Pre-analysis plan
Family and Childhood Development: Kizazi Kijacho ("The Next Generation") - a Cluster Randomised Controlled Trial

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Contents

1 Introduction

This is the pre-analysis plan for the early child development (ECD) research program in Tanzania entitled "Kizazi Kijacho" (The Next Generation)[1].

Digital solutions can significantly improve the delivery of ECD services in Low- and Middle-Income Countries (LMICs). Traditional home-visits and community group-based parenting approaches require intense levels of training, mentoring and supervision of Community Health Workers (CHWs) that is difficult to sustain when transitioning to scale. Context relevant digital tools can support CHWs in delivering high-quality, respectful, and standardised multi-sectoral household ECD services by tailoring services to pregnant women and engaging male caregivers. This could have significant impacts on child development, including stimulation, speech and language development, nutrition, and cognition. Moreover, cash delivered through digital modes of payment is faster, safer, easier to administer, is scalable and has potential to empower women, influence parental investment and affect household decision making. Our study will conduct a clustered multi-arm Randomised Controlled Trial (cRCT) targeting pregnant mothers across all 8 district councils in the Dodoma region in Tanzania. Following the study sample for 15 months from 5-7 months pregnancy. The study will test and compare the causal effects of (i) a digitally supported parenting intervention delivered by CHWs, which aims to improve caregivers' access to quality ECD services; (ii) a mobile unconditional cash transfer which aims to relax financial resource constraints; and (iii) a digitally supported parenting intervention when combined with a mobile unconditional cash transfer. Findings from our study are expected to have important policy implications for the design of scalable ECD interventions targeting pregnant mothers in Tanzania and other LMIC settings.

2 Research strategy

The clustered multi-arm RCT has been designed to test the causal effects of a novel ECD intervention on children's cognitive, speech and language development and children's nutritional status, as well as on two secondary outcomes: children's socio-emotional development and parents' child rearing practices.

2.1 Research Design

The clustered multi-arm RCT has four main study arms:

1. No Intervention - Control: This arm will serve as the Control group (81 Health Dispensaries (HDs), 81 communities, 810 households) to identify the effects of a Parenting only, Unconditional Cash Transfer (UCT) only,

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and Parenting+UCT interventions. Caregivers will continue benefiting from a traditional government CHW home visit program, focusing on maternal and child health and nutrition, which is currently in practice in Tanzania.

2. Experimental - Parenting only: 88 HDs, 77 communities, 770 households. Existing CHWs will be trained to use an innovative digital application for the delivery of integrated ECD services to mothers who are at least 20 weeks pregnant and less than 32 weeks pregnant for a period of 15 months. CHWs will provide tailored ECD services (e.g., prompting messages tailored to child age and triggering follow-up visits conditional on changing conditions), covering all aspects of the Nurturing Care Framework (Health, Nutrition, Responsive Caregiving, Early Learning, Safety and Security (WHO, UNICEF, World Bank Group, 2018)). Real time data will be recorded by the CHWs in each visit using the application. Data will include information on visit attendance, activities conducted, home environment, caregiver practices, and CHW observations. From when the target child is 6 months old, group sessions will be organised by CHWs, focusing on caregiver-child interaction and stimulation activities. The digital system will be an integrated digital ECD service delivery solution to support CHWs with this level of decision support and tailored care.

3. Experimental - Parenting+Unconditional Cash Transfer: 88 HDs, 77 communities, 770 households. In addition to the Parenting only intervention, pregnant women in the study sample will receive a bi-monthly unconditional mobile money transfer of 77,000 TZS (33 USD) from 5-7 months pregnancy over a period of 15 months (7 transfers in total).

4. Experimental - Unconditional Cash Transfer only fixed amount: 89 HDs, 80 communities, 800 households. Households, in addition to the CHWs delivering health and nutrition services as usual, will receive a fixed bi-monthly unconditional mobile money transfer each of 109,000 TZS (47 USD) from 5-7 months pregnancy over a period of 15 months (7 transfers in total). The bi-monthly cash transfer equals the sum of (i) the average of maximum and minimum bi-monthly cash transfer amount disbursed per family under Tanzania Social Action Fund (TASAF), i.e. Tanzania's flagship nationwide social protection scheme (77,000 TZS, 33 USD) and (ii) the bi-monthly cost per additional family of delivering a parenting intervention (32,000 TZS, 14 USD). The transfer will be randomly assigned between mothers and fathers/spouses within each community, where in half of the eligible households, mothers will receive the transfer and in the other half, fathers/spouses (or household head where the father/spouse is not available) will receive the transfer.

