Back-on-Track: Randomised controlled feasibility trial of behavioural activation in farmers with mood problems

Protocol

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Trial identifiers:	ANZCTN TBC

REVISION HISTORY

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1. TRIAL SUMMARY

World Health Organization Registration Data Set

Title	Back-on-Track: A randomised controlled feasibility trial of behavioural activation in farmers with depression
Primary registry and trial identifying number	ANZCTR: TBC
Sources of monetary or material support	Gardiner Foundation $492,661
Primary sponsor	Deakin University
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Brief title	Back-on-Track
Acronym	Back-on-Track
Countries of recruitment	Australia
Condition(s) or focus of study	Mild to moderation depression determined using the PHQ-9 (Patient Health Questionnaire, a standardised and validated screening measure for mood disorders (Kroenke et al., 2001))
Interventions	Back-on-Track (experimental) – Ten (approximately 30-40 minute) sessions of peer delivered behavioural activation Managing Stress on the Farm (comparator) – A self-help workbook (consistent with standard care practice guidance for people with mild to moderate depression (*Overview | Depression in Adults*, 2022))
Key eligibility criteria	Age eligibility: 15 years or older Sex eligibility: Any Accepts healthy volunteers: No Inclusion criteria: 1. PHQ-9 (Patient Health Questionnaire) score of between 5 and 19 (indicative of mild to moderate depression). 2. Self identifies as a member of the farming community 3. Not currently receiving any formal psychological treatment (e.g., Cognitive Behavioural Therapy) for any mental health problem.

	4. Does not have serious long term health conditions that may necessitate hospital admission or regular contact with secondary health services during the trial 5. Are not actively suicidal or have attempted suicide in the past two months 6. Does not have a diagnosis of psychosis, personality disorder, or cognitive impairment People that are currently taking antidepressant medication (for any duration) will be considered eligible for the trial as there is good evidence that psychological treatment confer additional benefits over treatment with medication (Cuijpers et al., 2014).
Study design	Study type: Interventional feasibility trial. Allocation: 1:1 Intervention model: Parallel group Primary purpose: Treatment
Masking	Investigator only
Date of enrolment	June 2024
Target sample size	40
Recruitment status	In set up
Primary outcomes	Outcome: PHQ-9 (Patient Health Questionnaire, mood) (Kroenke et al 2001) Timeframe: Baseline (week 0), week 10 and week 26.
Secondary outcomes	Outcome: Work productivity determined using the work productivity and activity impairment questionnaire (Reilly et al 2012). Outcome: Loneliness determined using the UCLA loneliness scale (Russell 1996) Outcome: Wellbeing, determined using the WHO-5 Wellbeing index (Topp et al. 2015)

	Outcome: Quality of life, determined using the AQoL-4D (Hawthorne et al 2009) Timeframe (for all secondary outcomes): Baseline (week 0), week 10 and week 26.

2. INTRODUCTION

2.1. Background and rationale

Farmers face up to twice the risk of suicide compared to the general Australian population (Kennedy et al., 2014; Klingelschmidt et al., 2018; Miller & Burns, 2008; Milner et al., 2017), yet do not appear to have higher rates of diagnosed mental illness (*National Survey of Mental Health and Wellbeing*, 2008). The association between mood and suicidal thinking seem to differ between members of the farming community and the general population. There is strong evidence for a range of situational factors (influenced by the farming context) that negatively influence farmer mental health and suicide risk (Austin et al., 2018; Fennell et al., 2016; Kunde et al., 2017, 2018; Perceval et al., 2018, 2019).

There is some evidence that farmers are generous at providing help to others but are reluctant to ask for help themselves (Kennedy et al., 2016). Most farmers live in communities in which accessing specialist mental health services is challenging (*Medicare-Subsidised Services - Mental Health*, 2023). Where support is available, health services and health care workers may not understand the realities of life and work in the farming environment (Brumby et al., 2017). These unique barriers to support seeking identified in farming communities may be a barrier to people seeking help for mood problems, particularly when they have had negative support seeking experiences in the past (Seiz & Downey, 2001).

There is sound evidence from systematic reviews of randomised controlled trials that Behavioural Activation (BA) is a safe and effective treatment for depression—a predictor of suicide (Ekers et al., 2014; Uphoff et al., 2020), A Cochrane review included fifty-three studies involving 5,495 participants and concluded that there was moderate-certainty evidence that behavioural activation was more effective than treatment as usual (Uphoff et al., 2020). The authors note, however, that included trials had important sources of bias and further research was necessary.

BA is a brief psychological therapy focused on increasing behaviours that people enjoy and enhance mood and reducing avoidance behaviours (e.g. sitting alone and ruminating). Unlike Cognitive Behavioural Therapy (CBT), health workers (that have not had specialist mental health training) can learn to deliver BA with minimal (typically around five days) training with ongoing supervision and support (Ekers et al., 2014). Consequently, BA could be delivered – at scale – to large numbers of people experiencing depression in communities where access to mental health services is limited, such as farming communities in rural Australia. There is growing evidence that peer-delivered services in mental health care reduce relapse and rehospitalisation as well as improve empowerment, hope, self-efficacy, engagement and recovery (Farkas & Boevink, 2018).

Working with farmers to deliver BA to their peers (enabling the shared context, characteristics and cultural awareness to 'walk in their shoes') has the potential to overcome many well-established barriers to mental health help-seeking and improve outcomes for this at-risk group (Kennedy et al., 2023).

The concept for Back-on-Track was seeded in earlier suicide prevention project discussions with a farming community working group. The project was led by the National Centre for Farmer Health with funding from the Western Victoria Primary Health Network, and support from leading clinicians and academics in the areas of farmer mental health, rural health, and behavioural activation. This generated evidence of the value and practical nature of BA with the identified lack of accessible and appropriate mental health support in farming communities. Initial engagement with community commenced face-to-face in August 2019 and transitioned to online methods during the COVID-19 pandemic. The co-design process was completed in February 2022, the findings have been reported in detail (Kennedy et al., 2023).

Our community consultation (Kennedy et al., 2023) identified gaps in rural mental health support that may benefit from a tailored, proactive approach to engagement, and a need for trusted support providers with an understanding of farming life and work. Community members saw an alignment between the concept of peer-led BA and farming community values—including a pragmatic, task-oriented mindset—and believed this approach would reduce barriers to help-seeking. They felt confident that the 'right' peer workers— with their shared language, familiar ways of engaging, and a shared understanding of the situational factors of farming—could successfully support their friends and colleagues to engage in BA.

Work to date aimed to co-design, with farming community members and community stakeholders, a model for delivering peer-led evidenced-based psychological intervention to farming community members experiencing depression. This included consideration of the needs for training and governance to ensure the safe and sustainable delivery – at scale – of any future program rollout.

We are currently conducting further community consultation process refine the design of the Back-on-Track trial. The community consultation has been reviewed and approved by Deakin University Human Research Ethics Committee (reference: 2021-138). The community consultation will involve people from the farming communities, where the intervention will be delivered, attending a workshop. We anticipate around 60 members of the farming community will attend one of the three workshops we are organising. Community consultation workshops will be facilitated by AG (trial coordinator). Findings of the community consultation will be summarised and inform necessary modification to our trial protocol.

Our feasibility trial will be supported by the teletrials program. This program is funded by the MRFF (Medical Research Future Fund) and has been designed to increase participation in clinical trials by people living in rural, regional and remote areas of Australia (Research, 2023).

2.2. Objectives

The objectives of our feasibility trial relate to both the recruitment of peer workers and involvement of people with depression in the study:

- Peer worker recruitment, training and employment
    - Can we successfully recruit peer workers to the trial?
    - How many peer workers successfully complete the Back-on-Track training package?
    - How many peer workers (that complete training) will be employed to deliver the Back-on-Track intervention?
    - How many peer workers will be retained for the duration the project?
- How many people with depression (members of the farming community):
    - Express an interest in taking part in the trial?
    - Consent to participate in the trial?
    - Complete baseline measures?
    - Agree to be randomised?
    - Commence the Back-on-Track program?
    - Complete the Back-on-Track program (defined as attending six of the ten sessions)?
    - Complete week 10 measures?
    - Complete week 26 measures?
    - Report adverse events during the trial?
- The number of Behavioural Activation (BA) sessions where a satisfactory level of fidelity to model is demonstrated.

2.2.1 Establishing Feasibility

We will consider we have established feasibility if we achieve the following:

- Peer workers
    - We recruit ten peer workers.
    - Eight trainee peer workers successfully complete the Back-on-Track training package.
    - Six peer workers are employed as peer workers to deliver the Back-on-Track intervention.
    - Five peer workers are retained at the completion of the project.
- People with depression (members of the farming community):

    - Approximately 120 members of the farming community express an interest in taking part in the trial.
    - Forty consent to participate in the trial.
    - Forty complete baseline measures.
    - Forty agree to be randomised.
    - Forty commence the Back-on-Track program.
    - Thirty-two complete the Back-on-Track program (defined as attending six of the ten sessions. The minimum duration of a session is ten minutes).
    - Thirty-two complete week 10 measures.
    - Twenty-eight complete week 26 measures.
- Ninety per-cent of the Behavioural Activation (BA) sessions are delivered to at least a satisfactory level of fidelity to model (determined using the BA fidelity assessment, Connolly Gibbons et al., 2023).

2.3. Trial design

Single blind (researcher), parallel group, 1:1 allocation, randomised controlled feasibility trial.

The teletrial model

A teletrial is a group of clinical trial sites working together to conduct a clinical trial, consisting of a Primary Site (assuming overall responsibility for the conduct of the trial) and one or more Satellite Sites (conducting the study under the direction of the Primary Site). This group of sites is called a teletrial cluster.

This feasibility trial will be conducted using the teletrial model to improve access to the study intervention for people living in regional, rural, and remote farming communities. This enhances the appropriateness of the trial for the target population (by consulting with farming community members in trial design and local adaptation), improves access to evidence-based psychological therapy in an underserved population, and enhances collaboration and networking between sites).

Deakin University will act as the Primary Site (coordinating centre) and will have the overall responsibility of the conduct of the trial within the cluster.

The Satellite Site (Western District Health Service) will be delegated some aspects of trial operation based on their level of experience, capability, and capacity.

3. METHODS

3.1. Study setting.

Back-on-Track is a community-based intervention that is delivered by peer workers either in a participant's home, their workplace (eg., the farm), or using video conferencing.

Participants will be recruited across the following farming communities (including the district surrounding each community):

- Northern Victoria (Tallangatta)
- South-West Victoria (Camperdown)
- Gippsland (Newry/Maffra).

3.2. Eligibility criteria

The trial will involve ten peer workers (responsible for the delivery of the intervention) and forty farming community members identified as having problems with their mood, as identified by a PHQ 9 score from 10-19.

Peer workers

Peer workers will be employed on casual contracts by Western District Health Services (WDHS) which provides acute services, high- and low-level extended care, residential aged care, independent living units, youth services, community and allied health services. Recruitment material will be drafted and then tailored in consultation with a Community Reference Group (CRG - a group comprising community members and service providers from each of the three trial communities to inform local delivery of the project).

Peer workers will be recruited in two ways:

(i) By inviting expressions of interest in the local communities we are looking to recruit from. This will involve advertising via local industry newsletters, social media and flyers.

(ii) By direct approach through the Community Reference Group

The Community Reference Group (CRG) will screen the EOIs based on local knowledge using a standardised scoring matrix drawing on the requirements stated in the Position Description (see appendix 1). CRG members will be eligible to apply to be peer workers, but these members will be exempt from the screening process. The screening process will inform the short listing of candidates to progress to pre-employment interview.

Peer workers will be employed by Western District Health Service on a casual contract as complementary therapy workers. We contacted the WDHS people and culture manager who advised that this was the most appropriate position description for this role (appendix 1). Potential peer workers will need to meet the usual requirements of employment with Western District Health Service e.g. pre-employment interview, reference checks, pre-employment medical check, police check, Working With Children Check. Additionally, we will also ask peer workers to complete a participant information and consent form (PICF) so that we can use data generated during the Back-on-Track training (e.g. competency assessments). Also, we will ask them to participate in interviews at the end of the trial about their experiences of delivering the Back-on-Track intervention.

All costs associated with the trial – including but not limited to – training, police checks, working with children check, travel will be reimbursed through the grant.

Peer workers will need to be aged over 18 years and have demonstrated experience living or working in a rural farming community. Whilst we expect that many peer workers will have personal experience of mental stress or distress, or previous mental ill-health this is not an explicit inclusion criterion for this trial.

People who express an interest in participating as a peer worker will be asked if they self-identify as currently experiencing severe mental ill-health (schizophrenia, hypomania and mania, personality disorder or similar). If they do, we will not consider including them as peer workers in this trial. We have sought advice from people with lived experience (KB) in framing these criteria. Also, we considered this issue when undertaking previous community consultations.

People with depression

People with depression will be included in the trial if they meet the following criteria.

Inclusion criteria

1. Aged over 15 years of age.
2. A PHQ-9 score of between 5 and 19 (indicative of moderate and moderately severe depression).
3. A member of the farming community (Farm owners and managers, farm workers, members of farming families, members of the farming dependent community).

4. Do not have serious long term health conditions that may necessitate hospital admission or regular contact with secondary health services during the trial.
5. Are not actively suicidal or have attempted suicide in the previous two months.

Exclusion criteria

1. PHQ-9 score 20 or higher.

   Because of the severity of illness, it would not be appropriate to offer a peer-delivered psychological intervention. People will be advised to urgently seek support from their primary care practitioner.
2. Commenced medication for the treatment of depression in the past four weeks.
3. Currently receiving any psychological (e.g. Cognitive Behavioural Therapy) treatment for a mental health condition.
4. Have previously been treated with Transcranial Magnetic Stimulation or ECT for depression.
5. Has a medically confirmed diagnosis of psychosis, personality disorder, or cognitive impairment.

3.3. Interventions

3.3.1. Back-on-Track

Back-on-Track is a ten-session psychological intervention based on Behavioural Activation. Back-on-Track encourages a person to develop or get back into activities which are meaningful to them by scheduling activities and monitoring behaviours and looking at specific situations where changing these behaviours and activities may be helpful. People will be asked to complete worksheets during and after the session. Peer workers will be encouraged to, generally, adhere to the structure of the Back-on-Track approach but can tailor sessions to address individual contexts. This Back on Track program will be supported by fortnightly supervision with the peer workers.

Back-on-Track is a peer worker led intervention that has been co-designed with people living in the farming communities of regional and rural Australia, targeting community members who are experiencing depression (Kennedy et al., 2023). The primary active component of the Back-on-Track package is behavioural activation. Behavioural activation is a brief intervention, typically around 8-12 sessions. Key elements of behavioural activation include mood monitoring and activity scheduling.

Back-on-Track Training

The Back-on-Track training package:

1. Introduction to Back-on-Track

2. Behavioural activation training – University of South Australia Professional Certificate in Behavioural Activation for Depression.
3. Peer worker fortnightly clinical supervision.

In total the Back-on-Track training package will take 76 hours to complete. Trainee peer workers will need to pass a standardised competency assessment to successfully complete the program to become a Back-on-Track peer worker.

The Back-on-track training will be led by MJ supported by other members of the research team.

Back-on-Track Peer Worker training (part 1)

Peer workers will attend (14 hours), face-to-face training at a Deakin University campus (Waurn Ponds). Training will be delivered by an experienced peer worker (KB) and members of the project team (AG and SM). The aim of the peer worker training is to ensure a good understanding of:

- The rational for peer delivered interventions,
- Overview of depression and depression treatments,
- Supporting people experiencing low mood or depression,
- Effective communication with people in farming communities,
- Confidentiality of people attending the Back-on-Track program,
- Working safely with people at risk of suicide,
- Peer-worker self-care and safety (standard operating procedures will draw on the existing WDHS Home Visiting Policy - where applicable),
- Dealing with difficult situations (e.g., expressing suicidal thoughts, disclosure of illegal behaviour, sexual abuse),
- Training on the trial distress management protocol (see Section 4.3.1),
- Planning meetings with member of the farming community experiencing depression,
- The importance of supervision,
- Handling conflicts of interest,
- Referral pathways when people are at risk (this will include internal 'Back on Track' referral pathways and external referral pathways to local services where available e.g. rural financial counselling service—developed with the support of the Community Reference Group)
- Documenting your meetings and record keeping.

Behavioural Activation training (part 2)

Part two of the package is focused on ensuring that trainees can safely and with a high degree of fidelity deliver behavioural activation within the Back-on-Track peer worker framework. Our Behavioural Activation training utilises the University of South Australia Professional Certificate in Behavioural Activation for Depression (https://study.unisa.edu.au/short-courses/professional-certificate-in-behavioural-activation-for-depression/). The online program prepares people to practice Behavioural Activation with people living with mild to moderate depression. The length of the course is 10 weeks, delivered over four modules, typically people take approximately 50 hours to complete the course. People who complete the course can

- Develop skills to build relationships with people who are depressed.
- Explore the links between behaviour and emotion and vice versa.
- Develop assessment skills in BA and the screening of mood disorders.
- Develop simple but practical skills to help people to better manage their mood.
- Develop skills to schedule activities that have a positive effect upon mood.

