ISRCTN75375136 https://doi.org/10.1186/ISRCTN75375136

Early Adolescent Skills for Emotions (EASE) for young adolescents in Lebanon

Submission date	Recruitment status	[X] Prospectively registered
08/03/2019	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/03/2019	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/07/2022	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Young adolescents living in adversity are at risk of psychological distress and a range of mental disorders. The aim of this study is to test a new intervention with young adolescents in vulnerable communities in Lebanon. The psychological intervention is designed to reduce high psychological distress.

Who can participate?
Young adolescents aged 10-14 who reside in the communities in which we will deliver the intervention, and are experiencing high psychological distress.

What does the study involve?
Young adolescents who are interested in participating and who have parental consent, will take part in a screening interview to determine their eligibility. If eligible, they will be randomly allocated into two groups. Young adolescents in one group are invited to participate in seven group sessions of approximately 90 minutes, and their caregivers will be invited to attend three separate group sessions. Young adolescents in the other group receive enhanced treatment as usual, consisting of a single home-visit session describing psychological distress, its causes, and what one can do to decrease psychological distress; and access to existing services. Various indicators of mental health and wellbeing are measured before, immediately after, 3 months, and 12 months after completion of the intervention.

What are the possible benefits and risks of participating?
Likely benefits include reduced psychological distress and improved wellbeing. Discussion of difficult feelings may lead to temporary increases in psychological distress. In small previous studies this risk has not been observed occurring.

Where is the study run from?
War Child Holland (Lebanon Office)

When is the study starting and how long is it expected to run for?
March 2019 to March 2021 (updated 07/10/2019, previously: December 2020)

Who is funding the study?
The European Commission under Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020).

Who is the main contact?
Dr Mark Jordans, mark.jordans@warchild.nl

Contact information

Type(s)
Scientific

Contact name
Prof Mark Jordans

ORCID ID
https://orcid.org/0000-0001-5925-8039

Contact details
War Child Holland , Helmholtzstraat 61
Amsterdam
Netherlands
1098LE
+31204227777
mark.jordans@warchild.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
EASELebanon

Study information

Scientific Title
Early Adolescent Skills for Emotions (EASE) in the treatment of psychological distress for young adolescents in Lebanon: A randomized controlled trial

Acronym
EASE Lebanon

Study objectives
We hypothesise that children and caregivers assigned to receive the EASE intervention, will show significantly greater improvements on all outcome measures, compared to enhanced

treatment as usual) at post-intervention (T1) and 3-month follow-up (T2), and that these gains will be maintained at 12 month follow-up (T3). We hypothesise that treatment effects will be mediated by increased caregiver and child use of coping strategies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/03/2018, St Joseph's University in Lebanon (Centre universitaire d'ethique, Campus des sciences medicales, rue de Dumas, BP 11-5076, Riad el Solh, Beyrouth, Lebanon; 961-1-421229; cue@usj.edu.lib) ref: ID: USJ – 2017 – 24 bis; and WHO Ethical Review Committee (ERC Secretariat, Avenue Appia 20, Geneva 1211, Switzerland; ercsec@who.int), ref: Protocol ID: ERC.0003000

Study design
Two-arm single-blind individually randomized group treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Psychological distress

Interventions
Adolescents in participating communities in Lebanon are randomised to the following two conditions.
1. The Early Adolescent Skills for Emotions (EASE) program. This is a group psychological intervention based on empiricallysupported strategies for emotional disorders in children and young people. It consists of 7 x 90-minute group sessions for adolescents and 3 x 120-minute group sessions for their caregivers. Adolescent sessions involve the following strategies: psychoeducation, problem solving, stress management (slow breathing), behavioural activation, and relapse prevention. The caregiver sessions involve: psychoeducation, active listening, quality time, praise, caregiver self-care and relapse prevention.

2. The control condition will consist of enhanced treatment as usual (ETAU), which will involve the provision of a single-session psychoeducation home visit termed "Psychoeducation for Young Adolescents". Both the adolescent and caregiver will be invited to the psychoeducation session (of approximately 30 minute duration) in which they will receive brief feedback that the youth indicated psychological distress, as well as scripted psychoeducation about (i) self-care strategies and (ii) seeking services from local health or community services offering MHPSS.

Previous:
Randomisation will occur following completion of the baseline assessment (T0). Randomisation sequences will be computer generated by an independent researcher who is not involved in any other aspects of the study, using a 1:1.6 allocation to EASE or ETAU group. To support practical implementation and to ensure adequate numbers in the EASE group programmes, separate randomisation sequences will be created for each location where EASE groups are being held, and within this, separate sequences will be used to create strata for age x gender (i.e. boys 10-

12; girls 10-12, boys 13-14, girls 13-14). To ensure that equal numbers are allocated to each group, blocking will be used. To ensure that the sequence cannot be guessed at any point in the procedure, random block sizes of 2 and 4 will be used. Group allocations (EASE or ETAU) will be recorded on pieces of paper, which will be folded and placed inside sealed, numbered, opaque envelopes. The numbered envelopes will be opened in sequence with the allocation assigned to the corresponding child on registration lists. This will be documented, and the implementing team will be informed of allocations. In cases where multiple siblings from one family are eligible for the study, all will be included, but randomized as a single unit to prevent children from the same family being allocated to different intervention arms.

Updated 19/06/2019:
Randomisation will occur following completion of the baseline assessment (T0). In cases where multiple siblings from one family are eligible for the study, all will be included, but randomized as a single unit to prevent children from the same family being allocated to different intervention arms. Randomisation sequences will be computer generated by an independent staff member who is not involved in study implementation, using a 1:1.6 allocation to EASE or ETAU group. To support practical implementation and to ensure adequate numbers in the EASE group programmes, separate randomisation sequences will be created for each location where EASE groups are being held, and within this, separate sequences will be used to create strata for males and females, and sibling pairs. To ensure that equal numbers are allocated to each group, blocking will be used with block sizes of 13 (ratio 5:8). Group allocations (EASE or ETAU) will be recorded on pieces of paper, which will be folded and placed inside sealed, numbered, opaque envelopes. The numbered envelopes will be opened in sequence with the allocation assigned to the corresponding child on registration lists. This will be documented, and the implementing team will be informed of allocations.

Intervention Type
Behavioural

Primary outcome(s)
Psychological distress, as assessed by the Paediatric Symptom Checklist 35 (PSC-35) youth-report. This will be assessed at baseline (T0), post-intervention (T1), 3-month follow-up (T2), and 12-month follow-up (T3). The primary outcome timepoint is specified as T2.

Key secondary outcome(s))
All secondary outcomes will be assessed at T0, T1, T2 and T3. The primary outcome timepoint is specified as T2.
1. Adolescent-reported outcomes
1.1 Symptoms of depression- measured using the 9-item adolescent version of the Patient Health Questionnaire (PHQ-A).
1.2 Symptoms of traumatic stress- measured using the 13-item Children's Revised Impact of Event Scale (CRIES-13).
1.3 Impairment of Daily Functioning- measured using a questionnaire was developed specifically for this study. It consists of 10 items pertaining to the level of impairment experienced with important daily activities; updated 19/06/2019: It consists of 9 items pertaining to the level of impairment experienced with important daily activities.
1.4 Wellbeing - measured using the 14-item Warwick Edinburgh Mental Wellbeing Scale (WEMWBS).
1.5 Child Use of Coping Strategies- measured via the 7-item Strategy Use Questionnaire (SUQ) developed specifically for the trial
2. Caregiver-reported outcomes

2.1 Caregiver-reported child psychological distress- measured by the PSC35 caregiver-version.
2.2 Caregiver level psychological distress- measured using the Kessler Psychological Distress Scale (K6)
2.3 Parenting- measured using the Alabama Parenting Questionnaire-42 (APQ42)
2.4 Caregiver Use of Coping Strategies- measured via the 8-item Strategy Use Questionnaire (SUQ) developed specifically for the trial
Where a caregiver has multiple children in the study, the APQ42, K6, and caregiver SUQ will only be completed once by the caregiver, while the caregiver-report PSC-35 will be completed separately for each child.
3. Mediator: Mechanisms of treatment, measured using the SUQ child and parent versions.
4. Moderators: The study is not powered for moderation effects, however, we will conduct exploratory analyses of potential moderators, which may include:
4.1 Child exposure to potentially traumatic events, measured at T0 via caregiver report, using a trauma checklist contextually developed for this site
4.2 Various demographic variables measured using a demographic questionnaire at T0.
5. Other:
5.1 Economic indicators (T0, T1, T2, T3) and barriers to accessing health care (T0) (for cost-benefit and health-system analyses), measured using survey questions designed for this study - partly based on the Client Service Receipt Inventory (CSRI); added 19/06/2019: assessed for one child per family only
5.2 Treatment contamination check, measured using survey questions designed for this study (T1, T2)
All outcomes are assessed by a masked team of interviewers not involved in service delivery.

Completion date
31/08/2021

Reason abandoned (if study stopped)
The trial was stopped as ongoing COVID restrictions, combined with other social and economic unrest in Lebanon, meant that study activities could not take place, which resulted in the team not being able to continue; related to the point before, the budget ran out to put a new team together and resume study activities.

Eligibility

Key inclusion criteria
1. Aged between 10 and 14 years;
2. Reside with a caregiver who is able to provide consent;
3. Able and willing to commit to attending the weekly EASE sessions;
4. Screens positive for psychological distress during screening (using 17 item PSC).
5. Children of any nationality and background will be eligible.

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 years

Upper age limit
14 years

Sex
All

Total final enrolment
198

Key exclusion criteria
1. Unaccompanied minor;
2. Caregiver is not a family member, as they would not be able to provide legal consent;
3. Significant cognitive impairment or severe neurological impairments or developmental difficulties as determined by caregiver-report during screening, where this would impair their ability to participate in a group programme;
4. Imminent risk of suicide;
5. Currently married.

Date of first enrolment
01/06/2019

Date of final enrolment
31/05/2020

Locations

Countries of recruitment
Lebanon

Netherlands

Study participating centre
War Child Holland
Hussein Oueini Street
Beirut
Netherlands
14-5693

Sponsor information

Organisation
War Child Holland

ROR
https://ror.org/01tq9ra93

Funder(s)

Funder type
Research council

Funder Name
European Commission (H2020)

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mark Jordans, War Child Holland (mark.jordans@warchild.nl).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes