Ethics Application

Application ID :	ETH22-7803
Application Title :	Assessment and Remote Treatment of Social Anxiety Disorder
Date of Submission :	16/01/2023
Primary Investigator :	A/Prof Bethany May Wootton (Chief Investigator)
Other Personnel :	Mrs Halaina Rose-Anne Joy Winter (5Research Student)
	Steven Passfield (Research Assistant)
	Ms Sylvia Steensma-Young (Research Assistant)
	Samantha Morgan-Basnett (Research Assistant)
	Sophie Berry (Research Assistant)
	Dr Alice Rosemarie Norton (3Assoc. Investigator)

Section 1: Ethics Portal

Select your application type

What type of application are you looking for?
Please **do not** change your application type without first consulting with the Ethics Secretariat (9514 9772).*

- (●) New application (including scope-checking for nil/negligible risk research)
- ( ) Ratification of existing approval
- ( ) Transfer of existing approval
- ( ) Evaluation of teaching and learning activities
- ( ) Amendment to existing approval
- ( ) Program approval

You have selected "new application (including scope checking for nil/negligible risk research)". This option allows you to create a new form. The system will check if your application can be approved by the Faculty or whether it requires full ethics approval by the HREC. Please click "save" before continuing.

What should I know before I start?

Would you like more information on:

- ( ) This system
- (●) The ethics process
- ( ) Purpose of the ethics review process

The ethics process

This form has a risk assessment which will help decide whether your research is nil/negligible risk or whether you will need to complete a full ethics application form. If you are unsure how to answer these questions or disagree with the outcome you can contact us by phone (02) 9514 9772 or by email the Ethics Secretariat.

Staff applications: If your research is nil/negligible risk, you will receive an email after submitting this form which will confirm this. If your research is low or high risk, it will be submitted automatically to your local research office after you click on Submit.

Student applications: Your application will first be reviewed by your supervisor. If your research is nil/negligible risk, you will receive an email after your supervisor has endorsed the application. If your research is low or high risk, it will be submitted automatically to your local research office after your supervisor has endorsed your application online.

For more information, go to our website.

What you should read when completing this form
This form should be read in conjunction with the relevant University policies and guidelines, the National Statement on Ethical Conduct in Research Involving Humans (PDF, 652Kb) and the Australian Code for the Responsible Conduct of Research (2007) (PDF, 829Kb).

Section 1A: Risk evaluation

Risk A

Determining the level of risk and review

- Please answer each question carefully **and consecutively**.
- For assistance with answering these questions please refer to the National Statement on Ethical Conduct in Human Research as per the chapters listed below.
- If you need to contact the Research Ethics Officer you can call (02) 9514 9772
- Click on the help buttons (?) for more information
- You can save your application at any time by clicking on the save button on the left hand side in the toolbar. For further information and help in completing your application go to our website.

Does your research involve:

Projects involving covert observation, active concealment, or planned deception of participants

e.g. covert observation of the hand-washing behaviour of hospital employees, undisclosed role-playing by a researcher, etc. Does NOT include observation in a public place WITHOUT the use of photographs, images, video or audio footage (Chapter 2.3, p.19)

*

- ( ) Yes
- (●) No

Targeted recruitment or analysis of data(?) from any of the groups listed below (or where any of these groups are likely to be significantly over-represented in the group being studied)

- Women who are pregnant and the human fetus (Chapter 4.1, p. 61)
- Children and young people (under 18 years) (Chapter 4.2, p. 65)
- People in dependent or unequal relationships (e.g. lecturer/student [except T&L], doctor/patient, employer/employee) (Chapter 4.3, p.68)
- People highly dependent on medical care who may be unable to give consent Chapter 4.4, p.68)
- People with a cognitive impairment, an intellectual disability, or a mental illness (may include the disadvantaged/homeless) (Chapter 4.5, p. 70)
- People who may be involved in illegal activities (including those affected e.g. victims of domestic violence) (Chapter 4.6, p.73)
- Aboriginal and Torres Strait Islander Peoples (Chapter 4.7, p.77)

*

- (●) Yes
- ( ) No

Targeted recruitment of people in / from countries that score <50 on the Corruption Perception Index (CPI) (check here)
This includes any cohorts from these countries, i.e. it is not restricted to marginalised groups within these countries*

- ( ) Yes
- (●) No

Collection, use or disclosure of personal information without consent of the participant(?)

- **a record which may include your name, address and other details about the participant (e.g. date of birth, financial information etc.)**
- **photographs, images, video or audio footage**
- **fingerprints, blood or DNA samples**

*

- ( ) Yes
- (●) No

Collection, use or disclosure of health information(?)

- personal information that is information or an opinion about
  - the physical or mental health or a disability (at any time) of an individual; or
  - an individual's expressed wishes about the future provision of health services to him or her, or
  - a health service provided, or to be provided, to an individual or
- other personal information collected to provide, or in providing, a health service, or
- other personal information about an individual collected in connection with the donation, or intended donation, of a individual's body parts, organs, body substances, or
- other personal information that is genetic information about an individual arising from a health service provided to the individual in a form that is or could be predictive of the health (at any time) of the individual or of a genetic relative of the individual, or
- healthcare identifiers

N.B Includes information collected through physiological testing or assessment. Examples include but are not limited to EEG, EMG, BMI, blood pressure, DEXA, etc.*

- (●) Yes
- ( ) No

Collection, use or disclosure of sensitive information
Racial, ethnic information, political, religious and philosophical beliefs, sexual activity or identity, and trade union membership
*

- ( ) Yes
- (●) No

Activity that potentially infringes the privacy or professional reputation of participants, providers or organisations
e.g. observation in the workplace, collection of commercially confidential information, etc.
Commercially confidential information = Any information which is not in the public domain or publicly available, and where disclosure may undermine the economic interest or competitive position of the owner of the information (TGA adopted definition from European Medicines Agency (EMA)).

N.B. if canvassing opinion via consensus methods i.e. Delphi (?), answer "No" here
*

- ( ) Yes
- (●) No

Establishment of a register or databank of identifiable data for possible use in future research projects (Chapter 3.2, p.27) (?)

*

- ( ) Yes
- (●) No

Collection, transfer(?) and/or banking of human biospecimens.
e.g. tissue, blood, urine, sputum etc.(?)

*

- ( ) Yes
- (●) No

Any significant alteration to routine care or service provided to participants
e.g. deviation from standard care or usual practice
*

- ○ Yes
- ◉ No

Prospective assignment of human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes(?) (Chapter 3.14-3.17) *

- ○ Yes
- ◉ No

Potential for participants to experience harm (i.e. anything more than discomfort)(?)
e.g. physical, psychological, devaluation of personal worth, social, economic and/or legal (Chapter 2.1, p.12)
*

- ○ Yes
- ◉ No

High Risk

Section 2: Project information

Project title

We recommend you save your application regularly while editing. You can save your application at any time by clicking on the save button.
For further information and help in completing your application go to our website

Application ID (automatically generated):

ETH22-7803

Application Title:*

Assessment and Remote Treatment of Social Anxiety Disorder

Please note that the HREC is now granting a standard approval period for the research proposals.
The approval period for your project will be specified in your approval letter.
Please also note that research should not commence until ethics approval has been granted. The Committee cannot grant retrospective approval for data that has already been collected.

