Assistant Professor of Clinical Psychology

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Main Information

Primary registry identifying number
LBCTR2021104870

Protocol number
SBS-2021-0102

MOH registration number
Pending

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
13/10/2021

Primary sponsor
Tania Bosqui

Primary sponsor: Country of origin
UK

Date of registration in primary registry
26/11/2021

Date of registration in national regulatory agency
13/10/2021

Public title
Assistant Professor of Clinical Psychology

Acronym

Scientific title
Dr

Acronym

Brief summary of the study: English

There is a small yet growing evidence base for psychosocial interventions in conflict and humanitarian emergencies, however adolescent mental health is often under-researched and drastically under-resourced. Families play a critical role in ensuring adolescent mental health and protection outcomes, yet there has been limited research evaluating family interventions in these settings. This study aims to develop and test a family systemic program that can be delivered alongside the existing UNICEF Focused-Psychosocial Support (FPSS) curriculum for at-risk adolescents in Lebanon. Phase 1 involved the development and piloting of the family module, while Phase 2 will evaluate the program using a single-blind hybrid effectiveness-implementation randomized control trial. Through the development and evaluation of an adjunctive family systemic program we will enhance current humanitarian programming by addressing the child's ecology, while also addressing a significant weakness of the current evidence base for at-risk adolescents and their families in conflict-affected contexts. The program aims to be systemic, culturally and contextually relevant, and sustainable. The participatory, hybrid effectiveness-implementation design will ensure that the intervention is optimally contextualized, and suited for wide-scale implementation.

Brief summary of the study: Arabic

هناك قاعدة أدلة صغيرة لكن متنامية للتدخلات النفسية والاجتماعية في حالات النزاع والطوارئ الإنسانية، وغالبًا ما تشهد الصحة النفسية للمراهقين قلّة في الأبحاث ونقصاً كبيراً في الموارد. تلعب العائلات دورًا أساسياً في ضمان الصحة النفسية للمراهقين وحمايتهم، ومع ذلك كان هناك بحث محدود لتقييم التدخلات الأسرية في هذه السياقات. تهدف هذه الدراسة إلى تطوير واختبار برنامج نُظمي للأسرة يمكن تقديمه جنباً إلى جنب مع منهج اليونيسف للدعم النفسي والاجتماعي المركز (FPSS) للمراهقين المعرضين للخطر في لبنان. تضمنّت المرحلة الأولى تطوير واختبار وحدة الأسرة، في حين أن المرحلة الثانية ستقيّم البرنامج باستخدام تجربة عشوائية مضبوطة وفردية التعمية تمزج بين الفعالية والتنفيذ. عبر تطوير وتقييم برنامج نُظمي عائلي مساعد ، سنعمل على تعزيز البرمجة الإنسانية الحالية من خلال معالجة بيئة الطفل، مع معالجة الضعف الكبير في قاعدة الأدلة الحالية للمراهقين المعرضين للخطر وأسرهم في السياقات المتأثرة بالنزاع. يهدف البرنامج إلى أن يكون منهجيًا ومستداماً وملائما ثقافياً وسياقياً. سيضمن التصميم التشاركي المازج بين الفعالية والتنفيذ أن يكون التدخل مثالياً لسياقه ، ومناسبًا للتنفيذ على نطاق واسع.

Health conditions/problem studied: Specify

Parent and adolescent mental health and wellbeing.

Interventions: Specify

A 7 session family focused psychosocial support program, named the Sawa A2wa Family Program.

Key inclusion and exclusion criteria: Inclusion criteria

Inclusion criteria for participation in the research study are 1) a single- or dual-headed household with an adolescent aged 12-18 (male and female), 2) identified as at-risk by the partner organization, 3) scoring above the cutoff on the Pediatric Symptom Scale for general mental health, and 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 referral 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). Once potential participants give verbal permission to be contacted by the research team, and have consented/assented to take part, they will be screened fully by the research team (including administering the short-form of the Pediatric Symptom Checklist) to ensure they meet the inclusion criteria and that the program is relevant to their needs.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

12

Key inclusion and exclusion criteria: Age maximum

17

Key inclusion and exclusion criteria: Exclusion criteria

Participants will be excluded if they have severe psychiatric disturbance or risks requiring specialist mental health services (assessed by partner organizations as part of usual routine assessment and referral systems), if they are in immediate high risk requiring case management, or if they do not consent/assent. Cases requiring specialized services will not be invited to participate because of the level of vulnerability, potential issues of capacity, and because the family intervention is unlikely to be pitched at the right level for their needs, though they will be offered alternative relevant services. The decisions are made using the usual protocol for focused PSS programs within each partner organization by experienced mental health and child protection teams. Due to the high level of need within all communities in Lebanon, and the need to prevent resource-based tension between groups, we will include families from all nationalities, religions, and refugee status.

