

Evaluation of the Iatrogenic Effects of Studying Persons Recently Exposed to a Mass Urban Disaster

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Abstract

Recently, it has been suggested that victims of community-wide disasters need extra protections to prevent emotional distress and exploitation by researchers. This study assesses the potential iatrogenic consequences of participation in a mental health study among individuals recently exposed to the September 11 attacks. Using cross-sectional telephone surveys, we interviewed random samples of English or Spanish-speaking adults living in New York City (NYC) during the attacks 1-year after this event. Altogether, 2,368 individuals completed the survey, including 1,173 respondents who reported receiving mental health treatment after the attacks. Results indicated that 15% of New Yorkers found some of the survey questions stressful, while 28% of those who sought treatment found this to be the case. However, less than 2% of New Yorkers reported being upset at survey completion and, among these persons, only 4 individuals consented to speak to the study's mental health consultant. Although the majority of those expressing adverse survey reactions had sought post-disaster treatment, even for these subjects, only 3% were still upset at survey completion and 2% wanted more information about counseling services. In addition, only 3% of New Yorkers overall and 5% of those who sought treatment reported that they participated in other post-disaster surveys. Finally, greater than 70% of participants expressed positive sentiments about participating in the survey. Predictive models indicated that respondents who met criteria for posttraumatic stress disorder (PTSD), depression, or anxiety were more likely to find questions stressful, with individuals having PTSD or depression the most likely to be upset and to consent to speak with the study's psychiatric consultant at completion. We suggest that, with the proper safeguards, undertaking research with persons exposed to a mass urban disaster generally can be conducted safely and effectively.

Introduction

Over the past decade, Institutional Review Boards (IRBs) have increased surveillance of researchers conducting studies involving human subjects. In part, this heightened vigilance has been due to high profile cases where the study's protocol resulted in the injury or death of research subjects in randomized controlled clinical trials (Figley et al., 1999; Piantadosi, 1997). Although these cases tended to involve clinical trial participants, these adverse outcomes have also led to greater oversight of observational research and examination of the costs versus benefits of participation in such studies (Appelbaum, 1998; Johnson and Benight, 2003; Shore 1996). Concurrent with this greater oversight has been a sensitivity towards past abuses of informed consent (Collogan et al., 2004), as well increases in studies focusing on exposure to psychologically traumatic events (Newman et al., 1999; North and Pfefferbaum, 2002), generating heightened concerns about human subject protection.

Researchers have identified several specific issues pertaining to the study of survivors of community-wide traumas (Fleischman and Wood, 2002; Henderson and Jorm, 1990; North et al., 2002; Ruzek and Zatzick, 2000). Recently, it has been suggested that research with populations affected by the September 11 terrorist attacks on the World Trade Center may require additional IRB protections to prevent emotional distress among participants, over-studying of subjects, and the general exploitation of a disaster-affected population (Fleischman and Wood, 2002). We label this perspective the "iatrogenic research effects" model, since it is based on the assumption that participants might be harmed by study participation. An underlying assumption has been that some direct (and even indirect) victims of community disasters will be too emotionally upset to provide fully informed consent or to anticipate the degree of distress that would accompany their study participation (Fleischman and Wood, 2002). Since informed consent is one of the pillars upon which ethical research has been based (Collogan et al., 2004), an inability to provide such consent has been a source of apprehension (Chen et al., 2002). In addition, the potential iatrogenic impact of conducting clinical research among such a population is a reason for increased ethical concern. In summary, although the approach to protect disaster victims after the Oklahoma City bombing recently has been documented (North et al., 2002), there is the belief that conducting research among victims soon after community-wide disasters may be unethical and harmful for study participants.

Despite these concerns, past research on the negative effects of participation in mental health research by trauma victims has been consistent. Although adverse reactions to interview questions have been reported among a small number of research participants, the vast majority appear to suffer little or no adverse effects of such participation, especially over the long-term (Griffin et al., 2003; Henderson and Jorm, 1990; Jorm et al., 1994; Newman et al., 1999; Parslow et al., 2000; Ruzek and Zatzick, 2000). In

their study of women who reported a history of childhood sexual abuse or adult domestic violence, for instance, Newman, Walker and Gefland (1999) reported that 19% of the women in their study were unexpectedly upset by the sensitive nature of the questions, but that 97% expressed “no regrets” over their participation. Similarly, a study of hospitalized victims of a motor vehicle accident or physical assault found that 89% of the respondents said it was completely true that they understood the consent form, 89% would have participated in the study again, and 65% said that they gained something positive from participating. In addition, 80% or more of the respondents felt that they could have said no to study participation, could stop the interview at any time, and could skip questions in the survey. In contrast, only 11% said that they were upset more than they expected (Ruzek and Zatzick, 2000). The one factor most often related to experiencing a negative reaction in a survey was meeting criteria for PTSD (or some other psychological problem such as depression or anxiety) (Newman et al., 1999; Parslow et al., 2000).

