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Research Article

Effectiveness of a Father-Inclusive Parenting Intervention on a Child's Diet, Early Stimulation, and Father Involvement in Childcare in Rural Malawi: A Study Protocol for a Four-Arm, Cluster-Randomized Controlled Trial

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Background. Increasing the engagement of fathers or couples in childcare may generate additional benefits on early child outcomes. However, parenting intervention that includes fathers and couples is limited in low-resource settings. Thus, this study designed a parenting intervention on child nutrition and responsive care that is inclusive of fathers and couples, using behavior change communication. First, we aimed to evaluate the effectiveness of the parenting intervention on a child's diet, early stimulation, and father involvement in childcare among parents of a child aged 6-23 months in rural Malawi. Then, we assessed the added benefit of including fathers and couples in the intervention to improve the outcomes. Methods. In this four-arm, cluster-randomized controlled trial, we assessed the effectiveness of a parenting intervention in rural Malawi. We randomly selected and allocated 40 communities to the intervention or control arms in a 3-to-1 ratio. Four arms included a mothers-only treatment arm, a fathers-only treatment arm, a couples treatment arm, and a control arm. Eligible households were a two-parent household having a child aged 6-23 months, a child having a mother as a primary caregiver living with a male partner, and a parent aged 18 or above. Intervention arms participated in two peer group sessions and two home visits focusing on child nutrition and responsive care. Behavior change communication was used to deliver key behavioral messages. Primary outcomes were child dietary diversity score, early stimulation, and father involvement in childcare. The analysis was done using difference-in-differences estimation.

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Discussion. The study will provide evidence of the effectiveness of the parenting program that can be replicated and scaled-across in other low-resource settings like rural Malawi.

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Introduction

Nurturing care in early childhood is critical for cognitive, social, emotional, and physical development [1][2][3], as the children's developing brain is highly sensitive and responsive to experiences and the environment [1][4]. However, an estimated 250 million (43%) children under five years are at risk of not attaining their full developmental potential due to inadequate nurturing care in low- and middle-income countries (LMICs) [1][2]. Additionally, the quality of children's diets has remained persistently poor. Approximately 29% of children aged 6-23 months met a minimum dietary diversity, and 45% consumed animal-sourced products in LMICs [5][6]. Meanwhile, unhealthy feeding practices have increased, such as the consumption of sweet beverages and unhealthy foods and zero intakes of fruits or vegetables [6][7].

Early stimulation and responsive care are positively associated with children's health and developmental outcomes [1][3][8]. Stimulation activities by parents include reading or looking at picture books, telling stories, singing songs, taking children outside the home, playing, and naming, counting and/or drawing. In many LMICs, parenting interventions combining responsive care with nutrition education were effective in improving short-term children's health outcomes [1][2][9]. Despite increasing evidence, levels of early stimulation and responsive care remain low in low-resource settings [10]. It is estimated that 40% of children were experiencing stimulation from their mothers, 12% from their fathers, and 21% from other caregivers [10]. Parental stimulation is least practiced in sub-Saharan Africa (maternal 15% and paternal 4%) [10].

Adequate nurturing care can be challenging for caregivers due to limited resources, time, knowledge, and skills [11]. In low-resource settings, social support is known to improve child feeding practices by providing instrumental, emotional, or financial support from families and others [11][12]. Mothers with high levels of social support are more likely to breastfeed and feed the child with higher dietary diversity [11][12][13]. In particular, fathers have a substantial impact on children's health and development through financial provision and resource accumulation [14][15].

Fathers are important for co-parenting, in which a couple works together as a team to achieve their parenting goals [16][17]. Studies have shown how the father's involvement influences the mother's childcare behaviors on the children's growth and development [9][18]. However, co-parenting or sharing responsibilities in childcare by involving fathers has not yet fully adapted to behavior change interventions, especially in LMICs. Relevant systematic reviews reported the lack of father participation in parenting intervention [18][19]. Frameworks focusing on co-parenting and the family as a unit should be considered to enhance the father involvement [19][20].

