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Randomized Controlled Trial of an Internet-Based Intervention Using Random-Digit-Dial Recruitment: The *Disaster Recovery Web* Project

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Abstract

Disasters occur with high frequency throughout the world and increase risk for development of mental health problems in affected populations. Research focused on the development and evaluation of secondary prevention interventions addressing post-disaster mental health has high potential public-health impact. Toward this end, internet-based interventions (IBIs) are particularly attractive in that they: (1) offer a low-cost means of delivering standardized, targeted, personalized intervention content to a broad audience; and (2) are easily integrated within a stepped care approach to screening and service delivery. We describe a unique study design intended to evaluate an IBI with a disaster-affected population-based sample. Description and rationale are provided for sampling selection and procedures, selection of assessment measures and methods, design of the intervention, and statistical evaluation of critical outcomes. Unique features of this intervention include the use of a population-based sample, telephone and internet-based assessments, and development of a highly individualized web-based intervention. Challenges related to the development and large-scale evaluation of IBIs targeting post-disaster mental health problems, as well as implications for future research and practice are discussed.

Keywords

Disaster mental health; Internet intervention; randomized controlled trial; Hurricane Ike; posttraumatic stress

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Disasters are a significant public health concern given their potential deleterious effects (e.g., death, limited access to basic necessities) and associated risk of physical and mental health-related problems. Most individuals are resilient or recover relatively quickly with regard to post-disaster mental health [1]. Nevertheless, the need for post-disaster resources is great because disasters often adversely affect thousands of individuals simultaneously [2,3,4]. Our primary aim for this project was to evaluate the feasibility and preliminary efficacy of a brief, innovative Web-based intervention targeting post-disaster mental health.

The availability of brief, effective, low-cost interventions to foster resilience and rapid recovery is potentially of tremendous value to disaster-affected communities. Brief interventions have been developed and tested with other traumatic stress populations (e.g., military personnel, victims of sexual assault and violence, accidents) with promising results [5,6,7,8] but these have not been tailored to – or tested with – disaster affected populations. Indeed, the role of *self-help* interventions in the post-disaster context is virtually unexplored. Self-help interventions can be accessible in a variety of formats, such as video (DVD, streaming video), workbook, bibliotherapy, and interactive Websites.

A rapidly growing body of literature suggests that self-help interventions for mental health problems have the potential to produce moderate-to-large effect sizes [9,10]. Data on Internet-based interventions (IBIs) have been particularly promising, and support for efficacy has been reported for a wide range of problems [11]. IBIs vary in their structure, time commitment [e.g., 1–10 weeks; 12,13], and clinician involvement [e.g., 14,15]. They have a number of advantages over other modalities, including being widely and highly accessible at low cost, ease of updating and individual tailoring, and ability to reach at-risk individuals with significant barriers to formal treatment [11,16].

The design of a clinical trial for disaster-affected populations presents numerous unique challenges. The population is unknown prior to initial design of the study, which necessitates a flexible approach to recruitment and assessment that meets budget requirements. Use of telephone-based recruitment and assessment addresses this need and has other major potential advantages such as the opportunity to recruit generalizable samples via randomized recruitment. This methodology, when merged with remote delivery of services (e.g., telehealth, e-health, *m*Health), establishes an innovative, cost-efficient approach to the conduct of clinical trials. The current project aimed to conduct a preliminary efficacy evaluation of a Web-based intervention targeting post-disaster mental health. An original, less sophisticated, version of the intervention had been evaluated in a pilot study with 285 adults, with findings supporting the feasibility and potential value of this approach [16]. Hurricane Ike, a major hurricane that made landfall in the upper Texas coast in the summer of 2008, was identified by our team as a recent large-scale disaster that was most appropriate for initial testing the intervention. Our expectation was that the relevance of the intervention for this population was high because mental health needs among victims of Ike were likely to have persisted into the field period for a significant minority of coastal residents.

Design and Method

Study Design

A population-based study was conducted to preliminarily examine the utility and efficacy of the Web intervention among victims of Hurricane Ike. Random-digit-dial methodology was used to obtain a baseline sample of 1,249 disaster-affected adults interviewed between September 10 and October 12, 2009. We chose to study victims of Hurricane Ike for purposes of this study due to the relative recency of Ike's landfall and numerous risk factors present in the coastal counties of Galveston and Chambers, TX. Optimally, our intervention

is designed for the 1–4 month period after disasters, consistent with a secondary prevention approach, but the unpredictable nature of disasters and the structure of the grant mechanism (i.e., 3-year timeline, limited budget) necessitated evaluation well outside of this timeframe. A 21-min structured baseline interview assessed demographics, disaster impact, and post-disaster mental health. At the end of the baseline interview, participants were introduced to the Web phase of the study and invited to access the Web intervention. They were provided the study Website (http://drw.musc.edu) and a unique password. They were told that the password would provide access to the Website for the full four-month period between the baseline and follow-up telephone interviews.

