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Family-focused psychosocial support for at-risk adolescents in Lebanon

Submission date	**Recruitment status**	[_] Prospectively registered
01/11/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/11/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/06/2024	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Adolescents living in adversity are at risk of psychological and behavioural distress. A nurturing family environment is key to the successful development and positive mental health and wellbeing of adolescents. However, very few programmes are available that address the family system. The aim of this study is to test a new family intervention with adolescents and their families in vulnerable communities in Lebanon. The family intervention is designed to improve adolescent and caregiver mental health and wellbeing and family functioning.

Who can participate?

Families with an adolescent aged 12-17 years who reside in participating communities and who are experiencing high psychological distress

What does the study involve?

Families 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. Families in one group are invited to participate in seven family sessions of about 2 hours. Families in the other group will receive the same programme but after a short delay. Various indicators of mental health and wellbeing are measured before, immediately after, and 3 months after the programme.

What are the possible benefits and risks of participating?

The likely benefits include reduced psychological distress, improved wellbeing, and improved family functioning for caregivers and adolescents. 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 (in Tripoli), Terre Des Hommes Italy, Lebanon Office (in North Beqaa), Danish Refugee Council Lebanon Office (in Tripoli)

When is the study starting and how long is it expected to run for?

September 2019 to July 2022

Who is funding the study?
1. Arts and Humanities Research Council (UK)
2. Foreign, Commonwealth and Development Office (UK)

Who is the main contact?
1. Dr Felicity Brown (War Child Holland), felicity.brown@warchild.nl
2. Dr Tania Bosqui (American University of Beirut), tb33@aub.edu.lb

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
FFPSSLebanon

Study information

Scientific Title
The effectiveness, mechanisms of change, and acceptability of Family Focused PsychoSocial Support (Family FPSS) for at-risk adolescents in Lebanon

Acronym
Family FPSS Lebanon

Study objectives
1.1. It is hypothesised that children in families assigned to receive the systemic family intervention programme will show significantly greater improvements in primary and secondary outcome measures compared to the waitlist group, at post-intervention.
1.2. It is hypothesised that these improvements will be maintained at the 3-month follow up time point for the treatment condition.
2.1. It is hypothesised that caregivers in families assigned to receive the systemic family intervention programme will show significantly greater improvements on caregiver-report secondary outcome measures compared to the waitlist group, at post-intervention.
2.2. It is hypothesised that these improvements will be maintained at the 3-month follow up time point for the treatment condition.
3. In the waitlist families who receive the intervention programme in a group format, we predict that there will be significant within-group improvements on outcome measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Approved 12/10/2021, American University of Beirut Institutional Review Board (PO Box 11-0236 F15, Riad El Solh, Beirut, 1107 2020, Lebanon; +961 (0)1 350000; irb@aub.edu.lb), ref: SBS-2021-0102
2. Approved 19/10/2021, National Mental Health Programme Lebanon (Ministry of Public Health Lebanon, Bir Hassan, Jnah, next to Ogero, Beirut, Lebanon; +961 (0)1 830300; clinicaltrials@moph.gov.lb, mentalhealth@moph.gov.lb), ref: LBCTR2021104870

Study design
Single-blind hybrid effectiveness-implementation multi-site randomized control trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Families identified as having medium to high protection risk, and an adolescent aged 12-17 years who scores above the clinical cut-off on a measure of psychological symptoms

Interventions
Randomisation will occur after T0 assessments are completed, and will be stratified by implementing partner/site. Participants will be randomly allocated to intervention or waitlist with a 1:1 ratio. The randomisation sequence will be computer-generated by a statistician located outside Lebanon, and independent of the study.

Families are randomised into the following conditions:
1. Intervention: The intervention is a six-session family intervention programme to be delivered by non-specialist facilitators. Family members will attend weekly 2-hour long sessions together, and the programme will be delivered by one facilitator with one family. The first 1.5 hours is delivered to the family unit. The final 0.5 hours consists of a brief session for the caregivers only. After the 6th session, a 7th booster session of 2 hours will be provided after approximately 1 month. The programme was developed by the study team and partners in Lebanon through formative research, and covers these main skills: identifying family values, goals, challenges, and strengths; emotional regulation; communication; problem management; managing disagreements; positive parenting for adolescents.
2. Waitlist: The waitlist families will receive the programme after post-intervention assessments (T1). They will receive the programme in a group format, and with or without concurrent child-focused programmes, to assess the feasibility and acceptability of different delivery formats.

Assessments will be conducted at pre-intervention (T0), post-intervention (T1), and 3-month follow-up for the treatment group only (T2).

Intervention Type
Behavioural

Primary outcome(s)
Child-reported mental health and behavioural symptoms measured with the 35-item Pediatric Symptom Checklist at T0, T1, T2 (the primary comparison is change from T0 to T1 between groups)

Key secondary outcome(s))
1. Child-reported wellbeing measured with the 5-item WHO-5 Wellbeing Index at T0, T1, T2 (the primary comparison is the change from T0 to T1 between groups)
2. Child-reported emotional regulation challenges measured with the 18-item Difficulties in Emotion Regulation Scale -Short Form at T0, T1, T2 (the primary comparison is the change from T0 to T1 between groups)
3. Child-reported family functioning measured with the 15-item Systemic Clinical Outcome and Routine Evaluation (SCORE) Index of Family Function at T0, T1, T2 (the primary comparison is the change from T0 to T1 between groups)
4. Caregiver-reported parenting skills measured with the War Child Parenting Scale at T0, T1, T2 (the primary comparison is the change from T0 to T1 between groups)
5. Caregiver-reported psychological distress measured with the Kessler 6 scale at T0, T1, T2 (the primary comparison is the change from T0 to T1 between groups)
6. Caregiver-reported emotional regulation challenges measured with the 18-item Difficulties in Emotion Regulation Scale -Short Form at T0, T1, T2 (the primary comparison is the change from T0 to T1 between groups)
7. Caregiver-reported family functioning measured with the 15-item Systemic Clinical Outcome and Routine Evaluation (SCORE) Index of Family Function at T0, T1, T2 (the primary comparison is the change from T0 to T1 between groups)

Mediators: The potential mediating effect of secondary outcomes on the primary outcome will be explored

Moderators: The study is not powered for moderation effects, however, the researchers will conduct exploratory analyses of moderating effects of key demographic variables (e.g. age, gender), and exposure to potentially traumatic events and current adversities (using a checklist developed for this study).

Completion date
31/07/2022

Eligibility

Key inclusion criteria
1. A single- or dual-headed household with an adolescent aged 12-17 years (male and female)
2. Identified as at-risk by the partner organisation
3. Scoring above the cutoff on the Paediatric Symptom Scale for general psychological distress
4. Gives assent and parental/legal guardian consent

One target child will be identified per family for the assessments (if multiple children meet the criteria in one family, the child who has the highest PSC score will be selected as the index child). At-risk status will be established as part of usual screening processes for focused PSS and clinical assessment by facilitators in partner organizations, who will identify and refer potential participants. Medium-to-high risk is defined for this study as being ‘vulnerable to a protection risk but not high with imminent risk (i.e. without a current protection risk that would require immediate referral to case management).

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
351

Key exclusion criteria
1. Participants will be excluded if they require immediate case management at the time of recruitment, or if they have severe psychiatric disturbance or risks requiring specialist mental health services (assessed by partner organisations as part of usual routine assessment and referral systems)
2. Unaccompanied and separated minors, and children who are married, will not be included in the study, due to challenges with the legal consent of guardians
3. Families engaged in case management or in immediate need of case management at the time of outreach, will not be included. This is because those in case management are likely to be receiving sufficient other services. If the need for case management arises during the program then families can be referred as usual and still receive the program

Date of first enrolment
02/11/2021

Date of final enrolment
08/04/2022

Locations

Countries of recruitment
Lebanon

Study participating centre
War Child Holland
Tripoli
Lebanon
-

Study participating centre
Terre Des Hommes Italy
North Beqaa
Lebanon
-

Study participating centre

Danish Refugee Council
Tripoli
Lebanon
-

Sponsor information

Organisation
American University of Beirut

ROR
https://ror.org/04pznsd21

Organisation
War Child

ROR
https://ror.org/01tq9ra93

Funder(s)

Funder type
Research council

Funder Name
Arts and Humanities Research Council

Alternative Name(s)
Arts and Humanities Research Board, AHRC, AHRB

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Funder Name

Foreign, Commonwealth and Development Office

Alternative Name(s)
Foreign, Commonwealth & Development Office, Foreign, Commonwealth & Development Office, UK Government, FCDO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Mark Jordans (Mark.Jordans@warchild.nl) and Tania Bosqui (tb33@aub.edu.lb). Requests for sharing of de-identified data sets without personal information will be considered after the publication of all planned primary and secondary analyses, for up to 10 years after the study is completed, and prior to deletion of raw data sets. Data sharing requests will be considered from researchers holding relevant IRB approvals to conduct planned analyses, and who:
1. Submit a request in writing to the study team, including their planned research question, planned analyses, publication plan, ethical approval, researcher CVs, and data management plan demonstrating data security complying with War Child and AUB data management policies
2. The research question is not addressed in the publication plan of our research team
3. The research question is deemed to be important and relevant by the research team
4. The analysis methods are deemed to be appropriate, and feasible with the data

Consent was collected from study participants to share de-identified data with external researchers.
Data will be shared for research purposes only. Anyone with whom the data is shared needs to sign a data-sharing agreement for data processors, including the GDPRs standard contractual clauses. Data will be shared as a complete data file with only the data requested, via secure transfer method specified in the Data Sharing Agreement, and will be de-identified by removing the study participant ID. Participant personal information will not be shared.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		18/04/2022	20/04/2022	Yes	No
Participant information sheet	Assent form in Arabic		05/11/2021	No	Yes
Participant information sheet	Assent form in English		05/11/2021	No	Yes

Participant information sheet	Consent form in Arabic	05/11/2021	No	Yes
Participant information sheet	Consent form in English	05/11/2021	No	Yes