REVIEW ARTICLE



We need to build the evidence: A systematic review of psychological first aid on mental health and well-being

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Abstract

Ensuring effective mental health and psychosocial support is crucial following exposure to a potentially traumatic event and can have long-term consequences for individuals, families, and communities. Psychological first aid (PFA) has become a widespread intervention of choice following exposure to conflict or disaster; however, its impact is unknown. This systematic review assessed PFA efficacy in improving the mental health and psychosocial well-being of individuals exposed to potentially traumatic events. We searched PubMed, PsycINFO, PTSDpubs, and EMBASE for peer reviewed studies evaluating programmatic outcomes of PFA, or an adapted intervention, published in English before March 9, 2021. Studies evaluating training outcomes or program feasibility were excluded. The primary outcomes were reported measures of participant mental health and psychosocial well-being, with narrative results presented for each. The Cochrane Risk of Bias tool was applied. Of 9,048 potentially eligible citations, 12 studies with a total of 1,437 participants met the inclusion criteria. Only one study was a randomized controlled trial. The findings from all studies suggest a positive impact of PFA, with most reporting reduced symptoms of anxiety, depression, posttraumatic stress, and distress, as well as improved ratings of mood, the experience of safety, connectedness, and a sense of control, among youth and adults. Risk of bias was generally high. Inconsistent intervention components, insufficient evaluation methodologies, and a high risk of bias within the reviewed studies present challenges in assessing PFA efficacy, and an imbalance between popular support for PFA and scant evidence of outcome data exists. Further research is needed to justify the proliferation of PFA.

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Exposure to potentially traumatic events (PTEs), defined in the Diagnostic and Statistical Manual of Mental Disorders (fifth ed.; DSM-5; American Psychiatric Association [APA], 2013) as those involving "actual or threatened death, severe injury, or sexual violence," can have longterm consequences on individuals, families, and communities (Bonanno et al., 2010; Norris, 1992; Overstreet et al., 2017). With few exceptions (Di Nota et al., 2021), prior efforts to respond to and improve mental health and wellbeing in communities affected by PTEs have too often not only failed to demonstrate their goals (Papola et al., 2020) but, at times, have harmed the individuals they sought to help (Rose et al., 2002). Intervention efforts have, thus, prioritized implementation supported by international guidelines (APA, n.d.a.; Inter-Agency Standing Committee [IASC], 2007) that support the cost-effective use of finite resources. Regrettably, the data are controversial and sparse.

First introduced during World War II, psychological first aid (PFA) is the widespread intervention of choice following PTE exposure (Brymer et al., 2006). PFA is a manualized approach to providing psychosocial support to individuals in the immediate aftermath of a stressful event (The National Child Traumatic Stress Network [NCTSN]), designed to reduce immediate distress and mitigate psychopathology risk (Vernberg et al., 2008). Although there are different PFA models, all involve a needs assessment, nonjudgmental listening and engagement, and service referral when indicated (Supplementary Table S1). PFA was originally designed for humanitarian settings, does not require specialist training, and can be delivered by non-mental health care workers (IASC, 2007). Interest in PFA has grown in recent years, and many organizations offer training (NCTSN, n.d.a.) or have published PFA information (APA, n.d.a.; Substance Abuse and Mental Health Services Administration [SAMHSA], 2005; World Health Organization [WHO] et al., 2011). Standard implementation guidelines developed by the WHO are widely endorsed (WHO et al., 2011). Although the WHO guide for PFA is unique in that it has been translated into more than 20 languages, PFA frameworks have been developed by organizations or for specific populations as well. This has resulted in significant heterogeneity of the PFA models (Supplementary Table S1).

Public mental health communities promote PFA implementation as a gold standard and assume effectiveness (Van Ommeren & Saxena, 2016) despite over a decade of calls to build the evidence base (Bisson & Lewis, 2009;

Dieltjens et al., 2014; Fox et al., 2012; Shultz & Forbes, 2014; Tol et al., 2012). Previous reviews have demonstrated insufficient evidence to evaluate efficacy (Bisson & Lewis, 2009; Dieltjens et al., 2014; Fox et al., 2012). With the most recent review in 2014 and funding and support for PFA implementation high, we conducted this systematic review of PFA to assess the efficacy of PFA in improving mental health and psychosocial well-being among individuals exposed to PTEs, identify best practices based on the extant data, and recommend research priorities that will produce the much-needed evidence base to guide similar interventions in humanitarian, postdisaster, and crisis settings.

