



End report on process and outcome evaluation of EASE implementation in Lebanon (children)

DELIVERABLE 4.5



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1. Executive summary

1.1. Introduction

There are approximately 82 million forcibly displaced people worldwide, of these, half are children or adolescents. These young people are vulnerable to developing mental health problems including symptoms of anxiety and depression due to exposure to war, emigration, acculturation difficulties, poverty, and exposure to parental stress. The majority (86%) of these young refugees are hosted in low- and middle-income countries (LMICs) where there are significant challenges in providing adequate support and care for mental health difficulties for existing populations and displaced young people. Key barriers to service provision include limited financial resources to pay for transport or treatment, under-resourced mental health workforces who can deliver services, and stigma associated with mental illness.

Due to these challenges, the World Health Organization advocates for the development and implementation of brief psychological interventions that can be delivered by non-specialists to increase accessibility of evidence-based care. One recently developed intervention is the Early Adolescent Skills for Emotions (EASE) intervention, a transdiagnostic intervention for 10-14 year olds which aims to mitigate the symptoms of internalising disorders such as depression and anxiety. It is a non-specialist led group-based intervention comprising seven 90-minute sessions teaching young people coping skills to enhance psychological wellbeing. Parents or caregivers are invited to three additional sessions; this is based on evidence that children's mental health is influenced by parents' and caregivers' mental health and parenting practices, and that adjunctive sessions for parents and caregivers can improve psychological outcomes for the children. EASE has four core features: (1) brief in duration; (2) delivered by non-specialist providers (such as community facilitators); (3) transdiagnostic addressing depression, anxiety, and general distress; and (4) designed for young people and their caregivers living in communities affected by adversity (such as exposure to armed conflict).

1.2. Key contributions

The STRENGTHS project has made significant contributions towards the development of EASE, its evaluation and future scaling.

1. Development of EASE

Through the STRENGTHS project we have worked closely with the World Health Organization to finalize the EASE intervention. EASE is a group intervention for young adolescents (about 10 to 14-year-olds) exhibiting internalizing problems (e.g. symptoms of depression or anxiety). Central to the development of EASE was the capacity to address comorbid emotional problems in one intervention and promote scale-up in LMICs with the use of briefly trained non-specialists. EASE aims to mitigate symptoms of internalizing disorders, such as depression and anxiety, by the provision of four core empirically-supported strategies delivered face-to-face over seven group sessions with adolescents, and three group sessions with their caregivers.

2. Cultural adaptation of EASE

Through the STRENGTHS project we have conducted the first cultural adaptation of EASE, and have thereby further contributed towards the finalization of the EASE manual. We conducted a 7-step process of adaptations, which has resulted in several changes to the materials—some were Lebanon-specific cultural adaptations, while others were incorporated into original materials as they were considered relevant for all contexts of adversity. Overall, our experience with adaptation of the EASE program in Lebanon is promising and indicates the acceptability and feasibility of a brief, non-specialist delivered intervention for adolescents and caregivers. We informed the wider field of global mental health in terms of opportunities and challenges of adapting and implementing low-intensity psychological interventions in settings of low resources and high adversity.

3. Implementation and testing of EASE

Through the STRENGTHS project we were among the first to implement and test the EASE intervention in a real-world humanitarian context. First, we conducted a feasibility study of EASE among 67 young adolescents. The EASE intervention and study procedures are acceptable and feasible for implementation with vulnerable adolescents in Lebanon, however several improvements are necessary prior to full-scale evaluation. Our findings indicated that the EASE intervention and study procedures were overall safe and acceptable for adolescents and caregivers in North Lebanon. This feasibility study allowed identification of several improvements to the EASE intervention and trial procedures to enhance effectiveness and implementation feasibility. Second, we conducted a Randomized Controlled Trial and process evaluation. Due to compounding adversities in Lebanon at the time of this research, we had to terminate the study prematurely, resulting in a under-powered trial sample (n=198 enrolled compared to n=445 targeted). No definitive conclusions on the effectiveness can be drawn given the underpowered final sample. Treating the analysis as more exploratory we infer; (i) no support for effectiveness of EASE; (ii) both EASE and single session psycho-education home visits result in meaningful improvements in reducing psychological distress; (iii) which can be explained by EASE not demonstrating its full potential due to implementation challenges or by the potential for single session family-based interventions. The process evaluation showed that the majority of interviewees expressed their positive experiences of participating in EASE, either as participants, providers, or trainers. At the individual child level, adolescent's behaviour improved, particularly regulating their reactions when feeling angry. Participants also noted improvement in adolescent's ability to express themselves; they can talk about their feelings, their problems and how to deal with them, their daily life, and their relationships with their communities, and they know their strengths and talk about it. Furthermore, the process evaluation provided information relevant for future implementation of EASE, including; (i) overcoming barriers for engagement and attendance; (ii) considerations for scaling up EASE, and; (iii) working with non-specialist facilitators.

4. Scientific outputs

Through the STRENGTHS project we have contributed to significant knowledge generation in relation to the implementation, evaluation and scaling of EASE; (i) 6 scientific publications published or under review, and another 3 in preparation; (ii) 1 new instrument developed and tested to assess the level of functional impairment amongst children in Lebanon and Jordan; (iii) 1 new instrument developed to assess EASE mechanisms of action, in order to gauge the degree by which participants adopt strategies underlying the EASE intervention.

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5. Scaling of EASE

Through the STRENGTHS project we have collaborated with partners in Jordan (Richard Bryant and colleagues) and Pakistan (Atif Rahman and colleagues) to demonstrate the effectiveness of EASE, which will subsequently be released by the World Health Organization in early 2023. In a single-blind, parallel, controlled trial, Syrian refugees aged 10 to 14 years in Jordan were identified through screening of psychological distress (a twin-trial to the STRENGTHS RCT on EASE in Lebanon). Intent-to-treat analyses indicated that at 3 months, EASE resulted in greater reduction on the PSC-internalising scale than EUC (estimated mean difference 0.69, 95% CI 0.19 to 1.19; $p = 0.007$; effect size, 0.38) but there were no differences for PSC-externalising (estimated mean difference 0.24, 95% CI -0.43 to 0.91; $p = 0.49$; effect size, -0.10), PSC-attentional problem (estimated mean difference -0.01 , 95% CI -0.51 to 0.54; $p = 0.97$; effect size, -0.01) scores, or on depression, posttraumatic stress, well-being, functioning, or school belongingness. In brief, EASE led to reduced internalising problems in young refugee adolescents and was associated with reduced distress and less inconsistent disciplinary parenting in caregivers. This intervention has the potential as a scalable intervention to mitigate young adolescents' emotional difficulties in LMIC. **As a result of the evaluations done to date, the World Health Organization has decided to release EASE into the public domain in the first quarter of 2023 – an important milestone in addressing the treatment gap for children and young adolescents with mental health problems, especially in humanitarian settings.**

2. Definitive RCT (phase 4)

2.1. Background and preparatory work

2.1.1. Description of context in which study took place

The study was implemented in the north of Lebanon (Akkar and Lebanon-North governorates), an area where large number of Syrian and Palestinian refugees reside. Lebanon has experienced prolonged conflict, political instability and a struggling economy. Especially in the north of Lebanon this has resulted in high levels of poverty and scarcely available services. The over 1.5 million Syrian refugees have further experienced significant adversity as a result of the Syrian conflict and forced migration. Syrian refugees living in Lebanon, many since the onset of the Syrian war in 2011, have severely restricted work rights, tightened in recent years, and do not have permanent status. This state of protracted displacement leads to additional risk factors for their mental health and wellbeing including lack of adequate housing, inconsistent livelihoods, limited access to health and education services, and community discrimination.

As our trial was underway in 2019, Lebanon experienced an unprecedented financial crisis from which it has yet to emerge. The local currency was severely devalued, resulting in exacerbated economic hardship for Syrian and low-income Lebanese families, and difficulty meeting daily needs. Following the economic hardship and political instability, protests erupted across the country, resulting in severe restrictions in movement and an increasingly volatile and violent situation – also in the study area. Then mid-way through our study, the COVID-19 pandemic struck Lebanon, leading to a strict national lockdown. All in-person activities conducted by War Child had to be stopped following nationwide restrictions, which lasted for over 12 months. At that point in time 44% of the intended sample had completed the intervention and post-intervention assessments. For the remainder of the sample baseline assessments were being conducted when COVID-19 hit, but the intervention could not be offered due to the lockdown, except administering phone-based follow-up interviews for the 44% of the sample. Due to logistic and financial reasons restarting the study was not possible after approximately 12 months of COVID-19-restrictions, and changing the intervention to online format was deemed infeasible and carrying too much risk. As a result the study was terminated, and we are reporting the results of the 198 adolescents for whom all assessments were completed (see details below).

2.1.2. Description of EASE

EASE consists of seven sessions for young adolescents and three sessions for their caregivers. The sessions for adolescents involve; psychoeducation about the effects of stressful events, and identifications of emotions (session 1); reducing arousal using relaxation and stress management techniques (i.e. slow breathing) (session 2); behavioural activation strategies (sessions 3 and 4); problem solving strategies, including seeking social support (session 5 and 6); relapse prevention to manage future stressors (session 7). The caregiver sessions involve; psychoeducation and skills to help their child cope with distress (session 1); positive parenting skills, including praise, reducing harsh punishment and promoting communication skills (session 2); strategies to manage caregivers' own stress (e.g. advice about sleep, nutrition, stress reduction exercises, and utilization of social

support) (session 3). During caregiver sessions, another staff member was available to provide child care as necessary. Adolescent and caregiver sessions are for groups of 6-10 people, and lasting 1.5-2 hours each, provided on a weekly basis. EASE facilitators, non-professionals recruited from the communities where the study took place, received an 8-day training in the delivery of the interventions, as well as basic counselling and communication skills, group facilitation, child protection, security, and self-care. Following the training, all facilitators completed a supervised practice cycle of EASE ahead of the study implementation. During the study weekly supervision was offered. Each group was conducted by two facilitators.