Ethics category code (automatically selected):*

Human

Is this a resubmission of a previous application?*

- ○ Yes
- ◉ No

Is this a pilot study? *

- ○ Yes
- ◉ No

Has a pilot study been conducted as part of this project? *

- ○ Yes
- ◉ No

Please save and continue to the next page

Consultation

We recommend you save your application regularly while editing. You can save your application at any time by clicking on the save button.
For further information and help in completing your application go to our website

Have you undertaken any consultation in preparing this application?*

◉ Yes
○ No

Please describe*

Consultation with primary and secondary supervisors, primary supervisor has also had consultation and completed a similar study with another student

Please save and continue to the next page

Section 3: Personnel

Investigators

We recommend you save your application regularly while editing. You can save your application at any time by clicking on the save button.
For further information and help in completing your application go to our website

Are there external investigators or personnel listed on this protocol?*

◉ Yes
○ No

Is this application for a student project?*

◉ Yes
○ No

Student applicants:

1. Please note that once your application is submitted it will go directly to your supervisor and not to the Committee.
2. We **strongly** recommend notifying your supervisor that you have submitted your application in case of any technical issues, to avoid potential delays in the review process.
3. Once your supervisor endorses your application it will go to your Local Research Office for endorsement before coming to the Ethics Secretariat for review.
4. Your electronic application must be endorsed by your supervisor by the Local Research Office (LRO) submission deadline.
5. Please also ensure that the Primary AOU at the end of this page is updated to your supervisor's AOU. This will show in the table under 'Internal personnel listed below', once you add them. If you need any assistance with this please contact Research.Ethics@uts.edu.au or call 9514 9772. Please note that this is particularly important if you have a dual role as a staff/student as your application could go to the wrong faculty for review through the automated process.

Positions in the personnel table

Position type:	In the personnel table use the following positions from the drop-down list:
Chief Investigator/Supervisor	1Chief Investigator (students must **not** be listed as Chief Investigator)
Co Investigator	3Assoc. Investigator
Co Supervisor	Co-Supervisor
Research Student	5Research Student
Project Administrator	7Project Administrator

Note: Further options are available in the drop down list.

Instructions on how to add a person to the personnel table:

1. Click on "Add"
2. Start typing the details (first name, last name or Staff ID) in the search bar.
3. Click on "Add selected"
4. The extra information panel will open, select their position from the drop-down list. If they are the primary contact (e.g. Chief Investigator/Supervisor), tick "Yes" under 'Primary contact' and then select "OK"

- **Student research:** Students must add their supervisors to their application and must mark their primary supervisor as a Chief Investigator and as a primary contact. Students must be listed as "5Research student" under the column 'Position' to ensure the application is properly submitted to their supervisor.
- **Ratifications/Transfers:** If this list differs from that of the original application, you must provide evidence that any additional investigators have been added via amendment to the lead/external HREC [attach relevant amendments and evidence of approval].

Internal personnel listed on this ethics protocol:*

1	Primary	No
	ID	14151981
	Surname	Winter
	Given Name	Halaina
	Full Name	Mrs Halaina Rose-Anne Joy Winter
	Position	5Research Student
	Type	Domestic
	AOU	GSH.Graduate School of Health
	Managing Unit	Faculty of Health
	Email Address	Halaina.Winter@student.uts.edu.au
	Work Number	

2	Primary	No
	ID	PER0137356
	Surname	Passfield
	Given Name	Steven
	Full Name	Steven Passfield
	Position	Research Assistant
	Type	External
	AOU	
	Managing Unit	
	Email Address	Steven.B.Passfield@student.uts.edu.au
	Work Number	
3	Primary	No
	ID	PER0159014
	Surname	Steensma-Young
	Given Name	Sylvia
	Full Name	Ms Sylvia Steensma-Young
	Position	Research Assistant
	Type	Not Specified
	AOU	
	Managing Unit	
	Email Address	Sylvia.Steensma-Young@student.uts.edu.au
	Work Number	
4	Primary	No
	ID	PER0137379
	Surname	Morgan-Basnett
	Given Name	Samantha
	Full Name	Samantha Morgan-Basnett
	Position	Research Assistant
	Type	External
	AOU	
	Managing Unit	
	Email Address	Samantha.Morgan-Basnett@student.uts.edu.au
	Work Number	
5	Primary	No
	ID	PER0137389
	Surname	Berry
	Given Name	Sophie
	Full Name	Sophie Berry
	Position	Research Assistant
	Type	External
	AOU	
	Managing Unit	
	Email Address	Sophie.L.Berry@student.uts.edu.au
	Work Number	
6	Primary	Yes
	ID	101454
	Surname	Wootton
	Given Name	Bethany
	Full Name	A/Prof Bethany May Wootton
	Position	Chief Investigator

	Type	Internal
	AOU	GSH.Clinical Psychology
	Managing Unit	Faculty of Health
	Email Address	Bethany.Wootton@uts.edu.au
	Work Number	+61 2 95143942

If any details are incorrect or missing please contact the Ethics Secretariat on (02) 9514 9772 or by email.

The ResearchMaster database has a very large number of external personnel so please conduct a search for them before adding them in the text box below. Please contact the Ethics Secretariat on 9514 9772 if you cannot find an external investigator through the system.

External personnel listed on this ethics protocol:
*

1	Primary	No
	ID	148253
	Surname	Norton
	Given Name	Alice
	Full Name	Dr Alice Rosemarie Norton
	Position	3Assoc. Investigator
	Type	Honorary
	AOU	GSH.Graduate School of Health
	Managing Unit	Faculty of Health
	Email Address	Alice.Norton@uts.edu.au
	Work Number	

Please provide additional (or preferred) contact details of any of the people listed on the project if necessary (4000 character limit)

Principal Investigator:
A/Prof Bethany Wootton
Address: Discipline of Clinical Psychology. Graduate School of Health. PO Box 123. Broadway. NSW 2007.
Telephone: (02) 9514 3942/ 0428690393
Email: bethany.wootton@uts.edu.au

Associate Investigators:
Dr Alice Norton
Address: Clinical Psychology Unit, School of Psychology, The University of Sydney. Building M02F, The University of Sydney, NSW, 2006.
Telephone: 0415 500 577
Email: alice.norton@sydney.edu.au

Student (PhD) Investigators:
Halaina Winter (Student number: 14151981)
Address: Discipline of Clinical Psychology. Graduate School of Health. PO Box 123. Broadway. NSW 2007.
Telephone: 0433 401 346
Email: Halaina.Winter@student.uts.edu.au

Student (Master of Clinical Psychology) Clinicians:
Steven Passfield (Student number: 24420337)
Address: Discipline of Clinical Psychology. Graduate School of Health. PO Box 123. Broadway. NSW 2007.
Email: Steven.B.Passfield@student.uts.edu.au

Sylvia Steensma-Young (Student number: 24418980)
Address: Discipline of Clinical Psychology. Graduate School of Health. PO Box 123. Broadway. NSW 2007.
Email: Sylvia.Steensma-Young@student.uts.edu.au

Samantha Morgan-Basnett (Student number: 24521650)
Address: Discipline of Clinical Psychology. Graduate School of Health. PO Box 123. Broadway. NSW 2007.
Email: Samantha.Morgan-Basnett@student.uts.edu.au

Sophie Berry (Student number: 24511091)
Address: Discipline of Clinical Psychology. Graduate School of Health. PO Box 123. Broadway. NSW 2007.
Email: Sophie.L.Berry@student.uts.edu.au

Please provide details of any formal qualifications (REF NS 1.1(e)) of each person listed on the project (4000 character limit)*

A/Prof Bethany Wootton: PhD (Psychology), MCP (Clinical Psychology), BA
Dr Alice Norton: Doctor of Clinical Psychology, Doctor of Philosophy Psychology
Halaina Winter: Master of Clinical Psychology
Steven Passfield: Psychology Honours
Samantha Morgan-Basnett: Psychology Honours
Sylvia Steensma-Young: Psychology Honours
Sophie Berry: Psychology Honours

Please outline the experience of each person listed on this project relevant to this application (4000 character limit)*

A/Prof Bethany Wootton: Conducted extensive research trials examining anxiety and related disorders nationally and internationally, clinical psychologist and clinical psychology supervisor
Dr Alice Norton: Conducted research trials examining social anxiety disorder nationally, clinical psychologist and clinical psychology supervisor
Halaina Winter: Conducted meta-analysis and literature review of social anxiety disorder cognitive behaviour treatment, registered psychologist
Steven Passfield: Master of Clinical Psychology candidate
Samantha Morgan-Basnett: Master of Clinical Psychology candidate
Sylvia Steensma-Young: Master of Clinical Psychology candidate
Sophie Berry: Master of Clinical Psychology candidate

Primary AOU*

GSH.Graduate School of Health

Managing Unit

Faculty of Health

Please save and continue to the next page

Student details

We recommend you save your application regularly while editing. You can save your application at any time by clicking on the save button.
For further information and help in completing your application go to our website

Degree being undertaken (500 character limit)*

PhD (Clinical Psychology)

Have you been successful in your doctoral/masters assessment? *

- ○ Yes
- ◉ No

Please indicate why you are applying for ethics approval at this stage, and when you will be seeking assessment or re-assessment? (4000 character limit)*

Stage 1 assessment is scheduled for January 2023. Ethics application is being submitted in December 2022 to allow time for HREC approval which we hope will align with starting the project in early 2023.

Students, please read carefully: Once you have completed this application and followed the submission instructions, your application will go to your supervisor for review. Once your supervisor has reviewed and endorsed your application it will come to the Ethics Secretariat for a pre-review. This pre-review process helps ensure that your application is complete, has all necessary attachments, and that the quality of responses to the questions meets the Committee's expectations. Your application should therefore be submitted as early as possible. If you do not submit your application in time, it may be delayed and held off until the next closing date.

Section 4: Funding and Disclosure of interests

Funding details

We recommend you save your application regularly while editing. You can save your application at any time by clicking on the save button.
For further information and help in completing your application go to our website

Have you received funding in relation to this research?*

- ○ Yes
- ◉ No

Do you intend to apply for funding in the future?*

- ○ Yes
- ◉ No

Please save and continue to the next page

Disclosure of Interests

We recommend you save your application regularly while editing. You can save your application at any time by clicking on the save button.
For further information and help in completing your application go to our website

Do any members of the research team (including persons not listed in this application), have any financial or non-financial interests related to this research?*

- ○ Yes
- ◉ No

Please save and continue to the next page

Section 5: Methodology

Description

We recommend you save your application regularly while editing. You can save your application at any time by clicking on the save button.
For further information and help in completing your application go to our website

The purpose of this section is to place your research in context for the HREC and demonstrate your ability to conduct the research. The HREC may only approve research which is methodologically sound. Remember to use simple language that can be understood by people from a variety of backgrounds. Avoid jargon and acronyms.

What are the hypotheses/goals/aims/objectives of your research? Please include a brief description using plain English explaining your research aims (approximately 100 words) (4000 character limit)*

Primary
The primary objective of this program of research is to examine the acceptability and efficacy of videoconferencing delivered cognitive behavioural therapy for social anxiety disorder.

Secondary
The secondary objective of this research project is to 1) examine the efficacy of an imagery rescripting enhanced cognitive behavioural therapy intervention for individuals with SAD; 2) examine the psychometric properties of a number of self-report and clinical-administered tools; 3) examine predictors of treatment outcome; and 4) examine comorbidity and other clinical features in individuals with SAD.

Note: Clinical Trials, Recruitment of Participants and Data Collection are dealt with later in the application so you do not need to describe them in detail below

Please provide a brief description of the research design including research questions and proposed methods for conducting the research (approximately 250 words) (4000 character limit)*

Study design: A CONSORT-R compliant randomized controlled trial (RCTs) comparing an immediate treatment group with a waitlist control group will investigate the primary research question.
Planned sample size: 39 participants in each group, with a total of 78 included participants.
Study procedures: Participants will be recruited via a number of methods (described below). Participants will access the PICF via a link provided on these advertisements. Those who provide consent will progress through the following stage:
• Online screening to assess for key inclusion/exclusion criteria
• Screening to assess diagnostic status and remaining inclusion/exclusion criteria
• Those who are deemed eligible will be randomised to either immediate treatment or waitlist control (randomisation procedures described below).
• Participants in the immediate treatment group will complete baseline questionnaires before commencing treatment (8 sessions of remotely delivered cognitive-behaviour therapy; described below)
• Participants in the waitlist control group will receive treatment after an 8 week wait period. Participants in the waitlist control group will receive imagery rescripting enhanced cognitive behavioural therapy delivered via videoconferencing (8 sessions; described below).
• Participants will complete self-report measures at pre-treatment, mid-treatment, post-treatment and 3-month follow up.
• Participants' diagnostic status will be assessed at pre-treatment, post-treatment and 3-months follow up.

What do you hope the outcome(s) of this research will be? (4000 character limit)*

The aim of this research study is to examine the efficacy and acceptability of high intensity remote treatment for SAD. A CONSORT-R compliant 2-group randomized controlled trial (RCT) will investigate the research questions. It is hypothesized that:
1) High intensity remote CBT will be acceptable to individuals with SAD;
2) High intensity remote CBT will result in significant reductions in symptoms, resulting in large within-group and between-groups effect sizes at post-treatment and three-month follow up; and
3) Imagery rescripting enhanced CBT will result in improved symptom reduction.

Who do you think will benefit from this research? (4000 character limit)*

Social anxiety disorder (SAD) is characterised by a fear of social or performance situations and consequent avoidance behaviours (American Psychiatric Association, 2013). SAD is a common anxiety disorder with an estimated lifetime prevalence of 2.8-13.0% and a 12-month prevalence of 0.6-8.0% (Bruffaerts et al., 2022). The median age of onset of is 13 years (Andrews et al., 2018) and 80% of SAD cases will manifest by 20 years of age (Stein & Stein, 2008). Despite the high prevalence of SAD, approximately one-quarter (22.8%) of lifetime cases report receiving treatment specifically for their SAD symptoms (Bruffaerts et al., 2022). Left untreated, SAD has a chronic and debilitating course (Stein et al., 2017).
We expect that participants will experience a reduction in their psychological symptoms after completing the treatment because CBT is already an established treatment for SAD. However, we cannot guarantee or promise that participants will receive any benefit from participating.

