

Helping refugee parents thrive: assessing the readiness of the caregiver support intervention for a fully powered evaluation with Syrian refugees in Lebanon

Submission date 05/08/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/08/2019	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/01/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

War and displacement lead to high levels of stress for parents and others who care for children. High stress has been shown to negatively affect parenting in refugee families (and other families affected by war). Several programs have been developed to strengthen parenting among refugees; however, they typically focus on improving parenting knowledge and skills, without helping parents cope with stress, anxiety, and frustration resulting from their difficult living conditions. In contrast, the Caregiver Support Intervention (CSI), developed by War Child Holland, aims to strengthen parenting among refugees in two ways: (1) by helping reduce stress and improve emotional wellbeing among parents, and (2) by increasing warm, responsive parenting and the use of non-violent discipline, and reducing the use of harsh parenting such as yelling at, insulting, or physically hurting children. The CSI is a 9 session group intervention, lasting 2 hours each session, and is co-led by trained community members. Groups are offered separately for women and men.

The primary aim of this study is to assess the effectiveness of our evaluation methodology, prior to conducting a fully powered study of the effectiveness of the CSI with Syrian refugees in North Lebanon.

Who can participate?

All Syrian parents in the three communities where the study will take place in greater Tripoli, Lebanon are eligible, provided they have a child between the ages of 3 and 12, have not previously taken part in a parenting program, and both parents or caregivers are willing to participate in the study. At least 75% of the sample will be Syrian; however, in keeping with War Child Holland's policy of making all its programs available to members of the host society, up to 25% of participants may be Lebanese or Palestinian.

What does the study involve?

A total of 36 families (72 parents/caregivers) will be recruited into the study. After completing a

20-30 minute set of questionnaires with the assistance of trained research assistants, participating families will be randomly assigned to be in a CSI group or a waitlist control group. Families in the CSI group will attend the 9 session CSI program in the office of a local community-based organization. After the 9th session, all participants, including those in the waitlist control group, will be asked to complete the questionnaires again. After the second assessment, all parents in the waitlist control group will be invited to participate in the CSI program. Participants in the CSI arm of the study will be invited to participate in a two-hour focus group, in which they will be asked about their experience in the intervention, to describe its benefits and any adverse experiences, and to offer feedback for how the intervention might be improved.

What are the possible benefits and risks of participating?

Possible benefits for participants include lower stress, improved emotional wellbeing, more effective parenting, and improved emotional and behavioral wellbeing of their children. We do not foresee any risks to participating, based on our prior implementation of the CSI during its development phase. Participants may experience some inconvenience from completing the questionnaires; however, the assessments will be brief, and transportation costs to and from the assessments, along with refreshments, will be provided.

Where is the study run from?

The study will run in Lebanon, and be managed on a day to day basis by the Lebanon-based team in War Child Holland's Lebanon offices. The study will be under the direction of the Principal Investigator, Dr. Kenneth Miller, who is based in War Child Holland's Amsterdam office.

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

The study will run from 1 November 2017 - 31 August 2019.

Who is funding the study?

1. Bernard van Leer Foundation
2. Open Society Foundations

Who is the main contact?

Dr Kenneth Miller

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

A pilot randomized controlled trial of the caregiver support intervention with Syrian refugees in Lebanon

Study objectives

The primary objective is to assess the evaluation methods through a pilot (feasibility) randomized control trial of the CSI with Syrian refugees in Tripoli governate in North Lebanon, and make any necessary adaptations before moving on to a fully powered RCT to test the effectiveness of the CSI in the same target population

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 19/11/2018, University of Balamand IRB (Faculty of Arts and Social Sciences, University of Balamund, 207 Fares Hall, El Koura, Lebanon; +9616930250; samer.annous@balamand.edu.lb), ref: n/a

Study design

A pilot randomized controlled trial with 1:1 allocation ratio and a waitlist controlled design

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

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

Caregiver stress and stress-related compromised parenting

Interventions

The Caregiver Support Intervention (CSI) is a nine session weekly group intervention aimed at strengthening caregiver psychosocial wellbeing and parenting in refugee and other war-affected communities. The study will use a waitlist control condition. 72 families in which both caregivers are participating will be randomized into the CSI or WLC arms. There will be two assessments: baseline and endline. All assessments and the intervention will be conducted in the offices of community-based organizations in the target communities.

