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Evaluation of an innovative intervention for traumatized children from a low resourced country

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Abstract
Asking children to care for a toy animal following a severe trauma has previously shown mental health benefits. In this study 129 children aged 5–9 from two shelter-homes in Bangladesh were randomly allocated to receive a toy animal plus rehearsal of positive statements or treatment as usual and were re-assessed after three weeks. Those receiving tau then received the toy only and were reassessed after another three weeks. The largest reductions in symptoms of post-traumatic stress, anxiety and depression were shown by those receiving the combined intervention. This procedure provides a potential very low-cost intervention for use in developing countries.

1. Introduction

1.1. Background

Traumatized children are at high risk for developing PTSD and other post-traumatic stress reactions (PTSR), including anxiety, depression, suicidal ideation, and substance abuse (Colman, Ploubidis, Wadsworth, Jones, & Croudace, 2007; Cloitre et al., 2009; Devries et al., 2011). Many children suffer high levels and long periods of PTSR following the experience of a trauma, and some will experience high levels of symptoms without meeting full diagnostic criteria for a disorder (Cohen, Goodman, Brown, & Mannarino, 2004). Traumatic events can have both short-term (La Greca, Silverman, Vernberg, & Prinstein, 1996) and long-term impact (Yule et al., 2000; Morgan, Scourfield, Williams, Jasper, & Lewis, 2003) on mental health in children and can produce lifelong changes at neuro-anatomical (Scheeringa, Zeanah, Myers, & Putnam, 2004) and physiological levels (Delahanty, Nugent, Christopher, & Walsh, 2005) that negatively impact on level of functioning. Regrettably many traumatic events, such as violent assault, abuse, injuries, and natural disasters are especially common in developing countries (Pynoos, Steinberg, & Piacentini, 1999; Coleman, Cole, & Wuest, 2010). In a study with adult participants from the Philippines 75% had been exposed to a traumatic event in childhood and such experiences had strong relationships with various health-risk behaviors, and poor health in adulthood (Ramiro, Madrid, & Brown, 2010).

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These experiences create a cumulative social and economic burden for such disadvantaged communities due to the life impairment associated with these psychological reactions.

On the positive side, studies have found that early intervention provided to treat post-traumatic reactions can accelerate adjustment following traumatic experiences among adults (Bryant, 2007). A number of evidence based interventions to reduce PTSR in young people have been demonstrated. These include, cognitive behavioral therapy (CBT; Smith et al., 2007), trauma-focused cognitive behavioral therapy (TF-CBT; Pine, Cohen, Gurley, Brook, & Ma, 1998; Cohen, Deblinger, Mannarino, & Steer, 2004; Cohen, Goodman et al., 2004), child-parent psychotherapy (CPP; Ellis, Nixon, & Williamson, 2009; Merikangas et al., 2010), and attachment, self-regulation and competency (ARC; Kinniburgh, Blaustein, Spinazzola, & van der Kolk, 2005). CBT-based interventions have proven effective relative to supportive group counseling even for children as young as three years (Scheeringa, Weems, Cohen, Amaya-Jackson, & Guthrie, 2011). TF-CBT is effective for treating children exposed to sexual abuse, domestic violence and various single or multiple-exposures to traumatic events (Cohen, Mannarino, & Knudsen, 2005; Cohen, Mannarino, & Staron, 2006; Gateway, 2012). In a meta-analysis of psychological interventions for traumatized children between 1997 and 2007, TF-CBT was described as a well-established intervention for 8–15 year old individual child clients (Wethington et al., 2008) and school-based or group CBT as a probably efficacious treatment for children exposed to traumatic events (Silverman et al., 2008).

Unfortunately, demonstrations of efficacy do not necessarily translate to effective service delivery especially in low resourced communities. Many barriers can limit effective delivery of efficacious treatments by community practitioners or clinicians including lack of knowledge, attitudes to psychological problems and practice-oriented barriers (Weisz, Weiss, & Donenberg, 1992; Higa & Chorpita, 2008). Many of these barriers are especially salient in developing countries where mental health expertise and psychological support systems are often scarce (Patel, Flisher, Nikapota, & Malhotra, 2008). In developing countries, the use of CBT oriented interventions is limited to very few services and very few RCTs have been reported using child populations (Patel et al., 2008). Further, most current, validated interventions are highly resource-intensive. For example, TF-CBT typically involves around 10, 60-min sessions from an experienced therapist to achieve positive outcomes. Practically it is not possible to train sufficient numbers of mental health professionals to deliver such empirically-validated interventions. Methods to increase access to empirically-validated interventions such as bibliotherapy (Rapee, Abbott, & Lyneham, 2006) or internet-based interventions (Holmes, March, & Spence, 2009) also have limited utility in many developing countries due to low levels of literacy, poor technological and telecommunication facilities, and limited access to such facilities. For such countries, the development of easily administered and inexpensive interventions is especially important.

One particularly simple and innovative intervention that may hold promise for use in developing countries was recently reported by Sadeh, Hen-Gal, and Tikotzky (2008) in a study of children affected by war. The intervention, known as the Huggy-Puppy Intervention (HPI) involved providing children who had been displaced by an intense conflict with a stuffed toy dog (called "huggy-puppy") and instructing them to care for the toy animal, through a simple story that assimilated the life events of the child. The brief intervention showed promising outcomes in reducing levels of distress among young children aged between 2 and 7 years. Relative to a waitlist comparison, HPI yielded a large effect size (Cohen's $d > .80$) reduction in symptoms of war-related stress reactions, including separation fear, strong reactions to noise, excessive crying, flashbacks, disinterest in play, and sleep problems. Sadeh et al. (2008) postulated that providing children under traumatic conditions with a toy animal to take care of invoked three key therapeutic mechanisms: 1) utilization of the child's sense of responsibility assisted the child to distract from their personal stress, project their own fear and anxiety onto the toy, and promote self-esteem; 2) the use of pretend play helped to enhance fundamental developmental milestones (Bornstein, Haynes, O'Reilly, & Painter, 1996; Haight, Wang, Fung, Williams, & Mintz, 1999; Lewis & Ramsay, 2004) and 3) age appropriate play and playful activities helped to create a safe and engaging procedure for children (Briggs, Runyon, & Deblinger, 2011), which helped them to facilitate insight and divergent thinking (Russ & Niec, 2011). Given its very low cost, ease of administration, and conceptual underpinnings, HPI appears to be a very promising intervention for possible application with traumatized children from low-resourced communities.

