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RESEARCH ARTICLE

Internet videoconferencing delivered cognitive behaviour therapy for generalized anxiety disorder: A randomized controlled trial

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Abstract

Objective: Generalized anxiety disorder (GAD) is a chronic mental health condition that results in significant individual and societal burden. Cognitive-behaviour therapy (CBT) therapy is an effective treatment for GAD, however, many individuals experience logistical barriers when accessing evidence-based care. Remote treatments may help to reduce these barriers, however, currently, there are few studies examining the efficacy of high-intensity remote methods for GAD treatment. The current study aims to examine the efficacy of CBT delivered via videoconferencing (VCBT) for GAD using a randomized controlled trial design comparing an immediate treatment group to a waitlist control.

Method: Seventy-eight adults (M_{age} = 36.92; SD = 12.92; 84.4% female) with GAD were enrolled in the study.

Results: Those in the treatment group demonstrated a statistically significant reduction in GAD symptoms from pre-treatment to post-treatment (d = 1.03) and pre-treatment to 3-month follow-up (d = 1.50). Large between-group effect sizes were also observed at post-treatment (d = .80). Twenty-five participants (64.10%) in the VCBT group no longer met diagnostic criteria for GAD at post-treatment, and 26/39 (66.67%) no longer met criteria at 3-month follow-up. Ninety-six per cent of participants were satisfied with the treatment.

Conclusion: The results contribute towards advancing our knowledge on the efficacy and acceptability of VCBT for patients with GAD.

KEYWORDS
cognitive behavioural therapy, generalized anxiety disorder, remote treatment, videoconference

Practitioner points

- Remotely delivered CBT via videoconference is a highly effective and acceptable treatment for patients with generalized anxiety disorder.
- Videoconference-delivered CBT may help to overcome some of the barriers that individuals with generalized anxiety disorder face when accessing treatment including those related to geographical isolation or difficulty accessing a trained therapist.

INTRODUCTION

Generalized anxiety disorder (GAD) is characterized by excessive and uncontrollable worry that is accompanied by a number of physical and/or cognitive symptoms (APA, 2022). The disorder is often chronic (Hoge et al., 2004) and results in considerable individual and economic burden (Konnopka & König, 2020). Globally, the combined lifetime prevalence of GAD is 3.7%, with a 12-month prevalence of 1.8% (Ruscio et al., 2017). GAD can be effectively treated with cognitive behavioural therapy (CBT) and has been shown to result in large effect sizes in a recent meta-analysis ($g = 1.01$; 95% CI: .44–1.57; Carpenter et al., 2018). However, numerous barriers to accessing treatment exist; these include affordability, difficulty accessing a trained clinician and geographical isolation (Coles & Coleman, 2010; Goetter et al., 2020; Mojtabai et al., 2011; Olfson et al., 2000; Trenoska Basile, et al. 2024). One way to overcome these barriers is to provide specialized treatment remotely, using digital health technologies.

Remotely delivered treatments do not require the clinician and the client to be in the same location and these interventions can be provided 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 (e.g. internet-delivered CBT, self-help books or application-based CBT). These treatments can also be accompanied by brief asynchronous clinician contact (i.e. 10 min per week by telephone or email) or delivered in a self-guided fashion, which does not involve any clinician support. High-intensity remote treatments, on the other hand, involve using digital health technologies to provide synchronous sessions that are analogous to standard in-person treatment (e.g. videoconference or telephone-delivered CBT). While low-intensity remote treatments have been demonstrated to be efficacious in the treatment of GAD, with several studies demonstrating medium to large pooled effects across studies (Andrews et al., 2018; Richards et al., 2015), there is limited evidence examining high-intensity remote treatments for this condition (Trenoska Basile et al., 2022b). The literature that does exist has considerable limitations and consists of largely uncontrolled studies with small samples sizes (Bouchard & Renaud, 2001; Rees & Maclaine, 2015; Théberge-Lapointe et al., 2015) or studies with specific populations that are considered non-representative, for example, studies limited to older adults (Brenes et al., 2015). Accordingly, the efficacy and acceptability of high-intensity remote CBT for GAD is an area that requires further investigation.

One promising remote high-intensity approach to treatment includes videoconferencing-delivered CBT (VCBT). VCBT involves the therapist and client working together over video-link, which in comparison to telephone-delivered options maintains the visibility of the therapist and clients' non-verbal cues. Previous research has demonstrated that high-intensity remote CBT results in equivalent outcomes compared to traditional in-person treatment across a number of common mental health disorders

including anxiety disorders, depressive disorders, post-traumatic stress disorder and adjustment disorder (Backhaus et al., 2012; Krzyzaniak et al., 2024; Varker et al., 2019). To our knowledge, there has only been one controlled trial exclusively focused on VCBT for GAD (Bouchard et al., 2022) and two controlled trials of VCBT that have included participants with GAD along with patients with other mental health disorders (Milosevic et al., 2022; Stubbings et al., 2013).

Bouchard et al. (2022) conducted a randomized controlled trial to examine the effectiveness of VCBT compared to in-person treatment for 148 individuals diagnosed with GAD. Large effect sizes were observed for both groups on measures of diagnostic severity (partial eta-squared = .59) and worry symptoms (partial eta-squared = .55). Time by condition interaction contrasts comparing VCBT and in-person CBT revealed very small between-group effect sizes on diagnostic severity (partial eta-squared = .000) and worry symptoms (partial eta-squared = .007), indicating that both groups achieved similar outcomes (Bouchard et al., 2022). Additionally, improved results were maintained at follow-up (Bouchard et al., 2022). It should be noted however that this study did not examine change in diagnostic status, thus excluding the reporting of remission rates and limiting the credibility of findings. Further, the study used older videoconferencing technology that required participants to travel to the treatment site to receive treatment.

Stubbings et al. (2013) examined the efficacy of VCBT compared with in-person therapy using a randomized controlled trial design for 26 patients with a range of mood and anxiety disorders. Findings showed that there was a significant effect for time, resulting in significant reductions in symptoms of anxiety across both treatment types ($d = 1.14$), stress ($d = 1.81$), depression ($d = 1.41$) and an increased quality of life ($d = 1.71$). There were no significant differences observed between the two treatment types across any of the measures (Stubbings et al., 2013). However, a major limitation of this study is the small sample size. Additionally, only one participant with a diagnosis of GAD was part of the VCBT treatment condition.

