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Internet videoconferencing-delivered cognitive behavioral therapy for social anxiety disorder: protocol for a randomized controlled trial

1. Introduction

Social anxiety disorder (SAD) is characterized by an excessive fear of performance or social situations, particularly ones in which the individual fears scrutiny by others or unfamiliar people ¹. Data from a World Mental Health survey estimate a lifetime prevalence for the disorder of 4%, and 12-month prevalence of 2.4% ². The median age of onset is 13 years and 75% of SAD cases will manifest by 17 years of age in high income countries ². Left untreated, SAD has a chronic and debilitating course that can lead to impairment in multiple domains of functioning, as well as the development of co-morbid mental health disorders later in life such as depressive disorders, panic disorder and generalised anxiety disorder ^{3,4}.

SAD can be effectively treated with cognitive behavioral therapy (CBT) ^{5,6}. CBT for SAD involves targeting the negative cognitions, self-focused attention and behavioral patterns hypothesized to maintain or exacerbate social anxiety ^{7,8} and has been shown to be an efficacious treatment in numerous meta-analyses ^{9,10}. There is also preliminary evidence to support the efficacy of imagery rescripting (ImR) for SAD ^{11–13}. ImR treatment for SAD centres on the negative self-imagery component of the Clark and Wells⁷ and Rapee and Heimberg⁸ models of social anxiety and involves updating negative self-images and beliefs encapsulated in memories of painful past events ¹⁴. The retrieval competition hypothesis proposes that ImR develops new adaptive memories that compete with the original memory in subsequent retrieval, thus reducing distress ¹⁵. A recent meta-analysis of ImR for aversive memories included six trials of ImR for SAD, three of which were RCTs¹⁶. Within-group effect sizes on SAD measures were large from pre-treatment to post-treatment ($g = 1.22$) and large from pre-treatment to follow-up ($g = 1.79$)¹⁶. Indeed, even a single session of ImR has

been found to facilitate significant shifts in memory-derived core beliefs and increases in positive and neutral but not negative memory details¹². This suggests that effect sizes associated with ImR for SAD are large and comparable to those seen in CBT. Despite the availability of efficacious treatments for SAD, environmental, logistical, and psychological barriers prevent a high proportion of individuals from seeking help in traditional in-person settings¹⁷. One way to overcome these barriers is to provide specialized treatment remotely.

Remotely delivered treatments do not require the clinician and client to be in the same location and these interventions can be provided as either a low-intensity or high-intensity treatment. Low-intensity treatments are predominantly self-help in nature either with or without the support of a clinician. In low-intensity treatments, a clinician will provide anywhere from nil to 10-minutes of support each week through telephone, email or encrypted asynchronous messaging service¹⁸. High intensity remote treatments are analogous to traditional in-person treatments in requiring the same level of clinician support (e.g., 50-minutes per week), but are delivered remotely through the internet using videoconferencing software, or telephone. Low-intensity remote CBT for SAD has been shown to be efficacious across the various administration formats including internet-delivered CBT (iCBT; $g = 1.08$), application- delivered CBT (aCBT; $g = 1.19$) and bibliotherapy- delivered CBT (bCBT; $g = 0.79$)¹⁹. Thus far, effect sizes of low intensity remote treatment for SAD are promising. Currently, the number of studies examining high-intensity remote CBT treatment for SAD is small with a recent meta-analysis finding only one such published study meeting the study criteria¹⁹.

In this study, Matsumoto²⁰ investigated videoconferencing-delivered CBT (vCBT) in an open trial format. This study found a significant reduction in social anxiety symptoms (Cohen's $d = 1.10$) following 16 sessions of individualized videoconference-delivered CBT.

In this study 4/9 participants (44%) met criteria for treatment response and 2/9 (22%) met criteria for remission. While the results of this study are promising, there are a number of limitations to the methodology including a small sample size ($n = 9$), no control condition, and limited clarity regarding the treatment manual and content of the intervention. Thus, the acceptability and efficacy of high-intensity remote CBT for SAD requires further investigation in controlled trials.

