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Participant Reactions to a Pretreatment Research Assessment During a Treatment Outcome Study for PTSD

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Abstract

Participants' reactions to pretreatment assessments have not been studied as part of a randomized clinical trial (RCT) for posttraumatic stress disorder (PTSD). The current study examined participants' reactions in women with PTSD who completed pretreatment assessments during an RCT. We assessed participant reactions (N = 100) to a pretreatment assessment that included self-report questionnaires, interviews, and psychophysiological assessment. Results indicated that participation in pretreatment assessment was well tolerated as measured by participants' reports of distress, interest level, perceptions of the appropriateness of assessment length, and willingness to participate in a similar assessment in the future. Participating in lengthy pretreatment assessments did not adversely impact treatment participation or outcome.

Participation in trauma-focused research is typically well tolerated as evidenced by modest levels of distress, willingness to participate in similar research in the future, and positive perceptions about the research experience (e.g., Becker-Blease & Freyd, 2006; Griffin, Resick, Waldrop, & Mechanic, 2003; Newman & Kaloupek, 2004). However, some research suggests that posttraumatic stress disorder (PTSD) symptoms may be associated with greater distress during trauma-focused research (Newman & Kaloupek, 2004). Additionally, participants' pretreatment assessment reactions have yet to be studied as part of a randomized clinical trial (RCT) for PTSD. The extant research typically involves a single assessment session that includes a single self-report questionnaire or interview (Newman & Kaloupek, 2004). Pretreatment RCT assessments differ from nontrial trauma-focused research because they are lengthy and include numerous forms of research assessment, including multimethod assessments of traumatic events, which could induce participant distress or exhaustion and adversely impact treatment participation and outcome. To garner information that can enhance PTSD treatment outcome research, it is imperative to investigate potentially adverse effects of research participation among individuals with PTSD who are participating in a lengthy pretreatment assessment as part of an RCT for PTSD.

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Data collection for this study was conducted when Patricia A. Resick was at the University of Missouri-St. Louis, St. Louis, MO.

This study examined participants' reactions to a three-session pretreatment assessment that included self-report questionnaires, interviews, and psychophysiological assessment that were administered as part of a larger RCT for PTSD (Resick et al., 2008). All participants met diagnostic criteria for PTSD and were seeking psychotherapy. Participants completed a self-report questionnaire to assess their reactions to pretreatment assessments. Assessment reactions were examined descriptively and comparisons were made to examine which assessment procedures were associated with the highest levels of distress. Assessment reactions were also examined in relationship to whether participants began and completed treatment and PTSD treatment outcome.

Method

Participants

Participants included 100 female survivors of childhood and/or adult interpersonal violence who were taking part in a larger clinical trial for PTSD (Resick et al., 2008). Participants were included in the parent study if they reported at least one discrete incident of sexual or physical assault in childhood or adulthood, met criteria for PTSD, and at least 3 months had passed since their most recent trauma. Standard exclusion criteria used in PTSD treatment research were used. In the parent study, participants completed 2 days of pretreatment assessment. Psychophysiological assessment on Day 3 was optional. Participants were informed about the specific assessment procedures included in Day 3 and were assured that participation in the psychophysiological assessment was completely optional. Participants in the current study completed all 3 days of assessment (3–4 hours/day).

Of the 150 women who comprised the intent-to-treat sample in the parent study, 18 did not complete the assessment reactions questionnaire and 5 had missing data on the questionnaire and were excluded from the current study. An additional 27 women completed only the required 2-day assessment and were therefore excluded from the current study because they did not complete psychophysiological assessment. Women who completed 2 versus 3 days of assessment reported higher pretreatment PTSD symptom severity, $F(1, 126) = 6.70, p < .05$. There were, however, no significant differences between the two groups on assessment reactions (i.e., no differences on distress associated with questionnaires and interviews, willingness to participate in future assessments, or perceptions regarding appropriateness of assessment length). Additionally, there were no significant differences between the two groups on starting and completing therapy or treatment outcome. There were also no differences based on types and number of traumas or rates of revictimization between women who completed two versus three days of assessment.

The majority (75%) of participants experienced multiple interpersonal traumas. Seventy-four percent endorsed childhood sexual assault, 71% childhood physical assault, 79% adult sexual assault, and 77% adult physical assault. Average age was 35.5 years ($SD = 11.9$; range = 18–69). Sixty-one percent were Caucasian, 34% African American, 3% Hispanic or Latino, and 2% other. Average years of education were 14 ($SD = 2.4$, range = 9–21).