Please provide a brief description of the significance of your research (approximately 100 words) (4000 character limit)*

Remote treatments do not require the clinician and the client to be in the same location and these interventions can be delivered in either a low intensity or high intensity fashion (Wootton, 2016). Low intensity remote treatments involve the client working through largely self-help materials either online or via a workbook, accompanied by brief clinician contact (i.e., 10 minutes per week). High intensity remote treatments involve using digital health technology to provide 'interactive' sessions that are delivered via internet videoconferencing. High intensity remote treatments have the same amount of contact and deliver the same content as a standard face-to-face session. While low intensity remote treatments have been demonstrated to be efficacious in the treatment of SAD (Carlbring et al., 2018; Guo et al., 2020) there is limited evidence examining high intensity remote treatments for this condition. The literature that does exist is currently of poor quality. Thus, the efficacy and acceptability of high intensity remote CBT for SAD still requires further investigation.
In addition to standard CBT, other adjunct treatments for SAD have recently been examined. Of particular note is Imagery Rescripting (ImR), which has been found to be efficacious in the reduction of SAD symptoms (Lloyd & Marczak, 2022; Romano et al., 2020; Takanashi et al., 2019). ImR targets psychological mechanisms that are hypothesised to maintain SAD symptoms, particularly negative core beliefs and self-imagery that can be notoriously difficult to change (Reimer & Moscovitch, 2015). ImR has been delivered as a standalone treatment (e.g. Brewin et al., 2009; Norton & Abbott, 2016; Wild et al., 2008) and an adjunct to CBT (e.g. Takanashi et al., 2019). The intervention has been found to be effective in as little as a single session (Knutsson et al., 2020; Norton & Abbott, 2016) and trialled in brief, manualised treatment settings of five to twelve sessions (Frets et al., 2014). To date, clinical trials of ImR have only examined the efficacy of the approach in face-to-face settings, and there are currently no known remote treatment studies for ImR. This study would be the first to examine the efficacy of ImR for SAD in remote treatment settings.

Please save and continue to the next page

Literature review & references

We recommend you save your application regularly while editing. You can save your application at any time by clicking on the save button.
For further information and help in completing your application go to our website

Please give a brief literature review. The aim is to explain how your research fits into the context of other research in the area (REF NS 1.1(c)) (4000 character limit with spaces)
Please note that you cannot paste links into the online form
*

Social anxiety disorder (SAD) is characterised by a fear of social or performance situations and consequent avoidance behaviours (American Psychiatric Association, 2013). SAD is a common anxiety disorder with an estimated lifetime prevalence of 2.8-13.0% and a 12-month prevalence of 0.6-8.0% (Bruffaerts et al., 2022). The median age of onset of is 13 years (Andrews et al., 2018) and 80% of SAD cases will manifest by 20 years of age (Stein & Stein, 2008). Despite the high prevalence of SAD, approximately one-quarter (22.8%) of lifetime cases report receiving treatment specifically for their SAD symptoms (Bruffaerts et al., 2022). Left untreated, SAD has a chronic and debilitating course (Stein et al., 2017).
Cognitive behaviour therapy (CBT) is a first-line treatment for SAD (APS, 2018; NICE, 2013). CBT for SAD typically includes strategies such as in-vivo exposure to address avoidance behaviours and cognitive strategies to address maladaptive automatic thoughts and core beliefs (Hofmann & Otto, 2018; Rodebaugh et al., 2004). Multiple meta-analyses demonstrate the efficacy of this treatment approach in a face-to-face settings, however consumers face numerous logistical and psychological barriers to accessing treatment. Logistical barriers include clinician shortages, long waitlists, financial barriers, and access to childcare (Shim et al., 2017). Further, psychological barriers reduce willingness to seek treatment due to the anxiety of in-person interactions that result in fear, shame and social stigma (Arditte et al., 2016; Olfson et al., 2000; Swee et al., 2021). Providing CBT remotely offers possible solutions to these barriers as it minimizes exposure to intensely anxiety-provoking experiences such as the necessary interactions that occur when attending a clinical service.
Remote treatments do not require the clinician and the client to be in the same location and these interventions can be delivered in either a low intensity or high intensity fashion (Wootton, 2016). Low intensity remote treatments involve the client working through largely self-help materials either online or via a workbook, accompanied by brief clinician contact (i.e., 10 minutes per week). High intensity remote treatments involve using digital health technology to provide 'interactive' sessions that are delivered via internet videoconferencing. High intensity remote treatments have the same amount of contact and deliver the same content as a standard face-to-face session. While low intensity remote treatments have been demonstrated to be efficacious in the treatment of SAD (Carlbring et al., 2018; Guo et al., 2020) there is limited evidence examining high intensity remote treatments for this condition. The literature that does exist is currently of poor quality. Thus, the efficacy and acceptability of high intensity remote CBT for SAD still requires further investigation.

In addition to standard CBT, other adjunct treatments for SAD have recently been examined. Of particular note is Imagery Rescripting (ImR), which has been found to be efficacious in the reduction of SAD symptoms (Lloyd & Marczak, 2022; Romano et al., 2020; Takanashi et al., 2019). ImR targets psychological mechanisms that are hypothesised to maintain SAD symptoms, particularly negative core beliefs and self-imagery that can be notoriously difficult to change (Reimer & Moscovitch, 2015). ImR has been delivered as a standalone treatment (e.g. Brewin et al., 2009; Norton & Abbott, 2016; Wild et al., 2008) and an adjunct to CBT (e.g. Takanashi et al., 2019). The intervention has been found to be effective in as little as a single session (Knutsson et al., 2020; Norton & Abbott, 2016) and trialled in brief, manualised treatment settings of five to twelve sessions (Frets et al., 2014). To date, clinical trials of ImR have only examined the efficacy of the approach in face-to-face settings, and there are currently no known remote treatment studies for ImR.

Please list the references only used in the literature review and cited in your application
NOTE: Do not include references you have not used in this application (4000 character limit)
*

American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders (5th ed.)
Andrews, G., et al. (2018). Royal Australian and New Zealand College of Psychiatrists clinical practice guidelines for the treatment of panic disorder, social anxiety disorder and generalised anxiety disorder. Australian and New Zealand Journal of Psychiatry, 52(12), 1109–1172
Arditte, K. A., et al. (2016). Interpersonal risk for suicide in social anxiety: The roles of shame and depression. Psychiatry Research, 239, 139–144
Australian Psychological Society. (2018). Evidence-based psychological interventions in the treatment of mental disorders: A review of the literature. In Australian Psychological Society (4th ed.)
Brewin, C. R., et al. (2009). Imagery rescripting as a brief stand-alone treatment for depressed patients with intrusive memories. Behaviour Research and Therapy, 47(7), 569–576
Bruffaerts, R., et al. (2022). Perceived helpfulness of treatment for social anxiety disorder: findings from the WHO World Mental Health Surveys. Social Psychiatry and Psychiatric Epidemiology, 57(10), 2079–2095
Carlbring, P., et al. (2018). Internet-based vs. face-to-face cognitive behavior therapy for psychiatric and somatic disorders: an updated systematic review and meta-analysis. Cognitive Behaviour Therapy, 47(1), 1–18
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Methods and methodologies

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For further information and help in completing your application go to our website

In order to consider your research, the HREC will need to know what it will involve for your participants (REF NS 3.1)

What kinds of methods and methodologies will you use in your research? (More than one box may be checked)*

- [x] Quantitative
- [ ] Qualitative

Does your research involve collection and/or use of secondary data? (e.g. existing / routinely collected data etc.)*

- ( ) Yes
- (•) No

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Quantitative

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Section 1: Quantitative Methodologies*

- [x] Experimental
- [ ] Quasi-experimental
- [ ] Correlational research
- [ ] Survey Design
- [ ] Meta analysis
- [ ] Other *(Please describe below)

Section 2: Quantitative methods*

- [ ] Written survey
- [x] Online survey/research
- [x] Pre-post/testing
- [ ] Telephone survey
- [x] Questionnaires
- [ ] Access to records
- [x] Clinical trial
- [x] Statistical analysis
- [ ] Content analysis
- [ ] Physiological testing/assessment
- [ ] Other* (please describe below)

What **quantitative** methodology and methods will you be using in this research? More than one box may be checked.

