Pre-Analysis Plan for "Scaling Technology Interventions for Vulnerable Children: A Cluster Randomized Evaluation with *Programa Nacional Cuna Más* in Peru"

Abstract

Introduction
Early childhood development (ECD) interventions that provide caregiving information via home visits or group sessions have improved child development outcomes in several contexts. However, the cost-effective scaling of these interventions with quality is a challenge. This cluster randomized evaluation trial (cRCT) analyzes the effects of a technology intervention designed to maintain quality at lower cost at scale.

Methods and Analysis
This cRCT analyzes the effects of two variations of a smartphone-based intervention on ECD outcomes compared to the Peruvian government's standard daycare and parental support program. A total of 240 daycare centers in the Cuna Más program will participate and 2400 households will be followed. Daycare centers will be randomized to receive (T1) regular day care and usage of the Volar app, (T2) day care, the Volar app, and parent learning groups, or (Control) regular day care. Outcomes include: i) children's cognitive skills and non-cognitive skills, ii) parental investment, iii) parental time-use, iv) childrearing practices, v) parental skills, vi) parental stress scale, and vii) parental mental health. Primary outcomes of interest are childhood development, including cognitive skills and non-cognitive skills, measured using CREDI and GSED. Secondary outcomes include intermediate caregiver outcomes and home interactions measured with three instruments: i) Parenting Attitudes Questionnaire Scoring (EAPQ) ii) Parenting Sense of Competence Scale (PSOC), and iii) Home Observation for Measurement of the Environment (HOME). We will estimate unadjusted and adjusted intent-to-treat effects. We will also analyze heterogeneous effects by child gender and either caregiver education or a household poverty.

Ethics and Dissemination
Study protocol was approved by the ethics board at Innovations for Poverty Action, #15956.

Trial Registration Number
AEA RCT Registry: TBD

Introduction

Children who grow up in environments where caregivers attend to their physical, cognitive, and socioemotional development are more likely to reach expected learning achievements in school, putting them on track to complete their basic education, foster deeper relationships, and earn higher incomes in the future. In 2019, prior to the COVID-19 pandemic, 43 percent of children under 36 months of age in low- and middle-income countries were at risk of not reaching their full development. In Peru, over 50 percent of children aged 9 to 36 months did not possess communication skills equivalent to their expected level. The negative effects of COVID-19 on household economic and health wellbeing likely made it even more difficult for these children to achieve development goals.

With the onset of COVID-19 in Peru, Cuna Más — the national early childhood development program implemented by the Ministry of Development and Social Inclusion — adapted its content to provide caregivers with parenting resources and tools for their child's wellbeing via WhatsApp and social media. This digital modality continued as in-person childcare centers reopened. In parallel, APORTA – a Peruvian social organization – developed an evidence-based mobile app, VOLAR, which builds on the Cuna Más program by communicating via videos, images, activities, and audio information to support early childhood development.

This project brings together the government and APORTA to develop an app-based complement to the existing Cuna Más at-home daycare program. The intervention will integrate the Volar app, WhatsApp-based messaging, and learning groups to allow caregivers to learn, interact, and share information with one another. The researchers will measure the intervention's impact on early childhood development outcomes. A total of 240 daycare centers in the Cuna Más program will participate and 2400 households will be followed. Households will be randomized to receive either at-home daycare and usage of the Volar app (T1); at-home daycare, usage of the Volar app, and parent learning groups (T2); or regular daycare (Control). Depending on the impact detected, Cuna Más will consider scaling the program nationally.

Study objectives

This study evaluates the effects of a smartphone-based parenting app and associated supports on the development outcomes of children 6-36 months. This intervention seeks to provide information to encourage quality interactions between primary caregivers and their children living in moderate or extreme poverty in urban and peri-urban areas of Peru. The study's contribution lies in generating rigorous evidence of the impact digital technologies and social networks to improve the quality of parental investment in early childhood development. Likewise, the evidence generated will complement the existing government intervention (Cuna Más National Program) and enable it to identify how to scale in a cost-effective manner.

This trial is designed to provide responses to the following research questions:
- Compared to the control group, is there a positive effect of the smartphone-based app and WhatsApp/audio messages (T1) on a) parental investment, b) skills of the main caregivers, and c) cognitive and non-cognitive abilities of children 6 to 36 months of age?

- Compared to the control group, is there a positive effect of the main intervention plus learning groups (T2) on a) parental investment, b) skills of the main caregivers, and c) cognitive and non-cognitive abilities of children 6 to 36 months of age?
- Is the main intervention (T1) a cost-effective way to deliver the ECD program at scale or is there an interaction with the learning groups (T2) that justifies the additional cost?

Methods and Analysis

Participant Eligibility Criteria
The target population consists of primary caregivers of children ages 6-36 months old who are part of Cuna Mas National Program (PNCM). We will conduct a cluster randomized controlled trial (RCT) in 240 urban and peri-urban daycare centers. To identify the sample, we will first select 240 daycare centers assuming an average distance of 2km between the clusters. Clusters will be randomized by the research team in equal numbers of treatments and control groups.

