# **Protocol**

## 1. Title:

A randomized, 5-month, parallel group, superiority study to compare the effectiveness of a behavior change intervention to improve on-site, peri-urban sanitation in Lusaka, Zambia.

## 2a. Trial Registration—registry:

Trial Registration Number: NCT03174015

## 2b. Trial Registration—WHO data set:

Primary registry and trial identifying number: ClinicalTrials.gov, NCT03174015

Date of registration in primary registry: June 2, 2017

Secondary identifying numbers: None

Source(s) of monetary or material support: Sanitation and Hygiene Applied Research for Equity (SHARE)

Primary Sponsor: London School of Hygiene and Tropical Medicine

Secondary Sponsor(s): None

Contact for public queries: James Tidwell

Contact for scientific queries: James Tidwell (ben.tidwell@lshtm.ac.uk)

Public title: Sanitation Demand Creation in Peri-Urban Slums of Lusaka, Zambia

Scientific title: Effect of a behavior change intervention to improve peri-urban sanitation quality in Lusaka, Zambia: a randomized controlled trial

Countries of recruitment: Zambia

Health conditions(s) or problem(s) studied: Sanitation quality/Diarrheal Disease

Intervention(s): Active comparator: Bauleni Secret landlord group meetings

 Control comparator: No intervention

Key inclusion and exclusion criteria:

* Ages eligible for study: ≥ 18 years; Sexes eligible for study: All
* Inclusion criteria: Landlords and tenants on plots with at least one landlord and tenant living on them most of the time
* Exclusion criteria: None

Study type:

* Interventional
* Allocation: randomized; Intervention model: Parallel assignment; Masking: partially single blind
* Primary purpose: Prevention

Date of first enrolment: 9 Jun 2017

Target sample size: 1072

Recruitment status: Active, not recruiting

Primary outcomes: Having a hole-cover or water-sealed pan, Having a latrine door that locks from the inside, Having a latrine door that locks from the outside, Having a rotational cleaning system in place

Secondary outcomes: Willingness to pay, Attitudes towards sanitation, Financial preparation for toilet improvement, Partial construction progress towards toilet improvement, Cleaning rota initiated, Peri-urban Healthy Toilet Index

## 3. Protocol Version:

Issue Date: 27 December 2017

Protocol Version: 1

Authors: JT

## 4. Funding:

The trial is directly funded by the SHARE consortium (Sanitation and Hygiene Applied Research for Equity) through the UK Department for International Development.

## 5a. Roles and Responsibilities—contributions:

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VC, RC, and RA conceived of the study. All authors participated in the design of this study, and JT and JC helped with implementation. RA and VC are grant holders. JT and SB conducted the primary statistical analysis and JT drafted the protocol and manuscript. All authors contributed to the refinement of the study protocol and approved the final manuscript.

## 5b. Roles and Responsibilities—sponsor contact information:

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## 5c. Roles and Responsibilities—sponsor and funder:

Neither the funding source nor the sponsor had any role in the design of this study and will not have any role in its execution, data analysis and interpretation, or the decision to submit results.

## 5d. Roles and Responsibilities—committees:

Trial Management Committee: Robert Aunger, Roma Chilengi, Val Curtis, James Tidwell, Jenala Chipungu

Responsibilities: Study planning, protocol approval, budget administration, ensure adequate institutional review board/ethics oversight, randomization, reviewing study progress, data verification, and publication of study reports and papers.

Study Coordination Centre: Joyce Chinyama Chilekwa, Jenala Chipungu, James Tidwell

Responsibilities: Day-to-day study management, recruitment of participants, collection and storage of consent forms and data, and monitoring adverse events.

Data manager: Jacob Mutale

Responsibilities: Maintenance of trial IT systems and data collection devices

## 6a. Introduction—background and rationale:

Background

Rapid expansion of informal urban settlements, where health outcomes are worse than rural or planned urban areas, presents a major public health challenge [1]. The population in these peri-urban areas (PUAs) is expected to more than double to 2 billion people by 2035 [1]. However, rates of improved urban sanitation have only increased from 79% in 1990 to 82% in 2015, while shared sanitation has also increased from 7% to 10% [2]. It has been argued that high-quality shared sanitation should meet the criteria for the Sustainable Development Goal for sanitation, “access to safely managed sanitation for all,” but much work remains to determine how to achieve that standard [2].

There is little evidence for the public health implications of shared sanitation quality [3]. Some studies suggest that as the number of users of a toilet increases, the structural quality increases [4], but cleanliness decreases [3, 5, 6], which is a key public health concern [7]. Some kinds of shared sanitation may have no more fecal contamination than improved latrines used by individual households [5]. Major efforts are currently underway to understand the health impacts of shared sanitation [8], though the impact of particular components has not yet been studied.