Even though these findings should reduce the concern about interviewing individuals who survived a severe trauma, none of these studies examined the issues raised by Fleischman and Wood (2002) for individuals who have experienced a community-wide disaster. In this study, therefore, we explicitly assessed the possible negative consequences of participation in a mental health study by individuals who survived such a recent traumatic event. More specifically, we focused on the issues of emotional distress, over-studying, and study perceptions among a large random sample of adults who lived in New York City (NYC) at the time of the World Trade Center Disaster (WTCD), including a large subsample of those who reported seeking mental health treatment after this event. In our study, we investigated the possible adverse effects of participation in our investigation, controlling for demographic factors, psychological resources, exposure to other traumas, and current mental health status, all of which would likely increase the vulnerability of respondents to post-disaster studies.

Data and Methods

Using random-digit dialing (RDD), we conducted 2 concurrent surveys a year after the WTCD. One was a cross-sectional household survey of city residents (the general population sample). The other was a cross-sectional household survey of city residents who reported receiving any mental health treatment within a year after the attacks (the treatment oversample). [The latter respondents were identified by means of screener questions at the beginning of the survey.] English or Spanish-speaking adults (18 years old or older) who were living in New York at the time of the World Trade Center attacks were eligible respondents for either survey. When interviewers reached a person at a residential telephone number, they obtained area of residence in New York City and verbal consent. Interviewers determined the number of adults in each household and selected one for an interview based on the adult with the most recent birthday. Interviews occurred between October and December 2002. The survey was translated into

Spanish and then back-translated by bilingual Americans to ensure the linguistic and cultural appropriateness of the items. Trained mental health interviewers using an advanced computer-assisted telephone interviewing (CATI) system and supervised by senior project staff conducted all surveys.

Overall, 2,368 individuals completed the survey (1,634 for the community sample and 734 for the treatment oversample). Since 439 individuals in the community sample also received mental health treatment, a total of 1,173 (i.e., 438 + 734) individuals received some kind of mental health treatment in the year since the WTCD and were included in the treatment sample. For our study “treatment” was defined broadly and included: visits to mental health professionals, visits to self-help groups (e.g., Alcoholics Anonymous), taking psychotropic medications, seeking professional help on the internet, using psycho-educational materials provided by health professionals, and receiving group interventions at worksites, community centers, etc.. Approximately, 7% of the interviews were conducted in Spanish. Using industry standards (American Association for Public Opinion Research, 2000), the cooperation rate (completed interviews + screen and quota outs/completed interviews + screen and quota outs + refusals) was approximately 63% for the entire sample. A protocol was in place to provide mental health assistance to all participants who required psychiatric counseling. The duration of the interview was about 45 minutes. For the entire sample, a sampling weight was developed to correct for potential selection bias related to the number of telephone numbers and persons per household, and for the oversampling of treatment-seeking respondents. This weight allowed us to treat the entire sample as representative of the NYC population. We also developed a sample weight for analyses using the treatment sample separately, which took into account the number of telephone numbers and persons per household for this subgroup. We applied the appropriate weights for entire and treatment sample analyses discussed below. The Institutional Review Board of the New York Academy of Medicine reviewed and approved the study’s protocols.

Study Outcome Variables

At the end of the interview, respondents were asked a series of questions related to how they felt at survey completion and about their perception of the interview. We also asked if they had participated in any other WTCD surveys. Based on previous research (Ruzek and Zatzick, 2000), we asked participants if “any of the survey questions were emotionally upsetting?” This question was designed to be sensitive to the possibility of the questions causing emotional harm to the respondent (i.e., it was sensitive, but not specific). If respondents answered “yes” to this questions, they were asked if they were “still upset” or if they were “feeling okay now?” Finally, those respondents who reported that they were still upset at survey completion were offered the following options: (i.) general information about available counseling services in the area, (ii.) a mental health consultant (a licensed clinical psychiatrist) to call them back immediately,

and *(iii)*) an 800 toll-free number for “Project Liberty” that they could call at their convenience to receive WTCD-related counseling. (Options *i*. and *iii*. were also available for those who reported no distress at survey completion as well.) For the purposes of the present study, we defined self-report of being upset at survey completion as a potential iatrogenic study effect and the consent to speak to the study’s mental health consultant as a likely iatrogenic study effect. In addition, following previous research (Ruzek and Zatzick, 2000), we also inquired about involvement in other WTCD surveys, whether the respondent’s perception of the survey was generally positive or negative, and whether or not the participant thought that “surveys like this one are helpful to New York City in providing and planning future services for those affected by the Trade Center disaster?” All the iatrogenic-related survey questions had been developed from previous surveys, had face validity, and were pre-tested before being used in the current survey.