Finally, using a non-randomized design, Milosevic et al. (2022) analysed outcome data from 413 adult outpatient clinic patients who received either disorder-specific manualized group CBT in-person or via videoconference for a range of disorders including GAD. Results from this study indicated that while both groups (group VCBT and in-person group treatment for GAD) significantly improved (VCBT: $d = -.61$, in-person: $d = -.97$), participants showed slightly greater symptom reduction in the in-person CBT group than the VCBT group ($d = .20$), however, the authors acknowledge that these sub-analyses may be lacking in statistical power (Milosevic et al., 2022). A limitation of this study is that treatment was not randomized. Additionally, the in-person and videoconference groups were facilitated during different time periods, with only the VCBT treatment being conducted during the COVID-19 pandemic when most people experienced an increase in anxiety symptoms (Santabárbara et al., 2021).

Given the limitations of the existing literature, the aim of the present study was to investigate the acceptability and efficacy of remotely delivered VCBT for GAD compared to a waitlist control group. Based on the limited existing literature, it was hypothesized that (1) VCBT would result in significant reductions in symptoms from pre-treatment to post-treatment and pre-treatment to 3-month follow-up with large within-group effect sizes; (2) VCBT would have significantly better outcomes at post-treatment when compared to the control group (with large between-group effect sizes) and (3) VCBT would be an acceptable treatment to individuals with GAD.

METHOD

Design

The study used a randomized controlled design comparing an immediate treatment group with a waitlist control group. Given that the efficacy of VCBT for GAD when delivered remotely has not been tested before, we believed that a waitlist control group is justifiable (Mohr et al., 2009). The study was approved by the University of Technology Sydney Medical Research Ethics Committee (REF

NO. ETH21-5843) and preregistered with the Australian and New Zealand Clinical Trials Registry (ACTRN12621000786897) on 22 June 2021. The study complies with the Consolidated Standards of Reporting Trials statement (CONSORT-R; Schulz et al., 2010). The study protocol was also published (Trenoska Basile et al., 2022a). After completing the post-treatment questionnaires, the control group was administered a brief version (5 sessions) of the same VCBT protocol (results described elsewhere; Trenoska Basile et al., 2023).

Participants

Three-hundred and sixty-nine participants provided consent to participate in the study between January 2022 and March 2023. Of these, 156 completed an initial online screening and were eligible to continue onto a telephone assessment interview to determine their diagnostic status and any comorbid conditions. The diagnostic interviews were administered by trained interviewers who were either provisionally registered or fully registered psychologists under the supervision of an experienced clinical psychologist. Of those that met eligibility for screening, 26 were lost to follow-up, 9 withdrew, 43 were screened out and 78 were eligible and included in the study. The mean age of the total sample was 36.92 years with a standard deviation of 12.92. The proportion of female participants was 84.4%, 13% were male and 2.6% identified as binary or gender diverse. Thirty-nine participants were randomly allocated (using a random number allocation tool; www.random.org) to the treatment group and 39 to the waitlist control group. Participant flow is shown in Figure 1, and demographic information of the sample is shown in Table 1. Baseline scores on the outcome measures for the sample are shown in Table 2. Participants were recruited via advertising on social media, posts on professional networking sites and direct email/letter to community-based clinicians, general practitioners and psychiatrists.

To be included in the study, participants were required to (1) be an Australian resident, (2) be aged 18 or above, (3) meet criteria for GAD as the primary disorder, (4) experience symptoms of at least 'moderate severity' as determined in the diagnostic interview (severity rating of 4 or more) and (5) be on a stable dose of psychotropic medication (i.e. on a consistent dose for at least 3 months). Participants were excluded if they had symptoms that would put them at risk of harming themselves or others or would confound the results of the treatment (i.e. indicated severe depressive symptoms on the PHQ-9). Participants were also excluded if they did not have regular access to the internet and a computer with a camera and/or were seeing a mental health practitioner for concurrent treatment of their GAD on a weekly basis. A complete list of inclusion and exclusion criteria is outlined in the published protocol (Trenoska Basile et al., 2022a).

Measures

A detailed description of the measures and the timepoints of administration of each measure are outlined in the published study protocol (Trenoska Basile et al., 2022a).

Diagnostic assessment

Diagnostic interview for anxiety, mood and obsessive-compulsive and related neuropsychiatric disorders (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. Severity scores range from 1 (indicating no impairment in functioning) to 7 (indicating extreme impairment

