Ethics Application

Application ID :	206384
Application Title :	Hearing Distressing Voices Simulation Workshop for regional (and rural) health and mental health workers: a feasibility Clinical Trial/Teletrial
Date of Submission :	13/08/2024
Primary Investigator :	Dr Pascale Dettwiller (Chief Investigator)
Other Personnel :	Ms Lee Martinez (Chief Investigator) Dr Chloe Fletcher (Chief Investigator) Dr Lee Puah (Other Investigator) Mr Michael Marsh (Other Investigator) Ms Carol-Ann Stanborough (Other Investigator) Mr Arana Pearson (Other Investigator)

Create New Ethics Application

Create New Ethics Application

The following provides brief information on how to complete an online ethics application. For more detailed information, please refer to the User Guides available at the UniSA website. Please note that there is also a User Guide for the Principal Supervisor to assist supervisors with the review of student applications. The User Guides also detail the process to follow should you be required to respond to reviewer's comments.

The System allows researchers to complete and submit human ethics applications electronically.

- Applicants navigate their way through the application by answering a number of questions.
- Sections, pages and/or questions appear based on the answers to previous questions, therefore it is advisable that you complete questions sequentially in order to avoid skipping questions unintentionally.
- If you receive an error message, click Save on the Toolbar after you have corrected the error to refresh the page and to confirm that the error has been cleared.
- At times, word limits may prevent you from providing all the information you need to include. If this is the case, please include the necessary information as either a separate document and add it as an attachment to the Attachments page, or as a page comment.
- Each section of the online form can be saved by clicking Save on the Toolbar. Each page is also saved automatically when you click the 'Previous Page/Next Page' buttons at the bottom of each page.

Refer to the User Guides if you are unsure how to use these functions.

ANSWERING QUESTIONS
It is important to take time to answer each question carefully and fully before progressing to the next question. By doing so, you will minimise the request for more details from the reviewers and/or prevent potential system errors. Please ensure you enter requested information in each page available in the Sections/Pages menu. Submitted applications that do not contain the required information will be returned to you and therefore the review process will be delayed.

Please note that the system will time out after 40 minutes of inactivity and any unsaved answers will be lost.

The research activity must not commence until ethics approval is finalised.*

☑ I agree

Investigator

Investigator

1 Is primary applicant a student? Please select 'Yes' if you are a student; if you are a staff member answer 'No'*

○ Yes
◉ No

2 **Please add investigators to the table below.**

- **Click the Add button and then use the Name/ID search function to search for and add other investigators.**
- **Please ensure that you mark the Primary Contact (usually the Chief Investigator) for this protocol by selecting 'Yes' on the person's record at Primary?**
- **For each investigator, select their position/role from the dropdown list.**
- **To save your changes for each investigator, click OK on the personnel record.**

Note for student applicants. DO NOT add your Principal Supervisor to this Investigator page, you will need to add them to the Supervisor page only. *

1	Given Name	Pascale
	Surname	Dettwiller
	Full Name	Dr Pascale Dettwiller
	Position	Chief Investigator
	ID	147656
	Primary?	Yes
	AOU	UniSA Allied Health and Human Performance
	Organisation	
	Organisation Name	
2	Given Name	Lee
	Surname	Martinez
	Full Name	Ms Lee Martinez
	Position	Chief Investigator
	ID	107024
	Primary?	No
	AOU	UniSA Allied Health and Human Performance
	Organisation	
	Organisation Name	

3	Given Name	Chloe
	Surname	Fletcher
	Full Name	Dr Chloe Fletcher
	Position	Chief Investigator
	ID	145076
	Primary?	No
	AOU	UniSA Allied Health and Human Performance
	Organisation	
	Organisation Name	
4	Given Name	Lee
	Surname	Puah
	Full Name	Dr Lee Puah
	Position	Other Investigator
	ID	116348
	Primary?	No
	AOU	UniSA Allied Health and Human Performance
	Organisation	
	Organisation Name	
5	Given Name	Michael
	Surname	Marsh
	Full Name	Mr Michael Marsh
	Position	Other Investigator
	ID	MARCHMI
	Primary?	No
	AOU	
	Organisation	FUNLHN
	Organisation Name	Lived experience, Mental Health Peer Worker, Flinders and Upper North Local Health Network
6	Given Name	Carol-Ann
	Surname	Stanborough
	Full Name	Ms Carol-Ann Stanborough
	Position	Other Investigator
	ID	STANBOC
	Primary?	No
	AOU	
	Organisation	0032
	Organisation Name	Flinders University Rural and Remote Health SA
7	Given Name	Arana
	Surname	Pearson
	Full Name	Mr Arana Pearson
	Position	Other Investigator
	ID	PEARSONAR
	Primary?	No
	AOU	
	Organisation	KEEPWEL
	Organisation Name	KEEPWELL (Aust) PTY LTD

2.1 Please provide your contact phone number if you agree to it being used by Ethics Administrators to follow up any points requiring clarification.

0433308284

Prior Assessment

Project Core Details

Primary AOU*

UniSA Allied Health and Human Performance

Ethics category code*

Human Ethics

Application Title*

Hearing Distressing Voices Simulation Workshop for regional (and rural) health and mental health workers: a feasibility Clinical Trial/Teletrial

Non-UniSA HREC

UniSA HREC seeks to avoid the unnecessary duplication of ethical review. If your ethics application has already been approved by another Australian Human Research Ethics Committee, you should attach a copy of the full application submitted to the other HREC and the approval letter. The remainder of this application form will then be automatically shortened. UniSA HREC will review these documents, and if satisfied, will ratify the decision of the other committee.

1.1 Has another Australian, NHMRC-registered Human Research Ethics Committee (other than UniSA) reviewed this research project before and does this clearance/approval accurately describe the project as it is to be conducted? *

- ○ Yes
- ◉ No

UniSA HREC

2.1 Is this application a resubmission of an application that was considered by UniSA HREC and the decision was 'Not Approved: Resubmit', 'Not Approved' or 'Approved subject to' and the status has expired (i.e. amendments were not made within the 6 month timeframe). Please note if your application is 'Approved subject to' and 6 months *has not* lapsed then you should use the original application submitted to make the required changes. *

- ○ Yes: Not approved: resubmit
- ○ Yes: Not Approved
- ○ Yes: Approved subject to and the status has expired
- ◉ No

Project Scope

Project Scope

It is important that upon completing the questions on this page you click Save on the Toolbar to ensure the page has a green tick in the Sections/Pages menu before moving to the next page.

11.1 Is the activity archival research? A large proportion of activity involving the analysis of documents, publicly available information, or previously collected data may be outside the scope of the University's human research ethics arrangements. *

- ○ Yes
- ◉ No

11.2 Is the work being conducted only for UniSA administrative / service delivery purposes? *

- ○ Yes
- ◉ No

12.1 Should the work be characterised as quality assurance or an audit, rather than human research within the scope of the University's human research ethics arrangements? *

- ○ Yes
- ◉ No

12.2 Is the work a practical exercise or test conducted for teaching purposes in a University administered facility? (Guidelines for Evaluation Activities Involving UniSA Students and Staff). *

- ○ Yes
- ◉ No

13.1 Is the work a routine experiment or procedure conducted for teaching purposes in a University administered facility? *

- ○ Yes
- ◉ No

13.2 Is the work / data collection conducted by a student only for teaching / learning purposes? *

- ○ Yes
- ◉ No

Initial Check

The purpose of this 'Initial Check' is to direct your ethics protocol to the appropriate level of review. After completing the Project Scope page, where it is relevant, the Exempt (Criteria 1) or Exempt (Criteria 2) page is revealed in the Section/Pages menu between the Project Scope page and the Initial Check page.

If you *were* notified that your protocol was assessed as Exempt (Criteria 1) or Exempt (Criteria 2), please select **Finish** and click on the Next Page button at the bottom of the page.