As participants accessed the site, they were randomly assigned to the experimental Web intervention or an assessment-only Web condition. Web usage, knowledge change, and user satisfaction data were collected during the four-month period between users' baseline and follow-up interviews. The follow-up interview assessed knowledge retention, symptom change, and barriers to use of the Web intervention. Interviewers were blind to study condition. These surveys were completed between January 7 and March 23, 2010. The average survey length was 18 minutes.

Rationale for Use of a Population-Based Sample-Most Web-intervention evaluation studies to date have used convenience or clinical samples [11], which can be advantageous with regard to cost, feasibility of recruitment, and smaller sample size needs for adequate statistical power. However, a population-based approach has numerous scientific advantages. First, a population approach increases what can be learned with regard to the community-level impact of an intervention. This includes community members who are not seeking treatment and individuals at low risk for mental health problems. Selfadministered interventions should include a valid screening component to allow efficient tailoring of content, as well as screen-outs for asymptomatic users; population-based recruitment ensures that this screening mechanism can be properly tested. Further, because our intervention is designed to serve participants with clinically elevated, as well as subclinical symptom levels, it is beneficial to recruit from an at-risk population with high variability in symptom presentation. Second, as we learned in our pilot study [16], use of a documented population-based sample from which Web participants are recruited provides valuable and reliable estimates of use and benefit of the intervention. Many studies using convenience samples and undefined recruitment pools yield little information about individuals who learn about the study (e.g., via newspaper ads, flyers, notices in clinics or on undergraduate research boards) but choose not to participate. In the current study, roughly half (53%) of our baseline interviewees accessed the study Website, providing an opportunity to examine key demographic, disaster-relevant, and mental health-related correlates of participation. Third, data from population-based samples, as compared to clinical or high-risk samples, may be more generalizable to disaster-affected communities, which typically have high demographic variability, variability in mental health and service utilization histories, and experience seeking health-relevant information online.

Justification of Sampling Strategy and Use of Telephone Survey Methods— We conducted the interview portion of the study via telephone instead of by mail, Internet, or in person for several reasons. First, mail questionnaires have low return rates and do not lend themselves to the complex skip patterns that will guide the interview process for the proposed study. Second, although use of online panels is feasible, participation rates for these panels—particularly nonprobability panels—tend to be low [17]. This calls into question the representativeness of findings from samples that are initially *recruited* via Internet, and also would hinder a detailed assessment of barriers to accessing the Web intervention. Third, *in-person* surveys are prohibitively expensive in a low-budget intervention-development project. Telephone survey methods are efficient for collecting

information from large samples at relatively low cost, with nonsignificant response bias or detection of critical variables of interest, as compared to in-person interview approaches [18,19,20]. These issues have been examined specifically in terms of detection of psychopathology and exposure to traumatic events using in-person versus telephone interview methods [19,21,22,23,24]

Setting

The use of an Internet-based intervention in disaster-affected settings poses unique challenges due to the possibilities of displacement, damage to infrastructure, and access to technology. These potential barriers may limit the reach of an internet resource to the most vulnerable families. This is a common concern and was a consideration when we outlined the initial concept for this study. However, a review of available data suggested that lack of access is not as widespread as is typically assumed. Indeed, the vast majority of US disasters do not affect telephone or Internet access for a prolonged period of time. For example, even for a disaster such as Hurricane Katrina that is rare in terms of magnitude of widespread destruction, telephone outages in the state of Louisiana were reduced from 890,000 to 350,000 as early as four weeks after Katrina made landfall, despite an additional 225,000 telephone outages caused by Hurricane Rita within the same period [25]. Further, data on post-Katrina communication systems suggest that most Web services and networks were restored and accessible within the first several days and weeks of Katrina's landfall *26+. Length of displacement and extent of damage to homes likely are among the strongest indicators of residents' ability to access the Internet in various phases of the post-disaster period, and in the case of Hurricane Katrina, this impact varied widely across communities. Data on Internet access in the aftermath of other disasters are limited, in part, due to the fact that household broadband Internet access has only recently become widespread-for example, 3% of households had broadband access in June 2000 vs. 63% in April 2009 [27]. As recently as 2004, dial-up access was the most common way Americans accessed the Internet from their households [27]. In addition, it is difficult to gauge Internet access rates because lack of household access does not necessarily preclude access-for example, via workplace, library, neighbors' or relatives' homes. Looking forward, advances in wireless technology are making broadband services much more accessible, and this may lead to higher rates of coverage in general and also increase displaced victims' opportunities to access Web-based resources. Hurricane Ike made landfall near Galveston, TX, as a strong Category 2 hurricane on September 13, 2008. Ike was an unusually large storm that nearly encompassed the entire Gulf of Mexico. It slammed into the coast with a massive storm surge of 15–20 feet at landfall [28]. Twenty US deaths were directly attributed to the storm; another 64 deaths were indirectly attributed via electrocution, carbon monoxide poisoning, pre-existing medical complications, and other causes [29,30]. Estimates of total damages indicated that Ike is the third most costly storm in US history, after Hurricanes Katrina (2005) and Andrew (1992). Chambers, Galveston, Harris, Jefferson, and Orange counties sustained the most damage from Ike, reflecting the majority of these costs [25]. We selected Galveston and Chambers counties for recruitment because both are coastal counties in the direct path of Ike's center.

