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# Helping refugee parents thrive: an evaluation of the caregiver support intervention with Syrian refugees in Lebanon

**Submission date**
31/07/2019

**Recruitment status**
No longer recruiting

**Registration date**
05/08/2019

**Overall study status**
Completed

**Last Edited**
04/07/2023

**Condition category**
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 aims of this study are to test the effectiveness of the CSI among Syrian refugee families in northern 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 240 families (480 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, and again 3 months later. After the third assessment, all parents in the waitlist control group will be invited to receive the CSI program.

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.

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 July 2019 - 31 December 2020.

Who is funding the study?
The study is funded by the Open Society Foundations, the ELMA Foundation, and the Fred Foundation.

Who is the main contact?
Kenneth Miller
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# Contact information

### Type(s)
Public

### Contact name
Dr Kenneth Miller

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
A randomized controlled trial of the caregiver support intervention with Syrian refugees in Lebanon

### Acronym
N/A

### Study objectives
The Caregiver Support Intervention will be superior to a waitlist control group on strengthened parenting, improved parental mental health and psychosocial wellbeing, and improved child psychosocial wellbeing at endline and three month follow up.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Current ethics approval as of 18/11/2019:
Approved 23/09/2019, University of Balamand IRB Committee (Institutional Review Board, University of Balamand Faculty of Arts and Science,
PO Box 100, Tripoli, Lebanon; +961 6 930 250; samer.annous@balamand.edu.lb), ref: N/A

Previous ethics approval:
Not provided at time of registration

### Study design
This is a parallel group randomized control trial (RCT), with an intent to treat design, a 1:1 allocation ratio, and a waitlist control comparison condition.

### 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
Compromised parenting due to armed conflict and forced migration

## Interventions
The Caregiver Support Intervention (CSI) is a 9 session weekly group intervention aimed at strengthening caregiver psychosocial wellbeing and parenting. The CSI will be compared to a waitlist control condition. 240 families in which both caregivers are participating will be randomized into the CSI or WLC arms. 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 colour, 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). The study will be conducted in two waves, with thee assessments per wave: baseline, endline, and 3 month follow up. 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. There will be two additional assessments: immediately post-intervention and at three months. After the three-month follow-up, WLC group participants will be offered the opportunity to participate in CSI groups.

Randomization: Randomization will be done at the family level to ensure that caregivers from the same family are not assigned to different arms of the study. To facilitate understanding and acceptance of the randomization process, we have adapted a methodology successfully used by Panter-Brick et al. (2017) in their research with Syrian families in Jordan. After participants have completed the baseline assessment, our a research staff member will explain the randomization process to participants, inviting them to draw a lollipop out of an opaque bag containing an equal number of red and green lollipops, corresponding to the number of participants at the assessment. The first caregiver to be assessed from each family will draw the lollipop that determines that family’s group assignment. Once all data are collected from the full sample, the group assignment represented by each color will be determined by a coin toss done by a WCH staff member based in Amsterdam who is unaffiliated with the study. We used this methodology successfully in our pilot RCT of the CSI.

## Intervention Type
Behavioural

## Primary outcome measure
Parenting is measured using a new parenting measure developed for this study (available on request) at baseline, endline, and 3 month follow up.

## Secondary outcome measures

1. Parental warmth and responsiveness will be measured using a subscale of a new parenting measure developed for this study, at baseline, endline, and 3 month follow up.
2. Child psychosocial wellbeing will be measured using the Kindle-Parent Report at at baseline, endline, and 3 month follow up.
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, endline, and 3 month follow up. This will be strictly an exploratory outcome. O-3 children will be assessed in addition to, not in place of, the index child (ages 3-12).
4. Caregiver distress will measured using the K10 at at baseline, endline, and 3 month follow up.
5. Caregiver psychosocial wellbeing will be measured using the Warwick Edinburgh Mental Wellbeing Scale at baseline, endline, and 3 month follow up.
6. Caregiver stress will be measured using the Caregiver Stress Questionnaire, at baseline, endline, and 3 month follow up.
7. Caregiver stress management will be measured using the Stress Management Questionnaire (developed for this study, available on request) at at baseline, endline, and 3 month follow up.

### Overall study start date
01/07/2019

### Completion date
31/12/2020

## 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
Adult

### Sex
Both

### Target number of participants
240 families with 480 parents/caregivers

### Total final enrolment
480

### Key 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
25/09/2019

**Date of final enrolment**
31/01/2020

# Locations

**Countries of recruitment**
Lebanon

Netherlands

**Study participating centre**
**War Child Holland**
Helmholtzstraat 61g
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# Sponsor information

**Organisation**
War Child Holland

**Sponsor details**
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**Sponsor type**
Charity

**Website**
http://www.warchild.nl

**ROR**
https://ror.org/01tq9ra93

# Funder(s)

**Funder type**
Charity

**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

**Funder Name**
ELMA Foundation

**Alternative Name(s)**

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
South Africa

**Funder Name**
Fred Foundation

# Results and Publications

**Publication and dissemination plan**
Current publication and dissemination plan as of 09/06/2022:
The main results of this trial have been accepted for publication in Journal of Child Psychology and Psychiatry.

Previous publication and dissemination plan:
We plan to submit the findings of this study for publication in a peer reviewed journal. Study findings will also be disseminated through professional networks and at a minimum of one professional conference. If the study shows the CSI to be effective, we will prepare an

adaptation manual to ensure that that the CSI is ready for scaling within and beyond the network of countries in which War Child Holland is active.

## Intention to publish date
30/09/2022

## Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing statement as of 09/06/2022:
The datasets generated and/or analyzed during the current study during this study are available on request from the authors

Previous individual participant data (IPD) sharing statement:
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

## IPD sharing plan summary
Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 18/03/2020 | 01/12/2020 | Yes | No |
| Results article | | 15/07/2022 | 18/07/2022 | Yes | No |
| Results article | | 01/07/2023 | 04/07/2023 | Yes | No |