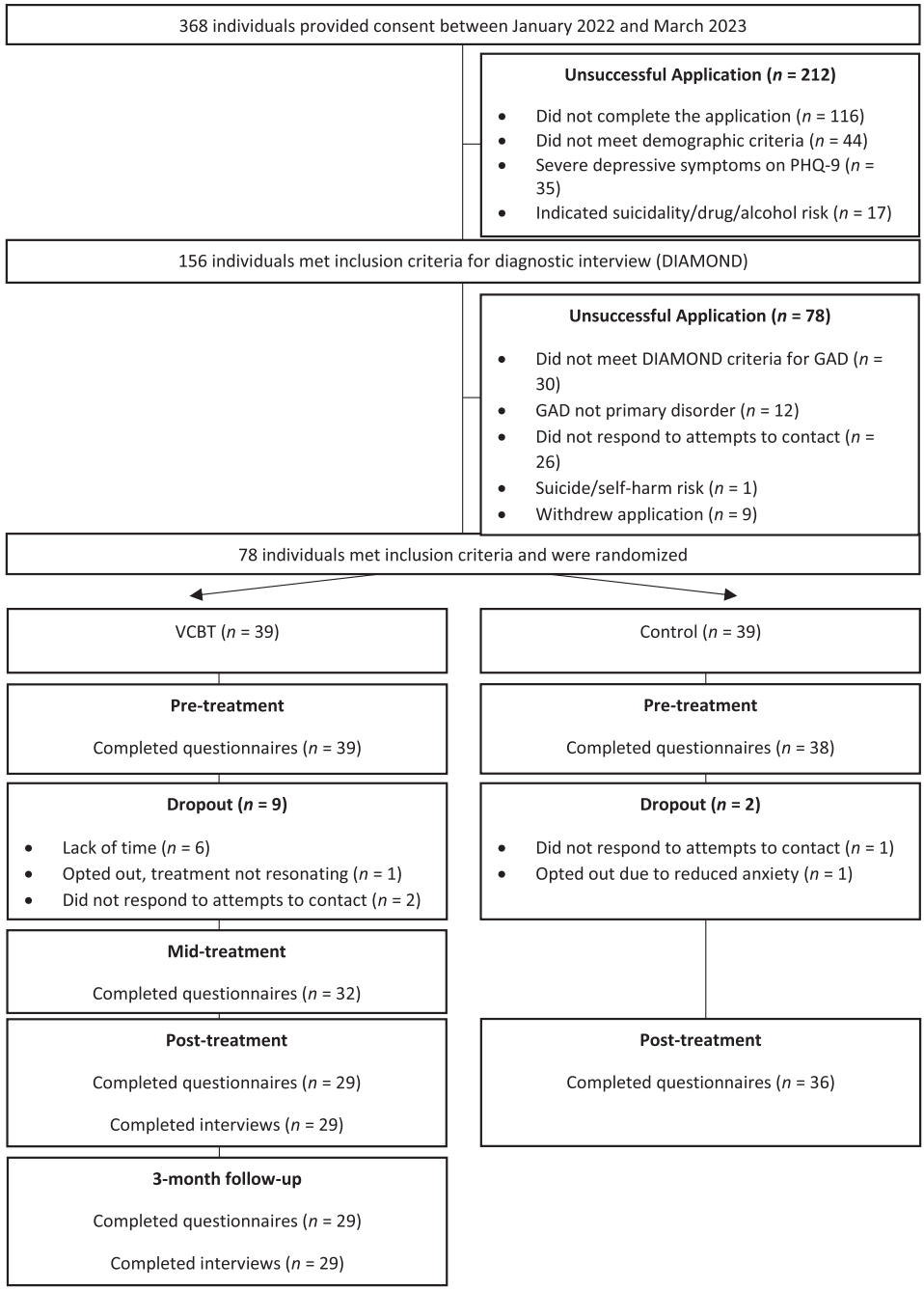

FIGURE 1 Participant flow chart. DIAMOND, Diagnostic Interview for Anxiety, Mood, and Obsessive-Compulsive and Related Neuropsychiatric Disorders; PHQ-9: Patient Health Questionnaire-9 item; VCBT, videoconference delivered cognitive behavioural therapy.

in functioning). The DIAMOND demonstrates very good inter-rater reliability (kappa = .71) and test–retest validity (kappa = .68) for the GAD diagnosis (Tolin et al., 2018). Prior to commencing assessments, therapists completed formal training using the DIAMOND (online DIAMOND training), and the inter-rater reliability for each clinician was ascertained. Kappa coefficients ranged from very good to excellent (.73–1.0) for the online training module. However, an assessment of inter-rater reliability

TABLE 1 Characteristics of the treatment and control groups as well as for the total sample.

Variable	VCBT ($n=39$)		Waitlist ($n=38$)		Significance statistics	Total ($n=77$)	
	n	%	*n*	%		*n*	%
Gender							
Female	36	92.3	29	76.3	$\chi^2(3, N=77)=4.342$[a], $p=.114$	65	84.4
Male	3	7.7	7	18.4		10	13
Non-binary/gender diverse	—	—	2	5.3		2	2.6
Age							
Mean (SD)	38.21 (13.51)	—	36.05 (12.37)	—	$t(75)=.729, p=.468$	36.92 (12.92)	—
Range	18–65		18–62			18–65	—
Marital status							
Single	16	41.0	19	50.0	$\chi^2(3, N=77)=2.245$[a], $p=.326$	35	45.5
Married/de facto	17	43.6	17	44.7		34	44.2
Divorced/separated/other	6	15.4	2	5.3		8	10.4
Education							
Highschool	10	25.6	11	28.9	$\chi^2(4, N=77)=1.521$, $p=.677$	21	27.3
Trade certificate/diploma	4	10.3	7	18.4		11	14.3
Bachelor degree	15	38.5	11	28.9		26	33.8
Master/Doctoral degree	10	25.6	9	23.7		19	24.7
Employment[b]							
Full time	13	33.3	11	28.9	$\chi^2(2, N=77)=.173$, $p=.678$	24	31.2
Part time/Casual	18	46.2	14	36.8	$\chi^2(2, N=77)=.687$, $p=.407$	32	41.6
Student	11	28.2	13	34.2	$\chi^2(2, N=77)=.324$, $p=.569$	24	31.2
At home parent	1	2.6	3	7.9	$\chi^2(2, N=77)=1.110$[a], $p=.358$	4	5.2
Unemployed/Seeking work	6	15.4	5	13.2	$\chi^2(2, N=77)=.078$, $p=.780$	11	14.3
Registered sick/Disabled	—	—	2	5.3	$\chi^2(2, N=77)=2.107$[a], $p=.240$	2	2.6
Retired	2	5.1	—	—	$\chi^2(2, N=77)=2.001$[a], $p=.494$	2	2.6
Medication	15	38.5	9	23.7	$\chi^2(2, N=77)=1.959$, $p=.162$	24	31.2
Comorbidities							
Obsessive compulsive disorder	11	28.2	10	26.3	$\chi^2(2, N=77)=.035$, $p=.852$	21	27.3
Body dysmorphic disorder	6	15.4	3	7.9	$\chi^2(2, N=77)=1.046$[a], $p=.481$	9	11.7
Hoarding disorder	3	7.7	4	10.5	$\chi^2(2, N=77)=.187$[a], $p=.711$	7	9.1
Excoriation disorder	3	7.7	4	10.5	$\chi^2(2, N=77)=.187$[a], $p=.711$	7	9.1

TABLE 1 (Continued)

Variable	VCBT ($n=39$)		Waitlist ($n=38$)		Significance statistics	Total ($n=77$)	
	n	%	*n*	%		*n*	%
Social anxiety disorder	19	48.7	14	36.8	$\chi^2(2, N=77)=1.108$, $p=.292$	33	42.9
Panic disorder	8	20.5	6	15.8	$\chi^2(2, N=77)=.289$, $p=.591$	14	18.2
Agoraphobia	5	12.8	5	13.2	$\chi^2(2, N=77)=.002$[a], $p=1.00$	10	13
Separation anxiety disorder	5	12.8	3	7.9	$\chi^2(2, N=77)=.502$[a], $p=.711$	8	10.4
Specific phobia	6	15.4	6	15.8	$\chi^2(2, N=77)=.002$, $p=.961$	12	15.6
Bipolar II disorder	1	2.6	—	—	$\chi^2(2, N=77)=.987$[a], $p=1.000$	1	1.3
Major depressive disorder	21	53.8	18	47.4	$\chi^2(2, N=77)=.323$, $p=.570$	39	50.6
Persistent depressive disorder	6	15.4	8	21.1	$\chi^2(2, N=77)=.416$, $p=.519$	14	18.2
Premenstrual dysphoric disorder	6	15.4	5	13.2	$\chi^2(2, N=77)=.078$, $p=.780$	11	14.3
Post-traumatic stress disorder	2	5.1	1	2.6	$\chi^2(2, N=78)=.320$[a], $p=1.000$	3	3.9
Adjustment disorder	3	7.7	3	7.9	$\chi^2(2, N=77)=.001$[a], $p=1.000$	6	7.8
Binge eating disorder	1	2.6	1	2.6	$\chi^2(2, N=77)=.000$[a], $p=1.000$	2	2.6
Somatic symptom disorder	3	7.7	2	5.3	$\chi^2(2, N=77)=.187$[a], $p=1.000$	5	6.5
Illness anxiety disorder	2	5.1	2	5.3	$\chi^2(2, N=77)=.001$[a], $p=1.000$	4	5.2
Substance use disorder	3	7.7	4	10.5	$\chi^2(2, N=77)=.187$[a], $p=.711$	7	9.1
Attention deficit/ hyperactivity disorder	8	20.5	6	15.8	$\chi^2(2, N=77)=.289$, $p=.591$	14	18.2
Tic disorder	1	2.6	—	—	$\chi^2(2, N=77)=.987$[a], $p=1.000$	1	1.3
DIAMOND GAD severity[c]							
Mean (SD)	4.54 (.505)		4.68 (.669)		$t(72)=-.981$, $p=.330$		

[a]Indicated that cells had expected counts less than 5 and should be interpreted with caution. Fisher's exact test was used in these instances.

[b]Counts do not equal 100 as some individuals belong to more than one category.

[c]$N=36$ (severity data for three participants were not recorded).

specifically for the GAD module was not conducted. A blind assessment approach was prioritized, such that the assessing clinician differed from the primary treating clinician. This was possible for all pre-treatment, post-treatment and follow-up assessments. However, assessment of the blind was not conducted in this study.

TABLE 2 Means and standard deviations for outcome measures at baseline for treatment and control groups as well as for the total sample.

Outcome measure	VCBT ($n=39$), Mean (SD)	Waitlist ($n=38$), Mean (SD)	Significance statistics	Total ($n=77$), Mean (SD)
GAD-7	12.59 (3.95)	12.47 (4.30)	$t(75)=.123$, $p=.902$	12.53 (4.10)
GAD-D	19.28 (7.41)	17.87 (6.80)	$t(75)=.872$, $p=.386$	18.58 (7.10)
PSWQ-3	10.79 (2.96)	11.11 (2.10)	$t(75)=-.530$, $p=.598$	10.95 (2.56)
PHQ-9	11.67 (4.97)	11.21 (4.53)	$t(75)=.421$, $p=.675$	11.44 (4.73)
OASIS	11.10 (3.50)	11.03 (2.86)	$t(75)=.104$, $p=.917$	11.06 (3.18)
IUS-12	39.38 (8.60)	39.79 (8.24)	$t(75)=-.211$, $p=.834$	39.58 (8.37)
CGI	4.10 (1.10)	4.05 (1.11)	$t(75)=.198$ $p=.843$	4.08 (1.10)
SDS	16.64 (6.04)	16.45 (6.19)	$t(75)=.139$, $p=.890$	16.55 (6.08)

Abbreviations: CGI, NIMH Clinician Global Impression; GAD-7, Generalized Anxiety Disorder Scale (7-item); GAD-D, Generalized Anxiety Disorder Dimensional Scale; IUS-12, Intolerance of Uncertainty Scale; OASIS, Overall Anxiety Severity and Impairment Scale; PHQ-9, Patient Health Questionnaire (9-item); PWSQ-3, Penn State Worry Questionnaire (3-item); SDS, Sheehan Disability Scale.

Primary outcome measure

Generalized Anxiety Disorder Questionnaire-7 item (GAD-7; Spitzer et al., 2006)

The GAD-7 is a 7-item measure of symptoms of GAD. Each of the seven items is rated on a 4-point scale from 0 (not at all) to 3 (nearly every day), and a total score is calculated by summing each of the seven items. The scale has demonstrated good psychometric properties in previous samples (Groves et al., 2023; Hinz et al., 2017; Johnson et al., 2019; Spitzer et al., 2006). A score of 10 or above indicates clinically significant symptoms of generalized anxiety disorder (Spitzer et al., 2006). The GAD-7 was used as the primary outcome measure given its sensitivity to measuring treatment change (Dear et al., 2011). The GAD-7 is a commonly used outcome measure in clinical trials assessing treatment efficacy for GAD (e.g. Dear et al., 2015; Titov et al., 2009). The Cronbach's alpha for the present sample was .809.

Secondary outcome measures

Generalized 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 (Groves et al., 2023; Lebeau et al., 2012). Higher scores indicate greater severity of GAD symptoms. The Cronbach's alpha for the present study was .859.

Penn State Worry Questionnaire-3 item (PSWQ-3; Berle et al., 2011)

The PSWQ-3 is a 3-item, self-report questionnaire designed to assess the core features of worry in GAD (uncontrollability, excessiveness and multiple worry domains). Participants rate items on a 5-point scale, and responses are summed, with higher scores indicating greater worry. The PSWQ-3 has demonstrated good psychometric properties in previous samples (Berle et al., 2011). A higher score indicates greater worry. The Cronbach's alpha for the present study was .807.

Overall Anxiety Severity and Impairment Scale (Norman et al., 2006)

The OASIS is a 5-item transdiagnostic self-report measure of anxiety symptoms. The OASIS has been shown to have strong psychometric properties in previous studies (Bragdon et al., 2016;

Norman et al., 2006), and a cut score of 8 (Campbell-Sills et al., 2009) has been used to indicate clinically significant anxiety symptoms in previous studies. The Cronbach's alpha for the present study was .821.

Patient Health Questionnaire-9 item (PHQ-9; Kroenke et al., 2001)

The PHQ-9 is a 9-item measure of depressive symptoms. Each item is assessed on a 4-point Likert scale from 0 (not at all) to 3 (nearly every day) and symptoms are assessed over the previous 2 weeks. Scores are summed, and total scores of ≥10 are used to indicate clinically significant depressive symptoms (Manea et al., 2012) with 88% sensitivity and 88% specificity (Kroenke et al., 2001). Total scores of 5, 10, 15 and 20 represent mild, moderate, moderately severe and severe depression, respectively. The PHQ-9 has been demonstrated to have excellent psychometric properties in previous samples (Kroenke et al., 2001; Zuithoff et al., 2010). The Cronbach's alpha for the present study was .767.

Intolerance of Uncertainty Scale (IUS-12; Carleton et al., 2007)

The IUS-12 is a 12-item self-report questionnaire measuring responses to uncertainty, ambiguous situations and the future. The 12 items are rated on a 5-point Likert scale ranging from 1 (not at all characteristic of me) to 5 (entirely characteristic of me). The IUS-12 has demonstrated robust psychometric properties in community (Fergus & Wu, 2013) and treatment-seeking samples (Shihata et al., 2018). A higher score indicates greater uncertainty. The Cronbach's alpha for the present study was .861.

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). The CGI has been shown to be a valid and reliable clinical outcome measure in previous studies (Berk et al., 2008; Zaider et al., 2003). The CGI is typically administered as a clinician-administered scale, however, the self-report and clinician-administered versions have been demonstrated to be highly correlated (Hannan & Tolin, 2007).

Sheehan Disability Scale (SDS; Sheehan et al., 1996)

The SDS is a commonly used 3-item measure that assesses how much psychiatric symptoms have interfered with work, social, and home life functioning. Each domain is scored from 0 (not at all) to 10 (very severely). The three domains can be summarized to evaluate global functional impairment by adding the scores of each of the three domains, resulting in global SDS score ranges from 0 (unimpaired) to 30 (highly impaired). Functional remission was defined as SDS ≤ 6 at endpoint (Sheehan et al., 2011). A cut score of 5 on any subscale has been used to identify individuals with clinically relevant symptoms in previous studies (Leon et al., 1992). The Cronbach's alpha for the present study was .738.

Process/acceptability measures

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). A score of 22 or above has previously been used to indicate adequate satisfaction with treatment (Kelly et al., 2017). The Cronbach's alpha for the present study was .930.

Acceptability Questionnaire (AQ)

The AQ is a 10-item measure of acceptability of remote treatments. The questionnaire asks participants to rate their experience of the treatment in relation to how satisfied they were with treatment, whether

they had noticed improvement in symptoms or would recommend the treatment to others. The questionnaire has been used in examining acceptability for remote treatments of other disorders (Wootton et al., 2019).

Treatment

Treatment was provided from a university outpatient clinic in Australia and followed a manualized VCBT intervention developed by the study team, which was adapted from existing treatment manuals informed by the Intolerance of Uncertainty Model of GAD (Dugas & Robichaud, 2007; Robichaud et al., 2019; Robichaud & Dugas, 2015). The treatment manual can be requested from the corresponding author. Those in the treatment condition received 10 weekly (50 min) treatment sessions conducted via Zoom (Zoom Video Communications Inc., 2016). The treatment for this group comprised seven modules and covered the following: (1) psychoeducation, (2) cognitive restructuring to challenge positive beliefs about worry, (3) cognitive restructuring to challenge identified worries, (4) problem-solving training to reduce negative problem orientation, (5) behavioural experiments to develop a greater tolerance to uncertainty, (6) imaginal exposure to address cognitive avoidance and (7) relapse prevention. Participants were also required to complete homework tasks between sessions. Treatment was delivered by seven provisionally registered or fully registered psychologist(s) (2 male and 5 female) under the supervision of an experienced clinical psychologist. All treating psychologists were familiar with delivering manualized treatments and thoroughly trained by the investigators in the administration of the treatment protocol. To ensure treatment fidelity, treating clinicians received weekly supervision to review client progress and address clinical issues arising from sessions. All sessions were recorded, and at least 10% of sessions were randomly selected for clinician competence, treatment adherence and integrity checking.

Statistical methods and analysis

Group differences in demographic data, pre-treatment measures and dropout were analysed with independent samples *t*-tests with Bonferroni-corrected *p*-values (continuous measures) and chi-square tests (categorical measures). Fisher's exact test was used to ascertain significance in instances where expected values were less than 5. Treatment acceptability was examined using descriptive statistics.

The main analyses comparing the treatment group to the control group were carried out using mixed-linear models with an unstructured covariance structure. Multiple imputation was used to handle missing data for all continuous dependent variables (Lee & Shi, 2021). Effect sizes using Cohen's *d* were calculated for within-group and between-group differences based on pooled standard deviations for the entire sample using the estimated marginal means (Feingold, 2015). All analyses were conducted based on the total score of the relevant outcome measure. All analyses were performed using IBM SPSS Statistics (Version 29).

Clinical significance was analysed in two ways. Firstly, the change in diagnostic status from pre-treatment to post-treatment and pre-treatment to 3-month follow-up was assessed using the DIAMOND in the treatment group. Secondly, clinically significant change was assessed in both groups and was defined as reliable change according to the Jacobson and Truax (1991) reliable change index criteria (in this case, a reduction of at least 4.68) as well as a total score of <10 on the GAD-7. Clinical deterioration was assessed via responses on the CGI improvement scale where a score of 5 or more (i.e. 'minimally worse', 'much worse' or 'very much worse' since starting treatment) indicates deterioration.

RESULTS

Adherence and attrition

Post-treatment questionnaires were completed by 29/39 (74.4%) participants in the VCBT group and 36/38 (94.7%) in the control group. Follow-up questionnaires were completed by 29/39 (74.4%) participants in the VCBT Group. Post-treatment telephone administered interviews (GAD module from DIAMOND) were completed with 29/39 (74.4%) participants in the VCBT group, and follow-up telephone interviews were completed with 29/39 (74.4%) participants in the VCBT group. The average number of completed sessions was 7.97 (SD = 2.68).

Dropout analysis

Participants were deemed to be a treatment completer when they completed at least 8 of the 10 sessions. This number of sessions was selected to reflect treatment completion to ensure that participants had completed the majority of the active treatment components outlined in the treatment manual. Twenty-nine out of 39 (74.4%) participants were deemed to have completed treatment. There were no significant differences between those who completed treatment and those who dropped out of treatment based on demographic variables such as age, gender, medication, employment status or pre-diagnostic severity ($p > .05$). Significant differences in education level were observed ($\chi^2(4, N = 39) = 9.192$, $p = .027$), with those with trade certificates/diplomas dropping out at a significantly higher proportion than other educational groups (i.e. high school qualifications or bachelor, master or doctoral degrees). However, it is worth noting that multiple groups had counts less than 5 in this analysis and should be interpreted with caution.

Efficacy

Pre-treatment, post-treatment and 3-month follow-up estimated marginal means and standard deviations on the primary and secondary outcome measures, and effect sizes with 95% confidence intervals are outlined in Table 3. On the primary outcome measure (GAD-7) the mixed-models analyses revealed a significant effect for time ($F(3, 50.817) = 25.589$, $p < .001$), group ($F(1, 75.017) = 7.491$, $p = .008$) and time by group interaction ($F(1, 75.001) = 25.781$, $p < .001$). Pairwise comparisons revealed that there was a significant change in the GAD-7 from pre-treatment to mid-treatment ($p < .001$; VCBT: $d = 1.04$, 95% CI: .56–1.50), pre-treatment to post-treatment ($p < .001$; VCBT: $d = 1.03$, 95% CI: .55–1.50; Control: $d = .15$, 95% CI: −.30 to .60) and pre-treatment to follow-up ($p < .001$; VCBT: $d = 1.50$, 95% CI: .98–1.99). Pairwise comparisons for the group effect showed that the VCBT group differed significantly from the control group at post-treatment ($p < .001$) with a large between-group effect size observed ($d = .80$; 95% CI: .33–1.26).

