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Acute effects of trauma-focused research procedures on participant safety and distress

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ABSTRACT

The ethical conduct of research on posttraumatic stress disorder (PTSD) requires assessing the risks to study participants. Some previous findings suggest that patients with PTSD report higher distress compared to non-PTSD participants after trauma-focused research. However, the impact of study participation on participant risk, such as suicidal/homicidal ideation and increased desire to use drugs or alcohol, has not been adequately investigated. Furthermore, systematic evaluation of distress using pre- and post-study assessments, and the effects of study procedures involving exposure to aversive stimuli, are lacking. Individuals with a history of PTSD ($n=68$) and trauma-exposed non-PTSD controls ($n=68$) responded to five questions about risk and distress before and after participating in research procedures including a PTSD diagnostic interview and a behavioral task with aversive stimuli consisting of mild electrical shock. The desire to use alcohol or drugs increased modestly with study participation among the subgroup ($n=48$) of participants with current PTSD. Participation in these research procedures was not associated with increased distress or participant risk, nor did study participation interact with lifetime PTSD diagnosis. These results suggest some increase in distress with active PTSD but a participant risk profile that supports a favorable risk–benefit ratio for conducting research in individuals with PTSD.

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1. Introduction

Conducting research with traumatized individuals poses an ethical challenge – such research seeks to improve the lives of trauma survivors, while simultaneously asking participants to recollect painful trauma experiences or recount their trauma narratives. Consequently, trauma-focused research involves the risk of producing distress and possible exacerbation of symptoms among participants (Newman and Kaloupek, 2009). The paramount ethical concern is ensuring that study procedures do not precipitate acute symptom changes, leading to serious thoughts of harming oneself or others. Such grave concerns for the safety of participants generally eclipse other risks typically associated with trauma-focused research. Previous studies examining distress in trauma-exposed participants have found that elevated distress is associated with recounting traumatic experiences, more severe symptoms, greater trauma exposure, or diagnosis of PTSD (Walker et al., 1997; Parslow et al., 2000; Deprince and Chu, 2008). These findings have led to ethical concerns about the effects of study participation among trauma-exposed individuals. However, traumatized participants consistently report a lack of regret of study participation at the conclusion of studies, even when they rate the study material distressing. Participants also report a willingness to enroll in similar studies in the future (Griffin et al., 2003; Cromer et al., 2006; Deprince and Chu, 2008) Therefore, the source of distress remains unclear.

Prior studies have examined distress (e.g., dislike of study procedures or regret about participation) and perceived benefits directly related to participation (Walker et al., 1997; Parslow et al., 2000; Cromer et al., 2006; Deprince and Chu, 2008; Resick et al., 2009) but have not examined participants' potential for harm to self or others. In their study, Cromer et al. (2006) found that undergraduates rated trauma-related questionnaires no more distressing, compared to everyday events, than other questionnaires about academic achievement, body image, parents' income,

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race, and sexuality. The students viewed trauma-related information as more important and possessing greater cost-benefit ratio than other questions. Deprince and Chu (2008) used the Reactions to Research Participation Questionnaire in undergraduate and community samples to find low ratings on the drawbacks scale and high ratings on scales measuring personal benefit, global evaluation, and participation, which indicated a positive study experience. Walker et al. (1997) found that a community sample rated study participation as a positive experience, but participants with a history of abuse rated the materials as more upsetting. In a military veteran sample, Parslow et al. (2000) found frequent reports of distress among people with a history of PTSD, which were unrelated to willingness to participate in future studies or an increased utilization of medical services. Resick et al. (2009) found that participants with PTSD rated study procedures with trauma-related material to be distressing but more interesting. Greater perceived burden of assessments at pretreatment predicted greater chance of treatment completion. These participants also reported experiencing strong emotions during participation, but most rated the study materials as interesting and not distressing (Griffin et al., 2003). To accurately make risk–benefit judgments in traumatized individuals (Newman and Kaloupek, 2009), the impact of study participation on homicidal and suicidal ideation needs to be assessed empirically. Thus, our primary goal was to study the effect of trauma-focused research procedures on clinical distress and potential for harm (e.g. suicidal ideation) in patients with PTSD.

A major source of uncertainty about the source of distress stems from the lack of pre- vs. post-study distress assessment, making it unclear whether participant distress is due to study procedures or other pre-existing factors. Pre- vs. post-study assessment in other at-risk populations showed decreased distress in borderline personality disordered patients with suicidality (Reynolds et al., 2006), but no change in recent HIV seroconverters (Scarvalone et al., 1996). Pre- vs. post-participation assessment of a traumatized population found that participants with PTSD reported a greater increase in sadness and tension from completing trauma-related questionnaires than from trauma-unrelated questionnaires (Ferrier-Auerbach et al., 2009). In addition, it remains unclear whether participants with PTSD are more distressed by study procedures than trauma-exposed participants without PTSD. The literature has rarely examined whether the effects of PTSD persist after remission, despite high rates of relapse (Solomon and Mikulincer, 2006). Veterans with current or past PTSD reported greater distress when asked about traumatic experiences than those who had not developed PTSD (Parslow et al., 2000). Thus, our secondary goal was to use pre- vs. post-study measures to ascertain distress associated with participation in trauma-focused study procedures (diagnostic interview) and exposure to aversive stimuli (mild electrical shock) in individuals with PTSD.

