

RESEARCH ARTICLE

A randomized clinical trial of prolonged exposure and applied relaxation for the treatment of Latinos with posttraumatic stress disorder

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Abstract

Robust evidence supports the use of prolonged exposure therapy (PE) as a first-line treatment for posttraumatic stress disorder (PTSD). However, Latinos have not benefitted equally from advancements in the treatment of PTSD and continue to face barriers to receiving care. There is consensus that it is necessary to support the expansion of high-quality culturally and linguistically appropriate treatment to address disparities experienced by racial and ethnic minorities in behavioral health care. The current study was a randomized controlled trial comparing a culturally adapted PE intervention with applied relaxation (AR) among Spanish-speaking Latinos with PTSD in Puerto Rico. Eligible participants ($N = 98$) were randomly assigned to PE ($n = 49$) or AR ($n = 49$). Both treatments included 12–15 weekly sessions each lasting 60–90 min. The primary outcome, clinician-rated PTSD symptom severity, was assessed using the Clinician-Administered PTSD Scale for *DSM-5* at baseline, posttreatment, and 3-month follow-up. Secondary outcomes were assessed using the Patient Health Questionnaire and State-Trait Anxiety Inventory. Results showed a large within-group effect of treatment on PTSD symptoms, PE: $d = 1.29$, 95% CI [1.12, 2.05]; AR: $d = 1.38$, 95% CI [1.21, 2.19]. The between-group effect on PTSD symptoms was small, $d = -0.09$, 95% CI [-0.48, 0.31]. Participants in both treatment conditions reported significant decreases in PTSD symptoms from baseline to follow-up; additionally, significant within-group reductions in depression and anxiety symptoms were observed. These findings underscore the potential benefit of PE and AR for the treatment of Spanish-speaking Latinos with PTSD.

Posttraumatic stress disorder (PTSD) is a debilitating condition that can develop in response to shocking and overwhelming traumatic events (American Psychiatric Association [APA], 2013). After an initial period of psychological distress and coping, most individuals exposed to traumatic events return to pretrauma levels of psychological func-

tioning within approximately the first month (American Psychological Association, 2017). Trauma survivors who develop PTSD continue to be highly distressed for months or years after the event (Bryant, 2019). Santiago and colleagues (2013) reviewed studies exploring the longitudinal course of illness and recovery for individuals experiencing

PTSD and found that untreated PTSD persists as a chronic disorder in approximately 40% of individuals with the condition.

Considerable research has focused on evaluating the efficacy of trauma-focused treatments for PTSD. Robust evidence supports the use of prolonged exposure (PE), one of the most extensively studied forms of cognitive behavioral therapy (CBT), as a first-line treatment for PTSD (Forbes et al., 2020; Lewis, Roberts, Andrew, et al., 2020). PE has been shown to significantly reduce symptoms of PTSD as well as comorbid symptoms of depression and anxiety (Lewis, Roberts, Andrew, et al., 2020). Even though access to evidence-based treatments for PTSD has increased over the past decades in the United States, racial and ethnic minorities have not benefitted equally from these advances (McClendon et al., 2020). In comparison with non-Latino Whites, minorities underutilize specialty mental health care, more often seek assistance in primary care settings than mental health-specific settings, and are less likely to receive guideline congruent care (Cabassa et al., 2006).

Latinos constitute the largest ethnic or racial minority group in the United States, reaching 60.6 million in the United States and almost 3.2 million in Puerto Rico (PR; U.S. Census Bureau, 2020). Research findings show that although Latinos may be at higher (McClendon et al., 2019) or similar (Alegria et al., 2013) risk of developing PTSD in comparison to non-Latino Whites, Latinos are less likely to initiate and remain in treatment for PTSD (McClendon et al., 2020). Using data from the National Epidemiologic Survey on Alcohol and Related Conditions, Roberts et al. (2011) found that almost 60% of Latinos with PTSD did not initiate mental health treatment, and among participants who received care, Latinos were significantly less likely to receive minimally appropriate care compared with non-Latino Whites. Stigma, access to culturally tailored services, underinsurance or lack of insurance, and language have been identified as common barriers to mental health care for Latinos (APA, 2017). As the Latino population continues to increase, there is a critical need to provide quality mental health care to this group.

Alegria et al. (2016) noted that the misleading assumption that evidence-based treatments are easily available for minority populations has contributed to the persistence of mental health care disparities. The authors highlight the limited availability of linguistic or culturally competent care as a key barrier to accessing treatment. To increase the acceptability, relevance, and effectiveness of behavioral interventions among minority populations, attention has focused on the cultural adaptation of existing interventions, particularly CBT. A number of cultural adaptation

models using a staged approach have been developed to systematically guide the adaptation process (Barrera et al., 2013). Naeem et al. (2016) proposed adapting psychosocial interventions using a sequence of four stages: (a) information gathering, (b) producing guidelines for adaptation of the CBT manual, (c) translation and adaptation of therapy material, and (d) field testing the adapted therapy. The authors underscored the relevance of conducting a feasibility study to examine the acceptability of the adapted interventions and, ultimately, a larger randomized controlled trial (RCT) to examine its effectiveness. In a study examining the efficacy of a culturally adapted CBT intervention for Latinas with PTSD, Hinton and colleagues (2011) found significant improvements in PTSD symptoms. Another study that used a staged model to guide the cultural adaptation of cognitive processing therapy (CPT) showed increased acceptability of the adapted version of CPT among Spanish-speaking Latinos with PTSD (Valentine et al., 2017).

