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Scaling up home-visiting to promote early childhood development and prevent violence in Rwanda: a hybrid type-2 effectiveness-implementation trial

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Background: Children in impoverished families–especially those affected by violence–face risks to healthy development. In the years of strong economic recovery since the 1994 Genocide Against the Tutsi, the Rwandan Government has invested in early child development, social and child protection and violence prevention, but few strategies for scaling evidence-based interventions (EBIs) in these areas have been studied. **Methods:** We present a Hybrid Type-2 Implementation-Effectiveness study of the PLAY Collaborative implementation strategy to engage government and other stakeholders in scaling Sugira Muryango (SM, "Strong Family") to families eligible for social protection in three rural districts. SM promotes nurturing care of children under three while reducing family violence. We assessed delivery quality (fidelity, competence) and perceptions of the PLAY Collaborative (e.g, feasibility, leadership, organisation, sustainability). An embedded trial of 538 households (778 caregivers, 555 children) tested SM effectiveness when delivered by child protection volunteers. **Results:** Child protection volunteers delivered SM with high fidelity and competence that improved with time and routine supervision. The PLAY Collaborative was rated moderately to highly across implementation outcomes. The embedded trial revealed improvements in children's stimulation at home (d = 0.20, 95% CI: 0.04–0.36) as caregivers involved them more in daily activities (d = 0.37, 95% CI: 0.18–0.57) and provided more learning materials (d = 0.37, 95% CI: 0.16–0.59). SM families increased stimulating care (e.g. singing, playing; d = 0.26, 95% CI: 0.07–0.46); involved fathers more in caregiving (*IRR* = 1.18, 95% CI: 1.03–1.37); reduced harsh discipline (*OR* = 0.34, 95% CI: 0.14–0.82); and increased dietary diversity (d = 0.25, 95% CI: 0.04–0.45). SM caregivers reported improved mental health (d = −0.13, 95% CI: −0.26 to −0.01). SM households increased safe water storage (*OR* = 3.14, 95% CI: 1.64–6.03) and water treatment (*OR* = 3.56, 95% CI: 1.80–7.05) practices. **Conclusions:** The PLAY Collaborative successfully overcame implementation barriers and maintained effectiveness across most outcomes while scaling delivery to N = 8,745 families, highlighting the value of systematically investigating implementation strategies while scaling an EBI as integrated into existing social and child protection systems. **Keywords:** Implementation science; implementation strategy; Hybrid Type-2 Trial; early child development; global health; violence prevention; father engagement; poverty; social protection; home-visiting.

Background

Nearly, 250 million children under five in low- and middle-income countries (LMICs) are at risk of not reaching their full developmental potential (Black et al., 2017, 2023; Black & Richter, 2022; Jensen et al., 2023; McCoy, 2022). Globally, in 2022, 148.1 million children under five were stunted, 45.0 million wasted and 37.0 million overweight (World Health Organization, 2023). Children living in poverty face an elevated risk of developmental delays, illnesses, harsh parenting practices and malnutrition without strengthened systems of prevention and care (Black et al., 2017). Inequalities in child care and early child development (ECD) programmes in LMICs remain persistent, especially in sub-Saharan Africa, where limited research has been available to guide governments and local partners on evidence-based investments to improve ECD outcomes (Lu et al., 2020) and decrease family violence (Tomlinson et al., 2017). To address these challenges, there is a need for multi-faceted, evidence-based programmes that incorporate health, nutrition, responsive parenting and safety net support to promote child development and reduce household violence (Akter et al., 2020; Black et al., 2017; Britto et al., 2017; Hossain, Tofail, Mehrin, & Hamadani, 2023; Howard & Brooks-Gunn, 2009; Richter et al., 2017).

Conflict of interest statement: No conflicts declared.

Parenting programmes focus on promoting responsive parent–child interactions, increasing stimulation and enrichment, encouraging opportunities for early learning and healthy discipline (Britto et al., 2017). Nurturing care supports holistic growth of social, emotional, physical and cognitive development and sets the foundation for lifelong learning, wellness, and the ability to contribute to society as responsible citizens. Parenting programmes can have significant long-term benefits for children, including enhanced productivity in adulthood, educational attainment, social connectedness, economic productivity and the promotion of peace and stability (Jeong, Pitchik, & Fink, 2021; Leckman et al., 2021; World Bank, 2022). Integrating high-quality parenting programmes to improve ECD and prevent violence into existing social protection systems can greatly advance the developmental needs of children (Arriagada, Perry, Rawlings, Trias, & Zumaeta Aurazo, 2018; Bacchus et al., 2024; Mikton, MacMillan, Dua, & Betancourt, 2014). When these programmes are implemented in partnership with local governments and communities, and successful strategies for quality improvement and stakeholder engagement are integrated, they are positioned to become more impactful, scalable and sustainable (Lansford et al., 2022; Milner et al., 2019).

Rwandan context

Rwanda has one of the highest rates of stunting (33%) in all of sub-Saharan Africa, and 38% of Rwandans live in poverty (defined as yearly consumption per adult equal to or less than RWF 159,375/US$207 in 2016). Rates of poverty are improving but remain concentrated in certain areas (e.g. rural regions). Given robust investments in health and nutrition, rates of childhood stunting in Rwanda are on the decline (down from 47% in 2000) but remain high—nearly 50%—among poor children (Rwanda National Institute of Statistics, 2021).

With a history of communal violence in the region, particularly during the 1994 Genocide against the Tutsi, which killed more than 800,000 people in just over 100 days (United Nations Security Council, 1999), intergenerational and family violence has been documented at high levels (Umubyeyi, Mogren, Ntaganira, & Krantz, 2014). For example, rates of intimate partner violence (IPV) among Rwandan women were 46% in 2020 (Bahati et al., 2022). Rwanda's Violence Against Children and Youth survey revealed that more than 50% of Rwandan children had experienced sexual, physical, or emotional violence before age 18, with most of the abuse occurring in the home (Rwanda Ministry of Health, 2016).

The Government of Rwanda is invested in improving both child development and reducing violence and recognises that affordable, scalable and effective interventions are needed to advance prospects for vulnerable children (Britto, Singh, Dua, Kaur, & Yousafzai, 2018). The Rwandan Government has developed a comprehensive ECD Policy (Rwanda Ministry of Gender and Family Promotion, 2016), as well as policies that impact ECD, including the Food and Nutrition Policy 2013–2018 (Rwanda Ministry of Local Government, Ministry of Health, and Ministry of Agriculture and Animal Resources, 2014); Economic Development and Poverty Reduction Strategy II (EDPRS2) 2013–18 (Rwanda Ministry of Finance and Economic Planning, 2013); the National Strategy for Transformation 2017–2023 (Republic of Rwanda, 2017) all of which link to the Sustainable Development Goals (United Nations, 2015) and the revised Vision 2020 targets (Republic of Rwanda, 2000). Their policy statements have led to action, including government training on interventions to support children's physical, cognitive, language, social, emotional and psychological development, including play and creativity; the establishment of a cadre of community-based child protection volunteers; and the roll-out of ECD centres across the country.

Although the number of ECD centres in Rwanda has increased—to 26,241 ECD centres in 2023 from 4,109 in 2018 (Rwanda National Child Development Agency, 2023)—these services are directed at children aged 2–6 years and often remain inaccessible for poor families living in rural areas. As of 2019, just 1% of children under three were enrolled in ECD programmes (Rwanda Ministry of Gender and Family Promotion, 2019). Among impoverished families with very young children, most are living without electricity (87.3%), lack toys or other playthings (80.5%), and are unable to provide a minimal acceptable diet[1] according to WHO standards (87.3%). Among the youngest children aged 0–11 months, 32.6% were estimated to experience inadequate care,[2] and nearly 20% were estimated to be exposed to violent discipline; exposure to violence was also observed to worsen as Rwandan children get older. Among children aged 24–35 months, 60% receive inadequate care while 80.7% were estimated to be exposed to violent discipline (UNICEF & Imbuto Foundation, 2015). Recognising these pervasive problems, likely linked to history of communal violence in the country, the Government of Rwanda established a national capacity development programme to train child protection volunteers to provide psychosocial support and referrals to services. The Inshuti Z'Umuryango (IZU, "Friends of the Family") are community-based, non-specialist volunteers tasked with child protection including addressing issues of child abuse, harm, or neglect in the community. Rwanda has also established Isange ("To Feel at Home") One Stop Centres to provide medical, psychological, legal and housing services to victims of gender-based violence and child abuse; however,

just 48 centres are available to serve the entire country and may be out of reach for the most impoverished families in hard-to-reach areas (Rwanda Gender Monitoring Office, 2024).

