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Delivering therapy over telephone in a humanitarian setting: a pilot randomized controlled trial of common elements treatment approach (CETA) with Syrian refugee children in Lebanon

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Abstract

Background In recent years, the number of forcibly displaced persons has risen worldwide, with approximately 40% being children and adolescents. Most of them are hosted in low- and middle-income countries (LMICs). Many individuals meet the criteria for mental health issues, which can also be exacerbated by a number of risk factors, including low socioeconomic status, displacement, and stressors linked to conflicts in their country or region of origin. However, the vast majority never receive treatment for their psychological problems due to multiple reasons, including a shortage of mental health professionals in LMICs, transportation challenges in accessing clinics, and clinic hours conflicting with family commitments. In the current study we investigated whether individual psychotherapy delivered by trained lay counsellors over telephone to Syrian refugee children living in Lebanon is effective and overcomes barriers to treatment access.

Methods After adaptation of Common Elements Treatment Approach (CETA) to remote delivery over telephone (t-CETA), preliminary effectiveness of the treatment modality was assessed with a pilot single blind randomised controlled trial including a total sample of 20 refugee children with diagnosed mental health problems. Data was analysed applying a Bayesian approach.

Results There was a significant session-by-session decrease in self-reported mental health symptoms over the course of treatment. Independent assessments showed that t-CETA resulted in a greater reduction of symptoms than standard in-person treatment as usual. There was no difference between groups for impairment. Importantly, the majority of children allocated to t-CETA completed treatment whilst no children in the treatment as usual condition were able to do so.

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Conclusion The study provides preliminary evidence that telephone-delivered psychotherapy in a humanitarian setting, delivered by lay counsellors under supervision, works and significantly increases access to treatment compared to traditional in-person treatment. However, findings remain to be replicated in larger trials.

Trial Registration ClinicalTrials.gov ID: NCT03887312; registered 22nd March 2019.

Keywords Telehealth, Mental health, Syrian refugee children, CETA, Phone, Psychotherapy

Background

In recent years, the number of forcibly displaced persons affected by war or other emergencies has increased to more than 108 million worldwide [1]. About 40% of them are children, and 76% are hosted in low and middle income countries (LMICs) [2], which often don't have the resources to meet the basic needs of displaced people, including education and mental health services for children. According to empirical studies, the prevalence of mental health problems in forcibly displaced populations is significantly elevated. It is estimated that between 15 and 50% of refugee children suffer from mental health problems [3]. Refugee children are at a heightened risk of developing mental disorders, often attributable to the protracted conflicts and adverse conditions in their countries of origin [3], the traumatic stressors endured during their flight [4], and the challenging living conditions experienced within refugee settlements [5]. However, most forcibly displaced persons in LMICs never receive treatment for their mental health problems [6]. There are several reasons for this treatment gap. Most importantly, mental health services tend to be very limited in LMICs which often have few mental health professionals. Furthermore, treatment is often only accessible through clinics that are difficult to reach due to limited and costly transport options, on top of frequent conflicts with work schedules of displaced families given that most clinics are only open during business hours [7]. Innovative solutions are required to overcome these common barriers to mental health treatment of forcibly displaced children in LMICs and humanitarian settings. In the current paper, we report, for the first time, the adaptation and evaluation of an established transdiagnostic mental health treatment programme with promising evidence of effectiveness, *Common Elements Treatment Approach* (CETA) [8], for the remote delivery over telephone to Syrian refugee children living in informal tented settlements in rural Lebanon with the help of trained lay counsellors.

Mental health needs of forcibly displaced children and treatment gap

Most forcibly displaced children do not only have a history of exposure to potentially traumatic events, such as war and other emergencies, but continue to experience severe disruption of their daily routines during and post migration [9]. This usually includes separation

from family and friends, the loss of their homes and most belongings, disruption of education, as well as living in unsafe, temporary and crowded accommodation such as refugee camps, with limited access to basic services, and often further victimisation and exploitation [10]. Given the substantial exposure to these risks, it is not surprising that many forcibly displaced children develop mental health problems. According to several meta-analyses on mental health problems in refugee children, prevalence rates range from 19 to 54% for PTSD, from 14 to 43% for depression, and from 13 to 42% for anxiety [3, 11–13]. However, despite the evidence of significant mental health problems among forcibly displaced children, most individuals in need of help never receive treatment. According to the few studies that investigated the treatment gap among forcibly displaced persons in humanitarian settings, estimates for the treatment gap among adults range from 89 to 96% [6, 14]. In other words, only 1 in 10 forcibly displaced persons with mental health problems receive treatment. Most likely, the treatment gap is even higher for displaced children and adolescents residing in LMICs [15].

Common barriers to mental health treatment

Several reasons for the large treatment gap among forcibly displaced persons, and more generally among LMIC populations, have been identified [16, 17]. Three barriers to accessing mental health services are of particular relevance for the current study (besides the belief that symptoms will get better and therapy won't help [7, 18]): (1) the low number of mental health professionals in LMICs, (2) logistical difficulties in accessing clinics, and (3) conflicts with work and school schedules. Generally, most LMICs lack sufficient numbers of mental health professionals, such as psychiatrists and clinical psychologists, to cover the mental health needs of the population. For example, the median number of psychiatrists in LMICs is on average 200 times lower than in high income countries [19]. As a result, many LMICs are simply unable to provide the required services. In addition, the limited mental health services in LMICs are often provided centrally through primary health care clinics which are difficult to access by displaced families that live further away [20]. This is compounded by often limited public transport options in LMICs which can result in significant costs for displaced persons that need to travel to access

mental health services in clinics. Finally, most of the limited mental health services provided through clinics tend to be available only during standard business hours. However, displaced children (and their caregivers) are often unable to visit clinics during business hours due to their work commitments and school schedules. Many of them are unable to afford forfeiting income that they desperately depend on to cover the basic needs of the family [21]. Consequently, work opportunities tend to be prioritised over mental health treatment of their children [7]. These are established and persisting issues among forcibly displaced children living in LMICs and humanitarian settings. The treatment gap among displaced children can only be reduced by addressing these common barriers, which is the aim of the current study.

The current study

The war in Syria, which has been on-going since 2011, has generated millions of internally and externally displaced persons and contributed significantly to the recent global increase in refugee numbers [2]. Most Syrian refugees fled to neighbouring countries, including Lebanon which has hosted more than 1 million Syrian refugees during the height of the Syrian conflict [22] (and currently still hosts close to 800,000 Syrian refugees). About 50% of them are children under the age of 18. On top of exposure to a brutal war, many of these displaced children live under very challenging conditions, often without access to school and other basic services. In our own recent study on mental health among 1,600 Syrian refugee children living in informal tented settlements in Lebanon, we found that every second child met criteria for at least one disorder [23]. Importantly, Lebanon has very limited mental health care provision, most of which is private and often provided centrally through clinics [24] which are difficult to access for many refugees given the costs and lack of formal public transport. However, the large majority of Syrian refugee families in Lebanon own mobile phones [25]. We aimed to leverage the common access to mobile phones among Syrian refugees by delivering psychological treatment for children's mental health problems remotely over phone. In order to do so, we carefully adapted *Common Elements Treatment Approach* (CETA), an evidence-based and established transdiagnostic treatment programme [8] for the delivery over phone to Syrian refugee children in Lebanon. CETA is based on the most effective components of cognitive behavioural therapy (CBT) and includes a range of scripted sessions that can be arranged according to the specific needs of the individual child. Given the limited number of mental health professionals, we recruited and trained lay counsellors from the local population to deliver CETA over the telephone. Once the CETA manual was adapted and tested for delivery by telephone, we

conducted a pilot randomized controlled trial with Syrian refugee children that met clinical diagnoses for significant mental health problems in order to evaluate the effectiveness of telephone-delivered CETA (i.e., t-CETA) under real world conditions. The control group received authentic and unaltered treatment as usual delivered by an established international humanitarian organisation.

Our main research question was to test whether t-CETA is effective in reducing common mental health symptoms and functional impairment compared to treatment as usual delivered in-person, taking a Bayesian approach to analysis which is more suitable for smaller samples and takes pre-existing differences between groups into account. Our second research question was to investigate whether the drop-out rate and the percentage of individuals who successfully completed the t-CETA programme differed from those receiving treatment as usual, in order to estimate whether t-CETA is successful in overcoming common barriers to accessing mental health treatment. We expected that t-CETA would perform at least as well as treatment as usual whilst also significantly improving access to mental health treatment.