METHOD

We conducted this systematic review based on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Statement (Page et al., 2021; Supplementary Tables S2 and S3). Because previous systematic reviews (Bisson & Lewis, 2009; Dieltjens et al., 2014; Fox et al., 2012) and a preliminary review of recent literature suggest insufficient evidence to quantitatively synthesize PFA programmatic effect (i.e., through meta-analysis), this review was not submitted to PROSPERO, as it is ineligible.

Search strategy and selection criteria

We searched the PubMed, PsycINFO, PTSDpubs, and EMBASE electronic databases using the search terms: "psychological first aid" or "mental health first aid" or "psychological crisis intervention" or "mental health crisis intervention" for English-language, peer reviewed papers published before March 9, 2021 (see Supplementary Materials).

Only published, peer reviewed studies evaluating a PFA programmatic outcome, irrespective of design required to evaluate efficacy (i.e., related to mental health or psychosocial well-being), or an adapted intervention were included. A programmatic outcome is the assessment of a PFA-based action taken to improve the mental health or psychosocial well-being of participants. Studies evaluating training outcomes or program feasibility were excluded, as they do not speak to the overall intervention efficacy, as were commentaries, opinion pieces, protocols, and reviews. There were no restrictions on study setting or population, and both qualitative and quantitative studies were considered.

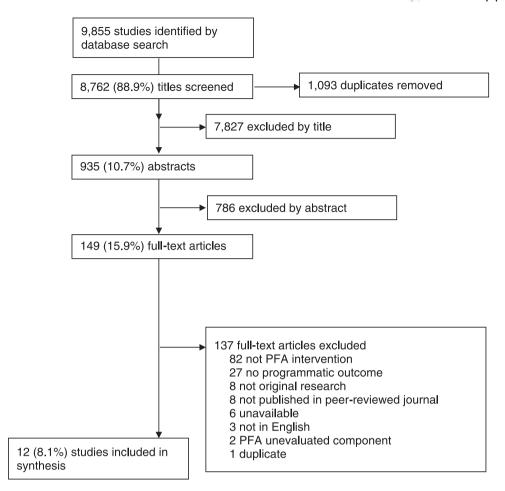


FIGURE 1 Study selection *Note*: PFA = psychological first aid.

After removing duplicate records, the remaining titles and abstracts were reviewed, and studies were selected for inclusion by three independent authors (Sarah Forthal, Karolina Sadowska, Elizabeth B. Magill) based on the predetermined inclusion and exclusion criteria (see Supplementary Materials). To ensure quality, a second author randomly reviewed 15% of titles and 10% of abstracts. The full texts of eligible studies were reviewed for inclusion independently by two authors (Sarah Forthal, Karolina Sadowska) and a third author (Sabrina Hermosilla) settled all conflicts.

Data analysis

Study-level data on setting, details, participant characteristics, facilitator characteristics, study design, and the programmatic outcomes evaluated were extracted. All programmatic outcome results were extracted. Risk of bias was assessed using the Cochrane Risk of Bias tool, which rates studies as having a low, high, or unclear risk of bias in the following domains: random sequence generation, allo-

cation concealment, participants and personnel blinding, outcome assessment blinding, incomplete outcome data, selective reporting, and other sources of bias (Higgins & Green, 2011). Two authors independently assessed risk of bias for each study using the tool's criteria (Higgins & Green, 2011) and settled disagreements among themselves.

Synthesis

Results for each study are presented narratively, by outcome, using the effect sizes and precision measures reported in the studies. Tables were structured by study, outcome, and intervention components.

RESULTS

The search identified 9,855 articles potentially eligible for study inclusion (Figure 1). After the removal of 1,093 duplicates, 8,762 titles were screened for eligibility based on title and abstract. This eliminated 8,613 studies, leaving 149 for

full-text screening. Most studies were excluded because the intervention tested was not PFA (59.9%) or the study did not analyze a programmatic outcome (19.7%). Other reasons for exclusion were that the paper was unavailable due to insufficient access privileges (researchers used the Columbia University Library, which offers access to over 163,000,000 articles), did not reflect not original research, was not a peer reviewed journal article, or was not published in English. Papers were also excluded if PFA was an unevaluated intervention component. In total, 12 studies were included in the systematic review.

