Testing Means to Scale Early Childhood Development Interventions in Rural Kenya

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Abstract

Recent neurobiological and psychological research has established that vital development occurs in language, cognitive, motor and socio-emotional development during the first few years of life, and early life outcomes are key determinants of adult outcomes such as educational achievement, labor market outcomes, and health. Yet more than 200 million children under age five in low and middle income countries (LMICs) will fail to reach their developmental potential as adults, predominantly due to poverty, poor health and nutrition, and inadequate cognitive and psychosocial stimulation. Early childhood development (ECD) interventions that integrate nutrition and child stimulation activities have been proposed as a powerful policy tool for the remediation of early disadvantages in poor settings, and numerous field studies have shown they can be effective in improving children's developmental and health outcomes, at least in the short-term. Key questions remain on what models of delivery are the most effective and cost-effective that can be potentially scalable in LMICs, as well as how to sustain parental behavioral changes over time, which can lead to long-term improvements in child development and the possibility of positive spillovers to benefit younger siblings. Having a better understanding of the underlying behavioral pathways leading from intervention, to parental behavior changes, to child impacts, is also key to inform policy about the optimal design of interventions to maximize their scalability and sustainability. Our study will conduct a multi-arm clustered randomized controlled trial across 60 villages and 1200 households in rural Western Kenya that tests different potentially cost-effective delivery models for an ECD intervention with a curriculum that integrates child psychosocial stimulation and nutrition education. Selected households will undergo baseline and follow-up surveys to measure short-term impacts in parental behaviors and children's developmental outcomes, and we will collect data on potential mediators of parental behavioral change to uncover the pathways leading to impacts. Two follow-up surveys, one immediately after the end of the planned intervention and a second two years later, will enable testing of the short term and midterm sustainability of impacts, as well as the presence of any spillovers onto younger siblings. In collaboration with a local NGO, the Safe Water and AIDS Project (SWAP), community health volunteers (CHVs) will be trained to implement the intervention by introducing the ECD curriculum in their villages.

The goal of this study is to provide policymakers with rigorous evidence of how best to expand ECD interventions in low-resource rural settings.

Contents

1. Background and Significance

Recent neurobiological and psychological research has established that vital development occurs in language, cognitive, motor and socio-emotional development during the first few years of life[1], and early life outcomes are key determinants of adult outcomes such as education achievement, labor market outcomes, and health. Yet, despite this, more than 200 million children under age five in low and middle income countries (LMICs) will fail to reach their full developmental potential as adults, predominantly due to poverty, poor health and nutrition, and inadequate cognitive and psychosocial stimulation.[2–4] A growing body of evidence shows that Early Childhood Development (ECD) interventions that integrate nutrition activities and parent-child psychosocial stimulation can effectively improve developmental and health outcomes;[5–7] furthermore, integrated interventions that address the co-occurring risk factors associated with poverty can deliver the largest effects.[1,2,7] Early childhood is also the most cost-effective period to improve such outcomes, as early investments have the potential to improve adult human capital.[8,9]

The two primary methods for delivering ECD interventions are individual home visits with mothers, or group-based meetings in a primary care or community setting. Individual home visits can offer personalized feedback and attention, but are expensive to implement at scale.[10,11] Group-based models enjoy potential economies of scale, and can offer mothers increased peer support, which our team has shown to be a key mediator to maternal behaviors and psychological well-being in LMIC settings.[12,13] However, groups may be comparatively weak in providing opportunities to practice and overcome personal barriers to behavior change, elements which are necessary to attain sustained parental behavior change and improved child development outcomes long-term.[7] A recent review argues that group-based models which include a limited number of home visits are the most promising means to achieve sustained impacts and remain cost-effective,[10] but the added impact and cost-effectiveness of such an approach is unknown. Moreover, few studies examine the behavioral pathways leading to intervention impacts,[14,15] which would foster their replicability. ECD interventions have also traditionally focused on mothers and children. Engaging fathers in their children's development has been suggested to be beneficial,[16,17] but has never been tested. Finally, there is no evidence of the sustainability of a group-based ECD intervention from a LMIC and whether these benefits spillover onto younger siblings. Key questions remain on what models of delivery are the most effective, parsimonious, and have the greatest potential for scalability in LMICs, as well as how to sustain parental behavioral changes over time, which can lead to long-term improvements in child development and the possibility of positive spillovers to benefit younger siblings. Having a better understanding of the underlying behavioral pathways leading from intervention, to parental behavior changes, to child impacts, is also pivotal to inform policy about the optimal design of interventions to maximize their scalability and sustainability.
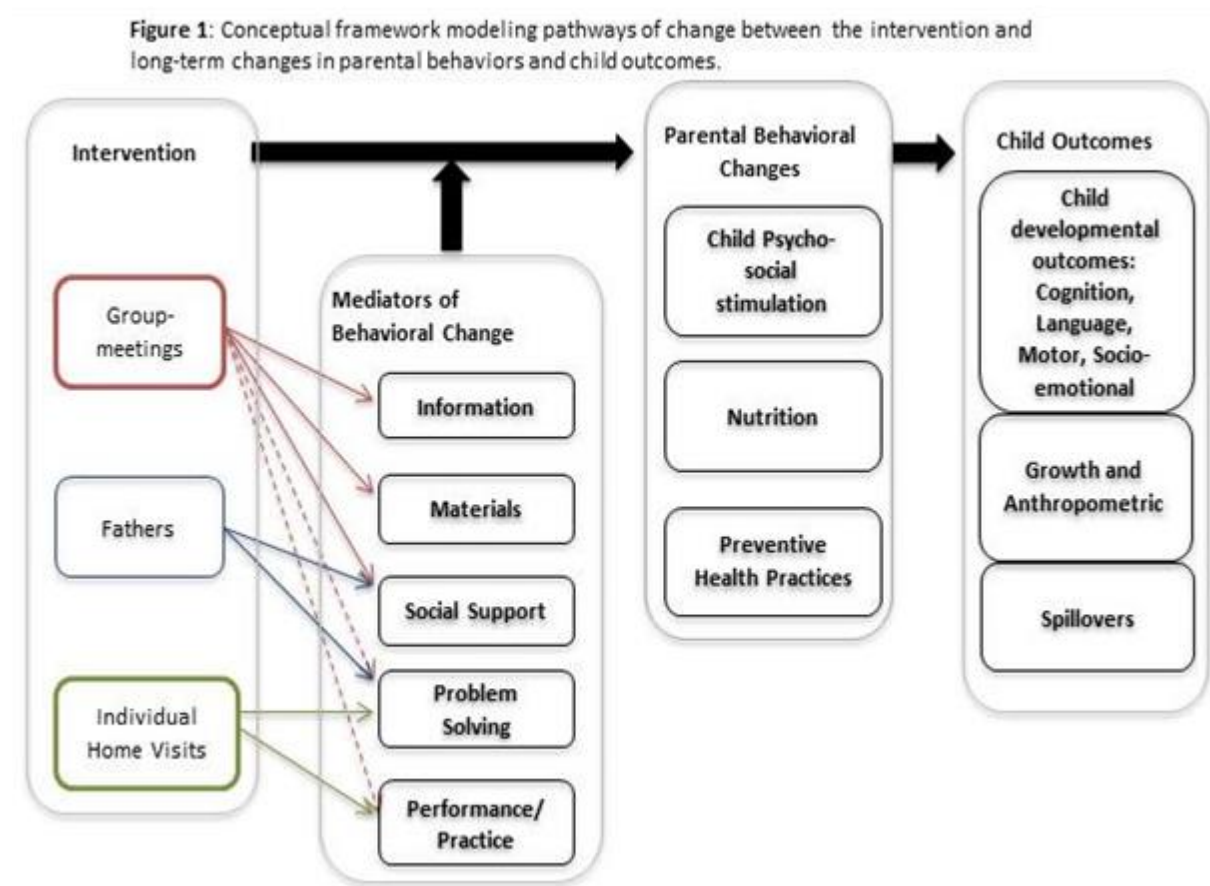
2. Rationale and Research Aims

The proposed research aims to experimentally test the effectiveness and cost-effectiveness of competing models of delivery of an Early Childhood Development (ECD) intervention in rural Kenya to determine how to maximize their reach to improve child cognitive, language and relevant psychosocial outcomes. The study will incorporate a longer-term evaluation of sustained impacts; an examination of the pathways of change leading to intervention impacts to inform policy; and examination of the role of paternal involvement on child development. Our study asks the following research questions:

1) What is the most effective and scalable model of delivery for an integrated early childhood development intervention in a LMIC setting?
2) Does father involvement matter for the adoption of better parenting practices at home and for child development?
3) How can we design an early childhood stimulation intervention that is able to attain sustained impacts over time?
4) What are the determinants of parental behavioral change towards better child-rearing practices? What role is played by parental beliefs, psychological wellbeing, knowledge, and social support?

