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Examining the Efficacy of a Telemedicine-Based Virtual Reality Clinic in Treating Adults with Specific Phobia: A Feasibility Randomized Controlled Trial

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Examining the Efficacy of a Telemedicine-Based Virtual Reality Clinic in Treating Adults with Specific Phobia: A Feasibility Randomized Controlled Trial

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Abstract

Background: Virtual reality (VR) has strong potential to enhance the effectiveness of telemental health care (TMH) by providing accessible, personalized treatment from home. While there is ample research supporting VR for in-person treatment, there is only preliminary data on the efficacy of telemedicine-based VR. Further, most VR applications used in therapy are not designed for mental healthcare. VR has the potential to enhance remotely delivered evidence-based practices if designed for use in clinical settings. This study aimed to address these gaps by piloting a novel, multiuser, telemedicine-based VR application, Doxy.me VR, equipped with animal phobia exposure stimuli.

Objective: The primary objective of this study was to assess the feasibility of conducting a randomized controlled efficacy trial (RCT) of Doxy.me VR in preparation for a fully powered trial. The secondary objective was to conduct a preliminary examination of clinical (ie, specific phobia symptom severity) and treatment-related outcomes (ie, therapeutic alliance, client satisfaction, system usability, presence, cybersickness, and treatment fidelity).

Methods: This single-site, fully remote RCT compared exposure therapy via Doxy.me VR versus standard TMH for adults with a clinically elevated fear of dogs, snakes, or spiders. Participants were recruited through online platforms and flyers. All self-report assessments and homework were partially automated using REDCap forms and surveys. Baseline, mid-treatment, and post-treatment assessment of phobia symptoms and exposure intervention were administered by the study therapist. Feasibility of the trial methodology was assessed using enrollment, retention, assessment completion, and treatment protocol fidelity benchmarks. Between-group differences in specific phobia, anxiety, and depression symptoms while co-varying for pre-treatment scores, were conducted using rANOVA along with differences in therapeutic alliance and presence.

Results: In total, 54 participants were enrolled between October 25th 2023 and July 26th 2024 (Doxy.me VR n=29, TMH n=25). All benchmarks for feasibility were met or exceeded. There were no significant differences between the Doxy.me VR and TMH groups for all clinical outcomes and all but one treatment-related outcome (ie, client satisfaction improved significantly more for the Doxy.me VR group compared to the TMH group).

Conclusions: This feasibility RCT comparing Doxy.me VR vs. TMH aims to enhance the delivery of evidence-based treatments via telemedicine and reduce barriers to remotely delivered exposure therapy. This feasibility trial will be followed by a fully powered efficacy trial on telemedicine-based VR for animal phobias. Clinical Trial: ClinicalTrials.gov NCT06302868; https://clinicaltrials.gov/study/NCT06302868

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Conclusion: This feasibility RCT comparing Doxy.me VR vs. TMH aims to enhance the delivery of evidence-based treatments via telemedicine and reduce barriers to remotely delivered exposure therapy. This feasibility trial will be followed by a fully powered efficacy trial on telemedicine-based VR for animal phobias.

Trial Registration: ClinicalTrials.gov NCT06302868; https://clinicaltrials.gov/study/NCT06302868

Keywords: Virtual Reality; Exposure Therapy; Anxiety; Mental Health; Phobias; Telemedicine; Telehealth; Telemental Health; Telemedicine-Based VR

Introduction

Background

The landscape of mental health care has changed substantially with the increased uptake of telemental health care (TMH) in recent years [1–3]. TMH provides numerous advantages to traditional in person care such as improved outcomes, appointment completion, access to care, and satisfaction, as well as reduced costs and the ability to overcome common barriers to mental health

care (eg, stigma, scheduling, and transportation) [4–8]. TMH usage has continued to grow post-pandemic, accounting for nearly 75% of all telemedicine services during 2024 [9]. Given this trajectory and a constantly evolving technology industry, innovative approaches to facilitating TMH will be of tremendous benefit [1,10,11].

Virtual reality (VR) is a burgeoning consumer technology with documented efficacy for enhancing mental health treatments [10,12–16]. Perhaps the most well-researched application of VR-based mental health care is exposure therapy [17]. Exposure therapy, the gold standard treatment approach for anxiety disorders involves repeated exposures to feared stimuli in a controlled and safe environment until that fear response and associated anxiety diminishes [18]. One approach to conducting exposure therapy via TMH includes exposure to multimedia stimuli (eg, screenshared photos or videos), but clients' affective responses to these exposure stimuli can be limited [19,20]. Another approach is to use interactive simulations for exposure exercises, termed VR-based exposure therapy (VRET). Delivering VRET over telemedicine has potential to provide an engaging and immersive treatment experience for patients [12]. Telemedicine-based VR may also improve important treatment-related factors such as therapeutic alliance (ie, the extent to which a patient and therapist experience a collaborative and trusting relationship) [21–24] and telepresence (ie, the extent to which digital places, activities, and other individuals feel real) [15,25]. However, most research has supported VR-based mental health therapy delivered in-person [26,27], while only a limited number of studies have investigated remotely delivered VR-based therapy [15,28–30].

Our prior work included qualitative interviews and surveys among TMH therapists and clients to better understand their perceptions of potential telemedicine-based VR therapy solutions [13,14,31]. We found that therapists preferred features to build rapport with their clients, exposure therapy features, and customizable components for individual client needs. Therapists also preferred clinical evidence supporting telemedicine-based VR, low costs of adopting VR into their TMH practice, and information on possible side effects for patients [13]. Therapists strongly favored telemedicine-based VR simulations related to social anxiety, flying, driving, and animals. Therapists rated between-session VR exercises and immersive cooperative activities as some of their most valued telemedicine-based VR features. Therapists' highest-rated factors for implementing telemedicine-based VR were HIPAA compliance, followed by affordability, insurance coverage, and accessibility [14].

We used insights from these studies and engaged with key stakeholders (ie, mental health therapists and clients) to develop Doxy.me VR–an innovative VR application for immersive, multiuser telemedicine-based VR [32]. A full description of Doxy.me VR and its development is provided in a previous publication [15]. In brief, Doxy.me VR enables therapists and clients to meet remotely in a private, comfortable VR clinic that looks and feels like a therapist's office (Figure 1). Therapists can use a menu to spawn animals such as dogs, snakes, and spiders with varying levels of intensity (ie, idle, calm, energetic, aggressive) for use in exposure therapy for specific phobias. Clients can also use Doxy.me VR to practice exposure exercises between therapy sessions for homework.



Figure 1. Provider helping clients tolerate a calm dog (left) and an aggressive dog (right)

This Study

We present the results of a feasibility randomized controlled efficacy trial (RCT) comparing exposure therapy delivered via Doxy.me VR *versus* standard TMH to adults with a clinically elevated fear of dogs, snakes, or spiders. The primary aim of this study was to assess the feasibility of and refine our study methodology in preparation for a fully powered RCT. The secondary aim was to preliminarily examine clinical and treatment-related outcomes, including specific phobia symptoms, therapeutic alliance, and presence.