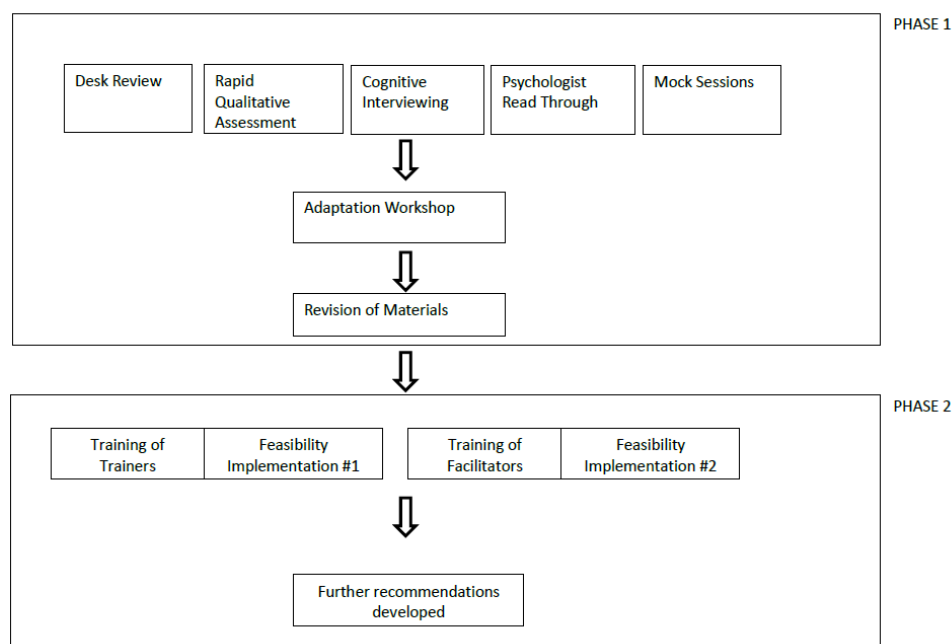
2.1.3. Cultural adaptation of EASE

Process

We conducted our cultural adaptation process in the North governorate, mainly in two vulnerable areas - Beb el Tebbeneh and Hay el Tanak. These were selected as representative areas, given the high vulnerability, and a mix of cultural groups (e.g. Syrian, Lebanese, and Palestinian). When considering cultural and contextual adaptations for psychological interventions in Lebanon, it is important to note that there are vast cultural and contextual differences amongst different regions of Lebanon including wide variations in income, living conditions, type and opportunities of employment, religion, language, and attitudes towards mental health and associated interventions. Therefore, results of this adaptation process cannot be assumed to be nationally representative.

We followed an iterative adaptation process based on an internal WHO draft guidance on cultural adaptation of scalable psychological interventions (available on request), which draws from various resources (23, 29, 30). In the first stage, we conducted: i) literature reviews on mental health in Lebanon, with a focus on Syrian refugees; ii) a rapid qualitative assessment with adolescents, caregivers, community members, and health professionals in Lebanon; iii) cognitive interviewing with EASE materials; iv) a psychologist Arabic read-through to reach optimal and consistent translation of key terms; v) 'mock sessions' of the intervention with field staff and clinical psychology experts. In an adaptation workshop, data from each of the five steps was reviewed to decide on necessary adaptations. Changes to materials were proposed to developers at WHO, and changes in line with the intervention model were implemented accordingly. The second phase involved: i) gathering data from the Training of Trainers workshop, and associated implementation of practice sessions; and ii) gathering data from the Training of Facilitators workshop, and associated implementation of practice sessions. Several recommendations were developed for further adaptations. This process is depicted in Figure 1. Ethical approval was obtained from Saint Joseph's University, Beirut (USJ-2017-24).

Figure 1: Overview of EASE adaptation process'



Results phase 1: Formative Research

Scoping Review of Literature. The review highlighted that conflict-affected Syrians experience a wide range of mental health problems including newly emerged mental health conditions caused by conflict-related experiences, as well as issues related to living conditions (31). Children and adolescents report war-related anxiety, worries about the future, and other emotional distress including grief, frustration and hopelessness (31, 32, 36, 37). Several barriers to accessing health care exist, including language barriers, stigma, and perceived power-dynamics in the therapeutic relationship (31, 32, 36). Children and adolescents experience high rates of family violence, contributing to emotional distress (36). Furthermore, high rates of substance use among adolescents are reported (36, 37). A pervasive daily stressor is poverty, and this is known to affect many other aspects of child and adolescent wellbeing, including lack of basic needs, poor attendance at school, child labour, substance use, and criminal activity (31, 32, 36, 37). In Lebanon, 70% of Syrian refugees live below the poverty line (26) and reports indicate that poverty and associated experiences can exacerbate new? hopelessness and frustration, and pre-existing mental health concerns (31, 36). Needs assessments conducted in Lebanon by War Child Holland confirm these findings and highlight the importance of interventions targeting the specific mental health and psychosocial needs of vulnerable populations in Lebanon.

Rapid Qualitative Assessment. The most common concerns reported through free listing, that were considered potentially viable to be addressed in a psychological intervention, were: i) physical violence and abuse (among children and adolescents, and from caregivers or teachers towards children and adolescents); ii) neglect and emotional abuse from parents; iii) emotional abuse among children and adolescents (primarily bullying and teasing); and iv) substance use (alcohol, tobacco, and other drugs) among children and adolescents.

Cognitive Interviewing. Results of the cognitive interviewing indicated that the content was relevant and comprehensible, and the language was simple and easy to understand. Importantly, several findings informed intervention delivery. Adolescents commonly endorsed that psychosocial

problems occurred for friends or neighbours, rather than reporting that these problems occurred in their own life. The local team perceived this to be due to a cultural expectation that events occurring within the family home should not be discussed with others. Furthermore, thorough explanation of the EASE strategies was required in order for adolescents to fully grasp them. For the Tired Cycle in particular, explanation on the linkages between mood and behaviours, and the directional nature of the cycle needed to be expanded. Caregivers were talkative and liked the opportunity to share experiences. Caregivers were worried that suicide would be discussed with their children, as this was perceived to increase the risk of suicide. When they were asked if it is acceptable to talk about suicide, one caregiver said: “With the parents yes, but with the child, no”. Another caregiver further explained: “No because the child will have this idea in their head and they will want to do it!”. This highlights the need for thorough explanation about the reasons for discussing suicide with young people. Physical punishment was openly discussed by caregivers, and reportedly very common, with many stating that it was necessary because they had no other options. Additionally, caregivers recognised the need for taking care of themselves, but found it hard to implement. This highlighted that discussing these topics would be suitable in the intervention, but with sensitivity.

Psychologist Read-through. The language of the EASE materials was generally perceived to be understandable, and several revisions were made for consistency, accuracy, and simplifying terminology. One example was a change in the word for ‘emotional problems’ in Arabic from “mashakel 3atifiah” (i.e. emotional problems) to “mashakel nafsiah” (i.e. psychological problems), as the first had connotations of “romantic problems”. Furthermore, the concept of suicidality was introduced via a culturally appropriate phrase: “Sometimes people have thoughts that their life is not worth living or they wish they would fall sleep and not wake up”.

Mock Sessions. Overall the experience of the mock sessions indicated that the content and ideas were largely relevant, acceptable, and understandable in the Lebanese context. Several suggested edits to the original version were identified, to improve facilitators’ ease of use of the manual and increase participant engagement more generally across all contexts. Furthermore, several cultural adaptations were identified for use in Lebanon.

Adaptation Workshop. All recommendations for changes from the previous five steps were summarized and discussed, and the changes implemented. One substantial change to EASE content was adapting the ‘Tired Cycle’ for behavior activation, which previously focused on the inactivity associated with depression. Given the critical prevalence and impact of aggression and violence in the communities, this was adapted to the ‘Vicious Cycle’, with examples provided for how behavioural cycles can also work to maintain anxiety and anger, and prevent engagement in personally valued activities.

Translation of Revised Materials. Professional translators translated the revised materials into English. We intended to translate the storybook into simplified, local language. However, based on feedback from trainers and facilitators, it was translated to simple, yet formal written Arabic, and facilitators could adapt the language during delivery. The glossary of key terms in Arabic for EASE, plus common terms for idioms of distress in Syrian Arabic, were provided to facilitators and they were encouraged to use them in their delivery of sessions.

Results phase 2: Implementation Data

Training of Trainers and Practice Cycle. Through this implementation, it was determined that separation of groups by gender (as recommended by the EASE manual) is beneficial to promote comfort and openness. Similarly siblings and relatives should be separated, where possible, to prevent reticence when discussing personal details. Further, it was determined that the presence of a male facilitator (alongside a female facilitator) was accepted by female adolescents. Significant behaviour problems (for example leaving the classroom, and bullying) were experienced in the male group, such that the group was discontinued and individual support provided to interested adolescents. This supports the RQA findings that externalizing problems are salient in this population, and highlights the importance of training facilitators in additional behavioural management strategies in Lebanon.

Training of Facilitators and Practice Cycles. On average, session duration was between 1.5 and 2 hours. Attendance was variable, particularly for later children and caregivers sessions, ranging between an average of 53% and 89% per session. Facilitator-reported fidelity to the major components of the intervention was generally high, with low-fidelity reported for some specific sessions, sometimes due to the shortening of session time due to practical issues, or only one participant attending and therefore some group activities not being completed. Trainer-observed fidelity was slightly lower, however overall, most facilitators were implementing the majority of the components in most session. Some items were not completed due to lack of time. Competency ratings for delivery of EASE content were rated high, and the majority of ratings on the core competencies of group facilitation and basic helping skills were the highest possible score. Facilitators gathered and documented feedback from adolescents and caregivers at the end of the programme. Overall, feedback was positive. Adolescents found the problem solving strategy (Managing my Problems) most useful, and were commonly practicing diaphragmatic breathing. Some adolescents could not personally relate to the vicious cycle, which described the link between mood and detrimental behavior patterns that took them away from meaningful activities. In cases where children could not identify meaningful activities that were being impacted, facilitators asked children to use the behavioural activation strategy (Changing my Actions) to increase pleasurable activities, or improve everyday planning. Caregivers reported finding the diaphragmatic breathing strategy, and the exercise about caregiver strengths useful and felt that they were using more supportive and less harsh parenting techniques. Caregivers reported challenges around the implementation of Quality Time, given the large family sizes and time limitations and facilitators handled this as specified in the manual in terms of emphasizing brief moments.

2.1.4. Pilot randomized controlled trial

We conducted a cultural adaptation of the EASE intervention for the context of Lebanon (20). Following recommendations for developing complex interventions (21), we first conducted this randomized feasibility trial to inform necessary adaptations prior to the implementation of a fully powered RCT. Specifically, the aims were to: (i) Determine recruitment, screening, completion, and retention rates for the EASE programme and follow up assessment. (ii) Evaluate the feasibility and acceptability of intervention delivery of EASE by trained non-specialists. (iii) Assess feasibility of outcome measures and their psychometric properties, and explore trends in changes over time and between groups. (iv) Assess feasibility and safety of trial procedures such as randomization, blinding of assessors, contamination, and occurrence and monitoring of adverse events. This study was a feasibility pilot, following the intended RCT design: a two-arm, single-blind, individually randomised

group treatment trial, with a 1:1 allocation of participants to EASE or enhanced treatment as usual (ETAU). We assessed: recruitment, screening, attendance, and retention rates of participants; fidelity and competence of facilitator delivery of the intervention; the feasibility of randomization and blinding procedures and the likelihood of contamination between treatment and control groups; psychometric properties and trends in outcome measures on a range of adolescent and caregiver outcomes at pre-intervention (“baseline”; T0), post-intervention (“endline”; T1), and 3-month follow-up (T2). At T1 we conducted a qualitative process evaluation using semi-structured interviews and focus group discussions with participants and stakeholders. We carried out the study in community centres in the North governorate of Lebanon, including urban areas in Tripoli and agricultural areas in Minieh-Dinnieh from September 2018 to July 2019. The trial was implemented by War Child Holland, an international non-governmental organization that has been responding to the Syrian crisis in Lebanon since 2012. Ethical approval was obtained via St Joseph’s University in Beirut (USJ-2017-24-bis), and the World Health Organization (ERC.0003000).

Adolescents aged 10 to 14 years were eligible to take part if they scored above a validated cut-off on the Child Psychosocial Distress Screener. Participants were randomized to EASE or enhanced treatment as usual (ETAU) control using a 1:1 ratio. Of 154 adolescents screened, 67 were eligible (43%), completed baseline, and were randomized. Sixty adolescents (90%) completed endline assessments (31 EASE, 29 ETAU), and fifty-nine (88%) completed three-month assessments (29 EASE, 30 ETAU). EASE consisted of seven group sessions with adolescents and three sessions with caregivers. ETAU consisted of a single brief psychoeducation home visit. Child and caregiver outcomes were measured by blind assessors at baseline, endline, and three month follow-up, with the primary outcome measure being child psychological symptoms on the Pediatric Symptom Checklist. Qualitative interviews were conducted with adolescents (n=13), caregivers (n=17), facilitators (n = 6), trainers (n = 3), and outreach staff (n= 1) at endline to assess barriers and facilitators related to the feasibility and delivery of EASE and study procedures.

We noted challenges with outreach and saw significant attrition between registration of interest and screening time-points, and between screening and baseline for those eligible. There were challenges among the EASE participants in terms of regular attendance at sessions, with only 63% of adolescents completing 5 or more EASE sessions; common reasons cited were school and work commitments, or transport issues. Nonetheless we found good retention rates among adolescents and caregivers in completing endline and follow-up assessments. Randomisation and blinding procedures were effective and feasible, and we noted minimal contamination. Fidelity and competency of EASE implementation was satisfactory, though time management and behaviour management was an issue in some sessions. Outcome measures showed good psychometric properties on total scale scores, with low item-level missing data for most questionnaires. Our screening measure resulted in a positive screening rate of 49%, while baseline levels of distress on outcome measures were relatively low. We did not identify substantial changes overtime on our outcome measures, (between or within groups) despite qualitative reports of positive impacts of EASE. We responded to a high number of adverse events throughout the study, necessitating referrals to other services, though none were deemed to be caused by or linked to participation in the study.

Our findings indicate that the EASE intervention and study procedures are overall safe and acceptable for adolescents and caregivers in North Lebanon. High levels of adversity and competing demands led to challenges with engagement and attendance in the intervention, and many

referrals to other services were needed throughout the intervention. This feasibility study allowed identification of several improvements to the EASE intervention and trial procedures to enhance effectiveness and implementation feasibility. The forthcoming fully powered trial will assess the impact of EASE in this population.

2.1.5. Ethics approval definitive RCT

This study is reported as per the Consolidated Standards of Reporting Trials (CONSORT) guideline (S1 Consort Checklist). Ethical approval for the conduct of this study was obtained from St Joseph University (USJ.201724) and the World Health Organization Ethical Review Committee (ERC.0003000).

2.1.6. Objectives and design

This two-arm, single-blind individually randomized group treatment trial was conducted in Lebanon to test our hypothesis that participation in EASE results in better outcomes compared to an enhanced treatment as usual (ETAU) control condition. Outcomes were assessed at baseline (T0), post-intervention (T2), 3-months follow-up (T2) and 12-months follow-up (T3), with the 3-months post intervention as the primary time point for testing the aforementioned hypothesis. The study was implemented by War Child, an international humanitarian organization. The research was prospectively registered on 11 March 2019 (ISRCTN75375136). The trial protocol has been previously published (Brown et al., 2019).

2.2. Methods

2.2.1. Sample

Participants were recruited into the study through several engagement activities, which included in-person community awareness sessions, communicating about the study through social media channels, NGO and United Nations programs, using scripted information to minimize risk of bias in recruitment. Participants were enrolled in the trial if they met inclusion criteria: (a) aged 10 to 14 years; (b) resided with a related caregiver who could provide consent; (c) willing to participate in weekly EASE sessions; and (d) demonstrating elevated levels of psychological distress measured with the Pediatric Symptom Scale (PSC-17) (Jellinek et al., 1999). An optimal cut-off point of 12 was established following a validation against a semi structured interview by a mental health professional (Brown et al, under review). For all eligible young adolescents, their caregiver was also invited, and required to consent, to participate in the study. Exclusion criteria were: (a) unaccompanied minor; (b) minors with an unrelated caregiver; (c) significant developmental, cognitive, or neurological impairments as determined by 4 items from an adapted version of the 10 Questions instrument (Durkin, Hasan, & Hasan, 1995); (d) currently married, and; (d) imminent risk of suicide measured using a 3-item questionnaire based on WHO's mhGAP Intervention Guide (WHO, 2016). Any potential participants reporting imminent risk of suicide were referred to relevant services. In case of multiple siblings meeting eligibility criteria, all were included in the study for reasons of fairness, but randomized as a single unit to avoid children from the same family being allocated to different treatment conditions. We followed a two-staged process to obtain

informed written consent from caregivers and assent from the young adolescents. First, to participate in the screening; second, for those meeting inclusion criteria to participate in the trial. Witnessed oral consent was accepted for illiterate participants.

2.2.2. Randomization and masking

Following baseline assessments, participants were randomly allocated to either the EASE program or ETAU (following a 1:1.6 ratio). Randomization was done by volunteers in the Lebanon office, using computer generated sequences, and putting allocations in numbered opaque envelopes. Stratification was applied for gender and sibling pairs. Block sizes of 13 were used to maintain the randomization ratio. Research assistants and investigators were masked to treatment condition allocation. Interaction between research assistant and intervention facilitators was avoided, and before each round of assessments research assistants instructed participants to not inform them about their allocation. At the end of each assessment research assistants guessed the allocation of the participant, to assess to what degree masking was maintained.

2.2.3. Control condition

EASE has been described above. The control group was an Enhanced Treatment As Usual (ETAU) condition consisted of home-visit single-session psycho-education. This enhancement was offered as treatment as usual in the study setting essentially meant no treatment at all, given the near absence of mental health services. Both caregiver and adolescent were invited to participate in the session, which lasted between 30-45 minutes. The scripted session consisted of; (i) sharing the screening results to the family; (ii) discussing some common and simple to use self-care strategies to manage high levels of distress, and; (iii) information about the few available mental health and psychosocial support services provided by international non-governmental organizations. ETAU facilitators, recruited following the same criteria and process as the EASE facilitators, received a 3-day training in the delivery of the psycho-education session instead of EASE; otherwise the training was content-matched between both groups. Only one supervision session was offered during the implementation period.

2.2.4. Instruments

Primary outcome

The primary outcome is psychological distress at 3 month follow up, measured using the Pediatric Symptom Checklist (PSC-35), a 35-item adolescent self-report instrument scored on a 3-point response scale (0 = never, 2 = often), with a higher total score indicating more severe problems (Jellinek et al., 1999). The instrument has been validated for use in Lebanon, demonstrating good internal consistency ($\alpha=0.80$) (Brown et al., under review). As 17 items of the instrument were used during the screening (see above), the remaining 18 items were asked during the baseline interviews. The PSC-35 has three sub-scales for internalizing-, externalizing-, and attention-problems (the internalizing sub-scale was used as a secondary outcome).

Secondary outcome

Several secondary outcomes were also completed by adolescents. Symptoms of depression in the last week were assessed using the Patient Health Questionnaire, adolescent version (PHQ-A)

(Johnson, Harris, Spitzer, & Williams, 2002), a nine-item measure scored on a 4-point scale (0 = not at all, 3 = nearly every day), with a total score ranging between 0 to 36 ($\alpha=0.83$; here and below we will report the internal consistency for all measures based on baseline reporting in the current study). Higher total scores reflect more severe symptoms of depression. Symptoms of traumatic stress were assessed using the Children's Revised Impact of Events Scale (CRIES), a 13-item instrument with items scored on a 5-point scale (0 = not at all, 4 = often), with a higher total score (0-65) indicating more severe symptoms ($\alpha=0.88$) (Perrin, Meiser-Stedman, & Smith, 2005). The CRIES has three subscales, intrusion (4 items), avoidance (4 items), and arousal (5 items). The Daily Functioning instrument has been developed in Lebanon, specifically for this study, replicating a procedure developed by Bolton and colleagues (Bolton & Tang, 2002). The nine-item instrument aims to assess impairment in daily activities, which adolescents had identified and rated as most relevant for them as part of the tool development process ($\alpha=0.82$). Scoring is done on a 4-item response scale (0 = not at all, 3 = very much), with a higher total score (0-27) indicating higher perceived impairment in daily functioning. The 14-item Warwick Edinburgh Mental Wellbeing Scale (WEMWBS) assesses wellbeing (Stewart-Brown et al., 2011), with respondents asked to indicate which score best describes their thoughts or feelings over the past week on a scale from 1 (none of the time) to 5 (all of the time) ($\alpha=0.85$). A higher total score (14-70) indicates greater positive mental wellbeing.

Several additional secondary outcomes were completed by the caregivers. The caregiver version of the PSC-35 to assess their perceptions of the psychological distress of their child is identical to the child version described above ($\alpha=0.83$). We used the Kessler Psychological Distress Scale (K6), a six-item measure of distress symptoms experienced in the past week (Kessler et al., 2002). Scoring is done on a 5-point scale (1 = all of the time, 5 = none of the time), with a higher total score (6-30) indicating more distress ($\alpha=0.73$). The Alabama Parenting Questionnaire (APQ-42) was used to assess parenting behaviors (Maguin, Nochajski, De Wit, & Safyer, 2016). The 42-item instrument measures 5 major parenting constructs: (a) parental involvement (10 items) ($\alpha=0.69$); (b) poor supervision and monitoring (10 items) ($\alpha=0.65$); (c) positive parenting (6 items) ($\alpha=0.65$); (d) inconsistent discipline (6 items) ($\alpha=0.39$); and (e) corporal punishment (3 items) ($\alpha=0.53$). Scoring follows a 5-point scale (1 = never, 5 = always).