If you *were not* notified that your protocol was assessed as being either Exempt (Criteria 1) or Exempt (Criteria 2), please select **Continue** and click on the Next Page button at the bottom of the page.

*

- (●) Continue
- ( ) Finish

Project Details

Ethics Training

3.1 Have you had human ethics training in the last 24 months? (Please do not include training you have attended regarding how to use the online ethics system)*

- (●) Yes
- ( ) No

3.2 Who provided the human ethics training?*

UNISA Research - Ethics training for all UNISA employees (academic and professional) engaging in research.
Pascale has completed research integrity training (UNISA 2023 online). Both Chloe and Pascale hold PhD and have supervised students at various research levels and contributed to research projects at IIMPACT and DRH.
Carol-Ann completed Flinders University research and ethics training in 2023 as part of her new academic employment with the Flinders Department of Rural Health.
Michael Marsh is involved in many research projects as a consumer and lived experience contributor and has received research training. (HREC #204496, 2022)
Arana is a lived experience researcher who works with mental health research in New Zealand and has previously worked with Lee Martinez on Hearing Distressing Voices workshop training. (ID#204496, 2022).
Lee Martinez is involved in mental health projects with the national Suicide Prevention network and collaborate with the CSAPHN in MH program evaluations. Lee undertook ethics training by UNISA.
Lee Puah holds a PhD and does data analysis for the DRH for many projects.
All involved researchers have completed a GCP training via A-CTEC (research training platform offered by ATP-SA Health for free).

3.3 Where was the training held?*

UNiSA and SAHMRI

Project Type

4.1 Main type of research (e.g. staff, PhD). *

Staff

4.2 **Are there any other types of research involved (not identified in 4.1). *Please select all that apply.*** *

- [x] None
- [ ] Honours
- [ ] Course Approval
- [ ] PhD
- [ ] Masters by Coursework
- [ ] Masters by Research
- [ ] Professional Doctorate
- [ ] Undergraduate
- [ ] Graduate Diploma/Graduate Certificate
- [ ] Staff
- [ ] Other

4.3 Please list which school(s) the UniSA researcher(s) is/are from?*

ALH and human performance, IIMPACT

Project Details

5.1 Plain English title*

'Hearing Voices that are Distressing' (HVD) simulation workshop will be delivered to regional (and rural) health and mental health workers practising in the health sector using a clinical trial (CT) leveraging from the regional Teletrial cluster model (National Australian Teletrial Program - ATP-SA) to build a higher level of evidence for lived experience (LE) added-value in simulation methods used for education and training for workers (and students).

5.2 What are the aims of your research?*

The aims of this project are to conduct a pragmatic clinical trial (PCT) approach of the 'Hearing Voices that are Distressing' (HVD) simulation workshops (previously delivered in 2018 and 2023) to determine the impact of having a co-facilitator with lived experience of voice-hearing on participants' levels of empathy and to explore whether this translates to a self-reported change in practice for health and mental health related settings staff, and undergraduate health sciences students who participate in the workshops in regional (and rural) South Australia. The PCT methodology will enable us to evidence the value of lived experience in simulation training in the mental health context. This research proposal is a stage two of an evaluation of the workshop undertaken in 2022 (ID# 204496).(NHI, https://rethinkingclinicaltrials.org/chapters/design/experimental-designs-and-randomization-schemes/experimental-designs-introduction/). (ATTACH #1 Pending to be attached email/letter of support from the Mental Health Commissioner for South Australia -Taimi Allen)

5.3 List your research questions or hypotheses. Your protocol should clearly identify the questions which you want your research to answer. *

The clinical trial/Teletrial will help the research team to answer the following questions:
1. Does having a person with lived experience of voice-hearing co-facilitating the HVD simulation workshops lead to a greater increase in empathy in participants?
2. Does having a person with lived experience of voice-hearing co-facilitating the HVD simulation workshops influence whether cognitive learnings are translated to changes in practice following participation?

Our hypotheses are:
1. Having a person with lived experience of voice-hearing co-facilitate the workshop will lead to an increase in empathy in participants, consistent with the findings of our previous studies (Protocol Approval ID #204496 in 2022 for project run in 2023; Protocol Approval ID #34712 in 2017, for project run in 2018).
2. Having a person with lived experience of voice-hearing co-facilitate the workshop will help to integrate participants' cognitive learnings and will lead to changes in practice when working with voice-hearers (as qualitative findings of Protocol ID #204496 indicated may be the case).

5.4 Explain the need for, and value of, your research. Place the aims in the context of existing research or practice AND what your study does to add to existing literature. (You must include a list of not more than 10 key references as an attachment to support your answer to this question. These are to be attached to the Attachments section of this application).*

Evidence suggests that health care professionals are often uncomfortable talking with people about hearing voices (Coffey & Hewitt, 2008; White et al., 2018), despite recommendations that voice-hearers be provided with opportunities to freely discuss their experiences. Voice-hearers themselves express a desire to discuss their experiences, but they also report concerns about how others might respond, fearing that they will be misunderstood, judged, or rejected (Watkins et al., 2020; Sheaves et al., 2020). Research has indicated that healthcare students and professionals report significant increases in their levels of empathy after participating in a voice-hearing simulation (e.g., Baisden & Gray, 2020; Chaffin & Adams, 2013). Specifically, they describe having a deeper understanding of voice-hearers' experiences and more knowledge about how to engage with voice-hearing consumers (Chaffin & Adams, 2013; Orr et al., 2013; Outlaw & Rushing, 2018), following their participation.

Our previous work (Protocol ID #34712 and Protocol ID #204496) produced similar findings among regional (and rural) health and mental health workers. However, the simulation is only one aspect of the HVD workshops that we have been running in regional and remote South Australia. Our HVD workshops are divided into four parts: 1) a video introduction from Arana Pearson (Keepwell (Aust) Pty Ltd) sharing his own story of voice-hearing, 2) a 45-minute theoretical lecture on current research and techniques that can be used to give voice-hearers power over their voices, and 3) a 35-45-minute simulation experience, and 4) a 30-minute debrief session with guided reflection. The workshops are co-facilitated by rural mental health academics and clinicians and a LE person of hearing distressing voices. The present study aims to determine the unique contribution of having a LE person co-facilitate the workshop and whether this leads to greater increases in empathy and self-reported changes in practice.

5.5 Please describe your research design and methodology (e.g. where will the data collection occur, what will participants be asked to do during the course of data collection, how long will the interview/focus groups/filling out the questionnaire take, etc).*

The half-day workshops are based on the Keepwell (Aust) Pty Ltd (2012) authorised adaptation of Dr Patricia Deegan's program). Although the flyer invitation is for 2 iterations of the workshop at the same location, the participants will only attend one half day session.

Participants will be invited to join a clinical trial/Teletrial to determine the unique contribution of having a LE person co-facilitate the workshop. Each workshop will include the same content, however workshops delivered to the intervention group will be co-facilitated by a person with lived experience , who will share their story and respond to participant questions. In consultation with the consumer representative, it was deemed that locations will be randomised (not individuals) for consistency of delivery. The workshop activities will be varies and complementing; A) Introductions / History Hearing Distressing Voices (HDV);B) Theory of HDV; C) HDV Simulation Exercise ; D) Group reflection and debrief (this section will be audio recorded as part of the study.

Mixed methods will be used to measure changes in empathy (pre-/post-workshop participation) and changes in practice (at one month and 3 months follow-ups via Telehealth). Participants will complete an adapted version of the Kiersma-Chen Empathy Scale (KCES) at two time points (pre-/post-workshop). Questionnaires (paper copy format and electronic format -ttps://forms.office.com/Pages) will be completed while participants are attending the workshop and should no require more than 10-15 minutes. Participants will be invited to a complete a survey immediately after the activities and via Telehealth as a personalised check-in at one month and 3 months follow-ups which will not take more than 15 minutes all up.

