# Project Protocol

## 1. Title: ‘First Step’ Implementation Trial

### 1.1. Study 1 title: Evaluating the 'First Step' in treatment for individuals seeking substance use interventions

## 2. Trial Registration:

### 2.1. Study 1: Yes, will be registered and updated with registration number.

## 3. Protocol version: 28 September 2020 version 1.2

## 4. Funding

### The project will be funded through a Department of Health grant, worth $200 000 and an additional $60 000 in funding from Lives Lived Well. The funding has been confirmed. This funding will cover costs for the clinicians conducting the intervention, the research assistants and participant reimbursement. Surveys will be administered through an online platform, Qualtrics, which is already owned by the University of Queensland (UQ).

## 5. Roles and Responsibilities

### 5.1. Chief Investigator/Researcher

### 5.1.1 Name: Professor Leanne Hides

#### 5.1.2 Affiliations: NHMRC Senior Research Fellow, Lives Lived Well (LLW) Chair in Alcohol, Drugs and Mental Health, School of Psychology, University of Queensland. Clinical Psychologist.

#### 5.1.3. Responsibilities: Professor Hides has leadership and responsibility for the overall project and has oversight responsibility for all sites. She will oversee all aspects of the research including design, protocol, execution, analysis and reporting.

### 5.2. Co-ordinating Principal Investigator/Researcher

### 5.2.1 Name: Dr Catherine Quinn

#### 5.2.2 Affiliations: LLW Research Fellow, School of Psychology, University of Queensland. Clinical Psychologist.

#### 5.2.3. Responsibilities: Dr Quinn will have responsibility for developing the First Step intervention, in collaboration with LLW, training the clinicians and preparing for implementation. She will be on maternity leave for most of the duration of project implementation and data collection. Upon return, she will contribute to data analysis, and preparation of research publications.

**5.3.** **Co-ordinating Principal Investigator/Researcher**

### 5.3.1 Name: Ms Leith Morris

#### 5.3.2 Affiliations: LLW Postdoctoral Research Fellow, School of Psychology, University of Queensland.

#### 5.3.3. Responsibilities: Ms Morris will have responsibility for the implementation of the program, co-ordination of clinicians, conducting baseline staff interviews and monitoring data collection, entry and analysis, and preparation of research publications.

### 5.4. Co-Investigator/Researcher

### 5.4.1 Name: Dr Zoe Walter

#### 5.4.2 Affiliations: Lecturer, School of Psychology, University of Queensland.

5.4.3. Responsibilities: Dr Walters will be involved in the design and guiding the overall direction of the program of research, data analysis, and report preparation, wider dissemination of the research.

### 5.5. Co-Investigator/Researcher

### 5.5.1 Name: Dr Molly Carlyle

#### 5.5.2 Affiliations: LLW Postdoctoral Research Fellow, School of Psychology, University of Queensland. Clinical Psychologist.

5.5.3. Responsibilities: Dr Carlyle will be involved in the design and guiding the overall direction of the program of research, conducting staff follow-up interviews, data analysis, and report preparation, wider dissemination of the research.

### 5.6. Co-Investigator/Researcher

### 5.6.1 Name: Dr Nick Kerswell

#### 5.6.2 Affiliations: Research Psychologist, School of Psychology, University of Queensland. Clinical Psychologist.

5.6.3. Responsibilities: Dr Kerswell is a board approved clinical supervisor. He will be involved in the design of the intervention and will be responsible for providing supervision to the clinicians conducting the intervention.

### 5.7. Investigator/Researcher

### 5.7.1 Name: Ms Rhiannon Ellem, Mr Calvert Tisdale, Ms Grace Newland, Mr Jack Killalea, Ms Angela Sunley, Ms Ella Cotterell

#### 5.7.2 Affiliations: Research Assistants, School of Psychology, University of Queensland.

#### 5.7.3. Responsibilities: The researchers listed above (5.7.1) will assist with data collection, participant follow-up, data entry and data analysis.

**6. Relationship between LLW and UQ**

In 2016 LLW formed a 5-year collaborative research partnership with UQ.  The partnership goals are to:

1. Better understand and improve the treatment of comorbid mental and drug use disorders
2. Improve training and education of staff working in alcohol and other drug (AOD) services in addressing issues related to comorbidity

The partnership includes the UQ appointment of a LLW Professor Alcohol, Drugs and Mental Health (Leanne Hides), and postdoctoral research fellow, as well as funding for one PhD scholarship. All these staff are employed by UQ, and are part of the School of Psychology, and are part of the LLW research team at UQ– everyone on this team is a UQ employee. They do not report to LLW from a performance management perspective, and do not have any LLW staff reporting to them. Governance arrangements for the partnership include monthly research meetings between UQ staff and LLW senior management, bi-annual UQ-LLW research partnership meetings (chaired by Professor Bruce Abernethy) and an annual review of the partnership by UQ (executive dean or equivalent) and a member of the LLW Board of Directors.

This collaboration closely aligns with two key strategic focus areas of UQ: to build engaged and strategic partnerships with local and global networks, and to enhance high quality research by improving the capacity to collaborate and achieve greater impact for research. It also aligns with the Faculty of Health and Behavioural Sciences’ mission, for researchers, educators and clinicians to work together with key partners from the health sector, to set directions for health and behavioural sciences nationally and internationally; and to ensure the healthcare Australians receive is evidence-based, cost-efficient and effective.

