BMC Pediatrics

STUDY PROTOCOL Open Access

A parenting program delivered through existing community-based peer groups to improve early child development in Homabay and Busia Counties, Kenya: study protocol for a cluster-randomized controlled trial

Joshua Jeong[1*], Juliet K. McCann[1], Silas Onyango[2] and Michael Ochieng[3]

Abstract

Background Poor early childhood development (ECD) is a major global health concern that is associated with various adverse outcomes over the lifecourse. Parenting interventions especially during the earliest years of life can benefit ECD. However, there is limited evidence from Kenya about the effectiveness of parenting interventions for improving ECD outcomes especially across rural disadvantaged communities. This paper describes the study protocol for an impact and implementation evaluation of a community-based group parenting program that aims to improve ECD in rural Kenya.

Methods We will conduct a cluster-randomized controlled trial to determine the effectiveness of a parenting program for caregivers of young children in Homabay and Busia counties in Western Kenya. Sixty-four village clusters will be randomly assigned to either the parenting intervention arm or the waitlist control arm with stratification by county. In each village, 10 primary caregivers with a child aged 0–24 months will be enrolled. The parenting program will be delivered through existing peer groups within communities whereby caregivers will receive counseling and psychosocial support to enhance their parenting skills and wellbeing to in turn promote ECD. The intervention curriculum comprises 21 sessions targeting various nurturing care messages, including early learning, responsive caregiving, child nutrition, health, protection, and caregiver mental health. Group sessions are facilitated by a trained volunteer biweekly for a total of 11 months. The primary trial outcome is an overall measure of ECD using the Global Scales of Early Development long form version. Secondary outcomes include various caregiver outcomes (e.g., parenting practices, mental health) and other child outcomes (e.g., socioemotional development, dietary diversity). All outcomes will be assessed at baseline and endline. We will also conduct a qualitative implementation evaluation at endline and interview various stakeholders to assess program fidelity, quality, and sustainability.

*Correspondence:
Joshua Jeong
joshua.jeong@emory.edu

Full list of author information is available at the end of the article

Discussion This trial will evaluate the effectiveness of a parenting intervention on ECD and caregiving outcomes and assess program implementation quality as delivered through existing community-based peer groups. This study will provide rigorous evidence that can be used to inform scale-up of this program model that leverages existing community social networks and resources for improving caregivers' parenting skills and promoting ECD in rural Kenya and other similar settings across LMICs.

Trial registration ClinicalTrials.gov #NCT06165315. Registered on December 11, 2023.

Keywords Early child development, Parenting, Intervention, Randomized controlled trial, Kenya

Background

It has been estimated that 250 million or approximately 43% of children under five years are at risk of not attaining their developmental potential [1]. Poor early childhood development (ECD) is associated with a host of adverse outcomes later in life – spanning health, education, psychosocial wellbeing, and economic productivity [2]. Various factors can contribute to poor ECD, including poverty, malnutrition, and sub-optimal parenting practices [3, 4]. Nurturing care interventions that address these risk factors while bolstering protecting factors such as early learning opportunities and responsive caregiving are critical for promoting healthy ECD [5].

One of the most effective strategies for improving ECD outcomes globally are parenting interventions [6]. Parenting interventions are social and behavioral programs intended to improve primary caregivers' knowledge, attitudes, practices, and skills to support children's development. Parenting interventions often target multiple behaviors such as increasing engagement in stimulation activities, promoting attachment and parental sensitivity and responsiveness, providing access to toys and other materials for play and learning, supporting positive disciplinary practices [7]. Furthermore, parenting interventions are increasingly being integrated with other nurturing care messages – such as nutrition, health, caregiver wellbeing, and gender – to achieve more holistic impacts for caregivers and young children [8, 9].

Although there has been a rapidly growing evidence base on the effectiveness of parenting interventions in low- and middle-income countries (LMICs), the majority of the global evidence is concentrated to a select subset of countries. For example, a global meta-analysis of parenting interventions revealed that most randomized controlled trials (RCTs) of parenting interventions in LMICs have been conducted in Bangladesh, Jamaica, and India [7]. There are relatively fewer rigorous evaluations of parenting interventions from countries in sub-Saharan Africa.

Specifically in Kenya, less than a handful of publications to date have evaluated the impacts of parenting interventions on ECD outcomes [10–12]. While this prior evidence has suggested benefits on certain caregiver-level outcomes (e.g., parenting knowledge and practices), program impacts on ECD outcomes have been more mixed with two studies finding null effects [10, 12] and one study observing improvements in child development [11]. One key limitation of this overall evidence base from Kenya pertains to questions of internal validity and specifically the lack of random assignment to the program, with only one of these prior studies using an experimental design [11].

This nascent and inconclusive evidence base underscores the need for additional research and particularly using robust study design to determine the effectiveness of parenting interventions relative to standard-of-care services for improving ECD in Kenya. In addition to impact evaluations, implementation evaluations can uncover additional insights regarding the successful ingredients of parenting programs, stakeholders' experiences participating in the program, the barriers and enablers to program delivery, and potential for scalability [13–15].This paper describes the study protocol for a combined impact and implementation evaluation of a community-based group parenting program for improving ECD in rural Kenya. The intervention model is unique by leveraging existing community-based peer groups and integrating parenting support within these networks. This mixed-methods evaluation will provide a holistic understanding regarding whether, why, and how the parenting program benefits ECD and caregiving outcomes. Study findings are expected to inform programmatic adaptations and actionable recommendations for enhancing the effectiveness, quality, and implementation of parenting programs in rural Western Kenya and other similar settings across LMICs.

Methods

Study design

This study design comprises a quantitative impact evaluation and a qualitative implementation evaluation. To quantitatively evaluate the effectiveness of the parenting intervention on ECD and caregiving outcomes, we will use a cluster-RCT design. Villages will be randomly allocated at a 1:1 ratio to either the parenting intervention arm or a waitlist, standard-of-care control arm. In each village, 10 primary caregivers with a child aged 0–24 months will be enrolled. We will conduct two

rounds of data collection in the study cohort at baseline and endline (i.e., immediately after the completion of the intervention, or a follow-up period of 11 months after baseline) to compare changes in outcomes between study arms and over time. After the endline evaluation is completed, then the villages in the waitlist-control arm will have the opportunity to receive the parenting program. To evaluate the implementation quality of this parenting program, we will incorporate a qualitative study as part of the endline evaluation and conduct in-depth interviews with various stakeholders to assess how factors such as program fidelity, quality, and acceptability influence program impacts on caregivers, children, and their communities. The trial is registered with ClinicalTrials.gov, #NCT06165315.

Study setting and enrollment

The trial will be conducted in Homabay and Busia counties in Western Kenya. In both counties, households are generally poor with the majority falling in the lowest two wealth quintiles relative to national distributions, and the predominant occupation being agriculture [16]. Homabay county the has the highest prevalence of HIV (20%) and proportion of children who are double orphans (3%) in the country [16, 17]. These counties were selected by program implementation and county government partners based on these county governments' commitments to improving the quality and access to maternal, child and adolescent health, nutrition, and early childhood education services. Busia and Homabay counties were identified by stakeholders as having inadequate information on nurturing care and the science of ECD, not having policies that anchor nurturing care, and not having prioritized allocation of funds for ECD. They were also identified as having weak stand-alone coordination structures that are department specific. Together this highlighted a key gap in these counties but also an opportunity for programming.

In consultation between ChildFund (i.e., the lead implementing organization) and its partners that included subnational government ministry representative, local community-based organization partners, and local community members, specifically Ndhiwa sub-county in Homabay County and Bunyala sub-county in Busia County were prioritized as the project sites. The teams used health and vulnerability criteria to prioritize locations. The criteria included: locations with a high rate of HIV and AIDS, teenage pregnancy, pregnant mortality, neonatal mortality, malnutrition, anemia and stunting, inadequate access to supplements and vitamins, child marriage and early pregnancy, as well as low access to health services such as pre-and post-natal services and low rates of birth registration. In Ndhiwa sub-county in Homabay county, the study will be conducted specifically in all 3 wards (North Kabuoch, Kanyamwa Kosewe, Kanyamwa Kologi). In Bunyala sub-county in Busia County, the study will be conducted in 3 out of the 4 wards (Bunyala North, Bunyala South, Bunyala West). This sampling frame and setting was determined by the program team during the planning phase through consultations with stakeholders and prior to the initiation of the research partnership.

Based off of the set plans for program implementation in 6 wards (3 in Bunyala sub-county and 3 in Ndhiwa sub-county), we obtained lists of all the villages and the estimated number of households per village across these selected wards. Villages with extreme accessibility challenges (e.g., islands) or those with relatively few households (i.e., less than 70 households per villages) were excluded for operational feasibility. From the remaining villages, we randomly selected 64 total villages with stratification by ward (approximately 10 villages per ward) and randomly assigned half to the intervention versus waitlist control (approximately 5 villages in the intervention vs. control per ward). We replaced any sampled villages that were neighboring with another randomly selected villages from the list of eligible villages. Final selection of villages was be made by the research team in collaboration with the implementing partner to ensure representation of the ward, feasibility of the site, while reducing the risk of contamination.

Eligibility criteria and recruitment

Once villages are selected, the research team will approach households to screen caregivers for eligibility. Study eligibility criteria will include: primary caregivers with a child aged 0–24 months, the household resides in the sampled village, and the primary caregiver provides informed consent for themselves and their child to participate. Only one caregiver will be sampled per household for a total of 10 caregivers per village.

