

CASITA: a controlled pilot study of community-based family coaching to stimulate early child development in Lima, Peru

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ABSTRACT

Objective To determine whether the 3-month, community-based early stimulation coaching and social support intervention 'CASITA', delivered by community health workers, could improve early child development and caregiver-child interaction in a resource-limited district in Lima, Peru.

Design A controlled two-arm proof-of-concept study.

Setting Six neighbourhood health posts in Carabayllo, a mixed rural/urban district in Lima. Sessions were held in homes and community centres.

Participants Children aged 6–24 months who screened positive for risk of neurodevelopmental delay (using validated developmental delay tool) and poverty (using progress out of poverty tool) were enrolled with their caregivers. Dyads with children born >21 days early were excluded.

Intervention 12-week parenting/support intervention plus nutritional support (n=41) or nutrition alone (n=19).

Outcome measures Development and home environment differences and mean changes from baseline to 3 months postintervention were evaluated using age-adjusted z-scores on the Extended Ages and Stages Questionnaire (EASQ) and the Home Observation Measurement of the Environment (HOME) scores, respectively.

Results Development in CASITA improved significantly in all EASQ domains, whereas the control group's z-scores did not improve significantly in any domain. The mean adjusted difference (MAD) in change in EASQ age-adjusted z-scores between the two study arms was 1.39 (95% CI 0.55 to 2.22); Cohen's d effect size of 0.87 (95% CI 0.23 to 1.50). Likewise, intervention significantly improved global HOME scores versus control group (MAD change of 6.33 (95% CI 2.12 to 10.55); Cohen's d of 0.85 (95% CI 0.28 to 1.41)).

Conclusions An evidence-based early intervention delivered weekly during 3 months by a community health worker significantly improved children's communication, motor and personal/social development in this proof-of-concept study.

BACKGROUND

Globally, 249.4 million children under age 5 were at risk of failing to reach full developmental potential^{1–3} as of 2010. Poverty and

What is already known on this subject?

- ▶ Poverty and its psychosocial manifestations contribute to increased developmental risk in young children in resource-poor settings.
- ▶ Parenting support programmes in low-income and middle-income countries are associated with increased scores in child cognitive, motor and psychosocial development.
- ▶ However, access to early stimulation programmes for caregivers remains a significant challenge in resource-limited areas where often transportation is difficult and services few and costly.

What this study hopes to add?

- ▶ Community health workers delivered CASITA, a 12-week, community-based early stimulation coaching and social support intervention, in Lima, Peru.
- ▶ This pilot compared CASITA plus nutrition with nutrition alone in 60 children aged 6–24 months at risk for delay.
- ▶ CASITA sessions significantly improved child development and caregiver behaviour compared with nutrition alone.

its psychosocial manifestations (including maternal depression and domestic violence) likely contribute to increased developmental risk among young children in resource-poor settings.^{4–8} Young children living in adversity suffer from 'toxic stress',^{9,10} which can interfere with early brain development by disrupting or slowing the growth of neuron connections.¹¹ Regular contingent and responsive interactions between parents and their young children can mitigate the adverse consequences of living with poverty and stress.^{11–13}

Teaching caregivers to practice stimulating and responsive interactions with their



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children is a simple way to promote healthy child development. Indeed, literature in high-income countries confirms the efficacy of early interventions that target nutritional supplements combined with caregiver stimulation coaching and support for children with neurodevelopmental delay.^{14–18} A recent comprehensive review found that parenting support programmes in low-income and middle-income countries were associated with increased scores in child cognitive, motor and psychosocial development.¹⁹ Yet, access to early stimulation programmes for caregivers remains a significant challenge in resource-limited areas.²⁰ Trained community health workers (CHWs) can be a valuable resource to teach early interaction to caregivers, particularly where homes are distant, transportation is difficult, trained doctors and nurses are few and costly and stigma or discrimination are barriers to clinic attendance. Data from community-based early childhood interventions and home visiting programmes suggest they are effective in delivering early child stimulation interventions in resource-limited settings due to their low cost and high health return.^{21 22}

Here, we report results of a pilot study of a community-based early child intervention ('CASITA') to assess its impact on early child development, home environment and caregiver behaviour.