More generally, videoconferencing CBT for internalising disorders are promising^{21,22}. A recent systematic review of videoconferencing psychological therapy compared to in-person therapy for anxiety disorders and synthesised data across randomized studies (6/21), quasi-experimental studies (4/21), and uncontrolled studies (11/21). CBT was the most common intervention evaluated with statistically significant improvement on validated anxiety measures in 14 of 21 studies included²². However, of the six RCTs included, only one examined anxiety as a primary outcome measure²². This particular RCT was a direct comparison of vCBT to in-person CBT for mood and anxiety disorders and found similar reduction in anxiety symptoms across both groups²³. However, only one participant included in this RCT had a primary diagnosis of SAD.

The literature examining the efficacy of vCBT using disorder-specific treatments for anxiety and related disorders is small but growing. For example, a recent meta-analysis examining remote treatment for obsessive-compulsive disorder included six high intensity remote treatment trials and found a large pre-treatment to post-treatment within-group effect size for vCBT ($g = 1.68$)²⁴. Similarly, a meta-analysis for remote treatment of panic disorder included three vCBT studies also resulting in a large within-group effect size ($g = 1.10$)²⁵. Although there is growing evidence in the literature of disorder-specific vCBT RCTs, there are currently no SAD disorder-specific vCBT RCTs to date despite the prevalence of SAD in

the community comparative to other anxiety disorders. Examining the acceptability and efficacy of vCBT and vImR for SAD in particular is important given the characterisation of the disorder. For example, it is yet unknown whether people with SAD find videoconferencing more or less confronting compared to in-person treatment, or whether videoconferencing is a less preferred method of treatment delivery. It is also not yet known whether treatment efficacy may be compromised should there be less opportunity to complete core interventions such as exposure and detection of safety behaviours. Further, although effect sizes of low intensity remote treatment for SAD compared to in-person treatment are promising¹⁸, it is unknown whether therapeutic alliance may be compromised in this virtual high intensity medium for people with SAD.

This protocol study describes the procedures and methodology of a randomized controlled trial (RCT) investigating the efficacy and acceptability of vCBT for SAD, and a further open trial of videoconferencing delivered ImR (vImR) for SAD utilising the waitlist control group (WLC). To date, there is no known vCBT RCT for SAD and clinical trials of ImR have only examined the efficacy of the approach in in-person settings. The study is purposefully designed to address these significant gaps in the literature. Although there is arguably less ecological validity in the use of a WLC, it provides a non-intervention evaluation and comparison of vCBT, an important early phase in the common standards of clinical trials²⁶. Based on the limited existing literature, it is hypothesized that high-intensity vCBT will (1) be acceptable to individuals with SAD; (2) result in significant reductions in symptoms, resulting in large within-group effect sizes from pre-treatment to post-treatment and pre-treatment to follow-up and large between-group effect sizes at post-treatment; (3) vCBT and vImR will result in similar reductions to standard in-person CBT and in-person ImR. It is anticipated that the results of the proposed study will add to the literature informing best-practice psychological treatment for SAD, and the findings may result in the improved

dissemination of CBT for SAD, resulting in more individuals who are able to access evidence-based treatment for this disorder. Additionally, the results of the study may provide an important justification for government policy and funding improvements to ultimately increase access for vulnerable populations living in non-urban areas who experience treatment inequity^{27,28}. Further, the results will inform future studies comparing vCBT to treatment as usual and/or in-person CBT.