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Section 6: Research participants/subjects part 1

Participant involvement

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What time commitment will the research involve for your participants?
NOTE: This information must be included in any information to participants
(4000 character limit)*

Online questionnaire: 30 minutes
Diagnostic interview pre treatment: 1-2 hours (dependent on each participant)
Treatment: 8 weekly (50-60 minute) sessions
Online questionnaires at 4 time-points throughout study: 20 minutes each
Diagnostic interview post treatment: 20 minutes

In what location will the research/data collection take place?
NOTE: This information must be included in any information to participants
(4000 character limit)*

All research components will be conducted online via internet-videoconferencing or online survey, or via telephone.
Data safety will comply with the National Statement on Ethical Conduct in Human Research. All electronic data will be de-identified and stored in a password protected Microsoft Excel spreadsheet on password protected and restricted-access UTS network drive. Only researchers listed on this protocol will have access to the data. Once data have been collected and analysed they will be stored on STASH in a de-identifiable manner and made available to other external researchers as requested in the spirit of open science. All hardcopy data will be kept in a locked filing cabinet in A/Prof Wootton's locked office at UTS. Electronic and hardcopy data will be destroyed 15 years after the final publication from this dataset.

What travel, if any, does the research involve for your participants?
NOTE: This information must be included in any information to participants
(4000 character limit)*

Nil travel.

Please include any additional information relating to participants that you think relevant
NOTE: This information must be included in any information to participants
(4000 character limit)*

Whilst participating in this research project, participants may not engage in other regular psychological treatment. It is important they tell the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. Participants should also tell study staff about any changes to these during your participation in the research project.

Describe and justify any benefit, payment or compensation the participants will receive. For research being conducted with Aboriginal and Torres Strait Islander People, the described benefits from research should have been discussed with and agreed to by the Aboriginal or Torres Strait Islander research stakeholders. (REF NS 2.1) and 4.7.8 & 4.7.9)
(4000 character limit)*

We expect that participants will experience a reduction in their psychological symptoms after completing the treatment because CBT is already an established treatment for SAD. However, we cannot guarantee or promise that you will receive any benefit from participating.

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Recruitment of participants

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In line with the National Statement, the definition of participants includes not only those humans who are the primary focus of the research but also those who will be affected by the research. The HREC regards the principle of respect for persons as of paramount importance. (REF NS 1.1 (d), 1.6-1.9, 1.10, 2.1).

How will you initially select and contact your participants? More than one box may be checked, if appropriate*

- ☑ Advertisement/flyer
- ☑ E-mail
- ☐ Telephone
- ☑ Internet
- ☑ Organisation
- ☑ Personal contact
- ☐ Letter
- ☑ Other contact method to be used

Please describe what other method you will use for recruitment*

Paid google advertisements

Outline how you will obtain participants' contact details*

Potential participants will read about the study on the study website or through other recruitment sources. They will then progress through stages.
Interested applicants will be directed to a study REDCAP link to read the online Participant Information and Consent Form (PICF). Consenting participants will then complete the demographic form, the DIAMOND screener, symptom screeners, and will provide their name, email address, and phone number for the clinician to contact them to conduct the diagnostic interview via videoconferencing. Participants will also be asked to indicate their preferences for days/times for the diagnostic screening (Appendix H). We anticipate that it will take participants 30 minutes to complete this section of the study.
Participants who do not meet study criteria at this stage will be taken to the end of the survey and will be provided with information on how to access support services, including crisis services. Non-eligible participants will also be informed if they likely meet criteria for one of the disorders and will be encouraged to access support from their GP or other appropriate services (Appendix H).

Please describe your recruitment plan/strategy*

The study will be advertised via social media advertising on Facebook, LinkedIn, and Instagram (Appendix A) and Twitter (Appendix B), via email on professional networking sites (e.g., large list serves of national psychologists), as well as direct email/letter to community based clinicians, general practitioners, and psychiatrists (Appendix C). Hardcopy flyers will be posted on community noticeboards (including on the UTS campus) (Appendix D) and applications will be made to have the study advertised on pages advertising for research participants of relevant not-for-profit websites/social media pages, such as SANE Australia (https://www.sane.org/adrc/external-research-projects) and One Door Mental Health (https://www.onedoor.org.au/research/research-participants-wanted) (Appendix E). Social media posts will be made on the research team's professional social media accounts and the moderators of relevant social media sites (i.e., educational or support groups for people with anxiety and related disorders) will also be approached to post the approved script. Agreement from all moderators will be obtained prior to posting on their social media group page. Periodically, paid Google Advertisements will also be posted (Appendix F). Participants may also be recruited from other MREC approved studies. For instance, individuals who did not meet criteria for a similar study because they have a different primary mental health condition (i.e. SAD), or individuals who have completed treatment in another MREC approved study, but also meet criteria for SAD (Appendix G). These individuals will be given the link for the PICF and can decide whether the study meets their needs.

How many participants do you intend to recruit? (If you are intending to recruit different groups of participants, please answer all relevant questions for each group, e.g. control group, test group, etc) (4000 character limit)*

Group 1 (n = 39): Immediate treatment group. Group 1 will receive immediate access to a manualised high intensity cognitive-behavioural therapy. The remote treatment will be delivered via online teleconferencing equipment (Zoom or Teams). Participants in Group 1 will be seen for one 50-minute session per week for a period of 8 weeks.

Group 2 (n = 39): Waitlist control group. Group 2 will commence the treatment after Group 1 has completed the treatment (Week 9). Once Group 1 has completed the treatment, Group 2 will receive a similar treatment, however this treatment will also include an imagery rescripting module.

Explain how and why you have chosen this number. If the research is quantitative, explain the power calculations; if the research is qualitative, explain why the proposed number is likely to result in adequate data based on evidence/literature. For guidance, check our Fact Sheets.*

With alpha set at 0.05, power set at 0.80 and a sample size of 39 in each group, the study is powered to enable the detection of large effect size (i.e., Hedge's g = 0.08) differences in symptoms, which would be the minimum expected reduction in the RCT based on existing research (Clark et al., 2006). Therefore we will recruit 39 individuals in the immediate treatment group and 39 individuals in the waitlist control group. Thus the total N for the study is 78.

Describe your inclusion and exclusion criteria for participants*

Inclusion criteria includes: (1) Currently residing in Australia;
(2) Aged 18+ years; (3) Fluent in English; (4) Meets criteria for social anxiety disorder as primary and the disorder is of at least 'moderate severity' (defined as a score of 4 on the DIAMOND module severity measure); (5) Medication free or on a stable dose of psychotropic medication; and (6) Not currently receiving regular psychological services for their social anxiety disorder symptoms (defined as sessions at least once a week with a qualified mental health professional)

Exclusion criteria: (1) Severe depressive symptoms as assessed by a score of 20 or above on the PHQ-9; (2) Suicide risk as assessed by a score of '2' (more than half the days) or higher on item 9 of the PHQ-9 on the screening questions or via clinician judgement during the diagnostic interview using the C-SSRS; (3) Daily alcohol use or daily illicit drug use; (4) The presence of a schizophrenia spectrum disorder as assessed by the DIAMOND; (5) Significant cognitive/intellectual impairment as assessed during the diagnostic interview; (6) A medical condition that may interfere with treatment; (7) Does not have access to a computer with a camera and stable internet on a regular basis; and (8) Is not willing to engage in treatment using internet-videoconferencing software

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Consent

We recommend you save your application regularly while editing. You can save your application at any time by clicking on the save button.
For further information and help in completing your application go to our website

Will you be obtaining written consent?*

- ○ Yes
- ◉ No

Please explain why and describe how you will obtain and record consent (4000 character limit)*

We will ask participants to consent to the research and indicate their consent by ticking a box that states that they consent. Ongoing involvement in the treatment is also considered to be an indication of ongoing consent.