Parenting interventions are particularly important in early childhood when children are most sensitive to the environment [21][22]. In LMICs, parenting intervention used behavior change communication (BCC) to improve nutrition, health, and social norms [11][23]. BCC is a combination of communication approaches intended to motivate behavior change by imparting knowledge or evoking emotions at multiple levels [24]. In BCC studies, father engagement was associated with improved child diet and feeding practices [12][23][25]. However, impact evaluations of father engagement in childcare or feeding practice are less available. Thus, designing a father-inclusive intervention is required to improve a child's diet and feeding practices [26].

In Malawi, children under five years old account for 15% of the total population and 86% of children live in rural areas [27]. An estimated 83% of young children are at risk of poor development, based on proxy measures of stunting and poverty [28]. Only 25% of breastfed children had an adequately diversified diet, while 29% had been fed the minimum number of times [29]. The Malawi Multiple Indicator Cluster Survey reported that only 2% of fathers and

12% of mothers were engaged in early stimulation and responsive care [30].

Parenting interventions hold great promise for improving children's diet and health as the parents' engagement in childcare is considered a core mediator [31]. However, current interventions mainly target mothers and are limited in engaging fathers or couples in their design [19]. Despite the benefits of father involvement in children's health, policies and interventions are often based on a father-deficit model, reflecting maternal-focused childcare and the gender bias in cultural stereotypes [32]. While involving fathers in childcare presents challenges, the need for father engagement is apparent. Thus, this study designed a parenting intervention on child nutrition and responsive care that is inclusive of fathers and couples using BCC.

Objectives

This four-arm, cluster-randomized controlled trial included three treatment arms (i.e., mothers-only, fathers-only, and couples arms) and a control arm to examine the following objectives. First, we aimed to evaluate the effectiveness of a parenting intervention on a child's diet, early stimulation, and father involvement in childcare among parents of a child aged 6-23 months in rural Malawi. Then, we assessed the added benefit of including fathers and couples in the intervention to improve the outcomes.

Materials and methods

Study design

This study is a four-arm, cluster-randomized controlled trial to evaluate the effectiveness of a parenting intervention to enhance a child's diet, early stimulation, and father involvement in childcare. Fig 1 presents the schedule of enrolment, interventions, and assessment using the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) [33]. The study flow chart is shown in Fig 2.

	STUDY PERIOD (Weeks)										
	Enrolment	Allocation	Post-allocation								Close-out
TIMEPOINT	0	0	1	2	3	4	5	6	7	8	9
ENROLMENT:											
Eligibility screen	X										
Informed consent	X										
Allocation		X									
INTERVENTIONS:											
Parenting intervention			◆	—	—	—	—	—	—	◆	
Control											
ASSESSMENTS:											
Baseline variables (Sociodemographic variables)		X									
Child dietary diversity		X									X
Early stimulation		X									X
Father involvement in childcare		X									X
Nutrition knowledge		X									X

Fig. 1. Schedule of enrolment, interventions, and assessment.