The designed ECD interventions have a curriculum that integrates child psychosocial stimulation and nutrition education. The group sessions will be biweekly lasting seven months and will be aimed at improving developmental outcomes of children aged 6-24 months in rural areas of Kisumu and Vihiga counties, Kenya. These are among Kenya's poorest regions, with rates of stunting ranging from 31-34%.[18]

RAND Cooperation will work in collaboration with the Safe Water and AIDS Project (SWAP), a well-established and local Kenyan Non-Governmental Organization (NGO). SWAP has been operating in 6 counties in Western Kenya with public health programs, research and emergency response since 2005. SWAP has been contributing towards the Ministry of Health's Community Health Strategy, whereby communities play an active role in their own health and development, SWAP is active member of the National Health NGO Network HENNET, and was elected as National Chair. HENNET stimulates linkages between the Ministry of Health, Private Sector and NGOs. During this study Community Health Volunteers (CHVs) will be trained to implement the intervention. The CHVs are local women recruited from Community Units and already trained on primary health care by the Ministry of Health and other development partners. They regularly conduct home visits and host community meetings on topics of community health in their respective villages. Our intervention integrates an experimental evaluation into this existing platform, a model of delivery that is potentially replicable in other similar contexts.

Figure 1 presents a conceptual framework for the pathways of change between the intervention and long-term changes in parental behaviors and child outcomes. The interventions presented in Figure 1 each feature one or more key mediators of behavior change in order to impact parental behaviors in the form of: i) more effective child psychosocial stimulation practices, ii) better nutrition practices; and iii) improvements in preventive health practices such as water treatment and hand washing. Changes in parental behaviors, in turn, can improve child outcomes including: a) child developmental outcomes that include cognition, expressive and receptive language development, motor skills and socio-emotional development; b) child health outcomes, captured by indicators of growth and anthropometrics; and c) potential spillovers of these impacts to children that are not targeted by the intervention (particularly to younger children at home). Our study's primary outcomes of interest are both children's development outcomes and associated parental behavioral changes, since the latter comprise the pathways of change leading to the former.

Figure 1: Conceptual framework modeling pathways of change between the intervention and long-term changes in parental behaviors and child outcomes.

2.1 Research Hypotheses

Our primary hypotheses are: 1) village-based group meetings that include a limited number of follow-up home visits to reinforce the messages and give greater opportunity to practice the new

behaviours and receive personalized feedback is the most cost-effective model able to achieve sustained impacts in parental behaviours and child outcomes; and 2) Engaging fathers in the sessions will lead to greater impacts on children's development and sustained parental behavioral changes

2.2 Study Aims

Our study will be carried out with the following Aims:

1. Adapt existing ECD curriculum to the local Kenyan context and evaluate its acceptance in a piloting phase. Incorporate strategies to involve fathers.

2. Test the most effective means of delivery – whether only group visits, or group-visits with added home visits and booster sessions, and with or without fathers' involvement - of an ECD intervention to improve child-rearing practices and child developmental outcomes using a clustered randomized control methodology.

3. Disentangle the underlying mechanisms through which the intervention drives behavioral changes and child outcomes combining the experiment and collected measures in a Decomposition Analysis.[14]

4. Examine the sustainability of any child impacts and associated parental behavioral changes as well as the presence of spillovers to younger siblings two years later.

5. Perform a cost-effectiveness analysis and a process evaluation to inform policy.

3. Population

3.1 Study Population

This study will take place in two counties, Kisumu and Vihiga, within the former Western and Nyanza Provinces, Kenya, an area characterized by high rates of poverty, child mortality, and stunting (31-34%), with the highest levels of reported spousal violence in Kenya (60%), and high levels of teenage motherhood (18%).[18]

3.2 Inclusion Criteria

• Kenyan mothers or equivalent female primary caretakers aged 15 and over with children aged 6-24 months (classified as mature minors)
• Kenyan fathers aged 18 and older with children aged 6-24 months with a mother present

The unit of observation for the study is the household or family, within which our primary focus is mother-child dyads and household eligibility hinges on the age of the child. For those households with a father present, we additionally include him in some analyses and surveys.

3.3 Exclusion Criteria

• Households without children
• Households with children that are outside the age range of 6-24 months at baseline
• Households with children aged 6-24 months who are found to have severe developmental delays.
• Households with a mother younger than 15 or one aged 15-18 still living with her parents
• Single fathers

Selection criteria for fathers are based on the mother-child eligibility criteria. Fathers will be included if and when appropriate per the details surrounding the mother-child dyads.

4. Study Design

4.1 Design Overview

Our evaluation design consists of a clustered Randomized Control Trial (cRCT) in which 60 CHVs and their associated villages will be randomly assigned to one of three equally-sized treatment arms. Arms 1 and 2 comprise a 2x2 factorial design, while Arm 3 will serve as a control group. Our experimental design features 3 treatments: group meetings only (Arm 1), group meetings with a limited number of individual home visits (Arm 2), and the involvement of fathers in the integrated intervention (one half of villages in Arms 1 and 2). All households, including the control group, will receive basic information about child feeding and a "hygiene pack" consisting of a bottle of WaterGuard (a chlorine water treatment product) and a bar of soap (total value 50 Ksh) during a baseline survey. Our study includes a control group in order to identify the effects of a parenting intervention and the most effective mode of delivery, as well as the sustained impacts from the intervention. Due to the nature of the ECD intervention, a comparison group is necessary to address our key research questions. Other analysis forms such as a before-after analysis do not work in the context of a child development intervention due to the rapid changes happening during the early years of life.

4.2 Sampling

The target population for the full study is comprised of 1200 households across 60 villages surrounding 3 Jamii ("community") centers operated by SWAP in Ahero, Sondu, and Kegondi towns within Homa Bay and Vihiga counties. In addition, prior to the full evaluation, we will pilot the curriculum in a formative stage among a total of 6 villages with 20 households meeting

similar eligibility criteria in each village (120 households total), with pilot villages stratified across the Jamii centers. (More details about the pilot sampling in 5.1.1.)

The sampling strategy of villages and households participating in the full study will follow three steps. In a first step, we will list all potential villages in the subcounties of East Racuonyo and South Rachuonyo in Homa Bay county, and in Sabatia subcounty in Vihiga county that satisfy three requirements: 1) There are estimated to be at least 20 households with children that will be between 6 and 24 months old at the time of the baseline survey (October 2018) for inclusion in our study based on CHV report; 2) There is at least one Community Health Volunteer assigned to that village by the local Community Health Unit (CHU) who can be trained into the study curriculum; and 3) Villages will be sufficiently geographically dispersed so that households within villages assigned to the control arm do not travel to access the intervention in treatment villages.

Second, we will randomly select a representative sample of 60 villages to participate in the full study stratified by each Jamii center (20 villages per center). The villages will form our study's clusters, from which we will sample households to participate in surveys and the village-based ECD sessions in Arms 1 and 2. CHVs associated to those villages will be made aware of the likely time commitment that may include attendance at the two-week training course as well as time to implement the interventions if assigned to Arms 1 or 2. We will pay all CHVs a stipend for their collaboration in the delivery of the study and the intervention. If CHVs refuse participation, we will resample from our pool of eligible villages for inclusion in the study.

Third, within each selected village, CHVs will conduct a census of all households in their village to identify all those with a child aged 6-24 months at baseline. From this list of households, we will draw a sample of 20 households using a random number generator, with 5 more names on a ranked waitlist in cases of study refusal.

In short, the sample shall consist of:

- For the piloting phase:
  - 6 villages with 20 households in each village, or 120 households total
- For the full evaluation, a total of 60 villages
  - 20 in Arm 1 (groups only), 20 in Arm 2 (groups plus home visits), and 20 in Arm 3 (Control group)
  - Among the 40 villages in Arms 1 and 2, 20 will have fathers invited; 20 without fathers invited and only mothers and children are invited
- 20 households per village are invited to the sessions
- Total sample of 1,200 households in the full evaluation
- A total of 46 Community Health Volunteers will be trained, 6 in the pilot and 40 in the full study (20 CHVs and associated villages will comprise a control group). Pilot households and CHVs will not participate in the full evaluation.

4.3 Study Timeline

We will begin the community entry and curriculum piloting activities upon IRB approval from all necessary review boards in roughly May-June 2018.

The baseline survey will be undertaken in late September-October 2018. Training of the 40 CHVs in villages assigned to an intervention arm will occur at the end of baseline activities. Immediately following, these 40 CHVs will implement the biweekly village sessions beginning in November 2018. The total 16 sessions will last from November through June 2019. A first follow-up impacts survey will be undertaken immediately following the end of the intervention period in July-August 2019. *Following completion of the follow-up survey, we will randomly select 20 of the 40 intervention villages stratified by study arm and subcounty to receive bimonthly group booster sessions for approximately 1.5 years until we undertake* a second and final follow-up impacts survey in May-June 2021.