## 7. Background

Almost 130,000 Australians sought treatment for AOD concerns in 2016-17 (Australian Institute of Health and Welfare, 2019a). Current AOD services are only able to meet between 27% and 56% of the demand for treatment (Ritter, Chalmers, & Gomez 2019). Outpatient care in the form of counselling is the most common form of treatment accessed, but on average clients only attend 1.6 treatment sessions (Australian Institute of Health and Welfare, 2019a). Failure to complete treatment, often referred to as “drop-out”, is common in AOD treatment settings. One review of 122 AOD treatment studies found a wide range of drop-out rates, with between 0.4% and 85% of clients not completing treatment (Brorson, Ajo Arnevik, Rand-Hendriksen, & Duckert, 2013). While drop-out has traditionally been associated with relapse (Brorson et al., 2013), a recent meta-analysis of randomised controlled trials (RCTs) of psychosocial treatment in alcohol outpatient settings found the length of scheduled or attended treatment did not impact long-term alcohol outcomes in adults who had attended at least two sessions (Kramer Schmidt, Bojesen, Nielsen, & Andersen, 2018). The authors of the meta-analysis suggested this may be because some clients leave treatment due to improvements in AOD use (Kramer Schmidt et al., 2018). Together these findings suggest that not all clients who present to AOD services need intensive psychosocial or pharmacological treatment to achieve their goals, and some clients may benefit from a brief intervention. Brief Interventions (assessment feedback and MI) are also typically the first components of most psychosocial treatments delivered in these settings. Kramer Schmidt et al. (2018) recommended a more flexible approach to AOD treatment that could include a stepped care model offering lower intensity BIs first, followed by more intensive AOD treatment to those who request it, who are assessed to require more (e.g., presence of withdrawal symptoms), or who do not respond to treatment (Bower & Gilbody, 2005; Sobell & Sobell, 2000). This model of healthcare could help meet unmet demand and maximise the cost-effectiveness of AOD treatment in Australia (Andreas et al., 2012). However, there is still limited research examining stepped care models, or the efficacy of BIs within specialist AOD settings (McKellar, Austin, & Moos, 2012).

A RCT of brief interventions for reducing risky alcohol use among young people found that QuikFix, a brief intervention that included motivational interviewing enhanced with individualised personality-specific coping skills training, was more efficacious than two sessions of motivational interviewing or one sessions of assessment feedback and information (Hides et al, 2020). These findings suggest that using a similar framework for initial treatment sessions for individuals seeking AOD treatment may enhance treatment outcomes.

### 7.1. Rationale

QuikFix is a two session brief intervention that has been successfully trialled with young people experiencing alcohol use problems. However, while the QuikFix model is likely to be applicable to a broader audience, it has not yet being adapted and trialled with a wider cohort of young people (18-35 year olds), presenting to AOD treatment settings for a range of substance related concerns (e.g., methamphetamine, cannabis). As stated earlier, young people who present for alcohol and other drug treatment, on average only attend 1.6 sessions. Hence First Step, a brief intervention, of 1-2 sessions, that is adapted and targeted towards their needs may result in maximum benefits for this shortened attendance period.

In addition to understanding the feasibility of the intervention itself, it is also essential to understand how the intervention can best be implemented. Historically, a 17-25 year gap has been identified from the time evidence is established for an intervention to the implementation of the intervention in clinical practice (Dougherty & Conway, 2008; Morris, Wooding, & Grant, 2011). Even when an intervention is implemented in practice, program sustainability is difficult, with one study finding only 47% of services maintained fully implemented evidence-based interventions for six years (Bond et al., 2014). Hence this project will also examine factors that have impacted on the implementation of First Step, within the community treatment settings, using the Consolidated Framework for Implementation Research (CFIR; Damschroder et al., 2009), as a means to guide the examination of the implementation and its effectiveness.

## 8. Objectives

**8.1. Study 1.** The aim is to conduct a pilot single arm uncontrolled trial testing the feasibility of First Step, a brief intervention of 1-2 sessions, which is based upon the Quikfix Intervention, and has been adapted through a co-designed collaboration between UQ and LLW staff. It is expected that First Step will result in significant reductions in substance use (as measured by the WHO ASSIST and ATOP), when comparing baseline to 1 and 3 month follow-up evaluations.

**8.2. Study 2.** To understand barriers and facilitators of implementing First Step, using the Consolidated Framework for Implementation Research.

## 9. Trial Design

**9.1. Study 1.** A single-arm, uncontrolled feasibility trial of First Step will be conducted with 400, 18 LLW clients aged 18 years and older. This cohort will complete standard LLW outcome measures when they enrol at LLW (baseline) and then all clients will complete the same 2-session brief intervention. Follow-up surveys will be conducted at 1-month, 3-months, and 6-months post baseline.

**9.2. Study 2.** A mixed-method study, using brief quantitative surveys and structured qualitative interviews, which will be conducted before the trial begins, mid-way through the implementation (approx. 6 months after commencement) and after the implementation is completed (approx. 12 months after commencement). All survey and interview questions will be based within the CFIR (Damschroder et al, 2009).

## 10. Study Setting

**10.1**. **Study 1.** First Step will be implemented both intensively at a single site, with all counsellors delivering the same intervention, and also across four additional sites with single counsellors within each of these sites. This ensures that the comprehensive site components for an intervention can be thoroughly evaluated, as well as differences between locations (i.e., metropolitan vs rural/remote, and across QLD and NSW).

The sites at which First Step will be implemented include AOD services in Brisbane North, Gold Coast, Brisbane South, Darling Downs, Mackay (all QLD) and Orange (NSW). These are all community AOD sites which service similar clients, namely adults with substance use concerns. All sites offer both face-to-face and telehealth services. In total there will be approximately 20 counsellors across all these sites who will be involved in delivering First Step. All LLW clients who are assigned to these counsellors throughout the trial period will receive First Step.

Data collection will take place online, with researchers contacting participants via phone or email, from their research offices at UQ.

10.2. Study 2. Quantitative surveys will be completed by staff online, and qualitative interviews will be conducted over-the-phone with UQ researchers. These interviews will be conducted in working hours, with the LLW staff member located in their office, or another private room, while completing the interview.