Table 1 briefly describes the studies and presents relevant effect sizes and results. The 12 included studies reported individual outcomes from a PFA or a PFA-based intervention; no studies reported community outcomes. Five studies were randomized control trials (Despeaux et al., 2019; Everly et al., 2016; McCart et al., 2020; Meir et al., 2012) or randomized trials (Ironson et al., 2020); study assignment was not randomized for most: One study was a pilot quasi-experiment (Ramirez et al., 2013), two were convenience sample pretest–posttest group designs (Cain et al., 2010; Kameno et al., 2021), one was a convenience sample uncontrolled longitudinal design (Blake et al., 2020), one was a qualitative comparative analysis (Schafer et al., 2016), and two were qualitative thematic analyses (Bakes-Denman et al., 2021; De Freitas Girardi et al., 2020). Four studies had control groups (Despeaux et al., 2019; Everly et al., 2016; McCart et al., 2020; Meir et al., 2012), and five included randomization with regard to the intervention condition (Despeaux et al., 2019; Everly et al., 2016; Ironson et al., 2020; McCart et al., 2020; Meir et al., 2012). Most studies did not include power calculations (Despeaux et al., 2019; Everly et al., 2016; McCart et al., 2020), and only one reported having sufficient power to detect medium effects for differences between the intervention and control groups (Meir et al., 2012). Eight studies included a pre-post analysis (Cain et al., 2010; Despeaux et al., 2019; Everly et al., 2016; Ironson et al., 2020; Kameno et al., 2021; McCart et al., 2020; Meir et al., 2012; Ramirez et al., 2013), and nine studies included postintervention follow-up (Bakes-Denman et al., 2021; Despeaux et al., 2019; Everly et al., 2016; Ironson et al., 2020; Kameno et al., 2021; McCart et al., 2020; Meir et al., 2012; Ramirez et al., 2013; Schafer et al., 2016), which ranged from 30 min (Despeaux et al., 2019; Everly et al., 2016) to 6 months (Ironson et al., 2020). None of the included studies were examined in previous PFA systematic reviews.

Studies were primarily conducted in the United States (Cain et al., 2010; Despeaux et al., 2019; Everly et al., 2016; Ironson et al., 2020; McCart et al., 2020; Ramirez et al., 2013). Interventions were conducted in school or university facilities (Cain et al., 2010; Despeaux et al., 2019; Everly

et al., 2016; Meir et al., 2012; Ramirez et al., 2013), hospitals or other health care settings (Bakes-Denman et al., 2021; Blake et al., 2020; Kameno et al., 2021), designated child-friendly spaces (Schafer et al., 2016), community settings (Ironson et al., 2020; McCart et al., 2020), or during home visits (Cain et al., 2010; De Freitas Girardi et al., 2020; Schafer et al., 2016). The target populations were adults (Bakes-Denman et al., 2021; Blake et al., 2020; Everly et al., 2016; Ironson et al., 2020; Kameno et al., 2021; Schafer et al., 2016), undergraduate college students (Despeaux et al., 2019), adolescents (Ramirez et al., 2013; Schafer et al., 2016), and children (Cain et al., 2010; De Freitas Girardi et al., 2020; Meir et al., 2012). All interventions except one (Despeaux et al., 2019) were conducted among individuals who reported PTE exposure. Study sample sizes ranged from 13 (Bakes-Denman et al., 2021) to 260 participants (Blake et al., 2020).

