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Award Number:
W81XWH-08-2-0022

TITLE:
Effectiveness of Cognitive Exposure, and Skills Group
Manualized Treatments in OIF/OEF Female Veterans

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REPORT DATE:
April 2009

TYPE OF REPORT:
Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE (DD-MM-YYYY) 04-30-2009		2. REPORT TYPE Annual		1 April 2008 – 31 March 2009	
4. TITLE AND SUBTITLE Effectiveness of Cognitive Exposure & Skills Group Manualized Treatments in OIF/OEF Female Veterans.				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-08-2-0022	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Diane T. Castillo, Ph.D.				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Biomedical Research Institute of New Mexico 1501 San Pedro Dr. SE, Bldg. 14 (151) Albuquerque, NM 87108				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Material Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited.					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The subject and purpose of the study are to evaluate and establish the effectiveness of three behavioral treatments--exposure, cognitive, and skills (assertiveness/relaxation) therapies--provided in a group format. Data began in February 2009, the last two months of the first annual reporting period. Therefore, the data have not yet been analyzed and there are no statistical results. The summary of the most significant findings of the study's progress are that the study has received IRB approvals, staff have been hired and trained, and study subject enrollment has begun.					
15. SUBJECT TERMS PTSD, Treatment, Female Veterans, OIF/OEF					
16. SECURITY CLASSIFICATION OF: U			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 27	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER (include area code)

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INTRODUCTION

The subject and purpose of the study are to evaluate and establish the effectiveness of three behavioral treatments--exposure, cognitive, and skills (assertiveness/relaxation) therapies--provided in a group format. Both exposure and cognitive have been well established in the individual literature to be the most effective, but have not shown the same superiority in a group format. The scope of the study is to conduct this examination utilizing a manualized group treatment approach in a sample of OIF/OEF female PTSD veterans. The intent is to establish the effectiveness of these two therapies, and in particular exposure therapy in a group format to inform the clinical application of these treatments in the systematic use of these approaches in outpatient clinics.

BODY

The research accomplishments of the study correspond to the Statement of Work timeline and milestones.

1) The first timeline was in months 1-6 to obtain approval by the Research and Development Committee at the NMVAHCS and Institutional Review Board at the University of New Mexico; and hire the psychologist and psychology technician and train both in primary assigned duties (psychology technician to conduct assessments and psychologist in group treatment).

IRB Approvals: Approval by the NMVAHCS R&D and UNM IRB committees were obtained by June 7, 2008. Review by the DOD IRB was conducted and completed with approval on December 7, 2008.

Staffing: The Psychologist was hired on July 7, 2008. The Psychology Technician was split into two half time positions and each was filled on 6/10/08 and 6/23/08. Additional funding (\$68,750) was provided by the DOD to collect pre/post neuropsychological pilot data to assess for the effects of treatment on Traumatic Brain Injury. The funding was to cover two years of a half-time neuropsychology technician position, and testing materials. The Neuropsychology Technician was hired on 1/8/09.

Training: The initial training of the Psychology Technicians was completed in September, 2008, however they could not practice on trainee subjects until DOD IRB approval of December, 2008, which began and was completed by January 30, 2009. The training of the Neuropsychology Technician was completed February 28, 2009.

It was anticipated the IRB approvals, hiring, and training would be completed in six months, but due to delay in approval by DOD IRB, the study was 4 months behind.

2) The second timeline was in months 6 through end of year 3 to primarily recruit participants, conduct assessments, and run study subjects through both arms of the study. Recruitment began once DOD IRB approval was confirmed in December, 2008 and has consisted of printing and distributing brochures to clinics throughout the Albuquerque VA Hospital, Albuquerque and Santa Fe Vet centers, and other VA organizations within study approval. Data from entry assessments is presently being entered into the data base stored on the VA network computers protected by password. To date, 7 study subjects have been assessed and randomized in groups of three. The first two groups

were randomized to the treatment arm, with the first group having completed 3 of the 16 sessions and the second group having completed 1 of the 16 sessions. The next three subjects will be randomized to the 16-week wait-list arm. All group sessions are being videotape recorded and are being reviewed for fidelity purposes.

