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Family-focused psychosocial support in Jordan

Submission date
19/10/2022

Recruitment status
No longer recruiting

Registration date
21/10/2022

Overall study status
Completed

Last Edited
14/06/2024

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
Families experiencing forced displacement and other adversities face multiple risk factors for poor caregiver and child mental health. The aim of this study is to test a new intervention with Iraqi, Syrian, and Jordanian families experiencing multiple challenges, in Amman Jordan. The family intervention is designed to reduce high psychological distress, improve positive parenting, and improve family relationships.

Who can participate?
Families with an adolescent aged 10-17 years, experiencing multiple psychosocial challenges, and with caregivers and at least one adolescent consenting to take part.

What does the study involve?
Families who are interested in participating will take part in a screening interview with caregivers to determine their eligibility. If eligible, all family members will complete baseline assessments. Following this, they will be randomly allocated into two groups. Families in one group are invited to participate in the intervention which consists of up to 15 sessions of 90 minutes each, some sessions are with the whole family, some with caregivers alone. The number and topic of sessions depends on the family's needs and preferences. Families in the other group receive enhanced treatment as usual, consisting of the provision of a list of services available by the implementing community-based organisation, as well as other organisations in the area, facilitation of referrals for urgent needs, and availability of a three-session financial literacy large group workshop. Various indicators of mental health, wellbeing, and family relationships will be measured before and after the completion of the intervention.

What are the possible benefits and risks of participating?
Likely benefits include improved family relationships, reduced psychological distress and improved well-being. Discussion of difficult feelings may lead to temporary increases in psychological distress. In small previous studies, this risk has not been observed to occur.

Where is the study run from?
Collateral Repair Project in Hashmi al Shamali, and War Child Jordan

When is the study starting and how long is it expected to run for?
December 2021 to July 2022

Who is funding the study?
This study was commissioned by the German Federal Ministry for Economic Cooperation and Development through the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) Regional Project “Psychosocial Support for Syrian/Iraqi Refugees and IDPs”

Who is the main contact?
Dr Felicity Brown, febrown@unicef.org

Contact information

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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
Feasibility trial of a family systemic intervention for families facing multiple psychosocial problems in Jordan

Acronym
Nurturing Families Jordan

Study objectives
1. The feasibility trial will provide estimates of recruitment, screening, completion, and retention rates for the Nurturing Families intervention and follow-up assessments
2. Delivery of Nurturing Families intervention by trained non-specialists with Iraqi, Syrian, and Jordanian families living an urban community in Amman Jordan will be feasible and acceptable
3. Outcome measures will be feasible, their psychometric properties will be sound, and there will be trends in improvement over time in the intervention group but not the control group
4. Trial procedures such as randomization, blinding of assessors, contamination, and occurrence and monitoring of adverse events will be feasible and ensure the safety of participants and validity of results.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/02/2022, Institutional Review Board of Jordan University of Science and Technology/King Abdullah University Hospital (PO Box 630001, Irbid 22110, Jordan; +962 (0)2 7200610), ref: 80/147/2022

Study design
Feasibility-pilot two-arm single-blind individually randomized group treatment study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple psychosocial problems within the family

Interventions
Families meeting eligibility criteria are randomised to the following two conditions.
1. The Nurturing Families program. This is a family systemic psychosocial intervention based on

empiricallysupported strategies for emotional distress, family functioning, and parenting. It consists of 7 x 90-minute whole-family sessions with additional 30-minute sessions for caregivers. Content includes: identifying family goals, values, strengths, and challenges; communication skills; emotion regulation skills; problem management skills; solving disagreements; accessing social support. Following this, families participate in optional advanced modules, dependent on their needs and preferences. Each advanced module is between 1-4 sessions and covers conflict management (whole family), positive parenting (caregivers only), caregiver emotional distress (caregivers only). Participants in this group also receive enhanced treatment as usual as outlined below in (2).

