**Assessment and Remote Treatment of Social Anxiety Disorder**

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**Summary**

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| **Study title** | Assessment and Remote Treatment of Social Anxiety Disorder |
| **Protocol version** | 1.1 |
| **Objectives** | **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. |
| **Study design** | A CONSORT-R compliant randomized controlled trial (RCT) 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. |
| **Selection criteria** | 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 |
| **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. |
| **Statistical considerations** | **Sample size calculation**  Using the sample size calculator developed by Westfall et al. (2014), which is used to calculate effect sizes for mixed linear models, a sample size of 39 in each group (78 participants in total) is sufficient to detect a large effect (*d*  = .80) with power set at 0.8. An effect size of .80 would be the minimum expected reduction in symptoms based on existing research. Therefore we will recruit 39 individuals in the immediate treatment group and 39 individuals in the waitlist control group (total number of included participants will be 78).  **Analysis plan**  The main analyses 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. |
| **Study duration** | 5 years |

**BACKGROUND**

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 (Australian Psychological Society, 2018; National Institute for Health and Care Excellence, 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.

**OBJECTIVES, DESIGN, AND HYPOTHESES**

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 over traditional CBT.

**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.

**PARTICIPANT NUMBERS & POWER**

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.

**PARTICIPANT RECRUITMENT**

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 (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 sent the link for the PICF via email and can decide whether the study meets their needs.

**STUDY PROCEDURES**

Potential participants will read about the study on the study website (<https://www.uts.edu.au/about/graduate-school-health/clinical-psychology/what-we-do/clinical-psychology-research/telepsych-laboratory>) or through other recruitment sources (described above). They will then progress through the following stages:

***Online Screening***

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).

***Diagnostic Screening***

Participants who meet all the study criteria based on the online screening questionnaires will complete a diagnostic interview to confirm their diagnostic status and assess comorbid conditions. Participants will also be asked to provide an email address and their preferences for treatment days/times. Diagnostic interviews will be conducted via videoconferencing and will be audio-recorded. Participants who meet all criteria will then be randomised. The diagnostic screening documents are outlined in Appendix I. We anticipate that the diagnostic screening will take between 1-2 hours, however may be longer for some participants.

Participants who do not meet study criteria at this stage will be informed via email by one of the research staff after a discussion between the student clinician and chief investigator (Appendix J). Participants who do not meet criteria for the study after completing the diagnostic screening will be contacted by an investigator to discuss treatment options. Excluded participants will be encouraged to access support from their GP or other appropriate services, including crisis services.

***Randomisation***

Participants who meet all the study criteria will then be randomised to either an immediate treatment group or a WLC group. Randomisation will be conducted by the PhD student using a random number generator and assessing clinicians will not be aware of the randomisation status. Participants will be informed about their acceptance into the study and group assignment via email. Participants in both groups will be asked to complete pre-treatment questionnaires online via REDCAP. The link for these questionnaires will be emailed to participants. Once these questionnaires are complete participants will be scheduled to start treatment (immediately for those assigned to Group 1 and 9 weeks later for those assigned to Group 2).

***Questionnaire Administration***

Prior to commencing treatment, participants will complete the study measures online using REDCAP. Participants will also complete self-report questionnaires at mid-treatment, post-treatment and 3-month follow up. These questionnaires will be automatically emailed to participants via REDCAP at the required time. We anticipate that the self-report questionnaires will take participants 20 minutes at each time point to complete.

Participants will also be contacted by telephone or internet videoconferencing to complete the relevant module (SAD) of the diagnostic interview (DIAMOND) at post-treatment and 3-months post-treatment. At post-treatment and follow up only the module of the primary condition (SAD) will be administered to participants (taking approximately 20 minutes to complete).

