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Assessing the efficacy of imagery-enhanced cognitive behavioral group therapy for social anxiety disorder: Study protocol for a randomized controlled trial

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ABSTRACT

Cognitive behavior group therapy (CBGT) is effective for social anxiety disorder (SAD), but a substantial proportion of patients do not typically achieve normative functioning. Cognitive behavioral models of SAD emphasize negative self-imagery as an important maintaining factor, and evidence suggests that imagery is a powerful cognitive mode for facilitating affective change. This study will compare two group CBGT interventions, one that predominantly uses verbally-based strategies (VB-CBGT) and another that predominantly uses imagery-enhanced strategies (IE-CBGT), in terms of (a) efficacy, (b) mechanisms of change, and (c) cost-effectiveness. This study is a parallel groups (two-arm) single-blind randomized controlled trial. A minimum of 96 patients with SAD will be recruited within a public outpatient community mental health clinic in Perth, Australia. The primary outcomes will be self-reported symptom severity, caseness (SAD present: yes/no) based on a structured diagnostic interview, and clinician-rated severity and life impact. Secondary outcomes and mechanism measures include blind observer-rated use of safety behaviors, physiological activity (heart rate variability and skin conductance level) during a standardized speech task, negative self-beliefs, imagery suppression, fear of negative and positive evaluation, repetitive negative thinking, anxiety, depression, self-consciousness, use of safety behaviors, and the EQ-5D-5L and TiC-P for the health economic analysis. Homework completion, group cohesion, and working alliance will also be monitored. The outcomes of this trial will inform clinicians as to whether integrating imagery-based strategies in cognitive behavior therapy for SAD is likely to improve outcomes. Common and distinct mechanisms of change might be identified, along with relative cost-effectiveness of each intervention.

1. Introduction

Social anxiety disorder (SAD) is characterized by significant and persistent fear of social situations where embarrassment, rejection, or scrutiny is possible [1]. SAD is one of the most common anxiety disorders [2], with 12.1% of adults suffering from the condition in their lifetime [3]. The National Institute for Health and Care Excellence (NICE) recommend cognitive behavioral therapy (CBT) as the first line treatment [4], and a range of CBT-based protocols have been evaluated and deemed efficacious, whether delivered in groups or individually [5]. However, in group CBT the majority of patients fail to return to normative functioning, so further treatment innovations are required [6].

CBT for SAD typically targets maintaining factors described in Clark and Wells' [7,8] and Rapee and Heimberg's [9] models. Individuals with SAD develop excessively high standards for social performance, leading to negative predictions about the consequences of such interactions (e.g., “If I express my opinion, I'll be rejected”), and unconditional

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negative beliefs about the self (e.g., "I'm unlikeable"). People with SAD also form a mental representation of the self and how others see them (i.e., from an observer perspective) [9,10]. Critically, this mental representation is not based on objective feedback, but is rather internally constructed based on a combination of long-term memory, internal cues, and observable feedback from others. The person's attention is focused on negative aspects of this mental representation (e.g., signs of anxiety perceived to be obvious to others), discrepancies between this mental image and the audience's perceived standards, and on monitoring for external evaluation from others. Avoidance and subtle safety behaviors (e.g., staying quiet in social gatherings to avoid sounding foolish) serve to maintain perceptions of social threat by depriving the individual of opportunities to challenge and modify their negative thoughts and images.

The aim of CBT in SAD is to assist clients to modify these processes via verbal-linguistic techniques such as identifying negative thoughts, considering contrary evidence, and developing more realistic probability and cost estimates of the feared outcome. Avoidance and safety behaviors are relinquished via behavioral experiments so that negative thoughts can be directly tested and, ultimately, more realistic memories of social situations can be created. Attentional biases and excessive self-focused attention are corrected via training to refocus on the task at hand [11,12], and negatively biased self-images are modified via video-feedback [12–14]. Some individual CBT protocols have included additional mental imagery-based techniques (e.g., imagery rescripting [11]). However, it has recently been argued that using imagery-based strategies more comprehensively in therapy may more powerfully exploit the particularly strong relationship between imagery and emotion both for reducing negative emotion and bolstering positive emotion [15–18].

In an attempt to potentiate larger therapeutic changes within group CBT, the current research group developed an imagery-enhanced cognitive behavioral group therapy (IE-CBGT) protocol for SAD [14,19]. The aims of the present study are to compare IE-CBGT with verbally-based cognitive behavioral group therapy (VB-CBGT) for SAD in terms of (a) efficacy, (b) mechanisms of therapeutic change across behavioral and physiological parameters, and (c) cost-effectiveness.