The present study studied a novel implementation strategy, the PLAY Collaborative, developed in close partnership with Rwandan government and university partners to scale an evidence-based, home-visiting intervention to promote nurturing care and reduce family violence while maintaining and improving quality. Adapted from the Interagency Collaborative Teams process model (Hurlburt et al., 2014), the PLAY Collaborative promotes multi-level buy-in and establishes structural and procedural supports necessary for system-wide scaling of SM while maintaining and improving quality as implementation unfolds over time. With support from Rwanda's Ministry of Health and Ministry of Gender and Family Promotion, SM was delivered by IZU child protection community volunteers, given their remit to support the national child protection system. In addition to their role in intervening in cases of child abuse and neglect, IZUs conduct at least two home visits per week to promote positive parenting behaviours, provide basic counselling to families in conflict and other psychosocial support, conduct community engagement to raise awareness about child rights, and refer cases as appropriate. In this context, SM provides a structured curriculum for IZUs to carry out several of their mandated activities. This social service workforce could facilitate further scaling of SM with quality if given adequate policy, workforce and budgetary supports. In the present trial, we also evaluated SM impact on children as young as 0–6 months, given that prior trials had focused on children 6–36 months.

Methods

Study design and participants

This study used a Hybrid Type-2 Implementation-Effectiveness design to evaluate the PLAY Collaborative implementation strategy in conjunction with an embedded effectiveness trial of SM as delivered by government-linked child protection community volunteers. Hybrid designs simultaneously assess effectiveness and implementation strategies and can help address gaps in knowledge on how to scale and sustain these programmes (Curran, Bauer, Mittman, Pyne, & Stetler, 2012).

Eligibility criteria for the effectiveness trial were: (a) households classified by the Government of Rwanda as living in extreme poverty; (b) primary caregivers of a child between the ages of 0–36 months; (c) caregivers cohabitate with and are legal guardians of the child; and (d) reside within the Nyanza, Ngoma, or Rubavu districts.

Caregivers provided written and/or oral consent for both themselves and their children prior to study enrolment. The Rwanda National Ethics Committee (Registration #00001497) and Boston College Institutional Review Board (Protocol #21.220.01) approved and oversaw the study. This trial was registered on ClinicalTrials.gov (NCT04257383) February 6, 2020.

Implementation strategy

We developed the PLAY Collaborative implementation strategy to scale the delivery of SM to the most impoverished households in three districts of Rwanda, as identified using criteria for extreme poverty by the Government of Rwanda. The PLAY Collaborative included the following core ingredients: (a) the use of a cross-site training and supervision Seed Team; (b) a signed common charter committing all stakeholders to quality improvement; (c) Plan-Do-Study-Act cycles conducted in PLAY Collaborative meetings at the National, District, Cell and Sector levels; (d) cross-site learning and exchange; (e) the use of digital tools to enhance communication; and (f) the identification and engagement of champions in the government and community to advocate for the programme's expansion and sustainment (Aarons, Sklar, Mustanski, Benbow, & Brown, 2017; Hurlburt et al., 2014; Miech et al., 2018; Powell et al., 2015; Tyler & Glasgow, 2021). These core features of the PLAY Collaborative were designed in alignment with the Exploration, Preparation, Implementation, Sustainment (EPIS) Framework (Moullin, Dickson, Stadnick, Rabin, & Aarons, 2019), an implementation science model distinguished by its focus on the role of contextual factors at different stages of the implementation process. Guided by these frameworks, the PLAY Collaborative focused on four areas of support: commitment, capacity, communication and quality. Achieving commitment entailed generating shared investment by establishing a charter and mission to establish a community of practice among ECD stakeholders and to remove implementation barriers. Capacity was established by incorporating local expertise to develop institutional knowledge via a cross-site Seed Team to lead ongoing training and supervision and engage local, regional and national government and other stakeholders from across the ECD ecosystem. Communication involved optimising resources to address challenges by using cross-site learning to encourage information exchange, communication and workload sharing. Embedded quality improvement tools established appropriate oversight and cultivated active learning and system improvements.

The EPIS framework guided selection of PLAY Collaborative members by mapping the active ingredients in SM and linking intervention components to key institutions and individuals within the Rwandan ecosystem. Membership ultimately included government officials, our local partners at a community-based Non-Governmental Organisation (NGO; FXB Rwanda), IZUs, and other ECD stakeholders. Government officials represented all levels of Rwanda's administrative structure (i.e. national, district, sector and cell) (Rwanda Ministry of Local Government, 2024). This structure was mirrored in SM staffing which included a national-level Coordination Office, district-level leads and associate leads, sector-level associate trainers, cell-level mentors and village/household-level IZUs. We also established a Rwanda-based expert Seed Team with previous experience with SM that trained new PLAY Collaborative members across district, sector and cell levels on either direct intervention delivery or on oversight and facilitation. The structure of training and oversight activities are described in Appendix S1. Allowing expertise to rest across multiple implementation levels and multiple individuals made the Seed Team resistant to turnover or other staff changes.

The intervention

SM is a home-visiting programme that supports local non-specialists to work directly with parents via "active coaching" to reinforce playful parenting skills and improve knowledge of ECD to create a safe, stimulating and nourishing environment for the growth of young children (Bacchus et al., 2024; Barnhart et al., 2020; Betancourt et al., 2020;

Jensen et al., 2021). SM is informed by the Nurturing Care Framework (World Health Organisation (WHO), United Nations Children's Fund (UNICEF), World Bank Group, 2018) on nutrition, health and hygiene promotion and includes: (a) active coaching of both male and female caregivers in playful, responsive interactions with their child(ren) to encourage stimulation, early language learning and school readiness; (b) developing a "family narrative" to highlight sources of resilience for addressing challenges and reducing the risk of violence; (c) strengthening problem-solving skills and the navigation of formal and informal community resources; and (d) building skills in parental emotion regulation and alternatives to harsh punishment. At each home visit, a 15-min play session is facilitated whereby male and female caregivers are actively coached in responsive play with their children. SM is delivered in 12 modules and two booster sessions ~60–90 min in duration delivered weekly over 3–4 months by well-trained, non-specialists embedded in the community.

According to our Theory of Change (Figure 1), we expect that immediately post-intervention, we will observe improvements in caregiver behaviours in terms of play and stimulation, responsive and nurturing care, provision of safer and more hygienic home environments, and reductions in family violence, both in terms of harsh disciplinary practices and IPV. Improvements in nurturing caregiving practices expected to lead to longer-term effects on child development which will be assessed 1 year following the home-visiting intervention (World Health Organisation (WHO), United Nations Children's Fund (UNICEF), World Bank Group, 2018). Consequently, we expect to see changes in child development outcomes after long-term follow-up (Jeong et al., 2021). Research to assess SM effects on child development outcomes 1 year after the intervention is currently underway.

A previous cluster-randomised trial of SM ($N = 1{,}049$ families; 1,498 caregivers and 1,084 children) tested its effectiveness in families with children aged 6–36 months who were receiving the Rwandan Government's Vision 2020 Umurenge Programme (i.e. a cash-for-labour public works programme), as delivered by Community-Based Coaches who were paid a monthly stipend (Betancourt, Jensen, et al., 2020; Jensen et al., 2021). Consistent with the SM Theory of Change (Figure 1), immediate post-intervention results revealed improvements in caregivers' responsive and stimulating care, provision of more diverse diets, increased care-seeking for child health problems, and reductions in family violence. Caregivers also experienced improved mental health, more shared decision-making, and used more hygiene-promoting practices (Barnhart et al., 2020; Betancourt, Franchett, et al., 2020; Betancourt, Jensen, et al., 2020). One year later, SM children demonstrated improvements in gross motor, communication, problem-solving and socioemotional development, while SM caregivers sustained reductions in family violence and SM fathers sustained increases in caregiving activities (Jensen et al., 2021).

