## A randomized wait list control study of 6 sessions of On-line Community Reinforcement and Family Training (CRAFT) on wellbeing of family members of people with substance dependence and mental illness

**Protocol**

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| --- | --- |
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| Trial identifiers: | Annual Workplan Project G |

**REVISION HISTORY**

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| Version | Date | Amendment Text | Description |
| 1 | 14/Jun/2023 15:09 | Added reference list | Reference list |
| 2 | 26/06/202311.59 | Methods  | Changed sample size and statistical analysis |
| 3 | 10 July 2023 | Updated training and FEP session details, PISCF | Added training information, PISCF for clinicians and referral agents, recruitment flyers |
| 4 | 22 August 2023 | Participant screening p. 16Participant flyer | Changed response to screening questions.Updated participant flyer |

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# 1. TRIAL SUMMARY

World Health Organization Registration Data Set

|  |  |
| --- | --- |
| Title | A randomized wait list control study of 6 sessions of Online Community Reinforcement and Family Training (CRAFT) to improve wellbeing of family members of people with substance dependence and mental illness |
| Primary registry and trial identifying number | Australian New Zealand Clinical Trials Registry |
| Secondary identifying numbers | RHRI Annual Workplan Project G |
| Sources of monetary or material support | This trial is funded by Department of Health and Aged Care (DoHAC), Australian Commonwealth Government. As part of the CSU Rural Health Research Institute’s approved workplan (Project G). |
| Primary sponsor | Rural Health Research Institute, Charles Sturt University |
| Secondary sponsors (if any) |  |
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| Study officials/Investigators | Chief Investigator – A/Prof Julaine Allan, CSUStudy coordinators – Nicole Snowdon & Heidi Gray CSUPartner Investigators * Dr Kedir Ahmed, CSU
* Dr Subash Thapa, CSU
* Dr Nicola Ivory, CSU
* Heidi Gray, CSU
* Prof Anthony Shakeshaft, Poche Indigenous Centre, UQ
* Dr Sara Farnbach, Senior Research Fellow, National Drug and Alcohol Research Centre, UNSW
 |
| Brief title | Family Empowerment Project |
| Acronym | FEP Trial |
| Countries of recruitment | Australia |
| Condition(s) or focus of study | Psychological wellbeing of family members negatively impacted by substance use/mental health condition of relative |
| Interventions |  |
| FEP intervention | Intervention type: BehavioralIntervention name: CRAFTOther names: Family Empowerment Program (FEP)Intervention description: FEP Online comprises 6 + 2 sessions of 60 minutes each delivered to individuals.  |
| Wait List Control | Intervention type: OtherIntervention name: Wait List Control + reading materialOther names: WLCIntervention description: Participants randomized to the wait list will receive a copy of the parents or partners Invitation to Change 20-minute guide while waiting to receive FEP |
| Key eligibility criteria | Age eligibility: 18 years or olderSex eligibility: BothAccepts healthy volunteers: NoInclusion criteria:1. Family member/s of someone with substance dependence and a mental illness2. speaks English3. over 18 years of age4. is able and willing to attend all FEP sessions5. Is able to provide informed consent6. having at least one contact/day on four days over the past month (in-person or electronic) with the Identified Relative (IR)7. access to a computer with internet or mobile phone with video conferencing capabilitiesExclusion criteria:1. Domestic and family violence from the person with substance dependence to the family member2. current participation in family support/therapy programs |
| Study design | Study type: Interventional trialAllocation: RandomizedIntervention model: Parallel groupPrimary purpose: Supportive Care |
| Masking | Trial participants, Care providers |
| Date of enrollment | October 3, 2023 |
| Target sample size | 260 |
| Recruitment status | Not yet recruiting |
| Primary outcomes | Outcome: improved psychological wellbeing of family member Timeframe: 18 weeks post baselineOutcome: Feasibility - extent of exposure to FEP by participants (number& length of sessions attended). Timeframe: number& length of sessions attended during intervention |
| Secondary outcomes | Outcome: the person with substance dependence engaged with health or substance dependence services Timeframe: in the period during which FEP was delivered Outcome: the person with substance dependence reduced their substance use as reported by a participating family member.Timeframe: 18 weeks post baseline interviewOutcome: Acceptability – FEP participants, clinicians and referral agents report the online program was acceptableTimeframe: 18 weeks post baseline interview or study end |

# 2. INTRODUCTION

## 2.1. Background and rationale

Community Reinforcement and Family Training (CRAFT) is a counselling approach that works with families and friends of people with alcohol or other drug (AoD) problems to provide structured, personalised training and support. Derived from Cognitive Behavioural Therapy (CBT), the aims of CRAFT are to teach family members how to effectively and safely remove positive reinforcement for problematic substance use behaviour, increase positive reinforcement for non-using behaviour, and help the person with problematic AoD use to enter, or be retained in, treatment. In addition, CRAFT aims to improve family members’ own social and emotional wellbeing.

Substance use is associated with poor outcomes for individuals with mental illness because it impedes treatment engagement and is associated with more severe psychiatric symptoms (1). Comprehensive reviews and meta-analyses consistently show that family-focused interventions are effective at improving substance treatment engagement and outcomes across the lifespan (2,3). Yet, substance treatment services rarely incorporate family members and concerned significant others (4). Integrated treatment, care and support for people living with mental illness and substance use is the goal of policy and practice in Australia and internationally. However, while the direction has been given by state and national governments to “do” integrated care, there are no frameworks or guidelines about what to do. Ways to address problematic substance use of people with a mental illness are needed.