5. Procedures

5.1 Formative Research

5.1.1 Community Entry

SWAP Management Members will seek approval and introduce the study to County Health Management Teams of **Homa Bay** and Vihiga followed by further orientation of the Sub County Health Management Teams of Sabatia (Vihiga), **South Rachuonyo and East Rachuonyo (Homa Bay County)** Courtesy calls will be made to the County Executive Committee members for Education and local administrative leaders prior to the start of the study. The approved protocol will be shared with the County Health Management Teams.

5.1.2 Curriculum Pilot

The curriculum will be piloted in six villages in order to adapt it for the rural western Kenya context. We will recruit six "mentor" CHVs who will be trained to deliver this intervention in the 6 pilot villages, and following this pilot these 6 CHVs will assist in the training of the 40 CHVs for the full study as well as help with monitoring of the sessions among intervention villages in a supervisory role.

Within each village selected for the pilot, 20 household participants will be recruited in a similar fashion as that for the full study described in 4.2, totalizing 120 households. Eligible participants will be 15(+) years old and the parent of a young child (aged 6-24 months). Within each household, both the mother and the father will be recruited. These pilot households will be invited to participate in up to 4 sessions to be piloted in their communities from the 16 total sessions that will form our main study's intervention curriculum.

5.1.3 Exit Interviews of Pilot Participants and CHVs

All mothers and fathers that attend a pilot session will be invited to participate in exit interviews immediately following a given pilot session. The exit interviews will probe key aspects related to curriculum content, acceptability and applicability. The exit interviews will inform the curriculum content and delivery mechanisms that will be implemented in the full intervention. The exit interviews have an open response structure, ensuring that we receive responses to well-defined questions while allowing room for open response. The data gathered will be used to improve operational aspects of the village-based ECD sessions as well as to adapt existing ECD curriculum to the local context, including incorporating fathers in a culturally-appropriate way.

At the end of the piloting phase, we will also perform exit interviews of the six pilot CHVs to understand their experiences delivering the program in order to finetune the training they underwent to improve it for the full study, as well as gather feedback on ways to improve the intervention and its associated activities.

The exit interviews for both parents and CHVs will be delivered by local research assistants who will be trained in qualitative methods.

5.1.4 Pilot Baseline Survey

A total of 144 households from villages not sampled for inclusion into the full survey will be selected to participate in the piloting of the baseline survey. The objective of the survey pilot is to ensure that each of our measures have the proper translation and understanding, as well as to test the application time and logistics. The protocol and research tools that will be used are presented with the baseline survey procedure in section 5.2.

5.2 Baseline surveys

Following the pilot for the full study sample, from the list of 20 names assembled by the CHV from the village census, the CHV will guide a trained interviewer to the households to invite them into the study and to undergo informed consent procedures for participation. All households, irrespective of their village's eventual group assignment, will receive written and verbal consent explaining the purpose and contents of the study as well as their anticipated time commitment for attending the village-based sessions and any home visits. We will also make clear that participation in the surveys is voluntary and participation in the ECD intervention is not guaranteed but based on their village's random assignment in a language understandable to the participants.

After consent, the interviewer will assess the child and interview the mother and, for married mothers, also the father for a subset of modules. Participants who provide informed consent will be asked to participate in this survey *before* the village randomization takes place to make sure that the group assignment does not influence the answers given. The measures will include

household socio-economic data, maternal self-report on child developmental outcomes, child-rearing practices, attitudes and beliefs towards child-rearing, and maternal psychological well-being, and paternal self-report about their involvement in child-rearing tasks. One-week training sessions will be conducted before the beginning of the fieldwork. In total, the survey will last between 60 to 90 minutes and will collect information on variables described below in the Survey Measures section. In addition, the baseline survey will record mobile phones and other sources of contacts for each of the household members. This will be done to facilitate invitations to ECD sessions (if assigned to a treatment arm) as well as to ensure successful tracking for follow-up surveys. Finally, at the end of the baseline survey all households will receive information about proper nutrition for young children as well as a hygiene pack consisting of a bottle of WaterGuard and a bar of soap as a token of appreciation for their time (valued at 50 Ksh).

5.3 Randomization

After the sampling procedure and the baseline surveys are complete, we will randomly assign the 60 CHVs and their associated villages to one of three study arms. Each arm will have 20 CHVs and 400 households (Figure 2). After assignment to study arm, villages assigned to Arms 1 or 2 will undergo a secondary randomization procedure to determine those villages that additionally will invite fathers to the sessions (in a 1:1 ratio among the 40 villages assigned to Arms 1 and 2). All randomizations will be stratified by Jamii center to ensure balance across treatment arms on any village-level characteristics that have the potential to have some relationship with intervention effects. CHVs assigned to Arms 1 and 2 will undergo the CHV Training in order to deliver the ECD intervention.

5.3.1 Arm 1 ("group" sessions)

Mother-child dyads in Arm 1 households will receive biweekly ECD sessions for a total of 16 sessions over 7 months. CHVs will record attendance at each session. To maximize participation, prior to each session the CHVs will send an SMS reminder of the session's topic, time and location to all participants. All attendees at a session who arrive within a half hour of the intended start time will receive a small bar of soap as a token of appreciation for their timely attendance.

5.3.2 Arm 2 ("group+home" sessions)

Households in Arm 2 will receive a total of 16 sessions with identical content similar to Arm 1, but 4 of those sessions will replace group sessions held at the level of villages for personalized home visits, in which the CHV will visit each participant household to deliver these sessions. These home visits will cover identical material and topics as the group sessions in Arm 1 villages, but will be delivered on a personalized basis in the home of the mother and child. Personal barriers to the practices will be discussed and an active resolution strategy developed in concert with the CHV.

5.3.3 Father Involvement ("fathers")

 In villages assigned to receive the father-focused sessions, fathers will be invited to attend the sessions along with the mothers. For some of the 16 sessions, they will be invited to attend separate sessions from the mothers.

5.3.4 Control group

Households in villages assigned to Arm 3 will receive the usual services of their CHV, which includes basic services for community health. In addition, control group households will receive the same information about child feeding and the hygiene packs as households in villages assigned to intervention arms during the baseline survey.

5.3.5 Booster sessions

Following the end of the 16 biweekly sessions, we will randomly select 20 of the 40 intervention villages stratified by study arm and subcounty to receive bimonthly group booster sessions for approximately 1.5 years from the end of the endline survey until we undertake a second and final follow-up impacts survey in August-September 2021.

5.4 ECD Intervention

Our integrated child psychosocial stimulation and nutrition education intervention will build on our team's combined previous work delivering and evaluating group-based ECD interventions in Uganda, Bangladesh, Madagascar, Mexico, and Chile. Most of these were implemented over a period of six months, and all were found to significantly improve child and maternal outcomes. The final curriculum will be informed by insights for achieving sustained behavior changes and will include session-specific lessons and materials.

Forty CHVs assigned to Arms 1 and 2 will undergo an intensive training course covering topics that will be addressed in each of the group sessions in order to prepare CHVs with the knowledge and ability to deliver the intervention to participant households in their villages. Luoto, Lopez Garcia, Aboud and Singla will deliver the trainings and have many collective years of experience delivering similar trainings in various LMIC settings. Competency assessments of the CHVs will be undertaken at the end to ensure the implementers are of high quality. This training will occur after randomization of villages, described below.

Following training, these 40 CHVs will implement the village-based ECD sessions for seven months in their villages. Mother-child dyads from the 20 households that gave consent and underwent baseline surveys in each village assigned to Arms 1 or 2 will be invited to attend the sessions, which will be located at a suitable central locale such as a school, church, or village chief's homestead.

5.4.1 ECD Group-based Curriculum

The curriculum for the group-meetings will be finalized in our pilot stage. A total of 16 sessions will be held biweekly in selected villages and lasting 60-90 minutes per session. The curriculum will be specific to each session, with sessions devoted to mother-child interactions covering topics such as play and language, cognitive simulation, socio-emotional stimulation, management of child behavior, and child health care practices including diet and hygiene, and sessions devoted to improving maternal self-image, self-efficacy and self-esteem. Active and interactive activities will be designed drawn from evidence-based cognitive, behavioral, interpersonal and stimulation interventions, including role-playing, group-based problem solving, and parent-child interactions, and will allow time for feedback, all of which are important mediators of behavior change (Figure 1). In half of villages, fathers will be invited to sessions and participate in group activities. Because of the high levels of domestic violence and young motherhood in the region, some sessions will also spend time devoted to address family barriers that limit the development of a nurturing home environment, and focus on the roles of love and respect and a positive home environment to improve overall family functioning. Aboud and Singla's experience in Uganda, as well as Luoto's and SWAP's experience in the study area, will serve as examples for how to broach sensitive topics. In all sessions, participants will hear about the benefits of the behavior and be encouraged to practice in the presence of the CHV and their peers through games and activities; following this practice, participants will discuss in a group setting any experienced barriers as well as strategies to overcome barriers in their homes. Participants will be encouraged to practice the new behaviors between sessions.

5.4.2 Individual home visits

Households in Arm 2 (group+home) will receive four total home visits that replace four group sessions. During these home visits, CHVs will review the key messages learnt in the group sessions; give mothers the opportunity to practice the strategies and receive individual feedback; and the CHVs and parents will work together to overcome family-specific barriers to adopting and sustaining the new strategies in a more personalized way. Figure 1 outlines how home visits reinforce these key mediators of parental behavior change.

5.4.3 Father Engagement Curriculum

A total of 5 of the 16 sessions is envisioned to aim to add greater social support and problem-solving abilities for whole families (Figure 1). The curriculum for these sessions will cover interpersonal topics relevant for behavior change at the family-level such as father involvement in child care, emotional regulation, and the types of emotional support that fathers could provide to their spouses that would be beneficial for their children's health and development. The same topics will be covered in all villages, but in half of villages fathers will participate in these discussions and activities. We will design group activities that indirectly show the benefits of a home environment free of domestic violence and which focus on love and respect.

5.4.4 Booster sessions

The extended bimonthly booster sessions over a 1.5 year span can achieve multiple aims for the families in villages selected to receive them. <u>First</u>, CHVs will continue to offer these families personalized social support, remind mothers and fathers of the key messages, and incorporate strategies to help parents adhere to the behaviors already learned. <u>Second</u>, CHVs will demonstrate new stimulation and communication activities that meet children's growing intellectual needs as they age, and which scaffold on practices they have already learned. And <u>third</u>, they will also introduce and discuss new topics relevant for older children including more advanced language development techniques such as "dialogic reading" using picture books, and more appropriate disciplinary strategies and behavioral regulation to manage children's adaptive behaviors.

5.5 Follow-Up Surveys

At the end of the seven-month village-based ECD sessions, and again during year 4, follow-up surveys will be conducted on households surveyed at baseline in all 60 villages. These follow-up surveys will enable evaluation of the intervention's short-term and medium-term effects on children's cognitive, psychosocial and health outcomes, as well as maternal mental wellbeing and mother-father interactions. The set of measurements for developmental outcomes is described in the Measures section.

5.6 Process Evaluation

5.6.1 ECD Session Attendance Records

During implementation, the 40 CHVs in Arms 1 and 2 will collect attendance records at each ECD session. They will also be asked to keep monitoring checklists of their activities following each biweekly session. These monitoring and attendance forms will be collected using encrypted data collection forms on SurveyCTO via tablets and uploaded to the study's server as detailed in the data safety and monitoring plan.

5.6.2 Observation of ECD group sessions

SWAP's Project Officers who manage the Jamii centers and oversee regular CHV operations will be trained to observe and monitor essential components of a selection of sessions hosted by the CHVs during the implementation in Arms 1 and 2, with assistance from the 6 mentor CHVs who undertook the pilot. They will use a monitoring form to report on activities and fidelity of the delivery to the intended design.

5.6.3 Reports made by CHVs on Home visits

In Arm 2, a subset of CHV who deliver home visits will be asked to make a series of observations on the extent to which mothers (and fathers if applicable) are practicing the ECD activities that were taught during the group ECD sessions held in their villages. This information

can be used to make improvements to the implementation of remaining sessions and to ascertain how much mothers report practicing the behaviors and experienced barriers and facilitators.

5.6.4 CHV Focus Groups

Midway through the implementation of sessions we will conduct interviews and focus groups with those CHVs assigned to the two treatment arms, and those who led ECD interventions in villages where fathers were included in order to learn what works and what does not from CHVs' perspective, and use the collected monitoring measures to undertake the Process Evaluation. The focus groups will follow a discussion guide with open ended questions and probes, ensuring that we receive responses to well-defined questions while allowing room for open discussion. It will be delivered by local research assistants who will be trained in qualitative methods.

6. Surveys and Measures

The survey measures chosen for the assessment module and how they relate to our primary and secondary outcomes of interest are described below. Each measure is guided by our conceptual framework (Figure 1) and have been successfully used in our previous research and ensure a reasonable interview duration. Piloting will further ensure we avoid respondent burden to keep the survey at reasonable length. All measures will be included in the assessment battery administered at each time point. We will measure child assessments using the Bayley III scale at the baseline and follow-up surveys. For those children who have aged out of the acceptable age range for the Bayley III by the second follow-up survey (up to 42 months), we will use the MDAT scale. All materials have been translated into Luo and Swahili using standard translation and back-translation methods. Our primary outcomes of interest are child developmental outcomes, as well as child psychosocial stimulation. Secondary outcomes are child growth and anthropometrics (which are usually more difficult to impact without food supplementation), child nutrition practices, preventive health behaviours, and the presence of spillover impacts onto younger children. We will also collect measures that relate to one or more mediators of behavioural change from our conceptual framework. Finally, socio-economic data for all households will include family composition, employment, wealth, and housing conditions.

6.1 Primary Outcomes of Interest and Associated Measures

6.1.1 Child cognition, language, motor skills, socio-emotional state

The Bayley Scales of Infant Development 3rd edition (Bayley's III),[19] is validated in African settings and provides measures for all dimensions of child cognitive, receptive and expressive language development up to 42 months of age. In the second follow-up survey for children in 2021, we will **use the Wechsler Preschool and Primary Scale of Intelligence (WPPSI) Block Design test[20] and adapted forms of the British Picture Vocabulary Scale – III (BPVS III) receptive and expressive language tests[21] which have been previously adapted to the local**

setting including in Swahili and Luo languages.[22] We will use the Wolke behavioral rating scale (Wolke et al., 1990)[23] to obtain observational measures of child socio-emotional development and emotional regulation. The test will be administered immediately after the child finishes the Bayley test to capture how unhappy, happy, fussy or cheerful the child appeared throughout the administration. At the 2021 follow-up, we will use the Strengths and Difficulties Questionnaire in place of the Wolke Scale for our children who are now older.[24]

6.1.2 Parental behaviors

At baseline we will use the Family Care Indicators [25], a self-reported scale of parenting practices which measures the quality time spent with children in learning and playing activities for young children at home. Examples of questions are how often parents take children out to the park, or other recreational activities, whether there is always an adult looking after children, the frequency of learning and play activities with children, and the amount and variety of play and learning materials. Five subscales can be created for analysis: 'play activities' (PA), 'varieties of play materials' (VP), 'sources of play materials', 'household books', and 'magazines and newspapers' (MN).

In the first follow-up survey we will complement the Family Care Indicators with observational measures of practices using the Home Observation for Measurement of the Environment (HOME) inventory, a 45 item structured survey combining mother self-report and observational measures, which has been used and validated to measure cognitive and non-cognitive stimulation strategies in both developed and developing countries. [26] Versions of the HOME inventory have already been adapted to African settings for children up to 4 years old. For the second follow-up, we will adapt a version of the Home Observation Measurement of the Environment-Short Form (HOME-SF) for parents of children of 3 to 6 years old.

6.2 Secondary Outcomes of Interest and Associated Measures

6.2.1 Child anthropometrics

Child weight and height, and arm circumference will be measured using techniques for the WHO Multicenter Growth Reference Study (MGRS). [27]

6.2.2 Nutrition and preventive health practices

Dietary diversity will be measured by maternal self-report of the foods eaten by the children in the last 24 hours, following WHO recommendation about youth and infant child feeding. [28,29] Food security will be measured using the **Household Hunger Scale derived from the HFIAS.[30]** These measures will be used to assess secondary outcomes of interest including child anthropometrics, nutrition practices, and preventative health.

6.3 Other Standard Measures

6.3.1 Perceived social support

We will measure perceived social support using the 6-item Lubben Social Network Scale (LSNS)[31], and perceived support from spouses will be measured using the Relationship Support Scale that asks questions about positive and negative behaviors of husbands with wives and children.[12] (Singla et al. 2015a). **We will also ask mothers about the networks to which they belong and ask if they discuss any health, nutrition and parenting tips with other households in their village.[32] These questions will include naming up to 5 individuals with whom respondents have regular contacts. To meet regular standards of confidentiality, enumerators will only save the initials of these individuas and therefore the data saved will be de-identified.**

6.3.2 Problem solving and social support

We will adopt measures from our work in Uganda to measure ways of coping with interpersonal conflicts and daily stressors.[33] Parental stress will be assessed using the Daily Stress Index [34]. The DSI measures on a 0-2 scale (never, sometimes, often) the difficult things that sometimes happen to people. This index has previously been used in Uganda, and the raw score will be aggregated over the 15 parts with a range of 0-30.[34] We will measure maternal psychological well-being using the widely used Center for Epidemiologic Studies Depression Scale (CESD) with proven psychometric properties. [35]

6.3.3. Maternal Knowledge

We will elicit maternal knowledge about child development through asking mothers about the ages at which they think the child would be able achieve certain developmental milestones, which are then compared with the expected ages reported in the literature. **We will also assess maternal receptive vocabulary. The Peabody Picture Vocabulary Test is among the most widely used receptive vocabulary tests in the world. The PPVT-4 (4th Edition), which was released in 2007, and was standardized through administration to more than 5,000 respondents in 2005 and 2006.[36] Form A consists of 228 test words for a respondent to identify among four color pictures as potential responses for each of the words. For each word, the respondent is instructed to point to the picture on the page that best represents the word's meaning.**

6.3.4 Maternal Beliefs

We will adapt and measure the scale to elicit beliefs developed by Cunha et al. (2013)[37] with the target of eliciting parental beliefs regarding the benefits of providing children better cognitive and non-cognitive stimulation. The instrument asks parents about developmental milestones in language and socio-emotional development under different home scenarios, which are constructed using data from the Family Care Indicators. **We will also we adopt a subscale of the Parental Cognitions and Conduct Toward the Infant Scale (PACOTIS) (Boivin et al.**

2005),[38] a 5-item Likert scale to assess the perceived parental impact of their behavior on the developing child. We will measure parental self-perceived competence in parenting using the Self-Efficacy for Parenting Tasks Indexes- Toddler Scale (SEPTI-TS) (Van Rijen et al. 2014),[39] which is aimed at measuring parental self-efficacy for parents of toddlers aged between 13-36 months.

6.3.4. Additional measures

Additional survey modules will collect information on household demographics, socioeconomic status, **household-level shocks and life stressors**,[40] time use, time preferences, and questions regarding fatherhood will be drawn from previous studies conducted in SSA context and adapted for use in Kenya.

In addition, the baseline survey will record mobile phones and other sources of contacts for each of the household members and close relatives. This will be done to facilitate invitations to ECD sessions (if assigned to a treatment arm) as well as to ensure successful tracking for follow-up surveys.

In 2021, we will drop modules on household-level shocks and life-stressors, time use and time preferences, all questions for fathers, and questions about social networks of mothers. We will add questions about prices for commonly purchased items in villages and other village characteristics, questions about a mother's views on how COVID has affected her household, questions about a mother's reproductive history, views and experiences with intrahousehold conflict, and childhood experiences. All new survey modules for mothers are highlighted in pink in the attached document.

7. Data Analysis

7.1 Aim 1: Adapt ECD curriculum

The formative research will form core components of this adaptation to ensure acceptability. The process evaluation will include measures of session attendance, mother interviews, and exit focus groups of CHVs, all of which can also inform the intervention's acceptability.

7.2 Aim 2: Test effective means of delivery

The aim is to get fully powered estimates of intervention effectiveness on child outcomes, parental behaviors, and mediators across the different arms of the study.

7.2.1 Power Calculations

The sample of 60 villages and 20 households per village for the full evaluation is calculated for measures of child developmental outcomes that will be measured using the Bayley III scale taken at the first follow-up survey. This scale has a usual mean of 100 with a standard deviation (SD) of 15.[19] Meta-analyses calculate a mean effect size from group ECD interventions of 0.59 SD[7] and our previous work in Uganda has an effect size of 0.36 SD.[12] Our previous work in this part of Kenya has found annual attrition rates of roughly 15% and we enjoyed roughly 80% compliance in a previous collaboration in the study area on a similar population of mothers with young children.[41] Similar group ECD interventions in Uganda and Bangladesh have found intra-cluster correlation coefficients (ICC) of 0.04.[42] We conservatively assume 75% compliance among those invited to the sessions, 15% attrition, and an ICC of 0.07 within 60 CHV catchment areas. In a side-by-side comparison between study arms our sample size of 400 mother-child dyads in each arm provides 80% power to detect an increase in children's cognitive and receptive language development of 0.30 SD at the 5% level of statistical significance. The impact from involving fathers has similar power. In a 2:1 test comparing the two treatment arms and the control arm we can detect a 0.26 SD effect size under similar assumptions. To detect spillovers effects in younger siblings at the second follow-up impacts survey we estimate that roughly 75% of households will have a younger sibling (average parity is about 5.4 children per mother in Nyanza[18]), implying we can detect 0.33 SD effects in comparing siblings of treated vs. untreated children at the second follow-up survey.

7.2.2 Empirical strategy

We plan to estimate two treatment parameters: Intention-to-Treat (ITT) and Average Treatment on the Treated (ATT), using the randomization as an instrumental variable. Let Y denote an outcome of interest at a follow-up survey (child outcomes, parental behaviors or mediators), and D is a dummy variable for the random allocation to treatment arms. ITT is captured by:

$$Y = \alpha_0 + \alpha^{ITT} D + X'\beta + \varepsilon \quad (1)$$

In equation (1), α^{ITT} is the ITT parameter, X are other covariates, and ε is an error term. The basic identifying assumption is the mean independence of the error term with respect to treatment status. In our intervention, it is perhaps more interesting to estimate ATT treatment effects among those who participated if there is imperfect compliance. These effects are captured in the following system of equations:

$$Y = \alpha_0 + \alpha^{ATT} P + X'\beta + \varepsilon \quad (2)$$

$$P = b_0 + b_1 D + X'\gamma + \eta \quad (3)$$

Here, equation (2) is the outcome equation where P is a dummy variable for observed participation, which can differ from the random allocation if there is imperfect compliance. Equation (3) corrects for selection bias into participation by modelling the participation decision using the randomization as an instrumental variable, and estimating by 2SLS methods. With this

framework, ITT estimates of the relative gains of the added home visits in Arm 2 against the group visits of Arm 1 and the control group in Arm 3 are captured by the simple mean differences in outcomes at follow-up between groups. To estimate the ATT, we instrument participation with dummy variables for the random assignment to Arms 1, 2 or 3.

7.2.3 Handling missing data and attrition

We will fit logistic regression models to assess whether this dropout is random and we will construct "nonresponse" weights to correct for non-random dropout in all our regressions and in the calculation of standard errors and tests of significance.

7.3 Aim 3: Decomposition analysis

Aim 3 is to uncover how different types of parental behaviors influence child outcomes, and how different mediators influence those parental behaviors. This information is perhaps more important than identifying treatment effects separately for different outcomes, as it allows us to understand why the intervention works, and in a prospective approach, such an analysis can inform policy on how to improve ECD interventions. We use Decomposition Analysis[15] to identify three different pathways via which we hypothesize our interventions affect child outcomes (Figure 1):
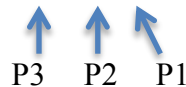
Pathway 1: Through changes in one or more mediators, the intervention changes parental behaviors. For example, mothers learn new strategies and drop old practices that did not benefit their children. This pathway is of key importance to understand how our interventions can achieve sustained changes in parental behaviors.

Pathway 2: Through changes in mediators, the intervention changes the productivity of parent behaviors, making them more efficient and thereby improving child outcomes. For example, mothers do not change their actions, but they perform those actions more efficiently.

Pathway 3: Through changes in mediators, the intervention changes some unobserved mediators and behaviors not captured in our survey measures. Denoting mediators by (Y^M), parental behaviors by (Y^B), and child outcomes by (Y^C), equations (4) and (5) capture these pathways in the following statistical model:

$$Y^B = \beta_0 + \beta_1 Y^M + \beta_2 X + \varepsilon^B \quad (4)$$
$$Y^C = \alpha_0 + \alpha_1 Y^B + \alpha_2 X + \varepsilon^C \quad (5)$$

P3 P2 P1

Equation (4) describes Pathway 1. It means that the intervention, through changes in different mediators, could change different parental behaviors at follow-up. To identify the set of parameters of interest, β_1, we need to measure all the relevant mediators for parental behaviors

that are likely to change with our interventions so there are no unmeasured mediators that correlate with the error term. We address potential concerns about this assumption by collecting very rich data on different mediators (Table 1), and by including parental behaviors at baseline in the vector X to control for time-invariant unobserved mediators.

Equation (5) summarizes the interaction of the three pathways of change in a production function of child outcomes.[43–47] The intervention, through changes in mediators, can change behaviors (Pathway 1 - Equation 4), or can change the productivity of those behaviors (Pathway 2). This parameter, α_1, is extremely important for the validation of our model of change in Figure 1 because it will inform how different behaviors affect child outcomes. For example, reading to the child might be important for child language and cognition, but not as important for socio-emotional development or health. Finally, the parameter α_0 will capture changes from the intervention on unmeasured inputs in the production of child outcomes (Pathway 3).

The estimation of equation (5) is a very difficult task if: i) measured and unmeasured inputs are correlated, and ii) unobserved inputs can change with the intervention.[15] To achieve identification, we need to minimize the number of unobserved behaviors that vary with treatment. We will collect a very rich set of variables both at baseline and at follow-ups to reduce the number of potentially unobservable behaviors and inputs that may change with treatment. Also, by incorporating baseline measures in the production function, we will control for unobservable inputs that are time-invariant. To account for potential measurement error in variables, we will use a latent factor model from our set of measurements, following standard methodologies used in the literature to identify and estimate all the relevant latent constructs.[45,48]

7.4 Aim 4: Spillovers

Assessing spillover impacts of the intervention onto younger siblings is straightforward and draws from the same analysis plan as in Aim 2. Instead of using the outcomes for age-eligible children in equations (1) and (2), we use outcomes measured at the second follow-up survey for younger children in the household.