Methods

Common Elements Treatment Approach (CETA; [26]) was carefully adapted for delivery via telephone (t-CETA) and then a single blind pilot randomized controlled trial (RCT) was conducted to evaluate t-CETA among Syrian children living as refugees in informal tented settlements in Lebanon. First, telephone-delivered CETA (t-CETA) was developed based on the face-to-face CETA manual, tested with healthy volunteers, and then piloted with Syrian children in the clinic and continually refined throughout the process. Following this, a pilot randomized controlled trial was conducted to explore the effectiveness, feasibility, and acceptability of t-CETA in the authentic context of a humanitarian setting. Data from the pilot RCT and a small number of children who received t-CETA outside of the RCT are reported here. Qualitative data on feasibility and acceptability are reported in McEwen et al. [27] and data on mechanisms of change of t-CETA are reported in Bosqui et al. [28]. Ethical approval was granted by the IRB of the American University of Beirut (ref: SBS-2017-0429) and the study was approved by the Ministry of Public Health in Lebanon (ref: 2017/4/49165). The RCT was preregistered at ClinicalTrials.gov (ID: NCT03887312). The study was sponsored by Queen Mary University of London, who were responsible for research governance oversight including ensuring that all regulatory approvals were in place.

Pilot RCT procedure

Children were recruited from a large cohort of Syrian refugee families living in Lebanon, (BIOPATH; 29) and via psychoeducation sessions provided in informal tented settlements (ITS). An intake assessment was completed in-person to determine eligibility, either in a local clinic or at families' homes in ITS. Informed consent was taken from the parent (or other primary caregiver) and assent from children. Children and their primary caregivers were then invited to complete the pre-treatment assessment. This was carried out via telephone by an interviewer who was independent of the team who would deliver the intervention. After the pre-treatment assessment was completed, children were randomised to receive either t-CETA or treatment as usual. Randomisation was stratified by age (8–12 years and 13–17 years) and gender to ensure balance across groups. Treatment was then initiated by trained staff. In-session assessments were completed by counsellors to monitor symptoms over the course of treatment using a *Client Monitoring Form* (CMF). After treatment had been completed (or terminated, in cases where the family chose to withdraw) the post-treatment assessment was completed via telephone by an interviewer who was independent of the treatment team and blind to treatment condition (see Figure S1 in the Supplement for a graphic illustration).

Participants

Participants in the RCT were Syrian families displaced by the civil war and living as refugees in informal tented settlements in the Beqa'a region of Lebanon. Children were eligible for the pilot RCT if they (1) were 8–17 years old at recruitment; (2) lived with a parent or other legal guardian who could provide consent; (3) met diagnostic criteria for a common mental disorder including depression, any category of anxiety disorder, post-traumatic stress disorder, or conduct or oppositional defiant disorder; (4) did not have problems for which CETA is inappropriate, such as bipolar disorder or psychosis, or problems that would preclude delivery over telephone, such as selective mutism; and (5) the child or caregiver had requested mental health services for the child (see Supplement for more information on inclusion criteria and recruitment). Recruitment was primarily from the BIOPATH cohort: of $N=1,595$ participating children, $n=656$ indicated a need for mental health services, $n=375$ of whom were considered at risk of mental health problems based on mental health measures completed as part of the cohort study. $n=175$ of these families agreed to an intake session, along with $n=17$ children who requested treatment following community psychoeducation sessions or participation in another linked study (VaST; [30, 31]). Of these $n=192$ children, $n=103$ attended and completed the intake session, $n=48$ of whom were eligible and consented to

participate in the research study (for a qualitative study on the reasons for the large pre-treatment drop out in this sample, see [7]). $n=23$ children participated in the development phase of the study (Phase 1) which had the aim of completing a cultural and linguistic adaptation of CETA for Syrian children and then an adaptation for telephone-delivery, receiving either face-to-face CETA ($n=13$) or t-CETA in the clinic during the pilot study ($n=10$). A different $n=25$ children participated in the evaluation phase of the study, consisting of the pilot RCT (Phase 2) reported in this paper. Of the $n=25$ children who completed the baseline assessment during Phase 2, $n=21$ agreed to randomization; $n=1$ withdrew after randomization leaving $n=20$ children in the pilot RCT. For ethical reasons and to ensure access to treatment, $n=4$ children who completed baseline assessment but did not agree to randomization, and the one child who withdrew after randomisation, were offered t-CETA outside of the RCT. These families stated that they could not travel to the clinic so could only access treatment via telephone. Of these $n=5$ children, $n=3$ started treatment and $n=2$ dropped out before receiving any treatment (see Fig. 1 for an overview of the recruitment process).

Importantly, the original goal was to recruit $N=120$ children to the RCT in order to achieve the sample size needed ($N=90$ after accounting for potential drop-outs) according to power analysis ($d=0.6$, $\alpha=0.05$ and $\text{power}=0.80$), but there were numerous challenges to recruiting the planned sample within the funded period of the project. These challenges included difficulties contacting families to arrange appointments due to phone numbers changing or families moving away, families having difficulty travelling to the clinic for intake sessions (due to lack of or expense of transport, or concerns about security when travelling). In addition to these logistical and practical challenges, concerns about stigma associated with accessing mental health services, misunderstanding about what mental health services involve, low expectation of services as well as no longer having a need for treatment emerged as further reasons in a related qualitative study [7]. We took various steps to try to address these challenges during the study, including offering to reimburse transport costs, offering intake sessions at home, conducting psychoeducation sessions in settlements to provide information about available treatment, and providing psychoeducation to parents during and after intake sessions to dispel myths about treatment (e.g., that it involved medication or surgery). Despite these steps, the resulting sample size was smaller than planned and findings should be considered exploratory. The study was also impacted by the 17 October Revolution in 2019, which began while most children in the RCT were receiving treatment. Widespread disruption and road closures resulted in temporary closure of

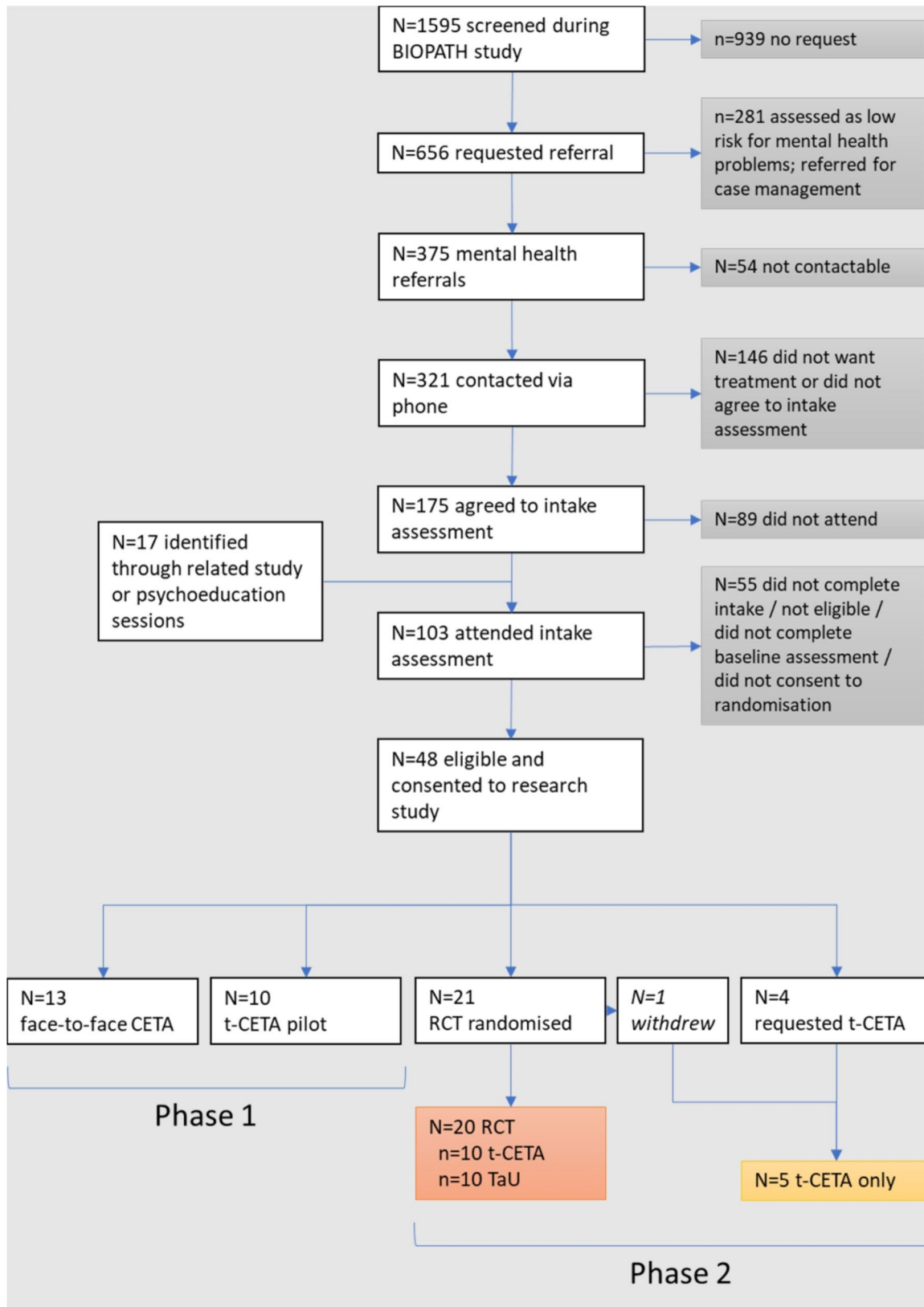


Fig. 1 Recruitment flowchart

clinics, including that in which children in the treatment as usual condition were receiving treatment. The impact on the trial is considered in the discussion.

