The PLAY Collaborative: Testing an Implementation Strategy for Scaling-Out Evidence-Based ECD+Violence Prevention Home-Visiting in Rwanda

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1. Background

1.1 Introduction

Rwanda has one of the highest rates of stunting (38%) in all of sub-Saharan Africa (The World Bank Group, 2018). This reality is in strong contrast to its ambition to be an upper middle-income country by 2035 and high-income country by 2050. Rwanda is invested in addressing stunting and similar indicators of underdevelopment in children, and recognizes that affordable, scalable, and effective interventions that address early childhood development (ECD) are needed to advance the prospects of vulnerable children. The comprehensive ECD Policy established by the government (2016), Food and Nutrition Policy (2013-2018); Economic Development and Poverty Reduction Strategy II (2013-18); and the National Strategy for Transformation (2017-2023) link the Sustainable Development Goals and the revised Vision 2020 targets and cement the Government of Rwanda's (GoR) commitment to integrated ECD approaches.

In the early years of life, the need for nutrients to fuel brain development and physical growth is particularly high. In Rwanda, eighty-seven percent of children less than 6 months old are breastfed, but stunting rates rise from 18% at 6-8 months of age to 38% at 18-23 months of age. Moreover, stunting is highlest in low income families, at 49% in the lowest poverty quintile at age 18-24 (National Early Childhood Development Programme, 2019). Dietary diversity is limited, especially among poor children, and a UNICEF/Rwanda Ministry of Health study found that a very limited diet for children—in terms of variety and nutritional content—is common in Rwanda, due both to poverty and poor feeding practices. The study found that a high percentage of children in the poorest households did not receive three meals a day and only 17% of children aged 6–23 months received the minimally acceptable diet. In addition, early childhood development knowledge is limited and engagement in responsive caregiving practices among Rwandan parents are not very common. A 2014 UNICEF study found that only 12% of primary caregivers for 2–3-year-old children engaged in three or more activities to promote learning or school readiness (e.g., singing songs, telling stories, teaching the child something new, or looking at pictures in books and magazines with the child). The ECD problem is further compounded by the fact that violent discipline is prevalent. An Early Childhood Development and Family Services UNICEF baseline evaluation across 20 sites in Rwanda showed that 19.8% of children 0-11 months old and 80.7% of children 24–36 months old are exposed to some form of violent discipline; 34.4% of caregivers believe that physical punishment is necessary to raise a child well (UNICEF, 2015). In addition, men are not commonly involved in child care practices including support for children's early development, and financial decision making is not equally shared by men and women.

Research has identified several leverage points for positively impacting ECD outcomes. A study by Larson and Yousafzai demonstrated that nutrition interventions alone (macronutrients, single micronutrients, multiple micronutrients) had small effects on mental development (Larson et al., 2015). A review of stimulation studies showed that parenting/early stimulation programs lead to better cognitive outcomes for children. A meta-analysis of 15 randomized control studies revealed that stimulation to improve ECD in children results in medium-to-large benefits for children (Jeong et al., 2018). However, ECD programs often fail to take a multi-pronged approach to intervention, neglecting the larger ecological context in which children grow, resulting in narrowed impacts.

The Research Program on Children and Adversity (RPCA) has successfully grown its evidence-based home-visiting program—Sugira Muryango—in Rwanda (Barnhart et. al. 2020, Betancourt et. al. 2018; Betancourt et. al. 2020, Jensen et. al. 2021), while several governmental programs and policies intended to promote ECD have evolved (NECDP, 2019; Rwanda Ministry of Health, 2014). The combination of ECD commitment by the government and the evidence-based Sugira Muryango intervention creates an ideal environment for further collaboration between RPCA and families at-risk of interpersonal violence,

malnutrition, and other factors crucial to successful development of children. Sugira Muryango was designed as a complement to other center- and community-based ECD interventions in Rwanda that may not adequately address issues such as limited stimulation in the home, hygiene, nutrition, father engagement, and violence in the home which is more prevalent among families living in extreme poverty (Bierksteker, 2012; Howard et al., 2009).

The PLAY Collaborative implementation science research project builds on research tools and partnerships first developed under the Family Strengthening Intervention research initiative for HIV-affected families (Betancourt et. al., 2017). The RPCA's long running work in Rwanda began as a collaboration between the Research Program on Children and Global Adversity at the Harvard TH Chan School of Public Health and Partners in Health/Inshuti Mu Buzima in 2007. By 2015 collaboration shifted to Francois Xavier Bagnoud-Rwanda (FXB) and the intervention was adapted to became more focused on early childhood development. Since then, the Research Program transitioned to Boston College as the *Research Program on Children and Adversity* but still works closely with FXB Rwanda to deliver the ECD-focused Family Strengthening intervention. During the development of the ECD focused version of the intervention, components on mental health promotion, violence prevention, problem solving and use of a strengths-based family narrative from the original HIV/AIDS intervention manual were blended with early childhood development curricular materials endorsed by the Government of Rwanda as well as content on early stimulation, hygiene and nutrition from the WHO Care for Child Development to create the *Sugira Muryango Intervention Manual*, a more comprehensive home-based approach to early childhood development, family violence prevention, and nurturing care (Betancourt et. al., 2020; Jensen et. al., 2021).

1.2 Gaps in Knowledge

Extensive research and evidence exist on the relevance and efficacy of ECD interventions related to child and maternal health, child development, parenting skills, home violence, and more (Black et. al., 2017; Donelan-McCall, 2009; Howard and Brooks, 2009; Jeong et. al. 2018; Luoto et. al., 2020; Knauer et al., 2020; Reynolds et al., 2009; Tomlinson et el, 2018). Evidence also exists on the potential of integrating scalable cost-effective ECD and violence prevention programs into poverty-reduction and other social welfare programs for promoting ECD and reducing familial violence in culturally diverse, low-resource settings. For instance, research in developing countries has shown that government social safety net programs can help ECD interventions in reaching at-risk populations and combat early development of disparities (Betancourt et. al. 2018; Britto et al., 2017), additional financial resources can foster investments in the home environment (Bastagli et al., 2016), and cash transfers may reduce stress related to financial strain, improving parents' psychological wellbeing and mental resources to engage with their chilrem (Fernald & Hidrobo, 2011), ultimately supporting children early cognitive development (Attanasio et. al, 2014). Overall, in the medium and long terms, this integration has proven to advance child development, school readiness, and health outcomes (Britto et al., 2017; Engle et al., 2011).

However, knowledge on the effective scalability of these efforts into regional or national programs and policies is still limited (Tomlinson et. al, 2018). As Yousafzai et. al. (2018) point out, only a few ECD interventions have been implemented in a large-scale and access to ECD interventions among disadvantaged children in LMICs is still extremely low. In particular, more research is needed regarding implementation processes, including but not limited to the elements that could affect implementation strategies, the mechanisms through which interventions are effectively introduced and linked to systems and policies, and the associated implications for program sustainability, among others (Lombardi, 2018; Radner et. al., 2018; Yousafzai et. al., 2018).

Data gathered during the Play Collaborative implementation study and the embedded effectiveness Sugira Muryango trial will provide information on both intervention effectiveness and the scaling implementation strategy, all of which will help in supporting and advancing the Rwandan government's vision for comprehensive decentralized ECD to help eradicate poverty and violence against children. Taken together, the objectives of this research seek to contribute to academia and research institutions' roles and responsibilities outlined in the ECD Policy housed under the Ministry of Gender and Family Promotion (MIGEPROF, 2016).

1.3 How this study addresses the Gaps

Rwanda is facing significant challenges, including chronic malnutrition (stunting), neonatal mortality, access to high-quality ECD services and education, and prevention of violence against children (UNICEF, 2015). However, its political stability, strong governance, fiscal and administrative decentralization, zero tolerance for corruption, and the commitment towards ECD programming reflected on several governmental policies and programs set the country among the prime locations where early childhood education interventions can have an immediate, medium, and long-term positive effects on children development and families' wellbeing. All these country strengths and the political momentum are regarded as key elements that can support effective large-scale ECD program implementation strategies (Lombardi, 2018; Radner et. al. 2018) that will contribute to Rwanda's future development by giving the younger generations of children opportunities to reach their full potential.

As such, the present study addresses these gaps and challenges by 1) evaluating the implementation of the ***P**romoting **L**asting **A**nthropometric Change and **Y**oung **C**hildren's **D**evelopment (PLAY) Collaborative*, a Collaborative Team Approach (CTA) intended to expand and scale up the evidence-based Sugira Muryango Intervention, and 2) assessing the intervention effectiveness in promoting ECD and reducing family violence while strengthening its ties with Rwanda's social protection programmatic and policy efforts.

Prior evaluations of the Sugira Muryango intervention have generated evidence of its effectiveness. Right after the intervention families enrolled in the program showed improved parent-child relationships, child's health-related caregiving practices (e.g., fever and diarrhea care seeking), and increased dietary diversity. Moreover, intervention families showed improved hygiene behaviors (e.g., proper treatment of water), improved caregiver mental health, and reduced intimate partner violence (Betancourt et. al., 2020). A 12-month follow-up has proven the intervention to be effective in improving children's gross motor, communication, personal-social, and problem-solving early development. The intervention has also shown effectiveness in improving father engagement in caregiving practices, and a sustained effect in reducing children harsh discipline and intimate partner violence (Jensen et. al., 2021).

With the intervention proven to be effective the next steps involve the evaluation of its large-scale implementation strategy, the PLAY Collaborative, which - if effective - will give Rwanda the option to bring such an intervention to scale at a national level, providing an opportunity to share impact, costing, and process evaluation lessons globally.

1.4 Aims and Hypotheses

The overall purpose of the PLAY Collaborative Research Initiative is to investigate the effectiveness of an evidence-based implementation strategy, the PLAY Collaborative, to engage local stakeholders as well as frontline providers and supervisors to ensure quality improvement and sustainability of Sugira Muryango and to repeat our previous intervention while including Ubudehe 1 families with children

outside the program's original age range. The aim is to build an evidence base, in the form of impact, process, and costing data for a strategy to expand the reach of the Sugira Muryango program by educating and engaging local stakeholders as well as frontline providers (the Inshuti z'Umuryango "IZU" workforce) to deliver the intervention at scale. In addition to testing the effectiveness of a new delivery platform for the Sugira Muryango, the current study also tests the effectiveness of an expanded curriculum to include families with children aged birth to six months.

Study Aims:

1. To replicate the Sugira Muryango intervention while expanding the target population and the children's age, to all Ubudehe 1 families with children between birth and 36 months in Nyanza, Ngoma, and Rubavu districts.

2. To Evaluate the implementation strategy of the PLAY collaborative and its relation to Intervention effectiveness.

Hypotheses:

1. Intervention effectiveness:
    a. The updated Sugira Muryango intervention, delivered by a government-supported community volunteer workforce, will lead to improvements in responsive parent-child relationships, improved child development and reduced violence.
    b. The updated Sugira Muryango intervention will lead to improvements in caregiver behaviors that support child health including increased care seeking for illness, improved hygiene, and improved dietary diversity as well as improvements in observed child health outcomes related to child growth and illness.