1.2. Enhancement of the Huggy Puppy Intervention

An extensive literature has demonstrated that following trauma young people develop negative beliefs about themselves and the world around them (Kliewer, Lepore, Oskin, & Johnson, 1998; Udwin & Boyle, 2000; Salmon, Sinclair, & Bryant, 2007) similar to that shown by adults (Dunmore, Clark, & Ehlers, 1999; Boelen, van den Bout, & van den Hout, 2003). Given the involvement of cognitive factors in the onset and maintenance of PTSR (Dunmore et al., 1999), some authors have pointed to the need to directly address cognitive components within treatments for PTSR (Dunmore, Clark, & Ehlers, 2001). Clinical observations on the remission of post-traumatic reactions in children in both natural and therapeutic settings have shown that negative beliefs in children following trauma gradually change if they are allowed to discuss or express their related beliefs. For instance, discussing the experiences and thoughts related to a traumatic event with supportive adults helped young children make meaning or sense of their experience, develop coping strategies and learn to control negative emotions (Kliewer et al., 1998; Dowd & McGuire, 2011). Similarly, successful TF-CBT interventions with children also require modification of negative thoughts related to the traumatic event by discussing, challenging and practicing positive alternative thoughts (Cohen, Goodman et al., 2004; Cohen, 2008; Gateway, 2012).

Cognitive interventions are easier to conduct with older children (above ten-year) who are more capable of verbalizing or articulating their personal ideas, concepts, and beliefs than younger children. However, children as young as five are able to understand thought–affect relationships and with the assistance of adults can learn to focus on positive thoughts over negative thoughts (Bamford, 2012). Age-appropriate play has been found to assist younger children to debrief from traumatic events and modify associated distorted cognitions (Haight, Black, Ostler, & Sheridan, 2006; Briggs et al., 2011; Russ & Niec, 2011). Hence the inclusion of supportive adults can result in better outcomes for children by assisting altering negative beliefs to helpful thoughts through play and effective parent-child interaction (as suggested by Patterson (2005) and Kotchick (2002)).

Unfortunately many poorly-resourced communities are located within cultures where discussion about previous traumatic events, especially with children, is discouraged. For example, disclosure of sexual abuse is lower in Asian than non-Asians communities (Futa, Hsu, & Hansen, 2001). In contrast, the importance of child play and encouragement of children to think positively are widely accepted. Hence a focus on increased play and positive self-statements can provide broadly acceptable methods to intervene with distressed children across a wide range of cultures.

1.3. Objectives

Based on the importance of developing positive perspectives of self, others, and the future to reduce the experience of negative emotional reactions, combined with the promising potential of the huggy puppy procedure to assist children affected by traumatic experiences, we decided to examine the efficacy of a combination of these strategies with traumatized children, from a low-resourced non-war affected community. The present study involved two primary objectives: 1) to explore the efficacy of a modified version of the HPI that incorporated rehearsal of positive statements (referred to as “enhanced HPI” in this paper) and 2) to replicate the efficacy of the basic HPI (referred to as standard HPI). The study was conducted in two stages. Stage 1 involved a comparison of enhanced HPI against children in a treatment-as-usual group. In Stage 2, the children in treatment as usual were provided with the standard HPI, which allowed a quasi-experimental comparison of the enhanced HPI against the standard HPI.

2. Method

2.1. Context: Bangladesh

Bangladesh is a poor and overpopulated country with 38% living below the poverty line (World Bank, 2013). Natural and man-made disasters are common and young people are often exposed to traumatic events (Deeba & Rapee, 2015) and are especially vulnerable to mental health problems (Izutsu et al., 2006; Rahman et al., 2012). The country has only limited resources to provide mental health support to its inhabitants due to a small mental health workforce, poor understanding of mental health needs, and limited access due to the costs of service provision (Ahmed, 2011; Bruckner et al., 2011; Maulik and Darmstadt, 2009). Although the median health expenditure on a Bangladeshi child can be less than $US0.20, especially among poor and rural communities (Patel & Kleinman, 2003), few caregivers have the income to afford professional fees or even travel to service centers. Added to this, mental health stigma and disbelief about the effectiveness of talking therapies further restrict the access of children to the limited available help (Deeba & Rahman, 2012).

2.2. Participants

The directors of two shelter homes, that provided support and safe accommodation for traumatized young people agreed to participate in the present study. The homes were matched as much as possible on several factors. Both were run by non-government international charity organizations, both were situated in semi-urban areas, one within and another outside the capital city of Dhaka, both housed large numbers (approximately, 500) of children of all ages (new born to below 18 years) and provided similar services for health, education, and vocational choices in their large premises. Children could live in either institution up to the age of 18 years. Children were accepted to both institutions following loss or abandonment by their parents and an absence of relatives able or willing to care for them. Most of the children (90%) had lost one or both parents following natural disasters or accidents or due to domestic violence and witnessed direct or indirect violence against a parent (mostly towards the mother). All children were vulnerable to symptoms of PTSR since they had witnessed or experienced at least one severe DSM-IV (American Psychiatric Association, 2000) defined traumatic event including natural disasters (e.g., flood, cyclone, tornado, avalanche, arsenic exposure, terminal disease), accidents (e.g., hit by a road transport vehicle, boat or launch accidents, train/plane accidents, building collapse, fire, fall from a height, drowning, explosions) and man-made traumas (e.g., hit by others, suffocated, attempted killing, acid attack, stalking, sexual abuse (penetrative and non-penetrative), trafficking and mugging).

All children in each home who were aged between five and nine years and who provided assent to participate were included in the study. Children with serious health conditions, psychotic features, severe ADHD, or any developmental disorders or an inability to comprehend simple instructions were excluded. Exclusions from participation were made by the caregivers of the children, based on the child's medical and psychiatric history. A group discussion covering inclusion and exclusion criteria was conducted with the caregivers before the study and they selected children for the intervention. Both institutions employed caregivers as the primary carer for the children and they were resident in each home. Caregivers were not professionally qualified, but were often selected following their own experience of negative life events. The educational qualifications (completion of primary, secondary school certificate (SSC), higher secondary (school) certificate (HSC) and higher degrees) of the caregivers differed significantly between the two shelter homes (see, Table 1).

A total of 152 children aged between 5 and 9 years in the two organizations (90 from the organization outside Dhaka and 62 from the organization inside Dhaka) were initially selected for the study. Following exclusion criteria, 129 children were finally engaged in the study. Of the 23

Table 1 Gender, age, and differences in the scores of the measures used at the baseline level.

