# Research protocol - Design and evaluation of an intervention to increase handwashing with soap after toilet use in Koumassi, Abidjan, Côte d'Ivoire: A cluster randomised trial

The randomised trial design was informed by the 2012 (Chapter 5) and 2014 (Chapter 6) studies. The PhD candidate was assisted by two fieldwork assistants in conducting the trial. Both received training on the trial's methods, and on their new role as fieldwork supervisors. In this chapter, we will use the term *fieldworkers* to refer to trial staff supervised by the PhD candidate and fieldwork assistants. These trial staff collected data linked to the evaluation of the interventions' effect. *Intervention providers* will be used to refer to the trial staff who delivered the interventions, and collected process evaluation data. The two teams were distinct and did not interact with each other. We obtained ethical approval from Côte d'Ivoire's Bioethics Committee (*Comité Consultatif de Bioéthique de Côte d'Ivoire*), Côte d'Ivoire's Ministry of Higher Education and Scientific Research (Ref. 0758/MESRS/CAB 1/gsy), and the London School of Hygiene and Tropical Medicine's (LSHTM) Research Ethics Committee (Ref. 7029).

## Research questions

The research aimed to answer the following questions:

1. Did handwashing practices after the key occasions improve in the intervention groups compared to the control/no intervention group?
2. Is there an association between norms-related constructs and HWWS after using the toilet?
3. Did the interventions have any impact on the norms-related constructs?

## 1. Trial design and overview of the study site

### 1.1. Study design

The study was a three-arm superiority cluster randomised trial (CRT), conducted in housing compounds, in Koumassi, from August 2014 to April 2017. Due to the nature of the intervention, which could only be delivered at compound level, the randomisation was at the compound (cluster) level rather than the individual level. We randomly assigned compounds to the TNSB-based handwashing intervention, the handwashing station (HWS)-only intervention, or non-intervention control, using a 1:1:1 ratio. The TNSB-based handwashing intervention consisted of compound sessions during which residents were shown short video clips and a Glow germ© demonstration, provision of posters promoting handwashing, and an HWS with an initial supply of soap (Chapter 8). The HWS-only intervention arm only received an HWS with soap, but without any promotional messages (Chapter 8). The third trial arm was a non-intervention control group. This latter group received HWS with soap, at the end of the trial.

### 1.2. Blinding

The PhD candidate and fieldwork assistants were not masked to the study objectives and hypotheses. However, they neither participated in data collection, except to supervise fieldworkers, nor in the intervention delivery.

Both participants and fieldworkers were masked to the study objectives and hypotheses, and fieldworkers were not told about the activities of the intervention providers. They were told that the study was part of a PhD research study aimed at understanding how housing compounds were organised, particularly as it pertains to gender roles and social cohesion among residents. However, fieldworkers were aware that there was a general hygiene component to the study. This was because, during their training, they were instructed not to mention anything related to hygiene, when they explained the study aims to participants. This was justified by explaining the notion of the Hawthorne effects to fieldworkers. Fieldworkers did not know that the hygiene component of the study was limited to handwashing, as there were masking items in their observation grids requiring them to collect data on other hygiene-related themes.

The intervention providers were not masked to the study objectives, and were aware of the work undertaken by the fieldworkers. Care was taken to ensure that the two trial teams never met in the field. On the days where field activities were carried out by the two trial teams simultaneously, the PhD candidate verified the list of all compounds to be visited (i.e. for data collection and interventions delivery), to ensure that there was no risk for the teams to meet. We also ensured that both teams never worked in the same area. Nevertheless, and as a precaution, intervention providers were instructed to ignore the fieldworkers, and supervision team, in the unlikely event they met in the field. This never occurred during the course of the trial.

Study participants were masked to the fact the intervention providers were part of the same study as that conducted by the team of fieldworkers. This was accomplished by having each team obtain separate informed consent, with different explanations given to residents regarding the purpose of their visits. The fieldworkers' information sheet, read to residents, explained that the research was related to the standard masking theme mentioned above. In both the TNSB-based handwashing and HWS-only intervention groups, the intervention providers introduced themselves to residents as volunteers from the Family Arc-en-Ciel association, as mentioned in Chapter 8. Section 2.2. details the informed consent methods for each trial teams.

The above masking measures were taken to both minimise the risk of reactivity among the study participants, and minimise the risks of differential misclassification[1] by fieldworkers.

There were no trial termination criteria.

**1.3. Study site**

The trial was conducted in six of Koumassi's eighteen neighbourhoods[2]. These were Inch Allah, Michigan, Port-Bouët II, Grand Marché, Adioukrou, and Grande Mosquée (Map 1). These neighbourhoods are divided into between two and six sub-neighbourhoods. We chose these neighbourhoods due to compounds being the predominant habitat type, and for their proximity to each other. The remaining neighbourhoods either had individual houses as the predominant habitat type, were industrial zones, or were known for having crime-related security issues.

[1] Differential misclassification refers to systematic differences between trial arms in errors in measuring/recording outcomes.
[2] Koumassi Town Wall's website is not up to date in terms of the administrative division of the commune, among other data. The administrative division was thus done with the help of the fieldwrok assistants, who are Koumassi residents.

