



Lay-worker Delivered Home Visiting Promotes Early Childhood Development and Reduces Violence in Rwanda: A Randomized Pilot

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Abstract

Early child development (ECD) programs are increasingly combined with targeted cash transfers for poor households to break intergenerational poverty. However, few evidence-based, scalable, and sustainable ECD programs that complement cash transfer programs exist in low- and middle-income countries. We conducted a cluster-randomized pilot study to assess whether Sugira Muryango, a strengths-based home-visiting intervention to promote child development and prevent violence among children aged 6–36 months, could be delivered by community-based lay workers to poor families participating in Rwanda’s cash-for-work Vision Umurenge Program (VUP). Data collection occurred among 38 families at baseline, endline, and 6 months after the intervention and included child-level (child engagement, caretaking, and health and development), caregiver-level (family unity and mental health) and household-level (water and sanitation practices and family conflict) outcomes. We compared trajectories of Sugira Muryango families vs. families receiving the cash transfer only over time using mixed-effect models. Sugira Muryango children experienced significantly greater ECD engagement than children in control families and marginally significant reductions in exposure to violent disciplinary methods. Sugira Muryango caregivers reported greater shared decision-making between parents and marginally significant improvements in family unity and anxiety. Conflict within intervention households halved between baseline and follow-up. Satisfaction was high. This randomized pilot demonstrates that Sugira Muryango can be delivered by community-based lay workers, improves access to nurturing care and stimulation among children living in poverty, and may reduce intra-family conflict. A large-scale effectiveness study is underway to assess the intervention’s impact on child development and health outcomes.

Keywords Early childhood development · Home-visiting · Community health workers · Rwanda · Social protection · Social safety nets

Highlights

- This study describes a randomized pilot study of Sugira Muryango, a strengths-based home-visiting intervention to promote child development among vulnerable children in Rwanda.
- The pilot study demonstrated that Sugira Muryango can be successfully delivered by community-based lay workers.
- This pilot study also provides evidence that Sugira Muryango improves access to nurturing care and stimulation among children living in poverty and may reduce intra-family conflict.

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Despite substantial progress in reducing global child mortality (Requejo et al. 2015), today, over 250 million children under 5 years old in the developing world risk not reaching their full potential because of deficient investments in nutrition, early stimulation, early learning, and nurturing care, as well as due to exposure to stress (Britto et al. 2017). When children are born into poverty, they face increased risk of malnutrition, infectious disease, exposure to family stress and violence, and suboptimal development outcomes (Walker et al. 2011, 2007). These effects are often intergenerational, with children raised in extreme poverty facing elevated risk of poverty and poor mental and physical health outcomes as adults (Black et al. 2017). Targeted early childhood interventions can help break intergenerational cycles of poverty by preventing disability and promoting child development, nutrition, and growth (Britto et al. 2017; Engle et al. 2011; Walker et al. 2015). In addition to complementing the global agenda to reduce child mortality (Chan 2013), promoting child development also has the potential to improve mental and physical wellbeing throughout the life course (Grantham-McGregor et al. 2007; Kessler et al. 2010; Norman et al. 2012) and to reduce poverty in adulthood (Gertler et al. 2014; Hoddinott et al. 2008).

Strategies for promoting child development are diverse and include increasing coverage for key medical services, improving child nutrition, protecting children from violence, and promoting environments and activities that stimulate mental and social development. There is growing evidence that multi-sectoral ECD interventions that span several domains of child health and wellbeing (i.e. health, nutrition, social protection, etc.) can be implemented at-scale in LMICs (Britto et al. 2017). Successful programs have been shown to improve children's developmental outcomes in a wide variety of settings including Bangladesh (Aboud et al. 2013), Colombia (Attanasio et al. 2014), Jamaica (Grantham-McGregor and Smith 2016), Pakistan (Yousafzai et al. 2014), Peru (Josephson et al. 2017), the Philippines (Armeccin et al. 2006), and Uganda (Singla et al. 2015). These successful ECD interventions share several traits that allow them to be effective, scalable, and sustainable in resource-limited settings. They often use a home-visiting approach, which can allow for individualized services to be delivered to hard to reach families (Peacock et al. 2013). They rely on task-shifting, where tasks traditionally conducted by specialized health professionals are conducted by less specialized or lay workers receiving targeted supervision and support (Lehmann et al. 2009). Finally, these ECD programs are often integrated into existing social services, which can both reduce costs of operation and improve continuity of care for children and families (Britto et al. 2017). When ECD programs are integrated with existing social protection and poverty reduction services (Arriagada et al. 2018; Attanasio et al.

2014) it can create additional opportunities to identify and reach extremely vulnerable households. However, despite highly prevalent violence towards children in LMICs (UNICEF 2010), very few ECD interventions in LMICs integrate violence reduction or prevention activities into their curriculums (Efevbera et al. 2018; Mejia et al. 2017).

In Rwanda, where 38% of all households live in poverty (National Institution of Statistics of Rwanda 2018) and 38% of children under five are stunted (World Bank Group 2018), the National Early Childhood Development Program (NECDP) is seeking to develop effective, scalable, and sustainable ECD programs. To better address the needs of vulnerable families with young children, the NECDP is currently collaborating with the Vision 2020 Umurenge Programme (VUP), the government's flagship social protection program that provides cash-for-work opportunities and direct support via cash transfers to Rwanda's poorest families. In this context and in collaboration with the Rwandan government, we developed Sugira Muryango (Strengthen the Family) a strengths-based, home-visiting intervention designed to complement Rwanda's existing NECDP and VUP programs by promoting family strengthening and child development among the most vulnerable families in Rwanda. While a previous open trial showed that Sugira Muryango can be delivered to families by bachelor's level interventionists (Betancourt et al. 2018), it was not known whether the intervention could be delivered by less specialized community based volunteers (CBVs). This 38-family clustered randomized pilot study was designed to assess whether Sugira Muryango can be successfully delivered using CBVs and to provide preliminary evidence on the impact of the intervention on key outcomes and to inform the design of a larger cluster randomized trial, currently under implementation.