	Enhanced HPI group (N=69)	Treatment as usual/Standard HPI (N=60)	Statistics
Child's age in years (Mean, *SD*)	7.40 (2.10)	7.01 (2.71)	$t(127)=-1.75$, $p=.08$
Gender (Boy, % in total)	38 (55%)	43 (71%)	$\chi^2(1, N=127)=3.78$, $p=.05$
Education (N, % in total)	65 (52.42)	59 (47.58)	$\chi^2(1, N=127)=1.47$, $p=.26$
Duration of stay in the centre in months (Mean, *SD*)	29.28 (20.26)	52.98 (29.98)	$t(127)=-5.32$, $p=.001$
Caregiver–child orientation time in months (Mean, *SD*)	7.91(13.07)	50.08 (27.78)	$t(127)=10.77$, $p<.001$
Age of caregivers in years (Mean, *SD*)	35.62 (6.78)	35.62 (6.34)	$t(31)=1.55$, $p=.28$
Educational qualifications of caregivers, SSC and above (N, % in total)	18 (13.95)	28.68 (37)	$\chi^2(1, N=31)=5.042$, $p=.025$

children who were excluded, 20 left the shelter home during the period of the study, two were excluded due to excessive symptoms of hyperactivity, and one was hospitalized during the study. Allocation to condition was conducted at an institution level with one institution randomly allocated to the enhanced HPI group condition and the other allocated to the remaining treatment as usual group. Thus 69 children (38 boys, 55%; Mean age=7.40, *SD*=2.10) were in the enhanced HPI group and 60 (43 boys, 71%; Mean age=7.01, *SD*=2.71) were in the treatment as usual group (later standard HPI group). Figure 1 describes the full design, participant flow and time-line for the study. Two children from treatment-as-usual discontinued before the post-wait assessment: one was hospitalized and the other refused to complete questionnaires. As can be seen in Table 1, there were significant differences between the groups on children's gender, duration of stay at the shelter home, length of relation with the caregiver, age of the caregiver and the level of educational qualification of the caregivers.

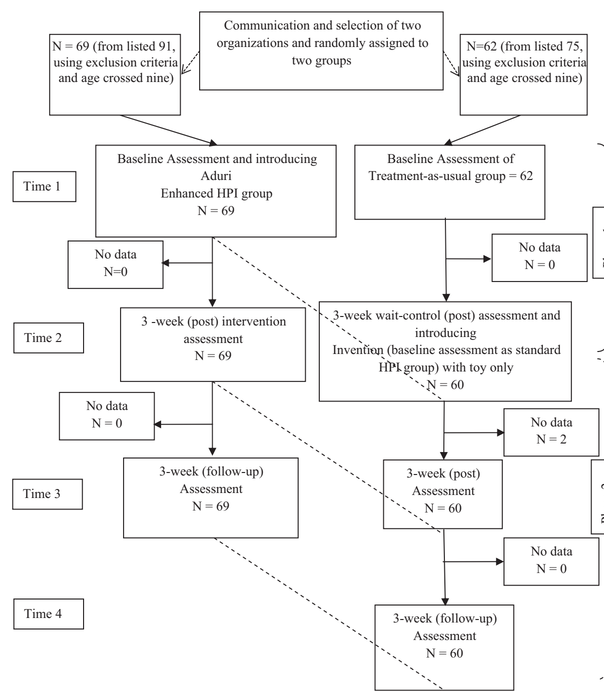

Figure 1 Participants flow through the study timeline.

2.3. Measures

Children and caregivers were administered the assessment tools at 3-time points in the enhanced HPI group and 4-time points for the standard HPI group, (see Figure 1). There was a 3-week interval between each assessment. Due to the low levels of education among the carers and the young age of the children, measures were kept to a minimum. Therfore, children completed two self-report measures (cognition and PTSD symptoms) and caregivers reported on children's anxiety, depression and implementation of the program (see below). Among these measures, only the measure of PTSD symptoms has published clinical cut-off scores. Hence we determined clinical presentation according to the measure of PTSD.

2.3.1. Translation

After receiving permission from the original authors of the English versions of the measures, they were translated according to accepted guidelines for the translation of instruments (Widenfelt, Treffers, Beurs, Siebelink, & Koudijs, 2005). Translation was done by the bilingual investigator of the study and then another bilingual professional psychologist (who did not see the original English versions of the scales) translated them back to English. Differences in the original and back translated versions were checked by the second author of the study, a native English speaker. Identified differences were discussed and resolved by the Bengali-speaking translators.

2.3.2. Child-report measures

2.3.2.1. Childrens Revised Impact of Events Scale-8 (CRIES-8; Children and War Foundation, 2005). To measure symptoms of post-traumatic stress reactions, children completed the CRIES-8. The measure has high internal consistency for the total scale (Cronbach's alpha=.90) as well as each sub-scale (Cronbach's alpha of Intrusion=.84 and Avoidance=.83) (Dyregrov & Yule, 1995) and has satisfactory validity, factor structure, and discriminant validity (Perrin, Stedman, Smith, & Patrick, 2005). Higher scores reflect more severe symptomatology and a cut-off score of 17 maximized sensitivity and specificity (Perrin et al., 2005). The measure has been translated and validated in a variety of cultures (for example, Giannopoulou et al., 2006; Zhao et al., 2009). For the present study, the Bengali translation of the CRIES-8 was used, which has also shown satisfactory psychometric properties (Deeba, Rapee, & Prvan, 2014). Cronbach's alpha was satisfactory (.85) within the current sample.

2.3.2.2. Cognitive Triad Inventory for Children (CTI-C; Kaslow, Stark, Printz, Livingston, & Ling Tsai, 1992). The 36-item CTI-C aims to assess both positive and negative cognitions covering three subscales: view of self, world, and the future. Higher scores on the measure reflect more positive beliefs. Internal consistency has been found to be moderate to strong for all subscales (Chronbach's alpha, Self=.83, World=.69, and Future=.85) and for the total score (α=.92). In the present study, the Cronbach's alpha for the total scale was satisfactory (α=.83).

2.3.3. Questionnaires used with caregivers

2.3.3.1. Spence Children's Anxiety Scale for parents (SCASp; , Nauta et al. (2004)). To measure symptoms of anxiety in children as observed by the caregivers, the 38-item SCASp was used. Items are rated on a 4-point Likert-type scale ranging from 0 (never) to 3 (always) and higher scores reflect stronger symptoms of anxiety. The parent version of the SCASp shows satisfactory to good psychometric properties with high internal consistency (.89) and satisfactory convergent and discriminant validity (Nauta et al., 2004). In the present study, Cronbach's alpha was .87 for the caregivers.

