The Key Ingredients of Supporting Conflict-affected Caregivers: A Randomized Controlled Trial with Mediation Analysis

Research Protocol

Version 1.0

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TRIAL REGISTRATION

The trial will be registered with the International Society for the Registration of Clinical Trials (https://www.isrctn.com).

This registration aims to ensure research transparency and that all healthcare decisions are informed by all of the available evidence, thus, overcoming publication bias and selective reporting. It also aims to strengthen future dissemination of health research outcomes. Registration provides opportunities for collaboration and reduces duplication of research efforts; it also improves awareness of studies for clinicians, researchers, patients and the public.

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Study Synopsis

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. As such, BeThere is a crucial innovation in the mental health and psychosocial support field for supporting parenting, caregivers, and ultimately children.

This project will conduct a two-armed, parallel-group randomized controlled effectiveness trial with a waitlist control, with an estimated sample of 960 caregivers and 400 children aged 7–14. Originally developed and tested in the Middle East, this second effectiveness study of BeThere will be conducted in Bor County, South Sudan and be fully-powered for mediation analysis. To support the transition to scale of the BeThere intervention, this project will have the following objectives:

Primary objective:

(1) To **evaluate the effectiveness** of the intervention in improving parenting among participating caregivers in a fully-powered trial in South Sudan. Taking place in a country outside the Middle East, this will also work to **validate the intervention in an additional setting** beyond the Middle Eastern context, a crucial step in scaling up BeThere to be a globally-relevant intervention.

Secondary objectives:

(2) To evaluate the effects of BeThere on participating caregivers' children using **child-reported outcomes** among a subsample of children aged 7–14 (an effect that was only assessed through parent-reported child outcomes in the initial trial).

(3) To conduct a study that is **fully powered to conduct sequential mediation analysis** that will allow the research team to confirm the hypothesized (and partially demonstrated in exploratory mediation analyses) mediation pathways of how BeThere contributes to downstream improvements in child wellbeing.

Tertiary objectives:

(4) To assess the **effect of group cohesion among beneficiaries** in the BeThere intervention group on caregiver wellbeing and distress. While group cohesion and social support in general have been shown to have a positive effect on mental health and wellbeing, the hypothesized effect of these from the intervention group as a collateral effect have not been empirically tested.

(5) Conduct a **cost-effectiveness** evaluation to facilitate the transition to scale of BeThere. This includes establishing start-up costs, comparative affordability, and cost per intervention group, per person, and per improvement in key life-improvement indicators.

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Abbreviations

DSMC	Data Safety Management Committee
ENACT	Enhancing Assessment of Common Therapeutic Factors
LMIC	Low- and Middle-income Country
NDE	Natural Direct Effects
NIE	Natural Indirect Effects
PI	Principal Investigator
R&D	Research & Development
RA	Research Assistant
RC	Research Coordinator
RCT	Randomized controlled trial
(S)AE	(Serious) Adverse Events
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials

Introduction

Background and rationale

Many interventions aimed at improving parenting in conflict-affected settings have implicitly assumed that sub-optimal parenting is caused by a lack of parenting skills and knowledge (Miller, et al., 2020). However, caregiver stress and mental health challenges due to war exposure can lead to sub-optimal parenting and have been linked to increased rates of child- and caregiver-reported child-abuse (Kadir et al., 2019) and parental rejection and harsh punishment (Sim et al., 2018), while caregivers have been shown to be one of the main perpetrators of child abuse in emergencies (Seddighi et al., 2021). A key contribution to the understanding of (sub-optimal) parenting in conflict has been the family stress model, which has shown that war exposure and daily stressors impact caregiver stress and wellbeing, which in turn affect the quality of parenting, negatively impacting a child's psychosocial wellbeing (Figure 1)(Conger et al., 2010; Masarik & Conger, 2017).

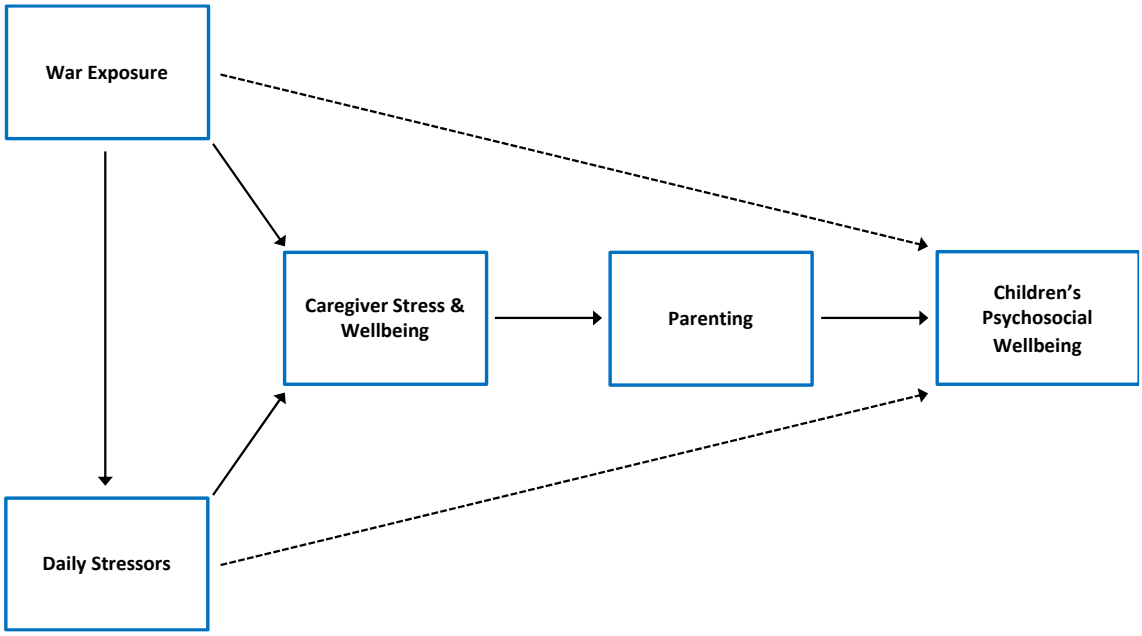

Figure 1 *The family stress model, the conceptual model underlying BeThere*

Developed by War Child (Miller, et al., 2020), the BeThere caregiver support intervention[1] is a nine-session preventive group intervention for caregivers of children aged 3–14 affected by armed conflict and forced migration. It takes the family stress model as its conceptual basis, seeking to strengthen parenting by improving the mental health and psychosocial wellbeing of caregivers (Figure 2).

However, within a child–caregiver relationship, it is not only parenting that affects the wellbeing of a child, but the mental health of caregivers has been shown to be directly associated with child mental health among refugee and conflict-affected populations (Betancourt et al., 2015; Feldman et al., 2013; Panter-Brick et al., 2014; Slone & Mann, 2016).

[1] What was known as the Caregiver Support Intervention was rebranded in 2022 by War Child and is now known as BeThere.

Interventions aimed at caregiver mental health and the family context have been shown to improve child-level mental health outcomes and may protect children from developing depression (Kadir et al., 2019; Simenec & Reid, 2022).

Figure 2 *The conceptual basis of BeThere*

It is within this context of recognizing the centrality of caregiver mental health to parenting and child wellbeing that BeThere incorporates significant components on caregiver mental health and psychosocial support in its design: of the nine weekly hour-long sessions—combined with extensive between-session home practice—the first four sessions focus on caregiver wellbeing, introducing evidence-based methods for managing stress and emotions. Meanwhile, sessions five-to-eight focus on parenting in adversity by promoting positive parenting, and session nine is a review and recap session. The nine sessions are outlined fully in Table 1 below.