For the qualitative implementation evaluation, we will focus on a sub-sample of intervention villages and use purposive sampling to recruit caregivers, program delivery agents, other community stakeholders (e.g., community health volunteers), and program staff to capture a diversity of perspectives and experiences with respect to the program implementation.

Intervention description

This parenting program was developed by ChildFund International with implementation being overseen by ChildFund Kenya. ChildFund is a non-governmental organization that works in 24 countries in Africa, including Kenya, as well as Asia, and the Americas to improve the lives of children living in poverty, bring positive change to their communities, and create societies that value, protect, and advance child rights and wellbeing.

The primary goal of this parenting program is to improve caregivers' knowledge, attitudes, and practices about nurturing care to in turn improve the developmental outcomes of young children aged 0–3 years. The primary program component are the community-based parenting group sessions. Parenting groups leverage existing peer-groups in the community (e.g., self-help groups, microfinance groups, women's groups) to bring together 10 eligible caregiver-child dyads per group. Group sessions are facilitated by one trained volunteer who either was nominated as the peer group leader among the existing group members or already serves in the capacity of a community focal person (e.g., community health promoters, community child protection volunteers, village elders). These group leaders will receive supportive supervision from a mentor. The manualized intervention curriculum includes 21 sessions and covers various content with respect to the Nurturing Care Framework for promoting ECD, including play and communication with young child, responsive caregiving, child health, nutrition, protection, and caregiver wellbeing [18]. Sessions focus on enhancing social and behavior change through counseling, participatory activities, problem-solving, and group discussion. Each group session is expected to last up to 2 h and at a frequency of every two weeks (i.e., 2 sessions per month) for a total implementation duration of approximately 11 months.

In addition to the universal group parenting program component, the program will provide targeted psychosocial support (e.g., referrals to health facilities for caregivers with mental health problems) and livelihood support (e.g., training on income-generating activities, provision of agricultural inputs) to a subsample of caregivers at greatest risk of adversity. In addition to supporting caregivers directly, the program will also strengthen existing community systems to promote enabling environment for nurturing care. The program will strengthen linkages with existing community-level maternal and child health and nutrition services through conducting trainings to group facilitators about maternal and child health and nutrition in collaboration with Ministry of Health at the subcounty level, strengthening referral channels, and improving coordination with community health volunteers and other health professionals (e.g., health facility staff, nutritionists). Finally, the program will also promote capacity development of local implementing organizations and child protection agencies to enhance local ownership and build multisectoral coordination for nurturing care at the subnational and national levels. See Fig. 1 for theory of change to the ChildFund parenting