Methods

Participants

Families were eligible to participate in Sugira Muryango if they were eligible for the flagship Vision Umurenge Program, which provides cash for work for families in the lowest level (level one, indicating extreme poverty) of the Rwandan government's household socio-economic categorization system, *Ubudehe*; had a child aged 6–36 months; and were willing to participate in the home-based intervention. Exclusion criteria were severe and active crisis in the family (e.g., divorce proceedings) or active mental health crises among caregivers (e.g., active psychosis or suicide attempts). A list of families who were eligible to participate in the VUP was provided by local government staff in the Rubona and Munyaga sectors of the Rwamagana

District. Families were visited by study staff to confirm eligibility for the study and enrollment in VUP. Because a single CBV is expected to provide Sugira Muryango to up to five families, enumerated families were grouped into geographic clusters which included at least five families that could feasibly be served by a single coach. To reach our target sample of 40 families, we selected eight clusters to participate in the trial and randomized each cluster to either the intervention or VUP cash-only control arm. In each cluster, five families were randomly selected for enrollment in the study. If, at enrollment, families were no longer eligible for the program or interested in participating, a replacement family was randomly selected from the remaining families in that cluster until no more families were available. Families from the intervention arm were also replaced if they moved away from the area after enumeration. Families in both the control and intervention arms remained eligible and able to participate in VUP and other social support programs throughout the duration of the trial. In practice, all families in both the intervention and control arms participated in the VUP program during the course of the study. Families also received 3000 RWF (equivalent to between 3–4 US\$) for participation in each of the endline and follow-up surveys.

Procedures

Intervention development

Sugira Muryango is an assets-based family intervention that integrates material adapted from the Family Strengthening Intervention for HIV (FSI-HIV), a parenting and family home-visiting intervention developed and tested among HIV-affected families in Rwanda (Betancourt et al. 2011a, b, 2014), and the WHO/UNICEF Care for Child Development Packages (UNICEF & World Health Organization 2012). Sugira Muryango uses active coaching to promote responsive parenting, reduce family conflict, and increase caregivers' abilities to access and navigate available resources. Sugira Muryango was developed for the Rwandan context using input from local and international ECD experts, Rwandan government stakeholders, and local community advisory boards. To help families internalize core skills, Rwandan songs and proverbs were incorporated into the curriculum. Between November 2014 and June 2015, 20 families were enrolled in an open-trial pilot to assess the feasibility of adapting the FSI-HIV intervention to the needs of economically vulnerable families (Efevbera et al. 2018). Lessons from this initial pilot study were used to refine the Sugira Muryango curriculum and training materials.

The final Sugira Muryango intervention consists of 12 modules targeting five key components: (1) Educating

caregivers on children's development, nutrition, health, and hygiene; (2) Coaching parents on responsive parenting and "serve and return" interactions (Center on the Developing Child 2007); (3) Reducing violence by promoting family resilience in the face of adversity, positive parenting, and skills in conflict resolution; (4) Strengthening parental problem solving skills and social support through improved navigation of available formal and informal resources; and (5) Promoting early language learning and school readiness (see Appendix). Modules are designed to be administered consecutively and to be able to be completed in a single 60–90-min session; however, the number of sessions required to complete the modules can be customized based on each family's needs, with a typical program including one session every week over the course of 3–4 months. This curriculum was reviewed by counterparts at the Ministry of Gender and Family Promotion, the National Commission for Children, UNICEF and Imbuto Foundation, the lead government agencies and organizations involved in the roll out of the NECDP.

Counselor training and supervision

CBVs were selected from the same communities as families assigned to receive Sugira Muryango. CBVs were required to be Rwandan; be 18 years of age or older; be able to read, write, and count in Kinyarwanda; be committed to young children and family values; have sufficient time to carry out Sugira Muryango training and delivery; and be recommended and approved by local community and authorities. Candidates were nominated by village chiefs and elected to the position during a village-level meeting. CBVs attended a 2-week training session prior to delivering the intervention. CBVs received expert supervision from the bachelor's level staff members with training in clinical psychology or social work who had delivered the intervention in the previous open trial. Once every other week, supervisors visited CBVs in their homes to provide supervision and pick-up audio-recorded sessions. Supervisors listened to these recordings to ensure that CBVs were delivering the intervention with fidelity and provided CBVs with feedback to improve their performance via phone conversations every other week. During the 3rd and 6th week of the intervention, supervisors provided CBVs with in-person shadowing in families' homes and provided feedback immediately after the session. During months two and three of the intervention, supervisors also facilitated monthly group discussions with the CBVs at the cell or sector office to address common challenges and support group problem solving. Supervisors received coaching from trained psychologists who listened to audio recorded sessions and met with the supervisors twice a month during fidelity assessment and strengthening sessions. CBVs received a monthly stipend

which covered communication between CBVs and expert supervisors (5800 RWF), transport to houses (6000 RWF), and compensation for an estimated 3 h of work per day (15,000 RWF). These parameters for recruitment and compensation were designed to be similar to existing volunteer workforce norms for community health workers and family focused community social workers, elements essential to the potential scalability of the model.

Measures Comprehensive quantitative batteries were administered verbally by expert supervisors immediately before the intervention (baseline), immediately after the intervention (endline), and 6 months after the intervention (follow-up). The primary caregiver, identified as the caregiver who stated that they knew the child best, was invited to provide information on each child aged 6–36 months in the household. If the primary caregiver was not available at the time of the interview, a secondary caregiver was invited to provide information on the child. Any self-identified caregivers who consented to data collection and were available at the time of the interview were invited to provide information on family functioning, their mental health, knowledge related to ECD, and household health practices. For intervention households, the endline batteries also included questions related to parental satisfaction with the intervention.