Table 1

BeThere sessions, modules, and stress management/relaxation techniques (SM/RTs) (from Miller et al., 2020b)

Session	Topic	Module
1	Introduction and Group Building *SM/RT: Participants' own methods of coping with stress*	Caregiver Wellbeing
2	Stress and Relaxation *SM/RT: Counting the Breath*	Caregiver Wellbeing
3	Lowering Our Stress *SM/RT: Stepping Back from Our Thoughts, Grounding*	Caregiver Wellbeing
4	Coping with Frustration and Anger *SM/RT: Peaceful Walking, various anger management techniques*	Caregiver Wellbeing
5	Parental Stress and Influence *SM/RT: Stepping Back from Our Thoughts (repeat)*	Parenting in Adversity
6	Increasing Our Influence as Parents, Part 1: Positive Attention *SM/RT: Guided Visualization: A Safe Space*	Parenting in Adversity
7	Increasing Our Influence as Parents, Part 2: Effective Discipline *SM/RT: Informal Breathing Practice*	Parenting in Adversity
8	Positive Parenting: Practice *SM/RT: Participants Choose Any SM/RT*	Parenting in Adversity
9	Looking Back, Looking Forward	Closure

As such, BeThere aims to strengthen parenting and child wellbeing through two pathways (Figure 3): (a) by strengthening participants' knowledge and skills related to evidence-based

parenting methods that have strong cross-cultural support, and (b) by improving the mental health and psychosocial wellbeing of caregivers.

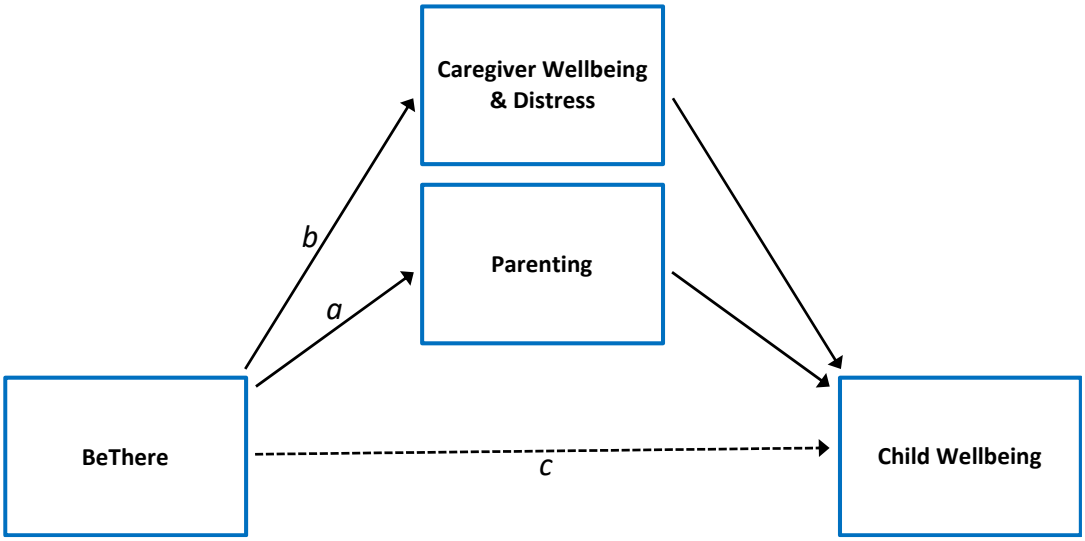

Figure 3 *The dual pathway model of BeThere*

Research to date

A pilot randomized controlled trial (RCT) was conducted among Syrian refugees in Lebanon in 2017–2019 to test the feasibility of the study methodology and to prepare and plan for a full-size RCT (Miller, et al., 2020). Results from the pilot RCT demonstrated that the proposed study measures and methodology were appropriate for evaluating the effectiveness of the intervention. In the pilot study, BeThere also had a significant, positive impact on parenting, caregiver mental health and psychosocial wellbeing, and child wellbeing, suggesting that it is a promising group intervention for improving parenting in low-resource settings.

Based on the experiences and findings from the pilot study, a fully-powered RCT was conducted in Lebanon among Syrian refugee caregivers in 2019–2020 to evaluate the effectiveness of BeThere (Miller, et al., 2023). However, the study was interrupted by strict COVID-19 lockdowns, a severe economic crisis, and widespread social unrest, which meant that implementation was sub-optimal as not all participants were able to receive the full intervention dosage, influencing trial outcomes.

Regardless of these challenges, the RCT showed that, compared to the control condition, caregivers participating in BeThere had slightly better parenting outcomes, with a reduction in harsh parenting, and a significantly greater decrease in distress. There were no significant between-group differences in caregiver wellbeing or parental warmth and responsiveness. Meanwhile, BeThere was shown to be effective in improving child wellbeing at endline, although this was not sustained at three-month follow up and was only measured as a caregiver-reported outcome instead of child-reported (Jordans et al., 2023). Positive outcomes were more pronounced among the group that received the full nine-session intervention, as opposed to those who received a lower dosage of sessions. The effects observed in the RCT are expected to be under-estimations due to the sub-optimal implementation of the intervention caused by the aforementioned environmental factors.

Furthermore, the findings from the pilot RCT showed stronger effects on participants than those found in the RCT, further suggesting these results are an under-estimation. Thus, the effectiveness of the intervention has not yet been conclusively demonstrated.

Exploratory mediation analyses conducted on the results of the RCT demonstrate that the effectiveness of BeThere at improving child-level wellbeing can be explained by outcomes in mediating variables (Jordans et al., 2023). These mediators were caregiver distress, caregiver wellbeing, and harsh parenting, suggesting that these are crucial variables in the conceptual model underlying BeThere.

Objectives

The current study will have the following key objectives:

Primary objective:

(1) To evaluate the effectiveness of the intervention in improving parenting among participating caregivers in a fully-powered trial in South Sudan. Taking place in a country outside the Middle East, this will also work to validate the intervention in an additional setting beyond the Middle Eastern context, a crucial step in scaling up BeThere to be a globally-relevant intervention.

Secondary objectives:

(2) To evaluate the effects of BeThere on participating caregivers' children using child-reported outcomes (an effect that was only assessed through parent-reported child outcomes in the initial trial).

(3) To conduct a study that is fully-powered to conduct sequential mediation analysis that will allow the research team to confirm the hypothesized (and partially demonstrated in exploratory mediation analyses) mediation pathways of how BeThere contributes to downstream improvements in child wellbeing.

Tertiary objectives:

(4) To assess the effect of group cohesion among beneficiaries in the BeThere intervention group on caregiver wellbeing and distress. While group cohesion and social support in general have been shown to have a positive effect on mental health and wellbeing, the hypothesized effect of these from the intervention group as a collateral effect have not been empirically tested.

(5) Conduct a cost-effectiveness evaluation to facilitate the transition to scale of BeThere. This includes establishing start-up costs, comparative affordability, and cost per intervention group, per person, and per improvement in key life-improvement indicators.

Trial design

Design

This study is a two-armed, parallel group randomized controlled trial, with an intent to treat design, a 1:1 allocation ratio, and a waitlist control comparison condition. The study will involve Dinka-speaking primary caregivers of children aged 3–14 and a subsample of their children aged 7–14 in five communities in Bor County, Jonglei State, South Sudan: Pariak, Ghoi, Taragok, Tibek, and Lenguet. Random allocation to intervention and control arms will be done at the family level to ensure caregivers from the same family do not participate in different arms of the study.

We will evaluate the effectiveness of BeThere—a nine-week preventative group psychosocial support intervention for primary caregivers of children aged 3–14—by measuring multiple parenting and psychosocial outcomes among participating caregivers compared to a waitlist control group of caregivers not participating in a parenting intervention. Quantitative data collection will be done by trained research assistants (RAs) using electronic tablets at four timepoints: baseline, midline, endline, and three-month follow up. Prior to the start of data collection, all research instruments will go through a process of translation, adaptation, cognitive interviewing, and pilot testing. The primary outcome of the study will be an overall score on parenting. Secondary outcomes will be child wellbeing (caregiver- and child-reported), caregiver stress, distress, and wellbeing, as well as harsh parenting and parental warmth and responsiveness. Additionally, demographics data will be collected from caregivers and children. We will also record participant attendance to intervention sessions, along with facilitator competence to deliver the intervention and their fidelity in delivering the intervention as planned. Additional qualitative data will be gathered via focus group discussions and key informant interviews. The study will be conducted between January and July 2025.

Methods: Participants, interventions, and outcomes

Study setting

South Sudan has suffered through decades of conflict. 13 years since the country's independence and following the end of a devastating civil war, conflict and insecurity persist throughout the territory, with women and children particularly vulnerable to violence, exploitation and abuse. Two million people are estimated to be internally displaced, while another 2.2 million have sought refuge in neighboring countries.[2] While there is sparse research on the prevalence of mental, neurological, and substance use disorders in South Sudan, the few studies that exist suggest alarmingly high rates of post-traumatic stress disorder and depression (Ayazi et al., 2015; Goldsmith & Cockcroft-McKay, 2019; Ng et al., 2017; Roberts et al., 2009)..

Bor County, situated in the southwest corner of Jonglei State, saw heavy fighting during the Second Sudanese Civil War and the South Sudanese Civil War. As part of the latter, Bor Town was destroyed in 2014, displacing around 50,000 people. Poverty is a significant issue in the county, with a prevalence rate of 48.3 percent in 2011. Inter-tribal conflicts have also contributed to displacement, with 6,119 people being internally displaced in 2010 alone, according to the Jonglei State Humanitarian Action Plan.

The county is predominantly home to the Nilotic Dinka tribe, while Bor Town Payam has a mix of other tribes from Jonglei State and South Sudan. The county's population according to the most recent census from 2008 is 218,950, with 31,354 households. This makes up 16 percent of Jonglei State's population. About 28 percent of the population resides in Bor Town. However, these numbers may have significantly increased since the census as citizens return to the state.

[2] https://www.unocha.org/south-sudan

Table 2: Bor South County Population Distribution by Payam

No	Payam	Population		
		Females	**Males**	**Total**
1.	Kolnyang	22,011	18,008	40,019
2.	Anyidi	13,219	10,816	24,035
3.	Makuach	16,181	13,240	29,421
4.	Baidit	28,073	22,968	51,041
5.	Jalle	7,266	5,945	13,211
6.	Bor Town	33,673	27550	61,223
Total		**120,423**	**98,527**	**218,950**

Bor County shares boundaries with Central Equatoria to the south, Lake State to the west, Twic East County to the north, and Pibor County to the east, bordering Eastern Equatoria State to the south-east. Bor is the southwest extremity of Jonglei state's River Nile and Toch flood plains, which are mainly level and rise to less than 320 meters. Its area is roughly 12,000 square kilometers. The county is vulnerable to floods during the rainy season due to its low-lying terrain and heavy clay soils. It consists of six Payams: Bor Town as the urban center, and Anyidi, Baidit, Kolnyang, Makuach, and Jalle as more rural areas. Perennial wetlands and lakes can be found from the central region (Toch) to the Nile River.

Twenty-two bomas, four Quarter Councils (located in Bor Town), and twenty-seven head chiefs in the Payams indicated in the table below comprise the county. Bomas are made up of villages, and inside each village are multiple homes. Homes are the basic organizational unit of society and rural livelihoods in the county.

Table 3: Number of Bomas/Quarter Councils and Head Chiefs by Payam

	Payam	No. of Bomas Quarter Councils*	No. of Head Chiefs
1.	Kolnyang	4	5
2.	Anyidi	3	3
3.	Makuach	4	4
4.	Baidit	6	6
5.	Jalle	5	5
6.	Bor Town	4*	4

This project will take in five villages/bomas across the Kolnyang, Anyidi, and Makuach Payams: Pariak, Ghoi, Taragok, Tibek, and Lenguet.

Table 4: List of Five Communities

Payam	Boma/ Village	Total Population	No. of households	% Population took part in parenting program in past 2 years	Type of community (e.g. IDP camp, host community, etc.)	Rural/semi-urban/urban
Kolnyang	Pariak	9,176	1,529	0.040	Host Community	Rural
Kolnyang	Ghoi	8,010	1,335	0.046	Host Community	Rural
Anyidi	Taragok	11,790	1,965	0.032	IDP	Rural
Makuach	Tibek	7,596	1,266		Host Community	Semi Urban
Makuach	Lenguet	6,817	1,136	0.055	Host Community	Rural

Participants

Participants will primarily be Dinka-speaking South Sudanese caregivers of children aged 3–14 years, with one index child per family. For families with more than one child in the stated age range, a random index child will be selected among families to be the focus in questionnaires. Thus, when caregivers are completing the parenting and child wellbeing questionnaires, they will do this only for the random index child. Similarly, the random index child will be the one to whom the child-reported questionnaire will be administered. The child-reported questionnaire will be administered to a sub-sample of index children aged 7–14. The total estimated sample size is 960 caregivers (equivalent of 480 families or more) and an estimated 400 index children aged 7–14. We will recruit caregivers from families with two caregivers, as well as from single-caregiver families (see section "Participant Recruitment" below). Thus, our sample of 960 caregivers consisting of: (i) dyads of caregivers for families with two caregivers; and (ii) individual caregivers from single-caregiver households. The total number of families therefore will be at least 480.

Inclusion criteria

- At least 18 years of age
- Family with at least one child aged 3–14
- Willing to participate in the study and willing to commit to attending all nine sessions of BeThere if randomized to the intervention arm
- If both caregivers are present, they are both willing to participate
- Fluent in Dinka

Exclusion criteria

- Under 18 years of age
- Participation by either caregiver in a parenting or stress management intervention in the past six months
- Family does not have a child aged 3–14 years

- Anyone who is unable, even with assistance, to complete the assessment questionnaires
- Unwillingness of either caregiver to give informed consent
- Not fluent in Dinka

Based on the successful implementation of the design in the pilot RCT and RCT in Lebanon, a waitlist control will serve as the comparison group in this study. Participants in the waitlist control group will be given the opportunity to participate in the intervention after the 3-month follow-up assessment has been completed.

This study will involve a waitlist control group for two key reasons:

1) While the risk of a nocebo effect among research participants randomized into the control group in waitlist-controlled psychological treatment trials has been raised (Furukawa et al., 2014; Gold et al., 2017; Steinert et al., 2017), there is currently little evidence to show that this is the case for preventative interventions (Gold et al., 2017; Miller, et al., 2023).
2) The BeThere intervention has already been shown to be effective among caregivers in Lebanon. Considering the vulnerability of the target population and the lack of existing mental health and psychosocial support services, we do not want to deny control group participants access to the intervention.

Facilitators

20 facilitators will be recruited to implement a total of 80 intervention groups, 40 in each arm of the trial. BeThere facilitators must fulfil the following criteria to be accepted into the facilitator training:

1) Fluent Dinka speaker
2) Preferably from the geographic locations of implementation
3) Aged at least 24 years
4) At least high school education completed
5) At least 2 years of experience implementing psychosocial interventions, preferably with adults, especially parents and caregivers
6) Affinity with the core ideas of the intervention regarding parental wellbeing and positive parenting
7) Able to commit to attend the full training, all sessions of the intervention, and all supervision meetings
8) Respectful and tolerant to different nationalities and religious groups
9) Being a parent is highly desirable but not required[3]

Prospective BeThere facilitators will participate in a 6-day training that covers the intervention material as well as key group facilitation skills and competencies. The competency of the trainees will be assessed with standardized competency measurement

[3] While being a parent introduces the risk of bias as facilitators may introduce their own experiences and attitudes about parenting, we have found that intervention participants view facilitators with children as having greater legitimacy to lead sessions on parenting knowledge and skills; in addition, facilitator-parents may have a deeper appreciation for the challenges and stressors that parents face. We make every effort, in training, supervision, and on-site coaching, to ensure that any bias introduced to the sessions by facilitators, whether due to having children or any other source, is minimized.

tools.[4] We will purposefully include more facilitators than we need in the training, with final selection of facilitators taking placed afterwards based on performance in the training. This will also ensure we have individuals who have been trained in the intervention as backup in the case of facilitator dropouts. The 6-day training will be followed by a practice run of the full 9-session intervention, during which the facilitators will receive close support and supervision from trained BeThere supervisors.

Intervention

BeThere (Miller et al., 2020) 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. Table 1 above lists session topics and corresponding modules, along with the stress management technique(s) taught in each session. 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.

Control condition

We will employ a waitlist control condition for this study. Same as the intervention arm, participating caregivers should not take part in a parenting intervention in the six months prior to the start of or during the main study period, including the three-month follow up. Existing mental health and psychosocial support services will remain in place and be available to participants in the control and intervention arms. We will explore what kind of services the control group may have used during the study period through key informant interviews. In addition, a checklist of updates of ongoing mental health and psychosocial support activities and services in the community will be collected monthly by the Research Coordinator.