7.5 Aim 5: Cost effectiveness and Process Evaluation

We will assess the relative cost-effectiveness of each study arm using standard methodologies described by Gold and colleagues.[49] Cost-effectiveness analysis (CEA) is a method of comparing the economic desirability of alternative health interventions by calculating the marginal cost of a unit of improved health.[49] Our measure of cost-effectiveness will be the incremental cost-effectiveness ratio (CER), defined by the difference in the per-capita cost of the treatments divided by the difference in the average effectiveness of the interventions. Costs in the analysis will be assessed using a societal perspective, taking into account all treatment costs (e.g. CHV payments, cost of materials) as well as costs that accrue to the participant (e.g. transportation costs). Specifically:

$$CER = \frac{\mu_{c2} - \mu_{c1}}{\delta_{e2} - \delta_{e1}} \quad (6)$$

where μ_{c2} is the per-capita cost of the group + home treatment in Arm 2, μ_{c1} is the per-capita cost of group visits alone in Arm 1, δ_{e2} is a measure of compliance with treatment such as share of attendance to the sessions, and δ_{e1} is the same measure for participants in Arm 1. We will perform a similar analysis comparing Arms 1 and 2 against our control group. We will estimate confidence intervals for our CERs using bootstrap methods.

We will follow guidelines from implementation science to analyze process evaluation measures and the report our findings. We will address the effectiveness of the different forms of delivery of the intervention in the context of a platform for health services at the village level with attention to the scalability and sustainability of the intervention.

8. Ethical Considerations

8.1 Human Subjects Involvement

In addition to this request for review by Maseno University Ethics Review Committee (MUERC), this protocol will be reviewed by the RAND Human Subjects Protection Committee (HSPC) in USA, and by Toronto Academic Health Sciences Network (TAHSN) Ethical Review Board (REB) in Canada.

Our research subjects will be Kenyan mothers aged 15 and over (classified as mature minors) and their children aged 6-24 months at baseline. For married mothers (the majority in this part of Kenya), fathers will also be invited participate as defined in Population section 3. Our study also engages Community Health Volunteers (CHVs) as research subjects in the process evaluation as described in Process Evaluation section 5.6. Tables 1 and 2 in Targeted Enrollment section 8.2 present the number of consents that will be requested for participation in research and intervention activities.

Our NGO partner SWAP operates in the proposed study area and has a successful history of implementing public health interventions and research studies in the area. Best practices from previous studies will be applied to the delivery of this study and intervention including communicating with village leaders and regional authorities in advance of the study. Care will be taken to ensure that there is no undue pressure to participate in the study from the researchers, SWAP personnel or local leaders. Parents who agree to participate in the ECD intervention will be encouraged and reminded to participate in the group sessions, but there will be no forcing, coercion or penalty for lack of attendance.

8.1.2 Study Participants

The main respondent of the baseline survey and follow up surveys is the mother, but in married households where the father is present we will interview fathers as well in some sections of the surveys. The content of the surveys is presented in Measures section 6. Children in the household aged 6-24 months at baseline will be included in cognitive and motor development assessments, as described in Measures section 6. A trained interviewer will administer informed consent procedures for participation. For those that express a willingness to continue in the study, the interviewer will administer the survey, the expected duration of each survey is 60-70 minutes. During this baseline survey we will collect contact information of the household including mobile phone numbers to facilitate contacting them in the future.

All households surveyed at baseline will be re-contacted to undergo a follow-up survey roughly 10-12 months later. Duration, procedures and measures will be identical to the baseline survey. The interviewer will reassess the child(ren) assessed at baseline and interview the mother (and the father as appropriate).

Roughly two years after this first follow-up survey, all households will again be re-contacted to undergo a second follow-up survey. Measures and procedures will be similar to previous survey waves. However, for those mothers that have a new child aged 6-24 months at this time point, we will additionally assess this (these) younger siblings using the same measures and procedures as used on their older siblings at earlier waves.

The pilot survey will follow the same protocol as the baseline survey, but the household will not be revisited.

The process evaluations will recruit SWAP CHVs who deliver ECD interventions in study arms 1 and 2. During the seven months when the group ECD intervention is delivered, SWAP supervisors will observe a subset of sessions. Following the end of the group ECD intervention, exit focus groups will be conducted with CHVs by a trained interviewer, these focus groups will be 60-90 minutes in duration.

Table 1 in Targeted Enrollment section 8.2 presents the number of consents that will be requested for participation in research activities for the study.

8.1.2 Intervention Participants

Following this baseline survey, the randomization of villages to one of three treatment arms will take place. Those households in villages assigned to an intervention arm (Arm 1 or 2) will be contacted and invited to attend the ECD village sessions, totaling 16 total sessions within the 40 treatment villages. These sessions will last approximately 90 minutes each and occur on a biweekly basis for 7 months from roughly November 2018 through June 2019. Mothers and

children will be invited to all 16 sessions. In half of the villages fathers will also be invited to the sessions. Sessions involving both parents will be scheduled on a case-by-case basis in villages to encourage maximum attendance by both parents but will fit within the seven-month timeframe of the implementation. Attendance at all sessions will be voluntary and recorded by the SWAP CHV who will conduct the sessions.

For the 400 households in the 20 villages assigned to Arm 2, they will receive a total of 4 home visits during the study's duration, each roughly 60 minutes in duration. These home visits will occur during the seven-month village intervention period to replace the biweekly group sessions. During the home visit the CHV will record a series of structured observations on the extent to which the mothers (and fathers) are practicing the ECD skills taught in the group sessions at home with their children.
Children between ages 6-24 months at baseline will be included in the study. We will exclude all youths outside of this age range for reasons discussed in Rationale for Exclusion section 8.3. Children in intervention villages should benefit from increased parental engagement and stimulation practices.

For those households in villages randomly selected to receive the extended booters following the end of the 16 biweekly sessions, they will be invited to attend roughly 8 additional booster group sessions in their villages on a bimonthly basis for an additional 1.5 years between surveys beyond the 2 booster sessions planned for the first six months after the main intervention. As with the biweekly sessions during the main intervention, attendance will be voluntary and record by the SWAP CHV who will conduct the sessions.

8.2 Targeted Enrollment

TABLE 1

TARGETED/PLANNED VOLUNTARY ENROLLMENT in study			
	Sex/Gender		
	Females	**Males**	**Total**
Mothers aged 15 and over with children aged 6-24 months [1]	1320	0	1320
Fathers who are aged 18 and older and who are married to mothers with children aged 6-24 months (as above) [2]	0	990	990
Children of mothers (as above) aged 6-24 months [3]	726	726	1452
Community Health Volunteers (CHV) who deliver ECD interventions [4]	40		40
Total	2086	1716	3802
[1] 120 mothers in the pilot, 1200 mothers in the baseline survey with repeated measures in two follow up surveys. (1200+120=1320)			

8.3 Rationale for exclusion

We will exclude households without children and households with children that are outside the age range of 6-24 months at baseline. We will also exclude households with children aged 6-24 months who are found at baseline to have severe developmental delays. The focus on this age range is driven by critical factors. One, most interventions in child psychosocial stimulation work with children older than 6 months because for younger children interventions are different in nature and more focused on breastfeeding, which is beyond the scope of our project. Another reason to focus on children at least 6 months in age is that cognitive and language assessments are well developed only for children older than 6 months. Though our initial proposal was to include only children aged 6-18 months at baseline, our census of available children in the sampled villages is proving that such a tight age range is potentially problematic in order to find our required sample size of 1200 children total. We therefore expand to our maximum age to 24 months for the same reasons. We restrict to children at most 24 months at baseline because younger children are more likely to benefit from integrated interventions as the one proposed, which should improve our overall ability to detect effects. Additionally, focusing on younger ages reduces the number of children who will age out of the Bayley's III scale by the second follow-up survey, which is our preferred primary outcome measure, validated in many low-income countries for assessing children up to 42 months of age.

As explained in the ECD Intervention Procedure section 5.4, group ECD sessions will have a cap of 20 mother-child dyads per group, who will be randomly invited through lotteries. The rationale for this exclusion comes from extensive research showing that group sessions should be conducted with no more than roughly 15 participants to be effective. As participation is voluntary and because similar interventions have achieved levels of compliance around 75-80%, in order to have enough power to detect impacts we will invite 20 households per village. Additionally, for purposes of analysis and sample size calculations, we will exclude from our sample households with children who are assessed at baseline to have severe developmental delays. Severely delayed children are likely to have needs that are beyond the scope of our study and thus are unlikely to benefit from a program focused on stimulation and nutrition topics. Any identified children with severe developmental delays will be referred by the enumerator to the SWAP CHV for consultation with the local health facility.