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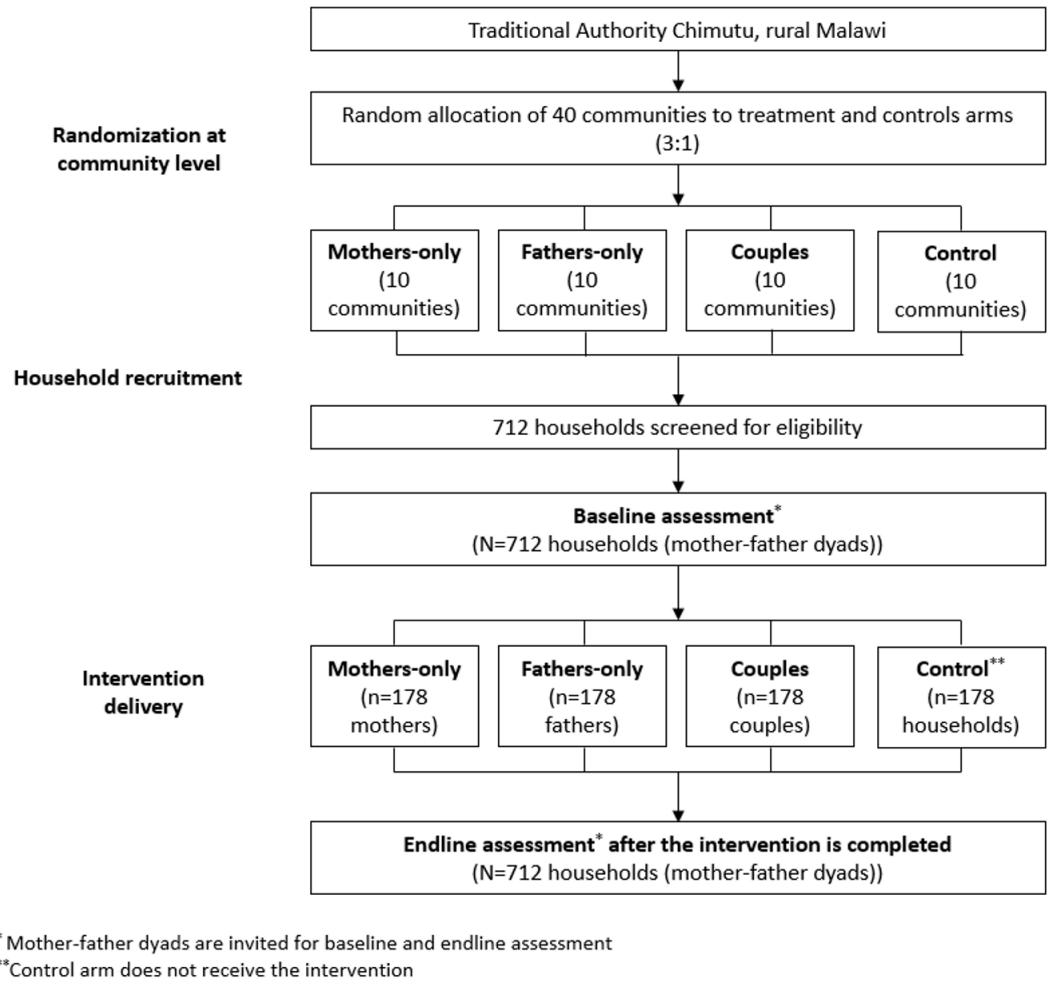

Fig. 2. Trial profile.

Study setting

The study was conducted in Traditional Authority (TA) Chimutu, the rural district of Lilongwe, Malawi [27]. The district has health surveillance assistants (HSAs) who are assigned by the government to provide essential health packages to the community. TA Chimutu population is estimated to be 112 118, predominantly from the Chewas tribe and speaks Chichewa. Literacy rates are 70.3% for women and 87.4% for men [13]. Most of the residents are farmers or unskilled informal workers. No other parenting programs promoting early childhood development were available in the area during the study implmentation. This study collaborated with REHA, a local Malawian Non-Governmental Organization, Chiwamba Health Center, HSAs, and village leaders.

Participants

The study selected a household with the following eligibility criteria: 1) a two-parent household having a child aged 6-23 months, 2) a child having a mother as a primary caregiver living with a male partner who is the child's father or stepfather, 3) a male partner living in a household with a mother and child at least ten months out of the year, and 4) parents aged 18 years old or above.

Sample size

Our sample size was estimated to be 712 households to detect a mean difference in the child dietary diversity

score of 0.31 between intervention and control arms, considering the intraclass correlation of 0.04 and design effect of 1.36 [34][35]. The calculation was set at an alpha of 0.05, a power of 0.8, and assumed 10% attrition. The sample size was calculated using OpenEpi (version 3.01).

