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Clinical Trial on the ASSYST for Groups Treatment Intervention Provided to Syrian Refugees Living in Lebanon

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Abstract

The aim of this clinical trial was to evaluate the effectiveness and safety of the Acute Stress Syndrome Stabilization for Groups (ASSYST-G) treatment intervention, provided by formally trained frontline workers, in reducing posttraumatic stress disorder (PTSD), depression, and anxiety symptoms in adult refugees from Syria living in Lebanon. A total of 41 adult females met the inclusion criteria and participated in the study. Participants' ages ranged from 18 to 64 years old (M = 38.09 years).

After the treatment intervention, results showed a large effect size in reducing PTSD symptoms associated with the identified worst memory of their experience as refugees. A statistical significance of the one-sample t-test, comparing pre- and post-treatments assessments, t (40) =7.54, p=.000; d= .98 is reported. Cohen´s effect size for this comparison was considered as large effect (d=.80). Anxiety analysis showed a statistical significance of the one-sample t-test, t (40) = 3.20, p=.003; d= .44, with a decrease in the post-treatment assessment. Mean score for depression was not high in the pretest, and no significant effect was found for this variable after the intervention.

No adverse effects or events were reported by the participants during the treatment procedure administration or at one-month post-treatment assessment. None of the participants showed clinically significant worsening/exacerbation of PTSD, anxiety, or depression symptoms after treatment.

Keywords: Acute Stress Syndrome Stabilization; Posttraumatic stress disorder; Anxiety; Depression; Refugees; Frontline workers

Introduction

Since violent civil war broke out in Syria in 2011, millions of Syrians have fled to neighboring countries. As of May 2017, there were 5.1 million Syrians registered as refugees in neighboring countries of Turkey, Lebanon, Jordan, and Iraq. One million of those registered as refugees in Lebanon specifically [1]. 40% of asylum seekers and refugees suffer from mental health problems due to the stressful nature of many of the experiences they are exposed to during forced migration and resettlement [2]. Much of the research on mental health and refugees has focused on posttraumatic stress disorder (PTSD), though anxiety and depression have been found to be equally prevalent in this population [2]. While there is a wide range in efficacy of psychological interventions in treating mental health within the refugee population, one metanalysis found that in general, psychological interventions are effective in reducing symptoms of PTSD and depression [3]. Another meta-analysis of psychosocial interventions with refugees found that cognitive behavioral therapy with a trauma-focused component (TF-CBT) and eye movement desensitization and reprocessing (EMDR) are the most effective in treating PTSD [4].

The shortage of mental health professionals in low-and-middle-income countries (LMIC) is widely understood. Relying solely on mental health professionals to address the mental health needs of the populations in LMIC (including the refugees resettled in these countries) is wholly insufficient [5]. Task-shifting is a process of shifting some tasks or psychological treatment (PT) interventions from professionals with higher qualifications to

those with fewer qualifications to greatly increase the delivery of psychological services. Various task-shifting PT interventions continue to be explored with promising results [6,7], and this study hopes to contribute to that body of evidence.

Acute Stress Syndrome Stabilization for Groups Treatment Intervention

The Acute Stress Syndrome Stabilization for Groups (ASSYST-G) treatment intervention was born in 2017 during humanitarian fieldwork immediately after the September 19 earthquake in Mexico City, and its reference is the EMDR Integrative Group Treatment Protocol for Ongoing Traumatic Stress (EMDR-IGTP-OTS) [7-15].

This treatment intervention is an evidence-based, carefully field-tested, and user-friendly psychophysiological algorithmic Adaptive Information Processing (AIP)-informed approach [16-18]. It is specifically designed to provide in-person or online support to clients who present Acute Stress Disorder (ASD) or Posttraumatic Stress Disorder (PTSD) intense psychological distress and/or physiological reactivity caused by the disorder's intrusion symptoms associated with the memories of the adverse experience(s) [19].

The objective of this treatment intervention is focused on the patient's Autonomic Nervous System sympathetic branch hyperactivation regulation through the reduction or removal of the activation produced by the sensory, emotional, or physiological components of the pathogenic memories of the adverse experience(s) to achieve optimal levels of Autonomic Nervous System activation, stop secretion of the three major stress hormones, and reestablish the Prefrontal Cortex functions (e.g., processing of information); thus, facilitating the AIP-system and the subsequent adaptive processing of information [20].