3) The third timeline was in month 9 through year 3.8 where data is to be entered, statistical programs developed, data analysis begun, and completed. Meetings with the statistician have been conducted to set up the data base for data entry. Data entry has begun and is ongoing. Data analysis has not begun. Data analysis of clinic outcome data is ongoing and manuscripts are being prepared.

4) The fourth timeline was in month 6 through year 4 and was to present at the International Society of Traumatic Stress Studies, beginning with protocol presentation in year 1, preliminary results in year 2 and 3, and final results in year 4. A workshop on the study structure was presented at ISTSS in November 2008. The study will also be presented at the VISN18 Research Forum in Phoenix in April, 2009 and at the Kansas City DOD conference in 2009.

5) The final timeline target was in year 3.8 through year 4 in manuscript write-up. This final timeline is not within review.

KEY RESEARCH ACCOMPLISHMENTS

- 1) Overall successful commencement of research project
- 2) Hiring and Training of Study Staff
- 3) Collaboration with Boston Consultants
- 4) Completed IRB approvals
- 5) Weekly staff meetings
- 6) Training materials (videotapes, cds) created
- 7) Ongoing monitoring of patient safety
- 8) Expansion of project to add neuropsychological component and staff
- 9) Successful initiation of recruitment and running of subjects
- 10) Successful interface with statistician for set up of data base

REPORTABLE OUTCOMES

- 1) Presentations to professional groups, including ISTSS, regional VA research conference (VISN 18 Research Forum), and National DOD research conference.
- 2) Although no data is yet available for analysis/presentation/write-up, manuscript writing on clinical support data continues with submission to one journal. Manuscript was rejected, revisions are being made, and manuscript will be resubmitted to another journal.

CONCLUSION

The only problem the study faced was in start up in the wait for DOD IRB review and approval, which delayed commencement of the study. The result was a four-month delay. Despite this delay and once approved, the study began quickly and has experienced no other problems. Data collection and entry is

going smoothly, regular meetings are held within the study staff, with the statistician, and with Boston consultants to assure fidelity of administration of interview instruments.

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APPENDICES

- A. Abstract for ISTSS
- B. Abstract for Kansas City DOD Research Conference
- C. Draft of manuscript from clinical data

APPENDIX A

ABSTRACT FOR ISTSS

The purpose of this workshop is to present a group protocol treatment for PTSD from a recently funded study and will detail how effective therapy interventions—exposure, cognitive, and behavioral—can be provided in structured, small groups. Therapies found most effective for PTSD are exposure and cognitive, with less support for other treatments (Rothbaum, et. al., 2000). Studies have been conducted individually, while most PTSD treatments in VA hospitals are conducted in groups (Garrick, 2000). The literature has shown no difference between specific interventions in groups, including exposure in a group format (Schnurr, et. al., 2003), while support for group exposure was found in a clinical setting (Castillo, 2004).

METHODOLOGY: Assessment: pre, post, 3-, and 6-month post treatment; between treatment blocks. Procedure: 72 female OIF/OEF veterans positive for PTSD randomized into a three-person, 16-week treatment group or wait-list control.

Blocks: Exposure: trauma and safety nets identified; imaginal exposure.

Cognitive: didactic cognitive restructuring, writing of beliefs on safety, trust, power/competence, and esteem/intimacy, distortions examined in session.

Behavioral: didactic and videotaped role-play assertiveness training, 4 relaxation techniques. Attendees will gain information on the application of evidence-based treatments for PTSD in a manualized treatment group.