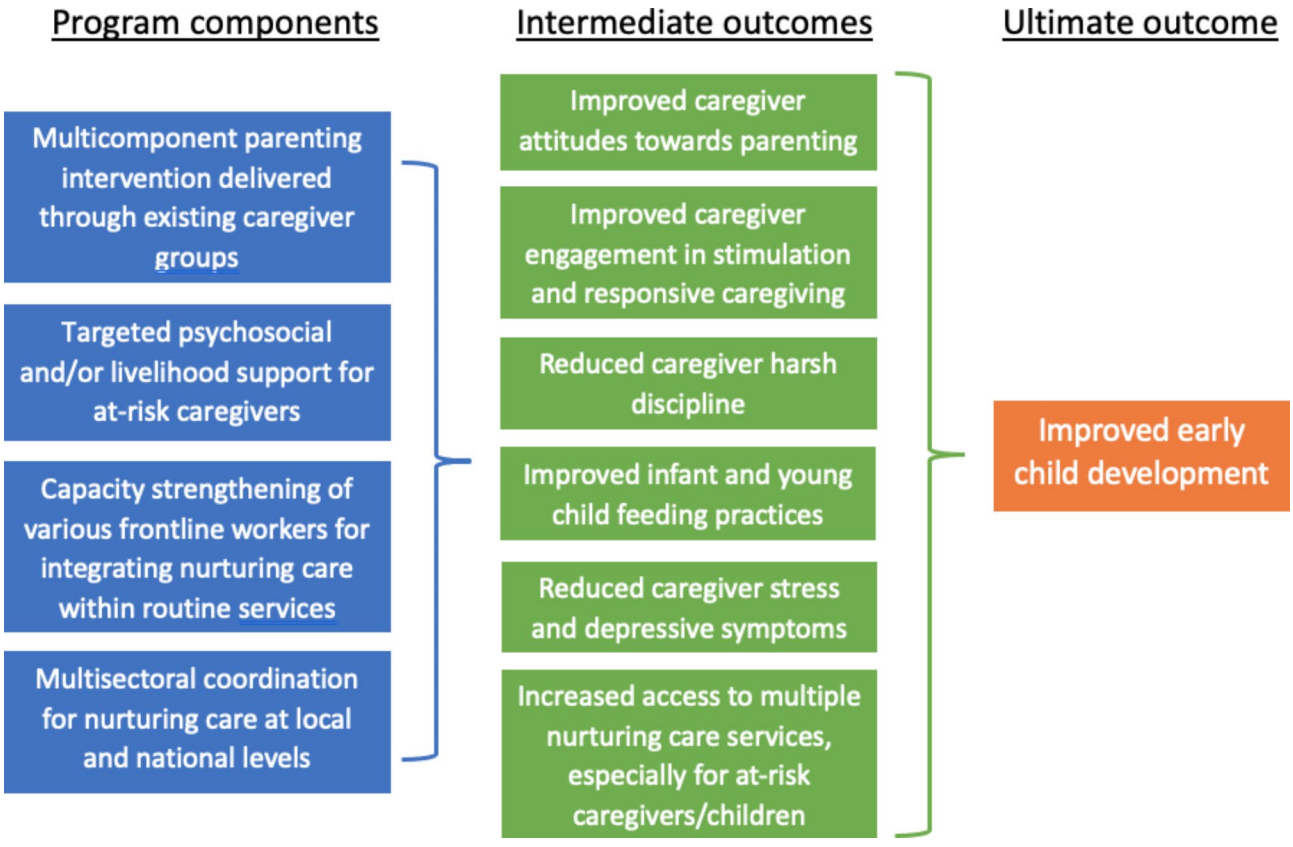

Fig. 1 ChildFund parenting program theory of change

program that guides the main outcomes for the effectiveness evaluation.

ChildFund Kenya will direct the overall program implementation through designing the program materials, leading technical trainings and supportive supervision for partners, and conducting routine program monitoring activities. Community-level program activities will be implemented by the Lake Region Development Program (LRDP) in Ndhiwa Sub-County and the Western Community Children's Programme (WCCP) in Bunyala Sub-County. ChildFund and community partners will engage relevant government stakeholders through ongoing training activities and multisectoral advocacy meetings to build capacity for implementing nurturing care activities and local ownership of the program. Implementation for the first parenting group session is expected to begin by end of January 2024, and program implementation for this first cohort is expected to be completed by November 2024.

Randomization and blinding

A total of 64 villages were randomly allocated at a 1:1 ratio using computer-generated random numbers in Stata 16 to either the parenting intervention arm or a waitlist, standard-of-care control arm with stratification by wards to ensure balance between sub-counties. Randomization was done prior to study initiation by a researcher at Emory University who was not involved in study procedures. Due to the nature of the community-based social and behavior change intervention, it is not possible to blind participants or the implementation team to the intervention group assignment. Survey enumerators and data analysts will be blinded to treatment group assignment.

Outcomes measures

Enrolled primary caregiver-child dyads will be assessed in a private setting at the caregiver's household. We will collect detailed information on various characteristics spanning sociodemographic factors, caregivers' knowledge, attitudes, and practices related to parenting, caregivers' mental health, and child development. See Table 1 for details of the trial primary and secondary outcome measures that will be assessed at both baseline and endline data collection. The primary endpoint will be at endline (i.e., following the implementation of the 11-month intervention). Survey questionnaires will be administered by trained enumerators to primary caregivers in their preferred language of Kiswahili, Luo, or Luhya, and data will be collected electronically using tablets (Kobotoolbox).

The primary outcome of this trial is children's overall development, which will be measured using the long form version of the Global Scales of Early Development (GSED) [19]. The GSED is a direct observational assessment of ECD whereby a trained research assistant conducts a series of activities to observe a child's developmental skills. The GSED provides one overall score of child development based on a variety of skills pertaining to cognitive, language, and motor development. Considering that the GSED is a relatively new tool that has not been validated previously in Western Kenya, we will analyze our baseline data to assess the reliability, validity, and appropriateness of the GSED for use in our study context. While we will set GSED as the primary outcome measure for child development, we will assess ECD at endline using two tools – not only the GSED but also the Caregiver Reported Early Development Instruments (CREDI) long form version that has been previously used in Western Kenya [20] – to corroborate study results using another outcome measure and one that can provide domain-specific effects, as GSED only provides an overall holistic score for ECD. Thus, CREDI will be measured as a secondary outcome measure.

Other secondary outcome measures will include primary caregivers' parenting (e.g., stimulation, disciplinary practices) and psychosocial wellbeing outcomes (e.g., depressive symptoms, parenting stress) that are conceptualized as intermediary outcomes in the program theory of change towards ultimately impacting ECD. In addition to the CREDI-long form version as an alternate tool for ECD, we will also assess children's socioemotional development. Research assistants will observe and provide ratings of children's socioemotional development using an adapted version of the Wolke Scales [21].