In addition to these four main treatment arms, there is another UCT only treatment study group where the levels of the cash amounts vary across communities. In this treatment group, the Unconditional Cash Transfers only vary amount

(89 HDs, 75 communities, 375 households), in addition to the CHWs delivering health and nutrition services as usual, communities will be randomised to receive one of the bi-monthly unconditional mobile money transfer amounts: 32,000 TZS (14 USD), 77,000 TZS (33 USD), 109,000 TZS (47 USD) from 5-7 months pregnancy over a period of 15 months (7 transfers in total). The transfers will be randomly assigned between mothers and fathers/spouses within each community, where in half of the eligible households, mothers will receive the transfer and in the other half, fathers/spouses (or household head where the father/spouse is not available) will receive the transfer.

3 Study setting

The clustered multi-arm RCT is planned to be conducted in Dodoma region of Tanzania, a region where EGPAF, the implementing partner, has substantial experience and networks but where CHWs have not yet provided any Care for Child Development services other than health and nutrition (e.g. child stimulation) and where CHWs have not yet been supported by a digital application in the delivery of ECD services. All 258 public health dispensaries catchment areas (with at least one registered CHW) across all 7 districts (and all 8 district councils) in Dodoma region will be included: Bahi DC, Chemba DC, Chamwino DC, Mpwapwa DC, Kongwa DC, Kondoa DC (town council and district council), and Dodoma City.

4 Randomization, participants, and recruitment

4.1 Randomization

The randomization will be done in the following steps:

- All public HDs will be identified in the Dodoma region with at least one officially registered CHW, 258 HDs in total.
- These study HDs will be randomized to either (i) the Control group (81 HDs), (ii) the UCT only group (89 HDs), or (iii) the Parenting group (88 HDs). The randomization will be stratified by district council and by whether there is more than one village or 'mtaa' (city block in urban areas) served by the HD (i.e. in the HD catchment area).
- In the 81 Control HDs, one village/mtaa with at least one officially registered CHW will randomly sampled to participate in the study. In the 88 Parenting HDs and the 89 UCT only HDs all villages/mtaas (with at least one officially registered CHW) in their catchment areas will be included to participate in the study. In total, that will give 390 study villages/mtaas in the study sample.
- Within each of these study villages/mtaas, one officially registered CHW will be randomly selected and include the catchment area of that CHW

as a study 'community' in the study sample, where study community is defined as CHW catchment area. This could be the entire village/mtaa or a sub-village/mtaa, depending on the size of the village/mtaa and the number of CHWs working in the village/mtaa.

- Within the UCT only group (155 study communities across 89 HDs), study communities will be randomly assigned, stratified by HD, to: (i) UCT only fixed amount treatment arm (80 communities) and (ii) UCT only vary amount treatment arm (75 communities). In the Parenting group (154 communities across 88 HDs), study communities will be randomly assigned, stratified by HD, to: (i) Parenting only treatment arm (77 communities) and (ii) Parenting+UCT treatment arm (77 communities).

4.2 Recruitment and participants

The aim is to sample and survey for the study a total of 3525 pregnant women aged 18 years or above, who are living in the select study communities and who are at least 20 weeks pregnant and less than 32 weeks pregnant at the time of the baseline data collection survey visit to the study community region, Tanzania: a target of 10 women per community in the Control group, in the Parenting only treatment arm and in the UCT only fixed amount treatment arm and a target of 5 women per community in the UCT only vary amount group.

5 Primary and secondary outcome variables and analysis

5.1 Primary outcome measures

- *Children's cognitive and speech and language development*: Cognitive and language development at the time of the endline survey will be assessed. To do so, direct assessment and parental report will be combined. For direct assessment, the third version of the Bayley Scales of Infant and Toddler Development 3rd edition (Bayley-III; Bayley (2006)) will be used, suitably adapted for the context and provides measures up to 42 months of age. Cognition, receptive and expressive language subtests will be used. For parental report, selected items of the Caregiver Reported Early Development Instruments (CREDI; McCoy et al. (2018)) for cognition and receptive and expressive language subtests which provides measures up to 36 months of age, and a short versions of the MacArthur-Bates Communicative Development Inventory (Jackson-Maldonado et al., 2013) that measures expressive language up to 30 months will be used. Both of these have already been adapted for Tanzania and are free. Raw scores will be standardized within the study sample for analysis.