Intervention fidelity assessment, quality control, and supervision

A fidelity checklist will be completed jointly by the co-facilitators immediately after each session of BeThere. The BeThere trainer-supervisors will conduct on-site observations of 10% of the sessions in each group and provide coaching to all facilitators based on these observations. Fidelity and competency ratings will be collected during these observations, which will be used to guide their feedback. They will also meet with all pairs of facilitators weekly for supervision. Registers will be used to record attendance at all sessions of all BeThere groups. These will be kept in the secure care of the research coordinator.

[4] https://equipcompetency.org/

Criteria for discontinuing the intervention for study participants
Any participant may elect to discontinue their participation in the study at any point for any reason, including participation in the intervention. Any participant who becomes repeatedly disruptive to the intervention may be asked to discontinue participation in the intervention, but not the study.

Outcomes

Outcome measures will be collected from all participating caregivers in both arms of the study (n=960). Additionally, outcome measures will be collected from assenting index children in the 7–14 age range (estimated n=400).

Primary outcome measures

Parenting
Parenting will be assessed using a 24-item parenting scale developed to assess change in parenting in the development and testing of BeThere (Miller et al., 2024). In addition to yielding a total score, the measure includes subscales assessing parental warmth and sensitivity (16 items) and harsh parenting (five items). Internal consistency for the full measure ($\alpha = 0.83$) and the parental warmth ($\alpha = 0.86$) subscale was good in the previous RCT, and was acceptable for the harsh parenting subscale ($\alpha = 0.76$). The measure was designed as a parent-reported measure, but for this study we will also develop a child-reported version to give us data on parenting from both caregivers and children. The overall parenting score will be considered a primary outcome, while the two subscales will be secondary outcomes.

Secondary outcome measures

Caregiver psychological distress
The Kessler Psychological Distress Scale-10 (Kessler et al., 2002) is a widely used ten-item measure of psychological distress. It has been used extensively in cross-cultural clinical and epidemiological research and has demonstrated excellent psychometrics in diverse populations, including Ethiopia, Kenya, Uganda, and South Africa (α=0.83–0.86; Ametaj et al., 2024).

Caregiver stress
Caregiver stress will be measured using an 18-item measure developed by War Child to measure specific experiences of stress targeted by the intervention. The scale showed adequate internal consistency in the previous RCT (α=0.76; Miller et al., 2023)

Caregiver psychosocial wellbeing
The Warwick-Edinburgh Mental Wellbeing Scale (Stewart-Brown et al., 2011; Tennant et al., 2007) is a 14-item measure of psychosocial wellbeing. It has been used extensively in cross-cultural mental health research and has demonstrated good psychometrics in diverse populations. It has shown good internal consistency in South Africa (α=0.88; Stewart-Brown, 2013) and Tanzania (α=0.88; Oyebode et al., 2023).

Child psychosocial wellbeing

Children's psychosocial wellbeing will be assessed with the Kiddy-KINDL for Parents for index children aged 3–6 years and the Kid-KINDL for Parents for index children aged 7–12 (Ravens-Sieberer & Bullinger, 1998). The four school items will be dropped to make the two versions identical, and four optional mental health items will be added to strengthen our measure of children's psychosocial health. Additionally, as we are looking to measure changes in parenting at the caregiver level, we will split up item 13 (*my child got on well with us as parents*) into two items to ask about both caregivers separately where applicable. This will yield a total of 25 items. All the items will be worded as questions rather than statements to enhance their understandability. Self-reported psychosocial wellbeing of the index children aged 7–14 will be assessed using the Kid-KINDL for Children which will have the same adaptations as the caregiver-version, allowing us to compare the child- and caregiver-reported versions. Internal consistency of the parent-completed KINDL in the previous RCT was good across measurement points (α=0.86–0.91; Jordans et al., 2023).

Group cohesion
Cohesion among participants in each of the intervention groups will be measured using the 7-item Group Cohesiveness Scale (Wongpakaran et al., 2013). The scale measures how engaged participants feel with each other as a whole in the group, including acceptance, trust, care, and participation.

Mechanisms of Action
A bespoke five-item measure will be used to assess the level of uptake of key strategies and techniques which are hypothesized to be the main mechanisms through which the intervention achieves its outcomes on participants. These include relaxation techniques, stress and anger management techniques, and positive parenting practices.

Additional Data Collected

In addition to the primary and secondary measures outlined above, the following data will be collected during the study period:

Demographics
A brief demographics form will be used to record family composition, caregiver nationality, sex, and age, and the ages and sex of all members of the household, and other demographic variables relevant to the study's outcomes.

Attendance
Attendance to each BeThere session by participants will be recorded by facilitators using attendance sheets.

Competence
The competence of facilitators to deliver the intervention will be measured using the 15-item Enhancing Assessment of Common Therapeutic Factors (ENACT) tool, a standardized competency measurement tool developed by WHO and UNICEF (Kohrt et al., 2015). Competence will be measured after the facilitators have completed their training (including the practice sessions) as the primary measurement, complemented by an in-session

assessment conducted by the supervisors during a session they observe in their role as supervisors.

Fidelity

A bespoke, eight-item fidelity checklist will be used to measure facilitators' fidelity to the intervention protocol. It will be filled by facilitators for all sessions, while supervisors will complete it for intervention sessions they observe in their role as supervisors.

Qualitative data collection

Key informant interviews and focus group discussions will be conducted with a sample of participating caregivers. With caregivers in the intervention group, we will explore issues around impact and perceptions of the content and implementation of the intervention, as well as barriers and facilitators to attendance in the sessions. Interviews will be conducted with members of the waitlist control group to explore the kind of services they utilized during the main study period.