Setting and Environment
The intervention will involve urban and peri-urban areas in seven regions in Peru: Lima, Cusco, Arequipa, Cusco, Huancavelica, Junín, Lambayeque, Lima, and Piura. Activities will take place between 2023 and 2025. As part of the Cuna Más National Program, the participants come from households living in poverty or extreme poverty.

Description of Intervention
Clusters will be randomized by the research team into three equal-sized groups: control and two treatments. This intervention is designed to complement the existing government intervention (regular day care) by integrating three components: (1) smartphone-based app; (2) text/audio messages; and (3) parent learning groups. The control group will consist of those enrolled only in regular day care.

The three randomized groups thus include:
- Control: Regular daycare.
- Treatment 1: Regular day care + "Volar" app/messages
- Treatment 2: Regular day care + "Volar" app/messages + learning groups.

1. Smartphone-based App
Volar seeks to lower the cost of in-person activities via an app-based intervention that will include content presented through videos, activities, audio, images, and text. The information covers quality interactions, routines, play, development of socio-emotional skills, nutrition, and hygiene. Activities proposed for children 6 to 36 months old follow the curriculum for the Cuna Más home visiting program. APORTA will help the households download and install the App through remote workshops and face-to-face meetings in specific zones.

2. Text/audio Messages
The intervention will build off pilot experience and other behavioral insights from messaging interventions to integrate text/audio messages into the app-based intervention. Messages may

include: (1) Concepts or evidence related to Early Childhood Development (ECD); (2) Practical advice on parenting practices; and (3) Motivational messages to continue carrying out the activities proposed.

3. Parent Learning Groups

The third component is a social intervention leveraging the Cuna Más daycare infrastructure. It consists of holding of group sessions to drive information sharing and foster parent-to-parent interaction. For the intervention, the groups would be led by a staff or volunteer of the program adopting the intervention. This person will be a member of the community who can facilitate the creation of trust and increase the likelihood of adopting and using the app-based platform. APORTA will train the staff or volunteer of the program adoption a month before the start of implementation. The parent learning groups will be carried out in workshops groups 6 times over the course of the 18-month intervention. These workshops will be attended at daycare centers.

Outcomes

We will conduct a comprehensive assessment of childhood development, encompassing various domains, including motor skills, language proficiency, cognition, socio-emotional development, and adaptive behavior. Simultaneously, we will assess intermediate caregiver outcomes and home interactions. To ensure cultural appropriateness for the Peruvian context, all assessment measures will undergo translation into Spanish and undergo a rigorous piloting process. Adjustments will be made, as needed, to align with the Peruvian context while preserving the fundamental constructs of the assessment items. We will also explore the creation of summary outcome measures through the creation of indices.

In addition, our study will involve gathering data on various aspects, including caregiver characteristics[1], household characteristics[2], child characteristics[3], primary caregiver's social networks[4], social media usage patterns[5], caregiver knowledge, and beliefs about child development, as well as assessments related to parental mental health and levels of stress[6].

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[1] We collect data on the characteristics of the primary caregiver based on the Household Member Characteristics module of the household survey of the National Institute of Statistics and Informatics of Peru (INEI, for its acronym in Spanish). This module contains the following: Gender, age, educational level, marital status, ethnicity, and mother tongue.

[2] We collect data on the household characteristics of the primary caregiver based on the Housing and Home Characteristics module of the household survey of the National Institute of Statistics and Informatics of Peru (INEI, for its acronym in Spanish). This module contains the following: Household assets, number of rooms, household members, household members under 18 years of age, access to electricity, water, and sewage; Internet connection.

[3] We collect data on child characteristics captured in other studies (Grantham-McGregor et al, 2020; Attanasio et al., 2020; Bernal, Attanasio and Vera-Hernandez, 2018; Attanasio et al., 2022; Andrew et al, 2019; Araujo and Rubio-Codina, 2016). We will collect the date for birth, age (in months), disability, type of disability, premature birth, height, and weight at birth, first child.

[4] We collect data on the primary caregiver's social network aligned with a previous study on mothers' social networks and socioeconomic gradients of Isolation (Attanasio et al., 2020)

[5] We will collect data on the primary caregiver's social media usage patterns based using the instrument from the Young Lives Study (Child Questionnaire Older Cohort).

[6] We collect data related to parental mental health and levels of stress using the Perceived Stress Scale (PSS) and Center for Epidemiologic Studies Depression Scale Revised (CESD-R10).

Primary Outcomes

Our primary outcomes of interest are **childhood development**, this will be assessed using two instruments.

We will use the **Global Scales for Early Development (GSED)** new tool developed from WHO. The GSED measures (Short Form) capture child development holistically through a common unit, the Developmental score (D-score). Dimensions GSED include a) language, b) motor, c) cognition, d) socio-emotional and e) adaptive. For the endline, we will use the GSED (Long Form).

