

Trauma and Sex Surveys Meet Minimal Risk Standards: Implications for Institutional Review Boards

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Abstract

Institutional review boards assume that questionnaires asking about “sensitive” topics (e.g., trauma and sex) pose more risk to respondents than seemingly innocuous measures (e.g., cognitive tests). We tested this assumption by asking 504 undergraduates to answer either surveys on trauma and sex or measures of cognitive ability, such as tests of vocabulary and abstract reasoning. Participants rated their positive and negative emotional reactions and the perceived benefits and mental costs of participating; they also compared their study-related distress with the distress arising from normal life stressors. Participants who completed trauma and sex surveys, relative to participants who completed cognitive measures, rated the study as resulting in higher positive affect and as having greater perceived benefits and fewer mental costs. Although participants who completed trauma and sex surveys reported slightly higher levels of negative emotion than did participants who completed cognitive measures, averages were very low for both groups, and outliers were rare. All participants rated each normal life stressor as more distressing than participating in the study. These results suggest that trauma and sex surveys pose minimal risk.

Keywords

trauma research, sex research, human subjects, risk, sexual victimization, psychological stress

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Institutional review boards (IRBs) are charged with deciding whether research exceeds minimal risk, meaning the level of risk encountered in daily life or during routine physical or psychological examinations. As the regulatory practices of IRBs have expanded over the years (a process referred to as *ethics creep*; see Haggerty, 2004), the issue of determining risk has become increasingly relevant for scientists who recruit college students in their research. For example, the IRB at the University of New Mexico has expressed many concerns about the use of this population in research that is judged as exceeding minimal risk (e.g., trauma and sex surveys). The IRB’s primary concern is that college students may experience extreme distress or be harmed as a result of participation. IRBs also have assumed that the risks involved in asking questions about such topics are greater than the risks for ostensibly more benign measures (e.g., cognitive test questions). Thus, such “sensitive” questions require special protection of participants and a full rather than expedited review. Such assumptions, though unsupported by data, have delayed and derailed research projects at the University of New Mexico and have dissuaded researchers from studying “sensitive” topics that allegedly present greater than minimal risk.

Regardless of the population sampled, research on two “sensitive” topics—trauma and sex—often intensifies IRBs’ concerns. As research in these areas has grown, so have fears that participants who have experienced traumatic events (e.g., rape) may be harmed by participating in these studies. However, research suggests that such fears are likely unfounded. Most participants report low levels of distress from participating in trauma research (Carter-Visscher, Naugle, Bell, & Suvak, 2007; DePrince & Chu, 2008; Jorm, Kelly, & Morgan, 2007; Newman & Kaloupek, 2004), find their research experience to be either positive or neutral (DePrince & Chu, 2008; Griffin, Resick, Waldrop, & Mechanic, 2003; Walker, Newman, Koss, & Bernstein, 1997), and say they would be willing to participate in the study again (Carter-Visscher et al., 2007). In addition, participants who report negative emotions from participating also report benefitting from the research (DePrince & Chu, 2008; Newman, Risch, & Kassam-Adams,

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2006) and do not regret or negatively evaluate their research experience (Ferrier-Auerbach, Erbes, & Polusny, 2009; Jorm et al., 2007; Newman & Kaloupek, 2004). Finally, there is evidence that participation in trauma research does not cause long-term harm (Carter-Visscher et al., 2007; Rabenhorst, 2006), even when participants report negative reactions (Jorm et al., 2007).

Despite these findings, a deeper investigation is needed into participants' reactions to "sensitive" research topics. For example, most studies have not compared participants' reactions to trauma and sex research with their expected reactions to normal stressors encountered in daily life. Work so far has shown that undergraduates perceive trauma questions to be neutral compared with general questions on daily life events (DePrince & Freyd, 2004), but it is unclear what specific life stressors are more or less upsetting than trauma and sex research. Most studies also have not evaluated participants' reactions to research on "sensitive" topics in light of protocols typically considered to pose minimal risk by IRBs. The limited evidence that exists on this issue suggests that undergraduates rate both trauma-related and seemingly minimal-risk questions (e.g., inquiries about Standardized Achievement Test scores and parents' income) as minimally distressing, yet perceive trauma-related questions as more important than minimal-risk questions (Comer, Freyd, Binder, DePrince, & Becker-Blease, 2006). Although some work on research risk has included college samples (e.g., Comer et al., 2006; DePrince & Freyd, 2004), most studies have been conducted with community or clinical samples. Thus, further inquiry into undergraduates' reactions to research on "sensitive" topics is warranted, especially since many researchers recruit participants for their studies from an undergraduate subject pool.

The focus of the present study was to evaluate undergraduates' reactions to participating in research considered to exceed minimal risk (trauma and sexual behavior questionnaires) compared with participating in research commonly considered to pose only minimal risk (cognitive tasks). Although past work has typically asked participants to complete only a few trauma measures, we included an extensive battery of both trauma and sex-related questionnaires. We selected questionnaires that inquired about experiences that would presumably be the most distressing (e.g., rape, childhood sexual abuse, casual sex, masturbation) to test the assumption that these questions are indeed risky. We also included a set of cognitive measures commonly considered to pose minimal risk by IRBs (e.g., Shipley Vocabulary and Raven's Progressive Matrices tests) that have yet to be compared with trauma-related questionnaires in the research literature.

Using prior research as a guide (e.g., Edwards, Kearns, Calhoun, & Gidycz, 2009; Newman, Willard, Sinclair, & Kaloupek, 2001), we assessed key areas of concern to IRBs—specifically, participants' positive and negative emotional reactions to surveys on "sensitive" topics and the perceived benefits and mental costs of participating in studies that use such surveys. We also assessed participants' changes in positive and

negative mood as a result of participation, something that has rarely been measured in similar studies (Edwards et al., 2009). We examined the extent of negative emotional responses to our study, as IRBs often are concerned with the minority of participants who might become distressed as a result of participation. We also asked participants to compare their research participation with their expected reactions to a set of normal life stressors (e.g., losing \$20, forgetting Mother's Day), thereby allowing us to compare study-related distress with distress encountered in daily life. Finally, we assessed whether sexually victimized women responded more negatively to the trauma and sex questionnaires than did nonvictimized women.

Method

Participants

Participants were 504 undergraduate men and women recruited from the psychology subject pool at a large Southwestern U.S. university. The mean age of the sample was 20.6 years ($SD = 4.6$ years); 68.5% of participants were women, and 31.5% were men. Most participants were either freshmen (43.7%) or sophomores (22.0%). The sample was diverse ethnically, including 38.9% White, 31.3% Hispanic, 2.8% African American, 4.0% Native American, and 3.4% Asian participants, with the remaining 19.6% classified as "other."

Measures and procedure

Participants were assigned randomly to either a trauma-sex condition ($n = 263$), in which they answered questionnaires about traumatic experiences and sexual behavior, or a cognitive condition ($n = 241$), in which they answered questionnaires assessing general cognitive ability. Questionnaires for both conditions used a paper-and-pencil format and took approximately 2 hr in total to complete. Participants were seen in groups of 2 to 100 and compensated with course credit for their participation.

Three separate packets of questionnaires were provided to participants. The first and third packets were the same across conditions: Participants were asked demographics questions assessing age, sex, ethnicity, and academic status; they also completed the Positive and Negative Affect Schedule (PANAS; Watson, Clark, & Tellegen, 1988), a measure of positive ($\alpha = .86$) and negative emotion ($\alpha = .78$).