Finally, we will also consider several exploratory outcomes that are addressed in the content of the parenting curriculum and relevant to the program theory of change. For example, child birth registration, child illness and care-seeking, caregivers' perceived social support, perceived financial security, positive coping strategies used, and father involvement.

Sample size calculation

We conducted a sample size calculation for a minimum detectable difference of 0.3 SD in the primary outcome of ECD over a 11-month period between the intervention and control group. With a power of 0.8, $\alpha = 0.05$, an intra-class correlation coefficient (ICC) for clusters of 0.03, an average cluster size 10 (i.e., the intended number of caregivers per parenting group accordingly to the program model), and a follow-up rate of 88%, the required number of clusters is 32 per study arm. Thus, we will enroll a total of 640 primary caregiver-child dyads (320 per study arm).

Qualitative implementation evaluation

In addition to the quantitative evaluation, we will conduct a qualitative implementation evaluation. The qualitative implementation evaluation will not only serve to

Table 1 Primary and secondary outcomes

Outcome measures	Description
Primary outcome	
Child development	Child development measured using the Global Scales of Early Development - Long Form (GSED-LF). GSED-LF is based on direct administration by a research assistant. GSED-LF provides one score for the overall development of children 0–36 months of age. GSED scores will be age-standardized to a mean of 0 and a standard deviation of 1. Higher scores will indicate improved early developmental skills.
Secondary outcomes	
Child development	Caregiver-reported measure of child development using the Caregiver Reported Early Childhood Index (CREDI) – long form version. The CREDI long form will provide separate domain-specific scores for children's cognitive, language, motor, and socioemotional development. CREDI scores will be age-standardized to a mean of 0 and a standard deviation of 1. Higher scores will indicate improved early developmental skills.
Child socioemotional development	Child socioemotional development based on observational rating by a research assistant using an adapted version of the Wolke Scales (e.g., child affect, vocalization, cooperation with the research assistant). An average score will be calculated across the items with higher scores indicating more positive child behaviors.
Attitudes towards parenting	Primary caregivers will report the extent to which they agree with various statements about parental roles and engagement in nurturing care practices. A total score will be calculated with higher scores indicating more supportive parenting attitudes.
Caregiving environment	Caregiving environment will be assessed using the Home Observation for Measurement of the Environment for infants and toddlers aged 0 to 3 years (HOME-IT). It combines caregiver-reported items and observations of parenting behaviors to assess early learning opportunities at home and responsive caregiving behaviors of primary caregiver with the child. A total score will be calculated with higher scores indicate more responsive caregiving and enriched home learning environments.
Caregiver stimulation practices	Caregiver stimulation practices reported by primary caregiver about their engagement in early learning activities with the child (e.g., singing, telling stories). Activities adapted from the Family Care Indicators. A total score will be calculated with higher scores indicating more engagement in stimulation activities.
Caregiver disciplinary practices	Caregiver disciplinary practices reported by primary caregivers in terms of harsh punishment (e.g., shook the child, shouted at child) and positive disciplinary practices (e.g., explained why the behavior was wrong) used towards the child. Items adapted from Child Discipline Module of Multiple Indicator Cluster Survey. Separate indicators will be created for use of any harsh disciplinary practices or any positive disciplinary practices.
Infant and young child feeding practices	Infant and young child feeding (IYCF) practices including caregiver-reported breastfeeding and exclusive breastfeeding practices and child dietary diversity score (number of food groups the child consumed in previous 24 h) based on WHO guidelines.
Parenting stress	Parenting distress reported by the primary caregiver using the Parenting Stress Index-Short Form, Parental Distress subscale. Higher total scores indicate greater parenting distress.
Depressive symptoms	Depressive symptoms reported by the primary caregiver using the Centre for Epidemiological Studies Depression Scale-10 items (CESD-10). Caregivers report on the frequency of depressive symptoms in the previous week. Items are summed to create an overall depression score, with higher scoring indicating greater depressive symptoms.

triangulate quantitative findings about changes in outcomes, but also assess program fidelity; determine stakeholders' satisfaction; understand the factors and contexts that influence program effectiveness (i.e., what, why, how, for whom); explore potential underlying mechanisms of program impact on ECD outcomes; and investigate potential sustainability and scalability of the program model. This implementation evaluation will be conducted at endline after the completion of the program delivery.

We will conduct in-depth interviews various stakeholders involved in the implementation of the program: participating primary caregivers, parenting groups facilitators, other community-based delivery agents (e.g., community health volunteers, child protection volunteers), program staff, and relevant government stakeholders. We will also conduct a few focus group discussions with participating caregivers and parenting group facilitators. The sample will be distributed across villages in both Bunyala and Ndihwa sub-counties to capture a diversity of implementation experiences and a range of contexts.