Harmful substance use and related deaths are more prevalent in rural Australia compared to cities (6) and substance treatment services are mostly located in large cities not in regional or rural areas (7). Services meet only one third of the demand for treatment (8). Few of these services provide support to family members.  Only 7% of the 139,300 clients receiving treatment in 2021 were family or friends of people with a substance problem (7).  In Australia, one in three individuals with a substance use disorder also has a mental health disorder and approximately 1 in 5 people experience a mental health disorder annually (9). Two or more disorders are so common among those experiencing mental health or substance use problems that “comorbidity is seen as the rule rather than the exception” (10 p8).  Further, comorbidity results in a greater care burden on the family and increased family conflict compared to single disorders (11-13). Community Reinforcement and Family Training (CRAFT) is an evidence-based approach that helps families to reduce substance use, engage in treatment, and improve family wellbeing (e.g.,14,15,2) but is not available in Australia and has not yet been studied for mental illness and substance use combined. CRAFT has been effective in as few as four to six sessions although was originally delivered as 12, 1-hour sessions (16,17).

The study will generate the first Australian outcome data, which will complement the USA outcome data and the Australian adaptation and acceptability data from the CI’s previous work (4-6). This research project can inform future health system policy on the provision of virtual care for rural families of people with substance dependence and mental illness.

An adaptive wait list control design has been selected because all participants will get access to the intervention. Restricting the active intervention from the control group for longer periods than necessary prevents participants from receiving a potentially beneficial treatment sooner. This restriction may cause threats to participant's health and well-being. An adaptive WLC (aWLC) design balances the Stage I duration between the groups and allows patients randomized to the control group to receive the study intervention sooner than traditional WLC design strategies where all intervention group participants have to finish the intervention period before the wait list participants can commence (18).

## 2.2. Objectives

**Research question: Is it effective, feasible, and acceptable to deliver FEP (CRAFT) online?**

The *primary aims* of this study are to a.) evaluate the effectiveness of an online delivery of FEP to family members with a loved one experiencing substance problems and mental health conditions; and b.) Feasibility - extent of exposure to FEP by participants (number& length of sessions attended). The *secondary aims* are to identify the factors associated with successful implementation as perceived by a.) participants, b.) clinicians & c.) referral agents; and 2. whether the person with substance dependence a.) engaged with health or substance dependence services in the period during which FEP was delivered and b.) reduced their substance use as reported by a participating family member.

*Hypothesis:* that FEP implemented online by accredited therapists will be more beneficial than the FEP self-help information provided to the wait-list group. Compared to the wait-list control group, the FEP group will show greater decrease in self-reported levels of depression, anxiety and stress and increase in life satisfaction and that these improvements will be maintained over a three-month period post intervention. The study will also examine the feasibility and acceptability of the online program. It is hypothesized that 1) improvements in depression, anxiety and stress scores as a function of FEP relative to the control group will be mediated by a) acceptability of receiving support online and b) ease of access. Given the lack of information regarding substance use interventions for families of people with a mental health condition qualitative methods will explore the experiences of study participants as well as clinicians and referral agents.

## 2.3. Trial design

Phase IV randomized wait-list control trial assessing the effectiveness, feasibility and acceptability of virtual FEP with a parallel group, two-arm, superiority design with a 1:1 allocation ratio comparing online FEP with a wait-list control. The primary endpoint of participant wellbeing will be measured 18 weeks after baseline data collection and will include an end of program (6 weeks) data collection also.

# 3. METHODS

## 3.1. Study setting

The study will be conducted in Australia. The FEP program will be delivered online to people who live in a rural area (Modified Monash Model 2-7) of NSW, Victoria and QLD. The program will be delivered from the worksites of the clinicians trained and accredited and employed to deliver it using Zoom as the delivery platform. The main study site where the project will be managed from is the Orange campus of Charles Sturt University.

## 3.2. Eligibility criteria

**Study Participants:** Study participants will be

i). self-selected people with a relative who has a substance problem and mental health condition responding to the call for participants (outcome measures and acceptability and feasibility interviews)

ii). Clinicians delivering FEP (acceptability & feasibility interviews and usage rating profile measure)

iii). People referring participants to the study (acceptability interviews)

**Training:** Clinicians delivering FEP will be trained and accredited using the standard procedures and assessments established by Robert J. Meyers (therapist certification - [Robert J. Meyers, Ph.D. - Workshops (robertjmeyersphd.com)](https://www.spiritprotocol.com/api/docx/https%3A//www.robertjmeyersphd.com/workshops.html) . Training will be held on 10 and 11 of August 2023. Minimum standard to be trained and accredited is a Bachelors degree in social science, social work, psychology or occupational therapy and 2 years counselling experience preferably in substance treatment. Intervention fidelity will be assessed by an accredited CRAFT trainer and supervisor reviewing 6-8 audio recordings of each clinician’s sessions.

### 3.2.1. Inclusion criteria FEP participants

1. Family member/s of someone with substance dependence and a mental illness
2. speaks English
3. over 18 years of age
4. is able and willing to attend FEP sessions
5. is able to provide informed consent
6. having at least one contact/day on four days over the past month (in-person or electronic) with the Identified Relative (IR)
7. access to a computer with internet or mobile phone with video conferencing capabilities

### 3.2.2 Exclusion criteria FEP participants

1. Domestic and family violence from the person with substance dependence to the family member
2. current participation in family support/therapy programs

### 3.2.3. Inclusion criteria clinicians and referral agents

Interviews will be held with consenting clinicians and referral agents who participated in the study to explore feasibility and acceptability of FEP.