Participants

The sample consisted of 1,249 adults aged 18 years and over residing in homes with Internet access. Eligibility criteria were that participants must have been living in Galveston or Chambers, TX, counties at the time of Ike's landfall; that they currently had household internet access; and that their primary language was English. Adults potentially excluded from this sample were non-English-speaking adults as well as those residing in institutional settings, in households without telephones, or in households without Internet access. Translation of intervention materials into Spanish was not feasible due to budget and

timeline restrictions. Our decision to exclude adults without household Internet access probably resulted in the exclusion of some individuals who, in a true disaster context, might have been inclined to access the Web intervention from work, libraries, or relatives' homes. However, privacy issues are complex in these settings in the context of a research protocol, where confidentiality requires a higher standard of protection than might be necessary outside of a research context.

Recruitment and Interview Procedures

Sample recruitment occurred via random digit-dial (RDD) telephone survey methods. This involves identifying telephone exchanges in the targeted geographic area, calling random telephone numbers to identify residential households within those areas, screening households for eligibility, and interviewing one randomly selected eligible adult. Our method involved use of telephone banks within each geographic area that were systematically selected using the comprehensive database of working telephone hundred banks containing three or more listed residential phone numbers. Once a block has been selected, a two-digit random number in the range of 00–99 is appended to the block to form a ten-digit telephone number. RDD was used to locate currently working, residential household telephone numbers with eligible respondents. Non-working numbers and nonhousehold (e.g., business) numbers were replaced by other RDD numbers selected within the same geographic area in the same fashion as the initial number. Ineligible households (e.g., no Internet access) were also replaced. Up to 21 attempts were made to contact an adult at each landline phone number (M = 4.6, SD = 4.0) at baseline. Call attempts occurred on different days and at different times to maximize likelihood of contact with a potential participant. Once contact was made with a potentially eligible household, interviewers applied the most recent birthday method to select a respondent. This common and accepted method has been demonstrated to be technically equivalent or superior to other respondent selection techniques, and involves less respondent burden (see Gaziano et al. [31]). Throughout recruitment, the gender balance in the sample was systematically monitored by supervisors nightly. On evenings where the gender distribution too-heavily favored women, the protocol was adjusted such that interviewers requested the adult male in the household with the most recent birthday. When possible, the designated adult was interviewed immediately after eligibility and respondent selection had been determined. Otherwise, appointments were scheduled when possible, or blind callbacks at different times of day and days of the week were made. The overall cooperation rate (#4), calculated according to American Association for Public Opinion Research (AAPOR) industry standards (i.e., [completed interviews + screen outs] divided by [completed interviews + screen outs + refusals]), was 50.2%.

After determining eligibility, the interviewer provided a brief introduction to the study as well as an opportunity to call a toll-free number to confirm the authenticity of the study. Verbal consent was obtained for the baseline interview. Interviews were conducted using Computer-Assisted Telephone Interviewing (CATI) technology. This technology has many advantages. It is better able to handle skip patterns in interview schedules such as those used in the proposed research. It ensures fidelity to the interview process because interviewers cannot proceed in the CATI program without entering participant responses (or refusals). CATI interviews typically take less time than alternative methods and result in less respondent fatigue, increasing adherence and reducing the likelihood of termination. It also greatly reduces the time for data management and cleaning. Surveys using the CATI method also appear to increase detection of sensitive incidents, such as sexual assault and other forms of crime [32]. Interviewers were employees of Abt SRBI who were well trained, highly skilled, and experienced in conducting this type of interview. Abt SRBI has conducted numerous successful projects assessing mental health effects among disaster

victims over the past 25 years, including victims of hurricanes, earthquakes, and the World Trade Center Disaster.