Training includes a series of homework tasks where trainees experience for themselves core behavioural activation activities (mood monitoring, activity scheduling, monitoring the relationship between behaviours and mood).

Knowledge is assessed by Multiple Choice Questionnaire examinations at the end of each module. Competency is assessed by participants submitting three video submissions practicing the core BA skills with a colleague. If competency is demonstrated, participants are awarded a professional certificate in BA.

Supervision (part 3)

Supervision for peer workers will be provided with the aim of maintaining a high degree of fidelity with the Back-on-Track approach. Peer workers will attend twelve fortnightly group supervisions lasting one hour (delivered via the ZOOM video conferencing platform). The group will be supported by two facilitators (MJ and PW – Phil Wilson Western District Health Service Psychologist). In these supervision sessions, peer workers will present the case formulation of a person they are currently working with to their peer worker colleagues, exploring what has worked well and what they might do differently at their next session.

Treatment Fidelity

Monitoring treatment fidelity is a stated aim of this feasibility trial. A random 10% sample of sessions conducted during the trial will be audio recorded, and blind rated using the behavioural activation fidelity checklist (Connolly Gibbons et al., 2023), by an independent (not part of the research group) researcher experienced in BA.

Consent to audio record sessions will be part of the consent process, participants will have the option to indicated that they do not want sessions to be audio recorded. Audio recording will made using a digital voice recorder (not a smart phone or tablet) that will be supplied to peer workers. Once audio-recordings have been completed peer workers will upload the audio recording to the participants case recoded form (as a .wma file) via REDCap. The original recording will then be deleted from the audio-recorder by the peer worker.

Conflict of interest

There is a potential for conflict of interest between peer workers and people with depression in small farming communities. For example, peer workers and people with depression may have a personal relationship (friendship, colleagues, relation).

As part of the consent process people with depression will be asked to indicate if they are happy to be allocated a peer worker from their local community. If they are – following allocation of the peer worker to the community member with depression – they will be asked to alert the trial co-ordinator (AG) if there are any personal relationships that may create a possible conflict of interest. If people with depression do not want to be allocated to a peer worker from the local community, we will allocate them to a peer worker from a different area.

When community members with depression are allocated to a peer worker, the peer worker will also be asked to indicate if there are any actual or perceived conflicts of interest that may impact the working relationship. If there are, the trial co-ordinator (AG) will allocate the community member to a different peer worker.

Control intervention

Participants allocated to the control intervention will receive treatment as usual and will be sent the Managing Stress on the Farm self-help workbook. This booklet provides information, practical activities and links to further resources to support the mental health of farmers, farm workers, farming families and the broader farming community.

Treatment as usual

Participants will be receiving standard primary care treatment if required for common health problems that may include asthma, diabetes, and hypertension. Participants may be being treated with antidepressant medication as part of standard of care for mood problems.

3.4. Outcomes

As this is a feasibility trial the aim is not to establish the safety and effectiveness of the intervention. The aim is to establish if study participants will complete study measures accurately.

The proposed primary outcome measure (that we would use in a full trial) is mood determined using change in PHQ-9 (Kroenke et al., 2001) scores, baseline to 26-week follow-up.

Secondary outcomes (proposed) are:

1. Enhance work performance – determined using the Work Productivity and Activity Impairment questionnaire (Reilly et al., 1993)
2. Reduce Loneliness – determined using the UCLA loneliness scale (Russell, 1996)
3. Enhance overall wellbeing – determined using the WHO-5 Wellbeing index (Topp et al., 2015)
4. Improve overall quality of life – determined using the AQoL-4D (Hawthorne et al., 2001)
5. Ensure treatment fidelity – determined using the behavioural activation fidelity Assessment (Connolly Gibbons et al., 2023)

The six outcome measures that we intend using in this trial are described below. We have estimated the amount of time it takes to complete each measure; in total we estimate that measures will take not more than 20 minutes to complete.

PHQ-9 - The Patient Health Questionnaire (PHQ; Kroenke et al., 2001) is a self-administered measure of depression symptoms that are been extensively used in clinical trials of psychological treatment. The PHQ-9 scores each of the 9 DSM-IV criteria as “0” (not at all) to “3” (nearly every day). a PHQ-9 score ≥10 had a sensitivity of 88% and a specificity of 88% for major depression. PHQ-9 scores of 0-4 indicate no depression, 5-9 is an indication of mild depression, 10-14 is an indication of moderate depression, whilst a score of 15-19 is an indication of moderate to severe depression and a score of 20-27 is an indication of severe depression.

Work Productivity and Activity impairment questionnaire (Reilly et al., 1993) - The Work Productivity and Activity Impairment (WPAI:GH) questionnaire is a 6-item validated instrument to measure impairments in both paid work and unpaid work. WPAI measures absenteeism, presenteeism as well as the impairments in unpaid activity because of health problems over the past seven days. WPAI outcomes are expressed as impairment percentages, with higher numbers indicating greater impairment and less productivity.

UCLA loneliness scale (Revised) *Russell, 1996)* - A 20-item validated scale designed to measure the participant's subjective feelings of loneliness as well as feelings of social isolation. Participants rate each item on a four-point scale. The scale takes 3-5 minutes to complete and has been used across a diverse range of teenage and adult populations. The total score ranges from 20 to 80. Higher scores indicate higher loneliness, ranging from 20–34 (a low degree of loneliness), 35–49 (a moderate degree of loneliness), 50–64 (a moderately high degree of loneliness), and 65–80 (a high degree of loneliness).

WHO-5 Wellbeing index (Topp et al., 2015) - The World Health Organisation – Five Well-Being Index (WHO-5) is a short self-reported measure of current mental wellbeing. The WHO-5 has been found to have adequate validity in screening for depression and in measuring outcomes in clinical trials. The WHO-5 consists of five statements, which respondents' rate according to the scale below (in relation to the past two weeks): All of the time = 5, Most of the time = 4, More than half of the time = 3, Less than half of the time = 2, Some of the time = 1, At no time = 0. The total raw score, ranging from 0 to 25, is multiplied by 4 to give the final score, with 0 representing the worst imaginable well-being and 100 representing the best imaginable well-being.

The Assessment of Quality of Life – 4 Dimensions (AQoL-4D) is a validated, health-related multi-attribute utility instrument (Hawthorne et al., 2001). It provides a global 'utility score' by evaluating four distinct dimensions: 'Independent Living' (self-care, household tasks, and mobility); 'Relationships' (friendships, isolation and family role); 'Mental Health' (sleeping, worrying and pain); and 'Senses' (seeing, hearing and communication).

Treatment Fidelity

Treatment fidelity will be determined using the behavioural activation fidelity assessment (Connolly Gibbons et al., 2023). The Fidelity assessment has been shown to be reliable, feasible and acceptable in a study of 11 patients and 10 therapists (Connolly Gibbons et al., 2023). Through correspondence

with the study authors, they confirmed no predefined competence threshold. As such, a pragmatic decision has been made. Firstly, peer workers who complete the online BA training and pass the competency assessments will be deemed competent. To ensure fidelity, peer workers will need to be rated as three (moderately) or higher against each of the ten items of the behavioural activation fidelity assessment (a total score greater than or equal to thirty). Ten percent of all sessions will be audio recorded and independently rated for treatment fidelity.

Economic data

We will calculate the cost of providing the Back-on-Track intervention that will include:

The cost of training:

1. Estimated total number of hours to develop the three training packages (fixed cost),
2. Training facilities (rooms),
3. Academic time to prepare and deliver Back-on-Track,
4. Accommodation, travel and catering while attending training,
5. Attendance at, and delivery of, clinical supervision,
6. We will ask Western District Health Service to provide a breakdown of the total number of hours each peer worker submitted to complete training. We will also extract information of the hourly rate paid (in AUD).

Cost of the comparator (Managing Stress on the Farm)

1. Cost of printing,
2. Cost of postage,
3. Researcher time to administer distribution.

Delivery of the Back on Track intervention

1. We will ask Western District Health Service to provide a breakdown of the total number of hours each peer worker submitted to deliver the Back-on-Track intervention. We will also extract information of the hourly rate paid (in AUD)
2. Travel costs (mileage, parking, public transport)
3. Participant (community member with depression) time to attend Back-on-Track sessions (we will not ask participants to estimate the numbers spent completing home tasks).