Methods

Trial Design

This study used a single-site, fully remote, parallel, feasibility RCT design and aimed to enroll between 40 and 60 adults with a clinically elevated fear of dogs, snakes, or spiders with the goal of completing treatment with 30 adults. Participants were randomly assigned using the REDCap (Research Electronic Data Capture; Vanderbilt University) [33,34] Randomization Module on a 1:1 allocation ratio to receive 12 weekly sessions of exposure therapy over the course of three months delivered via standard TMH *vs*. Doxy.me VR. Study assessments were conducted at baseline, each session, mid-treatment (ie, after completion of six therapy sessions, up to six-weeks post-baseline), and post-treatment (ie, 3 months post-baseline). A comprehensive description of the protocol for this study is provided in a previous publication [15].

Study Intervention

This study used an adapted version of the treatment protocol developed specifically for VRET by Bouchard et al [35], Côté and Bouchard [36], Michaliszyn et al [37], and St-Jacques et al [38]. After an initial baseline assessment, participants received 12 therapy sessions, each lasting up to 60 minutes. The treatment began with a single session focused on psychoeducation and planning (session 1), followed by 10 sessions dedicated to exposure therapy (sessions 2–11), and concluded with one session on relapse prevention (session 12). In the first session, participants were introduced to the core principles of cognitive behavioral therapy, including the development of anxiety and specific phobias, as well as the rationale and process of exposure therapy. With guidance from the therapist, participants constructed a fear hierarchy—an ordered list of anxiety-provoking situations ranging from least to most distressing. These hierarchies incorporated text descriptions of VR or multimedia scenarios featuring static and dynamic representations of feared animals and real-life “in vivo” exposures, such as petting a dog or handling a snake in a pet store. Sessions 2 through 11 began with a review of the previous week's homework, followed by an approximately 35-minute exposure exercise. During these exercises, participants rated their anxiety every 5 minutes on a scale from 1 to 100 (none to most extreme anxiety possible). They continued the exposure until they (A) achieved a 50% reduction in anxiety from their peak response after the stimulus was introduced,

following which they would advance to the next exposure in their hierarchy, (B) expressed an alternative functional belief that was sufficiently strong to counter the association with perceived threat, or (C) 35 minutes had passed. After completing the exposure, the therapist facilitated a discussion to help participants reflect on the exposure, challenge and reframe maladaptive beliefs about the feared stimuli using cognitive restructuring, and practice box breathing techniques.

Participants randomized to the Doxy.me group were provided with a Meta Quest 2 VR headset preloaded with the Doxy.me VR application, to be returned to the study team following completion of the study. These participants also received a separate 30-minute training on how to use the headset and open the Doxy.me VR app. All therapy sessions were conducted via remote videoconferencing, with the Doxy.me VR group transitioning to the Doxy.me VR clinic for the exposure exercise portion of the session, and the standard TMH group using multimedia (ie, photos and videos) screenshared by the study therapist during video calls. Once participants progressed through all situations in their hierarchy and were ready to complete their first in vivo exposure between therapy sessions for homework, weekly therapy sessions were devoted to processing and planning between-session in vivo exposures.

Homework

All therapy sessions except session 12 included the assignment of homework exercises during the following week. These included reading an informational handout after the psychoeducation and treatment planning session (session 1) and exposure therapy assignments after therapy sessions 2-11. Daily exposure-based homework assignments required participants to practice exposure exercises similar to those completed during that week's therapy session (ie, using VR or multimedia stimuli) for a minimum of 30 minutes. For participants who stated they were ready to progress to in vivo exposures, these included in vivo exposure exercises planned during therapy sessions. Participants received text/email reminders with links to REDCap surveys that included instructions for each homework assignment and the situation to be used in the exposure exercise, which was entered by the therapist during the session. The survey asked participants to report the date and time of the exposure, their baseline anxiety rating, their peak anxiety level during the exposure, and their anxiety level following completion of the exposure exercise.

Recruitment Strategy

Potential participants were recruited through Clinical Connection [39], ResearchMatch [40], Facebook advertisements [41], and flyers posted around the University of South Florida campus and off campus community centers. Interested individuals were provided a URL or QR code linking them to an online pre-baseline screening questionnaire hosted on REDCap. Those who met initial eligibility criteria were invited to schedule a consent and baseline assessment appointment using Microsoft Bookings, with automated text and email reminders sent 24 hours and 1 hour before the scheduled session.

Eligibility Criteria

Eligible participants: (1) were ≥ 18 years old*;* (2) had a self-reported fear of dogs, snakes, or spiders*;* (3) had Subthreshold or Present Specific Phobia symptoms as determined by the study therapist via administration of the Diagnostic Assessment Research Tool (DART) Specific Phobia Module [42]*;* (4) had access to the internet and a computer or smartphone with video conferencing capabilities*;* and (4) planned to reside in the state of Florida for the duration of the study. Individuals were ineligible to participate if they reported: (1) participation in ongoing mental health therapy from a non-study therapist*;* (2) changes to psychotropic medication use within six weeks preceding enrollment in the trial*;* (3) active suicidal or homicidal intent or plan as determined by the study

therapist via the DART Risk Assessment Module*;* (4) active auditory, visual, or tactile hallucinations via the DART Psychosis Module screening question*;* or (5) a diagnosis of photosensitive epilepsy by a medical doctor or a history of experiencing seizures caused by photosensitivity.

While we initially excluded individuals with a self-reported history of epilepsy or seizures, we modified this criterion five months into the trial to exclude individuals with a self-reported history of photosensitive seizures or belief that they had seizures resulting from photosensitivity. This change was made based on research suggesting that individuals with photosensitive seizures are at heightened risk of seizures during VR headset use, rather than individuals with a general history of seizures [43].

Criteria for Withdrawing Participants

Participants were withdrawn from the study if they reported any of the following: (1) initiating therapy with a non-study mental health therapist; (2) changes in psychotropic medication use; (3) the emergence of active suicidal or homicidal thoughts or plans; (4) the onset of auditory, visual, or tactile hallucinations; (5) the development of photosensitive epilepsy or seizures; and (6) relocation outside the state of Florida during the study period.

In cases of complete withdrawal—whether initiated by the participant or study team—study staff attempted to provide a referral to a local mental health provider. When contact was lost with participants after initiating treatment, study staff made efforts to administer mid-treatment and post-treatment assessments. All participants were informed of their right to fully withdraw from the study at any time, including the option to request removal of previously collected data.

Criteria for Wait-Listing Participants

If potential participants did not meet eligibility criteria due to ongoing mental health therapy with a non-study provider or recent changes in psychotropic medication use within the six weeks prior to enrollment, they were given the option to provide their contact information and be contacted by the study therapist to discuss their eligibility at a later date.

Consent and Baseline Assessments

The consent and baseline assessment visit was conducted via a videoconferencing platform and was not audio- or video-recorded. During this visit, study staff: (1) reviewed and confirmed the potential participant's responses from the online prescreening questionnaire; (2) provided detailed information about the study and obtained informed consent; (3) assisted participants in completing baseline questionnaires through a REDCap survey; (4) administered the Specific Phobia and Risk Assessment modules of the DART; and (5) made a final determination regarding the participant's eligibility. Participants deemed eligible were then randomized using the REDCap Randomization Module and scheduled for their initial therapy session. Neither participants nor study staff were blinded to the treatment condition.

Assessment Strategy and Measures

Overview

Study assessments and their corresponding assessment time-points are displayed in Table 1. All assessments were conducted remotely by the study therapist and took place at baseline, during each therapy session, at mid-treatment (ie, after completion of six therapy sessions, up to six-weeks post-baseline), and at post-treatment (ie, 3 months post-baseline). Participants completed self-report questionnaires via REDCap, with the study therapist available to address any questions. Structured diagnostic interviews were administered by the study therapist and documented within REDCap. The

Primary Outcome of the trial was specific phobia severity, as measured by the Severity Measure for Specific Phobia for Adults (SMSP) [44].

Table 1. Study assessments

Domain	Measure	Time-point				
		Pre	Baseline	Weekly	Mid	Post
Demographics	Demographics Questionnaire		✓			
Specific phobia severity	Severity Measure for Specific Phobia (SMSP)	✓	✓		✓	✓
Specific phobia diagnosis	Diagnostic Assessment Research Tool–Specific Phobia Module (DART-SP)		✓			✓
Risk	Diagnostic Assessment Research Tool–Risk Assessment (DART-RA)		✓			
Anxiety severity	General Anxiety Disorder-7 (GAD-7)		✓		✓	✓
Depression severity	Patient Health Questionnaire-9 (PHQ-9)		✓		✓	✓
Therapeutic alliance	Working Alliance Inventory- Short Revised (WAI-SR)				✓	✓
Presence	Single Item Presence Questionnaire (SIPQ)			✓		
Cybersickness	Cybersickness in Virtual Reality Questionnaire (CSQ-VR)			✓		
Treatment satisfaction	Client Satisfaction Questionnaire (CSQ-8)				✓	✓
Usability	System Usability Scale (SUS)				✓	✓

Specific Phobia Symptoms and Severity

The Severity Measure for Specific Phobia (SMSP) [44] is a 10-item self-report questionnaire that assesses the severity of specific phobia symptoms relative to an individual's feared stimulus. Total scores range from 0 to 4 with higher scores indicating higher phobia severity. The SMSP has excellent internal consistency, reliability, and criterion and discriminant validity [45].

Specific Phobia Diagnosis

The Diagnostic Assessment Research Tool (DART) [42] is a modular, semi-structured interview assessing criteria of the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) [46]. In this study, therapists administered the DART Specific Phobia Module (DART-SP), which classifies symptoms as *Absent*, *Subthreshold*, or *Present*. The DART has demonstrated strong construct, discriminant, and convergent validity across its modules [42,47].

Other Mental Health Symptoms

The Generalized Anxiety Disorder-7 (GAD-7) [48] is a 7-item self-report measure that assesses the severity of general anxiety symptomatology. Scores range from 0 to 21 with higher scores indicating higher anxiety severity. The GAD-7 has demonstrated excellent internal consistency, reliability, and good convergent validity [49].

The Patient Health Questionnaire-9 (PHQ-9) [50] is a 9-item self-report measure that assesses the severity of depression symptomatology. Scores range from 0 to 27 with higher scores indicating higher depression severity. The PHQ-9 has demonstrated good convergent validity and specificity for depression diagnosis as well as excellent internal consistency and reliability [50].

The DART-Risk Assessment Module (DART-RA)[42] was administered by the study therapist to

assess risk for suicidal and homicidal ideation, intention, and plans, and guide the development of safety plans as needed.

Treatment-Related Factors

The Working Alliance Inventory-Self Report (WAI-SR) [51] is a 12-item measure that assesses client-reported therapeutic alliance. Total Scores range from 12 to 60 with higher scores suggesting better therapeutic alliance. The WAI-SR includes 3 subscales: Goal (ie, the degree to which clients and therapists agree on goals of treatment), Task Agreement (ie, the degree to which clients and therapists agree on how to achieve those goals), and Bond (ie, the degree to which clients and therapists have developed a personal bond). Subscale Scores range from 4 to 20, with higher scores suggesting better alliance within each domain. The WAI-SR has demonstrated good convergent validity and excellent internal consistency and reliability [52].

The Client Satisfaction Questionnaire-8 (CSQ-8) [53] is an 8-item client-rated questionnaire that assesses satisfaction with treatment. Scores range from 8 to 32 with higher scores indicating increased satisfaction. The CSQ-8 is correlated with clinical outcomes and post-treatment functioning and has demonstrated good construct validity and internal consistency and reliability [53].

The System Usability Scale (SUS)[54] is a 10-item self-report questionnaire that assesses the usability of a particular software system, platform, or app. Scores range from 0-100 with scores >68 indicating good usability, scores >80 indicating excellent usability, and scores < 60 suggesting potential usability issues. The SUS has demonstrated good internal consistency and reliability [54].

The Single Item Presence Questionnaire (SIPQ)[55] is a 1-item self-reported measure of telepresence that asks respondents, “to what extent did you feel present in the environment, as if you were really there?” Ratings are provided on a scale of 0 “not at all present” to 10 “‘totally present.” The SIPQ has demonstrated good to excellent validity, reliability, and sensitivity [55].

The Cybersickness in VR Questionnaire (CSQ-VR) [56] is a 6-item self-report questionnaire that assesses nausea, vestibular, and oculomotor cybersickness experienced in VR. This measure was completed by participants in the Doxy.me VR condition after each therapy session that included VR-based exposures. Total scores range from 6 to 27 with higher scores reflecting increased levels of cybersickness. The CSQ-VR has demonstrated excellent internal consistency and convergent validity [57].

Fidelity to the Treatment Protocol

All therapy sessions were audio recorded and 20% were randomly selected and rated by the principal investigator using a Treatment Fidelity Checklist that was developed based on the treatment manual.

Feasibility of Study Methodology

We assessed the following pre-defined feasibility benchmarks during the 12-month trial: (1) enroll 30 participants during months 1-9 of the trial; (2) collect 70% of mid-treatment self-report data; (3) collect 70% of post-treatment self-report data; (4) collect 70% of weekly self-report data; and (5) achieve treatment fidelity ≥80%.

Partial Automation of Trial Data Collection Using REDCap

All feasibility trial data collection and most of the trial components were automated using REDCap.

This included administering the pre-baseline screening questionnaire; obtaining informed consent via the REDCap e-Consent Framework feature; administering and calculating scores for all study questionnaires; randomizing participants via the Randomization Module; recording therapy session data (ie, session number, date, time, and length; adherence checklists; session notes; and in-session exposure ratings); and sending automated survey invitations and reminders for participants to complete homework assignments. A complete description and a figure displaying specific REDCap automations and features used for each stage of the trial are provided in a previous publication [15].

Ethical Considerations

The protocol was approved by the University of South Florida Institutional Review Board (#006215). All participant data were stored in the University of South Florida REDCap database and only study staff members had access to the REDCap project. All data exported for analysis from REDCap were anonymized using participant study ID numbers. Participants were compensated US $50 for completing each baseline, mid-treatment, and post-treatment assessment at a total of US $150. Participants were compensated using e-gift cards.

Data Analytic Plan

The primary goal of this study was to assess the feasibility of the study methodology, the results of which are presented descriptively. Chi-square Tests of Independence were used to assess associations between conditions and categorical variables. Independent samples T-test and Analysis of Variance (ANOVA) were used to assess for significant differences between groups for continuous variables measured at one time point. Repeated Measures Analyses of Variance (rANOVA) were used to assess for significant differences between groups for continuous variables measured at multiple time points. All statistical analyses were conducted using SPSS [58]. G*Power [59] was used to conduct power analyses to inform sample size estimates for a fully powered trial.