At the completion of the baseline interview, participants were oriented to the Web phase of the study. Participants were told that the purpose of the Web phase was to evaluate the helpfulness of a Website that we designed specifically for adults who have experienced disasters. Participants were given the Website address (drw.musc.edu) and a unique six-digit numeric password by the interviewer over the telephone. A letter also was sent to the participant after the baseline interview to review this information (e.g., purpose of Web phase, consent process, and log-in). Interviewers were blind to study condition. Randomization to condition did not occur until the participant logged onto the Website. Participants were paid \$10 to complete the baseline telephone interview, \$30 to participate in the Web phase of the study, and \$10 to complete the follow-up telephone interview. Participants who did not access the study Website within roughly 2-3 weeks of the baseline interview were sent brief reminder e-mails/letters. Reminders were sent to participants up to three times between the baseline and follow-up interviews. Participants were contacted for a 4-month follow-up interview irrespective of their participation in the Web phase of the study. A total of 877 re-contact surveys were completed among the 1,249 cohort members (70% were re-interviewed). Up to 38 attempts were made to contact and re-interview respondents (M = 6.2, SD = 6.9) and the AAPOR cooperation rate (#4) was 86.9%.

Assessment

The assessment and evaluation process for this project was guided by Kirkpatrick's [33] conceptual model of program evaluation, which identifies four distinct levels: (a) reaction, (b) learning, (c) behavior, and (d) results. The first level, *reaction*, relates to participant satisfaction and interest. Although satisfaction is not a sufficient indicator of the Web intervention's success, it relates to conditions under which use of the site and success is likely. The second level, *learning*, considers such outcomes as knowledge gain, skill improvement, and attitude change. The third level, *behavior*, focuses on the extent to which symptom/behavior change occurs as a function of the intervention. The fourth level, *results*, entails a cost-benefit analysis. This preliminary outcome study involved assessment at the first three levels of evaluation, with plans to target the fourth level in future work. Levels one and two (i.e., reaction and knowledge change) were targeted via Web-based assessment that occurred at the time that participants completed the Web phase of the study. Levels two and three (i.e., knowledge retention and symptom/behavior change) were targeted via telephone interview.

Baseline Interview—The structured baseline interview collected information on demographics; history of exposure to traumatic life events; and current symptoms of PTSD, panic, depression, and generalized anxiety. Assessment of demographics included standard biographic information such as age, gender, educational achievement, marital status, racial/ ethnic status, and household income. History of potentially traumatic events was assessed via a modified interview module that we have used in the aftermath of other disasters [34,35,36] to assess exposure to prior disasters, serious accidents, interpersonal violence, and other severe life stressors. Assessment of past-year formal help seeking for mental health issues (i.e., defined as seeking help for "any personal or emotional problem" from a physician, psychiatrist, psychologist, or other professionally trained individual) was based on questions derived from the National Women's Study interview [37]. Assessment of mental health functioning, described below, centered on constructs that were targeted by the experimental Web intervention, specifically, past-year symptoms of PTSD, panic, depression, and generalized anxiety. These measures have been administered successfully orally and/or via telephone in previous clinical efficacy and epidemiologic research

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[16,38,39,40]. Each of these measures has well-supported psychometric properties and is relatively brief. Cost considerations and sample-size needs necessitated the use of brief measures. As such, whereas comprehensive structured diagnostic interviews would have increased methodological rigor, they would have been a prohibitive expense for a project of this scope.

Briefly, mental health measures included in the baseline and 4-month follow-up interview were as follows. The PTSD Checklist-Civilian version [PCL; 41] is a 17-item instrument that parallels DSM-IV criteria B, C, and D for PTSD. Research has provided significant support for its internal consistency, sensitivity and specificity, test-retest reliability, convergent validity, and discriminant validity [16,38,42,43]. The Body Sensations *Questionnaire* [BSQ; 44] is an 18-item instrument to assess fear of bodily sensations in adults with panic attacks. Participants provide a fear rating on a 5-point scale for each sensation. The BSQ has good psychometric properties, including good internal consistency, test-retest reliability, and construct and discriminant validity [44,45]. The Center for Epidemiologic Studies-Depressed Mood Scale-10 [CESD-10; 46] is a 10-item instrument that was designed as a screening tool to identify persons at risk for clinical depression. It was developed from the original 20-item CES-D measure, which has been validated in various populations with high internal consistency, satisfactory test-retest correlations, and strong concurrent validity, discriminant validity, and sensitivity to change [39,47]. The CESD-10 is widely used and has good predictive accuracy when compared to the full-length CES-D scale. The Penn State Worry Questionnaire [PSWQ; 48] is a 16-item measure of generalized anxiety designed to assess the generality, excessiveness, and uncontrollability dimensions of pathological worry. The PSWQ is psychometrically well-supported, including good internal consistency and test-retest reliability, good convergent validity [48], and strong discriminant validity and sensitivity and specificity [49,50,51].