Service use

To test our procedures for our economic evaluation of the Back-on-Track intervention, all study participants (n = 40) will be asked to give consent for us to extract relevant data from Medicare Benefits Schedule (MBS) and Pharmaceutical benefits scheme (PBS) via Services Australia, and the Victorian Emergency Minimum Dataset (VEMD) and Victorian Admitted Episodes Dataset (VAED) via Victorian Agency for Health Information (VAHI), to understand the effect of the intervention on healthcare service use. MBS data will allow an assessment of primary care attendances; PBS data for prescribed medications; and VAHI data for emergency department and inpatient hospitalisations, throughout the study period.

Refer to table below for variables to be requested from each organisation.

Data source	**Variables to be requested**
MBS (from Services Australia)	Date of service, MBS item number, MBS item description, provider charge, schedule fee, benefit paid, patient out-of-pocket, ordering provider postcode
PBS (from Services Australia)	Date of prescribing, PBS item code, PBS item description, patient category, patient contribution, net benefit, pharmacy postcode
VEMD and VAED (from VAHI)	Health service location, arrival date, visit type, triage category, principal diagnosis

Demographic and clinical information

As well as the four outcome measures, we will also record the following demographic and clinical information from people with depression:

- Demographic – age (coded in years), gender (coded female, male, other), post code (four digit), residential status (coded living alone, cohabiting), employment status (employed full-time, employed part-time, not working, other), self-identified occupation in the farming community (coded farm owner/manager, farm worker, service provider, other).
- Clinical – Self reported long term health conditions, previous depression treatments (coded medication, psychological, other).
- Participants will also be asked to provide us with their individual healthcare identifier. This can be accessed from either the My Medicare smart phone application or the My Health Record website.

Demographic information from peer workers

- Demographic – age (coded in years), gender (coded female, male, other), post code (four digit), employment status (employed full-time, employed part-time, not working, other), self-

identified occupation in the farming community (coded farm owner/manager, farm worker, service provider, other).

- Clinical – Self reported long term health conditions.

3.6. Sample size

The intended sample size is 40 participants (20 allocated to Back-on-Track, 20 controls) supported by ten peer workers.

3.7. Recruitment

Procedures for recruiting people with depression.

Based on figures provided by Agriculture Victoria (Victoria's agriculture and food industries | Agriculture in Victoria | About | Agriculture Victoria) we estimate that 69,000 people are employed in agricultural production in Victoria.

Trials of behavioural activation are typically able to recruit around 1 in 3 people that are asked to participate (Richards et al., 2016). We anticipate that around a third of people in the farming community will meet our inclusion criteria (REF).

To achieve our sample size requirements, we estimate needing to ask between 120 and 360 members of the farming community to identify 40 that meet trial inclusion criteria and will consent to participate.

The National Centre for Farmer Health has extensive engagement with the farming communities across Victoria. This includes over 4,500 stakeholders to a monthly e-newsletter, and 498,000 unique users of the Farmer Health website. The NCFH has a strong social media platform (Facebook, Instagram and Twitter) with over 8,100 followers. The NCFH also has existing collaborations with relevant government, industry and community bodies actively engaged in the geographical areas of interest (including Agriculture Victoria, Victorian Department of Health, Victorian Farmers Federation, Victorian Alliance of Rural and Regional Community Health Services, Victorian Drought Hub, Murray Dairy, WestVic Dairy, GippsDairy, Gippsland Jersey, The Unbreakable Farmer, Rural Aid and the Rural Financial Counselling Service).

Recruitment procedures

We will advertise the study through NCFH social media platforms, the Farmer Health website and the NCFH monthly e-newsletter. We will also ask government, industry and community partners and rural media contacts to promote the study through their communications networks (eg. posters, media [radio, print and online], social media and industry newsletters). The development of this material has been informed by a community consultation process.

Recruitment materials state that we are looking to involve people who are experiencing stress, anxiety, or worry but are not currently receiving treatment prescribed by any health care professional (GP, psychiatrist, psychologists, counsellor) for mental ill-health.

Screening procedures

Members of the farming community with an interest in participating in the research will be asked to either: telephone, email, or complete an online expression of interest and confirm that they meet the study inclusion criteria. By return (within 2 working days) we will send a participant information sheet and consent form (PICF) electronically (or a paper copy by post) we will also book a time to telephone/video conference potential participants to discuss the study, check they meet inclusion criteria and seek written informed consent. Written informed consent to participate in the trial will be obtained by the trial co-ordinator (AG).

Participants will be asked if they would like to provide information by directly entering responses to an online survey tool (REDCap).

At the start of the initial meeting with potential participants (community members with depression), we will check that they meet inclusion criteria, this will include completion and scoring of the PHQ-9.

Once the PHQ-9 has been completed, researchers will score the measure and feedback the interpretation to participants. We will use the cut-off scores from Kroenke et al (2001). People that score less than 5 or over 19 (on the PHQ-9) will be told that they do not meet trial inclusion criteria and are unfortunately not eligible to take part in the research. People with a score of less than 10 will be sent a copy of the Managing Stress on the Farm self-help workbook as a helpful resource and thank them for their time. They will then end the call/videoconference. A score of over 19 is indicative of severe depression. The researcher will tell the person that their score suggests that they are experiencing high levels of depression. The researcher will express concern/empathy as appropriate. Next, they will ask if the individual is receiving any psychological or pharmacological treatment for

their mental ill-health. If they are, the researcher will advise the individual to contact their mental health clinician as soon as possible. In instances where the individual does not have a mental health clinician, they will be advised that they should, as soon as possible, either (i) contact their general practitioner (or other relevant health professional), or (ii) contact an online mental health provider (e.g. Farmer Health Online Psychology service with a psychologist who has received tailored farmer health training). The researcher will also offer to obtain a referral letter (summarising the PHQ-9 score and interpretation) from a mental health clinician from the Western District Health Service (template referral letter). The researcher will then explain that because of the severity of their psychological symptoms they do not meet study inclusion criteria. The researcher will close the conversation, restating the advice to the individual and thanking them for their time.

For individuals that meet trial inclusion criteria we will next explain the study, paying close attention to – and checking understanding of – randomisation and that there is a 50:50 chance that they will not get any additional intervention beyond treatment as usual aside from the Managing Stress on the Farm self-help workbook.

Consent procedures.

Usually, we will obtain consent electronically using procedures in REDCap (an electronic case record form). If requested, participants will be able to complete a paper-based version of the consent form. We will monitor and report on the number of participants that request and complete a paper PICF as a feasibility outcome.

Following consent, participants will be allocated a trial identification number and asked to complete week 0 (baseline) measures, this can be done immediately following consent or at time that is more convenient to the participant. All measures will be completed using REDCap an online case record form. REDCap is an extensively used software package that has been approved for use in clinical trials by both Deakin and La Trobe University. Data are entered and stored on a secure platform that is password protected.

If participants indicate that they are not comfortable completing measures online there will be an option for researcher support. Essentially, the researcher will ask participants questions verbatim and enter their responses into the eCRF.

If participants have not completed measures within 48 hours of signing the consent form, we will send them a reminder. If measures are still not completed, we will send a second reminder on day five and a final reminder on day seven. If after three failed attempts to get participants to complete study measures, we will withdraw them from the study.

All measures must be completed within seven days of the participants giving consent. If measures are not completed, we will write to the participant informing them that they have been withdrawn from the trial.

When participants have completed week 0 measures the trial coordinator will receive an alert and the participant will be randomised.

3.8. Allocation

Randomisation will be undertaken using a web-based randomisation service (sealedenvelope.com). Online randomisation will be undertaken by AK who will enter the participant identifier and their own email address and the randomisation system password into sealedenvelope.com. Randomisation will be by random permuted blocks to Back-on-Track or Managing Stress on the Farm in ratio 1:1. AK is shown the treatment group on screen and will also be sent a notification email. AK will enter group allocation – against the participant identification number – in the trial logbook that will be kept separate from all other trial documentation.

Once participants have been allocated AK will either:

1. If participants are allocated to the Back-on-Track group AK will email the relevant peer worker informing that they have been allocated a new Back-on-Track participant (community member with depression). They will be provided with contact details (name, telephone number and email address) so that they can contact them and arrange sessions at a mutually convenient time.
2. For participants allocated to the Managing Stress on the Farm Group AK will send by post a printed copy of the self-help workbook with a cover letter.

3.9. Blinding (masking)

This is a single blind trial. Researchers (and all other research team members) will be masked to group allocation, except for AK who is responsible for group allocation. Peer workers will not be masked to group allocation.

Trial participants (people with depression) will not be masked to group allocation. As part of the consent process a full explanation of the trial design will be given to participants that will include a description the Back-on-Track (experimental) and Managing Stress on the Farm (comparator) interventions. Consequently, they will be aware of the group to which they have been allocated.

Blinding mechanism

Assessments will be completed online by participants or via videoconference with the assistance of a study researcher (a member of the research team) who will be masked to treatment allocation.

Part of the researcher's training will be around the importance of adherence to the trial protocol and maintaining blinding. For example, it will be emphasised that they should take care not to ask trial participants if they received the Back-on-Track or Managing Stress on the Farm intervention at the follow-up assessments.

Because this is a trial testing a behavioural intervention, participants cannot be blinded to group allocation, they will not be masked to whether they are receiving the experimental (Back-on-Track), or control (Managing Stress on the Farm) intervention. Participants will be made aware when the study is explained to them as part of the consent process which is the experimental and which is the control intervention.

To test if our allocation concealment procedures were effective, at the end of the trial we will ask the study researcher (SM) to indicate to which group they thought participants were allocated to. We will then and test if the prediction was greater than chance.

Emergency unblinding

It is possible that in exceptional circumstance – for example, if there are a sequence of adverse or serious adverse events that seem to be related to the intervention – that blinding will need to be broken. In such circumstance, the trial researcher (SM) will contact the chief investigator (AK) who would convene an emergency trial management group meeting to review the events and consider if unblinding is necessary.

The breaking of blinding would not necessarily be a reason for stopping the trial but would need to be clearly reported in any publication or reports of the trial findings.

3.10. Data collection

Trial procedures and evaluations

Participants can either complete the electronic CRF directly through their smart phone, tablet or computer (via the REDCap platform) or with the help of the trial researcher (SM), who will enter the information in the CRF on the participants behalf.

Participants will be contacted by the trial researcher (SM) a week prior to the end of treatment and week 26 assessments to check they are willing to continue participating in the trial (checking consent). Participants will be advised that they will be sent an email with a link so that they can complete the next set of study assessments (again researcher support will be provided if necessary). Participants will be asked to complete the survey as soon as possible, but necessarily within a week of receiving the email. At this time, we will inform the participant that they should allow for up to 20 minutes to complete the questionnaires. If participants have not completed the survey within five days of the initial email being sent, we will send a reminder email and text message to their telephone. A week after sending the first email a final reminder (by email and text message to their phone) will be sent inviting participants to complete the survey within the next 48 hours. No further reminders will be sent. If the survey is not complete the participants will be considered to have withdrawn from the trial.

Some participants will have opted to complete the survey with researcher assistance. If so, a mutually agreed time will be made to complete the survey within seven days following the email notifying participants that the assessment is due. If necessary, assessment meetings can be rescheduled as required but will need to be done within the 7-day assessment window.

3.11. Data management

We will use the REDCap Electronic Case Record Form (eCRF) for data entry with study participants directly completing measures via their own smart phone, tablet device or computer. Some participants may require support to complete measures, and this will be done by the study researcher. The eCRF was developed by the La Trobe Clinical Trials Platform. To promote data quality, the eCRF will be set up to restrict the entry of impossible data (e.g., age of 999). Wherever possible we will use drop down menus or tick boxes that are easy for participants to accurately complete. We will use survey logic to ensure that participants are not having to skip over or answer irrelevant questions.

Finally, participants will need to answer all required questions (compulsory survey items) before submitting the survey, eliminating the risk of missing data.

3.12. Statistical methods

We will use descriptive statistics (predominantly number and proportion) to summarise the feasibility outcomes from our trial.

Feasibility outcome	**Method of analysis**
Can we successfully recruit peer workers (lay-workers) to the trial?	How many people need to be asked to recruit one peer worker
How many peer workers successfully complete the Back-on-Track training package?	Proportion
How many trained peer workers will go on to deliver the Back-on-Track intervention?	Proportion
How many peer workers are retained in the project?	Proportion
Fidelity of delivering the intervention	Audio recording of 10 sessions - independently rated - using the Behavioural Activation Fidelity Assessment (Gibbons et al. 2023).
Trial process survey (*Study Participant Feedback Questionnaire Toolkit*, n.d.)	All peer workers (on recruitment, mid trial and on completion of Back-on Track delivery) and All community members with low mood or depression (baseline, week 10 and week 26)
Acceptability of the intervention	Qualitative interviews: - all peer workers on completion of Back-on-Track delivery - five community members with low mood or depression on completion of Back-on-Track sessions (post week 10) - five community members with low mood or depression who received the MSOF self-help workbook (post week 10)
Feasibility of delivering the intervention	Qualitative interviews: - all peer workers on completion of Back-on-Track sessions delivery - five community members with low mood or depression on completion of Back-on-Track sessions (week 10) - five community members with low mood or depression who received the MSOF self-help workbook (week 10)
Barriers and facilitators to delivery	Qualitative interviews: - all peer workers on completion of Back-on-Track sessions delivery

	- five community members with low mood or depression on completion of Back-on-Track sessions (week 10) - five community members with low mood or depression who received the MSOF self-help workbook (week 10)
People with low mood or depression who express an interest in taking part in the trial?	Total number
People with low mood or depression who consent to participate in the trial?	Proportion (denominator, number who expressed an interest in participating)
People with low mood or depression who complete baseline measures	Proportion (denominator, number who consented to participate)
People with low mood or depression who agree to be randomised	Proportion (denominator, number who consented to participate)
People with low mood or depression who commence the Back-on-Track program	Proportion (denominator, number who consented to participate)
People with low mood or depression who complete the Back-on-Track program	Proportion (denominator, number who consented to participate)
People with low mood or depression who complete end of treatment (week 11) measures	Proportion (denominator, number who consented to participate)
People with low mood or depression who complete week 26 measures	Proportion (denominator, number who consented to participate)
The number of Behavioural Activation (BA) sessions where a satisfactory level of fidelity to model is demonstrated (determined using the BA fidelity scale)	Proportion (denominator, total number of completed sessions)
Adverse events that have occurred during the trial	Number
Serious adverse event that occurred during the trial	Number

Variables, measures and methods of analysis

Variable/outcome	**Hypothesis**	**Outcome measure**	**Method of analysis**
<u>Primary</u>			
Mood	Improved mood	Change in PHQ-9 score	Mean (s.d.), effect size (cohen's *d*)
<u>Secondary</u>			
Work performance	Enhanced work performance	Change in Work Productivity and Activity Impairment Questionnaire	Mean (s.d.), effect size (cohen's *d*)
Loneliness	Reduced loneliness	Change in UCLA loneliness scale	Mean (s.d.), effect size (cohen's *d*)
Wellbeing	Improved wellbeing	Change in WHO-5 Wellbeing index	Mean (s.d.), effect size (cohen's *d*)

Economic evaluation.

The economic evaluation reporting will adhere to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. A cost-consequence analysis will explore the costs associated with the program and report these alongside potential benefits and outcomes. The analysis will be conducted from the 'funder perspective' which allows health care organisations to consider how much this and similar programs would cost to implement. We will also include societal perspective (secondary analysis), which considers 'societal costs' such as travel or productivity costs relating to participants. Cost consequence analysis is appropriate for complex interventions that generate outcomes that cannot be expressed using a single metric. The outcome measures and net costs will be tabulated to allow an analysis of the cost per net change. The outcomes of interest will include: changes in mental health-related outcomes (from trial data), healthcare service use (from MBS, PBS and VAHI data), quality of life (from AQoL-4D data) and productivity (from WPAI survey data). All costs will be adjusted using the Consumer Price Index (CPI). Sensitivity analysis will be conducted to assess the robustness of the results.

Process evaluation

Interviews with peer workers and study participants

Interviews with all peer workers to assess acceptability, feasibility and barriers and enablers to delivering the intervention. Interviews will be conducted at the end of the trial once peer workers have completed all Back-on-Track sessions.

Interviews with n = 10 participants (n = 5 intervention [People with depression], n = 5 control) to assess acceptability, feasibility and barriers and facilitators to engagement with the research and both study interventions. All interviews will be conducted as close as possible to completion of participation (i.e. post week 10)

Interviews will be conducted by SM (research assistant) following a semi structured interview schedule. Interviews will be transcribed using a transcription service that has been approved by Deakin university. We will use the framework method following the procedures described by (Gale et al., 2013) to analyse the study findings.

Post treatment (week 11) survey of study participants

All study participants (intervention and control) will be sent (via email or in the post, based on preference) a post-trial survey about their involvement in the study. Questions focus on the adequacy of information about the trial, benefit of participating, their motivation to take part in the research,

understanding of randomisation processes, perceived value of the work (*Study Participant Feedback Questionnaire Toolkit*, n.d.).

3.13. Data monitoring

3.13.1. Formal committee

The trial does not require a DSMB because BA has been established in previous studies as a safe treatment for depression with a low risk of adverse events.

3.14. Safety/harms

Participants will complete study measures at baseline (week 0), end of treatment (week 11) and week 26. At the week 11 and week 26 assessment point, participants will be asked to inform the research team of any medical occurrence, visit to a family doctor or hospital admission that occurred whilst they were enrolled in the trial. As well as at the assessment point participants can report harms by sending a text message or email to the trial co-ordinator.

We will send - through the REDCap platform (via TWILIO) - an SMS to trial participants every two weeks asking them to report if any adverse events have occurred. This will be achieved by asking them to report if they have been unwell in anyway or have seen a doctor or attended hospital or other healthcare provider for any reason.

At the week 10 and 26 assessments participants will be asked about any medical occurrence that has occurred between now and the last assessment. Participants will be asked if they have visited their family doctor or attended or been admitted to hospital for any reason. We will also ask if they have been sick or unwell (physically or mentally) in anyway. Finally, we will also ask about any suicidal thoughts or suicide attempts that have occurred.

We will immediately stop the trial if there are any suicide attempts of fatalities that are plausibly linked to either the study interventions or research procedures. The study sponsor (Western District Health Service) will be contacted as will the human research ethics committee.

3.15. Auditing

WESTERN DISTRICT HEALTH SERVICE is the sponsor of the trial. They will be responsible for determining when a sponsor-initiated audit of the trial is required.

4. ETHICS AND DISSEMINATION

4.1. Research ethics approval

The trial will be conducted in accordance with Good Clinical Practice Guidelines (GCP, REF). All investigators have completed GCP training and copies of certificates are keep in the trial master file.

Western District Health Service have reviewed and endorsed the trial protocol and have provided a letter of support for the research.

The trial protocol and relevant supplementary documents – participant information sheet and consent form, recruitment materials, screening documentation, case record forms, investigator training log (GCP certificates) – will be submitted for review and approval by the Human Research ethics committee. A copy of the study approval letter will be submitted to the La Trobe University and Deakin University HREC.

4.2. Protocol amendments

Protocol amendments will be reviewed and approved by the trial steering committee prior to being submitted as an amendment request to the HREC. Once approved, relevant trial documentation (trial master and site files) will be updated. We will also update the trial registration entry if necessary. In any publications emanating from this trial, we will clearly describe the protocol amendments have occurred.

4.3. Informed consent process

Informed consent process (peer workers)

As noted, candidate peer workers will be identified through the community consultation process. They will be invited to apply for casual positions as peer workers employed by the Western District Health Service. Information about the position will include details of the research and the potential for peer workers to participate, we will also make it clear that it is not a requirement of people joining the project that they provide consent to participate. Applicants that meet the essential selection criteria will be invited for interview. The panel will be chaired by the CIA (AK) and include two other members of the research team including at least one lived experience researcher. Towards the end of the interview the CIA (AK) will provide a verbal description of the research and indicate that there is an opportunity (but not a requirement) for successful applicants to participate in the research. Successful candidates will be offered a casual contract of employment with Western District Health Service and invited to provide written informed consent to participate in the research.

Participants, people with depression

All study participants will be required to provide written informed consent – by signing the Participant Information and Consent Form – prior to formally entering the trial. The consent documentation includes consent for Back-on-Track Sessions to be audio recorded and reviewed against fidelity criteria and consent to access MBS (medicare benefits schedule) Victorian Agency for Health Information (VAHI) and PBS (pharmaceutical benefits scheme) data for the purposes of conducting an economic analysis.

Additional consent processes for young people

Young people (mature minors) aged between 15 and 17 years are eligible to take part in this study. It is important – given the prevalence of depression in this age group – to offer the opportunity to participate in research. We also note that in farming communities' people often get involved working on the farm at an early age. As this study is above low risk, and as per the NH&MRC national statement we will seek written consent from young people and from their parent or guardian.

The process of obtaining consent will be as follows:

Members of the farming community that express an interest in participating in the research will be asked to contact the trial co-ordinator (AG) either by telephone or email. The trial co-ordinator (AG) will document the name and contact detail of the potential participant in the trial log (a paper-based document stored in the chief investigators (AK) office). Within two working days we will send (by email or in the post) potential participants a copy of the participant information and consent form (PICF). After a further day the trial co-ordinator (AG) will contact the potential participant and arrange a time to talk about the study further, check understanding of what is involved, and confirm that they meet study inclusion criteria. One of the key inclusion criteria is that they have a PHQ9 score of between 5 and 19. We will therefore asking potential participant to complete a PHQ-9. Because this is done ahead of the obtaining consent to participant in the trial, we will obtain verbal consent to complete and score the PHQ-9. Once we have verbal consent, potential participants will be asked to complete the PHQ-9. Once completed the researcher will score the measure and explain to the potential participant what the rating means. People who score less than 10 (on the PHQ9) will be told that they do not meet trial inclusion criteria and are not eligible to take part in the research because they are not currently experiencing mood problems. The researcher will offer to send them a copy of the Managing Stress on the Farm self-help workbook (MSOF) as a resource and thank them for their time. We will then end the meeting.

If the person scores over 19 on the PHQ-9 – indicative of severe depression – the researcher will tell the person that their score suggests that they are experiencing serious mood problems. The researcher will express concern and empathy as appropriate. The research will be required to follow the trial distress management protocol (4.3.1).

Next, they will ask if they are receiving any pharmacological treatment for their mental ill-health. If they indicate that are the researcher will advise that the individual should contact their mental health clinician as soon as possible to review their treatment. In instances where the individual does not have a mental health clinician, they will be advised that they should, as soon as possible, contact their general practitioner (or mental health crisis services) explaining that they have completed an assessment as part of a research project that indicates they are experiencing symptoms consistent with severe mental ill-health. The researcher will also offer to draft a referral letter (summarising the PHQ-9 score and interpretation) to give to a clinician explaining the PHQ-9 and what the score suggests. The researcher will then explain that because of the severity of their psychological symptoms they will not be able to take part in the study. The researcher will close the conversation, restating the advice to the individual and thanking them for their time.

For individuals who score between 5 and 19 on the PHQ-9 we will explain that it is necessary to check if they have any thoughts of suicide now by asking the question "have things been so bad lately that you have thought about killing yourself?" If they indicate they have, we will ask if they have a current plan about how they will take their own life (are actively suicidal). If they do, we will tell the individual that we are concerned about them, and they need to contact mental health crisis services immediately so they can get the help they need.

Once we have confirmed that an individual meets trial inclusion criteria and is not suicidal, we will verbally explain the study, paying particularly close attention to and checking understanding of the randomisation process (i.e. that there is a 50:50 chance that they will not get any additional intervention beyond the Managing Stress on the Farm self-help workbook) as it has been reported that often people do not clearly understand this aspect of the research process.

Usually, we will obtain formal consent electronically using procedures in REDCap (an electronic case record form). If requested participants will be able to complete and return – by post – a paper-based

version of the consent form. We will monitor and report on the number of participants that request and complete a paper PICF as a feasibility outcome.

Once consented, participants will be allocated a trial identification number (001, 002, 003 etc) - that will be recorded in the paper – based trial log-book – and asked to complete week 0 (baseline) measures. All measures will be completed using REDCap. REDCap is an extensively used electronic case record form that has been approved for use in clinical trials by both Deakin and La Trobe University. Data are entered and stored on a secure platform that is password protected.

If participants indicate that they are not comfortable completing measures online there will be an option for researcher supported completion. Essentially, the researcher will ask participants questions verbatim and enter their responses into the REDCap eCRF (electronic case record form).

As part of the consent process participants will be informed that information that they provide will be kept strictly confidential except in such circumstances where they indicate that they may harm themselves or other people. The risk of harm to self will be determined from discussion with participants.

Participants will be informed that if they feel that they are at imminent risk of harm to self or others it is important that they tell the researcher who advise the person to contact their GP, the Emergency Department of Emergency services as appropriate.

Distress management protocol.