Following the cluster randomised trial, we conducted a cost analysis in which three scenarios were considered (Desmond et al., 2023). As implemented, the cost per family was $456 USD. The cost of delivery decreased in the context of scaling based on the assumption that efficiency would improve over time and that international salaries and expenses would decrease. The second scenario considered programme expansion, delivering SM to 2000 families per quarter, and an estimated cost per family of $262 USD. The third scenario assumed government delivery of the intervention at the same rate of delivery as the second scenario, with management costs decreasing as management shifts from international to local staff. This scenario resulted in a cost per family of $199 USD.

Additionally, a cost-effectiveness analysis was conducted which estimates a cost per unit of outcome. While SM is a multi-component intervention designed to address a variety of outcomes, including responsive and nurturing care, early stimulation, nutrition and hygiene promotion and family violence prevention, for the purpose of the costing analysis, children's cognitive development was selected to estimate improvements in this outcome per home visit (Desmond et al., 2023). The results revealed cognitive improvement per session was 0.009 standard deviations; this intervention effect is comparable to similar home-visiting interventions delivered in low-resource settings. Moreover, SM achieved this effect with fewer sessions than comparable interventions.

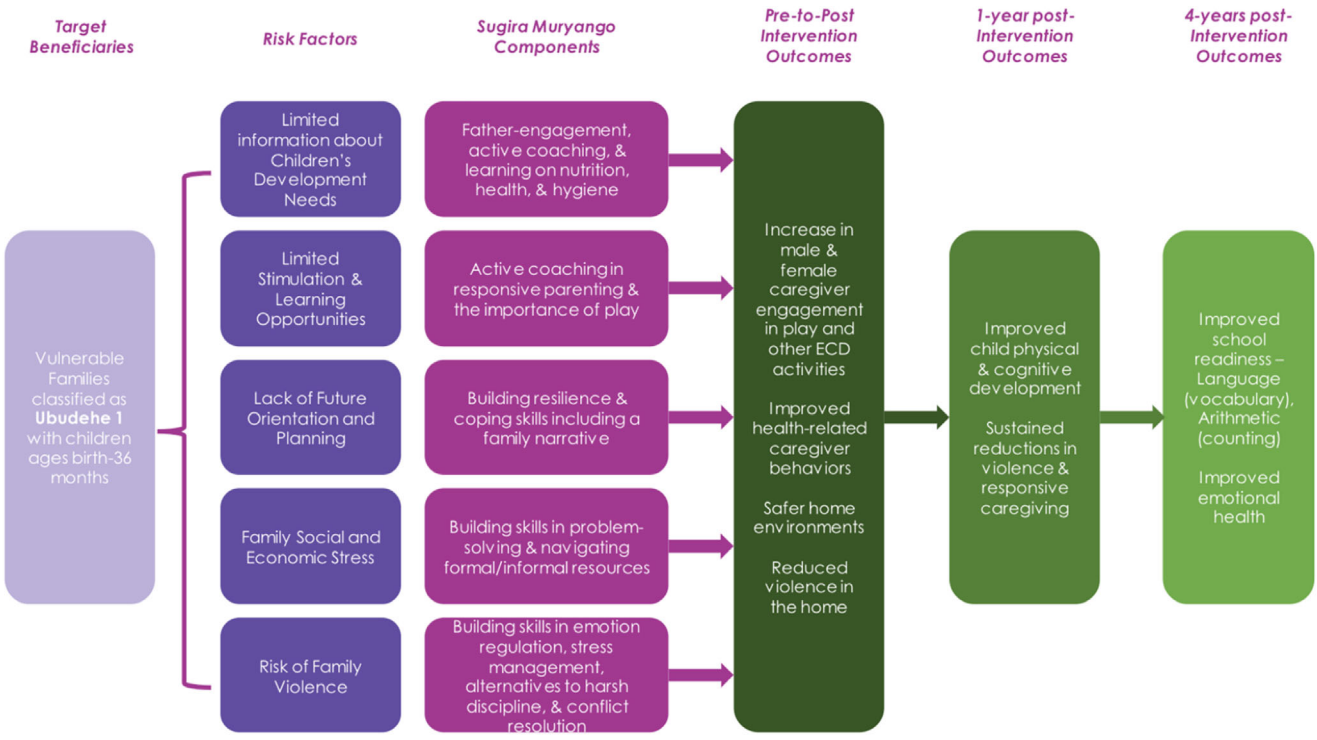

Figure 1 Sugira Muryango Theory of change

Randomisation for the effectiveness trial

Sectors within each district were stratified by geographic characteristics (urban–rural, bordering another country) and service availability (NGOs offering ECD, Nutrition and Water, Sanitation and Hygiene (WASH) programming), then statistically matched and randomly assigned to treatment or waitlist-control. Villages within sectors and households within villages were randomly selected. Local enumerators responsible for data collection were blind to site and family allocation to condition.

Procedures

Household surveys were completed at baseline (May 5–23, 2021) and immediate post-intervention (Oct 25–Nov 13, 2021). SM caregivers reported on implementation outcomes concurrently with post-intervention data collection. IZUs and PLAY Collaborative members reported on implementation outcomes between October 13–November 2, 2021. Fidelity and competence were assessed for two SM sessions per month for each IZU. All questionnaires were translated using a forward- and back-translation protocol from English to Kinyarwanda (WHOQOL Group, 1993).

Effectiveness outcomes

Effectiveness outcomes were selected in accordance with our Theory of Change (Figure 1) and previous research in Rwanda (Barnhart et al., 2020; Betancourt, Franchett, et al., 2020; Betancourt, Jensen, et al., 2020; Jensen et al., 2021). Primary child-level measures included stimulating and nurturing care, dietary diversity, child health and care-seeking and child discipline. The Home Observation for Measurement of the Environment (HOME) Inventory (Bradley & Caldwell, 1984) includes caregiver-reported assessments of stimulation in the home as well as observations of caregiver responsivity to the child (total score Cronbach's $\alpha = .78$). The Multiple Indicator Cluster Surveys (MICS) ECD items (UNICEF, 2015) assess caregiver-reported engagement in stimulating activities (e.g. reading, singing, playing) with the child in the past 3 days (total score Cronbach's $\alpha = .64$). The Observation of Mother–Child Interactions (OMCI) (Rasheed & Yousafzai, 2015) is an observer-reported assessment of mother–child interactions (total score Cronbach's $\alpha = .89$). Dietary diversity was measured according to the WHO Infant and Young Child Feeding Guidelines (World Health Organization, 2010) which assess nutritional intake across seven food groups within the past 24 h (dairy; eggs; meat, fish, poultry and organ meat; grains, roots and tubers; legumes and nuts; vitamin A rich fruits and vegetables; other fruits and vegetables). Care-seeking for child health issues was measured using the Rwanda Demographic and Health Survey (DHS) items that assess incidence of diarrhoea, fever and cough within the past 7 days, as well as whether caregivers sought care at health facilities (Rwanda National Institute of Statistics, 2021). We used the MICS Child Discipline module (UNICEF, 2015) to measure the frequency of caregiver-reported violent (physical, psychologically aggressive) and deprivation-based harsh disciplinary practices (total score Cronbach's $\alpha = .70$). Methods used to screen for developmental delays and poor growth using child anthropometrics are described in Appendix S2.

Caregiver-level family violence was measured using Rwanda DHS IPV items (Rwanda National Institute of Statistics, 2021) which assess physical, emotional and sexual victimisation in participants with romantic partners. Caregiver mental health was measured with the Hopkins Symptom Checklist-25 (HSCL-25; total score Cronbach's $\alpha = .92$) (Derogatis, Lipman, Rickels, Uhlenhuth, & Covi, 1974) which includes depression and anxiety subscales and has been previously validated in Rwandan adults (Bolton, 2001). Father engagement in caregiving decisions was measured in dual caregiver households using items on mother/father decisions about child feeding, bathing, soothing and healthcare, among others (Doyle et al., 2018; UNICEF & Imbuto Foundation, 2015).