Predictor Variables

To predict the potential consequences of participating in our study, we examined a number of key predictor variables, including demographic, exposure, and mental health status variables. Our demographic variables included age, gender, income, marital status, education, and race/ethnicity. Our analyses also assessed one psychological resource (self-esteem) and two stressor variables (exposure to WTCD events and lifetime trauma), which could have affected the respondent’s ability to deal with potentially stressful interview questions. Self-esteem was measured by a short version of the Rosenberg self-esteem scale (RSES) (Rosenberg, 1979). This scale was the sum of 5 items from the original scale (e.g., I certainly feel useless at times. On the whole, I am satisfied with myself.) (Cronbach’s $\alpha=0.73$). The RSES has been widely used in mental health research and both the reliability and validity of this measure are considered good (Blascovich and Tomaka, 1991). Our WTCD-event exposure measure was the sum of 14 possible events (coded yes/no) that the respondent could have experienced during the attacks (e.g., fear of being killed, friend or relative killed, forced to move from home, lost job as a result of the WTCD, etc.). This measure was developed from earlier studies (Freedy et al., 1993) and used in previous WTCD research (Boscarino et al., 2004). A second stress measure was based on the sum of 10 lifetime traumatic events the respondent could have experienced, other than the WTCD (e.g., being sexually assaulted, physically attacked, or being in a serious accident, etc.). This lifetime trauma scale also had been used in earlier studies (Freedy et al. 1993) and previous WTCD research (Boscarino et al., 2004). For both the WTCD-event exposure and traumatic events scales higher scores indicated greater exposure to these events. In our analyses, both of these scales were collapsed into several categories representing low to high exposures levels.

The survey also assessed the respondent’s psychological status. We included these variables, since past or current psychological problems could increase the vulnerability of a respondent to the negative

consequences of study participation. Using the same approach as the National Comorbidity Survey (NCS), we first asked participants if they had received help for any personal or emotional problems during the year after the WTCD from a helping professional (e.g., psychiatrist, counselor, physician, self-help group, etc.) for “problems with emotions or nerves or use of alcohol or drugs” (Kessler et al., 1997; Kessler et al., 1999). Respondents were divided into those who received mental health counseling during this timeframe versus those who did not receive counseling. Second, we determined whether or not the person met criteria for having a panic attack during the past year. This measure is a modification of the Diagnostic Interview Schedule (DIS) version (Robins et al., 1999), phrased to assess symptoms that occurred during the past year (American Psychiatric Association, 1994). The presence of 4 or more symptoms was sufficient to classify the person as having a panic attack, if the attack reached its peak within 10 minutes after it started. This scale had also been used in previous WTCD studies and consistent with the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) (American Psychiatric Association, 1994; Boscarino et al., 2004).

Our analyses also included measures of posttraumatic stress disorder (PTSD), depression, and anxiety. Our PTSD scale was based on the criteria for DSM-IV and was developed for telephone survey administration and used in the National Women’s Study (Resnick et al., 1993) and other general population studies (Kilpatrick et al., 2000). To meet the PTSD criteria in our study, first, a person had to be exposed to a traumatic event (Criteria A1) and then had to report experiencing intense feelings of fear, helplessness, or horror (Criteria A2). Second, the person had to re-experience the event in one of five ways (Criteria B), avoid stimuli associated with the event in three of seven ways (Criteria C), and had to have increased arousal in two of five ways (Criteria D). Third, the symptoms for Criteria B, C, and D had to last one month or longer (Criteria E). Our PTSD assessment involved evaluation of 3 sets of experiences. One asked specifically about the WTCD. Another asked about the most stressful traumatic event experienced “other than the WTCD.” The third asked about “any other” traumatic event experienced. To have PTSD, the person had to meet the A through E criteria for one or more of these traumatic events. The Cronbach’s alpha for the symptoms used in this scale was 0.90 (Boscarino et al., 2002). In addition, our PTSD scale had a kappa coefficient with the clinician-administered, Structured Clinical Interviews for DSM-III-R (SCID) of 0.71 for current and 0.77 for lifetime PTSD (Kilpatrick et al., 1998). To date, versions of this PTSD scale have been used in mental health surveys involving over 10,000 telephone interviews (Acierno et al., 2000; Kilpatrick et al., 2003; Resnick et al., 1993), including several WTCD surveys (Galea et al., 2003; Boscarino and Adams, 2003). In addition, results obtained with our PTSD scale were consistent with those obtained using the PTSD Checklist (PCL) (Boscarino et al., 2004). For depression, we adapted the SCID’s major depressive episode interview scale (Spitzer et al., 1987). More specifically, the survey included 10 mood disturbances symptoms from this scale (e.g., slept more or less

than normal, thought about hurting yourself, etc.). This scale also had been used in previous WTCD surveys (Galea et al., 2003; Boscarino et al., 2004). Cronbach's alpha for the 10 symptoms used in this scale in the current study was 0.87. When the diagnostic results for depression in the past 30 days using our depression scale were compared to those obtained by the Brief Symptom Inventory -18 (BSI-18) depression scale (Derogatis, 2000) among current survey participants, the results were consistent. The BSI-18 depression scale had 73% sensitivity and 87% specificity in detecting depression cases as classified by our depression instrument (Boscarino and Adams, 2003; Boscarino et al., 2004). In a receiver operating characteristic analysis, a BSI-depression score of ≥ 65 , which was a clinical cutoff for BSI-depression, also optimally predicted depression using our instrument (area under the curve = 0.89) (Boscarino et al., 2004). Overall, our results obtained for both PTSD and depression were consistent with those reported in other mental health population surveys including the NCS (Boscarino and Adams, 2003). Finally, anxiety in our survey was assessed using the BSI-18 anxiety scale. This scale is a general measure of psychological anxiety for the past 30 days (Derogatis, 2000). Following the scoring protocol for the scale, we converted this anxiety measure into standardized t-scores with a cut-off score of ≥ 65 to define a case. The BSI scale has been widely used in mental health research and has been extensively validated (Derogatis, 2000).