METHODS

Study location

Carabayllo District, Lima has both rural and urban areas, and a rapidly expanding population of >290 000 people due to immigration from the provinces, and 26.3% living in poverty. Carabayllo is the founding site of the non-governmental organisation Socios en Salud (SES, Partners In Health, Peru). Official estimates of the population under 2 years of age vary from 5000 (Ministry of Health) to 7500

(National Institute of Health). In Peru, CHWs reside in the community, work as volunteers and on average have completed high school.

Intervention

The CASITA intervention is a community-based early child intervention that was adapted from the SPARK Center at Boston Medical Center using the ADAPT-ITT (Assessment, Decision-making, Adaptation, Production, Topical experts, Integration, Training, Testing) guidelines for community participation in intervention adaptation.²³ CASITA provides parents with skills, resources and support to stimulate child development. Two modes of CASITA delivery were piloted: individual (one-on-one with a CHW) and group (one CHW to approximately 10 caregivers). Although modalities were piloted separately, results were combined into one study arm ('intervention') for analysis. The following core components were maintained across both delivery models: coaching on early child stimulation, teaching and practising contingent interaction and social support accompaniment (figure 1). All sessions were led by a trained CHW. All CASITA participants received 12 weekly sessions, organised in four sequential segments: 1) child observation and discussion of general child development; 2) demonstration and initiation of cognitive stimulation and social interaction activities tailored to the child's development; 3) encouragement of responsive parenting behaviour; 4) parent social support through referral assistance (eg, connection to Ministry of Health early child health visits), reassurance and discussion of parent concerns. Weekly sessions also included workshops to create toys from recyclable materials found in the home. Families received reimbursement for transportation costs. CASITA encounters were videotaped and assessed for fidelity using standardised forms with feedback to the CHW.

CORE COMPONENTS OF CASITA	
<ul style="list-style-type: none"> • 12 sessions all led by trained CHW • Teaching and practicing contingent interaction • Use of flipchart matched by age • Recyclable toys made jointly with caregiver • Social support accompaniment 	
VARIATIONS IN DELIVERY	
INDIVIDUAL	GROUP
<ul style="list-style-type: none"> • One health promoter per one dyad • More structured format • Locale: family in home 	<ul style="list-style-type: none"> • One facilitator + one health promoter per 6-8 dyads • More flexible format • Locale: community center or health post

Figure 1 Key components of individual and group modalities of CASITA. CHW, community health worker.

STUDY POPULATION

The CASITA pilot was conducted between April 2014 and October 2015. Individual sessions occurred from April 2014 to September 2014. Group sessions occurred from March 2015 to October 2015. Six health posts were selected based on prior collaboration with SES and greater need. We stratified health posts by urban (n=4) versus rural (n=2), then randomly allocated health posts (ratio 1:2) to receive either monthly nutritional support alone (control) or CASITA and monthly nutritional support (group intervention or individual intervention). Participants' study arm was based on the assignment of their local health post. The four health posts in the intervention arm were each randomly assigned to individual or group intervention. Children between 6 and 24 months old were screened per routine care at participating health establishments, using the developmental screening instrument Escala de Evaluación del Desarrollo Psicomotor (EEDP).²⁴ To reach children who did not attend health posts, CHWs also screened children using EEDP in the community. Primary caregivers of children who screened 'at risk' or 'delayed' in at least one of the four domains (motor, language, social and coordination) were invited to participate in the study and enrolled after providing informed consent. Exclusion criteria included dyads with: children born >21 days early; parents who declined participation; children who were screened 'not delayed' on the EEDP and households that screened above the poverty threshold as measured by the Progress Out of Poverty Index.²⁵ Budgetary constraints limited enrolment sample size to 60 dyads; children were screened until 60 eligible dyads were enrolled. Group and individual intervention arms were analysed together as 'intervention' to increase statistical power.

Data collection

Primary child development outcomes were measured using the Extended Ages and Stages questionnaire (EASQ). The EASQ, which was validated in a national sample of Peruvian children aged 3–24 months, contains all ASQ-3 items in a continuous format, allowing for comparison across age groups without relying on Western-established cut-off scores.^{26,27} The ASQ-3 is a parent-reported screening tool available in Spanish, often administered by trained laypeople such as CHWs^{27,28} to assess developmental domains including communication, fine motor, gross motor, problem solving and personal/social. Secondary outcomes were measured using the Infant Toddler Home Observation Measurement of the Environment (HOME) questionnaire,²⁹ which evaluates parenting and home influences on child development. Global HOME scores and subscores of responsivity and involvement (parenting behaviours most likely to be influenced by CASITA) were compared preintervention and postintervention.²⁹ Baseline assessments included EASQ, HOME, sociodemographic and health characteristics for the caregiver and child; as well as caregiver depression and social support, using the Hopkins Symptom

Checklist (HSC)³⁰ and Duke UNC social support scale (DUSSC),^{31,32} respectively. The EASQ, HOME, HSC and DUSSC have all been translated into Spanish and successfully used in prior studies by our team.^{33,34} Interviews were conducted by trained study staff. EASQ and HOME data were collected on handheld devices and other data were collected on paper, double-entered into a database developed in the SES local informatics system. Data entry errors and conflicts were reconciled.

At 3 months (postintervention), all dyads were assessed using the EASQ and HOME. Primary outcomes measured the difference between intervention and control arms in: 1) children's mean development postintervention indicators as measured by EASQ z-scores, 2) mean change from baseline to postintervention in children's development, 3) home environment and parent behaviour postintervention as measured by HOME and 4) mean change from baseline to postintervention in home environment and parent behaviour.

Analysis

Data were analysed using Stata V.13.³⁵ Two-by-two tables using X^2 or Wilcoxon rank sum, t-tests and univariable and multivariable logistic and linear regressions were conducted for binary and continuous baseline covariates and outcomes, respectively (using robust SEs to account for clustering by district for outcomes). Mean differences and SD in EASQ and HOME score change from baseline to 3-month follow-up between the two study arms were calculated using linear regression. Baseline covariates significantly different ($p < 0.05$) between intervention and control arms were adjusted for in the final model.

We calculated EASQ scores and converted to two sets of age-adjusted z-scores using age-category specific means and SD; the first z-score compares the CASITA study population with that of the World Bank normed Peruvian population ('WB z-score', valid for children aged 3–24 months), and the second z-score is based only on the study population ('Internal z', valid for children aged 3–31 months). The World Bank data only applies to children under 2 years so primary analysis was conducted on children under 2 years at the second data collection. HOME scores were calculated per the administration manual.²⁹ EASQ and HOME results are presented as overall scores and subscale scores; subscales for EASQ include motor, communication and personal/social domains; subscales for HOME include parent responsibility, acceptance and involvement, household organisation, learning materials and variety. Effect sizes were calculated in SD using Stata's *esize* command to calculate Cohen's *d*.

The study was reviewed and approved by the Partners Institutional Review Board at Brigham and Women's Hospital and by the Instituto Nacional de Salud del Niño (National Children's Institute) in Peru. Partners IRB reviewed and approved the study and designated it as exempt from clinical trial registration under FDAAA (Food and Drug Administration Amendments Act 2007);