Previous ASSYST Treatment Intervention Studies

Four previous ASSYST treatment intervention studies have proven their efficacy and safety with different populations: (I) General population in lockdown during the COVID-19 Pandemic. (II) TeleMental Health counseling to general population after adverse experiences. (III) Mental Health Professionals During the Covid-19 Pandemic. (IV) General population with non-recent pathogenic memories [21-24].

Objective

The objective of this clinical trial was to evaluate the effectiveness, and safety of the Acute Stress Syndrome Stabilization for Groups (ASSYST-G) treatment intervention provided by formally trained frontline workers in reducing posttraumatic stress disorder (PTSD), depression, and anxiety symptoms in adult refugees from Syria living in Lebanon.

Method

Study Design

To measure the effectiveness of the ASSYST-G on the dependent variables PTSD, Anxiety, and Depression, this study used a single-arm pre-post treatment design. PTSD, anxiety, and depression symptoms were measured in two-time points for all participants in the study: Time 1. Pre-treatment assessment and Time 2. Post-treatment assessment. Time 3. Follow-up assessment was not included in the research design because of the great mobility of the study population, and the high probability of not collecting the information.

Ethics and Research Quality

Due to the unstable political situation in Lebanon, it was impossible to register the research protocol with the Lebanon Control Trial Registry (LBCTR). Therefore, the research protocol was reviewed and approved by the EMDR Mexico International Research Ethics Review Board (also known in the United States of America as an Institutional Review Board) in compliance with the International Committee of Medical Journal Editors recommendations, the Guidelines for Good Clinical Practice of the European Medicines Agency (version 1 December 2016), and the Helsinki Declaration as revised in 2013.

Participants

A total of 41 adult female Syrian refugees living in unofficial camps within and around Tyre, Lebanon met the study inclusion criteria and participated in the study. Participants' ages ranged from 18 to 64 years old (M = 38.09 years). Participation was voluntary and the participants signed an informed consent in accordance with the Mental Capacity Act 2005.

Inclusion criteria for the participants receiving the intervention were: (a) being an adult 18 years or older, (b) being a refugee from Syria (c) voluntarily participating in the study, (d) not receiving specialized trauma therapy, (e) not receiving drug therapy for PTSD symptoms, and (f) having a PCL-5 total score of 22 points or more.

Exclusion criteria were: (a) ongoing self-harm/suicidal or homicidal ideation, (b) diagnosis of schizophrenia, psychotic, or bipolar disorder, (c) diagnosis of a dissociative disorder, (d) organic mental disorder, (e) a current, active chemical dependency problem, (f) significant cognitive impairment (e.g., severe intellectual disability, dementia), (g) presence of uncontrolled symptoms due to a medical illness.

Instruments for Psychometric Evaluation

To measure PTSD symptom severity and treatment response we used the Posttraumatic Stress Disorder Checklist for DSM-5

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(PCL-5) provided by the National Center for PTSD (NCPTSD) with the time interval for symptoms to be the past week. The instrument was translated and back-translated to Modern Standard Arabic. It contains 20 items, including three new PTSD symptoms (compared with the PTSD Checklist for DSM-IV) [25,26]: blame, negative emotions, and reckless or self-destructive behavior. Respondents indicated how much they have been bothered by each PTSD symptom over the past week (rather than the past month), using a 5-point Likert scale ranging from 0=not at all, 1=a little bit, 2=moderately, 3=quite a bit, and 4=extremely. A total-symptoms score of zero to 80 can be obtained by summing the items. The sum of the scores yields a continuous measure of PTSD symptom severity for symptom clusters and the whole disorder. Psychometrics for the PCL-5, validated against the Clinician-Administered PTSD Scale-5 (CAPS-5) diagnosis, suggest that a score of 31-33 is optimal to determine probable PTSD diagnosis, and a score of 33 is recommended for use at present [27,28].

To measure anxiety and depression symptom severity and treatment response we used the Hospital Anxiety and Depression Scale (HADS), which has been extensively used to evaluate these psychiatric comorbidities in various clinical settings at all levels of healthcare services and with the general population. The instrument was translated and back-translated to Modern Standard Arabic. It is a 14-item self-report scale to measure the Anxiety (7 items) and Depression (7 items) of patients with both somatic and mental problems using a 4-point Likert scale ranging from 0 to 3. The response descriptors of all items are Yes, definitely (score 3); Yes, sometimes (score 2); No, not much (score 1); No, not at all (score 0). A higher score represents higher levels of Anxiety and Depression: a domain score of 11 or greater indicates Anxiety or Depression; 8–10 indicates borderline case; 7 or lower indicates no signs of Anxiety or Depression [29,30].

