Phone-Delivered Psychological Intervention (t-CETA) for Mental Health Problems in 8-17 Year-Old Syrian Refugee Children

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Main Information

Primary registry identifying number
LBCTR2019040213

Protocol number
ReDA_012540

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency

Primary sponsor
Queen Mary University of London

Primary sponsor: Country of origin
United Kingdom

Date of registration in primary registry
17/02/2020

Date of registration in national regulatory agency

Public title
Phone-Delivered Psychological Intervention (t-CETA) for Mental Health Problems in 8-17 Year-Old Syrian Refugee Children

Acronym
t-CETA

Scientific title
Development, Piloting and Evaluation of a Phone-Delivered Psychological Intervention (t-CETA) for Syrian Refugee Children in Lebanon: Phase II

Acronym
t-CETA

Brief summary of the study: English

This study evaluates the effectiveness of t-CETA, a version of Common Elements Treatment Approach (CETA) adapted to be delivered over the telephone, in treating common mental health problems in 8-17 year old Syrian refugee children living in Lebanon. Children will be randomly assigned to receive either t-CETA or treatment as usual provided by Médecins du Monde, an NGO providing medical and mental health services to Syrian refugees in Lebanon. If families do not agree to randomisation, they will be offered t-CETA and their data will be used to evaluate implementation and acceptability of the intervention.

Symptoms of common mental health problems, including anxiety, depression, PTSD, and behavioural problems, and psychological well-being, will be measured before treatment, immediately after treatment, and three months after treatment is completed. Groups will be compared to determine if t-CETA is at least as effective as standard treatment provided by Médecins du Monde.

Brief summary of the study: Arabic

التي تم تكييفها ليتم تقديمها عبر الهاتف وذلك لعلاج (CETA) وهي نسخة من نهج علاج العناصر المشتركة، t-CETA تقيم هذه الدراسة فعالية عاماً والذين يعيشون في لبنان. سيتم تعيين16 و 8مشاكل الصحة النفسية الشائعة لدى الأطفال اللاجئين السوريين الذين تتراوح أعمارهم بين أو العلاج المعتاد المقدم من منظمة أطباء العالم، وهي منظمة غير حكومية تقدم خدمات الصحة الطبية t-CETA الأطفال بشكلٍ عشوائي لتلقي إما والنفسية إلى اللاجئين السوريين في لبنان.
إذا لم توافق الأسر على التوزيع العشوائي ، فستقدّم لهل خدمة تيستا وسوف يتم إستخدام بيانات هذه الجلسات لتقييم تطبيق و تقبل تيستا من قبل العائلات.

سيتم قياس أعراض مشاكل الصحة النفسية الشائعة، بما في ذلك القلق والاكتئاب واضطرابات ما بعد الصدمة والمشكلات السلوكية والرفاه النفسي، فعال على t-CETA وذلك قبل العلاج ومن ثم مباشرةً بعد العلاج وثلاثة أشهر بعد اكتمال العلاج. ستتم مقارنة المجموعات لتحديد ما إذا كان نهج الأقل بقدر العلاج المعتاد المقدم من منظمة أطباء العالم.

Health conditions/problem studied: Specify

Depression, anxiety, PTSD, conduct disorder, oppositional defiant disorder

Interventions: Specify

1. Telephone-delivered Common Elements Treatment Approach (t-CETA) [EXPERIMENTAL ARM]
Cognitive Behavioural Therapy (CBT) based approach delivered over the telephone. Components are available for common problems, including anxiety, depression, PTSD, conduct problems, substance abuse, and safety issues (including self-harm or suicidal ideation), and a tailored treatment package is produced for each child based on the presenting problem(s) and response to treatment. There are components for use with both child and caregiver. t-CETA sessions of up to 30 minutes will be delivered 1-2 times per week for approximately 8-16 weeks. The number and content of sessions will be tailored to each child, thus there will be some variation.

2. Médecins du Monde treatment as usual [ACTIVE COMPARATOR ARM]
Case manager-led care, with referral to a psychotherapist or psychiatrist as necessary. Médecins du Monde's approach is based on a joint collaboration between mental health trained case managers (who undergo extensive training by experts in the field on topics including Psychological First Aid, Child Protection, Gender Based Violence, etc.) and psychotherapists from different schools (providing Eye Movement Desensitization and Reprocessing [EMDR] for trauma, Interpersonal Therapy [IPT] for depression, Cognitive Behavioural Therapy [CBT], motivational counselling, familial or systemic therapy, and integrative approaches). The number and content of sessions, and the person delivering treatment (case manager, psychotherapist, psychiatrist) vary.
Treatment as usual provided by Médecins du Monde. The number and content of sessions will vary depending on the needs of the child.

Key inclusion and exclusion criteria: Inclusion criteria

1. Age 8-17 years, male or female
2. Live with a parent or other legal guardian
3. Child and/or parent identifies that the child has mental health difficulties and requests services
4. At high risk of having a mental disorder as indexed by falling in the top 40% of the distribution in any one of the following child-report questionnaires: (i) Screen for Child Anxiety Related Emotional Disorders (SCARED), (ii) Center for Epidemiological Studies Depression Scale for Children (CES-DC), (iii) Child PTSD Symptom Scale (CPSS); AND falling in the top 40% of the distribution in the following parent report questionnaire: Strengths and Difficulties Questionnaire (SDQ) total difficulties
[Criterion 4 is only applicable to children for whom these data are available from participation in the BIOPATH study; Criterion 5 takes precedence over Criterion 4 where both are available]
5. Confirmation of significant level of symptoms and functional impairment on clinical interview (MINI KID) as indicated by (i) meeting full or probable diagnostic criteria for ANY of the following: any category of mood disorder, any category of anxiety disorder, PTSD, conduct disorder, or oppositional defiant disorder; AND (ii) Clinical Global Impression severity (CGI-s) score of >3
6. Parent/legal guardian gives informed consent and child gives assent to take part

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

8

Key inclusion and exclusion criteria: Age maximum

17

Key inclusion and exclusion criteria: Exclusion criteria

1. Problem for which t-CETA would not be appropriate, including psychiatric disorders for which CETA treatment is not recommended (e.g., bipolar disorder, psychosis), severe distress (e.g., acute suicidal ideation), or problems that would preclude delivery over the telephone (e.g., selective mutism)
2. Parent or legal guardian is not able to provide consent
3. Child protection issues (e.g., acute maltreatment) that are judged by clinician to make trial inclusion inappropriate
4. Any inclusion criteria not met

Type of study

Interventional

Type of intervention

Behavioral treatment

Type of intervention: Specify type

N/A

Trial scope

Trial scope: Specify scope

Therapy

N/A

Study design: Allocation

Randomized controlled trial

Study design: Masking

Open (masking not used)

Study design: Control

Active

Study phase

N/A

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class

N/A - behavioural intervention

Therapeutic indication

Common mental health problems in children including depression, anxiety, PTSD, conduct disorder, oppositional defiant disorder.

Therapeutic benefit

It is anticipated that both the experimental therapy (t-CETA) and active comparator (Medecins du Monde treatment as usual) will show a therapeutic benefit by reducing symptoms of common mental health problems (depression, anxiety, PTSD, conduct problems) and functional impairment due to mental health problems.

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Biospecimen description

None retained

N/A

Target sample size

120

Actual enrollment target size

21

Date of first enrollment: Type

Actual

Date of first enrollment: Date

14/05/2019

Date of study closure: Type

Actual

Date of study closure: Date

30/09/2019

Recruitment status

Complete

Recruitment status: Specify

Date of completion

31/01/2020

IPD sharing statement plan

No

IPD sharing statement description

Data from the RCT will not be shared with researchers outside of the team.

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
ELRHA (funder)	28371

Sources of Monetary or Material Support

Name
ELRHA

Secondary Sponsors

No Sponsors

Contact for Public/Scientific Queries

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Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Medecins du Monde	Tania Bosqui	Clinical psychology	Approved
American University of Beirut	Tania Bosqui	Clinical psychology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
American University of Beirut Medical Center	07/12/2018	Michael Clinton	irb@aub.edu.lb	+9611350000 ext: 5445
American University of Beirut Medical Center	24/01/2019	Michael Clinton	irb@aub.edu.lb	+9611350000 ext: 5445
American University of Beirut Medical Center	18/02/2019	Michael Clinton	irb@aub.edu.lb	+9611350000 ext: 5445
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Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
Depression	Depressive episode (F32)	Depression
Anxiety	Anxiety disorder, unspecified (F41.9)	Anxiety
Post Traumatic Stress Disorder	Post-traumatic stress disorder (F43.1)	PTSD
Conduct Disorder	Conduct disorders (F91)	Conduct disorder
Oppositional Defiant Disorder	Oppositional defiant disorder (F91.3)	Oppositional defiant disorder