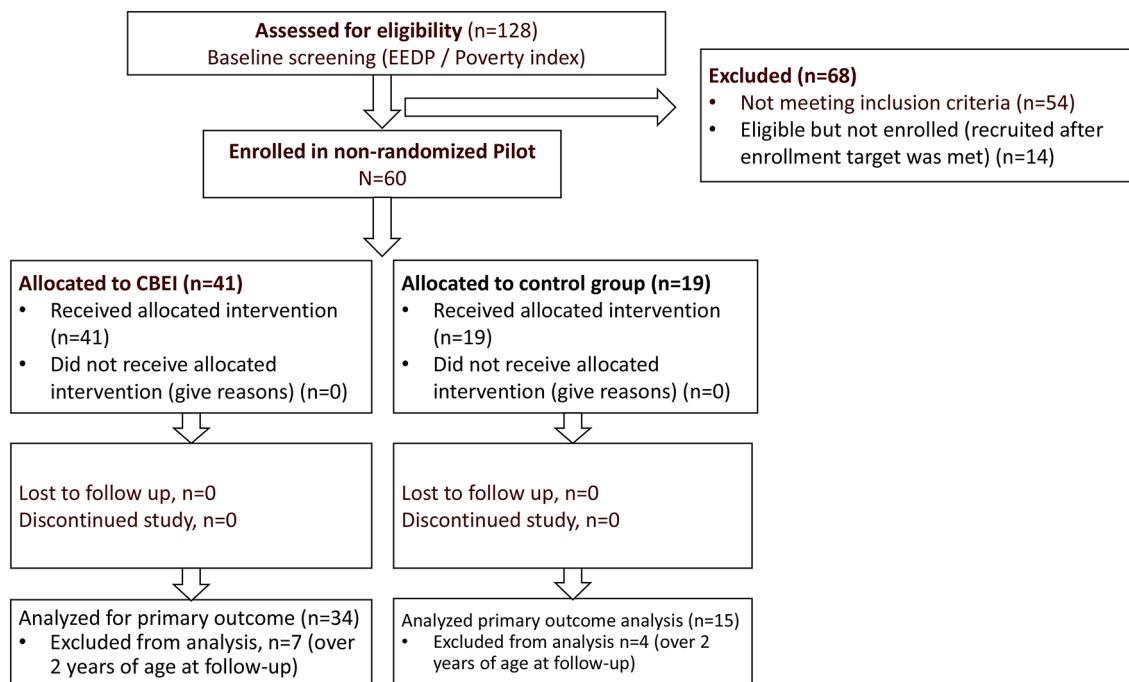


Figure 2 CASITA flow chart. EASQ, Extended Ages and Stages Questionnaire; EEDP, Escala de Evaluación del Desarrollo Psicomotor; HOME, Home Observation Measurement of the Environment.

nonetheless, the trial was registered in clinicaltrials.gov (ID# NCT03010306) to comply with ICMJE (International Committee of Medical Journal Editors) guidelines.

RESULTS

One hundred and twenty-eight children were screened. Of these, 68 were not enrolled; 54 (42.2%) were ineligible and 14 were being screened for eligibility when

the enrolment target was reached (figure 2). No families refused participation.

Sixty mother/child dyads (all primary caregivers were mothers) met eligibility criteria and were enrolled into the study; 41 into the intervention arm and 19 into the control arm. No significant differences existed between the study arms at baseline on EASQ or HOME scores (table 1). A few baseline differences between study arms were noted: more male children were enrolled in

Table 1 Baseline characteristics, EASQ, HOME and psychosocial scores, by study arm, n=60

Variable	Control arm (n=19) N (%) or mean (SD)	Intervention arm (n=41) N (%) or mean (SD)	P values
Child's age in months*	13.4 (5.9); range: 6–22	15.9 (4.2), range: 6–23	0.10
Male sex	7 (37)	22 (54)	0.22
Ever breast fed	16 (84)	35 (85)	0.91
In utero substance-use exposure (maternal self-report)	0	0	NA
Mean number of weeks gestation at birth	39.4 (0.9)	38.8 (1.3)	0.19
More than one primary caregiver	13 (68)	16 (39)	0.03
Parent has HIV	0	0	NA
Mother's education level higher than primary school	14 (73.6)	30 (73.2)	0.97
Mother's occupation is non-remunerative (housewife, student or not employed)**	17 (89.5)	34 (82.9)	0.71
Mother is married or living as married**	15 (79)	40 (98)	0.23
Maternal history of depression or attempted suicide**	2 (10.5)	5 (12.2)	1.0
Hopkins Symptom Checklist score	28.4 (6.8)	24.6 (5.9)	0.04
Social Support score	27.1 (5.9)	26.7 (6.5)	0.82

*P value calculated using Wilcoxon rank sum test.

†P value calculated using Fisher's exact test.

EASQ, Extended Ages and Stages Questionnaire; HOME, Home Observation Measurement of the Environment; NA, not available.