Results

Recruitment

Participant recruitment and follow up are displayed in Figure 2. The first participant was enrolled on October 25th, 2023, and the last therapy session and post-treatment assessment was completed on July 26th, 2024. Of the 234 individuals assessed for eligibility, 54 were enrolled and randomized to the Doxy.me VR (n=29) and TMH (n=25) conditions. Of these, 29 completed mid-treatment assessments and 28 completed post-treatment assessments. The main reasons for participant withdrawal from the study included economic (eg, housing, internet access), legal, and health related complications.

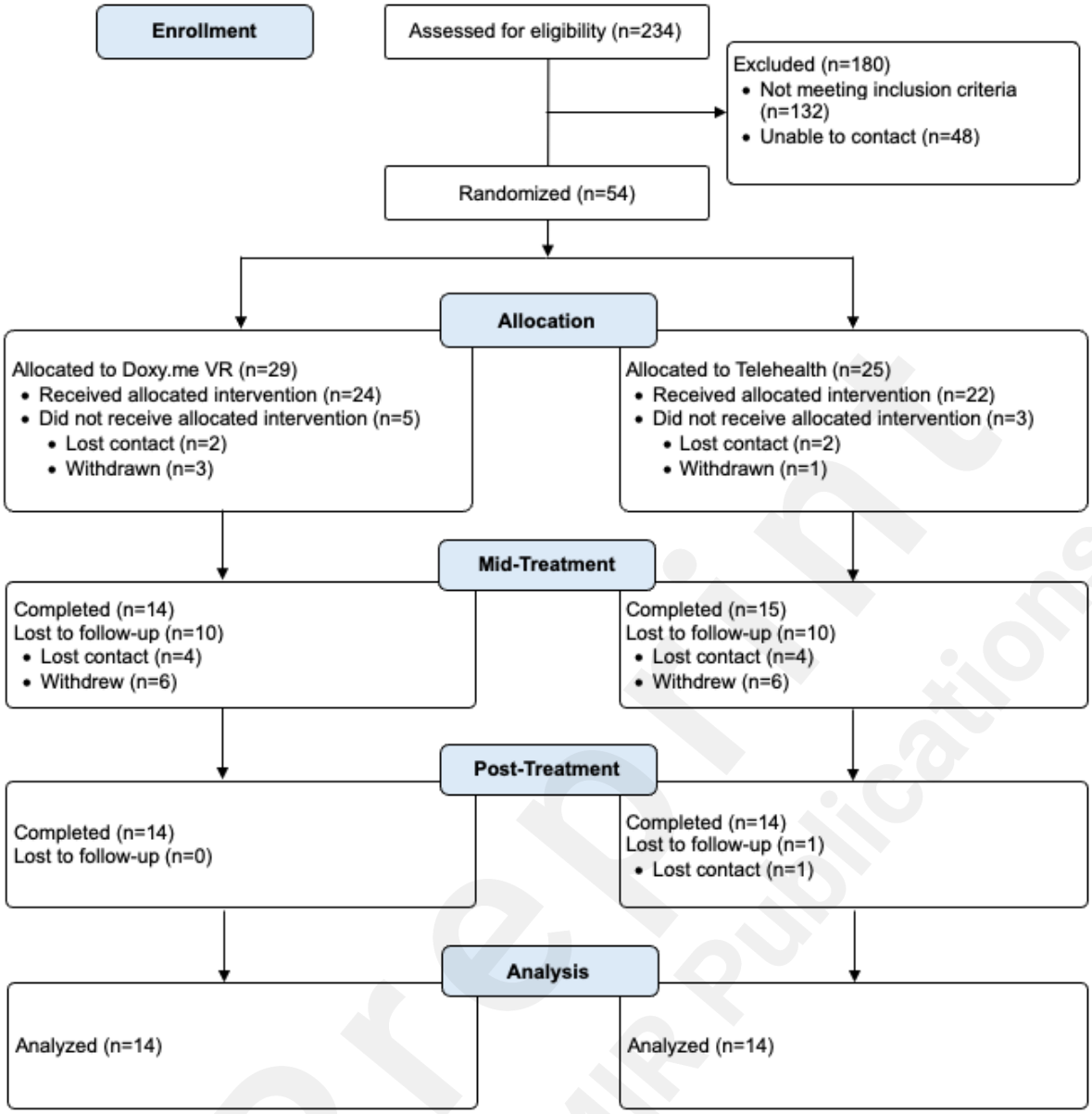


Figure 2. CONSORT Flow diagram

Sample Characteristics

Sample characteristics are displayed in Table 2. A total of 54 individuals completed the Baseline session and were randomly assigned. The sample was comprised of 25 (46.3%) individuals in the TMH group and 29 (57.3%) in the Doxy.me VR group. The average age of each group was approximately the same (TMH=45.20 and Doxy.me VR=46.10). The overall sample was largely female (n=42/54, 77.8%), white (n=32/54, 59.3%), and non-Hispanic (n=46/54, 85.2%). Roughly half of participants endorsed fearing snakes (n=28/54, 51.9%) and spiders (n=28/54, 51.9%), while only 13.0% (n=7/54) reported fearing dogs. Participants in the two treatment conditions did not differ significantly in age ($F[1,52]=.054$, $p=.818$, $\eta^2_p=.001$), sex ($\chi^2[1,54]=1.18$, $p=.554$), or race ($\chi^2[3,54]=1.28$, $p=.735$), ethnicity ($\chi^2[1,54]=3.11$, $p=.078$).

Table 2. Sample characteristics

	TMH (n=25)	Doxy.me VR (n=29)	Total (N=54)
Age M (SD)	45.20 (13.98)	46.10 (13.35)	45.69 (13.53)
Sex/Gender n (%)			

Female	19 (76.0)	23 (79.3)	42 (77.8)
Male	6 (24.0)	5 (17.2)	11 (20.4)
Non-Binary/Gender Fluid	0 (0.0)	1 (3.4)	1 (1.9)
Race n (%)			
White	14 (56.0)	18 (62.1)	32 (59.3)
Black/African American	7 (28.0)	8 (27.6)	15 (27.8)
Multiracial	3 (12.0)	3 (10.3)	6 (11.1)
Asian	1 (4.0)	0 (0.0)	1 (1.9)
American Indian/Alaska Native	0 (0.0)	0 (0.0)	0 (0.0)
Native Hawaiian/Pacific Islander	0 (0.0)	0 (0.0)	0 (0.0)
Ethnicity n (%)			
Hispanic/Latino	6 (24.0)	2 (6.9)	8 (14.8)
Non-Hispanic/Latino	19 (76.0)	27 (93.1)	46 (85.2)
Phobia n (%)			
Dog	2 (8.0)	5 (17.2)	7 (13.0)
Snake	13 (52.0)	15 (51.7)	28 (51.9)
Spider	13 (52.0)	15 (51.7)	28 (51.9)

Session and Homework Data

Session and homework completion data are presented in Table 3. Participants attended an average of 5.52 (SD=3.48) sessions, with 85.8% (n=46/54) attending at least one session. Participants in the two conditions did not differ in the number of sessions attended (F[1,44]=.145, p=.705, η^2_p=.003) or the proportion that attended at least one session (χ^2[1,54]=.292, *p*=.589). A total of 1,482 homework exercises were assigned based on session attendance. The overall completion rate for homework exercises was 25.3% (n=375/1,482) and participants in the two conditions did not differ significantly in the proportion of homework they completed, *t*(45)=.279, p=.781. Of the participants who attended sessions, 34.8% (n=16/46) completed at least one *in-vivo exposure exercise for homework*, and participants in the two conditions did not differ in the proportion who completed an in-vivo exposure, χ^2[1,46]=.698, *p*=.404. The average number of sessions attended until participants engaged in an in-vivo exposure exercise for homework was 5.94 (SD=1.06), and the average number of weeks was 7.81 (SD=3.14). Participants in the two conditions did not differ in the number of sessions (F[1,14]=.448, p=.514, η^2_p=.031) or the number of weeks (F[1,14]=.005 p=.944, η^2_p=.000) until engaging in in-vivo exposure.

Table 3. Session and homework completion

	TMH (n=25)	Doxy.me VR (n=29)	Total (N=54)
Sessions Attended M (SD)	5.70 (3.23)	5.35 (3.74)	5.52 (3.48)
Attended One Session n (%)	22 (88.0)	24 (82.8)	46 (85.8)
Homework Expected n (%)	731 (100)	751 (100)	1,482 (100)
Homework Completed n (%)	229 (31.3)	146 (19.4)	375 (25.3)
Completed in-vivo exposure n (%)	9 (40.9)	7 (29.2)	16 (34.8)
Sessions until in-vivo M (SD)	5.78 (1.06)	6.14 (0.89)	5.94 (1.06)
Weeks until in-vivo M (SD)	7.78 (2.13)	7.86 (1.68)	7.81 (2.13)

Clinical Outcomes and Treatment-Related Factors

Clinical Outcomes

Data for clinical outcomes and treatment-related factors are displayed in Table 4. Participants in both conditions exhibited decreased scores on the SMSP over time and the results of the rANOVA indicated that the two conditions did not differ significantly on SMSP scores across the three

assessment time points, F(2,26)=2.24, p=.117, η^2_p=.079 (Figure 3). All participants met Present or Subthreshold criteria on the DART-SP at baseline while 71.4% (n=15/21) of those who completed the DART-SP at post-treatment no longer met criteria (ie, designated as Absent) and 23.8% (n=5/21) met subthreshold criteria. Participants in the two conditions did not differ significantly in the proportion that met Present, Subthreshold, or Absent criteria on the DART-SP at baseline (χ^2[1,54]=2.41, *p*=.121) or at post-treatment (χ^2[2,21]=1.22, *p*=.543). Similarly, scores on the GAD-7 (Figure 4) and PHQ-9 (Figure 5) decreased over time and the results of the rANOVA indicated that the two conditions did not differ significantly on the GAD-7 (F[1,26]=.66, p=.422, η^2_p=.025) or PHQ-9 (F[1,26]=1.14, p=.296, η^2_p=.042) from baseline to post-treatment.

Table 4. Clinical and treatment-related factors outcomes

	Baseline		Mid-Treatment		Post-Treatment	
	TMH (n=25)	Doxy.me VR (n=29)	TMH (n=15)	Doxy.me VR (n=14)	TMH (n=14)	Doxy.me VR (n=14)
Specific Phobia Symptoms and Severity M (SD)						
SMSP Total	3.18 (0.82)	2.80 (0.80)	1.55 (0.89)	1.51 (0.83)	0.56 (0.47)	0.86 (0.68)
Specific Phobia Diagnosis n (%)						
DART-SP Present	23 (92.0)	29 (100)			0 (0.0)*	1 (10.0)*
DART-SP Sub.	2 (8.0)	0 (0.0)			3 (27.3)*	2 (20.0)*
DART-SP Absent	0 (0.0)	0 (0.0)			8 (72.7)*	7 (70.0)*
Other Mental Health Symptoms M (SD)						
GAD-7 Total	7.68 (6.95)	6.03 (4.48)			3.71 (4.41)	7.14 (5.63)
PHQ-9 Total	7.60 (7.39)	4.62 (4.25)			4.86 (7.59)	7.43 (5.40)
Treatment-Related Factors M (SD)						
WAI-SR Total			57.67 (1.98)	55.64 (3.82)	57.21 (4.17)	56.93 (4.14)
WAI-SR Bond			19.73 (0.59)	19.14 (1.83)	18.86 (2.24)	19.14 (2.07)
WAI-SR Task			18.13 (1.55)	17.79 (1.25)	18.86 (1.35)	18.50 (1.70)
WAI-SR Goal			19.80 (0.41)	18.71 (1.77)	19.50 (0.94)	19.29 (1.43)
CSQ-8 Total			31.47 (0.92)	30.36 (2.34)	31.07 (1.38)	31.43 (1.40)
SUS Total			90.33 (13.72)	76.43 (17.17)	88.39 (19.82)	80.89 (11.99)
SIPQ Total			7.69 (2.04)	8.38 (1.11)		
CSQ-VR Total				8.38 (3.25)		

Note. Sub=Subthreshold; SIPQ Total and CSQ-VR Total were calculated as the mean across sessions; Due to participant scheduling availability, the DART was administered to 10 (71.4%) Doxy.me VR participants and 11 (78.6%) TMH participants at post-treatment.

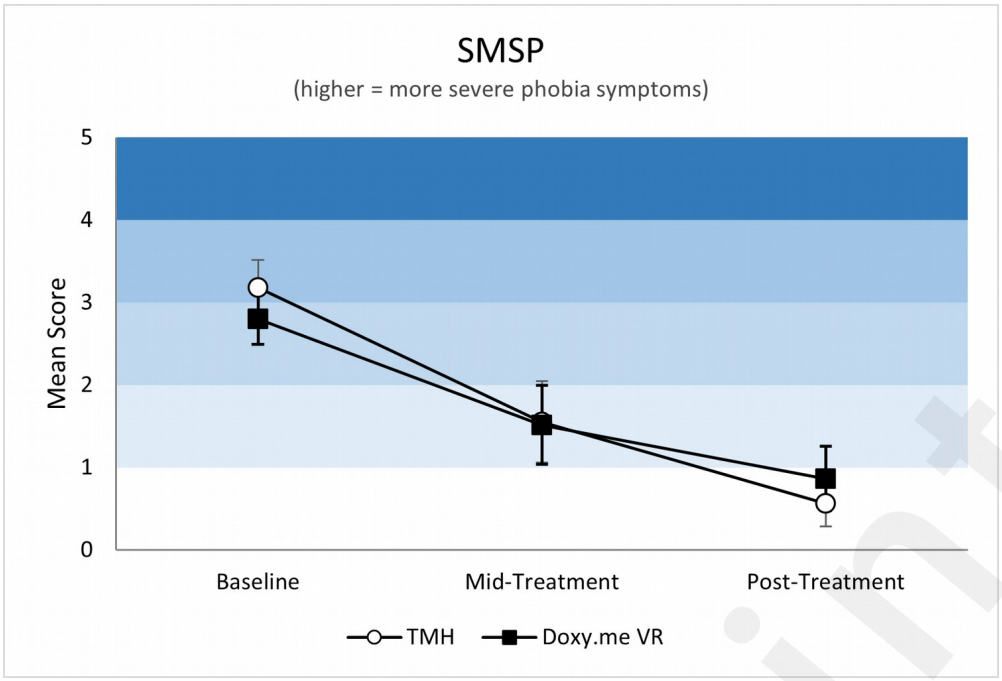


Figure 3. Mean SMSP scores across study timepoints. Error bars depict 95% confidence intervals