Data from $N=20$ children who were randomized into the RCT are reported here (male $n=10$ [50%], female $n=10$ [50%]; age range=9–17; mean age [SD]=11.1 [2.2] years). The primary caregiver was female in all cases: $n=18$ mothers, $n=1$ aunt, and $n=1$ grandmother (mean age [SD]=36.2 years [8.6], age range=25–56 years). Baseline data were available for all children, but post-treatment data were missing for $n=2$ children in the t-CETA condition. In order to provide information on within-group change over time in children who received t-CETA, data from the $n=10$ children who received t-CETA as part of the RCT were combined with additional data from $n=3$ children who were not in the RCT, but who also received t-CETA as part of the project (male $n=8$ [62%], female $n=5$, [39%]; age range=8–17; mean age [SD]=10.8 [2.4] years), resulting in a sample of $n=13$. All caregivers for this enlarged t-CETA group were female: $n=12$ mothers and $n=1$ grandmother (mean age [SD]=36.8 years [8.3], age range=29–56 years). More detailed information on all included children is provided in Table S1 in the Supplement.

Intake assessment

The MINI International Neuropsychiatric Interview for Children and Adolescents (MINI Kid 6-0 [DSM-IV]; [32]) was applied at the intake assessment to establish eligibility for inclusion in the study. The MINI Kid 6-0 was previously translated into Arabic for Lebanon via a standard process of forward and back translation and review by the MINI Kid author and local experts (Mapi; [33]). Additional questions were drafted by an experienced clinical psychologist (T.B.) and used at the same appointment to gain sufficient information to assign DSM-5 diagnoses. Assessments were conducted by a clinical psychologist or trained case managers, after receiving training from one of the authors of the MINI Kid 6.0. Assessments were conducted with children and their parent(s) / caregiver unless the child was over 12 years old, in which case, depending on the comfort level of the child, they were interviewed alone. In these cases, parental report was taken separately and incorporated into decision-making. A Clinical Global Impression–severity score (CGI-s; [34]) was assigned to quantify symptom severity, global functioning, and distress. The CGI-s is a summary measure based on clinical judgment using all available information, including symptoms, history, context, and functioning. All cases were reviewed in clinical supervision with T.B. and diagnoses and CGI-s scores agreed by consensus, taking into account contextual, cultural, and linguistic factors that might impact the diagnostic process [30, 31]. Inclusion criteria required a diagnosis of

at least one of moderate-severe depressive disorder, any anxiety disorder, posttraumatic stress disorder, or conduct or oppositional defiant disorder. Importantly, data from the clinical interview and the clinical global impression score were only used to carefully establish eligibility for inclusion in the study and were not considered in the pre- and post-treatment assessment to establish treatment efficacy.

Common elements treatment approach

The Common Elements Treatment Approach [8, 26, 35] is an established transdiagnostic intervention for children and adults presenting with common mental health problems and incorporates evidence-based psychotherapeutic treatments into one package, including treatments for depression, anxiety, trauma-related symptoms, externalizing behaviour problems, and substance use (see Table 1 for an overview of the components). Most components are delivered to the child, with the content repeated with the caregiver so that they can support their child to complete homework between sessions, other than the component for externalizing behaviour problems that is delivered only to caregivers. For the current study, the original CETA manual underwent linguistic and cultural adaptation to be suitable for Syrian children and then adaptation for telephone-delivery. First, a translator experienced in translating psychotherapeutic materials translated the face-to-face manual into Arabic, and this was reviewed and refined by a local psychotherapist (N.C.) and two case managers (S.Sa., D.A.R.; see acknowledgements) who had experience working with Syrian refugee families in Lebanon. Second, face-to-face CETA was delivered to Syrian children who met the trial criteria ($n=13$), allowing further refinement of the manual and materials. Third, CETA was adapted for remote telephone delivery (t-CETA) collaboratively by CETA experts at Johns Hopkins University (L.M. and S.S.) and the local team in Lebanon (N.C., S.Sa., D.A.R.) and trialled with a small number of healthy volunteers. Finally, t-CETA was piloted in the clinic with Syrian children ($n=10$) that met inclusion criteria for the trial (i.e., with significant mental health problems), using telephone delivery while the child and counsellor were in different rooms.

Face-to-face CETA and t-CETA were delivered by two trained lay counsellors under the supervision of a local psychotherapist (N.C.), who was supervised by a CETA expert (S.S.), using the apprenticeship model to train local providers [36]. Individual supervision and group supervision was conducted weekly with t-CETA counsellors, and the supervisor received weekly master supervision with the CETA expert. A six-day training course was provided to the local t-CETA team by S.S., followed by an eight-week period of practice through role-play and feedback, incorporating training on necessary clinical

Table 1 CETA elements employed in the current study

Component	Simplified Name	Description
Engagement	Encouraging Participation	<ul style="list-style-type: none"> • Specific attention to perceptual and concrete obstacles to engagement • Linking programme to assisting with client's problems • Includes one or more caregivers when appropriate or necessary for client participation (caregiver permission/engagement important for children)
Psychoeducation	Introduction	<ul style="list-style-type: none"> • Program information (duration, content, expectations); often using analogies • Normalization/validation of current symptoms/problems
Cognitive Coping/ Restructuring	Thinking in a Different Way – separated to Part I and Part II	<ul style="list-style-type: none"> • Understand what thoughts, feelings and behaviours are • Understand connection between thoughts, feelings, and behaviour • Learn to evaluate and restructure thinking to be more accurate and/or helpful
Behavioural Activation	Getting Active	<ul style="list-style-type: none"> • Identifying and engaging in pleasurable, mood-boosting, or efficacy-increasing activities • <i>Optional component</i>
Imaginal Gradual Exposure	Talking about Difficult Memories	<ul style="list-style-type: none"> • Facing feared and avoided memories (details and associated thoughts and feelings) • Gradual desensitization/exposure • <i>Optional component</i>
Parenting Skills (caregiver only)	Caregiver skills	<ul style="list-style-type: none"> • Provide positive one-on-one time, praise, reward and special thanks, giving effective commands, consequences • <i>Optional component</i>
Suicide/Homicide/Danger Assessment and Planning	Safety	<ul style="list-style-type: none"> • Assessing client risk for suicide, homicide, and domestic violence/child maltreatment • Developing a focused plan with the client and client's caregiver(s), where appropriate • Additional referral/reporting when needed • Used in varying degrees in each case

Note Adapted with permission from Murray et al. 2014 & 2018 [8, 35]. Additional CETA components that were not used in the cases reported here include: Anxiety Management Strategies, In Vivo Exposure, Screening and Brief Intervention for Alcohol

skills provided by the local supervisor. Additional supervision training was provided to the local supervisor by S.S. During this period, lay counsellors took on one case under close supervision. Following this, they gradually increased their caseload as their competence developed.

Treatment as usual

Children in the control condition were offered treatment as usual, comprising authentic and unaltered standard case management and psychotherapy provided by Médecins du Monde. Children and their caregiver(s) attended an intake session with a case manager to assess their specific needs and were then referred to a psychotherapist for further psychological treatment. Importantly, individual treatment varied greatly between children and included psychodynamic therapy, systemic therapy, or a mix of cognitive behavioural therapy, family, and systemic therapy, depending on the specialism of the therapist and the specific difficulties of the child. In other words, the control condition was not a specific programme with well-defined and standardised therapy components but differed substantially between children both regarding the type and the length of treatment. However, this highly variable treatment is an accurate reflection of the mental health services that Syrian refugee children in Lebanon receive. The treatment was provided during face-to-face appointments at a Primary Healthcare Centre in the area. Families were also offered referral for other needs identified during the intake assessment. Psychotherapists providing treatment as usual received weekly supervision from an experienced clinical psychologist through the

standard supervision model already in place at Médecins du Monde.

Measures

Independent pre- and post-treatment assessments

Assessments of mental health symptoms and impairment using self- and caregiver-report scales were administered via telephone before and after treatment for both arms of the trials. These assessments were conducted by independent Research Assistants (RAs), all graduate clinical psychology students at the American University of Beirut, under the supervision of T.B. RAs were trained by T.B. and N.C., with support from P.M., over two days, including extensive role playing. Symptom scales used were: Child PTSD Symptom Scale (CPSS; child self-report; [37]), Center for Epidemiological Studies Depression Scale for Children (CES-DC, abridged; child self-report; [38–40]), Screen for Child Anxiety Related Emotional Disorders (SCARED, abridged; child self-report; [41–43]), the Strengths and Difficulties Questionnaire (SDQ; parent report; [44–46]), and conduct disorder (CD) / oppositional defiant disorder items (ODD) (parent report; [47]). Arabic versions of all questionnaires were used. Details on psychometric properties and validation in the same population have been reported previously [30]. The two primary outcomes of the trial were (1) a composite score of emotional and behavioural problems calculated before and after treatment and (2) a measure of functional impairment. The mental health composite score aggregated scores from the CPSS, CES-DC, SCARED, SDQ externalising score

Table 2 Demographic factors and baseline scores on outcome measures

	RCT sample				Full t-CETA sample, from RCT and non-randomized group ^A
	All children, N=20	t-CETA, n=10	Treatment as Usual, n=10	Test statistic p-value, effect size	
Child gender, N (%) male	10 (50%)	5 (50%)	5 (50%)	χ^2 (df)=0.00 (1), $p=1.00$	8 (62%)
Child age in years, mean (SD) [range]	11.1 (2.2) [9–17]	11.0 (2.5) [9–17]	11.1 (2.0) [9–14]	t (df)=0.10 (18), $p=.923$, $d=0.04$	10.8 (2.4) [8–17]
Emotional and behavioural problems composite, mean (SD) [range]	16.87 (8.05) [2–34]	20.60 (8.68) [7–34]	13.13 (5.53) [2–23]	t (df)=2.29 (18), $p=.034$, $d=1.03$	17.15 (9.97) [5–34]
WHODAS global disability child-report, mean (SD) [range]	43.92 (19.44) [7.25–76.15]	46.75 (20.61) [10.37–72.65]	41.09 (18.85) [7.25–76.15]	t (df)=0.64 (18), $p=.530$, $d=0.29$	45.40 (18.32) [10.37–72.65]
WHODAS global disability caregiver-report, mean (SD) [range]	47.61 (18.55) [8.80–86.70]	51.30 (14.90) [25.15–65.60]	43.93 (21.78) [8.80–86.70]	t (df)=0.88 (18), $p=.389$, $d=0.40$	43.94 (21.27) [1.93–65.60]
PTSD, mean (SD) [range]	25.58 (11.29) [4–43]	30.80 (10.73) [12–43]	19.78 (9.24) [4–35]	t (df)=2.39 (18), $p=.029$, $d=1.10$	28.38 (10.56) [12–43]
Anxiety, mean (SD) [range]	22.35 (8.22) [7–35]	24.00 (7.24) [13–33]	20.70 (9.17) [7–35]	t (df)=0.89 (18), $p=.383$, $d=0.40$	21.85 (7.56) [12–33]
Depression, mean (SD) [range]	16.25 (6.32) [6–28]	19.50 (6.84) [6–28]	13.00 (3.77) [7–18]	t (df)=2.63 (18), $p=.017$, $d=1.18$	17.23 (7.66) [6–28]
Externalising behaviour problems, mean (SD) [range]	18.60 (7.04) [6–32]	18.30 (4.83) [10–24]	18.90 (9.01) [6–32]	t (df)=0.19 (13.78), $p=.855$, $d=0.08$	16.85 (5.16) [9–24]
Wellbeing, mean (SD) [range]	49.20 (20.77) [8–88]	50.80 (23.93) [8–88]	47.60 (18.23) [28–84]	t (df)=0.34 (18), $p=.740$, $d=0.15$	53.23 (21.38) [8–88]
Optimism, mean (SD) [range]	7.00 (2.99) [1–12]	6.90 (3.07) [1–12]	7.10 (3.07) [3–12]	t (df)=0.15 (18), $p=.886$, $d=0.07$	7.00 (2.68) [1–12]
Client Monitoring Form, mean (SD) [range]	27.65 (12.78) [10–48]	26.20 (12.13) [10–45]	29.10 (13.90) [10–48]	t (df)=0.50 (18), $p=.625$, $d=0.22$	25.92 (10.82) [10–45]
PSYCHLOPS, mean (SD) [range] ^B	6.79 (2.78) [3–10]	6.88 (2.80) [3–10]	6.67 (3.01) [3–10]	t (df)=0.13 (12), $p=.896$, $d=0.07$	7.20 (2.82) [3–11]

^A $n=2$ children were consented directly into t-CETA outside of the RCT because their caregivers did not consent to randomization; $n=1$ child was withdrawn from the RCT after being randomized to TaU, and re-consented into t-CETA outside of the RCT; this group constitutes all children who received t-CETA, whether as part of the RCT or outside of the RCT. ^B PSYCHLOPS data were collected during the first three treatment sessions so were missing for some children; $n=6$ for treatment as usual, $n=8$ for t-CETA (RCT), $n=10$ for full t-CETA sample. Text in **bold** indicates that the difference between groups was significant at $p<0.05$

and CD / ODD items. In order to create the composite, scores from the individual questionnaires were divided into deciles based on data from the population from which the study sample was drawn [29] and each decile converted into a score ranging from 0 (lowest decile) to 9 (highest decile). The four different decile scores were then summed for the composite mental health score, giving a total score ranging from 0 to 36. For the measure of functional impairment / disability (WHODAS; child self-report and caregiver report; [48, 49–51])—independently assessed before and after treatment—subscales (*getting along with others, life activities, participation in society, overall health, overall impairment, and activity limitation*) were averaged to produce a Global Disability score, expressed as a percentage.

In addition, all individual mental health scales (CPSS, CES-DC, SCARED, SDQ externalising and CD / ODD items) were also considered as secondary outcomes, alongside measures of well-being (WHO-5 Well-Being Index; child self-report; [52, 53]) and optimism (YLOT, Youth Life Orientation Test; child self-report; [54]).

These are reported in order to further investigate and interpret findings in regards to the primary outcomes.

In-session assessments

At the beginning of each treatment session, children’s symptoms were assessed by the counsellor using a self-report questionnaire, the Client Monitoring Form (CMF), derived from locally validated versions of the Center for Epidemiological Studies Depression Scale for Children (CES-DC), Screen for Child Anxiety Related Emotional Disorders (SCARED), and the Child PTSD Symptom Scale (CPSS) [30, 37–43]; and externalising behaviour and safety screening items from versions of the CMF used in previous CETA studies. Questions and response options were read to the child by the counsellor. A total score as well as scores for symptoms of depression, anxiety, PTSD, and externalizing behaviour problems were derived. Scores were used to examine change in symptoms over the course of treatment in order to monitor progress and inform treatment.

The PSYCHLOPS [55] measures progress on problems that the child defines as being the most salient to them, and covers three domains of problems, functioning, and well-being that are summed to provide a total score (higher scores indicate greater problems, poorer functioning, and lower well-being). The PSYCHLOPS was used at the beginning (within the first three sessions), mid-point, and at the final treatment session to measure change during treatment.

Data analysis

Effectiveness analysis of primary and secondary outcomes

Bayesian RCT analyses based on estimation with uncertainty rather than traditional null hypothesis significance testing were conducted [56]. Hence, the statistical model does not tell us whether effects are statistically significant, but provides probability estimates that take additional information into account (e.g., expected effect size, direction of effect etc.). Multiple imputation was applied using lasso linear regression implemented in R mice package [57]. A Bayesian model analogous to ANCOVA [58] was built for each of the primary and secondary outcomes. Importantly, baseline differences between the intervention and control groups are included as a parameter in our Bayesian model and thus explicitly taken into account. Moreover, separate additive effects for each individual subject are also included in the model (analogously to a mixed model in frequentist approach), which tackles putative differences in individual trajectories. In summary, we have used the most suitable modelling approach for a small sample RCT that addresses the most prevalent issues in small studies, particularly differences in baseline scores. Two separate models for the primary outcomes (i.e., the emotional and behavioural problems composite score and the disability score [WHODAS]) were computed. Moreover, models for the secondary outcomes included each individual mental health symptom scale (CPSS, CES-DC, SCARED, SDQ externalising and CD / ODD items), well-being (WHO-5) and optimism (YLOT). All models were specified and fitted in R using the *rjags* and *runjags* packages that use JAGS to run Markov Chain Monte Carlo simulations [59, 60].

For all outcomes, the Region Of Practical Equivalence (ROPE) was defined as two points increase or decrease on the scale score. In other words, a change of two points was considered as equivalent to no change for practical purposes [61]. For the emotional and behavioural problems composite score, as each point represents a decile of one of the individual symptoms questionnaires, practical equivalence was defined within a 20% change in any individual outcome or 10% change in two different outcomes. Hence, only improvements greater than 20% were considered as different from null; changes of less than this were considered to indicate negligible clinical effect

for the emotional and behavioural problems composite score. In other words, a clinically relevant improvement was defined in the model as a reduction in the mental health symptom score of at least 20%.

Comprehensive and properly shrinkaged priors built from combinations of gamma distributions were used. Priors construction were based on recent guidelines for priors choice in RCTs [62] and shrinkage priors were based on results from previous RCTs on CETA, delivered in-person [63–65]. All models and codes for the analyses in R are openly available and can be accessed at <https://osf.io/ux39m/>.