Based on previous findings of increased distress among participants with PTSD after trauma-related study procedures (Griffin et al., 2003; Ferrier-Auerbach et al., 2009), we hypothesized that participants with a history of PTSD would show increased concerns of clinical distress and potential for harm after undergoing trauma-focused diagnostic interview, but the addition of trauma-unrelated aversive stimuli would not increase this risk. We assessed risk by questioning the participants about thoughts of suicide, self-harm, harm to others, drug or alcohol use, and stress level. Potential for harm and clinical distress were assessed in traumatized individuals, with and without PTSD, before and after administration of a diagnostic interview for PTSD, and exposure to trauma-unrelated aversive stimuli consisting of mild electrical shocks.

2. Methods

2.1. Participants

Veterans enrolled in a post-deployment mental health registry of United States military personnel who served after September 11, 2001 (Dedert et al., 2009) were contacted by telephone for a series of studies on fear processing in PTSD. Participants were free from psychiatric disorders other than PTSD, major depression, and past substance abuse based on Structured Clinical Interview for DSM-IV (SCID) (First et al., 1997) evaluation. Of the 136 participants (see Table 1 for clinical and demographic data), 73 (54%) were Caucasian, 54 (40%) were African-American, and 9 (7%) were of other races. The majority of participants had experienced combat or a war zone as their primary trauma ($n=95$, 70%); other traumas experienced were sudden deaths ($n=11$, 8%), sexual assaults ($n=6$, 4%), transportation accidents ($n=6$, 4%), childhood abuse ($n=5$, 4%), or other forms of trauma ($n=13$, 10%). Five additional participants who were missing data for the post-study time point were excluded, four withdrew because of contraindication to magnetic resonance imaging (MRI), and one withdrew due to discomfort during the diagnostic interview. Participants provided informed consent to procedures approved by the Durham VA Medical Center and Duke University Health System Institutional Review Boards (IRBs). Participants were compensated $25/h plus travel costs.

2.2. Measurements

All participants completed the Clinician Administered PTSD Scale (CAPS) (Blake et al., 1995), a diagnostic structured clinical interview for current and lifetime PTSD symptoms and completed questionnaires about mental health and trauma exposure. For clinical characterization, all participants completed the Beck Depression Inventory (BDI) to obtain a continuous measure of depressive symptoms (Beck et al., 1988). As BDI scores were highly correlated with PTSD symptoms, the analyses reported focus on PTSD rather than depressive symptoms. Scores from the Alcohol Use Disorders Test (AUDIT (Saunders et al., 1993)) that is designed to assess recent misuse of elicit substances and the substance use disorders diagnoses from the SCID for secondary analyses concerning substance use urges, were obtained from the post-deployment registry (Dedert et al., 2009).

2.3. Procedures

We included data from behavioral and neuroimaging paradigms designed to understand fear processing in PTSD. As a part of study procedures, approximately half of the participants ($n=64$, 47%) received 12–16 mild electrical shocks delivered to the upper (wrist) or lower (ankle) extremity in a behavioral testing room or MRI scanner suite. The intensity (voltage) of shocks was determined on an individual basis prior to the start of each study by increasing intensity in 10-V increments (maximum of 100V) until the participant deemed the shock as "annoying but not painful." The balance of participants ($n=72$, 53%) underwent an MRI scan without

Table 1
Participant demographic and clinical data.

Clinical Measure	Control ($n=68$)	PTSD ($n=68$)	Comparison
Age, mean (S.D.)	40.3 (11.2)	39.1 (8.9)	$t(134)=0.71$; $p>0.4$
Gender, number (%) of women	6 (8.8)	13 (19.1)	$\chi^2(1)=3.0$, $p>0.05$
CAPS, mean (S.D.)	8.59 (10.2)	57.0 (27.7)	$t(134)=13.5$; $p<0.001$
BDI, mean (S.D.)	4.6 (6.1)	18.6 (14.9)[a]	$t(133)=7.2$; $p<0.001$
AUDIT, mean (S.D.)	2.8 (2.5)	4.4 (5.2)	$t(134)=2.3$; $p<0.05$
Depression diagnosis, number (%)	12 (18)	48 (71)	$\chi^2(1)=38.7$; $p<0.001$
Substance use diagnosis, number (%)	14 (21)	12 (18)	$\chi^2(1)=2.8$, $p>0.05$

CAPS=Clinician Administered PTSD Scale; BDI=Beck Depression Inventory; AUDIT=Alcohol Use Disorders Test

[a] $n=67$.