THE EFFECTS OF TRAUMATIC EVENTS ON VULNERABLE CHILDREN
IN INDIA

by

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A thesis submitted to the Faculty of the University of Delaware in partial fulfillment of the requirements for the degree of Master of Arts in Psychology

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by
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ABSTRACT
Childhood traumatic experiences and mental health outcomes are major global health problems, especially in low-resource communities. Research in low and middle-income country (LAMIC) contexts is needed in order to better understand the consequences of adverse experiences and trauma exposure in childhood. This study investigated the relations between trauma exposure, posttraumatic stress symptoms, and subsequent aggression and depressive symptoms in a sample of 288 children in rural Tamil Nadu, India. Of the children sampled, 66% reported having experienced a potentially traumatic event (PTE), with an average of 1.45 PTEs. There were marginal gender differences, with girls reporting a higher average number of PTEs. There were no significant gender differences in reported post-traumatic stress symptoms, but older children in the sample did tend to report higher levels of symptom severity. For this sample, PTEs and post-traumatic stress symptoms were highly intercorrelated, and these variables were also positively correlated with levels of depressive symptoms and aggressive behavior one year later. Results of mediation analyses were consistent with the hypothesis that post-traumatic stress symptoms act as a mediator between potentially traumatic events and aggressive behavior one year later. However, results showed that the post-traumatic stress symptoms did not mediate the direct pathway between potentially traumatic events and
depressive symptoms one year later. Implications of these results for psychological
theory and intervention development in LAMIC contexts are discussed.
Chapter 1

INTRODUCTION

The present study was designed to address an important gap in the low and middle-income country (LAMIC) literature by examining the prevalence, consequences, and mechanisms of influence related to potentially traumatic events (PTEs) in a sample of marginalized, at-risk children living in rural India. Although there is a robust literature in the United States and other high-income Western countries linking trauma exposure in childhood to adverse outcomes and evaluating the impact of related interventions, there has been relatively little research in LAMICs. Yet children who live in these countries are more likely to grow up under conditions of extreme adversity and to suffer significant negative consequences. For example, UNICEF (2003) reported that rates of child maltreatment leading to death are two to three times higher for children in LAMICs than they are in higher-income countries.

Within LAMICs, India has particularly high rates of poverty and disadvantage (Ayres & Torrijos Simon, 2010; Chauhan, 2009). According to a recent study by the McKinsey Global Institute (2014), about 680 million Indians live in poverty, with rural areas particularly impacted. Children in India also
suffer from high rates of PTEs. For example, a recent study of childhood maltreatment revealed that 33.1% of children had been victims of physical violence, 46.8% had experienced psychological violence, and 20.2% were victims of sexual violence (Dunne et al., 2009). Further, because the limited mental health resources in India and other LAMICs tend to be clustered in the most urban and affluent communities, children living in the poorest rural communities are not only more likely to suffer from extreme disadvantage, but are also more likely to have fewer resources to help them cope with the consequences (Morris et al., 2011). It is therefore critical to understand the impact of trauma and related mechanisms of influence in order to design culturally informed trauma interventions and to optimize use of scarce mental health resources.

An important first step is to examine empirically whether the effects of trauma on children growing up in these contexts are similar to effects found in higher income countries. Indeed, there is a substantial literature in high income, Western countries linking trauma exposure in children with a broad range of negative outcomes including neurobiological changes (for a review see Glaser, 2000), difficulties with interpersonal connections and trust (Kerig, Ward, Vanderzee, & Moeddel, 2009), physical health disorders (Leeb, Lewis, & Zolotor, 2011), mental health and behavioral disorders (Green, 1993; Shalev et al., 2013),
and other negative long-term health and mental health outcomes (Felitti et al, 1998).

Building on this literature, interventions such as trauma-focused cognitive-behavioral therapy (TF-CBT) have been developed to address these concerns. TF-CBT (Cohen, Mannarino, & Deblinger, 2006) is one evidence-based treatment for children presenting with post-traumatic stress disorder (PTSD) that utilizes a structured individual and caregiver-involved model to address PTSD symptoms through skills-based and trauma-focused components of treatment. TF-CBT has a solid evidence base and has been used flexibly to address the needs of children experiencing complex trauma presentations and significant behavioral problems (Cohen, Berliner, & Mannarino, 2010).

In contrast to the robust literature in the United States, past studies of trauma in LAMICs have focused primarily on prevalence rates and evaluations of psychosocial interventions for acute and time-limited traumas, such as natural disasters or war-related violence (Bhadra, 2012; Murray et al, 2013; Rajkumar, Mohan, & Tharyan, 2011). Recently, researchers have begun to adapt and utilize the TF-CBT intervention model with children in various LAMICs. The intervention has been evaluated with sexually-exploited war-affected children in the Democratic Republic of the Congo (O’Callaghan, McMullen, Shannon, Rafferty, & Black, 2013) and orphans and vulnerable children in Zambia (Murray
et al, 2013). It is also currently being implemented in Tanzania, China, Cambodia, and Indonesia (Dorsey, Briggs, & Woods, 2011).