2.3.3.2. Short Moods and Feelings Questionnaire-parent (SMFQp; Angold et al., 1995). The SMFQp comprises13 items to assess depression in children as reported by caregivers. Items are rated on a 3-point scale, with higher scores indicating more symptomatology. The unifactorial measure has high internal consistency (Cronbach's alpha=.87) and test retest reliability with satisfactory construct validity (Rhew et al., 2010). In the present study, Cronbach's alpha for the sample was .70.

2.3.3.3. Mechanisms questionnaire. In order to assess implementation of the intervention, a 10-item measure was developed to monitor potential mechanisms of change following questions in the original HPI study (Sadeh et al., 2008). Six questions assessed the child's engagement with the toy and three questions assessed use of postive statements with the toy as evidence of performing the cognitive tasks. These items were rated on a 5-point Likert scale ranging from 0 (no change) to 4 (a great deal of change). A final question asked caregivers to indicate how often they reminded children to play with the toy over the preceding three weeks on a 0–100 scale, where "0" indicated "not at all" and "100" indicated "regularly reminded". The questions were completed by caregivers based on their observations and were administered immediately following each intervention period.

2.4. Intervention

The intervention for both conditions in the present study closely followed that described by Sadeh et al. (2008). Children in both conditions received a small stuffed animal as a gift and were told a short story describing the animal's background that was relevant to the child's life and experiences. Because dogs are not typically kept as pets in Bangladesh for religious reasons, the current trial used a toy teddy bear named *Aduri*, a Bengali word, meaning, someone fond of being hugged and caressed.

In two separate group training sessions after baseline assessment both groups were given the following standard story when they received *Aduri*: "*This is my friend "Aduri". She has come from a faraway land. She can't tell where, as she is lost and young. Aduri is usually a very happy teddy. However, she is very sad and a little frightened now. Do you have any idea why she might be sad? Let us discuss.*" After children's replies, the story continued, "*Yes, you all are very right. She is sad because she has been separated from her home and family and does not know anyone here. She likes to be hugged a lot but she has no one to take care of her, here. What feelings might she have about being separated from her family? Do you think she has some of the same feelings that you might have? Can you name some of her feelings?*" After their reply, the instructions continued, "*Thanks. It seems you all are feeling for Aduri very much. Now, do you think you can be her friend who will take care of her, give her love and lots of cuddles, and take her to bed with you?*" They were instructed to keep the toy with them all the time except bath and school time and to care for the toy at least twice every day, before going to school and at bed before sleep.

For the enhanced HPI group a series of positive statements were included in addition to the standard instructions. Children were asked to use these statements or make up various statements related to self, others and future, (for instance, using I, you and any positive things that can happen in future) with the toy while taking care of it. The statements reflected positive views of the self, (e.g., *you are a strong teddy, you can cope with all difficulties, you are nice and good, you are lovable, you are capable of doing nice things, you make me feel good, you are a happy doll*, etc.), world (e.g. *people around you like you a lot, others are helpful and friendly, people around you praise you when you do something good, most of the people around us are nice and good, others help when you are in need*, etc.) and future (e.g. *you will always be loved, your future is bright, many nice things will happen in coming years in your life, your good qualities surely will make your future bright, you will be successful one-day*, and alike statements).

Caregivers also attended the group sessions as observers to learn the tasks children had to perform, so that they could remind the children to do their task each day. In the standard HPI, caregivers were to remind children to take care of the toy animal only, whereas in the enhanced

HPI group caregivers were to remind children both to take care of the toy and to encourage talking to the toy using the positive statements or similar. A leaflet listing examples of positive statements was provided to assist caregivers.

2.5. Procedure

The procedures were approved by the Macquarie University Human Research Ethics Committee. Institutions were searched from different available sources e.g. government registry, web-based lists of institutions in Bangladesh working with children, professionals' suggestions. Only three institutions were identified that appeared moderately matched and therefore were asked for permission to execute the study. Two institutions showed interest in participating and their directors met with the first author to discuss procedures and ethical principles and provide written permission. Both institutions gave consent on the condition that no discussion would occur with the children directly reflecting their previous traumatic experiences. The organizations were randomly assigned to either the enhanced HPI group or treatment-as-usual group (which later received the standard HPI) by using a lottery method. Children in the treatment-as-usual group completed measures initially and again three weeks later with no intervention, following which they were introducted to the standard HPI. At the initial session, the closest caregivers of the children attended a group discussion session to be introduced to the research team (the first author and a research assistant, a graduate in clinical psychology, who were present at all sessions), to discuss problem behaviors demonstrated by the children, to describe children's exposure to traumatic events and their impact on children, symptoms of emotional and behavioral problems, selection of participants and the assessments and tasks required during the research. Information on available services for children's emotional and behavioral problems was also discussed. Caregivers were then asked to complete baseline questionnaires. Children were tested in small groups ranging from 3 to 10 (younger children in smaller groups) after obtaining their assent. Following assessment of all children, they were taken to a group session where they received the instructions on how to take care of the toy.

Children in the enhanced HPI group received the toy and instructions immediately, while children in the waitlist received no toy or instructions initially, but received the standard HPI three weeks later. Thus, the treatment-as-usual group which was later introduced to standard HPI was assessed four times and the enhanced HPI group was assessed three times (see, Figure 1).

2.6. Data analysis

As mentioned, the study involved two stages. The first stage comprised a randomized control trial comparing the enhanced HPI group against waitlist while the second stage comprised a quasi-experimental design comparing the two active interventions (enhanced HPI group and standard HPI). Such studies have been referred to as either *experimentally staged introduction trials*, or a *stepped wedge design* (Cook, Campbell, & Day, 1979; Group, 1987). Since the main purpose of the study was to evaluate the intervention and thereby improve distress levels, analyses were made on participants who had completed all assessments and intervention initially (completers) and then with all the participants who enrolled in the study (intent to treat). Last observation carried forward (LOCF) was used to handle missing data. Continuous measures were analyzed using mixed model ANOVAs (Hussey & Hughes, 2007). Results of analyses of data based on these two methods were almost identical, hence only intent-to-treat analyses are reported here. All the demographic variables that differed significantly between groups (child gender, duration of stay at the shelter home, length of relation with the caregiver, age of the caregiver and the level of educational qualifications of the caregivers) were included as covariates. In the models, group was a fixed factor, time was included as a repeated measure and covariates were unstructured. Therefore, in Phase 1, results on intervention (enhanced HPI $\times$ treatment-as-usual), time (Time 1 $\times$ Time 2) and interaction of intervention and time (Group $\times$ Time) were checked. For the Phase 2 or quasi-experimental test, results on intervention (enhanced HPI $\times$ standard HPI), time [baseline assessment (Time 1 for enhanced HPI group and Time 2 for standard HPI) $\times$ post-intervention (Time 2 for enhanced HPI and Time 3 for standard HPI) and follow-up assessment (Time 3 for enhanced HPI and Time 4 for standard HPI)] and interaction of intervention and time (Group $\times$ Time) were examined. All post-hoc analyses were done using simple comparison tests. To denote the variances between groups within each time point, effect sizes are presented as partial η^2. In order to measure the extent to which change in PTSD symptoms was associated with the three process mechanisms assessed in the study, we combined the groups and ran separate stepwise multiple regressions (controlling for demographic covariates and institution at step 1) with the differences of the outcome measures at pre-intervention to post-intervention and post-intervention to follow-up assessment points as the dependent variables.