PFA intervention components varied across studies (Table 2). Four PFA interventions were conducted with individuals (Bakes-Denman et al., 2021; Everly et al., 2016; Kameno et al., 2021; Ramirez et al., 2013), and eight were conducted in group settings (Blake et al., 2020; Cain et al., 2010; De Freitas Girardi et al., 2020; Despeaux et al., 2019; Ironson et al., 2020; McCart et al., 2020; Meir et al., 2012; Schafer et al., 2016). Intervention components included promoting safety, calming, self- and community efficacy, connectedness, hope, reflective listening, knowledge, self-worth, and self-awareness. In six studies, PFA interventions were facilitated by mental health professionals (Bakes-Denman et al., 2021; Everly et al., 2016; Ironson et al., 2020; Kameno et al., 2021; Meir et al., 2012; Schafer et al., 2016), whereas six studies used PFA facilitators with non-mental health or nonspecified backgrounds (Blake et al., 2020; Cain et al., 2010; De Freitas Girardi et al., 2020; Despeaux et al., 2019; McCart et al., 2020; Ramirez et al., 2013). Intervention sessions ranged from a single, 10min session (Despeaux et al., 2019; Everly et al., 2016) to multiple sessions across 6 (Cain et al., 2010) to 17 (Blake et al., 2020) weeks. All interventions were conducted in person.

All studies reported improvement in mental health outcomes. Outcome measurements varied across studies (Supplementary Table S4). In total, 26 measures were used to assess 17 outcomes. Four studies found reductions in anxiety (Despeaux et al., 2019; Everly et al., 2016; McCart et al., 2020; Meir et al., 2012) and depressive symptoms (Ironson et al., 2020; McCart et al., 2020; Meir et al., 2012; Ramirez et al., 2013). Symptoms of posttraumatic stress disorder (PTSD) were also measured in four studies (Cain et al., 2010; Ironson et al., 2020; McCart et al., 2020; Ramirez et al., 2013), with all but one (Ramirez et al., 2013) reporting a statistically significant reduction in PTSD symptoms. Two studies evaluated mood scores, with





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Study characteristics and major outcomes	
TABLE 1	

				Research		PFA outcome-related main
Citation	Country	Population	PTE	approach	Control group	findings ^a
Bakes-Denman et al., 2021	Australia	Adult hospital staff, mental health facility	Occupational violence	Qualitative	None	Program supportive and useful in normalizing reactions to PTE
Blake et al., 2020	United Kingdom	Adult hospital staff, acute hospitals	COVID-19	Quantitative	None	Higher mental well-being (attendees: $M = 47.04$; nonattendees: $M = 45.11$, $p = .02$)
Cain et al., 2010	United States	Underage population, urban and rural areas	Hurricane Katrina displacement	Quantitative	None	Slight PTSD symptom improvement $(\Delta M = 2.85, t = 2.25, p = .027).$
de Freitas Girardi et al., 2020	Canada	Children aged 2–18 years, urban area	Asylum-seeking	Qualitative	None	Fostered emotional safety and sense of normalcy and new connections
Despeaux et al., 2019	United States	Undergraduate students, urban area	None	Quantitative	Group conversation	Anxiety symptoms $(d = 0.43)$ and negative and positive affect $(d = 0.29)$ improvements compared to control
Everly et al., 2016	United States	Adult population, location unspecified	Personally relevant stressful event	Quantitative	Social acknowledgment	Anxiety symptoms ($d = 0.82$) and mood ($d = 0.45$) improvements compared to control
Ironson et al., 2020	United States	Age group not specified, urban area	Any	Quantitative	EMDR, group-administered stress management with a trauma focus	PTSD ($d = 0.98$), depression ($d = 0.71$), and trauma-related thoughts and beliefs ($d = 0.76$) improvements comparable to other groups but with slower rates of improvement
Kameno et al., 2021	Japan	Nurses, COVID-19 inpatient ward	COVID-19	Quantitative	None	Psychological distress ($d = -1.50$; $p <$ 001), sleep disturbance ($d = -1.18$; $p =02$), and appetite ($d = -1.24$; $p =$ 03) improvements compared to control, none on alcohol misuse
McCart et al., 2020	United States	Adult crime victims, law enforcement agencies	Crime	Quantitative	Usual services	Global functioning (β = .24, t = 2.21, p = .03) improvement compared to control, no improvement in psychiatric or adaptive functioning
Meir et al., 2012	Israel	Underage population, urban areas	Threat of deportation	Quantitative	Drawing, given a teddy bear	Improvement in anxiety and depressive symptoms ($\Delta M = 0.39$) compared to control, no changes in depressed mood, aggressive communication, or hyperactivity (Continues)

