# TW14 Pre-analysis plan: [TW14.1006 *Implementing and evaluating low-cost interventions to improve latrine use among rural households in Odisha, India*]

## Intervention

## Theoretical framework

**Please describe the underlying behavioural theory - which will be used to guide your strategy for eliciting behaviour change through your intervention.**

*Note: The behaviour change theory provides the rationale for the hypotheses to be tested along the causal chain, in addition to the intervention and related activities. We assume that the concepts within the theory will become more context-specific during the course of the evaluation. In this way, describing the underlying theory in the pre-analysis plan will facilitate the interpretation of findings, which might vary from what was originally expected. Documenting changes or additions will better inform the underlying theory.*

Based on our formative research and a thorough literature review, latrine use in rural Puri District of Odisha State is influenced by: Risk perceptions, ability to use a latrine, Social Norms, Motivations, Self-regulation of the behaviour, and Physical Opportunity (i.e. the presence of a functional latrine in the household).

We expect that the various interventions we propose will impact these noted behavioural determinants and therefore encourage latrine use. Specifically, the intervention aims to make people aware of risks associated with open defecation and the health benefits of latrine use; instruct individuals as to how to use latrines and potties for safe child faeces disposal; shift social norms around latrine use; motivate latrine use; encourage continued use; and provide facilities (latrine repairs) and hardware (potties, scoops) to enable use by all. The overall delivery of the intervention is informed by the Trans-theoretical model’ (Prochaska, 2013) and is described in more depth in section 1.2.

A full depiction of our theory of change is in Appendix A at the end of this document, and a simplified theory of change is in Appendix B (Images could not be places within this template accurately, hence are at end).

## Intervention summary

**Please summarise your intervention.**

a) In treatment villages, a local NGO, Rural Welfare Institute (RWI), will deliver an intervention package that includes activities at the community and household levels, with additional activities and hardware for mothers of children under five. For households with non-functional latrines, RWI will hire masons to provide the appropriate repairs.

***Community Level Activities:***

At the community level, there are four activities..

*Palla:* The first activity is a traditional performance known as a ‘*palla*’, which includes a series of songs and skits that aim to increase practical knowledge of latrine use, pit emptying, and safe feces disposal and perceived benefit of latrines, and decrease preference for OD. The palla, which will be performed by local troops hired, managed and trained by RWI, introduces and repeats a slogan in Oriya: ‘our clean, healthy, beautiful community’. The palla targets the ‘status’ motive, encouraging villagers to think about their households and their village compared to others, to consider what others may see when they visit.

*Transect Walk:* The second activity is a ‘transect walk’, which aims to make community members aware of the true state of their village. Community mobilizers from RWI make a surprise visit to walk around and observe the village with members. They use holi powder to mark feces, which enables those not on the walk to observe its effects.

*Community meetings:* The third activity is a series of community meetings organized and led by RWI, one for women and one for men. During these meetings, participants come up with a vision for their community (like a goal) and decide on an action plan to achieve the vision. At this time, the participants are also asked to identify ‘positive deviant’ households that always use their latrines. These households are later given a banner by RWI to place in front of their house to publically recognize and praise their contribution to making the community cleaner, healthier and more beautiful.

*Wall Painting:* The fourth activity is a wall painting of a map of the village that identifies the positive deviant households. The painting aims to remind the village of their goal and motivate other households to use their latrines. RWI will hire and supervise local artisans to paint these murals.

***Household Level Activities***

*Household visits:* At the household level, an RWI mobilizer will make *houeshold visits* to all households with latrines, providing targeted information, repeating key messages, and encouraging commitment to the community vision of latrine use by all members of the household at all times. These visits personally reinforce community messages and secure household pledges; they are important for those members who may or may not have been able to participate in other community-level activities.

*Latrine Repairs:* Households that need latrine repairs will receive repairs from masons hired by RWI so that a key barrier to use—unavailability of a functional latrine— is removed. We will include latrine observation measures in our census survey of eligible households so we can determine if repairs are needed and if so, what the exact structural problems are for those non-functional latrines. In our experience from previous research in the area, many households had unfinished latrines. Organizations came in to the villages to build latrines and once completed enough, took a picture to send in and receive their payment. These pictures could easily hide unfinished aspects, like missing pipes. Households were then left with no recourse and no funds to make their latrines functional. We will develop a ‘latrine repair eligibility criteria’ as there may be some latrines beyond repair or that would cost too much too repair. From formative research, that included a census of 7 villages (N=1405 HHs), we expect the following to be common structural problems: missing slabs, missing pipes connecting pans and pits, and unconnected pans and pits (though pipe present). These repairs are well-within the capacity of masons. There may be other repairs needed that will be discovered via observation during the baseline census. These repairs will be considered based on mason capacity, cost, and time needed. After the baseline census of households with latrines, we can apply these criteria to identify the final list of eligible households for the study sample. Local masons will make repairs. By brining in masons to complete these latrines or make minor repairs to broken structures, we are simply providing households with the latrine they thought they were going to receive. We are not considering training masons at this stage. However, we will make it known to all villagers when the mason will be coming. We will provide very specific repairs, but villagers will be able to hire the masons when they are there to do additional work. They will also have their contact information should they need them in the future.