***Managing Study Procedure Risks***

It is expected that participants will experience clinically significant improvements in their SAD symptoms. It is also hoped that the techniques taught in this trial will be applied by participants after the trial is completed, resulting in improved long-term management of their symptoms. The treatment protocol encourages participants to learn and practice techniques for managing symptoms of their mental health condition. Importantly, in the short term, participating in psychological treatments can lead to an increase in symptoms; but, this increase is only temporary and diminishes as treatment progresses.

Participants will be given the option at pre-treatment, post-treatment, and follow up to select whether they would like their health care provider(s) to be made aware of their participation in the study. The template letters are provided in Appendix J.

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.

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.

**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.

**STUDY MEASURES**

***Online Screening Measures***

Participants will initially complete some screening questions online to assess their suitability for the study. The online screening questionnaires are outlined in Appendix H as they will appear in REDCAP.

* **Demographic Form:** This is a 15-item standard demographic questionnaire collecting information on age, location, gender, marital, employment and education status, medication use etc.
* **DIAMOND Screener** (Tolin et al., 2016)**:** The DIAMOND screener is a 30-item self-report questionnaire that indicates to the clinician which of the DIAMOND modules need to be administered during the diagnostic interview. Only items endorsed on the DIAMOND screener are delivered during the DIAMOND interview.
* Symptoms of depression will be examined using the ***Patient Health Questionnaire 9-Item (PHQ-9)*** (Kroenke et al., 2001). The PHQ-9 is a 9-item measure of depressive symptoms. For each of nine items, participants rated the accuracy of each statement using a 4-point Likert scale from 0 (*not at all*) to 3 (*nearly every day*) considering frequency over the previous two weeks. Scores of 10 or greater indicate major depression, with 88% sensitivity and 88% specificity (Kroenke et al., 2001). The scale demonstrates construct validity and criterion validity, and good internal consistency (.86 to .89) was established in a previous study involving two different populations (Kroenke et al., 2001).
* Risky behaviours including deliberate self-harm and problematic alcohol and/or illicit drug use will be assessed with the **Risk Questionnaire**. This five item questionnaire has been used in other remote treatment studies (Wootton et al., 2019b) to screen out individuals who may be too risky to be seen in a remote treatment service.
* Symptoms of obsessive-compulsive disorder (OCD) will be examined with the ***Dimensional Obsessive Compulsive Scale (DOCS)***(Abramowitz et al., 2010). This is a 20-item measure of OCD symptoms and measures the severity of the four most empirically validated subtypes of OCD (symptoms relating to contamination, harming, unacceptable thoughts, and symmetry). A cut score of 21 demonstrates clinically significant symptoms (Abramowitz et al., 2010) of obsessive-compulsive disorder.
* Symptoms of body dysmorphic disorder (BDD) will be examined with the ***Body Dysmorphic Disorder Dimensional Scale (BDD-D)*** (LeBeau et al., 2013). The BDD-D is a 5-item self-report measure of symptom severity based on the DSM-5 criteria for BDD. The items measure time occupied by thoughts and repetitive behaviours, distress, avoidance, interference, and control over symptoms. Each item is rated on a scale from 0 (None) to 4 (Extreme), with total scores ranging from 0 to 20. The BDD-D demonstrated high internal consistency (α = .80-.92) in previous studies (Hanley et al., 2020; LeBeau et al., 2013; Macfarlane et al., 2019).
* Symptoms of hoarding disorder (HD) will be examined with the ***Hoarding Disorder Dimensional Scale (HD-D)*** (LeBeau et al., 2013). The HD-D is a 5-item self-report measure which assesses hoarding disorder dimensionally. Each item is rated from 0 (none) to 4 (extreme) and total scores range from 0 to 20, with higher scores reflecting greater symptom severity. This scale has demonstrated excellent psychometric properties in clinical and non-clinical samples (Carey et al., 2019; LeBeau et al., 2013; Mataix-Cols et al., 2013).