Statistical Analysis

We first describe the combined sample, non-treatment sample and the treatment sample. Differences between the non-treatment and treatment samples are assessed using Chi-square tests. Next, since we expected the treatment sample to exhibit more psychological problems and greater exposure to traumatic event, we planned to limit our iatrogenic analyses to this sample population. We hypothesized that these individuals were the most likely to experience adverse reactions to the survey questions and were more likely to require mental health counseling. Based on our initial bivariate analyses, we planned to undertake logistic regressions to investigate the unique associations between the predictor variables and our outcome variables related to iatrogenic survey distress. Finally, based on our multivariate analyses, we planned to examine adverse reaction to the survey for those who had met criteria for either PTSD or depression in the past year.

We used the survey estimation (svy) command set in Stata, version 7 (Stata Corporation, 2001), to generate frequency distributions, cross-tabulations, Chi-square tests, and logistic regression models. This estimation procedure adjusted the data for our sampling design, which included stratification by 5 city boroughs and the sampling weights described earlier. All p-values presented were based on 2-tail tests.

Results

We compared the weighted age, gender, race/ethnicity, and geographic distributions obtained in our sample to the 2000 U.S. Census statistics for NYC (Boscarino and Adams, 2003), since the

distributions were similar, we concluded that our sample was representative of NYC. As expected, inspection of data presented in Table 1 indicates that the treatment population in our study had poorer mental health than the non-treatment population. In particular, the former were more likely to meet the criteria for panic attack, PTSD, and depression in the past year, as well as for anxiety in the past 30 days. The treatment population also was more likely to be exposed to more WTCD events, experience more lifetime traumatic events, and have lower self-esteem. In addition, as shown in Table 1, 15% of New York adults reported that some of the survey questions were stressful. Among those in the treatment group, 28% of the respondents stated that they found some questions stressful. On the other hand, less than 2% of New Yorkers were still upset at survey completion and only 4 participants consented to speak to the study's mental health consultant after survey completion. As seen, the majority of those expressing some adverse emotional reaction to the survey were in the treatment population (28%). Nevertheless, even for these respondents, only 3% were still upset at the end of the survey, 2% wanted information about counseling services, and only 4 respondents consented to speak to the study's mental health consultant at completion.

Turning to issues raised by previous researchers, only 3% of New Yorkers overall and 5% of the treatment population reported participating in another WTCD survey 1-year post disaster. In addition, the vast majority of New Yorkers expressed positive sentiments about participating in the current survey and the value of such surveys for NYC. Among the treatment population, 76% reported that participating in the survey was a positive experience and 82% reported that these types of surveys would help NYC. There were minor differences between the non-treatment and the treatment populations on these questions, but the difference was significant for reporting that the survey would be beneficial ($p < 0.05$), with the treatment population being more positive.

Given the general ethical considerations raised by other investigators, we focused on the treatment population when analyzing models predicting survey stress and for being emotionally upset at survey completion. The results of these multivariate logistic analyses (Table 2) revealed that respondents who found some of the survey questions stressful (column 2) tended to be women, those with low self-esteem, those exposed to greater WTCD events, and individuals who met criteria for panic, PTSD, or anxiety. Importantly, receiving mental health counseling in the previous year was *not* statistically significant here (Table 2).

Variables predicting being emotionally upset at the end of the survey are shown in Table 2 (column 3). Due to the small number of respondents emotionally upset at survey completion, we limited our analyses to five predictor variables that had a statistically significant association with this outcome variable or were of theoretical interest. Only two predictors remained statistically significant in the multivariate model -- meeting criteria for criteria for PTSD or depression. None of the other variables tested were

statistically significant. Table 3 shows the breakdown for the treated sample by our main iatrogenic-related outcomes. As can be seen, while nearly 30% of these persons reported that some survey questions were stressful (n=335), less than 10% (n=30) of these individuals reported still being upset at survey completion. Among these, a total of 16 persons indicated that they would like additional mental health information. Furthermore, of these 16 individuals, only 4 persons consented to speak to the study's mental health consultant, while the remaining 12 persons simply took the toll-free counseling information number to use at their own convenience. In order to better understand the mental health status of those who reported experiencing some stress during the survey, we stratified the Table 3 results by whether these individuals had PTSD or depression in the past year and these findings are displayed in column 4. As can be seen, among the 30 persons reporting being upset at survey completion, a majority (53% weighted) met the criteria for PTSD or depression. Particularly noteworthy is that among the 4 persons who consented to counseling, 3 persons (62% weighted) had PTSD or depression. Finally, it also should be noted that after these persons spoke with the study consultant, all cases were resolved without further incident.