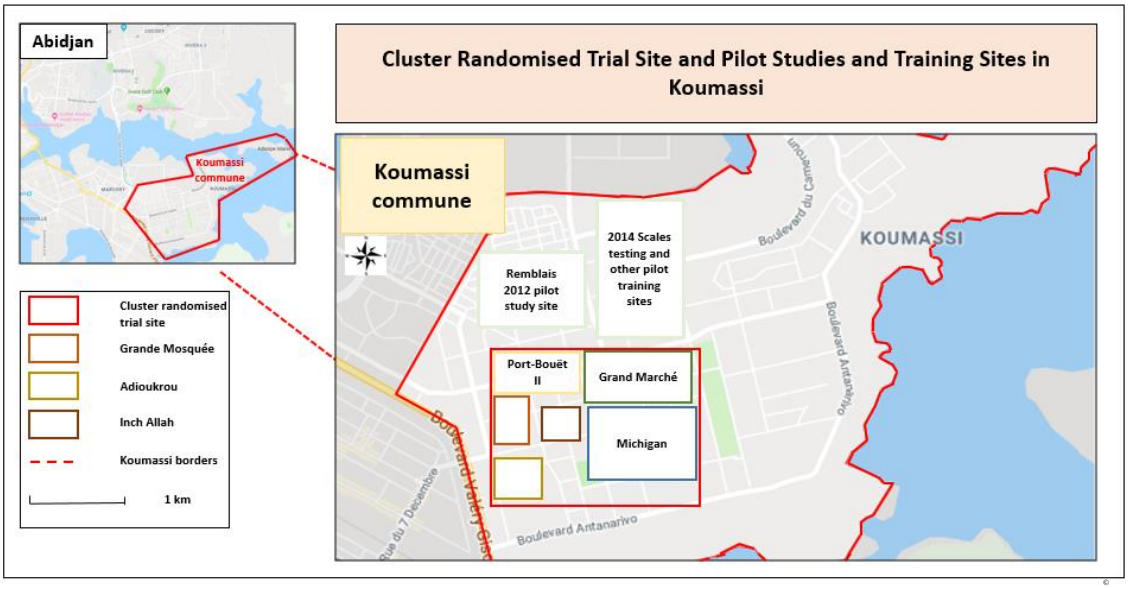
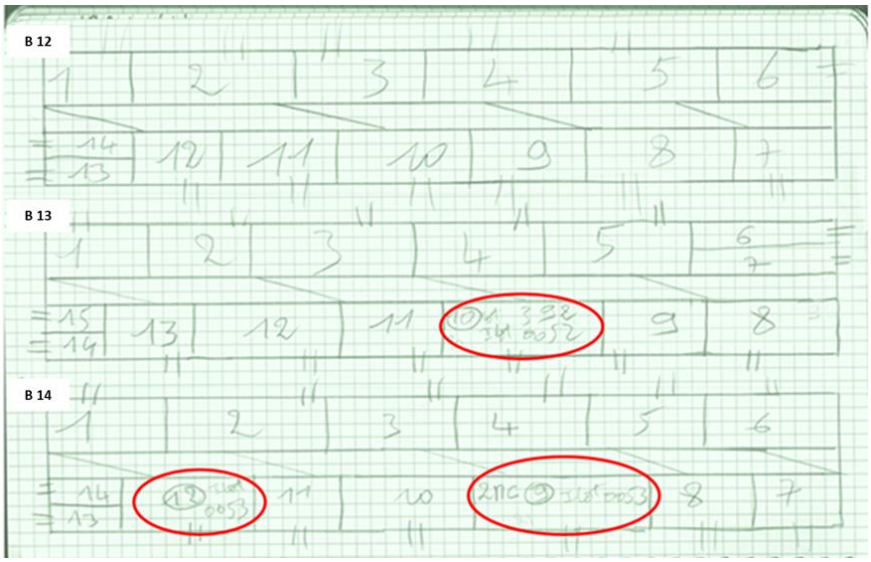



Figure 9. 1 Map of the cluster randomised trial site, pilot studies and training sites in Koumassi

## 2. Participants

In order to easily locate the study compounds, a sketch of the study area was prepared. The study area was laid out as a checkerboard, with each grid representing a block (islot), and each block separated from the next by a street. We started from the first block, when entering the study area, and attributed the number one to this block. Each compound on the block was then given a number in order (Picture 9.1).




**Picture 9.1.** Sketch of the study area showing Blocks 122 to 124, each separated by a street. The position of each compound on each block is represented. The circled compounds with administrative numbers are the ones which met the eligibility criteria on these blocks

### 2.1. Eligibility criteria

Eligible compounds were those with:

- 7≤N≤13 households per compound, as these were neither too small nor too big for the trial,
- with a maximum of two households with screens,
- predominantly shared water and sanitation facilities not located in corridors,
- and at least four children under five years old among residents.

The exclusion criteria were compounds with:

- predominantly single males as residents,
- where households were predominantly from the same family,
- and with handwashing facilities (e.g. sinks, HWS).

1,974 compounds were screened. The landlord of one compound refused to take part in the study. 92 out of 1,974 compounds (5%) met our inclusion criteria. The main reason for non-

eligibility was the presence of more than two households with screens per compound. We had assumed that having more than two screens would obstruct the views for observations.

### 2.2 Informed consent

Verbal informed consent was obtained separately by each trial team, as mentioned above.

#### 2.2.1. Informed consent from the fieldworkers

Provisional verbal informed consent was sought from eligible residents (i.e. permanent adult (≥ 16 years old) residents) and landlords who were present at the time of the visit, in eligible compounds. An information sheet was read to household heads, containing the standard masking theme. Any questions from potential participants were answered (Picture 9.2).

Participants were told that data would be collected at three different points in time in their compounds, via structured observations and interviews. We emphasized that, at any point in the study, and without having to give any explanation, residents could decide to withdraw their consent. We also asked permission to take pictures in the compounds, for illustrative purposes. We emphasised that, if residents appeared in the pictures, their faces would be masked, so that they could not be identified. We asked household heads, who were present at the time of the visit, if they would tell absent residents about the study on our behalf. We also informed them that, if their compound ended up being selected for the study, we would come back, prior to actual data collection, to obtain confirmation that the compound still agreed to take part in the study. If a compound inhabitant refused to be part of the study, the entire compound was excluded. Administrative identifiers[3] and geographic coordinates of each potential study compound were recorded in a spreadsheet (Picture 9.3). In cases where administrative identifiers were not visible, a unique identifier was allocated to the compound. Informed consent for data collection linked to the fieldworker's team was sought at the beginning of each trial phase (i.e. at baseline, one-month and five-month follow-ups).

