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The key ingredients of supporting conflict-affected caregivers: a randomized controlled trial with mediation analysis

Submission date	**Recruitment status**	[X] Prospectively registered
22/01/2025	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
27/01/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/09/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Research has shown that caregiver psychosocial wellbeing significantly affects parenting practices and child psychosocial wellbeing. However, most interventions aimed at improving parenting assume that sub-optimal parenting is caused by a lack of knowledge and skills. Therefore, the BeThere caregiver support intervention—a nine-week preventive group intervention for primary caregivers of children aged 3–14 affected by armed conflict and forced migration—aims to improve child wellbeing both by improving caregiver wellbeing and by directly addressing parenting practices.
This study aims to test the effectiveness of BeThere and to explore how it achieves its effects.

Who can participate?
The study is open to Dinka-speaking caregivers of children aged 3-14 years in five communities in Bor County, South Sudan. Caregivers must be at least 18-years of age and provide consent for their participation. We also seek to evaluate the effects of BeThere on participating caregivers' children using child-reported outcomes among a subsample of children aged 7–14. Caregiver consent and child assent is required for child participation.

What does the study involve?
960 caregivers will be recruited. After completing the baseline questionnaires administered by trained research assistants, participating families will be randomly assigned to be in a BeThere group or a waitlist control group. Families in the BeThere group will attend the 9-session program immediately. Halfway through the sessions, all participants, including those in the waitlist control group, will be asked to complete the questionnaires again. This is repeated after the last session and again 3 months later. After the third assessment, all parents in the waitlist control group will be invited to receive the full program. The primary change we will be measuring is the change in caregivers' parenting practices. We will also measure change in caregivers' and children's psychological wellbeing.

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. There are minimal risks involved, but participants can withdraw at any time without any impact on the support they receive. The study will ensure confidentiality and address any concerns participants may have.

Where is the study run from?
The study will run by the War Child Alliance Country Office in South Sudan. The study will be under the direction of the Principal Investigator, Prof. Dr. Mark Jordans, based in War Child Alliance's Amsterdam office.

When is the study starting and how long is it expected to run for?
January 2024 to September 2025.

Who is funding the study?
The study is funded by Sint Antonius Stichting Projecten (Netherlands)

Who is the main contact?
Prof. Dr. Mark Jordans, mark.jordans@warchild.net

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SS4027

Study information

Scientific Title
Evaluating the effectiveness of a nine-week preventative group psychosocial support intervention for primary caregivers of children aged 3-14 in Bor county, South Sudan: a randomized controlled trial with mediation analysis comparing parenting and psychosocial outcomes with a waitlist control group

Study objectives
The BeThere/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
Ethics approval required

Ethics approval(s)
approved 04/11/2024, University of Juba Ethics Committee (P.O. Box 82 University Street, Juba, - , South Sudan; +211 920505851; info@uoj.edu.ss), ref: -

Study design
Two-armed parallel group randomized controlled trial with an intent to treat design a 1:1 allocation ratio and a waitlist control comparison condition

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Compromised parenting due to armed conflict and forced migration

Interventions
BeThere/Caregiver Support Intervention is a nine-session weekly group intervention, co-facilitated by trained non-mental health professionals, who receive 6 days of training, three on-site observations with feedback, and weekly supervision. Groups are offered separately to women and men and are run with 10–12 participants. Sessions 1–4 are focused on strengthening caregiver wellbeing, with individual sessions on understanding and managing stress, disengaging from rumination, and coping with anger and frustration, all while developing the group as a socially supportive setting. Sessions 5–8 focus on strengthening parenting under conditions of

adversity (i.e., increasing awareness of the impact of stress on parenting, increasing positive parent–child interactions and the use of non-violent discipline methods, and reducing harsh parenting). Session 9 involves a review and closing of the intervention. In all but the final session, participants learn a new relaxation or stress management technique, drawn or adapted from the mindfulness and stress management practice. These techniques are also provided to participants in Dinka on mp3 files, which they can listen to on their smart phones or on mp3 players provided at the start of the program. Participants are encouraged to practice these activities at least three times each week. A considerable amount of time is spent at the start of each session reviewing the home practice and collectively problem-solving any barriers to practicing the techniques.

BeThere will be compared to a waitlist control condition. 960 caregivers will be randomized into the two arms. After caregivers have completed the baseline assessment, families will be randomized to the BeThere intervention or a waitlist control group. Randomization will be at the family level to ensure that caregivers from the same family are not randomized into different arms of the study. BeThere groups will be held separately for women and men, yielding a total of 480 caregivers per arm. As we are running the study in five communities, a block randomization design will be used: the total sample (n=960) will be divided equally across the five communities, resulting in a sample of 192 caregivers per community, randomly allocated to either the experimental or control arm (n=96 per arm). They will then be organized into eight intervention groups of approximately 12 caregivers per group in each arm.

For random allocation we will be using a participatory methodology implemented successfully in the previous pilot RCT and full-scale RCT (Miller, et al., 2020). At baseline assessment, after completing the questionnaires, one caregiver from each family will be asked by a research team staff member to draw a lollipop out of an opaque bag filled with an equal number of red and green lollipops to ensure an equal number of BeThere and waitlist control participants. Caregivers will be told that after baseline data have been completed, a coin toss will determine the meaning of each color: one color will mean BeThere and the other color will mean waitlist control. This process will be repeated in each of the communities where the study will be conducted, leading to an equal number of BeThere and waitlist control families in each community and in the study as a whole. After the coin toss, done by a staff member of War Child unaffiliated with the study, the outreach team will inform all participants of their group assignment and let BeThere participants know the day and time of their weekly group sessions. A research team member will manage the lollipop selection, while a War Child staff member unaffiliated with the study will toss the coin. The purpose of this two-step randomization process is to increase community buy-in to the randomization process by demystifying it and giving participants an active role in the process. We successfully randomized participants in previous studies in this way (there were no significant between-group differences on any variable following randomization). Moreover, participants understood the process and expressed a willingness to accept assignment to either the BeThere or waitlist control arm. This willingness was confirmed by the high percentage of waitlist control participants who completed the post-intervention assessment in the pilot study (99%) and the RCT (96%).