## 11. Eligibility Criteria

### 11.1. Study 1. Participants will include adults aged between 18 years and older, who engage with LLW community services and are allocated to the counsellors taking part in the treatment trial. Clients will be eligible to participate if they consent and complete their LLW baseline outcome measures. To ensure maximum representativeness of the sample, besides age, there is no other exclusion criteria.

### 11.2. Study 2. All counsellors participating in the trial, as well as their team leaders and managers, will have the opportunity to participate in the implementation evaluation.

## 12. Interventions

### 12.1. Study 1. First Step is a co-designed alcohol and drug brief intervention, tailored to meet the specific needs of the clients, based upon motivational interviewing and cognitive behavioural techniques. This was achieved through active consultation with UQ staff and nine LLW counselling staff across multiple LLW programs and regions (including staff from QLD and NSW), managers and upper managers. Components of First Step were adapted from other evidence-based brief interventions, namely the Quikfix intervention (Hides et al., 2020). Program content has been developed so that it can be delivered both face-to-face and over-the-phone.

The First Step brief intervention includes comprehensive materials (e.g., information sheets and worksheets) that can be used by all counsellors; and that have the flexibility that they can be applied to a wide range of presenting client concerns. It is designed to be the *first step* in a stepped care model of treatment. Therefore, while all clients will have the opportunity to complete the brief intervention, they will also have access to further treatment as needed.

The First Step brief intervention is comprised of three modules delivered over two treatment sessions.

**Module 1 - Assessment Feedback/Information:** focuses on providing comprehensive personalised feedback to the client based on the LLW outcome measures (Appendix E) they completed at baseline. The feedback topics include:

|  |  |
| --- | --- |
| **Substance Use****• Frequency and amount****• Severity and Risks****Mental Health****• Depression & Anxiety**• Suicide* Trauma

• Psychotic Symptoms• Gambling | **Social and Life Factors**Additional Factors• Domestic and Family Violence• Violence to Others• Child Safety/Protection• Justice Systems• Homelessness• Chronic Pain.  |

The bolded topics are discussed with every client, the remaining areas only discussed if the outcome measures indicate this is an area of concern for the client. Psychoeducation is then offered to the client using relevant substance-related fact sheets and information sheets on common comorbid conditions. This information will be discussed with the client in session and/or emailed to the client after the session (see Table 1 below for full list of fact/information sheets and worksheets included in First Step).

**Module 2 – Motivational Interviewing:** focuses on motivational enhancement and goal setting. Motivational interviewing techniques are used to build motivation and commitment to change. The client’s patterns of substance use are first explored, and, the pros and cons of making a change/not making a change in their substance use are discussed. Options for change (reduce substance use or the potential harm associated with use) are then explored. The module ends with the client setting a substance-related goal using an implementation intention framework. These are supported by worksheets and information sheets (see Table 1 below).

Module 1 and 2 are usually delivered in one session.

**Module 3 – Targeted Coping Skills Training:** explores risk profiles that may underlie the client’s substance use behaviours and provides training in 2-3 coping strategies to target them. It ends with the client setting a second substance use goal which incorporates coping, using an implementation intention framework. There are accompanying worksheets to assist clients to complete and practice their relevant coping strategies (see Table 1 below).

Table 1. List of all fact sheets, information sheets and worksheets used in First Step

|  |
| --- |
| **Module 1** |
| *Substance Use Fact Sheets* | *Comorbid Issues Information sheets* |
| * Alcohol
* Cannabis
* Methamphetamines
* Tobacco
* Cocaine
* MDMA
* Inhalants
 | * Hallucinogens
* Heroin
* Sedatives
* GHB
* Anabolic Steroids
* Opioids
 | * Depression
* Anxiety
* Psychosis
* Gambling
* Trauma
 | * Domestic and Family Violence
* Child Safety
* Justice Involvement
* Homelessness
* Chronic Pain
 |
| **Module 2** |
| *Worksheets* | *Substance specific harm min tip sheets* |
| * Patterns of Use
* Pros & Cons
* Getting the Balance Right
* Goal Card
 | * Alcohol
* Cannabis
* Methamphetamines
* Tobacco
* Cocaine
 | * MDMA
* Inhalants
* Hallucinogens
* Heroin
* Pharmaceutical opioids
 | * Sedatives
* GHB
* Anabolic Steroids
* Needle Use
 |
| **Module 3** |
| *Coping strategies* |
| * Belly breathing
* Mind Chill
* Urge Surfing from Unpleasant Emotions
 | * Mind Change
* Savouring
* Urge Surfing
* Stop-Think-Do
 | * Breathe-Ground-Centre-Focus
* Finding Purpose
* Future Me
* How do I get there
 | * Natural Highs
* Good Vibes
* Fund Finder
* Three Good Things
 |

## 13. Outcomes

### 13.1. Study 1 - Primary outcomes. Outcomes will be assessed at 1, 3, and 6 month follow-up using quantitative self-report measures. Primary outcome measures will include changes in problems associated with substance use as measured by the WHO-ASSIST (WHO ASSIST Working Group, 2002), and changes in the past 4 week frequency and typical quantity of substance use as measured by the ATOP (Ryan et al, 2014).

**13.2.** **Study 1 -** **Secondary outcomes.** Secondary outcomes will examine changes in symptoms of depression, as measured by the PHQ-9, and anxiety, as measured by be GAD-7. Changes in quality of life/functioning will be explored using the LLW quality of life measures (which are based on the ATOP and the BTOM) and the EUROHIS-QOL (Schmidt, Mühlan, & Power, 2005). Changes in emotion regulation will be examined using the Difficulties in Emotion Regulation Scale (DERS), and the 21-item Coping in Stressful Situations Scale (CISS-SF) (Endler & Parker, 1999; Victor & Klonsky, 2016).