***Mother Group Meetings***

Finally, RWI will hold a targeted meeting open to all mothers/caregivers of children under age five to provide them with action knowledge and hardware (scoops, potties) for safe child feces disposal. Costs are not high: scoops cost 39 rupees each and potties cost 300 rupees each, though there may be even cheaper models on the market. Members of RWI will provide the necessary instruction for how to use this hardware and why it is important. We believe this aspect of the intervention is sustainable and scalable because we believe Anganwadi workers or members of women’s groups could be trained to lead such sessions in the future if brought to scale. Additionally, once women start using potties and scoops, they could also train one another. In terms of hardware, there is an initial investment, but women could re-use the potties if they have another child or give them to another family if their children outgrow them. If the potties do break, the women can use the scoops. They can have the child squat over the scoop, instead of the potty, and simply use the scoop to dispose of the feces. If the scoop breaks, they can improvise by using other materials, like plastic or metal.

***Overall process of intervention delivery***

The ‘processes of change’ from the trans-theoretical model informed the order of intervention activity delivery (Prochaska, 2013). Prochaska et al note various stages of change, from pre-contemplation (has not considered change), to contemplation (intend to take action in future), preparation (some steps taken in appropriate direction of change), action, and maintenance (sustained behavior). Based on our formative research, we recognize that when the intervention team first enters the villages, most dwellers will not have participated in any pro-latrine use behavior change activities and may not be thinking at all about latrine use. They may be in the ‘pre-contemplation’ phase. As such, the ‘processes of change’, also outlined by Prochaska et al, are useful strategies for moving people from moving through these stages of change towards healthy behavior.

Specifically, the processes are as follows:

* ‘Consciousness raising’: This involves introducing people to new ideas and facts that support the healthy behavior change.
  + The palla performance, as a community wide event, introduces (and for some , perhaps) re-introduces facts and ideas about latrine use and safe child feces disposal. The ‘facts’ and ‘ideas’ of focus are those identified in the formative research that pre-ceded this trial.
* ‘Dramatic Relief’: This entails an experience of negative emotions that may be associated with the unhealthy behavior, which is open defecation in this case.
  + Following the palla, RWI holds a surprise transect walk to observe the village. In so doing, RWI also walks through open defecation sites and deposits holi powder on feces to make them stand out in the environment. This activity is intended to make people aware of the filth of the community and the potential risks to health that such filth could cause.
* ‘Self-reevaluation’: This is the realization that the behavior is associated with identity.
* ‘Environmental reevaluation’: This is the realization that the behavior—whether good or bad-- has an impact on a person’s physical and social environment.
* Self-liberation’: This is the commitment to make the behavioral change.
  + The community meetings combine self-reevaluation, environmental reevaluation and self-liberation ideas. They start with ‘consciousness raising’, recognizing that all participants may not have been able to attend the palls. They then discuss how the behavior impacts all, and specifically the identity of the community as a whole and how it is viewed by outsiders (self-reevaluation). It takes time to reflect on the transect walk and to discuss with all what open defecation does to their shared physical environment, and it also acknowledges and celebrates positive deviants in the community who use their latrine all the time, establishing a person or people to be considered socially positive contributors (environmental re-evaluation). The meetings then have participants identify action stps they can take and ends with a commitment to these actions (self-liberation).
* ‘Helping relationships’: This involves the use of social support to enable the behavior change.
* ‘Counter conditioning’: This involves the uptake of the alternative healthier behavior.
* ‘Stimulus control’: This is the addition of cues to engage the behavior.
  + While the palla performance and the community meetings do touch on ‘helping relationships’, ‘counter conditioning’ and ‘stimulus control’, the visits made to each household focus on them. The RWI mobilizer holds a meeting with each family as a group, focusing on promoting commitment of use among all household members (helping relationships), seeks commitment to establish the new latrine use behavior (self-liberation and counter-conditioning), and provides a banner to help people remember to use the latrine (stimulus control).
* ‘Reinforcement management’: This entails providing rewards or the positive behavior change.
  + This typically may come a step earlier, but in this intervention, we engage this with a wall painting in the village. This paining is a amp of the village. All households that have been identified as using the latrine all the time are painted in a special color. Those that later become recognized as having all members use the latrine can then have the mural changed to reflect this as a reward.
* ‘Social liberation’: This is the realization that the social norms are changing to promote the behavior.
  + We recognize that great change may not happen in a short period of time and social norms may not be shifted by the close of the intervention activities, but RWI engages this process of change at the end the intervention by having a closing ceremony that reviews all that has been done in the village, celebrating the engagement of households throughout all the activities, and by acknowledging that they are all taking positive steps to making their village cleaner and healthier.

\*\*Note: Those engaged in the mothers group meeting will go through the same activities as other members of the community, ideally. The primary difference is that they will also participate in a group meeting that will provide them with information about safe feces disposal, hardware to facilitate this behavior, and skills for practicing it effectively. Several of the ‘processes’ of change noted above will be re-engaged in these specific meetings.

## Evaluation Questions and Hypotheses

* 1. **What are the main evaluation question(s) the study seeks to answer?**

Main research question: Is latrine use among people who own a functional latrine in communities that received the intervention significantly different at endline than among people who own a latrine in communities that did not receive the intervention?

Secondary research question 1:Is latrine construction by endline among people who do not own a latrine in communities that received the intervention significantly different than among people who do not own a latrine in communities did not receive the intervention?

Secondary research question 2:Are behavioral determinant scores (i.e. scores for social norms, abilities, physical opportunity, risk perception, motivation, and self-regulation) significantly different at end line among owners of functional latrines in intervention villages compared to owners of latrines in control villages?