Household-level outcomes were measured with the MICS WASH module (UNICEF, 2015) which measures access to clean water, water treatment and hand washing practices. Additionally, given that SM was delivered in the wake of the COronaVIrus Disease of 2019 (COVID-19) pandemic, we asked about the impact of COVID-19 on household relationships, economic stability and access to basic needs using an adapted version of the Epidemic-Pandemic Impacts Inventory (Grasso, Briggs-Gowan, J. D., & Carter, 2020).

Implementation outcomes

Quality of delivery was assessed by Cell Mentors using a structured quality monitoring guide that included fidelity items (1–6 per module) developed based on the SM curriculum manual and competence items (16 cross-module items) that focused on cross-cutting, general skills in delivering the intervention (e.g. rapport building, collaborative goal setting) and items pertaining to the 15-min coached playful interactions.

We assessed implementation outcomes using the Mental Health Implementation Science Tools (Aldridge et al., 2022) which were designed and validated for use in LMICs and include different versions for different stakeholder groups (Haroz et al., 2019; Proctor et al., 2011). In the present study, caregivers reported on adoption, acceptability, appropriateness and feasibility. IZUs and PLAY Collaborative members reported on adoption, acceptability, appropriateness, feasibility, leadership and organisational climate. IZUs and PLAY Collaborative members also responded to the Implementation Leadership Scale (Aarons, Ehrhart, & Farahnak, 2014), a self-report measure of proactive, knowledgeable, supportive and perseverant leadership. PLAY Collaborative members completed the Programme Sustainability Assessment Tool (Luke, 2014) which measures Environmental Support, Funding Stability, Partnerships, Organisational Capacity, Programme Evaluation, Programme Adaptation, Communication and Strategic Planning. Finally, PLAY Collaborative members completed the Seed Team Assessment Battery (Agency for Healthcare Research and Quality, 2012) which measures team identity, climate, skills, performance, functioning and other general characteristics.

Statistical analysis

Statistical power was calculated to account for multiple levels of clustering at family, timepoint and village levels, such that the study had 0.8 power to detect a standardised effect of 0.21 for cross-sectional comparisons at post-intervention based on field preparation data. Following intention-to-treat analysis, multiple imputation by chained equations was used to address attrition (Plumpton, Morris, Hughes, & White, 2016). SM effectiveness was assessed using linear mixed-effects models, generalised mixed-effect models with a logistic link function and generalised mixed-effect Poisson models were fitted for continuous, binary and count outcomes, respectively. We report time-by-treatment interactions along with standardised effect sizes (Cohen's d for continuous outcomes, odds ratios (OR) for binary outcomes and Incidence Rate Ratios (IRR) for count outcomes) and 95% confidence intervals. Adjusted models include covariates at baseline, including sex, age, district, participation in other programmes relevant to the outcomes of this study, and COVID-19 impact (general, economic strain and household conflict). Results of unadjusted models are presented in Appendix S4. Means and standard errors for each model at each timepoint are provided in Appendix S5.

Implementation outcomes were evaluated by examining descriptive statistics (means, standard deviations), calculated separately for each stakeholder group. Fidelity and competence were evaluated by calculating a percentage score for each module by summing evaluation scores and dividing by the maximum possible score. All analyses were completed using Stata SE version 18 (StataCorp, 2023).

Adverse events

During the window between baseline and post-intervention, 47 control families (15%) and 38 treatment families (17%) received additional referrals for risk of harm issues including intimate partner violence (48%), severe malnutrition (17%), suicidality or other acute mental health crises (26%) or COVID-19 illness (5%). One caregiver and two children died due to unknown illness (2%) or congenital heart defects (1%).

Analytic sample and demographics

The effectiveness trial enrolled 538 households, including 778 caregivers and 555 children. The rate of loss to follow-up from baseline was 14 households (2.6%), 54 caregivers (6.9%), and 15 children (2.7%; Figure 2). Item-level missingness for the primary outcomes was <1% at both time points.

Table 1 displays descriptive statistics for the sample. Among children at baseline, 74.8% were flagged for potential developmental delay, most often for fine motor development (55.3%) followed by problem-solving (48.6%) and gross motor development (34.1%). We observed stunting in 34.4% of children, and 34.6% were exposed to harsh discipline within the past 30 days. The majority of caregivers were either biological mothers (65.7%) or biological fathers (29.4%); 90% had less than 6 years of schooling; 42.8% screened positive for internalising symptoms[3]; and 44.0% of females with intimate partners reported IPV victimisation within the past 12 months. Due to the COVID-19 pandemic, 67.5% of the households reported partial or complete loss of income, and 75.3% reported not being able to afford enough food for the family.

Results

Effectiveness

Results for multilevel models are shown in Table 2.

Positive parenting and responsive care

Children receiving SM experienced more nurturing and stimulating environments compared with children receiving Usual Care (UC). When evaluated using the HOME inventory, improvements in the quality of the home environment were, on average, 1.01 points larger in SM households ($B = 1.01$, 95% CI: 0.18–1.84; Cohen's $d = 0.20$, 95% CI: 0.04–0.36) compared with UC households. SM caregivers increased their involvement of children in daily activities ($B = 0.43$, 95% CI: 0.20–0.66; Cohen's $d = 0.37$, 95% CI: 0.18–0.57) and provision of learning materials ($B = 0.57$, 95% CI: 0.24–0.90; Cohen's $d = 0.37$, 95% CI: 0.16–0.59). SM families also showed greater improvements in the number of early stimulation activities ($B = 0.40$, 95% CI: 0.10–0.70; Cohen's $d = 0.26$, 95% CI: 0.07–0.46). We did not observe any effect on the quality of caregiver–child relationships as measured by the OMCI.

Dietary diversity, hygiene practices, child health and care-seeking

Compared with UC, caregivers receiving SM reported a 0.36 points larger increase in the number of food groups they provided children over the past 24 h ($B = 0.36$, 95% CI: 0.07–0.66; Cohen's $d = 0.25$,

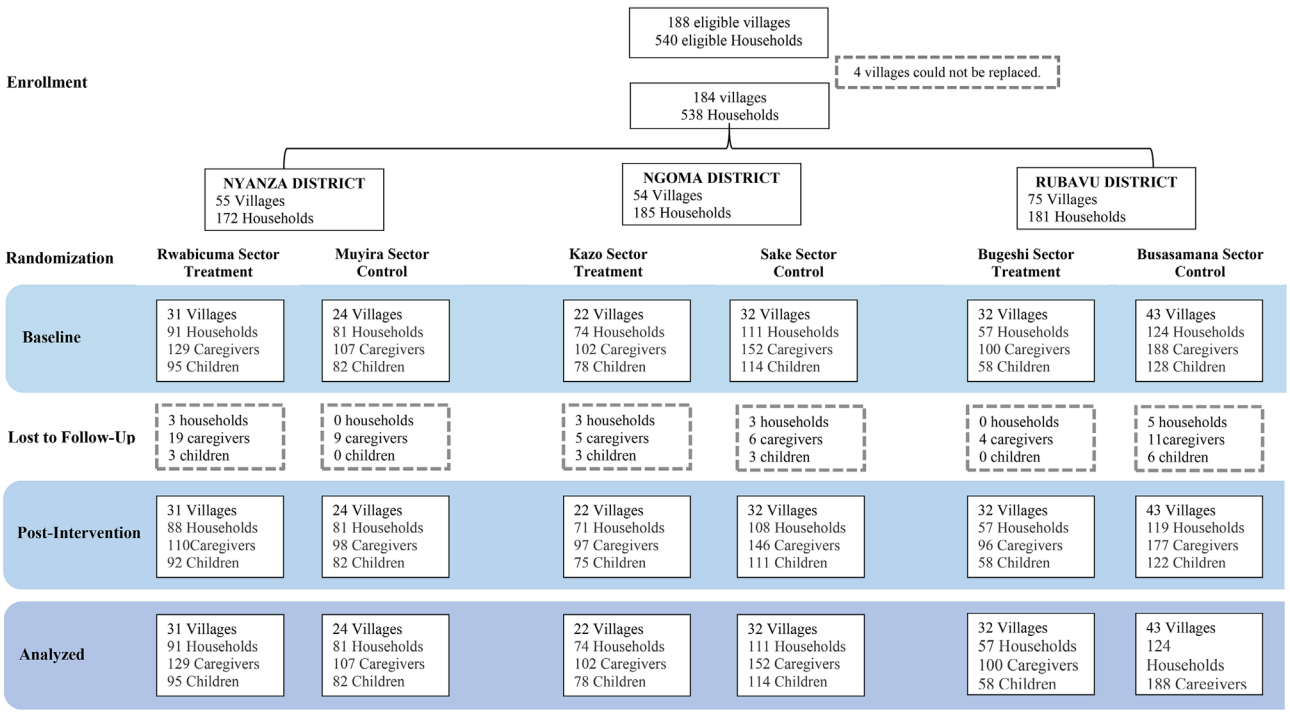

Figure 2 CONSORT diagram

Table 1 Descriptive statistics of study participants at baseline. Continuous variables reported as [mean (*SD*)] and binary variables reported as [frequency (%)]