On the GAD-D, there was a significant effect for time ($F(3, 53.412) = 19.418$, $p < .001$) and a significant time by group interaction ($F(1, 75.001) = 28.020$, $p < .001$). There was no significant effect for group ($F(1, 75.001) = 3.432$, $p = .68$) on the GAD-D. Pairwise comparisons revealed that there was a significant change on the GAD-D from pre-treatment to mid-treatment ($p < .001$; VCBT: $d = .78$, 95% CI: .31–1.23), pre-treatment to post-treatment ($p < .001$; VCBT: $d = 1.08$, 95% CI: .59–1.54; Control: $d = .12$, 95% CI: −.33 to .57) and pre-treatment to follow-up ($p < .001$; VCBT: $d = 1.34$, 95% CI: .84–1.82). Pairwise comparisons for the group effect showed that the VCBT group differed significantly from the control group at post-treatment ($p = .003$) with a large between-group effect size observed ($d = .82$; 95% CI: .35–1.28).

On the PSWQ-3, there was a significant effect for time ($F(3, 58.334) = 8.896$, $p < .001$), group ($F(1, 75) = 4.258$, $p = .043$) and time by group interaction ($F(1, 75) = 4.521$, $p = .037$). Pairwise comparisons

revealed that there was a significant change on the PSWQ-3 from pre-treatment to mid-treatment ($p = .005$; VCBT: $d = .52$, 95% CI: .06–.96), pre-treatment to post-treatment ($p = .001$; VCBT: $d = .55$, 95% CI: .10–1.00; Control: $d = .17$, 95% CI: −.28 to .62) and pre-treatment to follow-up ($p < .001$; VCBT: $d = .83$, 95% CI: .36–1.28). Pairwise comparisons for the group effect showed that the VCBT group differed significantly from the control group at post-treatment ($p = .002$) with a medium between-group effect size ($d = .53$, 95% CI: .07–.98).

On the PHQ-9, there was a significant effect for time ($F(3, 53.728) = 11.733$, $p < .001$) and a significant time by group interaction ($F(1, 75) = 13.954$, $p < .001$). There was no significant effect for group ($F(1, 75) = 2.833$, $p = .096$). Pairwise comparisons revealed that there was a significant change on the PHQ-9 from pre-treatment to mid-treatment ($p < .001$; VCBT: $d = .71$, 95% CI: .25–1.16), pre-treatment to post-treatment ($p < .001$) (VCBT: $d = .75$, 95% CI: .28–1.20; Control $d = .20$, 95% CI: −.25 to .65) and pre-treatment to follow-up ($p < .001$; VCBT: $d = .84$, 95% CI: .37–1.29). Pairwise comparisons for the group effect showed that the VCBT group differed significantly from the control at post-treatment ($p = .014$) with a medium between-group effect size ($d = .50$, 95% CI: .04–.95).

On the OASIS, there was a significant effect for time ($F(3, 57.202) = 14.778$, $p = <.001$) and a significant time by group interaction ($F(1, 75) = 7.437$, $p = .08$). There was no significant effect for group ($F(1, 75.001) = 1.499$, $p = .225$). Pairwise comparisons revealed that there was a significant change on the OASIS from pre-treatment to mid-treatment ($p < .001$; VCBT: $d = .79$, 95% CI: .32–1.24), pre-treatment to post-treatment ($p < .001$) (VCBT: $d = .98$, 95% CI: .50–1.44; Control $d = .27$, 95% CI: −.19 to .72) and pre-treatment to follow-up ($p < .001$; VCBT: $d = 1.11$, 95% CI: .63–1.58). Pairwise comparisons for the group effect showed that the active treatment group differed from the control at post-treatment ($p = .007$) with a medium between-group effect size ($d = .54$, 95% CI: .08–.99).

On the IUS-12, there was a significant effect for time ($F(3, 52.432) = 4.275$, $p < .009$). There was no significant effect for group ($F(1, 75) = .666$, $p = .417$) or time by group interaction ($F(1, 75) = 1.661$, $p = .201$). Pairwise comparisons revealed that there was a significant change in the IUS-12 from pre-treatment to post-treatment ($p = .048$; VCBT: $d = .35$, 95% CI: −.10 to .79; Control: $d = .16$, 95% CI: −.29 to .61) and pre-treatment to follow-up ($p = .016$; VCBT $d = .50$, 95% CI: .05–.95). No significant difference was found from pre-treatment to mid-treatment ($p = .070$). Pairwise comparisons showed that there was no significant difference between ($p = .099$) the VCBT and control group at post-treatment ($d = .23$, 95% CI: −.22 to .68).

On the CGI-S, there was a significant effect for time ($F(3, 52.453) = 12.961$, $p < .001$) and a significant time by group interaction ($F(1, 75) = 4.094$, $p = .047$). There was no significant effect for group ($F(1, 75) = 1.130$, $p = .291$). Pairwise comparisons revealed that there was a significant change on the CGI-S from pre-treatment to mid-treatment ($p < .001$; VCBT: $d = .74$, 95% CI: .28–1.19), pre-treatment to post-treatment ($p < .001$; VCBT: $d = .88$, 95% CI: .41–1.34; Control $d = .31$, 95% CI: −.14 to .76) and pre-treatment to follow-up ($p < .001$; VCBT: $d = 1.00$, 95% CI: .52–1.46). Pairwise comparisons showed that the active treatment group differed from the control at post-treatment ($p = .017$) with a medium between-group effect size ($d = .55$, 95% CI: .09–1.00).

Finally, analyses examining the SDS revealed a significant effect for time ($F(3, 53.622) = 10.439$, $p < .001$) and time by group interaction ($F(1, 75.001) = 5.372$, $p = .023$). There was no significant effect for group ($F(1, 75) = .955$, $p = .332$). Pairwise comparisons revealed that there was a significant change in the SDS from pre-treatment to mid-treatment ($p < .001$; VCBT: $d = .72$, 95% CI: .25–1.17), pre-treatment to post-treatment ($p < .001$; VCBT: $d = .63$, 95% CI: .16–1.07; Control: $d = .22$, 95% CI: −.23 to 1.07) and pre-treatment to follow-up ($p < .001$; VCBT: $d = .85$, 95% CI: .38–1.31). Pairwise comparisons showed that the active treatment group differed from the control at post-treatment ($p = .036$) with a medium between-group effect size ($d = .41$, 95% CI: −.05 to .85).

Clinical improvement and deterioration

Using the last observation carried-over method, where diagnostic status was carried forward from the last observation, 25/39 (64.10%) and 26/39 (66.67%) of treatment participants no longer met diagnostic

TABLE 3 Estimated marginal means, standard deviations and effect sizes (Cohen's *d*) for total sample.