Little is known about the effects of other types of extreme or chronic trauma on children in these contexts, and even less is known about the potential causal pathways between traumatic experiences and subsequent outcomes that could inform interventions. However, studies that examined post-traumatic stress (PTS) symptoms in LAMICs after acute events such as disasters have found generally that prevalence of PTSD varies significantly depending on the context and measures used. For example, reported rates of PTSD in Indian villages after the 2004 Asian tsunami ranged from 15% to 70% (John, Russell, & Russell, 2007; Rajkumar, Mohan, and Tharyan, 2011).

The present study focused on the impact of PTEs on aggressive behavior and depressive symptoms and whether PTS symptoms mediate these relations. PTS symptoms are commonly associated with difficulty regulating emotions and behaviors, and could be one potential mechanism through which PTEs in childhood could affect subsequent outcomes. Behavior and emotion regulation are important aspects of psychological adjustment and functioning for children, especially following trauma exposure or chronic maltreatment. Both aggression and depression can seriously compromise children's development, and there is much interest in developing related prevention and treatment programs that
incorporate awareness of the effects of trauma (Bhadra, 2012; Escueta, Whetten, Ostermannn, & O'Donnell, 2014; Morris et al., 2011; Nooner et al., 2012).

Studies in the United States have linked PTEs and both aggression and depressive symptoms (Attar, Guerra, & Tolan, 1994; Greeson et al., 2013; Kerig, et al., 2009; Nooner et al., 2012; Rosario, Salzinger, Feldman, & Ng-Mak, 2003). In some cases, trauma exposure has been associated with clinically significant outcomes. For example, Greeson et al. (2013) reported a significant dose-response relation between the numbers of trauma types children experienced and increased odds of scoring within the clinical range of externalizing and internalizing problems. Exposure to violence and child maltreatment has been linked to externalizing problems in general and also to violent or aggressive behavior in children and adolescents (Osofsky, Wewers, Hann, & Fick, 1993; Salzinger, 1999).

PTS symptoms also have been shown to strengthen the relation between exposure to traumas and subsequent aggressive behaviors among adolescents (Moretti, Obsuth, Odgers, & Reebye, 2006). For example, a study by Allwood and Bell (2008) found that in the United States, PTS symptoms (along with cognitions about violence) mediated the association between trauma exposure and aggressive behaviors in a sample of early adolescents. There also is a robust literature on the association between PTS symptoms and depression in the United
States, showing strong comorbidities between the two disorders (Kessler, Sonnega, Bromet, Hughes, & Nelson, 1995). Many treatments for PTSD have been shown to reduce depressive symptoms alongside reductions in PTS symptoms (Harvey, Bryant, & Tarrier, 2003).

In the LAMIC context, some preliminary work by Ruchkin and colleagues (2005) examined PTS symptoms across several countries. They found that the psychological consequences of trauma, including externalizing and internalizing behaviors, mirrored patterns in the United States and other Western countries. In a related cross-national study of adversity and vulnerability among children living in Southeast Asia and Sub-Saharan Africa, Escueta and colleagues (2014) reported that exposure to PTEs, male gender, and lower socioeconomic status were associated with emotional difficulties as well as lags in cognitive development. Previous work in India (Rasmussen, Karsberg, Karstoft, & Elklit, 2013) has demonstrated a significant link between number of PTEs a child has experienced and subsequent PTS symptoms.

The three aims of the present study were: (1) to examine overall prevalence of PTEs and PTS symptoms in a sample of poor, rural primary school children in India; (2) to examine relations between PTEs and aggression and depressive symptoms; and (3) to examine whether PTS symptoms mediate the relation between PTEs and aggressive behavior and depressive symptoms.
Building primarily on studies in the United States and high-income Western countries as well as the limited research in LAMICs, we hypothesized that exposure to trauma would predict aggressive behavior and depressive symptoms and that PTS symptoms would mediate the relationship between trauma exposure and these outcomes, with higher levels of PTS symptoms linked with increases in aggression and depressive symptoms one year later.
Chapter 2

METHOD

2.1 Overview and Context

The design and implementation of this study was guided by a Participatory-Based Action Research (PAR) approach that emphasizes the importance of understanding the local community cultural context and engaging community members and child participants (Shadowen, in press). The study was carried out with marginalized Dalit (Untouchable or Scheduled Castes) children in Villapurum, Tamil Nadu, India, in close collaboration with a local non-governmental organization, Communities Rising. This organization provides out-of-school education support to children and parents, and is actively involved in the local community. Bilingual staff provided input and cultural guidance on all aspects of the research. The Institutional Review Board (IRB) at the University of Delaware approved the project.

2.2 Participants and Procedures

Participants were recruited from 13 public (government-managed) and private (diocese-managed) schools in impoverished rural areas. Surveys were conducted in schools at two points in time approximately one year apart. At Time
1 a total of 339 children were surveyed, 150 who were fourth graders and 189 who were fifth graders. At Time 2, a total of 288 children were surveyed, representing 85% of the original sample and approximately the same age distribution. At Time 2, mean age for participants was 10.51 (SD=.629), and they were evenly distributed by gender with 50.5% (145) boys and 49.5% (143) girls.