With the substantial population of Spanish speakers with limited English-language proficiency in the United States and the Spanish-speaking U.S. citizens in PR, effective treatments for Spanish-speaking Latinos with PTSD are crucial. The scientific evidence to support the use of PE with Spanish-speaking Latinos is limited, as these individuals have routinely been underrepresented in clinical studies (Aponte-Rivera et al., 2014). To attain the goal of providing Latinos with quality mental health care in the 21st century, the APA (2020) stressed the importance of providing culturally and linguistically appropriate treatment. As an initial step to address these critical gaps in the treatment of Spanish-speaking Latinos with PTSD, Vera and colleagues (2011) culturally adapted the PE manual for Spanish-speaking Latinos and conducted a feasibility pilot study to examine whether the adapted intervention was acceptable to Latinos in PR, a population characterized by dominant Latino orientation. Pilot RCT study findings provided evidence in favor of the adapted PE intervention for Spanish-speaking Latinos as a feasible and acceptable intervention. Clinical interview data demonstrated statistically significant PTSD symptom improvement after treatment. The aim of the current study was to advance the literature by conducting an RCT comparing the culturally adapted PE intervention with an active comparison condition, applied relaxation (AR), among Spanish-speaking Latinos in PR. We hypothesized that PE for Spanish-speaking Latinos in comparison to AR would lead to significantly higher levels of improvement in primary (i.e., clinician-rated PTSD symptom severity) and secondary outcomes (i.e., self-reported PTSD symptom severity, depression, and anxiety).

METHOD

Participants

Individuals were eligible to participate in the study if they were between 18 and 64 years old, met the criteria for PTSD according to the Clinician-Administered PTSD Scale (CAPS) for the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (fifth ed. [DSM-5]; i.e., the CAPS-5; Weathers, Blake, et al., 2013), scored 33 or higher on the PTSD Checklist for DSM-5 (PCL-5; Weathers, Litz, et al., 2013), were fluent Spanish speakers seeking treatment in Spanish, and were willing to be randomized. The exclusion criteria were cognitive impairment; suicidal or homicidal ideation; change in psychiatric medications 2 months or less before study entry; involvement in a violent relationship; traumatic experiences that occurred less than 3 months before study entry; alcohol or drug abuse within the past 3 months; a history of bipolar, schizophrenia, or psychotic disorders; and current participation in therapy for PTSD. Figure 1 depicts the CONSORT flow diagram, which summarizes the recruitment process and allocation of participants. In total, 2,029 individuals were invited to participate in an initial face-to-face interview, 1,670 of whom were assessed for eligibility. Of this group, 1,509 did not meet the inclusion criteria, 35 met the criteria but did not return, 16 withdrew consent, and 12 had another reason for not continuing with the study. Eligible participants ($N = 98$) were randomly assigned to PE ($n = 49$) or to AR ($n = 49$). Session attendance was comparable between both groups. Three participants in each group did not initiate treatment; among those who started treatment, approximately 70% in each group (69.4% for PE, 71.4% for AR) completed 12 sessions or more. Previous research has identified seven or eight sessions or more as an adequate course of treatment for PE (Hale et al., 2019; Mott et al., 2014). By this criterion, approximately 80% of participants in care (i.e., 77.5% for PE, 81.6% for AR) received an adequate dose of treatment by completing at least eight sessions. Participants attended an average of 10.87 and 11.46 sessions of PE and AR, respectively, which was a nonsignificant difference. Treatment length was discussed during the course of treatment, allowing PE and AR participants to receive up to 15 sessions if they identified the need to reinforce the skills necessary to maintain treatment gains. Approximately 25% ($n = 12$) of PE participants and 34.7% ($n = 17$) of AR participants received more than 12 sessions. Assessments were conducted at pre- and post-treatment and 3-month follow-up. Participants who ceased therapy were asked to continue with study assessments. Of the 98 enrollees, 79.6% ($n = 39$) of PE participants and 75.5% ($n = 37$) of AR participants completed the posttreatment assessment, and 73.5% ($n = 36$) of PE participants and 71.4%

($n = 35$) of AR participants completed the follow-up assessment. The data collection period ended in April 2018.

An overview of participant characteristics is presented in Table 1. The mean age of participants was 43.6 years, 81.6% were women, approximately 60% were not married or cohabitating, and about half were employed. The most common traumatic experiences were physical assault, sexual assault, and unexpected or violent death. Other traumatic events reported included transportation accidents, war or combat exposure, and community violence (e.g., mugging, burglary, shooting). About 40% of the sample experienced an event more than 10 years previously and over two thirds received prior treatment for the trauma. Participants' characteristics were comparable across both groups, except for sex: There were more men in the PE group (26.5%) than in the AR group (10.2%). There were no significant differences in any outcome measure at baseline.

