Pre-Analysis Plan

Evaluation of Living Goods/BRAC entrepreneurial CHW model in Uganda

Phyllis Awor[1], Martina Björkman Nyqvist[2], Andrea Guariso[3], Jakob Svensson[4]

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[Revised plan registered before endline data collection]

1. Introduction

This document lays out the pre-analysis plan for the study titled "Evaluation of Living Goods/BRAC entrepreneurial CHW model in Uganda". The study was registered in accordance with WHO and ICMJE standards in the PACTR registry prior to baseline data collection, on 22/12/2015 (registration number PACTR201609001398349), as well as on AEA Registry (registration number AEARCTR-0002392).

This study evaluates the scaling up of an incentivized Community Health Worker program aiming at improving primary healthcare provision and reducing child mortality in rural areas of Uganda. The community health promoters (CHP) program is implemented in Uganda by two Non-Governmental Organizations – Living Goods (LG) and BRAC. One of the key innovations of this program is that, unlike most volunteer-based community health worker programs, it provides a set of financial incentives for the health workers. More specifically, there are two different categories of financial incentives. First, CHPs make profits by selling a range of health-related products to community members while carrying out their standard activities as community health workers. Second, they receive additional performance-based remuneration based on a set of key health activities that they perform, which include sick child assessment, registration and support of pregnant women, and visits to newborns in the first week of life.

The CHP program is organized into geographically based branches, and managed by branch managers and supervised by the two NGOs. The CHPs are selected through a competitive process among female

community members aged 18 to 45 who applied for the position in each village and who possessed basic writing and math skills. Eligible candidates receive 3 weeks of health and business training. At the end of the training, candidates need to pass a skills test in order to be equipped as an active CHP. The NGOs provide an initial set of products to all newly recruited CHPs, together with a uniform, a mobile phone, and a set of training materials and visual aids to use during household visits. CHPs also attend a one-day training each month to review and refresh key health and business topics.

The CHPs tasks mirror the standard Community Health Workers tasks (conduct home visits, educate households on essential health behaviors, provide basic medical advice, referring the more severe cases to the closest health center), but on top of that, as mentioned above, they also sell preventive and curative health products. The product line they have at disposal includes prevention goods (e.g. insecticide treated bednets, water purification tablets, and vitamins), curative treatments (e.g., oral rehydration salts, zinc, and ACTs), as well as other health-related commodities (e.g. diapers, hand soap, fortified food) and durables with health benefits (e.g. improved cook stoves, solar lights, and water filters). These products are sold by the CHP at a discount. The retail price is determined by the NGOs head office with a target of keeping prices for preventive and curative products about 20% lower than the prevailing local market prices. The CHPs in turn purchase these products directly from Living Goods or BRAC branches at wholesale prices between 30-50% below market prices and therefore earn an income on each product sold. Thus, the CHPs operated as micro-entrepreneurs with financial incentives to meet household demand. The broad product mix has three potential benefits: (i) driving up total sales and income for the CHPs; (ii) enabling the NGOs to cross-subsidize prices (dropping prices on essential health products and increasing the margins on other products); (iii) motivating CHPs to be out visiting households regularly by including high-velocity items (such as soap and fortified foods) in the product mix. The business training received by the CHPs stresses the importance of building up a customer-base by providing free services like health education, referrals, and newborn visits. As described above, the income deriving from the micro-entrepreneurial activity is then further increased through performance-based incentives, designed by the NGOs to further encourage key health activities such as household visiting, sick child assessment, registration and support of pregnant women, and visits to newborns in the first week of life. Since 2013, Living Goods and BRAC also equip the CHPs with smartphones that includes a rich mobile health application. The application helps guide the CHW through workflows, keep track of their stock, serve as a client management system, and prioritize certain activities based on timeliness (e.g. pregnancy follow-up) or household risk. Overall, this allows monitoring the CHPs' activity, while collecting real-time health data from the field.

A first evaluation of the impact of the CHP program began in 2010 (Björkman Nyqvist et al, 2019). The evaluation was based on a cluster-randomized controlled trial that involved 214 villages in 10 districts across Uganda. The villages were stratified by geographical zones and 115 villages were randomly assigned to the treatment group, where the CHP program started operating in January 2011, while 99 villages were assigned to the control group. The evaluation was based on an endline survey collected at the end of 2013, which covered 7,018 households and 11,563 children under-5 that lived in the same village throughout the trial. The study found that over the three years the CHP program reduced under-5 mortality rate by 27% (adjusted rate ratio 0.73, 95% CI 0.58-0.93) in the treatment compared to the control arm. The effects were of similar order of magnitude for infant mortality (adjusted rate ratio 0.67, 95% CI 0.51-0.87) and neonatal mortality (adjusted rate ratio 0.73, 95% CI 0.55-0.98).