Interventions

Intervention	Description	Keyword
t-CETA	Telephone-delivered Common Elements Treatment Approach (t-CETA). Cognitive Behavioural Therapy (CBT) based approach delivered over the telephone. Components are available for common problems, including anxiety, depression, PTSD, conduct problems, substance abuse, and safety issues (including self-harm or suicidal ideation), and a tailored treatment package is produced for each child based on the presenting problem(s) and response to treatment. There are components for use with both child and caregiver. t-CETA sessions of up to 30 minutes will be delivered 1-2 times per week for approximately 8-16 weeks. The number and content of sessions will be tailored to each child, thus there will be some variation.	t-CETA; CBT; cognitive behavioral therapy; telephone delivered therapy
Médecins du Monde treatment as usual	Case manager-led care, with referral to a psychotherapist or psychiatrist as necessary. Médecins du Monde's approach is based on a joint collaboration between mental health trained case managers (who undergo extensive training by experts in the field on topics including Psychological First Aid, Child Protection, Gender Based Violence, etc.) and psychotherapists from different schools (providing Eye Movement Desensitization and Reprocessing [EMDR] for trauma, Interpersonal Therapy [IPT] for depression, Cognitive Behavioural Therapy [CBT], motivational counselling, familial or systemic therapy, and integrative approaches). The number and content of sessions, and the person delivering treatment (case manager, psychotherapist, psychiatrist) vary.	Case manager-led care; psychotherapy

Primary Outcomes

Name	Time Points	Measure
Emotional and behavioural problem composite score	1. Baseline (pre-treatment); 2. Approximately 12 weeks (immediately after treatment has been completed); 3. Approximately 24 weeks (3 months following completion of treatment)	Measures common emotional and behavioural problems in children. Scores from the following questionnaire measures will be aggregated: Child PTSD Symptom Scale (CPSS; child self-report), Center for Epidemiological Studies Depression Scale for Children (CES-DC; child self-report), Screen for Child Anxiety Related Emotional Disorders (SCARED; child self-report), the Strengths and Difficulties Questionnaire (SDQ; parent report) externalising score, and conduct disorder / oppositional defiant disorder items (caregiver report). Arabic versions of all questionnaires are used. Scores on these questionnaires have been divided into deciles based on data from the population from which the study sample is drawn and each decile is converted into a score ranging from 0 (lowest decile) to 9 (highest decile). These decile scores are then summed for the four questionnaire measures, giving a total score ranging from 0 to 36. Higher scores indicate greater problems.
World Health Organization Disability Assessment Schedule for Children (WHODAS-Child, adapted): child report	1. Baseline (pre-treatment); 2. Approximately 12 weeks (immediately after treatment has been completed); 3. Approximately 24 weeks (3 months following completion of treatment)	WHODAS-child orginally adapted for Rwanda and then translated into Arabic for use with Syrian children (child self-report). Measures three domains of functional impairment: getting along with people, life activities (ability to carry out responsibilities at home and school), and participation in society (ability to engage in community, civil and recreational activities). Subscales are averaged to produce a Global Disability score. Scores are expressed as a percentage so range from 0-100, with higher scores indicating greater impairment.
World Health Organization Disability Assessment Schedule for Children (WHODAS-Child, adapted): caregiver report	1. Baseline (pre-treatment); 2. Approximately 12 weeks (immediately after treatment has been completed); 3. Approximately 24 weeks (3 months following completion of treatment)	WHODAS-child orginally adapted for Rwanda and then translated into Arabic for use with Syrian children (caregiver report). Measures three domains of functional impairment: getting along with people, life activities (ability to carry out responsibilities at home and school), and participation in society (ability to engage in community, civil and recreational activities). Subscales are averaged to produce a Global Disability score. Scores are expressed as a percentage so range from 0-100, with higher scores indicating greater impairment.

Key Secondary Outcomes

Name	Time Points	Measure
Child PTSD Symptom Scale (CPSS)	1. Baseline (pre-treatment); 2. Approximately 12 weeks (immediately after treatment has been completed); 3. Approximately 24 weeks (3 months following completion of treatment)	Child PTSD Symptom Scale, Arabic version, child self-report. Total post-traumatic stress disorder symptom scores range from 0-51 and higher scores indicate a higher level of symptoms.
Center for Epidemiological Studies Depression Scale for Children (CES-DC)	1. Baseline (pre-treatment); 2. Approximately 12 weeks (immediately after treatment has been completed); 3. Approximately 24 weeks (3 months following completion of treatment)	Center for Epidemiological Studies Depression Scale for Children, Arabic 10-item version, child-self-report. Total depression symptom scores range from 0-30 and higher scores indicate a higher level of symptoms.