Table 2 Mean baseline and 3-month EASQ z-scores, and comparison of z-score changes, by study arm, n=60
EASQ z-scores vs World Bank normed Peruvian data (limited to children aged 6–24 months at follow-up)

Variable	Baseline (n=49)				3-month follow-up (n=49)				Difference in differences, intervention-control (n=49)			
	Control arm mean (robust SE) (n=19)	Intervention arm mean (robust SE) (n=41)	Robust P values (n=15)	Control arm mean (robust SE) (n=15)	Intervention arm mean (robust SE) (n=34)	Robust P values (n=34)	Unadjusted mean difference (95% CI; P values)	Adjusted mean difference (95% CI; P values)	Unadjusted mean difference (95% CI; P values)	Adjusted mean difference (95% CI; P values)		
Total EASQ z-scores	-1.26 (0.26)	-1.52 (0.16)	0.39	-1.36 (1.67)	-0.55 (0.98)	0.08	1.06 (0.13 to 2.00; 0.025)	1.39 (0.49 to 2.29; 0.003)				
EASQ communication domain z-scores	-1.76 (0.21)	-1.82 (0.17)	0.81	-1.42 (1.45)	-0.83(0.77)	0.07	0.65 (-0.15 to 1.46; 0.11)	0.97 (0.23 to 1.71; 0.01)				
EASQ motor domain z-scores	-0.59 (0.25)	-0.52 (0.15)	0.82	-0.57 (1.27)	0.07 (0.91)	0.08	0.57 (-0.13 to 1.27; 0.11)	0.67 (-0.09 to 1.43; 0.08)				
EASQ personal/social domain z-scores	-0.85 (0.35)	-1.41 (0.21)	0.17	-1.31 (1.52)	-0.48 (1.07)	0.06	1.40 (0.42 to 2.39; 0.006)	1.72 (0.77 to 2.67; 0.001)				

Variable	Baseline (n=60)				3-month follow-up (n=49)				Difference in differences, intervention-control (n=49)			
	Control arm mean (robust SE) (n=19)	Intervention arm mean (robust SE) (n=41)	Robust P values (n=41)	Control arm mean (robust SE) (n=19)	Intervention arm mean (robust SE) (n=41)	Robust P values (n=41)	Unadjusted mean difference (95% CI; P values)	Adjusted mean difference (95% CI; P values)	Unadjusted mean difference (95% CI; P values)	Adjusted mean difference (95% CI; P values)		
EASQ total z-scores in local cohort	-0.39 (0.17)	-0.33 (0.14)	0.78	-0.31 (0.29)	0.36 (0.14)	0.04	0.67 (0.02 to 1.32; 0.04)	0.74 (0.13 to 1.35; 0.019)				
EASQ communication domain z-scores	-0.33 (0.13)	-0.46 (0.13)	0.51	-0.20 (0.29)	0.31 (0.14)	0.11	0.67 (0.00 to 1.33; 0.05)	0.88 (0.26 to 1.51; 0.007)				
EASQ motor domain z-scores	-0.38 (0.22)	-0.24 (0.14)	0.59	-0.33 (0.27)	0.22 (0.13)	0.07	0.46 (-0.16 to 1.07; 0.14)	0.37 (-0.23 to 0.98; 0.22)				
EASQ personal/social domain z-scores	-0.23 (0.21)	-0.14 (0.16)	0.73	-0.12 (0.24)	0.39 (0.15)	0.07	0.50 (-0.13 to 1.14; 0.11)	0.54 (-0.12 to 1.21; 0.10)				

EASQ, Extended Ages and Stages Questionnaire.