Bilingual trained youth surveyors collected the data. The research team identified seven local young adults who spoke fluent English and Tamil (the local language) and at a minimum had received a bachelor’s degree. The youth surveyors received an 8-hour training from the principal investigator on-site; the training discussed the theory and practice of research, data collection, and human subjects training and issues. Following a PAR approach, the primary researchers included the youth surveyors and local community in the strategic planning and logistics process and included strategies such as taking time to build relationships, establishing trust between the academic researchers and the local team, and capacity building for the youth surveyors (Hacker, 2013). The youth surveys administered the measures to participants individually and orally via a structured interview survey format. Data collection took place in the classrooms either immediately after the completion of the school day, or during a free-time period during the day. All survey interviews were conducted in Tamil. For most child-surveyor dyads, the interview took about 45 minutes to complete.
2.3 Measures

In selecting survey measures for the study we relied primarily on measures that had been validated previously in the United States and LAMIC contexts. For the psychological constructs we chose measures with evidence of reliability, validity, and cross-cultural validation studies. Our Indian youth surveyors analyzed each question for appropriateness in the Indian context. Questionnaire items were translated into Tamil by an Indian bilingual English professor and then back-translated. In some instances, it was necessary to adapt item wording to improve understanding or relevance to the local cultural context.

2.3.1. Demographic questions

Demographic questions included information about the child’s age and gender. Items about the construction of the roof of the child’s home (an indicator of level of poverty in this setting), the number of meals received a day, and the presence of running water or toilets in the home were combined to form a “poverty index” for each child. The index was developed in collaboration with the local partner organization and was partially based upon the methodology of the Demographic Health Surveys Program wealth index (Escueta et al., 2014). Items were designed to be easily reportable by a child and appropriately measure poverty in this context. This poverty index was then separated into “high poverty”
and “low poverty” groups based on high and low scores. The poverty index categories represent relative poverty within the sample.

2.3.2 Trauma exposure

The exposure questions from the *UCLA Posttraumatic Stress Disorder Index for DSM-IV* (PTSD-RI; Steinberg & Brymer, 2008; Steinberg, Brymer, Decker, & Pynoos, 2004) were used to specify whether or not the children had been exposed to nine PTEs. This well-validated measure is used to screen for exposure to various traumatic events. A “yes/no” scale was used to quantify the number of traumas experienced. These trauma exposure items were modified from the original 13 questions. The trauma exposure questions were adapted to reflect circumstances that would be likely experienced by an Indian child in this area (i.e., “Being in any kind of disaster, like a hurricane, tsunami, fire, or flood”). Additionally, due to the fact that appropriate child protection services were not available in this area in India, questions about direct victimization (i.e., sexual abuse and physical abuse directed toward the child) were removed from the exposure questionnaire.

2.3.3 Trauma symptoms

Trauma symptoms were measured using the severity index of the PTSD-RI (Steinberg & Brymer, 2008; Steinberg et al., 2004). The PTSD-RI has been
used extensively to assess posttraumatic stress disorder among children and adolescents ages 7 to 18 years old, both for research and clinical purposes (Steinberg, et al., 2013; Steinberg, Brymer, Decker, & Pynoos, 2004). The measure has been used internationally, and has been translated and employed in countries as diverse as Armenia (Pynoos, Goenijian, Tashjian, et al, 1993), Turkey (Laor, et al., 2002), Taiwan (Chen, Lin, Tseng, & Wu, 2002), Nicaragua (Goenjian, et al., 2001), Chile (Garfin, et al., 2014), and Zambia (Murray, et al., 2011).

The instrument consists of 20 items in the posttraumatic stress disorder symptom domains of numbing/avoidance, arousal, and re-experiencing symptoms. Items are rated based on whether symptoms were experienced over the past month on a scale from 0 (none of the time) to 4 (most of the time). These three symptom domains map directly onto the DSM-IV PTSD Criterion B (intrusion; 5 items), Criterion C (avoidance; 7 items), and Criterion D (arousal; 5 items). Two additional items assess the associated features of fear of recurrence and trauma-related guilt. The overall trauma scores were computed according to standard scoring instructions. Sample questions include “I have dreams about what happened or other bad dreams,” (Criterion B) and “I have trouble concentrating or paying attention” (Criterion D). Past studies have reported
internal consistency in the .90 range (Steinberg, Brymer, Decker, & Pynoos, 2004) and high test-retest reliability. Our study had a Cronbach’s alpha of .89.

2.3.4 Aggression

Aggression was measured using 8 items adapted from the physical and relational aggression subscales from the Farrell, Kung, White, & Valois (2000) Problem Behavior Frequency scale. In previous studies this scale has shown adequate reliability ($\alpha = .82-.85$) in youth samples. This scale also showed strong reliability ($\alpha = .84$) for Jamaican adolescents when items were included in the Jamaica Youth Survey (Gardner, Williams, Guerra, & Walker, 2011). For all items, children were asked to indicate how frequently they engaged in the particular behavior over the past two months. Responses were based on a 4-point scale: 0 (never), 1 (sometimes), 2 (almost always), and 3 (always). Some of the items addressed physical aggression (i.e., “Hit or slapped someone”) while others measured nonphysical verbal aggression (i.e., “Insulted someone’s family to the person’s face”) Reliability for the scale in our sample was high at .88.