		Mean (SD)				Within group effect sizes (95% CI)		Between group effect sizes (95% CI)
Outcome measure	Group	Pre-treatment	Mid-treatment	Post-treatment	Follow-up	Within group pre-treatment to post-treatment	Within group pre-treatment to follow-up	VCBT vs. Control (Post)
GAD-7	Treatment	12.59 (3.95)	8.35 (4.19)	7.20 (6.22)	6.44 (4.25)	1.03 (.55 to 1.50)	1.50 (.98 to 1.99)	.80 (.33 to 1.26)
	Control	12.47 (4.30)	—	11.76 (5.05)	—	.15 (−.30 to .60)	—	
GAD-D	Treatment	19.28 (7.41)	13.72 (6.86)	10.90 (8.10)	10.14 (6.18)	1.08 (.59 to 1.54)	1.34 (.84 to 1.82)	.82 (.35 to 1.28)
	Control	17.87 (6.78)	—	17.05 (6.84)	—	.12 (−.33 to .57)	—	
PSWQ-3	Treatment	10.80 (2.96)	9.35 (2.65)	9.03 (3.42)	8.20 (3.33)	.55 (.10 to 1.00)	.83 (.36 to 1.28)	.53 (.07 to .98)
	Control	11.11 (2.10)	—	10.68 (2.77)	—	.17 (−.28 to .62)	—	
PHQ-9	Treatment	11.67 (4.97)	8.39 (4.22)	7.34 (6.51)	7.64 (4.65)	.75 (.28 to 1.20)	.84 (.37 to 1.29)	.50 (.04 to .95)
	Control	11.21 (4.52)	—	10.25 (4.96)	—	.20 (−.25 to .65)	—	
OASIS	Treatment	11.10 (3.50)	8.62 (2.74)	8.01 (4.38)	7.07 (3.74)	.98 (.50 to 1.44)	1.11 (.63 to 1.58)	.54 (.08 to .99)
	Control	11.03 (2.86)	—	10.17 (3.50)	—	.27 (−.19 to .72)	—	
IUS-12	Treatment	39.39 (8.61)	34.65 (10.61)	36.01 (10.55)	34.85 (9.44)	.35 (−.10 to .79)	.50 (.05 to .95)	.23 (−.22 to .68)
	Control	39.79 (8.24)	—	38.34 (9.75)	—	.16 (−.29 to .61)	—	
CGI-Severity	Treatment	4.10 (1.09)	3.28 (1.12)	3.00 (1.38)	2.85 (1.40)	.88 (.41 to 1.34)	1.00 (.52 to 1.46)	.55 (.09 to 1.00)
	Control	4.05 (1.12)	—	3.70 (1.13)	—	.31 (−.14 to .76)	—	
SDS	Treatment	16.64 (6.04)	12.76 (4.70)	12.06 (8.41)	10.92 (7.32)	.63 (.16 to 1.07)	.85 (.38 to 1.31)	.41 (−.05 to .85)
	Control	16.45 (6.19)	—	15.07 (6.20)	—	.22 (−.23 to .67)	—	

Note: Effect sizes (Cohen's *d*) were calculated based on pooled standard deviations.

Abbreviations: CGI, NIMH Clinician Global Impression; CI, confidence interval; GAD-7, Generalized Anxiety Disorder Scale (7-item); GAD-D, Generalized Anxiety Disorder Dimensional Scale; IUS-12, Intolerance of Uncertainty Scale; OASIS, Overall Anxiety Severity and Impairment Scale; PHQ-9, Patient Health Questionnaire (9-item); PWSQ-3, Penn State Worry Questionnaire (3-item); SDS, Sheehan Disability Scale.

criteria for GAD at post-treatment and follow-up, respectively. Using pooled imputed data, 20/39 (51.3%) of participants in the treatment group met criteria for clinically significant change at post-treatment compared to 8/38 (21.1%) in the control group. These results were maintained at follow-up with 23/39 (59.0%) of treatment participants meeting clinically significant improvement. 1/39 (2.6%) and 2/39 (5.1%) of participants reported being 'minimally worse' on the CGI-I at mid-treatment and follow-up, respectively. No participants reported that they were 'much' or 'very much' worse on the CGI-I at any time point.

Treatment satisfaction and acceptability

The mean score on the CSQ was 28.55 (SD = 3.60). Of those who completed the post-treatment questionnaires ($n = 28$), 27/28 (96.43%) of participants in the VCBT group reported that they were 'satisfied' or 'extremely satisfied' with the treatment.

DISCUSSION

The aim of the current study was to investigate the acceptability and efficacy of VCBT for GAD using a randomized controlled design comparing immediate treatment to a waitlist control group. Overall, we hypothesized that (1) VCBT would result in significant reductions in symptoms from pre-treatment to post-treatment and pre-treatment to 3-month follow-up with large within-group effect sizes, (2) VCBT would result in significant reductions at post-treatment when compared to the control group with large between-group effect sizes and (3) VCBT would be an acceptable treatment to individuals with GAD. Our hypotheses were supported in this study.

The results indicated that participants in the VCBT treatment group improved significantly from pre-treatment to post-treatment on the primary outcome measure (within-group effect size of $d = 1.03$). These results were maintained at 3-month follow-up with significant reductions in symptoms from pre-treatment to follow-up (with large within-group effects sizes, $d = 1.50$). These results are consistent with those reported by previous meta-analyses of remotely delivered CBT for GAD ($g = .83$; Trenoska Basile et al., 2022b), other VCBT research for GAD (Bouchard et al., 2022; Milosevic et al., 2022; Stubbings et al., 2013) and demonstrate the efficacy of VCBT for GAD. The results are also consistent with the results seen in-person CBT, where large effect sizes (Hedge's $g = 1.01$) are typically seen (Carpenter et al., 2018). However, it is important for future research to directly compare VCBT and in-person CBT to examine the relative efficacy of these approaches.

Significant reductions in symptoms from pre-treatment to post-treatment and pre-treatment to follow-up were also seen in secondary outcomes. Specifically, the VCBT group demonstrated significant improvement with large effect sizes from pre-treatment to post-treatment on the GAD-D ($d = 1.08$) and OASIS ($d = .98$). These improvements were maintained at follow-up (GAD-D: $d = 1.34$, OASIS: $d = 1.11$). Similar results were also seen on the PHQ-9, with significant reductions in symptoms from pre-treatment to post-treatment ($d = .75$) and pre-treatment to follow-up ($d = .84$), suggesting that treatment was also effective in reducing depressive symptoms, which is particularly important given the high comorbidity between GAD and depressive disorders (Ruscio et al., 2017). We used a disorder-specific approach in this study, and future research may wish to examine the efficacy of transdiagnostic CBT when delivered via videoconferencing.