Qualitative interview guides will assess various aspects of program implementation. For example, questions in the semi-structured interview guides will cover the five dimensions of the RE-AIM framework: Reach, Effectiveness, Adoption, Implementation, and Maintenance [22]. We will also explore other key aspects like the degree of multisectoral coordination and systems strengthening relating to nurturing care and ECD at the village and sub-county levels. Interviews will be conducted by trained research assistants who are external to the program implementation.

Statistical methods and analysis

Quantitative data analysis

To estimate the effectiveness of the intervention on study outcomes, we will use mixed effects regression models to compare the difference in primary and secondary outcomes between intervention and control arms over time. We will use linear regression models for continuous outcomes and logistic regression models for binary

outcomes. We will run separate models for unadjusted results versus adjusted results that control for baseline covariates. All analyses will be estimated on an intention-to-treat basis. Missing data on covariates will be imputed using multiple imputation. Missing data on outcome variables will not be imputed. All hypothesis tests will be two-sided with a 0.05 significance level. Analyses will be conducted using the data analysis software Stata SE version 18.

Qualitative data analysis

Qualitative data analysis will be collaborative among study investigators and iterative using thematic content analysis. A codebook will be developed from the study objectives, research questions, and pilot interview transcripts. The analysis team will conduct open coding of the interview transcripts and document emerging themes using the qualitative data analysis software Atlas.Ti. Major and minor themes along with their respective sub-themes will be identified and continuously developed through consensus among all analysts. Key findings will be organized with respect to the various stakeholders' perspectives and dimensions of the implementation evaluation.

Ethics

This study protocol received institutional review board (IRB) approvals from the Emory Rollins School of Public Health (Protocol #: STUDY00006385) and the Jaramogi Oginga Odinga Teaching and Referral Hospital – Institutional Scientific Ethics Review Committee (Protocol #: ISERC/JOOTRH/736/23). A research license was also obtained for the study from the National Commission for Science, Technology, and Innovation in Kenya (License #: NACOSTI/P/23/30039). Written informed consent through signature or thumbprint was obtained from all participants in the quantitative evaluation. For any primary caregivers younger than 18 years, we obtained written assent from the adult caregivers or legal guardians of the young caregiver. Informed consent/asset processes will be obtained similarly for the qualitative implementation evaluation study. Study participants at each round of data collection will receive KES 400 (approximately $2.50 USD) as an appreciation for their participation. This amount of compensation is in line with prior studies and was determined in consultation with all study partners.

Dissemination plan

The study team will organize an in-person local dissemination event where we will share findings with various stakeholders of the project, including county and subcounty ministries (e.g., directors of health, early education), other non-governmental organizations implementing ECD programs in Kenya, academics, participating caregivers and parenting group facilitators, and other policy and advocacy stakeholders such as UNICEF. In addition to convening a dissemination event, we will prepare evidence briefs summarizing the high-level results, which we will tailor for different audiences (e.g., government, community leaders). The study team will also present results at regional and international workshops and conferences on ECD and prepare manuscripts for publication in peer-reviewed journals.

Discussion

The objective of this manuscript is to describe the trial design and research protocol for a mixed-methods impact and implementation evaluation of a community-based group parenting program for primary caregivers of children 0–24 months of age in Busia and Homabay counties in western Kenya. A novel aspect of the parenting intervention curriculum is how it is multicomponent and holistically addresses nurturing care with a strong focus on early learning and responsive caregiving, as well as other topics including positive discipline, child health and nutrition, and components that also directly target caregivers' psychosocial wellbeing. Another key strength of the program implementation approach is how it leverages existing peer group networks within the community to form parenting groups and delivering this program, rather than forming new peer groups for the sole purposes of this single program. Thus, this delivery approach has greater potential for harnessing existing and trusted relationship among community members, increasing program acceptability, and for future program sustainability and scalability. A strength of this research is its rigorous mixed-methods design that will jointly evaluate the effectiveness of the program through a rigorous cluster-RCT design and qualitatively assess and triangulate across various stakeholders' perceptions regarding the implementation of the program. Together, this combined impact and implementation evaluation will illuminate a comprehensive understanding of the program attributable changes in caregiver and child-level outcomes as well as the underlying reasons, conditions, and contextual factors that may have enabled or hindered program delivery and success.