Resources

Project Funding

6.1 Have you applied for funding for this project from any external source?*

- (●) Yes and application for the funds has been successful
- ( ) Yes but the outcome of the application is not yet known
- ( ) No

6.2 Please select the relevant project. If your project is not listed in the options provided, you may need to list all investigators involved on the project first as the funded project may be listed under their name.

This question is not answered.

6.3 Does your project appear in the list provided above? *

- ( ) Yes
- (●) No

6.3.1 What is the name of the fund source?*

Australian Teletrial Program South Australia - Clinical trial Coordinating Centre

6.3.2 What is the title of the funded project?*

HDV Simulation Workshop for regional health and mental health workers: a feasibility Teletrial study

6.3.3 How much funding have/will you receive? *

The University of South Australia Department of Rural Health, Whyalla, primary site (where the principal investigator is located) will receive $10,000.00 from the SA Australian Teletrial Clinical Coordinating Centre.
Each Teletrial cluster site (satellite site) (i.e., Port Pirie, Port Lincoln, Port Augusta, Victor Harbor, Berri and Mount Gambier DRH) will receive $700.00 per participant enrolled in attending the workshops.

6.4 Does the funding/support provider(s) have a financial interest in the outcome of the research?*

- ○ Yes
- ◉ No

6.5 Will the project be supported in ways other than direct funding (eg in-kind support/equipment by an external party)? *

- ◉ Yes
- ○ No

6.5.1 Describe the support and indicate the provider.*

Department of Rural Health at UNISA and Flinders University staff, with co-facilitators, will deliver the workshop (the same team as in 2023) and drive the research as part of their academic positions.
Arana Pearson Keepwell (Aust) Pty Ltd is lending material utilised in the previous project evaluation (2018 and 2023; service agreement between DRH and Arana Pearson was signed in 2017 and is on-going) and will assist in data analysis which will assist in the triangulation of the qualitative data analysis.
Michael Marsh from Flinders and Far North Local Health Network, Lived Experience facilitator and material developer.
The whole team has contributed and developed contextualised materials previously (from 2018-2023) that will be reused for this study.
The operational staff of the ATP-SA will assist in the management of the Teletrial administrative tasks or running a clinical trial (e.g. collecting consent form; survey distribution etc).

Project Funding cont.

7.1 Does any member of the research team have any affiliation with the provider(s) of funding/support, or a financial interest in the outcome of the research?*

- ○ Yes
- ◉ No

7.2 Does any other individual or organisation have a vested interest in the outcome of this research?*

- ○ Yes
- ◉ No

7.3 Are there any restrictions on the publication of results from this research?*

- ○ Yes
- ◉ No

Ownership of Data

8.1 **Detail who will own the data and the results of your research (student researchers normally own their own research and data unless there is a written agreement between the student and the University / third party; staff research and data is normally owned by UniSA). *Please select all that apply.****

- ☑ UniSA
- ☐ Student researcher
- ☐ Other

8.2 Does the owner of the information or any other party have any right to impose limitations or conditions on the publication of the results of this project?*

- ○ Yes
- ◉ No

Please note that it is the researcher's responsibility to ensure that, where required, an appropriate agreement is in place. If you are unsure whether this is needed, please consult the Intellectual Property website and then contact the Research Contracts team via the Research Contract/Advice Request Online Form.

Please note that a signed agreement will usually be required where:

- A research team includes both students and staff; or
- Where researchers from different institutions are collaborating on a project.

8.3 Do you require an agreement regarding ownership or do you currently have an agreement in place?*

- ○ An agreement is required
- ○ A signed agreement is in place
- ◉ An agreement is not required

Data: storage, access, disposal

9.1 **The information which will be stored at the completion of this project is of the following type(s). *Please select all that apply.*** *

- [x] Individually identifiable
- [ ] Re-identifiable
- [x] Non-identifiable

9.1.1 Give reasons why it is necessary to store information in identifiable or potentially identifiable form (coded).*

All surveys and transcripts will be non-identifiable, however voices of participants may be temporarily individually identifiable via audio recordings saved on a portable voice recorder and on the university server prior to transcription.

9.2 Where will the data be stored? University policy requires researchers to store a copy of the data onsite at UniSA, usually in the relevant School Office (please specify the campus and office/room location e.g. Mawson Lakes Campus, RM GP2-19). Please refer to the University's Ownership and Retention of Data Policy.*

An anonymous identifier (created with date of birth and mother's maiden name) will facilitate matching of surveys pre-/post-workshop for the purpose of data analysis. Non-identifiable survey data will be stored electronically on the secure university network. Data from paper-based surveys will be transferred to electronic files, with paper copies destroyed. Data collected via Microsoft (https://forms.office.com/Pages) UNISA licencing will be stored on the UNISA secured server and exported and stored electronically.

Audio-recordings (using pseudonyms) of guided reflection sessions (conducted at the end of the workshop) will also be stored electronically on the secure university network in MP4 format. It is not expected that the audio-recordings will permit re-identification of individual persons (names are unlikely to be used as part of the group discussion). Similarly, data from follow-up surveys will be stored electronically on the university secure network.

The researchers note that Consent forms will contain identifiable information but this data is not part of the data set that will be analysed for publication. These will be hard copies and will be stored at the DRH Whyalla -Teletrial secured office on campus.

9.3 For how long will the information be stored after the completion of the project? Why has this period been chosen? *

Consent forms, completed surveys and questionnaires, and audio-recordings and transcripts of guided reflection sessions will be kept for 15 years as per GCP and NH&MRC guidelines for clinical trials. This period will start immediately after the publication of the findings in compliance with the University regulations regarding data storage, the National Statement in Ethical Conduct in Human Research, the Australian Code.

9.4 In what formats will the information be stored during the research project? (eg. paper copy, computer file on floppy disk or CD, audio tape, USB memory stick, videotape, film) *

1-Paper-based consent forms will be stored in locked filing cabinets in secured room in DRH Whyalla -Teletrial secured and locked office. Electronic scans will be stored on the Secured University server.
2-Surveys/questionnaires, audio-recordings, transcripts will be stored electronically on the university server.

9.5 How will information, in all forms, be disposed of after the retention time has lapsed? (Please refer to the Ownership and Retention of Data Policy. The Head of School (or equivalent) must be aware of this process).*

Both the identifiable (consent forms, audio-recordings) and non-identifiable (surveys, transcripts) data collected as part of the project will be disposed of after 15 years as per NH&MRC guidelines and the University of South Australia regulations for research, and with written approval of the primary investigator's line manager.

9.6 Will any other individual(s), organisation(s) or researcher(s) (other than those listed on the Investigators & Supervisors section) have authority to use or have access to the information?*

- (•) Yes
- ( ) No

9.6.1 Who are they and what is the nature of the use or access?*

The UNISA Accredited and Appointed transcription services (SMARTDOCS) will be accessing the data for transcription of the guided reflective activity.

9.7 Specify the measures to be taken to ensure the security of information from misuse, loss, or unauthorised access while stored during the research project. (eg. Will identifiers be removed and at what stage? Will the information be physically stored in a locked cabinet?)*

Access to data will be restricted to the researchers listed in this application and it is not expected that any third party will access the data. Any paper copy data will be stored in a lockable filling cabinet at the DRH Whyalla -Teletrial secured and locked office, at the University of South Australia regional campus. The UNISA accredited and appointed transcription services will be accessing the data under the confidentiality UNISA agreement. The data will be exported from the online platform and deleted as soon as possible after the data has been collected to protect this information form potential unauthorised access.

9.8 If the principal researcher leaves UniSA prior to the finalisation of data collection and/or before the storage retention time has lapsed, the researcher(s) will comply with the Universities Ownership and Retention of Data Policy in relation to the storage of data / information collected for, used in, or generated by this project.*

- (•) I agree
- ( ) I do not agree

Insurance Cover

Insurance Cover for your research

Improvements have been made in the recording and assessment of the insurance cover for research projects. Your responses to selected ethics application questions will be assessed to determine whether your research activity is covered by the University's standard insurance cover or whether individual insurance assessment is required. Where individual insurance assessment is required the ethics team will email you to obtain any additional information not available from your ethics application.