2. Materials and method

2.1 Participants

Seventy-eight individuals will be recruited for this study. To be included in the trial, participants are required to (1) currently reside in Australia, (2) be aged over eighteen years, (3) be fluent in English, (4) meet criteria for SAD as the primary diagnosis, (5) be either medication free or on a stable dose of psychotropic medication (including benzodiazepines and anti-psychotic medications), (6) not currently be receiving regular psychological services for their SAD. Participants will be excluded if they have symptoms that will put them at risk of harming themselves or others or will confound results of the treatment. Participants will also be excluded if they do not have regular access to the Internet and camera. Given that individuals with SAD in Australia rarely receive an evidence-based treatment for SAD^{29–32}, this was not an exclusion criteria in the current study. A complete list of inclusion and exclusion criteria is outlined in Table 1.

Table 1. Inclusion criteria and rationale

Inclusion criteria	Rationale
1. Currently resides in Australia	Study population

2. Aged 18+ years	Study population
3. Fluent in English	Treatment confound/ participant concern
4. Meets criteria for SAD as primary diagnosis and the disorder is of at least 'moderate severity' (defined as a score of 4 on the DIAMOND module severity measure)	Study population
5. Medication free or on a stable dose of psychotropic medication	Treatment confound
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)	Treatment confound
Exclusion criteria	Rationale
1. Severe depressive symptoms as assessed by a score of 20 or above on the PHQ-9	Participant safety
2. Are at suicide risk 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 interview using the C-SSRS	Participant safety
3. Engage in daily alcohol use or daily illicit drug use	Treatment confound
4. Presence of schizophrenia spectrum disorder as assessed by the DIAMOND	Treatment confound

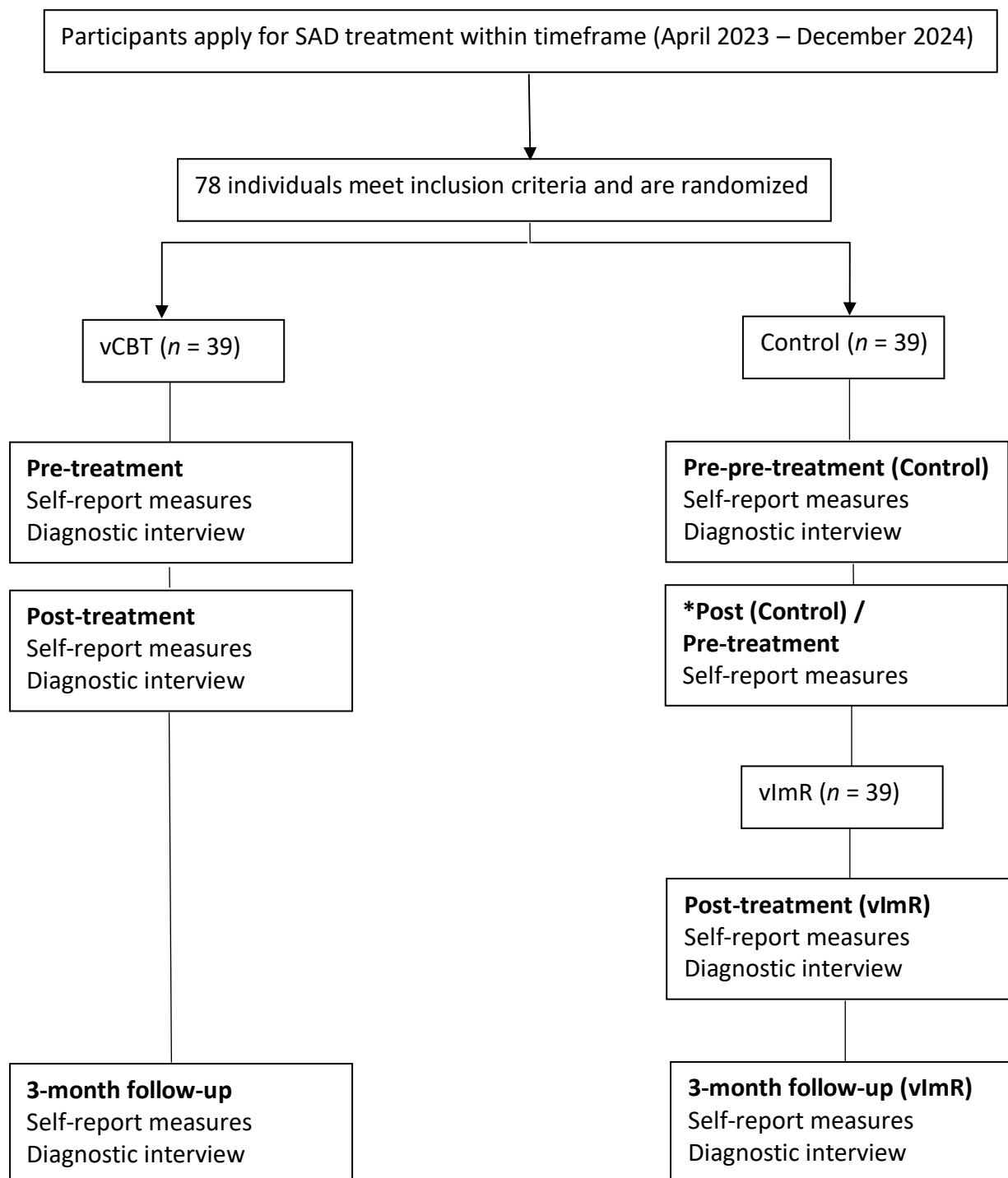
5. Significant cognitive/intellectual impairment as assessed during the diagnostic interview	Treatment confound
6. A medical condition that may interfere with treatment	Treatment confound
7. Does not have access to a computer with a camera and stable internet on a regular basis	Feasibility
8. Is not willing to engage in treatment via internet video-conferencing software	Feasibility