Randomization and recruitment

In this study, a cluster is defined as the catchment community of HSAs and the unit of randomization to minimize the risk of contamination. A researcher, who is not involved in any part of the study, randomly allocated 40 communities to the intervention or a control arm in a 3-to-1 ratio using the STATA random number generator. Four arms include: a mothers-only treatment arm, a fathers-only treatment arm, a couples treatment arm, and a control arm. Households were selected from the sampling frame using simple random sampling and visited until 17 to 18 households were recruited in each community. Eligible households were recruited from October 5, 2022.

Blinding

Participant recruiters (HSAs and village leaders) were blinded to the allocation at the time of recruitment. Participants were blinded as to their allocation status at the baseline and were informed of intervention participation after the baseline survey. Enumerators had no role in intervention delivery and were blinded while assessing outcomes during baseline and endline assessments. The author (SC) had access to information that could identify individual participants during or after data collection.

Intervention

BCC was used to design the parenting intervention, which is known to be effective in improving nutrition and health outcomes [36]. To motivate behavior change, BCC aims to impart knowledge and evoke emotions, positively influence social norms, and mobilize communities to improve nutrition and health practices [37]. BCC messages depict simple, cost-effective, doable actions appropriate for low-resource, community-based settings.

All parents assigned to treatment arms participated in parenting intervention, consisting of two group sessions and two home visits (Table 1). The program combined child nutrition and responsive care to promote early child health and development [38][39][40]. Three topics were featured: the infant and young child feeding (eat), early stimulation and responsive care (play), and co-parenting (love). The control arm did not receive any intervention.

Delivery model	Topic	Outline	Materials	Frequency
Group session	1. Infant and Young Child Feeding (Eat) 2. Responsive care and early stimulation (Play) 3. Co-parenting (Love)	Introduction Storytelling BCC message delivery Demonstration Discussion Group pledge	Facilitator flipchart Caregiver handbook Facilitator flipchart	2 times (60-70 minutes per session)
Home visit	1. Infant and Young Child Feeding (Eat) 2. Responsive care and early stimulation (Play) 3. Co-parenting (Love)	Positive counseling Review BCC messages Discuss challenges and solutions Monitoring Observe child-parent interaction	Facilitator flipchart	2 times (30-40 minutes per visit)

Table 1. Components of the parenting intervention

Formative research was performed to ensure that the curriculum, BCC messages, materials, and implementation strategies are appropriate in the local context. We conducted focus group discussions and in-depth interviews with HSAs, village leaders, and caregivers. Interview guides and checklists were prepared based on literature reviews. The intervention was delivered by facilitators from REHA who have extensive experience in maternal and child health community projects. Facilitators received training on the program contents and communication skills for positive counseling and motivational interviewing [41].

Two group sessions were provided to parents at community centers [9][21][42]. The sessions used activities and aspirational stories to amplify motivational drivers of healthy child feeding, responsive care, and paternal engagement in childcare. Session activities include BCC message delivery, storytelling, demonstrations, and problem-solving discussions with other parents. A group pledging ceremony was done to establish and reinforce the norm of childcare. Parents received a picture book and a parent handbook with a routine checklist for feeding and responsive care practices. Positive affect induction was used to reinforce behavior change with social interactions and the experience of pleasurable emotions [43]. The post-affect manipulation check was conducted using the International-Positive and Negative Affect Schedule-Short Form [44]. Sessions were designed in the same format for mothers-only, fathers-only, and couples arms. However, the BCC messages were refined based on the parenting role. The group sessions were 60-70 minutes. Facilitators delivered two home visits to monitor the target practices and provide positive counseling to caregivers [21]. The session focused on reviewing target BCC messages, discussing challenges and solutions, and observing parent-child interactions. Facilitators used the structured checklist to guide counseling. Home visits were scheduled for 30 minutes.