Standard insurance conditions

Standard insurance conditions continue to apply to your research. These are based on (1) obtaining full ethics approval prior to commencement of any research activities, (2) on the presentation of appropriate agreements in place with collaborators, and (3) on maintaining personal and professional integrity in all your research activities.

Further Information

Please refer to the Insurance website for further information about insurance cover.

If you have any questions about insurance for your project please contact humanethics@unisa.edu.au.

Research type and participants

Research type

14.1 **This project involves research using: *Please select all that apply.****

- [x] Qualitative methods
- [x] Quantitative methods, population level data or databanks, e.g. survey, epidemiological research
- [ ] None of the above

14.2 **What research methodologies will you use? *Please select all that apply.****

- [x] Anonymous questionnaires
- [x] Internet questionnaires
- [ ] Questionnaires requesting intimate personal, identifying, or sensitive information
- [ ] Other questionnaires
- [ ] Face to face interviews which do not request personal or sensitive information
- [x] Face to face interviews which request personal or sensitive information
- [ ] Telephone survey which does not request personal or sensitive information
- [x] Telephone survey which requests personal or sensitive information
- [ ] Focus groups
- [ ] Action Research
- [x] Evaluation research
- [ ] Observation of participant's usual activities
- [ ] Observation of an activity set up for the purposes of the study
- [ ] Access to medical records
- [ ] Access to records containing intimate, individually identifiable information, not publicly available
- [ ] Experiment or testing of a procedure, drug or equipment
- [ ] Use of biological hazards, GMOs or pathogenic organisms
- [ ] Use of carcinogenic and/or toxic chemicals, including heavy metals
- [ ] Use of Radiation (Ionising and/or Non-ionising, but not Ultrasound)
- [x] Other

14.2.1 Please describe what research methodology you will use.*

Workshop type delivery of the information and data collection for the activities.

14.2.2 Is it intended that the interview/focus group transcript will be shown or made available to participants?*

- (●) Yes
- ( ) No

14.2.2.1 Why is it considered important that participants have access to this information?*

Following standard practice recommendations (the COnsolidated criteria for REporting Qualitative research; Tong et al., 2007), participants will be provided with an opportunity to review the transcript of the guided reflection to contribute additional information or clarification as they see fit. Transcripts will not include participant names, and will therefore only be re-identifiable in the sense that those who participated in the guided reflection may be able to individually identify other participants.

The Telehealth component of the post-workshop surveys will not be audio-recorded.

14.3 **Will you be audio-taping, video-taping, or taking photographs of participants during the course of the study? *Please select all that apply.****

- [x] Audio-taping
- [ ] Videotaping
- [ ] Photographs
- [ ] No

14.3.1 Why is it necessary to collect data in this form?*

The guided reflective session at the end of the workshop will be audio recorded (with consent) to ensure that the insights shared are not missed, as per learnings from our previous studies in 2018 and 2023. The recording will be immediately saved directly to the local UNISA computer and then transferred to the UNISA shared research folder secured on the UNISA server to reduce the risk of potential unauthorised access by third parties.

Audio recordings of the guided reflection session will be transcribed by independent transcribers that are bound by confidentiality agreements.

Participant information

15.1 How many participant groups are involved in this research project? *

1

Please provide the details as an **attachment** for each participant group. **(To upload your attachment, please click on the Attachments section of the application in the Section/Pages menu).**

15.3 What is the expected total number of participants in this project at all sites?*

90

15.3.1 Please provide details of how many participant groups will be involved, the number of participants in each group, the age range of the participant groups, the relevant characteristics of each group and what each participant group will be required to do? e.g. pilot study group, main study group, interview group, focus study group, experimental group, control group etc. If required, please add a document to the Attachments page in response to this question.*

There will be only two groups made of the health and mental health workers (and students where applicable) who have enrolled voluntarily into the workshop; one control arm and one intervention arm.

The power of the study is calculated from previous projects in 2018 and 2023, it is expected that over 90 participants will enrol (approx. 16 participants per workshop) allowing for a control group (n=45) and an intervention group (n=45), with consideration for participants not wanting to be involved in the clinical trial/Teletrial research. The control group will receive the standard delivery workshop, while the intervention group workshop will involve a lived experience co-facilitator.

This will validate the feasibility of the delivery. Six sites will be explored (Port Pirie, Port Lincoln, Port Augusta, Victor Harbour, Berri and Mount Gambier) based on mental health needs for education and training, with sites being different from the 2023 project.

15.3.2 Please justify the chosen sample size.*

The research team is drawing on the results and findings of the 2018 project (Protocol ID #34712) and 2023 project (Protocol ID #204496). The Clinical Trial/Teletrial will involve one core participant group (health and mental health workers and students). Workshops will be delivered across six sites (Port Lincoln, Berri, Mount Gambier, Port Pirie, Port Augusta, Victor Harbor), half of which will receive the standard delivery (control) workshop (minimum n=45 participants), with the other half receiving the intervention workshop (minimum n=45 participants), which will involve a lived experience co-facilitator.

Participants who do not sign the consent form for the Teletrial study will receive the same training as other participants but will not contribute to the research data gathering. It is expected that most of the participants (from previous participation for the evaluation ProtocoI ID #204496) will consent to being involved in the research.

This method replicates the Teletrial research model proposed by A/Prof Martin Jones and colleagues (ID#205435) where the determination of the sample size was guided by the central limit theorem (Kwak et al. 2017).

Selection of participants

16.1 What process(es) will be used to identify potential participants?*

The workshops are based on the 'Hearing Voices that are Distressing (HVD); simulating tool kit' initially developed in 2008 (Arana Pearson and Colleagues) and later adapted to the Australian nursing context in 2015 to accommodate co-facilitation with the Lived Experience (LE) co-facilitator. The simulation workshops will be promoted on behalf of the researchers through organisational/agency websites, newsletters and email distribution lists to access general public who holds interest in health, and varied mental health workers will then voluntarily register to join the workshops in their regional area (hence 6 sites), The workshop coordinator (ATP-SA professional staff) will maintain the attendance register of all potential participants.

16.2 Will potential participants be 'screened' or given a test/questionnaire to assess their suitability as a participant for the study?*

- ○ Yes
- ◉ No

16.3 Describe how initial contact will be made with potential participants.*

The coordinators will advertise the HVD workshops by emailing governmental and non-governmental agencies at each study site and requesting that they promote the workshops through their websites, newsletters, and email distribution lists. Word of mouth will also be used.

Those who register to attend the workshop will be given ample notice of the research component. Where calendar days permit, registrants will be provided with the Participant Information Sheet and a Consent Form, several days prior to the workshop. The PIS will explain the purpose of the research, the voluntary nature of participation, and what participants will be asked to do at any project stage. Workshop facilitators will be able to provide additional clarification on the day as required, and participants will be able to provide/withdraw consent as they see fit. Workshop participants who have not signed the consent form will not have their data collected.

Where a workshop participant does not consent to the research component, they will be asked not to verbally contribute to the guided group reflection. At the conclusion of the guided group reflection (and when the voice recorder is stopped), non-consenting participants will be invited to engage in 1-on-1 reflection with a workshop facilitator. This will mean that they will still be able to engage in a reflective process. As with all other workshops we have conducted, participants will likely engage in an informal reflective process throughout the workshop as well.

16.4 Is an advertisement, e-mail, website, letter or telephone call proposed as the form of initial contact with potential participants?*

- ◉ Yes
- ○ No

16.4.1 Please detail how this will be used and/or whether any approval is needed to use this contact method. **Please attach any relevant documents to the Attachments section of this application.***

The workshops will be advertised through email invitations and flyers (ATTACH #5) sent to governmental and non-governmental agencies operating at each proposed regional (and rural) site and will be displayed on the public notice boards. Word of mouth will also be used as a recruitment strategy. All participants are considered the 'general public'.