Child engagement

We hypothesized that increased child engagement through early learning activities and responsive parenting would mediate the relationship between Sugira Muryango and improved child health and development outcomes. We assessed child engagement through multiple measures. Engagement in ECD activities reflected the number of different learning and school readiness activities among six activities (reading or looking at books; telling stories; singing songs; going outside; playing; or naming, counting, or drawing) the child was engaged in during the past three days prior to assessment. These items were taken from the Multiple Indicator Cluster Survey (MICS), a standardized survey used to assess child health and development in over 100 LMICs (UNICEF 2018). To assess the quality and availability of stimulating activities in the home environment, we used a version of the Home Observation for Measurement of the Environment (HOME) inventory (Bradley and Corwyn 2005) adapted for use in Uganda (Singla et al. 2015). This adapted inventory was calculated as a sum of 43 yes–no items and demonstrated adequate reliability (Cronbach's $\alpha = 0.73$). We assessed responsive parenting using the Observation of Mother-Child Interaction (OMCI) tool (Rasheed and Yousafzai 2015). This 19-item tool assessed the number of times various behaviors (e.g., caregiver shows positive touch, child smiles at

caregiver) were observed during a 5-min caregiver–child interaction by a well-trained local research assistant. Items were scored using a four-point Likert scale (never = 0, 1–2 times = 1, 3–4 times = 3, 5 times = 4), exhibited good reliability (Cronbach's $\alpha = 0.83$), and were summed to calculate the total score.

Caretaking indicators

To assess the impact of our intervention on positive parenting and use of harsh disciplinary practices compared to desirable practices, we used indicators for inadequate caretaking and child discipline practices from the MICS Child Development and Child Disciplinary Modules (UNICEF 2010). Inadequate caretaking was defined as being left alone or in the care of another child under the age of 10 in the past week. Exposure to violent disciplinary practices was defined as the child having experienced being insulted, shouted or screamed at, shook, slapped, or beat as a form of punishment. Exclusive exposure to nonviolent disciplinary practices was defined as the child having experienced no forms of violent discipline and at least one of nonviolent disciplinary practices, which included restricting the child's privileges, explaining why what the child did was wrong, or giving the child work (Kessler et al. 2010).

Child health indicators

To assess the impact of the intervention on child health, we investigated the prevalence of diarrhea, fever, or cough within the last 2 weeks. Among parents of children reporting illness, we also assessed whether parents sought medical care from a health facility. To assess children's nutritional status, we calculated a dietary diversity score reflecting the number of food groups (out of seven) the child had consumed in the past week (USAID et al. 2008).

Child development measures

We assessed cognitive, social, and physical development using the gross motor, fine motor, and language subscales of the Malawi Developmental Assessment Tool (MDAT) (Gladstone et al. 2010) and the communication, gross motor, fine motor, problem solving, and personal social subscales from the Ages and Stages Questionnaire-3 (ASQ-3) (Squires et al. 2009). For each subscale, we calculated age-standardized *z*-scores using means and standard deviations obtained from Malawi for the MDAT (Gladstone et al. 2010) and from Zambia and South Africa for the ASQ-3 (Hsiao et al. 2017). The MDAT exhibited excellent reliability for the gross motor (Cronbach's $\alpha = 0.91$), fine motor (Cronbach's $\alpha = 0.92$), and language (Cronbach's $\alpha = 0.95$) subscales. Because the ASQ-3 uses a distinct set of

questions for different age groups, our sample size was not sufficient to assess the internal reliability of the ASQ; however, when comparing z -scores for the MDAT and the ASQ-3, we observed significant and positive correlations between the language and communication subscales ($r = 0.63$), the fine motor subscales ($r = 0.58$), and the gross motor subscales ($r = 0.61$).

Family functioning

To assess the impact of Sugira Muryango on family functioning, we assessed shared decision making between caregivers, family unity, and presence of household conflict. Among households with a dual-caregiver mother–father structure, we assessed shared decision making between parents using items adapted from the Demographic and Health Surveys Women’s Status Modules (Measure DHS & ICF International 2013) by calculating the percentage of seven household decisions (e.g., “who usually makes decisions about what the child eats,” “who usually makes decisions about major household purchases”) where partners indicated that they shared equally in decision making. We used a 12-item version of a locally developed scale to assess family unity (*kwizerana*) (Betancourt et al. 2011b, a, 2018; Chaudhury et al. 2016). Both the shared decision making (Cronbach’s $\alpha = 0.86$) and the family unity (Cronbach’s $\alpha = 0.95$) scales demonstrated high reliability. Presence of family conflict was defined as having at least one caregiver in the home report serious conflict in the household (arguing, shouting, screaming, hitting, or violence or abuse due to alcohol or drug problems) in the past 6 months and was analyzed at the household level.

Caregiver mental health

Among caregivers, we assessed mental health status using the Hopkins Symptom Checklist (HSCL) for internalizing behaviors (Cronbach’s $\alpha = 0.93$), including the depression (Cronbach’s $\alpha = 0.88$) and anxiety (Cronbach’s $\alpha = 0.87$) subscales (Hesbacher et al. 1980). The scale and its clinical thresholds were previously validated for use in Rwanda (Bolton 2001). We also used an adapted Difficulties in Emotion Regulation scale (Gratz and Roemer 2004), which exhibited high reliability after omitting reverse-coded items (Cronbach’s $\alpha = 0.92$). The decision to omit reverse-coded items was based on poor psychometric properties of the reverse-coded items and is supported by previous research suggesting that negatively-worded items can be interpreted differently when they are translated into different languages and cultures (Lindwall et al. 2012; Schmitt and Allik 2005; Watkins and Cheung 1995) and that negatively-worded items in the DERS may contribute to method effect bias (Bardeen et al. 2016).

Caregiver knowledge of ECD

To assess the impact of the intervention on caregiver knowledge of ECD, we calculated the percentage of correct responses among nine yes–no items taken from the Rwandan knowledge, attitudes, and practices on early nurturing of children questionnaire (Ministry of Health, UNICEF 2014).

