

Mediators of focused psychosocial support interventions for children in low-resource humanitarian settings: analysis from an Individual Participant Dataset with 3,143 participants

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Background: Research on psychosocial interventions has been focused on the effectiveness of psychosocial interventions on mental health outcomes, without exploring *how* interventions achieve beneficial effects. Identifying the potential pathways through which interventions work would potentially allow further strengthening of interventions by emphasizing specific components connected with such pathways. **Methods:** We conducted a preplanned mediation analysis using individual participant data from a dataset of 11 randomized controlled trials (RCTs) which compared focused psychosocial support interventions versus control conditions for children living in low- and middle-income countries (LMICs) affected by humanitarian crises. Based on an ecological resilience framework, we hypothesized that (a) coping, (b) hope, (c) social support, and (d) functional impairment mediate the relationship between intervention and outcome PTSD symptoms. A systematic search on the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, PubMed, PsycARTICLES, Web of Science, and the main local LMICs databases was conducted up to August 2018. The hypotheses were tested by using individual participant data obtained from study authors of all the studies included in the systematic review. **Results:** We included 3,143 children from 11 studies (100% of data from included studies), of which 1,877 from six studies contributed to the mediation analysis. Functional impairment was the strongest mediator for focused psychosocial interventions on PTSD (mediation coefficient -0.087 , standard error 0.040). The estimated proportion of effect mediated by functional impairment, and adjusted for confounders, was 31%. **Conclusions:** Findings did not support the proposed mediation hypotheses for coping, hope, and social support. The mediation through functional impairment may represent unmeasured proxy measures or point to a broader mechanism that impacts self-efficacy and agency. **Keywords:** Mediation analysis; individual participant data; children; trauma; humanitarian setting.

Introduction

Evidence on the beneficial effects of psychosocial interventions for children exposed to adversity in humanitarian settings in low- and middle-income countries (LMICs) has grown in recent years (Morina et al., 2017; Purgato, Gastaldon et al., 2018; Purgato, Gross et al., 2018; Tol et al., 2011). A

systematic review and meta-analysis focused on young survivors (≤ 19 years) of mass violence in LMICs identified a moderate effect of psychosocial interventions versus control conditions in reducing post-traumatic stress disorder (PTSD) symptoms at post-treatment assessment (Hedges' $g = 0.57$, 95% confidence interval (CI) 0.27 to 0.88 ; 16 RCTs) (Morina et al., 2017). More recently, a Cochrane systematic review and meta-analysis of psychological therapies for adults and children in humanitarian settings identified three studies in children

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Conflict of interest statement: No conflicts declared.

showing a nonsignificant trend in favor of psychotherapies over control conditions in decreasing PTSD symptoms at study endpoint (standardized mean difference (SMD) = -1.56 , 95% CI -3.13 to 0.01 ; three RCTs) (Purgato, Gastaldon et al., 2018). Even though these meta-analyses are informative, they answer questions concerning *if* psychosocial interventions have impacts on mental health indicators, but do not explore *how* they may do so. Identifying the potential pathways through which interventions may achieve beneficial outcomes would potentially allow further strengthening of interventions by emphasizing intervention components specifically associated with such pathways.

To start addressing this gap in the literature, we examined mediators of intervention outcome of focused psychosocial support interventions for children living in low-resource humanitarian settings. Focused psychosocial interventions have been defined using the Inter-Agency Standing Committee Reference Group on Mental Health and Psychosocial Support in Emergencies (IASC, 2007), in which the idea of multilayered support interventions has been depicted using a pyramid, which indicates that populations in humanitarian emergencies might benefit from safe, socially appropriate, and protecting dignity services, but also from more focused and/or clinical support. The third layer in this pyramid is labeled 'focused psychosocial support interventions', that have generally been developed pragmatically to meet conditions in humanitarian settings, and may be characterized by their implementation by lay workers and targeting people with psychological distress or other psychosocial problems broadly, as opposed to people identified with specific mental disorders (IASC, 2007; Purgato, Gastaldon et al., 2018; Purgato, Gross et al., 2018). We defined a 'mediator' as a variable located in the causal path between intervention and outcome, that is a variable that is affected by the intervention and in turn has an effect on the outcome (Baron & Kenny, 1986; Emsley et al., 2010). We performed a mediation analysis using individual participant data from 11 randomized controlled trials that evaluated psychological symptoms and strength-based outcomes (Purgato, Gastaldon et al., 2018; Purgato, Gross et al., 2018; Purgato et al., 2014). We included children living in African countries (Sierra Leone, Uganda, Rwanda, Burundi, and Democratic Republic of Congo), Asian countries (Indonesia, Sri Lanka, and Nepal), Kosovo, and Occupied Palestinian Territory (Gaza Strip). All the interventions were group-based and delivered in nonclinical settings such as schools, camps for internally displaced people, or villages. The meta-analysis has been recently published (Purgato, Gross et al., 2018), and showed a beneficial effect of focused psychosocial support interventions on PTSD symptoms (SMD -0.33 95% CI -0.52 to -0.14), that was maintained at follow-up