Procedure

The study procedures were approved for human subject protection by the Institutional Review Board of the University of Puerto Rico, Medical Sciences Campus. Recruitment occurred from November 2014 to November 2017 and was carried out via press articles, media posts, posters, interviews on the TV and radio, and contact with health providers and key organizations. Eligibility assessments were conducted at the approving university's research center or community health care facility. After obtaining written informed consent, potential participants were assessed by graduate students who were supervised by experienced clinical psychologists. Assessors were trained in the administration of the interviews and were masked to treatment condition. Training included attending workshops, readings, training videos, mock interviews, and practice interviews. CAPS-5 interviewers received feedback and tutoring until they attained 100% agreement on PTSD criteria when compared to expert raters. Regular meetings to rate the consistency of evaluations were held throughout the duration of the study. Participants were assigned to each treatment arm using block randomization. Randomization took place in a 1:1 ratio according to a computer-generated random assignment sequence in blocks of 10–20 participants. The random allocation sequence was overseen by the study statistician, who also was responsible for printing treatment assignment codes and placing them in thick, sequentially numbered, sealed envelopes. Participants were enrolled by clinical psychologists. To assign participants to the intervention, they contacted central office staff, who selected the next sealed envelope, and reported the code corresponding to the assigned treatment

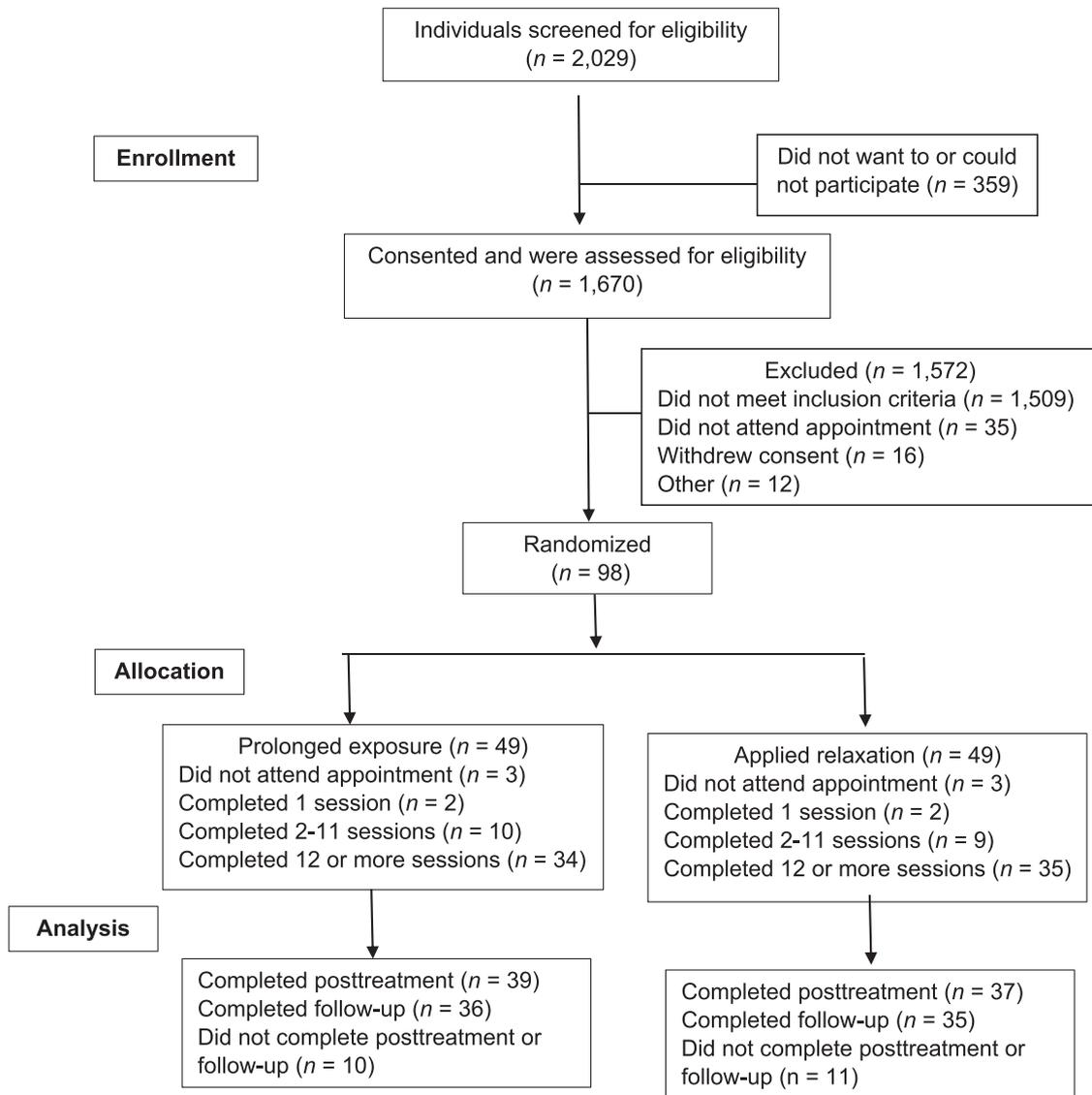


FIGURE 1 Consort flow diagram

condition. Study outcome assessors and the data analyst remained unaware of intervention assignments.