 Other outcomes of interest include the number of treatment sessions clients engage in, the length of time they are engaged with LLW, and whether they progress on to other treatment after the brief intervention.

**13.3. Study 2.** The key outcomes of interest are understanding the barriers and facilitators of the implementation trial, within the following CFIR domains: 1) Characteristics of what is to be implemented (e.g., an intervention; CRM); 2) Outer Setting (broad organisational and external influences); 3) Inner Setting (characteristics of the team and immediate working environment); 4) Provider characteristics (characteristics of the counsellors themselves); and 5) Process (the actual process of implementation and monitoring; Damschroder et al., 2009).

## 14. Project Duration

The full duration of the project is expected to be July 2020 to December 2022. Training of staff will take place from July-August 2020. Recruitment will take placed from August 2020 to October 2021 and follow-up surveys will be collected from September 2020 to April 2021. Data cleaning and paper write-up will take place from April 2021 to December 2022.

## 15. Participant Timeline

A timeline for the study is presented in Figure 1. The First Step intervention will be delivered in consecutive weeks where possible, or fortnightly. Regardless of whether a participant takes part in the trial they will receive the treatment and will take part in standard LLW assessment at baseline, 1-month and 3-months.

## 16. Sample size

A minimum of 200 participants will be included in the feasibility study. Sample size calculations were conducted using G\*Power, using an α error level of 0.01. With this sample size we will have 90% power to detect small to medium effects (0.25), accounting for multiple analyses and a retention rate of 60% at the 6-month follow-up (based on existing trials).

**Figure 1.** Timeline for participant participating in the evaluation



## 17. Recruitment and Consent

 **17.1 Study 1.** Recruitment to the study will occur through LLW community AOD Services. There are strong existing partnerships between the research team and these services. As part of the LLW consenting procedure and procedure to complete outcome measures, LLW clients will be informed about the research partnership between LLW and the University of Queensland, informed about the research project being conducted by UQ and asked if they would be willing for their contact details to be provided to UQ researchers, so that they could be provided more information about the study, and decide whether or not they would like to participate. Clients will be assured that in agreeing to provide their contact details they are not consenting to take part in any research.

Research assistants will regularly liaise with counsellors and intake officers to identify all clients who are aged between 18years and older who have provided permission to be contacted. If clients provide permission for their contact details to be provided to UQ, research assistants will contact the client within three days of this permission being provided. During this telephone call, the research assistant will provide the client with further information about the brief intervention study (see Appendix A); 2) will provide the client opportunity to ask questions about the study; 3) will assess the potential participant’s capacity to provide informed consent via an assessment of their mental state and cognitive ability based on their ability to engage with and understand the study procedures; and 4) will comprehensively obtain consent from the client to participate in the study. When obtaining consent, a number of questions are asked to ensure that the clients understands what they are consenting to, and clients individually consent to all core aspects of the project (see Appendix B). Clients will be provided with a copy (via email) of the information and consent form for their records. Upon consenting, clients will complete any outstanding survey measures (i.e., if they have not finished the LLW measures, and the few additional brief intervention measures).

As part of this consenting procedure clients will be reassured of the following: 1) that their participation is entirely voluntary and they can choose to withdraw from the study at any time; 2) that if they choose to withdraw, they will be contacted by a UQ researcher, with the opportunity to discuss what they would like done with their research data; 3) that their decision to participate will have no impact on their treatment – all clients will receive the First Step brief intervention, regardless of whether or not they chose to participate in the trial; 4) that in deciding to participate, there will be minimum duplication of the surveys they will be asked to complete – if they consent, LLW will share the outcome measures they have completed through LLW services with UQ, so that they only need to complete these measures once, and finally 5) clients will be assured that their decision to participate or not will have no impact on their relationship with their LLW worker, LLW services or the University of Queensland.

**17.2. Study 2.** Counsellors who will be delivering First Step with their clients, their team leaders and managers; will be asked if they would like to take part in a confidential survey and semi-structured interview aimed at evaluating the brief intervention. These staff will be informed about the research project and the Brief Intervention at team meetings, they will be provided the information form, to give them the opportunity to decide whether or not they would like to participate; and they will then be contacted by a UQ researcher, who has had limited prior contact with them, asking whether or not they would like to participate. They will be reassured that their participation is entirely voluntary; that they can withdraw at any stage (if they do choose to withdraw they will be contacted by UQ and asked what they would like done with their data); that the interview will only take 20-30 minutes, within their allocated work time; that they can still take part in delivering the brief intervention even if they choose not to participate in the evaluation; that their leaders and managers will not know if they decide to participate or not; and that their decision to participate or not will have no impact on their current or future relationship with UQ or LLW. See appendices C and D for information and consent forms.

Interviews will take place over the phone to ensure maximum confidentiality due to the privacy that can be obtained in completing the phone call in a private office.

## 18. Data Collection.

### 18.1. Data collection Methods. Study 1. Information will be collected via online surveys. No personally identifiable information will be collected on any of the survey instruments, with all participants identified by a unique code. There are two sets of survey instruments, detailed below, the first set is collected by LLW as part of their standard service evaluations (completed by all LLW clients regardless of whether they take part in the study), and the second set is some addition brief measures designed for the evaluation of the Brief intervention, and will only be completed by participants in the evaluation project. LLW send all prospective clients the suite of outcome measures to be completed via either SMS or email with a link to complete them online. Where requested by the client these measures can be completed over the phone with the assistance of a counsellor or UQ researcher.

Follow-up measures collected at 1-, 3-, and 6-months will be collected by UQ researchers and will incorporate both LLW measures and additional study measures. Participants will be actively followed-up and reimbursed ($20) for these measures by UQ. All participants who have consented to take part in the study will be contacted to complete the follow-up surveys, regardless of whether they complete the brief intervention.