(SMD -0.21 95% CI -0.42 to -0.01). We also identified benefits for functional impairment (SMD -0.29 95% CI -0.43 to -0.15) and for strengths: coping (SMD -0.22 95% CI -0.43 to -0.02), hope (SMD -0.29 95% CI -0.48 to -0.09), and social support (SMD -0.27 95% CI -0.52 to -0.02) (Purgato, Gastaldon et al., 2018; Purgato, Gross et al., 2018).

A popular conceptual framework for psychosocial interventions in humanitarian settings is that of 'ecological resilience' (Tol et al., 2013) that has been defined as 'those assets and processes on all socio-ecological levels that have been shown to be associated with good developmental outcomes after exposure to situations of armed conflict' (Tol, Jordans et al., 2008). Ecological resilience refers to a process whereby children and adolescents attain desirable outcomes despite significant risks to their adaptation and development. These processes are thought to involve dynamic relationships between risk, protective, and promotive factors at different levels of the young persons' social ecology (e.g. individual, family, school, neighborhood levels) (Betancourt & Khan, 2008; Betancourt et al., 2013; Brofenbrenner, 1979; Ungar, 2012; Ungar et al., 2013). In line with this framework, practitioners have designed interventions aimed at increasing protective and promotive factors, for example strengthening of effective coping strategies, problem solving, hope (defined here as the sense of agency, that is the perception that children can initiate and sustain actions toward a certain goal, and pathways, that is perceived capability to produce routes to those goals; Haroz et al., 2017), increasing social support networks, and resource building in order to shift outcomes from risk to resilience. This shift from a clinical/deficit approach to a resilience approach draws on the capacities of children to take steps that improve their protection and well-being (Wessels, 2018). According to this paradigm, psychosocial interventions work through resilience improvement, for example introducing creative expressive elements (cooperative games, structured movement, dance, relaxation, music, and drama), reinforcing self-esteem, social support (even group cohesion within the intervention group), empowerment, and emotion regulation. Reinforcing child resilience in terms of (re)building feelings of safety, coping resources, and hope in turn, reduces psychological suffering (Wessels, 2015; Wessels, 2018). Hope, positive coping, and social support are conceptualized as resilience outcomes.

The current study aims to test an ecological resilience pathway for psychosocial support interventions. We hypothesize that interventions lead to increased hope, positive coping, and social support (putative mediators), which in turn reduce psychological symptoms. Additionally, we hypothesize functional impairment as a mediator of interventions on PTSD symptoms, based on a potential pathway of

psychosocial interventions recently proposed by Kohrt and Song (2018), and considering a decrease in functional impairment as a proxy of the capacity of the children of being mobilized and able to engage in daily life activities (i.e. an ability of psychosocial interventions to target overall demoralization and learned helplessness in the face of ongoing adversity).

Methods

Search strategy and screening

We conducted a systematic review of randomized controlled trials and individual participant data meta-analysis on focused psychosocial support interventions in children (0–18 years) exposed to traumatic events in LMICs, compared with waiting list conditions. We refer to Purgato, Gross et al. (2018) for a detailed description of the review methodology.

In short, the search strategy included the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, PubMed, PsycARTICLES, Web of Science, and the main local LMICs databases according to the list of databases relevant to LMIC developed collaboratively by Cochrane and World Health Organization (WHO) Library (Cochrane Epoc Group, 2013), up to August 2018, with no limitations on year or language of publication. No restriction was applied on publication date and language.

This strategy included also studies searched through reference lists of relevant review papers, WHO mental health Gap Action Programme (mhGAP) and Inter-Agency Standing Committee (IASC) guidelines (IASC, 2007; World Health Organization, 2015), grey literature of a relevant systematic review published by Tol et al. (2011), and references of included/excluded studies. Additionally, the search strategy was cross-checked with the search performed by the Cochrane Common Mental Disorders Group for two Cochrane reviews on psychological interventions in LMICs (Purgato et al., 2016; Purgato, Gastaldon et al., 2018).

Study titles and abstracts were screened independently by two reviewers (MP and CG), and full-text papers were retrieved for all candidate studies. Studies were examined by two independent researchers (MP and CG), discrepancies were discussed with a third reviewer (CB), and a consensus reached. All studies were assessed for eligibility against the review protocol. The review protocol has been registered in PROSPERO (registration number CRD42018105054).

Inclusion criteria

Study design. We included RCTs assessing the effect of focused psychosocial support interventions delivered through any means (i.e. face-to-face meetings, internet, radio, telephone, or self-help booklets) versus control conditions (including no treatment, usual care, waiting list, attention placebo, and psychological placebo); conducted in low-resource humanitarian settings, that is LMICs as defined by the World Bank (The World Bank, 2018); recruiting children (aged 0–18 years) exposed to traumatic events. Focused psychosocial support interventions have been defined according to the Inter-Agency Guidelines for Mental Health and Psychosocial Support (IASC, 2007), characterized by: their implementation by lay workers, targeting people with psychological distress or other psychosocial problems broadly, as opposed to people formally diagnosed with specific mental disorders.

Participants and setting. We included children aged 0–18 years of any population group or religion exposed to traumatic events in humanitarian settings in LMICs. Humanitarian crises

involve a broad range of emergencies, including wars, armed conflicts, and disasters triggered by natural or industrial hazards (Josse, 2009) (Tol et al., 2011). They disproportionately affect populations living in LMICs (Guha-Sapir et al., 2014; UNICEF, 2009) and can have a wide range of effects on children's mental health and psychosocial well-being.

We included studies with populations during humanitarian crises, as well as in the period after acute humanitarian crises (for example, postconflict settings).

Variables. Mediators were coping, hope, social support, and functional impairment. The primary study outcome was PTSD symptoms. The primary outcome has been identified in consideration of the fact that children were exposed to traumatic events in humanitarian settings, and in accordance with the Kohrt and Song's model on the pathway of functioning of focused psychosocial interventions (pathway B) (Kohrt & Song, 2018). In pathway B, it is hypothesized that focused psychosocial interventions might work by reinforcing the sense of hope, coping, social support, and functioning, and that this in turn has a beneficial effect on PTSD symptoms. Depression and anxiety symptoms were common measures across studies, and in the full IPD meta-analysis, we did not identify a statistically significant relationship between focused psychosocial interventions and these outcomes (Purgato, Gastaldon et al., 2018; Purgato, Gross et al., 2018). For this reason, we reasoned that it was less plausible to conduct mediation analysis on these outcomes. We performed preliminary analyses to investigate depression and anxiety symptoms as potential mediators of the intervention effect on PTSD symptoms without identifying a mediation role.

To measure improvement in PTSD symptoms, the Child Post-traumatic Symptom Scale (Foa et al., 2001), the 8-item Impact of Events Scale (CRIES-8) (Yule et al., 1994), the Harvard Trauma Questionnaire (Mollica et al., 1992), and the University of California Los Angeles (UCLA) Post-Traumatic Stress Disorder Reaction Index (Steinberg et al., 2004) were used by study investigators. PTSD and the other constructs were collected using different instruments in each study, that were validated and/or culturally adapted rating scales (often preceded by preliminary qualitative work at local level), which we co-calibrated using item response theory methods as described previously (Purgato, Gross et al., 2018). Mediation analyses were conducted considering coping, hope, social support, and functional impairment as mediators of the intervention on PTSD symptoms.

Timing and effect measures. Since we hypothesized direct and indirect effects of the treatment on PTSD, both the mediators and the outcome were measured immediately after the end of the treatment (T1), controlling for their values at baseline (T0) prior to treatment implementation (Table S1A). However, following the recommendation from Pek and Hoyle (2016) to collect multiple measures of the variables involved in a mediation model when the timing of the full intervention/mediator and mediator/outcome effects are unknown, we also performed a sensitivity analysis to investigate a possible delayed effect of mediators, by using PTSD at 6-months follow-up (T2) as outcome (Table S2A). Moreover, given that, as noted by MacKinnon et al. (2007), mediation models cannot prove the correct specification of causal order and direction, as a further sensitivity analysis we explored the case of mediator-outcome reversal (Table S3A). Also, we performed the final model both including and excluding socio-demographic factors (i.e. age, gender, and years of education) to check robustness of results to omitted variables.

Risk of bias and quality assessment. Two reviewers (MP and DP) independently assessed the risk of bias with the Cochrane risk of bias tool (Higgins & Douglas, 2011; Higgins et al., 2011). Each potential source of bias was judged as high,

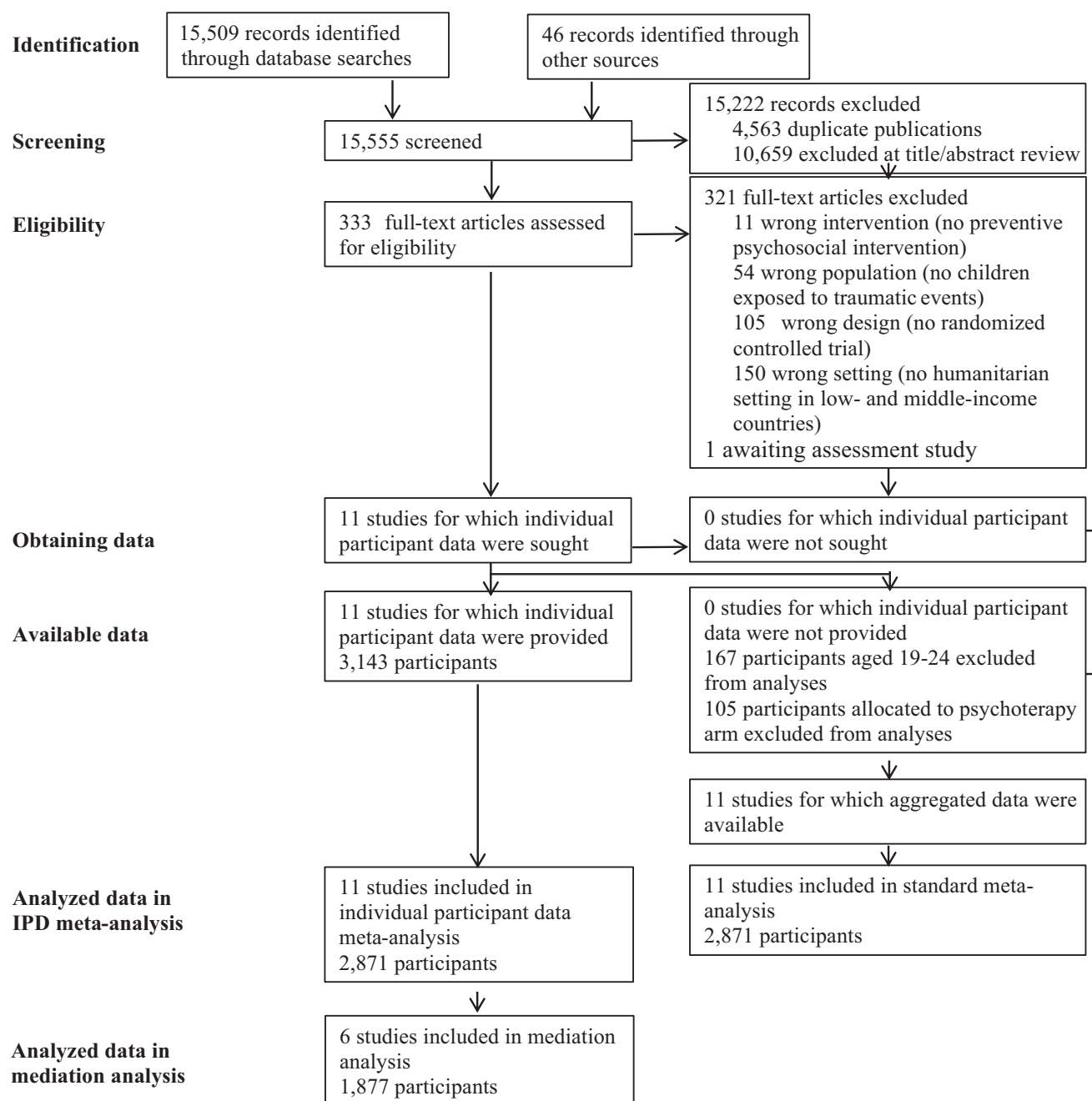


Figure 1 Studies included in systematic review, IPD meta-analysis, and mediation analysis. We included studies according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses guidelines for Individual Participant Data (PRISMA-IPD)

low, or unclear, with a supporting quotation from the study report together with a justification for the judgment.

The quality of evidence was evaluated using the Grading of Recommendation, Assessment, Development, and Evaluation (GRADE) assessment. This approach provides outcome-specific information concerning the overall quality of evidence from studies included in the comparison, the magnitude of effect of the psychosocial interventions examined, and the sum of available data on the outcomes (Guyatt, Oxman, Kunz et al., 2008; Guyatt, Oxman, Vist et al., 2008). Any discrepancies were resolved by consensus and arbitration by two other members of the review team (CB and WT).

Mediation pathway

We examined the following putative mediators of intervention on the outcome PTSD symptoms: coping, hope, social support, and functional impairment. We tested the mediating role of

each potential mediator by regressing PTSD symptoms on the mediator (path 'B') and treatment (path 'C'), and the mediator on treatment (path 'A'), in a structural equations modeling framework. The product of paths A and B represents a test of mediation. We also calculated the proportion of the effect mediated by each mediator.