Therapists were native Spanish speakers with high-level English proficiency. Weekly group supervision took place throughout the trial in both English and Spanish. All treatment sessions were video-recorded. Adherence to treatment elements also was ensured via ratings of treatment sessions by independent expert clinicians. Using rating forms modeled after standard checklists for PE and AR, expert raters were asked to determine if the therapist demonstrated each essential component described in checklist items. A total of 98 (i.e., 49 for PE, 49 for AR) sessions were rated. Sessions were randomly selected via a method that ensured that each phase of treatment (i.e., beginning, middle, end) was equally represented in the adherence ratings. Therapists completed 97% and 93% of

essential components prescribed in the protocol for PE and AR, respectively.

Treatments

PE. Treatment in the PE condition was delivered in 90-min weekly individual sessions. Therapy consisted of 12 sessions, with a possible extension of up to 15 sessions. The first session focused on discussing the rationale for PE, information gathering, and breathing training. The second session provided education about common reactions to trauma exposure and PTSD symptoms as well as a rationale for in vivo exposure. Items selected for in vivo exposure were arranged in a hierarchical order based on their predicted difficulty. The third session focused on the rationale for and implementation of imaginal exposure.

TABLE 1 Baseline participant characteristics and outcome measure scores

Variable	Total (N = 98)		PE (n = 49)		AR (n = 49)		p						
	N	%	M	SD	n	%		M	SD				
Age, mean (SD)			43.62	12.09			44.08	11.53		43.16	12.73	.709	
Sex													
Men	18	18.4			13	26.5			5	10.2		.037	
Women	80	81.6			36	73.5			44	89.8			
Marital status													
Not married	58	59.2			32	65.3			26	53.1		.218	
Married/ cohabitating	40	40.8			17	34.7			23	46.9			
Educational attainment													
Less than high school	13	13.4			8	16.3			5	10.4		.861	
High school or GED	8	8.3			4	8.2			4	8.3			
Some college	55	56.7			27	55.1			28	58.3			
Bachelor's degree or above	21	21.7			10	20.4			11	22.9			
Work status													
Working	51	52.0			25	51.0			26	53.1		.839	
Not working	47	48.0			24	49.0			23	46.9			
CAPS-5 score			42.93	9.12			43.18	10.10			42.67	8.11	.783
PHQ-9 score			16.70	5.74			16.57	6.09			16.83	5.44	.822
STAI-S score			60.23	9.82			60.65	10.54			59.81	9.13	.679

Note: CAPS-5 = Clinical Administered PTSD Scale for DSM-5; PHQ-9 = nine-item Patient Health Questionnaire; STAI-S = State-Trait Anxiety Inventory-State Version; PE = prolonged exposure; AR = applied relaxation.

Subsequent sessions included imaginal exposure, the processing of related thoughts and feelings, and discussions of in vivo and imaginal exposure homework. The final session also included a discussion of what the participant had learned, the progress they had made, and plans for continuing exposures as needed.

The PE manual for Spanish-speaking Latinos used in the present study was based on the protocol *Prolonged Exposure Manual-Revised Version* developed by Foa et al. (2002). A comprehensive stage model was followed to guide the cultural adaptation process of the PE manual. Extensive formative research using qualitative methods was conducted to determine the appropriateness of PE for the treatment of Spanish-speaking Latinos. Focus groups and key informant interviews with relevant stakeholders (e.g., individuals with PTSD, therapists) explored participants' views about PTSD, experiences receiving or providing treatment, barriers and facilitators to care, and the social and cultural contexts that may impact treatment engagement and outcomes. Following an iterative process, sections of the preliminary versions of the translated manual were reviewed with stakeholders to identify limitations

in the translation and find language, idioms, and examples pertinent to Latino culture, while preserving the intended meaning. Based on recommendations outlined by Bernal et al. (2005), particular attention was given to examining whether the language was culturally syntonic, metaphors and concepts used were common to Latinos, treatment concepts were concordant with Latino culture and context, and treatment methods were acceptable. Overall, the data gathered provided guidance on the elements of the intervention that could be adapted for Spanish-speaking Latinos while maintaining fidelity to the core components of the English PE manual. The resulting PE manual was evaluated by six Latino mental health clinicians with training in PE. Each clinician independently evaluated the content of the manuals and presented their recommendations in group meetings; the culturally adapted PE manual used in the present study incorporated the modifications agreed upon by these six clinicians. In addition to the use of language and wording better understood by Spanish-speaking Latinos and the inclusion of examples representing the types of traumatic events these individuals were more likely to experience, an engagement session

was added to the Spanish PE manual. The purpose of this session was to allow patients and clinicians to openly discuss PTSD and PE treatment elements and explore possible barriers to participation and strategies to address these barriers. Exposure homework assigned during PE therapy can place high demands on participants, and Latino core values and norms are highly oriented toward family. Relatives and friends can be a source of support to facilitate therapy attendance and homework completion. After the goals of the engagement session were discussed during the initial PE session, participants decided whether they wanted to attend the engagement session alone or invite a relative or friend they considered to be a source of support when coping with health conditions. Approximately 30% of PE participants invited a relative or friend to this session.