Improvements in depressive symptoms distress, applying calming practices, $(\Delta M = 7.0, p < .01)$ and total social sense of control, and hopefulness support ($\Delta M = 0.4, p < .01$), no Contributions to safety, reduced PFA outcome-related main changes in PTSS findingsa Control group None Quantitative Qualitative approach Research Flood or individual Political conflict and war trauma PTE population, urban population, urban adolescent Population Adolescent Adults and areas United States Country Gaza (Continued) Ramirez et al., Schafer et al., FABLE 1 Citation 2013 2016

Note: PTE = potentially traumatic event; EMDR = eye movement desensitization and reprocessing; PTSD = posttraumatic stress disorder; PTSS = posttraumatic stress symptoms. ^aMean values indicate mean scores nonstatistically significant improvement reported in one (Everly et al., 2016) and statistically significant increases in the other (Despeaux et al., 2019). Among qualitative studies, PFA was found to contribute to safety, reduce distress, foster connectedness, provide a greater sense of control among youth and adults, and improve the normalization of emotions (Bakes-Denman et al., 2021; De Freitas Girardi et al., 2020; Schafer et al., 2016).

Informed by the Cochrane Risk of Bias tool, the literature had an overall extremely high risk of bias, with only one study assessed as having a low risk across all categories (McCart et al., 2020; Table 3). Studies consistently failed to address bias across all measured domains, with several lacking random allocation to an intervention arm (Bakes-Denman et al., 2021; Blake et al., 2020; Cain et al., 2010; De Freitas Girardi et al., 2020; Kameno et al., 2021; Ramirez et al., 2013; Schafer et al., 2016), treatment group concealment (Cain et al., 2010; De Freitas Girardi et al., 2020; Despeaux et al., 2019; Meir et al., 2012; Ramirez et al., 2013; Schafer et al., 2016), and/or the blinding of participants and evaluators to treatment arm (Bakes-Denman et al., 2021; Blake et al., 2020; Cain et al., 2010; De Freitas Girardi et al., 2020; Despeaux et al., 2019; Ironson et al., 2020; Kameno et al., 2021; Ramirez et al., 2013; Schafer et al., 2016). Often, studies had very small sample sizes, making it difficult to distinguish between selective reporting and an inability to report (Bakes-Denman et al., 2021; De Freitas Girardi et al., 2020; Everly et al., 2016; Ironson et al., 2020; Kameno et al., 2021; Ramirez et al., 2013; Schafer et al., 2016), and researchers frequently did not perform subanalyses or sensitivity analyses (Bakes-Denman et al., 2021; Blake et al., 2020; Cain et al., 2010; De Freitas Girardi et al., 2020; Everly et al., 2016; Ironson et al., 2020; Kameno et al., 2021; Meir et al., 2012; Ramirez et al., 2013; Schafer et al., 2016).

DISCUSSION

This systematic review explored the programmatic effect of PFA and identified only 12 studies from over 9,000 reviewed citations. Although the results of these studies suggest that PFA may improve mental health and psychosocial well-being among individuals exposed to PTEs, inconsistent intervention components, insufficient evaluation methodologies, and high risks of bias within the included studies challenged our ability to evaluate PFA's programmatic effect.

Heterogeneous PFA programmatic specification (i.e, activity type and duration) is a primary challenge to its systematic implementation and evaluation (Dieltjens et al., 2014; Forbes et al., 2011; Shultz & Forbes, 2014). The interventions described in the included studies varied with