Other measures

To assess adolescents' exposure to potentially traumatic events, caregivers completed a 26-item traumatic events checklist, which was adapted from existing trauma exposure checklists (Mollica et al., 1992; Steinberg, Brymer, Decker, & Pynoos, 2004), by local mental health professionals selecting relevant items for the context in Lebanon. Items were scored dichotomously. Both adolescents and caregivers completed a Strategies Use Questionnaire (7 and 8 items, respectively), developed for the purpose of this study in order to assess the use of coping strategies. The selected strategies map onto the content of the EASE intervention, but formulated so that it can be scored independent of knowledge or experience of EASE, in order to gauge the degree by which participants adopt strategies underlying the EASE intervention. This mechanisms of action tool was included as a hypothesized mediator of change. Items are scored on a five-item response scale (0 = never; 4 = all of the time). A higher total score (0-28 for adolescents and 0-32 for caregivers), indicate higher degree of use of strategies ($\alpha=0.73$ and $\alpha=0.59$, respectively). Each pair of facilitators completed a session checklist following each EASE or ETAU session to evaluate fidelity. A sample of approximately 10% of the EASE and ETAU sessions was observed by a trained staff member, to complete a structured observation form to assess fidelity.

Administration

All symptom checklists were selected because these had been commonly used in Lebanon or other LMIC studies, demonstrating good psychometric properties. Details of translation are detailed elsewhere (Brown et al., 2019; van Ommeren et al., 1999). All instruments were interview administered delivered by trained research assistants, using Kobo electronic data collection software on tablets. Research assistants received a five-day training in basic research skills, interviewing techniques, consent-, adverse events reporting-, and ethics- procedures, and practicing the administration of research instruments.

2.2.5. Analysis

All analyses were conducted in Stata, version 15. We calculated descriptive statistics (means, standard deviations, percentages) to summarize baseline characteristics of the study sample separately by trial arm for both adolescents and caregivers. We estimated linear mixed effects models to estimate the difference in change from baseline to each follow-up timepoint (endline, 3-month, 12-month follow-up) between EASE and ETAU separately for each outcome. Fixed effects included treatment arm (0 = ETAU; 1 = EASE), time (0 = baseline; 1 = endline; 2=3 month follow-up; 3=12 month follow-up) and interaction terms between treatment arm and time. Random effects included participant ID, family ID (to account for the fact that some adolescents had siblings in the study), and intervention group. For models with caregiver-reported data, when each observation was unique for a child (e.g., PSC), all observations were included (n=198). When caregivers only reported once regardless of the number of children they had in the study, we included 155 observations (the number of unique caregivers) so that caregivers with multiple children in the study were not duplicated in the model (e.g., K6, Alabama outcomes). For these latter outcome models, random effects included Caregiver ID and intervention group.

For each outcome, we report predicted means at baseline and each follow-up for both groups from the mixed effects model, as well as the estimated difference in mean change in outcome score between groups at each timepoint with 95% confidence intervals. We calculated Cohen's d effect size as the difference in mean change divided by the pooled baseline standard deviation.

We ran post-hoc analyses to assess the response rates for depression and internalizing symptoms (defined as at least 50% reduction in PHQ-9 and score PSC Internalizing subscale compared with baseline). Missing data was assumed to be missing at random and addressed through multiple imputation with chained equations.

We also conducted a series of exploratory subgroup analyses for the following outcomes: PSC, PSC Internalizing, PSC Externalizing, PHQ, Wellbeing, and Caregiver PSC. For those outcomes, we re-estimated the above-described models separately within strata of the following characteristics: gender (males and females), age (10-12 year old and 13-14 year old), treatment status (completers and non-completers) and symptom severity (top and bottom 50% of baseline scores on PSC, PSC Internalizing, PSC Externalizing, PHQ, Wellbeing, Caregiver PSC, and K6). Models were identical to those in the main analysis except that we only analyzed difference in mean change for one follow-up timepoint (endline).

Sample size calculations were conducted using a conservative estimate of theta (ratio of variances) of 1.1 and of the intraclass correlation as 0.13. Assuming a 5% two-tailed significance test and 80%

power, it was estimated that data from 445 participants are needed to be available at the 3-month follow-up to detect an effect size of 0.4 (an allocation ratio of EASE to ETAU arms of 1:1.6), allowing for 30% loss to follow up.

2.3. Results

2.3.1. Participants

Study enrolment started on 19 June, 2019 and the final 12-months follow-up assessment was done on 8 March, 2021. From 604 adolescents that were screened, 198 (33%) met inclusion criteria and were randomly allocated (1:1.6) to EASE (n=80) and ETAU (n=118). The retention rates were within the margin that was projected, 88.4% for adolescents at baseline, at both 3 and 12 months follow up this was 77.8%. For caregivers, the retention rates were similar, 87.7% at baseline, 76.1% at 3 months, and 78.8% at 12 months follow-up. See Figure 2 for the full overview participant recruitment, retention and reasons for drop-out.

Sample characteristics are summarized in Table 1 (adolescents). Adolescents were 51% male and the average age was 11.8 (SD=1.3). Ninety-seven percent (n=192) were born in Syria and the mean number of trauma types experienced was 6.9 (SD=3.9) (most frequently reported: having been in danger during flight [71%]; lack of food and water [68%]; witnessing serious accident, fire or explosion [62%]). The majority of caregivers were mothers (83.2%; n=129) and the average caregiver age was 38.4 (SD=8.0). There were no meaningful differences in baseline demographic characteristics between EASE and PYA groups.

Figure 2: CONSORT flowchart

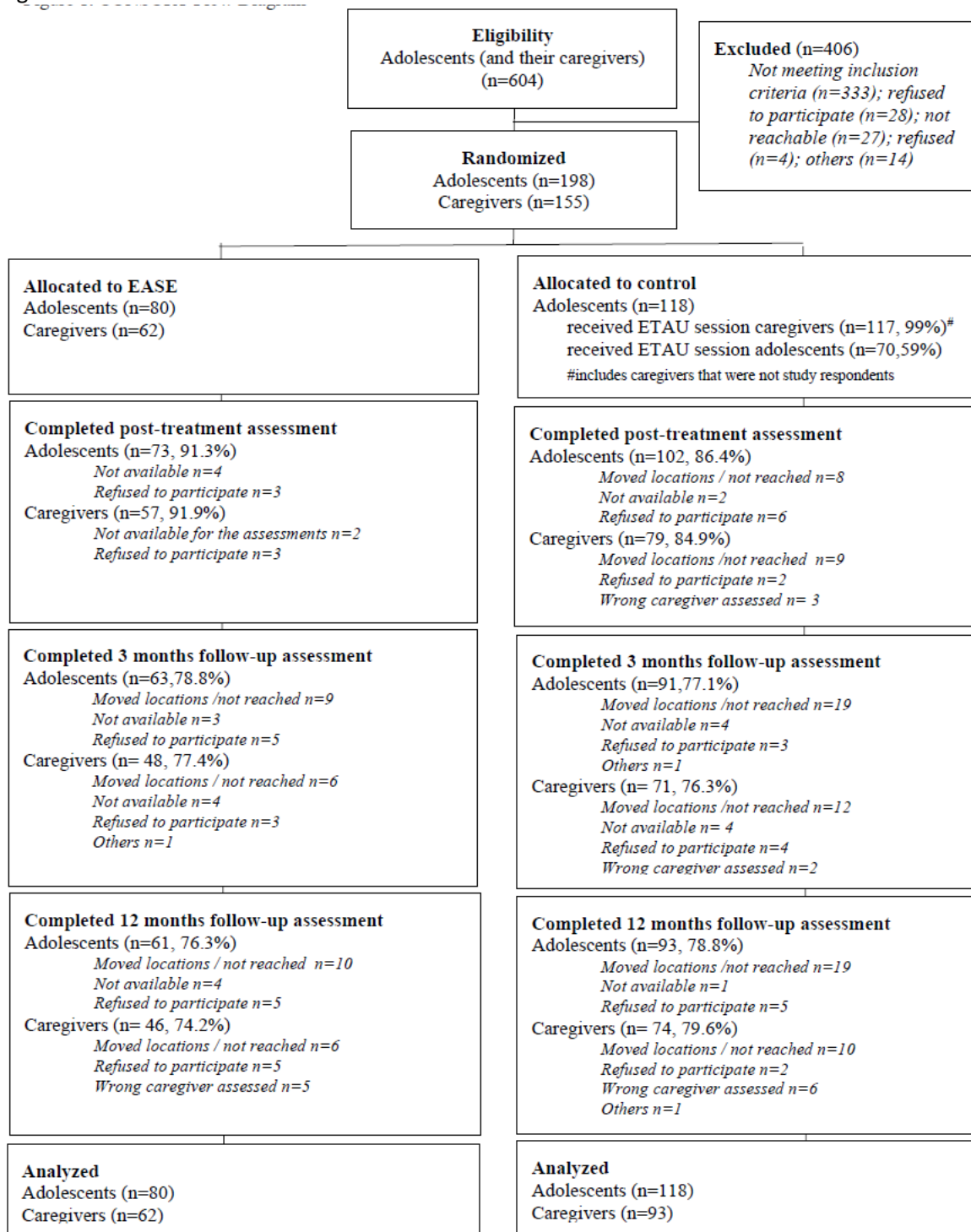


Table 1: Sample characteristics (children)