16.5 List the selection and, if appropriate to your study, the exclusion criteria for participants.*

Eligibility criteria: a) over 18 years or older; b) participants, including undergraduate health science students, working in one of the six regional sites: Port Augusta, Port Pirie, Mount Gambier, Port Lincoln, Victor Harbor and Berri; c) enrolled in the HVD simulation workshop; and, d) voluntary agreement to participate in the Teletrial research project (signed the consent form)
Exclusion criterion are a) participants who do not wish to participate to the research project and not signing the consent form to participate to the research; b) participants who have participated to previous HVD workshop (2023); c) participants' who have attended similar workshops.

16.6 If it became known that a person or participant group was recruited to, participated in, or was excluded from the research, would that knowledge expose the person to any disadvantage or risk?*

- ○ Yes
- ◉ No
- ○ Not Applicable

Project start, end, location details

17.1 Will the research be undertaken in Australia?*

- ◉ Yes
- ○ No

17.1.1 In which town(s)/city(ies)/State(s) of Australia will the research be undertaken in? *

The Teletrial will be implemented across the cluster of the 6 sites/towns in South Australia; Whyalla (primary site, is not counted in the cluster set up for Teletrial), Victor Harbor, Berri, Mount Gambier and Port Lincoln, Port Pirie, Port Augusta selected because they represent areas of gaps in mental health education and training and for the presence of DRH infrastructure (Flinders and UNISA) to run the workshop at low costs. The stakeholders to whom the training is promoted to include governmental and non-governmental organisations (and NDIS providers) and universities affiliates (students and staff) .

17.1.2 In how many Australian organisations will the research be conducted? (Please list all organisations where participants will be specifically recruited from e.g. if recruiting UniSA staff or students, you have at least 1 organisation)*

1

Please note: you must obtain written approval from the organisations where the research will be undertaken and either attach the letter to the application or forward this to the Ethics and Compliance Officer before final approval can be granted for the project. Please refer to UniSA/organisation approval for additional information on the type of approval needed.

17.1.2.1 Please enter the details for the Australian site(s) where participants will be recruited from, the location of the organisation, the anticipated start date for the site and the anticipated end date for the site.*

The coordinators of the research possess a vast experience in nursing mental health in the selected regional areas in South Australia and from the previous projects (ID#204496 & ID #34712). Interest for the training has been high and persistent (request for repeats) and new workers have arrived to the regions that will benefit from the workshops. Participants will be from the community, health and mental health sectors. It is anticipated that the workshops will commence as soon as ethics will be granted and finish one year later in 2025. In 2026, Q1 and Q2 are expected to be the data analysis period.

17.2 Will the research be undertaken overseas?*

- ○ Yes
- ◉ No

17.3 Are there any time-critical aspects of the research project of which the review committee should be aware?*

- ○ Yes
- ◉ No

Irregular consent process

Limited disclosure/waive consent

18.1 Does the research involve limited disclosure to participants? Refer to Chapter 2.3 of the National Statement. *

- ○ Yes
- ◉ No

18.2 Are you asking the HREC / review body to waive the requirement of consent? Refer to Chapter 2.3 of the National Statement.*

- ○ Yes
- ◉ No

Covert Observations

19.1 Does the research involve covert observation? Refer to Chapter 2.3 of the National Statement.*

- ○ Yes
- ◉ No

Deception

20.1 Does the research involve deception? Refer to Chapter 2.3 of the National Statement.*

- ○ Yes
- ◉ No

Project Type

Project Type

21.1 **Does the research involve any of the following? *Please select all that apply.****

- ☐ Drugs; narcotics; poisons; ingestion/injection of placebo, or an invasive procedure administered
- ☑ Clinical trials
- ☐ Cellular therapy
- ☐ Collection and/or use of human samples (eg tissue; blood or other body fluid collection/extraction)
- ☐ Genetic testing and/or genetic research
- ☐ Human gametes or use or creation of human embryos
- ☐ A practice or intervention which is an alternative to a standard practice or intervention
- ☐ Investigating workplace practices which could possibly impact on workplace relationships
- ☐ Conducting the research overseas and recruiting participants
- ☐ None of the above

Clinical trial/ Cellular therapy

You have indicated that this research involves clinical trials and/ or a cellular therapy. Please refer to Chapter 3 of the National Statement when answering the following questions.

23.1 **The project will be conducted as follows:**

23.1.1 Under the Clinical Trial Notification Scheme (CTN)*

- ○ Yes
- ◉ No

23.1.2 Under the Clinical Trial Approval Scheme (CTA)*

- ○ Yes
- ◉ No

23.2 Please detail your Data and Safety Monitoring Board (DSMB) and its nominee for this trial.*

The DRH employed Dr LEE PUAH will be responsible for the data safety monitoring. Dr Puah has participated in previous Teletrial work with A/Prof. Martin Jones and will be the preferred nominee.

23.3 **Type of research/trial**

23.3.1 Will a drug / medicine (including a complementary / alternative medicine) be administered?*

- ○ Yes
- ◉ No

23.3.2 Will a medical device be used?*

- ○ Yes
- ◉ No

23.3.3 Will a human somatic cell gene therapy be administered?*

- ○ Yes
- ◉ No

23.3.4 Will a xenotransplant be used?*

- ○ Yes
- ◉ No

23.3.5 Will stem cells (adult or embryonic) be used as therapy?*

- ○ Yes
- ◉ No

23.3.6 Is another type of therapy (not identified in previous questions) to be used?*

- ○ Yes
- ◉ No

Trial Details

24.1 **Provide the following details for the clinical trial protocol:**

24.1.1 Protocol name*

'Hearing Voices that are Distressing' (HVD) simulation workshop will be delivered to regional (and rural) health and mental health professionals using on a pragmatic clinical trial approach (PCT) using a Teletrial cluster model.

24.1.2 Protocol version number*

FINAL, version 1.0, 12.08.2024

24.1.3 Protocol version date*

12/08/2024

24.2 If you intend to/have registered this trial in a publicly accessible register, please provide the details.*

The protocol is registered with the Australian New Zealand Clinical Trial Registry (add weblink)
(ATTACH #6 and 6.1 email acknowledging registration #388281; to date awaiting for final CTR numberACTRN12624001098527p - https://www.anzctr.org.au/ACTRN12624001098527p.aspx) on 12/09/2024)

24.3 **Provide the following details for the investigator's brochure/product information (as relevant):**

24.3.1 Title of Investigator's Brochure or Product Information

The Teletrial will not develop a product - the protocol attached is the product information

24.3.2 Investigator's brochure version number

not applicable

24.3.3 Investigator's brochure version date

12/08/2024

Clinical Trial

28.1 **Provide a statement describing the following:**

28.1.1 Method of randomisation*

The pragmatic trial approach (NHI) is the method selected for this study, and we will randomise sites (using an independent allocator, computer-generated assignation) to control sites or intervention sites as randomisation of individuals has not been deemed feasible for this Teletrial. This method is recommended for small regional clusters where the number of participants is small (less than 20 in each group) and for ease of implementation of the Teletrial. Randomising individuals in the context of this protocol will not be of benefit and add complexity to the education intervention (NHI, 16.04.2024, https://rethinkingclinicaltrials.org/chapters/design/experimental-designs-and-randomization-schemes/choosing-between-cluster-and-individual-randomization).

28.1.2 Whether the hypothesis offers a realistic possibility that the intervention is at least as effective as standard treatment.*

Based on the findings of the previous 2018 (Protocol ID 34712, over 100 people, publication under review) and 2023 (Protocol ID #204496, over 60 people, manuscript in preparation) evaluations, the research team hypothesises that the intervention implemented as a clinical trial/Teletrial method will provide a high level of evidence for future educational development involving a lived experience co-facilitator and further publications.

Both the standard delivery and intervention workshops will contain the same content, however the intervention workshops will be co-facilitated by a person with lived experience of hearing distressing voices, who will share their story and respond to participants' questions.
A fidelity assessment based on time allocation to each of the four sections will be implemented.