Following the first study, the program has been massively scaled up across Uganda. The study presented in this submission takes advantage of the scaling up of the program to investigate the following two key questions: 1) Can the reduction in child mortality observed in the "proof-of-concept" study be sustained when the program is scaled-up? 2) What is the impact of scaling up an incentivized community health worker program on existing health service providers?

This new study involves the same main actors of the first one: program implementers, data collection agency, and funding agency. This helps ensuring that the design, the management, and the implementation of the research program remains the same as in the first study. There are, however, also few important differences: the new study will measure treatment effects over a longer time period , it relies on a much larger sample (500 villages and more than 12,500 households), it exploits a much richer set of data, including survey data from other providers in the community, and it relies on a panel of households identified at baseline, rather than on a cross-section.

## 2. Sample

Power Calculation

The sample size was designed to detect a reduction in under-5 mortality (primary outcome of interest), defined as number of under-5 deaths per 1,000 child-years of exposure to the risk of death under the age of 5. We used data from the control group in the proof-of-concept study conducted by the research team in similar settings (Björkman Nyqvist et al, 2019) to obtain the relevant inputs for the computation. A total sample of 500 clusters (250 per study arm) and 25 households per cluster at baseline (12,500 households in total) allows us to detect a reduction in child mortality of 20% or larger, at the 5% significance level with

80% power, assuming between-cluster coefficient of variation equal to 0.43 and attrition rate of 16% (or 4 households per cluster). Under the same assumptions, this design and sample size also has 80% power to detect a 21% reduction in infant mortality and a 25% reduction in neonatal mortality at the 0.05 significant level.

Villages Selection

The village selection proceeded in steps. First, the NGOs followed their standard procedures to identify and map villages that they considered eligible for expanding the CHP program, within the areas surrounding their branch offices.[5] This resulted in a list of 810 villages. From this list, we selected the 500 study villages in a way that maximized distance between villages, so to reduce the risk of contamination between treatment and control arms.[6] The villages are equally split between the two NGOs: 250 villages fall within the reach of a BRAC branch (11 branches in total) and 250 villages fall within the reach of a Living Goods branch (4 branches in total). Figure 1 show a map of Uganda where the 13 districts that are part of the study are colored in green.

Figure 1. Map of Uganda with Study Districts

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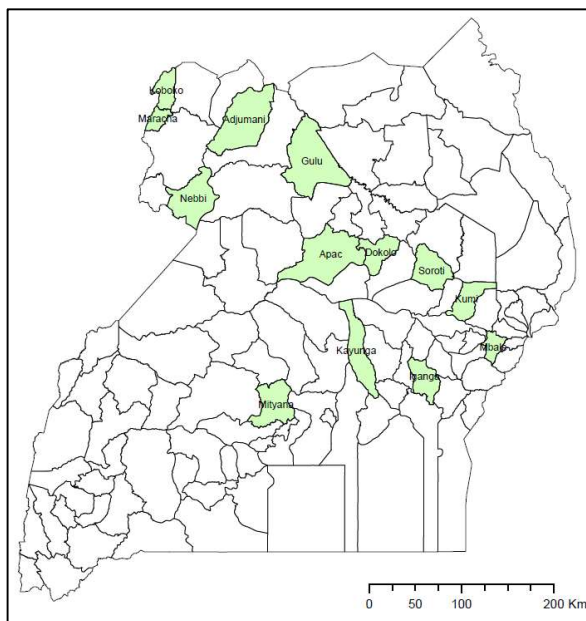
[5] The two organizations collected information on a number of different variables per village including: distance to branch office, number of households in the village, estimated population density, area economic status, distance to nearest health facility or clinic, MTN phone network, and presence of other NGOs with ICCM programs. The NGOs combined all these dimensions in a weighting index, which they then used to identify eligible villages, where the CHP program could take place.