**18.2 Lives Lived Well Instruments (Appendix E)**

18.2.1. Substance use: Will be assessed through the 8-item World Health Organisation Alcohol, Smoking and Substance Involvement Screening Test (WHO ASSIST). The WHO ASSIST is one of the better known substance use measures, with its reliability and validity demonstrated across a number of different age and cultural groups (Group, 2002; Humeniuk et al., 2008). The WHO ASSIST will measure participant substance use over the past 3 months. Substance use items from the Australian Treatment Outcome Profile (ATOP) will be used to measure the quantity and frequency of use of different drug types over the past 4 weeks.

#### 18.2.2 Quality of Life Measures: Past four week engagement in work and education will be assessed through the ATOP. The ATOP is a 22 item, one page assessment that is administered by the clinician that provides a general measure of the client’s substance use, functioning and well-being. The ATOP has been validated with young Australian adults and has been found to be valid and reliable for populations with substance problems (Ryan et al., 2014). Chronic pain is assessed by 3 items measuring the presence of pain, severity of pain and interference with general activity, using recommendations from Haefeli and Elfering (2006). The participant’s current ability to function socially and incidence of antisocial behaviour over the past 3 months will be measured using the 7-item social functioning sub-scale of the Brief Treatment Outcomes Measure (BTOM). The BTOM was developed and validated with Australian substance using populations (Lawrinson, Copeland, & Indig, 2005).

18.2.3. Mental ill-health: The 9 item Patient Health Questionnaire (PHQ-9) will be used to measure depression. The Generalised Anxiety Disorder 7 (GAD-7) is a 7 item measure that assess general anxiety. The PHQ-9 and GAD-7 both assess participant’s mood in the previous 2 weeks. Both the PHQ-9 and GAD-7 have been validated across a number of populations and will be suitable for assessing depression in young adults (Kroenke, Spitzer, & Williams, 2001; Richardson et al., 2010; Spitzer, Kroenke, Williams, & Löwe, 2006). A 5-item PTSD screen (Prins et al., 2015) and psychosis screen (Scott et al., 2006) is also included at baseline assessment. The PTSD screen and psychosis screen are only included at baseline.

18.2.4. \*\*Collected at baseline only\*\* Gambling: The Problem Gambling Severity Index (PGSI) is a 9-item measure which assesses how much of a problem gambling is for someone. The PGSI has sound psychometrics properties (Currie, Hodgins, & Casey, 2013; Orford, Wardle, Griffiths, Sproston, & Erens, 2010).

18.2.5. *\*\*Collected only at follow-up\*\** Client Satisfaction: The 5-item Patient Experiences Questionnaire (PEQ) will be used to collect feedback from the participants about their level of satisfaction with their treatment and to better inform treatment procedures. The PEQ was designed for use with clinical populations and will only be used at post-treatment assessment.

**18.3. Additional instruments not included in LLW Outcome Measures (Appendix F)**

18.3.1. Demographics: including age, gender, country of birth, ethnicity, postcode, years of education completed, family history of mental health issues, relationship status, employment status, and recent criminal history and engagement with medical services.

18.3.1. Impulsivity: \*\*Collected at Baseline only\*\* The SUPPS-P Impulsivity Behaviour Scale (Cyders et al., 2014) is a 20-item assessment that measures five impulsivity dimensions: negative urgency, lack of perseverance, lack of premeditation, sensation seeking, and positive urgency. This version of the questionnaire has been shown to be a reliable and valid alternative to the 59-item version (Cyders et al, 2014).

 18.3.3. Emotion Regulation: The 18-item Difficulties in Emotion Regulation Scale (DERS) will assess participant’s abilities to assess and process emotions (Victor & Klonsky, 2016). The task- and emotion-focused subscales of the 21-item Coping in Stressful Situations Scale (CISS-SF; 14 items included in current study), will assess participant’s coping styles. Both measures have been used in clinical settings and demonstrated their reliability and validity (Endler & Parker, 1999; Cohan, Jang, & Stein, 2006)).

18.3.4. Quality of Life: The 8 item EUROHIS-QOL will collect information about the patient’s quality of life across a number of domains. The EUROHIS-QOL has previously been tested with Australian populations and found to be a reliable and valid measure (Schmidt, Mühlan, & Power, 2005).

18.3.5. \*\**Collected only at follow-up\*\** Brief Intervention Client Feedback. This brief measure was designed to gain client feedback on the brief intervention. It includes questions related to the three core aspects of the brief intervention: assessment feedback, motivational interviewing and goal setting around substance use, and coping strategies, and some general feedback questions. This measure will be included at the 1-month follow-up.

**18.4. Data Collection Methods Study 2.** Surveys will be completed by staff online in their own time during work hours – these surveys will be confidential and will not contain any directly identifiable information (see Appendix G). The interviews will be conducted over the phone, during work hours, in a time specified by the LLW staff member (see Appendix H). The LLW staff member will be encouraged to find a quiet, private location.

### 18.5. Retention. Upon consenting to participate in the study, participants will also be requested to confirm their contact details to research staff to enable follow-up and survey completion (i.e., name, mobile number, email address, facebook username, as well as details for their next of kin). These contact details will be stored in a password protected excel document stored on the UQ server**.** For follow-up surveys, links to the online survey will be sent to participants via SMS or email, with participants also having an option to complete the survey verbally, over the phone, with a research assistant. Participants who are uncontactable by SMS or email will be approached through Facebook by a research assistant. Participants will be followed-up regardless of whether they complete the intervention programs. If a participant chooses to withdraw from the evaluation they will still be able to complete their allocated treatment program, without completing further follow-up surveys. For follow-up surveys, clients will complete one integrated LLW/UQ survey. Participants will be reimbursed $20 for every follow-up survey they complete, via paypal, direct debit or gift voucher.