8.4 Sources of Data

The proposed research involves new primary data collection and analysis. To maintain accurate attendance records at ECD sessions as well as to enable recontacting homes for follow-up surveys, it is necessary to have temporary access to personally identifiable information including name and mobile number. However, such access to study investigators will be made only temporarily and we will follow the Data Safety and Monitoring Plan outlined in Section 8.8.

8.5 Potential Risks

One potential risk of this study is that during baseline and follow-up surveys, or during the ECD interventions, we detect children with severe health problems that require immediate assistance. In that event, our CHVs and interviewers will be properly trained to assist the parents in taking the child to the closest local health center.

A second potential risk is that CHVs or interviewers detect cases of intra-household violence either during the group interventions or in the home visits. We will deal with intra-household violence with three approaches. First, these topics will be included within the curriculum of the intervention. Some sessions intend to cover topics of family dynamics and fathers' engagement. In half of the villages, fathers will be invited to these sessions and participate in group activities. The group activities of these sessions will be devoted to address family barriers that limit the development of a nurturing home environment, focusing on the positive roles of love and respect and a positive home environment to improve overall family functioning. Aboud and Singla's experience developing an ECD intervention in neighboring Uganda that also addressed domestic violence issues will serve as a guide for how to approach these sensitive issues in group dynamics either involving mothers and fathers, or working only with mothers. Second, we will also borrow from their experience for the training of CHVs on how to approach family conflicts and detected violence episodes during home visits. We will train CHVs and interviewers in the plan of action in those events, which will include advising the family to attend the closest local health or social assistance center, with a formal recommendation from SWAP as to local capabilities and services. They will be also trained to report the cases to the local authorities in cases in which the safety and health of the mother/child are seriously compromised. Third, a related but rare potential risk is that our joint sessions with mothers and fathers might trigger some family conflicts during or after the sessions. Our CHVs will have special supervision in how they conduct these sessions by members of the research team of SWAP. Both CHVs and supervisors will be properly trained to act accordingly to manage those situations and report them if needed.

Another potential risk is that CHVs detect severe cases of maternal depression that require urgent assistance. Similar to the case of domestic violence, CHVs will be trained to advise the family to attend the closest health center or social assistance center when required, and recommended by SWAP.

Another potential risk is that CHVs and/or interviewers may suffer any sort of accident when traveling to/from the village catchment areas. All the personnel hired by SWAP implementing the intervention and surveys are covered by medical insurance provided by SWAP and paid from the budget of the current proposal.

Another potential risk is that CHV participation in the process evaluation may reflect poorly on their performance as CHVs and risk influencing their relationship with SWAP. Information collected in the process evaluation will not be used to evaluate the CHVs themselves, instead the process evaluation will focus on the intervention. The outcomes of the process evaluation will not be used to evaluate individual CHV performance.

Finally, there is a potential risk of losing the data collected in surveys and violation of confidentiality, or losing the materials for the interventions.

There are no other risks involved in our project.

8.6 Recruitment and Informed Consent

As explained above, subjects will be asked for their informed consent for their participation. The informed consent will detail the topics to be covered in the group sessions and home visits so households know in advance the type of activities they will participate. Similarly, the consent will detail the survey measures that will be collected. Participation in surveys and any ECD intervention will be strictly voluntary.

8.7 Protection Against Risk

The preservation of participant confidentiality through the project use of the data is of utmost priority to the project team. Access to the data is carefully safeguarded by the RAND Corporation Data Facility, and the RAND Human Subjects Protection Committee that comprises RAND's Institutional Review Board. The protection of risks to participants is also safeguarded under the RAND "Federal-wide Assurance for the Protection of Human Subjects." The project team will comply with all aspects of data safeguarding specified in the RAND policies and procedures on confidential information protection. Protection against risks are described in detail in Potential Risks section 8.5.

SWAP has its headquarters in Kisumu, Kenya, where both the Country Director and Technical Advisor have private locked offices and where the computing environment consists of an Ethernet LAN connecting computers and printers for the Country Director, Technical Advisor and all SWAP personnel assisting with this project. We will protect the tools, data and materials,

saving these materials in the Country Director's office, or, as appropriate, inside of one of SWAP's closest Jamii (community) center's locked offices; the project will further protect the property by funding security alarms and guards during the time involving data collection and ECD interventions. All SWAP's research staff members have been trained on research ethics and signed confidentiality statements.

We will train CHVs and interviewers in the event of detecting urgent health care needed for any family member or the need of social assistance, including advising the family to attend the closest local health or social assistance center, or to make a formal report in cases of violence.

8.8 Data and Safety Monitoring Plan

8.8.1 Blinding

Due to the nature of the intervention, the participants will not be blinded to their study allocation. Data collection will, however, be blinded to the intervention allocation status of participants and villages at follow-up surveys. (Baseline surveys will be collected prior to randomization.) Likewise, data analysis will be blinded to the intervention status of participants and villages.

8.8.2 Plan for Independent Data Safety and Monitoring

Survey data collected are generally about individuals' parenting practices, well-being and health needs (their own, their families', their communities'), basic wealth indicators and basic attitudes towards parenting. We will also collect basic anthropometric data (height and weight) of children as well as perform assessments of children's cognitive and language development using standard scales described in our research strategy. Though personal in nature, these data are not highly sensitive but it will be equally treated with the maximum norms of confidentiality following the study protocols involving human subjects reviewed by the RAND Human Subjects Protection Committee (HSPC) as well as the Maseno University Ethical Review Committee (MUERC). Risk presented by disclosure of the identity or data provided by study participants is minimal.

Interviews, surveys, and the ECD program are low-risk, and therefore adverse events (AEs) are very unlikely and any experienced AEs will be likely due to factors unrelated to the study. Based on prior research with this population, we expect some level of maternal depression and, in some cases, cases of domestic violence. Thus, adverse events may be related more to these underlying issues than to the study itself.

8.8.3 Responsibility for Data Safeguarding

PI Luoto will oversee data safeguarding. Under her supervision, designated research staff will be trained in data safeguarding techniques and will be responsible for the secure transmission of

data from the study tablets using encrypted data collection forms on SurveyCTO in the field in Kenya to a secure encrypted server to secure research computers at RAND.

8.8.4 Training of the Data Collection Team

Prior to data collection, Dr. Luoto will conduct extensive trainings for the designated on-site interviewer staff. The training will address data safeguarding and confidentiality. All study staff will be trained to promote standardized and objective collection and recording of participant information. As part of their training, they will be instructed in the rules of confidentiality and data safeguarding for the study. After the initial data collection, RAND will be responsible for training the data collection team to manage the uploaded data.

8.8.5 Data Storage and Transmittal

We will not collect any form of biological samples that require medical procedures of any sort. Surveys will be collected via tablets and contain personal identifiers (names), anthropometric and psychosocial measures of children, and mobile telephone numbers. Data from tablet-based surveys using encrypted forms will be uploaded into SurveyCTO's encrypted server and analyzed using Stata software version 15 (College Station, TX). To increase security over paper questionnaires, these will be stored on password-protected mobile devices using encrypted data collection forms in the field, and removed at the end of the day by uploading to an encrypted, password protected SurveyCTO server. Participant names will be removed from the data and no longer stored in any table after the successful linking with a RAND-generated ID. Access to this linked file will be restricted only to authorized study staff. Data transfer from the study server to study investigators will be done with only encrypted, password-protected files.

All primary data made available to the analysis team will contain only the study ID. Following analysis, reports will be prepared. These reports will not contain any data that could identify individual clients or staff.

Exported administrative data files will be kept for at least one year following the publication of the final reports on the study. Upon the completion of the study, the link files will be destroyed.

Recordings of qualitative interviews will be uploaded to an encrypted RAND computer each day. Transcripts from the interviews will be identifiable only by study ID.

8.8.6 Disposition of Data after the Study

Soft copies of raw data will be kept at RAND offices. Linking files and identifiable information will be destroyed within a year after study completion.

8.8.7 Data Integrity

We have several mechanisms in place to ensure data integrity and confidentiality. All data will be stored in a password-protected database. Paper files (i.e., consent forms) will be stored in locked file cabinets, and electronic files will be stored in encrypted and password-protected files. Furthermore, electronic files will be identified only by participant ID numbers. Identifying information linking participants to their study ID number will be retained in an encrypted and password protected record management system on RAND's segmented secure server. Confidentiality policies and procedures will be reviewed with all new staff and reviewed annually with current staff.

8.8.8 Process for Handling and Reporting Adverse Events (AEs)

AEs will be handled the same way in which emergencies are handled. Study staff will intervene as necessary, assess the participant's state, and develop an appropriate plan. Incident reports will be written within one business day. The PI will inform the IRBs of all AEs.