[3] In Cote d'Ivoire, compounds' administrative identifiers are composed of two sets of numbers, the lot, which is a unique identifier, and the 'islot' (block), which is a number shared by all compounds on the same block.

**Picture 9.2:** The two fieldwork assistants responding to questions from a group of heads of households during ascertainment of informed consent.

**Picture 3:** The two fieldwork assistants exiting an eligible compound, with one circling its position on the sketched study area, and recording its administrative identifier, located on the wall at the top of the compound entrance.

### 2.2.2. Randomisation

STATA® 13 was used to randomly assign the 75 selected compounds to the three trial arms (control i.e. non-intervention, partial intervention and full intervention groups) in a 1:1:1 ratio (n=25 compounds per study arm), after baseline. No stratification, restriction or minimisation was used. Due to the nature of the interventions, the allocation sequence was not concealed.

### 2.2.3. Informed consent from the intervention providers

- **HWS-only intervention**

Intervention providers entered compounds in the typical fashion street vendors would do (i.e. speaking loudly upon entering the compound, to catch residents' attention), and announced that they were there to give a gift to the compound from the Family Arc-en-Ciel (Chapter 8). If residents agreed for the intervention providers to give them the gift, then the intervention was delivered, and if they refused, the intervention was not delivered.

- **TNSB-based handwashing intervention**

Intervention providers introduced themselves to residents in eligible compounds, as being volunteers from the Family Arc-en-Ciel. They explained that the purpose of their visit was to share happy moments with residents, through screening of funny videos, among other activities, and providing the compound with a gift (Chapter 8). If residents agreed for the intervention providers to spend time in their compounds, the intervention was delivered, and if they refused, the intervention was not delivered. At each subsequent intervention delivery visit, intervention providers told compound residents that they had come back to share more joyful moments with

them, and inquire whether there were any issues with the HWS. They sought verbal informed consent to interview eligible residents and/or deliver the intervention.

Intervention providers obtained informed consent every time they delivered the intervention or collected process evaluation data (see Section 3.4).

### 2.2.3. Withdrawal of participants

During the course of the trial, some compounds withdrew their consent to be part of the study. As mentioned above, both trial teams obtained informed consent separately, and care was taken to ensure that participants could not link both teams to the same study. In 2016 and 2017, the PhD candidate and fieldwork assistants sought informed consent again from all study compounds to be part of the trial. At the time informed consent was sought in 2016, intervention delivery had not started yet. Thus, if a compound withdrew their consent to be in the study, it was removed from the entire trial. On the other hand, after intervention delivery had started, a compound withdrawing consent from one trial team had no bearing on the activities carried out by the other trial team in the compound. In other words, if post-intervention delivery a compound withdrew consent from the fieldworker's data collection activities, intervention providers could still continue delivering the intervention and collecting process evaluation data in the said compound, and vice-versa. This was the case, unless the compound withdrew consent from both trial teams.

During the course of the trial, we also ceased to collect data and deliver the intervention in compounds in which structures were modified to a point where they no longer met the inclusion criteria (i.e. compounds with sanitation facilities becoming individual vs. shared).

## 2.3. Compound selection

We located all 92 eligible compounds on the sketched map of the study area. Due to the nature of the interventions, care was taken to ensure that there was sufficient distance between compounds. We did so to minimize the risk of contamination between the different arms. This would tend to dilute the apparent effect of the intervention, biasing the trial towards a smaller effect estimate [91]. We used Excel to organise compounds in two different groups. One group contained the list of compounds with the lowest contamination risk (n=41 compounds). These

were compounds on blocks with only one or two eligible compounds per block. In the latter case, the compounds were not on the same side of the block. All compounds in this group were selected. The remaining 51 compounds were the ones with moderate to high contamination risk. Examples of such compounds were blocks with more than one eligible compound per block and on the same block side; and compounds facing one or more compounds selected on an opposite block. 34 compounds were selected from this second group, after visiting the compounds again to exclude the ones with the highest contamination risk. In total, 75 compounds were selected in total, and from which formal verbal informed consent was obtained to take part in the trial.

## 3. Procedures

The PhD candidate and the fieldwork assistants acted as fieldwork supervisors for the trial.

### 3.1. Recruitment and training of fieldworkers

The trial was initially scheduled to last approximately 18 months, with data collected by the same fieldworkers for the entire trial duration. However, we encountered major issues with the production company contracted to produce the short intervention video-clips (e.g. failure to respect production timelines, refusal to finish editing the video clips). Consequently, the study was delayed by approximately a year (Table 9.1). There was thus a two-year gap between the baseline and the follow-up studies. As a result, not all fieldworkers who took part in the baseline study were available for the subsequent follow-up phases.

- **Baseline recruitment**

Fourteen potential fieldworkers went through a selection process during which we explained the study to them, and trained them on the data collection methods and tools. One of the recruitment criteria was that the potential fieldworkers spoke or had a good understanding of Dioula. Candidates underwent two weeks of theoretical and practical training on the data collection tools. For the questionnaire, we went through each item, and ensured that candidates understood the meaning of each statement. We had a strict script to be used to implement the questionnaire, to minimise between-interviewer variation in administration of the

questionnaire. However, it was still important for fieldworkers to be able to accurately reformulate the items during interviews, in case respondents did not understand them. As part of their training, fieldworkers were shown pictures of a variety of sinks and HWS, so that they would be able to recognise HWS, during the follow-up phases, without the fieldwork supervisors having to bring their attention to the facilities. Doing so, could have unblinded fieldworkers.