If a caregiver or family has only one child in the 3–14 age range, this child will act as the index child for the family. For participants with more than on child in the 3–14 age range, an index child will be randomly selected from these. The names of the children will be listed by the RC in order of age, with 1 being the youngest child, after which the RC rolls a die:
- Families with two children aged 3–14: If the die shows 1, 2, or 3 the younger child is selected; if 4, 5 or 6 then the older child.
- Families with three children aged 3–14: If the die shows 1 or 2, RC picks youngest child; if 3 or 4, RC picks middle child; if 5 or 6, RC picks oldest child.

- Families with four children aged 3–14: If the die shows 5 or 6, RC rolls the dice again to get a number between 1 and 4. If 1, 2, 3 or 4, RC picks child where 1 is youngest and 4 is oldest.
- Families with five children aged 3–14: If the die shows 6, RC rolls the die again to get a number between 1 and 5. If 1, 2, 3, 4 or 5, RC picks child where 1 is youngest and 5 is oldest.
- Families with six children aged 3–14: RC picks child according to the number on the die, where 1 is youngest and 6 is oldest.
- Families with more than six children aged 3–14: RC divides the list of children ordered by age equally into two, with the first group being the younger and the second the older children. If there is an uneven number of children, the RC will roll a die to decide if the middle child will go into the younger or older group: If the die shows 1, 2, or 3, the middle child will be assigned to the group of younger children; if 4, 5 or 6, they will be assigned to the older group. After this, RC will follow the procedures above depending on the number of children in each group to select one child from each group, ending up with two children, one from younger and one from older group. The RC will then roll a die again to select the index child: If the die shows 1, 2, or 3, the younger child is selected; if 4, 5 or 6, the older one is selected.

If the selected index child is within the 7–14 age range, the RC will ask whether the caregiver consents to the chosen index child also responding to a separate child questionnaire at baseline, endline, and 3-month follow up. If the caregiver agrees, consent will be obtained from the caregiver and assent from the child for child participation. If the caregiver or child does not agree, then the child will not participate in the study, but the chosen index child will remain the same.

Intervention Type
Behavioural

Primary outcome(s)
Parenting is measured using a 24-item parenting scale developed to assess change in parenting in the development and testing of BeThere, measured at baseline, midline, endline, and 3-month follow-up.

Key secondary outcome(s))
1. Caregiver psychological distress measured using the Kessler Psychological Distress Scale-10 (Kessler et al., 2002) at baseline, midline, endline, and 3-month follow-up.
2. Caregiver stress measured using an 18-item measure developed by War Child to measure specific experiences of stress targeted by the intervention at baseline, midline, endline, and 3-month follow-up.
3. Caregiver psychosocial wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scale at baseline, midline, endline, and 3-month follow-up.
4. Child psychosocial wellbeing measured using a modified version of the Kiddy- and Kid-KINDL at baseline, endline, and 3-month follow-up.
5. Parental warmth measured using the parental warmth subscale of the main parenting measure at baseline, midline, endline, and 3-month follow-up.
6. Harsh parenting measured using the harsh parenting subscale of the main parenting measure at baseline, midline, endline, and 3-month follow-up.
7. Group cohesion among participants measured using the Group Cohesiveness Scale at baseline, midline, endline, and 3-month follow-up.
8. Mechanisms of Action measured using a bespoke five-item measure that assesses the level of uptake of key strategies and techniques at baseline, midline, endline, and 3-month follow-up.

Completion date
19/09/2025

Eligibility

Key inclusion criteria
Caregivers:
1. At least 18 years of age
2. Family with at least one child aged 3–14 years
3. Willing to participate in the study and willing to commit to attending all nine sessions of BeThere if randomized to the intervention arm
4. If both caregivers are present, they are both willing to participate
5. Fluent in Dinka

Children:
1. Aged 7–14 years
2. Selected as the index child of family
3. Willing to participate in the study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
7 years

Sex
All

Total final enrolment
1283

Key exclusion criteria
Caregivers:
1. Under 18 years of age
2. Participation by either caregiver in a parenting or stress management intervention in the past six months
3. Family does not have a child aged 3–14 years
4. Anyone who is unable, even with assistance, to complete the assessment questionnaires
5. Unwillingness of either caregiver to give informed consent
6. Not fluent in Dinka

Children:
1. Under 7 or over 14 years of age
2. Not selected as the index child of family
3. Unwilling to participate in the study

Date of first enrolment
12/02/2025

Date of final enrolment
08/04/2025

Locations

Countries of recruitment
South Sudan

Study participating centre
War Child Alliance Country Office
Plot No 41B, Martyrs Street,
1st Floor - NPA Building,
Opposite UNICEF offices
Juba
South Sudan
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Sponsor information

Organisation
War Child

ROR
https://ror.org/01tq9ra93

Funder(s)

Funder type
Charity

Funder Name
Sint Antonius Stichting Projecten

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from War Child Alliance. Data will be stored on a secure server. The contact person for this study is Anthony Guevara (anthony.guevara@warchild.net). All data will be anonymized.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1	14/08/2024	19/03/2025	No	No
Statistical Analysis Plan	version 1.0	22/09/2025	23/09/2025	No	No