2.3.5 Depressive symptoms

To measure depressive symptoms we used the Patient Health Questionnaire, modified for children and adolescents (PHQ-9; Spitzer, Kroenke, & Williams, 1999). The PHQ-9 is a publically available multipurpose measure for
screening, measuring, and monitoring various depressive symptoms through a short self-report measure. DSM-IV diagnostic criteria are incorporated along with other leading major depression symptoms. These symptoms are rated on frequency as well as presence. The validity of the PHQ-9 has been established through many studies, including eight primary care studies in the U.S. (Kroenke, Spitzer, & Williams, 2001; Kroenke & Spitzer, 2002; Lowe, Unutzer, Callahan, Perkins, & Kroenke, 2004; Spitzer, Kroenke, & Williams, 1999). A sample item from this measure is “Over the past two weeks, how often have you been bothered by feeling down, depressed, or hopeless?” Cronbach’s alpha was .66 in our sample.
Chapter 3

RESULTS

3.1 Analysis Plan

The central study hypothesis was that the effects of PTEs and related PTS symptoms would develop over time. Consequently, analyses examining the effect of PTEs and PTS symptoms on aggressive behaviors and depressive symptoms were modeled using Time 1 (T1) scores of PTEs and PTS symptoms and Time 2 (T2) scores for aggressive behaviors and depressive symptoms, controlling for T1 scores. This approach tests for effects at a specific point in time approximately one year after a child has experienced a PTE and exhibits any PTS symptoms related to the trauma. We considered PTS symptomatology as a continuous variable rather than a binary or categorical variable associated with a diagnostic status. Often youth do not meet the threshold of 38 suggested by Rodriguez, Steinberg, Saltzman, and Pynoos (2001) for a full diagnosis of PTSD but they still experience symptoms of PTS to a degree that interferes with daily functioning (Kerig et al., 2009; Newman, 2002).

A parametric resampling approach using bootstrapping sampling procedures was used to test the mediation effect of PTS symptoms (MacKinnon, Lockwood, & Williams, 2004; Preacher & Hayes, 2008) on the change in
depressive symptoms and aggressive behaviors at T2, controlling for T1 levels of these variables. This bootstrapping procedure was used because it is robust to non-normality of the sampling distribution and to sample and effect size (MacKinnon et al., 2004). We used the Preacher & Hayes’ (2008) SPSS macro PROCESS to test mediation utilizing 5,000 bootstrap resamples. This bootstrap procedure is considered to be the most rigorous and powerful test of mediation effects, as bootstrap tests use sample data to estimate the sampling distribution of the indirect effects from re-sampling of the data, rather than relying on assumptions of normality in the indirect effect and standard error (Preacher & Hayes, 2008; Zhao, Lunch, & Chen, 2010). Bootstrapping procedures generate an estimate of the indirect effect, including a 95% confidence interval. If zero is not in the 95% confidence interval, it can be concluded that the indirect effect is significantly different from zero at $p < .05$, and that the effect of the independent variable on the dependent variable is mediated by the proposed intervening variable (Efron & Tibshirani, 1993).

### 3.2 Descriptive statistics and demographics

We first report descriptive statistics on PTEs for the T1 sample. A total of 66% ($n = 190$) of the children surveyed at T1 reported trauma exposure. The most common reported events were being in a place where people were physically
fighting (47.2%), seeing a family member being hit, punched, or kicked very hard at home (36.7%), and seeing someone being stabbed, badly beaten, or killed (31.1%). The mean number of trauma experiences in the whole sample was 1.45 ($SD = 1.43$). Of those children who had experienced at least one PTE, the average number of PTEs was 2.20 ($SD = 1.21$). On average, females were more likely to have experienced at least one event (PTE; 69%) than the males in the sample (62%). This gender difference in PTEs was not significant; however, there was a significant association between gender and the total number of PTEs experienced when analyzed in a one-way ANOVA ($F_{1, 272} = 3.97, p < .05$). On average, females experienced more traumatic events (1.61 events) compared to males (1.26 events).

Table 1 presents descriptive statistics for PTS symptoms (PTSD-RI scale) for the total T1 sample. Girls reported slightly higher levels of trauma severity compared with boys. Children in the older age group (11-13 years old) also reported higher overall levels of PTS symptom severity, and scores were higher for children who experienced multiple PTEs compared to just one PTE. High poverty children (as measured by the poverty index) reported greater severity of trauma symptoms. Table 2 presents these descriptive statistics for children who reported at least one PTE ($n = 190$).
Table 1.

*Mean, Standard Deviation, and Range of PTSD-RI Total Score by Gender, Age, PTE Frequency, and Poverty Index for All Participants*

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>M</th>
<th>SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Sample</td>
<td>288</td>
<td>10.84</td>
<td>11.37</td>
<td>0-51</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boys</td>
<td>146</td>
<td>9.93</td>
<td>11.33</td>
<td>0-51</td>
</tr>
<tr>
<td>Girls</td>
<td>143</td>
<td>11.77</td>
<td>11.37</td>
<td>0-41</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9-10</td>
<td>145</td>
<td>9.19</td>
<td>9.99</td>
<td>0-41</td>
</tr>
<tr>
<td>11-13</td>
<td>144</td>
<td>12.5</td>
<td>12.43</td>
<td>0-51</td>
</tr>
<tr>
<td>Trauma Freq.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>70</td>
<td>12.54</td>
<td>9.21</td>
<td>0-47</td>
</tr>
<tr>
<td>Multiple</td>
<td>120</td>
<td>18.58</td>
<td>10.28</td>
<td>0-51</td>
</tr>
<tr>
<td>Poverty Index</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Poverty</td>
<td>76</td>
<td>12.41</td>
<td>12.58</td>
<td>0-51</td>
</tr>
<tr>
<td>Low Poverty</td>
<td>129</td>
<td>11.29</td>
<td>11.23</td>
<td>0-47</td>
</tr>
</tbody>
</table>

*Note.* Poverty level split into highest and lowest scores on the Poverty Index
Table 2.

*Mean, Standard Deviation, and Range of PTSD-RI Total Score by Gender, Age, PTE Frequency, and Poverty Index for PTE-exposed Children Only*

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>M</th>
<th>SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Sample</td>
<td>190</td>
<td>16.36</td>
<td>10.30</td>
<td>0-51</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boys</td>
<td>91</td>
<td>15.80</td>
<td>10.62</td>
<td>0-51</td>
</tr>
<tr>
<td>Girls</td>
<td>99</td>
<td>16.87</td>
<td>10.02</td>
<td>0-41</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9-10</td>
<td>90</td>
<td>14.81</td>
<td>8.77</td>
<td>0-41</td>
</tr>
<tr>
<td>11-13</td>
<td>100</td>
<td>17.75</td>
<td>11.36</td>
<td>0-51</td>
</tr>
<tr>
<td>Trauma Freq.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>70</td>
<td>12.54</td>
<td>9.21</td>
<td>0-47</td>
</tr>
<tr>
<td>Multiple</td>
<td>120</td>
<td>18.58</td>
<td>10.28</td>
<td>0-51</td>
</tr>
<tr>
<td>Poverty Index</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Poverty</td>
<td>52</td>
<td>18.13</td>
<td>11.27</td>
<td>0-51</td>
</tr>
<tr>
<td>Low Poverty</td>
<td>86</td>
<td>16.78</td>
<td>10.37</td>
<td>0-47</td>
</tr>
</tbody>
</table>

*Note.* Poverty level split into highest and lowest scores on the Poverty Index
Correlations among the study variables are presented in Table 3. PTEs and PTS symptoms were included at T1 and aggressive behavior and depressive symptoms were included at T2. As expected, PTEs and PTS symptoms were highly positively correlated ($r = .66$) and PTS symptoms were significantly intercorrelated with Time 2 levels of aggressive behavior ($r = .35$) and internalizing symptoms ($r = .21$). Additionally, there was a significant dose-response relation between number of PTEs and PTS symptoms when analyzed in a one-way ANOVA ($F_{6, 282} = 53.41, p < .001$), such that a one-unit increase in PTEs was associated with an increase in PTS symptoms.

Independent samples t-tests were conducted using Bonferroni adjusted alpha levels of .0125 (.05/4) per test. These analyses revealed a marginal gender difference for number of PTEs experienced, $t (277.51) = 2.41, p = .02$, with girls showing increased PTEs. However, there did not appear to be significant gender differences on the PTS symptom severity scores, $t (287) = 138, p = ns$. Boys had higher T2 aggression scores, $t (281.5) = -2.56, p < .01$. Children with higher levels of poverty reported higher overall depressive symptoms, $t (122.83) = -4.80, p < .01$. Additionally, older children reported higher levels of PTS symptom severity, $t (273.51) = 2.49, p < .01$. Results are reported in Table 4.
Table 3.

**Bivariate Correlation Coefficients and Descriptive Statistics**

<table>
<thead>
<tr>
<th>Variable</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Trauma Exposure</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. PTEs (Time 1)</td>
<td>.73**</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. PTS Symptoms (Time 1)</td>
<td>.67**</td>
<td>.66**</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Depressive Symptoms (Time 2)</td>
<td>.11</td>
<td>.18**</td>
<td>.21**</td>
<td>-</td>
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</tr>
<tr>
<td>5. Aggressive Behaviors (Time 2)</td>
<td>.28**</td>
<td>.31**</td>
<td>.35**</td>
<td>.27**</td>
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Mean (SD)

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<tr>
<th></th>
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<th>1.45</th>
<th>10.84</th>
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<td></td>
<td>(0.48)</td>
<td>(1.43)</td>
<td>(11.37)</td>
<td>(2.38)</td>
<td>(5.28)</td>
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*Note. N = 288. * p < .05, ** p < .01.*
Table 4.