**18.5.1. Following up clients who are incarcerated.** Previous research conducted by our team with a similar cohort found that a number of participants became incarcerated during the follow-up period (4%). As our participants are people seeking treatment for substance use, this is likely to be the case in the current project. In other projects, when we have contacted the next of kin (who has subsequently told us that the participant has been incarcerated), the next of kin has indicated to us that the participant is still interested in being involved in the study. As such, we are planning to conduct follow-up assessments in person with study participants who become incarcerated during the course of the project, at the relevant correctional facility. A member of our research team will visit the participant and complete outcome measures with them, using a printed version of the Qualtrics survey.

The process we have used in other research projects, which we will replicate is: we have contacted the next of kin after being unable to reach the participant directly, who has informed us that the participant is incarcerated. If the next of kin is willing, they have spoken to the participant directly to determine whether he or she is still interested in being involved in the study. Additionally, next of kin have sought permission for the research team to visit the correctional facility and administer the survey in person.

Gatekeeper approval is also required during this process, and the research team will contact the relevant correctional facility directly to arrange an appointment with the incarcerated participant, through the “professional visit” process. This includes completing a Form 27A.

## 19. Data Management.

To ensure transparency of the research project procedures and confidentiality, participants will be informed that any files with identifiable information (i.e., contact information files) will be stored electronically in password protected files on the UQ secure server, with access restricted to approved members of the research team. None of the data collected through the online server, Qualtrics, will contain any identifiable information. Once surveys are completed, they will be downloaded from Qualtrics and stored on the UQ server.

UQ’s servers are encrypted and protected with state-of-the-art firewall technology. Any data not able to be protected with a password will be stored in non-identifiable format only. Electronic files stored on network drives will have restricted access so that only approved members of the research team are able to access them. Data will be stored electronically for a period of 15 years in accordance with Australian Code for Responsible Research.

## 20. Statistical Methods

Preliminary logistic regressions will be undertaken to check for baseline differences on demographic, primary and secondary outcomes. A similar analysis will be conducted to detect differences between those with missing data, and those without, on key baseline demographic and outcome variables. Any significant differences will be reported and controlled for wherever possible, to control for sampling bias and completion bias. To determine whether there are time effect improvements in primary substance use outcomes post treatment (1 month), 3 and 6 months follow up will be compared to baseline, using a series of repeated measures analyses of variance. This technique can also control for potential confounds (e.g. demographic characteristics, baseline factors). Intent to treat analyses will be performed, with all participants included in analyses, regardless of whether they withdraw from the treatment program, or did not complete all follow-up assessments.

### Outcome success will be determined by examining the significant difference in scores from baseline to each of the follow-up points, as well as whether the effect size is small (0.2), moderate (0.5) and strong (0.8) depending on the value of cohen’s d.

## 21. Monitoring

**21.1.** **Implementation of the project**

During the development phase, weekly meetings of the project team (including LLW staff members) will be held to guide the development of the brief intervention. Once the brief intervention goes live the staff members delivering the brief intervention will have weekly meetings with the project manager to ensure the smooth-running of the project and to discuss any research-related concerns. The larger UQ research team also has weekly meetings which will check on the running of the project. There are also monthly research meetings with the LLW management and UQ senior management to monitor the ongoing progress of the project.

**21.2**. **Treatment Adherence**

All clinicians delivering the brief intervention will receive training in the intervention delivered by the UQ project team. The clinicians will also receive a brief intervention manual which they will use to deliver the brief intervention. They will complete a treatment checklist at the conclusion of each session and attend fortnightly supervision, which will be provided by a board approved clinical psychologist.

## 22. Project Risks

Potential risks that may arise during the project, as well as their mitigations are clearly specified below.

**Study 1:**

**22.1**. **Psychological discomfort or distress arising from the survey questions**

22.1.1. **Risk.** It is possible that participants might experience emotional distress while completing some of the questionnaires. Any distress they experience is likely to be minimal and temporary.

22.1.2. **Mitigation.** The baseline outcome measures are administered in the context of the client’s treatment, therefore they will already have contact with LLW, a group that specialises in AOD treatment provision, and will have an allocated contact person they can connect with if any distress does arise. For follow-up measures, the UQ research team includes a senior clinical psychologist, a clinical psychologist and one clinical psychology registrar who are trained in assessing and managing stress and psychological problems, and whose expertise has supported the development of the trial materials and measures. Research team contact details are provided so that participants are able to contact the research team during office hours are receive support if they need it. Possible mental health services that participants might wish to be referred are also outlined on the Participant Information Sheet.

We have extensive experience in the conduct of clinical research trials and have found participants report finding research assessments a beneficial and positive experience. All participants receive personalised assessment feedback drawn from their responses on the baseline assessment, which enhances the meaning and beneficial impact of the baseline assessment.

**22.2**. **Disclosure of Illegal activity**

21.2.1. **Risk.** Given that the target population is substance users, many of whom will be engaged in the use of illegal substances, there is a potential risk for the disclosure of illegal activities.

21.2.2. **Mitigation.** The risk of disclosure of illegal substances will be mitigated by: 1) the surveys have a closed response format, precluding the ability for the participant to spontaneously disclose any illegal activity beyond their substance use; 2) All research data will be de-identified from personal information and kept confidential unless the research team is ethically (if the participant is at high risk of hurting himself or herself or someone else) or legally obliged to do so (e.g., if a subpoena is issued by a court or by legislation); 3) Information pertaining to the limits of confidentiality will be clearly detailed in the information sheet (i.e., “All responses will be treated confidentially and will not be shared, unless (in the unlikely event) that the research team is legally (e.g., a court order or subpoena) or ethically (e.g., “you are at risk of harming yourself or others”) required to do so; moreover, participants will be informed that anything discussed during the program is confidential, unless information is disclosed which places them, or others at risk, in which case there is a requirement to report this information; 4) None of the content of the program focuses on illegal activity specifically, reducing the likelihood than any illegal information will be disclosed; 5) The Lives Lived Well team routinely records this information on AOD use in their clinical records, so the collection of similar information as part of this research does not increase the level of risk in this information being used in legal proceedings.