- *Children's nutritional status*: Weight and height will be measured at the time of the follow-up survey to obtain the height-for-age-z-scores and

weight-for-height-age-z-scores, standard measures outlined by WHO. Mid Upper Arm Circumference (MUAC) will be also collected (WHO, 2006). Scores will be standardized within the study sample for analysis, so all measures are in the same metric.

We will aggregate the measurement of outcomes using Structural Equation Modeling (SEM) to get latent factor(s) that summarizes effectively the information given by the individual items. We will combine direct assessment and parental reports as well as the different child development domains and nutritional outcomes if the fit of the model(s) are better than using the original scoring techniques.

5.2 Secondary outcome measures

- *Children's socio-emotional development*: Socio-emotional development at the time of the endline survey will be assessed. To do so, direct assessment and parental report will be combined. For direct assessment, the Griffiths Developmental Scale III (Griffiths, 1970) personal-social-emotional subtest, suitably adapted for the context, will be used. For parental report, selected items of the Caregiver Reported Early Development Instruments (CREDI) (McCoy, Marcus and Gunther, 2018) for the socio-emotional subtest which is already adapted for Tanzanian context and is free to use will be used. Raw scores will be standardized within the study sample for analysis. The measurement of outcomes will be aggregated using SEM to get latent factor(s) that summarizes effectively the information given by the individual items. Direct assessment and parental reports will be combined if the fit of the model(s) are better than using the original raw scoring techniques were higher scores mean better outcomes.

- *Child rearing practices - level of stimulation in the home:* The presence of toys and learning materials in the house will be assessed together with parental involvement with the child, the child's routines and organisation of the child's time inside and outside the family house. This will be assessed using the Family Care Indicators, developed by UNICEF (FCI; (Kariger, et al, 2012)), and possibly selected subscales of the Home Observation for the Measurement of the Environment (HOME; (Bradley, 2014)) and the Parental Style (PSQ; (Bornstein et al, 1996)) for assessing social and didactic interactions. The measurement of outcomes will be aggregated using SEM to get latent factor(s) that summarizes effectively the information given by the individual items on time and monetary parental investments.

Additionally, information on household characteristics, family background variables and maternal depressive symptoms will be gathered.

How the impacts vary by gender of the child and maternal education at baseline will be further examined.

5.3 Evaluation of Parenting and Unconditional Cash Transfer – Focus on Child Development

For the impact evaluation of the Parenting and UCT, Parenting only, UCT only fixed amount, and Parenting+UCT will be compared to the Control group on outcome y_i for child i, and also the treatments arms (Parenting only, UCT only fixed amount, and Parenting+UCT) to each other. The child development outcomes will be scaled to have mean 0 and standard deviation 1 amongst target children in the Control group. Equation (1)[2] evaluates the impacts of each treatment.

$$y_i = \alpha + \theta_s T_{i,s} + \gamma age_i + \delta \mathbf{X} + \varepsilon_i, \tag{1}$$

where $T_{i,s}$ is the treatment status for individual i where s indicates the treatments (Parenting only, UCT only fixed amount, and Parenting+UCT, respectively). age_i is the age of the child (months) at endline and $\mathbf{X}$ is a vector of observable household characteristics and family background variables to increase precision of the estimates. The covariates are district, tester ID, gender of the child, and maternal education. In addition, the estimation will control for any potential imbalances between treatments arms and between treatments arms and Control group.

All standard errors will be clustered at the HD CHW catchment area level. Additionally, multiple testing for the two primary outcomes will be performed. Step-down p-values using the general results of Romano and Wolf (2010) will be reported.

5.4 Power calculations

A sample of 10 households within each of approximately 80 study communities in each of the study groups in the cRCT gives 80 percent power for a two-tail tests of size 5% to detect improvements in child development outcome larger than 18-27% of a standard score (for the primary outcomes), assuming attrition of 10% (yielding a target sample size of 9 households within each community) and intra–cluster correlations between 0.1 and 0.3 for any pairwise comparison with the Control group. This sample size also allows to detect impacts larger than 24-30% for boys and girls sub-groups (expected on average at least 4 boys and 4 girls in the random sample of 9 children).

[2]Note that for the child development measures, it is not possible to run ancova specifications, as the child is not born at baseline.

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