We will adopt a stepped approach to managing people who we identify as experiencing distress or thoughts or plans for self-harm at any point during the research. All members of the research team will attend a one-hour training session on the trial distress procedures and protocol. Attendance at this training will be recorded in the training log (which is part of the trial master file). Peer workers will also receive education around the distress protocol as part of their training package.

Step 1 (checking in)

At each assessment point or Back-on-Track session the researcher or peer worker will confirm their physical location (‘where are you located at the moment?’) and ask a ‘check in’ question (‘how has your week been, how about your day today, how have you been feeling?’). Some people, because of the nature of the research, will express distress or upset in response to this question. The researcher

or peer worker will express empathy by saying 'it seems as though things have been good/rough at the moment, thanks for letting me know.' If things have not been going so well the researcher/peer worker will ask the participant to elaborate, by asking them if they can tell them "A bit more about how they are feeling" paying close attention to how participants respond, particularly if any thoughts of suicide or self-harm are expressed for example, "I feel like I want to end it all." Where thoughts of this nature are expressed the researcher/peer worker will move to the next step of the distress protocol. If thoughts of self-harm are not expressed the researcher/peer worker will continue with the session, documenting what the participant has said in the additional information section of the participant case record form.

Step 2 (risk assessment)

Step 2 requires that the researcher/peer worker undertake an informal risk assessment by asking the participant to elaborate on current feelings of harm to self or others and/or suicide. For example, they may ask the participant to tell them 'More about the feelings of wanting to end it all?' During this assessment the researcher/peer worker must enquire about any specific plans to harm themselves or others that the participant may have. If there are no specific plans for harm/self-harm/suicide they should document their concerns in the participant case record form (there will be an automated alert to trial co-ordinator in REDCap when this occurs) and proceed with the study assessment or peer worker session. Where participants indicate specific plans (for example, 'I feel like going to the shed, taking my shot gun and blowing my brains out') but do not give a specific time frame the researcher or peer worker) will express concern and tell the participant that because they are expressing thoughts of harming themselves it is important that they refer the participant to the relevant mental health crisis team (or other identified crisis team). All research and peer workers will have identified the mental health crisis teams that serve the geographical region of participants. As part of the trial set up procedures, we will write to mental health crisis teams to advise them that we are conducting a trial and where participants are at risk of harm to self or others, we may contact them.

Step 3 (management of imminent risk)

If participants indicate that that have clear plans and a timeframe for harming themselves or others – they are at imminent risk – the researcher or peer worker will stay with the participant (either physically or via video conference) whilst they contact the mental health crisis team or emergency services (000). If a participant is on a video conference (or telephone) and they end the call, the researcher or peer worker will immediately contact emergency services via 000.

Extension of the distress management protocol for people aged 15 to 17 years.

Researchers and peer workers will be following the 3-step process as above when working with young people. Additionally, when young people express concern about harming themselves, it will be important to involve parents or guardians of the identified risk. Participants will be informed during the consent process that this may happen, if they do not wish for their parents/guardian to be contacted they will not be able to participate in the trial.

4.4. Confidentiality

Trial data will be directly entered into an electronic Case Record Form (eCRF) developed using the REDCap platform. REDCap is a secure web application for building and managing online databases and it use have been approved by both La Trobe and Deakin University.

There will be a physical log of participant group allocation (participant names, group allocation and study number) that will be stored in a locked cupboard in a locked room at La Trobe university.

4.5. Declaration of interests

The authors declare no conflicts of interest.

4.6. Access to data

The data set from this trial will be made freely available via the Deakin University Research DataSpace platform for checking and reuse.

4.7. Ancillary and post-trial care

People that participate in the trial are covered by indemnity for negligent harm through the Deakin University clinical trials insurance.

4.8. Dissemination policy

4.8.1. Trial results

The results of the trial will be reported in an open access peer reviewed journal. The draft manuscript will be reviewed and approved by the trial steering committee to determined that it is an accurate report of the finding of the research prior to being submitted for publication.

A summary of findings of the trial will also be published on the National Centre for Farmer Health website.

4.8.2. Authorship

Alison Kennedy [1], Richard Gray [2], Martin Jones [3], Anna Greene [4], Suzy Malseed [1], Vincent Versace [1], Feby Savira [1], Serene Yoong [1], Shilpa Aggarwal [1], Serene Yoong [1], Melanie Lum [1], Kate Gunn [3], Susan Brumby [4]

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3. University Department of Rural Health, University of South Australia, Adelaide, Australia
4. Western District Health Service, Hamilton. Australia.

5. STUDY ADMINISTRATION

5.1. Key contacts

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5.2. Funders

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5.3. Roles and responsibilities

5.3.1. Research contributors (and delegated responsibilities)

Alison Kennedy (AK) – Chief Investigator

Delegated responsibilities: Protocol development, overall project management, monitoring recruitment, ensuring compliance to protocol. Drafting of report to trial steering committee

Anna Greene (AG) – Trial Coordinator

Responsibilities: Day-to-day conduct of the trial and will be the primary point of contact for peer-workers . Organisation and management of trial meetings

Suzy Malseed (SM) – Investigator

Responsibilities: Explaining the study to potential trial participants, Data entry and checking, development of peer worker training materials, trial meeting secretariate.

Richard Gray (RG) – Chief Investigator

Responsibilities: Protocol drafting, development of intervention and training package, attendance at trial management group and steering committees. Drafting of final report.

Martin Jones (MJ) – Chief Investigator (Training)

Responsibilities: Development, delivery, and supervision of peer worker training. Development of training materials. Attendance at trial management group and steering committees. Drafting of final report.

Susan Brumby (SB) - Investigator

Responsibilities: Attendance at trial management group. Specialist input from farmer health perspective. Drafting of final report.

Vincent Versace (VV) – Chief Investigator

Responsibilities: Will draft the analysis plan for the trial and coordinate the statistical analysis for the project.

Feby Savira (FS) – Investigator (Health Economist)

Responsibilities: Develop the Health Economics data collection and analysis plan

Serene Yoong (SY) – Investigator (Implementation Scientist)

Responsibilities: Advice on the development of the implementation strategy

Meera Senthuren (MS) – Investigator, La Trobe University Clinical Trials Platform

Responsibilities: Development of standard operating procedures and case record form, maintenance of trial master file. Programming of case record in REDCap, setting up database. Preparation of ethics application and submission of amendments to the trial.

5.3.2 Project researchers (advisory)

Shilpa Aggarwal – Psychiatrist

Serene Yoong – Implementation Scientist

Melanie Lum – Implementation Scientist

Kate Gunn – Clinical Psychologist

5.3.3. Trial committees

The Trial Steering Committee (TSC) terms of reference and membership are to be drafted and reviewed. The TSC will meet four times during the course of the trial: March (set up meeting) 2024, August 2024, February 2025, and April (Close out meeting) 2025.

The TSC comprise:

Independent Chair: Adjunct A/Prof James Dollman, Allied Health and Human Performance, University of South Australia, Adelaide, South Australia

Independent Community Member: Mr Adam Jenkins (Farming Community Member)

Principal Investigator: A/Prof Alison Kennedy (AK)

Chief Investigator: A/Prof Martin Jones (MJ)

Secretariat (non-voting): Ms Suzy Malseed (SM)

A Trial Management Group (TMG) terms of reference are to be drafted and reviewed. Membership of the TMG will comprise AK (chair), AG, FS, SM, RG, MJ, SB, VV and AWD.

A Community Reference Group (CRG) (comprising community members, service providers and key stakeholders from the three trial communities) will inform strategies for the recruitment and engagement of peer workers and community members with low mood or depression, and provide input on tailoring of training materials to accurately reflect the farming context). The CRG will meet monthly for 6 months, then adhoc as required to problem solve e.g. how bushfire might impact the local trial outcomes.

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6. APPENDICES

Appendix 1: Position Description for Back-on-Track Peer workers

Position: Back-on-Track(Peer led mental health support in farming communities)
Visa sponsorship is NOT available for this role
EBA: Health and Allied Services, Managers and Administrative Workers (Victorian Public Sector) (Single Interest Employers) Enterprise Agreement 2021 - 2025
Classification: Complementary Therapy Worker: Grade One Pay code IN34
Salary: Remuneration reliant upon qualifications and experience ($61 - $64k p.a, $31.03/hr + 25% casual)
Superannuation: 11%
Working hours: Casual, approximately 10 hours/week
Basis of employment: Fixed term contract (9 months)

Location: Hybrid working arrangement requiring combination of online work and community work.