The practical training took place in compounds in Treichville commune. The fieldwork supervisors sought verbal informed consent from adult residents. The training consisted of 1.5 hours of structured observation and administration of the questionnaire to compound residents, every day for 12 days. Throughout the training, we visited each fieldworker in their compound, to observe and take notes on how they were collecting data. A debriefing session was held at the end of each training day. Fieldworkers were also trained on residents' eligibility criteria and informed consent procedures.

Table 9.1. Anticipated and actual trial duration by activity

| **Activities** | **Anticipated number of weeks** | **Actual number of weeks** |
|---|---|---|
| Trial set-up (e.g. screening and recruitment of participants and trial staff) | 8 weeks | 12 weeks |
| Baseline | 8 weeks | 8 weeks *(August-September 2014)* |
| Intervention design (including production) | 20 weeks | 72 weeks* |
| Intervention implementation (including intervention providers recruitment) | 16 weeks | 18 weeks *(July-November 2016)* |
| Follow up 1 | 8 weeks | 8 weeks *(September-November 2016)* |
| Follow up-2 | 8 weeks | 8 weeks *(January-March 2017)* |
| Process Evaluation | 4 weeks | 5 weeks *(March-April 2017)* |
| **Total duration** | **72 weeks** | **131 weeks** |
| * Large gap between anticipated and actual duration due to major issues with the intervention video clips production company. | | |

At the end of the training, the ten best candidates were hired. Eight out of the ten fieldworkers were selected to implement the handwashing norms questionnaire, in addition to conducting structured observations. The remaining two only undertook structured observations. Whilst the majority of fieldworkers had a good grasp of Dioula, we felt confident that only four were fluent in this dialect, and able to administer the questionnaire in Dioula. Therefore, they received additional training to do so. These four fieldworkers were instructed to administer the questionnaire in Dioula, when respondents were more comfortable using this language.

- **2016 One-month follow-up recruitment**

Twenty-five potential fieldworkers, including four from the 2014 baseline, went through the same selection process as that described above. Practical training took place in Koumassi, but outside of the study area (Map 1, Section 1.2). Among the ten candidates hired, four were selected to implement the norms questionnaires, in addition to conducting structured observations.

- **2017 Five-month follow-up recruitment**

Two additional fieldworkers from the 2014 cohort rejoined the trial, and replaced two fieldworkers from the 2016 cohort, who were no longer available. The eight fieldworkers from the 2016 cohort received a short training to refresh their skills, whilst the two new fieldworkers from the 2014 cohort received an intensive 12 day-training

### 3.2. Structured observations

#### 3.2.1. Piloting of the observation grids

Based on the 2012 pilot study results (Chapter 5) and the trial objectives, the trial observation grids were updated. The fieldwork supervisors conducted a pilot study within the study reported in Chapter 6. As a result of the latter pilot, an updated observation grid recorded handwashing practices at three key occasions (Appendix 9.1). Compound residents typically do not use toilet paper for cleaning after using the toilet, but rather use water. We thus made the distinction between two types of toilet events in the observation grid. One was handwashing after using the toilet, without a water container. The

second occasion was the same as before, but including a water container (usually a plastic kettle). The distinction was made between these two occasions, as it was likely that toilet events involving the use of water for cleansing would include defecation events. The third key occasion was after cleaning a child's bottom. A fourth masking occasion was also added, and included any handwashing practice occurring outside of the above-mentioned occasions. This was added as an attempt to mask fieldworkers to the study's primary and secondary behavioural outcomes (See Section 4). This observation grid also recorded data on the type of facilities used for handwashing (e.g. sink, HWS or other), and whether any handwashing involved the use of soap.

Two additional grids were also designed (Appendix 9.2). One was a grid aimed to mask the key behaviours of interest. It recorded domestic compound activities, such as who cooked and swept the floor in the compound, by gender and age group. The information collected was along the masking theme. The second grid aimed to collect handwashing-facilities-related information (e.g. presence of handwashing facility, presence of water and soap at the handwashing facility) (Appendix 3). This grid was masked with items recording sanitation-related facilities present in the compound.

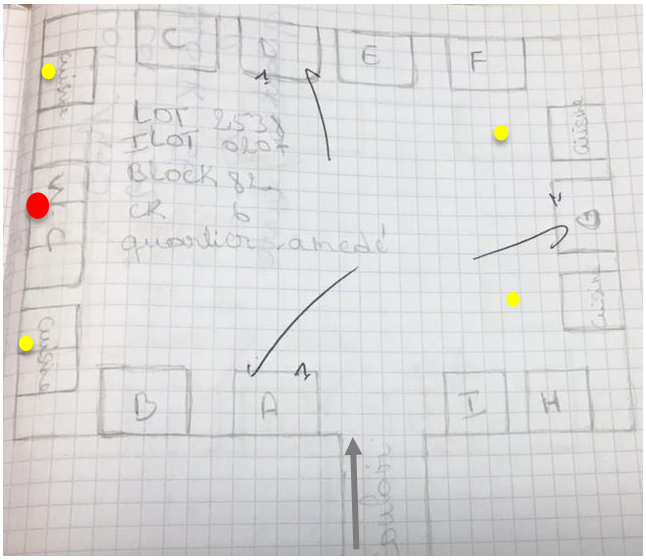
### 3.2.2. Structured observation procedures

The structured observation methods were the same as those in the 2012 pilot study (Chapter 5). Structured observations were conducted for three hours, from 4 p.m. to 7 p.m., on Saturdays and Sundays. The trial masking theme were used when obtaining confirmation of informed consent from compounds residents.

To record whether a participant had washed their hands with soap, at a key occasion, we allowed a time frame of three minutes, after the resident had performed the action requiring handwashing. This was done to account for the time participants might take to fetch soap from their households or elsewhere in the compound, as experienced during the 2012 pilot study. If the observed resident had not washed their hands after the key occasion, but started to engage in an activity involving the use of soap (e.g. doing the laundry or washing the dishes), within three minutes following the key occasion, this was recorded as the resident having HWWS. Past this time, and if the resident engaged in any other activity, before performing an activity requiring the use of soap, the event was recorded as the resident not having washed their hands with soap. If an HWS was present in the compound and had not been used during the entire observation session, fieldworkers were instructed to go to wash their

hands at the HWS, at the end of the observation, to determine whether there was any water in the HWS.

During the first two weeks of fieldwork, we visited each fieldworker in their compounds to draw a sketch of their compound, for the purpose of the household survey. The sketch showed the location of each household, sanitation facilities, and other relevant rooms (e.g. storage room, communal kitchen area) (Picture 9.4). A unique household identifier was created for each household by combining the compound lot number with a letter (e.g. 2538c indicates household c in compound lot number 2538). Fieldworkers were, subsequently, in charge of sketching their compounds, for the remainder of the trial. We checked each drawing, during supervisory visits.




**Picture 9.4.** Sketch of a study compound. Each household is codified with its identifying letter. The red dot indicates the location of the toilet, and the yellow dots, the shared kitchens. The grey arrow indicates the hall to the compound entrance. The check marks indicate to fieldworkers the households to be surveyed

### 3.3. Handwashing norms scales questionnaire

A questionnaire to measure four norms-related constructs around HWWS after using the toilet was developed, as described in detail in Chapter 6. The two items assessing handwashing publicness were reformulated, to remove the section referring to the lack of handwashing facilities or dedicated handwashing areas in compounds. This was done to reduce the risk of acquiescence bias. The two new

items expressed only the idea that it was hard to notice who washed hands with soap, after using the toilet, in the compound (Appendix 9.4).

Two masking statements were used to assess respondents' propensity for acquiescence bias (Statements 5 and 6). One statement posited that when men came back from work, they took over women's domestic chores in the compound, so women could rest. The second statement stated that men helped women in their domestic chores. In the absence of acquiescence bias, we expected most participants to disagree or strongly disagree with the statements. As described in Chapter 6, the questionnaire ended with one question which assessed the effectiveness of the masking items. The questionnaire administration time was approximately 20 minutes.

### 3.3.1. Sampling of households

The questionnaire was administered once to each household over the course of the study. We defined a household as a group of people who ate together. In cases where residents lived in different households but ate together, an eligible resident from only one of these households was surveyed. Households interviewed at each time point were selected by random sampling, with k=3 as the sampling interval. In compounds with nine households, three households were sampled per study phase. In compounds with more than nine households, more than three households were surveyed per study phase. For each trial phase, we indicated to fieldworkers the households to be surveyed, on the compound sketch. The fieldwork supervisors monitored all survey data collection, to ensure that there were no errors in sampling. They also verified again, at the beginning of data collection in a compound, that there were no mapping errors (e.g. incorrect number of households sketched, storage room wrongly coded as a household).

Verbal informed consent was obtained from eligible residents. On the rare occasions when both household heads were present, the male head of household preferred for the female head of household to be interviewed. This was on the basis that the female head of household spent more time in the compound compared to her male counterpart. The interviews were conducted in the respondent's household or away from other residents. Fieldworkers went to the designated household and inquired whether an eligible resident was present. An information sheet was read to residents, using the standard masking theme, and residents were then asked if they agreed to be interviewed.

In the case of absences, fieldworkers were instructed to inquire with present compound residents, when the best day and time would be to find the absent resident. Fieldworkers were instructed to visit the household two additional times (thus a total of three visits). If the resident was still absent, then no further attempt was made to survey them. A record was kept of participants' consents and absences. When feasible, data on population characteristics (e.g. gender, marital status), and other relevant information were collected for participants who were absent or refused to take part in the survey.

- **Deviation from protocol**

Two socio-demographic questions were dropped from the survey questionnaire (Q.30 and 31, Appendix 4), after the one-month follow-up phase had started. Question 30 asked the number of rooms there was in the respondent's household, and question 31, the amount of rent the respondent paid. The decision to discontinue using those two items in the trial was made, after a landlord withdrew their consent for their compound to be part of the trial. A resident had informed the compound landlord of the two questions being asked, which annoyed the landlord. Whilst the compound withdrew its consent from the trial activities linked to the fieldworkers, the intervention providers reported that they had no problems continuing their activities in the compound. This suggested that the methods used to prevent study participants linking the two trial teams were effective.

### 3.4. Process Evaluation

During intervention delivery and at the end of the trial, the fieldworkers and intervention providers collected data, as part of a process evaluation.

#### 3.4.1. TNSB-based handwashing intervention process evaluation

- **TNSB-based handwashing intervention disgust triggering assessment**

In order to assess whether the videos triggered disgust feelings in participants, a vote was conducted at the end of the screening of the negative videos and before the screening of the solution videos. The vote took place between these two video showings, because the solution videos were not designed to trigger disgust as the key emotion. The vote was implemented at each intervention delivery session

(i.e. at initial intervention delivery, and at one month, two months and three months post initial intervention delivery).

As part of their training, the intervention providers were taught how to conduct the vote. Eligible participants were permanent adult residents present at the screening, and who were willing to participate in voting. The intervention providers explained to participants that they would hold a vote to understand how the videos made participants feel. We used emojis to depict each answer option. Participants were instructed that a set of images would be distributed to them, and would act as ballots, such as during elections. They were told that, as in elections, voting would be anonymous. They should not therefore attempt to look at what their neighbours were voting.