Web-phase Assessment—Web usage data (e.g., participant access, module qualification, module completion), pre/post knowledge change data, and satisfaction levels were collected during the four-month period between participants' baseline and 4-month follow-up interviews. This information allowed for analyses examining (a) mental health, demographic, and disaster-relevant predictors of Web usage among disaster victims; (b) the validity of our Web-screening mechanism via comparisons with interview data; (c) knowledge change among experimental *vs.* comparison-group participants; and (d) satisfaction levels among experimental *vs.* comparison-group participants. Our general developmental strategy for Web-based screening and assessment is outlined in significant detail elsewhere [16].

Follow-up Interview—A four-month follow-up telephone interview was administered to assess symptom levels, barriers to participation in the Web component of the study, and retention of knowledge gains. Assessment of symptom levels involved re-administration of the mental health measures described for the baseline interview above. Assessment of knowledge retention used questions that were telephone-friendly adaptations of questions that were administered to a subsample of users on the study Website. Toward the end of the interview, participants were asked whether they accessed the Website, and those who indicated that they did not access it were asked six yes/no questions about barriers to participating in this phase of the project (e.g., Web security concerns, participants' perceptions of relevance and usefulness, difficulties accessing the site). Interviewers continued to be blind to intervention condition, although at the follow-up interview it was possible, but unlikely, that interviewers could have tried to guess which condition a participant was in based on their responses to knowledge questions. To minimize this possibility, interview questions relating to participants' knowledge and barriers in the Web phase of the study were assessed *after* assessment of symptoms.

Intervention

Our ultimate goal was to develop a Web-based intervention designed to address postdisaster mental health and general symptom distress in the acute aftermath of disasters. Because this was a small-scale, 3-year exploratory research grant (NIMH R34 mechanism), budget and timeline constraints limited our flexibility and we did not have the ability to delay the efficacy evaluation in an attempt to test the intervention in the *acute* aftermath of a future disaster. Instead, we identified an appropriate, relevant disaster-affected population with which to evaluate the site fully one year after Hurricane Ike affected the Galveston Bay area. We anticipate that future large-scale research will provide the opportunity to test the intervention in an acute post-disaster context.

The intervention was developed with attention to several literatures, including epidemiological research on mental health and health-risk correlates of disasters [16,35,52–60]; best practices in behavior therapy and brief interventions [61,62,63]; motivational interviewing and enhancement [64,65]; and sources on self-help, Web-based, and distance-learning interventions [11,66,67,68]. Consistent with expert recommendations [63,69], module development centered on translation of evidence-based cognitive-behavioral approaches into brief Web-deliverable formats, and users were screened into modules only when they endorsed relevant symptoms. The interactive Web modules provide education and recommendations regarding effective coping strategies to manage mental health and health-risk behavior. Co-investigators and consultants were recruited to the research team on the basis of their high level of expertise relating to various content domains, and each of these collaborators assumed a significant role in module development. The intervention tested for purposes of this study consists of four modules: posttraumatic stress, depressed mood, generalized anxiety, and panic. The modules are interactive, and include printable monitoring sheets, fact forms, and progress checks.

The basic physical structure of the Website is described in greater detail elsewhere[16]. Briefly, the PTSD module provided psychoeducation addressing post-disaster PTSD symptoms as well as evidence-based recommendations focusing on exposure, avoidance reduction, and controlled breathing. Exposure-centered recommendations emphasized the distinction between dangerous vs. non-dangerous cues to ensure safety in exposure exercises and to move toward breaking problematic patterns of avoidance, consistent with best practice recommendations [70, 71]. The Depression module is based on behavioral activation strategies, which have shown promise as efficacious, parsimonious and costeffective approaches in treatment of depression [72,73,74]. Psychoeducation addressed prevalence and risk factors associated with depressive symptoms. The goal of the activationbased component was to increase healthy activities that yield reinforcing consequences and improvements in mood and quality of life [75]. To accomplish this goal, pleasant activity lists were used to recommend specific activities based on users' reported reward value and frequency of engagement. The Generalized Anxiety module, like the PTSD and Depression modules, included psychoeducation relating to prevalence and risk and protective factors for generalized anxiety both in the general population and among individuals exposed to recent stressor events. This module also emphasizes evidence-based cognitive behavioral approaches in the treatment of severe worry and generalized anxiety disorder, including psychoeducation, self-monitoring, relaxation training (diaphragmatic breathing), problem solving, and cognitive restructuring [76]. Finally, the Panic module included psychoeducation and emphasized the use of interoceptive exposure techniques. A "myths and facts" section of the site offered education about the relation between panic reactions and physical health. Five interoceptive exposure exercises, designed to reduce the user's fear of the bodily sensations associated with panic, were demonstrated via video. This module was modified from an Anxiety Sensitivity Amelioration Training (ASAT) protocol developed and tested by Schmidt and colleagues [77].