28.1.3 The justification for the use of placebo or non-treatment control group, including alternative effective treatments and any risk of harm in the absence of treatment.*

The standard delivery (control) group will experience the workshop with video testimonials of lived experience, but will not be co-facilitated by a person with lived experience of hearing distressing voices. Based on the 2023 results, the coordinators do not expect any risk of harm in this delivery model. For equity, the participants who receive the standard delivery workshop will be offered a webinar with a lived experience person after the workshops if so they wish.

28.1.4 How variations in response will be treated*

Variations in participants' responses will be considered part of the validation of the hypothesis, and participants will be offered a webinar with a lived experience person who shared their story as part of the intervention workshops.

28.1.5 Endpoints*

Quarter 2, 2026.

28.1.6 Details of contingencies and management of these*

As the Teletrial will not be implemented before the ethics application is approved, there should not be any time delays or other foreseen contingencies.

28.2 Explain the arrangements in place to ensure there is adequate compensation for participants.*

Compensation for participation in the Teletrial will not be considered upfront, but an electronic voucher (PREZZEE) of $30 will be offered to all participants who complete all the study surveys. There are no foreseen risks in reference to the 2023 delivery findings.

28.3 How many drugs will be used in this research project? (not including the placebo)*

0

Participants

Recruitment

38.1 **Who will you be recruiting as participants for this study? *Please select all that apply.****

- [x] General public (over 18 years of age)
- [ ] Members of a collectivity
- [ ] People whose first language is not English
- [ ] People who are illiterate
- [ ] Pregnant women/human foetus
- [ ] Children
- [ ] People who are in a dependent or unequal relationship
- [ ] People who are highly dependent on medical care
- [ ] People with a cognitive impairment
- [ ] Aboriginal and/or Torres Strait Islander peoples
- [ ] People who may be involved in illegal activity
- [ ] UniSA staff
- [ ] UniSA students
- [ ] Not recruiting participants
- [ ] Other

38.2 Does the research involve issues likely to be considered significant to Indigenous peoples?*

- ○ Yes
- ◉ No
- ○ Not Applicable

Risk to Participants

Risk to Participants

51.1 **Please select all that apply. This research project:***

- [ ] Has the potential to expose participants to potential civil, criminal or other proceedings
- [ ] Makes it possible for third parties to identify participants
- [ ] Involves a risk of physical injury
- [ ] Involves human exposure to ionising and/or non-ionising radiation (including X-ray)
- [ ] Involves exposure to disease or infection
- [ ] Involves pain or significant discomfort
- [x] Involves psychological or emotional stress
- [x] Involves sensitive personal information
- [ ] May expose participants to potential loss of professional reputation,market standing; employability
- [ ] May result in significant negative impact upon personal relations
- [ ] Offers an inducement which could be considered coercive
- [ ] Involves participation of people who legally cannot provide voluntary & informed consent
- [ ] None of the above

Psychological or Emotional Stress

You have indicated that this research involves psychological or emotional stress. Please refer to Chapter 2.1 of the National Statement when answering the following questions.

59.1 Is prior warning given (ie is information about the risk - in plain language - included in the informed consent materials)?*

- ◉ Yes
- ○ No

59.2 If appropriate, will potential participants be screened on the basis of complicating mental health factors?*

- ○ Yes
- ◉ No
- ○ Not Applicable

59.3 Would a reasonable person attach significance to exposure to the stress?*

- ○ Yes
- ◉ No

59.4 Are the risks associated with the research easily minimised or managed?*

- ◉ Yes
- ○ No

59.4.1 Please provide details.*

The research team recognises and acknowledges that discussions about mental health with a focus on hearing distressing voices can evoke emotional feelings. The team will aim to mitigate the distress for participants (and coordinators of the workshop) by following the Distress Protocol (see attachment) and ensuring that there is at least one facilitators delivering the workshops with relevant mental health experience (i.e., MHFA or clinical experience). They will be available during and after the workshops to support distressed participants. Further to this, the team will include relevant resources on the Participant Information Sheet (PIS) such as Emergency Mental Health Triage Service 131465, Lifeline 131114, and Beyond Blue 1300 22 46 36 and will urge the participants to consult their GP or EAP for further assessment. Lee is a Mental Health Academic and Master Trainer, Carol-Ann is a clinical nurse with Mental Health expertise who understands the referral pathways, Michael Marsh is an experienced Lived Experience facilitator and long-term psychosocial mental health Peer Worker, and Arana Pearson brings the cross-cultural lived experience. Dr Chloe Fletcher has experiences and qualifications in mental health psychosocial work.

Sensitive Personal Information

You have indicated that this research involves sensitive personal information. Please refer to Chapter 2.1 of the National Statement when answering the following questions.

60.1 Is prior warning given (ie is information about the risk - in plain language - included in the informed consent materials)?*

- ◉ Yes
- ○ No

Right to Privacy

66.1 Does the Commonwealth Privacy Act apply to the research (eg access to identified personal data held by third parties subject to privacy regimes)? Refer to the Privacy law.*

- ○ Yes
- ◉ No

Collection Method

Collection Method

67.1 Data collected for this research project will be collected directly from participants (e.g. they are completing a question about themselves, their thoughts, their opinions etc).*

- ◉ Yes
- ○ No

Information which will be collected for this research project directly from the participant

67.1.2 Describe the information that will be collected directly from participants. Be specific where appropriate.*

Participants will be invited to complete an empathy survey at two time points: T1 at the commencement and T2 at the end of the workshops. Both surveys will be paper-based and electronic to make use of the captive audience. The Kiersma-Chen Empathy Scale (KCES) survey tool has been previously validated and used in several studies in the past to assess levels of empathy. The KCES survey contains 14 statements that are weighted against a 7-point Likert Scale (to allow further statistical analysis) and measures cognitive (understanding/ viewing from other's perspectives) and affective (relating to others' experiences/ feelings) qualities (ATTACH #8). In addition to the survey, participants will also be invited to participate in (a) guided reflection session at the end of the workshop and part of the learning plan; (b) follow-up surveys using the Kirkpatrick Model of Evaluation (Level 1 & 2) instrument at 1-month and 3 months post-workshop (ATTACH #9)

The guided reflection session (ATTACH #10) will assess the participant's reaction to the simulation experience and workshop content at the time of the workshop.

To obtain insights about the relevance and quality of the training, attitudes, and practice in a healthcare setting, for all consenting participants, the Kirkpatrick Model of Evaluation adapted instrument will enable the research team to evaluate the impact of teaching and retention using the simulation delivery model. The Teletrial nurses will administer the survey (calling the participants and sending the survey electronically, no audio-recording) to reduce any risk of coercion from the teaching team.

67.1.3 **The information collected by the research team about participants will be in the following form(s). *Please select all that apply.*** *

- ☑ Individually identifiable
- ☐ Re-identifiable
- ☐ Non-identifiable

67.1.3.1 Give reasons why it is necessary to collect information in Individually identifiable or Re-identifiable form.*

Although unluckily, the voices from the audio recordings could not be identified, hence 'individually identifiable' was selected.

67.2 Data collected for this research project will be collected from another person about the participant (e.g. asking participants' doctors about their patients medical history).*

- ○ Yes
- ◉ No

67.3 Will data collected for this research project involve the use or disclosure of information by an agency, authority or organization (other than UniSA)? (e.g. accessing participants' medical records)*

- ○ Yes
- ◉ No

67.4 Data collected for this research project will involve using information which you or your organisation collected previously for a purpose other than this research project?*

- ○ Yes
- ◉ No

67.5 Describe and justify how you will analyse the data collected from or about the participants.*

This mixed method study will involve collection of both quantitative and qualitative data using two surveys Quantitative data relating to empathy will be collected via the KCES survey immediately pre-/post-workshop. Data relating to learning/change in practice (collected via the Kirkpatrick instrument).

