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CLINICAL RESEARCH ARTICLE

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Effect of trauma on asylum seekers and refugees receiving a WHO psychological intervention: a mediation model

Riccardo Serra [a,b], Marianna Purgato[a], Federico Tedeschi[a], Ceren Acartürk[c,d], Eirini Karyotaki[e], Ersin Uygun[c,d], Giulia Turrini[a], Hildegard Winkler[f], Irene Pinucci[b], Johannes Wancata[g], Lauren Walker[h], Mariana Popa[i], Marit Sijbrandij[e], Maritta Välimäki[j,k], Markus Kösters[l,m], Michela Nosè[a], Minna Anttila[j], Rachel Churchill[n], Ross G. White[o], Tella Lantta[j,p], Thomas Klein[l,m], Thomas Wochele-Thoma[q], Lorenzo Tarsitani[b]* and Corrado Barbui[a]*

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ABSTRACT

Background: Scalable psychological interventions such as the WHO's Self-Help Plus (SH+) have been developed for clinical and non-clinical populations in need of psychological support. SH+ has been successfully implemented to prevent common mental disorders among asylum seekers and refugees who are growing in number due to increasing levels of forced migration. These populations are often exposed to multiple, severe sources of traumatisation, and evidence of the effect of such events on treatment is insufficient, especially for non-clinical populations.

Objective: We aim to study the effect of potentially traumatic experiences (PTEs) and the mediating role of symptoms of posttraumatic stress disorder (PTSD) on the improvement following SH+.

Method: Participants allocated to SH+ who received at least three sessions ($N = 345$) were extracted from two large, randomised, European prevention trials involving asylum seekers and refugees. Measures of distress, depression, functional impairment, and post-traumatic stress symptoms were administered at baseline and 6 months post-intervention, together with measures of well-being and quality of life. Adjusted models were constructed to examine the effect of PTEs on post-intervention improvement. The possible mediating role of PTSD symptoms in this relationship was then tested.

Results: Increasing numbers of PTEs decreased the beneficial effect of SH+ for all measures. This relationship was mediated by symptoms of PTSD when analysing measures of well-being and quality of life. However, this did not apply for measures of mental health problems.

Conclusions: Exposure to PTEs may largely reduce benefits from SH+. PTSD symptomatology plays a specific, mediating role on psychological well-being and quality of life of participants who experienced PTE. Healthcare professionals and researchers should consider the role of PTEs and PTSD symptoms in the treatment of migrants and refugees and explore possible feasible add-on solutions for cases exposed to multiple PTEs.

Efecto del trauma en solicitantes asilo y refugiados que reciben una intervención psicológica de la OMS: un modelo de mediación

Antecedentes: Se han desarrollado intervenciones psicológicas escalables, como *Self-Help Plus (SH+)* de la OMS, para poblaciones clínicas y no clínicas que necesitan apoyo psicológico. SH+ se ha implementado con éxito para prevenir trastornos mentales frecuentes entre los solicitantes de asilo y refugiados, cuyo número está aumentando debido a los crecientes niveles de migración forzada. Estas poblaciones a menudo están expuestas a múltiples y

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Post-traumatic stress; scalable interventions; self-help plus; mediation; psychological intervention; asylum seekers and refugees; migrants

PALABRAS CLAVE

Estrés post traumático; intervención escalable; psicoterapia de grupo; mediación; solicitantes de asilo y refugiados

HIGHLIGHTS

- Increasing numbers of potentially traumatic experiences can decrease the beneficial effect of a manualized group psychotherapeutic intervention in migrants and refugees across multiple countries.
- In absence of a full threshold diagnosis of post-traumatic stress disorder, post-traumatic stress symptoms still mediate the relation between potentially

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graves fuentes de traumatización, y la evidencia del efecto de tales eventos en el tratamiento es insuficiente, especialmente para las poblaciones no clínicas.
Objetivo: Nuestro objetivo es estudiar el efecto de las experiencias potencialmente traumáticas (EPTs) y el papel mediador de los síntomas del trastorno de estrés postraumático (TEPT) en la mejora después de SH+.
Método: Los participantes asignados al programa de intervención SH+ que recibieron al menos tres sesiones ($N = 345$) fueron extraídos de dos grandes ensayos de prevención europeos, aleatorizados, que involucraron a personas que solicitaron asilo y refugiados. Se administraron medidas de angustia, depresión, deterioro funcional y síntomas de estrés postraumático al inicio del estudio y 6 meses después de la intervención, junto con medidas de bienestar y calidad de vida. Se construyeron modelos ajustados para examinar el efecto de las EPTs en la mejora posterior a la intervención. A continuación se comprobó el posible papel mediador de los síntomas del trastorno de estrés postraumático en esta relación.
Resultados: Un número creciente de EPTs disminuyó el efecto beneficioso de SH+ para todas las medidas. Esta relación estuvo mediada por los síntomas del TEPT al analizar medidas de bienestar y calidad de vida. Sin embargo, esto no se aplica a las medidas de problemas de salud mental.
Conclusiones: La exposición a EPTs puede reducir en gran medida los beneficios de SH+. La sintomatología TEPT desempeña un papel mediador específico en el bienestar psicológico y la calidad de vida de los participantes que experimentaron EPTs. Los profesionales de la salud y los investigadores deben considerar el papel de las EPTs y los síntomas de TEPT en el tratamiento de migrantes y refugiados, y explorar posibles soluciones factibles complementarias para los casos expuestos a múltiples EPTs.

traumatic experiences and some outcome improvements at follow-up.
- While the moderating role of number of potentially traumatic experiences applies to all outcomes (depression symptoms, psychological distress, functional impairment, well-being, and quality of life), the mediating role of post-traumatic stress symptoms in this relation only applies to well-being and quality of life.

1. Introduction

'The increasing numbers of global migrations across the planet, often due to mass, forcible displacement from their home countries as a result of famine, war, and natural disasters, have drawn increasing attention to the mental health of migrants once they reach their destination' (Sijbrandij, 2018). Regardless of the driving motives, migration is considered a vulnerability factor for the development of mental health problems (Virupaksha et al., 2014; World Health Organization, 2021a), with refugees and asylum seekers showing a higher prevalence of mental disorders and psychological distress than natives (Blackmore et al., 2020; Patanè et al., 2022; Turrini et al., 2019). Governments and policymakers around the globe are therefore faced with the challenge of effectively addressing the mental health of an increasingly larger number of forcibly displaced people.

In this context, clinical trials of low-intensity, inexpensive psychological interventions have shown some promising results in both the short and the long term (Perera et al., 2018; Purgato et al., 2019; Turrini et al., 2019). The WHO has recently developed a series of scalable psychological interventions that can be implemented at scale and delivered by non-specialist helpers without extensive training, including Self-Help Plus (SH+) (World Health Organization, 2021b). SH+ is a group-based, guided self-help psychological intervention that aims to support participants to better manage their mental distress and well-being using evidence-based techniques and strategies (Epping-Jordan et al., 2016; World Health Organization, 2021a). SH+ was successfully implemented for reduction of depressive symptoms and improvement of well-being of asylum seekers and refugees in multiple settings (i.e. Europe, Turkey, Uganda) (Karyotaki et al., 2023). Emerging evidence on the effectiveness of SH+ in preventing mental disorders in this population also exists (Purgato et al., 2019). Being effective for multiple outcomes in large trials, SH+ and other scalable interventions necessarily apply a 'one size fits all' approach. Still, individual factors can vary widely and can affect psychological conditions and treatment outcomes across settings and interventions (Araya et al., 2007; Giacco et al., 2018; Schlechter et al., 2021).

One specific factor that can have a major impact on an individual's mental health and treatment outcomes is exposure to potentially traumatic events (PTEs) (Bolton et al., 2004; Boyer et al., 2009; Karsberg et al., 2021; Serra et al., 2020). PTEs disproportionately affect subpopulations of migrants such as refugees and asylum seekers adding to the challenges of post-migration life (e.g. socio-economic instability, language barriers, and discrimination) (Gleeson et al., 2020; Hynie, 2018; Johnson & Thompson, 2008; Steel et al., 2009). Although a body of research on trauma-focused treatments for migrants and refugees exists (Crumlish & O'Rourke, 2010; Sonne et al., 2021), the literature on the predictive role of PTEs in the effectiveness of scalable psychological interventions for mental health and the possible mediators of such an effect is still insufficient.

Evidence from research on psychosis (Hardy et al., 2016), substance abuse (White & Widom, 2008), eating disorders (Serra et al., 2020), depression (Klumparendt et al., 2019), and anxiety (Ruchkin et al., 2007) suggests that exposure to PTEs does not necessarily lead to psychopathological outcomes *per se*, and that their effect on mental health and psychological treatments may be mediated, among other things, by

post-traumatic stress symptoms. PTEs, irrespective of the possible development of a full threshold diagnosis of PTSD, may in fact lead to PTSD-related symptoms such as emotional dysregulation, intrusive memories, isolation and hyperarousal (McLaughlin et al., 2015). Exposure to PTEs, and possible consequent PTSD symptoms may therefore reduce the effect of scalable psychological treatments. As PTEs are common among migrants, determining their effects and mediators in the treatment of mental distress may be of relevance to the field of global mental health as part of the effort to provide condition-specific interventions and optimise the use of limited available resources.

2. Objectives

(1) To evaluate if the cumulative effect of exposure to multiple PTEs predicts level of improvement following SH+ participation in terms of psychological distress, well-being, and quality of life in a group of asylum seekers and refugees.
(2) To assess if the relationship between PTEs and response to SH+ in terms of psychological distress, well-being and quality of life is mediated by PTSD symptoms.

3. Methods

The research protocol for the present study was registered with the Open Science Framework and is available for consultation at https://osf.io/stgmh.

3.1. Participants

Participant-level data were retrieved from two large, randomised, prevention trials involving asylum seekers and refugees, one conducted in Western Europe and another in Turkey (Purgato et al., 2021). The studies followed the same research protocol and were conducted in parallel (Acarturk et al., 2022; Purgato et al., 2019). In both studies, participants were randomly assigned to the SH+ psychological intervention, consisting of SH+ combined with enhanced treatment as usual (ETAU), or to ETAU only. ETAU consisted of the social support and/or care routinely delivered according to local regulations. It also included baseline and follow-up assessments according to study protocol, information on available, free health and social services, and links to community networks dedicated to the support of refugees and asylum seekers. More information has been published elsewhere (Purgato et al., 2019).

Trial inclusion criteria were: (a) age 18 years or older; (b) able to speak and understand Arabic, Dari, English, or Urdu; (c) being under temporary protection with a refugee or asylum seeker status; (d) experiencing psychological distress, as shown by a score of 3 or more on the 12-item dichotomously-scored General Health Questionnaire; (e) having completed oral and written informed consent to enter the study. Exclusion criteria were: (a) presence of any mental disorder according to the Mini International Neuropsychiatric Interview (M.I.N.I.), a brief structured diagnostic interview for the major psychiatric disorders in DSM-III-R, DSM-IV and DSM-5 and ICD-10; (b) evidence of acute medical conditions contraindicating study participation; (c) evidence of imminent suicide risk, or suicide risk scored as 'moderate or high' on the M.I.N.I.; (d) signs of impaired decision-making capacity emerging from responses during the clinical interview.

For the purposes of the present analyses, only participants allocated to SH+ who received at least three sessions were included (Purgato et al., 2019).

3.2. Measures

Participants were asked to complete assessments at the following time points: T0: screening for eligibility including psychological distress and lack of any mental disorder; T1: baseline assessment; T2: 6 months post-intervention.

- *Exposure to potentially traumatic events* was measured at baseline using the Harvard Trauma Questionnaire-part I (HTQ) (Mollica et al., 1992). The HTQ-part I covers a variety of traumatic events that may affect refugee mental health, and the scoring represents the number of different types of traumatic events experienced by the participants (a higher score is associated with a high number of traumatic events). HTQ was administered at T1 to retrospectively assess lifetime PTEs.
- The T1 assessments also included the following sociodemographic and migration-related variables: *age* (number of years), *gender* (Male/Female), *travel duration* (number of days), *educational level* (number of years of schooling), *work status* (unemployed vs other), *country of origin*, and *length of stay in the host country* (number of months).

3.3. Measures of mental health problems

- *Psychological distress*, as measured by the General Health Questionnaire (GHQ-12) (El-Rufaie & Daradkeh, 1996; Goldberg et al., 1998; Kiliç et al., 1997). GHQ-12 was administered at T0 and T2.
- *PTSD symptoms,* as measured by the PTSD Checklist for DSM-5 (PCL-5), a 20-item questionnaire

that measures a variety of PTSD symptoms (score 0–80), with higher scores indicating higher levels of PTSD symptoms (Blanchard et al., 1996; Wortmann et al., 2016). PCL-5 was administered at T1 and T2.

