maximum likelihood approach to account for missing data through our use of mixed effects regression models. We will however require all participants to have complete data at the baseline assessment.

6. Exploratory analysis (optional)
   a. If you plan to explore your data set to look for unexpected differences or relationships, you may describe those tests here. An exploratory test is any test where a prediction is not made up front, or there are multiple possible tests that you are going to use. A statistically significant finding in an

exploratory test is a great way to form a new confirmatory hypothesis, which could be registered at a later time.

Script (Optional)

The purpose of a fully commented analysis script is to unambiguously provide the responses to all of the questions raised in the analysis section. This step is not common, but we encourage you to try to create an analysis script, refine it using a modeled dataset, and use it in place of your written analysis plan.

7. Analysis scripts (Optional)
    a. (Optional) Upload an analysis script with clear comments. This optional step is helpful in order to create a process that is completely transparent and increase the likelihood that your analysis can be replicated. We recommend that you run the code on a simulated dataset in order to check that it will run without errors.

Other
8. Other
    a. If there is any additional information that you feel needs to be included in your preregistration, please enter it here.

Appendix B: ERIC Protocol Version II for HNE

(See attached document)

Participant Information Sheet

16-17 year old providing own consent

Title	Emotion Regulation and Impulse Control (ERIC): a program for young people with AOD and mental health issues.
Short Title	ERIC
HREC Reference	18/12/12/4.01
Sponsor	Deakin University
Principal Investigator	Professor Adrian Dunlop
Location	Drug and Alcohol Clinical Services, Hunter New England Local Health District

1.   Introduction

The way in which we manage our emotions has been shown to impact our mental health and/or use of drug or alcohol issues in our lives. You are invited to take part in this research project, which aims to evaluate a program called ERIC (Emotion Regulation and Impulse Control) that helps you manage strong emotions.

This Participant Information Sheet tells you about the research project and the procedures involved. Knowing what is involved will help you decide if you want to take part

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or healthcare worker.

Participation in this research is **voluntary**. If you do not wish to take part, you do not have to. Your experience at your service won't be impacted whether you take part or not.

If you decide you want to take part in the research project, you will be agreeing that you:

- Understand what you have read;
- Consent to take part in the research project;
- Consent to participate in the research processes that are described; and
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet and Consent Form to keep.

What is the purpose of this research project?

The purpose of this study is to evaluate whether the exercises in ERIC help young people, between the age of 16 and 25, manage strong emotions and improve their wellbeing.

ERIC uses tools and exercises to develop healthy emotion regulation and impulse control skills. You and your practitioner will choose the ERIC exercises that will build skills that are helpful for you over the next 3 months (or as long as you are at the service).

There are 8 ERIC modules. Each module has 3 skills to learn and are summarised in the table below.

EMOTIONAL REGULATION				IMPULSE CONTROL			
REDUCING VULNERABILITY	EMOTIONAL LITERACY	FLEXIBLE THINKING	ALLOWING	MICRO MINDFULNESS	TOLERATING DISCOMFORT	DECISION MAKING	IDENTITY & VALUES
To reduce rumination and suppression	To identify emotions and recognise their purpose	To be able to look at a situation from another person's perspective	To accept yourself and others	To tune in to your mind and body	To sit with uncomfortable thoughts, feelings and body signals	To remain focused on goals despite strong emotions	To know your personal values, goals and strengths
To face up to avoidance	To identify how emotions impact thoughts, behaviours and body signals	To be aware of bias when interpreting a situation	To observe your thoughts and emotions without trying to change them	To remain present in each moment	To resist an urge to engage in unhelpful behaviours	To implement a considered plan to solve a problem	To be aware of what motivates you
To practice good self-care habits	To recognise the difference between helpful and unhelpful responses to emotions	To accept other people's point of view as valid	To be kind and compassionate to ourselves	To focus your attention	To use distraction and self-comfort strategies to get through difficult situations	To make decisions that are in line with how you want to feel	To know who you are and how you want to live your life

Each ERIC exercise only takes between 5-10 minutes to complete and you will receive worksheets and other tools to help you to remember to practice the exercises, even when you are not at your service.

2.   What does participation in this research involve?

If you decide to take part in the study you will be asked to sign a consent form. When you have signed the consent form your contact details will be passed on to a researcher who will be in touch to arrange a time to interview you (in person or over the phone) about your living situation and treatment. The researcher may also need to access information recorded in your medical records to help determine the answers to any questions that you are unsure about or don't know.

Your practitioner will arrange for you to participate in the ERIC program for three months. This will be in addition to your existing treatment.