3. Results

3.1. Baseline comparison between groups

Descriptive information across the two groups is presented in Table 1. As can be seen, the groups differed significantly on several factors. Compared with the enhanced HPI group, the treatment-as-usual group contained significantly more boys, a longer stay in the institution, longer child-caregiver relationship, and higher levels of caregivers' educational qualifications. These variables were entered as covariates in all following analyses. A series of t-tests comparing the two institutions on the standard measures revealed that the enhanced HPI group scored significantly higher on the CRIES 8, $t(127)=4.23$, $p<.001$, SCASp, $t(127)=9.69$, $p<.001$, and SMFQp, $t(127)=5.44$, $p<.001$, and lower on the CTI-C, $t(127)=-8.31$, $p<.001$, compared to the treatment as usual group.

Table 2 Statistics for mixed model ANOVA for treatment-as-usual/Standard HPI (N=60) and enhanced HPI group (N=69).

		Time 1 Mean (*SD*)	*Time* 2 Mean (*SD*)	*Time* 3 Mean (*SD*)	*Time* 4 Mean (*SD*)
CRIES-8	Treatment-as-usual/Standard HPI	16.11 (9.06)	16.88 (6.53)	14.85 (7.51)	16.31 (6.69)
	Enhanced HPI	22.19 (7.21)	16.99 (7.35)	11.83 (6.73)	-
SCAS-P	Treatment-as-usual/Standard HPI	8.31 (8.54)	5.18 (5.61)	5.41 (6.12)	6.17 (7.91)
	Enhanced HPI	23.82 (9.50)	8.80 (4.50)	5.49 (4.22)	-
SMFQ-P	Treatment-as-usual/Standard HPI	1.75 (2.68)	.95 (1.88)	1.25 (1.99)	.87 (1.70)
	Enhanced HPI	4.82 (3.58)	.81 (1.20)	.39 (1.20)	-
CTI-C	Treatment-as-usual/Standard HPI	63.55 (7.68)	57.50 (10.08)	62.05 (8.29)	61.13 (9.34)
	Enhanced HPI	50.71 (9.58)	56.55 (8.32)	64.29 (7.14)	-

Note: CRIES-8=Children Impact and Event Scale-8; SCASp=Spence Children Anxiety Scale for parents; SMFQp=Short Mood and Feelings Questionnaire for Parents; CTI-C=Cognitive Triad Inventory for Children.

Table 3 Number of children who scored above the clinical cut-off score on CRIES-8.

	Time 1 *N* (%)	*Time* 2 *N* (%)	*Time* 3 *N* (%)	*Time* 4 *N* (%)
Treatment-as-usual/Standard HPI (*N*=60)	26 (43.33)	31 (51.66)	24 (40.00)	29 (48.33)
Enhanced HPI (*N*=69)	51 (73.91)	28 (40.58)	13 (18.84)	_

3.2. Comparison of enhanced HPI and treatment-as-usual group (Phase-1)

Mixed model ANOVA was used to compare the two groups across baseline (Time 1) and -(Time 2) assessments after 3-weeks on measures used in the study. Estimated marginal means and standard errors are presented in Table 2.

3.2.1. Symptoms of PTSD

When comparing the groups on symptoms of PTSD measured with the CRIES-8 at baseline and post-intervention, there was no significant main effect for intervention, $F(1, 123)=2.73$, $p=.10$, $\eta_p^2=.02$, or time, $F(1, 123)=.77$, $p=.38$, $\eta_p^2=.01$, however there was a significant time by group interaction, $F(1, 123)=10.31$, $p=.002$, $\eta_p^2=.08$. Post-hoc analyses showed that children in the treatment-as-usual group failed to change significantly, $t(123)=.83$, $p=.41$, between Time 1 and Time 2, but mean scores on the CRIES-8 decreased significantly, $t(123)=4.70$, $p<.001$, among children in the enhanced HPI group from Time 1 to Time 2. Comparison between the groups at Time 1 showed a significant difference, $t(123)=2.82$, $p<.05$. However at Time 2 (postintervention) the groups no longer differed significantly, $t(123)=.21$, $p=.83$. Using cut-off scores on the measure, the number of possible PTSD cases (see Table 3) was significantly higher in the enhanced HPI group at Time 1 ($\chi^2(1, N=129)=12.47$, $p<.001$), however, there was no longer a significant difference between the two groups in the number of possible PTSD cases at Time 2 ($\chi^2(1, N=129)=1.59$, $p=.22$).

3.2.2. Symptoms of internalizing problems

3.2.2.1. Anxiety. On the SCASp there was a significant main effect difference found for intervention, $F(1, 123)=31.88$, $p<.001$, $\eta_p^2=.21$ and a significant main effect reduction in symptoms of anxiety over time, $F(1, 123)=5.06$, $p<.05$, $\eta_p^2=.04$, which were qualified with a significant interaction between time and group, $F(1, 123)=31.23$, $p<.001$, $\eta_p^2=.20$. Post-hoc analyses showed that mean scores on the SCASp reduced for both the treatment-as-usual group, $t(123)=2.40$, $p<.05$, and the enhanced HPI, $t(123)=11.76$, $p<.001$, from Time 1 to Time 2. Mean scores on the SCASp obtained by children in the enhanced HPI group were higher than the treatment-as-usual group at both Time 1, $t(123)=6.19$, $p<.001$, and Time 2, $t(123)=2.62$, $p<.01$ assessment.