In-session assessment score change

Change in CMF scores over the course of treatment was assessed using linear regression analysis, with CMF scores as the dependent variable and session number as the independent variable. Change in PSYCHLOPS scores was assessed using the related-samples Wilcoxon signed-rank test to compare scores at baseline to those at the mid-point and final treatment session, and to compare mid-point to final scores.

Results

Description of the sample

A description of the sample is provided in Table 2. There was no difference in age or gender between treatment conditions, nor was there a significant difference in disability, anxiety, externalising behaviour problems, wellbeing, or optimism scores. However, children who received t-CETA had significantly higher scores for the emotional and behavioural problems composite. This difference is likely explained by the small sample size rather than any systematic selection bias and was driven by higher scores for both PTSD and depression symptoms. Importantly, these differences were statistically controlled for in our Bayesian model. Clinical diagnoses at the intake assessment (before randomisation) included major depressive disorder; post-traumatic stress disorder (events described included witnessing bombing and houses destroyed, seeing people dying in bombings or being killed by soldiers, witnessing kidnapping, witnessing ISIS executions, soldiers entering the home, being beaten by other children in Lebanon); anxiety disorders including generalised anxiety disorder, panic disorder, agoraphobia, separation anxiety, social anxiety, specific phobia (triggers included snakes, fire, and darkness), obsessive compulsive disorder; and conduct or oppositional defiant disorder. In line with data from the larger BIOPATH cohort, most children met criteria for more than one disorder [23, 31]. ADHD was suspected in five cases, but it was not possible to confirm diagnosis due to the difficulty in getting an accurate developmental history in the context of war exposure and displacement.

Primary outcomes effectiveness analysis

The posterior distributions for the treatment versus time interaction are presented in Fig. 2. The mode of the posterior distribution of the interaction between intervention groups was 4.58 points and a mean general improvement of 4.4 points was observed for the emotional and behavioural problems composite score in the t-CETA group when compared with treatment as usual (TaU). The overlap of the posterior distribution with the Region of Practical Equivalence (ROPE) was of 10.1%, with 87% of the distribution being above the ROPE. Hence, the RCT data weakly supports a clinically relevant improvement (defined as a reduction of at least 20%) in the emotional and behavioural problems composite score for children receiving t-CETA in comparison with TaU (Fig. 2, top). The improvement is in the order of 4.4 points in the original scale, corresponding to an effect size of approximately 0.33. Regarding disability, no relevant differences were observed between t-CETA and TaU groups (Fig. 2, bottom).

Secondary outcomes effectiveness analysis

Analysis of secondary outcomes (i.e. individual symptom scores for depression, anxiety, PTSD, externalising behaviour problems, wellbeing, and optimism) are presented in Fig. 3; Table 3. Clinically significant improvements (defined as a reduction of at least 20%) in children receiving t-CETA compared to children receiving TaU was not consistently observed for the individual symptom scales, though findings were suggestive for depression symptoms and wellbeing scores.

Analysis of in-session measures in t-CETA cases only

Client monitoring form (CMF)

Change in CMF scores were examined by plotting total CMF scores against session number in children who received t-CETA (Fig. 4). There was a significant decrease in scores in children who received t-CETA in the RCT ($F(df)=145.36 [1, 62], \beta=-0.84, p<.001$) and in the larger sample of all children who received t-CETA ($F(df)=186.85 (1,86), \beta=-0.83, p<.001$). Due to a large

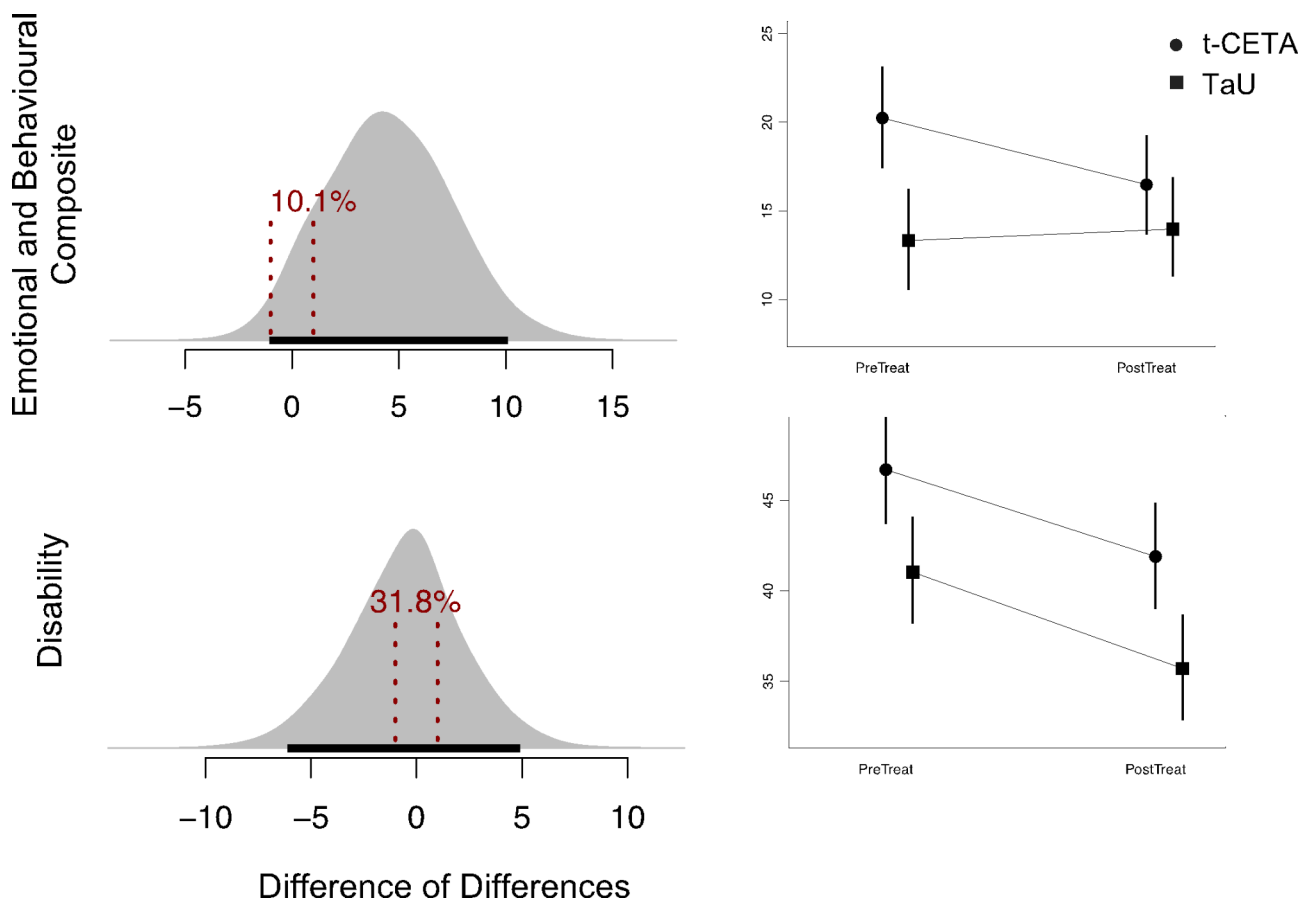


Fig. 2 Primary outcomes results. *Note.* Whole posterior distribution of the interaction between time and treatment (difference-of-differences) for the emotional and behavioural problems composite (top) and disability score (bottom); scores are represented on the right. The region of practical equivalence (ROPE) was defined as ranging between -2 and 2 points (dashed vertical lines). The percentages depicted above the distributions represents the area of the posterior overlapping the ROPE. The 95% High-Density Interval (HDI) is represented by the solid horizontal line over the x-axis. The right panels present the mean of the posterior distribution of emotional and behavioural problems composite score (top) and disability score (bottom) for the TaU and t-CETA groups before and after treatment. Vertical lines represent the 95% HDI