1. delivered FEP during the study period, or

2. referred someone to the FEP program who subsequently participated in the study

### 3.2.4. Exclusion criteria Clinicians and referral agents

Not involved with the Family Empowerment Program

## 3.3. Interventions

### 3.3.1. Intervention description

*Family Empowerment Program:* FEP aims to support the family and friends of people who are struggling with substance dependence. It derives from Cognitive Behaviour Therapy (CBT). It has specific components that teach family and friends techniques to identify ways to protect their own wellbeing, to strengthen the positive rewards they can provide when their loved one is not using drugs, and to positively encourage their loved one to use health and substance treatment services. The intervention will be called The *Family Empowerment Program.* The *Family Empowerment Program Online* comprises 6 sessions of 60 minutes each delivered to individuals. A further two sessions will be available if participants wish to consolidate any skills or revisit a topic. The key focus of sessions is on learning new skills and how to use them, so that participants can change the way they behave and interact with their loved ones. Skills that participants will learn include effective communication and problem-solving skills; how to be more assertive while not provoking conflict and how to improve their own sense of well-being.

**FEP Program schedule**

Six sessions make up the FEP program. The order of sessions can be moved around if required.

Session 1, building motivation and self-care, includes introducing the family member to FEP rationale, psychoeducation, and establishing self-care goals.

Session 2, communication, includes general positive communication strategies and role plays.

Session 3, functional analysis of client substance use, includes identifying the client's typical substance use behavior, internal and external triggers, short-term positive consequences, and long-term negative consequences.

Session 4, positive reinforcement, includes reinforcement of recovery-oriented non-substance use behaviors.

Session 5 problem-solving and natural consequences, includes practice of problem-solving procedures, provides guidelines for allowing for natural consequences of substance use to occur.

Session 6, discussing treatment engagement, includes “windows of opportunity” and “motivational hooks” for engaging a loved one in treatment. Program review and next steps, includes a summary and review of program topics, planning to maintain progress and skill work, and providing additional resources or 2 extra sessions if required by the participant.

Milestone conversations (weeks 2,3 & 6)

Designed to reduce the family members assumptions about what is important and rewarding about substance use to their relative and to ascertain the relative’s views on substance treatment.

(1) What is most important to their relative currently? What are they looking forward to? What do they enjoy doing?

(2) What are their relative's substance use patterns and what benefits do they get?

(3) How does their relative feel about substance treatment? What is their experience with it?

Milestone conversations are planned during the session in week 2, 3 or 6 and intended to be undertaken by the study participant with their relative before the next session.

## FEP Training

Training occurs one month prior to the study commencement. Training consists of 2 days of experiential sessions involving role plays and practice of the procedures. The participant training manual listing all sessions, procedures and milestone conversations is in Appendix 8.1 and training recruitment flyer in Appendix 8.2. Clinicians must attend both days of training and agree to participate in accreditation assessment to deliver FEP.

## Wait List Control reading materials

All participants randomized to the wait-list will receive one of two resources from the Centre for Motivation and Change - either *The parent’s 20 minute guide (second edition): A guide for parents about how to help their children change their substance use* or *The partner’s 20 minute guide (second edition): A guide for partners about how to help their loved one change their substance use* (available from <https://motivationandchange.com/family-services/resources-for-families/> ).

### 3.3.2. Modifications

There will be a check in with participants at the beginning of each FEP session and any issues raised will be addressed. In the event of participants experiencing difficulties in relation to their FEP practice the following actions may be taken: a) modify the type of practice for the coming week or b) provide a referral for unrelated concerns (e.g. finances, ill health). The 18-week follow-up questionnaire includes a question about the occurrence of any adverse effects or other difficulties thought to be because of FEP. The questions were taken from a recent study about the broad ranges of experiences that occur in association with relationship changes (21). The questions are:

1. “Did you have any unexpected, challenging, or difficult experiences that you associate with your practice of FEP?
2. “How did these experiences impact your life”?

### 3.3.3. Adherence

**Adherence assessments**

The schedule of FEP sessions for each participant will be established in advance during the baseline assessment. Participants will receive a text reminder including the date and time one day before their scheduled session. They will be asked to reply yes if they are attending and no if they wish to reschedule. Rescheduled sessions will be held within 1-2 days of the originally scheduled appointment where possible, otherwise the session will be delivered during the next previously scheduled appointment. An additional session will be planned at the end of the program. If participants do not respond to the reminder and/or do not attend their appointment three attempts to contact them to reschedule will be made in the following two weeks before considering they are withdrawn from the program. Data collection will still occur with participants who do not complete the program but who respond to contacts from the research team.

### 3.3.4. Concomitant care

Participants who commence an alternative family support program for their relative’s substance problems will be excluded from the study. Family support programs for their relative’s mental illness are allowed.

## 3.4. Outcomes

An outcome evaluation will be conducted and the within and between-group comparisons reported. The outcomes for participants who receive the FEP program will be compared to those who received reading material while on the waitlist. The primary outcome will be psychological wellbeing and the secondary outcomes will be Identified Relative (IR) substance use and engagement in treatment. Psychological wellbeing will be assessed at baseline (pre-program enrolment), post-treatment (6 weeks post enrolment), and follow-up (18 weeks post enrolment). Intervention fidelity will be assessed by an accredited CRAFT trainer and supervisor reviewing 6-8 audio recordings of each clinician’s sessions.

## 3.5. Participant timeline

Group A is the intervention group and Group B is the wait-list control group:

Baseline Assessment:

* 1. Week 1: Initial screening and eligibility determination
	2. Week 2: Baseline assessment, including demographic information, and measures (post randomization because measures are time dependent)

Enrolment and Interventions:

* 1. Week 1: Randomization and assignment of participants to either Group A (intervention group) or Group B (wait-list control group)
	2. Weeks 3-8: Community Reinforcement Approach and Family Training interventions for Group A (6 weeks of intervention)
		1. This period will involve regular weekly intervention sessions
	3. Weeks 3-8: No intervention for Group B (wait-list control group)

Run-in and Washout: None

Assessments:

* 1. Week 8: 6-Week assessment for both Group A and Group B participants, of included measures
	2. Weeks 9-14: Commence intervention sessions for Group B participants
	3. Weeks 9-14: No intervention for Group A participants

Assessments and Visits:

* 1. Week 18: Final assessment for both Group A and Group B participants, included measures
	2. Week 18: Final phone or zoom call to collect interview data on participant experience and address any participant concerns
	3. Week 18: Study completion and debriefing for participants

During the intervention period (Weeks 3-8), Group B participants in the wait-list control group will not receive any active intervention. Instead, they will be placed on a wait-list and serve as a comparison group.

Clinician and referrer experience interviews will be conducted at the end of the study.

Schedule of forms and procedures

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **TIMEPOINT (weeks)** | week 1  | week 2  | week 3  | week 4  | week 5 | week 6 | week 7 | week 8 | Week 9 | week 10 | Week 11 | Week 12 | Week 13 | Week 14 | Week 18 | Study end  |
| **VISIT NUMBER:** | 1  |  2 |  3 |  4 |  5 | 6 | 7 | 8 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |  1 |
| **ENROLLMENT:** |   |   |   |   |  |  |  |  |  |  |  |  |  |  |  |   |
| Eligibility screen  | x  |   |   |   |  |  |  |  |  |  |  |  |  |  |  |   |
| Informed consent  | x  |   |   |   |  |  |  |  |  |  |  |  |  |  |  |   |
| Allocation  | x  |   |   |   |  |  |  |  |  |  |  |  |  |  |  |   |
| **INTERVENTIONS:** |   |   | Group A FEP  | Group A FEP  | Group A FEP | Group A FEP | Group A FEP | Group A FEP |  |  |  |  |  |  |  |   |
|   |   |   | Group B waitlist  | Group B waitlist  | Group B waitlist | Group B waitlist | Group B waitlist | Group B waitlist | Group **B** FEP | Group **B** FEP | Group **B** FEP | Group **B** FEP | Group **B** FEP | Group **B** FEP |  |   |
| **ASSESSMENTS:****Dass21, SWLS, FS, COPE****Ease of use** |   |  Baseline |   |   |  |  |  | Group A & B 6 week measures |  |  |  |  |  |  | Group A & B 18 week measures |   |
|   |   |   |   |   |  |  |  |  |  |  |  |  |  |  | Group A & B Participant experience Interviews |   |
|   |   |   |   |   |  |  |  |  |  |  |  |  |  |  |  | Clinician and referrer experience interviews  |

Schedule of forms and procedures

## 3.6. Sample size

Based on a previously published cluster randomized trial study (17), 29% treatment engagement in the online FEP intervention group and 15% in the control group will be used to calculate the sample size. By assuming a 5% level of significance (α) and 80% power, the required sample size will be 216 (108 participants in each group). Allowing for a conservatively estimated attrition rate of 20% to follow up, a sample of 260 will be recruited.

## 3.7. Recruitment

Recruitment in this study will be constrained by practical factors such as time, cost factors, and clinician capacity. These constraints are common in RCTs conducted in 'real-world' clinical settings. As such, we aim to recruit 250 participants to achieve a sample size of 216 participants (108 per condition) after attrition.

Participants will be recruited from QLD, NSW and Vic by advertisements at different healthcare/substance treatment or advice internet sites and in local newspapers. In the advertisement, it will be expressed that important goals with the FEP program are to improve the participants own mental health and to increase the likelihood for their relative’s treatment engagement. Individuals who are interested in participating will register on a secure website or by calling the Study coordinator and completing a short telephone screening including age, sex, questions about the participant’s relation to the relative, amount of time spent with the relative, whether or not the relative would seek treatment if prompted and whether the relative had sought treatment during the last 6 months. To determine the presence of any domestic violence by the relative to the potential participant a short screen will be conducted. If potential participants indicate a risk of violence a violence risk assessment will be conducted and referral to support services made.

Screening for eligibility will be conducted by the study coordinator and post-doctoral researcher – Snowdon. She has more than 15 years’ experience as a asocial worker in child protection, mental health and drug and alcohol services with a comprehensive knowledge of community and health support services. Potential participants may disclose domestic violence as it is an exclusion criterion and the NSW Health support processes will be followed as detailed in the study protocol (<https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2006_084.pdf>). If participants are excluded from the study, they may be disappointed not to access the program. They will be directed to their local General Practitioner for a mental health care plan from where they can access 10 sessions of psychological support. If participants show signs during the screening of high levels of distress, for example, crying, expressing fear or immediate risks to themselves or others, the study coordinator will ask for their address and contact the police. All study processes will be suspended. A CSU HREC incident report will be completed by the study coordinator.

If participants are distressed during the screening but do not express fear or immediate risk to themselves or others, the study coordinator will ask them to call Lifeline as an immediate response and to contact their local General Practitioner for a mental health care plan from where they can access 10 sessions of psychological support. These potential participants will be screened out of the study.

If eligible to participate in the study potential participants will receive detailed study information including measures, processes, access to counsellors and consent to participate will be sought.

## 3.8. Allocation

All subjects will be allocated an identification number and then randomly allocated to either the FEP group or the wait list control group. individuals randomized to the control group will be adaptively assigned wait times based on the intervention duration of those in the treatment group (18), estimated to be approximately 42 days. A lead-in period, where the Stage II initiation times for the control group are determined according to a user-defined CDF will be used.

The randomisation procedure for this project will be carried out by an independent researcher (KA at RHRI) using Stata Version 14 17 SE. This researcher will not be involved in other aspects of project implementation, such as FEP facilitation and data collection. The random allocation will be stratified based on two variables: gender (M/F) and living with Identified Relative (Y/N). The process of randomization will involve the following steps: First, all eligible participants with their baseline characteristics will be provided to the randomization team. Second, a new random number will be generated for each eligible participant. Third, stratification variables will be created. Finally, the treatment and control groups will be randomly formed within each stratum. The purpose of stratification is to ensure a balanced distribution of participant characteristics in each group. Without stratification, the study groups may not be adequately matched in terms of baseline characteristics, including the level of interaction with the relative.

Participants will be randomised after consenting but before completing the first baseline survey because measures are time dependent e.g. relating to the past 7 to 21 days. The survey will be sent to participants by web link 5 days before their first scheduled FEP session.

## 3.9. Blinding (masking)

### 3.9.1. Blinding mechanism

All assessments are conducted online, thus minimizing the possibility of researcher bias. Analysis of results will be blinded to the clinicians delivering FEP. They will be provided with contact information of consenting participants and will deliver the program as scheduled without knowing which group the person is allocated to. Trial participants will be informed their start date for the intervention of 1. as soon as possible (Group A - within 7 days) or 2. within 6 weeks (Group B - WLC) without being informed which group they are in.

### 3.9.2. Emergency unblinding

Emergency unblinding is not anticipated. If a WLC participant contacts the study coordinator in crisis, they will be referred to an appropriate response agency such as mental health crisis line, domestic violence crisis line or the police.

Accidental unblinding to the clinician may occur if a WLC participant tells a clinician they have been waiting for weeks for an appointment and the clinician is aware this indicates they have been allocated to the wait list. However, the intervention will be delivered as scheduled and the clinician does not collect the measures.

## 3.10. Data collection

### 3.10.1. Trial procedures and evaluations

An outcome evaluation will be conducted and the within and between-group comparisons reported. The outcomes for participants who receive the FEP program will be compared to those who received reading material while on the waitlist. The primary outcome will be psychological wellbeing and the secondary outcomes will be IR substance use and engagement in treatment. Psychological wellbeing will be assessed at baseline (pre-program enrolment), post-treatment (6 weeks post enrolment), and follow-up (15 weeks post enrolment). Data will be collected using online self-report measures with the Qualtrics platform at the three measurement points - baseline, post-intervention, and 15 weeks post-baseline follow-up.

The information and screening process will take approximately 20-30 minutes to complete depending on how many questions the potential participant has.

The outcome measures will take participants approximately 30 minutes to complete. See appendix 6.2 for schedule of assessments, forms and time frames.

***Measures of psychological wellbeing***

**Depression, Anxiety, and Stress Scale (DASS-21)**

The DASS-21 is a 21-item version of the DASS-42 and is a self-report questionnaire designed to measure three domains: depression, anxiety and stress.

Each subscale contains 7 items, and items are rated on a four-point Likert scale. Higher scores indicate more severe symptoms. The DASS-21 is reported to have high internal consistency for each of the subscales (depression, r = .88; anxiety, r = .82; stress r = .90), and the total scale (r = .93).

**Satisfaction with Life Scale (SWLS)**

This is a widely used 5-item self-report measure of life satisfaction. The scale is conceptualized as having two components, a cognitive judgmental component and an affective or emotional component. The SWLS uses a 7-point Likert scale from 1 (strongly disagree) to 7 (strongly agree). The range of possible scores is from minimal satisfaction with life (5) to very high satisfaction with life. The SWLS has been shown to have convergent validity with other self-report measures of life satisfaction, including the Philadelphia Geriatric Center Morale Scale. The SWLS appears to tap a single life satisfaction factor. Internal consistency is good with a Cronbach’s alpha coefficient of .83.

**The Flourishing Scale (FS)**

The FS is an eight item self-report measure of psychological well-being [59]. The scale taps into aspects of human functioning such as feelings of competence, positive relationships, and purpose in life. It uses a 7-point Likert scale with responses from strong disagreement to strong agreement. Scores range from 8 to 56 and high scores indicate positive self-appraisal of psychological wellbeing.

The scale developers report strong correlations with other psychological well-being scales and good internal consistency with Cronbach’s alpha coefficient of 0.87.

**Brief-COPE**

The Brief-COPE is a 28 item self-report questionnaire designed to measure effective and ineffective ways to cope with a stressful life event. “Coping” is defined broadly as an effort used to minimise distress associated with negative life experiences. Functional coping strategies (eg, active coping) are linked to good self-esteem, to lower perceived stress, and to lower psychological distress, whereas less functional strategies (eg, denial or self-blame) are widely linked to poor self-esteem, to a high perceived stress, and to psychological distress.

The scale can determine someone’s primary coping styles with scores on the following three subscale: Problem-Focussed Coping; Emotion-Focussed Coping; Avoidant Coping. Subsequent analysis by Dias et al. (2012) divided the scale into three factors; (1) Problem-focused coping, (2) Emotion-focused coping, and (3) Avoidant coping. Poulus et al. (2020) validated the scale among 316 esports athletes and found the following means and standard deviations for each subscale. Problem focussed – 2.47 (0.63), Emotional focussed – 2.23 (0.49), Avoidant coping – 1.64 (0.45)

**Use of the online delivery methods**

Ease of use of the online session will assessed at each session with each participant via two questions using a 1 poor – 5 excellent Likert scale - How would you rate the **sound/video** quality? How would you rate the **ease of use**? And, Did you experience any technical challenges? Yes/No, and an open-ended question - Do you have any additional comments? (questions in appendix 6.3 FEP session record).

**Number and length of sessions attended**

Feasibility will be assessed via extent of exposure to FEP by participants (number& length of sessions attended). Each clinician will keep a record of how many sessions each participant attended and how long each session was, the topic of each session and a summary of the participant’s plan or goal for the week and if the plan for the previous week was achieved or not (See appendix 6.3 – FEP session record).

**Acceptability Interviews**

Audio-recorded semi-structured interviews will be conducted with consenting i.) FEP participants, ii). clinicians and iii). referral agents to explore their experiences of the FEP program, their perceptions of benefits and challenges related to the program and its availability, delivery and impacts and any suggestions for improvements. Interviews will be conducted by the research team online or by phone. FEP participants will be invited for an interview at the 18 week data collection time point. Clinicians will be invited to an interview when they have finished delivering the program or the program has concluded (whichever comes first) and referral agents will be invited to an interview after the FEP program has concluded (approximately December 2024). The acceptability interview schedules, and information and consent forms are in appendix 6.4 – Interview materials.

### 3.10.2. Retention

We acknowledge the limitations of this trial, including the risk of response-bias (due to the use of self-report measures) and the relatively long length of the survey, which may influence engagement levels and affect reliability.

Participants will be paid for survey completion which is likely to increase effort and retention rates (24). Participants who discontinue will be actively followed-up by phone calls and text messages. Five attempts over two weeks (day 1,3,7,11 and 14) to contact participants for measures completion will be made before they are considered lost to follow-up.

## 3.11. Data management

The study coordinator will be the data custodian who will maintain records and keep a log of data entry. Results of the assessments will be kept confidential. Participants will be allocated a unique identifier to be used when processing and communicating results. Personal details and results will be kept in separate databases and stored in accordance with Australian Psychological Society Ethical Standards. Any publication of the results will not be published in a manner that would reveal the identity of any participants. The research dataset, de-identified, may be made publicly available.

The study coordinator will:

a. Develop a standardized data entry form/template that captures all relevant data fields required for the FEP trial.

b. Use data validation techniques: Apply range checks, data type validations, and consistency checks to ensure accuracy and completeness of entered data.

c. Perform regular data quality audits monthly: Randomly select and review a subset of entered data to identify any errors or inconsistencies.

All hard copy data will be held securely on-site, in line with existing service processes and organisational requirements, and entered electronically into CSU’s Question Pro system. Question Pro is a widely used electronic data capture platform for online surveys and requires a CSU log in to access. Only members of the evaluation team and project leads will have access to this online database.

Following analysis, data will be stored securely on site at RHRI. The information will be physically stored in a locked cabinet and will only be accessible by members of the research team. This project material will be stored for a period of 7 years. Only aggregated/anonymised data will be presented in reports or at conferences.

All recorded data will be de-identified to ensure anonymity of the participants. These details in relation to any individual participant will not be published or made available. Pseudonyms will be utilised in all published material.

## 3.12. Statistical methods

### 3.12.1. Outcomes

We will compare the baseline characteristics of the participants in the treatment and control groups using different statistical tests: the chi-square test for categorical variables and the t-test for continuous variables. The study will estimate the difference in proportion (difference-in-difference) between the intervention groups. To examine the effects of the intervention on the primary outcomes, mixed effect regression modeling will be employed. The intervention effects will be measured using mean differences (MD) for continuous variables and relative risks (RR) for categorical variables, along with their corresponding 95% confidence intervals (CI). The main results will be based on the adjusted effect measures. All analyses will follow the intention-to-treat (ITT) principle. STATA version 17 will be used to perform all the analyses, and statistical significance will be determined by p-values <0.05.

## 3.13. Data monitoring

### 3.13.1. Formal committee

The establishment of a Data Monitoring Committee is not required for this study because the trial is small scale and of short duration. The population is not particularly vulnerable and the intervention has a known safety profile. Risk management processes will be established including reporting pathways for adverse events to Human Research Ethics Committee.