Table 3 Mean baseline and 3-month HOME scores, and comparison of changes, by study arm, n=60

Variable	Baseline (n = 60)			3-month follow-up (n=60)			Difference in differences, intervention-control		
	Control arm mean (robust SE) (n = 19)	Intervention arm mean (robust SE) (n = 41)	Robust P values	Control arm mean (robust SE) (n=19)	Intervention arm mean (robust SE) (n = 4)	Robust P values	Unadjusted mean difference (95% CI; P values)	Adjusted mean difference (95% CI; P values)	
HOME total scores	21.90 (1.39)	22.20 (0.78)	0.86	24.10 (1.44)	30.12 (0.90)	0.001	5.76 (1.77 to 9.83; 0.006)	6.33 (1.93 to 10.73; 0.006)	
HOME responsiveness	5.89 (0.48)	5.58 (0.30)	0.58	6.37 (0.54)	8.61 (0.31)	0.001	2.55 (1.15 to 3.94; 0.001)	2.69 (1.19 to 4.18; 0.001)	
HOME acceptance	4.89 (0.37)	5.19 (0.24)	0.50	5.26 (0.39)	5.87 (0.21)	0.17	0.31 (-0.99 to 1.61; 0.63)	0.52 (-0.82 to 1.87; 0.44)	
HOME involvement	1.74 (0.28)	2.02 (0.20)	0.41	2.15 (0.43)	3.85 (0.25)	0.001	1.40 (0.43 to 2.39; 0.006)	1.54 (0.42 to 2.66; 0.008)	

HOME, Home Observation Measurement of the Environment.

the intervention arm (53.7% vs 36.8%, $p<0.05$); more caregivers in the intervention arm were married or living as married (97.6% vs 78.9%, $p<0.05$) and fewer children in the intervention arm had more than one primary caregiver (39.0% vs 68.4%, $p<0.05$). Also, caregivers in the intervention arm had lower mean HSC scores (indicating greater depression symptoms) than those in the control group (24.7 vs 28.4, $p<0.05$). Analyses of score changes were therefore adjusted for child sex, caregiver marital status, baseline HSC score and number of primary caregivers (one vs more than one).

Child development outcomes

The mean baseline EASQ score was 602 (SD 195) and mean WB z-score was -1.38 (SD 0.93) (table 1). This compares with a mean score of 603 (SD 222) for the normed Peruvian population.²⁶ Analyses comparing the normed Peruvian population were limited to the 49 children (81.7%) who were under age 2 at study completion: 15/19 in the intervention arm, 34/41 in the control arm. The intervention group improved significantly in all domains, whereas the control group's z-scores did not improve significantly in any domain (table 2). The mean adjusted difference in change in WB z-scores between the two study arms was 1.39 (95% CI 0.49 to 2.29) (table 3), confirming that the differences in the intervention arm were significantly improved over differences in the control arm. Cohen's d effect size was 0.87 (95% CI 0.23 to 1.50). Local z-scores and mean changes for all 60 children demonstrated similar findings: no difference at baseline, but significantly higher raw and adjusted mean differences in the CASITA arm.

Home environment and parent behaviour outcomes

Mean baseline HOME scores were 22.1 (SD 5.27) (table 3). No significant baseline differences existed for any of the subdomains between study arms. HOME scores improved in both study arms at 3 months, with the intervention arm reporting both a significantly higher mean HOME score than the control arm (30.1 vs 24.1, $p<0.01$) and significantly greater improvement than the control arm after the intervention period (table 3), with a Cohen's d effect size of 0.85 (95% CI 0.28 to 1.41). The mean change in scores for both involvement and responsibility subscales were significantly greater in the intervention versus control arm (table 3).

DISCUSSION

CASITA plus nutritional supplementation was highly successful compared with nutritional supplementation alone at improving child development, the home environment and parenting behaviour. Findings are consistent with and generally better than those of other studies of comparable interventions.^{36–39} A recent community randomised trial in Uganda assessed a 12-session group parenting intervention (plus individual home visits). Children (aged 12–36 months) in the intervention group had significantly higher effect sizes

of cognitive (Cohen's $d=0.36$) and language scores ($d=0.27$) and mothers had lower depression after the intervention, compared with controls.⁴⁰ CASITA was based on successful programmes in other settings, so while this finding is not surprising, these results are encouraging in this challenging setting of urban poverty.