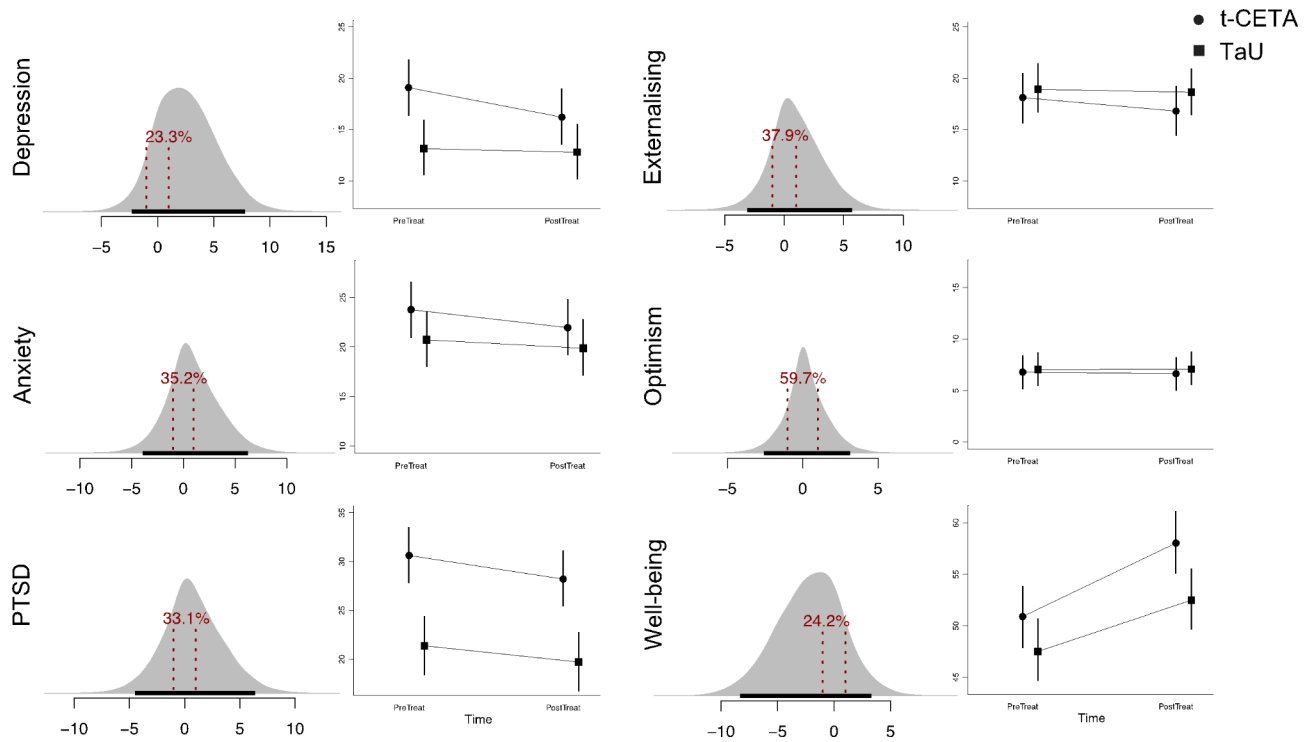


Fig. 3 Secondary outcomes results. Note Whole posterior distributions of the interaction between time and treatment (difference-of-differences) for the individual psychopathology scales and for the YLOT (optimism) and WHO-5 (well-being) measures are presented. The percentages depicted above the distributions represents the area of the posterior overlapping the ROPE. The 95% High-Density Interval (HDI) is represented by the solid horizontal line over the x-axis. The plots in the right of the distribution present the mean of the posterior for the TaU and t-CETA groups before and after treatment. Vertical lines represent the 95% HDI

Table 3 Summary of the posterior distribution results for the contrast t-CETA vs. TaU

	Mean	Mode	HDI low	HDI high	% in ROPE	% > ROPE ^A
Emotional and behavioural problems	4.40	4.58	-1.05	9.95	10.1	87.3
Disability	-0.52	-0.04	-6.12	4.93	31.8	27.1
Depression symptoms	2.53	1.79	-2.30	7.78	23.3	69.8
Anxiety symptoms	0.96	0.08	-3.96	6.26	35.2	45.2
PTSD symptoms	0.76	0.16	-4.50	6.36	33.1	43.3
Externalising symptoms	1.04	0.09	-3.11	5.68	37.9	47.3
Optimism	0.20	0.03	-2.60	3.13	59.7	15.8 ^A
Wellbeing	-2.14	-0.65	-8.32	3.30	24.2	63.1 ^A

Note. ^A % < ROPE shown for Optimism and Wellbeing

number of missed sessions, there was insufficient CMF data in children who received treatment as usual to allow for comparative analysis.

PSYCHLOPS

The PSYCHLOPS was completed at baseline, mid-point, and at the final treatment session. When children were asked to identify the problem that they were most worried about at the beginning of treatment, problems included memories of conflict (e.g., injury to family members, witnessing killings); a range of fears including of the army, kidnapping, leaving the house, fear at night; anxiety about school and exams; maltreatment by family members or bullying by other children; poor

living conditions in camps and material deprivations; worries about going back to Syria; and their own behavioural problems (e.g., being angry and aggressive with siblings). When asked how much the identified problem had affected them in the last week, children’s ratings averaged 3.70/4.00 (SD=0.82). When asked about the impact of these problems, some children mentioned sleep problems and nightmares, not having friends or not feeling able to go out with friends, and not being able to leave the house/tent other than for essential reasons; the mean functioning score was 1.70/4.00 (SD=1.83). The mean wellbeing score was 1.63/4.00 (SD=0.74), and the mean total score was 7.20/12.00 (SD=2.82). In children who received t-CETA in the RCT, there was a

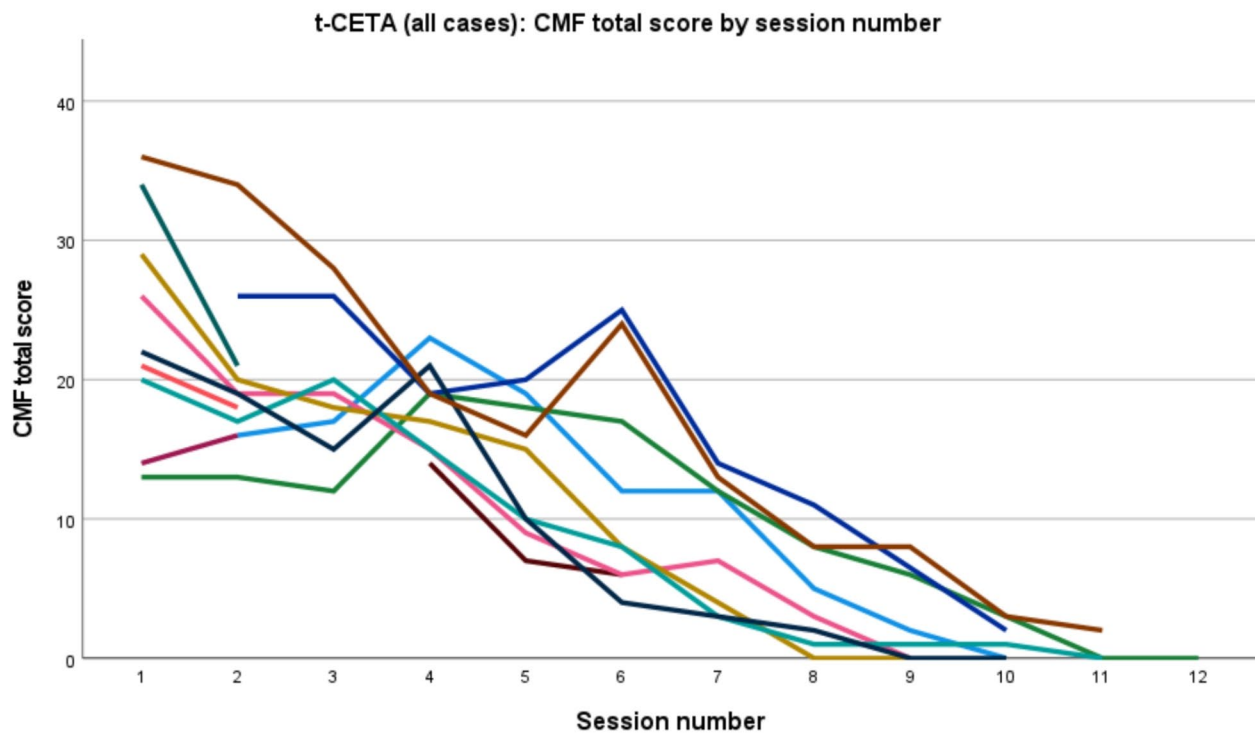


Fig. 4 Client Monitoring Form (CMF) scores plotted against session number in all children who received t-CETA ($n=13$)

Table 4 PSYCHLOPS scores at baseline, mid-point, and final treatment session in children who received t-CETA

	Baseline PSYCHLOPS, median (IQR) [range]	<i>N</i>	Mid-point PSYCHLOPS, median (IQR) [range]	<i>N</i>	Final session PSYCHLOPS, median (IQR) [range]	<i>N</i>	Baseline – mid- point change, test statistic ^a , <i>p</i>	Mid-point – final session change, test statistic ^a , <i>p</i>	Baseline – final session change, test statistic ^a , <i>p</i>
t-CETA (RCT)	8 (5) [3–10]	8	4 (3) [0–6]	6	0 (2) [0–2]	5	-1.75, <i>p</i> =.080	-1.84, <i>p</i> =.066	-2.04, <i>p</i>=.041
t-CETA (all cases)	8 (5) [3–11]	10	4 (3.5) [0–6]	8	0 (1) [0–2]	7	-2.21, <i>p</i>=.027	-2.21, <i>p</i>=.027	-2.38, <i>p</i>=.018

Note. ^a Related-Samples Wilcoxon-Signed Rank test. Results significant at $p < .05$ in **bold**

significant decrease in scores from baseline to final treatment session, and this was also true in the larger sample of all children who received t-CETA. In the latter sample, there was also a significant decrease from baseline to mid-point and from mid-point to final treatment session. See Table 4 for results. Due to a large number of missed sessions, there was insufficient PSYCHLOPS data in children who received treatment as usual to allow for comparative analysis.

