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Australian trial of behavioural activation for people with schizophrenia experiencing negative symptoms: a feasibility randomised controlled trial protocol

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ABSTRACT

Introduction Negative symptoms are frequently experienced by people with schizophrenia. People with negative symptoms often have impaired social functioning and reduced quality of life. There is some evidence that cognitive–behavioural therapy results in a modest reduction in negative symptoms. Behavioural activation may be an effective alternative treatment for negative symptoms.The study aims to examine the feasibility and acceptability of implementing a behavioural activation trial delivered in three community mental health services in South Australia to support adult consumers experiencing negative symptoms of schizophrenia.

Method and analysis This randomised controlled study will recruit a total of 60 consumers aged 18 years or above with mild-moderate negative symptoms of schizophrenia. The consumers will be randomly allocated to receive behavioural activation plus usual mental healthcare or usual mental healthcare alone. The intervention group will receive twelve 30 min sessions of behavioural activation, which will be delivered twice weekly over 6 weeks. In addition, we aim to recruit nine mental health workers from the three rural mental health services who will complete a 10-week online training programme in behavioural activation. Changes in negative symptoms of schizophrenia and depressive symptoms will be assessed at three time points: (a) at baseline, at 6 weeks and 3 month follow-ups. Changes in health-related quality of life (Short Form F36; secondary outcome) will be assessed at two time points: (a) at baseline and (b) immediately at postintervention after 6 weeks. At the end of the trial, interviews will be conducted with purposively selected mental health workers and consumers. Descriptive statistics and thematic analysis will be used to assess feasibility and acceptability.

Ethics and dissemination The findings from our feasibility study will inform the design of a fully powered randomised controlled trial to test the effectiveness of behavioural activation as a treatment for negative symptoms in schizophrenia. The study protocol was approved by the Central Adelaide Local Health Network Human Research Ethics Committee. The findings from this study will be disseminated through peer-reviewed scientific journals and conferences.

Trial registration number ACTRN12623000348651p.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This trial will occur in a real-world environment, which will provide insight into the delivery of the intervention in situ.
⇒ Interviews with clinicians and consumers will provide evidence as to practical limitations, potential adaptations, as well as acceptability.
⇒ As this is a feasibility study, no genuine conclusions will be able to be drawn regarding the feasibility of the intervention.

BACKGROUND

Schizophrenia is a serious mental illness.[1] Negative symptoms are common in schizophrenia with up to 60% of adults experiencing clinically relevant symptoms of the psychological condition.[2] Negative symptoms can occur at any point in the course of illness, although they are reported as the most common first symptom of schizophrenia. Typically people with schizophrenia present two symptom clusters: positive and negative symptom domains.[3] Positive symptoms consist of delusions, hallucinations and disorganised thinking[4 5] and respond well to antipsychotic medication and psychosocial interventions such as cognitive–behavioural therapy (CBT).[6 7] Negative symptoms are marked by the absence of normal functions, such as deficits in cognitive, affective and social interaction.[8] Negative symptoms can lead to poor prognosis and, if poorly managed, reduce the effectiveness of pharmacological treatments in the management of positive symptoms.[9]

However, successful treatment of negative symptoms can be challenging.[10] Studies have suggested that negative symptoms are associated with poor long-term physical and social functioning.[11 12] A systematic review of 12 studies that enrolled 1645 patients from 4 different countries indicated that quality of life and functioning is severely undermined in patients with negative symptoms of schizophrenia.[13] The psychological treatment with the broadest evidence base in schizophrenia is CBT.[7 14] When used to manage negative symptoms, CBT focuses on reduced levels of energy, motivation and pleasure, as well as diminished verbal and non-verbal expression/communication.[15–17] In a systematic review, Riehle *et al*[18] reported six studies investigating the efficacy of CBT on negative symptoms of schizophrenia and reported modest improvements.[18] However, the routine application of CBT is challenging in part due to service delivery constraints, and the intensity of training required for mental health workers to deliver the psychotherapy.[19 20] Accessing CBT in disadvantaged communities is particularly challenging because specialised mental health workers, such as psychologists are usually in short supply.[21 22] One potential treatment that could address these constraints is behavioural activation, a component of CBT that can be used as a stand-alone treatment.[23] To date, behavioural activation has demonstrated efficacy in the treatment of depression in adults[24 25] and is as effective as CBT.[24] We assume that if CBT can reduce negative symptoms, then its variant, behavioural activation could potentially be a candidate alternative treatment. To date, there have been two studies that have examined the effectiveness of behavioural activation in treating negative symptoms.[26] The two studies reported that behavioural activation was efficacious in reducing negative symptoms.[27 28] As both studies were pre–postdesign, there is a need to consider conducting randomised controlled trials to establish the potential evidence base.[26] However, a necessary first step is to undertake a feasibility trial to understand whether a fully powered randomised controlled trial is viable. If behavioural activation could be delivered by mental health workers for people with schizophrenia and negative symptoms, it may be an important development in the treatment of negative symptoms and lay the foundation for effectiveness studies to be completed. The proposed clinical trial will investigate the feasibility and acceptability of implementing a behavioural activation trial in three rural mental health services in South Australia to support adult consumers experiencing negative symptoms of schizophrenia. A unique aspect of the trial is that the mental health workers who have been prepared to use behavioural activation will be supervised by experts in behavioural activation via a telehealth platform to ensure fidelity to the psychological programme.

IMPLICATIONS OF THE PLANNED STUDY

To our knowledge, the current trial will be the third trial investigating the use of behavioural activation in treating negative symptoms in adults with schizophrenia. Our trial builds on the two previous studies by adhering to the good practice guidelines for conducting feasibility studies.[29 30] If our trial demonstrates the feasibility and acceptability of behavioural activation as a treatment for negative symptoms in adults with schizophrenia, it will deliver benefits including (a) informing the design of a full-scale randomised controlled trial and (b) updating the extant evidence base from the two studies identifying possible treatment options for adults with negative symptoms of schizophrenia. Behavioural activation is a simple and inexpensive psychotherapy that can be easily scaled up making it readily available in countries which have limited access to specialist mental health workers. A unique aspect of the study is the mental health workers will be supervised by a telehealth video link when delivering behavioural activation. This has two potential benefits. First, it will help the mental health workers maintain fidelity to the behavioural activation intervention. Second, should our study be successful, it will enable the application of behavioural activation across communities and countries in which travel can be problematic or time-consuming.