To test whether treatment had an effect on each putative mediator, we used a regression with each putative mediator post-treatment value as outcome and its baseline value and treatment as predictors. In particular, for each study and putative mediator, a regression with treatment arm and values at T0 as predictors and values at T1 as outcome was performed, and a random-effect meta-analysis of the resulting coefficients related to treatment arm was finally implemented.

Statistical approach for mediation analysis. In the original individual participant dataset, we used the item response theory (IRT) approach to harmonize questionnaire

items across datasets from each randomized trial (Gross et al., 2015; Gross et al., 2014). Questions more strongly correlated with other questions within and across the datasets were given greater weight. Additionally, the model defines appropriate locations or thresholds, for individual question responses on the latent variable metric based on prevalence in the sample of the question response. The effect of any particular test on the overall score is the same across studies with different numbers of tests, which provides a distinct advantage over approaches that standardize and average together different sets of items across different studies (Delis et al., 2003; Estabrook & Neale, 2013).

Given that IRT leads to a heterogeneous variance by construction, we conducted mediation analysis using symptom scores that turned out to be significantly affected by treatment as possible mediators. We adopted a one-step approach, that is a structural equation model (SEM) including a measurement and a structural part. In the measurement part, original questionnaire items were considered as indicators of latent symptom scores (including PTSD); in the structural part, each post-treatment symptom score was regressed on treatment and its baseline value and PTSD on post-treatment values of possible mediators as well.

We standardized relevant parameters by fixing the variance of latent factors to 1 (Cheung, 2009) and combined results across studies in a random-effects meta-analysis (Riley et al., 2011) by using the 'metan' command in Stata (Harris et al., 2008). The model was first applied for countries where items on all possible mediators were available, then for subset of mediators, in case this allowed to increase the number of countries included in the analyses. Among the socio-demographic variables that could be of importance in this population (e.g. family composition, types of traumatic events, social capital, number of years in education), we were able to consider gender, age, and (when available) number of years in education as confounders.

We used the software programs R 3.5.0 and Stata 15.1 for data analysis (Stata, 2017).

Results

Study characteristics

Overall, 15,555 citations were identified by the search, screened independently by two review authors (interrater reliability, $k = 0.840$, 95% CI 0.812 to 0.868), and 333 potentially eligible articles were retrieved in full text (Fig. 1).

We excluded 321 reports for reasons including psychotherapeutic treatment of diagnosed disorders instead of focused psychosocial support interventions, or the wrong population or study design, and we classified one study as awaiting assessment. This resulted in 11 included RCTs (Betancourt et al., 2014; Bolton et al., 2007; Gordon et al., 2008; Jordans et al., 2010; O'Callaghan et al., 2014; Punamaki et al., 2014; Qouta et al., 2012; Richards et al., 2014; Tol et al., 2014; Tol et al., 2012; Tol, Komproe et al., 2008; Unterhitzenger & Rosner, 2014) (3,143 participants; 100% of requested data) published between 2007 and 2014 comparing focused psychosocial support interventions versus waiting list conditions. We were able to trace the investigators for all 11 trials, and all agreed to participate in this project and shared the datasets.

Of these, six studies (Betancourt et al., 2014; Jordans et al., 2010; O'Callaghan et al., 2014; Tol et al., 2014; Tol et al., 2012; Tol, Komproe et al., 2008) (1,877 participants) contributed to the mediation analysis, as these studies provided data on putative mediators and on PTSD. The number of sessions ranged from 3 to 18, with a mean of 12 sessions. The mean study sample size was 250 participants. Children's age ranged from 7 to 18 years. Included studies evaluated with the Cochrane risk of bias tool were in general of good quality. We defined the overall risk of bias of a study as 'high' when at least one item was judged at high risk of bias, acknowledging that the item 'Blinding of participants and personnel' does not fit perfectly with the design of psychological intervention studies (Cuijpers et al., 2015; Schean, 2014). The GRADE methodology rating was low to moderate, mainly due to the high levels of heterogeneity across studies.

Mediation analysis

First, we tested whether the intervention had a significant relation with each one of the following putative mediators: hope, coping, social support, and functional impairment, by using the IRT estimates directly with a random effect (RE) regression, and using treatment arm and baseline value as regressors. Social support is only estimated in one study, so RE's were not needed in that case. This analysis led to the identification of social support (p -value .005), hope (p -value .041), and functional impairment (p -value .005) as the possible mediators (i.e. psychosocial intervention arm was found to be significant).

Second, the following set of SEM models with PTSD as outcome: one study with all the three mediators considered, four studies with two mediators (hope and functional impairment), and six studies with one mediator (functional impairment). In the model with three mediators (Table 1), we identified only functional impairment as significant. This finding excludes any possible evidence of social support as mediator. In the model with two mediators (Table 2), only the direct effect of intervention on PTSD symptoms was significant. This excludes any possible evidence of hope as mediator. Using the

Table 1 Analysis with three mediators

Studies contributing to the mediation analysis	SDE (Coeff; SE)	SIE via Social Support (Coeff; SE)	SIE via Functional impairment (Coeff; SE)	SIE via Hope (Coeff; SE)
Betancourt (2014)	.048 (.124)	.003 (.019)	-.253 (.093)**	.004 (.009)

SDE-Coeff, Standardized direct effect coefficient; SIE-Coeff, Standardized indirect effect coefficient; SE, standard error.

** p -value < .01.

model with one mediator (functional impairment) (Fig. 2), the mediation effect is significant, while the direct effect is not. Adding socio-demographic variables as confounders, changes in results were negligible (Table 3).

Table 2 Analysis with two mediators

Studies contributing to the mediation analysis	SDE (Coeff; SE)	SIE via Functional impairment (Coeff; SE)	SIE via Hope (Coeff; SE)
Tol, Komproe et al. (2008)	-.191 (.115)	.020 (.065)	-.001 (.014)
Tol et al. (2014)	-.473 (.184)*	-.260 (.100)**	.028 (.038)
Jordans (2010)	-.387 (.110)***	-.005 (.033)	-.076 (.039)
Betancourt (2014)	-.044 (.117)	-.262 (.084)**	.000 (.001)
Global effect	-.254 (.093)**	-.108 (.070)	-.002 (.008)

SDE-Coeff, standardized direct effect coefficient; SIE-Coeff, standardized indirect effect coefficient; SE, standard error.

* p -value < .05.