APPENDIX B

ABSTRACT FOR KANSAS CITY DOD RESEARCH CONFERENCE

This presentation will provide details from the DOD funded study intended to investigate a group therapy treatment protocol for PTSD in female OIF/OEF veterans. The presentation will consist of a literature review, rationale, and description of the study. The established effective therapy interventions for PTSD, exposure, cognitive, and behavioral, will be examined systematically in small, structured groups of three women. Therapies found most effective for PTSD are exposure and cognitive, with lower effect sizes for other treatments (Rothbaum, et. al., 2000). Most studies have examined the individual administration of these therapies, while most PTSD treatments in VA hospitals are conducted in groups (Garrick, 2000). In general, therapies for PTSD offered in groups have been found equally effective and specifically no differences were found between exposure therapy and present centered therapy in a group format (Schnurr, et. al., 2003). In a clinical setting (Castillo, 2004), support for group exposure was found in small structured groups. METHODOLOGY: The study assessment (SCID I/II, CAPS, LEC, others) will consist of an extensive pre, post, 3-, and 6-month follow up and the PCL will be administered between treatment blocks. After assessment, 72 female OIF/OEF veterans positive for PTSD randomized into a three-person, 16-week treatment group or wait-list/minimal attention control. The 16-weeks of treatment will consist of structured therapy in three blocks: Exposure: trauma and safety nets identified; imaginal exposure. Cognitive: didactic cognitive restructuring, writing of beliefs on safety, trust, power/competence, and esteem/intimacy, distortions examined in session.

Behavioral: didactic and videotaped role-play assertiveness training, 4 relaxation techniques. Attendees will gain information on the application of evidence-based treatments for PTSD in a manualized treatment group.

APPENDIX C

DRAFT OF MANUSCRIPT FROM CLINICAL DATA

Running Head: EFFECTIVENESS OF GROUP-BASED EXPOSURE

Effectiveness of Group-Based Exposure Therapy for PTSD:

A Preliminary Investigation

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Word Count: 2,246 plus 200 words (one table =100 words and one figure =100 words) = total
2,446 words

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Abstract

Exposure therapy has consistently been shown to be superior to other treatments for posttraumatic stress disorder (PTSD). However, the only systematic examination of exposure therapy conducted in a group format (Schnurr, et al., 2003) failed to show differential improvement over a present-centered approach. Exposure therapy was conducted in small, time-limited (6 weeks) groups within a larger outpatient clinical PTSD program for females in a VA setting. The results showed improvement in total PTSD scores and within the reexperiencing and avoidance/numbing symptom categories. Quadratic analyses were significant for expected increase/decrease in PTSD symptoms across sessions and order of exposure treatment was not relevant to outcome. The results support the utility of exposure therapy in small groups.

Effectiveness of Group-Based Exposure Therapy for PTSD:

A Preliminary Investigation

Exposure therapy, a behavioral intervention for the treatment of Post-traumatic Stress Disorder (PTSD), has consistently been shown to be effective (Marks, Lovell, Noshirvani, Livanou, & Thrasher, 1998) and efficacious (Foa, Hembree, Cahill, Rauch, Riggs, Feeny, Yadin, 2005) in reducing PTSD symptoms in various populations. Initial work examining the utility of exposure therapy focused on the treatment of PTSD among civilian rape victims (Foa, Rothbaum, Riggs, & Murdock, 1991) and male combat veterans (Boudewyns, Hyer, Woods, Harrison, & McCranie, 1990). Most recently, Schnurr and colleagues (2007) found that compared to present-centered therapy, exposure therapy was considerably more effective in reducing symptoms of PTSD in a sample of female veterans. The most developed model of exposure therapy is Prolonged Exposure (PE; Foa, Hembree, & Rothbaum, 2007), which consists of repeated imaginal exposure to a traumatic memory and in-vivo exposure to avoided current situations. The model contains lesser elements of psychoeducation about PTSD symptoms, rationale for treatment, and breathing retraining (Foa, Hembree, & Rothbaum, 2007).

The vast majority of PE efficacy trials have examined the protocol provided in an individual format. However, due to practical considerations such as cost, therapist time, and therapist-to-client ratios, most Veterans Administration (VA) outpatient programs offer PTSD treatments in a group format (Garrick, 2000). There is a paucity of research investigating the effectiveness of group PTSD treatments in general, and group exposure therapy in particular. The only systematic examination of PE delivered in a group format (Schnurr, Friedman, Foy, Shea, Hsieh, Lavori, et al., 2003) found no differential improvement in PTSD symptoms compared to a present-centered treatment approach in a sample of male Vietnam combat veterans. The active treatment group included only 2-3 in-session exposures to traumas and the

exposure component was embedded in a group with other treatment interventions including psychoeducation, cognitive restructuring, relapse prevention, and coping skills training over 30 sessions. The few in-session exposures and the group structure made it difficult to isolate the effectiveness of the exposure portion of treatment. Thus, while this study provided a necessary first step in systematically examining the effectiveness of a group prolonged exposure protocol, further examination of group exposure therapy is necessary. The aim of the present study was to examine the effectiveness of group exposure therapy in an applied setting when the exposure component is separated from other protocol treatments by groups, within a larger treatment protocol (Castillo, 2004).

Method

Participants

The sample consisted of 43 of 51 women who elected exposure therapy group within a larger sample of 230 women evaluated for PTSD treatment in the Women's Trauma Clinic (WTC) at the New Mexico VA Health Care System (NMVAHCS) between 1995 and 2003. The sample included 35 female veterans (81.4%) and 8 civilian women (18.6%; spouses of eligible male veterans). The subjects were diagnosed with current and/or lifetime PTSD due to childhood ($n = 12$, 27.9%), adult ($n = 9$, 20.9%), or both childhood and adulthood traumas ($n = 22$, 51.2%). Eighty-one percent reported more than one trauma, with 67% sexual, 3% other, including combat, and 30% a combination (sexual with other) of traumas. The average age was 43.7 ($SD = 8.7$). Thirty-three percent ($n = 14$) were married, 30% ($n = 13$) divorced, and 37% ($n = 16$) never married.

Measures

Entry Assessment. Assessment for the WTC program consisted of an initial semi-structured interview, computerized psychological tests, and the Clinician Administered PTSD Scale (CAPS; Blake, Weathers, Nagy, Kaloupek, Klauminzer, Charney, & Keane, 1990). The

17-symptom portion of the CAPS assessed for frequency and intensity of PTSD symptoms within the past month and lifetime. Other entry measures included the Minnesota Multiphasic Personality Inventory-2 (MMPI2; Butcher, 1989) and the Beck Depression Inventory (BDI; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

Outcome measure. The Post-traumatic Stress Disorder Checklist (PCL; Weathers Litz, Herman, Huska, & Keane, 1993) was administered prior to each exposure group session. The instrument is a 17-item self-report measure of PTSD symptoms in response to a traumatic life event on a 5-point Likert scale. The reliability and validity of the PCL has been demonstrated in several studies (Ruggiero, Del Ben, Scotti, & Rabalais, 2003; Weathers et al., 1993).

Procedure

Each six-session exposure treatment group consisted of three female patients and two female co-facilitators. Attendance in the exposure group was optional, and other groups consisted of protocol-specific group interventions, such as cognitive restructuring (Resick & Schnicke, 1993), assertiveness/relaxation/nightmare therapies, and sexual functioning (see Castillo, 2004). Twelve women received exposure group prior to other structured treatments and 31 received the exposure group after other treatments. The exposure therapy group utilized modified exposure techniques by Keane, Foa, and Resick, where the worst trauma was identified as the index trauma (Foa, et al., 2007), written at home by the patient, read aloud in session (Resick & Schnicke, 1993), and in-session guided imaginal exposure or flooding conducted in each session (Keane, Fairbank, Caddell, & Zimering, 1989). The trauma was re-written for each exposure session and the process was repeated weekly for a total of four in-session imaginal exposures. Within each 90-minute group session, 30 minutes was allotted with each patient for trauma reading, exposure, and processing. After the patient completed the third in-session exposure, she was instructed to read the written trauma account daily at home for two weeks to continue desensitization (Resick & Schnicke, 1992).