Independent T-Test Results for Mean Differences by Gender, Poverty Status, and Age

<table>
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<tr>
<th>Variable</th>
<th>Females</th>
<th>M</th>
<th>SD</th>
<th>Males</th>
<th>M</th>
<th>SD</th>
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<td>1.53</td>
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<td>4.78</td>
<td>7.42</td>
<td>5.62</td>
<td>-2.56</td>
<td>**</td>
<td>.01</td>
<td>281.5</td>
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<td>287</td>
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<tr>
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<td>12.50</td>
<td>12.43</td>
<td>9.19</td>
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<tr>
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Note. N=288. Adjusted p-values of †p< .05 * p< .0125 ** p< .01
3.3 Post-traumatic stress symptoms as a mediator

We first tested whether PTS symptoms mediated the relation between PTEs and aggression. This is illustrated in Figure 1. As shown, the direct path from PTEs to aggressive behavior was statistically significant ($B = -1.02, p < .001$), as was the path from PTEs to PTS symptoms ($B = 5.28, p < .001$), and the path from PTS symptoms to aggressive behaviors ($B = 0.10, p < .01$). There was a significant indirect effect of PTS symptoms on aggression using both a bootstrapped confidence interval (95% CI: [0.14, 0.91] with 5,000 resamples) and normal theory testing (Sobel $z = 2.56, p < .01$). Directions of the significant paths are consistent with the idea that trauma exposure (increased number of PTEs) leads to greater endorsement of PTS symptoms, which in turn leads to increases in levels of aggressive behavior one year later. The evidence for a significant negative direct effect and a positive mediated pathway effect is consistent with what is variously called a “competitive mediation” model (Zhao, Lynch, & Chen, 2010) or an “inconsistent mediation” model (MacKinnon, Krull, & Lockwood, 2000). In this type of model the direct effect and mediated effect are of different signs. This type of model indicates that although a portion of the effect of the independent variable on the dependent variable is explained, that there is likely an additional mediator of the same sign as the direct effect which “competes” as an explanatory variable with the mediator included in the model (Zhao et al., 2010).
The second mediation analysis examined the potential effect of PTS on the relationship between trauma exposure and depressive symptoms one year later (Figure 2). The model demonstrated that there was a positive total effect of PTEs on depressive symptoms ($B = 0.29, p < .01$). However, there was no significant direct path from the PTEs to depressive symptoms ($B = 0.24, p = .06$), or $b$ path from PTS symptoms to depressive symptoms ($B = 0.01, p = ns$). Results demonstrated that there was no significant indirect effect of PTS symptoms on internalizing symptoms (95% CI: [-0.18, 0.24] with 5,000 resamples; Sobel $z = 0.56, p = ns$). Although there is a total effect for this model, it does not appear that PTS symptoms mediate the relationship between PTEs and depressive symptoms one year later for children in this sample.
Figure 1. Simple mediation model, PTS symptoms mediating aggressive behavior
Figure 2. Simple mediation model, PTS symptoms mediating internalizing symptoms

![Diagram showing the relationship between PTE, PTS symptoms, and internalizing symptoms.](image-url)
Chapter 4

DISCUSSION

The current study examined PTEs, PTS symptoms, aggressive behavior and depressive symptom outcomes in a sample of rural marginalized Indian children. Looking at prevalence of PTEs, approximately two-thirds of the children surveyed had experienced a PTE. Youth in this study experienced, on average, 1.45 PTEs, which is slightly lower than might have been expected given results from the United States and samples in Western Europe (Steinberg et al., 2009). However, the survey was limited in the number and types of PTEs queried. The exclusion of PTE questions regarding sexual and physical abuse as well as chronic traumas may have limited the detectability of the full range of traumas experienced by children in this context. Additionally, past studies have shown that the mean number of experienced traumas tends to increase with age (John, Russell, & Russell, 2007; Steinberg et al., 2009). As our sample consisted of 9-to-13-year-old children, it is possible that an adolescent sample of Indian youth would yield results more comparable to other work on PTEs.