AIM OF STUDY

This study will examine the feasibility and acceptability of using telehealth behavioural activation support and supervision conjunctively with usual mental healthcare in the treatment of negative symptoms in adults with schizophrenia.

Study hypotheses

We hypothesise that telehealth behavioural activation support and supervision plus usual mental healthcare compared with usual mental healthcare alone is a feasible and acceptable strategy for helping people to better manage negative symptoms of schizophrenia.

METHOD

Study design

We will evaluate the feasibility and acceptability of telehealth behavioural activation support and supervision plus usual mental healthcare in supporting consumers to reduce negative symptoms of schizophrenia compared with usual mental healthcare (treatment as usual, (TAU). We have designed our protocol informed by the Standard Protocol Items: Recommendations for Interventional Studies statement: defining standard protocol items for clinical trials.[31]

Setting

Our feasibility trial will be implemented across three community mental health services located in rural South Australian communities in which psychological health services are provided to people living with a serious mental illness (figure 1).

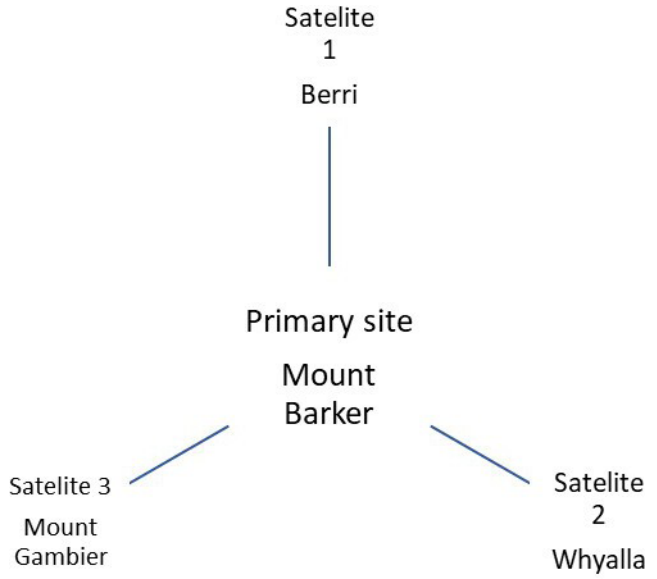

Figure 1 Telehealth cluster.

Population

The study will recruit adults experiencing mild to moderate negative symptoms of schizophrenia.

Eligibility criteria

Inclusion criteria

The study will comprise two groups of participants: mental health workers and consumers with a diagnosis of schizophrenia with negative symptoms. The eligibility criteria for the mental health workers include (a) employment by any of the three participating mental health services, (b) completion of the online training programme in behavioural activation offered by the University of South Australia and (c) provide informed consent to participate in the study. The mental health workers may include but are not limited to, mental health nurses, social workers, support workers and occupational therapists.

The consumers must be (a) aged 18 years or above (b) experiencing mild to moderate negative symptoms (greater than 3 on at least two negative symptom items from the Positive and Negative Syndrome Scale (PANSS)[29]), (c) current recipients of a mental health service from any of the three participating community mental health services and (d) able to understand, read, write and speak English.

Exclusion criteria

Mental health workers who have not completed the training in behavioural activation will be excluded from the study. Consumers will be excluded if they (a) have a baseline score of 15+ on the Patient Health Questionnaire 9 (PHQ-9) scale or acute depression and need to be seen by a psychiatrist for their safety (b) express suicidal ideation or are at risk of self-harm, or suicide, or present a risk to others. These potential participants will be referred to a general practitioner or mental health professional for support (c) have a disorder that impedes effective communication (eg, severe sensory impairment) or have trouble understanding or communicating effectively in English (d) have been assessed by mental health workers as being incapable of giving informed consent to participate in the study due to their medical circumstances. Consumers with multiple mental health diagnoses will also be excluded.

All the eligibility screening and assessments will be conducted by the clinical trial nurse.

Recruitment

Mental health workers

We will use a participant information sheet to inform mental health workers who complete the online training in behavioural activation about the aims of the telehealth trial. We will ask the mental health workers to volunteer their participation in the telehealth trial via an email that will be sent by one of the behavioural activation experts. The mental health workers who agree to participate will be asked to review an informed consent form and confirm their agreement to participate in the study by signing it (see online supplemental file 1). The mental health workers who agree to participate and sign the consent form will be recruited into the telehealth trial. We aim to recruit nine mental health workers trained in behavioural activation from the three community mental health services. The recruitment of mental health workers will commence in February 2024 and finish in May 2024.

After the trial, we will invite up to six mental health workers to participate in individual interviews. The clinical trial nurse will contact the mental health workers about the interviews. Separate consent will be required to participate in the interviews.

Initial identification of the potential consumers to participate in the telehealth trial will be done by the mental health workers, who will determine if the consumers meet the study criteria. The mental health workers will briefly inform the consumers about the study and offer them a participant information sheet. Consenting consumers will need to authorise the mental health workers to share their personal details with the clinical trial nurse. Consumers agreeing to have their personal details shared will be approached by the clinical trial nurse. The clinical trial nurse will provide the consumer with detailed information about the telehealth trial and their potential role in it. This will include the provision of a participant information sheet for the consumer to read and keep. The clinical trial nurse will offer the consumer further explanation or clarification, as required, and address concerns they may have. The consumer will be given at least 48 hours to consider their involvement with the study. Consumers who agree to participate in the telehealth trial will be invited to review and sign an informed consent form (see online supplemental file 2) in the presence of the clinical trial nurse. If informed consent is obtained by telephone, this will be recorded on the informed consent form and in the participant's trial record by the clinical trial nurse. We aim to recruit 60 consumers who access mental health services provided across the

three participating community mental health services. Consenting consumers will be enrolled in the study in either the behavioural activation group or the TAU group. The recruitment and enrolment of consumers will commence in June 2024 and finish in July 2025. Enrolment will proceed until 30 behavioural activation group consumers and 30 TAU group consumers have been recruited (a total of 60 consumers).

We will report on this feasibility trial using the Consolidated Standards of Reporting Trials (CONSORT) guidelines.[32] Figure 2 presents the CONSORT flow diagram showing the stages of screening, enrolment and follow-up.

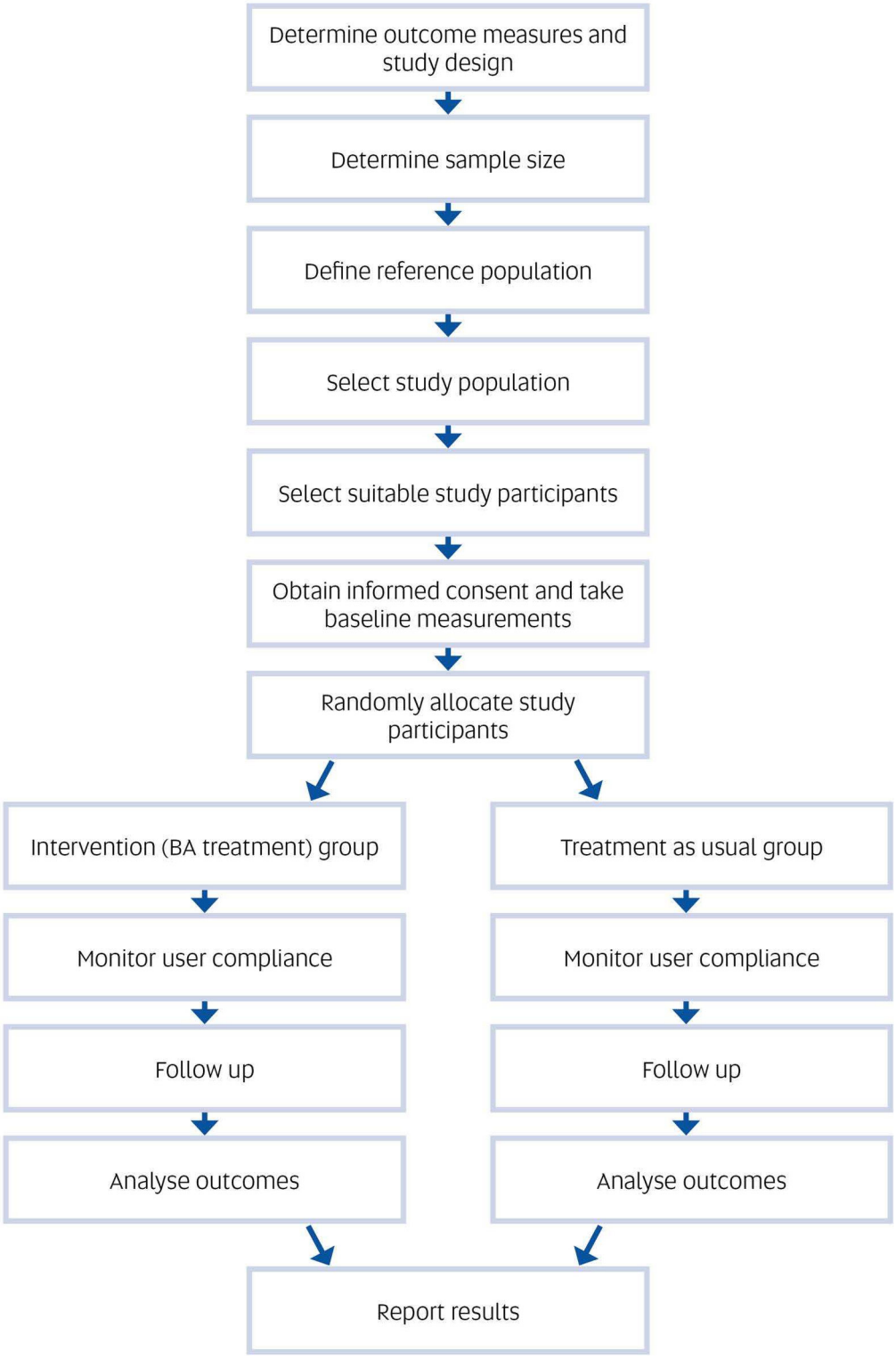

Figure 2

After the trial, we will invite 5–10 consumers to participate in individual interviews. The clinical trial nurse will contact the consumers about the interviews. Separate consent will be required for consumers to participate in the interviews. When reporting the findings of the interviews, we will follow the Consolidated criteria for Reporting Qualitative research guidelines.[33]

Randomisation and masking

The clinical trial nurse will collect baseline data from the consumers who voluntarily agree to participate in the study. The consumers will then be randomly assigned into either (1) the behavioural activation group, which will receive behavioural activation plus usual mental healthcare or (2) the TAU group, which will receive the usual mental healthcare alone.

Random allocation will be generated by an external computerised randomisation service that uses block randomisation with random permuted block sizes to ensure appropriate allocation concealment and equal sample sizes across groups. Following baseline data collection from consenting consumers, the clinical trial nurse will insert the unique participant ID into the online randomisation service (sealedenvelope.com) and receive an email confirmation of their group allocation.[34] The allocation sequence is retained by the service and the clinical trial nurse is unaware of group allocation until receiving confirmation for each participant. The clinical trial nurse will then inform the consumers and the mental health workers of treatment allocation. Allocation will be blinded to the data manager/statistician, but it will not be masked to the mental health workers and clinical trial nurse who will collect the baseline, postintervention and follow-up outcome data. We anticipate that 30 consumers will be assigned to the behavioural activation group and 30 consumers to the TAU group.

Intervention

Behavioural activation

The 30 consumers in the intervention group will receive behavioural activation plus usual mental healthcare.[35] The intervention will be delivered by the mental health workers who will be provided with ongoing live clinical supervision from an expert in behavioural activation via telehealth video link. Each consumer will be offered 12 sessions of behavioural activation (table 1), delivered twice weekly, in 30 min sessions, for 6 weeks. Specific behavioural activation techniques that will be applied to include (a) identification of depressed behaviours, (b) analysis of the triggers and consequences of depressed behaviours, (c) monitoring of activities, (d) development of alternative goal-orientated behaviours, (e) scheduling of activities and (f) the development of alternative behavioural responses to rumination.