Second, we will use **the Caregiver Reported Early Development Instruments (CREDI)** (Long Form) designed to measure the developmental functioning of infants in five dimensions. Dimensions include a) communication, b) gross motor, c) fine motor, d) problem solving, e) personal-social.

Secondary Outcomes

Secondary outcomes include the primary caregiver's intermediate outcomes and interactions in the home:

Parenting Attitudes: We will assess parenting attitudes with Parenting Attitudes Questionnaire Scoring (EAPQ). The EPAQ is a short instrument for assessing attitudes about parenting and child development. The EPAQ measures three sub-scales: rules and respect, affection and attachment, and early learning.

Parenting Skills: We will assess parenting skills with Parenting Sense of Competence Scale (PSOC), a 17-item scale developed to assess parenting self-esteem. The scale includes two rationally derived scales, Skill knowledge and Value-comforting, referred to as Efficacy and Satisfaction. The PSOC can be used to measure intermediate outcomes, and, in other contexts, to measure a parent's level of perceived competence. It can also be used to measure satisfaction in parenting, and confidence in parenting efficacy individually, or as a combined total measure.

Parental investment and quality of the home environment: We will assess parental investment and quality of the home environment with Home Observation for Measurement of the Environment (HOME), is an Indicators of Family Care for Development. The HOME instrument is based on information provided by the primary caregiver. This indicator includes parental investment in time and materials, and the child has a quality space for his needs at home.

Randomization and Blinding

Randomization will be conducted following baseline data collection. The research team will perform the randomization using a random number generator in Stata 17 with a reproducible seed. While it is not possible to blind the participants to their respective treatments, the cluster assignment data will not be shared with testers or surveyors so they will not know the assignment of respondents.

Sample Size and Power
The total sample will include 240 daycare centers and 2400 households, with 80 daycare centers and 800 households in each of the three study arms.

Data from the government's ENDES 2018 DIT Module and the randomized evaluation of SAF of Cuna Más (MEF, 2016) were used to calculate the intra-cluster correlation at the district and population center level. Based on the ENDES data, we assume the most conservative ICC between the two values and propose an even more conservative additional scenario to further minimize the likelihood of contamination and sample attrition. According to this estimate, the most conservative district ICC would be 0.06.

According to previous studies used as a reference, we expect interventions focused on the implementation of educational technologies aimed at parents (through videos or text messages) to demonstrate effect sizes between 0.1 and 0.2 standard deviations. For this intervention, we chose a detectable effect size of 0.175 standard deviations. Power calculations resulted in an average cluster size of 10. We plan to randomly select 10 households with children among the age ranges established within each sample cluster. Conventional levels of power (0.8) and statistical significance (0.05) are assumed.

Analysis Plan

General Analysis Approach
The main test outcomes will be scaled using standardized indexes (z-scores). We will analyze participants within an intent-to-treat framework and include unadjusted comparison of means and SDs for all primary hypotheses. All data and files used to estimate our parameters of interest will be publicly available once the trial is complete. Children who show signs of disability (marked as having a score less than 3 SD from the control mean) will be excluded from the analysis.

Heterogeneity of Impacts
We will examine how the impacts vary by gender and age of the child, and by education and age of the mother/primary caregiver.

Parameters of Interest
There are several key parameters of interest. Letting Y_i denote the outcomes variable for child i, and T_{i1} be a dummy variable equal to 1 if child I was assigned to treatment 1 ("Volar" using smartphones) and T_{i2} be a dummy equal to 1 if child I was assigned to treatment 2 ("Volar" using smartphones plus learning groups). The primary estimation equation for the trial then becomes the following:

$$Y_i = \alpha + \beta_1 T_{i1} + \beta_2 T_{i2} + \alpha X + \varepsilon_i$$

The parameters of interest are β_1 and β_2. β_1 is the Conditional Average Treatment effect for the "Volar" app using smartphones, and β_2 is the Conditional Average Treatment effect for the "Volar" app using smartphones plus the learning groups.

Estimation – precision and adjustments

To increase the precision of our estimates we will control for a group of covariates: region, child's age, child's sex, child's score on GSED and CREDI at baseline, mother's age, mother's schooling level.

Given the number of hypotheses tested, we will reduce the number of outcomes by constructing indices and adjusting for multiple hypotheses by adjust the estimates with the Romano-Wolf stepdown p-values. For robustness, we will compare it to the wyoung procedure. We will also group hypotheses according to families of outcomes and adjust estimates as described.

Differential attrition

We will carefully track sample children to minimize attrition and try to capture all sample children in each round. We will check for balance across baseline child, mother, and household's characteristics for attired and non-attrited children, and if a significant difference is found we will conduct sensitivity analysis using "worst case" imputation bounds. If attrition is high, we may also consider semiparametric weighting using baseline characteristics.

Interim Analysis

We plan to conduct a midline survey in February-April 2024 to track the progress of sample children and the quality of preschools. The analysis described above will be conducted at Midline and Endline.

Ethics

The trial is overseen by Innovations for Poverty Action's Institutional Review Board, which has reviewed the study protocols. Appendix A shows the approval consent and protocols of the study.