Measures and Procedure

On Day 1, participants gave informed consent, demographic information, and participated in structured clinical interviews, including the Clinician-Administered PTSD Scale (CAPS; Blake et al., 1995) to assess PTSD, three modules of the Structured Clinical Interview for DSM-IV Axis I Disorders-Patient Edition (First, Gibbon, Spitzer, & Williams, 1996), and a standardized trauma interview adapted from Resick, Jordan, Girelli, Hutter, and Marhofer-Dvorak's (1988) treatment study to assess lifetime history of sexual and physical assault. Participants were compensated \$20 upon completion. On Day 2, participants completed self-

report measures, including assessments of depression, shame, guilt, anger, anxiety, and PTSD (Resick et al., 2008). Participants were compensated \$20 upon completion. For Day 3, the psychophysiological assessment consisted of blood and saliva collections, a 5-phase laboratory assessment, and an auditory stimulus paradigm to assess startle response. The laboratory assessment included establishing baseline heart rate and skin conductance measurement, speaking about a neutral event, second baseline measurement, speaking about their trauma, and a final recovery period (Griffin et al., 2003). A standard auditory startle paradigm was then administered while measuring skin conductance and heart rate for 10 minutes (Blumenthal et al., 2005). Once finished, participants completed the Assessment Reactions Questionnaire, were debriefed, compensated \$30, and were randomized to treatment.

The Assessment Reactions Questionnaire was developed for previous studies examining trauma-focused research reactions (e.g., Griffin, Resick, & Mechanic, 1997; Griffin et al., 2003). Participants rated their distress level associated with assessment components, including self-report questionnaires, interviews, overall psychophysiological assessment, speaking of a neutral event, and speaking about their trauma (1 = *not distressing*, 7 = *very distressing*). Participants were also asked to rate their interest level regarding self-report questionnaires, interviews, and overall psychophysiological components (1 = *very interesting*, 7 = *very boring*), perceptions regarding the appropriateness of assessment length (1 = *about right*, 7 = *too long*), and the extent to which they would be willing to be assessed in the same manner again in the future (1 = *quite willing*, 2 = *might be willing*, 3 = *don't think I am willing*, or 4 = *definitely not willing*). For the current analyses, the distress items and perception of the appropriateness of length item were summed to create a burden index for the Assessment Reactions Questionnaire, with higher scores indicating greater subject burden. The items for interest and willingness to participate again in the future were excluded from the burden index because they are not indicators of assessment burden. The Assessment Reactions Questionnaire had an alpha coefficient of .76.

Data Analysis

Data were analyzed using descriptive statistics, paired *t*-tests, and regression analyses. *T*-tests examined differences between distress and assessment components. Logistic and linear regressions were used to explore whether assessment reactions were associated with beginning and completing treatment, and with PTSD treatment outcome. We examined these associations adjusting for potentially important confounders. Pretreatment PTSD severity was included as a covariate; however, the addition of this covariate did not change the pattern of results pertaining to the impact of assessment reactions on outcome measures and was therefore excluded from analyses. Additionally, we included revictimization exposure as a covariate in the regression analyses because it was associated with higher distress on one of the assessment procedures; however, it was not significantly associated with the outcome variables and was also excluded from analyses.

Results

Mean pretreatment PTSD severity on the CAPS for this sample was 69.4 ($SD = 18.85$; range = 31–120). Table 1 presents descriptive statistics for distress and interest ratings associated with the assessment components. Results suggest pretreatment assessments produced relatively modest levels of subjective distress. Despite any distress participants may have experienced, they generally indicated that assessment procedures were fairly interesting. Some components of assessment were more stressful than others. Planned contrasts indicated that talking about their trauma was more distressing than talking about a neutral event, $t(99) = 14.90, p < .001$. Talking about their trauma was also rated more distressing than participating in the overall psychophysiological assessment, $t(99) = 8.06, p < .001$, which was rated the

second most distressing component. Interviews were no more distressing than physiological assessment, $t < 1$, although interviews were more distressing than questionnaires, $t(99) = 3.60$, $p < .001$. Planned contrasts showed no differences on distress items based on types of trauma exposure experienced; however, participants who reported sexual and/or physical revictimization (75%) reported higher distress associated with questionnaires relative to participants who had only experienced one discrete interpersonal trauma, $t(99) = 4.91$, $p < .05$.

In terms of perceptions about the appropriateness of assessment length ($M = 5.22$; $SD = 1.65$), just over half the sample (53%) endorsed a rating of 1 or 2, indicating many participants deemed the length to be appropriate. Only 7% of participants rated the assessment as “too long” (endorsed 6 or 7 on this item). Similarly, when asked whether they would be willing to be similarly assessed in the future ($M = 1.45$; $SD = 0.63$), only 4% reported that they did not think they would be willing and 1% reported that they definitely would not be willing, whereas 34% reported that they might be willing to be assessed again and 61% reported they definitely would be willing to be assessed again.