2. The control condition consists of enhanced treatment as usual (ETAU), which involves the provision of a list of services available by the implementing community-based organisation, as well as other organisations in the area, facilitation of referrals for urgent needs, and availability of a three-session financial literacy large group workshop.

Randomisation occurs following the completion of the baseline assessment. Randomisation sequences are computer generated by an independent staff member not involved in study implementation, based in Amsterdam. Registration lists are sent to this staff member, who assigns the allocations to participants and shares allocations with the implementation team in Jordan.

Intervention Type
Behavioural

Primary outcome(s)
1. Adolescent- and caregiver-reported family functioning assessed using the SCORE at baseline and endline
2. Caregiver psychological distress assessed using the Kessler 10 at baseline and endline
3. Positive parenting assessed using a tool developed by War Child Holland at baseline and endline

Key secondary outcome(s))
Measured at baseline and endline:
1. Caregiver-reported adolescent symptoms assessed using the Pediatric Symptom Checklist 35
2. Adolescent-reported symptoms assessed using the Pediatric Symptom Checklist 17
3. Adolescent wellbeing assessed using the Kid-KINDL
4. Caregiver emotion regulation assessed using the Difficulties in Emotion Regulation Scale
5. Impact of self-defined problems assessed using the PSYCHLOPS
Measures are collected from each consenting caregiver and each consenting adolescent aged 10-17 years. Where there are multiple adolescents, the caregiver completes the PSC-35 for each.

As this is a pilot feasibility study, the researchers also collect measures on:
1. Attendance at sessions measured using attendance logs at each session during intervention delivery
2. Fidelity of implementation of the intervention measured using a structured checklist during intervention delivery
3. Facilitator competency of implementation of the intervention measured using a structured checklist during intervention delivery
4. Masking of research assistants measured using a structured questionnaire completed by assessors at endline
5. Spill-over effects between intervention and control groups measured using structured

interview questions asked to families at endline
6. Number and nature of adverse events measured using adverse event notification forms submitted by study staff during conduct of the study

Completion date
26/07/2022

Eligibility

Key inclusion criteria
Families must meet the following criteria:
1. Speak Arabic
2. Have a child aged 10-17 years
3. Have two or more psychosocial problems causing significant impact, from: adolescent distress, caregiver distress, parenting challenges, family relationship challenges
4. All caregivers provide consent for the family to take part, and at least one child assents to taking part
5. Families of any nationality will be able to take part, but in line with the research questions relating to Iraqi, Jordanian, and Syrian families, the researchers will aim to achieve a mixed sample representing each of these nationalities equally
6. Families of any composition (i.e. single-headed, dual-headed, mixed-generations) will be included, provided there is a legal guardian able to provide consent and take part in the programme and study

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Families where there are safety concerns around whole-family sessions will not be included
2. Participants will not be included if they have severe psychiatric disturbance or risks requiring specialist mental health or protection services (assessed by a psychologist), or if they do not consent/assent. Cases requiring specialised 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.
3. Family members with a significant disability that impacts participation in the programme or assessments (that cannot be overcome with reasonable adjustments) will not be included, and participants will instead be referred to other available services that are able to meet their needs
4. Unaccompanied minors, and children who are married, will not be included in the study, due to

challenges with the legal consent of guardians
5. Families engaged in 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

Date of first enrolment
01/03/2022

Date of final enrolment
27/03/2022

Locations

Countries of recruitment
Jordan

Study participating centre
Collateral Repair Project
Salti Al-Ibrahimi St. 13, Hashmi al Shamali
Amman
Jordan
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Sponsor information

Organisation
War Child

ROR
https://ror.org/01tq9ra93

Funder(s)

Funder type
Industry

Funder Name
Deutsche Gesellschaft für Internationale Zusammenarbeit

Alternative Name(s)
German Corporation for International Cooperation GmbH, German Corporation for International Cooperation GmbH), GIZ

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

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). 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 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 the secure transfer method specified in the Data Sharing Agreement, and will be de-identified by removing the study participant ID. Participants' 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?
Results article		11/04/2024	14/06/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes