A Randomized, Head-to-Head Study of Virtual Reality Exposure Therapy for Posttraumatic Stress Disorder

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Abstract

Virtual reality exposure therapy (VRET) is one of the few interventions supported by randomized controlled trials for the treatment of combat-related posttraumatic stress disorder (PTSD) in active duty service members. A comparative effectiveness study was conducted to determine if virtual reality technology itself improved outcomes, or if similar results could be achieved with a control exposure therapy (CET) condition. Service members with combat-related PTSD were randomly selected to receive nine weeks of VRET or CET. Assessors, but not therapists, were blinded. PTSD symptom improvement was assessed one week and 3 months after the conclusion of treatment using the clinician-administered PTSD scale (CAPS). A small crossover component was included. Results demonstrated that PTSD symptoms improved with both treatments, but there were no statistically significant differences between groups. Dropout rates were higher in VRET. Of those who received VRET, 13/42 (31%) showed >30% improvement was seen in 10/33 (30%) of VRET participants and 12/33 (36%) in CET. Participants who crossed over (n=11) showed no statistically significant improvements in a second round of treatment, regardless of condition. This study supported the utility of exposure therapy for PTSD, but did not support additional benefit by the inclusion of virtual reality.

Keywords: posttraumatic stress disorder, randomized trial, exposure therapy, military, active duty, veterans

Introduction

POSTTRAUMATIC STRESS DISORDER (PTSD) is a significant problem in United States Service Members returning from tours of duty in Iraq and Afghanistan.¹ Although randomized trials have supported the use of both medications and therapy for the treatment of PTSD,² evidence for interventions in Active Duty populations is more scarce.³ One of the few psychotherapy interventions that has been tested in this population is virtual reality exposure therapy (VRET).⁴

VRET is a form of exposure therapy that involves using a head-mounted computer display to create and interact with a simulated environment. There are slight variations in the technique,^{5–7} but all VRET involves a therapist working with a patient to challenge his or her anxiety, while experiencing a simulated situation related to the trauma. In theory, virtual

reality improves control over the exposure in session, prevents avoidance, and allows greater engagement with treatment.⁸ There is evidence from the treatment of other anxiety conditions that VRET provides for better clinical outcomes than traditional exposure therapy.⁹ Similarly, in PTSD, earlier studies have shown superiority of VRET over treatment as usual or waitlist.^{4,10} Case reports have also suggested the possibility of improvement with VRET even after traditional exposure therapy has failed.¹¹

Considering the training and disability costs of a Service Member with PTSD, the overall cost-effectiveness of VRET appears to be good,¹² but this does not, by itself, indicate that the virtual reality simulator is necessary. Although VRET offers theoretical advantages over traditional exposure therapy in the treatment of PTSD, it does require additional investments in technology and therapist training. A practical question therefore

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Trial Registration: https://clinicaltrials.gov/ct2/show/NCT00978484

arises as to if this investment is worthwhile. Could a clinic achieve similar results by using lower technology, less expensive, and more easily available options?

To address this issue, a randomized, head-to-head trial was conducted. This was designed not to address the pure effect of the virtual reality, but rather to test the clinical effectiveness of the therapy in the milieu of military treatment. In real military settings, Service Members with PTSD have a limited time to recover before facing potential discharge from the military. If VRET provides better outcomes either by encouraging therapy attendance or by showing better improvement per session, it would be a worthwhile investment. Conversely, even if VRET does have efficacy, it is unlikely to provide real-world benefits unless the advantage is evident in the context of the broad spectrum of treatment that is commonly offered to an individual with PTSD.

Of note, this study was not technically a head-to-head comparison of VRET versus traditional prolonged exposure therapy, as we were aware that another trial was being simultaneously conducted that compared those two forms of treatment.¹³ Rather, it was an attempt to find if the virtual reality (VR) system itself was essential to treatment outcomes. Thus, this study was a randomized controlled trial that pitted VRET against an active comparator that was essentially the same treatment as VRET, but without the virtual reality headset.⁵ This was called control exposure therapy (CET). Although very similar to prolonged exposure, CET was used to allow some degree of blinding, to minimize the degree to which participants in the control condition would feel they received a "low tech" intervention, and to allow the protocol in both arms to be as alike as possible. Participants in the CET viewed a still computer image in place of the VR.

The primary hypothesis was that PTSD symptom scores would be lower after VRET treatment than after treatment with the control condition. Although not specifically powered to address these issues, secondary hypotheses addressed in this study were that at longer term (3 months) followup this same effect would be seen and treatment response to VRET in individuals who failed CET would be greater than treatment response in individuals who failed VRET and went on to CET. A cost-benefit analysis was also planned should significant treatment differences be observed.

Methods

Overview

Service Members with deployment-related PTSD were recruited from multiple military facilities in Southern California. PTSD was verified using clinician-administered structured interviews, and quantified using the Clinician-Administered PTSD Scale (CAPS). Those who met inclusion and exclusion criteria were randomly assigned to receive 9 weeks of VRET or CET. Therapy could be conducted up to twice a week, with a goal of achieving 8-12 sessions during this period. Assessors, blinded to the treatment condition, assessed PTSD using the CAPS before, one week, and 3 months after the conclusion of treatment. Participants who continued to meet inclusion criteria after the completion of one round of treatment could elect to cross over into the opposite condition, but to keep group size symmetrical, crossovers to a particular treatment were not allowed when the sample size for a receiving group was more than two greater than in the opposite condition. This study was powered to require 40 participants per group at posttreatment. Details of study design have been described previously,¹⁴ and the study was registered at https://clinicaltrials.gov/ct2/show/NCT00978484.

Study sites

This study was conducted at seven clinics under the auspices of Naval Medical Center San Diego and Marine Corp Base Camp Pendleton.

Participants

Participants were all active duty military members with established diagnoses of PTSD related to service in Iraq or Afghanistan. They were recruited via posted fliers on bases, and via referrals from military medical providers. Participants had to be aged 18–60, have PTSD based on Diagnostic and Statistical Manual of Mental Disorders, 4th ed. (DSM-IV) criteria and confirmed by structured interview¹⁵ and CAPS¹⁶ score >40. The cutoff of 40 was chosen based on work by Shalev et al. that indicated a CAPS score of 40 yielded 93% sensitivity and 80% specificity for a diagnosis of PTSD.¹⁷ Participants were excluded if they were actively suicidal, homicidal, psychotic, or suffering from substance dependence that was not at least in early remission.

A total of 153 individuals were consented to participate in this study. Details of the population flow through the study are given in Figure 1. Demographics of the final population are given in Table 1.

Informed consent procedures

All protocols were approved by an Institutional Review Board and carried out under the supervision of the principal investigators (PI) and a medical monitor. All subjects gave informed consent to participate and could withdraw that consent at any time.

Therapists

Eleven therapists provided treatment for participants for whom data were included in this study. This included two psychiatrists (MDs), eight psychologists (PhDs), and one clinical social worker (MA). Three additional therapists treated a single case before leaving, and thus the participants in their care were not included in the randomized sample. All therapists had to have completed a course in prolonged exposure therapy, a training workshop in VRET, and to have completed at least one supervised case of VRET before participants under their care could be randomized between treatments and have data included in this study.

Protocol and protocol adherence

The VRET protocol was the same as was used in an earlier treatment-development study,⁵ which in turn was based on principals laid out in prolonged exposure therapy,¹⁸ and earlier work in VRET.¹⁹ Details of the methods have been published previously.^{5,14} Briefly, participants meet in 90-minute sessions up to twice a week for 9 weeks, with a goal of achieving 8–12 sessions during this time period. In the first session, a trauma interview was conducted, education provided, and the idea of *in vivo* exposure introduced. In the second session, the participant repeatedly recounted his/her most salient trauma



FIG. 1. CONSORT figure showing participant flow through the study. CET, control exposure therapy; VRET, virtual reality exposure therapy.

story to the therapist in a session of imaginal exposure therapy. In the third session, the therapist introduced the virtual reality, allowing the participant to explore a computer-simulated version of Iraq or Afghanistan using a head-mounted display, with the option to also introduce vibration or smells to enhance immersion. In the fourth session and beyond, the different aspects were combined, with the participant recounting a trauma story, while confronting simulated aspects of that trauma in virtual reality, and confronting real life stresses *in vivo* as homework between sessions. Each session also provided opportunities for symptom monitoring, discussion, and cognitive reframing. Intensity increased throughout therapy, focusing more on hot spots in trauma and increasing the stimuli in the simulation as tolerated.

CET followed the same protocol, but no virtual reality headset or any other aspects of the immersive technology were used. Rather, participants viewed the images from the simulator on a standard computer screen. Participants had the option of choosing a still shot (screen capture) from the simulator or using another still image (such as a digital photo of Iraq or Afghanistan) displayed on a computer on which they would focus during the remainder of in-session exposures. In sessions four and beyond, participants recounted their trauma narratives to the therapists, while viewing a single image on a computer screen (CET).

To maintain protocol adherence, therapists met with each other and the PI in a review session once a week in which therapists would review the course and methods of treatment, and view videotapes of each other's ongoing treatment. Initial tapes were also sent to an outside reviewer, an expert in VRET who had been involved in the original treatment protocol, to verify that the protocol was being adhered to.

Participants were allowed to seek other treatment, including medication changes, group therapy, or supportive treatment during the experimental protocol. No other individual therapy was allowed during the course of VRET/CET, however.

Randomization

Participants who were being treated by a therapist who had not yet completed a supervised VRET case were not randomized, but rather treated only with VRET. Data from this group were not used for the comparison. Randomization occurred at session three of treatment, the first session in which the

VIRTUAL REALITY FOR PTSD

Nominal data	CET N = 38	Mean (SD)	VRET N=43 Mean (SD) 33 (8.33) VRET		
Age Categorical data	32 (7	.71)			
	CE	Т			
	Frequency	Percent	Frequency	Percent	
Gender					
Male	38	100.0	40	93.0	
Female	0	0.0	3	7.0	
Marital status					
Married	26	68.4	23	54.8	
Not married	12	31.6	19	45.2	
Race					
White	22	57.9	21	48.8	
Non-white	16	42.0	22	51.2	
Highest education level attained					
High school/GED	12	31.6	17	39.5	
Some college or trade school	18	47.4	20	46.5	
Bachelor's degree or higher	8	21.0	6	14.0	
Military status					
Active duty	34	89.5	39	90.7	
Reserve/retired	4	10.5	4	10.3	
Military branch					
Army/Marines	24	63.2	63.2	63.2	
Navy/other	14	36.8	36.8	36.8	
Military rank					
Enlisted	34	89.5	38	88.4	
Officer	4	10.5	5	11.6	

TABLE 1	. Demographic an	d Descriptive	CHARACTERISTICS OF	PARTICIPANTS
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CET, control exposure therapy; GED, general equivalency degree; SD, standard deviation; VRET, virtual reality exposure therapy.

simulator or still image was introduced. Therapists drew randomly selected lots of two, four, or six paired selections for VRET and CET. This ensured that each therapist treated roughly the same number of participants in each condition, but was unaware of which condition their next participant would receive.

Virtual reality equipment

Two virtual reality systems were available and used interchangeably. The first system used the Virtual Iraq and Virtual Afghanistan system designed by the University of Southern California Institute for Creative Technology, and run on computer systems by the Virtually Better Corporation.⁵ This system also offered the option of including vibration and scent in the simulation. The second system used software and hardware by Virtual Reality Medical Center.¹⁹ In both simulators, simulations of wartime environments were viewed through a headmounted display rendering three-dimensional visual graphics and relevant sounds. Neither system provided photo-realistic images, but rather graphics and sounds similar to what might be seen in a video game.

Outcome assessment

The primary outcome of this study was the CAPS. Technicians, blinded to the treatment condition, assessed symptoms before treatment, one week after finishing treatment, and 3 months after completing treatment. The CAPS was used to assess symptoms in the previous week. When assessing outcomes at the 3-month followup, we did not include data from participants in crossover conditions who were engaged in a second round of treatment.