At the end of the three months a researcher will contact you again to participate in a follow up interview. The questions will be the same as the first interview but it will be quicker. The researcher may need to access your medical records again at this point.

You may also be asked to participate in a short interview to share your experiences of ERIC. All interviews will be audio recorded but your responses will be anonymous.

There are no additional costs associated with participating in this research. All medical care required as part of the research project will be provided to you free of charge. You will be reimbursed in a voucher (that cannot be spent on alcohol or cigarettes) after you have completed the first visit and the last. Your first reimbursements will be $10 and the last will be $30.

	Research Contact 1	Research Contact 2	ERIC Program 3 Months	Research Contact 3	Interview
If you decide to take part in the study you will be asked to sign a consent form. Your practitioner will pass on the signed consent form, with your contact details, to a researcher.	✔				
A researcher will be in touch to arrange a time to interview you (in person or over the phone)	✔			✔	
At the arranged time a researcher will complete an interview with you which will take about 30 minutes. This interview will include questions relating to you and your lifestyle, including your gender, age, country of birth, Aboriginal or Torres Strait Islander descent, children, family dynamics, housing, child protection involvement, number of days paid work or studies for past 14 days, criminal justice involvement, stable accommodation, exposure or participation in domestic violence, pro social and anti-social peers		✔		✔	
A researcher will also ask you questions about the way you manage your emotions, your mood, alcohol and drug use, living situation and mental health. The researcher may need to access information recorded in your medical records to help determine the answers to any questions that you are unsure about or don't know.		✔		✔	
You will participate in the ERIC program for three months with your youth worker as part of your usual treatment. The number of times you receive ERIC will depend on how often you see your worker over a three month period. The content of the ERIC program in explained over the page.			✔		
Each time you meet with your practitioner over the three months they will ask you about school, work, use of services and drug and alcohol use. This will take about 5 minutes.			✔		
You will be reimbursed for your time with a grocery voucher		✔		✔	

You may be asked to participate in a short interview to share your experiences of ERIC. All interviews will be audio recorded but your responses will be anonymous.					✔

3.   What do I have to do?

4.   What are the possible benefits?

Learning effective ways to manage your emotions may improve your wellbeing. In addition, the findings gained from this research will contribute towards improving treatment programs for young Australians.

5.   What are the possible risks?

It is possible, although unlikely, that you may find answering the questions during the interview upsetting. If this is the case, you can choose not to answer the questions and the research will connect you with the appropriate support.

6.   Do I have to take part in this research?

No. Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and then later change your mind, you are free to withdraw from the project at any time.

Your decision whether or not to take part, or to take part and then withdraw, will not affect your involvement at this service or your relationship to the practitioners treating you.

7.   What if I withdraw from this research project?

If you decide to withdraw from this study, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

8.   How will I be informed of the results of this research project?

If you would like to find out about the results of the research, please let the researcher know. If you request this information, you will be posted or emailed a one-page summary after the analysis is completed when the study is finished.

9.   What will happen if I disclose information relating to engagement in illegal activity?

Information that you disclose to researchers will remain confidential unless it is required by law to be disclosed.

10. What will happen to information about me?

By signing the consent form you consent to the practitioner and research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. All information that is collected about you for the purposes of this study will be marked with a code instead of your name. A list with your name and matching code will be kept at the clinic, with only non-identifiable information being sent off site. Your information will be used for the purpose of this research project and, with your permission, may potentially be used in some related future research. It will only be disclosed with your permission, except as required by law. Information about your participation in this research project may be recorded in your health records.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor (The University of New South Wales) the institution relevant to this Participant Information Sheet, Drug and Alcohol Clinical Services or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

In accordance with relevant Australian and/or NSW/South Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

After the study has been completed, all study-related documents will be stored securely for 15 years in line with national research guidelines, and then securely destroyed.

11. Who is organising the funding of the research?

This research project is being funded by the NSW Ministry of Health, Alcohol and Other Drugs Early Intervention Innovation Fund.

12.   Is this research project approved?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Hunter New England Local Health District. Approval has also been given by Drug and Alcohol Clinical Services for this research to be carried out at this site.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

13.   Complaints and compensation

Any person with concerns or complaints about the conduct of this study should contact Dr Nicole Gerrand, Manager of Ethics and Governance Unit for Hunter New England Local Health District HREC on the number provide below and quote HREC Reference 18/12/12/4.01

If you suffer any problems or difficulties as a result of this research project, you should contact the study team as soon as possible and they will assist with arranging appropriate referrals. If you are eligible for Medicare, you can receive medical treatment free of charge as a public patient in any Australian public hospital.