Data collection and management

The household survey was collected by trained enumerators using a digital data collection application called Commcare. The interviewer-administered questionnaire was translated into the local language (Chichewa) by the research team and then back-translated into English for verification. The research team undertook the cultural adaptation of

tools and pre-testing of the assessment tools. The survey took about 30-40 minutes per parent. All outcomes were measured twice, once at the baseline and again at follow-up after the intervention was completed.

Data was entered on a password-protected tablet and uploaded to an online server regularly by the field supervisor. The participant was assigned a unique ID, and identifying information linked to the ID was kept separately in password-protected files until the information was needed again for intervention and endline survey rounds. The purpose of collecting identifying information was to allow for follow-up. Data was downloaded and stored in a highly secured, password-protected personal computer. After completion of the endline assessment, all data was anonymized, removing the identifying information.

Primary outcomes

Child dietary diversity score

Child dietary diversity score (CDDS) is defined as the number of food groups out of eight food groups consumed by children aged six months or older in the last 24 hours [45]. CDDS was assessed using the validated food frequency questionnaire containing locally adapted food items [29]. A list-based recall method was used. Food items were categorized into eight food groups as follows: 1) breast milk, 2) grains, roots, tubers, and plantains, 3) pulses (beans, peas, lentils), nuts and seeds, 4) dairy products (milk, infant formula, yogurt, cheese), 5) flesh foods (meat, fish, poultry, organ meats), 6) eggs, 7) vitamin-A rich fruits and vegetables, and 8) other fruits and vegetables. A higher child dietary diversity score (CDDS) means a higher probability of reaching a nutritionally adequate diet.

Early stimulation

Early stimulation practices by parents were assessed using a self-report questionnaire adapted from the UNICEF Multiple Indicator Cluster Surveys [46]. Paternal early stimulation information was collected from mothers and fathers. The questions asked whether the parent (mother and father) engaged in any of the following activities with the child in the past three days: 1) reading books or looking at picture books, 2) telling stories, 3) singing songs or lullabies, 4) taking the child outside the home, 5) playing with the child, and 6) naming, counting, or drawing things for or with the child. These practices have adequate predictive validity in early child development [8][40].

Father involvement in childcare

Father involvement in childcare was assessed using the gendered division of childcare questions from Promundo's Bandebereho study in Rwanda [47]. Both mothers and fathers were asked how they divided eight childcare tasks with their partners. The childcare tasks include: 1) providing financial support for childcare; 2) feeding the child; 3) bathing the child; 4) soothing the child if he or she is crying or upset; 5) taking the child to the health center if sick or for vaccination; 6) telling a story, singing a song, or playing with the child; 7) teaching the child something, and 8) disciplining the child. A higher score reflects higher father involvement in childcare.

Secondary outcome

Infant and Young Child Feeding knowledge

The mother's knowledge of infant and young child feeding (IYCF) was assessed using a questionnaire adapted from the WHO-UNICEF guideline [45]. A higher score represents a higher level of knowledge of IYCF practices.

Data analysis

The analysis was conducted following an intention-to-treat approach to evaluate the impact of the intervention. We estimated the following difference-in-differences model (DID):

$$y_{ijt} = \beta_0 + \beta_1 T_{ij} + \beta_2 A_{ij} + \beta_{DID} T_{ij} A_{ij} + X_{ij}\beta + \varepsilon_{ijt}$$

where y_{ijt} is the outcome of interest for parent i from community j at the timeline of assessment t (0=baseline; 1=endline), T_{ij} is the dummy variable for the timeline of assessment, A_{ij} is the dummy variable for the intervention arm (0=control; 1=treatment), X_{ij} is a set of the covariate from the baseline, and ε_{ijt} is the error term. Primary outcomes include CDDS, early stimulation, and father involvement. The intervention effect (DID) was estimated as the coefficient (β_{DID}) of the interaction variable of T_{ij} and A_{ij}. To assess the impact of the intervention on the outcomes of interests, a mixed effects model was used to account for clustering effects [48]. Pairwise comparisons between arms were conducted using the F-test. This study used the Holm-Bonferroni test to adjust for

multiplicity [49]. The attrition rate of enrolment and drop-out were reported and compared between the arms. The analysis was conducted using Stata version 15.1 (StataCorp, College Station, Texas, USA).