One key limitation of this study is that our impact evaluation of the program model will primarily focus on assessing the overall effectiveness of the parenting curriculum and program activities associated with the group sessions, which is one piece of the overall program model. In addition to manualized curriculum and the universal parenting group sessions, the program model also includes some targeted services for caregivers and children facing additional risks (e.g., livelihood support for the poorest families, psychosocial services for caregivers with mental health problems). However, our study

is not powered to detect program effects associated with these targeted services that will be delivered to a subsample of the main program beneficiaries. Thus, we likely will be unable to capture the full range of program effects (e.g., on caregivers' financial security) and therefore will consider a set of measures more as exploratory outcomes. Nevertheless, our findings will inform future research directions including whether a larger study should be pursued. Additionally, although we had replaced some villages during the sample selection process for being contiguous with others belonging to another treatment arm, villages particularly in Bunyala sub-county are relatively smaller and more geographically contained and nearer to one another than in Ndhiwa sub-county. There remains a possible risk across both sub-counties for contamination between the intervention and control villages with a cluster-RCT study design and given the sampling constraints set out at the project inception. We will work together with the implementing partners to monitor this throughout the program rollout as well as in the qualitative implementation evaluation and incorporate any information about potential contamination into our analysis.

In conclusion, our study will shed light on the effectiveness and implementation of this parenting program in Ndhiwa and Bunyala sub-counties in Western Kenya, where to our knowledge a parenting program has not been evaluated previously. Our findings will directly inform adaptations to the program model and approach as it continues to be scaled out across these sub-counties in the coming years. These results will provide an important extension to the limited evidence base on community-based parenting programs for promoting ECD in rural Western Kenya and can also more broadly inform research and programs in other similar low-resource settings globally.

Abbreviations

ECD	Early childhood development
GSED	Global Scales of Early Development
IRB	Institutional review board
LMIC	Low- and middle-income country
RCT	Randomized controlled trial

Acknowledgements

We thank implementing partners at ChildFund Kenya, ChildFund International, Lake Region Development Program, and Western Community Children's Programme for their support with the planning and community entry for this research. We thank Wilson Ochuka and the field supervisors and research assistants at B&M Consult for their efforts with data collection. We thank the Conrad N. Hilton Foundation for providing funding for this study. JJ is supported in part by a grant from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (R00HD105984).

Author contributions

JJ led the conceptualization, study design, methodology, study supervision, and drafted the manuscript. JKM contributed to study tools and project administration. SO contributed to the study design and study tools. MO contributed to the study design, management of participant recruitment, and oversaw data collection activities. All authors reviewed and approved the final manuscript.

Funding

This project is funded by the Conrad N. Hilton Foundation. The funder had no role in the study design or data collection and will have no role in data analysis, interpretation of results, or manuscript preparation.

Data availability

Upon completion of the study, the datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request and with a data sharing agreement.

Declarations

Ethics approval and consent to participate

This study protocol received ethics approvals from the institutional review board (IRB) at Emory Rollins School of Public Health (Protocol #: STUDY00006385) and the Jaramogi Oginga Odinga Teaching and Referral Hospital – Institutional Scientific Ethics Review Committee (Protocol #: ISERC/JOOTRH/736/23). A research license was also obtained for the study from the National Commission for Science, Technology, and Innovation in Kenya (License #: NACOSTI/P/23/30039). Written informed consent was obtained through signature or thumbprint from all enrolled participants in the cluster-RCT. Similarly, written informed consent will be obtained from all participants enrolled into the qualitative implementation evaluation.

Competing interests

The authors declare no competing interests.

Consent for publication

Not applicable.

Author details

[1]Hubert Department of Global Health, Rollins School of Public Health, Emory University, Atlanta, GA, USA
[2]African Population and Health Research Center, Nairobi, Kenya
[3]B&M Consult, Nairobi, Kenya

Received: 20 March 2024 / Accepted: 6 September 2024
Published online: 17 September 2024

References

1. Lu C, Black MM, Richter LM. Risk of poor development in young children in low-income and middle-income countries: an estimation and analysis at the global, regional, and country level. Lancet Global Health. 2016;4(12):e916–22.
2. Heckman JJ. Skill formation and the Economics of investing in Disadvantaged Children. Science. 2006;312(5782):1900.
3. Walker SP, Wachs TD, Grantham-McGregor S, Black MM, Nelson CA, Huffman SL, Baker-Henningham H, Chang SM, Hamadani JD, Lozoff B, et al. Inequality in early childhood: risk and protective factors for early child development. Lancet. 2011;378(9799):1325–38.
4. Onyango S, Kitsao-Wekulo P, Langat N, Okelo K, Murdock DE, Utzinger J, Fink G. Maternal stimulation and early child development in sub-saharan Africa: evidence from Kenya and Zambia. BMC Public Health. 2023;23(1):2418.
5. Black MM, Walker SP, Fernald LCH, Andersen CT, DiGirolamo AM, Lu C, McCoy DC, Fink G, Shawar YR, Shiffman J, et al. Early childhood development coming of age: science through the life course. Lancet. 2017;389(10064):77–90.
6. Britto PR, Lye SJ, Proulx K, Yousafzai AK, Matthews SG, Vaivada T, Perez-Escamilla R, Rao N, Ip P, Fernald LC, et al. Nurturing care: promoting early childhood development. Lancet. 2017;389(10064):91–102.
7. Jeong J, Franchett EE, Ramos de Oliveira CV, Rehmani K, Yousafzai AK. Parenting interventions to promote early child development in the first three years of life: a global systematic review and meta-analysis. PLoS Med. 2021;18(5):e1003602.
8. Fisher J, Tran T, Tran H, Luchters S, Hipgrave DB, Nguyen H, Tran T, Hanieh S, Simpson JA, Biggs BA, et al. Structured, multicomponent, community-based programme for women's health and infant health and development in rural

