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Feasibility trial of a psychological intervention with young adolescents in Lebanon

Submission date
03/10/2022

Recruitment status
No longer recruiting

Registration date
04/10/2022

Overall study status
Completed

Last Edited
02/03/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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 years old who reside in the communities where the intervention will be delivered, and who 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, what one can do to decrease psychological distress, and access to existing services. Various indicators of mental health and wellbeing will be measured before, immediately after, and 3 months after completion of the intervention.

What are the possible benefits and risks of participating?
Likely benefits include reduced psychological distress and improved well-being. 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?
December 2017 to July 2019

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)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Feasibility randomised controlled trial of the Early Adolescent Skills for Emotions (EASE) psychological intervention with young adolescents in Lebanon

Acronym
EASE

Study objectives

1. The feasibility trial will provide estimates of recruitment, screening, completion, and retention rates for the EASE programme and follow-up assessments
2. Delivery of EASE by trained non-specialists will be feasible and acceptable
3. Outcome measures will be feasible, their psychometric properties will be sound, and there will be trends in improvement over time in the intervention group but not the control group
4. Trial procedures such as randomization, blinding of assessors, contamination, and occurrence and monitoring of adverse events will be feasible and ensure the safety of participants

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. 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
2. Approved 14/12/2017, WHO Ethical Review Committee (ERC Secretariat, Avenue Appia 20, Geneva 1211, Switzerland; telephone not available; ercsec@who.int), ref: ERC.0003000

Study design
Feasibility-pilot two-arm single-blind individually randomized group treatment study

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 consists 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.

Randomisation occurs following completion of the T0 assessment. Randomisation sequences are computer generated by an independent staff member not involved in study implementation,

using random block sizes of 2 and 4. To support practical implementation and to ensure adequate numbers in the EASE group interventions, separate randomisation sequences are created for males, females, and sibling pairs. Group allocations (EASE or ETAU) are recorded on pieces of paper, which are folded and placed inside sealed, numbered, opaque envelopes. The numbered envelopes are opened in sequence by the research coordinator with the allocation assigned to the corresponding adolescent on registration lists.

Intervention Type
Behavioural

Primary outcome(s)
Psychological distress measured using the Paediatric Symptom Checklist 35 (PSC-35) youth report at baseline (T0), post-intervention (T1), and 3-month follow-up (T2)

Key secondary outcome(s))
All secondary outcomes are assessed at T0, T1, and 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 that was developed specifically for this study. The questionnaire consisted of 10 items pertaining to the level of impairment experienced with important daily activities; updated 19/06/2019: to consist 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)

2. Caregiver-reported outcomes:
2.1 Caregiver-reported child psychological distress measured using 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)

Where a caregiver has multiple children in the study, the APQ42 and K6 will only be completed once by the caregiver, while the caregiver-report PSC-35 will be completed separately for each child.

Moderators: The study is not powered for moderation effects, however, we will conduct an exploratory analysis of the potential moderating effect of child exposure to potentially traumatic events, measured at T0 via caregiver report, using a trauma checklist contextually developed for this site

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
26/07/2019

Eligibility

Key inclusion criteria
1. Aged between 10 and 14 years old
2. Reside with a caregiver who is able to provide consent
3. Screens positive for psychological distress during screening (using Child Psychosocial Distress Screener)
4. 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
67

Key exclusion criteria
1. Unaccompanied minor
2. Caregiver was not a family member, as they were not 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 intervention
4. Imminent risk of suicide
5. Currently married, due to legal consent and protection concerns

Date of first enrolment
18/09/2018

Date of final enrolment
14/02/2019

Locations

Countries of recruitment
Lebanon

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

Sponsor information

Organisation
War Child

ROR
https://ror.org/01tq9ra93

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

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?
Results article		01/03/2023	02/03/2023	Yes	No
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