TAU group

Each of the 30 consumers in the TAU group will receive the usual mental healthcare provided by mental health

Table 1 Overview of 12 sessions of behavioural activation

Session	Topic
Session 1	Getting to know each other and overview of the 12 sessions. ► Introductions, building rapport. ► Introduction to behavioural activation. ► Structure of sessions.
Session 2	Behavioural activation ► Introduce behavioural activation tools. ► Explore with the client how behavioural activation is going to be used to identify different behaviours and impact on mood.
Session 3	Mood monitoring Explain mood monitoring and activity in context of behavioural activation. a. Explain depression cycle. b. Explain activity cycle. c. Collaboratively explore links between increased activity and mood. Introduce Mood Monitoring. a. Explain what a mood diary is. b. Collaboratively explore how best to complete mood diary. c. Negotiate that mood diary to be reviewed next session.
Session 4	Reviewing the mood diary and activity. Review mood diary. a. Collaboratively explore fluctuations in mood with client. b. Collaboratively explore periods of good mood with the client. c. Collaboratively explore periods of low mood with the client. Collaboratively explain the link between fluctuations in mood and activities. a. Fluctuations in mood will occur. b. Activities can have a positive, negative or neutral effect on mood. c. The purpose and meaning of activity influence effectiveness.
Session 5	Reviewing the mood diary and activity.
Session 6	Activity scheduling. Developing Activity Schedule: a. What is activity? b. When activities are going to be done? c. Where you do it? d. Who can you do activity with? Collaboratively discuss importance of continuing to monitor mood and to follow activity schedule.
Session 7	Activity scheduling. Explore activity planner and mood diary. a. Collaborative with the client to explore how client found completing the activity schedule and mood diary. b. Collaborative with the client to explore any gaps/or reason for non-completion. c. Collaborative with the client to explore if they noticed anything in particular while completing the activity schedule and mood diary. Collaborative with the client to explore activities associated with the highest mood. Collaboratively with the client to explore what they were doing when mood at its lowest. Use the activity schedule and mood diary to explore relationship between inactivity and low mood. Use the activity schedule and mood diary to explore relationship between avoidance behaviour and low mood. Use the mood diary and activity schedule explore alternative coping behaviours for avoidance behaviours. Use the mood diary and activity schedule identify behaviours which align with values. Review and update activity planner with the client which focuses on: a. Reducing avoidance behaviour. b. Reducing or moving activities associated with low mood. c. Increasing activities that are associated with good mood. d. Making links between activity and meaning.
Session 8	Activity scheduling
Session 9	Activity scheduling

Continued

Table 1 Continued

Session	Topic
Session 10	Activity scheduling
Session 11	Activity scheduling
Session 12	Relapse prevention

services.[35] No other specific intervention will be provided to this group. Participants in the TAU will be able to access behavioural activation after the study has finished.

The CONSORT diagram illustrating participant flow is shown in figure 2.

Behavioural activation training

The mental health workers who join the telehealth trial will be trained to deliver behavioural activation. The training will focus on behavioural activation techniques based on an academically accredited and established online 'Professional Certificate in Behavioural Activation for Depression' programme offered and has been accredited by the University of South Australia. The training will be facilitated by behavioural activation experts MJ, SD and SW. The 12-week online training programme consists of five modules: (a) the evidence base of behavioural activation, (b) introduction to behavioural activation, (c) assessment and mood monitoring, (d) functional analysis and (e) activity scheduling. The professional certificate has been informed by various authors and approaches to behavioural activation and is congruent with established programmes such as behavioural activation for depression.[36]

On completion of the online training programme, we expect mental health workers to have achieved the following learning outcomes: (a) gained a sound understanding of the behavioural activation intervention, (b) attained the relevant core behavioural activation skills and (c) demonstrated competency in behavioural activation delivery. The mental health workers will be assessed using multiple-choice questionnaires at the end of each module. Competency will be measured by assessing an audiorecorded behavioural activation assessment and an activity schedule with a work colleague. Each mental health worker will have submitted three recorded conversations. The course is designed in such a way that each of the three recorded conversations increases in complexity as the practitioners complete the training.

After the mental health workers have completed the training and commenced working with participating consumers, the behavioural activation experts (MJ, SD and SW) will provide supervision via a telehealth supervision and support structure. Each participating mental health worker will deliver behavioural activation to a minimum of four and a maximum of five consumers.

Informed consent

No consumers will be included in the study unless written informed consent has been obtained from the consumers or their legal guardians. If consent is revoked at any point during or after participation, all assessments done in this study will be cancelled immediately for this participant.

Intervention fidelity

We will assess the quality of and adherence to the behavioural activation treatment protocol via the telehealth supervision and support structure.

Feasibility outcomes

Recruitment

We will determine the proportion of consumers with negative symptoms of schizophrenia who agree to participate in the study. We will do this by dividing the number of consumers who agree to participate in the study by the number of consumers identified as experiencing mild to moderate negative symptoms of schizophrenia across the three participating sites.

We will assess the proportion of eligible consumers who agree to participate in the study and go on to be randomised. We will do this by dividing the number of consumers who are randomised by the number of consumers who agree to participate in the study.

Completion of clinical outcome measures

We will determine the proportion of consumers who complete the outcome measures at baseline, 6 weeks and 3-month follow-up. We will do this by dividing the number of consumers who complete the outcome measures at each time point by the number of consumers who are randomised.

Completion of behavioural activation treatment programme

We will assess the proportion of consumers who complete the behavioural activation treatment. We will do this by dividing the number of consumers who complete the behavioural activation treatment by the number that are randomised. Completion of treatment will be determined by attendance at a minimum of 8 out of 12 behavioural activation sessions over 6 weeks.

Reporting preliminary efficacy on negative symptoms

We will assess the preliminary efficacy of behavioural activation treatment on negative symptoms. We will do this by comparing PANSS scores achieved at baseline, 6 weeks and 3-month follow-up stages across the two telehealth trial groups.

We will also assess the preliminary efficacy of behavioural activation on depressive symptoms. We will do this by comparing the PHQ-9 scores achieved at baseline, 6 weeks and 3-month follow-up stages across the two trial groups.

We will determine the preliminary effect of behavioural activation treatment on health-related quality of life. We will achieve this by comparing the scores on the Short Form Health Survey questionnaire (SF 36) at two time points: (a) at baseline and (b) immediately at postintervention after 6 weeks across the trial groups.

Outcome measures

Primary outcome measure: negative symptoms

The clinical trial nurse will be trained to use the PANSS.[33] After completing the training, the clinical trial nurse will use the PANSS to screen consumers for negative symptoms of schizophrenia. The PANSS is a 30-item, clinician-administered scale for measuring the presence and severity of positive and negative symptoms. The items are anchored against a seven-item Likert-type scale. Seven items measure negative symptom domains: blunted affect, emotional withdrawal, poor rapport, passive/apathetic social withdrawal, difficulty in abstract thinking, lack of spontaneity and flow of conversation and stereotyped thinking.[34] The outcome measure will be completed at three time points (a) at baseline (0 weeks), (b) at 6 weeks postintervention and (c) at 3 months postintervention.

Secondary outcome measure: depressive symptoms

Consumers will be assessed for depression by the clinical trial nurse using PHQ-9. The scale is anchored on a 4-point Likert-type scale (0, absent; 1, mild; 2, moderate and 3, severe) with nine items that correspond to the Diagnostic and Statistical Manual version IV Diagnostic Criterion A symptoms for major depressive disorder.[36] The secondary outcome (depression) will be assessed at three time points (a) at baseline (0 weeks), (b) at 6 weeks postintervention and (c) at 3 months postintervention, simultaneously with the primary (negative symptoms) outcome data collection.

Secondary outcome measure: quality of life

Consumers will complete the SF 36 at two time points: (a) at baseline (0 weeks) and (b) immediately at postintervention after 6 weeks. The secondary outcome measure will assess the level of health-related quality of life based on eight physical and mental health-focused domains, including physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotion and mental health.[35]

Acceptability of behavioural activation

We will interview mental health workers (minimum of 4) and consumers (minimum of 10) to explore their experiences of practising and using behavioural activation. Interviews will be conducted with the mental health workers to gain insight into their experiences of completing the behavioural activation training programme and delivering the psychotherapy as well as their perceptions about the supervision provided by the behavioural activation experts via a telehealth platform. The interviews with the consumers will focus on their experiences of, and perceived impact of, engaging in the behavioural activation treatment. General topic areas (for consumers and mental health workers) will include what worked; what did not work; what could be done differently; what could be improved and what were the facilitators and barriers to engaging with behavioural activation (see online supplemental files 3 and 4). The interviews will be conducted by the clinical trial nurse (in-person or by phone) and will be audiorecorded, where feasible. We anticipate that the interviews will last no more than 30 min. Data collection will cease once the information becomes too repetitive and no new insights are added by the interviews. A preliminary interview topic guide has been developed for each group of interviewees (see online supplemental files 3 and 4). Separate consent will be required for the interviews (see online supplemental file 5).

Other data to be collected

Sociodemographic information

In this study, we will also collect personal data including gender, date of birth, marital status and educational level. This information will be collected by the clinical trial nurse at the assessment and recruitment stage.

Contextual factors

We will collect information about the three participating telehealth trial sites at baseline and 6 weeks postintervention. The information will be important in understanding the implementation process. These factors (including organisational changes, staffing changes, etc), will be collected by the clinical trial nurse through conversations with the mental health workers and senior managers, and clinicians.

Sample size

A priori sample size of 60 consumers and 9 mental health workers was calculated based on the median sample size per arm of 30 recommended for feasibility studies with continuous outcome measures such as levels of negative symptoms, depressive symptoms and quality of life.[30] The subsequent effectiveness study would adopt the effect size calculated in this pilot study to calculate the required sample size.

Data collection and management

The data manager will facilitate the data collection process. With prior written consent, participant demographic information will be collected through the three telehealth trial sites. The data for the primary outcome measure (negative symptoms) will be collected at baseline, 6 weeks postintervention and 3 months postintervention. One of the second outcome measures (depression) will be collected at the same time points. For the secondary outcome of health-related quality of life, data will be collected at two time points: (a) at baseline (0 weeks) and (b) immediately at postintervention after 6 weeks. With consumers' permission, all outcome data will be collected and analysed from consumers who discontinue the study or deviate from the intervention protocol. The interviews with the consumers and the mental health workers will, where feasible, be audiorecorded with permission from the interviewees. The audio recordings will be transcribed verbatim by independent transcribers who are contracted to the University of South Australia. The professional transcription service entered into confidentiality and data security agreements with the university. We will ensure

transcriptions are deidentified to ensure anonymity. For data security, consent forms and paper copies of assessment tools that have any identifying information on them such as name, address or phone number of participants will all be stored in locked filing cabinets at the Department of Rural Health, Whyalla campus of the University of South Australia. All electronic data will be stored on password-protected computers and servers at the university. Only the relevant members of the research team will have access to these files. As per the National Health and Medical Research Council guidelines for clinical trials, data will be retained for 15 years and then securely destroyed. Data will be managed following the National Statement on Ethical Conduct in Human Research[37] and the University of South Australia Research Data Management Procedures.

Data analysis

Qualitative data analysis

We will use thematic analysis to help us draw meaning from the interviews.[38] The planned data analysis will encompass a thematic examination of the interview transcripts. Participants will be invited to review their transcripts for accuracy before data analysis. This will be followed by the identification and description of themes and subthemes. We will revise the themes and subthemes with an independent researcher to validate them. We will later invite the participants to check and validate the identified themes. NVivo Pro software V.12 or Qualtrics will be employed to facilitate coding.[39 40]

Quantitative data analysis

We will describe the demographic characteristics of the mental health workers and consumers using Microsoft Excel software[41] or the SPSS Statistics software V.29.[42] The descriptive data will be presented and reported using mean, SD, median, and range or counts and percentages.

All data collected by the outcome measures will be entered and analysed descriptively. Our primary analysis is intended to determine whether conducting a subsequent fully powered randomised controlled trial is feasible. Therefore, the analyses will be descriptive by exploring all feasibility outcomes and will include measures of uncertainty, such as 95% CIs. As feasibility trials are not designed to establish efficacy, we will estimate the variance of outcome measures and calculate the effect size differences (with 95% CIs) on outcome measures from baseline to both follow-up points (on an intention-to-treat basis) in both groups. Where appropriate, the generalised estimating equation (GEE) will be employed to analyse the preliminary effects of behavioural activation across the two time points (baseline and 6 weeks). The GEE analysis will account for intracorrelated repeated outcome data and accommodate data missing at random.

Patient and public involvement

An advisory committee will be established to develop, refine and review the study recruitment materials. Two consumers at each of the three sites will be invited to be part of the clinical trial advisory group. They will provide advice and guidance on the suitability of behavioural activation and help us understand the interview data. In addition, the two consumer representatives will have an active role in the dissemination of the research findings. The advisory group members will be reimbursed for their time.

Ethics and dissemination

The implementation of the telehealth trial has been authorised by the Human Research Ethics Committee at the Central Adelaide Local Health Network (Ref. 2023HRE00120). The authors give assurance that telehealth trial will be conducted in full conformance with the principles of the 'Declaration of Helsinki', as revised,[43] the Good Clinical Practice (GCP) guidelines,[44] and the National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia.[45] This study is registered with the Australia and New Zealand Clinical Trials Registry (registration number ACTRN12623000348651p). We will report the findings of the teletrial at public seminars, conferences and in peer-reviewed journals.

Informed consent

Consumers will be informed that participation in the telehealth trial will be entirely voluntary and that they may withdraw from the study at any point without any repercussions. Some consumers may lack the capacity to give informed consent. In such a case, the consumers will be advised to find a person of their choice to decide on their behalf. Before any data are collected, written informed consent will be obtained from all consumers or their legal guardians. Consumers will also be informed that the study will not involve potential harm beyond what they usually experience because of their psychological condition. There will be no payment for participation in this study except as reimbursement of proven expenses.

Adverse event reporting and harms

We anticipate that there will be no adverse events caused by participation in the study. As we reported, research evaluating the impact of behavioural activation on negative symptoms has only been conducted twice and these two studies had several methodological concerns. Thus, safety considerations are formulated based on studies conducting similar interventions and/or those using psychosocial interventions with people who experience problems with their mood. A randomised controlled trial investigating the cost-effectiveness of behavioural activation compared with CBT for adults with depression reported that depression-related, but not treatment-related, serious adverse events occurred in three participants in the behavioural activation group and eight participants in the CBT group.[22]

To mitigate the risk of adverse effects, we will put in place several procedures. We will ensure that mental

health workers engage the consumers at each assessment or the start of each behavioural activation session to check how they are feeling and if they experienced any unexpected effects of the intervention.

Mental health workers may find it psychologically distressing to work with consumers with negative symptoms. Opportunities will be provided for the mental health workers to debrief with the behavioural activation experts via the telehealth supervision and support structure. In addition, all the mental health workers will be invited to attend monthly supervision sessions with the behavioural activation experts.

We will report all adverse events to the telehealth trial steering committee. If the telehealth trial steering committee considers that adverse events are a result of the intervention, we will suspend the trial. Adverse events will be analysed and where related to delivery mechanisms, will inform modifications to future trials. In addition, this study is subject to periodic audits by the Central Adelaide Local Health Network Human Research Ethics Committee.

Tele health trial steering group

This study represents a collaborative arrangement between the University of South Australia and three rural mental health services in South Australia. We will establish a telehealth trial steering group (TSG) that reflects this collaboration and comprises the research team and independent members. The TSG will oversee the telehealth trial processes and review outcome data and assess any adverse events or complaints relating to the trial. The TSG will meet at least twice per year for the duration of the telehealth trial.

Insurance and indemnity

Appropriate insurance and indemnity documentation covering the telehealth trial will be provided by the university.

Availability of datasets

The datasets used and/or analysed at the end of the telehealth trial will be made available to the public on reasonable request being made to the corresponding author, KM, SW or the chief investigator, MJ.

Anticipated timeline

It is anticipated that the online behavioural activation training programme will commence in February 2024 and finish 12 weeks later in May 2024. Recruitment to the trial will occur from June 2024 to July 2025 to be followed immediately afterward by the collection of baseline data. Follow-up will occur at 6 weeks and again at 3 months postintervention. The trial, including dissemination, is anticipated to conclude December 2026.

DISCUSSION

Negative symptoms in schizophrenia can be difficult and can impact prognosis. Our proposed study builds on the work conducted by Choi *et al*[28] and Mairs *et al*.[27] If feasible, our study could enable a larger randomised controlled trial to examine the effectiveness of behavioural activation in reducing negative symptoms. The studies by Choi *et al* and Mairs *et al* used a face-to-face training programme, however, areas of geographical remoteness can be difficult to reach with these kinds of training programmes. Using a fully online training programme to prepare workers to practise BA will help overcome this potential barrier. Adopting electronic group supervision will provide additional support for the workers applying behavioural activation.

In this protocol, the trial sites are located in rural and remote Australia; where access to specialist mental health workers and treatments, such as CBT, are challenging. Behavioural activation is relatively easy and inexpensive to implement. As an intervention, this may be of benefit for communities that do not have access to clinical psychologists, such as rural Australia.[25 46] Further, there could be opportunities for scaling up behavioural activation across rural sites in Australia and overseas in areas where accessing specialised mental health workers is challenging for people living with negative symptoms of schizophrenia.

Relevance of study

The major value of this study is its potential contribution to clinical practice in the treatment of negative symptoms in adults with schizophrenia. The study will demonstrate the potential of telehealth in supporting the conduct of clinical trials in rural, regional and remote areas. Furthermore, the study will create opportunities for geographically disparate communities to participate in clinical trials, an achievement that hitherto has skipped many rural populations.

CONCLUSION

Our feasibility study will help us to understand what we need to conduct a fully powered randomised controlled trial. Potentially, the findings will also enable us to understand if people with schizophrenia who have negative symptoms derive benefits from using behavioural activation.