TABLE 2 Psychological first aid (PFA) intervention components

Mental health Self and Self						Common	interve	Common intervention principles	inles			
Mental health				Individual/				Self- and				
Mental health Mental healt				group		Promote		community		Self-	Self-	Reflective
ual ual ual	Citation Length n		=	modality	Trainee	safety	Calm	efficacy	Connected	Hope aware	Knowledge worth	listening
ual ual	Bakes-Denman Up to 3 Inc et al., 2021 sessions over 10 days	ons over ys	Inc	Individual	Mental health hospital staff or laypersons	`	`		`		`	
nal ual	Blake et al., 2020 Varied Ind		Ind	Individual	Hospital staff or laypersons	`	`		`	`	`	`
ual ual	Cain et al., 2010 6 weeks Group		Gro	dn	Mental health professional	`	`	`		`	`	
ual ual	de Freitas Single, Group Girardi 1–2 hr et al., 2020	i.	Grou	dı	Layperson	\	`	\	\	`		
ual ual	Despeaux Single 10-min Individua et. al 2019; session Everly et al., 2016	Single 10-min session	Indiv	idual	Layperson	`	`	,				`
ual ual	Ironson4 sessionsGroupet al., 2020over 4 weeks	reeks	Group		Mental health professional	`	、		`			
ual ual	Kameno 2 sessions over Individua et al., 2021 3 months, 30–60 min		Indivi	dual	Mental health professional		`		`	`		
ual	McCart 2–3 sessions Individual et al., 2020		Indivi	dual	Victim advocate	`	、		`			`
ual	Meir et al., 2012 Single, 20–30 Group min session	_	Grou	d	Mental health professional	`	`	`	`	`	`	
	Ramirez et al., 2013 NS Indi		Indiv	Individual	Lay person	`			`			`
	Schafer et al., 2016 NS Group		Grou	dı	Lay person	,	,		`	,		vv

Note: NS = nonspecified.

TABLE 3 Cochrane risk of bias ratings from each study included in the systematic review

Study	RSG	AC	В	OA	IOD	SR	0
Bakes-Denman et al., 2021	High	High	High	High	Unclear	High	High
Blake et al., 2020	High	High	High	High	Unclear	Unclear	High
Cain et al., 2010	High	High	High	Unclear	Unclear	Unclear	Unclear
de Freitas Girardi et al., 2020	High	High	High	High	High	High	High
Despeaux et al., 2019	Low	Unclear	High	Low	Low	Unclear	Low
Everly et al., 2016	Low	Low	Low	Low	Low	Unclear	Unclear
Ironson et al., 2020	Unclear	Unclear	High	Low	Low	Unclear	High
Kameno et al., 2021	High	High	High	High	Low	Unclear	High
McCart et al., 2020	Low	Low	Low	Low	Low	Low	Low
Meir et al., 2012	Low	Unclear	Low	Low	Unclear	Unclear	Unclear
Ramirez et al., 2013	High	High	High	Unclear	Low	Unclear	Unclear
Schafer et al., 2016	High	High	High	High	Unclear	Unclear	Unclear

Note: RSG = random sequence generation; AC = allocation concealment; B = blinding of participants and personnel; OA = outcome assessment; IOD = incomplete outcome data; SR = selective reporting; O = other sources of bias.

regard to timing, duration, mode of delivery, previous experience of trainers and trainees, and key intervention principles. For example, the Wellbeing Centres described by Blake et al. (2020) delivered a 17-week program, whereas RAPID PFA (Despeaux et al., 2019; Everly et al., 2016) is delivered in a single session. Although all "five essential elements" of PFA (Shultz & Forbes, 2014) are represented across the included studies, only the promotion of safety was included in all studies. A framework approach to programming (Forbes et al., 2011) could address this, providing a structure for standardized localization and adaptation to support program fidelity and evaluation.

Even accounting for programmatic heterogeneity, the existing study designs are largely inappropriate to test PFA efficacy. Consistent with previous reviews of the PFA literature (Bisson & Lewis, 2009; Dieltjens et al., 2014; Forbes et al., 2011; Fox et al., 2012), of the reviewed articles, the methodology was inconsistent, often lacked rigor, and included studies that had an overall high risk of bias. PFA is, thus, evidence-informed but not evidence-based (Brymer et al., 2006). Given the dearth of programmatic evidence, and its near nonexistent increase, since previous systematic literature reviews (Dieltjens et al., 2014; Fox et al., 2012), now is the time to build the evidence base. To address complicating factors of core implementation, these evaluations should apply program evaluation best practices and, where possible, standardize rigorous measurement methods to allow for cross-context comparisons. As PFA intends to serve a diverse population of survivors, future studies should consider evaluating the roles of demographic moderators such as gender, age, ethnicity, and race.