Each emoji was explained to participants. Initially, there were two response options. One was an emoji depicting a neutral emotion (i.e. neither happy nor sad) (Image 9.1). Participants were told that they should use this ballot, if the videos had not triggered any feeling in them. A second emoji depicted an alarmed emotion (Image 9.2). Participants were told that they should use this ballot, if the videos had *'made them feel bad in their bodies'*, the common local expression used to express disgust. The intervention providers then went around the audience with an envelope, and participants were instructed to place only one image in the envelope.

However, after conducting voting in the first seven intervention compounds and debriefing with the intervention providers, it was decided that only having two emotions to choose from, with none being positive, would risk bias. Indeed, it seemed unlikely that the intervention had not triggered any emotion in participants. Participants could thus tend to vote for the image expressing disgust, even if this was not what they had felt. Therefore, a third voting option with a picture depicting a laughing emoji was added. Participants were told that they should use this ballot, if the videos had made them laugh (Image 9.3). Given the videos scripts had been written to include some comical elements, we thought that this third answer option was appropriate. These three answer options were used in the remainder of the trial.

After voting, the intervention providers counted the votes and the result was revealed to participants, before moving to the next section of the intervention. In order to verify that voting for the disgust emoji really meant participants had been disgusted by the videos, intervention providers asked willing participants to explain what they meant when they voted that the videos had *'made them feel bad in*

*their bodies.'* The expressions they used to explain what they meant were then recorded on the questionnaire. The questionnaire was implemented at each intervention video screening.

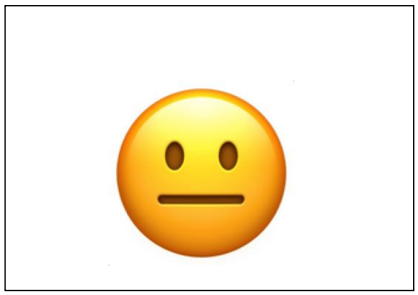


**Image 9.1.** Neutral emoji answer option

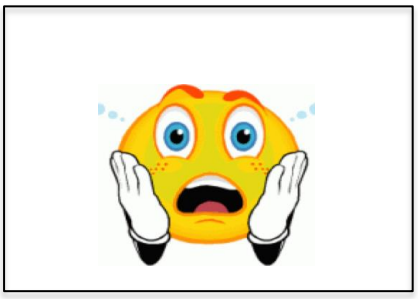


**Image 9.2.** Disgust emoji answer option

**Image 9.3.** Laughing emoji answer option

- **TNSB-based handwashing intervention process evaluation form**

A process evaluation questionnaire was also administered at household level to eligible residents, in compounds having received the TNSB-based handwashing intervention (Appendix 9.5). This was only done once at the end of the trial. The aim of the questionnaire was to evaluate the intervention coverage; assess how many and which intervention components respondents had been exposed to; whether respondents remembered the primary and secondary intervention messages; and their opinion of the intervention. The process evaluation also included questions to assess whether respondents had indeed been exposed to the intervention components they mentioned. For instance, if a respondent stated that they had seen the intervention posters, they were asked for the location of the posters.

We trained the intervention providers extensively on how to administer the questionnaire and on the sampling methods. The household coding used by the fieldworkers was explained to the intervention providers, using the compound sketches. Systematic random sampling was used to select the households to be interviewed in each compound, with k=2 as the sampling interval. We used this interval so that at least one household from each trial phase (i.e. baseline, one-month and five-month follow-ups) would be sampled in each compound. We sampled 3 households in compounds with less than 9 households, and 4 households in compounds with n≥9.

**3.4.2. Handwashing station questionnaires**

Three data collection forms were used to collect information relating to the HWS (Appendix 9.6). As part of their training, the intervention providers were taught how to fill in the form. All HWS data collection tools were implemented at the compound level to a group of eligible residents who were present at the time of the visit, and agreed to take part in the interviews. One form (HWS delivery form) was to be completed when the HWS was first delivered to a compound. It captured information such as where the HWS had been placed in the compound (e.g. at the toilet entrance, at the centre of the compound), and how residents had decided to organise themselves to ensure that there was always water and soap at the HWS (e.g. specific person designated or turns taken by household).

A second form (HWS follow-up form) collected information such as whether there were any issues with the HWS (e.g. damaged tap, broken stand), whether it had been moved from its initial location, and whether there were any maintenance issues. This questionnaire was administered within two weeks of supplying the HWS, so that any damaged HWS could be replaced as early as possible. In the TNSB-based handwashing intervention group, there were additional questions regarding the intervention posters (e.g. whether they were still present, and if not, why). In these compounds, the questionnaire was also administered every time the intervention was implemented (at one month, two months, and three months post the initial intervention implementation).

The third form (HWS process evaluation form) was administered at the end of the trial. The form collected the same information as the HWS follow-up form, but with additional questions regarding residents' views on the HWS, and how they would improve it. The form was implemented seven months post initial intervention delivery. Based on the answers given on the questions assessing the HWS maintenance, we added an additional question to the questionnaire. The question assessed whether respondents thought that there would be less maintenance issues, if each household had its

own HWS. By the time, the form was amended, all compounds in the HWS-only intervention group had already been visited. Thus, only compounds in the TNSB-based handwashing intervention group answered this question.

For the second and third forms, the intervention providers were instructed to first go to the HWS to assess whether there were water and soap at the facility, before approaching residents. This was done to minimise the risk that residents rush to replenish the HWS at the sight of the intervention providers, and while they were administering the forms.

### 3.4.3. Informed consent for the process evaluation

The intervention providers sought verbal informed consent from eligible residents to conduct the interviews. At the visit following the first intervention delivery session, in both intervention groups, intervention providers told compound residents that they had come back to greet residents, and inquire whether there were any issues with the handwashing HWS.

- **HWS-only study group**

In the HWS-only intervention group, at seven months post-intervention delivery, the intervention providers told residents that they had come back to greet residents, and gather their opinions of the HWS, in addition to assessing if there had been any issues with the HWS.