2.2 Design

A CONSORT-R compliant 2-group randomized controlled trial (RCT) will investigate the research questions. Randomisation will be conducted using a computer-generated list of random numbers to assign participants on a 1:1 basis to one of two groups using the website www.random.org. Allocation will be concealed from assessing clinicians where possible. As outlined in Figure 1, the larger RCT will randomise participants to either vCBT (8 weeks) or a waitlist control group (8 weeks). Once the waitlist period is over the waitlist control group will receive vImR (8 weeks).

2.3 Recruitment

Participants will be recruited via advertising on social media, via email on professional networking sites, as well as direct emails to community-based clinicians, general practitioners, and psychiatrists. Hard copy flyers will also be posted on community noticeboards and applications will be made to have the study advertised with relevant not-for-profit organisations. Participants will provide informed consent prior to commencing the screening process.

Figure 1. Participant flow.

Note: *Participants in the control group commence the vImR treatment 8-weeks after pre-treatment measures.

2.4 Screening measures

Demographic questionnaire. A 15-item standard demographic questionnaire will collect information on age, location, gender, marital, employment and education status, and medication use.

Risk Questionnaire. 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 studies³³ to screen out individuals who may have symptoms characterised by higher levels of risk.

Diagnostic Interview for Anxiety, Mood, and Obsessive-Compulsive and Related Neuropsychiatric Disorders (DIAMOND)³⁴. 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. Relevant modules from the DIAMOND will be delivered by provisional psychologists in their final year of Master of Clinical Psychology at the University of Technology Sydney or registered psychologists under the supervision of a senior clinical psychologist. All clinicians administering the DIAMOND will receive formal training in this specific tool and adherence to the interview procedures will be monitored by project investigators. The DIAMOND demonstrates very good interrater reliability ($\kappa = .70$) and excellent test-retest validity ($\kappa = .86$) for the SAD diagnosis³⁴. The DIAMOND will be readministered at post-treatment and follow-up to measure diagnostic change. Participant allocation will be concealed from the clinicians administering the DIAMOND at these time points where possible.