AR. Treatment in the AR condition was based on the manual developed by Hayes-Skelton et al. (2013), which was adapted from the relaxation protocols established by Bernstein et al. (2000) and Öst (n.d.). AR was delivered in 12–15 weekly sessions that ranged from 60–90 min, depending on session content. The main AR treatment strategies include detecting early signs of stress, learning relaxation skills, and applying relaxation at the initial sign of stress (Hayes-Skelton et al., 2013). The first AR session focused on the rationale presentation, underscoring the importance of acquiring new coping methods for reducing stress. To interrupt the stress reaction cycle early and create new coping habits, treatment involved self-monitoring internal reactions to recognize early signs of distress and learning several relaxation techniques that could be used as an alternate response when an individual noticed the early signs of distress. The first relaxation exercise, diaphragmatic breathing, was introduced in the first session; other exercises and techniques were introduced in subsequent sessions. Patients practiced relaxation skills during the session and were assigned homework to practice these skills twice daily. Sessions 2–8 focused on early cue detection exercises and progressive muscle relaxation skills, which began with 16 different muscle groups and decreased to seven and finally four muscle groups as participants progressed. Once they learned this “tense and release” relaxation technique, subsequent sessions focused on release-only (i.e., learn to relax muscles without first producing tension), cue-controlled (i.e., use of words “inhale” and “relax” to facilitate relaxation), differential (i.e., learning to relax muscles in the body that are not being used), and rapid (i.e., relaxation in less than one minute) relaxation exercises. Participants were encouraged to use early cue detection skills and apply relaxation in response to unplanned stressful situations they experienced during the week and when these situations occurred during sessions. The last session addressed relapse prevention and strategies for maintaining gains.

Although it maintained fidelity to the core components of the English AR manual, the Spanish version was modified to change the specific focus from generalized anxiety disorder (GAD) to PTSD. Additionally, an engagement session with the participant was included to collect information about trauma exposure, reactions to the traumatic event, presenting problems, and possible barriers to participation and strategies to address these barriers.

Measures

Primary outcome

Clinician-rated PTSD. The CAPS-5 (Weathers, Blake, et al., 2013) is a semistructured interview considered to be the gold standard for PTSD assessment. The measure is used to establish diagnostic status and past-month symptom severity. Severity scores are obtained by adding the scores for 20 symptom items, rated on a scale of 0 (*absent*) to 4 (*extreme/incapacitating*). A symptom was considered to be present if it occurred at least twice a month or some of the time and was rated with a minimum intensity of *clearly present* or higher (Weathers et al., 2018). A PTSD diagnosis was determined using this scoring rule in combination with the DSM-5 algorithm (Weathers et al., 2018). The total PTSD scale from the CAPS-5 has demonstrated high internal consistency (Cronbach's $\alpha = .83$) and good convergent validity with the CAPS-IV ($r = .83$; Weathers et al., 2018). PTSD remission was specified as a total score less than 12 at follow-up. Norman et al. (2019) reported that CAPS-5 developers recommended this cutoff because it is impossible to have a PTSD diagnosis with a score lower than 12. We received authorization from one of the instrument's codevelopers (F. W. Weathers) to translate this measure to Spanish. The translation process was completed taking into consideration elements of the World Health Organization (2016) process of translation and adaptation of research instruments. As recommended, we used the well-established methods of forward-translation, expert panel review, back-translation, and pretesting and cognitive interviewing. The CAPS-5 was administered at the pretreatment, posttreatment, and 3-month follow-up assessments. In the current sample, Cronbach's alpha for the total scale at baseline was .80.

Secondary outcomes

Self-reported PTSD. The PCL-5 (Weathers, Litz, et al., 2013) is a 20-item measure designed to assess PTSD symptoms as defined by the DSM-5. In the present study, the PCL-5 was administered at the pretreatment assessment session and immediately prior to each treatment session. Respondents are asked to rate the degree to which they

have been bothered by each symptom on a 4-point Likert scale ranging from 0 (*not at all*) to 4 (*extremely*), with a total score ranging from 0 to 80. The PCL-5 has demonstrated high reliability as well as convergent and discriminant validity (Bovin et al., 2016). PCL-5 cutoff scores of 31 to 33 have been identified as optimally efficient for diagnosing PTSD (Bovin et al., 2016). The PCL-5 was administered in Spanish. After receiving authorization from one of the instrument's codevelopers (F. W. Weathers), we followed the procedures previously described to translate this measure to Spanish. In the current study, the internal consistency of the scale scores was good at the initial assessment, Cronbach's $\alpha = .83$.

Depression. The Patient Health Questionnaire (PHQ-9; Spitzer et al., 1999) is a nine-item, self-report measure used to assess the diagnostic criteria for major depression as defined by the *DSM-IV*. In the present study, the PHQ-9 was completed at pretreatment, posttreatment, and follow-up assessments. Participants were asked to indicate the frequency with which they experienced each depressive symptom, rating items on a scale of 0 (*not at all*) to 3 (*nearly every day*); total scores range from 0 to 27. The scale has demonstrated excellent discriminatory power to identify individuals with depression (Kroenke et al., 2001). Psychometric studies support the validity of the Spanish version of the scale (Baader et al., 2012). In the present sample, Cronbach's alpha for the total score at pretreatment was .83.