The second packet consisted of measures specific to each condition. Participants in the trauma-sex condition completed the Dating Behavior Survey (Yeater, Viken, McFall, & Wagner, 2006), a measure of dating and social behaviors, including number of lifetime sexual partners and frequency of unprotected sex; the Heterosocial Perception Survey (McDonel & McFall, 1991) and Rape Myth Acceptance Scale (Burt, 1980), measures of the extent to which a person believes rape is justifiable; the Sociosexuality Questionnaire (Bailey & Kirk, 2000), a measure of willingness to engage in casual sex; the

Sexual Awareness Questionnaire (Snell, Fisher, & Miller, 1991), a measure of sexual assertiveness and self-confidence; the Trauma Symptom Checklist (Elliot & Briere, 1992) and Posttraumatic Stress Disorder Checklist (Blanchard, Jones-Alexander, Buckley, & Forneris, 1996), measures of the degree to which people experience posttraumatic stress symptoms, including flashbacks, nightmares, and the desire to hurt themselves or others; the Childhood Sexual Experiences Questionnaire (Finkelhor, 1979), assessing sexual experiences before age 14, including child sexual abuse; and the Childhood Trauma Questionnaire (Bernstein & Fink, 1998), assessing traumatic childhood experiences, including physical, emotional, and sexual abuse.

Sex-specific questionnaires were also given to participants assigned to the trauma-sex condition. Women completed a series of questions about their bodies, such as what their weight and bra size was; an Ovulatory Cycle Questionnaire, including questions such as how many days ago their last menstrual period

was and whether they used hormonal contraception; and the female version of the Sexual Experiences Survey (Koss, Gidycz, & Wisniewski, 1987), assessing incidents of sexual victimization since age 14, such as having a man use physical force or provide alcohol or drugs to obtain sexual intercourse. Men also completed a series of body questions, such as what their chest and neck size was; a Masturbation Questionnaire, including questions about how many days ago they last masturbated and whether they used personal lubricant when masturbating; and the male version of the Sexual Experiences Survey (Koss et al., 1987), assessing incidents of sexual aggression against women since age 14, such as using physical force and giving women alcohol or drugs to obtain sexual intercourse. Example items from each of the trauma and sex measures are given in Table 1.

Participants assigned to the cognitive condition completed a set of well-established cognitive tests. These included the Shipley Institute of Living Scale Vocabulary and Abstract Thinking subtests (Shipley, 1940); an 18-item, medium-length

Table 1. Example Items From the Trauma and Sex Questionnaires

Questionnaire	Item
Dating Behavior Survey (Yeater, Viken, McFall, & Wagner, 2006)	How many different sexual partners have you had in your lifetime?
Heterosocial Perception Survey (McDonel & McFall, 1991)	A man is on a date with a woman whom he has known for about two weeks. They went to a movie, and then to the woman's apartment and ordered pizza. They are sitting on the sofa. The man begins to kiss her, and they kiss for several minutes. How justified is it to continue to make sexual advances if: The man puts his hand on her breast, and she moves the hand away and says: "No, don't."
Rape Myth Acceptance Scale (Burt, 1980)	If a woman gets drunk at a party and has intercourse with a man she's just met there, she should be considered "fair game" to other males at the party who want to have sex with her too, whether she wants to or not.
Sociosexuality Questionnaire (Bailey & Kirk, 2000)	If I were invited to take part in an orgy, I would accept.
Sexual Awareness Questionnaire (Snell, Fisher, & Miller, 1991)	When it comes to sex, I usually ask for what I want.
Trauma Symptom Checklist (Elliot & Briere, 1992)	How often have you experienced a desire to physically hurt yourself in the past month?
Posttraumatic Stress Disorder Checklist (Blanchard, Jones-Alexander, Buckley, & Forneris, 1996)	Have you had repeated, disturbing memories, thoughts, or images of a stressful experience?
Childhood Sexual Experiences Questionnaire (Finkelhor, 1979)	Did another person attempt sexual intercourse (get on top of you, attempt to insert his penis) but penetration did not occur?
Childhood Trauma Questionnaire (Bernstein & Fink, 1998)	Did someone threaten to hurt you or tell lies about you unless you did something sexual with them?
Ovulatory Cycle Questionnaire (women)	How many days ago was your last menstrual period?
Body Questions (women)	What is your current bra size?
Sexual Experiences Survey (women; Koss, Gidycz, & Wisniewski, 1987)	Have you had sexual intercourse when you didn't want to because a man threatened or used some degree of physical force to make you?
Body Questions (men)	How many body piercings do you have?
Sexual Experiences Survey (men; Koss, Gidycz, & Wisniewski, 1987)	Have you had sexual intercourse with a woman when she didn't want to because you threatened or used some degree of physical force to make her?
Masturbation Questionnaire (men)	When you masturbate, do you use any form of sexual lubricant?