3.2.2.2. Depression. According to scores on the SMFQp, there was no significant main effect difference found for intervention, $F(1, 123)=3.73$, $p=.06$, $\eta_p^2=.03$ and no significant main effect reduction in symptoms of depression over time, $F(1, 123)=1.99$, $p<.16$, $\eta_p^2=.02$. However this was a significant interaction between time and group, $F(1, 123)=15.51$, $p<.001$, $\eta_p^2=.11$. Post-hoc analyses found that level of depressive symptoms in children in the treatment-as-usual group did not change significantly from Time 1 to Time 2, $t(123)=8.71$, $p=.102$, but there was a significant reduction from Time 1 to Time 2 in the enhanced HPI group, $t(123)=1.64$, $p<.001$. Children's mean scores on the SMFQp in the enhanced HPI group were significantly higher than the treatment-as-usual group at Time 1, $t(123)=3.13$, $p<.01$, but there was no significant difference at Time 2 $t(123)=5.44$, $p=.15$.

3.2.3. Changes in cognitions

There was a significant main effect difference in negative cognitions as measured by the CTI-C between groups, $F(1, 123)=19.22$, $p<.001$, $\eta_p^2=.14$, but no significant main effect reduction over time, $F(1, 123)=.022$, $p=.88$, $\eta_p^2=.00$. There was a significant interaction between time and group, $F(1, 123)=33.69$, $p<.001$, $\eta_p^2=.22$. Post-hoc analyses showed a significant change in cognition from Time

1 to Time 2 in both the treatment-as-usual group, $t(123) = .847$, $p < 001$, and the enhanced HPI group, $t(123) = 4.723$, $p < .001$. The mean scores on the CTI-C obtained by children in the enhanced HPI group were significantly lower (higher negative cognition) than those in the treatment-as-usual group at Time 1, $t(123) = -6.96$, $p < .001$, but there was no significant difference at Time 2, $t(123) = -.85$, $p = .39$.

3.3. Quasi-experimental comparison of enhanced HPI and standard HPI (Phase-2)

As described above, a quasi-experimental analysis was conducted by comparing scores on the various measures in the enhanced HPI condition at assessment times 1, 2 and 3 with scores in the standard HPI condition at assessment times 2, 3, and 4. Estimated marginal means and standard errors, of the two groups are presented in Table 2.

3.3.1. Symptoms of PTSD

There was no significant main effect difference between interventions, $F(1, 123) = .09$, $p = .77$, $\eta_p^2 = .01$, $\eta_p^2 = .02$ but there was a significant main effect reduction in symptoms of PTSD measured with the CRIES-8 over time, $F(1, 123) = 4.82$, $p = .009$, $\eta_p^2 = .04$. This was qualified by a significant interaction between time and group, $F(1, 123) = 17.01$, $p < .001$, $\eta_p^2 = .12$. Post-hoc analyses showed no significant change in PTSD symptoms from pre-intervention (Time 2) to post-intervention in the standard HPI group, $t(123) = 1.20$, $p = .23$, (Time 3), or post-intervention (Time 3) to follow-up (Time 4), $t(123) = -1.09$, $p = .28$, or from pre-intervention (Time 2) to follow-up (Time 4), $t(123) = .019$, $p = .98$. On the other hand PTSD symptoms decreased significantly among children in the enhanced HPI group from pre-intervention (Time 1) to post-intervention (Time 2) $t(123) = 5.65$, $p < .001$, post-intervention (Time 2) to follow-up (Time 3), $t(123) = 10.20$, $p < .001$, and from pre-intervention (Time 1) to follow-up (Time 3) $t(123) = 4.56$, $p < .001$. At baseline symptoms were higher in the enhanced HPI group than standard HPI, $t(123) = 3.18$, $p < .01$, but there was no significant difference between groups at post-intervention (Time 2 for enhanced HPI and Time 3 for standard HPI), $t(123) = .59$, $p = .56$, and the enhanced HPI groups scored significantly lower on PTSD symptoms at follow-up, $t(123) = -3.01$, $p = .01$. The number of possible PTSD cases (see Table 3) was significantly higher in the enhanced HPI group than in the standard HPI (Time 2) group at the pre-intervention (Time 1) point ($\chi^2(1, N = 129) = 6.86$, $p < .05$) however, there was no difference between the two groups ($\chi^2(1, N = 129) = .01$, $p = 1.00$) at Time 2. At the follow-up assessment points there were fewer possible PTSD cases in the enhanced HPI group (Time 3) than the standard HPI (Time 4) group ($\chi^2(1, N = 129) = 12.71$, $p < .001$).

3.3.2. Symptoms of internalizing problems

3.3.2.1. *Anxiety*. On the SCASp there was a significant main effect difference between groups, $F(1, 123) = 25.76$, $p < .001$, $\eta_p^2 = .173$, and a significant main effect reduction over time, $F(1.56, 190.62) = 21.50$, $p < .001$, $\eta_p^2 = .15$. These were qualified by a significant interaction between time and group, $F(1.56, 190.62) = 47.57$, $p < .001$, $\eta_p^2 = .28$. Post-hoc analyses showed a significant reduction in anxiety symptoms for the enhanced HPI group from pre-intervention to post-intervention, $t(123) = 12.74$, $p < .001$, post-intervention to follow-up, $t(123) = 4.56$, $p < .001$, and pre-intervention to follow-up $t(123) = 13.47$, $p < .001$. There was no significant reduction for the standard HPI group between any time points (Time 2 to Time 3, $t(123) = .67$, $p = .51$, Time 3 to time 4, $t(123) = -1.23$, $p = .22$ and Time 2 to Time 4, $t(123) = -.17$, $p = .87$). Children in the enhanced HPI group scored significantly higher on the SCASp than those in the standard HPI group at baseline, $t(123) = 8.14$, $p < .001$, and at post-intervention $t(123) = 2.73$, $p < .01$ but there was no significant difference between the two groups at follow-up, $t(123) = -.58$, $p = .56$.