Following the baseline assessment, participants will be randomized into an intervention group (the Caregiver Support Intervention or CSI) or a waitlist control group. Participants in the CSI group will be offered a nine-session weekly group intervention focused on (1) reducing stress and strengthening psychosocial wellbeing, and (2) strengthening parenting (increasing warm and responsive parent-child interactions and decreasing harsh parenting). The sessions last two hours, and are co-facilitated by trained and supervised non-mental health specialists.

Groups will be offered separately for women and men.

Randomization will occur following baseline assessment. One caregiver from each family will draw a lollipop from an opaque bag filled with an even number of green and red lollipops corresponding to the number of families in the study. The color will be noted on the master spreadsheet. After all participating families have chosen a color, a coin will be tossed by an employee of the organization, who is unaffiliated with the study, to determine the group assignment of each color (CSI or WLC).

After the endline assessment, WLC group participants will be offered the opportunity to participate in CSI groups.

Outcomes of this pilot RCT will be the feasibility and acceptability of the evaluation methodology for the CSI intervention. Findings will inform the methodology of the definitive RCT. Although this is not an effectiveness study and is not powered to reliably assess between-group differences, within group changes on all outcome measures will be assessed to see whether there are changes in the expected direction in the CSI group.

Intervention Type

Behavioural

Primary outcome measure

Parenting assessed using a new measure developed for this study. It was assessed at baseline and endline (9 weeks).

Secondary outcome measures

1. Parental warmth and responsiveness will be measured using a subscale of a new parenting measure developed for this study (developed for this study, available on request), at baseline and endline.
2. Child psychosocial wellbeing will be measured using the Kindler-Parent Report and Kindler Child self-report by index children ages 7-12, at baseline and endline.
3. For families with a child between 0-3 years old, an additional assessment will be made of infant and toddler mental health using the CREDI, at baseline and endline. This will be strictly an exploratory outcome. 0-3 children will be assessed in addition to, not in place of, the index child (ages 3-12).
4. Caregiver distress will be measured using the K10 at baseline and endline.
5. Caregiver psychosocial wellbeing will be measured using the Warwick Edinburgh Mental Wellbeing Scale at baseline and endline.
6. Caregiver stress will be measured using the Caregiver Stress Questionnaire (developed for this study, available on request), at baseline and endline.
7. Caregiver stress management will be measured using the Stress Management Questionnaire (developed for this study, available on request) at baseline and endline.

Overall study start date

01/11/2017

Completion date

30/04/2019

Eligibility

Key inclusion criteria

1. Syrian refugee or Lebanese host society parents or other primary caregivers of children aged 3-12.
2. Both parents/caregivers are willing to participate in the study.

Participant type(s)

Carer

Age group

Mixed

Sex

Both

Target number of participants

36 families with 72 caregivers, and 36 index children.

Total final enrolment

151

Key exclusion criteria

Participant exclusion criteria

1. Unable to complete questionnaires even with the assistance of research assistant.
2. Previous participation in a parenting intervention.

Date of first enrolment

20/01/2019

Date of final enrolment

28/01/2019

Locations

Countries of recruitment

Lebanon

Netherlands

Study participating centre

War Child Holland

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Sponsor information

Organisation

War Child Holland

Sponsor details

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Sponsor type

Charity

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ROR

<https://ror.org/01tq9ra93>

Funder(s)

Funder type

Charity

Funder Name

Bernard van Leer Foundation

Alternative Name(s)

Fundación Bernard van Leer

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Netherlands

Funder Name

Open Society Foundations

Alternative Name(s)

Open Society Institute, OSF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Results and Publications

Publication and dissemination plan

Findings from the study will be submitted for publication in at least one peer reviewed journal and shared in an international conference.

Intention to publish date

30/11/2019

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2020	23/11/2020	Yes	No
Other publications		29/01/2025	30/01/2025	Yes	No