Note: Items without citations were created specifically for this study.

version of Raven's Advanced Progressive Matrices (Raven, Raven, & Court, 1998); and a 25-item version of the Miller Analogies Test (Miller, 1960).

Finally, to assess participants' reactions to the study, we constructed a posttest-reactions questionnaire composed of four scales. Some of the items were selected from previous study-reaction questionnaires (e.g., Griffin et al., 2003; Walker et al., 1997), but most were developed by us to reflect key areas of concern to IRBs. These scales assessed (a) negative emotions (21 items; e.g., "This study made me feel like crying," "This study made me feel emotionally unstable"; $\alpha = .94$), (b) perceived benefits (10 items; e.g., "This study gave me insights into myself," "I wish I had never signed up for this study" (reverse-scored; $\alpha = .77$), (c) positive emotions (6 items; e.g., "This study helped me to feel better about myself," "This study made me proud of what I have survived"; $\alpha = .81$), and (d) mental costs (5 items; e.g., "This study was mentally exhausting," "This study gave me a headache"; $\alpha = .69$). For these four scales, participants rated their agreement with each statement on a 7-point Likert scale ranging from 1, *strongly disagree*, to 7, *strongly agree* (a complete list of these posttest-reaction items is available from the first author).

We also developed a Normal Life Stressors Scale ($\alpha = .88$), in which participants rated how stressful each of 15 ordinary life stressors was in comparison with participating in this study. Items included "Getting a bad grade in an important class" and "Waiting in line for 20 minutes at a bank" (see Table 2 for the complete list of stressors). Participants rated each item on a 7-point Likert scale (1 = *This study was much worse than the event described*, 4 = *This study was about equally bad as the event described*, 7 = *The event described would be much worse than this study*). Each of the five posttest scales was scored by computing participants' average rating for those items. After completing these scales, participants completed the PANAS again as a measure of poststudy affect (positive-affect scale: $\alpha = .91$; negative-affect scale: $\alpha = .80$).

Table 2. Items on the Normal Life Stressors Scale

Getting a \$100 speeding ticket
Getting a bad grade in an important class
Having a cavity drilled and filled by a dentist
Being fired from a summer job
Being told I have bad breath on a first date
Taking a difficult math test for an hour
Forgetting Mother's Day
Losing \$20
Spilling coffee all over a new shirt
Standing alone at a party where I don't know anyone
Having blood drawn from my arm for a routine medical test
Waiting in line for 20 minutes at a bank
Getting a paper cut on my thumb
Finding that a pet goldfish has died
Watching a horror film that's scarier than I like

Data-analysis strategy

The first set of analyses included all participants and investigated the effect of condition (trauma-sex vs. cognitive) on the study outcomes (i.e., change in affect, negative emotions, positive emotions, perceived benefits, mental costs, and comparison with normal life stressors). Change in negative affect was analyzed using a repeated measures general linear model, with pre- and post-PANAS scores as the within-subjects factor and condition as the between-subjects factor. Independent samples *t* tests were used to evaluate the effect of condition on the other study outcomes.