Girls in our sample were marginally more likely to have experienced a PTE, and also, on average, had experienced more PTEs. However, the reported
rates of PTS symptoms among boys and girls in this sample were similar, which differs from the general finding in the Western literature that females tend to report higher PTS symptomatology (Cohen et al., 2010; Kimerling, Ouimette, & Wolfe, 2002; Steinberg et al., 2013; Tolin & Foa, 2006) but consistent with a prior study in India that found no gender differences in reported prevalence of PTSD (Rasmussen, et al., 2013). Still, researchers are uncertain why there are gender differences in PTS symptoms in the general Western literature. Such a difference may be due to differences in types of traumas experienced, differences in the stress response between genders, or greater willingness of girls to report and endorse distress symptoms (Nooner et al., 2012; Steinberg et al., 2008). The lack of gender differences among young children in India may be due to cultural norms regarding willingness to discuss and endorse distress regardless of gender. Alternatively, it could be that girls and boys have similar rates of PTS symptoms following PTEs. Additionally, we found a positive dose-response relationship between number of traumas experienced by the children and their reported PTS symptoms. This is concordant with the literature in both Western and LAMIC countries (Ruchkin, Schwab-Stone, Jones, Cicchetti, Koposov, & Vermeiren, 2005; MacDonald et al., 2010; Steinberg et al., 2008) and provides some preliminary evidence for the validity of the PTSD-RI scale for use with this population.
The results of the mediation model for aggressive behaviors suggest that PTS symptoms partially mediate the relationship between PTEs and aggressive behaviors one year later. The overall indirect pathway between PTEs and aggressive behaviors through PTS symptoms is positive, suggesting that children who experience a PTE and then develop PTS symptoms tend to exhibit increased aggressive behaviors over a one year period. This is consistent with the literature showing the negative effects of trauma and early childhood adversity on subsequent externalizing behavior among children and adolescents. Research suggests that trauma experiences can cause a state of physiological and psychological distress such that executive functions of the brain are overtaken by fear and alarm (Ford et al., 2010). If distress symptoms continue past the duration of the trauma (as may happen when children develop PTS symptoms), the trauma symptoms may lead to hypervigilance and “survival coping” and to externalizing behaviors such as defiance and callousness (Ford et al., 2010; Kerig et al., 2009). Trauma exposure and PTS symptoms may influence aggressive behaviors through loss of self-regulation, hypervigilance that leads to “lashing out”, and difficulties interpreting and responding to social cues (van der Kolk, 2003). Past studies have also demonstrated a link between PTS symptoms and increased incidence of feelings such as “hatefulness” and “revenge” (Lopes Cardoza, Kaiser, Gotway, & Agani, 2003).
However, for children who experience a PTE but do not subsequently experience the intrusion, arousal, or avoidance symptoms typical of PTSD there appears to be a negative association between trauma exposure and aggressive behavior. In other words, without accounting for PTS symptoms, the direct relation between the experience of PTEs and aggressive behaviors is negative. This is an unexpected finding and is somewhat difficult to interpret without follow-up interviews with the children. Aggression and more serious antisocial behaviors are multiply determined outcomes (Dodge & Pettit, 2003); therefore variation in aggressive behavior following experience of a PTE likely depends on many contextual and individual factors. It may be that whereas some children become more hypervigilant and ready to fight as a coping strategy, other children who do not experience PTS symptoms withdraw following traumatic experiences and interact less with others, leading to less opportunities to be aggressive or to less aggressive behavior. This is consistent with the Indian cultural context where it often is culturally adaptive to avoid confrontation or potentially conflictual situations.

These findings suggest that trauma exposure predicts individual differences in future aggressive behaviors partially through the effect of PTS symptoms. However, due to the nature of “competitive mediation” models, it is possible, and likely, that there is at least one other mediator between trauma
exposure and aggressive behavior that was not captured by our study, such as social withdrawal (Bolger & Patterson, 2001; de Paul & Arruabarrena, 1995).

The model examining the pathway from trauma exposure to depressive symptoms was not mediated by PTS symptoms. This is at odds with studies in the United States that demonstrate a link between PTS symptoms and internalizing disorders such as anxiety and depression (Green, 1993; Singer, Humphreys, & Lee, 2013; Steinberg et al., 2009). However, the model did reveal a total positive effect of PTEs and PTS symptoms together on later depressive symptoms, such that earlier trauma exposure and PTS symptoms led to increases in later depressive symptoms. This is consistent with literature that describes the development of depression in traumatized children and adolescents who do not develop comorbid PTS symptoms (Lipschitz, et al., 1999).

These findings highlight the potential importance of psychosocial support and interventions aimed at alleviation of PTS symptoms in order to prevent mental health problems in LAMICs such as India, particularly with the poorest and most marginalized children. Although it clearly is best to prevent trauma experiences, in many communities around the world these stressors are simply part of daily life. However, through targeted interventions to reduce PTS symptoms and help children understand and cope with trauma, it may be possible
to reduce the link between exposure and aggression, a behavior that further compromises children's development and ability to perform well in school.

It is important to understand the relations between PTEs experienced in childhood and externalizing and internalizing symptoms in children, as these factors can impact many negative subsequent areas of children’s lives (Greeson et al., 2013; Liu, 2004). This study has attempted to address the paucity of empirical research on the association between children’s exposure to stressors and subsequent psychological outcomes. Most empirical knowledge about trauma and childhood has been conducted in the West, and it is crucial that the topic be assessed within LAMIC where interventions will be applied (Deb & Walsh, 2012). By including understudied populations in different cultures and countries it is possible to learn more about psychological processes that are similar across cultures, as well as nuanced details of how they may differ. Similarities across cultures in these mechanisms allow for development of interventions that may be used across settings. As the results show, trauma exposure in this rural and poor LAMIC population is associated with negative behavioral and mental health outcomes similar to findings in the United States and other high income countries. Still, there are some differences, particularly in the relation between trauma exposure and aggression when PTS symptoms do not develop, that suggest culture specific modifications, at least with this rural Indian population. Indian
children in this context may benefit from tailored, flexible intervention approaches that assess trauma-related symptoms as well as depressive systems.