Participant timeline

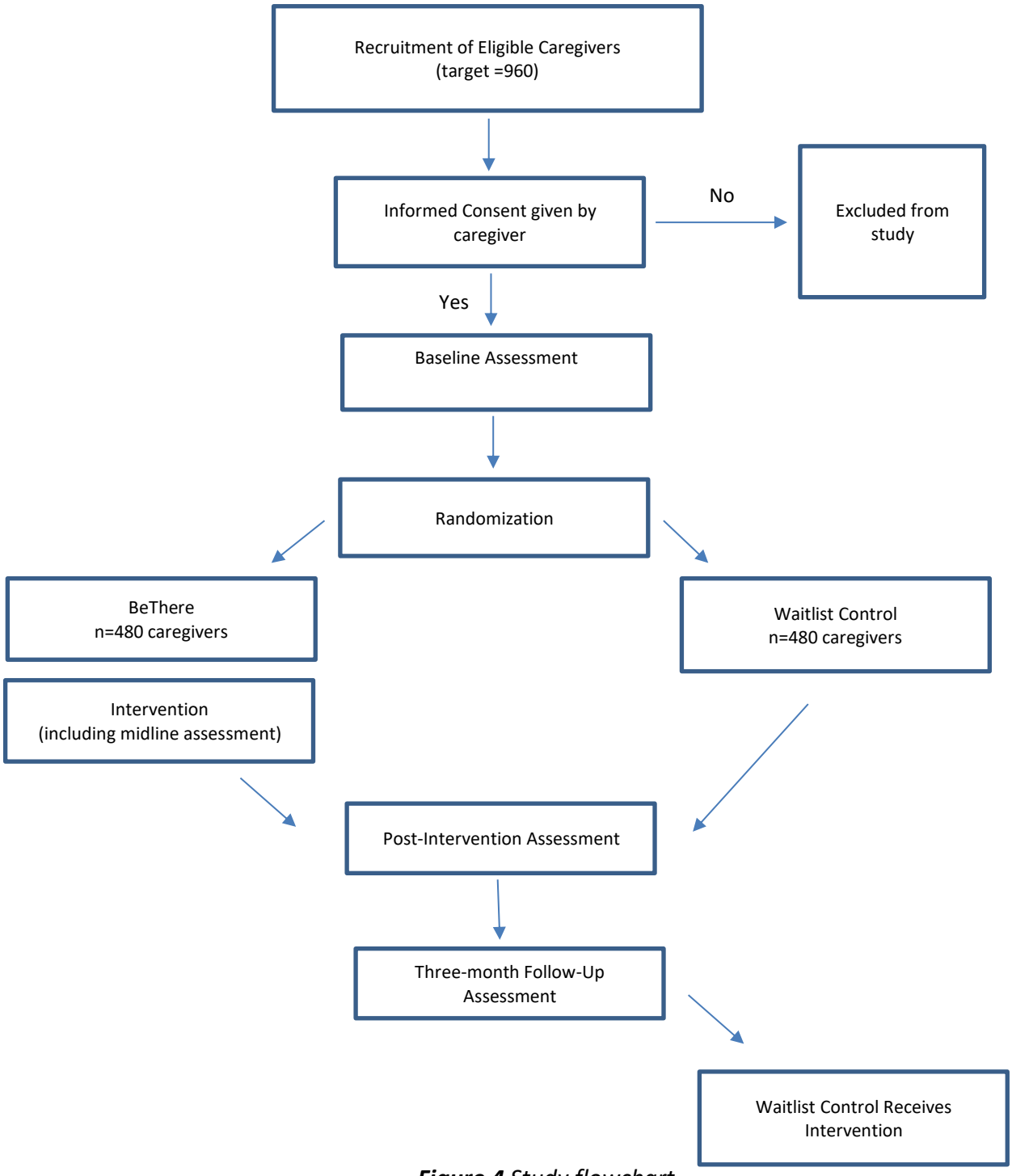

Figure 4 *Study flowchart*

Recruitment

Recruitment of participants from the target communities will take place through local, community-based organizations and structures, chiefs, and networks that War Child has a working relationship with. These are entities that are already active in the communities and which have a close relationship with community members. Approaches here will include flyers and awareness raising sessions to announce the study, recruiting door-to-door, and word of mouth. This recruitment strategy will be carried out until the target sample (n=192) per location is reached. Several strategies which were found to be successful in the pilot RCT and RCT will be utilized to recruit male caregivers. These include scheduling sessions and data collection during times that do not conflict with income-generating activities and including messaging that has been found to appeal to male caregivers.

Methods

Randomization

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.

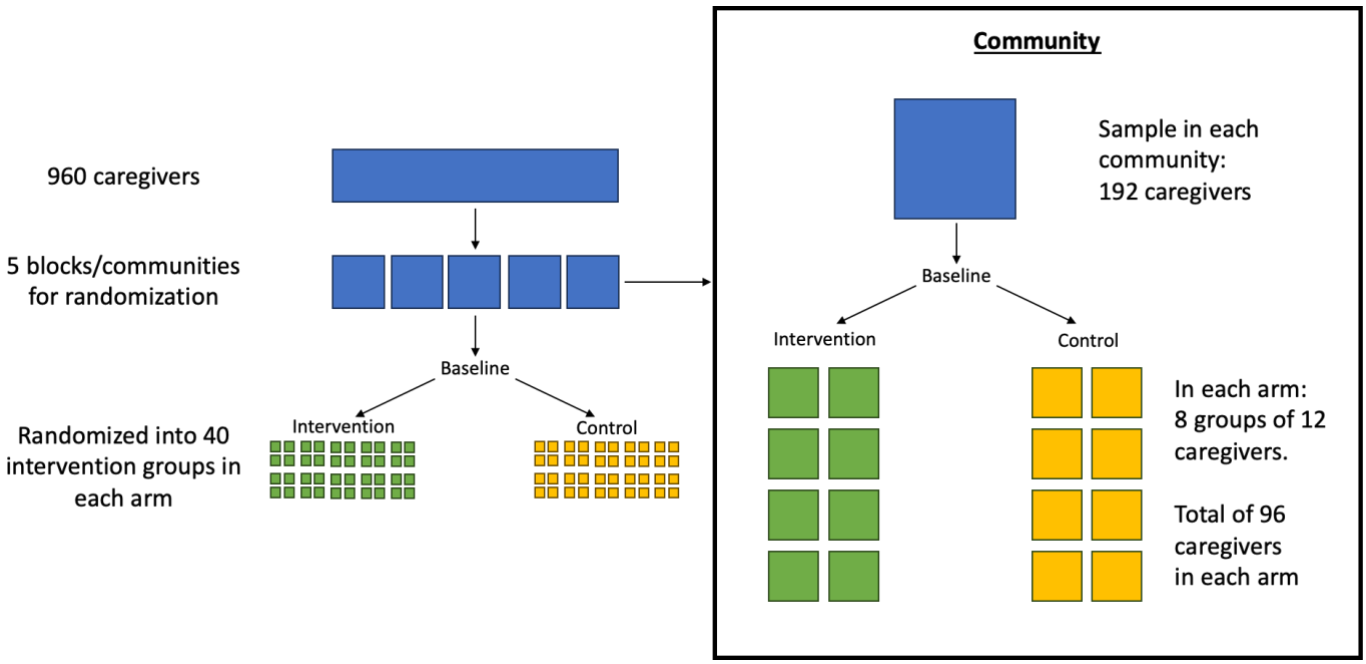

Figure 5 *Randomization and allocation flowchart*

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.

A master list will be created that includes each caregiver's group assignment and selected index child. This list will be kept in a secure location in the War Child Bor office, with a copy in a similarly secure location in the War Child Office in Juba. Only the scientific coordinator and the research coordinator will have access to this master file during the study.

The BeThere participants will be separated by gender for the sessions. This gender-segregated approach was selected in order to be culturally sensitive and also allow caregivers the privacy to discuss marital or parenting difficulties without their spouse present. This approach was implemented successfully in the pilot RCT and RCT. Randomization and implementation will be done in the communities, so that families assigned to the BeThere arm in each community can easily attend BeThere groups at a nearby location. Participant feedback from previous studies has made clear that proximity to the centers has been a key factor contributing to high attendance rates.

Masking

Given the nature of the study, participants and facilitators will not be masked to group assignment. The research coordinator and BeThere trainer/supervisor will also not be masked to group assignment, as they will be involved in scheduling participants into specific groups. All assessments will be carried out by trained research assistants (see the "Research Assistants" section below for details about their background and training). RAs completing the baseline and follow-up assessments will be masked to group assignment and therefore will not be involved in the randomization process. As we did in the pilot study and trial in Lebanon, the rationale for keeping the RAs masked is explained to participants at each assessment, along with a request that they not reveal their group assignment. RAs will be instructed never to ask any participant to reveal their group assignment, and to gently stop participants from revealing their group assignment if they begin to do so during assessments. Efforts will also be made to minimize interactions between the intervention and research teams during the study and there is no planned contact between the RAs and BeThere facilitators. We will instruct RAs to never discuss any research participant outside of the data collection process, except with the research coordinator, both for confidentiality and to ensure against any possible breach of masking to participant assignment. The RAs will convene at the War Child Bor office during data collection periods, while the BeThere facilitators will be community-based. If a need arises for the facilitators to visit the Bor office, we will ensure that the RAs will not be present during those times. We will assess the level of (un-)masking amongst the RAs at each measurement timepoint. RA masking was accomplished successfully during the pilot study and RCT, and we anticipate no difficulties replicating this in the present study. The principal investigator (PI), co-PIs, and trial statisticians will all be masked to group assignment.

Minimization of contamination

Randomization will be at the family rather than individual parent level to minimize contamination by avoiding having parents/caregivers within the same family assigned to different arms of the study. To minimize contagion between the BeThere and control arms, participants in BeThere groups will be asked to avoid sharing program content, including the relaxation and stress management exercises, with anyone outside of their immediate household. We will be assessing the level of contamination amongst participants during endline assessments.

Data collection

Research assistants

A team of 15 research assistants will be trained for a period of at least 5 days and will undergo extensive practice periods with the study questionnaires prior to the baseline assessment. Research assistants are native Dinka speakers, preferably with experience serving refugee and vulnerable communities, and will be recruited by open recruitment and based on recommendations from local colleagues. Selection will be done based on a thorough review of a CV, cover letter, and qualifications, reference checks, and an interview with key research staff. Research assistant training will include extensive practice in administering all the research instruments using tablets, as well as research ethics, participant consent and assent, child safeguarding, handling adverse events, building rapport with participants, communication with children, and troubleshooting, among other topics.

Instrument translation and transcultural adaptation

In the period leading up to baseline data collection, all data collection instruments will be translated into Dinka, followed by a detailed review and adaptation by a bilingual (English- and Dinka-speaking) group of mental health professionals based on the comprehensibility, acceptability, and relevance of each of the items. This will be followed by cognitive interviewing of all of the items with Dinka-speaking children aged 7–14 and caregivers (total n<20). Further review and adaptation will follow the cognitive interviewing. Pilot data will be collected by the RAs from caregivers and children (total n≤100) following their training to assess the psychometrics and test-retest reliability of the instruments.

Baseline, midline, endline, and follow-up assessments

Questionnaire data will be gathered at four time points: baseline, mid-intervention, post-intervention, and three-month follow-up. This is depicted in the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) figure chart in Figure 2. Participant flow, from enrolment through the three-month follow-up assessment, can be seen in Figure 4.

Table 5: SPIRIT Flow Chart

	STUDY PERIOD				
	Enrolment	**Baseline**	**Midline**	**Endline**	**3-month Follow-up**
TIMEPOINT	**$-t_1$**	**T0**	**t_1**	**t_2**	**t_3**
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
BeThere		⟷	⟷	⟷	
Waitlist-control		⟷	⟷	⟷	
ASSESSMENTS:					
Caregivers:					
Demographics		X		X	X
Parenting		X		X	X
Caregiver wellbeing		X	X	X	X
Caregiver stress		X	X	X	X

Caregiver distress		X	X	X	X
Child wellbeing		X		X	X
Group cohesion		X	X	X	X
Mechanisms of Action		X	X	X	X
Contamination				X	
<u>Child</u>:					
Child wellbeing		X		X	X
Parenting		X		X	X

All questionnaire data will be gathered using tablets, using the software program Kobo, which allows questionnaires to be completed and uploaded without paper and pencil. Kobo is available free of charge from the Harvard Humanitarian Initiative (https://www.kobotool-box.org/). Measures will be administered in Dinka to each caregiver and child individually by trained and supervised research assistants.

The 15 research assistants will work together under the direction of the research coordinator during data collection periods. Data collection and the start of the intervention groups will take place in a staggered approach over a five-week period with one location starting each week, outlined in Table 2. We estimate that the total sample size when including index children aged 7–14 will be 1,360 (960 caregivers and 400 children), with an average sample of 272 participants per location.

est. # of participants	Week1	Week2	Week3	Week4	Week5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Wk 13	Wk 14	Wk 15
272	Baseline, consent, randomi-zation	Session1	Sesssion2	Session3	Session4	S5 Midline	S6	S7	S8	S9	End line				
272		Baseline, consent, randomi-zation	Session1	Sesssion2	Session3	S4	S5 Midline	S6	S7	S8	S9	End line			
272			Baseline, consent, randomi-zation	Session1	Sesssion2	S3	S4	S5 Midline	S6	S7	S8	S9	End line		
272				Baseline, consent, randomi-zation	Session1	S2	S3	S4	S5 Midline	S6	S7	S8	S9	End line	
272					Baseline, consent, randomi-zation	S1	S2	S3	S4	S5 Midline	S6	S7	S8	S9	End line

Table 6 *Baseline, midline, and endline data collection schedule*

Qualitative Data Collection

Key informant interviews (n≤30) and focus group discussions (n≤5) will be conducted by the RC and two RAs (different from the RAs involved in quantitative data collection), who will receive training in qualitative data collection. Participants for qualitative data collection will be purposively selected from the main study sample to represent variation in participants, based on variation in attendance and engagement levels, as well as sociodemographic factors. Attendance lists and BeThere facilitators will be consulted in the process of identifying suitable participants. Additionally, waitlist control group participants will be interviewed during data collection periods (baseline, midline, endline, and three-month follow-up) to determine what psychosocial support services—if any—they may have utilized during the study period. The topic guides that will be used for the semi-structured key informant interviews and focus group will be developed prior to the interviews and data collection.

Childcare during BeThere sessions

Childcare will be provided on-site for up to two children per participant. Trained and experienced animators (childcare providers) trained by War Child in childcare and child safety will care for children, with two animators available during each session. The childcare sessions are not structured, and no formal activities are facilitated, to avoid providing any index children attending the childcare with a substantive psychosocial experience that might

confound the results of the study. Various play materials and snacks will be provided, and the childcare workers will ensure the safety and comfort of all children.

Compensation for participation/defraying costs of participation
As the assessments and intervention sessions will take place in the communities where participants live, within walking distance from their homes, no transportation costs will be reimbursed. However, refreshments will be provided at both intervention and assessment sessions. This compensation is considered minimal and in line with regular War Child implementation programming and was chosen to avoid difficulties of jealousy within the community amongst non-eligible families, and potential coercion of families to participate in sessions and assessments.

Cost-Effectiveness Evaluation
The implementation costs of BeThere will be measured using expenditure records, staff time tracking and ingredients-based costing as necessary. Included will be start-up costs as appropriate (e.g. adapting materials, translation, training facilitators, supervisors, and master trainers, etc.), annualized over several years, and recurrent costs. Only "real life" implementation and coordination costs will be included, i.e. costs related to the research such as randomization or trial-related administration will be excluded. For the present research, the cost-effectiveness evaluation will assess costs for the 9 sessions, on average per participant. We will estimate the cost-effectiveness of each arm as a cost per unit change in the caregiver wellbeing and/or child wellbeing by dividing total costs by total score change. We will assess affordability in the greater context of humanitarian assistance by estimating cost per participant and comparing with humanitarian funding globally. Additional sensitivity analyses on the above results may be performed depending on trends observed in the data.

Data management

This proposed research follows the data management guidelines of War Child's Research & Development (R&D) department (available upon request). All electronic data files will be stored on a password protected cloud server (SharePoint), accessible only on password protected and encrypted laptops. Access to this data will only be available to the core research team. Research assistants will sign a confidentiality clause. The detailed War Child Data Management Policy will serve as guidance on all data management and data sharing issues.

All survey data will be collected via Kobo Toolbox. Research Assistants will upload data to the Kobo server at the end of each data collection day. Only the core research team will have access permissions to edit the questionnaires and download the data from the Kobo server. Data will be downloaded from the Kobo server every day and stored as a backup on a secure data server of the R&D Department of War Child. This server is password protected and accessed from password protected and encrypted laptops.

At the end of data collection, the complete data file will be downloaded at the War Child head office from the Kobo server and the master-file will be saved securely on a separate server and uploaded into relevant software for data analysis. All data cleaning and analysis processes will be tracked through saved syntax from data analysis software.

Any hardcopies of data, including informed consent forms, will be stored in a dry, lockable cabinet. Data sets will be accessible by the War Child core research team members. The Research & Development department at War Child has, in all cases, ownership of the research data, except where there is an alternative contractual relationship between War Child and an individual research committee member organisation.

Statistics

Power and sample size

To gain a general appreciation for the required sample size to detect an indirect effect through the primary mediators (Caregiver Distress, Wellbeing, and Harsh Parenting), we used the sample size estimator for joint significance indirect effects developed by Vittinghoff and Neilands (2015). With a two-sided alpha of 0.05, for an intervention-mediator error term correlation coefficient of 0.2, a standard deviation of the mediator of 0.2, and a standard deviation of the random error term of 0.5, a sample of 425 caregivers per group would be sufficient to detect a mean difference of 0.4 (Vittinghoff & Neilands, 2015). All parameter estimates are based on our previous work. Sample size estimators for multiple mediator models are currently unavailable (VanderWeele, 2016); however, O'Rourke and Mackinnon (2015) provide evidence that multiple mediator models have more power than single mediator models. Thus, we expect this study to have sufficient power for multiple mediator models. With a 10% attrition we expect to have 468 families per group with 234 children, totaling 936 caregivers and 468 children. With a total of 40 intervention groups, the final sample size is 960 caregivers (equivalent of 480 families or more) and 400 index children.

Analyses

The statistical analyses will be carried out by the trial statistician, who will remain masked to the group randomization until the main analyses are complete. The analyses outlined in this strategy will be primarily based on an intention to treat; a per protocol analysis will be the secondary analysis. The per protocol analysis will include participants who complete the intervention, with completion defined as attending at least seven of the nine sessions, and will exclude any participant who attended fewer than seven sessions. We have powered the study (see the "Sample size" section) as a superiority study at 10 weeks. The first stage of analyses will be a descriptive model of the data to assess completeness of data and the integrity of the data collection system. Participants and area characteristics and demographics will be summarized at baseline. Clinical characteristics that have been measured repeatedly will be summarized at baseline and at the post-randomization follow-up assessments. In addition, patterns of missing data will be described.