* Symptoms of trichotillomania (TTM) will be examined using the***Trichotillomania Dimensional Scale (TTM-D)***(LeBeau et al., 2013)*.*The TTM-D is a five-item self-report scale of TTM symptom severity over the last seven days. Respondents rate their answers on a 5-point Likert scale and total scores are summed and range from 0-20. The scale has demonstrated good reliability and validity in previous samples (Cheyne et al., 2018; LeBeau et al., 2013).
* Symptoms of excoriation (Skin Picking Disorder; SPD) will be examined using the ***Excoriation (Skin-Picking) Disorder-Dimensional Scale (SPD-D)*** (LeBeau et al., 2013). The SPD-D is a 5-item self-report measure assessing the severity of skin-picking symptoms over the previous week. Each item is rated on a 5-point Likert scale and higher scores indicated greater symptom severity. The SPD-D has previously demonstrated good internal consistency in previous samples (LeBeau et al., 2013; Russell et al., 2020).
* Symptoms of social anxiety will be examined using the ***Social Anxiety Disorder Dimensional Scale (SAD-D)*** (Lebeau et al., 2012). The SAD-D is a 10-item self-report measure of social anxiety symptoms. Each item is rated on a five-point Likert scale ranging from zero (“never” or “none”) to four (“all the time” or “extreme”). The SAD-D has previously demonstrated good validity and internal consistency in previous samples (Lebeau et al., 2012).
* Symptoms of panic will be examined using the ***Panic Disorder Dimensional Scale (PD-D)*** (Lebeau et al., 2012). The PD-D is a 10-item measure of panic disorder symptoms. Items are rated on a 5-point scale, which ranges from 0 to 4. The overall assessment is made by a total score, which is calculated by summing the scores for all ten items. The total scores range from 0 to 40. The PD-D has demonstrated good psychometric properties in previous studies (Lebeau et al., 2012).
* Symptoms of agoraphobia will be examined using the ***Agoraphobia Dimensional Scale (AG-D)*** (Lebeau et al., 2012). The AG-D is a 10-item scale with each item rated on a 5-point scale (0=Never to 4=All of the time). The total score can range from 0 to 40 with higher scores indicating greater severity of agoraphobia. The average total score is calculated by dividing the raw total score by number of items in the measure (i.e., 10).
* Symptoms of generalised anxiety will be examined using the ***Generalised Anxiety Disorder Dimensional Scale (GAD-D) (LeBeau et al., 2012):*** The GAD-D is a 10-item measure of generalized anxiety symptoms. Participants rate the frequency with which they have experienced GAD symptoms over the past month on a 5-point Likert scale ranging from 0 (Never) to 4 (All of the time), resulting in a total score ranging between 0 and 40. Previous studies have established acceptable psychometric properties (LeBeau et al. 2012).
* Symptoms of a specific phobia will be examined using the ***Specific Phobia Dimensional Scale (SP-D)*** (Lebeau et al., 2012). The SP-D is a 10-item measure that assesses the severity of specific phobia in individuals age 18 and older. Each item asks the individual to rate the severity of specific phobia symptoms during the past 7 days. Each item on the measure is rated on a 5-point scale (0=Never to 4=All of the time). The total score can range from 0 to 40 with higher scores indicating greater severity of specific phobia.
* Symptoms of adult separation anxiety will be examined using the ***Separation Anxiety Disorder Dimensional Scale (LeBeau et al., 2012):*** The Separation Anxiety Dimensional Scale is a 10-item self-report questionnaire that examines the severity of separation anxiety symptoms in adults. Each item is rated on a 5-point scale (0=Never to 4 =All of the time). Total scores range from 0-40. Previous samples have demonstrated adequate psychometric properties of the scale (Lebeau et al., 2012).

***Diagnostic Screening***

The diagnostic status of all participants will be assessed via with the *Diagnostic Interview for Anxiety, Mood, and Obsessive-Compulsive and Related Neuropsychiatric Disorders (DIAMOND)* (Tolin et al., 2018). The DIAMOND is a structured clinical interview that systematically assesses the DSM-5 diagnostic criteria for anxiety disorders, mood disorders, obsessive compulsive and related disorders, trauma and stressor related disorders, schizophrenia spectrum disorders, eating disorders, somatic symptom and related disorders, substance use disorders, and selected neurodevelopmental disorders. The DIAMOND demonstrates good reliability and validity for the anxiety and related disorders (Tolin et al., 2018).