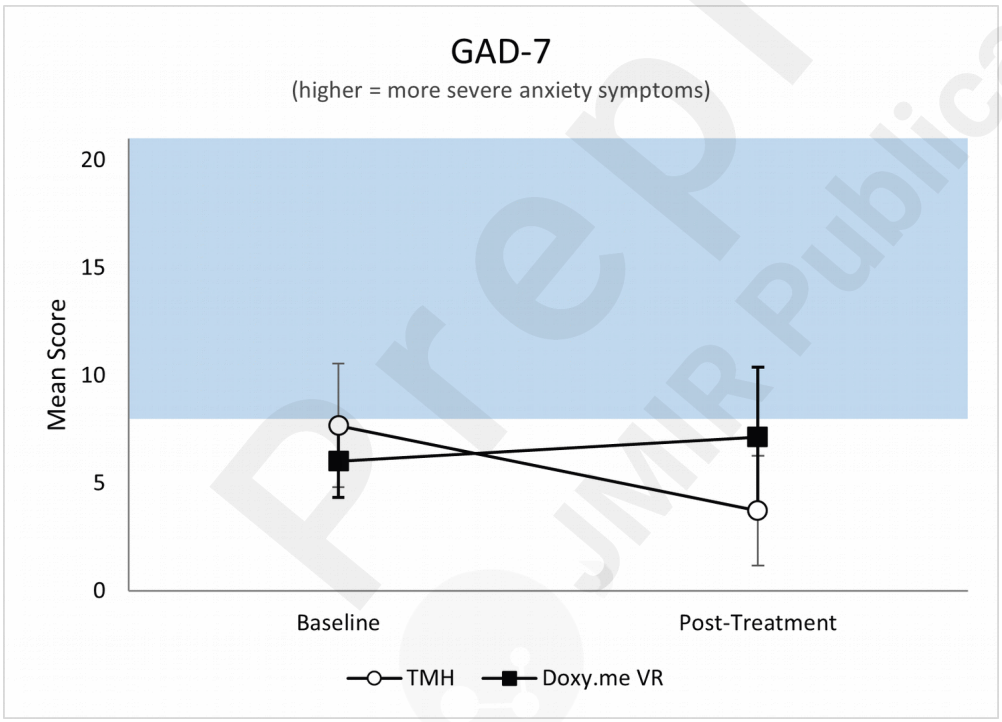


Figure 4. Mean GAD-7 scores across study timepoints. Error bars depict 95% confidence intervals

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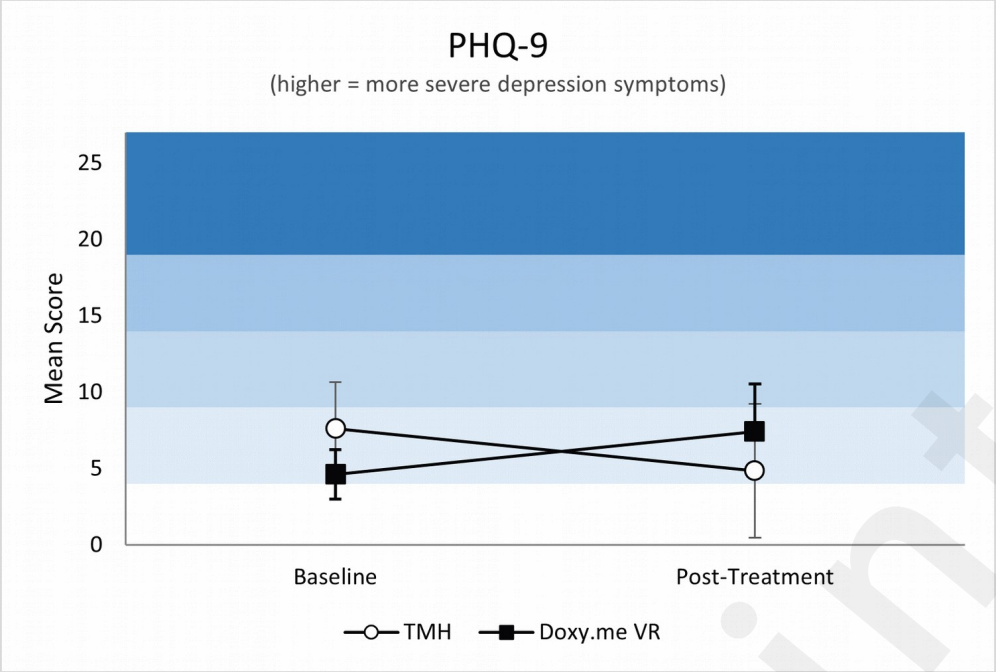


Figure 5. Mean PHQ-9 scores across study timepoints. Error bars depict 95% confidence intervals

Treatment-Related Factors

Scores on the WAI-SR remained consistent from mid- to post-treatment. The results of the rANOVA indicated that the two conditions did not differ significantly on WAI-SR Total ($F[1,26]=1.79$, $p=.192$, $\eta^2_p=.065$), Bond ($F[1,26]=1.81$, $p=.190$, $\eta^2_p=.065$; Figure 6), Task ($F[1,26]=.00$, $p=1.000$, $\eta^2_p=.000$), and Goal ($F[1,26]=3.02$, $p=.094$, $\eta^2_p=.104$) scores from mid- to post-treatment. The results of the rANOVA indicated that the two conditions differed significantly on CSQ-8 scores ($F[1,26]=4.64$, $p=.041$, $\eta^2_p=.151$) scores from mid- to post-treatment, with the Doxy.me VR condition demonstrating a slight improvement in satisfaction compared to the TMH condition. Scores on the SUS remained fairly consistent from mid- to post-treatment, with the results of the rANOVA indicating that the two conditions did not differ significantly on SUS Total Scores ($F[1,26]=2.99$, $p=.096$, $\eta^2_p=.103$; Figure 7). Lastly, the two conditions did not differ significant on weekly averaged SIPQ scores ($F[1,35]=.09$, $p=.759$, $\eta^2_p=.003$).

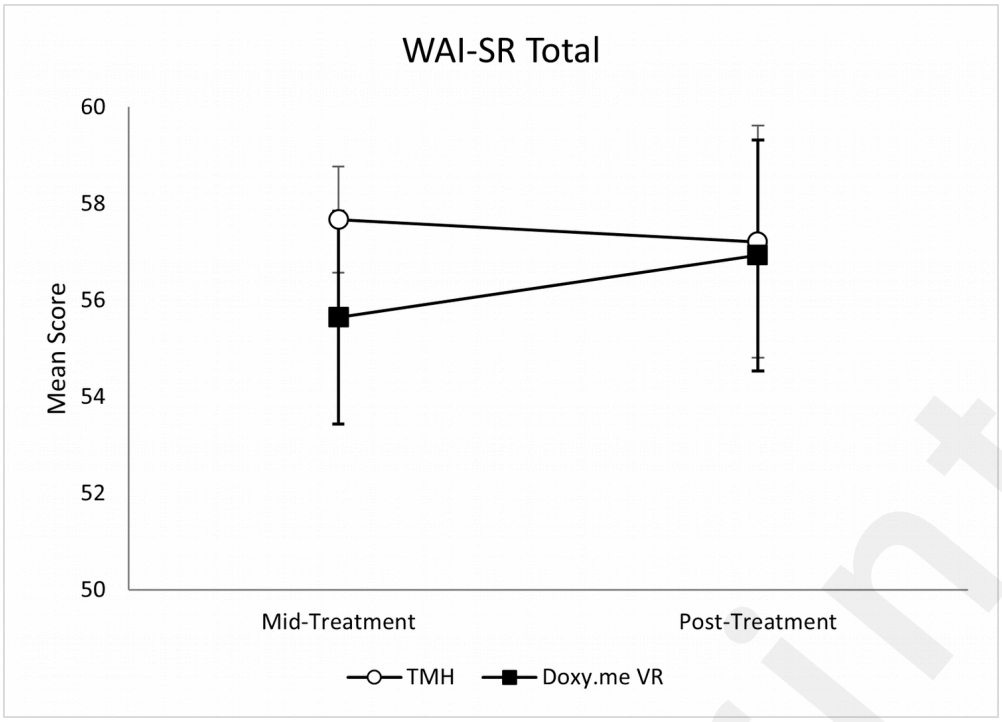


Figure 6. Mean WAI-SR Total scores across study timepoints. Error bars depict 95% confidence intervals