Household health practices

At the household level, we assessed self-reported access to health insurance among children in the household and Water, Sanitation, and Hygiene (WASH) indicators including use of improved water source (e.g., piped water, covered well), use of improved sanitation source, (e.g., pit latrine), appropriate water treatment (e.g., boiling), and presence of a handwashing station with soap (World Health Organization & UNICEF 2006).

Data Analysis

Respondent characteristics at baseline were examined among all respondents. We compared the trajectories of outcomes over time among families receiving the Sugira Muryango intervention and control families using linear mixed models for continuous outcomes and generalized linear mixed models with a logit link and binomial distribution for binary outcomes (Fitzmaurice et al. 2011). We modeled time using discrete indicators and used Wald tests to assess the joint null hypothesis that there were no differences over time between the treatment and control groups at both endline and follow-up. For outcomes assessed at the child level, we included a random effect for cluster and family and adjusted for household structure, child sex, child age at baseline, and presence of birth complications or preterm birth. For outcomes assessed at the caregiver level, we included random effects for randomization cluster, family, and caregiver and adjusted for family structure, caregiver age at baseline, caregiver relation to child, and caregiver educational attainment. For outcomes assessed at the household level, we included random effects for randomization cluster and family and adjusted for family structure. We used multiple imputation by chained equations to impute item-level missingness (as would occur when a single item was missing from a scale) and total outcome missingness (as would occur if a respondent was unavailable at a given time point) (Plumpton et al. 2016; Royston 2014). Regression-based multiple imputation methods have been demonstrated to perform well even in sample sizes as small as 20 (Barnes et al. 2006), and formulas and additional details on calculating degrees of freedom in multiply imputed data can be found in van

Ginkel and Kroonenberg (2014). Our exclusion of families who migrated from their cluster between the time of enumeration and the time of enrollment in the intervention but not control arm could have introduced selection bias into our study, so we conducted a sensitivity analysis where we also excluded the two control families who moved between enumeration and enrollment. Finally, to assess the acceptability of delivering Sugira Muryango using CBVs rather than bachelor's level interventionists, we used Fisher's Exact tests to compare parental satisfaction reported in the current trial to parental satisfaction reported in our previous open trial (Betancourt et al. 2018). Qualitative interviews with caregivers who received the intervention were also collected at this time but will be reported on elsewhere. All analyses were conducted using STATA 15 (StataCorp 2017).

Results

Participants and Sample Characteristics

Of the 227 Households identified from the list of families eligible for VUP public works, 83 were also eligible for participation in the trial. The eight clusters selected for randomization included 50 families. We enrolled 18 of the 23 families from the intervention clusters and 19 of the 27 families from the control clusters (Fig. 1). Forty-one children and 64 caregivers participated in at least one round of data collection. Caregiver participation in data collection was similar in both the intervention and control groups at baseline (25 versus 26), endline (29 versus 31), and follow-up (30 versus 29). There were no significant differences between the intervention and control groups in family structure, caregiver relation to child, caregiver age, or caregiver education (Table 1). All intervention families

completed all 12 modules before endline assessment. Relative to the control group, children in the intervention group were more likely to be male, less likely to have been premature or reported birth complications, and were significantly younger ($t(39) = 2.25, p = 0.03$) though the difference was small in magnitude. One child in the intervention group reported to be 6 months old at baseline was later determined to have been 5 months old at baseline, but was retained in the study.

Child Engagement, Caretaking, Health, and Development

Compared to control children, children receiving Sugira Muryango experienced significantly greater improvements in child engagement when assessed by engagement in ECD activities ($F(2, 2161.9) = 6.95, p = 0.001$), the HOME ($F(2, 726.8) = 4.63, p = 0.01$), and the OMCI ($F(2, 77,6597.6) = 4.54, p = 0.01$) (Table 2). At endline, children in the intervention group were engaged in more ECD activities in the last 3 days (4.3 vs. 3.3), had higher HOME scores (29.3 vs. 23.5), and exhibited greater improvements in OMCI scores compared to the control group. There were no significant changes in either the proportion of children who experience inadequate caretaking or who experienced the exclusive use of nonviolent punishment. Despite similar prevalences of violent punishment among children in intervention (63%) and control households (78%) at baseline, by endline violent punishment among children in intervention households (32%) was about a third of that in control households (93%). However, at follow-up visit the difference between the proportion of children experiencing violent punishment in intervention (40%) and control (60%) households had diminished such that the test for an overall difference over time was only marginally significant.