- **TNSB-based handwashing study group**

For the end-of-trial process evaluation, the intervention providers informed residents that they would conduct individual interviews, after the HWS group discussion mentioned before, to gather information on what residents remembered of the intervention and their opinion of the intervention. After administering the HWS process evaluation questionnaire, the intervention providers identified the households to be sampled, and sought verbal informed consent from an eligible resident to interview in each of these households. As with the fieldworkers, intervention providers were instructed to conduct the interviews in respondents' households or away from other residents.

## 4. Outcomes

### 4.1. Co-primary outcomes

The primary outcome measure was the observed proportion of occasions after using the toilet, on which hands were washed with soap. A second analysis restricted to toilet visits with a container for cleansing was also conducted. The primary outcomes were measured at baseline and at the one-month and five-month post-intervention delivery.

### 4.2. Secondary outcomes

#### 4.2.2. Binary behavioural outcomes

The secondary binary behavioural outcomes measures were:

- The observed proportion of occasions on which hands were washed with soap after cleaning a child's bottom;
- The observed proportion of occasions, on which any form of handwashing took place after using the toilet;
- The observed proportion of occasions on which any form of handwashing took place after cleaning a child's bottom.

These were measured at baseline, at the one-month and at the five-month post-intervention delivery.

#### 4.2.3. Ordered categorical behavioural outcomes

The secondary ordered categorical behavioural outcome measures were:

- The proportion of occasions on which hands were washed with soap, with water or antibacterial gel only, or not cleaned at all after using the toilet.

- The proportion of occasions on which hands were washed with soap, with water or antibacterial gel only, or not cleaned at all, after cleaning a child's bottom.

These were measured at baseline, and at the one-month and at the five-month post-intervention delivery.

#### 4.2.4. Handwashing norms-related constructs

The norms-related constructs were the perceived descriptive and injunctive norms around HWWS after using the toilet, and perceived HWWS publicness after using the toilet. For each respondent, the mean of the items related to each construct was calculated, and the scales mean scores were then computed. These were measured at baseline, at the one-month and at the five-month post-intervention delivery.

## 5. Sample size

The sample size for this study was calculated based on the observed proportion of occasions on which hands were washed with soap after visiting the toilet, and using parameter estimates from previous HWWS studies in comparable settings, including the 2012 pilot study [57, 88]. The formula below [91], was used to compute the sample size:

$$c = 1 + (z_{\alpha/2} + z_{\beta})^2 \frac{\pi_0(1-\pi_0)/m + \pi_1(1-\pi_1)/m + k^2(\pi_0{}^2 + \pi_1{}^2)}{(\pi_0 - \pi_1)^2}$$

Where:

- $\beta$ is the power
- $z$ is the standard normal distribution value for upper tail probabilities
- $\pi_0$ is the true proportion of the primary outcome in the absence of the intervention
- $\pi_1$ is the true proportion of the primary outcome in the presence of the intervention
- $m$ is the harmonic mean (HM) for the number of events observed in each cluster
- $k$ is the between cluster coefficient of variation

From the 2012 pilot study, the HM of events observed over a period of 4 hours was 16 for the primary outcome. The total period of observation in the actual trial was longer (6 hours). Thus, the estimated HM of 16 is likely to be conservative. We assumed that the frequency of HWWS after using the toilet would be 5% in the control group, and that it would increase to 25% in the full intervention group. With a between-cluster coefficient of variation (k) estimated at 0.25 [91], a sample size of N≥66 compounds (n≥22 compounds per arm), with 80% power, and N≥87 (n≥29 compounds per arm), 90% power, was required to detect a 20% absolute increase in HWWS after using the toilet, with $\alpha$=0.05. Assuming a 10% loss to follow-up/refusal, N≥73 (n=24 compounds per study group) would be required. We used the formula [213] below to compute this estimate:

$$N' = \frac{N}{(1-q)}$$

Where:

- *N'* is the required sample size accounting for loss to follow-up
- *N* the required sample size
- *q* is the expected proportion of refusal or loss to follow-up

The maximum sample size which was feasible, due to resource constraints, was N=75 (n=25 compounds per study group). The study was not powered to detect a difference in the absolute increase in HWWS after cleaning a child's bottom, given the small number of observed events during the 2012 pilot study (HM=2) (Chapter 5).

## 6. Statistical methods

Quantitative data were analysed using the statistical package STATA® 15. For the primary and secondary behavioural and norms-related outcomes, the analyses were conducted for each follow-up point (i.e. at the one-month follow-up point, for short-term interventions effects, and at the five-month follow-up point, for longer-term intervention effects). Complete case analyses were performed. As four compounds did not receive the intervention to which they were assigned (three control compounds erroneously became HWS-only intervention compounds, and one HWS-only

compound became a control compound), both intention-to-treat and on-treatment analyses were performed.

All statistical analyses took into account the cluster randomisation [91]. For descriptive statistics, robust standard errors were used to account for clustering, using STATA®'s *svy* command. When assessing the intervention effects, for binary outcomes, random effects logistic regression models were used to compare the key outcomes between the intervention groups and within each intervention group. Random effects models were used as the preferred method to account for clustering, as the between-cluster variation is explicitly taken into account in these models, and included in the likelihood, compared to other approaches (e.g. generalised estimating equations or robust standard errors). Compounds were included as random intercepts. The following model was used: *Logodds(outcome) = overall intercepts + dummy variable for treatment arm + covariates*. As the outcomes were binary, the reliability of the estimates was checked by using the *quadchk* command in STATA®.

For non-normally distributed continuous (norms-related) outcomes, Kruskal-Wallis one-way ANOVA ranks test was used to compare continuous outcomes between the intervention groups. For ordered categorical outcomes, random effects ordered logistic regression models were fitted to look at the association between the key outcomes and the intervention groups. We tested the proportional odds assumption using the *omodel* command in STATA®.