Team: National Centre for Farmer Health
Line manager: Anna Greene – Trial Coordinator
Contact for enquiries: Suzy Malseed – Research Assistant
Please do not send your application to this contact

How to apply: Online applications. Go to https://wdhs.net/v2/home/careers/ then find the position by title or number and apply

ABOUT US

At Western District Health Service (WDHS) we pride ourselves on our strong teamwork and our shared commitment to providing person-centred high-quality healthcare to the Southern Grampians community. We encourage and celebrate diversity, inclusion and accessibility for our staff and visitors to our services and we are dedicated to living our values of: **I**ntegrity, **I**nnovation, **C**ollaboration, **A**ccountability, **R**espect and **E**mpathy.

With a population of approximately 10,000 and a catchment of 16,500, Hamilton is the regional centre of Victoria's Southern Grampians region and WDHS is the largest employer in the region. WDHS provides a comprehensive range of acute inpatient services, residential aged care and primary and community health services. To find our more information about WDHS you can visit https://wdhs.net/v2/about-us/.

The Greater Hamilton region is rich with lifestyle opportunities and facilities. Working for WDHS will enable you to pursue your profession, build your career and enjoy a great work/life balance. With the Grampians National Park and stunning beaches on your doorstep in Warrnambool, Port Fairy and Portland and wineries dotted in-between, a better lifestyle is waiting for you! To find our more information about the Greater Hamilton region you can visit https://wdhs.net/v2/home/careers/community-information/

Be Yourself - We value the unique backgrounds, experiences and contributions that our staff and visitors bring to our service. First Nations people, those identifying as LGBTQIA+, people of all ages, with disabilities and culturally and linguistically diverse people are encouraged to apply.

The National Centre for Farmer Health (NCFH) is a partnership between Western District Health Service and Deakin University and is in Hamilton, Victoria. The aim of the National Centre for Farmer Health is to improve the health, wellbeing and safety of farmers, agricultural workers and their families across Australia through leadership, advocacy, service, research and education. The vision of the National Centre for Farmer Health is to make a difference to farmers' lives. The NCFH achieves this through inspiring quality education, research and service delivery through innovative partnerships that advance farmer health locally and globally.

PRIMARY OBJECTIVES: To deliver the Back-on-Track program, as part of a research trial, to members of farming communities in accordance with the program guidelines.

About the Role:

NCFH is conducting a Research Trial and will be delivering a Behavioural Activation program (**B**ack-on-Track). Back-on-Track is a peer led program designed to empower farming community members to take control of their own well-being, with the support of a peer worker who understands the challenges of life and work in a farming community and can support them to improve their mental wellbeing through Behavioural Activation. A peer worker is someone from the farming community trained to provide support to others in the community seeking to improve their mental wellbeing through behavioural activation (the Back-on-Track program). Full training and ongoing support will be provided to ensure competency in role. We are seeking positive, community-minded people with experience of life and work in a farming community to join us to improve mental health.

Responsibilities and Duties

- Actively participate in the Back-on-Track training program and ongoing group supervision
- Ensure that the Back-on-Track objectives are attained by delivering a consistent high-quality program and maintaining required reporting
- Establish respectful and empathic relationships.
- Maintain required communication with program staff and participants.

- Maintain a professional manner, upholding the values of Western District Health Services and National Centre Farmer Health

All Peer workers will report to Anna Greene as Trial Coordinator of Back-on-Track at The National Centre for Farmer Health.

About You:

Selection Criteria

- Commitment to the WDHS Values of Integrity, **I**nnovation, **C**ollaboration, **A**ccountability, **R**espect and **E**mpathy and ability to exhibit behaviour which reflects our values.
- Ability to work collaboratively and cohesively with colleagues, supervisors, and other stakeholders
- Experience living and/or working in a farming community and stressors involved in farming businesses
- An understanding of poor mental health in farming communities is required, however, applicants do not need to have personally experienced poor mental health

Staff benefits

- Internal training and development opportunities to support professional and personal growth.
- Enterprise Bargaining Agreement based remuneration.
- Salary packaging including capped expenses ($9,010), meals ($2,600), novated vehicle leasing.
- Free on-site car parking
- Social club membership offering a range of events, functions and local community discounts.
- A culture which supports staff health and wellbeing including:
  - Green Bean Café on site at the Hamilton hospital
  - Discounted leisure memberships
  - Gym membership at corporate rates
- Access to Employee Assistance Program (EAP)

Other Requirements

- *Current police check is required for this role*
- *Current working with children check is required for this role & must demonstrate an understanding of appropriate behaviours when engaging with children*
- *Current Victorian driver's licence is required for this role*
- *May require some driving in own vehicle*
- *Some work may be required outside of standard business hour in this position*

Occupational Health and Safety Responsibilities

All Western District Health Service employees share responsibility for occupational health and safety, (OH&S) with specific responsibilities and accountabilities allocated to positions within the organisational structure. Any employee who fails to meet his/her obligations concerning health and safety may, depending on the circumstances, face disciplinary action up to, and including, dismissal.

Employees have a responsibility to comply with all relevant WDHS OH&S management system Policies, Procedures and programs. This includes the WDHS Injury Management Program.

Employees have a responsibility to take all reasonable care to prevent incident or injury to themselves or to others in the workplace. Employees are expected to learn and follow approved standards and Procedures that apply to their activities and check with their Manager when they have any doubts concerning potential hazards.

Employees have a responsibility for:

- Looking after their own health and safety and those of others in the workplace;
- Follow safe work practices and use personal protective equipment as required;
- Participate in OH&S consultation and OH&S training initiatives;
- Report any accidents, incidents, injuries "near misses", safety hazards and dangerous occurrences, assist with any investigations and the identification of corrective actions;
- Cooperate with managers and supervisors so that they can meet their OH&S responsibilities;
- Don't wilfully interfere with or misuse anything provided in the interest of health and safety or wilfully put anyone at risk;
- Performing only those tasks for which they have received appropriate training and instruction;
- Ensuring that they understand and comply with those responsibilities which apply to them while performing their duties at the workplace;
- Participate in emergency evacuation exercises.

INHERENT PHYSICAL REQUIREMENTS:

Western District Health Service has a duty of care to all staff. The purpose of this section is to ensure that you fully understand and are able to perform the inherent requirements of the role (with reasonable adjustments if required) and that you are not placed in an environment or given tasks that

would result in risks to your safety or others. The role may require the following tasks among other things:

1 Nursing / Patient Care Role	2. Maintenance / Hotel Services Staff Role	3 Clerical / Administration Role
▪ manual handling (pushing, pulling equipment) ▪ general patient handling and clinical nursing duties ▪ sitting, standing, bending, reaching, holding ▪ pushing pulling trolleys and equipment ▪ general clerical, administration work, computer work ▪ use of personal protective equipment and handling ▪ handling general and infectious waste, ▪ **shift work in most roles**	▪ generic maintenance work, working at heights ▪ generic out door work / pushing, pulling trolleys ▪ sitting, standing, bending, reaching, holding ▪ computer work ▪ general clerical, computer and some admin work ▪ use of personal protective equipment and handling ▪ handling general and or infectious waste, ▪ **shift work in some roles**	▪ sitting, standing, bending, reaching, holding ▪ computer work, data entry ▪ general clerical at varying levels , ▪ use of personal protective equipment ▪ handling general waste ▪ pushing and pulling trolleys / filing, ▪ **shift work in some roles**

Note to all employees

- You must work within the policies, procedures and guidelines of WDHS
- You must participate in the WDHS integrated risk management and quality improvement systems by being aware of responsibilities to identify, minimise and manage risks and identifying opportunities for continuous improvement in your workplace through communication and consultation with managers and colleagues.
- You must ensure that the affairs of WDHS, its patients, clients and staff remain strictly confidential and are not divulged to any third party except where required for clinical reasons or by law. Such confidentiality shall extend to the commercial and financial interests and activities of WDHS.
- Statements included in this Position Description are intended to reflect in general the duties and responsibilities of this position and are not to be interpreted as being all inclusive.
- Management may alter this Position Description if and when the need arises. Any such changes will be made in consultation with the affected employee(s).
- A Performance Review will occur within three (3) months of commencement, then annually taking account of the key roles and responsibilities outlined in this Position Description. In addition to reviewing performance (individual and work team), the annual meeting provides an opportunity to ensure role clarity, revise key performance activities/measure and set development objectives and goals for the year ahead.

APPROVALS	*Name*	*Signature*	*Date*
Divisional Head:			
Department Head:			
Employee:			

Position code: *People, Culture & Development use only*	
Date revised: *People, Culture & Development use only*	

When revised please forward electronic copy to:

People, Culture & Development Department email: people.culture@wdhs.net