- *Depression symptoms*, as measured with the four-point scale Patient Health Questionnaire-9 (PHQ-9) (total score 0–27) (Kroenke et al., 2001); PHQ-9 was administered at T1 and T2.
- *Functional impairment* assessed by means of the WHO Disability Assessment Schedule 2.0 (WHO-DAS) using a five-point scale (Üstün et al., 2010). WHODAS was administered at T1 and T2.

3.4. Measures of psychological welfare

- *Well-being*, assessed with the WHO-5 Well-being Index (WHO-5) (Topp et al., 2015) that contains five questions using a six-point scale (score 0–25). WHO-5 was administered at T1 and T2.
- *Quality of life*, measured using the EQ-5D-3L questionnaire. It asks participants to measure five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) using a three-level scale: 'no problems', 'some problems', and 'extreme problems' (EuroQol G., 1990). EQ-5D-3L was administered at T1 and T2.

4. Intervention

The intervention delivery period ran from September 2018 to March 2020. The SH+ programme was developed by the WHO. It consists of a prerecorded audio course delivered in a group setting by briefly trained facilitators and complemented with an illustrated self-help book adapted for the cultural groups included in the study (World Health Organization, 2020; World Health Organization, 2021b). Each of the five sessions lasted approximately 2 hours. It was designed to help people cope with adversity and mental distress, and its format enables delivery by non-specialist facilitators in low-resource settings and areas with limited access to mental health care. SH+ is based on acceptance and commitment therapy (ACT), a form of cognitive behavioural therapy that helps people learn new ways to accommodate difficult thoughts and feelings, while taking actions consistent with personally-identified values. SH+ includes guided exercises for practicing mindfulness, clarifying values, and responding to oneself and others with compassion.

5. Statistical analysis

We initially tested whether the number of types of PTEs, as assessed by the HTQ global score, predicted SH+ response in terms of 6-month follow-up measures. Measures included well-being and quality of life, as assessed with the WHO-5 and EQ5D (i.e. measures of psychological welfare), as well as depression symptoms, functional impairment, and psychological distress, as assessed with the PHQ-9, GHQ12 and WHODAS (i.e. mental health problems). We used both unadjusted and adjusted models. In adjusted models, sociodemographic variables were included as additional predictor measures, as follows: age, gender at birth, travel duration, educational level, work status, country of origin and length of stay in the host country.

In particular, a global model with Seemingly Unrelated Regression (SUR) equations (Zellner, 1962) having the two measures of psychological welfare as outcome was performed; in case of global statistical significance of the coefficients associated to number of PTEs, we proceeded to perform the two regression analyses separately; similarly, we performed a global SUR model having GHQ-12, WHODAS, PHQ-9 scores as outcome. In case of statistical significance of the coefficients associated to number of PTEs, we proceeded to perform the three regression analyses separately. In all regression analyses, we controlled for baseline outcome values.

We additionally tested the mediating role of post-traumatic symptomatology, as assessed with the PCL-5, in the relationship between PTE exposure and SH+ response in terms of well-being and psychological distress. For this purpose, we considered PTEs retrospectively assessed with the HTQ at baseline, the possible mediator (i.e. PCL-5 total score) assessed at baseline, and measures of well-being and psychological distress assessed at the six-month follow-up. A stepwise procedure was followed. A global SUR model was developed having the three measures of well-being as outcome, with PCL-5 included among predictors, and a further regression having the number of PTEs as predictor and PCL-5 as outcome. In case of joint statistical significance of the estimated indirect (the product of the effect of the number of PTEs on PCL-5 and of PCL-5 on the outcome) and total effects (the sum of the indirect effect and the parameter associated to the number of PTEs in the final regression models) effects, we further tested the estimated indirect and total effects separately. We then proceeded to perform regression analyses for each outcome only in case of statistical significance of such tests, and the mediation models were performed only in case of significance of the indirect effects.

Similarly, a global SUR model having the three measures of psychological distress as outcome was developed, with PCL-5 included among predictors, and a further regression model having the number of PTEs as predictor and PCL-5 as outcome. In case of joint statistical significance of the estimated indirect

and total effects, we further tested the estimated indirect and total effects separately. We then proceeded to perform regression analyses for each outcome only in case of statistical significance of such tests, and the mediation models were implemented only in case of significance of the indirect effects.

At each step, multiple testing was addressed through the Benjamini and Hochberg correction (1995).