Anxiety. The State-Trait Anxiety Inventory State Version (STAI-S; Spielberger et al., 1983) is a 20-item self-report measure designed to assess the intensity of a person's feelings of tension, apprehension, and fear. In the present study, the measure was administered at pretreatment, posttreatment, and follow-up assessments. STAI-S items are rated on a 4-point scale ranging from 1 (*not at all*) to 4 (*very much so*), with higher scores indicating more severe anxiety. The scale has shown excellent reliability and validity (Spielberger et al., 1983). The Spanish version of the STAI has demonstrated high internal consistency and good discriminant validity (Fonseca-Pedrero et al., 2012). In the current sample, the reliability of the scores was excellent at pretreatment, Cronbach's $\alpha = .91$.

Data analysis

Based on the findings from a meta-analysis of PE studies (Powers et al., 2010) and an earlier trial that evaluated PE among a sample of Latinos (Vera et al., 2011), it was determined that to detect an effect size of 0.6 or higher for the analysis of PTSD symptoms, a sample of 100 participants (i.e., 50 in each group) would allow us to have 80% power with 30% loss to follow-up and a 5% significance level for a two-sided test. Because dropout was lower

than the estimated rate, 49 participants were allocated to each group. All analyses were conducted on the intent-to-treat sample using data from all randomized participants regardless of whether they completed treatment. To test the study hypothesis, mixed-effects regression models were used with PROC MIXED in SAS software (Version 9.4; SAS Institute Inc., Cary, NC). This approach allowed us to test the effects of PE and AR on changes in the primary and secondary outcome measures. Separate analyses were run for each of the outcome variables across assessment points. The more conservative restricted maximum likelihood estimation was used to estimate model parameters. An unstructured covariance matrix was specified to handle within-participant correlations among repeated assessments. Models were run assuming random intercepts to account for heterogeneity within participants over time. Sex was included in the initial analyses as a covariate but dropped from the final model because it did not alter the main group effects. PTSD remission was compared across treatment groups by examining the percentage of participants who scored less than 12 on the CAPS-5 at follow-up. Between-group and within-group effect sizes were calculated according to Cohen's *d*, with an effect size of 0.6. We considered *p* values less than .05 to indicate statistically significant differences.

RESULTS

Clinical outcomes

Summary statistics and mixed-effects regression estimates are shown in Table 2, and mean PCL-5 scores over the course of treatment are shown in Figure 2. Mean scores for the primary outcome, clinician-rated PTSD symptom severity, decreased in both groups. At baseline, participants who received PE and AR had similar mean CAPS-5 scores (PE: $M = 43.18$, $SD = 10.10$; AR: $M = 42.67$, $SD = 8.11$). There was a substantial decrease in CAPS-5 scores for participants in both groups at posttreatment (PE: $M = 7.51$, $SD = 9.77$; AR: $M = 10.97$, $SD = 13.24$) and follow-up (PE: $M = 8.67$, $SD = 12.17$; AR: $M = 12.49$, $SD = 14.29$). Mixed-effect regression models showed a significant main effect of time on CAPS-5 scores, $F(1, 143) = 189.05$, $p < .001$. There was no significant effect of treatment and no significant interaction effect between treatment group and time. The between-group effect size was small, $d = -0.09$, 95% CI $[-0.48, 0.31]$, and the within-group effect sizes were large $d = 1.29$, 95% CI $[1.12, 2.05]$ for PE and $d = 1.38$, 95% CI $[1.21, 2.19]$ for AR. Clinician-rated PTSD symptoms significantly decreased from baseline to follow-up in both groups. Remission rates were also high and did not differ significantly between groups (i.e., 71.8% for PE, 63.2% for AR).

TABLE 2 Summary statistics and mixed models for study outcomes

Outcome	PE			AR			Group		Time		Group x Time	
	N	M	SD	N	M	SD	B	SE	B	SE	B	SE
PTSD severity (CAPS-5)												
Baseline	49	43.18	10.10	49	42.67	8.11	.09	2.19	-1.30	.09*	.09	.13
Posttreatment	39	7.51	9.77	37	10.97	13.24						
Follow-up	36	8.67	12.17	35	12.49	14.29						
Depression symptoms (PHQ-9)												
Baseline	46	16.57	6.09	48	16.83	5.44	.44	1.14	-.42	.05*	.01	.07
Posttreatment	32	4.38	4.76	34	6.03	6.74						
Follow-up	33	5.36	5.81	33	6.42	7.17						
Anxiety symptoms (STAI-S)												
Baseline	48	60.65	10.54	48	59.81	9.13	-.10	2.09	-.92	.09*	.08	.13
Posttreatment	38	30.03	13.09	34	36.76	14.12						
Follow-up	33	36.12	13.07	33	38.79	15.83						

Note: CAPS-5 = Clinical Administered PTSD Scale for DSM-5; PHQ-9 = nine-item Patient Health Questionnaire; STAI-S = State-Trait Inventory-State Version; PE = prolonged exposure; AR = applied relaxation.

* $p < .001$.

Self-reported PCL-5 PTSD symptoms yielded results that were similar to the CAPS-5 findings. At baseline, mean PCL-5 scores for participants in both treatment groups were above 33, the cutoff score indicative of probable PTSD. Mean PCL-5 scores showed that PTSD symptoms decreased from a high level at baseline to a lower range over the course of treatment among participants in both treatment groups (Figure 2). The model for the session-by-session PCL-5 scores showed a significant main effect of time, $F(1, 777) = 127.61$, $p < .001$, but nonsignificant, small effects for group and for the Group x Time interaction, indicating that PCL-5 scores improved for participants in both treatment conditions over the course of therapy.