Fig. 1 Participant selection

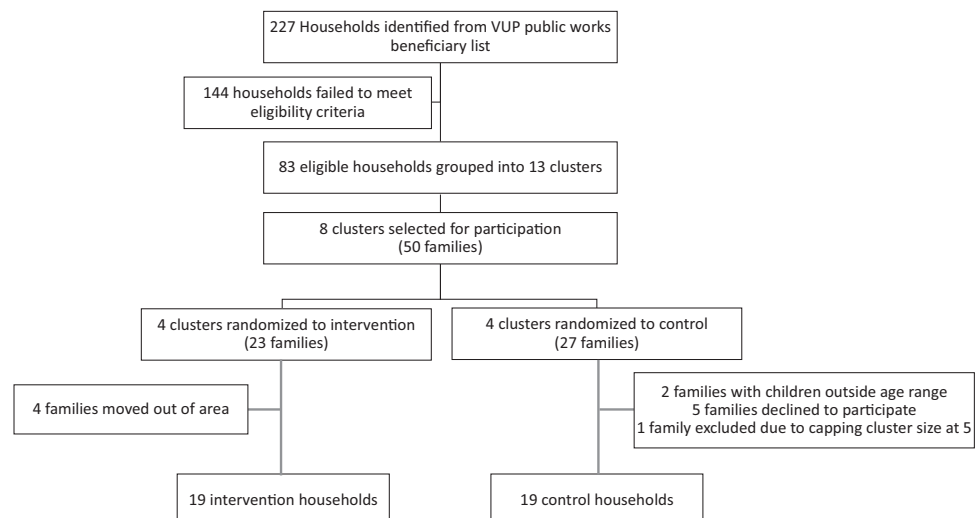


Table 1 Descriptive statistics at baseline by intervention arm

	Intervention <i>N</i> (%) Mean (SD)	Control <i>N</i> (%) Mean (SD)	<i>p</i> value
Households	<i>N</i> = 19	<i>N</i> = 19	
Family structure			
Single caregiver	6 (32%)	7 (37%)	1.00
Dual mother/father	10 (53%)	10 (53%)	
Other dual caregivers	3 (16%)	2 (11%)	
Caregivers	<i>N</i> = 32	<i>N</i> = 32	
Relationship to child			0.83
Biological mother	19 (59%)	17 (53%)	
Biological father	7 (22%)	9 (28%)	
Grandparent	6 (19%)	5 (16%)	
Aunt/uncle	0 (0%)	1 (3%)	
Age	39 (13)	39 (12)	0.96
Educational status			0.17
No school			
<6 years primary	7 (22%)	7 (22%)	
≥6 years primary	20 (62%)	20 (62%)	
Secondary/ vocational school	1 (3%)	1 (3%)	
Children	<i>N</i> = 19	<i>N</i> = 22	
Male	10 (53%)	8 (36%)	0.35
Age (month)	21 (7.9)	26 (6)	0.030
Premature/birth complications	3 (16%)	8 (36%)	0.17

Categorical variables were assessed using Fisher's Exact Test. Continuous variables were assessed using a two-sample *t*-test

Generally, children receiving Sugira Muryango did not experience different health or development outcomes compared to children in the control arm—dietary diversity, prevalence of diarrhea, and prevalence of fever were similar in the two groups across all time points. Although the prevalence of cough exhibited a significantly different trend over time ($F(2, 19,849.5) = 3.70, p = 0.0248$) this difference largely reflected a low baseline prevalence in the intervention arm rather than a positive effect of the intervention. Although not significant, parents in the intervention group were markedly more likely to seek health care for their children who experienced diarrhea, fever, or cough than parents in the control group at both baseline and endline. In this small pilot study with a 6-month follow-up, we did not observe significant differences in physical, cognitive, or social development as measured by the MDAT or the ASQ.

Family Strengthening, Caregiver Mental Health, and Knowledge about ECD

Among caregivers living in households with a dual mother–father caregiver structure, shared decision making

increased significantly in intervention households relative to control households ($F(2, 33.0) = 3.37, p = 0.047$), Table 3). Caregivers in intervention households also reported marginally greater increases in family unity, and family unity in intervention households continued to improve in intervention households even after the end of the intervention. Similarly, the proportion of household reporting serious family conflict was very stable in the control group but more than halved in the intervention group (24 to 9%), although the trend over time was not significant (Table 4). Caregivers in intervention households also experienced marginally significant decreases in internalizing problems and anxiety (Table 3). While non-significant, depression and DERS also decreased in the intervention arm, but remained stable in the control arm. Caregivers receiving the intervention also reported a non-significant improvement in knowledge about ECD, while knowledge remained stable among controls.

Household Health Practices

The intervention and control households did not differ in terms of access to insurance, improved water sources, or improved sanitation sources (Table 4). We observed a significant change in the proportion of intervention households using a water treatment method ($F(2, 23,943.1) = 3.19, p = 0.04$), which was driven by differences at endline (68 vs. 8%) but not sustained at follow-up (32 vs. 24%). While not reaching the $p < 0.05$ level of statistical significance, intervention households were three times as likely to have a handwashing station with soap at the 6-month follow up compared to control households (15 vs. 5%).

Sensitivity Analysis

Results were substantively unchanged in a sensitivity analysis where we excluded families from the control arm who moved between enumeration and enrollment.

Caregiver Satisfaction

At the end of the program, 29 caregivers from intervention households reported on being satisfied (vs. dissatisfied or neutral) with the intervention. Compared to caregivers in the open trial who received an intervention delivered by a bachelor's level interventionist, caregivers who received the intervention delivered by CVBs were equally likely to report overall satisfaction (100 vs. 97%), satisfaction with the information gained (100 vs. 97%), satisfaction with the information content (93 vs. 100%), a willingness to return to the program in the future (86 vs. 97%), and a feeling that Sugira Muryango met their needs (79 vs. 80%). In both

Table 2 Model-based population estimates and (95% CI) for key outcomes among children (N = 41)