15.   Further information and who to contact

The person you may need to contact will depend on the nature of your query:

For queries relating to your participation in the study please contact:

Name and Position	Elaine Murray (Research Officer)
Telephone	0438064232

For matters relating to the site at which you are participating, the details of the local site complaints person are:

Name	Dr Nicole Gerrand
Position	Manager of Ethics and Governance Unit
Telephone	02 4921 4950
Email	Nicole.Gerrand@hnehealth.nsw.gov.au

Dr Gerrand may also be contacted if you have any complaints about any other aspect of the project, the way it is being conducted or any questions about being a research participant in general.

Consent Form - *16-17 year old providing own consent*

Title	Emotion Regulation and Impulse Control (ERIC): a program for young people with AOD and mental health issues.
Short Title	ERIC
HREC Reference	18/12/12/4.01
Sponsor	Deakin University
Principal Investigator	Professor Adrian Dunlop
Location	Drug and Alcohol Clinical Services, Hunter New England Local Health District

Declaration by Participant

I have read, or a member of the research team has read to me, the Patient Information Sheet

I understand the purpose and risks of the research described in the Patient Information Sheet.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I agree for a researcher to contact me via phone or email to arrange interview times.

I agree for the researcher interviewing me to contact my treating practitioner if I become distressed at any time during the baseline or follow up interview.

I understand that a researcher may need to access my medical records

I understand that all interviews will be audio recorded

Name of Participant (please print): _____

Phone: _____ Email:_____

Name of Witness* to Participant's
Signature (please print) _____

Signature _____ Date _____

* Witness is <u>not</u> to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may <u>not</u> act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Practitioner

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Practitioner (please print): _____

Withdrawal of Consent Form - *16-17 year old providing own consent*

Title	Emotion Regulation and Impulse Control (ERIC): a program for young people with AOD and mental health issues.
Short Title	ERIC
HREC Reference	18/12/12/4.01
Sponsor	Deakin University
Principal Investigator	Professor Adrian Dunlop
Location	Drug and Alcohol Clinical Services, Hunter New England Local Health District

By signing this consent form I give notice to WITHDRAW my consent to participate in the above research project. I understand that such withdrawal WILL NOT jeopardise the treatment that I receive now or in the future, my relationship with the staff caring for me or my ongoing care at this clinic.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the practitioner or researcher will need to provide a description of the circumstances below.

Appendix D: In session data collection measure

Extra Research Details

emotion   regulation   impulse   control

Use these sheets when you don't deliver an ERIC skill or when you repeat an ERIC skill used in a previous session.

Client Name or Initials .... Date ....

Content of session (briefly describe what you delivered this session, for example case management, housing support) ....

Emotion regulation strategies employed (if relevant) ....

SOFAS	Social and Occupational Functioning Rating [from 0-100]				
In the last 2 weeks....					
Housing	How many nights have you had stable accommodation?				........nights
School	How many days have you been at school?				.........days
Work	How many days have you been to work?				.........days
Extracurricular Activities	How many days have you done exercise or hobbies?				.........days
Friends	How many days have you socialised ('hung out') with friends?				.........days

Social Health — How happy are you with your social life?

0	1	2	3	4	5
Not at all					Very much so

Physical Health — How healthy do you feel physically?

0	1	2	3	4	5
Not at all					Very much so

Mental Health — How would you rate your mental health?

0	1	2	3	4	5
Very poor					Excellent

Service utilisation — Using the below scale, how frequently have you had contact with services in the past two weeks? (Please circle)

Centrelink	0	1-2	3-4	5	5+
AOD	0	1-2	3-4	5	5+
Housing	0	1-2	3-4	5	5+
FACTS/DOCS	0	1-2	3-4	5	5+
Physical health/ GP	0	1-2	3-4	5	5+
Justice/Legal/Police	0	1-2	3-4	5	5+

Alcohol Use

How many days have you consumed alcohol in the past two weeks? ..../14 days
What is the most you had to drink on one occasion?
Type/s of alcohol .... Number of drinks on that occasion ....
What is the typical amount that you drink on each occasion?
Type/s of alcohol .... Number of drinks ....

Substance Use

How many days have you used drugs in the past two weeks? ..../14 days
What is the most you have used on one occasion? Drug .... Quantity ....
What is the typical amount that you use? Drug .... Quantity ....

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Figure 13. An example of the form that practitioners were required to complete at each ERIC session with a young person.

Appendix E: ERIC Manual

See attached Document

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