[6] Concretely, we calculated the pairwise distance between villages, by district, and we dropped the villages closest to their next neighboring village. We then made cross-district adjustments to maintain even numbers of villages in each district, to enable us to have an equal amount of villages in the treatment and control arms of the RCT in each district. Distance was computed based on the location of the local chairman's house. We also verified the village location against administrative maps of Ugandan districts provided by UBOS, updated in 2012, using QGIS (v2.12.0).

3. Survey Components

The study covers 500 villages, spanning 13 districts of Uganda. There are 15 different branches of the two NGOs implementing the program located across the stud area. Villages were randomly allocated into a treatment (250 villages) and a control (250 villages) group after baseline data collection. The randomization was done within each one of the 15 areas (randomized block design). The CHP program started being implemented soon after baseline data collection only in the 250 treatment villages.

The baseline data collection took place in the first half of 2016 and had 4 different components:

1) *Household survey.* Based on the above power calculation, we targeted 25 households within each village. Our goal at baseline was to identify households with the highest likelihood of having (at least) one child born during the study period (i.e. within 4 years following the baseline survey). This selection was meant to increase the power of the study, compared to a purely random sample, given that the primary health outcomes we are interested in relate to maternal and child health. On the basis of conversations with local informants and pre-testing, four simple criteria were identified as best predictors of whether a woman in the study areas was likely to deliver during the evaluation timeline: 1) currently pregnant, 2) aged 16-35 years old, 3) with a young child less than three years old, 4) married (formally or informally). We therefore defined an eligible household as a household with a female permanent resident aged 16-35 years old, and either currently pregnant, and/or with a young child, and/or married. A preference was placed on pregnant women, then women with a young child, then married women. The woman was then identified as the primary respondent of the baseline household survey. When multiple women in one household met the same criteria, we selected the woman most likely to remain in the household (i.e. household head or wife of household head), and if we still needed to choose, we prioritized the youngest eligible woman. In practice, to identify the 25 study households we proceeded as follows. First, we performed a village census listing activity to collect a comprehensive list of households within each village. During this exercise the field officer sat with a Listing Committee, typically composed of the Local Chairman of the village, members of the Village Health Team (VHT), and other knowledgeable village members that the chairman deemed helpful for this exercise, and they provided a list of all households in the village. Second, for each household in the list, the Listing Committee reported the eligibility criteria. Third, we digitized the lists and used Stata software to rank the households within each village, following the priority of our criteria. Within the same category, we randomized the order of the households in the list. In

this way we identified the first 25 households of each list as our sample households and noted additional eligible households as potential replacements. Replacement households were selected following the (random) order of appearance on the list.

2) *Anthropometric survey.* We recorded anthropometric data on all children below five years of age in the selected households.

3) *Community Health Worker survey.* We surveyed the entire universe of active CHWs in the village. In practice, this included all CHWs that had conducted any community health work in the preceding six months. CHWs were first identified during the village census activity thanks to the help of the Listing Committee. To ensure full coverage of active CHWs in the village, the list was checked and updated when the survey team was in the village to administer surveys, by asking village members about any CHW operating in the village. Finally, all surveyed CHWs were asked about any additional CHWs that might have been operating in the village.

4) *Drug quality survey.* At baseline we collected sample drugs from the entire universe of drug stores operating in the study villages. In order to identify the stores, a field officer asked a few village members (at least three) all places where they could purchase medicine within the village. The field officer then visited all locations mentioned by the village members. These included shops, pharmacies, medical clinics, and informal locations such as personal stores or households. In villages without any drug outlets, the field officer visited the closest drug shop that village members typically attended for purchasing medicines, even if outside of the village boundaries. We collected samples of medicines to treat malaria (ACT drugs) and pneumonia (amoxicillin), using covert shopper approach, and we then tested the quality of the drugs.

A midline survey will be collected towards the end of 2017. The survey will have only a short household component.

Endline data collection will start in late-2020 and will have the same components as baseline plus a short LC1 chairperson survey to collect any relevant village-level event that took place during the study period. This will include major investments, NGO interactions, natural disasters, and government funding.

4. Outcomes

Primary Outcome

To assess the impact of the scaled-up program, in relation to the *first* research question, the primary outcome of interest is *under-5 mortality*. We will compute mortality at the cluster level using information

contained in the household survey. The survey records: 1) detailed birth information on all children under five living in the households at the time of the survey; 2) detailed birth and death information on all children that died under the age of five during the study period.