	Intervention			Control			p value ^a
	Baseline	Endline	Follow-up	Baseline	Endline	Follow-up	
Health indicators							
Dietary Diversity Score	2.3 (1.8, 2.9)	2.8 (2.2, 3.4)	3.2 (2.6, 3.8)	2.3 (1.8, 2.9)	2.7 (2.2, 3.2)	2.8 (2.3, 3.3)	0.75
Prevalent diarrhea ^b (%)	23 (6, 59)	4 (1, 27)	2 (0, 20)	24 (6, 59)	42 (16, 73)	10 (2, 40)	0.15
Care-seeking for diarrhea ^c (%)	18 (0, 99)	64 (1, 100)	100 (-, -) ^d	95 (13, 100)	5 (0, 91)	50 (1, 99)	0.46
Prevalent fever ^b (%)	23 (9, 49)	23 (9, 49)	69 (44, 86)	60 (37, 79)	66 (43, 83)	61 (39, 80)	0.06
Care-seeking for fever ^e (%)	91 (44, 99)	61 (18, 92)	91 (60, 98)	81 (43, 96)	47 (22, 73)	47 (21, 75)	0.47
Prevalent cough ^b (%)	25 (9, 55)	25 (9, 55)	71 (40, 90)	81 (54, 94)	17 (5, 44)	95 (78, 99)	0.02
Care-seeking, cough ^f (%)	49 (6, 94)	94 (27, 100)	96 (53, 100)	61 (18, 92)	32 (1, 94)	59 (20, 89)	0.24
Child caretaking							
Inadequate care (%)	64 (37, 85)	57 (31, 80)	76 (49, 92)	72 (45, 89)	71 (45, 88)	65 (40, 84)	0.54
Violent punishment (%)	63 (33, 86)	32 (11, 64)	40 (16, 70)	78 (49, 93)	93 (69, 99)	60 (32, 83)	0.10
Nonviolent punishment only ^g (%)	4 (0, 31)	19 (4, 54)	10 (2, 40)	5 (1, 30)	5 (1, 30)	12 (2, 44)	0.38
ECD engagement							
ECD activities in last 3 days	2.9 (2.1, 3.8)	4.3 (3.5, 5.1)	4.2 (3.4, 5.0)	3.4 (2.6, 4.2)	3.3 (2.5, 4.0)	2.4 (1.6, 3.1)	0.001
HOME	25 (23, 26)	29 (28, 31)	28 (27, 30)	24 (22, 25)	24 (22, 26)	25 (24, 27)	0.01
OMCI	38 (35, 41)	42 (39, 45)	43 (40, 46)	42 (39, 45)	37 (34, 41)	42 (39, 46)	0.01
Child development							
MDAT gross motor	0.2 (-0.4, 0.8)	0.4 (-0.2, 1.0)	0.3 (-0.3, 0.9)	-0.2 (-0.8, 0.3)	-0.0 (-0.6, 0.5)	-0.0 (-0.6, 0.5)	0.97
MDAT fine motor	0.0 (-0.6, 0.6)	0.4 (-0.1, 1.0)	0.6 (0.1, 1.2)	-0.2 (-0.8, 0.3)	0.2 (-0.4, 0.7)	0.4 (-0.1, 0.9)	1.00
MDAT language	0.2 (-0.5, 0.8)	0.4 (-0.2, 1.0)	0.8 (0.2, 1.5)	-0.3 (-0.9, 0.3)	0.4 (-0.2, 0.9)	0.2 (-0.4, 0.8)	0.32
ASQ communication	-1.5 (-2.4, -0.6)	-1.2 (-2.0, -0.3)	-0.7 (-1.5, 0.2)	-2.3 (-3.3, -1.4)	-2.0 (-2.7, -1.2)	-1.3 (-2.1, -0.5)	0.87
ASQ gross motor	-1.5 (-2.7, -0.3)	-1.7 (-2.9, -0.5)	-1.5 (-2.6, -0.4)	-2.9 (-5.2, -0.5)	-3.0 (-4.0, -2.0)	-2.1 (-3.1, -1.1)	0.85
ASQ fine motor	-2.1 (-3.3, -0.8)	-1.1 (-2.1, -0.1)	-1.1 (-2.1, -0.1)	-1.9 (-4.3, 0.4)	-1.8 (-2.7, -0.8)	-1.4 (-2.3, -0.5)	0.63
ASQ problem solving	-1.9 (-3.1, -0.7)	-0.9 (-1.8, -0.1)	-0.7 (-1.5, 0.2)	-1.6 (-2.8, -0.4)	-1.1 (-1.8, -0.3)	-1.2 (-2.0, -0.5)	0.21
ASQ personal social	-1.6 (-2.5, -0.7)	-0.7 (-1.5, 0.1)	-0.8 (-1.6, 0.0)	-1.7 (-3.4, 0.1)	-1.2 (-2.0, -0.5)	-1.3 (-2.0, -0.6)	0.61

Outcomes analyzed using a logistic mixed model are noted with a (%). All others were analyzed with a linear mixed model. All models included random intercepts for cluster and child and were adjusted for family structure, child's age at baseline, sex, and presence of birth complications/premature birth unless otherwise noted

^aTest for treatment by time interaction
^bPrevalence defined as within the past 2 weeks
^cAmong those reporting diarrhea, N = 31 child-visits
^dCare was sought for all intervention children reporting diarrhea at the 6-month follow-up; standard errors not available
^eAmong those reporting fever, N = 62 child visits
^fAmong those reporting cough, N = 66 child visits; family structure excluded from the model due to collinearity with outcome
^gPremature/birth complication excluded from the model due to collinearity with outcome

Table 3 Model-based population estimates and (95% CI) for key outcomes among caregivers ($N = 64$)

	Intervention			Control			<i>p</i> value ^a
	Baseline	Endline	Follow-up	Baseline	Endline	Follow-up	
% of tasks with shared decision making ^b	38 (21, 55)	52 (33, 71)	57 (38, 75)	61 (45, 78)	40 (25, 56)	48 (32, 64)	0.05
Family unity	2.3 (2.0, 2.6)	3.0 (2.7, 3.3)	3.2 (2.9, 3.5)	2.5 (2.2, 2.8)	2.9 (2.6, 3.2)	2.9 (2.6, 3.2)	0.09
HSCL internalizing	2.0 (1.8, 2.2)	1.9 (1.7, 2.1)	1.8 (1.6, 2.0)	1.8 (1.6, 2.0)	1.9 (1.7, 2.0)	1.8 (1.7, 2.0)	0.08
Hopkins Symptom Checklist: anxiety	2.1 (1.8, 2.3)	1.9 (1.7, 2.2)	1.9 (1.6, 2.1)	1.7 (1.5, 2.0)	1.9 (1.6, 2.1)	1.9 (1.7, 2.1)	0.06
Hopkins Symptom Checklist: depression	2.0 (1.8, 2.2)	1.9 (1.7, 2.1)	1.8 (1.6, 2.0)	1.8 (1.6, 2.0)	1.8 (1.7, 2.0)	1.8 (1.6, 2.0)	0.22
Difficulties with emotional regulation	2.4 (2.1, 2.7)	2.3 (2.0, 2.5)	2.0 (1.8, 2.3)	2.3 (2.0, 2.5)	2.4 (2.2, 2.7)	2.3 (2.0, 2.5)	0.17
% correct on knowledge and attitudes on ECD	73 (67, 79)	84 (78, 90)	83 (77, 89)	76 (69, 82)	78 (73, 84)	75 (69, 80)	0.12