### 3.13.2. Interim analysis

An interim analysis will be conducted after 20 participants have completed the FEP program to evaluate the treatment effectiveness and assess the data quality and integrity. The analysis will be conducted by an independent statistician at the CSU Rural Health Research Institute who is not involved with the study.

Stopping Guidelines are as follows:

*Adverse Events:* If the intervention shows a significant increase in adverse events or serious adverse events compared to the control group, the trial will be stopped early to protect participant safety. Adverse events will include increased substance use by the identified relative, domestic violence incidents, suicide attempts or complaints about the practice of the clinicians.

*Ethical Violations:*  or breaches including clinicians or researchers contacting participants relatives about the study, disclosure of confidential information about participants to third parties when not clinically indicated or clinician misconduct.

*Futility*: If the intervention shows no signs of effectiveness or if the trial is unable to recruit or retain participants, the trial will be stopped due to futility.

## 3.14. Safety/harms

Risks identified in the risk management plan established at project commencement and those that may arise during the project will be addressed early. Research team meetings will be held monthly and will include risk management as a standing agenda item where the risk register and ratings for each item will be reviewed and updated and items added where necessary. The Chief Investigator will be responsible for leading risk monitoring and reporting. The study coordinator will be responsible for maintaining the risk register.

The risk register will regularly update the 3x4 risk analysis matrix that includes severity (S1 Acceptable – S4 extreme) and likelihood (L1 Improbable – L3 Probable). Risks in the low to medium range will be managed within the research team and Institute notified in quarterly reporting. Risks occurring in the high to extreme range will be reported to the CSU research office and HREC (if relevant) and support sought for addressing them. Unmitigated risks and those in the extreme range will be reported immediately to HREC for advice and assistance and the project will be placed on hold until the risk is addressed. Risk reports will include the nature of the risk, the events that have occurred, the impact on the project and participants, mitigation plans and the outcome of those if completed or strategies for mitigation and who and what is involved.

Program delivery: It is expected that study participants will be experiencing some distress because they are seeking support from a therapeutic family support program. All counsellors delivering the program will be trained psychologists or social workers, registered by AHPRA, who deal with distressed people daily. Mandated and legislated processes for reporting child abuse, domestic violence and risks of harm to self and others will be followed. For all incidents a CSU HREC incident report will be completed by the study coordinator. Counsellors will report all adverse events to the study coordinator who will offer de-briefing. Counsellors will be encouraged to access their workplace EAP or clinical supervision for additional support.

## 3.15. Auditing

The frequency of audits will be determined through the comprehensive risk monitoring framework. The key audit elements will be

a.) intervention fidelity audited via viewing 2 randomly selected recorded participant sessions of each clinician each month.

b.) participant safety audited via risk register records of number of participant contacts outside the program, participant or referrer complaints, clinician reports of risks or harms to participants, number and type of adverse events recorded.

c.) data integrity - monthly data quality audits

# 4. ETHICS AND DISSEMINATION

## 4.1. Research ethics approval

Ethics committee approval will be sought from the Charles Sturt University Human Research Ethics Committee.

## 4.2. Protocol amendments

The protocol will be updated on the ANZCTR website if any changes to the study are made.

## 4.3. Informed consent process

**Consent process: FEP participants**

Potentially eligible participants will be informed about the project by the Study coordinator and will receive oral and written information about the project.

Informed consent will be completed by the Study coordinator before the first FEP session during a project assessment session. The Study coordinator will introduce FEP, explain the aims, procedures and expected benefits of the project using the information sheet as a guide. Sufficient time will be allowed for potential participants to raise and discuss any questions or concerns. Once the potential participant is comfortable with the project, they will be asked to complete informed consent.

The decision to participate is voluntary and will be based on a clear understanding of what is involved. The Study coordinator will inform the potential participant about the project and provide the participant information sheet and consent form. If willing, and after sufficient time (up to one week) is allowed for potential participants to consider their participation, informed consent process will be completed.

To ensure participation is available for those on-line or who have low literacy the following verbal consent process will be followed.

1. The participant information sheet will be read to the participant.
2. The Study coordinator will explain the project processes including randomization and what is provided for people on the wait list.
3. The participant will be asked to sign the consent form emailed to them and email it back at the time of consenting. The Study coordinator will also sign the consent form when it is returned. Verbal consent will be recorded via zoom recording and saved with consent documents.

**Consent process: Clinician and referral agent interviews**

Eligible participants will include any counsellors who have delivered FEP or people or representatives of services who have referred someone to FEP. Potential participants will be informed about the project by the Study coordinator and will receive oral and written information about the project.

Informed consent will be completed by the Study coordinator before the interview takes place. The Study coordinator will explain the aims, procedures and expected benefits of the project using the information sheet as a guide. Sufficient time will be allowed for potential participants to raise and discuss any questions or concerns. Once the potential participant is comfortable with the project, they will be asked to complete informed consent.

The decision to participate is voluntary and will be based on a clear understanding of what is involved.

To ensure participation is available for those on-line or who have low literacy the following verbal consent process will be followed.

1. The participant information sheet will be read to the participant.
2. The Study coordinator will explain the project processes including randomization and what is provided for people on the wait list.
3. The participant will be asked to sign the consent form emailed to them and email it back at the time of consenting. The Study coordinator will also sign the consent form when it is returned. Verbal consent will be recorded via zoom recording and saved with consent documents.