The primary outcomes (total score of parenting scale and proxy-reported child psychosocial wellbeing) will be analyzed using linear mixed models to model the mean difference in the total score of parenting scale 10 weeks post-randomization. The linear mixed models will be adjusted for baseline total scores and stratification. A two-level hierarchical model will be employed to improve power and take into account clustering of the parents at the family level. These models utilize maximum likelihood estimation and thus allow for missing outcome data under the missing at random assumption. Associations between post-randomization variables and missingness will be dealt with by multiple imputation, again

under the missing at random assumption. Departures from this assumption will be assessed with a sensitivity analysis. Secondary outcomes, including parental warmth and responsiveness, harsh parenting, caregiver psychosocial wellbeing, stress, and distress, and self-reported child psychosocial wellbeing will be assessed with a similar methodology used for the primary outcomes, using generalized linear mixed models depending on the type of outcome (normal, ordinal).

We will investigate the mediation process of different aspects of caregiver wellbeing and parenting and, through that, examine how these factors affect child wellbeing, helping us understand how best to achieve downstream effects on child wellbeing through psychological interventions. Some of the pathways of interest are illustrated in Figure 4.

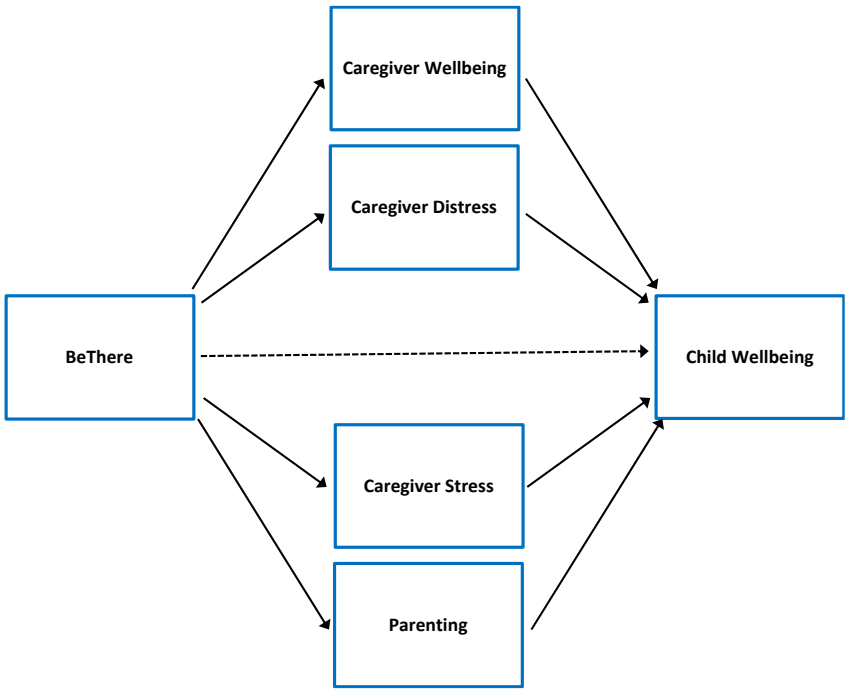

Figure 6 Primary mediation pathways

If the efficacy analysis shows significant between-group differences in the mediators (caregiver stress, caregiver distress, caregiver psychosocial wellbeing, and parenting), then we will use parametric regression models to:

- Test for mediation of the intervention on child wellbeing through caregiver stress
- Test for mediation of the intervention on child wellbeing through caregiver distress
- Test for mediation of the intervention on child wellbeing through caregiver psychosocial wellbeing
- Test for mediation of the intervention on child wellbeing through parenting

Since all the measures are continuous, the indirect effects will be calculated by multiplying relevant pathways and bootstrapping will be used to produce valid standard errors for the indirect effects. All analyses will adjust for baseline measures of the mediators (caregiver stress, caregiver distress, caregiver psychosocial wellbeing, and parenting), the outcome (child wellbeing) and putative measured confounders (e.g., socioeconomic status).

Furthermore, these factors will also be analyzed through three sequential mediation models (Figure 5), to assess how the downstream effect of BeThere on child wellbeing is mediated first through (1) caregiver wellbeing, (2) caregiver distress, and (3) caregiver stress, and then through parenting.

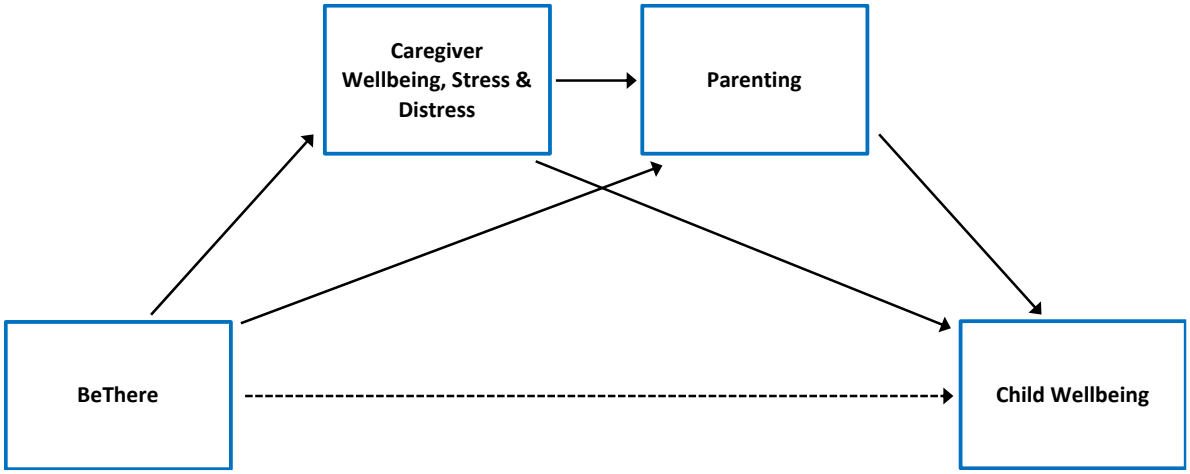

Figure 7 Full sequential mediation model

Finally, we will also measure the effect of BeThere on caregiver wellbeing, stress, and distress, as mediated through cohesion among the intervention group (Figure 6).

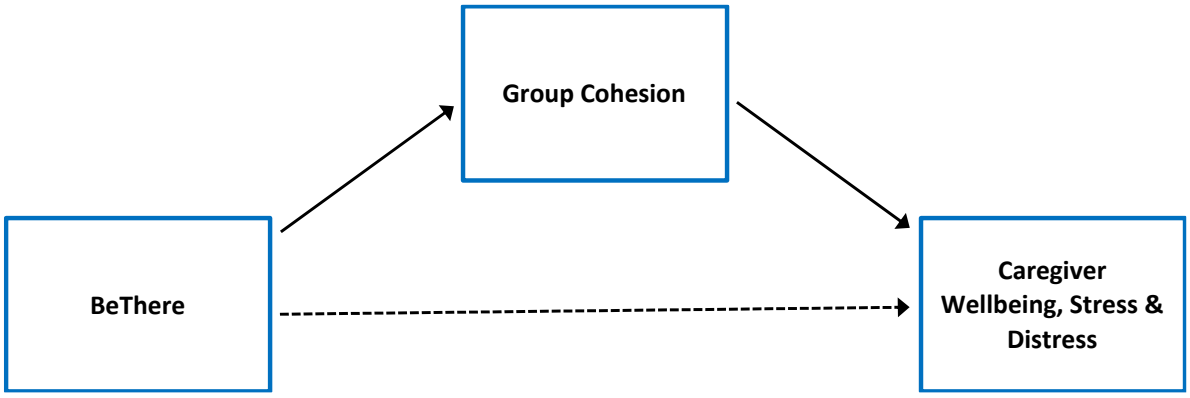

Figure 8 Group cohesion mediation model

We will assess for the effect of the BeThere intervention on each one of the multiple continuous mediators with the use of linear regression models. We chose an a priori *p*-value of lower than 0.15 to select the appropriate mediators to include in our final mediation analysis (VanderWeele & Vansteelandt, 2014). Multiple mediators require independence with each other. Therefore, we will test independence by examining partial correlations between our mediators after accounting for treatment allocation.