Type of study

Interventional

Type of intervention

Other

Type of intervention: Specify type

Family systemic focused psychosocial support

Trial scope

Other

Trial scope: Specify scope

Family systemic focused psychosocial support

Study design: Allocation

Randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

Active

Study phase

1 to 2

Study design: Purpose

Other

Study design: Specify purpose

Psychosocial family support

Study design: Assignment

Single

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

Not applicable.

Therapeutic indication

Not applicable.

Therapeutic benefit

It is expected that the research directly and immediately benefits the participants in the RCT (through receiving family psychosocial support) at no cost to participants. Research clearly indicates benefits of family-based interventions but this not currently available for most vulnerable families living in Lebanon. If successful, we aim to integrate the module into standard care alongside existing focused PSS activities. These benefits to the community are likely to occur gradually in the 1-2 years following the analysis and publication of the trial data.

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

None retained

Biospecimen description

Not applicable.

Target sample size

270

Actual enrollment target size

351

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

15/11/2021

Date of study closure: Type

Anticipated

Date of study closure: Date

30/09/2022

Recruitment status

Pending

Recruitment status: Specify

Date of completion

IPD sharing statement plan

Yes

IPD sharing statement description

Collection and management of data will be in accordance with IRB and American Psychological Association (APA) standards, as well as the EU General Data Protection Regulation (since WCH is headquartered in Europe). All project staff will be provided with Good Clinical Practice (GCP) training through AUB, and additional training addressing research ethics, assent/consent, and child interviewing.

Short term storage and backup
Data will be stored, short-term, on secure servers, accessed through individual password protected accounts on password protected encrypted computers. Only project members who require access will have an account. Unique participant identifiers will be used, with outcome data stored separately from personal information. Identifying information will be stored on REDCap, a secure web-based system specifically designed for clinical trials, and measures will be completed and data stored on LimeSurvey, a secure survey software tool accessible through AUB. Excel files will also be used to track progress, and these will use only unique identifiers (no names), will be password protected, and stored on Dropbox, with encryption via Boxcryptor.

Long term storage
Personal identifiers and audio recordings of semi-structured interviews will be destroyed after 5 years from publication of the study, in keeping with APA and IRB ethical standards for psychological research. All other data (raw outcome data, qualitative transcripts) will be preserved by the Department of Psychology, AUB, for long term archiving in AUB's secure data bank. This is appropriate because it provides security against loss of data, and access if needed in the longer term.

Data sharing
Data will be co-owned by AUB and WCH. Non-identifiable data (such as unlinked questionnaire data) will be held by the research team for up to 3 years, for analysis. After 3 years, non-identifiable data will be made available through AUB's data bank (see http://aub.edu.lb.libguides.com/data_services/databank). The PI will be responsible for managing data and responding to access requests from external users, provided data sharing agreements detailing responsibilities of users in handling and sharing data have been agreed and signed. In line with open science initiatives, external researchers will be able to access non-identified data via information provided in publications. Identifiable data will be archived on RedCap, in a locked filing cabinet in the implementing partner organization (consent/assent forms), or on a password protected encrypted computer (audio recordings) for 5 years and then deleted/destroyed, in keeping with usual practice for psychological research. This data will not be shared with external users to protect confidentiality and anonymity.

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
American University of Beirut	Family ID

Sources of Monetary or Material Support

Name
AHRC/ DfID (award number:103916)

Secondary Sponsors

No Sponsors

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Tania Bosqui	Department of Psychology, AUB	Lebanon	AUB ext: 4370	tb33@aub.edu.lb	American University of Beirut
Scientific	Tania Bosqui	Department of Psychology, AUB	Lebanon	AUB ext: 4370	tb33@aub.edu.lb	American University of Beirut

Centers/Hospitals Involved in the Study

No Centers/Hospitals

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Other American University of Beirut	12/10/2021	Nadine Kamal	nk93@aub.edu.lb	AUB ext: 5455

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
Mental health and wellbeing	Mental disorder, not otherwise specified (F99)	Mental health, wellbeing

Interventions

Intervention	Description	Keyword
Sawa A2wa Family Program	The 7 session family focused psychosocial support program includes 90 minute weekly family session and 30 minute weekly parenting sessions, with the exception of the 7th booster session delivered one month after the end of the program. The program will be delivered via non-specialists and aims to improve family functioning and adolescent mental health.	Family systemic, psychosocial

Primary Outcomes

Name	Time Points	Measure
Adolescent mental health	Pre, post, 3 month follow-up	Pediatric Symptom Checklist

Key Secondary Outcomes

Name	Time Points	Measure
Wellbeing	Pre, post, 3 month follow-up	WHO-5 Well-Being Index
Family functioning	Pre, post, 3 month follow-up	SCORE Index of Family Functioning and Change
Emotion regulation	Pre, post, 3 month follow-up	Difficulties in Emotion Regulation Scale
Child protection risk, stress and adversity	Pre, post, 3 month follow-up	Standardized measure developed for the study
Parenting	Pre, post, 3 month follow-up	Parenting Questionnaire
Caregiver mental health	Pre, post, 3 month follow-up	Kessler 6

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