Discussion

This study provided further evidence of the relatively modest adverse impact among respondents surveyed about recent traumatic events. Only 15% of residents from NYC surveyed following the WTCD reported that some of the interview questions were upsetting. This figure is slightly higher than reported in some studies (e.g., Henderson and Jorm, 1990; Jorm et al., 1994; Newman et al., 1999), but lower compared to another (e.g., Parslow et al., 2000). Fewer than 2% were still upset at the end of the survey. In addition, a large majority felt positive about participation and also felt that such surveys could help NYC provide future services for those affected by the WTCD. Finally, our results suggested that NYC residents were not likely unduly burdened by researchers, as only 3% of New Yorkers had participated in another WTC surveys 1-year post disaster. We conclude, therefore, that there is little support for the iatrogenic research effects and for the over-surveying hypotheses in NYC following the WTCD.

These relatively positive findings held even when we focused on the treatment subsample. That is, few of these treatment seekers were upset at the conclusion of the survey, while the vast majority felt positive about study participation. In addition, only 5% of the latter individuals had participated in other WTCD studies. Thus, even for this more vulnerable population, there was little support for the notion that survivors of a community-wide trauma were negatively affected by study participation. In fact, participation actually seemed to be associated with positive feelings about the study. As seen in Table 2, mental health service use after the attacks was positively related to poorer mental status and greater exposure to lifetime trauma, recent stressful life events, and greater exposure to WTCD events, so this treatment population was clearly a higher risk group.

In attempting to explain the positive effects of participating in trauma studies, some researchers have employed inhibition theory (Pennebaker and Beall, 1986; Pennebaker et al., 1990; Smyth et al., 1999). The central argument of this theory is that inhibiting thoughts, feelings, and behavior requires physiological effort. Within the context of this model, inhibiting discussion and thought about traumatic events over a long period of time is believed to be physiologically stressful and may result in increased vulnerability to stress-related diseases. Discussing these events in written or verbal context is believed to relieve this tension, lower stress, and believed to reduce the likelihood of future negative health outcomes. In other words, disclosing past traumas may not be harmful, but beneficial to the individual. For example, research on trauma disclosure among patients with asthma or rheumatoid arthritis suggest that writing about the “most stressful event” of their lives resulted in clinical improvement in their symptoms when evaluated by physicians two weeks, two months, and four months after the writing exercise (Smyth et al., 1999). However, more research needs to be done to evaluate the usefulness of this approach, since there are reasons to suspect that simple cognitive approaches to emotionally charged events may be limited (Boscarino, 2004; Shean, 2001).

Our analyses suggest, however, that researchers still need to be careful when interviewing victims exposed to psychological trauma. Similar to other studies (Newman et al., 1999; Parslow et al., 2000), individuals who met criteria for PTSD or depression were more likely to be upset at the end of the interview, to consent to receiving information about counseling services, and to consent to speak to a mental health consultant at survey completion. Thus, particular attention should be given to respondents who screen positive for psychological problems in a trauma study and mental health consulting and/or referral services should be offered to these persons. In addition, as Fleischman and Wood (2002) have suggested, the informed consent form should contain a statement that participation in studies of responses to potentially traumatic events can be stressful for some people, but that many find this to be a positive experience.

The results of this study need to be viewed within the context of its limitations and strengths. First, the survey may have missed individuals who left NYC due to the attacks. However, the impact of this is likely a minor, since over 90% of the persons surveyed were living in the same place they were at the time of the WTC. Second, we omitted individuals without a telephone and those who did not speak either English or Spanish. Given that the sample matched the 2000 Census for NYC (Boscarino and Adams, 2003), however, elimination of households without telephones did not appear to have introduced significant demographic bias. Nevertheless, we are limited in generalizing to other ethnic/language groups in NYC. Very little research focuses on how the WTC affected immigrant communities or the wide variety of ethnic groups living in NYC. Participation may have more deleterious effects on individuals within such groups. Third, the data are cross-sectional and cannot be used to test causal relationships. It is

possible that other factors may be related to reactions to our survey questions. Fourth, our survey was conducted 1-year post disaster and the results may have been different if we surveyed more recently following the attacks, although NYC residents were on a heightened state of alert during the 1-year WTC anniversary when we conducted our survey. (New York City was under a high terrorism alert [Code Orange] at the time of the survey.) Fifth, although we focused our analyses on those who sought some kind of treatment and these persons tended to have more psychopathology and potential trauma exposures (Table 2), this group should not be considered the highest exposure/risk group as a whole, compared to those who were at the World Trade Center site at the time of the attack.

These limitations should not overshadow the strengths of the study. Some of these included the use of large random samples representative of NYC, the assessment of mental status using standard scales, and the focus on a specific event that meets the criteria for community-wide disaster, since the WTC was one of the most deadly disasters in US history. Although we found little evidence to support the notion that participation in community disaster research results in adverse respondent reactions, it is possible that other negative consequences of participation may emerge. Thus, continuing investigation and respondent protections clearly seem warranted (Collogan et al., 2004). As Fleischman and Wood (2002, p. 320) noted, “Investigators must ensure that studies are designed to minimize harms and risks to the subjects, that subjects are given the opportunity to provide voluntary and uncoerced decisions about participation, and that participation is not overly burdensome to specific individuals or populations.” Individuals give researchers the privilege of their time and energy so that they can obtain information to improve the quality of life. We need to make sure that we do not abuse that privilege. On the other hand, policies restricting trauma research based on presumed iatrogenic effects appear flawed. Overcautious policies may prevent research leading to greater understanding of who is most vulnerable following traumatic event exposures and what should be done (or avoided) to facilitate resiliency and recovery from these catastrophic human events.

Table 1: Characteristics of Combined, Non-Treatment, and Treatment Populations.

	Combined Sample (2368)		Non-Treated Sample (1195)		Treated Sample (1173)	
	Unweighed N	Weighed %	Unweighed N	Weighed %	Unweighed N	Weighed %
Gender						
Male	1016	46.20	578	51.39	438	39.60***
Female	1352	53.80	617	48.61	735	60.40
Race						
White	1015	39.25	505	38.67	510	39.72
African American	606	26.32	322	27.11	284	24.57
Hispanic	559	25.72	267	25.36	292	27.64
Other	188	8.71	101	8.86	87	8.08
Education						
Less than College Degree	1304	59.88	706	62.58	598	54.74***
College Degree +	1053	40.12	485	37.42	568	45.26
Rosenberg Self Esteem Scale						
Low	890	34.52	357	31.22	533	45.45***
Medium	573	24.52	302	25.15	271	22.48
High	893	40.96	529	43.63	364	32.08
Exposure to WTCD						
Low	510	26.50	374	30.88	136	10.90***
Medium	1003	43.96	541	45.37	462	38.26
High	590	22.00	224	19.28	370	32.18
Very High	261	7.53	56	4.47	205	18.66
Life-Time Traumatic Event Exposure						
Low	1222	57.03	683	59.68	539	47.42***
Medium	667	26.19	328	25.53	339	28.33
High	479	16.78	184	14.78	295	24.25
Received MH Counseling Since WTCD						
No	1602	80.01	1058	89.49	544	48.41***
Yes	766	19.99	137	10.51	629	51.59
Met Criteria for Panic Attack Past Year						
No	1884	84.31	1061	88.73	823	68.60***
Yes	484	15.69	134	11.27	350	31.40
Met Criteria for PTSD Past Year						
No	2172	94.76	1163	97.05	1009	86.94***
Yes	196	5.25	32	2.95	164	13.06
Met Criteria for Depression Past Year						
No	2059	91.85	1141	95.47	918	79.24***
Yes	309	8.15	54	4.53	255	20.75
Met Criteria for Anxiety Past Month						
No	1981	89.72	1100	93.29	881	76.59***
Yes	363	10.28	83	6.71	280	23.41
Reported Some Survey Questions Stressful						
No	1898	84.65	1060	88.45	838	72.04***
Yes	470	15.35	135	11.54	335	27.96
Reported being Emotionally Upset at Survey Completion						
No	2331	98.64	1188	99.22	1143	96.62**
Yes	37	1.36	7	0.78	30	3.38
Consented to Counseling Support Info						
No	2348	99.14	1191	99.46	1157	97.88*
Yes	20	0.86	4	0.54	16	2.12
Consented to Speak to Mental Health Consultant						
Yes	4	0.15	0	0.00	4	0.64*
No	16	0.71	4	0.54	12	1.48
NA	2348	99.14	1191	99.46	1157	97.88
Participated in Other WTCD Surveys						
No	2289	96.98	1169	97.59	1120	94.78**
Yes	79	3.02	26	2.41	53	5.22
Overall Rating of Present Survey						
Generally Positive	1728	74.06	862	73.92	866	75.64
Neither Positive nor Negative	512	20.93	268	21.21	244	19.22
Generally Negative	72	2.47	31	2.14	41	3.37
Don't Know/No Opinion	56	2.54	34	2.73	22	1.77
Reported Surveys May Help NYC						
No	157	7.10	102	7.64	55	4.49*
Somewhat/Depends	152	6.19	74	6.23	78	5.93
Yes	1839	77.73	903	77.12	936	81.90
Don't Know/No Opinion	220	8.98	116	9.01	104	7.67

Difference between Non-Treated and Treated Samples:

* p<.05

** p<.01

*** p<.001, χ^2 test

Table 2: Predictors Related to Reports of Any Stressful Questions Survey and Being Upset at Survey Completion among Treatment Population

Predictor Variable	Reported Some Questions Stressful (n=335)		Reported Emotional Upset at Completion (n=30)	
	Odds Ratio	95% CI [†]	Odds Ratio	95% CI [†]
Gender				
Male (References)	1.00	---	1.00	---
Female	1.80***	1.29-2.53	1.69	0.58-4.93
Race				
Other (Reference)	1.00	---		
White	1.06	0.76-1.48		
Rosenberg Self Esteem Scale				
Low	1.87**	1.23-2.85		
Medium	1.53	0.98-2.39		
High (Reference)	1.00	---		
Exposure to WTC Events				
Low (Reference)	1.00	---		
Medium	1.10	0.63-1.95		
High	1.03	0.58-1.83		
Very High	2.07*	1.12-3.80		
Life-Time Traumatic Event Exposures				
Low (Reference)	1.00	---		
Medium	1.14	0.76-1.66		
High	1.46	0.98-2.19		
Received MH Counseling Since WTC [†]				
No (Reference)	1.00	---		
Yes	1.37	0.98-1.93		
Met Criteria for Panic Attack Past Year				
No (Reference)	1.00	---		
Yes	1.35	0.95-1.92		
Met Criteria for PTSD Past Year				
No (Reference)	1.00	---	1.00	---
Yes	1.72*	1.09-2.72	2.36*	1.11-5.05
Met Criteria for Depression Past Year				
No (Reference)	1.00	---	1.00	---
Yes	1.51*	1.00-2.27	2.17*	1.00-4.68
Met Criteria for Anxiety Past Month				
No (Reference)	1.00	---	1.00	---
Yes	1.76**	1.20-2.59	2.57	0.96-6.89
Surveys Like This Are Helpful to NYC				
Not helpful/DK (Reference)	1.00	---		
Helpful	1.13	0.56-2.31		
N =		1158		1161

[†]CI=Confidence Interval; WTC=World Trade Center Disaster; Blank cell means that the variable was not used in the analyses.

*p<0.05

**p<0.01

***p<0.001

Table 3: Outcomes Among Treatment Population Participant that Reported Some Interview Questions Stressful (N=1173)

Outcome Variables	% of Treated Sample	Number of Cases (Unweighted)	% of Cases w/ PTSD or Depression (unweighted n)
Reported Some Questions Stressful	27.96	335	41.74 (144)
Reported Emotional Upset a Completion	3.38	30	52.60 (17)
Consented to Information on Counseling Services	2.12	16	52.58 (9)
Consented to Speak to Consultant at Completion	0.64	4	61.54 (3)
Did not Consent to Consultation, but Accepted Toll-Free 800 Number	1.48	12	48.68 (6)

References

- Acierno R, Kilpatrick DG, Resnick H, Saunders B, De Arellano M, Best C. 2000. Assault, PTSD, family substance use, and depression as risk factors for cigarette use in youth: findings from the National Survey of Adolescents. *Journal of Traumatic Stress*, 13:381-396.
- American Association for Public Opinion Research. 2000. Standard definitions: Final dispositions of case codes and outcomes rates for surveys. Ann Arbor, MI: American Association for Public Opinion Research.
- American Psychiatric Association. 1994. *Diagnostic and Statistical Manual of Mental Disorders*, 4th Ed. Washington, DC: American Psychiatric Association.
- Appelbaum PS. 1998. Missing the boat: competence and consent in psychiatric research. *American Journal of Psychiatry*, 155:1486-1488.
- Blascovich J, Tomaka J. 1991. Measure of self-esteem. In: Robinson JP, Shaver PR, Wrightsman LS. (eds.). *Measures of Personality and Social Psychological Attitudes*. New York, NY: Academic Press. Pp.115-160.
- Boscarino JA. 2004. Posttraumatic stress and physical health: results from clinical and epidemiologic studies. *Annals of the New York Academy of Sciences* (in press).
- Boscarino JA, Adams RE. 2003. Mental health and psychotropic medication use in New York 1-year after terrorist attacks. Presented at: International Society for Traumatic Stress Studies Annual Meeting, Chicago, IL, November 2003.
- Boscarino JA, Galea S, Adams RE, Ahern J, Resnick H, Vlahov D. 2004. Mental health services and psychiatric medication use following the terrorist attacks in New York City. *Psychiatric Services*, 55 (in press).
- Boscarino JA, Galea S, Ahern J, Resnick H, Vlahov D. 2002. Utilization of mental health services following the September 11th terrorist attacks in Manhattan, New York City. *International Journal of Emergency Mental Health*, 4:143-155.
- Chen DT, Miller FG, Rosenstein DL. 2002. Enrolling decisionally impaired adults in clinical research. *Medical Care*, 40(Supplement): V20-V29.
- Collogan LK, Dolan-Sewell R, Tuma F, Borja S, Fleischman AR. 2004. Ethical issues pertaining to research in the aftermath of disaster. *Journal of Traumatic Stress*, 17: (in press).
- Derogatis LR. 2001. *Brief Symptom Inventory 18 (BSI-18) Manual*. Minnetonka, MN: NCS Assessments.
- Figley CR, Carbondale JL, Boscarino JA, Chang J. 1999. A clinical demonstration model for assessing the effectiveness of therapeutic interventions: an expanded clinical trials methodology. *International Journal of Emergency Mental Health*, 3: 155-164.
- Freedly JR, Kilpatrick DG, Resnick HS. 1993. Natural disasters and mental health: Theory, assessment, and intervention. *Journal of Social Behavior and Personality* [Special issue: *Handbook of Post-disaster Interventions*], 8: 49-103.
- Fleischman AR, Wood EB. 2002. Ethical issues in research involving victims of terror. *Journal of Urban Health*, 79: 315-321.
- Galea S, Vlahov D, Resnick H, Ahern J, Susser E, Gold J, Bucuvalas M, Kilpatrick D. 2003. Trends in probable posttraumatic stress in New York City after the September 11 terrorist attacks. *American Journal of Epidemiology*, 158: 514-524.
- Grayson DA, O'Toole BI, Marshall RP, Schureck RJ, Dobson M, Ffrench, Pulvertaft B. 1996. Interviewer effects on epidemiologic diagnosis of posttraumatic stress disorder. *American Journal of Epidemiology*, 144: 589-597.
- Greenberg MA, Stone AA. 1992. Emotional disclosure about trauma and its relation to health: Effects of previous disclosure and trauma severity. *Journal of Personality and Social Psychology*, 63: 75-84.
- Griffin MG, Resick PA, Waldrop AE, Mechanic MB. 2003. Participation in trauma research: Is there evidence of harm? *Journal of Traumatic Stress*, 16: 221-227.

- Henderson AS, Jorm AF. 1990. Do mental health surveys disturb? *Psychological Medicine*, 20: 721-724.
- Johnson LE, Benight CC. 2003. Effects of trauma-focused research on recent domestic violence survivors. *Journal of Traumatic Stress*, 16: 567-571.
- Jorm AF, Henderson AS, Scott R, Mackinnon AJ, Korten AE, Christensen H. 1994. Do mental health surveys disturb? Further evidence. *Psychological Medicine*, 24: 233-237.
- Kessler RC, Frank RG, Edlund M, Katz SJ, Lin E, Leaf P. 1997. Differences in the use of psychiatric outpatient services between the United States and Ontario. *New England Journal of Medicine*, 336:551-557.
- Kessler RC, Zhao S, Katz SJ, Kouzis AC, Frank RG, Edlund M, Leaf P. 1999. Past-year use of outpatient services for psychiatric problems in the National Comorbidity Survey. *American Journal of Psychiatry*, 156:115-123.
- Kilpatrick DG, Acierno R, Saunders B, Resnick HS, Best CL, Schnurr PP. 2000. Risk factors for adolescent substance abuse and dependence: data from a national survey. *Journal of Consulting and Clinical Psychology*, 68:19-30.
- Kilpatrick DG, Resnick HS, Freedy JR, Pelcovitz D, Resick P, Roth S, van der Kolk B. 1998. The posttraumatic stress disorder field trial: evaluation of the PTSD construct – criteria A through E. In: *DSM-IV Sourcebook --Volume 4*. Edited by T Widiger, A Frances, H Pincus, et al., Washington, DC: American Psychiatric Association Press: 803-844.
- Kilpatrick DG, Ruggiero, KJ, Acierno, R, Saunders BE, Resnick HS, Best CL. 2003. Violence and risk of PTSD, major depression, substance abuse/dependence, and comorbidity: results from the national survey of adolescents. *Journal of Consulting and Clinical Psychology*, 71:692-700.
- Newman E, Walker EA, Gefland A. 1999. Assessing the ethical costs and benefits of trauma-focused research. *General Hospital Psychiatry*, 21: 187-196.
- North CS, Pfefferbaum B, Tucker P. 2002. Ethical and methodological issues in academic mental health research in populations affected by disasters: The Oklahoma City experience relevant to September 11, 2001. *CNS Spectrums*, 7: 580-584.
- North CS, Pfefferbaum B. 2002. Research on the mental health effects of terrorism. *JAMA*, 288: 633-636.
- Parslow RA, Jorm AF, O'Tolle BI, Marshall RP, Grayson DA. 2000. Distress experienced by participants during an epidemiological survey of posttraumatic stress disorder. *Journal of Traumatic Stress*, 13:465-471.
- Pennebaker JW, Beall S. 1986. Confronting a traumatic event: Toward an understanding of inhibition and disease. *Journal of Abnormal Psychology*, 95:274-281.
- Pennebaker JW, Colde M, Sharp LK. 1990. Accelerating the coping process. *Journal of Personality and Social Psychology*, 58: 528-537.
- Piantadosi S. 1997. *Clinical Trials: A Methodological Perspective*. New York, NY: John Wiley and Sons.
- Resnick HS, Kilpatrick DG, Dansky BS, Saunders BE, Best C. 1993. Prevalence of civilian trauma and posttraumatic stress disorder in a representative national sample of women. *Journal of Consulting and Clinical Psychology*, 61:984-991.
- Rosenberg, M. (1979). *Conceiving the self*. New York, NY: Basic Books.
- Robins LN, Cottler LB, Bucholz KK, Compton WM, North CS, Rourke KM. 1999. *Diagnostic Interview Schedule for DSM-IV*. St. Louis, MO: Washington University School of Medicine, Department of Psychiatry (Revised January 9, 2002).
- Ruzek JI, Zatzick DF. 2000. Ethical considerations in research participation among acutely injured trauma survivors: An empirical investigation. *General Hospital Psychiatry*, 22: 27-36.
- Shean C. 2001. A critical look at the assumptions of cognitive therapy. *Psychiatry*, 64: 158-164.
- Shore D. 1996. Ethical principles and informed consent: an NIMH perspective. *Psychopharmacology Bulletin*, 32: 7-10.

- Smyth JM, Stone AA, Hurewitz, A, Kaell A. 1999. Effects of writing about stress experiences on symptom reduction in patients with asthma or rheumatoid arthritis: a controlled trial. *JAMA*, 281:1304-1309.
- Spitzer RL, Williams JB, Gibbon M. 1987. Structured Clinical Interview for DSM-III-R – Non-Patient Version. New York, NY: Biometrics Research Department, New York State Psychiatric Institute.
- Stata Corporation. 2001. Stata, version 7.0. College Station, TX: Stata Corporation.