3.3.2.2. *Depression*. On symptoms of depression assessed by the SMFQp, there was no significant main effect found for intervention, $F(1, 123) = 1.00$, $p = .32$, $\eta_p^2 = .01$, but there was a significant main effect reduction over time, $F(2, 176.78) = 17.48$, $p < .001$, $\eta_p^2 = .12$, which was qualified by a significant interaction between time and intervention, $F(2, 176.78) = 29.13$, $p < .001$, $\eta_p^2 = .19$. Within the standard HPI group, there was no significant reduction in depressive symptoms from baseline to post-intervention, $t(123) = .76$, $p = .45$, or from baseline assessment to follow-up, $t(123) = .52$, $p = .61$, but there was a significant decrease in scores from post-intervention to follow-up assessment, $t(123) = 2.37$, $p < .05$. Within the enhanced HPI group there were significant symptom reductions from baseline to post-intervention, $t(123) = 9.86$, $p < .001$, and from pre-intervention to follow-up assessment, $t(123) = 10.06$, $p < .001$, but no significant change was observed from post-intervention to follow-up assessment, $t(123) = 1.08$, $p = .28$. Group-wise comparison showed that mean scores on SMFQp in the enhanced HPI group were significantly higher than that of the standard HPI group only at pre-intervention, $t(123) = 4.24$, $p < .001$. Symptoms of depression were significantly lower among children in the enhanced HPI group compared to the standard HPI group at both post-intervention, $t(127) = -2.78$, $p < .01$, and follow-up assessment, $t(123) = -2.14$, $p < .05$.

3.3.3. Changes in cognitions

There was a significant main effect of intervention on scores on the CTI-C, $F(1, 123) = 4.98$, $p < .05$, $\eta_p^2 = .04$, and a significant main effect of time, $F(2, 232.01) = 15.36$, $p = .000$, $\eta_p^2 = .11$, however this was qualified by a significant interaction between time and group, $F(1, 232.01) = 13.54$, $p < .001$, $\eta_p^2 = .09$. Follow-up analyses showed significant reductions in negative cognitions from pre-intervention to post-intervention in both the standard HPI group, $t(123) = -2.76$, $p < .01$, and the enhanced HPI group, $t(123) = -6.09$, $p < .001$. There was no significant reduction from post-intervention to follow-up in the standard HPI group, $t(123) = -.02$, $p = .98$, however the enhanced HPI group showed increased positive cognition from post-intervention to follow-up, $t(123) = -6.55$, $p < .001$. Overall, there was a significant increase in positive cognition from pre-intervention to follow-up in both the standard HPI group, $t(127) = -2.38$, $p < .05$, and the enhanced HPI group, $t(123) = -10.63$, $p < .001$. Group comparisons revealed that children in the standard HPI had higher positive cognition at both pre-intervention $t(123) = 3.50$, $p < .001$ and post-intervention, $t(123) = -2.59$, $p < .01$, than those in the enhanced

HPI group, however there was no significant difference between groups at follow-up, $t(123) = -.60$, $p = .55$.

3.4. Process factors predicting symptom reduction

Three process mechanisms were used in our study, caregivers' reminders, engagement with the toy and use of positive statements, which were assessed by ratings from caregivers following the two active interventions. To examine differences in utilization of these processes within each intervention, scores were compared between the two groups using t-tests. Utilization of all three process mechanisms was significantly higher in the enhanced HPI than the standard HPI: use of caregiver's reminders, $t(127) = 17.1$, $p = < .001$, $M = 78.62$, $SD = 13.17$ for enhanced HPI and $M = 39.00$, $SD = 13.77$ for standard HPI; utilization of engagement with toy, $t(127) = 6.30$, $p < .001$, $M = 13.84$, $SD = 4.31$ for enhanced HPI and $M = 5.40$, $SD = 5.42$ for standard HPI; and use of positive statements, $t(113.31) = 13.52$, $p < .001$, $M = 11.67$, $SD = 2.78$ for enhanced HPI and $M = 4.13$, $SD = 3.45$ for standard HPI.

In order to measure how much the change in PTSD symptoms was associated with the three process mechanisms assessed in the study, we ran separate hierarchical multiple regressions (controlling for demographic covariates). As there was no a priori hypothesis regarding the order of entry for the predictor variables, the three process mechanisms were entered into the model simultaneously.

The first model predicted change on the CRIES-8 from pre-intervention to post-intervention. Entering the demographic covariates and process variables as a single block resulted in a significant model with an adjusted R^2 of.11, F $(1, 127) = 14.88$ $p < .001$. The only significant predictor was the educational level of the caregivers, $\beta = .71$, $t = -3.86$, $p < .001$. None of the process variables contributed additional significant variance to the model: caregivers' reminders, $\beta = .08$, $t = .84$, $p = .40$, engagement with the toy, $\beta = .07$ $t = .77$, $p = .44$, and use of positive statements, $\beta = -.02$, $t = -.17$, $p = .87$.

The second model predicted change on the CRIES-8 from postintervention to follow-up. The overall model was significant with an adjusted R^2 of.15, $F(2, 126) = 12.44$, $p < .001$. The strongest predictor was the duration of the child's relationship with the caregiver, $\beta = -.33$, $t = -4.00$, $p < .001$. Among the three predictors, the use of positive statements added significant additional variance to the model, $\beta = .27$, $t = 2.83$, $p = .005$, while the other two predictors did not account for significant unique variance, caregivers' reminders, $\beta = .08$, $t = .63$, $p = .53$, engagement with the toy, $\beta = -.13$ $t = -1.10$, $p = .27$.

4. Discussion

An innovative, low-cost, and easy to administer intervention, originally developed by Sadeh et al. (2008) and referred to as the Huggy Puppy Intervention (HPI), was modified in the current study through the addition of a simple enhancement and evaluated with traumatized young children from a low-resourced non-war affected community. The original HPI involved responsibility and care for a stuffed toy and our modified version included the additional use of simple positive statements. The current study tested the efficacy of these two interventions in a two staged partially randomized quasi-experimental trial. Results supported the efficacy of the enhanced HPI in reducing symptoms of PTSD, anxiety, and depression, and increasing positive thoughts among children who had experienced a variety of severe traumas. Further, the quasi-experimental evaluation that compared the two forms of the intervention suggested that for this chronic sample, the enhanced HPI resulted in slightly better results than the standard intervention. These outcomes suggest that the modified version of the HPI is a promising intervention that can be delivered to a number of children using minimum resources, expertise and costs.

One potential limitation of the research was the small number of shelter homes that were included in the sample. A limitation that this introduced was a difference between the two groups on several baseline measures. It is possible that the changes demonstrated in the enhanced HPI condition reflected regression to the mean effects rather than intervention-produced reductions. However, the fact that children in the enhanced HPI condition continued to show improvements from post-intervention to follow-up and reached levels on most measures that were better than those in the standard HPI condition, mitigates this possibility. Nonetheless, future studies would benefit from inclusion of a broader and more representative cross-section of homes and hopefully this initial positive demonstration will stimulate larger replications.