Attendance and treatment completion

Of those children randomised to receive TaU, $n=4$ (40%) never started treatment and $n=6$ (60%) only partially completed a course of treatment. Of children randomised to receive t-CETA, $n=1$ (10%) never started treatment, $n=3$ (30%) partially completed treatment, and $n=6$ (60%) completed a full course of t-CETA. The difference in treatment completion between conditions was significant (Fisher-Freeman-Halton Exact Test, $p=.015$).

The total number of t-CETA sessions delivered ($n=68$ to children, $n=41$ to caregivers; $n=109$ in total) was substantially greater than the number of TaU sessions delivered ($n=22$). See Fig. 5.

Discussion

The current study aimed to adapt the established trans-diagnostic treatment CETA [8] to remote delivery over phone with the help of trained and closely supervised lay counsellors in order to address several barriers to treatment. After careful adaptation to remote delivery, a pilot randomised controlled trial with Syrian refugee children and their caregivers was carried out under authentic real-life conditions in informal refugee settlements in Lebanon. It was hypothesised that t-CETA would perform at least as well as treatment as usual and that phone delivered psychological treatment would facilitate access to treatment compared to therapy provided face-to-face in clinics.

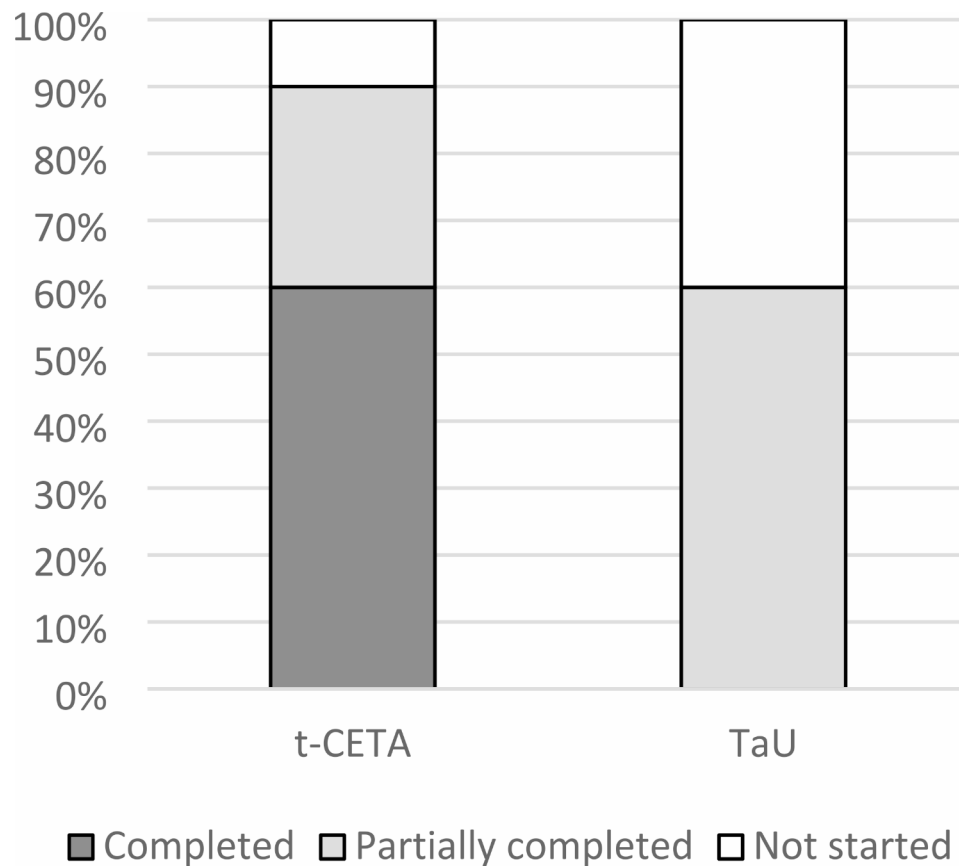


Fig. 5 Treatment completion and number of sessions completed by condition. *Note.* t-CETA, $n = 10$; Treatment as usual (TaU), $n = 10$

Results within the group receiving t-CETA showed significant reduction in self-reported mental health symptoms over the course of treatment. Results of the pilot RCT suggest that t-CETA was effective in reducing emotional and behavioural problems to a marginally greater degree than treatment as usual provided through clinics. For global disability and the individual mental health symptoms and well-being scales, t-CETA resulted in change that was comparable to treatment as usual (though results were suggestive for a greater reduction of depression symptoms and positive change in well-being). Importantly, t-CETA significantly improved access to treatment in that more children in the t-CETA group completed treatment and more sessions were delivered compared to treatment as usual.

Efficacy of t-CETA

A first important finding of our study is how challenging it was to recruit children with mental health problems for inclusion in the trial and treatment more generally. Although there was initially significant interest in mental health services with several hundred Syrian refugee families requesting the referral of their children with elevated mental health symptoms, only 12.2% of them ended up engaging with the offered treatment. According to a

related qualitative study we conducted, the main reasons for the pre-treatment dropout was that families (1) no longer perceived a need for treatment of their children, (2) experienced practical and logistical problems such as transportation issues, (3) were concerned about matters related to stigma and shame, and (4) had a limited understanding of mental health treatment [7]. This confirms the importance of making mental health services more accessible and more culturally relevant but also points to the importance of psychoeducation among populations less familiar with mental health problems and the treatment thereof. As a result of the challenges we faced, the trial ended up being much smaller than planned and findings need to be considered preliminary until confirmed in a larger trial.

Despite the small sample, findings provide first evidence that t-CETA is at least as effective as treatment as usual in reducing emotional and behavioural symptoms measured as a composite score based on symptoms of PTSD, depression, anxiety, and externalizing problems. t-CETA did not reduce global disability ratings to a greater degree than treatment as usual (although there was a trend towards disability scores reducing in both groups). When considering the individual mental health dimensions (i.e., the secondary outcomes), we observed

a trend towards greater improvement in the t-CETA condition for depression and wellbeing. The finding that t-CETA reduced the emotional and behavioural problems composite score rather than individual disorder scores may reflect heterogeneity in the sample and the modular structure of t-CETA. For example, we would expect that depression symptoms would reduce most in children presenting with depression and receiving a depression treatment flow, PTSD symptoms most in children presenting with PTSD and receiving a trauma treatment flow, etc.; while the composite score would detect relevant symptom change for all children, the individual disorder scores would be expected to decrease primarily in the subset of children with that disorder. However, the small sample size precluded subgroup analysis to explore this possibility. Importantly, the effect size of 0.33 is at the lower end of detected effect sizes for previous evaluations of CETA which range from 0.30 to 2.40 [63–66]. For example, one study that evaluated CETA delivered in-person to 38 Somali refugee youth found effect sizes for pre-post changes (no control group) ranging from 0.75 to 1.71 [35]. The effect size of the current study needs to be considered in light of the small sample and heterogeneity in diagnosis but likely also reflects the influence of other factors such as the extremely challenging context for participating families that got worse over the course of the trial (e.g., chronic adversity experienced in settlements, political and economic crisis in Lebanon from late 2019 onwards, etc.) and in some cases significant delays of multiple months between first expression of a need for treatment and recruitment into the trial, and variable number of weeks delay between final treatment session and post-intervention assessment by independent assessors.

Importantly, whilst the effect size was small when considering independent assessment pre- and post-treatment across both conditions of the trial, the effectiveness of t-CETA is strongly supported by the significant changes in symptoms over time reflected in both the Client Monitoring Form (CMF) and the PSYCHLOPS. Data on the CMF, which was reported by the child at each session, shows a strong and consistent decline of symptoms for all children that received t-CETA with most scoring 0 by the end of the treatment course (after 8–12 sessions). Similar results emerged for the PSYCHLOPS which was assessed at the beginning, during and after treatment, suggesting that participating children felt that t-CETA significantly reduced the problems that were most relevant to them. This positive experience of t-CETA is also reflected in a separate qualitative study on the feasibility and acceptability of t-CETA among our sample according to which children and their caregivers, as well as the counsellors, reported that t-CETA works and is helpful [27]. Further detailed investigation into these positive

effects of t-CETA revealed that the trauma and depression modules were associated with a decrease in mental health symptoms and that supportive counsellors as well as the active engagement of caregivers were of particular importance for treatment success [28].