This study’s findings should be considered in light of several important limitations. Conducting rigorous research in the LAMIC context provides many logistical and research process challenges. Due to the lack of community resources available to assist children if they had reported specific instances of abuse, we did not include specific types of interpersonal violence PTEs such as physical and sexual abuse directed at the child. The exclusion of these types of stressors from our study may have impacted the rates at which children reported PTEs. Additionally, although every effort was made to ensure the cultural validity of the measures employed, the measures were developed in a United States context and have not been extensively tested with children in LAMIC settings or in India. Further research is needed in order to rigorously evaluate and develop psychosocial measures for children in LAMIC contexts, as the lack of such existing measures is a serious barrier to providing evidence-based research and care to youth in these areas (Kohrt, et al., 2011). Additionally, due to challenges related to inclusion of parents and teachers in the study, the children completed all measures in the current study, increasing the potential for shared method variance to bias findings.
The current study provides an initial framework for understanding how PTS symptoms may function in relation to certain types of negative outcomes among children living in rural India. Future work should include more diverse types of acute PTEs, and should also investigate more chronic types of trauma such as abuse and neglect, daily harassment, parental separation, and alcohol abuse in the family. A growing area of study in the U.S. has been the examination of long-term chronic stressors such as poverty, family instability, and chronic violence exposure and the harmful effects of these events on children’s development and outcomes (Bolger & Patterson, 2001). Given the general marginalization of many communities in LAMIC and for the Indian Dalit caste in particular, levels of deprivation and poverty itself should be studied as a potential factor in the relations between acute stressors and negative outcomes. Youth who are exposed to repeated and chronic stressors often may exhibit different patterns of PTS symptoms than those who have experienced acute trauma, which in turn could lead to different developmental trajectories (Kerig et al., 2009). A greater understanding of chronic childhood adversity and impacts on negative outcomes and overall childhood well-being can help providers best deliver services for children in marginalized contexts.

Additionally, future work could take a developmental approach to the understanding of childhood risk factors in LAMIC contexts. A careful
longitudinal analysis of the effects of chronic and acute stressors on psychosocial outcomes over time would provide additional information on the role of PTS symptoms as a mediator. Future studies in LAMIC contexts should also examine the links between PTEs and other important childhood outcomes which have been found to be related in the United States, such as academic success (McGill et al., 2014) and school engagement (Voisin & Elsaesser, 2013). Further research is also needed to examine other potential mediators that may link PTEs with negative outcomes in childhood. External factors such as social support, parental engagement, and poverty level may act as mediators. Individual symptomatology such as hypervigilance, social withdraw, and coping style could also be examined to understand the role of each specific element. A greater understanding of the role of individual symptomatology in the development of PTS symptoms and negative outcomes in this population could help inform intervention development.

Finally, additional work is needed to identify and implement effective interventions targeted at PTS symptoms among children in low-resource LAMICs that take into account the various cultural and contextual needs of this setting. As evidence-based interventions from the United States, such as TF-CBT, are increasingly adapted to LAMIC contexts it is important to understand the cultural and societal differences which may impact treatment delivery and implementation.
REFERENCES


[White Paper]. Retrieved from:


psychosocial research instruments: Adapting the Depression Self-rating Scale and Child PTSD Symptom Scale in Nepal.

*BMC Psychiatry, 11,* 127-144. doi: 10.1186/1471-244X-11-127


Salzinger, S. (1999). Determinants of abuse and effects of violence on children and adolescents. In A.J. Goreczny & M. Hersen (Eds.), Handbook of
pediatric and adolescent health psychology (pp. 429-449). Boston: Allyn and Bacon.


Appendix

IRB LETTERS
DATE: April 26, 2013

TO: Noel Shadowen
FROM: University of Delaware IRB

STUDY TITLE: [438615-2] Communities Rising: Program Evaluation & Research in Tamil Nadu, India

SUBMISSION TYPE: Revision

ACTION: APPROVED
APPROVAL DATE: April 26, 2013
EXPIRATION DATE: April 16, 2014
REVIEW TYPE: Full Committee Review

Thank you for your submission of Revision materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Full Committee Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.
If you have any questions, please contact Jody-Lynn Berg at (302) 831-1119 or jlberg@udel.edu. Please include your study title and reference number in all correspondence with this office.
DATE: April 17, 2014

TO: Noel Shadowen
FROM: University of Delaware IRB

STUDY TITLE: [438615-5] Communities Rising: Program Evaluation & Research in Tamil Nadu, India

SUBMISSION TYPE: Continuing Review/Progress Report

ACTION: APPROVED
APPROVAL DATE: April 16, 2014
EXPIRATION DATE: April 16, 2015
REVIEW TYPE: Full Committee Review

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Full Committee Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

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Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.
If you have any questions, please contact Nicole Farnese-McFarlane at (302) 831-1119 or nicolefm@udel.edu. Please include your study title and reference number in all correspondence with this office.
DATE: June 16, 2015

TO: Noel Shadowen
FROM: University of Delaware IRB

STUDY TITLE: [438615-8] Communities Rising: Program Evaluation & Research in Tamil Nadu, India

SUBMISSION TYPE: Continuing Review/Progress Report

ACTION: APPROVED

APPROVAL DATE: June 16, 2015

EXPIRATION DATE: April 16, 2016

REVIEW TYPE: Expedited Review

REVIEW CATEGORY: Expedited review category # (9)

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

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Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

If you have any questions, please contact Nicole Farnese-McFarlane at (302) 831-1119 or nicolefm@udel.edu. Please include your study title and reference number in all correspondence with this office.