Results

Descriptive Data

Select scales of entry assessment psychological testing and attendance data are shown in Table 1. The subjects had higher lifetime than current PTSD based on the CAPS; showed peaks on the F, 2, 8, PK, and PS scales of the MMPI-2; and a mean BDI score in the severely depressed range. Subjects with incomplete entry assessment data, CAPS ($n = 17$) and MMPI2/BDI ($n = 9$) were compared to subjects with entry data on baseline PCL scores using t -tests and no significant differences were found.

Outcome Analyses on PCL

Paired t -tests computed for pre- and post-PCL scores were significant for overall PTSD ($M_{pre} = 3.43$, $SD = 0.78$; $M_{post} = 3.11$, $SD = 0.97$; $p = .008$) and within the two symptom categories of reexperiencing ($M_{pre} = 3.42$, $SD = 0.94$; $M_{post} = 3.08$, $SD = 1.11$; $p = .05$) and avoidance/numbing ($M_{pre} = 3.44$, $SD = 0.96$; $M_{post} = 2.90$, $SD = 1.00$; $p = .0004$). While effect size analyses typically require comparison of groups, the baseline standard deviation was used to compare means resulting in an effect size equal to $-.47$ for the total PTSD score (Becker, last accessed 5/30/08). An ANOVA was computed on PCL scores to compare order effects (exposure first versus last) with order and pre/post as predictor variables. No significant interaction was found, suggesting order of exposure treatment did not have an effect on treatment differences (pre/post).

A quadratic regression was computed on mean PCL totals across the six sessions within subjects and the quadratic effect was found significant ($p = .003$; Figure 1). In order to assure generalizability of results, the 8 subjects eliminated from the outcome analyses due minimal attendance data were compared to the 43 (total of 51 in exposure treatment) who completed treatment on baseline PCL scores and no significant differences were found using a logistic regression.

Discussion

The aim of the present study was to provide preliminary data on the feasibility and effectiveness of exposure therapy in a group setting among a sample of female veterans. Overall PTSD symptoms decreased from pre to post-therapy with group exposure therapy regardless of previous therapeutic interventions. This is particularly notable as the cognitive therapy module (Resick & Schnicke, 1992) has been shown to have similar effect sizes as PE (Rothbaum, Meadows, Resick, & Foy, 2000). The temporary increase followed by a decrease in PTSD symptoms also replicated past exposure therapy research.

Beyond the change on global PTSD symptom severity, it is important to note that the overall PTSD symptom reductions were driven by reductions in reexperiencing as well as avoidance/numbing symptoms. This finding is especially notable, as these symptom subsets are considered to be hallmark symptoms of PTSD (e.g. Foa, Riggs, Dancu, & Rothbaum, 1993). Moreover, current theory and empirical work indicate that emotional and behavioral avoidance is a key factor in the maintenance of the disorder (Foa, et al., 2007). Similarly, previous studies have shown that emotional numbing predicts the maintenance of PTSD over time (Feeny, Zoellner, Fitzgibbons, & Foa, 2000). Thus, the significant reduction in reexperiencing and avoidance/numbing clusters of PTSD symptoms further testifies to the utility of group exposure therapy.

Although the current results are interesting and suggest future research endeavors, it is important to note the methodological limitations, which consist of lack of randomization, reliance on a single self-report outcome measures, and the lack of follow up data. As such, future research would benefit from the inclusion of a control group, as well as the use of semi-structured interviews for outcome analyses. Finally, it would be clinically useful to examine the lasting effects of the treatment results over time, perhaps the standard three to six months after treatment.

Despite limitations, the current study provides encouraging preliminary results for the feasibility and effectiveness of exposure delivered in a group format. In turn, these results set the stage for larger-scale, future studies that improve on the methodology of the current work. This line of future research will ultimately lead to bridging the gap between treatment need and therapist supply by allowing the delivery of effective and efficacious treatments to higher numbers of patients experiencing PTSD symptoms.

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Table 1. Means and Standard Deviations for Entry Assessment and Attendance Data.