Multiple imputations were adopted to address the issue of missing data in all the variables included in the model. In case of missing values on clinical measures, the imputation was performed on single-item scales. Specifically, imputation followed the approach reported by Plumpton et al. (2016), that is we used scale totals within prediction equations and, for imputations of responses to individual scale items, we additionally included the responses to the other scale items, using the 'ice' Stata routine (Royston, 2005; Sterne et al., 2009), and considering single-item scores as ordered categorical variables. Upper and lower bounds were set for continuous variables with missing values as appropriate. The number of imputed samples was determined by following the rule of thumb suggested by White et al. (2011), that is: 'at least equal to the percentage of incomplete cases'. We rounded such number to the nearest multiple of 10 above.

We used the software programmes Stata 17.0 (StataCorp., 2021) and R 4.2.2 (Team, R.C., 2021) for data analysis.

6. Results

Of the 1,101 participants in the two trials, 552 were randomised to SH+. Of these, 345 participants completed at least three SH+ sessions and were included in the analysis. The mean age was 33.09 years (S.D. = 10.5) and 55.0% were women. Participant characteristics are presented in Table 1. At baseline, measures of mental health problems indicated mild depressive symptoms (PHQ9 mean = 7.07; S.D. = 5.12) and PTSD symptoms (PCL5 mean = 22.07; S.D. = 15.52) in the presence of mild impairment (WHODAS mean = 18.73; S.D. = 6.55) and moderate distress (GHQ12 mean = 17.33; S.D. = 4.54). Measures of psychological welfare indicate low average values of well-being (WHO-5 mean = 10.71; S.D. = 5.95) and of quality of life (EQ5D mean = 0.710; S.D. = .0.259). Outcomes at T2 (see Supplementary Table 2) showed a mean decrease of 1.49 per PHQ9, of 1.50 for WHODAS and of 3.97 for GHQ12, and a mean increase of 0.089 for EQ5D and of 2.61 for WHO-5.

In the unadjusted models without indirect effects, evidence of an association with the predictor 'number of PTEs' was found by SUR for both outcome groups:

Table 1. Sociodemographic and clinical characteristics at baseline.

	Mean	S.D.
EQ5D*	0.710	0.259
PCL5*	22.07	15.52
PHQ9*	7.07	5.12
HTQ*	5.82	4.60
GHQ12*	17.33	4.54
WHODAS*, **	18.73	6.55
WHO-5*	10.71	5.95
Age	33.09	10.50
Years of schooling	9.18	4.30
Length of stay in the host country (months)	45.13	40.90
	N	**%**
Gender at birth (female)	193	55.94
Travel Duration		
Less Than 1 Month	92	44.44
From 1 To 3 Months	59	28.50
More Than 3 Months	56	27.05
Unemployed	140	40.58
Country of origin		
Syria	253	73.33
Iraq	18	5.22
Nigeria	39	11.30
Other	35	10.14
Trial		
Turkey	228	66.09
EU	117	33.91

Note: **PCL5**: Post-traumatic stress disorder checklist for DSM5; **PHQ9**: Patient health questionnaire; **HTQ**: Harvard trauma questionnaire; **GHQ12**: General health questionnaire; **WHODAS**: WHO Disability Assessment Schedule 2.0; **WHO-5**: WHO five well-being index; **EQ5D**: EuroQol 5 dimensions **S.D.**: Standard Deviation;
*Summary statistics in MI datasets, applying Rubin's combination rules
**Two observations were excluded since all items were missing

the measures of mental health problems ($p < .001$) and the measures of psychological welfare ($p = .001$). Testing each outcome separately, all turned out as significantly correlated with 'number of PTEs'. In detail, the estimated effect was −0.147 ($p = .049$) for WHO-5 well-being, −0.011 ($p < .001$) for EQ5D quality of life, 0.406 ($p < .001$) for WHODAS functional impairment, 0.245 ($p = .001$) for PHQ9 depressive symptoms, and 0.166 ($p = .029$) for GHQ12 psychological distress. In the adjusted models without indirect effects (Table 2), the evidence of an association was confirmed, both in global models ($p = .003$ for the mental health problems measures, $p = .005$ for psychological welfare measures), and considering each outcome separately. In particular, the estimated effect was −.219 ($p = .010$) for WHO5 well-being, −.009

Table 2. Adjusted, non-mediated model of HTQ predicting outcomes.