Columbia-Suicide Severity Rating Scale (C-SSRS) ³⁵. The C-SSRS is a semi-structured interview of suicide risk designed to examine the severity and lethality of suicidal ideation and behaviour in both paediatric and adult populations. The scale assesses multiple features related to suicidal ideation and suicidal behaviour across the entire lifespan and in the recent past by asking questions related to the severity and frequency of ideation and behaviour. The C-SSRS demonstrates good convergent and divergent validity and high sensitivity for suicidal behaviour classifications and is suitable for assessment of suicidal ideation and behaviour in research settings ³⁵.

2.5 Primary outcome measure

Social Interaction Anxiety Scale and Social Phobia Scale – Short Form (SIAS-6 and SPS-6) ³⁶. The SIAS and SPS are a companion set of measures designed to assess two similar yet distinct aspects of social anxiety which constitute the core features of the disorder^{37,38}. Specifically, the SIAS-6 measures the more generalized social interaction anxieties such as making eye-contact with others, talking to friends and strangers, and attending a social gathering or party, and the SPS-6 measures specific scrutiny fears such as attracting the attention of others, or eating, drinking and writing in the presence of others³⁷. 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 ³⁷. The short forms have demonstrated sound psychometric properties displaying adequate to good internal consistency ($\alpha = .75 - .85$), convergent and discriminant validity, diagnostic discrimination, test-retest reliability and treatment sensitivity in previous studies ^{37,39}.

2.6 Secondary outcome measures

Social Anxiety Disorder Dimensional Scale (SAD-D)⁴⁰. The SAD-D is a 10-item self-report measure of social anxiety symptom severity that can be conceptualized on a continuum aligned with the dimensional approach of the DSM-5-TR^{1,41}. 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 demonstrated good validity and internal consistency in previous samples⁴², including within an Australian community sample^{41,43}, and good to excellent test-retest reliability⁴³. Currently, the SAD-D is the only social anxiety scale that is based on the DSM-5 criteria and reflects the dimensional nature of the disorder⁴⁴.

Patient Health Questionnaire – 9 item (PHQ-9)⁴⁵. 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). The sum of these 9 items provides an indication of depression severity, with scores of 10 or above indicating clinically significant depression^{46,47}. The PHQ-9 has been widely demonstrated to have excellent psychometric properties including internal consistency, test-retest reliability and discriminative validity^{47,48}.

NIMH Clinician Global Impression (CGI) Scale (self-report version)⁴⁹. The CGI is a commonly used single item measure of severity of symptoms and improvement of 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). The CGI ratings have been found to be positively correlated with both self-report and clinician-administered measures of symptom-specific improvement among individuals with social anxiety disorder with good test-retest reliability⁵⁰.

Sheehan Disability Scale (SDS) ⁵¹. 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 studies⁵² with high reliability in primary care settings⁵³. Further, it has been identified to be a valid tool in the study of disability in SAD ^{54,55}.

2.7 Process/acceptability measures

Working Alliance Inventory-Short Form Revised (WAI-SR) ⁵⁶. The WAI-SR is a shortened version of the original Working Alliance Inventory (WAI)⁵⁷. 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’, with higher scores associated with better treatment outcomes. The WAI-SR has high internal consistency and reliability in previous samples ⁵⁸.

Client Satisfaction Questionnaire (CSQ) ⁵⁹. 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 studies⁶⁰ and has wide-ranging use in primary care medical and mental health treatment ⁶¹.

Acceptability Questionnaire (AQ). The AQ is a 10-item measure of acceptability of remote treatments. The questionnaire has been used in other remote treatments ³³.