Screen for Child Anxiety Related Emotional Disorders (SCARED)	1. Baseline (pre-treatment); 2. Approximately 12 weeks (immediately after treatment has been completed); 3. Approximately 24 weeks (3 months following completion of treatment)	Screen for Child Anxiety Related Emotional Disorders, Arabic 18-item version, child-self-report. Total anxiety symptoms scores range from 0-36 and higher scores indicate a higher level of symptoms.
Externalising behaviour problems score	1. Baseline (pre-treatment); 2. Approximately 12 weeks (immediately after treatment has been completed); 3. Approximately 24 weeks (3 months following completion of treatment)	Score derived from the Strengths and Difficulties Questionnaire (SDQ; parent-report) externalising score (10 items) and items measuring behaviours associated with conduct disorder (CD) and oppositional defiant disorder (ODD) (12 items). Arabic version, caregiver report. The SDQ externalising score ranges from 0-20 and the CD/ODD items range from 0 -24. These will be summed to given an externalising behaviour problems score ranging from 0-44 and higher scores indicate a higher level of problems.
WHO-5 Well-Being Index (WHO-5)	1. Baseline (pre-treatment); 2. Approximately 12 weeks (immediately after treatment has been completed); 3. Approximately 24 weeks (3 months following completion of treatment)	WHO-5 Well-Being Index, Arabic version, child-self-report. Total well-being scores range from 0-100 and higher scores indicate higher well-being.
Youth Life Orientation Test (YLOT)	1. Baseline (pre-treatment); 2. Approximately 12 weeks (immediately after treatment has been completed); 3. Approximately 24 weeks (3 months following completion of treatment)	Youth Life Orientation Test, measuring optimism, Arabic 4-item version, child self-report. Total optimism scores range from 0-12 and higher scores indicate higher optimism.
PSYCHLOPS Pre-Therapy (Kids or Teen)	At first treatment session, approximately 1-2 weeks after baseline	Psychological Outcome Profiles (PSYCHLOPS) Pre-Therapy, Kids version (for children aged 8-12 years), Teen version (for age 13-16 years). Arabic version, child self-report. Three subscale scores are used, Problems (range 0-4 [Kids], 0-10 [Teen]), Functioning (range 0-4 [Kids], 0-5 [Teen]), and Wellbeing (range 0-4 [Kids], 0-5 [Teen]). These are summed to give a total score (range 0-12 [Kids], 0-20 [Teen]). Scores from the Kids version will be scaled to be equivalent to the Teen version so scores are comparable across both age groups. Higher scores indicate greater problems, impaired functioning, and poorer wellbeing.
PSYCHLOPS During Therapy (Kids or Teen)	At mid-point treatment session, approximately 5-6 weeks after baseline	Psychological Outcome Profiles (PSYCHLOPS) During Therapy, Kids version (for children aged 8-12 years), Teen version (for age 13-16 years). Arabic version, child self-report. Three subscale scores are used, Problems (range 0-4 [Kids], 0-10 [Teen]), Functioning (range 0-4 [Kids], 0-5 [Teen]), and Wellbeing (range 0-4 [Kids], 0-5 [Teen]). These are summed to give a total score (range 0-12 [Kids], 0-20 [Teen]). Scores from the Kids version will be scaled to be equivalent to the Teen version so scores are comparable across both age groups. Higher scores indicate greater problems, impaired functioning, and poorer wellbeing.
PSYCHLOPS Post-Therapy (Kids or Teen)	At final treatment session, approximately 8-12 weeks after baseline	Psychological Outcome Profiles (PSYCHLOPS) Post-Therapy, Kids version (for children aged 8-12 years), Teen version (for age 13-16 years). Arabic version, child self-report. Three subscale scores are used, Problems (range 0-4 [Kids], 0-10 [Teen]), Functioning (range 0-4 [Kids], 0-5 [Teen]), and Wellbeing (range 0-4 [Kids], 0-5 [Teen]). These are summed to give a total score (range 0-12 [Kids], 0-20 [Teen]). Scores from the Kids version will be scaled to be equivalent to the Teen version so scores are comparable across both age groups. Higher scores indicate greater problems, impaired functioning, and poorer wellbeing.

Client Monitoring Form (CMF)	1. Baseline (pre-treatment); 2. Approximately 12 weeks (at final treatment session)	Client Monitoring Form developed for this study to measure mental health problems, substance use, and safety issues during treatment, Arabic version, child self-report.

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files