The mechanisms by which this simple intervention can reduce distress among children reporting such extreme events is not clear, although several possibilities can be speculated. Three possible mechanisms (engagement with the toy, caregiver's reminders, use of positive statements) were evaluated in this study. Interestingly, all variables were higher in the enhanced HPI condition, reflecting its stronger outcomes, but only the use of positive statements accounted for unique variance in changes on symptoms of PTSR. Previous research has shown that exposure to an inanimate pleasant object (such as a stuffed animal) can create nuturing motivations in children (Hinde & Barden, 1985; Morris, Reddy, & Bunting, 1995) and Tai, Zheng, and Narayanan (2011) have shown that holding toy teddy bears can increase both prosocial behaviors and positive mood in adults. In their original paper, Sadeh et al. (2008) suggested that reductions in distress may have followed the engagement the children developed to the toy combined with subsequent distraction from their circumstances under war conditions. Similarly, it is possible that the toy was used as a transitional object to cope with everyday life stress. The greater change on engagement produced by the enhanced HPI provides some support for this suggestion, although the regression analysis did not provide evidence indicating engagement with the toy as a core factor underlying change. The similar effect of the enhanced HPI on enhancing caregivers' reminders is consistent with research showing that adults' attention towards children can reduce children's distressing symptoms (Luborsky, Barber, & Beutler, 1993; Taylor Tl, 2004; Westen, Novotny, & Thompson-Brenner, 2004). Again, the fact that this variable did not account for unique variance in reduction of PTSR limits conclusions that can be drawn. However, our results pointed to the importance of the use of positive statements in predicting outcome, a finding that is consistent with other research (Cohen & Mannarino, 1996, 1997; Deblinger, Lippmann, & Steer, 1996; Cohen, Mannarino, Berliner, & Deblinger, 2000). This possibility is also consistent with the overall finding that the enhanced HPI appeared to produce improvements that were somewhat stronger than use of the toy animal alone. Encouraging children to consciously verbalize positive statements may have increased the effects of engagement with the toy. On the other hand, it is possible that repetition of positive self-statements may have directly led to reductions in distress, independently of the toy. These possibilities can only be evaluated in future studies through the use of a properly controlled trial should include a full 2×2 design in which one condition receives only the positive statements factorial design in which one group receives positive statements only. It is important to note that overall, the regression models only explained a small amount of variance in symptom reduction and hence it is clear that a number of relevant variables are yet to be assessed.

The fact that the standard HPI appeared to be associated with little improvement in our study was somewhat surprising but might reflect fundamental differences between the original study (Sadeh et al., 2008) and ours. In the original study, Sadeh and colleagues provided a toy animal to children who were under current threat through dislocation and possible bombing. In this context responsibility and care for the toy may have provided a much-needed distraction from intense fear and uncertainty. Although children in the current study had been through severe trauma, they were currently largely beyond threat and lived in a safe and secure environment. The toy animal in this case may have served more of a focus for positivity rather than distraction and this focus may have been especially amenable to enhancement by positive statements.

Sadeh et al. (2008) conceptualized the use of pretend play to create an innovative, low-cost intervention. As argued by Stein and Kendall (2004), effective interventions for childhood traumatic cases that use play allow children to learn about themselves, their world and how to adapt. Pretend play provides children with the opportunity to integrate emotions with cognitions by expressing their positive and negative feelings (Seja & Russ, 1999; Jent, Niec, & Baker, 2011). When children perform pretend play in a group or their social context it enhances linguistic development and social functioning (Fisher, 1992), consequently improves empathetic interactions (Ashiabi, 2007) and appropriate emotion regulation (Haight et al., 2006). When children use pretend play in a group context, representation of others' perspectives helps to develop empathy and appreciation for social norms (Rubin & Howe, 1986; Kavanaugh & Harris, 1999; Jenkins & Astington, 2000; Nourot, 2006)

4.1. Clinical implications

The simplicity of the current intervention has several benefits for application in low-resourced, developing communities. First, the enhanced HPI seems to be an effective intervention that may provide value for children who experience trauma within a disadvantaged community like Bangladesh. Second, even poorly qualified and in some cases illiterate caregivers were able to be trained to motivate and engage children to create positive changes. Whereas more traditional, empirically validated interventions require high levels of expertise and training, the current intervention was able to deliver some basic components using adults with very limited training. In turn, this is likely to have powerful benefits for communities with very limited resources. Finally and most importantly, this intervention has the flexibility to accommodate large numbers of children simultaneously thereby reducing costs and facilitating extensive accessibility. The flexibility of the enhanced HPI is especially valuable, allowing easy modification for different ages, genders, cultures, or communities of children. It has particular value for cultures where the expression of private feelings and use of psychological concepts is not well accepted.

4.2. Study limitations

The primary limitation of the study was the lack of randomization to the two active conditions, thereby limiting the extent to which comparisons can be drawn between these conditions (quasi-experimental design). It was also very difficult to select institutions that were fully matched on all relevant variables and this, combined with the small number of institutions means that the results need to be accepted with some caution. In particular, the fact that the two groups differed on baseline symptom severity in addition to the caregiver–child orientation time and the educational qualifications of the staff are potentially serious limitations that need to be taken into account in interpretation of the results. These factors might have led to lower distress and created more stable life conditions in the control group. Indeed, this might explain the lower distress scores among children in the control condition at baseline. For example, at baseline 74% of the active intervention group scored in the clinical range on the CRIES, compared with only 43% of the comparison. However, despite this baseline difference, children in the active intervention ended up lower on several measures of distress at post-intervention. For example, the percentage in the clinical range on the CRIES reduced to 41% in the active condition compared to a small increase in the comparison condition to 52%. It is also possible that variation in the caregivers' own psychological state and trauma history might have influenced their involvement in the process and thereby affected results. Given that playing with the toy would have partially acted as a transitional object, it is also possible that the results were influenced by other transitional objects used by the children. Future assessment of the use of toys and potential reminders of parents or other safety cues would be of value. Additional qualitative evaluation of the nature of the engagement with the toy or whether the toy was engaged into posttraumatic play might help to elucidate relevant mechanisms. On the positive side, a strength of this research is the use of a highly relevant, real world population who have urgent needs. The use of carefully controlled and fully randomized designs with such populations is difficult and there is an extensive literature that demonstrates the value of real-world applications using quasi-experimental or non-randomized designs (Goenjian et al., 1997; Sherman, 1998; Bonell et al., 2009; McClatchey, Vonk, & Palardy, 2009; Handley, Schillinger, & Shiboski, 2011).

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Conflict of interest

No conflicts of interests to disclose.

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