Table 2. Administration schedule for outcome measures

	Screening	Pre- treatment	Mid- treatment	Post- treatment	3-month follow- up
Screening Measures					
<i>Demographics</i>	+				
<i>Risk questionnaire</i>	+				
<i>DIAMOND</i>	+			+	+
<i>C-SSRS</i>	+				
Primary Outcome Measure					
<i>SIAS-6/SPS-6</i>		+	+	+	+
Secondary Outcome Measures					
<i>SAD-D</i>		+	+	+	+
<i>PHQ-9</i>		+	+	+	+
<i>CGI</i>		+	+	+	+
<i>SDS</i>		+	+	+	+
Process/Acceptability Measures					
<i>WAI-SF</i>			+	+	
<i>CSQ</i>			+	+	
<i>AQ</i>			+	+	

Note. DIAMOND = Diagnostic Interview for Anxiety, Mood, and Obsessive-Compulsive and Related Neuropsychiatric Disorders; C-SSRS = C-Suicide Severity Rating Scale; SIAS = Social Interaction Anxiety Scale; SPS = Social Phobia Scale; SAD-D = Social Anxiety Disorder-Dimensional Scale; PHQ-9 = Patient Health Questionnaire-9 item; CGI = NIMH Clinician Global Impression Scale (self-report version); SDS = Sheehan Disability Scale; WAI-SF =

Working Alliance Inventory-Short Form; CSQ = Client Satisfaction Questionnaire, AQ = Acceptability Questionnaire.

2.8 Risk management

Risk assessments will be completed during the recruitment process, screening process and throughout treatment. Any participant who discloses suicidal risk during the recruitment or screening process will be excluded from the study and will be supported to find more suitable treatment. All participants are also made aware of the steps they can take in a mental health emergency. Additionally, each participant in the study will receive an individualized safety plan during the first session and risk will be monitored during the treatment sessions. Participants whose risk becomes high or who experience deteriorating symptoms will be contacted by the research team and encouraged to contact their health professionals or emergency services.

2.9 Treatment

The vCBT and vImR treatment protocols described are outlined in Table 3. The vCBT intervention is based on the Rapee and Heimberg⁸ model of SAD. The treatment protocol has been used in previous clinical trials for SAD⁶² and comprises 5 modules covering the following topics: (1) psychoeducation, (2) challenging automatic thoughts, (3) challenging core beliefs, (4) exposure, and (5) relapse prevention/consolidation. The vImR enhanced CBT protocol includes 4 modules based on the previously published Wild and Clark¹⁴ treatment procedure for SAD and covers the following topics: (1) psychoeducation, (2) identification and exploration of negative self-imagery and core beliefs, (3) imagery rescripting, and (4) relapse prevention/consolidation. After the post-treatment assessment, participants will be

encouraged to consult with the primary care physician if they require ongoing treatment for their symptoms of SAD or other mental health conditions.

All treatments are manualised and are individually administered in 8 x weekly (50 min) sessions. In both treatments, participants will also be required to complete homework tasks between sessions. Treatment will be delivered by either provisionally registered psychologists in their final year of a Master of Clinical Psychology degree or a clinical psychology registrar under the supervision of an experienced clinical psychologist. All treating psychologists will be familiar with delivering manualised treatments and thoroughly trained in the administration of the treatment protocol by the project investigators. All sessions will be recorded and at least 10% of sessions will be randomly selected for clinician treatment compliance and integrity checking. This clinician compliance with the treatment manual will be assessed by the Chief Investigator of the study. Treating clinicians will receive weekly supervision to review client progress and address clinical issues arising from sessions. Participant compliance with the treatment will be monitored through homework completion rates, homework reviews, direct observation, and session attendance.

2.10 Analysis

2.10.1 Data storage and analysis

In order to maintain confidentiality, all electronic data will comply with data safety standards and the National Statement of Ethical Conduct in Human Research. All electronic data will be de-identified and stored on a restricted-access network drive and only researchers will have access to the data.