Procedure

Enrollment, Assessments Times, Data Collection, and Confidentiality of Data

Participants for the study were recruited from among Syrian refugees living in or around Tyre, Lebanon, receiving aid or enrolled in literacy classes with the partnering organization, Words of Isa. A call for volunteers was put out by word of mouth and WhatsApp groups. Respondents who met the inclusion criteria were registered on a first-come basis. Participants were provided with transportation, or money for transportation, to the site to receive the ASSYST-G intervention and for both data collection times. Participants all volunteered their time and were not otherwise financially compensated.

During Data Collection Time 1, participants completed the demographic information (e.g., name, age, gender, and contact information) in-person, including the inclusion and exclusion criteria, the informed consent to participate in the research study, and the two assessment instruments. Research assistants, otherwise uninvolved in the study, aided participants unable to read or write in completing the informed consent, demographic information, and assessment instruments.

Participants utilized a mental movie of their whole experience as Syrian refugees to select their worst memory of their refugee experience. Participants were asked to write a sentence or two onto a notecard indicating the identified worst memory. These notecards were utilized during the ASSYST-G intervention as well as for data collection times to ensure participants were focusing on the same memory when they received the intervention as well as the time when they completed the post-treatment assessment tools. For participants unable to write, they were asked to draw a picture of the event onto their notecard and a research assistant also added a sentence about the memory, as dictated by the participant, to the notecard to ensure continuity of focus on the same memory during the intervention and the post-treatment data collection.

For completion of the assessment instruments, the research assistants read each question out loud as it was written in Modern Standard Arabic (translated from the English versions of the assessments) and each question was also given to them verbally in an Arabic vernacular spoken in Syria. All research assistants were also Syrian refugees.

Time 2 post-treatment assessment was conducted in person 30 days after the ASSYST-G treatment completion following the same above-mentioned procedure. All data was collected, stored, and handled in full compliance with the EMDR Mexico International Research Ethics Review Board requirements to ensure confidentiality. Each study participant gave their consent to collect their data, which was strictly required for study quality control. All procedures for handling, storing, destroying, and processing data were in compliance with the Data Protection Act 2018. All persons involved in this research project were subject to professional confidentiality.

Withdrawal from the Study

All research participants had the right to withdraw from the study without justification at any time and with assurances of no prejudicial result. If participants decided to withdraw from the study, they were no longer followed up in the research protocol. There were no withdrawals during this study.

Treatment

Clinicians and Treatment Fidelity

Participants received the ASSYST for Groups intervention as part of the fieldwork practice portion of a cutting-edge mental health training program provided to a carefully selected team

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of four non-mental health professional (non-MHP) frontline workers, working with Words of Isa, a non-profit organization operating in Tyre Lebanon.

Trainees received a two-day in-person training which included a demonstration of the ASSYST-G procedure, lecture, and discussion regarding the administration of the procedure, and practicum within the training team. Trainees were also taught how to utilize the ASSYST-Individual in-person as an individual intervention to be offered on an as needed basis. Treatment fidelity was achieved through in-person supervision and feedback from the trainer, a mental health professional (MHP), licensed in the United States, during the fieldwork practicum treatment intervention. Follow up consultation from the trainer along with continued work with the head of the partnering organization (the second author in this paper MT), is being provided to trainees on an ongoing basis as they continue to utilize the ASSYST-G within the Syrian refugee population in Tyre, Lebanon.

From the group of trainees, two were selected to lead the ASSYT-G during the fieldwork practicum. These two trainees were selected primarily because of their demonstrated competence as leaders and teachers, and because they were already in contact with and serving the refugee population in Tyre, Lebanon. These two ASSYST-G leaders were initially hired by the partnering organization to work primarily as teachers. One frontline worker has an Egyptian degree in social work and works primarily in the children's educational program teaching Arabic literacy, mathematics, and ethics. The other frontline worker has a background as a pharmacy technician in Syria, and currently works primarily with adult women teaching Arabic literacy, women's health care, and childbirth. The partnering organization is working to develop their trauma therapy program and the training provided as part of this research project is a part of those efforts. Both frontline workers in this study are a part of the development of the trauma therapy program.