**22.3.** **Involvement of persons with a mental illness, and increased vulnerability that may arise**

21.3.1. **Risk.** All the participants taking part in the trial will have substance use problems, with likely substance use disorders. Often, substance use disorders are comorbid with mental health concerns, including depression and anxiety, hence it is likely that in addition to substance use concerns, participants will also be experiencing mental health concerns. Individuals experiencing mental health and substance use concerns often experience increased vulnerability and decreased social engagement.

21.3.2. **Mitigation.** The risk of vulnerability arising from mental health concerns will be mitigated by: 1) The project is specifically designed for a substance using population, and the interventions evaluated have been specifically designed for populations at elevated risk of substance use and mental health disorders, with a specific focus reducing substance use and mental ill-health concerns; 2) The brief intervention aims to reduce substance use and improve psychological, and emotional wellbeing, through evidence-based intervention; therefore, the brief intervention is likely to provide participants with the skills needed to better manage their substance use and mental health concerns, having the potential to reduce, not increase, the vulnerability of this population; 3) The staff at LLW are trained to work with these populations, and the researchers at UQ also have training in psychology and experience working with these populations; 4) Care will be taken by clinicians to ensure young people are in an appropriate setting during treatment consultations to ensure privacy and confidentiality; 5) Regular supervision will be provided to the LLW staff delivering the brief intervention, by a board approved supervisor in clinical psychology; to ensure the program is appropriately implemented, and the clients’ needs are appropriately met; 6) A comprehensive consent procedure is being used in this study to ensure that the participant understands the requirements of the study and freely agrees to take part. Information pertaining to consent for individuals experiencing mental illness is clearly detailed in the HREA, under participant specific information.

Our approach is consistent with the NHMRC (2007, p. 65-6) guidelines, which recognises that people with mental illnesses are entitled to participate in research, and their consent and thus participation, should be sought when their mental illness does not interfere with their capacity to give informed consent.

**22.4.** **Involvement of Persons in dependent or unequal relationships**

22.4.1. **Risk.** Participants are undertaking treatment through LLW community AOD services, so there is some risk that they may feel compelled or coerced to also participate in the evaluation trial.

22.4.2. **Mitigation**. We will mitigate this risk by ensuring that at every step of the recruitment and consent process the participant knows that their participation is voluntary and that they will receive First Step regardless of whether they agree to participate. LLW will ask for the client’s permission to pass their details onto the research team. It will be made clear that regardless of whether or not they decide to share their contact details, their decision will have no impact on their treatment, their relationship with the worker, LLW organisation, UQ, or any other organisation.

 Clients who agree to their details being passed on to UQ will be contacted by a UQ researcher (independent of LLW – not a LLW employee). The client will be fully informed about the study, what their participation will involve, the benefits and any potential risks. The client will also be informed that their participation is entirely voluntary, and that they can withdraw at any time without comment or penalty. They will be informed that if they choose to withdraw they have the right to decide what happens to their data. Clients will be assured that their decision to participate or not will have no impact on their substance use treatment or relationship with their LLW worker or LLW services, or their **relationship with UQ, or any other relevant organisation. We will ensure that the client fully understands the research project and what participation entails.**

This will be achieved by: using language which is appropriately accessible to the client; by checking in with each potential participant as to whether they have understood all of the information presented to them, by asking to tell us about the aims of the study and what participation involves, and whether they have any questions about the information provided; and by completing a checklist with the client (as seen on the Consent Form) to ensure that they have understand core aspects of the study, and that they agree to core components of the research.

Independent researchers will also obtain all follow-up data. The treatment delivery being kept independent of survey collection for the evaluation (i.e., all participants will receive the breif intervention regardless of whether they take part in the evaluation or not), is another way that the impact of any dependent relationships on participation will be minimized.

**22.5**. **Suicidal ideation and risk of self-harm**

22.5.1. **Risk.** There is a possibility that some of the clients participating in the study will be experiencing suicidal ideation and may be at risk of self-harm.

22.5.2. **Mitigation.** Any safety or urgent treatment issues will be managed as per usual safety and risk management procedures by the LLW clinicians. As part of intake procedure LLW intake staff complete a suicide risk assessment, if somebody does screen positive for suicide risk, their caseworker is made aware, and they are followed up by LLW treating staff.

If the clinician requires any additional assistance with management or possible referral, the research psychologists from UQ, who are trained clinical psychologists, will provide support and assist with management or possible referral if needed. The research psychologists have post-graduate training in the assessment and management of suicide risk. Dr Leanne Hides will be available to support the research psychologists with suicide risk assessment/management and can provide additional telephone support to the young person if required.

Throughout the course of the trial, participants will complete the Patient Health Questionnaire (PHQ-9) which includes a question pertaining to suicidal ideation. If the client indicates that they have been experiencing suicidal ideation nearly every day in the past 2 weeks, the LLW case manager for the client will instantly be informed through their system (as this measure is also collected by LLW staff) to follow-up the client.

Participants will be presented with a suicide risk screening measure, which assesses lifetime and past month self-harm behaviour, suicidal ideation, plans and attempts. Participants will then be presented with support resources and asked if they would like to speak with someone on the team, to help them find further support.

During the follow-up period, when the client is not in active treatment, a trained research UQ clinician, will contact the participant if requested, conduct a risk assessment, and provide the client with LLW counselling and community support services as required. A suicide protocol is submitted as Appendix I.