Assessment-only condition—At the time that participants accessed the study Website with their user ID, they were automatically randomly assigned to one of two conditions: (a) the full Web intervention, as described above, or (b) a comparison condition that consists only of the assessment components of the Web intervention. That is, the comparison condition lacked all of the educational components of the Website featured in the full, experimental version. The assessment components of the comparison condition, which were also used in the experimental condition, included: (a) symptom assessments, (b) "myths and facts" quiz questions, and (c) other questions asked in the context of education. Whereas correct answers to the myths/facts and educational questions were provided in the experimental conditions are comparable in structure with the exception of the educational content, participants assigned to the comparison condition likely were unaware of their assignment at least until the point at which they had completed a full module on the Website.

Statistical Methods

Our data analytic strategy entails a five-step process. First, we examined Census estimates of gender, age, and racial/ethnic characteristics of the sampling frame respondents (i.e., adults in Galveston and Chambers Counties) and those found in our sample. These comparisons were used to guide decisions around sample weightings. Second, descriptive statistics were used to fully characterize the sample on the different variables of interest at each point in time. These are presented in the *Results* section. Weighted contingency tables with appropriate statistical tests will be constructed to test for differences in key variables between the experimental and comparison group at baseline interview.

Third, descriptive statistics (e.g., percentages, means, medians, standard deviations) were based on data that emerged from the Web component of the study. These statistics summarized basic Web-usage statistics, such as how many participants in each group accessed the Web intervention, how many participants in each subsample accessed the Web intervention, how many participants screened into each of the four modules, what percentage of qualifying participants completed each of the modules, satisfaction estimates, and pre-intervention and post-intervention knowledge performance.

Fourth, correlational and chi-square analyses are being conducted to examine baseline variables associated with participation in the Web component of the study. That is, participants who *access* versus *do not access* the Web-based component of the study are being compared on demographics, traumatic event histories, and mental health outcomes.

The fifth step in data analysis is to examine the relative efficacy of the Web intervention modules in the experimental versus comparison conditions. Note that assignment to a particular condition is *not* sufficient to qualify the user for intent-to-treat (ITT) analyses. Rather, to qualify for ITT analyses under a particular Web module, participants must first have screened into the module as determined by symptom endorsements upon logging into the Website. For example, the study Website only recommended the PTSD module to participants who endorsed PTSD symptoms, regardless of condition.

For between-group analyses, only individuals in both the experimental and comparison groups with sufficient symptomatology to screen into a given module are being compared for each of the four mental health domains targeted by the intervention. Moreover, consistent with the intent-to-treat doctrine, data from participants in the experimental condition who screen into a module but do not complete the module will be included in analyses and compared to participants in the comparison condition who meet similar screening criteria (see Friedman et al., [78]). This will allow us to test the efficacy of the

intervention "as prescribed." As recommended by Friedman et al., secondary analyses are also being conducted that isolate participants in the experimental versus comparison conditions who *complete* a given module to measure the efficacy of the intervention "as delivered." Moreover, in post-hoc analyses, participants who screen into, but do not complete, a module are being compared on key baseline variables with participants who both screen into and complete the same module.

Loss to Follow-Up—With this randomly sampled population cohort, follow-up rates and their potential impact on conclusions drawn from this work are important. To maximize our follow-up of participants, we employed proven retention techniques. Participants were contacted at times that were most preferable for them. All efforts were made to minimize the likelihood of refusal and to re-contact individuals instead. Ultimately, we will manage the anticipated, inevitable, loss during follow-up assessments via statistical procedures. We will carry out analyses that consider the implications of any loss to follow-up, including comparisons of respondents versus non-respondents. Based on our earlier research [e.g., 35,79], we anticipated a retention rate of approximately 70%. Here, our retention rate was 70.1%.

Results

The sample is characterized in this paper, including demographic and hurricane-impact data. Other papers currently in preparation and under review describe mental health prevalence estimates and correlates, predictors of accessing the Web-based intervention, and feasibility and efficacy data.