** p -value < .01.

*** p -value < .001.

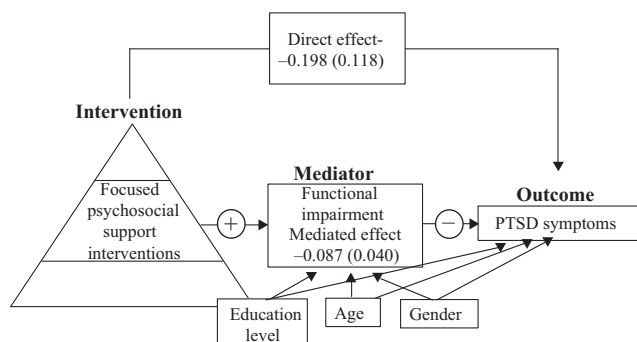


Figure 2 Results of mediation model

Table 3 Analysis with one mediator

Studies contributing to the mediation analysis	No confounders		Confounders	
	SDE (Coeff; SE)	SIE via Functional impairment (Coeff; SE)	SDE (Coeff; SE)	SIE via Functional impairment (Coeff; SE)
Tol (2014)	-.192 (.114)	.020 (.065)	-.208 (.116)	.014 (.065)
Tol (2008)	-.432 (.183)*	-.272 (.102)**	-.387 (.190)*	-.262 (.106)*
Jordans (2010)	-.457 (.102)***	-.012 (.033)	-.440 (.103)***	-.010 (.031)
Tol (2012)	.172 (.079)*	-.175 (.04)***	.177 (.079)*	-.176 (.047)***
Betancourt (2014)	-.049 (.117)	-.252 (.080)**	-.042 (.118)	-.251 (.085)**
O'Callaghan (2014)	-.355 (.165)*	-.007 (.014)	-.380 (.163)*	-.007 (.015)
Global effect	-.203 (.119)	-.091 (.041)*	-.198 (.118)	-.087 (.040)*

SDE-Coeff, standardized direct effect coefficient; SIE-Coeff, standardized indirect effect coefficient; SE, standard error.

Adjusted for age, gender, level of education.

* p -value < .05.

** p -value < .01.

*** p -value < .001.

Sensitivity analyses

Two sensitivity analyses were conducted (results available as supporting materials in the Tables S1–S3): one using PTSD as a mediator and functional impairment as outcome and one with values at T1 for mediators and at T2 for outcome (controlling for its value at T1). In the model reversing mediator and outcome, we did not find a significant indirect effect of treatment on functioning through PTSD (standardized indirect effect coefficient $-.037$, SE 0.030); in the model with PTSD at T2 as outcome neither the direct nor the indirect effect (standardized indirect effect coefficient $-.030$, SE 0.023) reached statistical significance. Such results corroborate the choice to consider functioning as the mediator and PTSD as the outcome.

Discussion and Conclusion

In the present study, we aimed to examine mediators of psychosocial interventions for children exposed to traumatic events in humanitarian settings in LMICs. Based on an ecological resilience conceptual framework (Betancourt & Khan, 2008; Brofenbrenner, 1979; Tol et al., 2013), we hypothesized that hope, coping, and social support would mediate associations between interventions and the outcome PTSD symptoms. In addition, we analyzed the mediation role of functional impairment on PTSD symptoms. We generally identified a statistically significant association between intervention and functional impairment, which is one of the requirements to determine mediation, and a relation with changes in the outcome PTSD symptoms. We did not identify associations between the interventions and the putative expected mediators coping, hope, and social support.

To our knowledge, this is the first analysis focused on understanding the mediators of psychosocial interventions in humanitarian settings using

individual participant data from a large dataset of RCTs. In our opinion, the current work represents an innovative contribution to the field of psychosocial interventions in humanitarian settings in LMICs. The methodology adopted in this study aims to improve understanding of how psychosocial interventions work, in order to match interventions with smaller group of individuals presenting specific socio-demographic and clinical characteristics, and exploring potential causes of heterogeneity (Cuijpers & Christensen, 2017; Cuijpers et al., 2016; Cuijpers et al., 2012; Dorrestijn et al., 2011). We believe this approach is critical to the field of global mental health to help unpack mechanisms of change as well as future subgroup analyses to understand 'what works for whom under what circumstances' given that the numbers affected are large but the human and financial resources to respond are limited.