	Total (n=198)	EASE (n=80)	PYA (n=118)
	N (%) or Mean (SD) [Range]		
Female	97 (49.0)	37 (46.3)	60 (50.9)
Male	101 (51.0)	43 (53.8)	58 (49.1)
Age*	11.8 (1.3) [10-14]	11.7 (1.3) [10-14]	11.9 (1.3) [10-14]
Country of Birth*			
Lebanon	5 (2.5)	2 (2.5)	3 (2.5)
Syria	192 (97.0)	77 (96.3)	115 (97.5)
Missing	1 (0.5)	1 (1.3)	0 (0.0)
Birth order of child*			
1	56 (28.3)	24 (30.0)	32 (27.1)
2	32 (16.2)	15 (18.8)	17 (14.4)
3	35 (17.7)	12 (15.0)	23 (19.5)
4	26 (13.2)	9 (11.3)	17 (14.4)
5	20 (10.1)	8 (10.0)	12 (10.2)
6+	28 (14.1)	11 (13.8)	17 (14.4)
Missing	1 (0.5)	1 (1.3)	0 (0.0)
Child currently in school*			
Yes, formal education	101 (51.0)	47 (58.8)	54 (45.8)
Yes, informal education	13 (6.6)	6 (7.5)	7 (5.9)
No	83 (41.9)	26 (32.5)	57 (48.3)
Missing	1 (0.5)	1 (1.3)	0 (0.0)
Child ever been in school (among those not currently in school)*			
Yes	64 (77.1)	19 (73.1)	45 (79.0)
No	19 (22.9)	7 (26.9)	12 (21.0)
Child brings income to the family*			
Yes	81 (40.9)	37 (46.3)	44 (37.3)
No	116 (58.6)	42 (52.5)	74 (62.7)
Missing	1 (0.5)	1 (1.3)	0 (0.0)
Child helps with childcare*			
Yes	98 (49.5)	42 (52.5)	56 (47.5)
No	99 (50.0)	37 (46.3)	62 (52.5)
Missing	12 (0.5)	1 (1.3)	0 (0.0)
Participated in other WC/NGO activities in past month			
Yes	12 (6.1)	5 (6.3)	7 (5.9)
No	186 (93.9)	75 (93.7)	111 (94.1)
Mean number of trauma types experienced	6.9 (3.9) [0-17]	7.1 (4.0) [0-17]	6.8 (3.9) [0-15]

*Denotes caregiver report

2.3.2. Results main outcomes

Adolescents allocated to the treatment arm were divided over 11 EASE groups, and caregivers over 8 groups. Adolescents attended an average of 4.56 sessions, with 70.0% (n=56) attending to 5 sessions or more (a priori established as 'completers'). Further, 13.8% did not attend any of the EASE sessions. Caregivers attended on average 1.5 sessions, and 48% (n=30) attended at least 2 sessions. Further, 12% of all EASE sessions (adolescent and caregivers combined) were supervisor-observed for assessment of intervention fidelity. For adolescent and caregiver sessions combined, 96% of fidelity items were assessed to be satisfactory (62% done well, 34% done partially). For adolescent sessions alone the results were similar (95% overall, with 57% done well, and 38% done partially).

The primary and secondary outcomes for adolescents and caregivers are provided in Tables 2 and 3, respectively. For the primary outcome, PSC (adolescent report), there were significant reductions in mean score from baseline to both endline and 3-month follow-up within both groups; by 12

months, mean scores had rebounded close to the baseline level in both groups. A similar trend, though less pronounced, is seen on the PHQ. There was no statistically significant difference in mean change between groups at 3-months follow-up, the primary endpoint (-0.53, 95% CI: -3.4, 2.3; $p=.71$) or any other timepoint. Further, we see a response rate of 23.8 (95% CI: 13.1, 34.4) (EASE) and 21.5 (95% CI: 12.8, 30.1) (ETAU) on PHQ, and 35.7 (95% CI: 22.3, 49.0) and 37.5 (95% CI: 26.3, 48.7) (respectively) on PSC internalizing problems; these between-group differences were not statistically significant (risk ratio 1.11 [95% 0.44, 1.78], $p=.74$; and 0.95 [95% 0.50, 1.4], $p=.94$, respectively). There were also no significant differences in mean change between groups for any other outcome (adolescent or caregiver).

Table 2: Predicted means, mean changes, and effect sizes for adolescent primary and secondary outcomes

Outcome	Timepoint	Estimated mean (se)		Difference in mean change (95% CI)	p-value	Cohen's d effect size
		EASE (N=80)	PYA (N=118)			
Child psychological symptoms: Total	Baseline	27.4 (1.3)	26.9 (2.6)			
	Endline	22.0 (1.3)	22.5 (2.6)	-0.90 (-3.6, 1.8)	.52	0.11
	3-months	21.6 (1.4)	21.7 (2.6)	-0.53 (-3.4, 2.3)	.71	0.07
	12-months	26.0 (1.4)	25.6 (2.6)	-0.01 (-2.9, 2.9)	.99	0.001
Child psychological symptoms: Internalizing	Baseline	5.3 (0.3)	5.3 (0.5)			
	Endline	3.8 (0.3)	3.8 (0.5)	0.01 (-0.7, 0.7)	.97	0.005
	3-months	4.0 (0.3)	4.1 (0.5)	-0.10 (-0.8, 0.6)	.78	0.05
	12-months	4.4 (0.3)	4.7 (0.5)	-0.30 (-1.1, 0.4)	.42	0.16
Child psychological symptoms: Attention	Baseline	5.9 (0.3)	5.9 (0.5)			
	Endline	4.2 (0.3)	4.4 (0.5)	-0.3 (-1.1, 0.4)	.40	0.19
	3-months	4.6 (0.3)	4.5 (0.5)	0.07 (-0.7, 0.8)	.86	0.04
	12-months	5.1 (0.3)	4.9 (0.5)	0.2 (-0.6, 1.0)	.60	0.12
Child psychological symptoms: Externalizing	Baseline	3.6 (0.2)	3.7 (0.2)			
	Endline	3.1 (0.3)	2.9 (0.2)	0.3 (-0.4, 1.0)	.45	0.14
	3-months	3.3 (0.3)	3.3 (0.2)	0.05 (-0.7, 0.8)	.88	0.03
	12-months	3.6 (0.3)	3.4 (0.2)	0.3 (-0.5, 1.1)	.48	0.15
PHQ	Baseline	9.5 (0.8)	9.6 (1.4)			
	Endline	8.3 (0.8)	8.3 (1.4)	0.10 (-1.7, 1.9)	.92	0.02
	3-months	7.4 (0.9)	8.3 (1.4)	-0.8 (-2.8, 1.1)	.39	0.13
	12-months	9.7 (0.8)	10.7 (1.4)	-0.9 (-2.8, 1.0)	.35	0.14
WEBWBS	Baseline	44.7 (1.2)	44.3 (1.0)			
	Endline	45.5 (1.2)	44.0 (1.0)	1.1 (-2.3, 4.6)	.52	0.10
	3-months	44.6 (1.2)	43.8 (1.1)	0.4 (-3.2, 3.9)	.84	0.03
	12-months	42.7 (1.3)	41.3 (1.1)	1.1 (-2.4, 4.6)	.55	0.10
CRIES	Baseline	26.1 (2.2)	26.3 (4.0)			
	Endline	26.7 (2.2)	24.8 (4.0)	2.0 (-3.1, 7.2)	.44	0.12
	3-months	24.9 (2.3)	25.0 (4.1)	0.2 (-5.0, 5.3)	.95	0.01
	12-months	28.2 (2.4)	27.5 (4.1)	1.0 (-4.4, 6.3)	.73	0.06
Coping	Baseline	15.0 (0.6)	14.6 (0.5)			
	Endline	15.2 (0.6)	14.7 (0.5)	0.1 (-2.1, 2.2)	.96	0.01
	3-months	14.6 (0.7)	13.8 (0.6)	0.3 (-1.8, 2.5)	.75	0.06
	12-months	14.5 (0.7)	14.6 (0.6)	-0.6 (-2.7, 1.6)	.60	0.10

Note. Means, SEs, difference in mean change are based on coefficients and combination of coefficients from mixed effects model following multiple imputation. Cohen's d effect size was calculated by dividing the predicted difference in mean change from the mixed effects model by the pooled baseline standard deviation. Model included fixed effects of arm, time and arm X time interaction, and random effects of pt_code, family ID, and Ease group.

Table 3: Predicted means, mean changes, and effect sizes for caregiver outcomes

Outcome	Timepoint	Estimated mean (se)		Difference in mean change (95% CI)	p-value	Cohen's d effect size
		EASE (N=80)	PYA (N=118)			
Caregiver PSC: Total	Baseline	28.5 (1.4)	27.5 (2.6)			
	Endline	27.2 (1.4)	27.6 (2.6)	-1.4 (-4.3, 1.5)	.36	0.14
	3-months	25.4 (1.4)	26.2 (2.6)	-1.8 (-4.8, 1.1)	.22	0.01
	12-months	30.2 (1.5)	28.6 (2.6)	0.6 (-2.6, 3.8)	.71	0.06
Caregiver PSC: Internalizing	Baseline	5.1 (0.3)	5.0 (0.4)			
	Endline	4.8 (0.3)	5.0 (0.4)	-0.3 (-1.0, 0.4)	.41	0.13
	3-months	5.1 (0.3)	5.1 (0.4)	-0.1 (-0.9, 0.6)	.73	0.05
	12-months	5.7 (0.3)	5.4 (0.4)	0.2 (-0.6, 1.0)	.65	0.08
Caregiver PSC: Externalizing	Baseline	4.6 (0.4)	4.3 (0.8)			
	Endline	4.2 (0.4)	4.1 (0.8)	-0.2 (-1.0, 0.5)	.54	0.09
	3-months	4.1 (0.4)	4.1 (0.8)	-0.4 (-1.2, 0.4)	.33	0.14
	12-months	4.9 (0.4)	4.3 (0.8)	0.2 (-0.6, 1.1)	.60	0.08
K6	Baseline	22.6 (0.7)	23.0 (0.5)			
	Endline	21.9 (0.7)	22.3 (0.6)	-0.01 (-1.9, 1.9)	.99	<.001
	3-months	23.0 (0.7)	23.2 (0.6)	0.2 (-1.7, 2.1)	.83	0.04
	12-months	22.9 (0.7)	23.2 (0.6)	0.1 (-1.9, 2.2)	.89	0.03
Alabama: Parental Involvement	Baseline	34.2 (1.0)	34.3 (1.0)			
	Endline	32.9 (1.0)	34.2 (1.1)	-1.2 (-4.0, 1.7)	.42	0.17
	3-months	30.7 (1.0)	31.7 (1.0)	-1.0 (-3.9, 2.0)	.52	0.13
	12-months	32.3 (1.0)	32.1 (1.1)	0.2 (-2.6, 3.0)	.90	0.03
Alabama: Positive Parenting	Baseline	24.9 (0.6)	24.7 (0.5)			
	Endline	23.4 (0.6)	23.4 (0.5)	-0.2 (-2.0, 1.6)	.83	0.05
	3-months	22.0 (0.6)	21.5 (0.5)	0.2 (-1.7, 2.1)	.83	0.05
	12-months	23.4 (0.6)	23.7 (0.5)	-0.6 (-2.5, 1.3)	.54	0.14
Alabama: Inconsistent Discipline	Baseline	16.7 (0.5)	17.3 (0.4)			
	Endline	16.8 (0.5)	16.7 (0.4)	0.8 (-0.8, 2.4)	.34	0.19
	3-months	16.5 (0.6)	16.8 (0.5)	0.3 (-1.6, 2.1)	.79	0.06
	12-months	17.0 (0.6)	17.5 (0.5)	0.1 (-1.7, 1.8)	.93	0.02
Alabama: Corporal Punishment	Baseline	7.7 (0.3)	7.9 (0.3)			
	Endline	7.9 (0.4)	7.9 (0.3)	0.3 (-0.7, 1.3)	.57	0.09
	3-months	7.7 (0.4)	7.8 (0.3)	0.2 (-0.8, 1.2)	.70	0.06
	12-months	7.8 (0.4)	7.5 (0.3)	0.6 (-0.5, 1.6)	.29	0.18

Note. Means, SEs, difference in mean change are based on coefficients and combination of coefficients from mixed effects model following multiple imputation. Cohen's d effect size was calculated by dividing the predicted difference in mean change from the mixed effects model by the pooled baseline standard deviation.