2. Implementation via the PLAY Collaborative:
    a. Engagement and buy-in of the PLAY Collaborative will strengthen dissemination and implementation of Sugira Muryango.
    b. High fidelity and home-visitor competence when delivering Sugira Muryango core components will enhance Sugira Muryango clinical effectiveness and improve caregiver and child outcomes.
    c. Implementation science constructs related to acceptability, feasibility, and appropriateness will be strongly and positively correlated with program satisfaction.

2. The Intervention

Sugira Muryango is a home-visiting model to support playful parenting, father engagement, improved nutrition, care seeking, and family functioning in order to promote ECD, positive parent-child relationships, and healthy child development. The intervention, informed by the UNICEF/World Health Organization (WHO) Care for Child Development package, (a) builds parenting skills and improves knowledge of ECD to create a safe, stimulating, and nourishing environment for the growth of young children with a focus on nutrition, health, and hygiene promotion; (b) coaches parents of young children in "serve and return" interactions and playful parenting; (c) develops a "family narrative" to build hope and highlight sources of resilience for addressing challenges and reducing the risk of violence; (d) strengthens problem-solving skills as well as the navigation of formal and informal community resources; and, (e) builds skills in parental emotion regulation and alternatives to harsh punishment. Sugira Muryango integrates these core components into 12 modules (Figure 1) and two booster/follow-up

sessions (3 and 6-months after intervention). A group welcome and graduation session has been added to support community engagement and provide an opportunity for Community Health Workers to conduct anthropometric assessments and disability screening of children enrolled in the program. The 12 core modules last approximately 60–90-minutes and include a 15-minute active play session between caregivers and children with coaching and feedback, are delivered weekly over 3–4 months by well-trained lay interventionists embedded in the community. The intervention is also trauma-informed as it works with caregivers to identify the supports and sources of strength that helped parents make it through difficult times in the past while directing them toward a more hopeful future.

Considering current COVID-19 related risks and challenges, in addition to the curriculum, various additional materials have been added to educate families about COVID-19. These include a curriculum insert with information about the symptoms and prevention of the virus using educational images released from the Rwanda Biomedical Center (RBC), which are reviewed in a group setting during the Welcome Session and an individual household platform during Module 1. This is complemented by a pre-visit COVID-19 checklist, which reviews prevention measures and ensures beneficiaries are not demonstrating symptoms or at high risk of having the virus prior to the start of delivery for each module. If a member of the household is suspected to have COVID-19 or matches the symptoms, Inshuti z'Umuryango (IZU—friends of the family) are trained to refer according to the government guidelines.

Table 1. Overview of Updated Sugira Muryango Intervention Modules

Module	Theme	Goals
Welcome Session [Group]		• Group-based session that introduces caregivers to Sugira Muryango • Explain the Sugira Muryango goals and structure • Establish a plan for regular meetings together • Community Health Worker Screening for Nutritional Status and IZU facilitated disability screening • Community Health Worker collection of anthropometric data • Additional COVID-19 Curriculum insert to educate about symptoms and prevention of the Coronavirus.
Module 1	Family Narrative	• Discuss the family's priorities and goals • Learn about the family and their children (hopes/goals), Family Narrative • Introduce concepts related to family relationships and ECD • Individual family review of additional COVID-19 Curriculum inserts to educate about symptoms and prevention of the Coronavirus.
Module 2	The importance of early stimulation	• Coach on the importance of diverse play opportunities, early stimulation and brain development • Coach positive, responsive parent-child interactions and early stimulation • Expand and strengthen caregivers' repertoire of stimulating activities for their children (toy making, early stimulation activities)
Module 3	Building early communication skills	• Coach on the importance of early communication skills and language development • Identify and practice ways to incorporate language learning into play and daily routines • Coach and practice additional techniques to support early speech and language development
Module 4	The importance of good hygiene	• Identify hygiene practices that promote good health • Coach on the obstacles to good hygiene and sanitation

Module 5	The importance of good nutrition	• Teaching about food consumption in the home • Identify nutritional practices that promote child health and growth, including the infant and young child feeding practices and the importance of deworming • Discuss ways to maximize nutrition from available foods • Ensure enrollment for eligible food supplements and discuss proper usage
Module 6	The importance of good health	• Talk with caregivers about health practices in the home, particularly their response to sick children • Discuss the family's Mutuelle de Sante (health insurance) coverage • Ensure immunizations are completed/take steps to complete immunizations • Educate on the importance of children attending monthly growth monitoring
Module 7	Managing the stresses of parenting and family life	• Identify risk factors and coach caregivers on ways to effectively manage household stresses and frustrations • Explain the importance of adults' consistent emotional self-control for young children
Module 8	Resolving conflicts in the home	• Identify and actively coach conflict resolution strategies that promote peace, resilience, and well-being in the home • Coach on alternatives to harsh punishment and harmful impact of angry or violent responses to conflict on ECD • Coach on the role of positive, responsive parenting in creating a safe and stimulating environment for all family members • Branching curriculum for single-headed and dual-headed households
Module 9	The important role that everyone plays in raising a baby well	• Discuss the diverse roles of all family members in supporting ECD • Highlight the important role of fathers in raising children • Branching curriculum for single-headed and dual-headed households • Coach on effective discipline strategies • Facilitate discussion on economic stability and saving for the future
Module 10	Good parenting is better than being born well	• Coach on the importance of a positive, nurturing parent-child relationship • Coach and practice skills related to responsive, stimulating child-caregiver play and interactions • Explain Serve & Return interactions and coach caregivers on this practice
Module 11	Making the home a place where a baby's brain can grow	• Discuss the importance of safety, cleanliness, and support in the home for young children's early learning • Discuss and carry out active coaching on early stimulation activities
Module 12	With a united family, anything is possible	• Review program goals and content • Address any remaining questions or concerns • Discuss how the family will use newly learned skills and strategies to promote healthy ECD going forward • Provide family with information on local health/support services
Graduation Session [Group]		• Reflect on experience within the Sugira Muryango Program • Group discussion on additional ECD programs and resources in the community for families • Community Health Worker collects anthropometric data

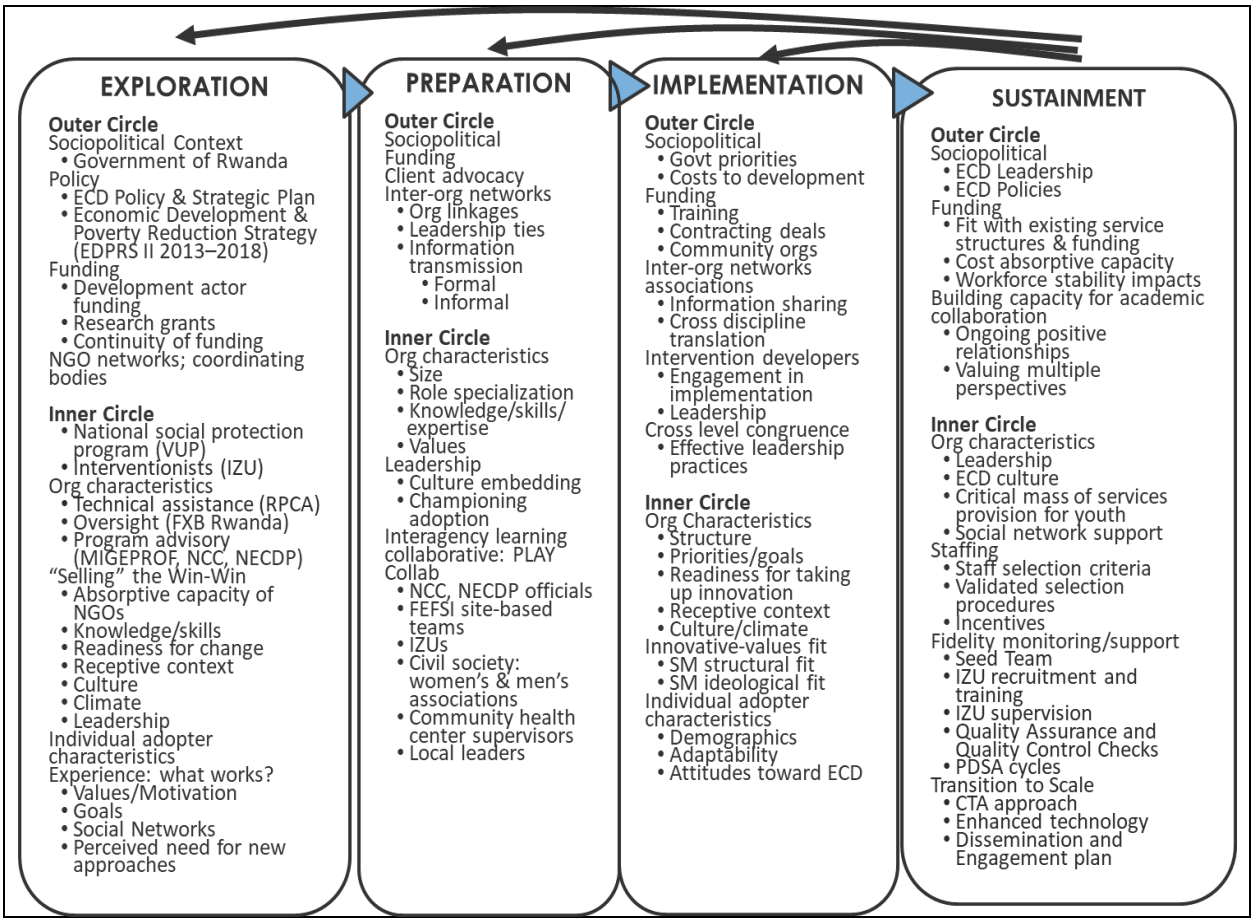
3. The Play Collaborative

3.1 Implementation Strategy

The Sugira Muryango intervention incorporates implementation science strategies into its design and delivery that, to date, have focused on 1) determining fidelity to curriculum content and delivery and developing strategies for quality improvement, 2) evaluating how features of program delivery moderate or mediate outcomes on children and families, and 3) identifying evidence-based practices pertaining to delivery, supervision, and monitoring to support a systems-level scaling-up of the program. Sustainment and scaling of Sugira Muryango requires, however, strong local buy-in and government commitment. To achieve this local commitment, Sugira Muryango will use the Collaborative Team Approach (CTA), referred to in the Sugira Muryango expansion program as the **P**romoting **L**asting **A**nthropometric Change and **Y**oung Children's Development (PLAY) Collaborative, to oversee program implementation.

The PLAY Collaborative utilizes a multi-level implementation strategy, drawn from Interagency Collaborative Teams (Hurlburt et al., 2014) and the IHI Breakthrough Learning Collaborative methodology (Institute for Healthcare Improvement, 2004), and is intended to promote multi-level buy-in across different layers of the ECD delivery ecology in Rwanda. In addition, the PLAY Collaborative approach uses the EPIS (Exploration, Preparation, Implementation, Sustainment) framework to guide the roll-out of the intervention. EPIS is a phased, multi-level implementation model that draws on principles of system-wide implementation in order to: (a) generate shared investment in implementation of evidence-based practices; (b) create a process for incorporating local expertise within multiple organizations to build institutional knowledge; (c) optimize resources to address known implementation challenges; (d) focus on quality assurance and appropriate oversight within systems change; and (e) develop an implementation structure that focuses on communication and workload sharing.