Outcome	Coef. (Std. Coef.)	95%C.I.	*p*
WHO5	−0.219 (−0.174)	(−0.385; − 0.054)	.010
EQ5D	−0.009 (−0.179)	(−0.016; − 0.003)	.007
WHODAS	0.276 (0.161)	(0.038; 0.513)	.023
PHQ9	0.256 (0.219)	(0.095; 0.417)	.002
GHQ12	0.236 (0.198)	(0.067; 0.406)	.007

Note: **PHQ9**: Patient health questionnaire; **HTQ**: Harvard trauma questionnaire; **GHQ12**: General health questionnaire; **WHODAS**: WHO Disability Assessment Schedule 2.0; **WHO-5**: WHO five well-being index; **EQ5D**: EuroQol 5 dimensions; **Std. Coef.**: Standardised Coefficient **C.I.**: Confidence Interval.

($p = .007$) for EQ5D quality of life, 0.276 ($p = .023$) for WHODAS functional impairment, 0.256 ($p = .002$) for PHQ9 depressive symptoms, 0.236 ($p = .029$) for GHQ12 psychological distress.

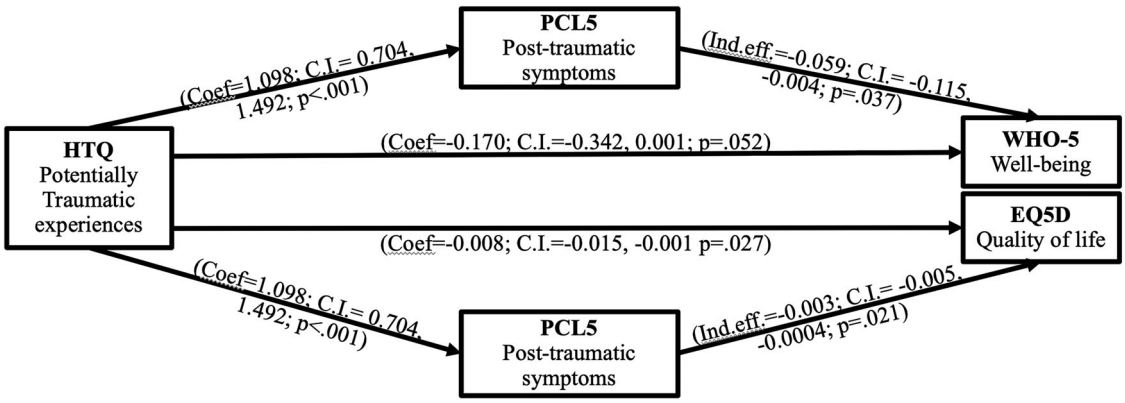
As for models including indirect effects, in the unadjusted model, a joint significance was found for total effects ($p < .001$), but not for indirect effects ($p = .348$) for the measures of mental health problems. Such results were confirmed by the adjusted model, with statistical evidence of total effects ($p = .002$), but not of indirect effects ($p = .468$). Specific results for all measures of mental health problems are presented as supplementary material (shown in Figure S1).

In the case of psychological welfare measures, in the unadjusted model, evidence was found for both total ($p = .003$) and for indirect ($p = .030$) effects. By performing the two regression analyses separately for the two well-being outcomes, statistical significance was found in both cases: as for WHO-5 well-being, with a $p = .041$ for total and $p = .036$ for indirect effects, while, in the case of EQ5D quality of life, p-values were $< .001$ and .020 for total and indirect effects, respectively. In the case of the adjusted model, significance was confirmed both globally (with $p = .002$ for total and $p = .035$ for indirect effects) and separately for WHO5 well-being (with $p = .007$ for total and $p = .037$ for indirect effects) and EQ5D quality of life (with $p = .003$ for total and $p = .021$ for indirect effects). A visualisation of the model is shown in Figure 1. As shown in Figure 1, adjusted models also show a residual, significant direct effect of 'number of PTEs' on EQ5D quality of life (Coef = −0.008; CI = −0.015; −0.001 $p = .027$) indicating partial mediation, on the other hand 'number of PTEs' direct effect on WHO-5 well-being resulted non-significant (Coef = −0.170; CI = −0.342; 0.001; $p = .052$), possibly indicating complete mediation of the effect of 'number of PTEs' on WHO-5 well-being by PCL5 PTS symptoms. The adjusted effect of PCL-5 on welfare measures is shown in Supplementary Table 1. The estimated total effect (combined direct and indirect effect) of 'number of PTEs' on WHO5 well-being is −.230 (95% CI = −.395; −.064), while the one of 'number of PTEs' on EQ5D quality of life is −.010 (95% CI = −.017; −.004).