Suicide risk will be assessed with the C-Suicide Severity Rating Scale (C-SSRS), a standardized assessment of suicide risk. The diagnostic screening will occur via videoconferencing and will be recorded.

***Outcome Measures***

***Primary measures***

The following disorder specific measures will be completed by participants at pre-treatment, mid-treatment, post-treatment and 3-month follow up.

1. ***Social Interaction Anxiety Scale and Social Phobia Scale – Short Form (SIAS-6 and SPS-6) (Peters et al., 2012).*** The SIAS and SPS are a companion set of measures designed to assess two similar yet distinct aspects of SAD: scrutiny fears, and more generalized social interaction anxieties (Mattick & Clarke, 1998). The short forms are self-report measures, each comprised of six items. The items are rated on a 5-point Likert scale ranging from 0 (not at all characteristic or true of me) to 4 (completely characteristic or true of me). The optimum cut-off scores for discriminating between those with and without a diagnosis of SAD are 7 or higher on the SIAS-6 and 2 or higher on the SPS-6 (Peters et al., 2012). The short forms have demonstrated sound psychometric properties displaying adequate to good internal consistency (α = .75 - .85), convergent and discriminant validity, diagnostic discrimination and treatment sensitivity in previous studies (Le Blanc et al., 2014; Peters et al., 2012).

***Secondary Measures***

All participants will complete the following secondary self-report outcome measures at pre-treatment, mid-treatment, post-treatment, and three-month follow up:

* ***Social Anxiety Disorder Dimensional Scale (SAD-D)*** (Lebeau et al., 2012). The SAD-D is a 10-item self-report measure of social anxiety symptoms. Each item is rated on a five-point Likert scale ranging from zero (“never” or “none”) to four (“all the time” or “extreme”). The SAD-D has previously demonstrated good validity and internal consistency in previous samples (Lebeau et al., 2012).
* ***Patient Health Questionnaire – 9 item (PHQ-9) (Kroenke, Spitzer, & Williams, 2001):*** The PHQ-9 is a widely used 9-item measure of depressive symptoms. Each item is rated on a 4-point Likert scale from 0 to 3 (0 = not at all, 1 = several days, 2 = more than half the days, 3 = nearly every day; Kroenke et al., 2001). The sum of these 9 items provides an indication of depression severity, with scores of 10 or above indicating clinically significant depression (Manea et al., 2012). The PHQ-9 has been demonstrated to have excellent psychometric properties in previous samples (Kroenke et al., 2001; Zuithoff et al., 2010).
* ***NIMH Clinician Global Impression (CGI) Scale (self-report version) (Guy, 1976):*** The CGI is a commonly used single item measure of severity of symptoms and improvement in symptoms. Severity scores range from 1 (normal) to 7 (severely ill) and improvement scores range from 1 (very much improved) to 7 (very much worse).
* ***Sheehan Disability Scale (SDS) (Sheehan, 1983):*** The SDS is a commonly used 3-item measure that assesses how much psychiatric symptoms have interfered with work, social, and home life functioning. A cut score of 5 on any item has been used to identify individuals with clinically relevant symptoms in previous studies (Leon et al., 1992).
* ***Core Beliefs Questionnaire (CBQ) - Trait Version (Wong et al., 2017):*** The CBQ (Trait Version) is a 17-item measure of core beliefs. It instructs participants to rate how much they believe each belief item (e.g., “I am unlikeable”) on a 6-point Likert scale from 1=strongly disbelieve to 6 strongly believe. Higher scores indicate greater endorsement of negative core beliefs about the self.
* ***Clinical Perfectionism Questionnaire (CPQ) (Fairburn et al., 2003)*.** The CPQ is a widely used 12 item measure of perfectionism. Participants are asked to rate the degree to which each item describes them over the past month on a scale from 1 (*not at all*) to 4 (*all of the time*).
* ***The Experience of Shame Scale (Andrews et al., 2002).*** The EES is a commonly used 25-item self-report questionnaire assessing eight aspects of shame. This includes (1) four areas of characterological shame: (i) shame of personal habits, (ii) manner with others, (iii) sort of person you are, (iv) personal ability; (2) three areas of behavioural shame: (v) shame about doing something wrong, (vi) saying something stupid, (vii) failure in competitive situations; and (3) bodily shame (viii) feeling ashamed of (your) body or any part of it. For each of these shame areas there are three items addressing the experiential, behavioral and cognitive components of shame. Participants rate the degree to which they feel each item applies to them on a scale from 1 (*not at all*) to 4 (*very much).*
* ***Self-Compassion Scale – Short Form (SCS-SF; Raes et al., 2011).*** The SSC-SF is a 12-item self-report measure of self-compassion. It measures six facets of self-compassion, as well as a single higher order factor of self-compassion. Participants are asked to rate how they typically act toward themselves in difficult times (e.g., “I try to see failings as part of the human condition”) on a scale from 1 (*almost never*) to 5 (*almost always*).