Outcomes analyzed using a linear mixed, included random intercepts random intercepts cluster, household, and caregiver and were adjusted for family structure, caregiver's age at baseline, educational attainment, and relation to child

^aTest for treatment by time interaction

^bAmong caregivers living in households with a mother and father

Table 4 Estimated percentages for hygiene and sanitation outcomes from logistic mixed models adjusted for family structure with random intercepts for cluster and household ($N = 38$)

	Intervention			Control			Test for treatment by time interaction
	Baseline	Endline	6-month follow-up	Baseline	Endline	6-month follow-up	
Children are insured (%)	89 (44, 99)	94 (54, 99)	99 (74, 100)	98 (61, 100)	100 (77, 100)	100 (77, 100)	0.66
Uses improved water source (%)	79 (32, 97)	72 (26, 95)	94 (57, 99)	89 (45, 99)	90 (49, 99)	99 (76, 100)	0.89
Uses improved sanitation source (%)	85 (62, 95)	85 (62, 95)	80 (57, 93)	64 (40, 83)	85 (61, 95)	63 (40, 81)	0.64
Treats water (%)	26 (8, 58)	68 (37, 89)	32 (11, 64)	25 (7, 59)	8 (1, 35)	24 (7, 57)	0.04
Handwashing station with soap (%) ^a	–	2 (0, 83)	15 (2, 68)	–	5 (0, 68)	5 (0, 69)	0.54
Report of family conflict (%)	24 (6, 60)	13 (3, 46)	9 (1, 38)	45 (15, 80)	55 (21, 85)	47 (16, 80)	0.52

^aNo household had handwashing station with soap at baseline; standard errors not available. Model was fit for endline and 6-month follow-up timepoints only

groups, all caregivers reported satisfaction with the sessions and with their facilitators, and all would recommend the Sugira Muryango intervention to their neighbor or friend. Caregivers who received the intervention from the CBV were significantly less likely to be satisfied with the length of the sessions (86 vs. 100%, $p = 0.05$), with an equal number of families expressing a desire for longer sessions as for shorter sessions. Despite these high levels of satisfaction, conversations with caregivers, CBVs, and supervisors revealed many ways to improve the intervention, including helping families identify and access available social supports; providing CBVs with additional training, supervision, and support; placing greater emphasis on father engagement; and providing additional follow-up sessions to encourage long-term behavior change.

Discussion

This pilot study demonstrates that Sugira Muryango is a feasible and acceptable family home visiting intervention. While this pilot was underpowered to detect significant differences in child health or development outcomes as well as differences in many process outcomes of interest, we did observe large and statistically significant improvements in child engagement among children receiving Sugira Muryango. Because increased child engagement in ECD is hypothesized to mediate the relationship between Sugira Muryango and improved child development outcomes, this finding suggests that Sugira Muryango may be an effective intervention for improving child development outcomes among economically vulnerable families in Rwanda. In

comparison with our previous open trial, where the intervention was delivered by bachelor's-level interventionists, families receiving Sugira Muryango in the present study had similar HOME (28 vs. 27) and OMCI (43 vs. 40) scores during follow-up (ECD activities in the past 3 days was not reported in the open trial). These findings, in conjunction with the high caregiver satisfaction, suggests that delivering Sugira Muryango using CBVs is a feasible strategy for scale-up.

In addition to observing improved ECD engagement among children, our data suggests that Sugira Muryango may reduce family conflict and promote nonviolent family functioning. The proportion of families receiving Sugira Muryango who reported conflict in the home more than halved between baseline and follow-up, and the proportion of children experiencing violent discipline also decreased. Concurrently, caregivers in intervention families reported increased shared decision making; improved family unity; and decreasing levels of depression, anxiety, and difficulties in emotion regulation. These outcomes remained stable over time among control families. Although many of these findings did not reach statistical significance in this small pilot study, the direction of these associations was consistent and magnitude of the differences was often large, suggesting that the Sugira Muryango intervention has the potential to produce meaningful improvements in family functioning.

Evidence for change among health-related outcomes was mixed. Among outcomes requiring access to material resources, such as adequate caretaking, dietary diversity, access to an improved water source, and use of improved sanitation sources, we did not observe improvements. In contrast, among health-related outcomes that primarily required behavior change, such as presence of a hand-washing station, use of appropriate water treatment, and care-seeking behavior for diarrhea, fever, and cough, we observed differences between the two groups that were large in magnitude, though they were not always significant or sustained over time. These findings may suggest that, although Sugira Muryango can promote behavior change, other structural interventions may be necessary for vulnerable families to be able to provide their children with adequate, food, sanitation, hygiene, and childcare. Although this study did not include a “pure control” arm that received neither Sugira Muryango nor the VUP cash transfer program, previous research suggests that VUP participation can increase households' access to food and livestock, which may help to address some of these barriers (Hartwig 2014), and current improvements to VUP, such as the recent introduction of a nutrition support grant and plans to provide childcare to public works households, may further improve the effectiveness of the VUP cash-transfer program. Continued investment in the quality, reliability, adequacy, and accessibility of the Rwandan Government's

ECD and VUP programs and the strengthening of linkages between these programs and other behavioral change interventions like Sugira Muryango may reduce these structural barriers even further.

Our results resonate with recent findings on other home visiting interventions for families living in extreme poverty. As has been reported by Attanasio et al. in Colombia (2014) and by Fernald et al. in Mexico (2017), explicitly linking ECD programming to existing social protection programs is a feasible method of simultaneously targeting vulnerable families and addressing the impact of structural factors like poverty on child development. Our findings that home-based interventions can encourage parents to adopt behaviors that promote ECD reflect what has been previously reported in other LMIC settings including those in Bangladesh (Aboud et al. 2013), Pakistan (Yousafzai et al. 2015), and Uganda (Singla et al. 2015). Although our findings related to reduced family conflict did not reach statistical significance, likely due to the small sample size of this pilot study, they contribute to a small but growing body of literature that suggests that combined ECD and violence prevention programs can make meaningful reductions in children's exposure to violence (Efevbera et al. 2018). The ongoing large-scale trial will provide more robust evidence on Sugira Muryango's impact on family conflict.