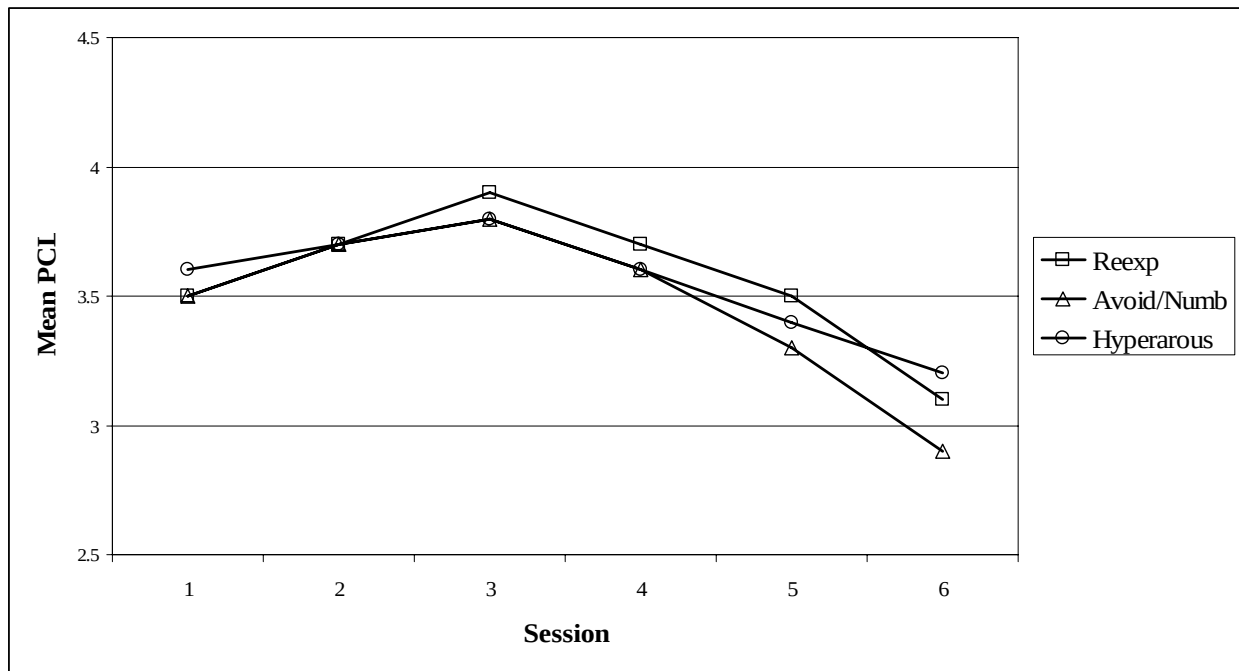
	Frequency		Intensity	
CAPS (<i>n</i> = 26)	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Current	33.5	10.3	33.6	11.6
Lifetime	53.4	9.3	52.7	9.7
MMPI2 (<i>n</i> = 34)	<i>M</i>	<i>SD</i>	Completed PCL	
F	81.2	19.3	<u># of Sessions</u>	<u><i>n</i> (%)</u>
2 (Depression)	80.1	11.4	3	1 (2.3)
8 (Schizophrenia)	81.4	12.8	4	2 (4.7)
PK (Keane PTSD)	77.7	13.4	5	7 (16.3)
PS (Schlenger PTSD)	78.2	12.4	6	33 (76.7)
BDI (<i>n</i> = 34)	22.9	10.9		

Note: CAPS = Clinician Administered PTSD Scale; MMPI2 = Minnesota Multitphasic

Personality Inventory-2; BDI = Beck Depression Inventory; PCL = PTSD Symptom Checklist.

Figure Caption

Figure 1. Mean PCL scores for three symptom categories across six group exposure sessions.



Note. PCL = PTSD Symptom Checklist; Reexp = Reexperiencing symptoms; Avoid/Numb = Avoidance and Numbing symptoms; Hyperarous = Hyperarousal symptoms.