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Contributors MJ, PD, RJG, SW and SD conceived the original idea and designed the study. KM prepared the manuscript with support from MJ and SW. MJ, RJG,

PD, DB, KLT, SW, SD, AM and KM reviewed and approved the final version of the manuscript. MJ provided supervision and oversight including the decision to publish.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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Consent Form- Clinical trial-Staff

This project has been endorsed to proceed as a research project by the Central Adelaide Local Health Network Human Research Ethics Committee. If you have any ethical concerns about the project or questions about your rights as a participant, please contact the CALHN Research Services, Telephone: (08) 7117 2224; Email: Health.CALHNResearchLNR@sa.gov.au

SECTION 1: CONTACT AND PROJECT DETAILS	
Researcher's Full Name	Associate Professor Martin Jones, University of South Australia Department of Rural Health
Contact Details	Email: martin.jones@unisa.edu.au.; Mobile Phone contact details: +61 8 8647 6011
Supervisor's Name *(students only)*	
Contact Details	
Project Number	2023/HRE00120
Project Title	Co-delivery of teletrial Behavioural Activation in people with negative symptoms of Schizophrenia: a Feasibility Randomised Controlled Trial
Short title	Tele trial Behavioural Activation for People with negative symptoms
Project sponsor	University of South Australia
Location	Rural South Australia

SECTION 2: PARTICIPANT CERTIFICATION

In signing this form, I confirm that:

1. I confirm that I am over 18 years of age.
2. I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
3. I have had an opportunity to ask questions and I am satisfied with the answers I have received.
4. The nature, purpose, and risks of the research project have been explained to me. Details of procedures and any risks have been explained to my satisfaction. I understand them and agree to take part.
5. I do not intend to leave my role as mental health worker within the next 12 months.
6. I understand that I am being invited to deliver behavioural activation sessions to people with negative symptoms of schizophrenia assigned to the experimental group.
7. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my status with my employer or the University of South Australia, now or in the future.
8. I understand that signing below constitutes my voluntary informed consent to participate in the research project.
9. I understand that I will be given a signed copy of this document to keep.
10. I understand that should I choose to withdraw from the study, I have until two weeks after completing the consent form to request that my data be removed from the project.
11. I understand that the de-identified information that is accessed as part of the project will be stored separately from any identifying information on secure and access-restricted computer servers of the University of South Australia for 15 years; after which time it will be destroyed.
12. I understand that while the information gained during the project may be published, I will not be identified and my results will remain confidential in accordance with relevant Australian and/or South Australian privacy and other relevant laws unless required by law.

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13.	I understand that participation in the research may be potentially emotionally and psychologically distressing and cause discomfort. However, it is not anticipated that there are risks to participation in this study beyond those encountered in everyday life. I understand that I will have opportunities to debrief with peers, my line supervisor, and the researchers if required.
14.	Although I understand that the purpose of this research project is to improve access to support for people with negative symptoms of schizophrenia, it has also been explained that my involvement may not be of any benefit to me.
15.	If I want to know the findings of the research study, I can do so by contacting any of the researchers.

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

SECTION 3: RESEARCHER CERTIFICATION		
I have given a verbal explanation of the research project, its procedures and risks, and the implications of withdrawal from the research project and I believe that the participant has understood that explanation.		
Researchers name (please print)	Researcher Signature	*Date*

Muyambi K, *et al. BMJ Open* 2024; 14:e080245. doi: 10.1136/bmjopen-2023-080245

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Consent Form- Clinical trial_Patients

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Researcher's Full Name	Associate Professor Martin Jones
Contact Details	Email: martin.jones@unisa.edu.au.; Mobile Phone contact details: +61 8 8647 6011
Supervisor's Name *(students only)*	
Contact Details	
Project Number	2023/HRE00120
Project Title	Co-delivery of teletrial Behavioural Activation in people with negative symptoms of Schizophrenia: a Feasibility Randomised Controlled Trial
Short title	Tele trial Behavioural Activation for People with negative symptoms
Project sponsor	University of South Australia
Location	Rural South Australia

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2. I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
3. I have had an opportunity to ask questions and I am satisfied with the answers I have received.
4. The nature, purpose, and risks of the research project have been explained to me. Details of procedures and any risks have been explained to my satisfaction. I understand them and agree to take part.
5. I understand that I may be allocated to an experimental or control group.
6. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my status with my mental health worker, the local health network, or the University of South Australia, now or in the future.
7. I understand that I may not directly benefit from taking part in the project.
8. I understand that I will be given a signed copy of this document to keep.
9. I understand that should I choose to withdraw from the study, I have to contact the research tele trial nurse.
10. I understand that should I choose to withdraw from the study, I have until two weeks after completing the consent form to request that my data be removed from the project.
11. I understand that the de-identified information that is accessed as part of the project will be stored separately from any identifying information on secure and access-restricted computer servers of the University of South Australia for 15 years; after which time it will be destroyed.
12. I understand that while the information gained during the project may be published, I will not be identified and my results will remain confidential in accordance with relevant Australian and/or South Australian privacy and other relevant laws,unless required by law.

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Consent Form- Clinical trial_Patients

13.	I understand that participation in the research may be potentially emotionally and psychologically distressing and cause discomfort. However, it is not anticipated that there are risks to participation in this study beyond those encountered in everyday life. I understand that I will have opportunities to debrief with peers, my family members, mental health worker, another local health worker, or my general practitioner if required.
14.	Although I understand that the purpose of this research project is to improve access to support for people with negative symptoms of schizophrenia, it has also been explained that my involvement may not be of any benefit to me.
15.	If I want to know the findings of the research study, I can do so by contacting any of the researchers.

Name of Participant	(please print)	*Date*
Participant's Signature		
Name of Witness to participant's signature	(please print)	
Witness signature		Date

SECTION 3: RESEARCHER CERTIFICATION

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

Researcher's name (please print)	Researcher's signature	*Date*

University of South Australia | Department of Rural Health

Supplementary file 3

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates. This statement has been developed to protect the interests of people who agree to participate in human research studies. The project has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee. If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact CALHN Research Services, Telephone: (08) 7117 2224; Email: Health.CALHNResearchLNR@sa.gov.au	
Research Team	Associate Professor Martin Jones, Dr. Pascale Dettwiller, Dr. Kuan Tan, Professor Richard Gray, Professor Dan Bressington, Shaun Dennis, Audrey McCall, Sandra Walsh, Kuda Muyambi
Protocol Number	2023/HRE00120
Project Title	Co-delivery of teletrial Behavioural Activation in people with negative symptoms of Schizophrenia: a Feasibility Randomised Controlled Trial
Chief Investigator	Assoc Professor Martin Jones University of South Australia Department of Rural Health

Interview topic guide- Staff

Quality of supervision

We would like to invite your feedback about the supervision provided by the behavioural activation experts.

1. Can you tell me how many supervision sessions you had with the experts in behavioural activation?
2. Tell me about the behavioural activation supervision sessions with the BA experts you found most helpful.
3. What did you particularly like about these supervision sessions with the behavioural activation experts?
4. Can you tell me about the behavioural activation supervision sessions with the experts you found least helpful?
5. How could the supervision sessions be improved?
6. What else could the BA experts do to improve the supervision?

Experience implementing behavioural activation

1. Can you tell me how many people with negative symptoms of schizophrenia you have delivered behavioural activation to? (b) On average, how many sessions of behavioural activation have you delivered for each of the people with negative symptoms of schizophrenia? (c) What was the approximate length of each session of behavioural activation you delivered?

2. How did the online training in Behavioural Activation for Depression support you in your work? Can you give some practical examples/ de-identified cases?
3. What challenges did you experience using behavioural activation with people experiencing with negative symptoms of schizophrenia?
4. What worked well with the people experiencing with negative symptoms of schizophrenia?
5. What did not work well?
6. What were the barriers to you using behavioural activation with people experiencing with negative symptoms of schizophrenia?
7. What aspects of the Behavioural Activation training are most relevant in your work?
    a. Providing information about depression
    b. Structuring your session
    c. Behavioural Activation Assessment
    d. Mood monitoring
    e. Activity scheduling
8. What did you find most helpful about these things?
9. What support would you require in your workplace to support your use of behavioural activation for negative symptoms of schizophrenia?

Demographic details
Now, let us talk about you.

1) What is your age?
2) What is your sex?
3) What is the level of the highest educational qualification that you have completed?
4) Have you completed any other educational qualifications? If so, what was the main field of study for that qualification?
5) With which organisation/agency are you currently employed?
6) What is your current position in this organisation?
7) How long have you worked in this organisation?

P/S A summary of the research study findings will be available to all participants upon request. Should you wish to receive a summary of the study findings, please contact the chief investigator via the contact details provided.

Muyambi K, *et al. BMJ Open* 2024; 14:e080245. doi: 10.1136/bmjopen-2023-080245

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Supplementary file 4

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Chief Investigator	Assoc Professor Martin Jones University of South Australia Department of Rural Health

Interview topic guide- Patients

Experience receiving behavioural activation

1. Can you tell me about the behavioural activation sessions provided to you by your mental health worker? Can you recall approximately how many sessions of behavioural activation were provided to you by your mental health worker? (b) What was the average length of the behavioural activation sessions you received?
2. How did the behavioural activation assist you? Can you give me some examples of any changes you experienced because of the behavioural activation delivered by your mental health worker?
3. Did you find anything challenging about the behavioural activation delivered to you by your mental health worker? If so, can you describe the experience for me?
4. What did you find most helpful about the behavioural activation delivered by your mental health worker?
5. What did you find least helpful about the behavioural activation provided by your mental health worker?
6. What have been the changes to your life because you participated in the research project?
7. What would you say to a family member or friend wanting to join the research project?
8. What were the barriers to you applying the behavioural activation techniques?
9. What needs to be done differently to improve your experience of behavioural activation?
10. What additional support do you need from your mental health worker to maintain the changes you have made?

11. Is there anything we have not talked about that you want to share with me?

Demographic details
Now, let us talk about you.

1) What is your age?
2) What is your sex? (Male, Female, Prefer not to say)
3) What is your status (Married, not married, prefer not to say)
4) What is the level of the highest educational qualification that you have completed?
5) What is the name of the town in which you received behavioural activation?

P/S A summary of the research study findings will be available to all participants upon request. Should you wish to receive a summary of the study findings, please contact the chief investigator via the contact details provided.

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Consent Form- Interviews- Staff/Patients

Supplementary file 5

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2. I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.
3. I have had an opportunity to ask questions and I am satisfied with the answers I have received.
4. The nature, purpose and risks of the research project have been explained to me. Details of procedures and any risks have been explained to my satisfaction. I understand them and agree to take part.
5. I understand that I may be asked to participate in an interview to share my opinion about the support that I received from the mental health worker, what I most liked, what I did not like and suggestions for improvement.
6. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my status with my local health network or the University of South Australia, now or in the future.
7. I understand that I may not directly benefit from taking part in the project.
8. I understand that I will be given a signed copy of this document to keep.
9. I understand that should I choose to withdraw from the study, I have to contact the research tele trial nurse.
10. I understand that should I choose to withdraw from the study, I have until two weeks after completing the consent form to request that my data be removed from the project.
11. I understand that the de-identified information that is accessed as part of the project will be stored separately from any identifying information on secure and access-restricted computer

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Consent Form- Interviews- Staff/Patients

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12. I understand that while the information gained during the project may be published, I will not be identified and my results will remain confidential in accordance with relevant Australian and/or South Australian privacy and other relevant laws, unless required by law.
13. I understand that participation in the research may be potentially emotionally and psychologically distressing and cause discomfort. However, it is not anticipated that there are risks to participation in this study beyond those encountered in everyday life. I understand that I will have opportunities to debrief with peers, my family members, mental health worker, other local health worker or my general practitioner, if required.
14. Although I understand that the purpose of this research project is to improve access to support for people with negative symptoms of schizophrenia, it has also been explained that my involvement may not be of any benefit to me.
15. If I want to know the findings of the research study, I can do so by contacting any of the researchers.

Name of Participant	(Please print)	*Date*
Participant's Signature		
Name of Witness to participant	(Please print)	
Witness signature		Date

SECTION 3: RESEARCHER CERTIFICATION		
I have given a verbal explanation of the research project, its procedures and risks, and the implications of withdrawal from the research project and I believe that the participant has understood that explanation.		
Researcher's name (please print)	Researcher's signature	*Date*

University of South Australia

Consent Form- Interviews- Staff/Patients