The CASITA intervention was successfully delivered both individually and in groups. For both modalities of delivery, well-trained and supervised CHWs consistently delivered the intervention with high fidelity, requiring minimal support from health professionals. The use of CHWs to identify at-risk children in the community and deliver a structured intervention is a strength of this study. Our data add to existing literature of CHW-delivered early child interventions in resource-poor settings. In a 2002 study, CHWs in South Africa delivered a home-based intervention for maternal depression and parenting skills, resulting in significant increases in maternal sensitivity and positive affect during feeding, and infant physical development.³⁶ Community health aides in Jamaica provided a parenting and development coaching intervention to the caregivers of undernourished children aged 9–30 months, resulting in improved child development and greater maternal knowledge and childrearing practices.⁴¹

This was a small pilot study in one urban setting in Peru; findings may not be generalisable elsewhere. Although most baseline characteristics did not significantly differ between arms, caregiver marital status and number of caregivers did differ, with potential bias in favour of the intervention group. Although we controlled for these baseline factors, unmeasured or residual confounding remains a possibility. Because of resource constraints, our sample size is small; we did not conduct a priori power calculations and did not randomise at the level of the individual. Although we used robust standard errors during regression to mitigate the possible effects of clustering at the clinic level, it is possible that non-independence may have biased our results. Combining group and individual CASITA in the analysis, while weakening our ability to compare the effects of different modalities, increased our sample size; of note, outcomes did not differ significantly between individual and group study arms.

This pilot demonstrates that community-based early parenting and support interventions can improve child development and home environment characteristics in this resource-limited setting. CASITA is well-poised to scale to a wider area, given its low cost and reliance on CHWs to identify vulnerable children and deliver the structured intervention. Expansion to all of Carabayllo is underway, including screening of 6000 children and a randomised controlled trial of >350 children. This larger research study will, we hope, determine how effective and cost-effective CASITA is at scale and over longer periods of time.

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Contributors AKN helped to design the study, co-wrote the protocol, provided training and data collection oversight during the project, helped to analyse data, co-drafted the initial manuscript and co-wrote the final manuscript. ACM helped to design the analysis plan and the study design, collaborated on the protocol, conducted all quantitative analysis and provided interpretation, co-drafted the initial manuscript and co-wrote the final manuscript. MM oversaw the implementation of the project as Program Manager and Co-Principal Investigator, helped to design the CASITA protocol, trained the community health workers, oversaw data collection reviewed and approved the final manuscript as submitted. NR as Project Coordinator coordinated and supervised all study activities including data collection and quality control in Peru, assisted with early drafts of the manuscript, reviewed and revised all versions of the manuscript and approved the final manuscript as submitted. BK contributed to the selection of instruments, conducted training and data collection oversight, provided interpretation of data analysis, reviewed and revised all versions of the protocol and manuscript and approved the final manuscript as submitted. MV helped to design the initial intervention, helped to select tools for evaluation, participated in the adaptation of the intervention to the local setting, reviewed and revised all versions of the manuscript and approved the final manuscript as submitted. SL contributed to the selection of instruments, conducted training and data collection oversight, provided interpretation of data analysis, reviewed and revised all versions of the protocol and manuscript and approved the final manuscript as submitted. GS contributed significantly to the design of the CASITA intervention and the fidelity and monitoring activities of the CHWs, assisted in data collection, reviewed and revised the manuscript and approved the final manuscript as submitted. LL is the Co-Principal Investigator for the CASITA study. He collaborated on the protocol, contributed significant knowledge of the political landscape in Carabayllo to the study, reviewed and revised the final version of the manuscript and approved it as submitted. AC: collaborated on the protocol and helped to adapt and implement study instruments such as the HOME and EASQ in Carabayllo to the local setting, provided interpretation of results and reviewed and revised the final version of the manuscript and approved it as submitted. YV: contributed to data collection, assisted to modify study instrument application to suit local context, contributed to the early draft sections of the manuscript, reviewed and revised the final version of the manuscript and approved it as submitted. SAA designed statistical programs for analysis, assisted in conducting analyses and reviewed and revised all versions of the manuscript and approved the final manuscript for submission. SSS conceptualised and designed the study, wrote the protocol, provided analysis interpretation, co-wrote the first version of the manuscript and reviewed and revised all versions of the manuscript.

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Patient consent Not required.

Ethics approval Partners Institutional Review Board at Brigham and Women's Hospital and by the Instituto Nacional de la Salud del Niño (National Children's Institute) in Peru.

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