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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

Registration date
06/08/2019

Overall study status
Completed

Last Edited
30/01/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] 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 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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Prevention

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

Key secondary outcome(s))
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 Kindle-Parent Report and Kindl Child self-report by index children ages 7-12, at 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. 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 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 at baseline and endline.

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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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
Helmholtzstraat 61g
Amsterdam
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Sponsor information

Organisation
War Child Holland

ROR
https://ror.org/01tq9ra93

Funder(s)

Funder type
Charity

Funder Name
Bernard van Leer Foundation

Alternative Name(s)

The Van Leer Foundation, Van Leer Foundation, Fundación Bernard van Leer, La Fundación Van Leer, Fundação Van Leer, De Van Leer Foundation,

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

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