Consistent with population distributions [80], 90.8% of participants resided in Galveston county, 9.2% in Chambers county. Notably, the Galveston-county population is primarily (91.6%) urban, whereas the Chambers-county population is primarily (64.3%) rural [80]. Three-fourths (74.3%) reported having left their home for at least one day because of Hurricane Ike. Of these, 835 (89.9%) evacuated prior to Ike's landfall, 65 (7.0%) after landfall, and 24 (2.5%) both before and after landfall. Most participants who left their homes returned to their homes in one week or less (58.3%). Another 18.2% was displaced for 1–2 weeks; 7.4% for 2–4 weeks; 4.6% for 1–2 months; 4.0% for 2–4 months; and 7.3% for greater than 4 months (26 were still displaced at the time of interview). Galveston-county residents were displaced an average of 24.8 days (SD = 68.1), Chambers residents 17.4 days (SD = 64.9).

Half (49.7%) of the sample reported being personally present when hurricane-force winds or major flooding occurred because of Hurricane Ike. Nearly one quarter (22.4%) reported that they were afraid they might be killed or seriously injured during Ike. Thirty-one participants (2.5%) reported physical injury as a result of the storm. One third (33.7%) reported being unsure about the safety or whereabouts of family members or close friends. Many participants experienced loss or damage with regard to their (a) place of residence (76.7%); (b) furniture, appliances, or other household contents (35.9%); (c) sentimental possessions such as photographs (19.6%); (d) cars or trucks (20.2%); (e) pets (4.6%); (f) crops, trees, or garden (73.2%); or (g) other property loss (31.7%). Participants also reported being without electricity for an average of 13.0 days (SD = 24.1); enough drinking water for 2.7 days (SD = 12.4); enough food for 1.0 days (SD = 4.0); shelter for 1.7 days (SD = 13.6); enough clean clothing for 1.9 days (SD = 10.2); adequate transportation for 2.4 days (SD = 22.8); and sufficient money for living expenses for 5.5 days (SD = 25.8).

Discussion

The goal of this research was to develop a web based intervention that is cost-effective (i.e., low cost to launch and maintain) and have broad applicability, targeting a range of mental health problems for which disasters increase risk. Consistent with sound practices in trauma-focused psychiatric epidemiology [81], we used a population-based epidemiologic strategy to evaluate the efficacy of an intervention that is designed to foster post-disaster resilience and recovery. The sampling strategy implemented was selected for its potential to maximize sample representativeness and the intervention was designed to be relevant for the majority of disaster affected adults. Strengths, challenges, and considerations for future research in this arena are discussed.

Strengths of the Current Methodology

There were several strengths of the current study that speak to both the advantages of the methodology and the utility of IBIs in assessing and addressing post-disaster mental health. First, as noted by Zatzick and Galea [81], it is critical to the external validity of this type of research to be able to characterize the study sample in terms of the population it represents. The entire affected population is expected to vary in terms of multiple important domains, including demographic characteristics, post-disaster functioning, and coping skills. The representative sampling approach used here allowed for the identification of survivors for whom this IBI was appropriate. Later comparisons between those who did and did not access the website and those who screened into specific modules, as well as between those selected for the study and those who participated in the larger telephone interview but were not selected for the IBI, will provide valuable information regarding the representativeness of the study sample, as well as differences between these groups. These comparisons may inform dissemination initiatives and improve predictions with regard to percentages of those in the total affected population who may use, screen into, and benefit from the intervention. Additionally, because there may be failure to replicate findings or other problems that arise when interventions are applied outside of the specific research setting due to unique elements of the population, including risk or protective factors that are not taken into account [81], the methods used in the current study allow us to develop and refine IBI content that may be useful for other disaster affected populations.

Random-digit dial methods of recruitment were chosen to enhance representativeness of the sample. However, recruitment via telephone did not necessitate that assessments be conducted by telephone. This decision has cost implications (e.g., lower cost to complete assessments via Web), but also may affect participation adversely because it affects to the burden of the participant. Despite cost implications, we chose to administer assessments via telephone for several reasons. First, telephone follow-up assessments may be less biased by potential demand characteristics that might be present if post-intervention assessment was completed over the web on the same site as the intervention. The survey interviewers are blinded to any web study information and this information is made clear to participants. Second, post intervention telephone assessment also offers the opportunity to contextualize the representativeness of web follow-up completers to other study participants at follow-up. Finally, telephone assessments allow for the use of empirically supported measures that efficiently gather information on factors such as disaster exposure, prior history of traumatic event exposure, prior mental health functioning, post-disaster functioning at critical time intervals, social and community support, and coping. Gathering this rich contextual data via computer-assisted telephone assessment with appropriate skip patterns allows for characterization of the study sample.