At endline, for each child, we will define the number of month of exposure to the risk of death during the trial period, defined as the difference between the birth date of the child, or the start date of the trial if the child was born before that date, and the date that the child turned five years if that occurred during the trial period, or the date of the endline household survey if the child was less than five years old at that time, or the date of the death of the child. Under-five mortality will then be calculated as number of under-five deaths over the trial period per 1,000 child-years of exposure to the risk of dying under the age of five. We will also compute infant mortality as number of deaths during the trial period arising within the first year of life per 1,000 infant-years of exposure, with infant-years of exposure calculated in a similar way as the child-years of exposure described above. Finally, we will compute neonatal mortality as the number of deaths during the trial period within the first month of life per 1,000 births. All three measures will be defined at the village level. [7]

To study how other health actors react to the scaling-up of the CHP program, in relation to the *second* research question, we will look at both the extensive and the intensive margins. We will start by studying the impact on the extensive margin. Here, we will focus on the number of drug shops and the number of active CHWs operating in the study villages at endline. These outcomes will be defined at the village level. We will identify as active CHW any CHW that carried out any CHW-related activity over the six months preceding the survey. Next, we will look at the intensive margin. Here, we will focus on the quality of the drugs sold in the drug shops, as well as the level of interaction and type of activities carried out by the CHWs operating in the study villages. In these case the outcomes will be defined at drug sample and CHW level, respectively.

Secondary outcomes

By relying on the different survey tools mentioned above, we will collect a range of additional outcomes that will allow us to dig deeper into the mechanisms behind the main result.

Concerning the first research question, the secondary outcomes will serve to investigate the following secondary hypotheses:

1.1)   The program increased the chances that a household interacts with and benefits from services provided by the CHPs;

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[7] International organizations such as UN and WHO typically express mortality in terms of deaths per 1,000 live-births. Such organizations use data collected over long periods of time and rely on a life-table approach to compute mortality as a probability. Given that our evaluation lasts only for four years, the most appropriate approach in our case is to compute mortality as a ratio, following the steps described above, and to express it in terms of years of exposure. For completeness and in other to facilitate comparisons with other estimates, we will in any case also report results obtained using a life-table approach. Finally, and for completeness, we will report child mortality measures simply expressed in terms of number of child deaths in the village during the study period.

1.2)   The program increased the overall amount and quality of health services received by households;

1.3)   On top of the impact on child mortality, the program improved additional health outcomes, related to family planning, pregnancy, newborn and child health;

1.4)   The program improved the basic health knowledge of the households;

1.5)   The program improved the health behavior (both preventive and curative) of the households;

Concerning the second research question, the secondary outcomes will serve to investigate the following secondary hypotheses:

2.1)   The program increased the (average) satisfaction, motivation, and confidence of the CHWs operating in the village;

2.2)   The program lowered the turnover of the CHWs in the village;

2.3)   The program increased the (average) health knowledge of the CHWs operating in the village;

2.4)   The program increased the amount of (self-reported) activities of the CHWs operating in the village;

2.5)   The program impacted the supply of drugs in the community, by reducing the number of drug stores operating in the local markets, raising the quality of their service, and lowering the price of the drugs;

Below we report the full list of the variables we plan to investigate in our analysis, arranged by category. The first column reports a short description of the variable as well as the specific questions from the endline survey that we plan to use to generate it. The questions should be considered only indicative, as we are going to revise and edit the survey during piloting phase. The second column of the table reports the source used to generate the variable, while the third and last column indicates to which one of the secondary hypotheses listed above it refers.

Variable Description	Source	Hypothesis
1. Households interactions with CHWs		

a.   Household interactions with CHWs in general and CHPs in particular
   -   *HH visited by any CHWs/CHPs over the previous 30 days*
   -   *HH received any health service from the CHWs/CHPs (health products / education / diagnosis / referral / maternal care / follow-up visit)*
   -   *HH knows how to contact the CHWs/CHPs in the village*
	HH survey	1.1

2. Health services		
a. Household received follow-up health visits by any health staff… - *…following health-related problems with children under-5 (malaria, diarrhea, pneumonia) to specifically find out about child's recovery*	HH survey	1.2