2.3.3. Results sub-group and exploratory outcomes

Sub-group analyses on the PSC and PHQ are lifted out because of the aforementioned within-group changes on these outcomes. Table 4 presents outcomes among adolescents in the top 50% of baseline PSC scores and Table 5 presents outcomes among adolescents in the top 50% of PHQ scores. Among adolescents with the top 50% of PHQ scores at baseline, the ETAU group had a significantly greater reduction in PHQ scores from baseline to endline compared to the EASE group (difference in mean change= 2.7, 95% CI: 0.1, 5.3; $p=.04$; $d=0.59$). Similarly, among adolescents in the top 50% of PHQ baseline scores, PSC Internalizing scores had a significantly greater reduction among ETAU than EASE (difference in mean change 1.0, 95% CI: 0.08, 1.9; $p=.03$; $d=0.56$). And reversely, among adolescents with the bottom 50% of PHQ scores at baseline, the EASE group had a significantly greater reduction in PHQ scores compared to ETAU (difference in mean change -2.7, 95% CI: -5.0, -0.42; $p=.02$; $d=0.93$), and greater reduction in PSC Internalizing scores (difference in mean change -0.98, 95% CI: -2.0, .02; $p=.05$; $d=0.49$). During the entire trial period 17 severe adverse events were reported. The Data Safety Management Committee reviewed and approved the actions that were taken for all of these cases.

Table 4: Predicted means, mean changes, and effect sizes for adolescent outcomes among adolescents with top 50% PSC scores

Outcome	Timepoint	Estimated mean (se)		Difference in mean change (95% CI)	p-value	Cohen's d effect size
		EASE (N=43)	PYA (N=59)			
Child psychological symptoms: Total	Baseline	33.3 (1.4)	33.4 (1.2)	0.8 (-3.2, 4.8)	.70	0.13
	Endline	27.3 (1.5)	26.6 (1.3)			
Child psychological symptoms: Internalizing	Baseline	6.1 (0.3)	6.1 (0.3)	0.4 (-0.6, 1.3)	.42	0.21
	Endline	4.8 (0.3)	4.4 (0.3)			
Child psychological symptoms: Externalizing	Baseline	4.2 (0.4)	3.9 (0.3)	0.2 (-0.8, 1.3)	.67	0.10
	Endline	3.6 (0.4)	3.1 (0.3)			
PHQ	Baseline	13.0 (1.0)	13.5 (0.8)	2.3 (-0.3, 4.9)	.08	0.40
	Endline	12.0 (1.0)	10.2 (0.9)			

Note. Means, SEs, difference in mean change are based on coefficients and combination of coefficients from mixed effects model following multiple imputation. Cohen's d effect size was calculated by dividing the predicted difference in mean change from the mixed effects model by the pooled baseline standard deviation. Model included fixed effects of arm, time and arm X time interaction, and random effects of pt_code, family ID, and Ease group.

Table 5: Predicted means, mean changes, and effect sizes for adolescent outcomes among adolescents with top 50% PHQ scores

Outcome	Timepoint	Estimated mean (se)		Difference in mean change (95% CI)	p-value	Cohen's d effect size
		EASE (N=40)	PYA (N=61)			
Child psychological symptoms: Total	Baseline	32.0 (1.5)	31.7 (29.3)	1.5 (-2.5, 5.5)	.46	0.21
	Endline	27.6 (1.5)	25.9 (1.3)			
Child psychological symptoms: Internalizing	Baseline	5.6 (0.3)	6.0 (0.3)	1.0 (0.1, 1.9)	.03	0.56
	Endline	5.0 (0.3)	4.4 (0.3)			
Child psychological symptoms: Externalizing	Baseline	3.8 (0.4)	3.7 (0.3)	0.4 (-0.7, 1.5)	.48	0.19
	Endline	3.5 (0.4)	3.1 (0.3)			
PHQ	Baseline	14.7 (1.1)	15.0 (2.1)	2.7 (0.1, 5.3)	.04	0.59
	Endline	12.6 (1.1)	10.2 (2.1)			

Note. Means, SEs, difference in mean change are based on coefficients and combination of coefficients from mixed effects model following multiple imputation. Cohen's d effect size was calculated by dividing the predicted difference in mean change from the mixed effects model by the pooled baseline standard deviation. Model included fixed effects of arm, time and arm X time interaction, and random effects of pt_code, family ID, and Ease group.

2.4. Conclusion

2.4.1. Summary of findings

As a result of an unprecedented combination of adversity in Lebanon at the time of this research, we had to terminate the study prematurely, leaving us with an under-powered trial sample of 198 adolescents ([44%] as opposed to the 445 that were targeted). Note that the EU has been informed about stopping the RCT in Lebanon before the target sample size was reached, which was discussed during the project review meeting in September 2021 and has been approved (see the 3rd Periodic Technical Report). However, this makes any conclusions challenging and non-definitive. Still, the sample was large enough to allow for important exploratory analyses. These demonstrate that there were no between-group differences on any of the outcome measures between the experimental and control groups. We do observe a significant improvement on the primary outcome, psychological distress and internalizing problems, though equally in the EASE and ETAU

groups – sustained at 3 months post intervention and largely lost at 12 months. This improvement appears clinically relevant with a response rate for internalizing problems between 36 and 38% (EASE vs ETAU) and for depression between 24 and 22%, respectively. Seeing change only on the primary outcome and not on any of the other outcomes is compatible with what was found in the twin trial evaluating EASE in Jordan (Bryant et al, 2022), with the difference that in our study the control condition sees the same improvement. In fact, when looking at sub-group analyses we see that the control condition significantly outperforms EASE on psychological distress and internalizing problems for the subgroup with higher distress; and reversely EASE significantly outperforms the control groups on the same outcomes for the subgroup with lower distress.

In brief, it appears that EASE does have the potential to result in reducing psychological distress, as intended (Dawson et al., 2019) (though not resulting in any other improvements), however equally does the control group, which appears to do so even better for those experiencing higher distress at baseline. What is going on here? Explaining this as a regression to the mean is unlikely given that none of the other indicators show a significant change over time. Instead, we hypothesize that; (i) the control condition may have been too active as a comparator, and/or (ii) EASE may have been implemented in a way that did not allow it to demonstrate full potential.

First, the equal change on the primary outcome, combined with a significantly better result for the subgroup with higher distress, reveals the possibility that participation in the single session family psycho-education home visits has resulted in more improvement than expected. Even if the sessions were scripted and time-limited, it still entailed individualized attention in a private setting, compared to the group sessions of EASE. Also, because it concerned home-visits, scheduling was easier allowing for high levels of attendance among control group participants (compared to relatively low attendance amongst EASE groups). The first hypothesis on the potency of a single home-visit session is supported by evidence from a meta-analyses including 50 trials showing that single session interventions outperform control groups by 58%, especially for anxiety and conduct problems (Schleider & Weisz, 2017). Also for adolescents with depression and anxiety a single growth mindset session demonstrated to be effective in reducing internalizing distress (Schleider & Weisz, 2018). In humanitarian and LMIC contexts where resources are so scarce, and barriers to accessing mental health care so pronounced, and drop-outs common, the potential for scalable single session interventions should be more explored (Paul & van Ommeren, 2013).

Second, the hypothesis that EASE did not yield its full potential is based on; (i) the relatively low attendance among the adolescent sessions (an average of 4.6 session), and; (ii) not seeing any significant before to after change in the utilization of strategies that map onto the content and hypothesized mechanisms of action of EASE. For an intervention to be effective one expects a change on the exact strategies that the intervention aims to instil in participants. For example, in a trial in Nepal evaluating the adult-version of EASE, group PM+, a significant increase in use of intervention specific strategies explain up to 33% of the treatment effects (Jordans et al., 2021). It raises the question whether young adolescents, especially when experiencing severe adversity can genuinely adopt strategies in a group format and apply them to their own life. This may also explain the mixed results from trials evaluating psychological interventions for children with depression and anxiety (Barbui et al., 2020).

While interventions for PTSD and conduct problems amongst adolescents in adversity have shown promising results (Barbui et al., 2020; Purgato et al., 2018), there is still a serious need for

interventions addressing depression and anxiety, as these conditions make up most of the burden of disease amongst adolescents (Erskine et al., 2015). Based on results from the trial in Jordan EASE shows potential in reducing emotional distress (Bryant et al, under review). As the improvements on emotional distress amongst the EASE participants in our underpowered study is similar to that of the control group, more trials on the effectiveness of EASE are needed. Furthermore, research should investigate why EASE seems to only result in changes in internalizing problems, and no other intended outcomes. Finally, while unintended, this study raises the question about the potential of single session interventions as a cost-effective alternative. In addition, our results may speak to the potency of working with whole families through home visits, which is supported by recent review concluding that family-based mental health interventions, including home visits, are potentially effective for refugees (Bunn et al., 2022).

2.4.2. Limitations

A few limitations need to be reported. First and foremost, the study did not reach its intended sample size. As noted, premature termination of the trial was the result of a unprecedented combination of adverse events, including COVID-19 restrictions, dramatic economic downfall, political instability and violent demonstrations, which made continuation of the study impossible. This may also have influenced the results amongst the sample that is included in this paper. At the same time, it is important to note that interventions such as EASE have been developed by the WHO especially for situation of adversity and humanitarian crises. Second, the study raises questions about what the optimal control condition is in settings where essentially no treatment as usual exists, and not offering anything is deemed unethical. For a fairer comparison the experimental group could be offered the same as the ETAU condition, a strategy that was applied in the above-mentioned evaluation of Group PM+ in Nepal (Jordans et al., 2021). The downside is that one does not test EASE in isolation, but only in combination with the brief psychoeducation session for example. This dilemma continues to deserve attention, given that meta-analysis have shown that the selection of control condition affects the results of psychotherapy trials for depression (Gold et al., 2017; Mohr et al., 2009).

2.4.3. Conclusion

No definitive conclusions can be drawn given the underpowered final sample. Treating the analysis as more exploratory we infer; (i) no support for effectiveness of EASE; (ii) both EASE and single session psycho-education home visits result in meaningful improvements in reducing psychological distress; (iii) which can be explained by EASE not demonstrating its full potential due to implementation challenges or by the potential for single session family-based interventions.

3. Process evaluation (qualitative research)

3.1. Introduction

Process evaluations are recommended in the Medical Research Council's guidance for conducting evaluations of complex intervention, in order to promote understanding of the dynamic interactions between human, technical, and contextual elements of a trial that lead to, and impact upon, the outcomes. These evaluations may be particularly important in humanitarian settings, which are characterized by complexity, socio-political instability, limited resources, variety of actors implementing diverse services, and a multitude of dynamic stressors impacting on participants. Understanding the experience, challenges, and facilitators of implementation is essential both to understand the process by which trial outcomes were achieved, and to inform future implementation and roll-out, outside the trial context. While their importance is generally recognised, process evaluations are not uniformly conducted in RCTs of MHPSS interventions in humanitarian settings, and there is considerable heterogeneity amongst researchers as to the perceived aim and optimal processes of such evaluations.

Since the EASE RCT in Lebanon was ended before reaching the target sample size, we decided to perform an in-depth analysis of barriers for recruitment including the demand for psychosocial interventions such as EASE to address psychological distress in children and adolescents in Lebanon (see the 3rd Periodic Technical Report). This process evaluation was therefore specifically aimed to address these barriers – mainly presented by Theme 2 below in the results section.

This study presents the qualitative process evaluation from the EASE RCT in Lebanon to understand participant and stakeholder experiences and perceived impact of the program, identify barriers and facilitators for implementation, and explore considerations for scaling up including benefits and challenges of integrating and scaling such interventions into service provision. The aims were to ensure a depth of understanding of participant and implementation experiences in a complex humanitarian setting, place quantitative findings in context, and inform future implementation and scale-up efforts. It must be noted that the qualitative analysis was completed prior to learning the findings of the quantitative analysis, however we discuss the results in line with the quantitative findings. This paper outlines the findings of this analysis and presents recommendations for future research and scaling efforts.

3.2. Method

3.2.1. Design

This qualitative study was nested within a larger randomized controlled trial (Brown et al, 2020), whereby a sample of participants were interviewed, alongside implementation staff, and key stakeholders and actors in Mental Health and Psychosocial Support in Lebanon such as International and National NGOs, and staff of the National Mental Health Program. A total of 19 interviews (6 Focus Group Discussions [FGDs] and 13 Key Informant Interviews [KIIs]) were

conducted between October 2019 - December 2020 in North and Akkar governorates of Lebanon. Ethical approval are as mentioned above.

3.2.2. Setting

The study was conducted in Akkar governorate, a largely agricultural area bordering Syria and hosting a high population of Syrian refugees along with vulnerable Lebanese populations (Daher, 2022) . It has been estimated that 59% of households in Akkar lack the ability to meet basic costs of education, healthcare, and nutritious food (Devonald. et al, 2022). The EASE sessions and assessments were conducted in community centers in Akkar, with transportation provided to bring adolescents and caregivers from their homes to the sessions.

3.2.3. Participants

The RCT involved young adolescents of Lebanese, Syrian, or Palestinian background aged 10-14 years, who were identified as experiencing emotional distress via screening with the Paediatric Symptom Checklist (Brown et al., 2019). Additional inclusion criteria included being unmarried and having a caregiver to consent for participation. A sample of participants from the larger RCT were purposively selected for this qualitative study through convenience sampling. This ensured a suitable sample in terms. of sex, age, nationality, and other demographics. All the children and caregivers participating in the interviews and the FGDs were of Syrian nationality, living in rural areas of Minieh in North Lebanon, or Akkar governorates.

3.2.4. Procedure

Consent to take part in the qualitative interviews was collected for EASE participants at their enrolment in the study, however verbal assent and consent to the interview and audio-recordings was taken prior to the interviews for children and caregivers, respectively. For other participants, written informed consent was collected using a detailed participant information sheet read aloud by the interviewer before the interview commenced. The interviews were conducted in Arabic for children and caregivers, facilitators, and outreach workers, and were offered in English or Arabic for stakeholders, upon the preference of each interviewer. FGDs and KIIs were conducted by one or two interviewers, supported by a note taker, and followed a structured interview guide. The semi-structured interview guides were developed collaboratively by research partners, informed by previous research on scale up of MHPSS interventions , and were translated into Arabic. Training was given to local research assistants who conducted the interviews, which included qualitative research basics, child safeguarding and adverse events, interviewing using the guides, using the recorders, and taking field notes. With participant consent, interviews were audio-recorded, however one participant declined to be audio recorded and details/information were taken by a note taker. Interviews were on average 60–90 min in duration.

3.2.5. Analysis

The 6 English interviews were transcribed verbatim, while the 13 Arabic interviews were transcribed and translated from Arabic audio directly to English. This work was conducted by trained bilingual research team members (KT, MA, RA, JE, BM). After each transcription was

complete, another team member conducted a quality check for accuracy and completeness. Prior to data analysis, a reflection workshop was conducted with the transcription team to learn about recurrent patterns and emerging themes they noted in the data.

Data analysis was conducted via inductive and deductive thematic analysis (Braun and Clarke). Two researchers (FB and RA) with different levels of experience in research analysis read the finalised transcripts to familiarise themselves with the data, and separately open coded to identify and label any segments of data perceived to be relevant to the research questions. In order to develop the codebook, two workshops were conducted. In the first workshop, FB and RA compared their individual open coding and compiled one draft codebook where major categories of data were assigned labels (codes) and working definitions. In the second workshop, the Lebanon study team reviewed and revised the proposed codebook structure and content. A series of revisions were then conducted by a core analysis team (RA, FB, KS, and DF) to iteratively organize the codes into a coherent final version of the codebook. Lead author (RA) applied this codebook to 4 transcripts, using NVIVO (12) software (released in March 2012). This coding sample was checked by second author (KS) and discrepancies discussed together, with minor changes made to the codebook, to better fit the data. At the end of this stage both coders reached consensus on the application of the codebook. RA coded the remaining transcripts, and codes were populated with data from the transcripts. Once all transcripts were coded, RA, KS, FB, and DF met to review coding and structure data into sub-themes and themes. Six main themes were identified from the data through merging the codes. These were reviewed for consistency, as well as the applicability and comprehensiveness of all themes for the full data set. Names and definitions were agreed for each theme, and illustrative quotes identified. Themes were reviewed and validated with the full study team, including those closely involved with implementation. During analysis of final transcripts, no major new ideas from participant transcripts emerged, suggesting that data saturation was reached.

3.3. Results

We identified four major themes and 13 subthemes related to the implementation and potential for scale up of EASE in this setting. They are outlined below, with illustrative quotes.

3.3.1. Theme 1: Impact of the program

The majority of interviewees expressed their positive experiences of participating in EASE, either as participants, providers, or trainers. They appreciated the opportunity to attend an activity outside the home, and share feelings and thoughts with others, one trainer described that “they were happy to have a space where they can go out and talk”. EASE participants, facilitators, and trainers also reported significant benefits obtained for adolescents, caregivers, and relationships inside and outside the family.

Impact on adolescents. Adolescents, caregivers, and facilitators highlighted positive impacts on children at different levels. Firstly, at the individual level, adolescent’s behaviour improved, particularly regulating their reactions when feeling angry. For example, one child noted that the strategy of slow breathing helped him to remain calm and control his anger. Participants also noted improvement in adolescent’s ability to express themselves; they can talk about their feelings, their problems and how to deal with them, their daily life, and their relationships with their communities, and they know their strengths and talk about it. One facilitator noted: “There were

two girls, they didn't talk at all, no any word, no reaction, no eyes expressions, and after the third session, they talked and express considerably" (facilitator, female) . At the family level, caregivers noted improved caregiver-child relationships, although this did not always extend to extended family members. And at the community level, participants noted improvements in relationships with others in the community, including playing and talking with others, and reduced bullying or aggression with peers.

Impact on caregivers. Facilitators noted a positive impact on parenting behaviours. Several caregivers and facilitators noted that physical punishment remains an ingrained disciplinary technique for parents. However, EASE taught alternative strategies which many caregivers very helpful. Additionally, caregivers noted that they learned the rationale for giving praise and how to deliver praise effectively to children. This was found to be very helpful, despite not being a well-known concept previously. One caregiver described: "I stopped the violence, I approached them with nice words, with coping words" (Caregiver, Female).

Facilitators and caregivers also noted a positive impact on parents' own wellbeing and behaviour. For example, some parents used EASE strategies to improve their relationships and communication with their partners. They also applied the strategies of self-care to themselves to improve their overall well-being, for example: "They knew that they should have space (take a break) during the day to look after themselves, maybe drink a coffee with a neighbour, walk a little..." (facilitator, female).

3.3.2. Theme 2: Barriers for engagement, attendance, and impact

Basic needs are a priority for families. Outreach workers, MH stakeholders, facilitators, and participants stated the predominant barrier for engagement of children and caregivers was unmet financial and basic needs, where individual's efforts just to achieve these have made them really "exhausted not only tired" (who?). With the deterioration of the economic situation, families prioritise direct income generating activities rather than a programme that does not provide financial support. Competing scheduling priorities were a major issue for attendance, including families moving for work opportunities, children attending school or work, children or caregivers needing to care for younger children or other family members, or UN agency appointments including for financial support. Since EASE is a group intervention, scheduling around individual participants' competing priorities was particularly difficult. "it's the biggest difficulty we face, that the child doesn't come when it's agriculture season...when it's potato season then no children come" (Facilitator, female). Outreach workers and facilitators stressed that recruitment of new participants became even more challenging with wide scale protests commencing October 2019 causing closures and roads blocks, and subsequent further deterioration of the economic situation. Unfortunately, interviewees noted that the most vulnerable adolescents were even less likely to access the programme, for example: "...Tripoli and Akkar, where EASE was implemented, have the highest rate of children involved in the worst forms of child labor, long hours in agriculture or on the streets, with those long working hours, they will not have time to attend EASE sessions." (PSS Actor).

