Baseline Survey – Methods Report
The Reduction in Anemia through Normative Innovations (RANI) Project

Methods

Study Design

The Reduction in Anemia through Normative Innovations (RANI) project is a norms-based intervention to reduce anemia among women of reproductive age in Odisha, India. The project is being implemented in two blocks (Athamalik and Kishorenagar) in Angul district of Odisha. We evaluate the RANI Project using a cluster randomized controlled trial (RCT) and a longitudinal study design. In this design, villages were randomized on a 1:1 ratio to receive the treatment or continue with usual care (defined as the currently existing and ongoing efforts to reduce anemia in Odisha). Treatment is defined as exposure to one or more components of the RANI project. As this is a community-level intervention, we used a cluster design to prevent contamination across communities. Data collection occur at three time points: baseline, midline, and end line. The overall schema of the study design is depicted in Figure 1.

Randomization of Clusters

We grouped together villages in Athamalik and Kishorenagar Block into clusters of 1 to 4 villages, resulting in eighty-nine total clusters. A geographical buffer of at least one village or natural structure (e.g., a mountain) was maintained between clusters to limit contamination. We first segmented clusters by proportion of minority populations (in India they are called scheduled castes and scheduled tribes) and then used a random number generator to randomly assign clusters into treatment (k = 50 clusters) and control arms (k = 38 clusters). We selected three clusters from each stratum for data collection so that 15 clusters (which comprised 41 villages) from the treatment arm and 15 (comprising 40 villages) from the control arm were selected for data collection. Data collectors and program implementers were blinded with regard to treatment and control status of villages.

Participants

All women between 15 and 49 years old, a resident of the village, and speak Odia were eligible for the study. Additionally, as this is a longitudinal study, participants who indicated that they are not planning to move out of the village for the next two years were included in the study. We excluded women with an active fever at data collection and referred them to the closest health center. We also referred those with severe anemia to the local health center, but they were not excluded from the study. Although pregnancy status was not an inclusion or exclusion criterion, we excluded currently pregnant women from certain components of data collection that could put them at risk. They only took part in the survey and were provided hemoglobin measurement.

Statistical Power and Sample Size Calculations

We assumed a 7% reduction in anemia (from 47 to 40 percent), which is a lower effect size than typically found, alpha level of .05 with 80% power, the required sample size was 787 per arm (Bharti, Bharti,

Naseem, & Attri, 2015; Riviera et al., 2004). Further assuming a design effect of 2.0 to account for clustering effects within villages, the required sample size with 20% loss to follow up is N = 1,968 per arm, which were rounded up to 2,000 per arm for a total of N = 4,000 across the treatment and control arms at baseline.

Procedures

Recruitment of Staff and Training: We engaged a team of 51 female data collectors, 8 female data quality assurance persons and 8 male support staff during the baseline. The 51 data collectors comprised of 35 interviews, 8 Lab Technicians and 8 Physical test members. Additionally, we engaged a team of 18 persons for the household listing which consisted one Household Listing Coordinator, 3 Household Listing Supervisors and 14 Household Listing Persons. Apart from the above teams, the entire survey was managed and supervised by a core team consisted of 4 persons from DCOR.

Prior to the data collection, we conducted a three-day training of Household Listing team (from July 13 to 15, 2019); four-day training of physical & cognitive test team (from July 15 to 18); six-day training of interviewers (from July 19 to 24, 2019); and two-day field practice (from July 25 to 26, 2019).

Recruitment of Participants: As mentioned earlier, the sample size required for the evaluation was 4,000 women between the ages of 15 and 49 residing in treatment (n = 2,000) and control (n = 2,000) clusters. Since there were more than one eligible woman in some households, the evaluation required to recruit one-woman participant per household. In total, the evaluation aimed at recruiting 4,000 households having eligible woman for the study.

Sampling of participants was stratified by treatment/control, village size and household. The sample size from each cluster was proportional to population so that 60% of women in each arm come from high-population areas, 30% come from medium population areas, and 10% come from low population areas. To do so, we created a household listing of eligible women within the selected clusters. We carried out census listing of households in the 15 treatment and 15 control clusters; and based on the household listing data, we identified the eligible households applying the above-mentioned participant inclusion criteria. The household listing exercise identified 7,997 households having women between the ages of 15 and 49. Some households identified had more than one eligible participant.

Once we knew the total number of eligible women from the household listing data, we determined the number of eligible women to be recruited from each cluster on proportion-to-size principles. Accordingly, we sampled the required number of households having eligible women for each selected cluster applying computer generated random number method. During the sampling of households, we recruited an additional 15% households to adjust the attrition. In total, we approached 4,535 households having eligible women, of them, we were able to cover 4,110 women in the evaluation.