Benefits of remote delivery

Regarding the question of whether remote delivery of CETA over the phone would reduce barriers and facilitate access to treatment, we found that children allocated to t-CETA were significantly more likely to start and complete treatment, as well as receiving more sessions. In fact, whilst 60% of children allocated to t-CETA completed a full course of treatment and 90% received some treatment, not a single child in the treatment as usual group completed treatment and only 60% of them began treatment. There was also a stark contrast in the number of sessions delivered, with t-CETA sessions outnumbering treatment as usual sessions by a factor of five. There are likely various reasons for the higher drop-out rate in the control condition. According to a follow-up mixed methods study in the same sample [7], practical and logistical challenges, stigma and shame, perceptions of mental health services, and of mental health, were the main reasons for non-attendance. A further reason for the big differences between the two treatment conditions regarding attendance and completion may be that during the time of the trial Lebanon experienced the 17 October Revolution which led to extended road closures across the country. As a result, it was not possible for counsellors and participants to attend treatment as usual sessions at the clinic. In contrast, t-CETA sessions were still taking place despite road closures and civil unrest because counsellors were able to make calls to study participants from their homes (protocols to ensure privacy and safety of children receiving t-CETA remotely were extended to include counsellors working from home [67]). Although this was a unique situation, it nevertheless showcases that remote delivery of psychological treatment can be more resilient in an unstable and unpredictable context given that it overcomes common issues of transportation. In addition, we were able to offer t-CETA sessions outside of typical business hours in the evening and on weekends, which was key for the success of t-CETA. These advantages also came up in our related qualitative study with both participants and counsellors mentioning that t-CETA solved several practical and logistic challenges, such as poor transportation, by offering a more flexible and accessible service [27].

Strengths and limitations

The current study features several strengths. First and most importantly, it was conducted in the challenging context of informal refugee settlements in a lower

middle-income country under natural conditions rather than among displaced people resettled in a high-income country. The current context reflects the reality of the vast majority of forcibly displaced children [2]. Secondly, the trial only included refugee children with clinically relevant mental health problems confirmed through in-person clinical assessment rather than relying on self-reported symptoms that do not take impairment into account. Thirdly, pre- and post-intervention assessment for the main outcome measures were conducted by independent assessors who were blind to the treatment condition of participating children. Fourth, fidelity of treatment delivery was high given detailed documentation of t-CETA sessions by counsellors and weekly supervision. Finally, t-CETA was carefully adapted to the local context by first translating the manual into the local language (i.e., Arabic), then delivering CETA face-to-face to refugee children, testing telephone-delivered CETA components with healthy individuals before delivering t-CETA to a small number of refugee children with clinically relevant problems, before running the trial.

However, reported results need to be considered in light of several limitations. First, the sample for the trial was much smaller than planned due to difficulties recruiting and retaining Syrian refugee children that met inclusion criteria. Many families that initially expressed an interest in mental health services for their children dropped out between first contact and the in-person intake assessment before randomisation to t-CETA or control condition. As a result, findings of this small RCT need to be considered preliminary until confirmed in an adequately powered trial. However, we applied a Bayesian approach to analyses which is more suitable for small samples and focuses on probability estimates rather than rigid p -values [56]. Second, and relatedly, given that only a small proportion of the referred children ended up in the trial, it is unclear to what degree the final sample is representative of refugee children with mental health problems. Third, there were significant baseline differences in the composite score for mental health despite careful randomisation, with scores being higher in the t-CETA condition compared to the control condition. This is likely due to the small sample size rather than a selection bias. However, these baseline differences were statistically accounted for in the Bayesian model in order to reduce their impact on the RCT findings [58]. Fourth, the control condition “treatment as usual” contained a wide range of possible activities, from very little active treatment to counselling sessions with a specialist mental health professional. However, although we collected information on the number of sessions (see Table S1 in the Supplement), the actual content of these sessions for each participating child was not available to the research team. Hence, the control condition against which t-CETA

was evaluated is not well defined. Importantly, though, this reflects the typical treatment delivered by humanitarian health organisations and therefore reflects the reality experienced by the majority of children seeking mental health treatment in LMICs and humanitarian settings. Furthermore, the goal of this study was to investigate whether t-CETA is effective in relation to the treatment that refugee children typically receive in reality rather than testing how it compares to another standardised treatment. Fifth, we did not establish interrater agreement between the different research assistants that conducted the independent pre- and post-treatment assessment over phone. Finally, the economic and political crisis in Lebanon may have impacted the trial and reduced effectiveness due to increasing stress levels across the nation, especially towards the end of the trial. This means that effect size might have been stronger in a more stable and less challenging context. However, according to our study on symptom change across the course of t-CETA, most children in the trial that experienced the onset of the revolution did not show a change in symptoms in response to the political crisis [28].

Implications and future directions

The current study provides first but preliminary evidence that it is possible to deliver effective psychological treatment to refugee children in a humanitarian setting over telephone with the help of trained lay counsellors. Findings from (1) the pilot trial with independent assessment of pre- post-intervention changes, (2) trajectories of self-reported symptoms across the course of treatment, as well as (3) associated qualitative research [27] all agree that t-CETA is effective in reducing mental health problems, albeit with a small to moderate effect size when measured using independent assessments. The successful involvement of lay counsellors emphasises that it is possible to provide effective treatment even in contexts with low numbers of mental health professionals by recruiting and training lay counsellors. This means that t-CETA is likely scalable in most LMICs and humanitarian settings. However, it is important to provide regular and high-quality supervision from experienced clinicians. The fact that more t-CETA sessions could be delivered than traditional in-person sessions suggests that telephone-delivered treatment reduces some of the common barriers to treatment such as transportation and scheduling issues. However, retention across the pre-treatment recruitment process was still poor despite remote delivery. This was likely exacerbated by the need to do the first assessment in-person during the trial, though may also suggest that t-CETA does not address all the reasons for the observed treatment gap and may not be equally suitable for every child. In order to reduce barriers further, all activities and interactions could be conducted remotely over the

telephone. In addition, it is important to provide psychoeducation in a culturally appropriate and relevant way when informing displaced populations about available services.

More research is needed to evaluate t-CETA. This should include large randomized controlled trials in different settings, ideally comparing t-CETA as well as in-person CETA to a more defined control condition (wait-list or standardised and evidence-based treatment programme) featuring a sample that is representative of typical refugee children. Most recently, a large RCT has been conducted with several hundred adolescents and young adults in Zambia, finding that t-CETA was as effective as in-person CETA, and both t-CETA and in-person CETA were more effective than the control condition [68]. However, this study did not feature a refugee population in a humanitarian setting. Future research should also consider how to further reduce the treatment gap in LMICs and humanitarian settings, for example, by running accessible psychoeducation in communities with the help of community members building on the sessions that we ran in settlements for the current study. Importantly, as our findings suggest, the treatment gap among forcibly displaced children does not just reflect a lack of mental health treatment but also a reluctance of displaced populations to engage in available services due to various barriers to treatment access.

Conclusions

We presented first preliminary evidence that CETA delivered remotely over telephone is effective in reducing mental health symptoms among Syrian refugee children living in informal settlements in Lebanon. Remote delivery addressed several established barriers to treatment, such as difficulties finding transportation to get to clinics and not being able to access treatment outside business hours. In addition, findings suggest that lay counsellors are able to successfully deliver t-CETA with adequate training and supervision provided by experienced clinicians. This means that t-CETA is scalable in contexts with limited numbers of mental health professionals. In summary, t-CETA should be considered a promising treatment option in low resource settings. However, positive effects of the pilot trial remain to be confirmed in larger studies.

Abbreviations

CETA	Common Elements Treatment Approach
CBT	Cognitive behavioral therapy
CMF	Client Monitoring Form
LMICs	Low and Middle Income Countries
PTSD	Post-traumatic stress disorder
RCT	Randomized controlled trial
t-CETA	Telephone-Common Elements Treatment Approach
UNHCR	United Nations High Commissioner for Refugees

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13031-024-00616-2>.

Supplementary Material 1

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Author contributions

MP, LM, RW, PB, and EK secured funding for the project and MP, FM, NC, and TB were responsible for research administration and supervision. FM and CB conducted the statistical analyses. SS and NC were responsible for clinical supervision of counsellors. MP, FM and CB drafted the manuscript and all authors discussed results, critically reviewed the manuscript, and agreed the final version.

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Data availability

The datasets generated during the current study as well as the scripts are available in the Open Science Framework (for data: https://osf.io/tb9e/?view_only=82a023e8c9dd4c3a940d1f277d4cbee8, for scripts: https://osf.io/dj4bv/?view_only=0dfacc3b32e6463a9178b07b38f98dc0).

Declarations

Ethics approval and consent to participate

Ethical approval was granted by the Institutional Review Board of the American University of Beirut (ref: SBS-2017-0429) and the study was approved by the Ministry of Public Health in Lebanon (ref: 2017/4/49165). Caregivers provided informed consent and children provided assent for participation in the RCT.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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