The following measures will be administered to all participants at mid-treatment and post-treatment:

* **Working Alliance Inventory-Short Form *(WAI-SF) (Hatcher & Gillaspy, 2006):*** The WAI-SF is a shortened version of the Working Alliance Inventory (WAI). It is used to measure the therapeutic alliance in an ongoing client-therapist interaction. It comprises 12 items that are scored on a 5-point Likert scale, ranging from ‘seldom’ to ‘always’.

The following measures will be administered to all participants at post-treatment only:

* ***Client Satisfaction Questionnaire (CSQ) (Larsen et al., 1979):*** The CSQ is an 8-item measure of the participant’s satisfaction with the treatment they were provided. The scale has demonstrated adequate psychometric properties in previous studies (Kelly et al., 2017; Larsen et al., 1979).
* **Acceptability Questionnaire (AQ).** The AQ is a 10-item measure of acceptability of remote treatments. The questionnaire has been used in other remote treatments (Wootton et al., 2019a, 2019b)

The following measures will be administered at pre-treatment only:

* **The Experiences in Close Relationships Revised Questionnaire (ECR-RQ; Fraley et al., 2000).** The ECR-R is a 36-item self-report measure of adult attachment, assessed across two subscales: avoidance and anxiety. Participants are asked to rate how they *generally* feel in emotionally intimate relationships, responding to each statement (e.g., “I’m afraid that I will lose my partner’s love”) on a scale from 1 (*strongly disagree*) to 7 (*strongly agree*).

All self-report data will be collected via REDCap. The outcome measures are outlined in Appendix K. The questionnaire administration schedule is outlined in Table 1 below. Participants in the control group will be re-assessed with the pre-treatment measures prior to starting treatment.

*Table 1. Administration Schedule for Outcome Measures*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Screening | Pre-treatment | Mid- treatment | Post-treatment | 3-month follow-up |
| Screening Measures |  |  |  |  |  |
| *Demographics* | + |  |  |  |  |
| *Risk questionnaire* | + |  |  |  |  |
| *DIAMOND Screener* | + |  |  |  |  |
| *DIAMOND Interview* | + |  |  | + | + |
| *C-SSRS* | + |  |  |  |  |
| *DOCS* | + |  |  |  |  |
| *BDD-D* | + |  |  |  |  |
| *HD-D* | + |  |  |  |  |
| *TTM-D* | + |  |  |  |  |
| *SPD-D* | + |  |  |  |  |
| *PD-D* | + |  |  |  |  |
| *AG-D* | + |  |  |  |  |
| *GAD-D* | + |  |  |  |  |
| *SP-D* | + |  |  |  |  |
| *Separation Anxiety Disorder Dimensional Scale* |  |  |  |  |  |
| Primary Outcome Measure |  |  |  |  |  |
| *SIAS-6/SPS-6* |  | + | + | + | + |
| Secondary Outcome Measures |  |  |  |  |  |
| *SAD-D* | + | + | + | + | + |
| *PHQ-9* | + | + | + | + | + |
| *CBQ* |  | + | + | + | + |
| *CPQ* |  | + | + | + | + |
| *CGI* |  | + | + | + | + |
| *SDS* |  | + | + | + | + |
| *EoSS* |  | + | + | + | + |
| *SCS-SF* |  | + | + | + | + |
| *ECR-RQ* |  | + |  |  |  |
| Process Measures |  |  |  |  |  |
| *WAI-SF* |  |  | + | + |  |
| *CSQ* |  |  | + | + |  |
| *AQ* |  |  | + | + |  |