Participants will each create and use an anonymous identifier that will allow their responses to be matched across time. Data sets will be descriptively analysed using either Microsoft Excel or SPSS software. Repeated measures analyses (ANOVA) will be used to determine the impact of participation in the workshops on changes in empathy and practice across time and to identify differences between groups (standard delivery vs. intervention).

Audio recordings of the guided reflection session will be transcribed by independent transcribers that are bound by confidentiality agreements. Qualitative data will be subjected to reflexive thematic analysis, using an inductive approach and guided by Braun and Clarke's six phase process (Braun and Clarke, 2006). NVIVO Pro software version 12 will be used to facilitate coding. Codes and themes will be reviewed by the research team at key points in the analysis. The results will be compiled into a paper for publication in a peer-reviewed journal.

67.6 **Select all that apply to this project from the following. Information collected for, used in, or generated by, this project:** *

- ☑ Will not be used for any other purpose
- ☐ Will/may be used for another purpose by the researcher for which ethical approval will be sought
- ☐ Will establish a database/collection or register for future use (ethical approval will be sought)
- ☐ Will/may be made available to a 3rd party for subsequent use (ethical approval will be sought)
- ☐ Other

Participants Relationships

68.1 Is there an existing relationship or one likely to arise during the research, between the potential participants and any member of the research team or an organisation involved in the research?*

- ○ Yes
- ◉ No

68.2 Does the researcher / investigator have another role in relation to the participant?*

- ○ Yes
- ◉ No

68.3 Will the research impact upon, or change, an existing relationship between participants and researcher / investigator or organisations?*

- ○ Yes
- ◉ No

Consent

69.1 Will consent for participation in this research be sought from all participants? Refer to Chapter 2.2 of the National Statement.*

- ◉ Yes
- ○ No

69.1.2 Will there be participants who **have** capacity to give consent for themselves?*

- ◉ Yes
- ○ No

69.1.2.1 What mechanisms / assessments / tools are to be used, if any, to determine each of these participant's capacity to decide whether or not to participate?*

Participation in this research study will be voluntary. To facilitate informed consent, participants will be provided with a Participant Information Sheet (ATTACH #3) to assist with their decision whether or not to take part in the project. Consenting participants will be invited to fill in and sign a Consent form (ATTACH # 4) that will emailed to them prior to the workshop or handed out on the day and signature will be witnessed by a researcher of the team on the day.
There will be no assessment as such, although the follwing criteria will apply at enrolment:
• each participant's qualifications / training / expertise (and/ or current position of employment) will be considered sufficient evidence that they have capacity
to decide whether or not to participate in the study
• their decision to take part in the research element based on details provided in the participant information will be considered indicative of their capacity to
give consent for themselves
• all participants will be adults (18 years of age or older)

69.1.3 Will there be participants who **do not have** capacity to give consent for themselves?*

- ○ Yes
- ◉ No

Consent Process

70.1 Describe the consent process, ie how participants or those deciding for them will be informed about, and choose whether or not to participate in, the project.*

Participation in the study will be entirely voluntary. A Participant Information Sheet (ATTACH #3) will be shared with all participants to invite them to participate in the Teletrial study part of the HDV simulation workshop. The PIS will explain the purpose of the study including the Teletrial component and the voluntary nature of participation. The PIS explains that participants have the option to participate or can choose not to participate in the study, and there will be no repercussions of any kind, and they can still attend the workshop. Furthermore, participants will be able to withdraw from the research study at any time, again without any repercussion. All research study participants will be invited to complete and sign a Consent Form (ATTACH #4).

70.2 If a participant or person on behalf of a participant chooses not to participate, are there specific consequences of which they should be made aware, prior to making this decision?*

- ○ Yes
- ◉ No

70.3 If a participant or person on behalf of a participant chooses to withdraw from the research, are there specific consequences of which they should be made aware, prior to giving consent?*

- ○ Yes
- ◉ No

70.4 Can individual participants be identifiable by other members of their group? (e.g. co-workers, focus group members etc.)*

- ○ Yes
- ◉ No

70.7 Will consent be specific or extended or unspecified? Refer to Chapter 2, Items 2.2.14-2.2.18 of the National Statement.*

- ◉ Specific
- ○ Extended
- ○ Unspecific

Risks and Benefits

Risks and Benefits

Please note that when answering the following questions, only risks beyond those encountered in everyday life are relevant. Refer to Chapter 2.1 of the National Statement.

71.1 Are there any risks to participants as a result of participation in this research project (eg physical, psychological, spiritual, emotional, legal, social, financial well-being, employability or professional relationships)?*

- ◉ Yes
- ○ No

71.1.1 Please identify what risks are involved in participation and explain how they will be minimised, monitored and reported.*

Because of the nature of the workshop, it is possible that participants may become distressed. Participants will be advised of this prior to the workshop and are invited to indicate to facilitators if they are needing support. Participants who become distressed during the workshop will be provided with support (by one of the facilitators) following a triage pathway (see ATTACH #7). Adverse effects will be reported to the Steering Clinical Trial Committee.

71.2 What expected benefits will this research have for the wider community?*

Although the wider community is unlikely to benefit directly from this study (feasibility and acceptability), the potential for indirect benefits is immense, especially through access to consumer-centred care. The project is expected to generate even more insight into the quality, relevance, and impact of the 'Hearing Voices that are Distressing' (HVD) simulation workshops on workers' practice and whether there may be justification/evidence to scale up the workshops across South Australia.
The participants are unlikely to benefit from the research project. The Participant Information Sheet (ATTACH #3) explains that there will be no direct benefits for participants; however each participant who has attended the workshop and completed the sequence of surveys over time will receive a $30 voucher (electronic gift card PREZZEE).

71.3 What expected benefits (if any) will this research have for participants?*

They will gain knowledge about HVD and skills in mental health care and how to improve their practice when engaging with such clients/patients. Their overall care for these voice-hearers will improve from their upskilling.

71.3.1 Explain how the likely benefit of the research justifies the risks of harm or discomfort to participants.*

The team does not expect any harm and recognise that discomfort might occur by recall process of previous encounters. The distress plan is robust and has already been in place for the 2023 workshop (Protocol ID # 204496) with no harmful events occurring at the time.

71.4 Are there any other risks involved in this research? eg. to the research team, the organisation, others (eg physical, psychological, spiritual, emotional, legal, social, financial well-being, employability or professional relationships)*

- ○ Yes
- ◉ No

Risks and Benefits cont.

72.1 Is it anticipated that the research will lead to commercial benefit for the investigator(s) and or the research sponsor(s)?*

- ○ Yes
- ◉ No

72.2 Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, legal, social or financial well-being, or to their employability or professional relationships - or to their communities?*

- ○ Yes
- ◉ No

72.3 Describe how the members of the research team will monitor the conduct of the research. (e.g. Will regular meetings be held between researchers? Will student researchers be in regular contact with their supervisors? etc)*

The research and training team will meet regularly for the duration of the research study to review progress and to identify and resolve emergent challenges. Routine meetings will be used by the research and training team to debrief, mentor and support each other. The research project team meetings will have a standing agenda item asking if there have been any adverse events which need to be reported to the human ethics office and/or workplace health and safety (WHS) team or
any need to seek a variation to the approved protocol. A steering committee led by an external Chair (Professor Judy Taylor, JCU) will be establish and the committee will review twice a year the progress of the study and any adverse events (TOR ATTACH #11)

It is sometimes mandatory for researchers to report suspected cases of child abuse/neglect, domestic violence, bullying, illegal activities, use of illicit substances, abuse of elderly persons, professional negligence etc.