The majority of the peri-urban population in Lusaka, Zambia have access to limited sanitation (shared, but otherwise considered technologically adequate). However, a recent study has revealed significant variations in quality for toilet superstructures, interfaces, and containment systems [9]. Open defecation is rare (~1%) [10], but constructing toilets for each individual household is infeasible in the area, so attention should be paid to understanding how to improve the quality of existing toilets. While the Lusaka Water and Sewerage Company is planning heavy investment in sewerage lines and treatment plants, it also aims to provide higher-quality shared toilets, but lacks an evidence-based plan for increasing demand to provide for cost-sharing or improved sustainability.

Existing Knowledge

Attempts to improve sanitation in peri-urban areas have included outright provision, subsidies, regulation, and promotion. Providing improved toilets and sewage systems is costly [11], and delivering subsidies to reduce the costs of provision has been challenging [12]. Local government institutions in PUAs are often ineffective and cannot enforce regulations, and heavy-handed enforcement may simply displace residents to less regulated settlements [13]. Promotion has been successful in some rural settings [14, 15], but there is a lack of comparable evidence in urban settings [16].

A systematized literature search [17] on the drivers of sanitation demand in peri-urban settings was conducted as a part of this trial, with some potentially relevant studies from rural and urban settings provided by several sanitation experts consulted. A search of Medline, Embase, Scopus, Web of Science, and PubMed Central databases was conducted, with title and then abstract screening, with selected full texts evaluated for quality and findings classified based on the BCD model of behavioral determinants. Evidence for the impact of health knowledge was mixed [18, 19], while comfort [20, 21], status [22, 23], fear [20, 24], disgust [25, 26], and affiliation [27, 28] were all suggested as motives for improving sanitation. Several studies focused on the importance of the social environment, whether through a sense of collective efficacy [29], direct peer influence [30, 31], or the role of “network communities” [32]. Access to subsidies, financing, or existing financial wealth were also associated with sanitation quality [14, 33-35]. Land tenure security was found to be a particularly strong determinant in peri-urban settings [19, 36, 37].

Need for a trial

Reaching the Sustainable Development Goal (SDG) for sanitation (6.2) of “Access to safely managed sanitation for all” is estimated to cost about USD $1 Trillion from 2015-2030 [11]. Most of this expenditure is for urban areas, where investments will largely go towards infrastructure. Little user contribution to sanitation costs is expected, and many existing toilets are not of sufficient quality to be connected to any sewerage lines constructed. Formative research has identified several promising possibilities for peri-urban sanitation quality improvement interventions [38], and observational evidence suggests that latent tenant demand communicated to landlords could lead to substantial gains in sanitation quality [39]. However, the lack of rigorous evidence prevents the implementation of such demand-creation interventions on a large scale, and so a trial is both necessary and has the opportunity to have a major impact on meeting the sanitation SDG.

## 6b. Introduction—choice of comparators:

As there is no intervention for increasing on-site, peri-urban sanitation known to be effective, the control group received no intervention other than responding to a baseline and endline survey asking basic questions about preferences for sanitation and including observations of the existing sanitation system.

## 7. Specific objectives or hypotheses:

Research hypothesis:

1. The SanDem intervention will increase the prevalence of specific on-site sanitation system components (inside locks, outside locks, sealed toilets [with a water or solid seal], and well-functioning cleaning systems).

Primary objectives:

1. To determine if the SanDem intervention increases the prevalence of on-site sanitation system components (inside locks, outside locks, sealed toilets [with a water or solid seal], and well-functioning cleaning systems).

Secondary objectives:

1. To determine if the SanDem intervention increases the prevalence of other aspects of on-site sanitation enumerated in the Peri-Urban Healthy Toilet Index (PUHTI) Score [9].
2. To determine if the SanDem intervention increases demand (measured by stated willingness to pay) for sanitation components specified in the primary objectives.

## 8. Trial Design:

The SanDem trial is designed as a randomized, controlled, superiority trial with two parallel groups and a primary endpoint 5 months after the intervention delivery begins. Plots with a landlord household residing on them and with at least one tenant household were individually randomly allocated with a 1:1 ratio.

## 9. Study Setting:

The trial took place in Bauleni Compound, a peri-urban area in Lusaka, Zambia with approximately 64,000 people living on about 4,000 plots of land. Bauleni was selected in consultation with the Lusaka Water and Sanitation Corporation, the private company responsible for providing water and sanitation to the Lusaka District. It was chosen as a typical peri-urban area in terms of age, socio-economic status of residents, and sanitation quality. Plots of land are demarcated by the government and owners possess official title deeds, though the original intention was only for one household to live on each plot. The intervention was delivered at local meeting places (schools and churches), with follow up at participants’ homes to monitor changes in sanitation quality. To minimize contamination, every fourth plot was selected for enrollment and plots were randomly allocated to intervention and control groups, with every second home included in limited circumstances to reach the desired sample size.

## 10. Eligibility criteria:

Plots were eligible for selection when the adult landlord (at least 18 years old) lived on the plot and at least one tenant household with an adult (at least 18 years old) also lived on the plot, which was about 80% of plots in the target area.

## 11a. Intervention—explanation:

Participating landlords were invited to an exclusive meeting limited to other landlords in the area where they would learn to build wealth and reduce conflict on their plot. Four meetings were held targeting specific outcomes (improving cleaning rota, adding an inside door lock to the toilet, adding an outside door lock to the toilet, and adding a seal between the toilet interface and waste containment). Each meeting consisted of locally-produced videos shot “hidden camera”-style revealing the perspective of tenants on sanitation issues on the plot; interactive sessions where demonstrations or games led participants do effective solutions to these problems; and practical sessions where implementation details were covered such as where to purchase materials and how to make improvements or find masons who could make them. Program staff made one follow up visit per meeting to each participant to observe any improvements made and offer suggestions for overcoming any barriers faced. Prizes were distributed by lottery (approximately one per 150 participants), with entries being given for meeting attendance and having made the desired toilet improvements.

See Appendix A for a more detailed description of the intervention based on the TIDieR checklist.

## 11b. Intervention—modifications:

Due to the content of the intervention, discontinuing the intervention occurred only if the participant wanted to leave the trial. Modifications were made only when participants failed to attend the groups/meeting times to which they were originally assigned (usually due to work schedule or other time conflicts)—“catch all” groups were started a few weeks after the beginning of the intervention and those allocated to the intervention who had not attended any meetings (about ¼ of all those allocated to the intervention) were re-invited to these groups. The same content was delivered at both meetings, but the group size was somewhat larger (20-24 invited to original meetings, with about 2/3 attending on average, compared to 30-40 at “catch all” meetings).

## 11c. Intervention—adherence:

Adherence consisted primarily of ensuring that participants attended meetings. Low attendance was a major early problem. A few issues were identified in discussions with non-attendees. First, invitations were given by program staff, but no one living in the community was involved in the invitation. This was initially due to the desire to have a sort of “secret society” branding with no health associations, but led to suspicion within the community. Second, invitation content was erroneously disregarded by the delivery agency, and landlords were told that the meetings would be an opportunity to have additional discussions related to the topics covered in the baseline survey, which was unappealing to many. Third, invitations given a week beforehand were judged too far in advance and easy to forget. Fourth, the solicitation of official government plot numbers during the baseline, done to allow for a unique program identifier, was thought by many participants to be a precursor to a visit by a government tax agent, as this was the primary reason for use of the number in the past. Fifth, many were unable to make the meeting times, even though they were selected with feedback from the community as the times most would be available. To deal with these challenges, follow-up visits were made the day before the meetings by a two-person team consisting of a program staff member and a local community health worker, more was revealed about the purpose of the meetings while retaining the wealth (non-health) focus, reassurances were given about not sharing participant information with the government, and “catch all” meetings discussed above were planned. The number of participants attending the first meeting grew from about ¼ to about ¾ using these methods, with about 2/3 of participants attending the fourth meeting.

## 11d. Intervention—Concomitant care:

There were no restrictions on participant activities during the trial. One aspect of selecting Bauleni for the trial was the lack of previous or planned sanitation interventions in the area and local government officials were asked to report the presence of any new sanitation products, business, or initiatives in the area.

## 12. Outcomes:

All outcomes were assessed at baseline (approximately one month before intervention delivery began) and endline (about 5 months after intervention delivery began) for both arms of the trial. Primary outcomes were observed (P1-P3, S4, most of S5) or reported by landlords (P4, S1-3, some of S5) and differences in changes in proportions from baseline to endline (P1-P4, S3-S4) or in mean values (S1-S2, S5) were calculated. More detail about the reasons for selecting these specific outcomes is reported elsewhere [40].

Primary Outcome Measures:

1. Having a hole-cover or water-sealed pan
*Toilet has a solid or liquid barrier between user and waste containment*
2. Having a latrine door that locks from the inside
*Toilet has a solid, lockable door from the inside to give a user privacy*
3. Having a latrine door that locks from the outside
*Toilet has a solid, lockable door from the outside to exclude those not living on the plot from the toilet*
4. Having a rotational cleaning system in place
*Hygienic condition of the toilet interface is maintained through regular cleaning*

Secondary Outcome Measures:

1. Landlord willingness to pay for toilet improvements  *Landlords state increased willingness to pay for specific improvements*
2. Landlord attitudes towards the importance of sanitation
*Landlords report increased scores for 5-point Likert-scale questions about sanitation in general and specifically related to each primary outcome*
3. Financial preparation for toilet improvement
*Landlords report saving money, either individually or by participating in a rotating savings scheme, for toilet improvement*
4. Partial construction progress towards toilet improvement
*Landlords have either amassed raw materials on the plot (concrete blocks, wood, etc.) for toilet improvement or new construction/upgrading of toilet has begun (hole dug for new toilet, new slab poured for flushing toilet, etc.)*
5. Peri-urban Healthy Toilet Index (PUHTI) Score
*Score on a theory-based, comprehensive index of on-site peri-urban sanitation status increases (PUHTI score was developed for the intervention and covers hygienicity, accessibility, desirability, and sustainability of sanitation systems [9])*
6. Cleaning rota initiated
*Landlord reports taking any action directed at establishing a rotational cleaning system (e.g., holding a plot meeting explicitly for this purpose, posting a written rota, or otherwise tangibly indicating rota responsibilities)*

## 13. Participant Timeline:

Figure 1: Timeline of enrolment, interventions, and assessments

|  |  |
| --- | --- |
|  | **STUDY PERIOD** |
|  | **Enrolment** | **Allocation** | **Post-allocation** | **Close-out** |
| **TIMEPOINT (months)\*\*** | **-1**  | **0** | **0** | **.5** | **1** | **1.5** | **2** | **2.5** | **6** |
| **ENROLMENT:** |  |  |  |  |  |  |  |  |  |
| **Eligibility screen** | X |  |  |  |  |  |  |  |  |
| **Informed consent**  | X |  |  |  |  |  |  |  |  |
| **Allocation** |  | X |  |  |  |  |  |  |  |
| **INTERVENTIONS:** |  |  |  |  |  |  |  |  |  |
| ***Primary Intervention*** |  |  |  |  |  |  |  |  |  |
| ***“Catch All” groups*** |  |  |  |  |  |  |  |  |  |
| **ASSESSMENTS:** |  |  |  |  |  |  |  |  |  |
| ***Baseline (Participants/Toilet Observations/Tenants)*** | X |  |  |  |  |  |  |  |  |
| ***Participant monitoring: Primary Intervention (Follow-up Visits)*** |  |  | X | X | X | X |  |  |  |
| ***Participant monitoring: “Catch All” groups (Follow-up Visits)*** |  |  |  |  | X | X | X | X |  |
| ***Endline (Participants/Toilet Observations/Tenants)*** |  |  |  |  |  |  |  |  | X |

## 14. Sample size:

The sample size was determined by estimating existing from our formative research and setting target levels based on practical, public health significance. As we are using multiple outcomes, we calculated sample size based on a family-wise error rate (FWER) rather than only one p-value. The study was originally planned and budgeted to be powered for 5 outcomes to be tested, though we decided to drop “having a place for handwashing with soap” from the intervention during the design phase. Since the outcomes were not assumed to be totally independent, we assessed the significance level using the Family-wise Error Rate (FWER), calculated by a standard formula that adjusts the p-value required for each individual test based on the non-independence assumption [41].



Here, h is the number of outcomes considered (5), so α = .0227 yields a 95% confidence with an 80% power to detect each outcome. The FWER-adjusted α was calculated based on an initial plan of including 5 outcomes, though one was removed during the formative research process. Sample sizes were calculated for each of the five planned primary outcomes using a 5 percentage point change for sealed toilet and 10 for the others as the minimum targets of public health importance. The largest required sample size was selected, and revised target levels were calculated for the four final primary outcomes (FWER α=.0253, 80% power)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Primary Outcome | Existing Prevalence | Initial Target Prevalence | Sample size required (per arm) | Final Detectable Target Prevalence |
| Sealed Toilet | 5% | 10% | 539 | 9.9% |
| Inside Lock | 52% | 62% | 476 | 61.3% |
| Outside Lock | 46% | 56% | 486 | 55.4% |
| Cleaning Rota | 54% | 64% | 470 | 63.2% |

## 15. Recruitment:

As the enrolment criteria were not very restrictive, reaching an adequate sample size at our study site was not difficult. Participants were recruited by local research assistants who went door-to-door within Bauleni. The purpose of the trial was communicated as learning how to improve sanitation in peri-urban areas of Lusaka for improving health. Refusal rates were low (<5%), so the main challenge was finding landlord heads of household at home to complete enrolment and administer the baseline questionnaire. Recruitment took place over 4 weeks using 24 research assistants primarily during business hours, with follow up appointments made in the evenings and weekends to reach those otherwise unavailable. No financial incentives were provided for participation.

## 16a. Allocation—sequence generation:

Participants were randomly assigned to either the intervention or control arms using a simple computer-generated randomization sequence with no blocks or stratification.

## 16b. Allocation—concealment mechanism:

Allocation lists were not accessible to research assistants during enrolment and allocation was done by researchers using the random sequence once all baseline data was collected.

## 16c. Allocation—implementation:

A member of the study team generated the randomization sequence, research assistants with no access to this list performed enrolment and data collection, and a separate member of the study team simply merged these two lists in the order received to assign participants to interventions.

## 17a. Blinding (masking):

Participants and research assistants did not know the participants’ enrolment status at baseline. Due to the nature of the intervention, no blinding of trial participants or intervention delivery staff was possible during the intervention. Research assistants were blinded to allocation during the endline data collection during all of the data collection possible until asking questions specifically about their experiences in the program.

## 17b. Blinding (masking)—emergency unblinding:

Due to the nature of the intervention and the unblinding of participants at the point of intervention delivery, no explicit emergency unblinding procedures were necessary.

## 18a. Data collection methods:

Research assistants collected baseline, monitoring, and endline data using electronic tablets and Open Data Kit (ODK) version 1.4.10. Questionnaires captured primarily self-reported measures of respondent demographics for tenants and landlords, plot residence (e.g., turnover of tenants) and characteristics, attitudes towards sanitation using Likert-scale responses. Tenant willingness to pay was assessed through Discrete Choice Experiments (described here: [39]) and toilet quality was assessed using a primarily observational tool created to measure peri-urban sanitation for this intervention (see [9] for more detail).

Research assistants were trained by the study team for one week on using tools for both baseline and endline. Questions were translated into two local languages (Nyanja and Bemba) and checked for accuracy by multiple assistants. The questionnaire (excluding the toilet quality observations) was field-tested by each research assistant multiple times and revisions made for any questions that were unclear.

The toilet quality assessment tool was intensively tested for validity and reliability. Each research assistant assessed 8 toilets chosen by the study team as representing the range of toilet options seen within Bauleni. Accuracy of most items and reliability of all were assessed using a combination of Krippendorf’s alpha for composite measures and Burt’s prevalence-adjusted, bias-adjusted kappa to assess inter-rater reliability on individual items. The overall composite measure had a Krippendorf’s alpha value of .885, considered “highly reliable.” The accuracy and reliability of items associated with the three observable primary outcomes are given below. More detail, as well as an extensive discussion of evaluating the validity of the measure and the implications of high accuracy with moderate reliability of some measures (especially inter-temporal reliability of items that may change over time, such as the presence of an outside lock), are given elsewhere (see supplemental material with [9]).

Figure 2: Primary Outcome Accuracy and Reliability Assessment

|  |  |  |
| --- | --- | --- |
| **Measure** | **Accuracy** | **Byrt's PABAK** |
| Solid Door | 1.000 | 0.916 |
| Inside Lock | 0.970 | 0.833 |
| Outside Lock | 0.970 | 0.693 |
| Containment Seal | 0.994 | 0.945 |

Data collection forms are provided in the attached appendices.

## 18b. Data collection methods—retention:

Participants were included in the endline data collection regardless of their level of intervention adherence. Participants were unlikely to relocate during the trial due to the short duration between baseline and endline (6 months) for plot-owning households. Research assistants sought to locate any participants who could not be immediately located on the plot through soliciting contact information from nearby residents or new owners and meetings were setup at times convenient to those unable to be present during normal business hours.

## 19. Data management:

All data was entered electronically by research assistants. Data integrity was ensured during electronic data collection through requiring responses to all questions (making “doesn’t know or won’t say” one of the responses), avoiding short text answers, validating and range-limiting directly-entered numerical values. No entered data was edited in the database itself. All modifications were made in the R code used for analysis.

Some manual edits were made where the errors were clear when data validation was inadequate, but daily monitoring limited the number of edits required. Length of plot ownership, recorded in years, was occasionally entered as a year of purchase. The biggest challenge was in matching landlord and tenant data from the same plot. In 112 cases, there was not an exact 1:1 correspondence, but in all but one case (a tenant for whom no landlord from the same plot was surveyed), examining the data entry sequence and matching data from each kind of respondent resulted in a high degree of certainty of a match.

Very limited coding of responses occurred for analysis. Number of years of education completed was recoded from an integer to a categorical variable (Primary or less (grades 1-7), some or completed secondary (grades 8-12), and beyond secondary (any post-secondary education).

All data was stored in a password-protected, regularly backed up server. Only a limited number of study team members had access to the data directly. Data will be retained by the study PIs in cloud-based, password-protected backups for at least 5 years after the study ends.

## 20a: Statistical methods for analyzing primary and secondary outcomes:

Primary analysis will be conducted on an Intention-to-treat (ITT) basis to assess whether the intervention was effective as delivered. (ITT means that we will carry out primary analysis by comparing the whole intervention group with the whole control group, irrespective of the dose of the intervention actually delivered to individual participants). For each primary outcome measured on binary scale, we will use conditional fixed-effects Poisson models with robust standard errors to estimate the effect of the intervention. The Poisson model is preferred to logit models in estimating risk ratios when the outcome is common. The model will include an interaction term between time of outcome assessment (baseline=0, endline=1) and the intervention variable taking a value of 1 if a participant was randomized to receive the intervention and 0 otherwise. The coefficient for the interaction term corresponds to the parametric difference in differences (pDiD). The parametric model is expected to provide unbiased and precise estimate of the average treatment effect. The significance of the result will be judged by the 5% FWER (α=.0253) to evaluate the primary outcomes of the intervention. We will also present results adjusting for imbalance in baseline characteristics. All analyses will be performed using R.

For the secondary outcomes, we will use Likert-scale questions capturing attitudes toward sanitation; stated willingness to pay for sanitation improvements; observed steps taken towards constructing improvements; self-reported financial preparation for improvements, and a composite measure of peri-urban sanitation quality developed for this intervention, the Peri-Urban Healthy Toilet Index (PUHTI) score [9]. We will again use conditional fixed-effects Poisson models, with robust standard errors, with interaction terms for all secondary outcomes measured on binary scale, but with a standard 95% confidence level unadjusted for multiple comparisons, as the secondary outcomes are inherently more speculative. For the analysis of the PUHTI scale, a continuous outcome, as well as the 5-point likert scale outcome, we will opt for fixed-effects linear regression model (or lognormal regression as appropriate) with interaction term to estimate average treatment effect. The likert scale variable will be coded such that 1 represents a negative attitude (usually, “strongly disagree”) and 5 represents a positive attitude (usually, “strongly agree”).

The model specification of the conditional fixed-effects logit model is:

$log (λ\_{it})=α\_{0}+β\_{1}Period\_{t}+β\_{2}Treat\_{i}+δPeriod\_{t}\*Treat\_{i}$ (Equation 1)

where $δ$ is the average treatment effect or difference-in-difference estimator,$ λ\_{it}$ is the incidence rate. Equation (1) can be implemented in Stata using xtpoisson, fe vce(robust) command with interaction term.

The model specification of the fixed-effects linear model is:

$y\_{it}=α\_{0}+β\_{1}Period\_{t}+β\_{2}Treat\_{i}+δPeriod\_{t}\*Treat\_{i}+v\_{i}+u\_{it} $ (Equation 2)

where $δ$ is the average treatment effect or difference-in-difference estimator, $y\_{it}$ is the outcome variable measured on continuous scale for the *ith* plot at period *t*, $v\_{i}+u\_{it}$ is the error term we have little interest in: $v\_{i}$ is the plot-specific error term, which differs between plots but for any particular plot, its value is constant. $u\_{it}$ is the regular error term with the usual properties (normally distributed, mean 0, uncorrelated with itself, uncorrelated with the independent variables, uncorrelated with *v*, and homoskedastic). Equation (2) can be implemented in Stata using xtreg, fe command with interaction term.

## 20b. Statistical methods for additional analysis:

In a secondary analysis based on per-protocol (PP) study sample, we will assess dose-response to understand the effect of our content versus the dose delivered through our chosen intervention delivery mechanism. The dose of the intervention will be measured using a binary indicator of whether the participant attended the meeting that covered the relevant primary outcome, an additional measure of attendance capturing the number of other meetings attended (integer valued from 0 to 3), and an interaction term between the two, assuming that attending additional meetings may have different levels of impact based on if the participant was exposed to the messages directed at a specific primary outcome. Conditional fixed-effect Poisson regression model with robust standard error will be used to estimate the effect of intervention dose:

$log \left(λ\right)=α\_{0}+ β\_{1}RelevantMeeting\_{i}+ β\_{2}OtherMeetings\_{i}\_{ }+β\_{3}RelevantMeeting\_{i}\*OtherMeetings\_{i}+ βx\_{i}$

 (Equation 3)

where $x\_{i}$ represents personal factors for plot income, education, baseline sanitation quality, and number of tenant households on the plot, $β\_{1}$ represents the effect of attending the relevant meeting, $β\_{2}$ the marginal effect of attending each meeting other than the relevant one if the relevant one was not attended, and $β\_{2}+ β\_{3}$ the marginal effect of attending other meetings in addition to the relevant one. Equation (3) can be implemented in Stata using xtpoisson, fe vce(robust) command with interaction term.

## 20c. Definition of analysis population and handling missing data:

Primary outcome data could be missing for participants in either arm of the trial due to refusal to allow observation of the toilet, known relocation of the participant to another plot, or loss to follow-up for unknown reasons (such as being simply unable to locate the participant). We will report refusals to allow toilet observations or who have relocated and compare these qualitatively, as there is likely to be bias if this result is large. Primary analysis will be conducted based on “intention to treat” (ITT)—that is, all participants included as randomized. A secondary, per protocol (PP) analysis will be done based on attendance at meetings specifically related to individual primary outcomes, but results will be regarded as hypothesis generating due to the high possibility of bias in these estimates. For either ITT or PP analysis, if on average more than 10% of primary outcomes are missing due to a refusal to allow observation or loss to follow-up for unknown reasons, we will use Markov Chain Monte Carlo-based multiple imputation based on the following covariates: Plot income, if landlord has a separate toilet, landlord education, presence of a water tap, number of tenant households on the plot (and for PP, attendance at any meeting and attendance at outcome-relevant meeting). We will use Rubin’s method of repeated imputation [44] to create 50 imputed datasets for analysis and pooling of results.

## 21a. Data monitoring—formal committee:

Due to the short duration of the trial, the single endpoint assessment of the primary outcomes, and the minimal risks to individuals in each arm, a formal data monitoring committee was not formed.

## 21b. Data monitoring—interim analysis:

Due to the short duration of the trial and the low risk to participants, there is no monitoring of program outcomes for considering premature termination. Attendance at the planned group meetings was identified as one of the primary concerns for understanding the efficacy of the intervention messages versus the effectiveness of the delivery mechanism, and so attendance was constantly monitored. Group and individual follow-up occurred and was thoroughly documented to allow both ITT and PP evaluations.

## 22. Harms:

The following harm reporting plan was in place during the trial:

*Potential risks are limited as the intervention only seeks to communicate new information to enrollees, though potential conflicts may occur between landlords and tenants if landlords improve sanitation and correspondingly increase rent levels. Therefore, monitoring of harms will be only passive, with bi-weekly follow-up visits by monitors providing sufficient opportunity for reporting of incidents.*

Table 1: Definition of Study Participation Harms

|  |  |
| --- | --- |
| **Term** | **Definition** |
| Adverse Event (AE) | Any untoward medical occurrence in a patient or study participant  |
| Serious Adverse Event (SAE) | A serious event is any untoward medical occurrence that:Results in deathIs life-threateningRequires inpatient hospitalisation or prolongation of existing hospitalisationResults in persistent or significant disability/incapacityConsists of a congenital anomaly or birth defectOther ‘important medical events’ may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.  |

*All non-serious adverse events (AEs) reported during the trial will be recorded by the field staff receiving the information and the on-site coordinator will be informed of and keep a record of all such reports. Detailed records will be kept in accordance with established CIDRZ policies and the PI will review all such AEs during the evaluation period. Serious Adverse Events (SAEs) should be reported to the study coordination centre within 24 hours of the local site being made aware of the event. An SAE form should be completed and submitted to the study coordination centre with as much detail of the event that is available at that time. If awaiting further details, a follow up SAE report should be submitted promptly upon receipt of any outstanding information.*

## 23. Auditing:

An independent “activation consultant” was hired by CIDRZ to ensure that the intervention was delivered as designed by attending at least one meeting of each team of delivery staff (a total of 4 pairs of staff delivered intervention content) as well as performing spot checks of the follow-up activities. This individual had no vested interest in the outcome of the trial, no role beyond observing the logistics of program and data collection activities, and no access to any data collected.

## 24. Research ethics approval:

Ethical approval was obtained from the sponsoring institution (LSHTM ref: 12157) and from a local ethics board (University of Zambia Biomedical Research Ethics Committee ref: 002-02-17). Approval for running the trial was obtained from the Government of Zambia’s Ministry of Health and local government officials. These bodies approved the protocol, informed consent forms, subject information forms, questionnaires, and intervention materials included in the appendices.

## 25. Protocol amendments:

Major modifications of the protocol, which may have affected the content of intervention, altered the potential benefit to the participant, or affected participant safety were required to be recorded through formal modification of the protocol, trial registration, and notification of the ethical approval bodies mentioned above. Administrative changes requiring only minor corrections or clarifications that have no effect on the way the study was conducted were agreed to by the trial management group and documented in the study protocol.

## 26a. Consent or assent:

Informed consent was obtained prior to enrolment. Participants (landlords) were given a verbal explanation and a written subject information form for their records. Written consent was obtained when participants were literate, or otherwise verbal consent obtained and a signature of an impartial, literate witness. Consent to have data collected was also obtained prior to data collection from tenants (who do not receive the intervention). The right of the participant to refuse to participate without giving reasons will be respected. All participants are free to withdraw at any time from the protocol treatment without giving reasons. The PI is responsible for ensuring that all vulnerable participants are protected and participate voluntarily in an environment free from coercion or undue influence.

## 26b. Consent or assent—ancillary studies:

No data was collected that is not for use directly in this study and no biological specimens were collected or stored for future investigations. De-identified data will be made available to other researchers with approval from the study PIs.

## 27. Confidentiality:

Any participants’ identifiable data collected will be stored securely and their confidentiality protected in accordance with the Data Protection Act of 1998.

Enrolled participants were allocated a unique identification number. These numbers will be used to identify all records relating to the participant. Data will be stored in an electronic spreadsheet and will be identifiable by ID number only. A separate list will be kept listing participant names, locations, and ID numbers. This list will be password protected only be accessible to senior project staff.

Participants were not be identified in reports using any personally-recognisable means. Reported quotes will be anonymised and deductive disclosure will be avoided by ensuring that there are at least five individuals in any sub group of analysis. Participants were asked specifically whether they consent to photos or videos being used for research purposes or to communicate findings.

Upon completion of the research a copy of all electronic field notes and audio-visual data will be stored in a password-protected file on the computer of the lead investigator. A copy of all hand written field notes will be retained by project staff in a sealed envelope and kept in a safe at CIDRZ.

## 28. Competing Interests:

The authors (JT, RA, VC, JC, and RC) declare no competing interests.

## 29. Access to Data:

All data will be stored in files requiring passwords for access as well as stored on network locations that require passwords for access. Data will be retained by PIs (RA and RC) as well as the lead analysis/author (JT) for at least 5 years following the study. Data will be stored locally on study team computers during analysis in password-protected formats, and then online in a shared, password-protected Dropbox folder.

## 30. Ancillary and post-trial care:

Due to the low probability of harms arising from this trial, there are no plans for ancillary or post-trial care. However, the sponsor’s indemnity policy covers participants in the case of serious adverse events.

## 31a. Dissemination policy—trial results:

All publications and presentations relating to the study will be authorised by the PIs. The first publication of the trial results will be in the name of all protocol authors. Authorship of additional studies will be according to the individuals involved in the project but must acknowledge the contribution of the Trial Management Group. Results will be published in a peer-reviewed journal and reports issued by the funder (SHARE) and will be made available to local political leaders and study participants upon request.

## 31b. Dissemination policy—authorship:

Authors on each paper will be based on contributions in keeping with the ICMJE criteria of:

* Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
* Drafting the work or revising it critically for important intellectual content; AND
* Final approval of the version to be published; AND
* Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

No outside professional writers will be employed in drafting manuscripts based on this study.

## 31c. Dissemination policy—reproducible research:

Research protocols, de-identified datasets, and statistical code will be made available upon request by the study PIs no later than 2 years after publication of the trial results.

## 32. Informed consent:

Informed consent forms are included in the attached appendices.

## 33. Biological specimens:

No biological specimens were collected in the course of this research.

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# **Appendix A**

TIDieR Checklist for Intervention Replication

1. Brief Name: Creating Demand for Peri-Urban Sanitation (SanDem)
2. Why: The development and theory of change behind intervention components are described in detail elsewhere [40]. Briefly, latent tenant demand for improvements in peri-urban sanitation quality was uncovered, but landlords were unaware and rarely discussed sanitation with tenants and landlords rarely learned from each other directly. A series of meetings of groups of landlords were used to facilitate such discussions, and an overarching model of surprise/revaluation/performance was included in each meeting. Surprising “hidden-camera” style videos were used to reveal secret information from tenants, games and demonstrations were used to cause landlords to understand the value of sanitation to tenants, and practical sessions facilitated performance by discussing how to make improvements and providing accountability structures.
3. What—materials: A campaign manual was used to train facilitators and for their reference, which also describe the revaluation games/demonstrations and the practical sessions. A series of videos were produced for the “surprise” portion of the intervention. Rota symbols were used to facilitate better cleaning systems. “Secret cards” were given to each landlord, which were designed for a tenant to sign that a given improvement had been made. Posters showing each key message from the campaign manual were printed for reference at the meetings. All intervention materials are available at the project website[[1]](#footnote-1).
4. What—procedures: The campaign manual provides the necessary detail for all relevant procedures during meetings. The only activity outside of the meetings was the household-level follow-up, where data collectors asked a series of basic questions about the primary outcome targeted by the previous lesson. A sample is provided below.

|  |
| --- |
| **Lesson 1 Monitoring form** |
| Date |
| Monitor Name |
| Plot ID assigned by CIDRZ (looks like 1234) |
| Landlord name |
| Plot Number assigned by government (looks like 34/12) |
| Did you have a rota before attending the last meeting? |
| Have you had a meeting with your tenants about a pamodzi rota? |
| Have you started a pamodzi rota? |
| Have you changed to using a weekly rota system? |
| Are you using the rota symbol? |
| Are there any barriers you face to using the pamodzi rota? |
| What did you learn at the last meeting you attended? |
| What parts of the meeting were confusing or could be improved? |

1. Who provided: Lessons were conducted by pairs of presenters. One was a community health worker, who had completed secondary school and could read and write, and also had experience working in the target community. The second was a trained actor, whose role was to lead on engaging the crowd and make sure there was energy and interaction during the presentation. Monitors had at least a bachelor’s degree and had experience in data collection with research organizations.
2. How: Lessons were provided by pairs of presenters in face-to-face group meetings with up to 24 landlords, “catch-all” groups that might have had slightly higher numbers in some cases, and in summarized form directly to participants by data collectors for those unable to attend.
3. Where: Central locations within the community were chosen, which were three churches and one school. The only requirements were that they were close to the population of interest, there was no stigma associated with attending, and there were chairs for participants to sit in.
4. When and how much: The intervention was delivered in one series of four meetings to 24 groups of up to 24 landlords, in four series of four “catch-all” meetings, and then on individual plots. Meetings were held every two weeks, usually at 10am on weekdays or Saturdays, with catch-all meetings held at 6pm on weekday evenings. Meetings lasted up to two hours.
5. Tailoring: The only “personalization” was adjusting presentation formats for those unable to attend regularly scheduled group meetings—first, through “catch-all” meetings, and then, with individual follow-up if necessary.
6. Modifications: Presenters received feedback on how to better engage the audience from a supervisor, but no substantive changes were made during the delivery of the intervention.
7. How well—planned: Presenters recorded meeting attendance and worked to ensure high attendance/retention rates. Follow-up visits also encouraged high adherence.
8. How well-actual: Actual adherence rates are shown below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Meeting Number** | **Meeting Attendance** | **Catch-All Attendance** | **Individual Follow-up** | **Did not receive intervention** |
| Secret 1 | 352 | 52 | 15 | 124 |
| Secret 2 | 313 | 36 | 20 | 174 |
| Secret 3 | 289 | 36 | 15 | 203 |
| Secret 4 | 273 | 36 | 15 | 219 |

1. <http://bentidwell.com/sandem/> [↑](#footnote-ref-1)