Secondary research question 3:Are behavioral determinant scores (i.e. scores for social norms, abilities, physical opportunity, risk perception, motivation, and self-regulation) associated with latrine use?

* 1. **What are the hypotheses to be tested throughout the causal chain?**

Main research question:

H1: Latrine use among people who own a functional latrine in communities that received the intervention will be significantly higher compared to latrine owning households in control communities.

Secondary research question 1:

H2: Latrine construction among non-latrine owners in communities that received the intervention will be significantly higher compared to controls.

Secondary research question 2:

H3: Latrine use behavioral determinant scores are significantly higher at endline among latrine owners in intervention villages compared to latrine owners in control villages.

H4: Child feces behavioral determinant scores are significantly higher at endline among latrine owners with children under age 5 in intervention villages compared to latrine owners in control villages.

Secondary research question 3:

H5: High latrine use behavioral determinant scores are significantly associated with latrine use.

H6: High child feces behavioral determinant scores are significantly associated with safe child fees disposal.

## Sampling

* 1. **Sampling frame**

**The eligible population for the study is households that have latrines (defined as having a pit, pan, and pipe connecting the two).**

* + 1. **Please list any additional inclusion and/or exclusion criteria for the eligible population.**

We will include all households that own latrines, not just households that own functional latrines. As part of the intervention, we will make latrines functional by making low cost repairs (pipe connections, etc.).

Research (i.e. survey administration, qualitative interviews and discussions) will only be carried out with women and men over age 18. We will specifically target women in the household to respond to questions because we feel most confident that they would be able to most accurately respond about the behaviour of others in the household, especially children and other dependents.

* + 1. **What are the main characteristics of your population?**

The current research will take place in the rural district of Puri, Odisha State, India. Some of the communities will potentially have been engaged previously in a cluster-randomized trial (CRT) (Registration No. NCT01214785)([Clasen, Boisson et al. 2012](#_ENREF_6)). In Puri district, 86% of households live in rural areas, 57% of households are living below the poverty line (BPL) and 19% of women are illiterate([MDWS 2011](#_ENREF_14)). Approximately 15% of households in rural areas were estimated to have had sanitation in 2008, prior to the previous trial ([MDWS 2011](#_ENREF_14)).

According to the 2015-2016 Indian National Family Health Survey, 37% of rural households in Puri district have an improved sanitation facility – the same percentage at the national level (37% in rural India)—albeit somewhat higher than the overall state level (23% in Odisha) (NFHS-4, 2015-2016).

* + 1. **What is the expected sample size?**

*Main trial villages*

66 communities will be engaged in the trial, 33 in the intervention arm and 33 in the control arm

We will aim for community sizes that range from 50-150 households each and that have 60% latrine coverage or higher. However, community sizes and coverage may be outside of those ranges as we go through a process of identifying suitable villages via a mapping exercise, which will provide the most up-to-date data.

We anticipate households to have an average of 4 people each. In these main trial villages, we will conduct a baseline and endline census. All households in each village will be asked if they have a latrine. If they do not, the survey ends; if they do, further questions will be asked, including questions about latrine use for all family members. Observations of latrine facilities will also take place.

We anticipate an average of 100 households per village with an average of 4 members each*.* Given that we will be targeting villages that we expect to have 60% latrine coverage or more, we expect to collect latrine use information from at least 3,960 households (66 villages\*100 households \* 0.6 coverage) with data on 15,840 individuals (3,960 latrine owning households \* 4 persons per household).

We will also randomly select a subset of 20 households per trial village to answer questions on determinants to latrine use behaviours. We are aiming for 10 women and 10 men. With 66 villages and 20 individuals per household, we aim to engage a total of 1320 individuals (660 women and 660 men).

Further, all caregivers of children under age 5 who own a latrine will be asked about child feces disposal knowledge and practices. From our previous work, we anticipate that there will be approximately 10 households per village (average size 100) that will have at least 1 child under age 5. As such, we anticipate engaging 660 caregivers of children under age 5 across the 66 trial villages.

Finally, after endline, we aim to conduct follow-up qualitative research to get more detailed feedback about how the intervention may or may not have influenced their reported behaviours. Specifically, we will carry out in-depth interviews (IDIs) with individuals in the intervention communities that initiated latrine use by endline compared to baseline, with individuals who did not change behaviour at all, and with individuals from households that did not have a latrine at baseline but had one by endline. We will also carry out focus group discussions (FGDs) with men and women in intervention communities that saw the greatest overall change in latrine use and the least overall use to determine what factors contributed to change and if and how the intervention components influenced that change. The endline data will enable us to identify who to target and how many individuals. As such, sample size numbers are not final at this stage. We anticipate approximately 30 IDIs and 8 FGDs with approximately 6-10 participants in each. Further information about activities is provided in section 4.1.1.

*Subset of Qualitative Villages*

We will engage 6 additional non-trial villages for qualitative research. Three of these villages will receive the intervention and 6 will not. The establishment of these village will allow us to ask questions about the intervention and latrine use more broadly in the weeks and months following intervention delivery without disrupting the actual trial. We anticipate approximately 30 IDIs and 8 FGDs with approximately 6-10 participants in each. Further information about activities is provided in section 4.1.1.

* + 1. **Is there any reason to believe that the sample differs from the population? If so, how does it differ?**

To be eligible for inclusion in the study, we are seeking villages with 50-150 households (mean 100 households) and a minimum of 60% latrine coverage. These criteria reflect the both the study needs (coverage and household size influence sample size estimates) and the limits of our funding (larger villages ould require more inputs and thus more costs).

As such, it is reasonable to believe that our sample does not reflect all villages in Puri or even in the three blocks we will be working specifically. Our pre-trial rapid assessment identified villages that were smaller, larger, and that had less that 60% latrine coverage.

* + 1. **Please describe the anticipated subgroups, if relevant, which will be studied.**

*Note: Since behaviour change interventions require village-level clustering to prevent spillovers, studies will likely not be adequately powered to conduct sub-group analysis, and subgroup analysis is not expected. Proposals to do subgroup analysis should be accompanied by an explanation of how studies will be able to detect differences between subgroups.*

We do not anticipate conducting any sub-group analyses.

* 1. **Statistical power**
     1. **What is the effect size that you will be able to detect?**

We are powered to detect an absolute increase of **10%** in latrine use among intervention group.

We used a Monte Carlo simulation approach to determine the sample size required for the proposed cluster-randomized controlled trial of latrine use (Arnold et al 2011). The simulation parameters were estimated from previously collected data on latrine use among participants in the Odisha sanitation trial (Clasen et al 2014). Because the proposed intervention is targeted to households with existing latrines, only households with a latrine at baseline of the Odisha sanitation trial were used to generate simulation parameters. A rapid assessment of villages in the study area was conducted to determine the number of households and latrine coverage rates. As the design of the proposed study includes both randomization at the village level and repeated measures (baseline and follow-up) among study participants, the data-generating model used for these simulations was a 3-level mixed effects model with cluster (village) level and person-level random effects. The parameters used in our sample size simulations were as follows:

1. Average number of households in eligible villages = **98**
2. Coefficient of variation in village size = **0.35**(eligible villages ranged in size from 50-150 households)
3. Latrine coverage among eligible villages = **75%** (minimum of 60% coverage required for eligibility)
4. Average number of households per village with latrines = 98\*0.75 = **73**
5. Average number of persons per household = **4**
6. Average number of eligible persons per village=73\*4 = **292**
7. Proportion of persons who reported using latrine the previous day = 0.47 (**0.45**used in simulation)
8. Village­-level standard deviation = **1.43**
9. Person­-level standard deviation = **3.88**
10. Village-­level ICC = **0.10**
11. Correlation of individual use over time (rainy, winter, and summer seasons) = lowest was **.60**(most conservative)

In addition, the following parameters were specified by the study team

1. Alpha = **0.05**
2. Beta = **0.80**
3. Effect size = Absolute increase of **10%** in latrine use among intervention group
4. Minimum Latrine coverage = **60%**
5. Attrition = **10%** loss to follow-up between baseline and follow-up.

Latrine use is a binary outcome for each individual. It will be aggregated to a percentage for the village. This question is in use by all 3ie grant recipients. The question is asked for each household member is:

*The last time [NAME] defecated, did [NAME] defecate in the open or use the latrine?*

01= Open; 02= Latrine; 03= Somewhere else (potty, nappy, etc.)

\*if the respondent chooses 3, the follow-up questions enable classification of the feces disposal as safely disposed of in the latrine or not.

* + - 1. **What are your assumptions about your alpha level?**

The alpha level is 0.05.

We assume village size between 50-150 households, an average of 5 persons per household, minimum village level latrine coverage of 60%, 10% loss to follow-up between baseline and endline, village level ICC of 0.1, village level standard deviation of 1.43, person-level standard deviation of 3.88, and correlation of individual use over time of 0.6.

* + - 1. **What are your assumptions about your statistical power?**

The beta is 0.80.

* + - 1. **What are your assumptions about variability in your effect size?**

Based on our analysis (mixed-effects modelling) of latrine use data from a previous sanitation trial in Odisha state, we assume a village-level standard deviation of 1.43 and a person-level standard deviation of 3.88. These parameters were used in empirical sample size calculations via Monte Carlo simulation.

* + - 1. **How many clusters will you have?**

We will have 66 clusters (villages); 33 will receive the intervention, 33 will act as controls.

* + - 1. **How many people will you have in each cluster?**

We anticipate collecting latrine use data on all members of households that own latrines. We will aim for clusters sizes that will range from 50-150 households, have at least 60% latrine coverage and expect that households will have an average of 4 people each. As such:

On average, we anticipate villages will have an average of 97 households with 75% coverage and 4 people per household. Thus, we anticipate collecting latrine use data on an average of 292 people per cluster. [97 \* 0.75 \* 4 = 292] or 9,636 people per arm.

At minimum, in a village of 50 households with 60% coverage and 4 people per household, we anticipate collecting latrine use data on 120 people per cluster.

[50 \* 0.6 \* 4 = 120].

At maximum, in a village of 150 households with 100% coverage and 4 people per household, we anticipate collecting latrine use data on 600 people per cluster.

[150 \* 1 \*4 = 600].

* + - 1. **How sensitive is your effect size to changes in your parameters?**

Our minimum detectable effect size (MDES) for latrine use is fairly robust to potential changes in the parameters of our sample size calculations. For example, with an increase in the village-level ICC from 0.10 to 0.15 we are powered for a 12.1% increase in latrine use. Similarly, a reduction in the within-person (pre-post) correlation in latrine use from 0.6 to 0.5 would result in our MDES increasing from 10% to 11%. Nevertheless, we are confident in the accuracy of the parameters used in our sample size calculations as they were calculated from recent longitudinal latrine use data collected in Odisha state using a similar methodology to that used in the current study.

* + 1. **If you plan to include covariates in your analysis, what share of variance do you expect to predict with your co-variates?**

*Note: It is not required that you include covariates*

Covariates we aim to include are noted in response to 5.1.2. We did not calculate our sample size based on assumptions about shared variance from covariates. Ours is a more conservative approach.

* 1. **Assignment to treatment**
     1. **How will individuals be assigned to treatment and control conditions?**

We will assign entire villages to treatment and control conditions, not individuals. We will engage 66 villages in the main trial, 33 of which will receive the intervention and 33 that will serve as controls. We will engage another 6 villages in qualitative work alone so that we may learn about experiences and perceptions of the intervention closer to the time of implementation and not post endline. Three of these 6 villages will receive the intervention; three will not and will enable us to ask other latrine use related questions.

*Village selection: Trial Villages*

In the summer of 2017, our research team carried out a rapid assessment of villages in three block in Puri: Delang, Pipili, and Nimapada in order to generate approximate data on village sizes (number of households) and latrine coverage. We focus on these blocks due to the ability of our team and our partner to access them. We carried out this exercise as we know village sizes and coverage are always changing and that visiting and talking with village leaders would give the most up-to-date sense of current village status. In total, 282 villages were visited. We use this list and the data generated as our sampling frame. From this list, we identified all potentially eligible villages that are suitable for inclusion (between 50 and 150 households per village, at least 60% latrine coverage, and not declared open-defecation free). Prior to baseline we will visit the villages to map the villages for future visits and, during this process, also verify the total number of households in the villages and the number that have latrines to confirm latrine coverage. At this time, we will also be able to assess the location of villages and determine their proximity to one another. If villages are immediately adjacent, we will only select one so as to minimize the likelihood of spillover. We will collect baseline data from those villages that we have verified to fit our criteria.

Following the baseline, we will randomize the 66 villages, 33 to an intervention group that will receive the intervention package and 33 to a control group that will not receive any intervention and will serve as comparisons. We will use stratified randomization to ensure balance on significant criteria. While there are many potential criteria (program under which latrines were provided, proportion constructed with household funds versus government subsidy, etc.), we will prioritize village size and latrine coverage. We also will ensure that villages are not immediately adjacent to minimize the likelihood of spillover or might otherwise be influenced by contamination.

*Village selection: Qualitative Villages*

We will engage 6 additional village in qualitative activities only. These villages will be selected from the same pool as the 66 trial villages using the same processes noted. We will not collect baseline data on these villages, but will collect basic information from community stakeholders to understand under what program (TSC, NBA, SBM) the village received their latrines, whether a large portion was constructed at the cost of the householder rather than by subsidy, village size, and latrine coverage. As with the 66 villages engaged in the trial, we will randomize the 6 villages along these criteria, assigning 3 to the intervention and 3 to serve as controls.

The implementers will not be made aware which villages are in the formal trial (with endline and baseline data collection on latrine use, etc.) and which will be engaged in qualitative work. We want to be sure that all villages receiving the intervention do so as consistently as possible.

* + 1. **How will you check that individuals in the treatment condition received treatment as anticipated?**

We will monitor but not participate in the intervention delivery. Guided by the approach noted by Saunders et al (2005), we will use quantitative and qualitative tools to carry out a process evaluation of the intervention, which will include observations of the activities to understand recruitment, reach, dose delivered, fidelity, and dose received. To understand *satisfaction* with the intervention, we will carry out qualitative research with household members who received the intervention after endline and with a subset of households shortly after intervention delivery from a distinct set of villages not engaged in the impact evaluation. We will also conduct interviews with the partner staff to understand contextual factors that may have influenced delivery, challenges associated with delivery, and recommendations for improvements.

## Data Collection

* 1. **Primary data collection instruments**
     1. **What data collections instruments will you employ for quantitative and qualitative analysis?**

The table below provides details regarding the proposed instruments (Q 4.1.1), and the target interviewees (Q 4.1.2).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Activities during the 66 village impact evaluation (CRT)** | | | | |
| **Activity** | **Participant type** | | **Sample Size** | **Purpose** |
| Census  *To be carried out at baseline and endline.* | | Representative from each village household. | ~6600-7260 HHs per round; 13,200-14,520 inclusive of baseline and endline  (assuming average community size is 100-110 households across 66 villages) | To determine latrine coverage rates;  To identify households with latrines for additional questions on use, latrine history/funding.  Non latrine owning households will provide basic demographic information. Latrine owning households will provide expanded information on demographics, latrine use, etc. See following table for more information. |
| Latrine Observations  *To be carried out at baseline and endline.* | | To be carried out after administration of census at all households with latrines | ~ 5808  [Assuming 110 households per village with 80% latrine coverage] | Aim is to understand if latrines are functional, if repairs are needed, what repairs are needed, and if latrine meets criteria for repair. To be carried out at baseline and endline. |
| Child Feaces Behavioral Determinants Supplement  *To be carried out at baseline and endline.* | | Caregivers from all latrine-owning households with children under age 5 per village | 660 per round; 1,320 inclusive of baseline and endline  [assuming average of 10 households per village with latrines *and* children under age 5: 66 villages \* 10 households] | To identify drivers of child feces handling behavior in latrine owning households that have children under age 5. |
| Latrine Use Determinants Supplement  *To be carried out at baseline and endline.* | | Representative from 20 randomly selected latrine-owning households per village | 1320 per round  [66 villages \* 20 households] | To identify drivers of latrine use among a subset of adults in latrine owning households. The same respondents answering at baseline will be followed-up with at endline. |
| **Total for Impact evaluation/CRT related activities in 66 villages, at both baseline and endline** | | | 18,480 [Max, for survey activities]  11,616 for observation activities |  |
| **Qualitative Activities post trial endline** | | | | |
| **Activity** | | **Participant type** | **Sample Size** | **Purpose** |
| In Depth Interview | | Adults (men and women) with latrines | 10 | To identify perceptions of various intervention components and if/how the intervention may have influenced personal behavior |
| In Depth Interview | | Adults (men and women) without latrines | 10 | To identify perceptions of various intervention components and if/how the intervention may have influenced perceptions of latrine use and interest in building a household latrine |
| In Depth Interview | | Adults (men and women) with latrines | 10 | To identify emerging barriers and drivers to latrine use and not-use (in villages not receiving interventions) |
| Focus Group Discussion | | Adults (men and women) who became latrine users in intervention villages | 40  Approx. 4 FGDs (sex specific) with 6-10 participants each | To identify perceptions of various intervention components and if/how the intervention may have influenced personal behavior; to discuss if and how the intervention influence social norms |
| Focus Group Discussion | | Adults (men and women) who continued to not use latrines in intervention villages | 40  Approx. 4 FGDs (sex specific) with 6-10 participants each | To identify perceptions of various intervention components and why the intervention did not influence behavior |
| In Depth Interview | | NGO Partner Staff (men and women) | 10 | To gin perceptions of the intervention from the implementer, how it can be improved, challenges faced, etc. |
| **Total Qualitative Activities post trial endline** | | | 120 |  |
| **Qualitative Activities in a subset of 6 villages not engaged in the trial (3 receiving intervention, 3 not)** | | | | |
| **Activity** | | **Participant type** | **Sample Size** | **Purpose** |
| In Depth Interview | | Adults (men and women) with latrines | 10 | To identify perceptions of various intervention components and if/how the intervention may have influenced personal behavior |
| In Depth Interview | | Adults (men and women) without latrines | 10 | To identify perceptions of various intervention components and if/how the intervention may have influenced perceptions of latrine use and interest in building a household latrine |
| In Depth Interview | | Adults (men and women) with latrines | 10 | To identify emerging barriers and drivers to latrine use and not-use (in villages not receiving interventions) |
| Focus Group Discussion | | Adults (men and women) who became latrine users in intervention villages | 40  Approx. 4 FGDs (sex specific) with 6-10 participants each | To identify perceptions of various intervention components and if/how the intervention may have influenced personal behavior; to discuss if and how the intervention influence social norms |
| Focus Group Discussion | | Adults (men and women) who continued to not use latrines in intervention villages | 40  Approx. 4 FGDs (sex specific) with 6-10 participants each | To identify perceptions of various intervention components and why the intervention did not influence behavior |
| **Total for qualitative activities in subset of 6 villages** | | | 110 |  |

* + 1. **What is the hypothesised list of interviewees/targets (i.e types of actors or stakeholders who will be interviewed, anticipated interview formats and expected number of respondents)? You may wish to present this information in a table.**

See table above.

* + 1. **What (groups of) indicators will each instrument cover?**

The table below describes the indicators each instrument will cover (Q 4.1.3) as well as how each tool was or will e developed (Q4.1.4).

* + 1. **How will each instrument be developed?**

The table above describes how each instrument was or will be developed.

* + 1. **Please comment on the validity and reliability of each instrument, including any anticipated validation checks.**

For Latrine Use*:* Researchers, and 3ie and rice affiliates determined the key indicators for latrine use collectively. Observations of the latrines will be carried out as a validation check. If latrines are deemed to be non-functional (i.e. missing pipe connections, etc.) or to not have evidence of any recent use (i.e. used for storage, no water vessels/shoes/ worn path to facility, etc.), reports of use will be called into question.

For Behavioural Determinants: Indicators for the various behavioural determinants under investigation (see table above and survey document) were created based on a review of relevant literature and with support from relevant technical documents (See: Mosler, H.-J., & Contzen, N. (2016). Systematic behavior change in water, sanitation and hygiene. A practical guide using the RANAS approach. Version 1.1. Dübendorf, Switzerland: Eawag.; Bicchieri, C. (2016). *Norms in the wild: How to diagnose, measure, and change social norms*. Oxford University Press). Construct validity for each of these determinants will be assessed using confirmatory factor analysis (CFA). Reliability will be assessed using chronbach’s alpha.

For Socio-economic status: We will use principle components analysis (PCA) to assess construct validity of our SES index. Reliability will be assessed using chronbach’s alpha.

* 1. **Secondary data sources**

**Please describe the anticipated secondary sources of data, if any, which will be used for this study.**

Not applicable.

## Analysis

* 1. **Outcome Variables**
     1. **Your primary outcome is latrine use. Please describe the primary and any secondary outcome variables of interest using the following table:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Outcome** | **Description** | **Hypothesis** | **Level** |
| *“Outcome 1”*  *(e.g. latrine use)* | *(brief description of outcome with associated indicators and constituent parts)* | *(E.g. related to Hypothesis 1; related to H1 and H2, etc.)* | *(E.g. individual, household, etc.)* |
| *Latrine Use* | As defined a priori in the guidelines:  “For every household member, as part of a household roster (where household is defined as living under this roof): “The last time [NAME] defecated, did [NAME] defecate in the open or use the latrine?”  Options: Open, Latrine, Somewhere else | Related to H1 and H5 | Individual |
| *Latrine Coverage* | Assessment of latrine coverage in villages. Noted by self-report and confirmed by observation. | Related to H2 | Village/ Community |
| *Latrine Use Determinants, specifically Risk Perceptions, Ability, Social Norms, Motivation, Physical Opportunity, and Self-Regulation* | For each determinant, there are several indicators that define the associated constructs. | Related to H3 and H5 | Individual |
| *Latrine Use Determinants, specifically Risk Perceptions, Ability, Social Norms, Motivation, Physical Opportunity, and Self-Regulation* | For each determinant, there are several indicators that define the associated constructs. | Related to H4 and H6 | Individual |

* + 1. **If you plan on including covariates in your analysis, please provide a list of covariates that may be included.**

Baseline latrine use, age, sex, educational attainment, household size, household socio-economic status

We will run both unadjusted and adjusted models and compare models as a sensitivity analysis.

* + 1. **If you plan to aggregate multiple variables into an index, which variables will you aggregate and how?**

1. Socioeconomic status: We will ask respondents if they own various household items and use that information to create an asset index using Principle Components Analysis (PCA), resulting in an score for each household.
2. Latrine Use Determinants: For each of the latrine use determinants (Risk Perceptions, Ability, Social Norms, Motivation, Physical Opportunity, and Self-Regulation), we have a series of questions. (See Survey; determinants to which the questions correspond are noted on the left-side column). The number of questions per determinant ranges from 3-20 per. We will carry out confirmatory factor analysis to confirm the factor structure for each determinant (eliminating questions as appropriate), check reliability (cronbach’s alpha), and then determine scores based on final questions per determinant and the responses provided.
   1. **Qualitative Analysis**

**Which methods will be used to analyse qualitative data (e.g. content analysis with criteria for codification)?**

Transcripts from qualitative activities will be analysed using thematic content analysis.

Members of the research team will begin analysis by reading through transcripts and writing memos about the issues discussed in the location where they collected the data. The memos will inform the creation of a preliminary codebook. The preliminary codebook will be shared among members of the research team and refined. Researchers will then use the final codebook to apply codes to the data collected. This may be done in duplicate to compare coding strategies and make certain that coding is consistent across all researchers.

Once coding is complete, researchers will write thematic memos. Some memo topics will be pre-determined (deductive). Other memos will be created that are not anticipated based on what is learned from the data collected (inductive).

* 1. **Quantitative Analysis**
     1. **Balance Checks**
        1. **How will you check balance between treatment and control groups?**

We will use the baseline data to calculate descriptive statistics and compute the standardized difference between arms in order to compare groups on all outcome measures as well as individual and village-level sociodemographic characteristics. The standardized difference is a metric that expresses the difference between groups in standard deviation units.

For continuous covariates, the standardized difference (*d*) is calculated as

where and denote the sample mean of the covariate and and denote the sample variance of the covariate in the intervention and control groups.

For dichotomous covariates, the standardized difference (*d*) is calculated as

where and denote the prevalence in the intervention and control groups.

If the standardized difference indicates an important imbalance between groups at baseline, we will perform sensitivity analysis by adjusting for that variable in statistical models and comparing effect estimates to the unadjusted models.

In accordance with CONSORT guidelines, we will not perform significance testing of between-group differences in baseline characteristics or outcomes to assess balance.

* + - 1. **What is the specification that you will run and what variables will you include?**

Not applicable. The computation for standardized difference is presented above

* + - 1. **If there is an imbalance (between treatment and control groups) in one or more baseline covariates, how do you plan to address this?**

Statistical models will be adjusted for covariates that are observed to be severely imbalanced between groups at baseline.

* + 1. **Contamination**

**How will you detect and manage any potential differential contamination between treatment and control groups?**

Given the nature of the intervention (community performances, meetings, household visits, latrine repairs) and our intention to have intervention and control arms geographically separated, we do not expect contamination. However, at endline, we will ask a series of questions to determine exposure to the intervention in both the intervention and control villages.

* + 1. **Attrition**
       1. **What is your anticipated attrition rate and what evidence is this prediction based on?**

The expected attrition rate is 10%. This estimate is based on our previous experience conducting sanitation trials in the region.

* + - 1. **What can you do anything to prevent or remedy sample attrition?**

For our primary outcome, latrine use, we are aiming to get latrine use data from all households in the villages that have latrines. Given that we are sampling all eligible households that have latrines, we are not able to do anything to increase the sample size to remedy attrition. To prevent attrition, we can simply train our field team to carry out the data collection in a respectful and confidential manner so as to encourage participation again at endline.

* + - 1. **How does expected attrition change your power calculations?**

Our power calculations incorporate the estimated 10% attrition rate.

* + - 1. **How will you check balance between attritors and non-attritors? What is the specification that you will run and what variables will you include in these balancing checks?**

We will compare attritors and non-attritors on baseline latrine use and coverage as well as sociodemographic characteristics (age, gender, SES, household size, and caste).

* + 1. **Missing Data**

**How will you deal with incomplete or missing data?**

Given our study design, we anticipate that the primary cause of missing data will be loss to follow-up. As GEE is robust to missing data under the MCAR mechanism, we will conduct Little's test to evaluate whether the MCAR assumption is supported. If the MCAR assumption is not supported, we will assume a MAR mechanism and conduct sensitivity analyses by conducting weighted (inverse-probability weighting) GEE and comparing model results.

* + 1. **Treatment Effects**

*Note: Many studies may have awareness campaigns where one may not be able to know whether a household participated or heard the message or not. In these cases, it may not be possible to estimate a Treatment on the Treated (TOT) effect. We therefore do not expect that all studies will provide estimates of TOT.*

* + - 1. **Intent to Treat**
         1. **How will you estimate the (causal) effect of the offer of the treatment?**

We will conduct an intent to treat analysis of differences in the specified outcomes between the treatment and control groups following delivery of the intervention. We will employ generalized estimating equations (GEE) with robust standard errors to account for village-level clustering in the outcome. Models will be adjusted for baseline latrine use and pre-specified confounders such as age and sex. We will also report a “difference-in-difference” between the study arms, though with balanced study arms, this is not expected to be different from the main comparison.

* + - * 1. **What is the specification that you will run and what controls will you include in your specification?**

We will use GEE with robust standard errors to estimate a marginal (population average) model with the general form

whereg(.) is the link function**,**  is the outcome of interest for the jth observation in the ith cluster, is a vector of covariates**, and** is a vector of regression coefficients.We will specify an exchangeable correlation matrix as the most plausible and parsimonious choice of working correlation structure, noting that GEE with robust estimation yields valid estimates of model coefficients and standard errors when the correlation structure is misspecified. We will use a log-binomial link function, which will yield the prevalence ratio of post-intervention latrine use in persons receiving the intervention relative to controls, adjusting for baseline latrine use and control variables. Specifically, we will estimate the model

* + - 1. **Treatment on the Treated**
         1. **How will you estimate the (causal) effect of the receipt of the treatment?**

It will not be possible for us to estimate a Treatment on the Treated effect. Our intervention involves various events, including community level performances to raise awareness, community meetings and demonstrations, and household level visits and latrine repairs. While tracking household level engagement will be possible, it will not be feasible to accurately track anticipation in the community-wide events and understand if messages were received.

* + - * 1. **What is the specification that you will run and what controls will you include in your specification?**

Not applicable.

* 1. **Heterogeneous Effects**

*Note: Since behaviour change interventions require village-level clustering to prevent spillovers, studies will likely not be adequately powered to conduct sub-group analysis, and subgroup analysis is not expected. Proposals to do subgroup analysis should be accompanied by an explanation of how studies will be able to detect differences between subgroups.*

* + 1. **Which groups do you anticipate will display heterogeneous effects?**

We are not planning sub-group analyses.

* + 1. **What is the broad theory of action that leads you to anticipate these effects?**

Not applicable.

* 1. **Standard Error Adjustments**
     1. **How will you address clustering in your data?**

We will employ generalized estimating equations (GEE) with robust standard errors to account for village-level clustering in the outcome.

* + 1. **How will you address false positives from multiple hypothesis testing?**

As described in this analysis plan, we are fitting a small number of pre-specified models. The number of planned analyses is not sufficient to warrant concerns about multiple testing.

* + - 1. **If you plan to adjust your standard errors, what adjustment procedure will you use? (e.g., Family Wise Error Rate, False Discovery Rates, etc.)**

Not applicable.

* + - 1. **How will you deal with outcomes with limited variation? For instance, one option could be to decide in advance that outcomes that vary below a certain threshold will be omitted from the analysis.**

Based on our previous experience, we do not anticipate there to be limited variation in outcomes. If we have outcomes with limited variation, we will test those outcomes. If we have covariates for which over 95% carry the same value, we will drop those.

## List of optional attachments

**Script (Optional)**

You may wish to upload an analysis script with clear comments. This optional step is helpful in order to create a process that is completely transparent and increase the likelihood that your analysis can be replicated. We recommend that you run the code on a simulated dataset in order to check that it will run without errors.

**Data Collection Tools (Optional)**

You may wish to attach any qualitative or quantitative data collection tools, if available.

**References**

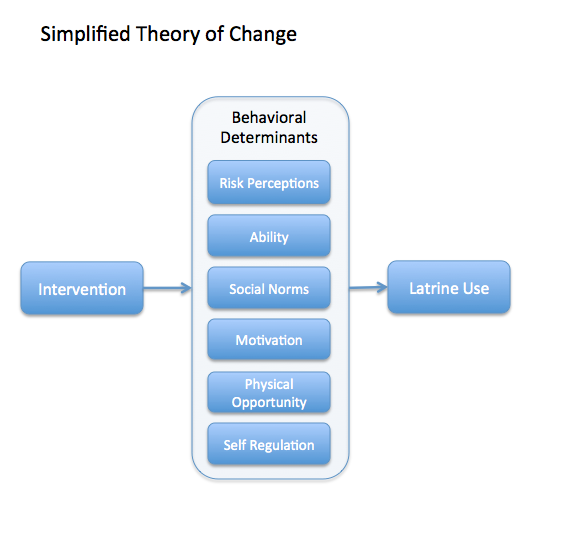
Prochaska, J. O. (2013). Transtheoretical model of behavior change. In *Encyclopedia of behavioral medicine* (pp. 1997-2000). Springer New York.

**APPENDICES**

**Appendix A.**

Macintosh HD:Users:bcaruso:Dropbox:Research:Orissa:3ie:Pilot:report:Final:G. TOC.pdf

**Appendix B.**

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