	Sugira Muryango	Usual care	Total
Households	*N* = 222	*N* = 316	*N* = 538
Dual caregiver households (Cohabitating partner)	119 (53.6%)	142 (44.9%)	261 (48.5%)
Impact of COVID-19 Pandemic			
Partial or complete loss of income	145 (65.3%)	218 (68.9%)	363 (67.5%)
Unable to afford enough food	165 (74.3%)	240 (75.9%)	405 (75.3%)
Children	*N* = 231	*N* = 324	*N* = 555
Average Age in Months – Mean (*SD*)	13.25 (6.54)	13.34 (6.73)	13.30 (6.65)
[Range]	[0.5–24]	[1–24]	[0.5–24.5]
Gender, Female	108 (46.6%)	147 (45.3%)	255 (45.9%)
Health Status and Wellbeing			
Stunted (HAZ ≤ −2 *SD*)	83 (35.9%)	108 (33.3%)	191 (34.4%)
Wasted (WHZ ≤ −2 *SD*)	3 (1.3%)	11 (3.4%)	14 (2.5%)
Underweight (WAZ ≤ −2 *SD*)	27 (11.7%)	45 (13.9%)	72 (12.9%)
Screens Positive, Developmental Delay[a]	162 (70.1%)	253 (78.1%)	415 (74.8%)
Any Violent Discipline, Past 30 days[b]	83 (36.8%)	105 (33.0%)	188 (34.6%)
Caregivers	*N* = 331	*N* = 447	*N* = 778
Average Age in Years – Mean (*SD*)	33.58 (9.47)	34.04 (10.27)	33.84
[Range]	[18–79]	[18–73]	[18–79]
Gender, female	222 (67.1%)	316 (70.7%)	538 (69.2%)
Marital status			
Single, separated, divorced, widowed	96 (29.0%)	161 (36.0%)	257 (33.1%)
Married/cohabitating	235 (71.0%)	286 (63.9%)	521 (66.9%)
Relationship with child			
Biological Mother	209 (63.1%)	302 (67.6%)	511 (65.7%)
Biological Father	105 (31.7%)	124 (27.7%)	229 (29.4%)
Aunt/Uncle	0 (0%)	1 (0.2%)	1 (0.1%)
Grandparent	16 (4.8%)	19 (4.3%)	35 (4.5%)
Aunt/Other	1 (0.3%)	1 (0.2%)	2 (0.3)
Educational attainment			
No school/don't know	52 (15.71%)	97 (21.7%)	149 (19.2%)
Primary or less (<6 years)	243 (73.4%)	318 (71.1%)	561 (72.1%)
Secondary or less (≥6 years primary)	30 (9.1%)	17 (3.8%)	47 (6.0%)
Secondary/vocational school	6 (1.8%)	15 (3.4%)	21 (2.7%)
Health and safety			
Screens Positive, internalising symptoms[c]	118 (35.7%)	215 (48.1%)	333 (42.8%)
Any IPV Victimisation, past 12 months[d]	52 (45.2%)	62 (43.1%)	114 (44.0%)

HAZ, height-for-age *Z*-score; WHZ, weight-for-height *Z*-score; WAZ, weight-for-age *Z*-score.
[a]Based on Ages and Stages Questionnaire-3 Total Score Western Cut-offs.
[b]Total *N* = 544, 1.98% baseline missingness.
[c]Scored ≥1.75 on the HSCL-25 Questionnaire.
[d]Among females with intimate partners: *N* = 259.

95% CI: 0.04–0.45). SM households had significantly greater odds of using safer water storage practices (OR = 3.14, 95% CI: 1.64–6.03) and treating water prior to drinking (OR = 3.56, 95% CI: 1.80–7.05) compared with UC households. The prevalence of acute illness among children did not change from pre- to post-intervention; nor did we observe significant increases in appropriate care-seeking for child health symptoms.

Harsh discipline and intimate partner violence

SM caregivers reported a 66% larger decrease in the odds of using any type of deprivation-based harsh discipline, such as withholding food and toys, compared with UC caregivers (OR = 0.34, 95% CI: 0.14–0.82). While we observed trends showing a decrease in the odds of using any type of violent discipline, these results were not statistically significant. We did not observe any effect of SM on IPV victimisation.

Parental mental health, father engagement and shared decision-making

Compared with UC, SM caregivers showed larger decreases in overall mental health symptoms ($B = -0.07$, 95% CI: −0.14 - -0.01; Cohen's $d = -0.13$, 95% CI: −0.26 - -0.01), as well as decreases in depression symptoms ($B = -0.07$, 95% CI: −0.14 to −0.00; Cohen's $d = -0.13$, 95% CI: −0.26 to −0.00). Fathers in SM households engaged in a significantly more caregiving decisions (IRR = 1.18, 95% CI: 1.03–1.37) compared with fathers in UC households. We did not observe SM effects on father involvement in decisions using single-item measures of what the child eats or actions taken when the child is sick.

Table 2 Difference in difference ("time-by-treatment") interaction estimates and effect sizes for primary outcomes (adjusted models)