Limitations

While the inclusion of randomized concurrent controls in this study provides stronger evidence that Sugira Muryango has positive causal effects than in previous studies, this pilot study has several limitations. First, the small sample size likely limited our power to detect meaningful differences between the two groups. Although we investigated multiple outcomes, we did not correct our analysis for multiple testing due to this small sample size. However, because we consistently found significant improvements in all three of the child development outcomes we investigated, we do not believe these findings are the result of a spurious association due to Type I error, which is the primary concern associated with multiple testing. Additionally, in this small sample, randomization may not have been sufficient to ensure a perfect balance of covariates between the treatment and control groups at baseline, although we included key covariates in our models to adjust for potential residual confounding. Second, many of our outcomes are based on self-reported data. Since families in the intervention group were exposed to messages about child development and family functioning, our study is vulnerable to differential social desirability bias, which we would expect to bias our findings in favor of the intervention. However, because the HOME, which combines both directly observed and self-reported data, and the OMCI, which is based exclusively on

directly observed data, both showed significant improvements in the intervention group compared to the control group, we do not believe that social desirability bias can fully explain our findings. Third, due to the nature of the intervention, treatment assignment was not blinded to the families or to the data collectors. While data collectors were trained to gather data in the same way among both intervention and control families, conscious or sub-conscious bias could have led the data collectors to rate intervention and control families differently. To avoid this bias, in the full-scale evaluation, data collection will be conducted by an independent data collection service. Finally, while the exclusion of intervention families who migrated from their cluster between the time of enumeration and the time of enrollment could have resulted in bias, we believe any bias to be minimal as we did not observe substantive changes after also excluding control families who migrated from their cluster in our analysis.

Despite these limitations, this randomized pilot study with concurrent controls demonstrates that it is feasible and acceptable for lay-workers to deliver Sugira Muryango to economically vulnerable families. We also found strong evidence to suggest that Sugira Muryango can promote increased child engagement and some evidence that Sugira Muryango may also work to reduce intra-family conflict and improve family functioning. This pilot study also illuminated several opportunities to adapt the intervention for the full-scale trial, including using an independent data collector to avoid bias; placing stronger emphasis on helping families navigate available resources; providing CBVs with additional training, supervision, and support; and providing families with “booster” sessions to promote sustained behavior change, that have been incorporated in the ongoing effectiveness trial of Sugira Muryango currently underway across three Districts in Rwanda. Should Sugira Muryango demonstrate continued evidence of effectiveness in this fully-powered trial, its emphasis on using local trained lay workers and relatively brief and simple format all increase its potential to be deployed as a national child development program in Rwanda.

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Author Contributions D.A.B.: conducted the analysis and drafted the manuscript. J.F.: contributed to the revising of the manuscript writing and interpretation of the data. S.M.M.: oversaw intervention implementation and data collection. R.T.B.: contributed to study concept and design, data analysis, and interpretation of the data. C.M.A.: contributed to writing and editing the final manuscript. V.S., C.I., K. G., S.B., and O.U.: conducted data collection and engaged in direct supervision of the community-based volunteers and families. A.K. supported linkages to poverty reduction programming. B.W. and L.B. R. supported linkages to poverty reduction programming and contributed to the revising of the manuscript writing and interpretation of the data. T.S.B.: conceptualized the study, obtained funding, led intervention development, and provided supervision.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval All caregivers were invited to give written informed consent for their own participation and then for the participation of their eligible children (aged 36 months or younger) at baseline. Study procedures were approved by the Rwandan National Ethics Committee and the Harvard T.H. Chan School of Public Health Institutional Review Board.

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Appendix: Sugira Muryango Modules

Module number	Module theme	Goals
Welcome Session	Introduction of Sugira Muryango	<ul style="list-style-type: none"> • Introduce caregivers to the “Sugira Muryango” • Explain the “Sugira Muryango” goals and structure • Establish a plan for regular meetings together
Module 1	Family narrative	<ul style="list-style-type: none"> • 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
Module 2	The importance of early stimulation	<ul style="list-style-type: none"> • 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

Table (continued)

Module number	Module theme	Goals
Module 3	Building early communication skills	<ul style="list-style-type: none"> their children (toy making, early stimulation activities) • 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 nutrition	<ul style="list-style-type: none"> • Learn about food consumption in the home • Identify nutritional practices that promote child health and growth, including the importance of deworming • Discuss ways to maximize nutrition from available foods
Module 5	The importance of good hygiene	<ul style="list-style-type: none"> • Identify hygiene practices that promote good health • Coach on the obstacles to good hygiene and sanitation
Module 6	The importance of good health	<ul style="list-style-type: none"> • Talk with the caregivers about health practices in the home, particularly good health their response to sick children • Discuss the family's Mutuelle de Sante (health insurance) coverage • Ensure immunizations are completed/take steps to complete immunizations
Module 7	Managing the stresses of parenting and family life	<ul style="list-style-type: none"> • Identify 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	<ul style="list-style-type: none"> • Identify and actively coach conflict resolution strategies that promote peace, resilience and wellbeing in the home • Coach on alternatives to harsh punishment and harmful impact of angry or violent responses to conflict on early childhood development

Table (continued)

Module number	Module theme	Goals
Module 9	The important role that everyone plays in raising a baby well	<ul style="list-style-type: none"> • Coach on the role of positive, responsive parenting in creating a safe environment for all family members • Discuss the diverse roles of all family members in supporting early childhood development • Highlight the important role of fathers in raising children • Coach on effective discipline strategies
Module 10	Good parenting is better than being born well	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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

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