	- *…during pregnancy to monitor pregnancy* - *…after delivery to check the mother and child health* - *If so, was the visit performed during the first week of life?*		
b.	Household received referrals to a health facility due to health-related problems with children under-5, or pregnancy	HH survey	1.2
c.	Pregnant woman received counselling and health recommendations… - *…on where to deliver* - *…on medicines to take (Folic Acid, Iron and/or Vitamins / Malaria Prophylaxis / Deworming medicine)* - *…on newborn feeding practices*	HH survey	1.2
3.	**Health Outcomes**		
a.	Anthropometric measures for children under-5 - *Height-for-age (expressed in z-scores)* - *Weight-for-height (expressed in z-scores)* - *MUAC-for-age (expressed in z-scores)*	Anthropometric survey	1.3
b.	Malaria, diarrhea and pneumonia prevalence among children under-5 - *Child fell sick with malaria in the previous 3 months* - *Child fell sick with diarrhea in the previous 3 months* - *Child fell sick with pneumonia in the previous 3 months*	HH survey	1.3
c.	Share of miscarriages and stillbirths during the study period	HH survey	1.3
d.	Unmet need for family planning and unwanted pregnancies	HH survey	1.3
4.	**Health Knowledge**		
a.	Respondent knowledge concerning causes and treatment of malaria, diarrhea, and pneumonia - *Respondent believes mosquito bites are the only cause of malaria* - *Respondent believes one can make environmental changes to prevent malaria* - *Respondent knows Zinc can be used to treat diarrhea* - *Respondent knows diarrhea can be transmitted by drinking un boiled/untreated water?*	HH survey	1.4
b.	Respondent knowledge concerning nutrition and breastfeeding practices - *Respondent knows about vitamins & added nutrients* - *Respondent knows colostrum is healthy*	HH survey	1.4

	- *Share of correct answers on a short case study presented to the respondent, which compares health evolution of two children treated differently in terms of nutrition and breastfeeding.*		
c.	Respondent knowledge concerning family planning - Respondent knows about family planning methods (share)	HH survey	1.4
5.	**Household Health Behavior**		
a.	Household standard prevention and treatment practices for diarrhea, malaria, and pneumonia - *Respondent washes hands with soap most of the time* - *HH treats malaria with ACT drugs* - *HH treats pneumonia with antibiotic* - *HH treats diarrhea with ORS and Zinc*	HH survey	1.5
b.	Household food consumption habits - *Child has varied diet (based on number of different food categories consumed the previous date, obtained from a detailed food consumption section)*	HH survey	1.5
c.	Ante-natal and post-natal care practices, including breast-feeding practices - *Women sought ANC at least 4 times* - *Woman fed newborn within 1hr of birth* - *Woman fed baby non-breastmilk fluids after 6 months* - *Woman during pregnancy took Folic Acid / Iron and/or Vitamins / Malaria Prophylaxis / Deworming medicine* - *Woman took Vitamin A and/or folic acid in first two months after delivery* - *Woman gave birth outside a health facility* - *Woman devised a birth plan*	HH survey	1.5
6.	**Community Health Workers knowledge and activity**		
a.	Level of satisfaction and confidence of health workers - *First principal component from on a set of questions related to satisfaction (e.g. "I am satisfied with the community thanks and recognition I receive for my work")* - *Self-reported level of confidence that the CHW provides correct advise and/or treatment services for the community* - *Revenues as health worker*	CHW survey	2.1

b. Level of CHW turnover (*village level variable*) - *Measure constructed using information provided by CHWs on when they joined the organization and whether / how often the organization changed workers*	CHW survey	2.2
c. Knowledge of health workers concerning malaria, diarrhea, and nutrition - *CHW believes mosquito bites are the only cause of malaria* - *CHW believes one can make environmental changes to prevent malaria* - *CHW believes combination ORS & Zinc can treat diarrhea* - CHW knows correct signs/symptoms of Pneumonia and Malaria - *Share of correct answers on a short case study presented to the respondent, which compares health evolution of two children treated differently in terms of nutrition and breastfeeding.* - *CHW knows which food contains more protein value than others* - *CHW knows danger signs during pregnancy*	CHW survey	2.3
d. Level of self-reported activity of the health workers - *Days worked as CHW if last 30 days* - *Number of Activities in last 30 days (Pregnant women visited; Newborn babies visited; Children < 5 years visited; Family planning visits; People tested for malaria; People treated for malaria; Patients referred to health center)* - *Number of Health forums / health education campaigns held*	CHW survey	2.4
7. Drugs availability		
a. Number of drug stores that opened (closed down) during the study period (*village level variable*)	Drug quality survey	2.5
b. Drug store provided the appropriate medicine to treat the disease (malaria and pneumonia)	Drug quality survey	2.5
c. Price of the drugs sold by the store	Drug quality survey	2.5