A similar pattern of results emerged for the other secondary outcome measures such that mean scores significantly improved on self-reported depressive (i.e., PHQ-9) and anxiety symptoms (i.e., STAI-S). As shown in Table 2 there were significant main effects of time on PHQ-9 and STAI-S scores. There were no significant effects of treatment group nor was there a significant interaction effect between treatment group and time. The between-group effect sizes were small for the PHQ-9, $d = 0.01$, 95% CI [-0.39, 0.42], and STAI-S, $d = 0.04$, 95% CI [-0.36, 0.44]. The within-group effect sizes for the PHQ-9 were large for PE, $d = 0.94$, 95% CI [0.69, 1.50], and AR, $d = 1.10$, 95% CI [0.86, 1.70]. Large within-group effect sizes were also observed for both groups on the STAI-S scores, PE: $d = 1.02$, 95% CI [0.76, 1.56]; AR: $d = 1.13$, 95% CI [0.88, 1.71]. Overall, the findings revealed a significant improvement from baseline to follow-up in PHQ-9 and STAI-S scores for both PE and AR participants.

DISCUSSION

The current study was a randomized controlled trial comparing PE and AR, an active control condition, for the treatment of PTSD. To our knowledge, this was the first study to examine the efficacy of PE in a fast-growing yet highly underserved population of Spanish-speaking Latinos. The findings revealed significant reductions over time on both clinician-assessed and self-reported PTSD symptom severity measures. However, contrary to our hypotheses, similar improvements in PTSD symptoms were evidenced for both PE and AR. There were no significant differences between these interventions in the reduction of PTSD, depressive, or anxiety symptoms. Although this contradicts our hypothesis, the results seem

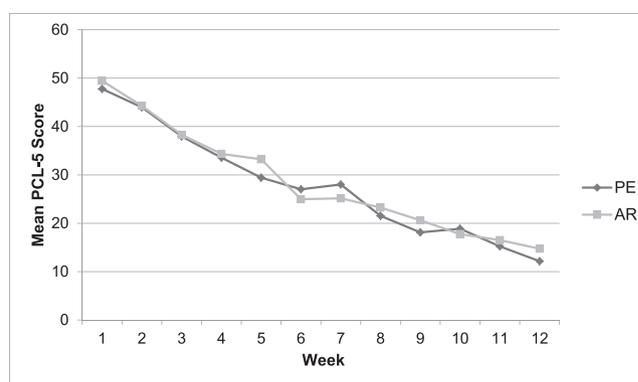


FIGURE 2 Weekly mean Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5) scores during treatment. Note. PE = prolonged exposure; AR = applied relaxation

consistent with the existing body of research that suggests considerable symptom improvement among individuals who receive relaxation therapy for PTSD. A recent meta-analysis examining RCTs of relaxation for PTSD identified three studies that used relaxation as an active control to compare against PE (Niles et al., 2018). In these studies (Markowitz et al., 2015; Marks et al., 1998; Taylor et al., 2003), within-group pre-to-post analyses yielded large effect sizes for relaxation, indicating that relaxation had a significant impact on PTSD symptom improvement over time. The findings for between-group analyses revealed that in two studies, PE did not show greater treatment efficacy in comparison to relaxation relative to clinician-assessed PTSD severity symptoms (Markowitz et al., 2015; Taylor et al., 2003) and self-reported PTSD symptoms (Marks et al., 1998; Taylor et al., 2003).

Similar findings were observed in the current study for the secondary outcomes. Although significant reductions in depression and anxiety were evidenced over time, contrary to our hypotheses, PE did not yield significantly higher degrees of improvement in any of these outcomes compared to AR. Our findings show that there was a significant improvement over time in all secondary outcome measures for participants in both treatment conditions. We also examined clinical improvement operationalized as the loss of a PTSD diagnosis. A high proportion of both PE (71.8%) and AR (63.2%) participants no longer met the criteria for PTSD at follow-up. Markowitz et al. (2015) and Marks et al. (1998) also reported that the proportions of participants who no longer met the criteria for PTSD were comparable for PE and relaxation. Conversely, Taylor and colleagues (2003) found that significantly more patients who received PE lost their PTSD diagnosis compared with those who underwent relaxation training.

In a review of recent clinical practice guidelines for PTSD, Hamblen and colleagues (2019) noted that all guidelines consistently gave strong recommendations for PE. On the other hand, the guidelines regarding relaxation concluded that the evidence was insufficient to provide a recommendation of its effectiveness. However, the authors underscored that the classification of insufficient does not imply that the treatment is ineffective but rather that the available evidence at that time was insufficient to show the intervention's effectiveness in the treatment of PTSD. Kazlauskas (2017) sustains that avoidance, one of the main symptoms of PTSD, may contribute to trauma survivors' reluctance to disclose traumatic experiences and seek health care services, particularly trauma-focused treatments. Additionally, limitations in the availability of providers with proper training and expertise may be a significant barrier to the delivery of trauma-informed evidence-based treatments. The favorable findings for relaxation reported in several PTSD studies, as well as the

present results with Spanish-speaking Latinos, support the need for more studies that further examine the potential of relaxation as an evidence-based treatment for PTSD.

Investigators frequently maintain that although relaxation training has been shown to be useful, it is not as efficacious as PE (Cahill et al., 2008; Foa et al., 2005). An unexpected finding in the current study was the markedly strong efficacy of AR in comparison to previous trials. One possible explanation for these findings was the focus of the main treatment strategies of our AR protocol. According to Hayes-Skelton and colleagues (2011), most trials examining AR as a control condition have focused mainly on the relaxation component. As such, these authors designed an AR protocol, in consultation with one of the AR developers (T. D. Boskovic), with the goal of achieving maximal potency by also highlighting the application component of AR. Hayes-Skelton et al. (2011) combined the elements from manuals by Öst (unpublished) and Bernstein et al. (2000), placing particular emphasis on the practice of detecting early anxiety cues and applying alternate responses both during and out of session. Moreover, this AR protocol has other features of excellent CBT treatments, including a credible, compelling rationale and the inclusion of psychoeducation about the stress reaction cycle. When describing their experience in the implementation of the AR protocol with GAD clients, Hayes-Skelton et al. (2013) stated "we were continually struck by the depth and breadth of change that we witnessed in our clients" (p. 2). Our experience in the implementation of the AR protocol with PTSD clients was similar. Thus, it is possible that the current findings may be due to different but equally efficacious therapeutic mechanisms in each of the comparison treatments. Alternatively, because AR places emphasis on applying relaxation skills to reduce anxiety when confronted with anxiety-provoking situations, it is possible that the positive outcomes for AR may be due to common strategies in each treatment. More research is needed to understand the similarities and differences in the mechanisms of change underlying these treatments.

Regarding treatment retention, approximately 80% of individuals in both the PE and AR conditions completed eight sessions or more. PE was designed and tested as a short-term treatment consisting of between eight and 15 sessions (Foa et al., 2019). In the present sample of Spanish-speaking Latinos, 22.4% in PE and 18.4% in AR completed fewer than eight sessions. These rates are comparable to those reported in a systematic review of dropout rates from RCTs of PTSD in which the authors reported average dropout rates of 22% for PE and 10% for relaxation training (Lewis, Roberts, Gibson, et al., 2020). In a previous review, Hembree and colleagues (2003) obtained similar results for PE, leading the authors to conclude that contrary to misconceptions about exposure therapy,

dropout rates were similar to those for other established PTSD treatments, such as cognitive therapy (22.1%) and eye movement desensitization and reprocessing therapy (18.9%). The level of nonadherence observed in our sample of Spanish-speaking Latinos was similar to those reported in United States-based community samples from other PTSD trials. These findings are important, as misunderstandings about the tolerability of exposure therapy could limit its adoption in clinical practices serving Latinos. Furthermore, the retention rates in the present study of Spanish-speaking Latinos are encouraging, as studies have shown that when Latinos access PTSD treatment, early dropout is common (McClendon et al., 2020).

To better leverage participants' engagement in treatment, all participants were offered an additional session to explore perceptions about treatment, potential barriers to participation, and strategies to address these barriers. PE participants were provided the option of inviting a relative or friend they considered to be a source of support to this engagement session. Approximately one third of PE participants invited a relative or friend to the engagement session. The opportunity to discuss potential barriers to participation and possible strategies in the engagement session may have contributed to the favorable retention rates for both PE and AR. However, future research is needed to further understand any contribution of this session in treatment engagement.

The present study had several limitations that should be noted. The first limitation was the use of a brief, 3-month follow-up period. Studies using a longer follow-up period are needed to evaluate whether treatment gains can be maintained over time. Second, the study was conducted with Spanish-speaking Latinos in PR, characterized by a strong Latino cultural orientation. Future studies with other Spanish-speaking Latino groups are needed to further evaluate treatment effects. Third, although English versions of the PTSD assessments were available, we did not have access to Spanish versions of the measures. The translated Spanish PTSD assessments used in this study have not been validated with Spanish-speaking Latinos. There is a need for research to evaluate the psychometric properties of PTSD assessments for this population.

Notwithstanding these limitations, the present findings provide relevant information for the treatment of Spanish-speaking Latinos, a group traditionally underrepresented in PTSD trials. There is wide consensus among governmental and mental health professional organizations that addressing disparities experienced by racial and ethnic minorities in behavioral health care requires the incorporation of cultural elements into the design and delivery of services (APA, 2020; American Psychological Association, 2014). Over the past few decades, increased efforts have focused on the development and testing of mental

health practices that are both evidence-based and culturally and linguistically appropriate (Chu & Leino, 2017; Morales & Norcross, 2010). More recently, these efforts have been strengthened by the 21st Century Cures Act, a law signed by U.S. President Barack Obama in December 2016, which aims, in part, to support the expansion of high-quality treatments that are culturally and linguistically appropriate. Although further study is needed to confirm and expand the present findings, they underscore the potential benefit of two culturally and linguistically appropriate evidence-based practices for the treatment of PTSD in Spanish-speaking Latinos.

OPEN PRACTICES STATEMENT

The preregistration for this study can be accessed at <https://clinicaltrials.gov/ct2/show/NCT02134691>. Neither the data nor the materials have been made available on a permanent third-party archive; requests for materials should be sent via email to the lead author at mildred.vera@upr.edu.

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