Table 3. Treatment protocol

vCBT Treatment		vImR enhanced CBT Treatment	
Session	Module	Session	Module
1	Psychoeducation	1	Psychoeducation
2	Challenging automatic thoughts	2	Identification and exploration of negative self-imagery and core beliefs
3	Challenging automatic thoughts	3	Imagery rescripting
4	Challenging core beliefs	4	Imagery rescripting
5	Exposure	5	Imagery rescripting
6	Exposure	6	Imagery rescripting
7	Exposure	7	Imagery rescripting
8	Relapse prevention	8	Relapse prevention

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 data⁶³ 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 random⁶³. In the case data is missing not at random, appropriate analysis methods will be used to reduce bias⁶⁴. Sensitivity analyses will be used to evaluate potential impact of missing data on the findings⁶⁴. Effect

sizes will be calculated according to Cohen's d where .20 is considered a small effect, .50 a medium effect and .80 a large effect⁶⁵. Both within-group and between-group effect sizes will be calculated. Within-group effect sizes will be calculated for the vCBT group from pre-treatment to post-treatment and pre-treatment to 3-month follow up. Once the vImR group commences treatment (after completing their time as the waitlist control) within-group effect sizes will be calculated from pre-treatment to post-treatment and pre-treatment to 3 month follow up. Between-group effect sizes will be calculated at post-treatment comparing the vCBT group to the waitlist control group. The vCBT and vImR protocols will be compared with standard in-person treatment by benchmarking effect sizes⁶⁶ from the immediate treatment arm of the RCT (vCBT) and open trial (vImR) with existing data available from meta-analytic studies of in-person CBT^{67,68} and RCTs of in-person ImR⁶⁹⁻⁷¹. This approach will be consistent with the approach outlined by Minami et al⁶⁶. Such an approach has been used in other published studies^{72,73}

Clinically significant change will be measured in three ways. Firstly, diagnostic change will be assessed at post-treatment and 3-month follow up using the DIAMOND³⁴. Secondly, consistent with previous studies of social anxiety^{74,75}, treatment response will be defined using the Jacobson & Truax⁷⁶ reliable change index (RCI) to indicate a change score that is likely to be statistically reliable and not attributable to measurement error⁷⁶. Reliable change will be completed on the SIAS and SPS. Finally, clinically significant change (CSC) at post-treatment and 3-month follow up will be defined as meeting the RCI and a SIAS score below 7 and SPS score below 2³⁷. Reliable deterioration will be defined as increased symptoms by the RCI magnitude of change on the SIAS and SPS at post-treatment.

2.10.2 Power

With alpha set at .05, power set at .80, and a sample size of 39 in each group, the study is powered to enable the detection of large effect size (i.e., Cohen's $d = 0.80$) difference in symptoms, which would be the minimum expected reduction in the RCT based on existing research⁷⁷. Therefore, the total N for the study is 78 with 39 individuals in the immediate treatment group and 39 individuals in the waitlist control group.

2.10.3 Ethical approval and trial registration

The study was approved by the University of Technology Sydney Health and Medical Research Ethics Committee (UTS MREC REF NO. ETH22-7803). The trial is registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12623000313639) and includes the full study protocol and participant information sheet and consent form. While not anticipated, any changes to the protocol will be updated through the ANZCTR registry.

3. Conclusion

SAD is a chronic and impairing mental health condition². CBT is effective for SAD^{5,10}; however, many individuals experience logistical barriers to accessing this treatment^{78,79}. High-intensity remote treatment may assist patients in overcoming these barriers. The primary aim of this study is to examine the acceptability and efficacy of vCBT for SAD. A secondary aim is to examine the acceptability of vImR enhanced treatment for SAD. This will be the first study to examine the efficacy of vCBT for SAD in a controlled design and the only study to examine remote vImR for SAD. It is anticipated that the results will contribute to the evidence base of remotely delivered vCBT and vImR for SAD and provide important data on the acceptability and efficacy of treatment approaches.

Trial status

Protocol version 1.1 was approved on 28 March 2023. Recruitment commenced in April 2023 and is expected to be completed by December, 2024.

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