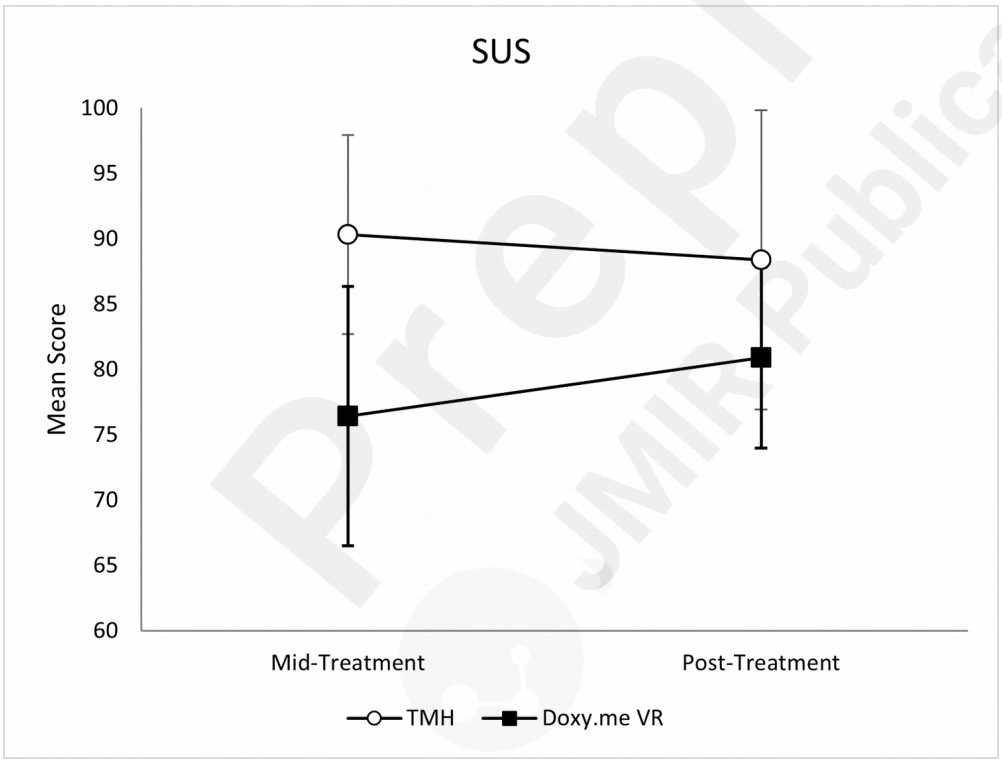


Figure 7. Mean SUS scores across study timepoints. Error bars depict 95% confidence intervals

Fidelity to the Treatment Protocol

Fidelity to the treatment protocol was 90% based on ratings of a random sample of 41 (20%) of session recordings.

Feasibility of Study Methodology and Lessons Learned

All benchmarks for feasibility were exceeded for this trial, and we identified opportunities to optimize the procedures (see Table 5). We exceeded our recruitment goal of 30 by enrolling 54

(180%) participants during months 1-9 of the trial. We obtained mid-treatment self-report data from 29 (96.7%), and post-treatment self-report data from 28 (93.3%) of the 30 participants we aimed to complete the study. Participants completed 180/208 (86.5%) of weekly self-report assessments. Lastly, fidelity to the treatment protocol was 90% based on ratings of a random sample of 41 (20%) of session recordings.

Table 5. Lessons learned and strategies for optimizing a fully powered trial

This Feasibility Trial	Optimization for Fully Powered Trial
Recruitment and Assessment	
Recruiting largely through Clinical Connection limited recruitment to individuals seeking compensated participation in clinical trials.	Partner with additional clinical trial advertising companies to recruit via community mental health groups and clinics.
Some participants appeared to malinger for incentives and seemed more likely to withdraw or disengage.	Include a malingering assessment at baseline to exclude participants simulating mental health symptoms.
28% of participants withdrew due to economic (eg, housing, internet access), legal, and health related complications.	Screen for health, housing, internet, and legal issues likely to interfere with participation prior to enrollment.
46% of participants were withdrawn or lost contact.	Recruit 1.5x the sample required for final analyses.
Study Coordination	
Budgetary limitations resulted in one study therapist managing most aspects of the trial (ie, setup, mailing, and troubleshooting VR headsets, scheduling, compensation, advertising).	Hire a full-time study coordinator to manage all study coordination tasks to enable study therapists to focus on providing the study intervention.
Intervention	
Participants found 12 sessions cumbersome, as most showed marked improvement within the first 6 sessions.	Reduce the number of sessions required from 12 to 7.
Some participants who enrolled were not retained past the first therapy session.	Improve retention strategies such as providing compensation for attending sessions.
VR Technical and Equipment Problems	
Meta Quest updates changed underlying software infrastructure and caused VR sessions to be rescheduled or missed.	Set up Automated Testing to minimize downtime and fix issues before sessions.
Several sessions were delayed/rescheduled due to uncharged headsets and controller batteries.	Study coordinator will send participant reminders to charge headsets/controllers.
20% (3/15) of VR headsets were not returned.	Budget for 20% more headsets than needed.
Protocol Training and Development	
Formal study intervention training was abbreviated and iterative due to time constraints and nature of the feasibility trial.	Conduct formal protocol training and regular fidelity checks to prevent protocol drift. Begin recruitment after study therapists reach fidelity.

Power Analysis and Sample Size Estimation for Fully Powered Trial

Based on the results of this feasibility trial, which showed effect sizes up to $d=0.65$ ($\eta^2_p=.001$ to .165), we conservatively assumed a group × time effect of $f=0.25$ for sample size estimation. Using G*Power, we conducted two power analyses:

- **MANOVA (repeated measures, within-between interaction)**: $f^2(V)=0.25$, $\alpha=0.05$, power=0.80, 2 groups, 3 time points → required $N=158$ (80 per group).
- **ANCOVA (fixed effects with 2 covariates)**: f=0.25, $\alpha=0.05$, power=0.80, 2 groups → required $N=158$.

Thus, a sample of 160 (80 per group) ensures ≥ 0.80 power. To accommodate attrition, we will recruit 240 adults; even with 25% loss (~58), ≥ 86 per group will remain, exceeding requirements. Based on prior experience, this sample is feasible to recruit and retain.

Discussion

Overview

This feasibility RCT tested exposure therapy delivered via a multiuser telemedicine-based VR clinic (Doxy.me VR) versus standard TMH among adults with severe fears of dogs, snakes, or spiders. All a priori feasibility benchmarks were met or exceeded, and clinical symptom reductions were comparable across conditions. Treatment-related factors including presence, therapeutic alliance, were also comparable, with client satisfaction improving significantly more in the Doxy.me VR condition.

Principal Findings

We exceeded all our pre-defined benchmarks for feasibility while gaining valuable insight toward improving a future fully powered trial. Specifically, we recruited 180% of our enrollment target during the first 9 months of the trial. We accomplished this largely through a single source of recruitment (ie, Clinical Connection). However, we found that this limited the pool to individuals seeking compensation for participating in clinical trials. This proved problematic as we lost contact with 10 (18%) participants and withdrew 15 (28%) additional participants, largely due to socioeconomic and health related circumstances. Thus, we plan to use additional recruitment sources that will help diversify the recruitment pool for a fully powered trial. We also plan to conduct assessments of malingering and screen for health, housing, internet, and legal issues that are likely to interfere with participation prior to enrollment.

We obtained mid-treatment self-report data from 29 (97%), and post-treatment self-report data from 28 (93%) of the 30 participants we aimed to complete the study, exceeding our benchmark of a 70% retention rate for these assessment time points. This was accomplished by enrolling more participants than we initially planned, which provided insights into the number of participants we should expect to enroll in a fully powered trial (ie, 1.5 times our target enrollment). Participants completed 180/208 (87%) of weekly self-report assessments, which again exceeded our benchmark of 70%. Lastly, based on ratings of a random sample of 20% of session recordings, fidelity to the treatment protocol was excellent (ie, 90%), indicating that the study therapist was able to provide the intervention as intended despite an abbreviated training period.

Regarding other study related logistics, we experienced difficulty reclaiming VR headsets from 20% of participants. Some equipment loss is expected in clinical trials and thus, we will budget for additional headsets in future trials. We also experienced delays in session start times and rescheduled due to VR headsets not being charged and other technical difficulties. In future trials we will send out reminders for participants in the Doxy.me VR group to charge their headsets prior to their weekly appointment.

Contrary to an a priori expectation that immersive, shared VR might produce larger symptom gains, clinical outcomes (ie, DART-SP, SMSP, GAD-7, PHQ-9) improved similarly across conditions over time. The one significant between-group difference (ie, higher CSQ-8 scores in the Doxy.me VR group) suggests that the immersive clinic may enhance perceived value or engagement even when symptom change is comparable, although this finding is preliminary given the small sample size.

Comparison with Prior Work

Numerous RCTs have compared VRET to null and positive controls [60,61]. However, these previous studies applied VRET either in-person with a therapist (eg, [62]), or as a self-led at-home intervention without direct interaction with a therapist (eg, [63]). To our knowledge, the current study

is the first systematic demonstration of feasibility for therapists and clients interacting in a shared, remote VR experience on an accessible consumer device.

The phobia measures used in this study are well established; less so are measures of VR experience. Researchers are currently expanding and consolidating constructs such as immersion, presence, embodiment, and telepresence as elements of the VR experience [64,65]. There is growing evidence these measures may predict treatment outcomes and may become increasingly useful if refined for ease and practicality in clinical settings [66,67].

We found that phobia symptom severity, as measured by the SMSP, decreased substantially and approximately the same for both TMH and Doxy.me VR interventions. Meta-analyses have consistently found VRET and conventional exposure treatments to be equally effective for anxiety. While clinically significant, our planned larger RCT will be fully powered to detect statistical significance as well. Previous studies found that technical issues with VR equipment could negatively affect patient engagement [68]. We experienced such technical issues in this feasibility study and explored plans to minimize their impact in future research (Table 5). Mobile device management platforms allow remote monitoring and updating of headsets to support troubleshooting by participants. We will also dedicate more time to training the study therapists, especially given that lack of formal training is the leading barrier to adoption of VR [69]. Collectively, the lessons learned in this feasibility trial will help ensure practical and successful implementation of a fully powered RCT.

Limitations

As noted throughout this report, the primary aim of this study was to examine the feasibility of our trial methodology. Although preliminary analyses of within and between-group differences in clinical outcomes were reported, they should be interpreted with caution given the small sample size.

This trial employed one study therapist, limiting our ability to control for therapist effects. However, VRET is empirically supported [70], and this research demonstrates its effectiveness remains when conducted remotely in a multiuser VR arrangement. These findings can extend the established utility of VRET, facilitate collaboration between industry and clinical care, and lead to further research on the clinical utility of remote multiuser VR.

Comparing Doxy.me VR to conventional telemedicine approaches allowed for broad comparison of outcomes but lacks insight into mechanisms of change. Sham VR controls, in which participants experience VR with inactive intervention components, are common in modern clinical research [71]. An example of sham VR for the current study may have been for participants to view flat 2D videos of small animals alone in VR, which would have allowed comparison with the interactive and immersive components of Doxy.me VR. However, such VR functionality was out of scope for this project, and we chose to highlight the additive benefits of VR and replicate exposure procedures which have become common since the recent popularization of telemedicine [72]. It will be important for future research to dismantle the various effects of remote, multiuser VR-based mental health treatments to understand its specific benefits compared to self-led or in-person variations.

There is justifiable concern about user privacy with consumer devices such as the Meta Quest 2. Nevertheless, the ubiquity and usability of consumer VR devices make them important to study for use in healthcare. Health data policies such as HIPAA and GDPR permit privacy exceptions with transparent and documented consent from patients [73,74]. It would be ideal to use VR devices designed for use in healthcare settings, including strict security and privacy features. Researchers,

clinicians, and patient advocates should collaborate with industry to achieve these goals.

Conclusions

Telemedicine -based, multiuser, synchronous VRET is feasible and preliminarily efficacious based on preliminary data. These findings are promising and opportunities to improve procedures identified in this feasibility trial will directly inform the protocol for a lfully powered RCT evaluating telemedicine-based VR and its potential to improve treatment of mental health disorders.

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Conflicts of Interest

TO and BMW are employees of Doxy.me Inc., a commercial telemedicine company. BEB received compensation from Doxy.me Inc. at the time the study was conducted. The authors declare no other conflicts of interest.

Abbreviations

ANCOVA: analysis of covariance
ANOVA: analysis of variance
CONSORT: Consolidated Standards of Reporting Trials
CSQ-8: Client Satisfaction Questionnaire-8
CSQ-VR: Cybersickness in Virtual Reality Questionnaire
DART: Diagnostic Assessment Research Tool
DART-RA: Diagnostic Assessment Research Tool – Risk Assessment Module
DART-SP: Diagnostic Assessment Research Tool – Specific Phobia Module
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
GAD-7: Generalized Anxiety Disorder-7
HIPAA: Health Insurance Portability and Accountability Act
MANOVA: multivariate analysis of variance
PHQ-9: Patient Health Questionnaire-9
RCT: randomized controlled trial
REDCap: Research Electronic Data Capture
rANOVA: repeated measures analysis of variance
SIPQ: Single Item Presence Questionnaire
SMSP: Severity Measure for Specific Phobia
SPSS: Statistical Package for the Social Sciences
SUS: System Usability Scale
TMH: telemental health care
VR: virtual reality
VRET: virtual reality–based exposure therapy
WAI-SR: Working Alliance Inventory – Short Revised

Multimedia Appendix 1

CONSORT-EHEALTH Checklist

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