All the households (N=4,535) that we visited, first underwent the screening procedure to verify the eligibility of participant/s in the households and their availability for the entire period of evaluation followed by obtaining of informed consent from the participants. So, of the 4,535 households approached,

we excluded 107 households for not fulfilling the inclusion criteria e.g. the participant is either over age or physically/mentally handicapped; or had any major illnesses or fever at the time of survey. The remaining 4,428 households were eligible of those 318 households did not participate in the survey (47 did not consent or refused to participate in the evaluation and 271 did not participate due to their absence in the village at the time of survey). The rest 4,110 households participated in the evaluation out of the 4,428 eligible households. The response rate was 92.8%. In case of households where there was more than one eligible woman, the listing of eligible women was done and then, one woman was randomly recruited using Computer Assisted Personal Interview (CAPI) application.

The sampling design also included a greater-intensity subset of participants, who provided additional data. Procedures for this group are described below. Only a smaller sub-set i.e. 350 non-pregnant women (n=175 in treatment and n=175 in control clusters) were required to participate in the greater-intensity activities for reasons related to participant burden. Expecting a higher non-response based on the experience gathered from pilot testing, we recruited and approached much higher number of women i.e. 487 to achieve the sample size of 350 non-pregnant women required for work capacity, cognitive functioning, and physical activity assessments. Out of those 487 women approached, 36 were pregnant women, hence they were not eligible and were excluded. Of the remaining 451 eligible women, 75 refused to participate (83.4% response rate was achieved). So, the rest 376 women participated in the work capacity, cognitive functioning, and physical activity assessments.

Participant Consent and Confidentiality: Informed consent was obtained in Odia by the local data collectors. In case of participants under the age of 18 years, written permission of one parent or legal guardian and assent of the participants were obtained. All data from participants were de-identified by the local principle investigator and stored in secure, password-protected computers that only the study team and its affiliates have access to.

Data collection methods and samples: The evaluation uses multiple innovative methods to triangulate self-reported data through questionnaires to assess Iron Folic Acid (IFA) consumption, knowledge and perceptions about anemia and IFA, self-efficacy, social norms, mental health status, diet, and quality of life. In addition, we assessed: hemoglobin levels with a HemoCue photometer; anthropometric measures for body mass index; work capacity through Queens College Step test; Simon (computerized) and Corsi Blocks (non-computerized) tasks for cognitive functioning; and three-day physical activity (reclining, sitting, standing, and walking) tests through ActivPAL accelerometers.

We collected the baseline survey data over six-weeks during July to September 2019. The participants recruited for the evaluation first underwent a one-on-one survey interview to assess demographic information, psychosocial factors, and anemia-related behaviors followed by a point-of-care hemoglobin test to assess anemia status and anthropometric measurements (height and weight). Then a smaller sub-set of participants participated in work capacity assessment through Queens College Step test; Simon (computerized) and Corsi Blocks (non-computerized) tasks for cognitive functioning; and three-day physical activity (reclining, sitting, standing, and walking) tests through ActivPAL accelerometers. The

pregnant women were excluded to participate in the anthropometry measurements, work capacity, cognitive functioning, and physical activity assessments.

Interview: All participants (n=4,110) were administered a structured interview by a team of 35 interviewers. This survey measured self-reported IFA consumption and anemia status, as well as other secondary outcomes: knowledge, attitudes, and perceptions among participants; social norms; mental health (via the CES-D scale); quality of life (via the SF-12); and diet (via the MDD-W questionnaire).

To minimize the participant burden, we executed a planned missingness design in which participants were divided into four groups, one of which received the full questionnaire battery, and three others received only the primary variables (approximately 75% of survey items) and a subsample of other variables. Questions in the survey instrument were divided into two groups: core questions and ancillary questions. We prepared four versions of the questionnaire such that each version has a set of core questions (comprising the main study outcomes and basic demographics) and a smaller set of ancillary questions. The 4,110 participants were randomly assigned to receive one of the four versions (Version 1 was administered on 1,023 households, Version 2 on 1,031 households, Version 3 on 1,030 households and Version 4 was administered 1,026 households). This process significantly reduced participant burden (in comparison to having all participants answer all questions).

We collected interview data; hemoglobin & anthropometry measurement data; and step-test data using Computer Assisted Personal Interview (CAPI) application developed using the android application software known as Open Data Kits (ODK) installed and used on android operating system-based tablets during data collection. The software is supported by a backend server, a mobile client, 'ODK collect' for data collection and ODK Aggregate as a database application to visualize data, and to export data in CSV files. The ODK software with its Xforms technology was used to design the data collection forms. The finalized paper questionnaire was converted into data collection survey forms, through XLS Form syntax in Excel. We ensured minimizing data entry errors by programming acceptable data value ranges, skips, and error messages into the data collection forms. ODK application used for data collection was protected using passwords. Interviewers had to login to the system to access the surveys and to upload data. All uploaded data were stored under password protection and only authorized team members had access to the password(s). All data were transmitted electronically from the mobile ODK application via secured SSL connection to the server. The data were extracted in CSV. files for ensuring data quality in real time and for the data analysis.