The choice to deliver intervention content via the internet conferred clear advantages. First, the content included in the intervention and its targeted internet-based delivery was

consistent with the aforementioned guidelines for intervention delivery for disaster survivors at-risk for poor outcomes [81] and provided a range of user experiences dependent on their level of risk. At the outset of the intervention, participants screened into specific modules (e.g., PTSD, depression). Although content delivery was automated and standardized, it was also flexible and adaptable to the needs of each individual user, creating a more effective and engaging experience [82]. Second, compared to traditional modes of intervention delivery, online interventions are well-poised to be widely and efficiently disseminated postdisaster. Despite potentially high startup costs, research health economics research suggests that IBIs appear to be more cost effective than other interventions (e.g., mailing out informational resources) as the reach of the intervention increases [83]. Christensen [82] described some of the additional benefits of using IBIs in addressing standard barriers to seeking care for mental health-related concerns. The consumer benefits of IBIs include: anonymity, convenience, flexibility in timing, and low cost. Finally, resources necessary for implementation are decreased by providing consumers with tailored assessment, feedback, and (when necessary) brief intervention without the cost associated with individual therapists [84].

Challenges Associated with the Current Methodology

Although all inter-disciplinary research faces the challenge of coordination of effort, the involvement of several teams across sites with distinct roles and responsibilities presented the main challenges to efficient and successful execution. There were three primary teams: MUSC investigative team, Abt SRBI survey team, and KeySurvey web programming team. The MUSC team was responsible for coordination of data collection. Abt SRBI's team of interviewers coordinated and conducted phone interviews and distributed participant incentives. KeySurvey was responsible for coordination and collection of all web-based intervention data. As a result of this division of labor, two independent data sets were produced; only participants' unique and randomly assigned passwords linked the data set variables and allowed for merger upon completion of the project. Whereas this approach had several advantages (i.e., affording high levels of confidentiality, allowing phone interviewers to remain blind to condition, and allowing for randomization to occur at the last possible moment prior to treatment administration), this complex division of labor also created communication difficulties. For example, any problems with web-intervention login resulted in participants calling SRBI, who possessed the means for participant identification; however, Abt SRBI lacked the capacity to access or amend any features of the webintervention necessary to problem solve internet user concerns. These issues required Abt SRBI to contact the project investigator's team, who then communicated with Keysurvey to resolve login problems beyond a lost/forgotten password. The MUSC team then reported Keysurvey's solutions back to Abt SRBI to communicate the solution to the user. In addition to requiring several steps, this process added time, cost, complexity, and the potential for additional burden to the participant.

Throughout the RCT, the MUSC team developed several approaches to reduce communication mishaps and lag time. These included considerable communication before data collection began regarding each team's roles for the RCT and well-outlined scheduled communications. The continued use of carbon copying emailing during the RCT helped keep communication within and between the teams up to date. Although limiting Abt SRBI as the main point of contact for participants added some lag time to problem solving, participant confusion was reduced, multiple participant contacts for one problem were avoided, and participant concerns about the web safety of their personal information was significantly reduced. Abt SRBI's use of the CATI interview programming system also enabled interviewers to remain blind to condition.

Considerations for Future Research

Access to the internet is widespread and increasing, with approximately two-thirds of individuals reporting broadband internet in their homes [85]. Although there are many understandable concerns about the availability of internet resources in the wake of a disaster, significant efforts are made by a number of groups to restore connectivity and provide access to the internet to survivors post-disaster, as was demonstrated following Hurricane Katrina [86]. Further, internet accessibility in public facilities (e.g., libraries) and via use of mobile devices continues to grow [87], increasing the viability of widespread IBI dissemination in the wake of disaster. National surveys show that eight out of ten internet users look for health-related information online [87], and approximately 22% look for information regarding mental health [88]; these numbers are expected to continue to increase [87]. However, several essential questions remain "next steps" for this line of research. The current study provided disaster-affected adults access to the intervention approximately one year after the disaster due to budget and timeline constraints; however, consistent with secondary prevention models, we would hypothesize that the intervention would have maximum benefit in the more acute aftermath of disaster; evaluation of intervention timing is an important next step for this line of research. Participants were incentivized for accessing the intervention for the purposes of the study; however, future research should explore effective dissemination strategies that employ more sustainable and cost-effective strategies in the long-term. Finally, future projects should examine the integration of IBIs (such as the one described here) into stepped-care models of intervention and treatment delivery [82]. Initial screening would direct users to psychoeducation/healthy coping information, brief intervention, or formal treatment referral based on indicated symptom levels, thus enhancing the applicability and public health impact of the intervention by addressing post-disaster needs ranging from bolstering resilience to referral for formal services.

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