Vietnam: a parallel-group cluster randomised controlled trial. Lancet Child Adolesc Health. 2023;7(5):311–25.
9. Jeong J, Ahun MN, Gunaratna NS, Ambikapathi R, Mapendo F, Galvin L, Kieffer MP, Mwanyika-Sando M, Mosha D, O'Malley SF, et al. Effects of engaging fathers and bundling parenting and nutrition interventions on early child development and maternal and paternal parenting in Mara, Tanzania: a factorial cluster-randomized controlled trial. J Child Psychol Psychiatry. 2024;65(5):694–709.
10. Kim ET, Opiyo T, Acayo PS, Lillie M, Gallis J, Zhou Y, Ochieng M, Okuro S, Hembling J, McEwan E, et al. Effect of a lay counselor delivered integrated maternal mental health and early childhood development group-based intervention in Siaya County, Kenya: a quasi-experimental longitudinal study. J Affect Disord. 2021;292:284–94.
11. Luoto JE, Lopez Garcia I, Aboud FE, Singla DR, Fernald LCH, Pitchik HO, Saya UY, Otieno R, Alu E. Group-based parenting interventions to promote child development in rural Kenya: a multi-arm, cluster-randomised community effectiveness trial. Lancet Glob Health. 2021;9(3):e309–19.
12. Kitsao-Wekulo P, Okelo KO, Murdock D, Donfouet HP, Onyango SO, Mwangi B, Illboudo P, Wanjohi MN, Nyamor G, Munsongo K, et al. An evaluation of the effectiveness of a community-based parenting empowerment program to improve nurturing care of young children in Kenya and Zambia. In. Nairobi, Kenya: The African Population and Health Research Center; 2021.
13. Jeong J, Bliznashka L, Ahun MN, Karuskina-Drivdale S, Picolo M, Lalwani T, Pinto J, Frey M, Velthauz D, Donco R, et al. A pilot to promote early child development within health systems in Mozambique: a qualitative evaluation. Ann N Y Acad Sci. 2022;1509(1):161–83.
14. Smith JA, Baker-Henningham H, Brentani A, Mugweni R, Walker SP. Implementation of Reach up early childhood parenting program: acceptability, appropriateness, and feasibility in Brazil and Zimbabwe. Ann N Y Acad Sci. 2018;1419(1):120–40.
15. Jeong J, McCann JK, Bhojani A, Kim Y, Uyehara M, Maguet Z, Ochuka W, Ochieng M. Process evaluation of the initial implementation of the Moments that Matter parenting program in Kenya Abstract Annals of the New York Academy of Sciences. 2024 https://doi.org/10.1111/nyas.15212
16. KNBS, ICF. Kenya Demographic and Health Survey 2022. In. Nairobi, Kenya and Rockville. Maryland: KNBS and ICF; 2023.
17. Masaba RO, Herrera N, Siamba S, Ouma M, Okal C, Mayi A, Kose J, Ndimbii J, Ochanda B, Mwangi E, et al. Advanced HIV disease in Homa Bay County, Kenya: characteristics of newly-diagnosed and antiretroviral therapy-experienced clients. Med (Baltim). 2023;102(51):e36716.
18. World Health Organization, United Nations Children's Fund, World Bank Group. Nurturing care for early childhood development: a framework for helping children survive and thrive to transform health and human potential. 2018.
19. McCray G, McCoy D, Kariger P, Janus M, Black MM, Chang SM, Tofail F, Eekhout I, Waldman M, van Buuren S et al. The creation of the global scales for Early Development (GSED) for children aged 0–3 years: combining subject matter expert judgements with big data. BMJ Glob Health 2023, 8(1).
20. McCoy DC, Waldman M, Fink G. Measuring early childhood development at a global scale: evidence from the caregiver-reported Early Development instruments. Early Child Res Q. 2018;45:58–68.
21. Wolke D, Skuse D, Mathisen B. Behavioral style in Failure-To-Thrive infants: a preliminary Communication1. J Pediatr Psychol. 1990;15(2):237–54.
22. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, Ory MG, Estabrooks PA. RE-AIM planning and evaluation Framework: adapting to New Science and Practice with a 20-Year review. Front Public Health. 2019;7:64.

Publisher's note