5. Analysis

Empirical Model

Our primary specification is straightforward and will entail the regression of the outcome variables on a dummy for the treatment status of the village,

$$Y_{i,v,b} = \beta T_{v,b} + \tau_b + \varepsilon_{i,v,b}$$

where Y is the outcome for individual i (depending on the outcome, it might be a child, a woman, or a community health worker), living in village v, in the catchment area of branch b. In some cases the outcomes will be defined at the village level (e.g. child mortality or drugs quality). Given that we considered the NGOs' branches as blocking variable when performing the initial randomization, all specifications will include branch fixed effects τ_b. Standard errors will be clustered at the village level. The coefficient of interest β will capture the impact of the program on outcome Y.

We will also run two augmented versions of our main regressions, where we will include a control for the baseline value of the outcome variable in order to increase the precision of the estimates.

Correction for Multiple Hypothesis Testing

Given the number of outcomes in our study, multiple testing is a concern. We will therefore follow Kling, et al (2004) and calculate standardized effects for each family of outcomes (see table above for the detailed list of variables). We will also report both robust standard errors as well as the p-values of tests of the null that treatment has no effect computed using randomization inference. [8] The do file attached to this submission includes the specific commands that will be used to run the analysis.

Sample

Households

The main analysis will include the full sample of households that we have identified at baseline and that we have been able to track till endline, plus the replacement households. At endline we will track back and survey baseline households even if they moved outside the study village (as long as we will be able to track them) and these households will always be included in our analysis. Whenever we will not be able to track back a baseline respondent, in order to preserve power, we will replace the household, following the procedure described above.

We will show the robustness of all our results by excluding the replacement households from the analysis as well as by including baseline controls.

CHW and Drugs stores

For CHWs and drug stores we will have two repeated cross-sections covering all active health workers and stores, which will be included in the analysis. Outcomes in this case will be mostly defined at the village level.

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[8] We will construct these p-values using 1,000 randomly selected permutations of the randomization allocation. The p-value is then constructed based on the proportion of test statistic values (squared of the estimated coefficients) that are greater than the actual test statistic value.

Data Checks

Balance checks

Following standard practice, in our analysis we will report balance checks performed on the variables collected at baseline. These checks will allow us to credibly attribute to the program any difference that we will observe between the groups at endline.

Attrition

We will check that any attrition caused by households that moved to a different district (or that we are not able to track in any way) is non-systematic. In practice, we will run the empirical model mentioned above, using baseline data and replacing the dependent variable Y with an indicator for whether the households could be tracked till endline or not. Non-systematic attrition would imply the coefficient β to be not statistically distinguishable from zero.

On top of comparing the level of attrition across study arms, we will also assess whether the composition of the households lost at follow-up varied across the two study arms. We will start by simply checking the characteristics of the households that we lost at follow-up as and compare them to those that we could track back[9]. We will then interact these characteristics with the treatment indicators, to assess whether certain specific types of households were more or less likely to drop out from one study group.

Because of all the precautions taken during survey work, we do not expect to observe differential attrition. However, in case the analysis will suggest otherwise, we will present bounds of treatment effects, using the approach of Lee (2009).

Missing values and Outliers

We plan to identify unusual missing values and outliers straight away during data collection, through the high frequency checks that we will perform on a daily basis on incoming data. This will give us the opportunity to double check and revise any missing entry or outlier due to errors that might have taken place during data collection. We will therefore consider the final dataset to contain only "true" missing values and unusual values. We therefore do not plan to introduce any correction in our main results. As a robustness check, we will in any case generate our main results by geographic zone, to check that our results are not driven by any one specific zone.

Heterogeneous effects

Although we might not have enough power to clearly identify heterogeneous effects, we plan to analyze few relevant interactions, as they could provide additional insights on the effectiveness of the program. In particular, we plan to examine heterogeneous effects of the treatment with respect to:

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[9] We will consider baseline household wealth, household composition, presence of a pregnant woman, and basic health indicators.

1) *household characteristics*: baseline wealth[10]; baseline distance from the CHW and CHP houses.
2) *village characteristics*: BRAC vs Living Goods area; baseline average health knowledge of the CHWs operating in the village; baseline average wealth in the village; baseline size of the village and density of CHWs.

6. Bibliography

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[10] Wealth will be constructed using principal component analysis and combining all the asset-ownership and household-related questions included in the survey.