Crossover

Participants who still met entry criteria after their first round of treatment were eligible to cross over and receive treatment in the converse condition, but this was only offered when group size was not asymmetrical (n different by two or more per group). Except in one individual participant, crossover therapy was provided by the same therapist who provided the original treatment.

Data analysis

Primary outcome, PTSD symptoms as assessed by the CAPS over the course of treatment, was conducted by repeatedmeasures analysis of variance (ANOVA). Covariates were not included in the model. We used intention-to-treat methods in this analysis, and therefore any participant who was randomized and who completed a posttreatment assessment was included in the calculation regardless of how many therapy sessions they attended.

A second repeated-measures ANOVA was used to examine changes from pretreatment, to posttreatment, and including the 3-month followup. This was run as a separate analysis because dropout between posttreatment and the 3 month followup would otherwise substantially reduce the study power.

	Posttreatment			3-month followup				
	CET (n=43)	±SD	VRET (n=42)	±SD	$\overline{CET(n=33)}$	±SD	VRET $(n=33)$	±SD
Baseline CAPS score	74.5	16.6	76.8	15.0	71.9	16.8	74.9	61.3
Posttreatment CAPS score	56.8	25.1	65.7	28.4	62.6	28	58.2	29.2
CAPS improvement (points)	18.4	28.6	9.2	26.7	18.0	33.7	11.0	24.4
CAPS improvement (%)	54.0	50.4	44.8	52.7	22.5	47.6	15.3	32.6
Response ($>30\%$ improved). %	37.2		31.0		36.4		30.3	
Remission (CAPS ≤ 20), %	4.7		9.5		6.1		15.2	

TABLE 2. RESPONSE TO TREATMENT

CAPS, clinician-administered PTSD scale.

For crossover participants, a three-way ANOVA was used to compare their response to VRET and CET and to first vs. second round of treatment.

Secondary, *post hoc*, analyses examined the influence of number of therapy sessions on treatment outcomes. We reran the above analysis only in participants who completed a minimum of eight therapy sessions. We also examined simple correlations between the number of sessions completed and the percent improvement on the CAPS.

Because dropout was asymmetric, we did not attempt to model missing scores for participants who dropped out of the study without completing any sort of posttreatment assessment.

For descriptive purposes, we report the following: dropout rates in the groups; those who had a treatment response, as defined as a CAPS improvement of 30% or greater; and those who were in remission from PTSD, as defined as a CAPS score of 20 or lower. These definitions were based on previous work in the field.⁴

Although a cost–benefit analysis was initially planned, this was not performed as there were no significant differences between the treatment conditions.

Results

For pretreatment–posttreatment outcomes, there was a significant effect of time (p < 0.001), but not of group (p > 0.05), or time x group interaction (p > 0.05) when examining CAPS scores in 42 participants who received VRET and 43 who received CET. This indicates that participants with deployment-related PTSD improved in both treatments, but there was no significant advantage to the virtual reality treatment in the short term.

For the 3-month followup, there was a significant effect of time (p < 0.001), but not of group (p > 0.05), or time *x* group interaction (p > 0.05) when examining CAPS scores in 33 participants who received VRET and 33 who received CET. This demonstrates that treatment benefits for both interventions persist at least 3 months, but that, again, there is no significant advantage of VRET.

Table 2 shows CAPS scores as treatment progressed, as well as descriptive statistics outlining how the population improved.

There was no significant correlation between the number of therapy sessions and the percent improvement on the CAPS (R = -0.0197). Participants in CET averaged 9.24 sessions and those in VRET averaged 10.28 sessions, a difference that showed no statistically significant difference (p = 0.14). Calculating the ANOVA so that only participants who completed eight or more sessions were included likewise did not reveal any significant differences between VRET and CET outcomes.

For crossover participants, there was no significant effect of time, group, or first-versus-second round of treatment on CAPS outcome. This indicates that regardless of if a participant went from control treatment to virtual reality or virtual reality to control treatment, a participant who did not respond to the first round of treatment was unlikely to respond to the second. Group size was very small, however.

Table 3 shows CAPS scores among crossover participants, as well as descriptive statistics outlining how the population improved.

In VRET, seven participants dropped out before providing a posttreatment assessment. No participant dropped out of the control condition without providing data.