2. Material and methods

2.1. Design

This study is a parallel groups (two-arm) single-blind randomized controlled trial (RCT) comparing the efficacy, mechanisms of change, and cost-effectiveness of a novel group cognitive behavioral therapy (IE-CBGT), with VB-CBGT in patients with SAD. The unit of randomization will be the patient. Primary outcomes will be measured in both arms at baseline (intake assessment), 1-month, and 6-month follow-ups. In addition, the primary self-report symptom measure will be measured prior to treatment sessions 4, 8, and 12 of both 12-session treatments. Patients will complete a video-recorded speech task with concurrent physiological monitoring at baseline and 1-month and 6-month follow-ups. The resulting videos will be blind rated for behavioral manifestations of anxiety. Other mechanism and/or symptom measures will be administered prior to every session (i.e., depression, anxiety, fear of negative and positive evaluation, probability and cost of a reference negative social outcome), or prior to the 1st, 4th, 8th and 12th sessions (i.e., negative self-portrayals, imagery suppression, imagery ability, self-consciousness, performance anxiety, safety behaviors, self-beliefs), in addition to the follow-up sessions. A measure of repetitive negative thinking will be administered at baseline and at the follow-ups only. For the health economic analyses, a measure of health-related quality of life will be administered at baseline and both follow-ups, and a measure of medical consumption and productivity losses associated with psychiatric illness will be administered at baseline and 6-month follow-up. A measure of homework completion will be administered prior to sessions 2, 5, 8, and 11, a measure of working alliance will be administered prior to sessions 3, 6, and 9, and a measure of group cohesion will be administered prior to sessions 4, 7, and 10. The trial will be conducted in a community mental health clinic that administers additional measures for service evaluation that will not be used as primary or secondary outcomes of this trial. Any subsequent studies exploring outcomes on these additional measures will explicitly state that they were not pre-registered as primary or secondary trial outcomes.

2.2. Hypotheses

Our primary hypothesis is that IE-CBGT will be superior in reducing social anxiety symptoms as measured by the Social Interaction Anxiety Scale (SIAS) [20], the percentage of individuals with a SAD diagnosis as measured using the Structured Clinical Interview for DSM-5 (SCID-5) [1], and clinician-rated severity (8-point severity scale) at 1-month and 6-months post-treatment. Clinician-rated severity at 1-month follow-up will be based on current severity, not 6-month severity. Our secondary hypotheses are that patients receiving IE-CBGT will show more adaptive behavioral and physiological responding to a social stress task [21] at 1-month post-treatment. In addition, changes in negative self-beliefs [22], repetitive negative thinking [23], self-focused attention [24], and avoidance and safety behaviors [25,26] are expected to mediate symptom change for both treatments, but IE-CBGT is expected to result in larger decreases in these mediators. A reduction in imagery suppression [27] is expected to only mediate symptom change for IE-CBGT. It is further hypothesized that IE-CBGT will be more cost-effective than VB-CBGT in terms of i) cost per quality adjusted life years (QALYs) gained, and ii) cost per unit symptom improvement, as measured using the TiC-P [28] and EQ-5D-5L [29].

2.3. Eligibility criteria

All patients referred to the clinical service for SAD will initially be invited to participate. Patients who are over 18 years of age, who have had stable medications for ≥ 1 month, who are willing to be randomized, and who meet criteria for SAD on the SCID-5 [1], will be eligible to participate. Patients will be excluded if they meet diagnostic criteria for bipolar disorder, psychosis, or substance use disorder on the SCID-5, are currently receiving CBT elsewhere, or are deemed to be of high suicidal or self-harm risk (i.e., with plans and/or intent). All participants will remain under the care of their referring psychiatrist or general practitioner and may hence be offered psychotropic medication (e.g., antidepressants) if needed. There are no restrictions on the use of medications in the trial (except stable dosage/type for ≥ 1 month prior to trial enrolment) but any changes in the type of medication taken or dosage used will be recorded.

2.4. Recruitment

The primary recruitment port will be the Centre for Clinical Interventions (CCI) located in Perth, Australia. The CCI is a specialist public mental health service that 1) treats adults suffering from complex anxiety, affective and eating disorders, 2) conducts clinically applied research, and 3) provides training and supervision for mental health practitioners in psychotherapy. As a clinical facility that regularly conducts clinically applied quality improvement and research studies, the CCI accepts referrals from across the state (Western Australia) from general practitioners (GPs), psychologists and psychiatrists, and has systems in place for undertaking basic research (e.g., using self-report questionnaires) with all patients undergoing treatment, as well as conducting more complex studies (e.g., RCTs). We plan to recruit a minimum of 96 patients, 48 in each treatment arm.

The psychologist conducting the initial evaluation via telephone will invite patients who are deemed suitable for the service to discuss the study with a treating clinical psychologist at their first in-person