*Note*. DIAMOND = Diagnostic Interview for Anxiety, Mood, and Obsessive-Compulsive and Related Neuropsychiatric Disorders; C-SSRS = C-Suicide Severity Rating Scale; DOCS = Dimensional Obsessive Compulsive Scale; BDD-D = Body Dysmorphic Disorder Dimensional Scale; HD-D = Hoarding Disorder Dimensional Scale; TTM-D = Trichotillomania Dimensional Scale; SPD-D = Excoriation (Skin-Picking) Disorder- Dimensional Scale; PD-D = Panic Disorder Dimensional Scale; AG-D = Agoraphobia Dimensional Scale; SP-D = Specific Phobia Dimensional Scale; SIAS = Social Interaction Anxiety Scale; SPS = Social Phobia Scale; SAD-D = Social Anxiety Disorder-Dimensional Scale; PHQ-9 = Patient Health Questionnaire-9 item; CBQ = Core Beliefs Questionnaire; CPQ = Clinical Perfectionism Questionnaire; CGI = NIMH Clinician Global Impression Scale (self-report version); SDS = Sheehan Disability Scale; ESS = Experience of Shame Scale ; SCS-SF = Self Compassion Scale Short Form; ECR-RQ = Experiences in Close Relationship Revised Questionnaire; WAI-SF = Working Alliance Inventory-Short Form; CSQ = Client Satisfaction Questionnaire; AQ = Acceptability Questionnaire.

**INCLUSION/EXCLUSION CRITERIA**

Inclusion criteria:

(1) Currently residing in Australia;

(2) Aged 18+ years;

(3) Fluent in English;

(4) Meets criteria for SAD as primary disorder 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 SAD 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.

(8) Is not willing to engage in treatment via internet video-conferencing software.

**TIMELINE**

It is estimated that this research program will run for 5 years.

**TREATMENT**

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). Participants will also be required to complete homework tasks between sessions (as is standard practice in CBT). The CBT treatment manual has been used in previously published studies of SAD (Wootton et al., 2018). 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 based on previously published treatment manuals for SAD (Wild & Clark, 2011): 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). 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.

**TRIAL REGISTRATION**

The RCT will be registered with the Australian and New Zealand Clinical Trials Register (ANZCTR) prior to commencing treatment. The study protocol will also be published.

**DATA STORAGE**

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.

**ANALYSIS PLAN**

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. 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).

**REPORTING OF ADVERSE EVENTS**

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.

**FUNDING**

This study is currently unfunded and there are no reportable conflicts of interest. Should future funding be obtained to support this research the MREC will be notified via an amendment.

**COMMUNICATION WITH HEALTH PROFESSIONALS**

In the pre-treatment and post-treatment/follow up questionnaires participants will be asked if they would like their treating health professional(s) to receive a letter outlining a) that they are participating in the study (pre-treatment) and b) their outcomes (post-treatment and follow up). Participants will be asked to tick a box to indicate their consent and to provide the name and postal details of their health professional(s). Those who are interested will be sent a template letter providing this information (see Appendix J).

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