Written consent is not practical in this study because of the remote nature of the study.

Do you believe there will be any special issues relating to consent in your research? (REF NS 1.13, 2.2, 2.3, Chapter 4)*

- ○ Yes
- ◉ No

Are the participants able to consent fully? (REF NS Chapter 2, 4.4, 4.5)*

- ◉ Yes
- ○ No

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Clinical trials

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You have indicated in the Methodology section that your research involves a clinical trial.
If your research does not involve a clinical trial, you will need to change your answer on Quantitative page

You should be familiar with Chapter 3.3 (Interventions and Therapies, including Clinical and Non-Clinical Trials, and Innovations) of the National Statement on Ethical Conduct in Research Involving Humans. Your research must conform to the National Statement and other relevant documents. (REF NS 3.3)

Please note that clinical trials applications must include the clinical trials SOPs and templates as per the UTS HREC website. Please contact the Ethics Secretariat for more information on 9514 9772.

Do you plan to use any drugs, devices or preventative procedures in this research? *

- ○ Yes
- ◉ No

Is the research being conducted under the Clinical Trial Notification (CTN) Scheme?*

- ○ Yes
- ◉ No

Is the research being conducted under the Clinical Trial Exemption (CTX) Scheme?*

- ○ Yes
- ◉ No

Is this research being conducted on behalf of or in conjunction with another institution? *

- ○ Yes
- ◉ No

Has this research been approved by another accredited Human Research Ethics Committee?*

- ○ Yes
- ◉ No

Provide details of how you intend to carry out the research, including dosing regime or other relevant information (4000 character limit)*

Treatment will generally be provided to participants by a different student to the one who completed the assessment.

Treatment will follow a manualized CBT intervention based on the Rapee and Heimberg (1997) CBT model of SAD. The treatment has been found to be effective in previous clinical trials for SAD (Wootton et al., 2018). This treatment does not differ significantly from standard/traditional care apart from the fact that it will be delivered in a remote fashion via videoconferencing software (rather than face-to-face). Videoconferencing delivered treatment has however been standard practice for many clinicians over the last 30 months due to the COVID-19 pandemic.

The treatment for the immediate treatment group (Group 1) will comprise five modules delivered over 50 minute weekly appointments over eight weeks and will cover: 1) psychoeducation on the symptoms of SAD and the principles of CBT (1 session), 2) challenging automatic thoughts (2 sessions), 3) challenging core beliefs (1 session), 4) exposure (3 sessions), and 5) relapse prevention/consolidation (1 session) (Appendix L). Participants will also be required to complete homework tasks between sessions (as is standard practice in CBT). As treatment for Group 1 concludes, the control group will receive an imagery rescripting based treatment. The intervention will still consist of 8 weekly 50-60 minute sessions but will include 4 modules: 1) psychoeducation on the symptoms of SAD, assessment of images/memories, and formulation (1 session), 2) identification and exploration of core beliefs using the imagery interview (1 session), 3) imagery rescripting (5 sessions), and 4) relapse prevention/consolidation (1 session) (Appendix M). Imagery ratings, memory ratings and core belief ratings will be taken at the start and end of each session.

The treatment will be delivered by registered and provisionally registered psychologist(s) under the supervision of a registered psychologist (A/Prof Wootton, Dr Norton, Ms Winter). These provisionally registered psychologists are UTS Master of Clinical Psychology students who will count the hours obtained from the assessment and treatment of these participants as part of their clinical placement hours. As new provisionally registered psychologists commence the program the MREC will be informed via an amendment. All new clinicians providing the treatment will receive a training session delivered by Ms Winter. Treatment sessions will be recorded to ensure treatment fidelity and a minimum of 10% of these sessions will be reviewed by the chief investigator/associate investigator.

At post-treatment and three month follow up participants will receive feedback on their progress either in writing via email or in person. Those participants who do not respond will be encouraged to consult with their General Practitioner who will be able to refer on to local treatment options.

Provide details of how you intend to monitor the effects of the research on participants, including possible side effects (4000 character limit)*

Regular team meetings are conducted between clinicians and supervisors and treatment integrity is monitored by registered psychologists. Participants are monitored regularly throughout treatment during their treatment sessions and via self-report questionnaires. The Chief Investigator and Student Investigator have completed the good clinical practice training at UTS. Any serious adverse events identified by the team will be reported to the MREC via SAE documentation and emails.

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Limited disclosure

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Does this research involve limited disclosure to participants? (REF NS 2.3)*

- ○ Yes
- ◉ No

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Ethical considerations specific to participants

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Indicate if your research will involve the following populations (as per the National Statement) other than as incidental participants (i.e. they are not included in the design of the project but may be participants) (REF NS Chapter 4) *

- ☐ Women who are pregnant and the human foetus
- ☐ Children and young people
- ☐ People in dependent or unequal relationships
- ☐ People highly dependent upon medical care who may be unable to give consent
- ☑ People with a cognitive impairment, an intellectual disability or a mental illness
- ☐ People who may be involved in illegal activities
- ☐ People who are incarcerated
- ☐ Aboriginal and Torres Strait Islander Peoples
- ☐ People in other countries
- ☐ None of the above

Describe how you will respect the ethical considerations specific to your participants, in accordance with Chapter 4 of the National Statement (4000 character limit)*

SAD is a common mental health condition in Australia. We will respect the ethical considerations specific to people with a mental illness as follows.
- Participants are able to fully consent to the research after reading the participant information and consent form, which clearly outlines, using layperson language, what is involved in the research.
- Participants are provided with the contact details of the Chief Investigator and are encouraged to contact them should they have any questions about the research.
- Individuals who are at risk of suicide or who have very high levels of comorbid depressive symptoms will not be eligible for the study.
- While it is unlikely due to the nature of the conditions being studied, individuals who are not able to provide informed consent because of their impairment will not be able to take part in the study.
- The treatment involved is not experimental - thus the risks are reduced. Cognitive behaviour therapy is an established and widely used treatment for GAD. Imagery rescripting is an emerging treatment for SAD. We are only examining the acceptability and efficacy of an alternative format for delivery of the treatment.
- Participants are able to withdraw from the research at any time without penalty.

If your research is being conducted in Australia, does it involve Culturally and Linguistically Diverse (CALD) People (other than incidentally)?*

- ○ Yes
- ◉ No

Does your research involve Defence or the Department of Veteran Affairs in any way?*

- ○ Yes
- ◉ No

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Section 7: Research participants/subjects part 2

Risk/harm

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Risk or harm could be described as damage or hurt to the wellbeing, interests or welfare of an individual, institution or group. Harm could range from physical hurt or damage such as illness or injury, to psychological or emotional hurt or damage, such as embarrassment or distress.
Please note that as a researcher, you are not necessarily immune from risk yourself and should give careful consideration to this question (REF NS 2.1).

NOTE:
It is **really** important that you carefully consider all ***potential*** risks that could occur, even if they seem negligible.
Please **do not** provide one-word answers to any of the questions below.
Describe, as best as you can, any possible risks to research participants, subjects and related groups
NOTE: This information must be included in any information to participants (4000 character limit)*

It is possible that some individuals may experience a short term increase in anxiety or sadness when completing the questionnaires, participating in the assessment process, or during the treatment. This increase is likely only temporary and diminishes as treatment progresses. Any potential increase in symptoms is likely to be minimal.