22.6 **Involvement of Incarcerated Persons**

22.6.1. **Risk.** There is the additional risk that participants who are incarcerated may feel an added pressure to complete the survey, as their freedoms have been restricted and they may feel as though they do not have sufficient control over what they can or cannot do

22.6.2. **Mitigation.** We will take active steps to ensure that participants do not feel compelled to participate in the study.

1. To ensure that we do not further add to the reduction of their autonomy, we will remind the participant that participation is completely voluntary; and
2. Remind the participant that they can withdraw at any time, without penalty from any organisation including the University of Queensland and the incarceration service.
3. Information pertaining to the limits of confidentiality will be clearly detailed verbally by the researchers when discussing consent (i.e., “All responses will be treated confidentially and will not be shared, unless (in the unlikely event) that the research team is legally (e.g., a court order or subpoena) or ethically (e.g., “you are at risk of harming yourself or others) required to do so”).
4. As previously described, the participant has the opportunity to decline the interview through their next of kin before we seek approval to visit the correctional facility.
5. Further, incarcerated participants are not required to attend a scheduled appointment, and are free to decline on the day.

Conducting follow-up surveys with participants in prison presents the risks of disclosure of illegal activity, and/or disclosure of risk of harm to the participant or others. However, this level of risk is not different from that for all participants. This will be managed by following all usual procedures already detailed, in addition to the risk management procedures at the correctional facilities.

There is a potential risk that completing the survey face to face, compared to over the phone, may cause additional distress to the research assistant conducting the survey. To mitigate this risk, only research assistants who have had extensive (>12 months) experience in conducting the follow-up surveys with the study’s population (people who use substances) will be involved in face-to-face data collection. While the topic is potentially distressing or causing discomfort, it is a topic that the research assistants are routinely engaged in. Additionally, the researchers at UQ also have training in psychology and receive supervision from the CIs on the project, who are registered psychologists.

This procedure has been approved in another trial we are currently conducting (HREC approval number 2018001185) and there have been nil complaints from participants or other issues arising from this.

**Study 2**

22.7. The risks from participating in Study 2 are considered relatively low or negligible. Participation in this study is entirely voluntary. Participants can decline to participate in any aspect of this study and still attend the training or participate in the delivery of the brief intervention. Participants’ decision to participate, or not to participate will not impact in any way on their relationship with their employer, as their employer will not know whether or not they are participating in the evaluations. It is possible that completing the surveys or interviews may cause some discomfort in participants by rating their personal capabilities, or commenting on their work environment. However, any discomfort experienced is likely to be minimal and temporary and likely to be mitigated by the fact that they will be administered by someone whom they have had minimal previous contact with. All questionnaires and data will be confidential and participants will be assured that individual responses will not be shared with anyone outside of the research team and that results will be grouped for analysis. If individuals would like to omit or edit any of their responses during data collection or before their data is de-identified, this request will be accommodated by the research team.

## 23. Project Benefits

**Study 1**

23.1. **Benefits at an individual level**

LLW community programs aim to reduce substance use and mental ill-health and enhance wellbeing. Including the brief intervention as a structured, first treatment in a stepped-care approach is a way to further enhance program outcomes and improve the outcomes of those seeking treatment from LLW. Participants receiving the brief intervention may see reductions in substance use and improvements in mental health as a result of the intervention. Although participants are not expected to directly benefit from completing the surveys for the evaluation, participants’ time and effort in completing the survey will be acknowledged through a reimbursement of $20 for each survey completed.

If the brief intervention proves to enhance standard care then it can be implemented across LLW in the future, so that it is the first step for all clients seeking treatment.

23.2. **Benefits at an organisational level**

In conducting the brief intervention, LLW staff will be trained in theory, clinical strategies and delivery. They will deliver the intervention, and be provided with clinical supervision by a board approved supervisor, throughout the course of the program implementation. This training and supervision both enables LLW staff to be upskilled in new techniques to better meet the needs to clients seeking services for alcohol and other drug problems. If the program proves to be effective, there will be a wider dissemination of the program, across all community services at LLW, which would result in further professional development of staff, and the inclusion of evidence-based programs to enhance the recovery and wellbeing of clients attending LLW services. Information from the evaluation will also provide LLW with useful feedback on the efficacy of the brief intervention, which is likely to inform their future service delivery, further improving outcomes for substance using clients.

23.3. **Benefits at a societal level**

 The results of this research may help to improve treatment services aimed at increasing engagement and recovery of substance using clients. This may ease some of the social and economic burden associated with substance use in the wider community.

**Study 2**

23.4. **Benefits of study 2**

This research will likely help to improve the translation of the Brief intervention into the alcohol and other drug field, by understanding the support required for the use of this intervention and the barriers that may exist preventing the successful utilisation of this intervention. Further, we anticipate that participants might gain increased knowledge about brief interventions and coping skills training and that participants’ skills and confidence in using these tools will be enhanced as a result of participating in the training and supervision that this study offers.

## 24. Results, Outcomes, Future Plans

### 24.1. Results to participants

Results of the study can be disseminated to research participants via email upon request. The results will also be made available on the LLW website.

### 23.2. Dissemination and Publication

Results will be published via conference presentations, and peer reviewed publications. As stated above, a report would also be made available through the LLW website.

### 24.3. Other potential use for the data

 Data may be used as comparative data in future projects for secondary analysis. Participants are asked to explicitly consent to their data being used in this way prior to beginning the evaluation. One of the ways data may be used in future studies is to compare the findings to other study populations with which the program may be implemented, and to use the baseline data to examine characteristics of substances users seeking treatment. For study 2, data could be used to compare implementation feedback to other implementation trials, to examine similarities and differences across different AOD programs.

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