Bounce Back Now! Protocol of a population-based randomized controlled trial to examine the efficacy of a Web-based intervention with disaster-affected families

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ABSTRACT

Disasters have far-reaching and potentially long-lasting effects on youth and families. Research has consistently shown a clear increase in the prevalence of several mental health disorders after disasters, including depression and posttraumatic stress disorder. Widely accessible evidence-based interventions are needed to address this unmet need for youth and families, who are underrepresented in disaster research. Rapid growth in Internet and Smartphone access, as well as several Web based evaluation studies with various adult populations has shown that Web-based interventions are likely to be feasible in this context and can improve clinical outcomes. Such interventions also are generally cost-effective, can be targeted or personalized, and can easily be integrated in a stepped care approach to screening and intervention delivery. This is a protocol paper that describes an innovative study design in which we evaluate a self-help Web-based resource, *Bounce Back Now*, with a population-based sample of disaster affected adolescents and families. The paper includes description and justification 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 study design include the use of address-based sampling to recruit a population-based sample of disaster-affected adolescents and parents, telephone and Web-based assessments, and development and evaluation of a highly individualized Web intervention for adolescents. Challenges related to large-scale evaluation of technology-delivered interventions with high-risk samples in time-sensitive research are discussed, as well as implications for future research and practice.

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1. Introduction

Disasters are a significant public health concern because they can affect the wellbeing of a substantial number of families simultaneously [29,54]. Disasters confront youth and families with a wide range of stressors, including threat of death or injury, loss of loved ones, limited access to basic needs, and financial strain. The prevalence of mental health disorders (e.g., PTSD, depression, substance abuse) increases in the post-disaster period (e.g., [18,31,42,53,55,61]). Widely accessible, evidence-based interventions are needed [33]. Tailored and automated interventions (i.e., do not require provider navigation) are of particular interest because they may address common access-to-care barriers.

Disaster mental health interventions for youth are a major priority. Pfefferbaum et al. [56]) and Soltis and Ruggiero [72] reviewed post-disaster intervention studies for youth. Most (n = 32 of 48) evaluated behavioral and/or cognitive interventions. Thirty were conducted outside of the US (i.e., [32,44,71]). Most were conducted with hurricane-affected samples (e.g., [39,67,68,75]). Many interventions were implemented several months or years after the disaster, and none was delivered with Web-based or mobile technology.

Rapid growth in Internet and Smartphone access presents an opportunity to deliver evidence-based resources widely and cost-efficiently [28,48]. Research has supported the feasibility of Web-based interventions [16,63], and Web-based interventions have performed well in efficacy evaluations among adults (see [4,7,58]). The few studies relating to child and adolescent mental health intervention programs have generally yielded encouraging findings, suggesting high potential for population-level impact [12,74].

The primary aim of this study was to evaluate the efficacy of *Bounce Back Now (BBN)*, a Web-based intervention for disaster-affected adolescents and parents. Address-based sampling was used to recruit adolescents and parents in Alabama and Joplin, MO; areas that experienced costly, deadly tornados in the spring of 2011 [49]. A secondary aim was to inform the knowledge of biologic underpinnings of PTSD and related phenotypes in youth via collection and analysis of adolescent saliva samples. Heritability estimates are moderate for PTSD (see [5]), but little is known about the molecular variation that accounts for genetic influence. Last, this study will inform the growing field of therapy genetics as the first to explore gene-by-treatment outcome interactions with a Web-based intervention. A small number of PTSD treatment studies have found that individuals carrying risk variants of certain genes, such as the *s'* allele of the *5-HTTLPR* and the Met-66 allele of the *BDNF* polymorphism, were less responsive to therapy than individuals homozygous for the major alleles for these genes [11,26].

2. Method

2.1. Study overview

A population-based randomized controlled trial (RCT) was conducted to examine the initial efficacy of *BBN*. A sample of 2000 disaster-affected families was recruited between September 2011 and June 2012. Structured baseline, 4-month, and 12-month interviews were conducted with an adolescent and a designated parent. When multiple eligible adolescents lived in the home, the adolescent participant was randomly selected using the most recent birthday method. Parents and adolescents were invited to access the Website after the baseline interview. Families were randomized to one of the three experimental conditions only after accessing the Website: (a) Web intervention for disaster-affected *youth* (i.e., addressing only adolescent outcomes via the adolescent and parenting modules), (b) Web intervention for disaster-affected *families* (i.e., addressing both youth outcomes but also adult outcomes via self-help modules accessible to the parents), or (c) an assessment-only Web-comparison. Web use and knowledge change data were collected. Adolescents also were invited to contribute a saliva sample. DNA was isolated from the received samples, and genotyping was conducted for the purpose of identification of genetic variation that contributes to post-disaster mental health symptoms in youth. All follow-up interviews were completed by August of 2013. We describe below the methodological aspects of the project as well as the rationale for critical methodological decision points.

2.2. Setting

The current project focused recruitment on two regions of the United States sustaining particularly severe impact from this spree of tornadoes. On April 27, 2011, northern Alabama experienced a historic 39 tornados ranging from Enhanced Fujita (EF) scale categories 4 (winds 166–200 mph) to EF 5 (winds greater than 200 mph). The tornadoes caused significant property damage, injury, and death. Over 14,000 homes were destroyed or deemed uninhabitable, 2200 people were injured, and 240 individuals lost their lives as a result of tornadoes impacting northern Alabama [3,49,51,77]. On May 22, 2011, an EF 5 Tornado struck the city of Joplin, Missouri, leaving more than 150 dead and over 1000 injured (Federal Emergency Management Administration [FEMA]; [50]), as well as leaving a wake of significant destruction in the town, including almost 7000 homes destroyed [23]. Households within these two regions that were within 5 miles of these tornadoes were included in our recruitment sample.

3. Rationale for selection of disaster-affected areas

Disaster-affected children and adolescents are at-risk for a variety of mental health problems [8,10,15] with the experience of PTSD and depressive symptoms being among the most prominent of outcomes [6,14]. Tornadoes occur more frequently than other disasters, and are unique in that they can strike with little warning, specific paths are largely unpredictable, patterns of damage are selective, and they have a devastating impact [21,51].

To date, there have only been a handful of studies examining mental health outcomes post-tornado [21,36,57]. Optimally, *Bounce Back Now* is designed for the 1–6 month period after disasters. We chose to recruit families affected by the spring 2011 tornado outbreaks for purposes of this study due to the relative recency of the outbreak and numerous risk factors present in the areas of Joplin, MO, and several areas of Alabama.