The second set of analyses included only women in the trauma-sex condition ($n = 156$) and investigated the effect of a sexual victimization history on the study outcomes. The Sexual Experiences Survey was used to measure past incidents of sexual victimization. Participants were assigned to a severity category based on the most severe victimization experience they reported having since the age of 14 (0 = no unwanted experiences, 1 = unwanted sexual contact, 2 = sexual coercion, 3 = attempted rape, and 4 = rape). Pearson product-moment correlations were used to examine the relationship between sexual victimization history and the study outcomes.

Results

Preliminary analyses

Participants assigned to the trauma-sex condition and the cognitive condition did not differ significantly on any demographic characteristic (e.g., age, gender, ethnicity, or academic status) or on their baseline PANAS scores. Age, gender, and ethnicity were not significantly correlated with the study outcomes (all $ps > .05$); thus, these variables were not included in the analyses.

Effect of condition on changes in PANAS scores

Participants in both conditions reported a decrease in negative affect during the course of the study, $F(1, 478) = 48.01, p < .001, \eta_p^2 = .10$, mean change = $-1.27, SD = 3.97$. There was no significant interaction between condition and change in negative affect ($p = .091$), which indicates that reduction of negative affect did not vary by group. There was a significant interaction between condition and positive affect, $F(1, 480) = 7.39, p < .01$, however. Although there were no significant differences between conditions with respect to pretest positive affect ($p = .792$), participants in the trauma-sex condition, relative to participants in the cognitive condition, reported greater positive affect after participation, $F(1, 482) = 5.12, p < .05$.

Effect of condition on posttest reactions

Participants in the trauma-sex condition, relative to participants in the cognitive condition, reported lower mental costs,

$t(501) = -12.28, p < .001, d' = -1.09$, and greater perceived benefits, $t(501) = 5.64, p < .001, d' = 0.51$, but higher negative emotions, $t(501) = 4.30, p < .001, d' = 0.39$. Although the means for negative emotions were significantly different between conditions, the absolute means were very low (trauma-sex condition: $M = 1.99$; cognitive condition: $M = 1.65$), which indicates that participants, on average, did not feel negative emotions as a result of participation. There were no significant differences between conditions in positive emotions, $t(501) = -1.84, p = .066, d' = -0.161$. Means for each of these four scales for each condition are presented in Figure 1. (Although scores were skewed for some scales, nonparametric Mann-Whitney U tests yielded the same results as the t tests.)

Extent of strong negative reactions

To determine the extent of strong negative reactions to the study, we examined the frequency distributions of responses to the negative-emotions scale of our posttest questionnaire. Five out of 241 (2.1%) participants in the cognitive condition and 9 out of 263 (3.4%) participants in the trauma-sex condition had scores above the midpoint (4.0), which indicates that they agreed to some extent that participation resulted in negative emotions. None of the participants' scores on the negative-emotions scale came close to the ceiling (7.0) of the rating scale. (The distributions of posttest PANAS negative-affect scores were very similar.) The maximum scores in the cognitive and trauma-sex conditions were 4.15 and 5.52, respectively, which reflect slight to moderate distress. As depicted in

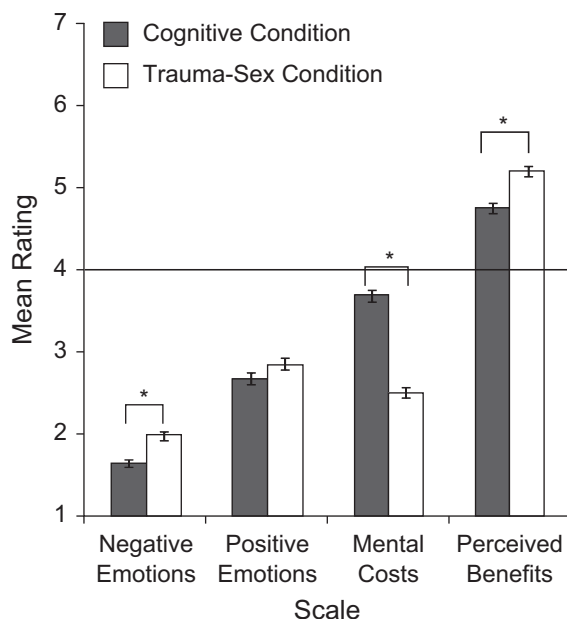


Fig. 1. Mean ratings on scales assessing participants' reactions to research participation in the two conditions. Asterisks indicate significant differences between conditions ($p < .05$). The horizontal line indicates the midpoint of the scale. Error bars show standard errors of the mean.

Figure 2, the majority of participants in both conditions had negative-emotion scores below the scale midpoint, which indicates that they felt that participation in the study did not produce negative emotions.

Effect of condition on scores on the Normal Life Stressors Scale

There were no significant differences between conditions on the Normal Life Stressors Scale, $t(500) = -1.57, p = .118, d' = -0.140$. This means that, overall, participating in the trauma-sex condition was no more upsetting, relative to normal life stressors, than was participating in the cognitive condition. Moreover, inspection of the mean ratings for each stressor indicates that participants in both conditions felt that each stressor would be worse than participating in this study (cognitive condition: mean range = 4.66–6.78; trauma-sex condition: mean range = 4.97–6.76; see Fig. 3).

Effect of sexual victimization history on study outcomes

There was no significant relationship between victimization history and change in negative affect ($p = .338$). Victimization history also did not predict scores on three of the reaction scales (i.e., negative emotions, positive emotions, and perceived benefits) or on the Normal Life Stressors Scale ($r_s = -.106-.126, p_s = .056-.488$). However, more severely victimized women reported greater mental costs to participating in the study than did less severely victimized women, $r(155) = .173, p = .031$. Our trauma-sex questionnaires were extensive, requiring more time to complete than typical trauma or sex surveys. Thus, these mental costs may be lower among sexually victimized women in studies using fewer questionnaires.

Discussion

Our results suggest that IRBs' concerns about trauma- and sex-related research, although well intentioned, may be misguided. We exposed undergraduates in the trauma-sex condition to the most provocative (and potentially distressing) questionnaires we could find. These questionnaires were exhaustive—we asked over 300 questions about such topics as casual sex, sexual fantasies, child abuse, rape, masturbation, and trauma symptoms. Despite the number, variety, and extremity of questions in the trauma-sex condition, the overwhelming majority of participants—even women who reported a history of sexual victimization—were not distressed. Five key findings support this view.

First, answering the trauma and sex questionnaires did not increase participants' negative affect; on the contrary, answering these surveys decreased it, and did so as much as completing the cognitive tasks did. Moreover, participants in the trauma-sex condition experienced higher positive affect after participation than did participants in the cognitive condition.

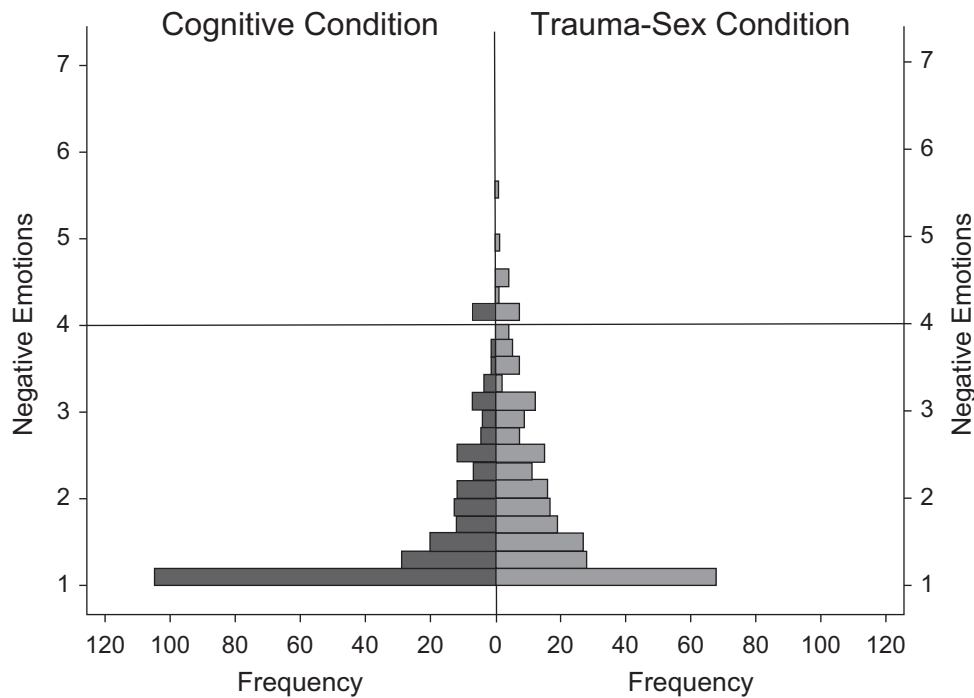


Fig. 2. Frequency distribution of negative-emotion scores in the two conditions. The horizontal line indicates the midpoint of the scale.

Second, although participants in the trauma-sex condition reported slightly higher negative emotions than participants in the cognitive condition did, the mean score was well under the neutral midpoint; this result indicates that these participants

were not, in fact, distressed. In addition, participants in the trauma-sex condition, relative to participants in the cognitive condition, found the study to have greater benefits (e.g., engendered more insight) and fewer mental costs (e.g., less

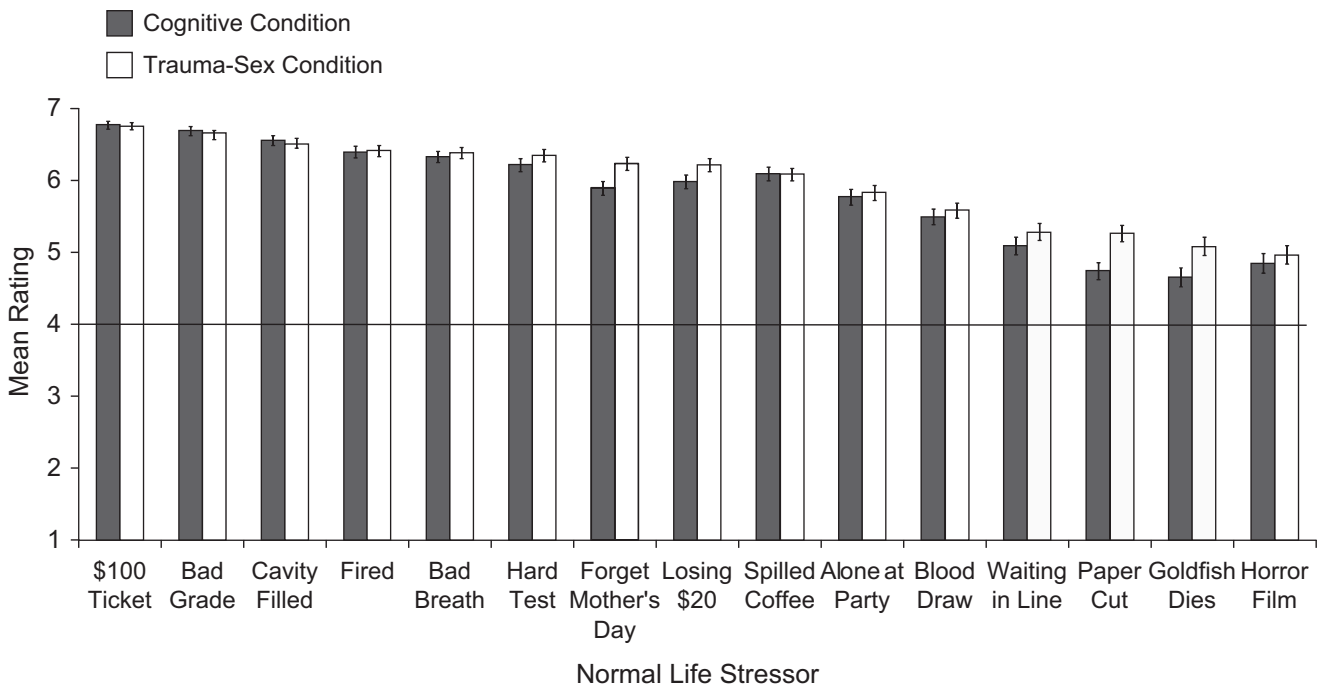


Fig. 3. Mean ratings on each item of the Normal Life Stressors Scale in the two conditions. A rating of 1 indicated that the study was “much worse than” the stressor, a rating of 4 indicated that the study was “about equally bad as” the stressor, and a rating of 7 indicated that the stressor was “much worse than” the study. The horizontal line indicates the midpoint of the scale. Error bars show standard errors of the mean.

mentally exhausting). Third, less than 4% of all participants scored above the midpoint on the negative-emotions scale, with no participant coming close to maximum distress. Fourth, participants in both conditions rated participating in the study as less stressful than several normal life stressors ranging from the trivial (e.g., getting a paper cut) to the serious (e.g., getting fired from a job), and less distressing than routine physical examinations (e.g., having blood drawn) and psychological examinations (e.g., taking a difficult math test). Fifth, among women in the trauma-sex condition, there was no relationship between sexual victimization history and negative emotions. Thus, the common IRB assumption that victimized women are especially vulnerable and likely to experience emotional distress by participating in trauma research appears to be unfounded.

The standard definition of minimal-risk research is that the probability and magnitude of harm or discomfort anticipated in the research are not greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations. Our first three findings show that the trauma and sex surveys were no more distressing than the routine psychological tests used in the cognitive condition. Furthermore, even the handful of participants indicating some negative emotions were no more than mildly distressed, so these surveys could be considered as posing minimal risk by that criterion. Our fourth finding shows that participating in the trauma-sex condition was less distressing than many stressors experienced in daily life, so it could be considered as presenting minimal risk by that standard. Our fifth finding shows that the trauma-sex condition was reasonably benign even for sexually victimized women, who might be expected to be especially vulnerable.

We suggest that many IRB committees have systematically underestimated the maturity and resilience of 21st-century adult research participants, such as college students. Our results suggest that even extensive questionnaires about provocative topics are not distressing to the vast majority of college students. Indeed, we found only a handful of participants in both conditions who agreed that the study produced negative emotions, and many experiences that provoke negative emotions (e.g., being stuck in traffic, revising papers for journal submission) do not cause lasting harm. We hope that our findings help psychologists persuade IRB committees that most questionnaire research in fact carries low risk and that this research helps counteract the IRB ethics creep that is stifling research at universities. We also hope that IRBs will take note of the cogent argument made by Becker-Blease and Freyd (2006) about trauma-related research—that there is a significant cost to science (and, consequently, to victims themselves) when we fail to ask about traumatic experiences.

In assessing risk, it may be useful to consider the cultural background of today's U.S. college students. The undergraduates in this study completed it around 2009, around age 20, so they were born around 1989. They grew up with cable TV and YouTube. They have been exposed to Oprah, Dr. Phil, and other daytime TV personalities who routinely discuss child

sexual abuse, rape, and mental illness. They share intimate details of their lives on Facebook. They fill out sex surveys in *Cosmopolitan* or *Maxim*. The TV shows they watch (e.g., *South Park*, *Oz*, *Dexter*) depict graphic levels of sex, violence, and trauma. Thus, they are not likely harmed by questionnaires that inquire about "sensitive" topics. IRB standards should reflect this reality.

Declaration of Conflicting Interests

The authors declared that they had no conflicts of interest with respect to their authorship or the publication of this article.

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