The other trainees were part of the ASSYST-G Emotional Protection Team (EPT) with the important roles of providing the perception of security for the participants, bringing support to participants to follow the protocol's instructions correctly, answering participants' questions, and being the leader's eyes and ears during the group work.

Treatment Description and Treatment Safety

The pathogenic memories participants identified from their refugee experiences were an average of 463.12 weeks (8.91 years-old). Most participants identified memories of either their departure from Syria, or the events that led up to their decision to leave. Participants received two in-person administrations of the ASSYST-G, with a twenty-minute break between the two administrations. The ASSYST-G treatment focused only on the pathogenic memory that was selected during Time 1 pre-treatment assessment to answer the HADS and PCL-5 assessment instruments. To ensure the continuity and congruency of the intervention and measurement of its efficiency and efficacy, during the fieldwork intervention, participants were asked to look at the notecard in which the identified worst memory of their refugee experience had been written or drawn when answering the Time 1 pre-treatment assessment tools. Participants were then asked to run a mental movie of that specific memory and to then chose the worst part of the memory.

Treatment safety was defined as the absence of adverse effects, events, or symptoms worsening. Therefore, the training team also offered participants an individual procedure (the ASSYST-I) after the two administrations of the ASSYST-G for anyone needing more intervention. No participants stayed to receive the ASSYT-I. All participants were provided contact information should they feel the need for more assistance after the intervention. No adverse effects, events, or symptom worsening were reported during the treatment intervention, or the 30-days between the intervention and Time 2 post-treatment data collection.

Examples of the Pathogenic Memories Treated with the ASSYST-G

Examples of pathogenic memories treated during the ASSYST-G sessions were: a) the army storming a house and severely beating several family members inside; b) an individual witnessing her house being destroyed before her eyes; c) a pregnancy that was miscarried at seven months when a woman's house was bombed by the army; d) a husband who was arrested by security forces over seven years ago and his wife not having any information about him since his arrest; e) being woken up by bombing that resulted in the family home being destroyed, and multiple family members dying, "it was the worst night of my life."

Statistical Analyses

A one-sample t-test was run to evaluate the effect of the Acute Stress Syndrome Stabilization for Groups (ASSYST-G) treatment intervention on three variables: 1) posttraumatic stress disorder (PTSD symptoms); 2) anxiety symptoms and 3) depression symptoms. Cohen's d [31] for paired (repeated) samples t- tests (within groups design), was calculated for each variable to report the effect size.

Result

PTSD Symptoms

Results showed a statistical significance of the one-sample t-test, t (40) =7.54, p=.000; d= .98. The effect size for this comparison (d=.98) was found to exceed Cohen´s convention for a large effect (d=.80). Mean score for PTSD was significatively lower in Time 2 (post-treatment assessment). See Table 1 and Figure 1.

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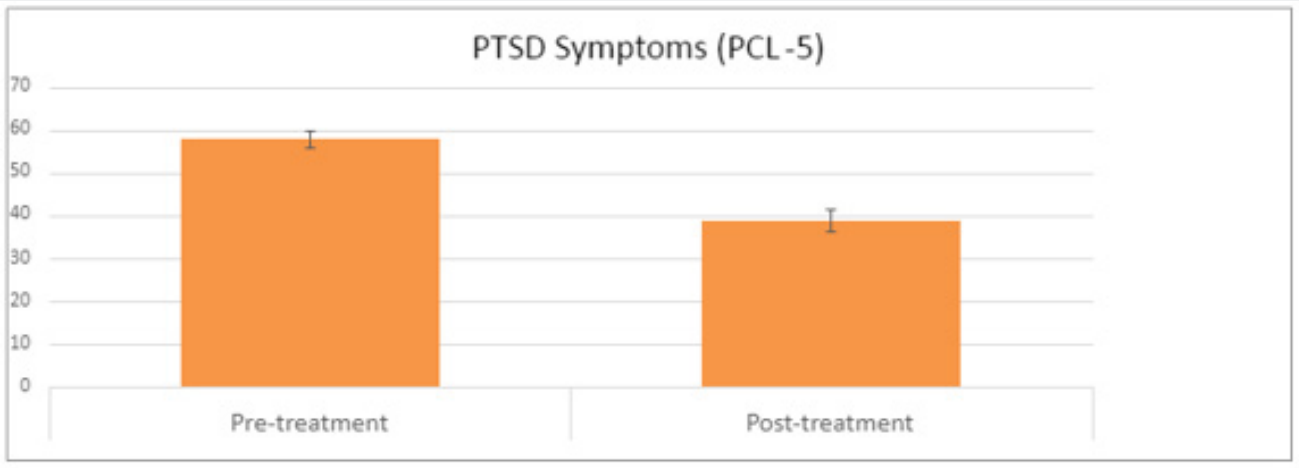

Figure 1: PTSD symptoms. Mean scores with standard error across time.

Table 1: Mean scores (M) and standard deviations (SD) at Time 1 (Pre-treatment), and Time 2 (Post treatment) assessments.

	Time 1		Time 2	
	M	SD	M	SD
PTSD*	57.98	12.27	38.8	15.26
Anxiety*	13.44	4.32	10.95	3.61
Depression	9.1	3.78	8.51	3.86

*Statistically significant differences, p= .00

Anxiety

Results showed a statistical significance of the one-sample t-test, t (40) = 3.20, p=.003; d= .44. The effect size for this comparison is closed to a medium effect according to Cohen´s convention for a medium effect (d=.50). Mean score for Anxiety was significatively lower in Time 2 (post-treatment assessment). See Table 1 and Figure 2.

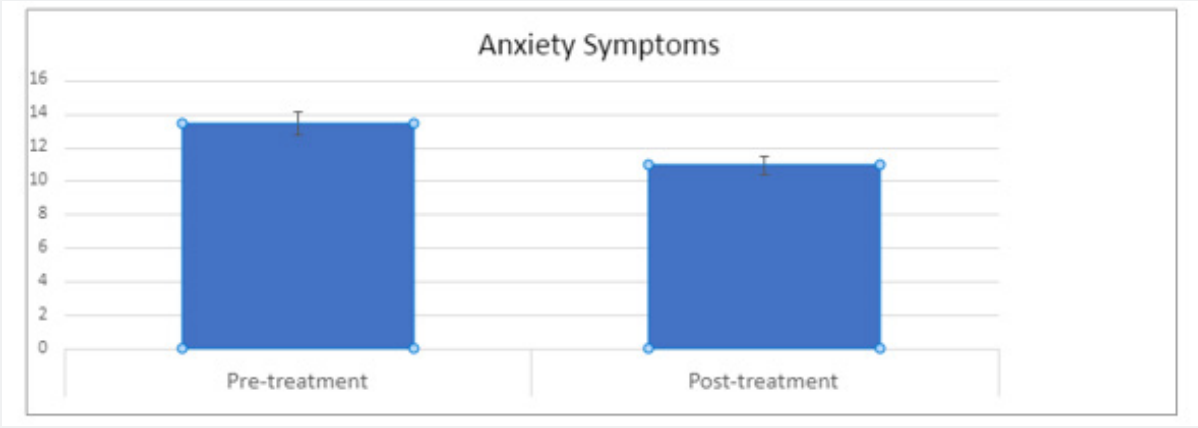

Figure 2: Anxiety symptoms mean scores with standard error across time.

Depression

No statistical significance applying one-sample t-test, was found for depression. Mean score for depression is lower in Time 2 (post-treatment assessment). See Table 1 and Figure 3.