7. Discussion

In the present study in refugees and asylum seekers, the total number of PTEs reduced the beneficial effect of participation in SH+ on measures of mental health problems (i.e. distress, depression, and functional impairment) as well as on measures of psychological welfare (i.e. well-being and quality of life). The effect of PTEs on psychological well-being and quality of life is mediated by PTSD symptoms, even in the absence of a full-threshold PTSD diagnosis. This was not the case for measures of depression symptoms, mental distress, and functional impairment.

The present findings builds on evidence from previous research on the SH+ showing how exposure to more PTEs (especially inter-human violence) is



Multivariate adjusted effect of PCL5 on Welfare Measures					
Outcome	Coef.	95%C.I.	p	Total effect	Indirect effect on total effect %
WHO5	-0.054	(-0.101; -0.008)	.023	-0.230 (-0.395; -.064)	25.86%
EQ5D	-0.002	(-0.004; -0.001)	.011	-0.010 (-0.017; -.004)	26.01%

Note

The model includes confounders as covariates.

Coef= Coefficient; **Ind.eff.**= Indirect effect; **HTQ**= Harvard Trauma Scale; **PCL5**= Post-traumatic stress disorder Check List; **WHO-5**= WHO five well-being index; **EQ5D**= EuroQol 5 dimensions **C.I.**= 95% Confidence Interval

Figure 1. The model includes confounders as covariates. **Coef**: Coefficient; **Ind.Eff.**: Indirect effect; **HTQ**: Harvard Trauma Scale; **PCL5**: Post-traumatic stress disorder Check List for DSM5; **WHO-5**: WHO five well-being index; **EQ5D**: EuroQol 5 Dimensions; **C.I.**: 95% Confidence Interval.

associated with a lack of effect in preventing the onset of mental health disorders, even in the absence of criteria for a clinical diagnosis of PTSD at baseline (Barbui et al., 2023). This is generally consistent with the grounding framework of the agenda of the *Lancet* Commission on global mental health, which states that '… The binary approach to diagnosing mental disorders, although useful for clinical practice, does not accurately reflect the diversity and complexity of mental health needs of individuals or populations' (Patel et al., 2018). Furthermore, the finding is specifically in line with the existing literature on 'subthreshold PTSD' which stresses the clinical relevance of psychological traumatisation even in the absence of a full-threshold diagnosis of PTSD (e.g. McLaughlin et al., 2015).

This conceptual framework may help to understand and explain the present findings on the effect of PTEs in this group of distressed asylum seekers and refugees treated with SH+. Indeed, results showed that, compared to participants with an average amount of PTEs (i.e. 5.82), the estimated improvement following SH+ in absence of PTEs would be 35% higher for general distress, 49% higher for well-being, 59% higher for quality of life, double for depressive symptoms and more than double (+ 107%) for functional impairment. Still, SH+ has been proven effective for participants, regardless of a history of trauma (Acarturk et al., 2022; Karyotaki et al., 2023; Purgato et al., 2021). There could be several possible explanations for this finding. First, the structure and aims of SH+ do not specifically focus on traumatic experiences and PTSD symptoms. This could lead to SH+ retaining effectiveness on outcomes measures (e.g. depression) without directly affecting one of the driving sources of suffering (i.e. psychological trauma), in a manner akin to stitching a wound without removing debris. Another hypothesis is related to the SH+ group-intervention design. Although this setting may be particularly effective in groups sharing a common traumatic experience (e.g. survivors of an earthquake), participants experiencing PTSD symptoms tend to isolate and may benefit less from this kind of setting especially in the first sessions (Dagan & Yager, 2019; Nietlisbach & Maercker, 2009; Stein & Tuval-Mashiach, 2015). However, this hypothesis needs to be tested empirically.