Full structural model

For the post-intervention showing a significant intervention effect on children's psychosocial wellbeing, a parametric structural equation modelling approach, which is a statistical technique to test different pathways of the intervention effect on children's psychosocial

wellbeing (Structural Equation Modeling package in Stata version 18.0) will be used. We will estimate the total effect: the natural indirect effects (NIE), and natural direct effects (NDE) of BeThere on child psychosocial wellbeing for; (i) caregiver's scores (primary) and (ii) caregiver's scores (secondary) on Caregiver Distress, Caregiver Psychosocial Wellbeing and Harsh Parenting. The NDE represented the effect of BeThere on Child Psychosocial Wellbeing-parent report that was independent of Caregiver Psychological Distress, Caregiver Psychosocial Wellbeing, Caregiver Harsh Parenting. Caregiver Stress and Caregiver Stress Management. An NIE represented the proportion of BeThere that could be explained by its effect with changes in Caregiver Psychological Distress, Caregiver Psychosocial Wellbeing, Caregiver Harsh Parenting. Caregiver stress and Caregiver Stress management. To quantify the magnitude of mediation, the study will estimate the proportion of the effect mediated by Caregiver Psychological Distress, Caregiver Psychosocial Wellbeing, Caregiver Harsh Parenting., Caregiver stress and Caregiver Stress management (NIE/[NDE + NIE]). All analyses will be estimated using bootstrapping (500 replications) to recover the correct SEs for direct and indirect effects Results are presented as coefficients and 95 % confidence intervals from linear regression. Statistical significance was set a priori at $p < 0.05$ with no adjustment for multiplicity. Primary mediation analyses will be conducted using data from female caregivers, and secondary mediation analysis using combined data from male and female caregivers for each one of the multiple mediators.

Oversight, ethics and dissemination

Trial oversight

First, a Trial Management Committee will consist of the Principal Investigator, the Co-Investigators, the Scientific Coordinator, and the in-country Research Coordinator. This committee will monitor the progress of the trial. Trial monitoring will also comprise the collation and reporting of routine trial process indicators and (serious) adverse events ([S]AEs). The research coordinator will receive weekly supervision from the scientific coordinator and senior research staff, and the BeThere trainer and supervisors will receive their own supervision weekly from War Child's psychosocial advisors. The PI will hold weekly meetings with the scientific coordinator and research coordinator to review all activities and issues and ensure fidelity to the research protocol.

Second, a Data Safety Management Committee (DSMC) will be set up to review the SAEs and subsequent actions taken and monitor whether the trial poses a risk to the participants. Summary statistics and graphs showing trends over time will be compiled for the process indicators. No interim analyses are planned.

Adverse events

As standard procedure throughout the research, the occurrence of specific adverse events will be monitored and acted upon using the War Child's Adverse Events (AE) Reporting Mechanism. The DSMC will provide oversight on AEs and safety protocols for the study. The DSMC will be composed of individuals to be named prior to the start of the trial, none of whom will be a part of this study. The key terms of reference for the DSMC will be to review reports of AEs (within 48 hours of notification). The purpose of the DSMC is to monitor the occurrence of AEs and where required make decisions on further actions to be taken to determine whether AEs are likely to be related or unrelated to the intervention. The DSMC

will have the mandate to recommend stopping the study if it is determined that the risks of the study outweigh the benefits. All AEs reported spontaneously by participants or observed by the investigators or other staff members will be recorded by the research team on WCH's Adverse Event reporting form. AEs can be detected by anyone as all study staff will be trained in their detection and management. Intervention facilitators will initially discuss AEs reporting with their supervisor, who will report this to the research coordinator and scientific coordinator. Research assistants will initially discuss AE reporting with the research coordinator and scientific coordinator. The scientific coordinator will subsequently share all AEs with the PI, who will be responsible for ensuring appropriate responses to all AEs. All AEs will be reported to the DSMC. This will occur within 24 hours for AEs. The chair or nominated person from the DSMC will review AEs within 48 hours and the DSMC will review all AEs monthly and where necessary to determine whether AEs are likely to be related or unrelated to the intervention.

Research ethics approval

This research protocol will be submitted for approval to the institutional review board at the University of Juba in Juba, South Sudan. Written (or witnessed, in the case of illiterate participants) informed consent by caregivers will be mandatory for enrollment in all research activities. Consent from caregivers and verbal assent from children will be mandatory for all children participating in data collection. We will protect the confidentiality of personal data principally through procedures to separate study data and participant identifiable data.

Protocol amendments

All potential amendments will be immediately communicated to the University of Juba and approval will be sought from the institutional review board.

Consent or assent

Informed consent will be gathered by the research coordinator at the baseline assessment, prior to gathering any data. A session will be held to explain all the procedures outlined in the consent/assent forms. The procedure will include: (1) oral and written information to consider participation; (2) a variant for illiterate participants, who may give consent through a signature of a literate witness (not a member of the research team). Full information on the study will be provided in local, lay language before obtaining consent (written or oral as described above) from each participant. To participants who are illiterate the information will be read out in the presence of an independent witness not affiliated to the study. It will be ensured that potential participants fully understand what it means to participate and that they can withdraw their consent at any time without having to give an explanation. It will also be made clear that refusal to participate will not have an impact on any type of support they receive. The research coordinator will allow time to address all questions and concerns from participants.

The informed consent procedure for the participation of children (7–14 years of age) will follow a two-stepped process: First, caregiver consent will be obtained for their child to participate in the study as part of their informed consent process, involving the same caregivers and process as outlined above. A child-specific consent section is included in the informed consent form for caregivers. Second, if consent from the caregiver is obtained,

verbal assent to participate in the study will be obtained from children prior to tool administration.

Confidentiality

Data collection will be conducted in a private space in or near the school so that participants' answers cannot be overheard or identified by the school principal. For instance, an empty classroom or under a tree. We will ensure sufficient distance between the duo of children and Research Assistants, and other 'duos', who are collecting data at the same time, while assuring children are not left alone with an adult to warrant Child Safeguarding. If data collection is conducted in community settings, a quiet, private space outside will be identified by the research team and respondents.

Participant confidentiality is protected at all times and War Child data collection, storage and analysis are all General Data Protection Regulations-compliant. In the case of a participant requiring specialist mental health care or protection services due to imminent risk of harm, research and programme staff are trained to take the appropriate steps to maximise participant confidentiality, whilst protecting participant safety and ensuring that adequate care is received. This is explained to participants during consent sessions.

See the section on data management for details on the measures taken to protect participants' data privacy, on safe and secure data storage and de-identification of participant data prior to analysis and write-up.

Access to data

This proposed research follows the data management guidelines of War Child's R&D department (available upon request). All electronic data files will be stored on a password protected cloud server (SharePoint), accessible only on password protected and encrypted laptops. Access to this data will only be available to the core research team. Research Assistants and transcribers will sign a confidentiality clause. The detailed War Child Data Management Policy will serve as guidance on all data management and data sharing issues.
All survey data will be collected via Kobo Toolbox. Research Assistants will upload data to the Kobo server at the end of each data collection day. Only the core research team will have access permissions to edit the questionnaires and download the data from the Kobo server. Data will be downloaded from the Kobo server every day and stored as a backup on a secure data server of the Research &Development Department of War Child. This server is password protected and accessed from password protected and encrypted laptops.

At the end of data collection, the complete data file will be downloaded at the War Child head office from the Kobo server and the master-file will be saved securely on a separate server and uploaded into relevant software for data analysis. All recording devices will be stored directly after data collection in a locked cabinet. All data cleaning and analysis processes will be tracked through saved syntax from data analysis software. Any hardcopies of data, including informed consent forms, will be stored in a dry, lockable cabinet. Data sets will be accessible by the War Child core research team members. The Research & Development Department at War Child has, in all cases, ownership of the research data.

Ancillary and post-trial care

War Child is familiar with the communities and the existing mental health and psychosocial support services available. However, a full service landscape mapping will nonetheless be conducted prior to the start of implementation for referral and follow up. War Child will provide immediate case management support to participants or their family members that exhibit signs of suicidal ideation or self-harm, or who might need more specialized psychological support. These cases will be referred to appropriate services. When those services are not present in the community, War Child will facilitate transportation costs for participants to travel to locations where more specialized services are available.

Dissemination policy

The results of this project will be published in English in peer-reviewed journals (we always aim to publish in open access journals). Summary results will be disseminated in Dinka and English to key stakeholders through reports and presentations. Dissemination meetings will be held in target communities to inform stakeholders and participants of trial results.

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Appendices

1. CVs of research team
2. Informed consent materials
3. Data Collection Instruments
4. Facilitator manual