Hemoglobin measurements: Of the 4,110 participants, we obtained hemoglobin levels from 4,088 participants, through point-of-care hemoglobin tests, using a HemoCue photometer (in line with India's National Family Health Survey methodology). This instrument provides hemoglobin levels immediately and accurately (Sanchis-Gomar, Cortell-Ballester, Pareja-Galeano, Banfi, & Lippi, 2012). Although they participated in the interview, the remaining 22 participants refused to participate in the hemoglobin test.

Anthropometry measurements: Excluding the 193 pregnant women, 3,917 participants were approached for the anthropometry measurements (height and weight). Of them, the same 22 participants who

refused to participate in the hemoglobin test, also did not consent for the anthropometry measurements. The rest 3,895 participants underwent anthropometry measurements.

Work capacity: The Queens College Step Test assesses aerobic fitness (McArdle et al., 1972). The participant steps up and down on the 16.25-inch (41.3 cm) high platform at a rate of 22 steps per minute (88 beats per minute), assisted by the use of a metronome to maintain the right speed. Participants use a four-step cadence, 'up-up-down-down' for 3 minutes, and heartbeat is assessed at five points: t0 to t4, corresponding to the beginning (before starting the step test), at the 1-, 2-, and 3-minute marks, and then at the end (one minute after completing the step test). During our pilot study, we learned that the 16.25-inch height was too high for our sari-wearing participants and that a 12-inch height was found to be ideal. Thus, we used this (12-inch) height in our study. Although using this lower height will not make our study readings directly comparable with other published studies, it will help us address our study objective (to compare longitudinally and across treatment-control arms).

Out of the 376 women who gave consent for the work capacity, cognitive functioning, and physical activity assessments, one woman chose not to participate in the step test. The rest 375 participated in the step test out of the 451 eligible women approached (response rate was 83.1%).

Cognitive functioning: We also measured cognitive functioning within this sub-cohort through attention and working memory tasks. We used the Simon Task to measure attention, Simple Reaction Time (SRT) task to measure perception, the Corsi Blocks task and the Word Span test to assess working memory. To account for low computer literacy, these tests included both computer (Simon Task and SRT) and non-computerized tests (Corsi Block Tapping test and Word Span test). The computerized tests like Simon Task and SRT were conducted using Psychology Experiment Building Language (PEBL) platform. Prior to administering these tests, pre-test instructions were given to the participants. The participants also underwent practice trials before the computer (Simon Task and SRT) tests. All the 376 women participated in each of these 4 cognitive tests viz. Simon Task, SRT, Corsi Block Tapping test and Word Span test.

Physical Activity: The 376 participants in the sub-cohort also wore an ActivPAL (PAL Technologies, LTD; Glasgow, UK) for three consecutive days to establish baseline measures of daily reclining, sitting, standing, and walking. The ActivPAL is small (53 x 35 x7 mm), light-weight (15g) and is attached to the mid-thigh. Excluding the non-eligible women, we approached 451 women for wearing the ActivPAL of them 75 either refused to wear or took-out before completion of 48hrs (response rate was 83.4%). Those who took out the ActivPal before 48hrs, we considered them under refusal. The rest 376 participants wore ActivPal for 48hrs or more. In spite of counseling and showing demos by the study team and also taking help of the community health workers, the non-response for participating in ActivPAL test was found to be highest.

Data quality assurance: The following key measures were taken to ensure data quality.

- We used technology-enabled data collection methods, which helped to access and review the quality of data and enable providing feedback in real-time.

- We recruited and engaged data collection team having past experience and record of collecting quality data. After their recruitment, we imparted rigorous training (both classroom and field training) to build their capacity for ensuring quality in data collection.
- During the data collection, we conducted 480 back-checks and 240 spot-checks for monitoring the data quality. Every day, after returning from the field, the data collectors were provided feedback and were motivated to ensure quality in data collection.
- We ran intra- and intercoder reliability statistics and provided feedback in real time on a regular basis.

Data collection challenges:

- Heavy rain, water logging and flooding in the study sites created mobility problem for the survey team.
- Some of the clusters were found inaccessible due to hilly and thick forest areas, which posed challenges for the survey team to reach-out to the sampled participants.
- Due to agriculture season, the participants in most villages were found busy in showing or planting activities. Hence, the data collectors had to wait and take 2 to 3 visits to conduct the interviews.
- Lack of concrete or plain surface in some villages created difficulty for the Lab Technicians to administer the height and weight measurements.
- Due to lack of proper space or public infrastructures, setting-up work stations to conduct the physical and cognitive tests was difficult in some of the villages. Hence, the participants from one village had to be taken to the other village in the cluster for conducting such tests.
- Some participants complained of red rashes on their body because of wearing the activPal for 3 days.
- Some participants had removed the ActivPal before the due date, hence the test had to be discarded. In some cases, the survey team had to again visit and administer the ActivPal to the participant.
- A number of participants refused to participate in ActivPal test due to suspecting the intention of data collection.
- Some participants did not agree for providing time to do the back checking of the interviews.
- In one of the hamlets of a village, the villagers abused the female data collectors and did not allow to complete the data collection in that hamlet.

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Figure 1. Custer Randomized Control Trial Schema