### 4.3.1. Ancillary studies

Not Applicable

## 4.4. Confidentiality

Participant confidentiality will be maintained via;

**Informed Consent** processes that clearly explain the purpose of data collection, how participants personal information will be used, and the measures in place to protect confidentiality. Participants will have a clear understanding of their rights, including privacy and data protection.

**Data Collection**: a.) *only essential personal information* necessary for the trial will be collected. b.) *Anonymization:* Participant data will be anonymized, replacing identifying information with unique identifiers to reduce the risk of re-identification.

c.) *Secure Data Transmission* will be used (e.g., encrypted channels) when transferring participant data between sites, collaborators, or data management systems to prevent unauthorized access.

## 4.5. Declaration of interests

None to declare

## 4.6. Access to data

Only members of the research team listed on this protocol will have access to the final trial dataset.

## 4.7. Ancillary and post-trial care

Referrals will be made to support agencies for any participants needing ongoing psychological support following the completion of FEP. If at the post-program data collection participants scores remain elevated, they will be informed of their results and encouraged to seek assistance.

Some participants may be excluded from FEP because of severe distress unrelated to their relative’s substance use. If the counsellors determine that the participant’s distress is caused by factors other than the relatives substance use and mental health condition, they will explain to the participant they cannot continue in the trial, refer them to another provider for support and complete a critical incident response form for the study coordinator. The study coordinator will follow up with the excluded participant within 3 days to ensure they have been provided with enough information to access support for their situation.

## 4.8. Dissemination policy

### 4.8.1. Trial results

Following agreement of the findings, any manuscripts will be circulated and agreed upon by the researchers prior to sharing externally. Before findings are finalised, participating clinicians will be provided with feedback via project updates and will have the opportunity to comment on findings.

To disseminate progress and findings from this project to key professional bodies including the funding body, the research team will provide an update in 2025.

A one-page summary of the project aims, findings and next steps will be developed and provided to participants, clinicians and referral services. During informed consent, participants will be asked if they wish to receive feedback about the project and with their consent will be contacted by the team with the one-page report.

# 5. STUDY ADMINISTRATION

## 5.1. Key contacts

**Central contact**

Julaine Allan, PhD

Charles Sturt University

Leeds Pd, Orange NSW 2800

0437869033

juallan@csu.edu.au

## 5.2. Funders

This trial is funded by Department of Health and Aged Care (DoHAC), Australian Commonwealth Government. As part of the rural Health Research Institute’s approved workplan (Project G).

## 5.3. Roles and responsibilities

### 5.3.1. Trial committees

The following organising structure and responsibilities will be followed;

**Principal Investigator**

Design and conduct of FEP online

Preparation of protocol

Preparation of clinician and participant recruitment brochures

Chairing team meetings

Recruitment and accreditation of clinicians

Randomization

Risk management and reporting

Publication of study reports

**Study coordinator**

Maintenance of protocol and version control

Ethics application and PISCFs

Management of clinicians

Screening of potential participants

Gaining informed consent

Day to day management of the study and delivery of the intervention

Data management

**Research team members**

Reviewing progress of study and if necessary, agreeing changes to the protocol to facilitate the smooth running of the study.

Data verification and assessment of results

Preparation and submission of manuscripts

**Clinicians**

Attending training in FEP

Participating in FEP accreditation

Delivery of FEP

Maintaining participant case notes and records

Professional registration and insurance

Reporting risks and adverse events to the research team

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# 7. APPENDICES: Appendix 7.1 FEP participant recruitment flyer



## 7.2 Schedule of forms and procedures with times to complete

**Schedule of forms and procedures**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Activity/assessment | Who  | Time to complete(mins) | Pre-study screen & consent | -T 1Pre-study baseline data  | Session 1 – 6 - weekly | T1Post CRAFT data collection | T2 Follow-up data collection 18 weeks | T3 Follow-up interview  |
| Pre-screening consent | SC | 5 mins | X |  |  |  |  |  |
| MINI assessment | SC | 15 | X |  |  |  |  |  |
| Risk of violence assessment | SC | 10 | X |  |  |  |  |  |
| Screening log | SC | 5 | X |  |  |  |  |  |
| PISCF | SC | 15 |  | X |  |  |  |  |
| Randomisation AND allocation of participant no. | SC |  |  |  |  |  |  |  |
| scheduling appts | Sc + clinicians |  |  | X | X |  |  |  |
| demographics | online | 4 |  | x |  |  |  |  |
| DASS21 | Online | 8 |  | X |  | X | X |  |
| Satisfaction with Life Scale (SWLS) | Online | 3 |  | X |  | X | X |  |
| The Flourishing Scale (FS) | Online | 5 |  | X |  | X | X |  |
| Brief-COPE |  | 10 |  | x |  | x | x |  |
| Use of the online delivery methods | Clinicians  | 3 |  |  | x |  |  |  |
| Text message reminders | SC |  |  | x | X | x | x |  |
| Interview | SC/JA |  |  |  |  |  |  | X |
| Usage rating profile | Clinicians | 10 | x |  |  |  |  | X |
| Termination form | SC |  | X |  |  |  |  | X |
| Serious adverse event form | AS NEEDED THROUGHOUT use CSU HREC Incident report form |
| Session summary form | Clinician |  |  |  | X |  |  |  |
| Communication log | All | FOR ALL PARTICIPANT CONTACTS OUTSIDE SCHEDULED SESSIONS |