8.9 Potential Benefits

Our project involves three potential benefits. First, the direct benefits of our ECD interventions on households. We target teaching households in the intervention arms new child-rearing and nutrition practices that potentially can lead to improvements in their children's health and developmental outcomes. Previous experience of our team members in Kenya and other contexts is that there will be great interest on the part of mothers to learn the new information and practices, and the additional focus on fathers and how they can contribute to their children's positive development could be of significant value to the community. Through Luoto's and SWAP's previous work with the community leaders, we are hopeful that engagement of fathers will also be significant.

Second, there are potential indirect benefits through spillover effects. At the household level, while our interventions will target at only one child per family, younger children can potentially benefit as well by the adoption of new parenting practices acquired during the intervention. At the community level, participants can also potentially transfer knowledge of the new practices to non-participants and expand the impacts of our intervention to non-intended targets.

Finally, households that are surveyed at baseline and follow-up either in the treatment or control arms can benefit from the intervention by learning from the survey results. Our evaluation team is committed to feedback to the families about the results of maternal and child assessments and with individualized recommendations to improve parental practices and child developmental outcomes and has budgeted for travel in the final year of the project to disseminate findings locally. In the final year of the project, research team members plan dissemination workshops to share findings with the County Health Management Teams, County Executive Member of Education and Local Administrative Leaders.

9. Implications of Research

Our study will provide policy makers with rigorous evidence of how best to expand ECD interventions in low-resource rural settings to improve child developmental outcomes for both the short-and longer-term. The study will try to understand how to maximize the reach and sustained impact of evidence-based early child development curriculum and materials to improve child cognitive, language and psychosocial outcomes. In low-income and middle-income counties 43% of children under five years of age have compromised cognitive and psychosocial development, and these deficiencies are tightly linked to inadequate nutrition, lack of psychosocial stimulation and other poverty correlates. We test potentially scalable and sustainable models of delivery and explore via complex Decomposition Analysis whether and how the intervention's impacts can be sustained over time. Our project will also be the first to experimentally test for the presence of spillovers of impacts within families onto younger children, which is a clear sign of sustained behavioural change on the part of the parents.

By integrating delivery into the ongoing operations of a well-established local NGO, our project has the potential to make a real and sustainable contribution in a resource-limited setting and lessons learned are potentially adaptable to other similar settings and organizations. Because our main goal is to test the most cost-effective model of delivery for rural Kenya, important lessons from our project can be extracted to scale-up similar intervention in similar contexts.

Due to the fact that very minimal risk is placed on the participants through the proposed research, the importance of the knowledge to be gained is greater than the risks to the subjects

10. Challenges and Limitations

The proposed intervention seeks to attain sustained changes in parental child-rearing practices and child developmental outcomes to test for the most cost-effective and scalable models of delivery of this intervention, and to evaluate the impact of involving fathers in such an intervention. We acknowledge several challenges and limitations that might prevent us to achieve these goals and strategies to overcome them.

First, an important challenge to achieve one of the study goals is to engage fathers so they participate in the group sessions in villages in which fathers are included. While engaging mothers has been proven to be successful in similar interventions conducted by co-Investigators Aboud and Singla in Uganda (where more than 75% of mothers invited showed-up to the sessions), we anticipate that encouraging father's participation and adherence will be more challenging. Fathers

usually work during the day or they are absent during longer periods of time working in another region, but even if they are present, they typically are less involved in child-rearing activities. At this point it is not obvious to us whether conducting sessions with fathers and mothers together or having at least few sessions separately first is more convenient, an issue we will address during piloting. In order to increase father participation we have adopted several strategies. First, prior to research activities SWAP will conduct community entry work to promote our intervention in the villages committing village elders to encourage fathers to participate and attend some of the sessions themselves. Second, we will pilot group sessions only with fathers (particularly the first ones) so they feel more comfortable with the topics discussed, scheduling them at times of the day that are more appropriate for them. Third, the piloting schedule will test different orders of sessions and modalities of attendance (fathers only and mothers only v/s together) to test for the design that maximizes attendance and adherence. Finally, the pilot will also evaluate alternative incentives to increase participation such as providing certificates of attendance, etc.

A second potential limitation of our study is our ability to inform policy about what drives sustained impacts and spillover effects onto younger siblings if we find any during the second follow-up survey. In particular, we will have the challenge to explain what aspects of our intervention induced sustained changes in maternal and paternal behaviors driving our results. Is it because of our intervention improved maternal or paternal mental health? Or they improved the social support? Or changes in behaviors are instead due to a higher knowledge of child development or to a change in beliefs and attitudes? While all these questions would ideally be tested incorporating more treatment arms, that would make the study too costly to be implemented. Instead, our strategy to address these questions would rely on collecting very rich data about each potential mediator of behavioral change such as mental health, social support, self-efficacy, knowledge and beliefs and test for their relative importance as shown in Figure 1 combining this data with state-of-the-art statistical methods of mediation analysis. To the extent that our interventions would show impacts two years after the group sessions take place in child outcomes and behaviors, our methods would open the black box addressing the pathways of change, allowing us to design better interventions in the future.

Third, we will face several challenges regarding measurement. For example, the application of the Bayley III scale to assess child development has been reported to be logistically difficult and expensive because it involves direct assessment with children using a complete kit of manipulatives. This requires the child to be in the appropriate mood for the test and the presence of the mother to assist the enumerator in accomplishing each activity with the child. To address this issue we have adopted two strategies. First, at baseline we will use a child assessment that is based on maternal self-report (the MDAT scale) and therefore is simpler to implement. The baseline data will be collected only for the purposes of testing the balance of the sample, so there is no need to use more sophisticated scales such as the Bayley, which will be used instead to measure impacts. Second, before implementing the Bayley III in the follow-up survey we will pilot its application in subsample of mothers.

Finally, although the pilot study did not identify a significant risk of participant contamination, this remains a possible risk in a cRCT of this nature. While CHVs catchment areas will be mapped and selected villages will not overlap to secure that households in control villages do not attend the sessions in contiguous treatment villages, this risk cannot be eliminated entirely. Thus, our sampling strategy will incorporate mapping villages separated by a healthy distance, with the expectation that the high costs of travelling to more distant treatment villages will outweigh the perceived benefit of participating in the intervention. Moreover, we will work closely with SWAP during the sample stage to identify concurrent interventions from other NGOs in the pool of pre-selected villages to avoid overlapping whenever possible, and when it is not possible, to document those interventions to incorporate this information to our statistical analyses.

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12.   List of attachments

12.1 Roles and responsibilities

Dr. Jill Luoto, Ph.D. Dr. Luoto is an Economist at RAND and will be the Principal Investigator (PI) for this project. As Principal Investigator, she will lead the research team assembled and be responsible for designing and executing the proposed research in pursuit of its Aims. She has served as PI on randomized field studies implemented by SWAP before in this part of Kenya on related topics to those proposed here, and is well prepared to handle these tasks.

Dr. Italo Lopez Garcia, Ph.D. Dr. Lopez Garcia is an Associate Economist at RAND and will serve a central role as co-investigator in this project to assist Dr. Luoto in all aspects of project execution. He brings key topical expertise in structural econometric techniques to the study team. He will lead the design and piloting of the survey questionnaires and the decomposition analysis in study Aim 3 using both rounds of follow-up survey data.

Dr. Frances Aboud, Ph.D. Dr. Aboud is Full Professor of Psychology at McGill University and a seminal figure in early childhood development programs and interventions in LMIC settings. She is an internationally recognized expert in developmental psychology with specific expertise on infants and toddlers who brings considerable expertise with decades of invaluable experience. She will offer senior guidance and advice on key elements of intervention and curriculum design and interpretation of findings. She will lead the trainings of CHVs into the curriculum and will supervise implementation of some ECD village sessions at the midway point as a quality control measure.

Dr. Lia Fernald, Ph.D. is an Associate Professor in Community Health and Human Development at the School of Public Health at the University of California, Berkeley. Dr. Fernald is an internationally recognized nutrition and child development expert with numerous studies evaluating the impacts of programs and interventions for child development in developing countries and studying the role of poverty on child outcomes. Dr. Fernald will oversee the design and implementation plans for the home visits in study Arm 2 and will offer senior guidance.

Dr. Daisy Singla, Ph.D. is Assistant Professor and Senior Scientist at the Department of Psychiatry at the University of Toronto and Mount Sinai Research Institute. She has conducted integrated randomized trials related to parenting interventions in Uganda and Bangladesh, and has particular expertise in maternal mental health. She will assist in the training of CHVs and will lead the formative exit interviews of pilot participants as well as the process evaluation.

Alie Eleveld, MPH. Ms. Eleveld is the PI on the subcontract to SWAP and will be the main point of contact between foreign and Kenya-based implementation team members. She oversees all SWAP operations and provides technical support and strategic direction, will monitor compliance with MOUs and reporting guidelines. She will lead dissemination efforts in Kenya and assist with writing reports.

George Aol Otieno. Mr. Otieno will be the survey manager for the survey data collection and will oversee the team of enumerators and manage field logistics for the baseline and follow-up surveys as well as the piloting of the survey instrument and its measures.