Data monitoring

Implementation activity was monitored by the supervisors of the local implementing organization (REHA). The supervisors documented a daily log of implementation activities and reported to one of the authors (SC) on a weekly basis.

Ethics approval and consent to participate

Ethics approval was received from the University of Tokyo Research Ethics Committee (SN: 2022027NI) and the Malawi National Health Sciences Research Committee (NHSRC) (Approval number: 22/07/2936). Written consent was obtained from all participants. Participation was voluntary and participants could withdraw from the study at any time. All methods were carried out in accordance with the relevant guidelines and regulations.

Trial status

This study was registered with the UMIN Clinical Trial Registry (UMIN000048566) on August 3, 2022. Trial enrolment started on October 5, 2022 and data collection was completed on May 9, 2023.

Discussion

Parenting intervention holds great promise to advance early childhood health and development. Increasing the engagement of fathers or couples in childcare may generate additional positive benefits on early child outcomes [19][50][51]. Thus, this study designed a parenting intervention that is inclusive of fathers and couples using BCC. The intervention integrated child nutrition and responsive care using the combination of group sessions and home visits to maximize the impact [38][39]. Then, we evaluated the effectiveness of the intervention on a child's diet, early stimulation, and father involvement in childcare.

Global health programs recently seek ways to enhance male partner involvement in maternal and child health [9][19][52]. This parenting intervention makes an effort to be father-inclusive by incorporating culturally accepted masculine roles in rural Malawi and valuing fathers as an asset in childcare [53][54]. In Africa, meaningful male partner involvement is defined as his contribution as a financial provider for the family [53][55][56]. It is critical to recognize and acknowledge existing male involvement. Thus, this intervention used BCC messages to reinforce how fathers can provide financially and allocate resources to promote child health and development. To ensure successful implementation, we considered recruitment and delivery approaches such as the timing and the location by conducting formative research with community members [19].

This study has several strengths. First, the intervention is designed to be father-inclusive and locally constructive to both fathers and mothers as co-parents. By assigning multi-arms, the disaggregated and joint effects of intervention evaluation are possible. Our study can demonstrate the impact of individual parents' and couples' participation on parenting outcomes via the intervention and provide evidence on engagement and delivery strategies. Second, data was collected from mothers and fathers. Previous studies used maternal reports on paternal information, which are potentially susceptible to biases [57]. Third, the intervention was managed and delivered by a local organization and community members with limited resources. By engaging local organizations, we can find culturally appropriate and sustainable strategies to design, recruit, and deliver interventions to fathers. It then may be replicated in other similar resource-limited settings like rural Malawi. Last, the effect of unknown confounders can be minimized by RCT study design.

Despite these strengths, the study has some limitations. First, the outcomes were measured using self-reports rather than observational assessments, which are potentially susceptible to social desirability and other biases. To mitigate outcome overestimation, the behavioral outcomes were collected from mothers and fathers. Second, the follow-up time frame was two months which is short to assess behavior changes and sustained effects. However, previous studies reported that behavior change of similar outcomes was achieved and sustained within ten months of intervention [58]. In addition, this study focuses on initiating behavior changes and evaluating the short-term effects of the intervention. Third, the study is potentially subject to biases due to the lack of double blinding [59]. To minimize the risk, enumerators were blinded to the allocation of participants and were not part of delivering the intervention.

Statements and Declarations

Competing interests

The authors declare that they have no competing interests.

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