The widespread support and use of PFA in an environment absent rigorous evaluations reflects a failure

to fund, document, or disseminate rigorous PFA evaluations. The imprecise nature of "evidence-informed" as opposed to "evidence-based" could dampen downstream donor agency funding, as many consider PFA efficacy already "established." Given the complexity of conducting program evaluation research in emergency settings, donor agencies should clearly identify program evaluation as a key funding priority, such as Elrha's (n.d.) urgent appeal for COVID-19–related studies rather than including language that explicitly discourages research and is unclear about programmatic evaluations (Centers for Disease Control and Prevention, 2020).

The dearth of rigorous PFA evaluations could stem from methodological challenges inherent to conducting program evaluations in complex emergency settings. PFA is a flexible model that recommends efficiently adapting actions depending on the affected individual's needs. Standard manualized protocols and objective documentation of the intervention are not only difficult but also potentially contraindicated. Flexible designs that consider the overall PFA framework yet allow for individual-level heterogeneity of activities and outcomes are required. Evaluators can look to other fields, such as reproductive health (Casey, 2015) and child protection (Ager et al., 2011; Hermosilla et al., 2019), and increasingly, other mental health interventions (Bolton et al., 2007) for examples on how to deal with this complexity.

Conducting research within chaotic postdisaster contexts is challenging, specifically with respect to securing rapid research funding and institutional review board approvals, mobilizing research, obtaining informed consent and assessment information, ensuring model fidelity, and developing randomization and control group designs. Although staff capacity is improving, it is often

insufficient to adequately document and evaluate programmatic outcomes (Madfis et al., 2010).

Supporting innovative and rigorous study designs and measurement will address these challenges. Future PFA evaluations should include randomization, control groups, long-term follow-up periods, and sophisticated analytic designs and methods—in short, building the efficacy data that can inform future effectiveness studies. A growing body of literature documents how such practices, applied in humanitarian crises (Bolton et al., 2014; Brown et al., 2018; Charlson et al., 2019; Hermosilla et al., 2019; Rahman et al., 2016; World Health Organization, 2015), can lead to improved programming and response efforts.

When considering which tools to use to evaluate PFA, researchers should focus on both outcome measurement and process indicators. Although identifying locally valid instruments that map onto standardized nosological frameworks within the constraints of humanitarian response is challenging (Mollica et al., 2004), researchers should rely on and help build the growing body of psychometric research (Bell et al., 2015). Distress measures and trauma coping scales could be applied and tested (Bovin et al., 2018; Kessler et al., 2002). When examining PFA, researchers could employ phased evaluation approaches (Forbes et al., 2011), theoretical domains frameworks (Birken et al., 2017), adaptive study designs (Kilbourne et al., 2014), and optimized strategies (Collins et al., 2007).

These systematic review results must be understood within the context of their limitations. First, all included studies were in English, and it is possible that some studies were missed. Second, this evaluation focused explicitly on PFA efficacy rather than intermediate indicators, such as training, which could, with a larger sample of included studies, begin to disentangle varied programmatic effects across studies. Third, although some studies included information exploring potential subpopulation trends and impacts of complementary interventions and treatments, their risks of bias were too high to extend analyses to these topics.

While acknowledging unique challenges that exist in these settings, a growing body of rigorous, ethical research tasks humanitarian actors to adapt and adhere to the highest standards not despite challenges presented in humanitarian settings but because of them. Exemplars demonstrating that researchers and clinicians can apply the highest standards of research to the most complex emergency settings exist (Bolton et al., 2014; Brown et al., 2018; Charlson et al., 2019; Hermosilla et al., 2019; Rahman et al., 2016; World Health Organization, 2015). People in distress everywhere have a right to evidence-based practices that do no harm, and researchers today have the skills and expertise to develop this evidence. The time to fund the work is now.

There is scant evidence on the programmatic effect of PFA. Inconsistent intervention components, insufficient evaluation methodologies, and high risks of bias within the studies reviewed challenge our ability to evaluate PFA's programmatic effect. Large crises, such as the current COVID-19 global pandemic, provide unique opportunities to focus responders, leverage new funding, and build an evidence base to guide response efforts. Future studies must effectively evaluate PFA.

OPEN PRACTICES STATEMENT

Our research protocol adhered to PROSPERO guidelines, and protocol data are available from the corresponding author.

AUTHOR NOTE

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