Importance of caregiver engagement. Despite the program being offered to adolescents, the consent of both caregivers was considered by interviewees as essential for ensuring attendance. Some caregivers prevented attendance for different reasons including lack of financial support,

needing their child to work inside or outside the home, or not wishing their daughter to attend a centre at the same time as males. Outreach workers noted that some Lebanese caregivers did not wish for their child to participate due to feeling that the programme was for Syrian adolescents. Again, financial considerations also played a large role in caregivers preventing their adolescent from taking part, for example one facilitator describes “the biggest difficulty is that there’s no financial allowance, the most difficult thing is that the parent tells the child go to work instead of going to play and have fun” (Facilitator, female)

Misconceptions and stigma around mental health and the programme. Most MHPSS stakeholders stressed the fact that the stigma around mental health is prevalent in the community, and that it affects the engagement. Different interviewees mentioned that it would be very important to have a combination of outreach strategies to present the project in a way that it is not perceived as a mental health programme, which would hinder participation. This highlights the importance of carefully framing EASE in the context of healthcare or other interventions, and ensuring it is embedded in routine service provision. “Stigma is an issue nationally, it’s an issue for all interventions related to mental health and PSS. But I think when we don’t say mental health it’s even easier, for when we say PPS and when we frame it in the sense that the intervention not in mental health” (UN agency actor, Female). This was particularly linked to knowledge of others knowing that their child is taking part in an intervention targeting adolescents with heightened distress. For example, “From the parents’ side linked to the stigma of like other people in the community knowing that their children are taking part in such an intervention.” (MHPSS Actor, Female). Additionally, there were often misunderstandings about the programme with facilitators, trainers, and outreach workers noting that at different stages some participants were confused about the content of the program, and sometimes children believed they were coming to “play”. Additionally, stakeholders emphasize that research assessments can be time intensive, and the importance for evidence-generation is not recognised amongst participants, which can be reason for not engaging in the intervention.

Intervention access. Finding suitable locations for intervention delivery that were close to family homes for easy access was challenging. Families in this study lived in underserved agricultural areas, resulting in long commutes to the intervention venue. Buses were provided to take children to sessions, however, all children attending one group had to be picked up at various locations which led to lengthy trips for some children. Some children did not mind the long drives, however facilitators noted that it could impact the sessions starting on time and the performance of participants, while parents noted that it required children and parents to be out of the home for considerable periods. “I received multiple complaints, from the people participating with us, that the distance is too far away for them, also the roads of *Samounieh* (agriculture area) are hard, especially in winter, and the bus needs a lot of time to make his way there” (outreach worker, male). Furthermore, in these areas, finding suitable and comfortable venues for intervention delivery was difficult, and venues were often restricted by space and not all activities could be implemented as planned. “It’s a school style, floors, classes, and seats, you enter and you don’t feel that the child is comfortable to enter such a place” (Facilitator, female)

Intervention content. Although overall the feedback on the content and structure of the intervention was very positive, some aspects were noted to make it challenging for some adolescents and caregivers. Some interviewees felt that the illustrations and story book used in EASE were more suited to younger adolescents than older adolescents, and one illustration of a

character perceived to be male sweeping the floor was perceived to be unrealistic of the setting. Facilitators and trainers stressed that some components of the intervention were complicated for children to grasp, such as explaining the Vicious Cycle of unhelpful behaviours and emotions, and the Changing My Actions strategy for changing behaviours in a stepped approach. It was felt that more sessions would be needed in order to cover these concepts adequately with adolescents and more training for facilitators to learn how to apply them to the problems faced by adolescents in this setting. Facilitators additionally reported that the caregiver sessions were very dense with information, which was challenging to deliver and at times caused boredom in caregivers.

3.3.3. Theme 3: Working with non-specialist facilitators

Positive experience of facilitators delivering EASE. Stakeholders stressed that non-specialist facilitators are well placed to deliver EASE, as long as they are well supported by a multidisciplinary team. Facilitators said they had a positive experience with EASE, they said they benefited from EASE on a personal level, and applied some of the strategies in their daily lives like “Slow Breathing”. “In EASE, it’s the first time I work in such a program. Like detailed to this extent and very specific, then this is for sure this is so much positive for my professional experience” (facilitator, female)

Challenges for facilitators. Facilitators faced many challenges including being unable to meet families’ needs as participants saw them as psychologists, the irregular work hours because of the wide intervals between the waves, perceived low pay, and potential for burn out. MHPSS stakeholders announce that non-financial incentives for non-specialists, including professional development opportunities, are as important as financial ones, and stressed the importance of self-care.

Training and supervision needs. Facilitators, trainers, and MHPSS stakeholders stressed that regular group supervision sessions were important and allowed facilitators to share their experiences and vent with a specialist supervisor. In parallel, individual coaching or individual follow-up is needed. EASE facilitators particularly liked the structure of the training, and perspectives from multiple trainers, stating “The training wasn’t like the other ones”. There was a perceived need to provide additional training on some topics, like the type of distress the adolescents pass through, communication skills, and the complaint mechanism. Facilitators and trainers requested a more phased approach to training, rather than two weeks of daily workshops.

3.3.4. Theme 4: Considerations for scaling Up EASE

Need for EASE to bridge the care gap. Interviewees, including facilitators, outreach workers, trainers, and MHPSS stakeholders, stressed there is a significant need for focused psychosocial support services, such as EASE, for children and adolescents in Lebanon. The recent successive crises (economic crisis, COVID-19 pandemic, and Beirut blast) have impacted basic needs, security, and mental health and wellbeing of the population. This has exacerbated the need for mental health and psychosocial support programmes. Given the rapidly changing context in Lebanon, the need is not only to implement such a program, but also to have “flexibility” with this program as mentioned by one of the facilitators, to ensure the programme meets the evolving needs of adolescents and caregivers. For example, if there are higher psychological needs than can be addressed in EASE, additional supports will be needed as referrals to another needed services.

COVID “Now regarding what is happening with Lebanon, it is being crises, political and everything I mean, I feel EASE, it is his time now” (outreach worker, female).

Target group criteria. When reflecting on who EASE should be offered to, there was a consensus that EASE should be delivered to youth of all nationalities and not focused only on refugee or migrant communities, given the stressors that all young people in Lebanon are facing. Furthermore, participants emphasized the need to ensure inclusion of the most vulnerable adolescents, including working adolescents, those living in Palestinian camps, and those with disabilities. Participants noted that youth are most impacted by the country's decline; they lose hope, and they need to feel valued and have a role in life; for this reason, they emphasized the need to increase the age range of EASE, given the mental health needs of older adolescents and young adults, though this may require a different approach than EASE.

Coordination to implement EASE. The majority of interviewed stakeholders stressed that EASE “cannot be as a stand-alone”. Integrating EASE with other general healthcare services” (MHPSS Stakeholder, female). is a way to avoid stigma surrounding mental illness. EASE has to be complementary to other provided services such as educational, recreational, or health packages. Different interviewees stated that it’s important to imbed EASE within “structures that are sustainably available”, (PSS Stakeholder, Female), for example, the Lebanese University, schools, primary healthcare or community mental health centres, grass root organisations, and the referral pathway at the national level. It should be in coordination with the overall mental health system in the country, Child Protection actors, Ministries of Public Health and Social Affairs, MHPSS Taskforces.

Financial barriers for scaling. Many different stakeholders and trainers stated that scaling up always results in financial barriers. Government funding (internal) it is a huge challenge in the context of the Lebanese economic crisis and the political situation, and globally mental health funding is limited. However, some stakeholders were optimistic the negative situation in Lebanon might lead to more interest and funding opportunities for mental health services including EASE.

3.4. Discussion

This study looked at the feasibility of the EASE program, as well as its acceptability. This study aimed to evaluate how well the newly developed EASE program is received by Syrian refugees in terms of its usability and efficiency, and analyses the factors for scaling up and incorporating EASE into the service offering. We identified four themes, relating to barriers and facilitators for implementing and scaling up a focused psychological intervention in a protracted refugee crisis. The main research question in the study is: What does it take to implement a non-specialist delivered psychological intervention for young adolescents in a protracted refugee setting?

In terms of the impact of the program, there were positive impacts on children at different levels, with improvements seen in behaviour, ability to express themselves, and caregiver-child relationships. It was not always the case that this translated to better relationships with extended family members. The same finding reveals a positive impact on parents' well-being and behaviour. Improvement in relationships and communication with their partners as a result of using EASE

strategies. Physical punishment remains an ingrained disciplinary technique for parents, but it has a positive impact on parenting behaviours.

The findings show that some children found the "The Vicious Cycle" concept to be difficult to understand, but they liked the storybook elements of the program more.

The storybook and illustrations were more appropriate for younger children, and the best problem-solving technique for children was "Understanding Big and Difficult Feelings for Children". While the "Changing my Action" strategy needs some improvements. Others thought it would be a great idea to have an introductory session.

In terms of barriers to engagements, the data also reflect that the economic and security situations in Lebanon impeded the participation of many people. Participants have other responsibilities and commitments that conflict with the timing of EASE sessions. Misunderstanding and stigma associated with the program and mental health. Based on this result, our suggestion is to make EASE a "complementary program" and not a "stand-alone" to avoid the stigma surrounding mental health.

In terms of outreach workers and facilitators' challenges, our results showed that the location of sessions wasn't appropriate for such sessions, it would be better if the centres are closer to participants, safer for children, and with other compositions of space to better implement activities. It was a unique experience for the facilitators they face challenges in terms of the wide interval between waves, we could make the timing of waves closely so their commitment and motivation might increase. Facilitators were at risk to burn out so more supervision sessions are in need even if the program is at the end of its implementation, parallel, individual follow-up is needed. Having 10 days of training was tiring then we could split the days into 2 packages.

In term of scaling up of EASE, this study showed that with the successive crises in Lebanon, there will be a high need for mental health services for different categories of people and especially the vulnerable adolescents with higher ages than 12 years old including persons with specific needs. In addition, our results also showed that we had challenges with the commitment and engagement of participants, these results suggest to imbed EASE within "structures that are sustainably available" for example schools and grace root organizations. Our study found that an "expert body" should be responsible for quality assurance during implementation and scale-up. A system for handling complaints is needed, with clear guidelines and a tracking system to ensure that complaints are resolved quickly. Overall, there was a lot of agreement that something like this intervention is needed, but there are some challenges in terms of funding that need to be overcome. These results suggest that if this intervention is done in a coordinated way with other government and non-governmental sectors, it may be more sustainable.

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