

Consent Form- Clinical trial_Patients

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: 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			
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 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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- 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	Researcher's signat	ure	Date				
(please print)							

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