A significant decrease in worry, a core symptoms of GAD (APA, 2022), as measured by the PSWQ-3, was also seen from pre-treatment to post-treatment and pre-treatment to 3-month follow-up, although the magnitude of effects was smaller ($d = .55$ and .83, respectively). This is consistent with other CBT studies where treatment effects for worry are often smaller than those for GAD severity measures (Dear et al., 2011; Trenoska Basile et al., 2022b). For example, in a meta-analysis of remote CBT for GAD, the outcome measure used was shown to have a moderating effect on the within-group effect of treatment

outcome, with the GAD-7 ($g = 1.51$) demonstrating significantly larger effects than the PSWQ ($g = .74$; Trenoska Basile et al., 2022b). Similarly, in a study comparing the psychometric properties of both the GAD-7 and PSWQ, Dear et al. (2011) found that the effect sizes observed for the PSWQ ($d = .71$) were smaller than those observed for the GAD-7 ($d = 1.10$), concluding that the GAD-7 provided greater sensitivity to change in symptoms. It is also possible, however, that the reduced effect of worry may be due to the sequencing of interventions in this study, as worry exposure was conducted as the final intervention. Alternatively, it is possible that the treatment reduces the distress associated with worry rather than the worry itself.

Similarly, while intolerance of uncertainty (IoU) reduced significantly from pre-treatment to post-treatment and pre-treatment to 3-month follow-up, treatment effects were in the small to medium range ($d = .35$ and $d = .50$, respectively). While the treatment was based on the IoU model (Dugas et al., 1995), not all participants endorsed experiencing an IoU. This may also explain the non-significant interaction effect seen in this study. This brings to light the importance of matching treatment models to individual needs using a formulation-driven approach. Such an approach may allow practitioners to better target the maintaining factors of GAD for each individual. While IoU has been heavily studied in GAD (Behar et al., 2009), it is a transdiagnostic phenomenon that is seen in multiple presentations, including obsessive-compulsive disorder, major depressive disorder, social anxiety disorder and panic disorder (Boelen & Reijntjes, 2009; Boswell et al., 2013; Gentes & Ruscio, 2011). Treatments based on other theoretical models, such as the Emotion Dysregulation Model (Mennin et al., 2002), the Acceptance-Based Model (Roemer & Orsillo, 2002), Metacognitive Model (Wells, 1995) or transdiagnostic approaches that are relevant to all participants with GAD may be more applicable to patients and thus should be studied in future research.

Our second hypothesis that individuals with GAD being treated with VCBT would demonstrate reduced symptoms of GAD compared to waitlist controls was also supported, with large between-group effects seen on the primary measure (GAD-7: $d = .80$) and medium to large between-group effect sizes across most of the secondary outcome measures (GAD-D: $d = .82$; OASIS: $d = .54$, PSWQ-3: $d = .53$; PHQ-9: $d = .50$). While comparison with a waitlist control group was considered appropriate in this study, given that this was the first study to examine remotely delivered VCBT for GAD, future studies may wish to compare VCBT against more active treatments to ensure that VCBT is more effective than general effects of mental health care.

Our final hypothesis that individuals with GAD would find VCBT treatment acceptable was also supported. Individuals who completed the VCBT treatment reported high levels of satisfaction across the various acceptability measures. For instance, 96.43% reported that they were 'satisfied' or 'extremely satisfied' with treatment, which is consistent with other remotely delivered interventions, such as internet-delivered CBT (Titov et al., 2009). Similarly, the mean score on the CSQ ($M = 28.55$, SD = 3.60) is consistent with Bouchard et al. (2022) who also found high levels of satisfaction in a VCBT treatment ($M = 28.32$, SD = 3.78) (Bouchard et al., 2022). The dropout rate in the current study (10/39; 25.6%) is comparable to those seen in other randomized controlled trials examining the efficacy of in-person CBT, for example, 8/29 (27.6%) in Timulak et al. (2022) and 14/46 (30.4%) in Westra et al. (2009). However, it will also be important to assess the acceptability of VCBT compared with in-person treatment, as some studies examining treatment preferences have found that in-person treatment is preferred to VCBT (Black et al., 2023; McCausland et al., 2020; Robertson et al., 2020; Smith et al., 2021; Trenoska Basile et al., 2024). Notably, perceptions of VCBT may have become more favourable since the COVID-19 pandemic, where many consumers switched their in-person treatments to those conducted via videoconferencing.

While the results of the current study demonstrate the efficacy and acceptability of VCBT for GAD, it is important to highlight some of the limitations of the study. Firstly, the diagnostic interview was not administered post-treatment for the control group which limited our ability to compare the rates of diagnostic change between the VCBT and the control group. Future studies should consider reconfirming the diagnostic status of the control group at post-treatment. Secondly, the sample was overwhelmingly female (84.4%), and while GAD is more prevalent in women than men (Ruscio et al., 2017), the results

of the current study may not be generalizable to all individuals with GAD. More studies with larger sample sizes that are representative of a GAD population are necessary to draw more concrete conclusions. Finally, this research was conducted at a time when VCBT was already being implemented by clinicians due to the COVID-19 pandemic. Future research should continue to explore the efficacy of technologically advanced treatments as they emerge to ensure that an evidence base is available for early adopters of these delivery modes.

Notwithstanding these limitations, the present study was able to address gaps in previous studies by focusing on ensuring diagnostic status was examined post-treatment for the treatment group. Secondly, the study used up-to-date videoconferencing technology and allowed participants to receive treatment at their choice of location, thus replicating real-world applications. Overall, the results of the current study provide preliminary evidence to suggest that VCBT is an acceptable and efficacious treatment for patients with GAD. This may help to overcome some of the barriers that individuals with GAD face when accessing treatment, including those related to geographical isolation or difficulty accessing a trained therapist. However, it is important for future studies to examine the acceptability and efficacy of VCBT in contrast with other more active treatments, including in-person CBT.

AUTHOR CONTRIBUTIONS

Vesna Trenoska Basile: Investigation; writing – original draft; methodology; writing – review and editing; data curation; project administration; formal analysis. **Toby Newton-John:** Methodology; writing – review and editing; supervision. **Sarah McDonald:** Supervision; writing – review and editing. **Bethany M. Wootton:** Conceptualization; investigation; writing – review and editing; supervision; project administration.

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CONFLICT OF INTEREST STATEMENT

The authors report there are no competing interests to declare.

DATA AVAILABILITY STATEMENT

Data for this study are not publicly available for ethical reasons regarding participant confidentiality and compliance with ethics approval.

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