Importantly, if a participant becomes distressed or concerned about their symptoms, they are encouraged in the PICF and in sessions to speak about these issues with their General Practitioner, who will be able to assist them with finding local treatment options. Participants are also welcome to withdraw from the research at any time if they do not wish to continue.

Participants who identify as a suicide risk during screening or clinician judgement during the diagnostic interview will be excluded from the study.

How would you categorise the magnitude of potential risk? (e.g. inconvenience, discomfort, harmful, painful)
Explain why you believe this is so (4000 character limit)*

Discomfort.
Our priority is to support participants to stay safe and to maximise their emotional wellbeing. In the unlikely event that someone is distressed or requires psychiatric attention the investigators are mental health clinicians who will be able to assess the situation and refer the person to their primary physician or emergency services as needed. It is important to note that almost all individuals presenting for treatment with anxiety and related conditions have experienced symptoms of their disorder for several years and in that time have consulted numerous medical and mental health practitioners and have exhausted all available treatment options.

NOTE: All participants are provided with information about what to do and which services they can contact in the event of a mental health crisis at multiple times. For example, this information is provided: (1) in the PICF, (2) on the self-report questionnaires; (3) in every email sent to participants. Clinicians will also monitor risk of suicide and self-harm during the treatment sessions.

How would you categorise the likelihood of risk? (i.e. slight, possible, likely, probable, unavoidable)
Explain why you believe this is so (4000 characters)*

We expect that the likelihood of risk is 'possible'. It is possible that participants may experience increased anxiety, but this is usually minor and short-lived once the participant progresses further in the treatment.

What strategies will you use to minimise and/or manage the risks? (4000 character limit)*

Risk management will occur throughout the project. All participants will be made aware of the steps they can take in a mental health emergency, and participants' responses to the questionnaires will be monitored. Consistently elevated or deteriorating symptoms will trigger contact from the research team encouraging people to contact their health professionals or emergency services. All communications with participants will be documented.

Discuss likely or possible risk to researchers (including yourself), and your strategies for minimising such risks (4000 character limit)*

We do not anticipate any risks to researchers as this is a remotely delivered intervention. All researchers are psychologists, or psychologists in training, who are accustomed to working with individuals with mental health disorders.
Researchers will be provided supervision onsite throughout all stages of research. Weekly team meetings and scheduled supervision will be provided to all researchers throughout the research.

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Pre-existing relationships

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Are there likely to be any pre-existing relationships with research participants? (e.g. employer/employee, colleague, friend, relation, student/teacher, etc) (REF NS 4.3)*

- ○ Yes
- ◉ No

Will you be recruiting UTS staff and/or students as research participants?*

- ○ Yes
- ◉ No

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External organisations

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Indicate if your research will involve any of the following:*

- ☐ Institution
- ☐ Organisation
- ☐ Community Group
- ☑ None of the above

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Section 8: Data

Data collection & use

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Does your research involve access to student records at this University?*

- ○ Yes
- ◉ No

Provide an analysis plan outlining how the aims/objectives will be met, the statistical methods to be used, and who will be carrying out the analysis. *

The main analyses looking at treatment outcomes from the RCT will be carried out using conservative intention-to-treat principles and using mixed-linear models analyses to handle missing data. Mixed-models are a robust statistical approach for analysing longitudinal clinical trial data and these analyses will employ an appropriate covariance structure and maximum likelihood estimation, which provides unbiased estimates in the case of missing data; under the assumption that data is missing at random.
The analyses will be conducted by Halaina Winter under the supervision of A/Prof Wootton.

Describe any foreseeable future use of this data; such as sharing with other researchers, secondary use for related research, publishing for unrelated research and non-research purposes and any other possible uses. Please note this information must be included in the participant information sheet.*

Other appropriate analyses arising from secondary papers from this dataset will also be conducted. These may include investigating the psychometric properties of various measures included in the research program, investigating predictors of outcome, and examining clinical features of each diagnostic group. Participants have been informed in the PICF that other secondary data analyses will be conducted on the data that they provide during their participation in the research trial. Comparisons between the standard treatment and the imagery rescripting enhanced protocol will be compared using benchmarking analyses (Minami et al., 2008).

Do you have a research data management plan?*

- ◉ Yes
- ○ No

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Section 9: Additional information

Other ethical issues

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If there are any additional ethical issues which you do not believe have been covered by this form,
please explain them for the HREC: (4000 character limit)*

No

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Section 10: Attachments

Attachments

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I have attached the following supporting documents

Sample research advertisement/announcement

- ◉ Yes
- ○ N/A

Participant Information Sheet(s)*

- ◉ Yes
- ○ No

Evidence of approval from the Therapeutic Goods Administration (TGA)*

- ○ Yes
- ◉ N/A

Explanations of any technical terms used *

- ○ Yes
- ◉ N/A

Research data management plan (RDMP)*

- ◉ Yes
- ○ No

Standard Operating Procedures

N.B. May include a distress or disclosure protocol [see UTS HREC Disclosure Guidelines under University policies and guidelines], Faculty of Health - Low Risk protocol; procedures for participant screening, physiological, or biological sampling and/or laboratory or safety procedures where relevant.

*

- ◉ Yes
- ○ No

Please explain why any of the above items have not been attached (either softcopy/hardcopy) and when they will be provided (4000 character limit)*

All required items have been attached in soft copy.

Documents attached to this application:

How to attach documents

1. Click on 'Add'
   Ensure the fields are as follows:
   - Document type- soft copy
   - Name: Include the document name and version number
   - Description: This field is optional
2. You can then either select the file you want to upload OR drag and drop it where it says 'Drop file here'
3. Click on 'OK'

Note: Please use the following HREC templates when creating an information sheet, consent form, verbal script, etc.: HREC templates. All submitted documents should be titled, and have have version control included in the footer.*

1	Document type	Soft copy
	Name	Research Data Management Plan - SAD_V1.0
	Reference (Document Title)	Research Data Management Plan - SAD_V1.0.pdf
	Description	
2	Document type	Soft copy
	Name	PICF V1.0
	Reference (Document Title)	SAD PICF-interventional_V1.0.doc
	Description	
3	Document type	Soft copy
	Name	Protocol V1.0
	Reference (Document Title)	SAD Protocol_V1.0.docx
	Description	
4	Document type	Soft copy
	Name	Appendix
	Reference (Document Title)	SAD Appendix_V1.0.docx
	Description	
5	Document type	Soft copy
	Name	ETH22-7803 - WOOTTON (for WINTER) - MREC outcome and comments
	Reference (Document Title)	ETH22-7803 - WOOTTON (for WINTER) - MREC outcome and comments.docx
	Description	
6	Document type	Soft copy
	Name	Response to MREC comments
	Reference (Document Title)	ETH22-7803 - WOOTTON (for WINTER) - MREC outcome and comments 2023 03 04_BW.docx
	Description	
7	Document type	Soft copy
	Name	PICF (Version 1.1)
	Reference (Document Title)	SAD PICF-interventional_V1.1 10.03.2023_BW.doc
	Description	
8	Document type	Soft copy
	Name	Redcap questionnaires
	Reference (Document Title)	SAD - RedCap Questionnaires Complete.pdf
	Description	
9	Document type	Soft copy
	Name	Revised protocol (v1.1)
	Reference (Document Title)	SAD Protocol_V1.1 09.03.2023_BW.docx
	Description	

Reminder to student applicants:

1. Please note that once your application is submitted it will go directly to your supervisor and not to the Committee.
2. We **strongly** recommend notifying your supervisor that you have submitted your application in case of any technical issues, to avoid potential delays in the review process.
3. Once your supervisor endorses your application it will go to your Local Research Office for endorsement before coming to the Ethics Secretariat for review.
4. Your electronic application must be endorsed by your supervisor by the Local Research Office (LRO) submission deadline.
5. Please also ensure that the Primary AOU listed at the end of the Investigators page is updated to your supervisor's AOU. This will show in the table under 'Internal personnel listed below', once you add them. If you need any assistance with this please contact Research.Ethics@uts.edu.au or call 9514 9772. Please note that this is particularly important if you have a dual role as a staff/student as your application could go to the wrong faculty for review through the automated process.

Declaration

Declaration

I have answered all questions in the risk assessment truly and completely to the best of my knowledge

I will notify the UTS Human Research Ethics Committee of any variation to this research that may alter the level of risk associated with it

This research will be undertaken in compliance with the UTS Research Policy or any replacement or amendment thereof

This research will be undertaken in compliance with the Australian Code for the Responsible Conduct of Research and National Statement on Ethical Conduct in Human Research

Please click on the "Submit" button in the Actions menu.

Confirmation

Confirmation by Local Research Office High Risk

Application type*

Research (student project)

Internal personnel listed on this ethics protocol*

1	Primary	No
	ID	14151981
	Surname	Winter
	Given Name	Halaina
	Full Name	Mrs Halaina Rose-Anne Joy Winter
	Position	5Research Student
	Type	Domestic
	AOU	GSH.Graduate School of Health
	Managing Unit	Faculty of Health
	Email Address	Halaina.Winter@student.uts.edu.au
	Work Number	
2	Primary	No
	ID	PER0137356
	Surname	Passfield
	Given Name	Steven
	Full Name	Steven Passfield
	Position	Research Assistant
	Type	External
	AOU	
	Managing Unit	
	Email Address	Steven.B.Passfield@student.uts.edu.au
	Work Number	
3	Primary	No
	ID	PER0159014
	Surname	Steensma-Young
	Given Name	Sylvia
	Full Name	Ms Sylvia Steensma-Young
	Position	Research Assistant
	Type	Not Specified
	AOU	
	Managing Unit	
	Email Address	Sylvia.Steensma-Young@student.uts.edu.au
	Work Number	
4	Primary	No
	ID	PER0137379
	Surname	Morgan-Basnett

	Given Name	Samantha
	Full Name	Samantha Morgan-Basnett
	Position	Research Assistant
	Type	External
	AOU	
	Managing Unit	
	Email Address	Samantha.Morgan-Basnett@student.uts.edu.au
	Work Number	
5	Primary	No
	ID	PER0137389
	Surname	Berry
	Given Name	Sophie
	Full Name	Sophie Berry
	Position	Research Assistant
	Type	External
	AOU	
	Managing Unit	
	Email Address	Sophie.L.Berry@student.uts.edu.au
	Work Number	
6	Primary	Yes
	ID	101454
	Surname	Wootton
	Given Name	Bethany
	Full Name	A/Prof Bethany May Wootton
	Position	Chief Investigator
	Type	Internal
	AOU	GSH.Clinical Psychology
	Managing Unit	Faculty of Health
	Email Address	Bethany.Wootton@uts.edu.au
	Work Number	+61 2 95143942

External personnel listed on this ethics protocol*

1	Primary	No
	ID	148253
	Surname	Norton
	Given Name	Alice
	Full Name	Dr Alice Rosemarie Norton
	Position	3Assoc. Investigator
	Type	Honorary
	AOU	GSH.Graduate School of Health
	Managing Unit	Faculty of Health
	Email Address	Alice.Norton@uts.edu.au
	Work Number	

Checked by:*

Ed Dharmadji

Date of review:*

23/12/2022

The Local Research Office has confirmed that: All information in this application and supporting documentation is correct and as complete as possible *

◉ Yes
○ No

Confirmation by ADR

Application type

Human

Internal personnel listed on this ethics protocol

1	Primary	No
	ID	14151981
	Surname	Winter
	Given Name	Halaina
	Full Name	Mrs Halaina Rose-Anne Joy Winter
	Position	5Research Student
	Type	Domestic
	AOU	GSH.Graduate School of Health
	Managing Unit	Faculty of Health
	Email Address	Halaina.Winter@student.uts.edu.au
	Work Number	
2	Primary	No
	ID	PER0137356
	Surname	Passfield
	Given Name	Steven
	Full Name	Steven Passfield
	Position	Research Assistant
	Type	External
	AOU	
	Managing Unit	
	Email Address	Steven.B.Passfield@student.uts.edu.au
	Work Number	
3	Primary	No
	ID	PER0159014
	Surname	Steensma-Young
	Given Name	Sylvia
	Full Name	Ms Sylvia Steensma-Young
	Position	Research Assistant
	Type	Not Specified
	AOU	
	Managing Unit	
	Email Address	Sylvia.Steensma-Young@student.uts.edu.au
	Work Number	
4	Primary	No
	ID	PER0137379
	Surname	Morgan-Basnett
	Given Name	Samantha
	Full Name	Samantha Morgan-Basnett
	Position	Research Assistant
	Type	External
	AOU	
	Managing Unit	
	Email Address	Samantha.Morgan-Basnett@student.uts.edu.au

	Work Number	
5	Primary	No
	ID	PER0137389
	Surname	Berry
	Given Name	Sophie
	Full Name	Sophie Berry
	Position	Research Assistant
	Type	External
	AOU	
	Managing Unit	
	Email Address	Sophie.L.Berry@student.uts.edu.au
	Work Number	
6	Primary	Yes
	ID	101454
	Surname	Wootton
	Given Name	Bethany
	Full Name	A/Prof Bethany May Wootton
	Position	Chief Investigator
	Type	Internal
	AOU	GSH.Clinical Psychology
	Managing Unit	Faculty of Health
	Email Address	Bethany.Wootton@uts.edu.au
	Work Number	+61 2 95143942

External personnel listed on this ethics protocol

1	Primary	No
	ID	148253
	Surname	Norton
	Given Name	Alice
	Full Name	Dr Alice Rosemarie Norton
	Position	3Assoc. Investigator
	Type	Honorary
	AOU	GSH.Graduate School of Health
	Managing Unit	Faculty of Health
	Email Address	Alice.Norton@uts.edu.au
	Work Number	

Date of LRO review

23/12/2022

Declaration:

- I am aware that this research is being conducted within this Faculty/School/Centre.
- I am satisfied that the researchers have met all Faculty/School/Centre requirements in relation to this research
- This research will be undertaken in compliance with the UTS Research Ethics and Integrity Policy or any replacement or amendment thereof
- This research will be undertaken in compliance with the Australian Code for the Responsible Conduct of Research and National Statement on Ethical Conduct in Human Research

*

◉ Yes
○ No

Comments

Suitable for review by MREC

Research Office use only

Research Office use only

Application Status

Approved

Approval Purpose

Research (student project)

Current Committee

0Health and Medical Research Ethics Committee (Human)

TRIM number

RES23/5

Date received

16/01/2023

Date Reviewed

16/02/2023

Date Approved

28/03/2023

Start date

28/03/2023

End date

28/03/2028

Date Withdrawn

This question is not answered.

Special conditions

n/a