Separate binary logistic regression analyses were conducted to determine whether reactions to pretreatment assessments were associated with beginning treatment (i.e., attended at least one therapy session) and completing treatment (i.e., attended all 12 of the available treatment hours as defined in Resick et al., 2008). Of the 100 participants, 84 began treatment and 16 did not. Participants' Assessment Reactions Questionnaire burden index was entered as a predictor of beginning treatment. Results indicated that participants' assessment reactions were not associated with whether or not participants began treatment, $\chi^2(1, N = 99) = 1.58$, *ns*, OR = 1.05, 95% CI = 0.97–1.14. Next, we examined assessment reactions as a predictor of treatment completion. Sixty-one participants completed treatment and 39 did not (including those participants who never started treatment). Results indicated that participants' assessment reactions were associated with treatment completion, $\chi^2(1, N = 99) = 10.10$, $p < .001$, OR = 1.11, 95% CI = 1.03–1.18, such that participants who endorsed more burden associated with pretreatment assessment were more likely to complete treatment.

Linear regression analysis was used to examine assessment reactions using the Assessment Reactions Questionnaire burden index as a predictor of treatment outcome as measured by posttreatment CAPS PTSD symptom severity. Of the 100 participants, 78 completed posttreatment assessments. Results indicated that assessment reactions were not related to posttreatment PTSD ($\beta = .201$, *ns*), accounting for only 0.02% of the variance associated with posttreatment PTSD symptoms.

Discussion

Participation in extensive and sensitive pretreatment assessment during an RCT was not particularly distressing for interpersonal trauma survivors with PTSD. Instead, participants perceived assessments as interesting and reported willingness to participate in similar assessments again in the future. Importantly, participants did not perceive the pretreatment assessment to be too lengthy. Assessment reactions did not impact whether or not participants began treatment or treatment outcome; however, those who endorsed greater burden on the Assessment Reactions Questionnaire were more likely to complete treatment.

Some assessment procedures were more distressing than others. It is likely that trauma narratives and interviews cause more temporary distress because participants are asked to talk about the memories they have been avoiding as part of their PTSD. Additionally, women who experienced sexual and/or physical revictimization reported higher distress associated with the self-report questionnaires relative to women who had experienced a single victimization. It is possible that during questionnaires women with revictimization think about more than one of

their victimizations leading to more distress. Fortunately, there was no evidence from this study that assessment distress interfered with receiving or benefiting from treatment. In fact, individuals who endorsed more assessment burden were more likely to complete treatment. These participants may have been more motivated to complete treatment to gain relief from their PTSD. It should also be noted that steps were taken during the assessments that may have minimized distress and maximized completion (e.g., same-sex interviewers, highly trained assessors, comprehensive informed consent, frequent breaks, and assessing for adverse reactions).

Limitations must be acknowledged. Reactions to assessments were analyzed only among those individuals who completed 3 days of pretreatment assessment limiting the generalizability of the current findings. As noted, individuals who chose not to participate in the third day of assessment endorsed higher PTSD severity. It is therefore possible that individuals with higher PTSD severity may anticipate greater distress from the psychophysiological assessments as they may be considered more invasive and/or because they were informed they would be asked to speak directly about their trauma. Additionally, this study included only female survivors of interpersonal trauma and it remains unknown whether current findings would generalize to male samples and to other forms of trauma, such as combat. More research is needed to examine the generalizability of these findings to other clinical trials for PTSD. Perceived benefits of participating in pretreatment assessments were not examined. It is possible that discussing traumas with a supportive interviewer could have a therapeutic effect. Future studies should compare the current measure to other validated measures of participant reactions (e.g., Kassam-Adams & Newman, 2002). Finally, it is unknown how the assessment reactions measured in the current study relate to other relevant constructs in trauma-focused research, such as harm and cost (Becker-Blease & Freyd, 2006).

In summary, current findings provide additional support for the growing consensus that trauma survivors, even those with PTSD who have experienced multiple traumas, seem to tolerate well lengthy, multimethod assessments. Participants did not perceive pretreatment assessments as overly distressing or too lengthy. Likewise, participating in pretreatment assessments did not adversely impact treatment participation or outcome.

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Table 1
 Self-Reported Rating of Interest and Distress for Each Pretreatment Assessment Procedure and Percentage of Participants' Ratings of Distress Levels ($N = 100$)

Assessment reaction items	Interest ratings (1-7) ^a		Distress ratings (1-7) ^b		Rating % for distress levels		
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	Endorsed 1 or 2	Endorsed 3, 4, 5	Endorsed 6 or 7
Self-report questionnaires	3.04	1.69	2.78	1.70	53	39	8
Clinical interview	2.50	1.35	3.44	1.91	37	44	19
Physiological procedures	2.55	1.38	3.61	1.80	30	52	18
Speaking about a trauma	-	-	5.81	1.56	12	35	53
Speaking about a neutral topic	-	-	1.98	1.30	76	22	2

^a 1 = Very interesting, 7 = very boring.

^b 1 = Not distressing, 7 = very distressing.