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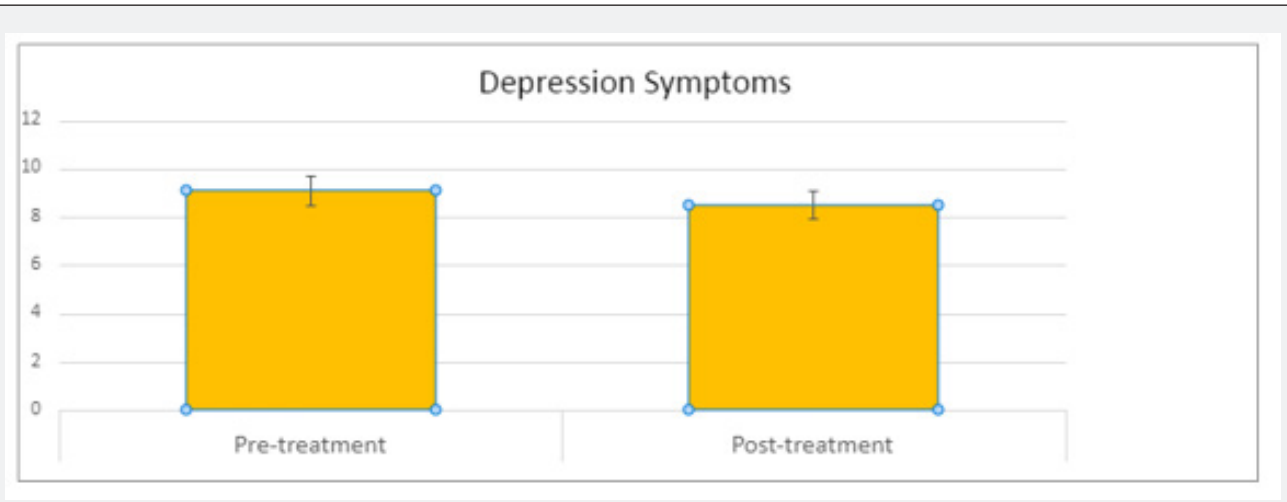

Figure 3: Depression symptoms mean scores with standard error across time.

Discussion

The aim of this clinical trial was to evaluate the effectiveness and safety of the Acute Stress Syndrome Stabilization for Groups (ASSYST-G) treatment intervention provided by formally trained non-MHP frontline workers in reducing posttraumatic stress disorder (PTSD), depression, and anxiety symptoms in adult refugees from Syria living in Lebanon. A total of 41 adult females met the inclusion criteria and participated in the study. Participants' ages ranged from 18 to 64 years old (M = 38.09 years).

After the intervention, results showed a statistically significant decrease with a large effect size in reducing PTSD symptoms associated with the identified worst memory of their refugee experience. Anxiety symptoms also showed a statistically significant decrease in the post-treatment assessment. However, depression symptoms did not show a statistical difference comparing pre- and post-intervention assessments. The lack of statistical difference in depression scores may be attributed to the hopelessness refugees often experience due to their migration being forced, and there being little to no end to their situation in sight. Refugees would often prefer to return home than resettle in another country. Particularly in this situation where the political and economic situation in Lebanon is quite unstable. The Lebanese government isn't bombing their homes as happened to many of them in Syria, but the current lack of government stability in Lebanon makes life very difficult for anyone living in Lebanon right now, and that includes the refugees that have fled Syria. Refugees from Syria have fled the bombs of a civil war only to end up in Lebanon where a life of poverty with little to no opportunity to improve their situation is their reality.

Conclusion, Limitations, and Future Directions

As various task-shifting interventions are explored, this study has shown how non-MHP frontline workers, formally trained in the ASSYST-G, can safely and effectively reduce PTSD, depression, and anxiety symptoms within their own communities, where access to mental health services is scarce or non-existent. In this study, three of the four trainees, all intervention participants, and the research assistants were Syrian refugees, and the remaining trainee is an immigrant from Egypt who lives and works within this community. The need for effective psychological intervention within refugee populations is well known, and the gap between the need for mental health intervention and the availability of service providers continues to be unacceptably large. Only by equipping non-MHP frontline workers with quality training and tools that are culturally effective, will that gap begin to shrink. Relying solely on the availability of highly credentialed mental health professionals will only serve to widen that gap. Additionally, the value of the cultural continuity in providing mental health interventions to Syrian refugees by Syrian refugees cannot be over-stated.

The study results showed that the ASSYST-G treatment intervention can effectively, and safely be provided in-person by formally trained and supervised non-MHP frontline workers to reduce posttraumatic stress disorder (PTSD) and anxiety symptoms in adult refugees from Syria living in Lebanon.

No adverse effects or events were reported by the participants during the treatment procedure administration or at one-month post-treatment assessment. None of the participants showed clinically significant worsening/exacerbation of symptoms on the PCL-5 or HADS after treatment.

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Limitations of this study are the lack of a control group, the small sample, and no follow-up. Therefore, we recommend a randomized controlled trial with a similar population with larger samples, and with 30- and 90-days follow-up to evaluate the long-term treatment effects.

Conflict of Interest and Founding

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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