The current analysis presents some limitations. First, given the small number of included studies estimation of the actual strength of the mediation effect could be imprecise. Second, we included studies assessing the effects of psychosocial interventions on defined outcomes, measured at baseline and through one and/or two post-intervention assessments, without multiple assessment time points during the interventions or at longer-term follow-ups, that would have been the optimal choice for studying the mechanism of action of focused psychosocial interventions (Cuijpers et al., 2019). We did not consider the role of variables (and their interaction) different from those that have been measured in the original studies, for example child self-esteem, self-regulation, self-efficacy, and family/social/community connectedness (Lubans et al., 2016; Wessels, 2015). Moreover, our analysis is limited to children exposed to challenging contexts, without considering in depth the role of subgroups of other events that children may have experienced (for example, loss of family members, direct or indirect exposure to physical and/or psychological violence), and the search strategy for the development of the dataset is dated August 2018, and since then new RCTs on focused psychosocial interventions might be published.

Another important aspect is that the 'active ingredients' were not well specified across all of the interventions; therefore, we cannot exclude that unmeasured mechanisms might have been in operation strengthening effective coping strategies, problem solving, hope, or increasing social support. Consequently, failure to show an association between the interventions and coping, hope, or social support should be interpreted with caution, as the present analysis was necessarily based only on those mechanisms that were formally measured by means of rating scales.

In light of these limitations, future research should be specifically focused on the exploration

of all the individual and social prognostic factors that explain the natural response that a child might have in humanitarian contexts regardless of the intervention.

Despite these limitations this study advanced knowledge in several ways. First, we found a mediation effect of functional impairment on the outcome PTSD and not vice-versa. This would suggest that the mediating pathway of focused psychosocial interventions is different from the mechanism of more specialized clinical interventions, which are firstly directed to psychological symptoms and may subsequently generate an improvement in other outcomes including functional impairment (Kohrt & Song, 2018). From this perspective, the process may be explained from a 'demoralization' point of view: a first explanation could be that the interventions help children to reverse a sense of 'learned helplessness', that is they provide children with a general sense that the world can be positively improved, and that children are not helpless to deal with the human consequences of humanitarian crises (Bosqui & Marshoud, 2018). A second explanation, possibly more consistent with our findings, is that the improvement can be measured as an improved ability to engage in daily activities, that generates and/or reinforces a sense of competency. This more general subjective satisfaction subsequently translates into reductions in specific symptoms. These mechanisms of change have been recently described in a systematic review of reviews, designed with the aim of exploring the key mechanisms of change intrinsic across interventions aimed at improving resilience and well-being in children exposed to war and armed conflicts (Bosqui & Marshoud, 2018). Factors like helpfulness, engagement in social and daily activities, and an internal locus of control have been considered within those that might improve strength (Bosqui & Marshoud, 2018).

If psychosocial interventions that target large-scale populations have an impact on the capacity of children in better engaging in daily life activities, that in turn may protect them from the development of psychological distress, this mechanism may be built on to prevent the need of more structured and expensive clinical services.

Further qualitative research may be helpful to develop hypotheses on the complex processes described here, and future RCTs should be designed to test what matches between intervention and subgroups of children produce the best results in terms of symptom decrease, functional impairment, and resilience outcomes.

Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article:

Table S1. Analyses on putative mediators.

Table S2. Analyses on functional impairment post-treatment as a mediator for PTSD at follow-up.

Table S3. Analyses on PTSD as a possible mediator for functional impairment.

Acknowledgements

The authors have declared that they have no competing or potential conflicts of interest.

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Key points

- Previous systematic research has demonstrated positive effects of psychosocial interventions on PTSD symptoms at short-term follow-up and identified subgroups of children that might benefit more than others from receiving psychosocial interventions.
- We conducted a mediation analysis using individual participant data from randomized controlled trials to understand *how* interventions achieve beneficial effects on children mental health.
- We showed that the effects of psychosocial interventions on PTSD outcomes is mediated by levels of functional impairment.
- The methodology of this study goes toward an in-depth understanding of the mechanism of action of focused psychosocial interventions that allows creating an evidence-based match between interventions and subgroups of individuals presenting specific socio-demographic and clinical characteristics.

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Accepted for publication: 3 October 2019

First published online: 7 November 2019