Regarding the mediating effect of post-traumatic symptoms, SH+ has been shown to provide stress-management tools that help reduce mental health problems such as depression or psychological distress which can be consequent to PTEs as well as unrelated (Mahmood et al., 2019; Shalev et al., 1998). This could explain the observed direct negative effect of PTEs on post-treatment improvement in measures of mental health problems which is not mediated by PTSD symptoms. On the other hand, more complex constructs such as well-being and quality of life may be affected by post-traumatic sequalae, even in the absence of a full-threshold diagnosis of PTSD (Ojeahere et al., 2021; van Zelst et al., 2006). Indeed, absence of symptoms is not necessarily equivalent to well-being or having a good quality of life (Duckworth et al., 2005; Ryff & Singer, 1996).

8. Limitations and future research

The present study needs to be interpreted in the light of several limitations. First, the original research design was a multicenter, randomised controlled trial aimed at testing the efficacy of SH+ in reducing psychological distress and preventing the onset of mental disorder in a non-clinical population of asylum seekers and refugees. Rather than using the whole sample, in the present analysis we selected a subsample of SH+participants who completed at least three sessions, therefore introducing a potential selection bias. However, the exclusion of non-completers and controls allow for an in-depth study of the possible effect of SH + on participants who actually participate to the majority of the sessions. Still, any conclusion regarding effectiveness of the intervention should be corroborated by a RCT study. Second, our model tested the role of PTSD symptoms as measured by the PCL-5 considered as a total score, which may not be an optimal measure of PTSD symptoms. Future research is therefore needed to test other more complex models which would require a larger sample size. Third, the population included (asylum seekers and refugees) is typically characterised by traumatisation and exposure to a variety of PTEs. Consequently, generalisation to other target populations may require additional research in other less traumatised populations, testing the possible role of specific subsets of PTEs (e.g. exposure to natural disasters versus inter human violence). Finally, it is not currently possible to test whether these findings apply only to SH+ or also to other scalable psychological interventions. Future research should test the present findings in other psychological interventions and compare them with SH+. In the light of the present results, additional research to develop and evaluate the feasibility and effectiveness of adding a trauma-focused module may be warranted. When resources are available to provide interventions targeting PTSD, this population should be screened for past and present exposure to PTEs as well as for PTSD symptoms, and the addition of PTSD-specific interventions should be evaluated by the clinicians. In the absence of such additional resources, SH+ alone should be administered as it still proved beneficial to this sub-group for reducing symptoms of depression, mental distress and functional impairment, and fostering well-being and quality of life.

9. Conclusions

Participants exposed to multiple PTEs may benefit less from SH+ in terms of their mental health problems and psychological welfare as compared to those exposed to fewer types of PTEs. PTSD symptoms play an important role in the participants' psychological well-being and quality of life and may reduce the benefits of participation in scalable interventions, such as SH+. Healthcare professionals and researchers should be aware of the role of trauma and PTSD symptoms in the treatment of asylum seekers and refugees and explore possible feasible solutions for this population.

Statement of Ethics

The two trials received ethical clearance from the local Ethics Committees of the participating sites (seven sites), as well as from the WHO Ethics Committee. Trials registration numbers NCT03571347, NCT03587896.

More in detail, the study protocols have been approved by: Local Ethics Committees and WHO ERC: Verona: Comitato Etico per la Sperimentazione Clinica delle province di Verona e Rovigo; Approval ID 1682CESC Ulm: Furdie Ethikkommission der Universitat Ulm; Approval ID 93/18 Vienna: Ethik Kommission, University of Vienna; Approval ID 1199/2018 Liverpool: Central University Research Ethics Committee B; Approval ID 3198 York: Health Sciences Research Governance Committee; Approval 16-03-2018 Turku: Varsinais-Suomen sairaanhoitopiirin kuntayhtymä Eettinen toimikunta; Approval ID 19/1801/2018 Istanbul: Istanbul Sehir Universitesi; Approval 8-03-2018 WHO: WHO ERC Ethics Committee Approval ID: ERC.0003021.

In order to take part in the study, all participants underwent a two-step informed consent procedure providing their informed consent before screening and before study inclusion.

Author contributions

The study was conceived and designed by RS, LT, and CB. RS, MP, FT, LT, and CB drafted the manuscript. CA, EK, EU, GT, HW, IP, JW, LW, MP, MS, MV, MK, MN, MA, RC, RGW, TL, TK, TWT contributed to the study design and data gathering and the manuscript drafts. All authors provided comments, editing, and revisions to the manuscript drafts and approved the last version to be submitted

Disclosure statement

No potential conflict of interest was reported by the author(s).

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Data availability statement

Data will be available upon reasonable request.

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