	Mixed models difference-in-difference estimates[a]			Cohen's D[h] for continuous outcomes[i]	
Outcomes	Estimate	95% CI	*p*-Value	Estimate	95% CI
Child outcomes					
ECD and stimulation in the home					
HOME – Total Score	1.01	0.18 to 1.84	.017	0.20	0.04 to 0.36
HOME – Involvement	0.43	0.20 to 0.66	<.001	0.37	0.18 to 0.57
HOME – Learning Materials	0.57	0.24 to 0.90	.001	0.37	0.16 to 0.59
HOME – Acceptance	0.06	−0.09 to 0.21	.422	0.08	−0.11 to 0.26
HOME – Organisation	−0.13	−0.36 to 0.10	.274	−0.12	−0.33 to 0.10
HOME – Responsivity	0.07	−0.36 to 0.46	.737	0.03	−0.16 to 0.22
HOME – Variety	−0.03	−0.20 to 0.15	.766	−0.03	−0.21 to 0.15
OMCI – Total Score[b]	−0.35	−2.91 to 2.21	.788	−0.04	−0.29 to 0.22
OMCI – Caregiver Subscale[b]	0.26	−1.36 to 1.89	.752	0.04	−0.21 to 0.29
OMCI – Child Subscale[b]	−0.61	−1.86 to 0.63	.332	−0.13	−0.39 to 0.13
MICS5 – ECD stimulation	0.40	0.10 to 0.70	.008	0.26	0.07 to 0.46
Child nutrition, health, and safety					
Dietary Diversity[c]	0.36	0.07 to 0.66	.017	0.25	0.04 to 0.45
Diarrhoea Prevalence[j]	0.80	0.45 to 1.40	.426	–	–
Diarrhoea Care seeking[d,j]	2.72	0.91 to 8.14	.074	–	–
Fever Prevalence[j]	1.51	0.89 to 2.56	.129	–	–
Fever Care seeking[e,j]	1.18	0.48 to 2.93	.718	–	–
Cough Prevalence[j]	1.47	0.86 to 2.50	.157	–	–
Cough Care seeking[f,j]	1.41	0.63 to 3.14	.402	–	–
Child caretaking practices and safety					
Use of any violent discipline[j]	0.63	0.34 to 1.18	.146	–	–
Use of any deprivation-based discipline[j]	0.34	0.14 to 0.82	.016	–	–
Use of any psychological aggression[j]	0.54	0.25 to 1.16	.113	–	–
Use of any physical discipline[j]	0.70	0.37 to 1.33	.279	–	–
Caregiver outcomes					
Mental health					
HSCL Total score	−0.07	−0.14 to −0.01	.030	−0.13	−0.26 to −0.01
HSCL Depression score	−0.07	−0.14 to −0.00	.042	−0.13	−0.25 to −0.00
HSCL Anxiety score	−0.07	−0.15 to 0.00	.061	−0.13	−0.26 to 0.01
Screen Positive for Internalising[j]	0.78	0.40 to 1.50	.451		
Father engagement and shared decision-making					
Action when child sick[j]	0.79	0.36 to 1.77	.571	–	–
What child eats[j]	1.22	0.64 to 2.34	.553	–	–
Father engagement in caretaking[k]	1.18	1.03 to 1.37	.022	–	–
Intimate partner violence (female victimisation)[g]					
Any emotional abuse[j]	1.10	0.46 to 2.63	.824	–	–
Any physical abuse[j]	0.87	0.36 to 2.11	.750	–	–
Any sexual abuse[j]	1.44	0.28 to 7.53	.664	–	–
Any abuse[j]	0.71	0.31 to 1.60	.403	–	–
Household outcomes					
Water, hygiene, and sanitation					
Place with soap to wash hands[j]	1.98	0.99 to 3.68	.058	–	–
Water treatment[j]	3.56	1.80 to 7.05	<.001	–	–
Safe water storage[j]	3.14	1.64 to 6.03	.001	–	–
Wash after using toilet[j]	2.68	0.67 to 10.82	.165	–	–
Accessing clean water[j]	0.79	0.30 to 2.08	.637	–	–

[a]Treatment by Timepoint Interaction Coefficient from Mixed Models. Reported as a continuous outcome unless otherwise noted.
[b]Among children aged 12 months and older at baseline: $N = 324$.
[c]Among children aged 6 months and older at baseline: $N = 459$.
[d]Among children with diarrhoea: $N = 291$.
[e]Among children with fever: $N = 349$.
[f]Among children with cough: $N = 448$.
[g]Among females with intimate partners at baseline: $N = 288$.
[h]*Cohen's d* is estimated from the regression coefficient (covariates-adjusted mean difference) for continuous outcomes using the variance explained by null multilevel models.
[i]Binary and count outcomes reported as OR or IRR, respectively, in the difference-in-differences parameter estimates column.
[j]Reported as OR.
[k]Reported as IRR, the outcome is a count of the number of activities the father is engaged in.

Implementation

The PLAY Collaborative successfully trained 2,608 IZUs to deliver SM, and 2,461 IZUs actively delivered the intervention, reaching 19,548 caregivers and 9,483 children in 8,745 households. On average, IZUs were assigned 3.76 households (*SD* = 1.76) to deliver SM, and 94.7% were assigned six households or less.

Fidelity and competence

Quality of delivery was evaluated by 191 Cell Mentors on the Seed Team who provided feedback to 2,611 IZUs for an average of 9 sessions per IZU. Figure 3 presents mean fidelity and competence scores across the 12 SM modules by district. Fidelity scores ranged from 83.6% to 94.5%, while competence scores ranged from 84.3% to 94.4%; both trended positively across modules. On average, IZUs in Nyanza received higher fidelity (*M* = 94.03%, *SD* = 9.59) and competence (*M* = 92.66%, *SD* = 9.59) scores compared with Rubavu (fidelity *M* = 88.69%, *SD* = 13.24; competence *M* = 88.73%, *SD* = 11.31) and Ngoma (fidelity *M* = 89.24%, *SD* = 11.85; competence *M* = 89.02%, *SD* = 9.50).

Implementation outcomes

We assessed implementation outcomes among 194 IZUs, 358 PLAY Collaborative members (Cell Mentors, *N* = 173; SM staff, *N* = 40; and government officials, *N* = 145), and 327 SM caregivers (see Table 3 for demographic characteristics).

Table 4 displays descriptive statistics for implementation outcomes by respondent type. Acceptability and Appropriateness were rated more positively than Adoption and Feasibility on average. Self-reported leadership skills were moderate to high across respondent types, while IZUs rated Cell Mentors more positively than Cell Mentors were willing to rate themselves. Respondents reported highly positive views of organisational climate. All PLAY Collaborative members reported highly positive perceptions of the Seed Team. PLAY Collaborative members reported moderate to high ratings of Programme Sustainability. Across all respondents, Communications were perceived most positively, while Supportive Environment and Funding Stability were perceived least positively.

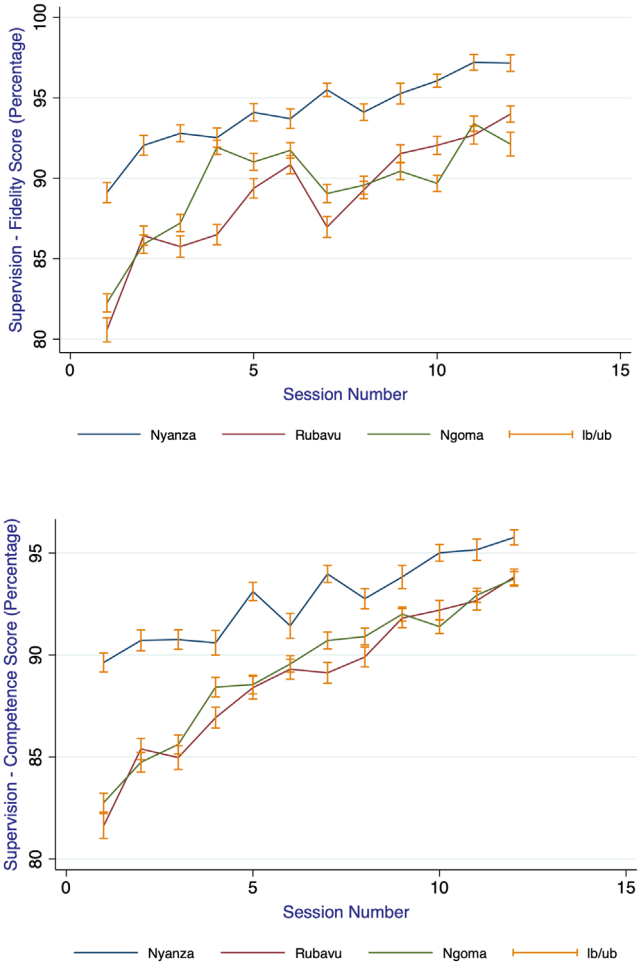

Figure 3 Fidelity and competence trends by district. Each panel (A: Fidelity, B: Competence) displays scores as a percentage of the total possible score

Discussion

We conducted a systematic investigation of the PLAY Collaborative, an adaptation of Interagency Collaborative Teams (Hurlburt et al., 2014), as a strategy to scale delivery of an evidence-based parenting programme to promote ECD and prevent violence with quality using a Hybrid Type-2 Implementation-Effectiveness design. Many of the effects observed in our previous cluster randomised trial with delivery by community non-specialists were maintained, demonstrating that SM effects are quite robust, even after expanding the curriculum to include families with children 0–36 months (from 6–36 months) and transitioning to a new delivery approach with a completely different implementation workforce. As an implementation strategy to support scaling with quality, the PLAY Collaborative demonstrated that front-line IZU volunteers receiving both training and routine supervision improved in trajectories of fidelity and competence with time (Aboud et al., 2023). Furthermore, the PLAY Collaborative was able to achieve its ambitious plan to reach all eligible families across three rural Districts despite coinciding with a period of considerable social and economic upheaval due to the global COVID-19 pandemic.

The effectiveness trial revealed that SM's holistic home-visiting approach engages both male and female caregivers in playful parenting and content to promote ECD and prevent violence. Caregivers receiving SM increased ECD stimulation (e.g. playing, singing with children; improved stimulating

Table 3 Demographic characteristics of the sample completing implementation measures. Continuous variables reported as [mean (*SD*)] and binary variables reported as [frequency (%)]

		PLAY Collaborative $N = 358$			
	IZUs $N = 194$	Supervisors $N = 173$	SM Staff $N = 40$	Government $N = 145$	Caregivers $N = 327$
Age	43.6 (9.4)	35.26 (7.33)	36.10 (6.66)	42.37 (10.18)	–
Gender					
Male	99 (51.0%)	63 (36.4%)	26 (65.0%)	79 (54.5%)	104 (31.8%)
Female	95 (49.0%)	110 (63.6%)	14 (35.0%)	66 (45.5%)	211 (64.5%)
Missing	–	–	–	–	12 (3.7%)
Education					
No formal school	25 (12.9%)	2 (1.2%)	–	9 (6.2%)	111 (33.9%)
Primary	153 (78.9%)	41 (23.7%)	–	58 (40.0%)	181 (55.4%)
Secondary	12 (6.2%)	85 (49.1%)	1 (2.5%)	30 (20.7%)	23 (7.0%)
Institutional degree	4 (2.1%)	1 (0.6%)	–	2 (1.4%)	–
Bachelor's or higher	–	44 (25.4%)	39 (97.5%)	46 (31.7%)	–
Missing	–	–	–	–	12 (3.7%)
Marital status					
Single	–	–	–	–	69 (21.1%)
Married	–	–	–	–	215 (65.8%)
Widowed	–	–	–	–	11 (3.4%)
Divorced	–	–	–	–	20 (6.1%)
Missing	–	–	–	–	12 (3.7%)

home environments by providing more learning materials and engaging children in daily activities; increased children's dietary diversity; and reducing deprivation-based harsh discipline). Moreover, in-home visits facilitated father and other caregiver participation in SM, strengthening father engagement in caregiving decisions and improving overall mental health as well as depression symptoms for male and female caregivers. Household hygiene practices improved, particularly with respect to water storage and treatment.

We did not replicate all previous findings with regard to IPV and some forms of harsh discipline; appropriate care-seeking for child health symptoms; and certain caregiver–child interactions. These discrepancies may be at least partially attributable to the timing of intervention delivery which, spanning May to November 2021, coincided with the second largest spike in new COVID-19 infections in Rwanda, prior to the mass distribution of vaccines (Institute for Health Metrics and Evaluation, 2022). The child illnesses we measured–diarrhoea, cough and fever–corresponded with COVID-19 symptoms in babies and children (Mustafa & Selim, 2020). Monitoring these symptoms in children may have been elevated during the height of the pandemic while care-seeking for these conditions may have been impeded by dwindling availability of service resulting from the unprecedented pressure on healthcare systems during that time. Similarly, dynamics related to COVID-19 may have impacted intervention effects on family violence, including IPV and harsh disciplinary practices. Almost immediately following the mass closures and lockdowns designed to mitigate the impact of COVID-19 on healthcare systems globally, organisations including the United Nations and WHO sounded alarms about rising reports of IPV and other forms of family violence (Soeiro et al., 2023; Thiel et al., 2022; van Gelder et al., 2020).

Our ability to detect a treatment effect on IPV within SM households may also have been affected by a change in the instruments used to assess IPV. The present study asked about abuse victimisation within the previous 12 months, in contrast to the original cluster randomised trial, which referred to victimisation within the prior t3 months. Given that SM is a brief, 12-week intervention, lack of alignment with the reference window may have obfuscated some treatment effects. With that said, a violence prevention programme delivered to Rwandan couples over 15 weeks, Bandebereho, significantly reduced IPV even when measured over the past 12 months (Doyle et al., 2018).

It must also be noted that in contrast to the prior cluster randomised trial of SM (Betancourt, Jensen, et al., 2020), the present study enrolled younger children (0–24 months of age compared with 6–36 months in the prior trial). In Rwanda, the risk of violent discipline of children has been observed to increase with child age (Betancourt, Franchett, et al., 2020) which may have meant lower average levels of harsh child discipline to begin with. Indeed, while the baseline prevalence of violent discipline in the current study was 34.6%, we observed a rate of 46.7% in the previous cluster randomised trial that involved older children (Betancourt, Jensen, et al., 2020). The younger age range of the current study may have also impacted our ability to detect effects on caregiver–child interactions as measured by the OMCI, as this measure has been validated for use in children aged 12 months or older. In the current study, just 58% of enrolled children met this criterion at baseline.

Table 4 Implementation outcomes by respondents reported as [mean (SD)]

		PLAY collaborative			
	IZUs	Cell Mentors	SM Staff	Government	Caregivers
Adoption[a]	3.36 (0.74)	3.88 (0.20)	3.85 (0.24)	3.60 (0.33)	3.20 (0.17)
Acceptability[a]	3.92 (0.14)	3.94 (0.11)	3.97 (0.11)	3.75 (0.33)	3.92 (0.17)
Appropriateness[a]	3.94 (0.15)	3.93 (0.11)	3.90 (0.15)	3.82 (0.21)	3.89 (0.20)
Feasibility[a]	3.49 (0.30)	3.54 (0.30)	3.52 (0.34)	2.59 (0.36)	3.49 (0.30)
Implementation Leadership (Self-Report)[b]					
Proactive	3.47 (0.55)	3.49 (0.49)	3.40 (0.56)	–	–
Knowledgeable	3.58 (0.48)	3.82 (0.32)	3.93 (0.22)	–	–
Supportive	3.83 (0.34)	3.88 (0.27)	3.94 (0.13)	–	–
Perseverant	3.47 (0.55)	3.52 (0.48)	3.49 (0.53)	–	–
Overall	3.59 (0.39)	3.68 (0.31)	3.69 (0.27)	–	–
Leadership (report on cell mentors)[a]					
Implementation	3.90 (0.20)	–	–	–	–
Leadership skills	3.90 (0.17)	–	–	–	–
Organisational climate[a]	3.70 (0.25)	3.78 (0.19)	3.80 (0.19)	–	–
Seed team assessment[c]					
Assessment	–	4.70 (0.31)	4.50 (0.40)	4.50 (0.33)	–
Functioning	–	4.81 (0.30)	4.63 (0.51)	4.60 (0.37)	–
Performance	–	4.80 (0.31)	4.69 (0.43)	4.54 (0.40)	–
Skills	–	4.78 (0.32)	4.66 (0.40)	4.56 (0.36)	–
Climate	–	4.71 (0.34)	4.53 (0.42)	4.54 (0.37)	–
Identity	–	4.91 (0.20)	4.91 (0.16)	4.72 (0.33)	–
Overall	–	4.77 (0.26)	4.63 (0.32)	4.57 (0.30)	–
Program sustainability[d]					
Supportive environment	–	6.07 (0.69)	6.12 (0.62)	5.41 (0.95)	–
Funding stability	–	6.08 (0.77)	6.04 (0.81)	5.43 (1.04)	–
Partnerships	–	6.16 (0.73)	6.22 (0.67)	5.61 (0.95)	–
Organisational capacity	–	6.60 (0.52)	6.54 (0.64)	6.00 (0.76)	–
Program evaluation	–	6.66 (0.47)	6.71 (0.39)	6.18 (0.71)	–
Program adaptation	–	6.44 (0.64)	6.50 (0.56)	5.84 (0.84)	–
Communications	–	6.76 (0.44)	6.73 (0.43)	6.27 (0.70)	–
Strategic planning	–	6.56 (0.49)	6.43 (0.67)	5.96 (0.94)	–
Overall	–	6.47 (0.45)	6.41 (0.49)	5.90 (0.74)	–

[a]Uses a 4-point Likert scale where 1 = Not at all and 4 = A lot.
[b]Uses a 5-point Likert scale where 0 = Not at all and 5 = Very great extent.
[c]Uses a 5-point Likert scale where 1 = Strongly disagree and 5 = Strongly agree.
[d]Uses a 7-point Likert scale where 1 = No extent and 7 = To a very great extent.

Delivery by IZUs may have also influenced our ability to detect an intervention effect on family violence outcomes. The UC condition in this study reflects the usual activities conducted by IZUs that include identifying and intervening in cases of child abuse or neglect, as well as counselling families in conflict. It may be that IZUs are providing effective support to reduce family conflict and violence in UC families, and as a result, intervention effects on these outcomes are attenuated. In this manner, our findings may reflect a confluence of pandemic-related effects on family violence, reduced measurement sensitivity, increased exposure to coaching on family violence in the UC group, and lower ability to detect intervention effects due to the younger average age in this study.

With that said, more research is needed to understand why certain outcomes persisted in the context of scaling while others did not. We have considered a number of factors that may have influenced our results, including the COVID-19 pandemic, changes in instrument sensitivity, shifting patterns in child care and harsh discipline as children get older, and utilisation of child protection volunteers whose usual care activities involve intervening in circumstances of family conflict and child abuse/neglect. However, other possibilities may explain our results, including 'voltage drop', that is, a decrease in intervention benefits due to increasing complexity associated with the scaling process. In line with the dynamic sustainability framework (Chambers, Glasgow, & Stange, 2013), our view is that intervention optimization occurs through ongoing evaluation and refinement while scaling delivery. Thus, our study presents an opportunity to better understand the contextual factors that could improve fit between SM and the context of implementation. Toward these ends, we are reviewing the curriculum and training materials, as well as meeting minutes and other documentation from PLAY Collaborative meetings, while also examining the implementation context to identify areas for improvement.

Implementation outcomes indicate that the PLAY Collaborative quality improvement cycles were able to maintain and improve the quality of SM delivery by IZU volunteers, demonstrated in our assessments of fidelity and competence, which never fell below 80% and achieved >90% by the end of the intervention. Caregivers, PLAY Collaborative members and IZUs all perceived SM to be adoptable, acceptable, appropriate and feasible. Cell Mentors, FXB staff and government officials perceived the PLAY Collaborative positively as well, as evidenced by their high endorsements of the Seed Team, leadership and organisational climate. Perceptions of programme sustainability were slightly more variable, particularly with regard to the more practical aspects, such as funding stability, but overall, the results suggest that the PLAY Collaborative successfully acquired buy-in, which may support further scaling and expansion.

Collectively, our findings indicate that the PLAY Collaborative implementation strategy may be a useful model for scaling a parenting programme to promote ECD and prevent violence while also establishing the necessary structural and procedural supports that will enable further system integration and sustainment. SM addresses a key gap in ECD and child protection systems in Rwanda by reaching the most vulnerable, hard-to-reach families who lack access to ECD centres and other services due to extreme poverty, but who are a focus of government initiatives aimed at graduation from poverty. The PLAY Collaborative linkages both to government social protection and child protection initiatives presented a "win-win" by which extending the reach of an EBI with quality to the most impoverished households also helped address social protection goals of human capital formation as well as further capacitating and providing support to the extant cadre of child protection volunteers. By engaging the most vulnerable families in playful parenting and stimulation involving both male and female caregivers and by bolstering family resilience and conflict resolution, caregivers receiving SM may be better able to help their young children have the foundations of numeracy, language and self-regulation crucial for school readiness. As demonstrated by other early intervention research with long-term follow-up (Abimpaye, Dusabe, Nzabonimpa, Ashford, & Pisani, 2020; Attanasio et al., 2014; Atukunda et al., 2019; Campbell & Ramey, 1994; Cooper et al., 2009; Gertler et al., 2014; Grantham-McGregor, Powell, Walker, Chang, & Fletcher, 1994; Grantham-McGregor, Walker, Chang, & Powell, 1997; Jeong et al., 2021; Justino et al., 2023; Kakwangire et al., 2024; Muhoozi et al., 2018; Rockers et al., 2016, 2018; Walker, Chang, Powell, Simonoff, & Grantham-McGregor, 2006; Walker, Chang, Vera-Hernández, & Grantham-McGregor, 2011; Walker, Chang, Younger, & Grantham-McGregor, 2010; Walker, Grantham-Mcgregor, Powell, & Chang, 2000; Yousafzai et al., 2016), such investment may enhance future success with implications for social and economic outcomes.

Study limitations must be noted. A longer horizon of follow-up is needed to evaluate whether the changes in caregiver behaviour we observed immediately following the intervention led to improvements in child development outcomes. Previous research examining the effects of SM 1 year after the intervention found improvements in children's gross motor, communication, problem-solving and socioemotional development (Desmond et al., 2023; Jensen et al., 2021); a follow-up of the present study is underway to evaluate whether intervention effects are maintained and whether children's development improves with time. Fidelity and competence evaluations by the Seed Team on IZUs that they trained may also have been biased. In future assessments, independent observers would be a more rigorous means of assessment. In addition, the sustainment of SM within the three Rwandan Districts where it was scaled out in the present study will require budgetary commitments and the adoption of the quality improvement strategies assessed in the PLAY Collaborative trial. These strategies were co-developed in close partnership with Rwandan stakeholders in an iterative manner, including both government and university partners (several included as co-authors in the present manuscript). Current efforts are underway to expand and sustain the programme with its quality improvement tools maintained after scale-out. Finally, SM was developed to meet the needs of the most impoverished families with young children in rural areas of Rwanda, so the findings may not generalise to other populations or settings.

Conclusion

The PLAY Collaborative implementation strategy successfully extended the reach and maintained most effective outcomes when moving an evidence-based home-visiting intervention from a trial-selected workforce to child protection volunteers linked to the Government of Rwanda. Continued sustainment of the intervention with quality will require scaffolding in terms of policy, financing, human resources and quality improvement investments at greater scale.

Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article:

Appendix S1. Training and oversight structure of the PLAY Collaborative.

Appendix S2. Assessment of developmental milestones and anthropometrics.

Appendix S3. Quality of delivery measures.
Appendix S4. Unadjusted results.
Appendix S5. Raw means, standard deviations, and observed sample sizes by treatment group and time-point.

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The authors want to thank the families who have been involved in the front-line effort to improve the prospects for their young children and the many Rwandan Government leaders who are committed to ensuring their success. They thank their partners at the University of Rwanda Centre for Mental Health, and the Government of Rwanda's Ministry of Gender and Family Promotion and National Child Development Agency. They also thank all of the personnel who played a role in designing and assessing a strategy for scaling Sugira Muryango and the funders of this work, including LEGO Foundation, Oak Foundation, Echidna Giving, The ELMA Foundation, and Wellspring Philanthropic Fund.

The authors have declared that they have no competing or potential conflicts of interest.

Ethical considerations
Caregivers provided written and/or oral consent for both themselves and their children prior to study enrolment. The Rwanda National Ethics Committee (Registration #00001497) and Boston College Institutional Review Board (Protocol #21.220.01) approved and oversaw the study.

Endnotes
1. Among children aged 6–11 months.
2. Inadequate care is defined using the MICS 5 definition: being left in care of someone under 10 years for more than 1 hr or being left alone for 1 hr or more in the past week.
3. Indicated by an Hopkins Symptom Checklist score of 1.75 or higher (Mollica, Wyshak, de Marneffe, Khuon, & Lavelle, 1987; Winokur, Winokur, Rickels, & Cox, 1984).

Trial registration
This trial was registered on ClinicalTrials.gov (NCT04257383) February 6, 2020.

Data availability
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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Key points

What's known
- There is a critical need for evidence-based implementation strategies that support large-scale implementation and integration of EBIs within service systems globally.

What's new
- In a Hybrid Type-2 Implementation-Effectiveness trial, we studied the PLAY Collaborative implementation strategy to engage government and other stakeholders in scaling a parenting programme to promote ECD and prevent violence, Sugira Muryango, as linked to the social protection system and delivered by child protection community volunteers across three districts in rural Rwanda.

What's relevant
- The PLAY Collaborative successfully scaled delivery of Sugira Muryango, maintaining impact and quality while overcoming implementation barriers and using a new child protection volunteer workforce coordinated by the Rwandan Government.

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