Figure 1. EPIS Framework



To manifest these EPIS principles within the PLAY Collaborative (see Figure 2), elements of the Institute for Healthcare Improvement (IHI) Breakthrough Learning Collaborative (Institute for Healthcare Improvement, 2004) will be incorporated. Specifically, (a) a shared charter and mission across all the PLAY Collaborative regional teams to commit to problem solving and removing barriers to Sugira Muryango delivery; (b) cross-site learning where supervisors and mentors at the Cell, Sector and District level exchange information on effective core Sugira Muryango strategies related to promoting father engagement and play and nutrition strategies and reducing violence in the home; (c) Plan-Do-Study-Act (PDSA) cycles whereby PLAY Collaborative regional teams identify challenges (e.g., father engagement, playful parenting, violence, food insecurity, health care access, etc.) and test strategies to address the problem, analyze the success of such initiatives, and then share findings across teams; (d) recruitment of community members and village leaders to disseminate messages about the importance of father engagement, addressing violence in the home, responsive/playful parenting and nutrition in the care of children; and (e) incentives (e.g., t-shirts, lanyards, baby books, etc.) that will underscore the importance of father involvement, a violence-free home, playful parenting and nutrition. The idea is to create a community of practice among ECD stakeholders (Hurlburt et al., 2014; Institute for Healthcare Improvement, 2004) to reinforce knowledge-sharing, problem solving, and strengthen intervention oversight between government agencies and programs (National Commission for Children, NCC; National Early Childhood Development Program, NECDP; Ministry of Gender and Family Promotion, MIGEPROF), interventionists, civil society groups, community health workers, as well as sector and village leaders. Within this community of practice, cross-site learning and Plan-Do-Study-Act (PDSA) cycles, which have a strong evidence base for accelerating quality improvement, are used to create shared

ownership within the PLAY Collaborative while its members identify challenges and creative solutions that can be implemented immediately (Aarons et al., 2011) (IHI, 2017).

Building from this approach, in order to embed Sugira Muryango within the targeted communities the PLAY Collaborative will leverage an existing government-supported community child protection workforce linked to the National Commission for Children (NCC) known in Rwanda as the Inshuti z'Umuryango "IZU" (UNICEF, 2018). The use of the IZU workforce is a direct result of continued engagement with and buy-in from the Government of Rwanda (GOR), as well as direct alignment between Sugira Muryango goals and local government policy and programmatic priorities that have resulted from years of collaboration. A key feature of the PLAY Collaborative towards the transition of the evidence-based Sugira Muryango model to ownership by local stakeholders is the development of a cross-site Seed Team that will assume a leadership role in ongoing training, supervision and fidelity across a regional set of IZU interventionists (see figure 4). As the in-country Sugira Muryango expert, with a strong presence in the target districts, François Xavier Bagnoud (FXB)-Rwanda (hereafter FXB) will staff and lead the development and activities of the Seed Team. This local expertise development process through regional collaborative teams and a Seed Team that shifts ownership to local partners for training and ongoing supervision is intended to enhance cross-site learning, dissemination, and sustainability of the implementation strategy and the program itself.

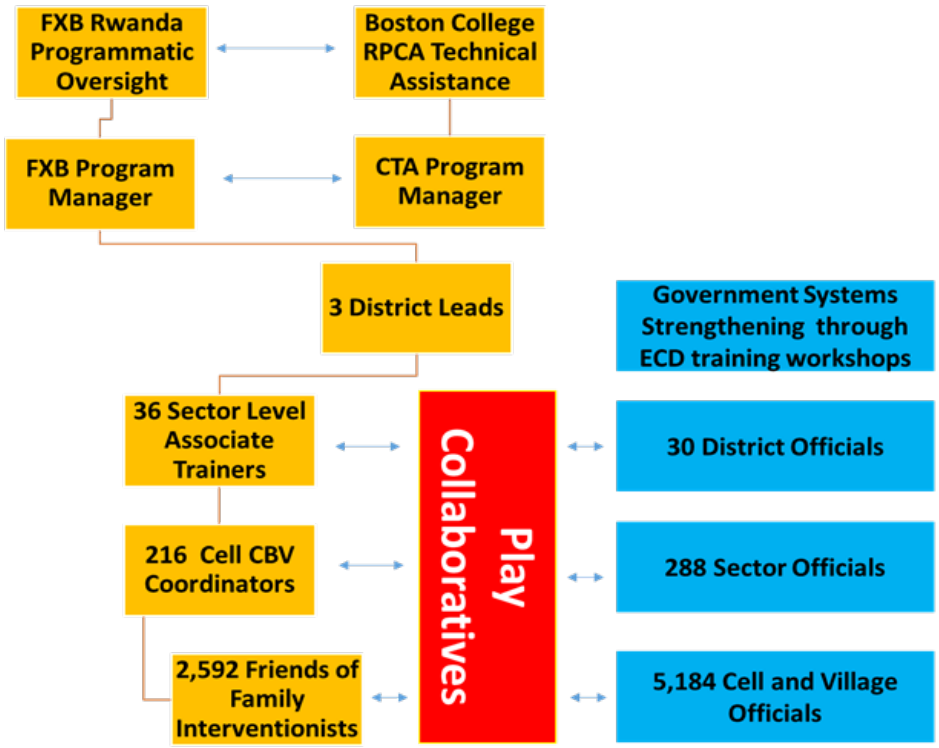
Within the PLAY Collaborative, collaboration primarily involves in-country Sugira Muryango experts (FXB), ECD stakeholders (NCC, NECDP, MIGEPROF), Sector Associate Trainers, Cell Coordinators, and service providers (IZU interventionists). The PLAY Collaborative roles and relationships include:

- **Boston College Program Manager & FXB Rwanda Program Manager (Masters Level- CTA experience):** National level stakeholder engagement; Train, implement and monitor PLAY Collaborative Approach. Experience in technology, training and supervision strategies.
- **Boston College Program Coordinator & FXB Rwanda Program Coordinator (Masters Level- Program Manager experience):** National and District Level Government Relations; Management and monitoring of District Field Staff; Assist District Leads in the design, execution and evaluation of trainings. Experience using technology in training, supervision strategies, and quality improvement.
- **District Lead (Bachelors Level- 0-3 ECD experience):** Design, conduct and evaluate all trainings within the District; Local level stakeholder engagement; Monitor and provide ongoing technical assistance to sector level associate trainers; Contribute technical expertise and content to trainings and monthly refresher sessions for Sector Associate Trainers; Keep district level stakeholders informed of the program process and challenges.
- **Sector Level Associate Trainers (Bachelors Level or Technical Certificate):** Selection and Training of Cell-Level Community-Based Volunteers (CBV) Coordinators; Training of IZU interventionists; Identify eligible households and 3rd Party Stakeholders; Supervisor Cell Level CBV Coordinators; Hold monthly meetings with CBV Coordinators; Monitor CBV delivery and ECD indicators of participating families; Keep sector and cell level stakeholders informed of the program process and challenges.
- **Cell-Level Mentors (Secondary School):** Assist Sector Associate Trainers with Household Identification and resource mapping exercise; Supervisor Village Level Interventionists; Hold Bi-Weekly Meetings; Attend two home visits per month per CBV; Keep cell and village level stakeholders informed of the program process and challenges; Collect "run-chart" (IHI, 2017) data on indicators (e.g. fidelity, no shows, growth monitoring, referrals) for children and families for Sector Level Associate Trainer.

- **Village Level Interventionists (< Secondary School):** Caseload of Maximum of five household weekly visits to families; attend training; bi-weekly meetings; Monitor child development indictors utilizing workbook and other data collection methodologies.
- **Government Officials:** At all administration levels Government Officials will participate in a 1-day ECD training. After the completion of the training officials will be encouraged to attend and participate actively in the PLAY collaborative meetings at Cell, Sector and District levels.

The Seed Team comprising Sugira Muryango experts with ECD and family violence prevention experience, will be employed by FXB and physically based near and linked to IZU interventionists at the village level. The Seed Team will work across our three target districts to oversee Sugira Muryango delivery while establishing regional teams of IZU interventionists, Cell Coordinators and Sector Associate Trainers to embed the Sugira Muryango practice in the community. This model is uniquely aligned to sustain and scale the evidence-based Sugira Muryango ECD home-visiting intervention by building local capacity and buy-in because reliance on remote expertise in low-resource settings is neither feasible nor sustainable. The Sugira Muryango PLAY Collaborative Scale Up Structure is presented in Figure 2.

Figure 2. Sugira Muryango PLAY Collaborative Scale Up Structure



3.2 Geographic Areas and Target Population

The Sugira Muryango team will work with government and other stakeholders to further integrate its evidence-based home-visiting model by linking it to the National Poverty Reduction Strategy, the Vision

Umurenge Program (VUP) and identifying ***all the* Ubudehe 1 *families with children ages 0-36 months in the Nyanza, Ngoma, and Rubavu*** districts over a three-year period. Under the assumption that at least 30% of the of the Ubudehe 1 households will be eligible for the intervention, it is estimated that the PLAY collaborative will reach around 9,967 children and 14,380 parents living in extreme poverty. In cases where the team is unable to reach target sample size, the team will work with community leaders to identify Ubudehe 2 families who are expected to be recategorized as Ubudehe 1 when the government recategorization launches mid-2021.

Since 2007, Rwanda has increasingly moved towards a decentralized leadership with national ministries providing minimum standards for districts to use for implementation at the local level. Each district has a Joint Action Development Forum (JADF), which ensures sustainable socio-economic development and improved service delivery for Rwandan communities through active participation, dialogue, and accountability by sharing information and effective coordination of stakeholders' interventions in decentralized entities. Through JADF, service delivery agencies are connected with the appropriate ministry focal point at the district level for guidance and collaboration. These collaborations and ECD implementation and outcomes data have a direct impact on the annual district evaluations, called *Imihigo,* which contribute to strong political will for the intervention both at the district and national level. In FY 2017/2018, Ngoma and Nyanza ranked in the bottom ten out of 30 districts with Nyanza ranked last. Both districts over the course of the past three years have declined in their ranking. The National Institute for Statistics cited strong engagement with district stakeholders and good collaboration within both districts, however there was a noted lack of necessary infrastructure and supervision in delivering key projects, especially those related to education. Across Rwanda, early childhood stunting is prevalent In Ubudehe 1 families where approximately 49% of children are stunted (The World Bank Group, 2018). Although Rubavu District was ranked 9th out of 30 and has made great strides in the past three years, it still has one of the highest rates of childhood stunting (46%, well above the national average). Beginning in FY 18/19, ECD indicators have been added to the annual district evaluation report in order to achieve NECDP's goal to increase the utilization of Rwanda's ECD services from 13% to 45% by 2024, which presents the opportunity for Sugira Muryango to further strengthen our partnership, capacity building and impact in Nyanza, Ngoma and Rubavu districts.

3.3 Selection of Interventionists (IZUs).

Across Rwanda, there are two IZUs per village, one male and one female. As such, both IZUs in our target villages will be selected to deliver the Sugira Muryango program. The IZUs are selected by village level community members during community meetings, with the primary criteria being individuals with integrity and rapport in the community. Other requirements to be considered for the role are listed on page 12 of the Kinyarwanda version of the Standard Operating Procedures for the IZU and include, but are not limited to the following: must be Rwandan, must reside within the village, must be over the age of 25, must be able to keep confidentiality, must be trustworthy to families and children, must be able to do the work of an IZU, must be able to read, write and do math in Kinyarwanda, must have at least finished primary 6, and must be confirmed by the leader of the village.

3.4 Training, supervision, and fidelity monitoring

To successfully launch the PLAY Collaborative, the following trainings and supportive structures will be implemented:

Table 2. Play Collaborative trainings and supportive structures

Role	Initial Training	Continuous Training	Technical Assistance & Ongoing Support
Boston College Program Manager	10-day virtual training at RPCA conducted by RPCA Associate Director for Research	Supervision during weekly leadership meetings with FXB and RPCA leadership groups. Monthly cross-site exchange meetings with RPCA Program Mangers	Weekly calls or video conferencing with RPCA. Daily email contact and updates.
FXB Program Manager	Monitor and provide ongoing technical assistance (TA) to district level field staff. Assist District Leads in the design, execution and evaluation of all trainings.		
District Lead	10-day training conducted at the coordination level followed by a 4 day follow up training on REDCap, Risk of Harm and Community Stakeholder Mapping.	Quarterly in-person workshops at the coordination office. Weekly video conferencing with the coordination office and the other district-level staff.	Continuous TA from coordination office via weekly video conferencing and in person visits from the Program Managers. Additional support through group-based WhatsApp messaging.
Sector Level Associate (SLA) Trainers	10-day foundational training held at the national level by the coordination office, followed by a 5-day follow up training on REDCap, Risk of Harm and Referrals, and Community Stakeholder Mapping at the district level.	Monthly meetings with the District Level Staff and Weekly Telephone Supervision with the District Lead.	Continuous TA from District Lead and via in person visits. Monthly meetings and weekly telephone supervision. Additional support through group-based WhatsApp messaging.
Cell Level Mentors	5-day initial training on introduction to Sugira Muryango, Ethics, and Household and IZU Enrollment followed by a 10-day training held at the district level, conducted by SLA Trainer and supported by the District Lead	3-week Virtual Continuous Training via WhatsApp on Curriculum content and delivery. Monthly Meetings with the SLA Trainer and weekly telephone supervision with the SLA Trainers. Refresher training for 3 month and 6-month booster visits.	TA from the SLA Trainers in person during monthly meetings and weekly telephone supervision. Randomized site visits to ensure supervision of Interventionists twice monthly throughout the delivery of the intervention. Following the site visit, individual feedback will be provided. Additional support through group-based WhatsApp messaging.

Village Level Interventionists (IZUs)	10-day training held at the sector level, conducted by SLA Trainer and supported by the Cell Mentors for small group learning. Additional support will be given by District Lead.	Weekly peer support groups with Cell Level Coordinator and weekly telephone or in person supervision. Refresher training for 3 month and 6-month booster visits.	Cell level coordinators will accompany the IZUs on two home visits per month, either planned or unannounced and weekly telephone supervision. Following the site visit, weekly individual feedback will be provided for continuous improvement.

While content of the training will not change, adaptation brought on by the global COVID-19 pandemic means that training may be spread out over more days to accommodate smaller training groups in line with government COVID guidelines.

Fidelity data will be collected from the IZU interventionists (the providers), within key informant stakeholders and within organizational staff. The monitoring and evaluation of program implementation and fidelity to the program will be led by leaders at all levels within the PLAY collaborative. Engagement of the PLAY collaborative leadership across levels will allow the program to utilize existing work forces and enhance ownership and problem solving related to the Sugira Muryango program at all levels.

The monitoring and evaluation of program implementation will include run chart data on instances of playful parenting during the home-visiting sessions/responsive interactions between caregivers and their children, frequency of nutrition-related discussions, number of referrals made, caregiver attendance (with interest in male caregiver participation), as well as attendance related to supervision, cross-site learning meetings, trainings, and workshops. Data will also be collected on quality of IZU coaching pertaining to Sugira Muryango active play sessions (of all caregivers and their children), observations of good sanitation, toileting and handwashing facilities, nutritious and varied food, and methods for monitoring child growth. The run chart indicators will be easily accessible for review across regional teams whereby cross-site learning and exchange can ground problem solving in what is happening in the home (e.g., low father attendance as evidenced by run chart data demonstrating low male caregiver involvement in Sugira Muryango sessions).

The monitoring and evaluation of family-level program implementation will also utilize an SMS short code mechanism that will collect data on approximately 20 indicators, including indicators relevant to this program such as instances of child abuse, intimate partner violence, number of households visited by the IZU interventionists, and number of children reached. Sugira Muryango will build on this newly implemented technological platform to enhance the roles, training, and technical assistance of providers.

Fidelity monitoring data will be entered into REDCap, a data collection and management platform. Data will be organized by IZU interventionist and family ID. Using a structured fidelity monitoring guide, Cell-level Mentors will collect data on IZU interventionist fidelity to Sugira Muryango content (adherence and competence). Cell Mentors will directly observe at least two Sugira Muryango sessions per IZU each month, aiming for each household to be observed at least twice over the course of program delivery. This process ensures the evidence-based Sugira Muryango intervention is delivered as intended. Analysis of fidelity data will use multilevel linear and nonlinear models (see below). Findings will allow us to answer whether overall fidelity to the intervention, measured at the IZU interventionist level, correlates with better overall child development and whether fidelity to specific intervention modules correlates with improvements in the specific outcomes the module content was intended to improve.

Additional quantitative data related to Sugira Muryango dissemination and implementation will also be collected at the interventionist (IZU), household (caregivers), organizational staff, key informants, cell

coordinators, and PLAY Collaborative level. Information regarding Sugira Muryango adoption, acceptability, appropriateness, and feasibility will be collected at each level. Overall satisfaction and Sugira Muryango sustainability will also be collected. Given the unique role of the PLAY Collaborative, a Seed Team Assessment Battery will assess cohesion, functioning, and collaboration with the PLAY Collaborative. These data, collected post-intervention, will provide insight into barriers and facilitators of delivering Sugira Muryango via the PLAY Collaborative as well as those key inner and outer contextual factors (e.g., EPIS Framework) that are necessary for scaling and sustaining evidence-based interventions.

3.5 Program Enrollment

The Sector Level Associate Trainers will work with the Cell Level Mentors to enroll households for participation in the program. Eligibility criteria are: ***1) Participants must be the primary caregiver to a child between the ages of 0-36 months; 2) Caregivers must live in the same household as the children and must be the child's legal guardian. Legal guardians may be aunts, uncles, grandparents, or foster parents; 3) Participants must be categorized as*** **Ubudehe 1** ***families under the socio-economic categorization of households.*** Vulnerable Ubudehe 2 households may be included as well if there are issues reaching the intended sample size of 10,000 households.

All Sector Level Associate Trainers and Cell Level Mentors will receive strong training on enrollment protocols to ensure that all households understand the voluntary nature of the program as well as the Risk of Harm protocols, lengths we go to protect participants' privacy, and possible instances that would require breaking confidentiality protocols. All households will be informed that they are being approached given their status as a Ubudehe 1 as well as having a young child(ren) in the home. Families will also be clearly informed that refusal to participate in the program will not hinder their continued access to Ubudehe 1 social protection benefits. None of the study staff, including the IZUs, control the delivery of benefits to Ubudehe 1 families, which is a designation that is put forth by the Government of Rwanda in partnership with the Ministry of Finance and Economic Planning and the Ministry of Local Government. If challenges arise in reaching the intended sample size of 10,000 households of Ubudehe 1 families, the implementation team will work with government officials and local leaders in the intervention areas to identify vulnerable Ubudehe 2 households that have been flagged by the government socio-economic categorization.

3.6 Consent Procedures

All households will go through an informed consent process. Households will provide consent to participate in the program as well as the data collection. All caregivers over age 18 will provide informed consent for themselves and their children to participate. Given lower levels of literacy among Ubudehe 1 individuals, the consents are orally communicated to the caregivers. The caregivers either sign their name or make a mark (thumbprint) on the consent form. The field team carries additional copies of the consent in case the family would like to keep one. The consent forms are stored in a portable lock box until they are transferred to Kigali and stored in locking file cabinets at the FXB-Rwanda office. Study participants are reconsented prior to each follow-up data collection timepoint.

3.7 COVID-19 safety measures

The Coronavirus Disease (COVID-19) has been spreading rapidly across the world. Since the appearance of the first cases of COVID-19 in Rwanda in early 2020, many projects implemented by NGOs have adapted operations to meet the government-mandated preventative measures against the spread of the

disease. At this time, more than a year after the first confirmed COVID-19 case (March 14th, 2020), Rwanda has established several mechanisms and strict protocols, including mask mandates, national curfews, occupancy limits for businesses, social distancing measures, and hygiene recommendations, all of which have allowed the country to fight the pandemic and to safely reopen services. To date, Rwanda has recorded around 25,500 COVID-19 cases, and only 337 COVID-19-related deaths.

As an evidence based ECD home visiting program, Sugira Muryango had also adapted the intervention to include the following:

- A COVID-19 impact questionniare has been added to the assessment battery
- PPE (masks) and hand sanitizer will be provided to all IZU, Cell Level CBV Coordinators, and members of the PLAY Collaborative
- Masks will be provided to all families throughout program implementation and IZU will have extra masks at all time
- All families will be provided with a tippy tap and hand soap and will wash their hands with the IZU prior to and after each Sugira Muryango session
- Training and meeting group size will be reduced in line with government guidelines
- Increased use of technology (SMS, WhatsApp) will be used to decrease the amount of face-to-face meetings when possible

4. Hybrid Type-2 Embedded Effectiveness-Implementation Study

The effectiveness trial to evaluate the expanded Sugira Muryango program delivered within the PLAY collaborative will utilize a Hybrid Type 2 Effectiveness-Implementation study design. This design blends components of a clinical effectiveness trial with implementation science research methodology (Curran et. al, 2012). The blending of these two lines of research has several advantages over pursuing each line of research independently including more rapid translational gains, more effective implementation strategies, and more useful information for decision makers. This Hybrid Type 2 Effectiveness-Implementation Design trial will utilize the EPIS conceptual model, which guides the anticipation, identification, and response to common issues when transitioning evidence-based practices to larger delivery systems such as those in the public sector where they can have the most impact.

A quasi-experimental design with randomization at the village level will be used such that each village will either receive the treatment or care as usual. This distinction between treatment and usual care villages will help in avoiding the risk of diffusion of the treatment (i.e., treatment families sharing practices learned with others who did not receive the treatment). Both quantitative and qualitative data will be collected at three timepoints (baseline prior to the intervention, immediate post-intervention, and at 12-months follow-up) by local research assistants who are blind to site and family condition assignments. Data will allow us to investigate implementation processes and impact of the Sugira Muryango intervention at multiple levels: family level, interventionist level, supervisor level, and district level.

4.1 Power and Randomization procedures

4.1.1 Power and Sample Size

Among families that are eligible and have consented to receive the Sugira Muryango intervention we will identify and select a total of n=665 households located in one treatment sector and one control sector in each of three districts as described in the power calculations below.

To enroll the participants, one treatment sector and one waitlist control sector were statistically matched and randomly selected in each of the three districts. Eligible households are those who have an infant aged birth–24 months.

Power calculations consider clustering of families into IZU interventionists and of IZU interventionists into villages and that all primary and secondary outcomes are at the family level (i.e., child, caregiver, or household outcomes). IZU interventionists will either be in a treatment village or a waitlist usual care village determined by the location in a treatment or waitlist control sector. Each IZU interventionists serves approximately five families, although we will randomly sample three families per IZU interventionist. Considering the IZU interventionists as a level of clustering is important because issues related to programming, such as fidelity may create intraclass correlation at the level of IZU interventionist, and because questions relating to implementation are relevant to the study; by limiting to one IZU interventionist per village, this level will also accommodate the, typically very small, degree of intraclass correlation attributable to village. By sampling 191 (total treatment and control) villages (distributed across six sectors in the three districts), an average of 1.33 IZU interventionists per village serving an average of 3.4 families per village each at a common α level of .05 (two-tailed), the study will have 0.8 power to detect a standardized effect size of 0.21 for cross-sectional comparisons at either the immediate postintervention (3-month) or follow-up (12-month) time point assuming an estimated intraclass correlation of 0.10 for IZU interventionist and an intraclass correlation for village of 0.03. For linear growth curve models using all three time points, the minimal detectable effect size under the same assumption is estimated to be approximately 0.31. All families will be assessed at three time points: baseline, immediate post-intervention (three months after baseline), and at 12 months from baseline (follow-up). All power calculations were undertaken using PowerUp v. 1.04 and Optimal Design v. 3.01. Parent and child data will be collected regardless of the degree of participation in Sugira Muryango under an intention to treat model. Study drop-out will be addressed through missing data imputation techniques described in section 6.3.

Table 3, below, shows effect size estimates from the midline assessment (pre- and post-treatment) expressed in terms of Cohen's d for continuous outcomes and odds ratios (with d equivalents) for binary outcomes. These effect sizes demonstrate that the minimum detectable effect size estimates used in our statistical power calculations are realistic for many important outcomes in the study. For small effects and statistically insignificant effects, it is not possible to determine whether they are associated with small sample size or sampling error. While main analyses will focus on the combined sample of families of children aged 0-24 months, specific analyses will be performed to examine program effects within the added age-range of infants aged 0-6 months.

Table 3. Model-based estimates and effect sizes from the Cluster Randomized Trial (Betancourt et al., 2020)

	Means and mean differences at midline			**Model for change over time**	
Outcomes	**Sugira Muryango**	**Controls**	**Effect Size**	**Difference-in-difference effect (95% CI)**	**p-value[1]**
Continuous [range] Binary (%)			Continuous: Δ (95%) and Cohen's *d*		
			Binary: OR (95%)		
CHILD DEVELOPMENT (N=1,084)					

ECD stimulation in the home					
HOME [0-43]	28.9	25.4	3.5 (2.9, 4.2) *d=0.*78	3.9 (3.2, 4.5)	<0.001
OMCI [0-57]	43.3	41.7	1.6 (0.14, 3.1) *d*=0.29	3.1 (1.6, 4.6)	<0.001
FCI (ECD activities)	4.6	3.4	1.2 (0.99, 1.4) *d=0.*71	1.2 (1, 1.5)	<0.001
Child nutrition, health and safety					
Dietary Diversity [0-7 food groups] groups]	3.46	3.02	0.44 (0.27, 0.61) *d*=0.34	0.45 (0.26, 0.64)	<0.001
Diarrhea prevalence (%)	0.32	0.35	0.9 (0.65, 1.2) (*d* equivalent=-0.06)	-0.28 (-0.67, 0.11)	0.158
Diarrhea care seeking (%)[3]	0.68	0.49	2.2 (1.5, 3.1) (*d* equivalent=.43)	0.75 (0.25, 1.2)	0.005
Fever and cough prevalence (%)	0.68	0.69	0.96 (.71, 1.3) (*d* equivalent=-.02)	-0.18 (-0.56, 0.19)	0.345
Fever and cough care seeking (%)[4]	0.71	0.42	3.3 (2.3, 4.8) (*d* equivalent=.66)	1.3 (0.76, 1.8)	<0.001
Child caretaking practices and child safety					
Use of any violent discipline (%)	0.21	0.43	0.34 (0.22, 0.51) (*d* equivalent=-.59)	-1.2 (-1.7, -0.76)	<0.001
Exclusive non-violent discipline (%)	0.14	0.07	1.9 (1.3, 3.0) (*d* equivalent=.35)	0.92 (.17, 1.7)	0.019
CAREGIVER OUTCOMES (N=1,498)					
Caregiver mental health					
Screens for internalizing problems (%)[5]	0.21	0.23	0.9 (.58, 1.4) (*d* equivalent=-.06)	-0.54 (-0.96, -0.13)	0.010
Shared decision making[6]					
Action when child sick (%)	0.37	0.23	2.0 (1.3, 2.9) (*d* equivalent=.38)	0.72 (0.27, 1.2)	0.002
What child eats (%)	0.17	0.11	1.6 (1.0, 2.6) (*d* equivalent=0.26)	0.35 (-0.18, 0.89)	0.193
Intimate partner violence					
Perpetration, male caregivers (%)[7]	0.07	0.08	0.93 (0.42, 2.1) (*d* equivalent=-.04)	-0.11 (-0.97, .75)	0.804
Victimization, female caregivers (%)[8]	0.17	0.23	0.67 (0.33, 1.3) (*d* equivalent=-.22)	-0.72 (-1.4, -.0.005)	0.048
HOUSEHOLD OUTCOMES (N=1,049)					
Water, hygiene and sanitation					
Place with soap to wash hands (%)	0.88	0.81	1.7 (1.2, 2.5) (*d* equivalent=.29)	0.86 (0.42, 1.3)	<0.001

Water treatment (%)	0.65	0.34	3.6 (2.4, 5.5) (*d* equivalent=.71)	1.2 (0.77, 1.7)	<0.001
Accessing clean water (%)	0.97	0.97	1.0 (0.43, 2.3) (*d* equivalent=0.0)	0 .65 (0.009, 1.3)	0.047

HOME =Home Observation for Measurement of the Environment; OMCI =The Observation of Mother-Child Interaction; FCI =Family Care Indicators.

1: Assesses the significance of the "difference-in-difference" or "time-by-treatment" interaction between the two groups.

2: Cohen's *d* is reported for continuous outcomes were calculated by dividing the difference-in-difference effect by the pooled standard deviation of the outcome at baseline

3: Among those with prevalent diarrhea (N=376 at baseline and N=394 at midline)

4: Among those with prevalent fever or cough (N=595 at baseline and N=707 at midline)

5: Scored ≥1.75 on the Hopkins Symptom Checklist-25 Questionnaire

6: Among married or cohabitating mothers and fathers (N=913)

7: Among male caregivers reporting a current intimate partner at baseline (N=450)

8: Among female caregivers reporting a current intimate partner at baseline (N=523)

4.1.2 Randomization of Clusters (Sectors)

To avoid an unfortunate misbalance on background characteristics of sectors during randomization to treatment and control condition, sectors will be stratified within district on urban/rural and on whether they border on a neighboring country. Furthermore, because there may be more than two sectors in each stratum, they were sorted on the presence, if any, and number of NGOs offering ECD and Nutrition and WASH programming in the sector. Within each district any sector that was the only sector in a stratum or was in some other way unique, such as a center for refugee transit, was eliminated before random assignment to treatment. After randomly assigning a treatment sector via random numbers pick, if the treatment occupied a stratum with only two sectors the other sector of the stratum was assigned to the control condition. If there was only one member of the stratum adjacent to the treatment sector assigned that was assigned to control. Lastly, if the treatment sector was between two sectors in the same stratum, one of the two neighbors was chosen at random as the control sector. Due to the small number of clusters randomized, this is not a true cluster randomized trial, but a quasi-experiment with randomization, using randomization to treatment and random selection at both the village and family levels to avoid the introduction of bias.

4.1.3 Selection of villages (clusters) and IZU interventionists

A key consideration in the household identification strategy is the proportion of households in each village that will be eligible for the study. Initial validation work has been undertaken in order to estimate the number of households that will participate in the intervention in the treatment sectors.

Current assumptions estimate that there will be approximately three eligible households per village, but we recognize that some villages may only have 1 to 2 eligible households while others may have as many as 12 eligible households. Working in partnership with the field team at Laterite and the statisticians at Boston College, once the household lists have been validated, we will institute a cap at a maximum of four randomly selected households chosen per village in the control sectors to participate in the embedded research study, while in the treatment sectors, due to a relative shortfall of households as compared with estimates used during the matched pairing and original random assignment all eligible households will be

included. Thus, 90 villages containing 274 households will be included in the treatment sample, while according to simulations conducted by randomly selecting 391 households in 101 villages is expected to yield a total sample size to the target of n=665 households. If in practice 274 households cannot be enrolled by visiting 101 villages, we will visit additional villages until reaching the target of 274 control households. While the original design called for a balanced design with equal numbers of villages and households in treatment and control conditions, a February 2021 household survey revealed the likely shortage of eligible treatment households. Balanced designs are more efficient with regard to statistical power, still the proposed unbalanced design retains more power than would be obtained by reducing the control group size to the size of the treatment group.

Because the sectors across districts are not of comparable size, efforts will be made to select villages per sector proportionally to the available villages. For example, Kazo Sector has 22% of the 101 available villages in the treatment sectors, so is intended to have a similar proportion of villages in the treatment group. Considering the current 90 villages in the treatment sample, Kazo villages represents 24.4% of the villages in the sample. Table 4 below shows the proportional split of villages per sector with 90 villages in the treatment arm and 101 villages in the control arm, as described above.

Table 4. Proportional split of villages among treatment and control sectors

District	Sector	Number of villages	Proportion available villages in treatment	Number of villages in sample	Proportion of villages in the sample	Estimated number of hhs in sample	Estimated avg number eligible hhs per village*
		Treatment					
Ngoma	**Kazo**	22	21.8%	22	24.4%	91	4.1
Nyanza	**Rwabicuma**	31	30.7%	31	34.5%	109	3.5
Rubavu	**Bugeshi**	48	47.5%	37	41.1%	74	2
Total		**101**	**100%**	**90**		**274**	
		Control					
Ngoma	**Sake**	34	31.5%	33	32.7%	150	4.5
Nyanza	**Muyira**	25	23.1%	24	23.7%	104	4.3
Rubavu	**Busasamana**	49	45.4%	44	43.6%	137	3.1
Total		**108**	**100%**	**101**		**391**	

Table notes: avg = average, hhs = households

* If a maximum of 4 households sampled per village. Estimates are based on simulations of village and household sampling; data underlying simulations from initial validation work of Ubudehe 1 households in these districts and information from the 2014-2015 DHS.

4.2 Piloting

Prior to launching the embedded quasi-experimental effectiveness study, a small pilot study will be conducted in Ngoma District, where two sectors have been selected: Gashanda and Rugenge. Gashanda is

close to town and is the preferred location; Rugenge was selected as an alternative in case Gashanda is not possible due to COVID-19 restrictions. This pilot has the following objectives:

- To familiarize the enumerator team with the data collection tools and field protocols, check for any errors in the coding of the research instruments, test the timing of the instruments, and to clarify any questions that were confusing to enumerators or respondents.
- To collect repeated observations in order to calculate inter-rater and test-retest reliability. This is particularly relevant for the observational components of the instruments such as the Observation of Mother Child Interaction (OMCI), Home Observation for Measurement of the Environment (HOME), Ages and Stages Questionnaire (ASQ), Malawi Development Assessment Tool (MDAT) and Anthropometrics.

The contracted third-party data collection firm will travel to the selected district and stay for two consecutive pilot days. The plan is that the household survey team will interview 36 unique households per day, with part of the survey (OMCI and HOME components) being simultaneously observed and/or retested for 12 households each day. The MDAT team will observe and measure 24 unique children per day, with each child being observed by a pair of enumerators (48 children's observations per day). The data collection firm will work with FXB-Rwanda, the implementing partner, to identify 72 households to participate in the pilot (and 3 replacement households identified for a total of 75 households). Reliability analyses will be conducted on a sample size of about 50 participants selected from the 72 households.

For Inter-Rater Reliability (IRR), independent simultaneous observations will be conducted for the MDAT and the Report on Child Assessment battery. The most relevant components in the Report on Child are the caregiver-child interactions. However, in order to limit potential bias among enumerators they will complete the full Report on Child, which is also logistically a bit easier. During the process a variety of monitoring strategies (e.g., audio audits to check if enumerators are communicating with each other) will be used in other studies to avoid and/or flag any suspicious responses. Test/re-test reliability assessment will be implemented for the anthropometrics measurements and the observational component on the home environment.

4.3 Study Visits and Data Collection

Data collection will occur at three timepoints, referred to as baseline (pre-intervention), immediate post-intervention (3 months after baseline) and end-line (12 months after midline). All assessments will be carried out in the homes of the families or at a central point in the village. Once endline data has been collected, households in the waitlist control sectors will receive the Sugira Muryango program.

At each time point, the participant identified as the primary caregiver (who states that he or she knows the child best —most often the biological mother) will provide reports on child development, health, and feeding practices. This primary caregiver will also participate in the assessment of caregiver-child interactions and will provide information about the household, including family composition, economic status, household assets, social protection, and finances. Both the primary caregivers, their intimate partner or other secondary caregivers living in the households (e.g., grandparents, adoptive parents, aunts and uncles) will respond to a battery of questionnaires that cover aspects of caregivers' mental health, trauma exposures, daily hardships, family functioning, decision making, alcohol consumption, and intimate partner violence. Measures have been drawn from previous pilot and research studies in Rwanda (Barnhart et al., 2020; Betancourt et al., 2020; Betancourt et al. 2018; Jensen et. Al. 2021) and followed a rigorous translation protocol, including forward- and back-translation from English to Kinyarwanda.

The order in which the different surveys (The Report on the Child and the Caregiver Report on Self) are administered depends on whether the child is able to be assessed at the time of the visit. If the child is present and awake, the Report on the Child is administered first, then the other surveys follow. If the child is asleep or not available, the enumerator starts with the caregiver surveys instead. Due to the sensitive nature of the intimate partner violence questions in the Caregiver Report on Self, this survey is conducted only by enumerators of the same gender as the respondent and in as private a location as possible. In the case that a survey is not completed during the first visit—because there is a mismatch in the genders of the enumerator and respondent, for example—a follow up appointment is communicated to the household immediately and an enumerator will return at the earliest opportunity.

Participants will attend appointments for the child assessment on the Malawi Development Assessment Tool (MDAT) and anthropometric measurements at a central location. A community health worker will select a safe place—such as an office, a church, or school—to serve as the data collection site. Participants will be notified in advance regarding the location and timing of these assessments.

Enumerator training for baseline data collection will occur in stages. Training for quantitative assessments will occur in April 2021 followed by a pilot test in Ngoma District. Training for qualitative data collection will occur the beginning of May 2021 followed by a pilot test in Ngoma District. Training for surveys completed at the household included an overview of the study's objectives and methodology, sampling and replacement strategies, research ethics, the field team's responsibilities, adverse event reporting and the risk of harm protocol, and a thorough review of the survey instruments. Refresher trainings will occur prior to each data collection timepoint.

4.4 Study Assessments Tools

4.4.1 Quantitative Tools

4.4.1.1 Sugira Muryango Intervention Clinical Effectiveness Instruments

A robust quantitative assessment battery including household-level, parent-level, and child-level assessments was developed for Sugira Muryango pilot studies and the cluster randomized trial (CRT) in Rwanda during which measures were forward- and backward-translated from English to Kinyarwanda (Barnhart et al., 2020; Betancourt et al., 2020; Betancourt et al. 2018; Jensen et. Al. 2021). Measures were also cognitively tested to ensure comprehension and cultural relevance. Child outcomes will be assessed using observations and caregiver reports. Survey assessments include read-aloud procedures to address issues of literacy.

Table 5. Intervention effectiveness instruments

Survey Name	Measure/Indicator	Respondent	Estimated Sample Size	Timepoint(s)
Caregiver Report on Self	● Rwanda Demographic & Health Survey Items (intimate partner violence) ● Hopkins Symptom Checklist- mental health (depression and anxiety) ● Shared Decision Making (caregiver relationship) ● Father Engagement and Shared Decision Making (father engagement, roles and responsibilities)	Primary & Secondary Caregiver	810 caregivers	Pre-intervention (baseline), post-intervention (midline) and 12-month follow-up (endline)

	● Difficulties in Emotion Regulation- mental health (emotion regulation) ● World Health Organization Alcohol Use Disorders Identification Test (substance use) ● General Impact of COVID-19 Questionnaire (COVID impact and stress).			
Caregiver Report on Child	● MICS5, Selected Items ECD Module ● MICS5, Child Discipline Module ● Observation of Mother-Child Interaction (OMCI) ● Home Observation for the Measurement of the Environment ● MICS5, WASH indicators ● Rwanda DHS items on health status and health services access ● MICS5, 24 hour dietary recall ● WHO Infant & Young Child Feeding Practices ● Ages and Stages Questionnaire ● Malawi Development Assessment Tool ● Anthropometrics	Primary Caregiver reporting on enrolled child	560 children	Pre-intervention (baseline), post-intervention (midline) and 12-month follow-up (endline)

4.4.1.2 Sugira Muryango Fidelity of Implementation Instruments

The following instruments, referred to as Dissemination and Implementation (D&I) measures, will be collected from caregivers, IZU interventionists, and members of the PLAY Collaborative team. Dissemination and Implementation quantitative data will be collected only after the intervention (post-intervention).

Table 6. Fidelity of implementation instruments

Survey Name	Measure/Indicator	Respondent	Estimated Sample Size	Timepoint(s)
Dissemination & Implementation Measures	**Dissemination & Implementation Survey.** Created by the Applied Research Group at Johns Hopkins University, assesses core implementation science constructs such as: adoption, acceptability, appropriateness, feasibility, and reach/access. The survey for the IZU includes additional domains related to organizational climate and leadership. The survey for PLAY Collaborative members includes an additional domain related to sustainability.	Primary and Secondary Caregivers	810 caregivers	Post-intervention
		Inshuti z'Umuryango interventionists	225 IZU	
		Members of the PLAY Collaborative	390 PLAY Collaborative members	

	Program Satisfaction Survey. 19-items instrument that assess caregiver satisfaction with the Sugira Muryango intervention.	Primary and Secondary Caregivers	810 caregivers	Post-intervention
	Implementation Leadership Scale. 12-items instrument that assess leadership, covering the following domains: proactive leadership, knowledgeable leadership, supportive leadership, and perseverant leadership.	Inshuti z'Umuryango interventionists	225 IZU	Post-intervention
		Members of the PLAY Collaborative	390 PLAY Collaborative members	
	Program Sustainability Assessment Tool. 40-items instrument that assess program sustainability, covering the following domains: environment, funding stability, partnerships, organizational capacity, program evaluation, program adaption, communications, and strategic planning.	Members of the PLAY Collaborative	390 PLAY Collaborative members	Post-intervention
	Perceived Cohesion Scale. 6-item instrument that assess cohesion within the PLAY Collaborative.			
	Researcher Collaboration Survey. includes 15 items to evaluate collaboration within the PLAY Collaborative.			
	Seed Team Assessment Questionnaire. 55-item questionnaire that assesses several domains within the PLAY Collaborative including functioning, identity, and climate.			

4.4.2 Qualitative Tools

4.4.2.1 Individual Interviews

A subsample of households, interventionists, cell mentors and key informants will be selected at two time points (baseline and post-intervention) to respond to a qualitative guide to identify core competencies of lay workers, effective training and supervision strategies, and mentorship that enables support of lay worker agency and empowerment to function optimally within health, education and other delivery systems. The aim of these interviews is to identify best practices and quality of early childhood and nutrition services delivery and sustainability of ECD programming in Rwanda.

Sixty households (60 total), with an equal number of single and dual caregiver (i.e., opposite sex dual caregiver) households will be randomly selected for qualitative interviews. Approximately 20 households will include new parents with only one child. The baseline interviews will be conducted before the intervention and post-intervention interviews will be conducted immediately following the 3-month booster visits.

Sixty interventionist interviews will occur across the three districts (20 in each district) with a target of equal distribution of male and female IZUs at three timepoints: before any study activities begin, once Sugira Muryango begins, and post-intervention. The guide administered prior to any study activities begin will be used to understand burden and current roles and responsibilities so that we can adjust Sugira Muryango delivery and supervision structures as needed. This data is vital to the implementation science aims of the study. Thirty Cell Mentors will be interviewed across the three districts (10 in each district) with a target of equal distribution of male and female Cell Mentors at one time point post intervention. Forty-five interviews will be collected at all levels of local government: District, Sector, Cell, and Village

at one time point post-intervention. Efforts will be made to interview local officials with the same job title across all three districts and corresponding level.

At the national level, 15 interviews (6 months post intervention) will be collected with government officials and with ECD stakeholders such as NGOs, INGOs, and international funding agencies. The aim of these interviews is to better understand perspectives on ECD within communities, ECD policy, and coordination of ECD services in Rwanda. The sampling framework will reflect the holistic approach to ECD in Rwanda by targeting organizations and government agencies focused on nutrition; water, sanitation and hygiene (WASH); social protection; and parenting education.

4.4.2.2 Focus Group Discussions

Focus group discussions will occur at the 12-month follow-up with PLAY Collaboratives at the cell, sector and district level to include: three PLAY Collaboratives at the district level, four PLAY Collaboratives at the sector level across the three districts, and eight PLAY Collaboratives at the cell level across the three districts. The aim of the focus groups is to understand the effectiveness of the collaboratives, program sustainability and barriers to implementation.

4.4.2.3 Participatory Workshops

Participatory workshops will be held at the national level with the Sugira Muryango Advisory Board and will seek Advisory Board member opinions, extract their knowledge and to solve problems in a collaborative and creative environment. The Sugira Muryango Advisory Board was established in April of 2018, chaired by NECDP and is comprised of representatives from NCC, MIGEPROF, the Local Administrative Development Agency (LODA), Rwanda Biomedical Center, and University of Rwanda. The aim of the Advisory Board is to understand challenges in program implementation to inform policy and also guide the Sugira Muryango program to ensure alignment with NECDP's Minimum Standards to increase sustainability.

4.5 Quality Control

Field Supervision

Throughout data collection, the field supervisor for the surveys at the household chooses one sub-team to accompany each day to confirm that interviews are conducted in the right households, protocols are followed, and ethical considerations are met. A chain of command allows enumerators to raise issues to the field coordinator, who then reports them immediately to the field supervisor, who communicates them to the data manager for the final decision.

At the end of each day, the field supervisors update the log of surveys completed and issues to be cleaned in the data and compile a daily field report for the data manager. The teams for both the surveys at the household and the MDAT and anthropometric assessments also attend a daily debrief session led by the senior field supervisor and data manager. During the debrief, the team discusses issues from the day's surveys, and the data manager provides solutions and communicates any changes in the survey. Before heading to the field each morning, the team meets with the data manager who updates the list of households with any replacements from the previous day, reviews the schedule, and addresses quality concerns from the data collected in the previous days.

Real-time Completion Tracking

Laterite uses SurveyCTO's feature of real-time publishing of form submission data into Google Sheets to track the progress of data collection compared to the targets in the field plan. Dashboards are created to track the completion of the required surveys for each household (household completion status) and then the completion of surveys for all households in a cluster (cluster completion status.) The cluster completion status is shared with the Boston College team in real time, which allowed them to start the intervention in the households of completed clusters as soon as possible. The Google Sheets are also used to track replacements of caregivers and households and flag duplicate surveys.

Routine Monitoring

Laterite uses proprietary audit algorithms to review survey metadata to flag unusual submissions such as those with changes of location, early or late starting times, comparatively short or long durations, and simultaneous submissions. Concerning surveys are flagged to the Data Manager and Senior Field Supervisors for further investigation. In addition to the real-time monitoring using Google Sheets, Laterite routinely monitors the cleaned data for survey duplication, household and caregiver replacement, household dropout, child dropout and mortality, and household survey completion. Laterite reports this information to Boston College in the Weekly Data Collection Reports.

Audio Audits

Audio from a sample of all surveys conducted at the household are automatically recorded using the in-built recording feature of SurveyCTO. The questions that triggered the audit are pre-selected and recordings are reviewed to assess whether (i) the interviews actually took place; (ii) enumerators are following proper interview procedures such as: explaining confidentiality and sticking to the script while asking sensitive questions; (iii) enumerators are asking questions with a respectful tone and without pushing the respondent or leading them towards a certain response; and (iv) explaining to the respondents that they could opt out of taking part (or answering questions in some parts of) in the survey. A random sample of 5% of all surveys are recorded for each question.

No audio audits are set for the MDAT and anthropometrics surveys since the proper administration of these assessments relies less on enumerator-participant dialogue and observation. These surveys are instead administered under supervised conditions and enumerator behavior is closely monitored.

Throughout data collection, Kinyarwanda-speaking data auditors review the audio recordings to confirm that there is dialogue between the enumerator and the respondents (i.e., that responses are not entered without actually asking the questions) and that enumerators are following proper interview procedures like explaining confidentiality and ensuring privacy for sensitive questions and asking questions in a respectful tone without pushing the respondent or leading them toward a certain response. Issues identified by the auditors are recorded and relayed to the data manager for proper follow-up and resolution with the field supervisors.

4.6 Ethical Considerations, Safety and Adverse Events

4.6.1 Informed Consent Process for the Hybrid Type 2 Study

Based on the enrollment criteria, trained local study personnel will approach prospective participants and invite them to participate in the program through informed consent. This study involves Ubudehe 1 households, caregivers, and their children between 0 and 24 months; children between the ages of 0 and 24 months will require a caregiver to provide consent. Only if the caregiver provides informed consent will the child be enrolled in the study.

The informed consent forms will be in Kinyarwanda and will be read aloud to all prospective participants by trained research assistants, given the low literacy level in the potential catchment area(s) for the study. The form emphasizes that the decision to participate (or not) will not have any impact on care and services available to the potential participant or "coach." Consenting participants will sign the consent form whenever possible and for illiterate participants, a thumb print can be applied in place of a signature. Formal written consent forms will be read and provided to participants in paper format at each wave of data collection. Participants will be asked to either sign or provide a thumbprint indicating their consent to participate at each wave of data collection and will be offered a copy of the consent form at each wave of data collection. Furthermore, study staff have devised a basic agreement/contract detailing the scope of work and topics discussed in the delivery of Sugira Muryango to beneficiary households.

4.6.2 Potential Benefits to Participants

All households participating in the entire program as well as the embedded Hybrid Type 2 study stand to benefit from participation in the study through the receipt of the Sugira Muryango intervention. Other benefits include generation of knowledge about evaluating ECD and parenting in Rwanda, increased knowledge of ECD in Rwanda, and increased knowledge regarding family-based ECD interventions to improve child development outcomes in low-resource settings. Intervening in early childhood has been demonstrated to be highly cost-effective for improving child development and life outcomes, yet interventions in low-resource settings—particularly in sub-Saharan Africa—are limited and not always well evaluated or systematically implemented. Given the immense need for ECD in low-resource settings, the potential benefit of developing a family-based ECD intervention outweighs the minimal risks to individual study participants. All households will have increased contact with local Community Health Workers and will be able to receive anthropometric testing and disability screening of their children. If flagged, appropriate referrals will be made and followed up on allowing us to connect vulnerable households with needed services.

4.6.3 Compensation of Participants

The amount that has been decided for compensation has been carefully created in coordination with the Government of Rwanda, FXB-Rwanda, and other in-country collaborators. Monetary compensation for each administrative level and program participants with the conversion to USD are detailed below:

a) Household beneficiaries enrolled in treatment and control as part of the Hybrid Type 2 study will receive 15,000 RWF ($15) in compensation for the completion of assessments.

b) Community Based Interventionists that partake in delivering the intervention will receive funds to compensate their transportation and training.

    - IZU interventionists will be provided a mobile phone, data/mobile top-up, rain boots, a bag, an umbrella, and shirt to support their role as a Sugira Muryango interventionist

- Where IZU interventionists participate in full day trainings they will be compensated 10,000 RWF ($10) for transportation.
- Where IZU interventionists participate in weekly Collaborative Team Meetings they will be compensated 3,000 RWF ($3) for transportation.
- IZU interventionists selected by randomization to participate in data collection (quantitative surveys or qualitative interviews) will be compensated 5,000 RWF per assessment completed.

c) Cell Level Mentors will receive 62,700 RWF per month ($63.5)

d) Sector Level Associate Trainers will receive 650,750 RWF per month ($659)

e) District Leads will receive from 749,550 to 899,650 RWF ($759 to $911)

4.6.4 Participants' privacy and sensitive information concerns

Data collected via tablets consist of responses to questions about psychosocial symptoms, individual, family, and community strengths, and functioning. All assessments will be conducted orally by trained research assistants in Kinyarwanda given the overall low literacy rates in Rwanda. Because most study questionnaires ask about aspects of children's behavior that are apparent and already well-known by the community, these surveys are unlikely to cause embarrassment or damage to a person's reputation. Furthermore, in the context of Rwanda, common mental disorders are not seen as medical conditions, and therefore symptoms of psychosocial distress are not stigmatized like clinical depression or anxiety disorder might be in the US.

However, some of the content of the questionnaires is personal and sensitive in nature and may cause some level of discomfort for participants. In order to reduce this risk for discomfort, the informed consent and assent forms will clearly indicate this for the prospective participants, so that those who may not want to discuss personal matters can choose not to participate. In addition, we will emphasize that those who decide to participate can choose to withdraw from the study at any time, refrain from answering a specific question, or refrain from engaging in any activity that makes them uncomfortable.

4.6.5 Potential Risks to Participants

All household beneficiaries in the study have an Ubudehe 1 poverty categorization or are considered vulnerable Ubudehe 2 households. As such, all study procedures are created and implemented with provisions for vulnerable participants. Specifically, risk of harm/adverse event procedures are in place to identify any risk of harm situations related or not related to participation in the study. Further, funds are available if any participant requires a referral or transfer to a higher level of care, such as transport to and treatment at a district hospital.

The "Risk of Harm" protocol details the referral system to be used by research assistants and other study staff in the event that a participant is suspected of being at risk of significant harm not due to the research (e.g., the participant is discovered to be suicidal or is being abused by a family member). We have developed a Referral Form for systematically documenting these cases and ensuring that they are referred to appropriate services at local clinicals or to the District Hospital if necessary.

The following risks were identified and submitted to the and Rwanda National Ethics Committee:

1. Participation in the intervention may lead adults to confront stressful personal or family issues or generate concern about social harm resulting from loss of confidentiality, which may elicit distress in some participants.
2. In some cases, fatigue from the psychosocial assessment administered pre/post-intervention and at 12-months follow-up may occur.
3. There is a small risk of loss of confidentiality.
4. Participation in the intervention may create issues within the community if a household receiving the SM intervention is viewed as receiving additional services or monetary support.

We consider most risks associated with participation in the study to be unlikely, something confirmed by previous pilots and the prior CRT study. Previous study iterations have demonstrated that processes related to confidentiality are upheld throughout the entire study. Further, no participants have indicated distress or fatigue with the assessments. Weekly field reports from the data collection contractor enumerators have not indicated any issue with the assessments, length of time to administer, issues with confidentiality, or distress caused.

There are, however, other risks to consider: intimate partner violence in the home and tensions with neighbors may increase due to participation in the intervention as such issues are being discussed during home visiting sessions. The interventionists will receive comprehensive training on recognizing intimate partner violence in the home as well as how to activate our risk of harm protocol to ensure we assess the harm and make the necessary referrals. The risk related to community tensions due to participation, caused for e.g. jealousy from neighbors, have resulted in several study changes. First, in the event that an issue arises with a neighbor, the interventionists are instructed to immediately alert their supervisor and the village leader or elder to better understand the source of the issue. During this time, the intervention is paused. The family will then be given the option to conduct the intervention offsite at the local government offices at the cell level.

A Risk of Harm decision tree, along with flagged questions from the assessment battery, provides a structured protocol for monitoring and responding to adverse effects on participants. Interventionist supervisors have daily phone check-ins with the interventionists as well as weekly face-to-face meetings. These check-ins provide an opportunity for monitoring families in the study and ensuring all study risks are addressed appropriately. Further, these check-ins allow the supervisor to anticipate any potential risks and work with the interventionist to initiate support or a referral to mitigate any potential risks. The intervention will be paused or stopped if a participant is experiencing active psychosis or is experiencing harm as a result of participation in the intervention. While these instances are expected to be rare, formal procedures are in place to address them should they emerge. If an adverse event or risk of harm is detected, a study supervisor works with the IZU to collect as much information on the issue, and then conducts an in-person assessment of the situation. Depending on the case, this assessment may include discussion with local Community Health Workers and village leaders to gain further information about the participant or family.

5 Data Collection, Management, and Analysis

5.1 Data Collection

Data collection will include the collection of quantitative data regarding intervention effectiveness, dissemination and implementation (D&I) data regarding key domains of implementation science (e.g. acceptability, appropriateness, feasibility), qualitative data via face-to-face key informant interviews, and fidelity data collected throughout intervention delivery. Data for the study will primarily involve

information obtained through direct interviews conducted in a private room or private outdoor area. All records will be assigned a participant identification number and no names will appear in connection with data.

Quantitative data will be collected in Rwanda electronically using mobile devices running on an android platform by trained independent local enumerators blinded to intervention status and supervised by the Principal Investigator, the Program Manager, and Boston College School of Social Work staff in partnership with FXB—Rwanda. All data will be collected using SurveyCTO, referred to as SurveyCTO Collect, a secure mobile data collection platform that can be used offline and will allow enumerators to collect participant data using a password protected mobile phone or tablet. Upon finalizing each interview enumerators will be instructed to mark forms as finalized. Once each interview is finalized the Survey CTO will automatically encrypt the data. The data on the tablets then cannot be read without the private decryption key, which will only be known by management team directly working on the project (e.g. Data Manager, Research Program Manager). Therefore, even in the event of loss or unauthorized access to tablets intruders would not be able to read the confidential data. The data is then uploaded to the secure SurveyCTO cloud-based server. Whenever form data is transmitted via a 3G or other internet network, it is encrypted in transit. SurveyCTO also has a built-in data monitoring and visualization tool that will allow Field Coordinators and Supervisors, who are based in the field during data collection, to monitor the uploading of study data as well as any inconsistencies in the data.

Qualitative key informant interviews will be collected from primary caregivers (program beneficiaries), IZUs, local and national government officials and other ECD and nutrition stakeholders such as International and local nonprofit organizations and international funding agencies. The aim of these interviews is to identify best practices and quality of early childhood and nutrition services delivery in Rwanda. A semi-structured interview guide is used to guide the qualitative interviews.

In order to assist with matching data to each family member for follow-up assessment, participant initials and contact information will be recorded on the devices. The coding system crosswalk will be kept on a secure, password protected laptop. De-identified data will be stored on the tablets and will be uploaded to a secure, password protected laptop, where they will be transmitted to study investigators for password-protected viewing and analysis through an online secure file transfer. Similarly, all qualitative data will also be properly de-identified so no names will appear in connection with the data. Hard copies will be kept in a locked cabinet in the FXB—Rwanda office; electronic audio recordings will be encrypted, loaded onto a Boston College encrypted computer, and uploaded to the Boston College network via a secure connection (Accellion). All data transmission will use HTTPS secure protocol.

Lastly, field research staff's access to data will be removed once they no longer have a reason under the research protocol to access the information. All research staff will be trained in general information security and will be responsible for reporting any breach in confidentiality to the Boston College IRB/RNEC.

5.2 Data Analysis Plan

Standard descriptive statistics will be used to describe the study sample. Frequencies and percentages will be reported for categorical variables and mean, median, standard deviation, interquartile range, maximum and minimum values will be reported for continuous variables. Anthropometric data will be checked for extreme or out-of-range values and further investigated whenever possible. Histograms and boxplots will be used for outlier identification.

Psychometric analyses, including point-biserial correlations, internal consistency (e.g., Cronbach alpha), and dimensionality assessment, will be conducted for all the psychological and cognitive measures using baseline data. Scale scores will be computed according to scoring instructions.

Prior to evaluating intervention effectiveness, baseline equivalence will be checked comparing treatment and control groups, considering both program participants (caregivers, child) and IZUs sociodemographic characteristics (e.g., age, gender, educational attainment, etc.). If the treatment and waitlist control groups significantly differ in any of these observed characteristics, appropriate variables will be included as statistical controls in the models.

Considering the study design and the nested structure of the data, in order to determine the effectiveness of the Sugira Muryango intervention multilevel regression models will be used. Intervention effectiveness for continuous outcomes will be evaluated by fitting linear mixed effect models. Also known as hierarchical linear models (HLM) or multilevel regression models, they are a flexible tool for analyzing associations and changes over time in longitudinal studies that involve nested data structures. Given the clustered design, the analytical approach considers four levels of nesting: families nested within IZUs, both families and IZUs nested within measurement waves, and measurement waves nested within randomization cluster (i.e., villages). Because the number of sectors and districts is too small to be treated as a level in multilevel modeling, these will be treated as fixed effects (represented by dummy variables in the models). A mathematical representation of this model is presented below:

$$Y_{ijkl} = B_0 + b_{0i} + B_1 * Treatment + B_2 * Time + b_{1i} * Time + B_3 * Time * Treatment + b_{2k} + b_{3k} * Time + B_{4l} + \gamma_m + \delta_n + w_j\alpha + y_k\eta + e$$

where, Y_{ijkl} represents the value of the i^{th} family *(i = 1 . . . 540)*, at the j^{th} time point *(j=1,2,3)*, with the k^{th} IZU *(k = 1, . . 180)* in the l^{th} village (*l=1,..,90*). The set of b_{0i} variables represent subject-specific intercepts and are assumed $b_{0i} \sim N(0, \sigma_I)$. The b_{1i} are subject specific slopes and assumed $b_{1i} \sim N(0, \sigma_{I\_slopes})$. The b_{2k} are IZU-specific intercepts and assumed $b_{2k} \sim N(0, \sigma_K)$ and the $b3k$ ~are IZU-specific slopes and assumed $b3k \sim N(0, \sigma_{K\_slopes})$. The b_{4l} are the village specific intercepts and are assumed $b_{4l} \sim N(0, \sigma_L)$. γ_m and δ_n are sector- and district-specific fixed effects, respectively. The value *e* represents residual variation and is assumed $e \sim N(0,\sigma)$. w_i, and y_k are vectors of individual-, and IZU-level control variables that will be included if baseline equivalence does not exist between the treatment and control groups. Effectiveness across time points will be evaluated by looking at the significance of the Time by Treatment interaction coefficient (B_3), which represents the average growth difference between the treatment (Treatment=1) and control (Treatment=0) groups.

Model assumptions will be verified. In particular, distributions of the residuals will be examined using residual plots to verify that normality assumptions hold. Panel plots will also be examined to look at functional shape assumptions within subjects. In the case of non-normality of outcomes, we will consider response transformations or the use of models that do not require the normality assumptions including the class of generalized linear mixed effect models.

Dichotomous outcomes will be analyzed using similar multilevel models with accommodations to the model link function that takes into account the binomial distribution of binary variables. Mixed Effect logistic regression models will be used, a form of generalized linear mixed models (GLMM) with a binomial distribution and a logistic link that also account for nested data structures. Regarding predictors, random, and fixed effects, final models will be specified in the same way as the linear mixed models described above. Finally, for count data that highly likely will resemble a Poisson distribution multilevel mixed- effects negative binomial models will be used. Once again, final models will be specified in the same way as the linear mixed models described above.

Some responses are scales or derivations of scales in particular the MDAT and the ASQ. We will examine the psychometric performance of these scales. We are especially concerned with internal consistency and item reliability. If these scales do not show at a minimal amount of internal consistency (Cronbach's Alpha > 0.6) these items will not be considered for analysis. If particular items are an issue they may be dropped from the scale based on detailed analysis of the scales.

5.3 Outcomes of Interest

The outcomes of interest, aligned to each of the specific study hypotheses, are presented below:

I. Intervention effectiveness:

a. The updated Sugira Muryango intervention, delivered by a government-supported community volunteer workforce, will lead to improvements in responsive parent-child relationships, improved child development and reduced violence.

Primary Outcomes:
- HOME Inventory,
- Observations of Mother-Child Interactions
- MICS Family Care Indicators
- MDAT: gross, fine, language, socio-emotional
- ASQ-3: gross, fine, communication, problem solving
- Rwanda Demographic Health Survey: Intimate Partner Violence
- UNICEF MICS Child Discipline: harsh discipline

b. The updated Sugira Muryango intervention will lead to improvements in caregiver behaviors that support child health including increased care seeking for illness, improved hygiene, and improved dietary diversity as well as improvements in observed child health outcomes related to child growth and illness.

Secondary Outcomes:
- Anthropometrics: height-for-age, weight-for-age, weight-for-length, MUAC
- Child health (diarrhea and fever with a cough), and care seeking behaviors (WASH)
- WHO Infant and Young Child Feeding: dietary diversity/nutritional intake

C. Sugira Muryango will lead to improvements in caregiver mental health and emotion regulation.

Other outcomes:
- HSCL: caregiver anxiety & depression
- DERS: caregiver emotion regulation

Inyetvention effects will be observed across the full sample and specifically among families with infants aged 0-6 months.

CI. Implementation via the PLAY Collaborative:

a. Engagement and buy-in of the PLAY Collaborative will strengthen dissemination and implementation of Sugira Muryango.

b. High fidelity and home-visitor competency in delivering Sugira Muryango core components will enhance Sugira Muryango clinical effectiveness and improve caregiver and child outcomes.

c. Implementation science constructs related to acceptability, feasibility, and appropriateness will be strongly and positively correlated with program satisfaction.

Other Outcomes:

- Program Satisfaction Survey - Households
- Sugira Muryango Fidelity Rating Guide - Interventionists
- Dissemination & Implementation Survey - Households
- Dissemination & Implementation Survey - Interventionists
- Dissemination & Implementation Survey - Organization/ PLAY Collaborative Stakeholders
- Implementation Leadership Scale - PLAY Collaborative Stakeholders
- Program Sustainability Assessment Tool- PLAY Collaborative Stakeholders
- PLAY Collaborative Assessment Questionnaire- PLAY Collaborative Stakeholders
- PLAY Collaborative Collaboration Survey - PLAY Collaborative Stakeholders.

5.4 Missing Data

The Intention to Treat (ITT) strategy, according to which the analysis of clinical trials compares subjects in the groups to which they were originally randomly assigned (Hollis and Campbell, 1999), will be applied to all statistical analyses. Under this approach, the subjects are kept in the analysis sample regardless of whether they receive or complete the intervention/treatment, and regardless of deviations from protocols or study withdrawals. Considering that, the existence of missing data will be addressed through multiple imputation by chained equations (Plumpton et. al., 2016), a method that addresses two common types of missing data: missing items within scales, or completely missing scales or indicators within a time point.

Generally speaking, as posed by Graham et. al. (2007), the core idea of multiple imputation techniques is to find *plausible values* that can fill the missing information, making possible the estimation of unbiased parameters with the uncertainty of the parameter being estimated in a reasonable way (Graham et. al. 2007). In summary, multiple imputation techniques prevent bias that is associated with analysis of only complete cases (i.e., listwise deletion of missing values).

6 Study Limitations

A primary study limitation is the reliance on caregiver-reported measures, which could suffer from differential bias because parents who are exposed to the intervention may be more knowledgeable about or more pressured to provide a socially desirable answer. However, the quality monitoring approaches utilized by study enumerators (described in detail above) provide important checks for ensuring the data are collected as intended and that enumerators are not engaging in any sort of behaviors to coerce specific answers from caregivers. A second study limitation regards the reliance on western-created measures to assess primary and secondary study outcomes. Extensive work was done to refine and adapt measures to fit the Rwandan context with assessment questions forward- and back-translated into Kinyarwanda

following best practices (Van Ommeren et al., 1999). Further, psychometric analysis of study measures assessing primary and secondary study outcomes indicate strong reliability and validity.

7 Data archiving and dissemination

Results from the study will be published in peer-reviewed journal articles and presented at high level conferences. A formal dissemination event involving study funders and stakeholders will be held in Kigali, Rwanda. Study quantitative data will also be uploaded to a publicly accessible and secure server as part of study funding deliverables.

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