

Feasibility trial of a psychological intervention with young adolescents in Lebanon

Submission date 03/10/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/10/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/03/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

Study website

<https://strengths-project.eu/en/strengths-home/>

Contact information

Type(s)

Principal Investigator

Contact name

Prof Mark Jordans

ORCID ID

<http://orcid.org/0000-0001-5925-8039>

Contact details

War Child Holland
Helmholtzstraat 61G
Amsterdam
Netherlands
1098LE
+31 (0)204227777
mark.jordans@warchild.nl

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Feasibility pilot trial

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 empirically supported 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 measure

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)

Secondary outcome measures

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.

Overall study start date

01/12/2017

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

Age group

Child

Lower age limit

10 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

64

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

Sponsor details

Helmholtzstraat 61G

Amsterdam

Netherlands

1098 LE

+31 (0)204227777

info@warchild.nl

Sponsor type

Charity

Website

<https://www.warchild.nl>

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

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

Intention to publish date

15/10/2022

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