Pre-Specified Analysis Plan for LENNS Cluster Randomized Trial in Tamil Nadu

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1. Scientific background and rationale

The rationale, design and procedures of the LENNS CRT, an ex-ante, parallel cluster-randomized trial evaluating the impact of a demand-side, norm-centric behavior change intervention on improving exclusive toilet ownership, use and maintenance in peri-urban Tamil Nadu, India has been published [1] [ClinicalTrials.gov NCT04269824]. Here we pre-specify the analysis plan for the primary and secondary outcomes.

Preliminary studies

In formative studies conducted in Tamil Nadu between 2017-2018, we investigated whether toilet use behavior is driven by beliefs that most other people are using one (empirical expectations) or whether others think one should use it (normative expectations) [2]. By measuring social expectations and other social determinants, we found that toilet use was socially conditional on empirical expectations in these communities. This led to the development of a theory of change that informed the behavior change strategy of the Nam Nalavazhvu intervention. Further details have been published elsewhere [1].

2. Study objectives and hypotheses

We designed Nam Nalavazhvu intervention to shift empirical expectation or belief that others also own and use a clean toilet. Our assumption s that exposure to the intervention activities will influence the beliefs of the target population that relevant others in their communities have improved sanitation behaviors, and therefore, will encourage them to do the same through positive peer pressure. In addition, the intervention also aims to connect them to relevant community members and resources for them to achieve their sanitation goals, specifically to build a toilet, keep it clean and use it exclusively for defecation.

Primary hypothesis

- The intervention will increase exclusive use of toilets for defecation among those above 5 years in the target peri-urban communities. The primary outcome is defined as the proportion of households where all the members report use of toilet (last time they defecated).

Secondary hypotheses

- The intervention will increase access to sanitation facilities in the target wards, as reported by surveyed respondents.
- The intervention changes empirical and normative expectations in favor of improved sanitation behaviors in the target population in these peri-urban communities.

3. Exposure

The exposure is a demand-side, norm-centric behavioral intervention (Nam Nalavazhvu). The intervention activities were delivered at the individual, household, group and community levels to influence toilet ownership, use and maintenance among ward members. The intervention was delivered to 38 randomly assigned wards within 5 town panchayats each in Karur and Pudukkottai districts. Details of the intervention has been published earlier (1).

4. Outcomes

Outcomes were measured approximately prior to and a year after the intervention. Details of measurements are included in the supplementary appendix (S1).

Primary outcomes:
Exclusive toilet usage

1. Proportion of households where all members above the age of 5 years report to use the toilet the last time they defecated. This will be measured by self-report or proxy report, i.e., as reported by the respondent on behalf of other members in the household at the endline compared to baseline.

Secondary outcomes:
Toilet access

2. Change in the proportion of households with access to any sanitation facility at the endline compared to baseline.
3. Changes in defined behavioral antecedents such as empirical expectations (i.e., what other people do) and normative expectations (i.e., what others expect them to do) of improved sanitation behaviors.

5. Study design
The study is a cluster randomized controlled trial in 78 wards across two districts in Tamil Nadu. Each cluster is defined as a ward. These wards were selected based on eligibility criteria to ensure they were residential wards and did not have full toilet coverage according to the latest official records. In each ward, 34 age-eligible (18+) individuals were sampled and interviewed about toilet behavior and social beliefs. They were followed up at the end of the intervention. The impact will be assessed through a longitudinal analysis, where we will report a difference-in-difference of the pre-specified outcomes. Ward characteristics at the baseline will be used to adjust for potential disbalances in the exclusive usage to improve the estimates of the intervention effect. We will also attempt to longitudinally measure changes in toilet-use behavior, but we expect substantial drop-out due to the unusual circumstances of the study (COVID-19 pandemic), so the possibility to longitudinally observe individuals might be limited.

6. Participants
We will enroll 76 clusters into the study and survey 2571 randomly selected individuals, one per household, from 34 households per ward during the baseline. They are expected to be followed up at the endline conducted one year later.

Attrition
In case of attrition, another age-eligible member of the same household will be enrolled whenever possible. If none of the household members are available, interviewers will list neighboring households in the visible vicinity of the original household, randomly sample one household and sample eligible household members.

7. Statistical power
This study is powered to detect differences in the prevalence of exclusive toilet use, as measured by self-reported place of last defecation between study arms of at least 10 percentage points.

We incorporated findings from our formative research that collected data from peri-urban communities in Tamil Nadu 8 months apart during formative research in 2017-2018 and asked individuals about their defecation place the last time they defecated. We incorporated the correlation between these two measures in our sample size calculation.

We powered our study at 80% based on the prevalence of reported toilet use during last defecation in peri urban Tamil Nadu (estimated at 64.4% in 2018) and assumed a 10-percentage-point improvement as the minimum important effect. To detect such a minimal effect in exclusive toilet use (given observed intra-cluster correlation of 11% and correlation of last use with the one measured in the fall of 2017 of 47.5%), we estimated a requirement of 76 clusters (38 clusters per arm) with 30 individuals per cluster. Assuming 10% loss to follow up, we aim to survey 34 individuals per cluster for a total of 2584 individuals.

8. Additional analyses

We will also assess impact of the intervention on reported diarrheal prevalence in children under 5 years, well-being of adults measured using the WHO-5 well-being index. We will also conduct toilet observations of private toilets as a proxy indicator for toilet use. These will be used in addition to the primary outcomes to support the conclusions on the effectiveness of the intervention but will not serve as the basis for the effectiveness evaluation. These analyses will be done as a cross sectional analyses at endline. Indicators not measured at baseline will be analyzed as prevalence difference between intervention and control group.

9. Covariates

Our study is powered at the ward level and no covariates are required. As robustness check for balance, we will run analyses with and without controls for gender, age, household size, caste, and socioeconomic status using an asset index. This will be constructed using a principal component analysis of eight household assets: color TV, mobile phone, motorcycle/ scooters, fridge, internet, computer, AC/cooler, and washing machine.

Additional exploratory and non-causal analyses may be conducted and will include other variables we collected data on. These will not be used to decide on the effectiveness of the intervention.

9. Statistical analyses

We will apply multilevel poisson and logistic regression analyses to estimate the effect of the intervention on toilet use.

The right hand side of the regressions will follow the following specification:

$$\beta_0 + \beta_1 * Treat + \sum(\beta_i * Covariate_i) * \gamma + \theta + \mu + \nu + \epsilon$$

The primary coefficient of interest is $\beta 1$, the effect of treatment. We will run the analysis without $(\gamma=0)\gamma=0)$ and with $(\gamma=1)$ $\gamma=1)$ covariates as robustness check and include a series of random effects (θ for households and μ for wards).

Prevalence ratios and differences will be estimated using generalized linear regression models, adjusting for clustering at the ward level and using robust standard errors. The primary analyses will be done using unadjusted models with an intention-to-treat analysis.

Sensitivity analyses

In secondary analyses, we will check for major imbalance in age, sex, education, caste, number of household members, and an aggregate measure of household assets at baseline and report adjusted prevalence ratios. We will also assess ID of the staff member who recorded the measurement. These will be done to confirm our confidence in the results obtained from unadjusted analyses.

Effect modifiers

We are not powered to estimate effects in different groups, but we will conduct exploratory analyses to see between-cast and between-gender differences. These will not be used to estimate the effectiveness of the intervention.

References

1. Ashraf S, Bicchieri C, Delea MG, Das U, Chauhan K, Kuang J, Shpenev A, Thulin E Norms and Social Network–Centric Behavior Change Intervention (Nam Nalavazhvu) for Improved Toilet Usage in Peri-Urban Communities of Tamil Nadu: Protocol for a Cluster-Randomized Controlled Trial, JMIR Res Protoc 2021;10(5): e24407
2. Bicchieri C, Ashraf S, Das U, Delea MG, Kohler HP, Kuang J, et al. Phase 2 project report. Social networks and norms: sanitation in Bihar and Tamil Nadu, India. Center for Social Norms and Behavioral Dynamics. Philadelphia; 2018.

Table S1: Key indicators used to assess sanitation practices, beliefs, expectations, and behavioral outcomes

Outcome	Indicator	Questions	Type of data
Sanitation Outcomes	Access to Toilets	*Do your household members have access to any toilet facility?* *How many toilets do your household members have access to?* *Spot observation to categorize type of toilets (JMP definitions[1])*	Reported and spot observation
	Toilet Ownership	*Who owns the toilet you use primarily?* *Out of 10 households with toilets in your community, how many do you think own a toilet?*	Reported
	Toilet Use	*Where did you defecate the last time you needed to?* *During the last two days, where was your primary place of defecation?*	Self-reported Proxy reported for family members if unavailable Spot observation for signs of use
	Toilet cleaning/ maintenance	*During the last 7 days, including today, how many times was this toilet cleaned?* *In the past one year, have you made any repairs to the toilet? (i.e., have you fixed anything that became broken, damaged, or worn out on this toilet)* *In the past one year, have you added or improved anything on this toilet to upgrade it?*	Reported Supplemented by spot observation of toilet facilities
Beliefs and Expectations	Empirical Expectations	*Out of 10 households in your community, how many do you think own a toilet?* *Think about ten members of your community. Out of them, how many do you think use a toilet every time to defecate?* *Think about members of your community who don't have a private toilet. Out of them, how many do you think used a community latrine the last time they needed to defecate?* *Out of 10 households with toilets in your community, how many do you think keep it clean?*	Reported[2]
	Personal Normative Beliefs	*Some people who have a toilet still defecate in the open. Society may think that this is right or wrong. Do you personally think it's right, wrong, or neither for someone who has a toilet, to defecate in the open?* *Some people who defecate in the open do not have a toilet. Society may think that this is right or wrong. Do you personally think it's right, wrong, or neither for someone who does not have a toilet, to defecate in the open?*	Reported
	Normative Expectations	*Out of ten members of your community, how many do you think believe one should use a toilet to defecate?* *What do you think about the following statement [5 point- Likert scale]:* *"Members of my community think it is acceptable to defecate in the open"* *"I think my neighbors should use a toilet"*	Reported
	Causal vignette	*Please imagine an area similar to where you live. Someone from your area, whom you don't know, moved there one year ago. He/she has access to both a toilet, and a field he/she could use to defecate. He/she learned that [most]/[few] people disapprove of defecating in the open [and]/[, but] he/she also learned that [most/few] people do it. What do you think he/she will do? [Response: Likely use a toilet, Either way, Unlikely to use a toilet]*	Reported
	Health outcomes	*Mental wellbeing* *Diarrhea prevalence in children less than 5 years*	World Health Organization- Five Well-Being Index (WHO-5)[3] 7- day recall (at least 3 or more loose or liquid stools per day)*[4]

**Primary caregivers will be asked to report for children*

The complete questionnaire and all other surveys used in this trial is available on request.

1. WHO/UNICEF.*WHO | Progress on Drinking Water, Sanitation and Hygiene*. World Health Organization; 2017.http://www.who.int/water_sanitation_health/publications/jmp-2017/en/. Accessed August 22, 2017.
2. Bicchieri C.*Norms in the Wild*. Oxford University Press; 2017. doi:10.1093/acprof:oso/9780190622046.001.0001
3. World Health Organisation. Wellbeing Measures in Primary Health Care/ The Depcare Project.*Rep a WHO Meet*. 1998.
4. WHO IMCI. Integrated Management of Childhood Illness (IMCI) Chart Booklet.*Distance Learn Course*. 2014