72.4.1 Is it possible that this will be disclosed during the course of the project?*

- ○ Yes
- ◉ No

Researcher Training

73.1 List the relevant qualifications, experiences and /or skills of the research team which equip them to conduct this research.*

The training coordinators (Lee Martinez, Dr Chloe Fletcher and Carol-Ann Stanborough) are experienced academics and clinicians with strong backgrounds in mental health service delivery, education and research. Michael Marsh has lived experience of mental illness, is an experienced mental health educator, a Master trainer in the delivery of Hearing Distressing Voices and mental health lived experience / psychosocial Peer Worker. Michael Marsh will contribute lived experience of mental illness during workshops. All the research team members have wide experience conducting quantitative and qualitative research studies. Pascale is a seasoned researcher supporting the team in the clinical trial set up and the Teletrial documentation. Lee Puah is an experienced data analyst that have created dashboards for the DRH to inform health gaps in SA regional areas and one of them is used by the ATP-SA for their decision making in supporting regional research project matching up with the specialty(ies) gap analysis.

73.2 Do the researchers involved in this research project require any additional training in order to undertake this research?*

- ○ Yes
- ◉ No

Reporting of Results

74.1 Is it intended that results of the research that relate to a specific participant be reported to that participant?*

- ○ Yes
- ◉ No
- ○ Not Applicable

74.1.4 Explain/justify why results will not be reported to participants.*

The study's results will not be reported directly to participants, although they will be able to access the aggregated findings, which will be posted in the public domain.

74.2 Is the research likely to produce information of personal significance to individual participants?*

- ○ Yes
- ◉ No

74.3 Will individual participant's results be recorded with their personal records?*

- ○ Yes
- ◉ No
- ○ Not Applicable

74.4 Is it intended that all or some of the results that relate to a specific participant be reported to anyone other than that participant?*

- ○ Yes
- ◉ No

74.5 Will research participants have the opportunity to receive a copy of your final report or summary of the findings if they wish?*

- (●) Yes
- ( ) No

74.5.1 How will you provide a copy of the final report or summary of the findings?*

The summary of the findings will be made available in the public domain and through seminars, conference presentations and journal publications. Also, the summary of the study findings will be available to all participants upon request.

Reporting of Results cont.

75.1 Is the research likely to reveal a significant risk to the health or well being of persons other than the participant (eg family members, colleagues)?*

- ( ) Yes
- (●) No

75.2 Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, social or financial well-being, or to their employability or professional relationships - or to their communities?*

- ( ) Yes
- (●) No

75.3 How is it intended to disseminate the results of the research? Please select all that apply.*

- [ ] Thesis/dissertation
- [x] Journal article/s
- [x] Research paper
- [x] Conference presentation
- [ ] Commissioned report
- [ ] Other

75.4 Will the confidentiality of participants and their data be protected in the dissemination of research results?*

- (●) Yes
- ( ) No
- ( ) Not Applicable

75.4.1 Explain how confidentiality of participants and their data will be protected in the dissemination of research results.*

Only the de-identified and aggregated data will be published therefore confidentiality will be maintain at all times.

Attachments

Attachments

Note: You can upload additional documents by clicking on the "Add New Document" link. Types of documents which should be attached include Reference List/Bibliography, Participant Information Sheet, Consent Form, Copy of Research Tools, Internet Questionnaire, Interview/Focus Group Questions, Details of Observational Aspects, Details of Action Research Process, Organisational Approval, international government research approvals where required, safety & distress protocols, communication plans with Indigenous communities involved in research ,etc. Please refer also to the additional Application Considerations.

The Human Research Ethics Committee pays particular attention to Participant Information Sheets and considers them to be public documents.

HREC requires researchers to conform to the Participant Information Sheet Guidelines. Please refer to Chapter 2.2 of the National Statement.

A consent form template is available at Model Consent Form. Please ensure all irrelevant information is deleted as there are numerous notes to the researcher included in the model consent form to assist researchers to draft their form.

Please note:

- the following are MANDATORY ATTACHMENTS : 1. Reference List and 2. Research Tools (or reasons as to why there aren't any)
- each attachment must have a unique Name

*

1	Document type	Soft copy
	Name	1. Reference List
	Reference (Document Title)	ATTACH # 12 HVD_Reference list.docx
	Description	HVD 2024 Reference list.
2	Document type	Soft copy
	Name	2. Research Tools (or reasons as to why there aren't any)
	Reference (Document Title)	ATTACH #10 ver2.0. HVD_TT_Guided reflection_03.10.2024.docx
	Description	Guided reflective tool
3	Document type	Soft copy
	Name	3. Participant Information Sheet (as applicable)
	Reference (Document Title)	ATTACH #3 ver 2.0.HVD_TTrial PIS_recruit participants-03.10.2024_V2.docx
	Description	Participant information sheet (workshops and Teletrial)

4	Document type	Soft copy
	Name	Consent Form (as applicable)
	Reference (Document Title)	ATTACH #4 HVD_TT_ver2.0.03.10.2024.Consent Form and Withdraw Form Combinedocx.docx
	Description	Consent form & withdraw from
5	Document type	Soft copy
	Name	Others (as applicable)
	Reference (Document Title)	ATTACH # 7 HVD_TT_ver 2.0-Distress protocol_03.10.2024.docx
	Description	HVD_ Distress protocol
6	Document type	Soft copy
	Name	Insurance email
	Reference (Document Title)	ATTACH #2 Insurance email 206384.pdf
	Description	insurance email for the research project
7	Document type	Soft copy
	Name	Shared storage space approved.
	Reference (Document Title)	storage space for 206384.pdf
	Description	Shared storage space email
8	Document type	Soft copy
	Name	FLYER
	Reference (Document Title)	ATTACH #5 ver2.0 FLYER 'Hearing Voices that are Distressing' simulation workshop. 4.10.2024.docx
	Description	FLYER ver2.0_ Recruitment_HVD
9	Document type	Soft copy
	Name	Protocol
	Reference (Document Title)	ATTACH #6_ver2.0.Proposal_Hearing Distressing Voices Simulation Workshop Clinical Trial_Teletrial.docx
	Description	Proposal (protocol ID 206384)
10	Document type	Soft copy
	Name	survey tool (Kirkpatrick's tool)
	Reference (Document Title)	ATT#9 HVD_TT_ ver2.0-Kirkpatrick after workshop & 1.3 months surveys03.10.2024.docx
	Description	Kirkpatrick learning evaluation tools
11	Document type	Soft copy
	Name	Empathy/Demo Tool KCES
	Reference (Document Title)	ATTACH# 8 HVD_TT_ver2.0.Demographics and empathy questionnaire_participants_03.10.2024.docx
	Description	KCES empathy tool
12	Document type	Soft copy
	Name	Steering committee TOR
	Reference (Document Title)	ATTACH #11 HVD_ 206384_ver2.0.03.10.2024.Steering committee and TOR .docx
	Description	TOR steering committee HVD protocol # 206384 -
13	Document type	Soft copy
	Name	Email from ANZCTR
	Reference (Document Title)	ANZCTR - Registration.26.08.2024.pdf
	Description	Email from ANZCTR (registration pending)
14	Document type	Soft copy
	Name	Letter of supprt from Taimi Allen SAMHCommissioner
	Reference (Document Title)	DI#206384 - Letter of Support - Hearing Distressing Voices Simulation Workshop and Australian Teletrial Program (ATP) - Taimi Allan SAMHC - Aug2024.pdf
	Description	Letter of Support SAMHCommissioner

Declaration

Declaration

The Primary Contact for this project is responsible for the application that is submitted and must be the one to agree to the following statement.

"On behalf of the research team for this project, I confirm that all members of the research have read the current NHMRC *National Statement on Ethical Conduct in Human Research*. The research team accepts responsibility for the ethical and appropriate conduct of the procedures detailed in this application, confirm that the research team will conduct this project in accordance with the principles described in the *National Statement*, and confirm that the research team will comply with any other condition laid down by the University of South Australia's Human Research Ethics Committee."*

☑ I Agree

Please submit the application by clicking Submit on the Toolbar.

Instructions

Instructions

Please submit the application by clicking Submit on the Toolbar.

Set Date

Approved Subject To Date

Please set the Approved Subject To date, then click Set Date Approved Subject To on the Toolbar.

This question is not answered.

Instructions

Please click the appropriate 'Set Date' action on the Toolbar.