Discussion

Contrary to expectations, we did not observe any significant difference in PTSD outcomes when comparing the results of exposure therapy offered with and without a virtual

TABLE 3. RESULTS FROM CROSSOVER PARTICIPANTS

	First round of treatment			
	$CET \\ (n=6)$	±SD	VRET (n=5)	±SD
Pretreatment CAPS score	83.0	17.3	82.0	8.5
Posttreatment CAPS score	74.3	12.8	79.0	18.3
CAPS improvement (points)	8.7	17.9	3.0	12.4
CAPS improvement (%)	8.4	19.0	4.3	15.1
Response (30% or greater improvement), %	16.7		0.0	
Remission (CAPS ≤ 20), %	0.0		0.0	
	Second round of treatment			
	<i>CET</i> (n=5)	±SD	<i>VRET</i> (n=6)	±SD
Pretreatment CAPS score	76.6	15.2	74.3	12.8
Posttreatment CAPS score	72.2	18.4	75.0	32.4
CAPS improvement (points)	4.4	14.5	-0.7	32.5
CAPS improvement (%)	5.3	20.8	-2.3	46.0
Response (30% or greater improvement), %	0.0		33.0	
Remission (CAPS ≤ 20), %	0.0		0.0	

reality simulator. This was true both at posttreatment, 3-month followup, and in a limited number of participants who crossed over to the opposite condition. We also found no evidence that virtual reality encouraged greater engagement in treatment, as assessed by number of sessions attended or dropout rates. Average number of sessions/patient was similar between the two conditions; and, of those who stayed long enough to get to randomization, dropout occurred exclusively in the virtual reality group. This finding is consistent with previous trials that many forms of therapy for PTSD, including VRET,^{20–22} produce relatively equivalent results.²³ It is also consistent with other studies in progress that so far have found no advantage of VRET over traditional prolonged exposure therapy.¹³

VRET may still offer a useful option for the treatment of combat-related PTSD. Participants in both conditions improved significantly, with rates of symptom reduction similar to what have been reported for evidence-based therapies in military populations.²⁴ Of note, this response rate is below the response rate typically reported in civilian PTSD,²¹ and it is possible that VRET could offer advantages in different populations. An advantage to VRET over traditional exposure therapy has been previously suggested for individuals with anxiety related to fear of flying,⁹ and with at least one survivor of the September 11, 2001 attacks.¹¹

Other factors that could have minimized differences in this study include a design that allowed cooccurring treatment and a variable number of treatment sessions. This study also used a CET condition that still involved the use of a computer. It is a limitation that the CET condition has not itself been previously studied as an independent therapy. The use of CET rather than traditional exposure therapy was intended to minimize bias, but might have offered some benefit compared with purely traditional exposure therapy. Of note, however, results that have been released, but not yet published in peer-reviewed journals, have likewise indicated that head-to-head comparisons of VRET versus traditional prolonged exposure do not show advantages from VRET.¹³

Results of this study suggest that military clinics are unlikely to see dramatic improvements in their average PTSD outcomes simply by offering VRET. Relatively few individuals in this study, or in other studies of long-term followup of PTSD,²⁵ found full remission after a single course of treatment.

This does not mean that any individual with PTSD should abandon hope. Although not all treatments work for PTSD, several comparative studies now indicate that at least a number of therapy options can offer a reasonable chance at success.²³ It was disappointing that, in this study, individuals who attempted a second round/type of exposure treatment by crossover were unlikely to improve if they had failed to respond to the first attempt at exposure therapy. However, this was performed only in a very small portion of the overall study sample. Also, the same therapist generally offered both forms of treatment to an individual, so provider and patient fatigue may have contributed to the lack of response in ongoing treatment. We thus caution against overinterpreting the crossover findings. It will be important to conduct larger studies that look if a different followon treatment works if one has failed. Also, it will be key to investigate characteristics that may better guide patients to their best treatment option. For example, another work has suggested that physiological reactivity may

be a good marker for those likely to benefit from exposure treatments.²⁶ Finally, virtual reality and other technologies continue to improve, and as more options are offered, any given individual with PTSD is more likely to find a treatment that helps his or her condition.

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