**6.1. Strategy to adjust for covariates**

Both unadjusted and adjusted analyses were performed. The adjusted analysis was chosen as the primary analysis for assessing the intervention effect. Both the primary behavioural outcomes and secondary norms related outcomes were adjusted for the same covariates.

These were selected based on *a priori* knowledge from past studies (e.g. [42, 64, 88, 214, 215]). individual-level covariates were gender and age group. These were data collected from handwashing events observed during structured observations. Compound-level covariates were the median level of education of the female head of household, average level of household rent, and median level of household crowdedness (i.e. number of inhabitants per room in a given household). These were collected from the norms-related handwashing questionnaire, administered at household level. Baseline levels of the behavioural outcomes were also adjusted for.

Studies have shown associations between handwashing and age group (e.g. [64, 88]), handwashing and education level (e.g.[64, 214, 215]), and handwashing and household wealth (e.g. [42, 214, 215]). Women were the compound residents for whom there would be the most observations, and the residents who would be exposed to the intervention the most. Therefore, only their education level was considered for covariate adjustment. Household rent and crowdedness were used as proxy indicators of household wealth/socioeconomic status [216-218]. These have been used in previous handwashing and hygiene studies to explain hygiene behaviours (e.g. [42, 214, 215]).

**6.2. Baseline analysis**

Data collected at baseline (i.e. 2 years pre intervention delivery) were analysed to assess compounds' background characteristics, and examine baseline comparability of the trial arms with respect to the key outcomes and covariates [91].

For the norms-related constructs, descriptive statistics were computed for each item within each construct to assess the distribution of the data and identify items with highly skewed or unbalanced responses [192]. Given this was the second time the norms-related scales were used, the psychometric properties of each scale were tested again, using data from the entire trial. We did so to ensure that the scales' psychometric properties were not previously obtained by chance [191]. Confirmatory Factor Analysis (CFA) was used to assess the measurement properties of the HWIN scale [200]. Generalised structural equation modelling (GSEM) was used to fit an ordered probit model to the data for this scale [201]. The variances of the latent variables were constrained to equal 1 to obtain the loadings of each scale item. The internal consistency of each scale was assessed by either computing the Cronbach's alpha (α) and/or Spearman-Brown coefficient (ρ), depending on the number of items in the scale [202]. Confidence intervals for α and ρ were computed. The Spearman-Brown inter-item correlation coefficient was also computed to assess the strength of the relationship between pairs of items in each scale. The mean score for each norms-related construct and scale item was computed at household level, by study arm.

Random effects logistic regression models were used to look at the association between HWWS after using the toilet and each norm-related construct. For each construct, the adjusted analysis comprised the household-level and compound-level covariates stated above, as well as the level of the other two

norms-related constructs. The following model was used: *Logodds(outcome) = overall intercepts + dummy variable for treatment arm + covariates*.

### 6.3. One-month and five-month follow-up time-points

At each follow-up point (one month and five months), the following analyses were performed.

#### 6.3.1. Primary and secondary behavioural outcomes

Random effects logistic regression models were used to estimate the interventions' effects on the primary and secondary handwashing outcomes at each trial phase. Both unadjusted and adjusted ORs were estimated. p-values were obtained using likelihood-ratio tests. For ease of comparability of results with the studies included in the systematic review reported in Chapter 3, risk ratios (RRs) were also computed using the xtgee command in STATA®, and adjusting for clustering and covariates.

Random effects ordered logistic regression models were fitted to examine the association between the three-level categorical handwashing outcome after using the toilet, (i.e. with soap (ranked 3), with water or antibacterial gel (ranked 2), and no handwashing (ranked 1), and the interventions. Both unadjusted and adjusted ORs were estimated. p-values were obtained using likelihood- ratio test. The same analysis was performed for the handwashing occasion 'after cleaning a child's bottom.'

#### 6.3.2. Secondary norms-related outcomes

Descriptive statistics were computed for each variable to assess the distribution of the data and identify items with highly skewed or unbalanced responses [192]. The frequency distribution of each norm-related scale item was examined, and the mean and median scores of each norm-related construct computed. Random effects logistic regression models were used to look at the association between HWWS after using the toilet and each norm-related construct. Both unadjusted and adjusted ORs were estimated. p-values were obtained using likelihood-ratio tests. The same approach was used to assess the changes over time in each norm-related construct, and to look at the association between the way respondents rated the scales items and the intervention arms.

### 6.4. Process evaluation

#### 6.4.1. Disgust-triggering intervention effect

The TNSB-based intervention's ability to trigger disgust as the dominant emotion was measured at the initial intervention delivery time-point, and one month, two months and three months post initial intervention delivery. The proportion of participants who picked disgust as the main emotion that the intervention videos triggered was computed, using robust standard errors to account for clustering, and calculate 95% CIs.

#### 1.4.2. Process evaluation questionnaire

Descriptive statistics were used to analyse the data from the TNSB-based intervention process evaluation questionnaire. To assess the intervention coverage, we calculated the proportion of respondents who said that they were present during intervention delivery. We also calculated the proportion of respondents who remembered the primary and secondary intervention messages. Robust standard errors were used to account for clustering, and to compute 95% CIs around each proportion.

### 6.5. Handwashing station sustainability

The proportion of handwashing stations which had water and soap was computed for the TNSB-based handwashing intervention group and the HWS-only intervention group, at the one-month, five-month and seven-month post-intervention delivery. 95% CIs were computed. Pearson's Chi-Squared test was used to compare the proportions between the two treatment groups at each time point.

## 7. Qualitative data analysis

The qualitative data collected in the trial pertained to open questions around the HWS (i.e. HWS maintenance issues, participants' opinions of the HWS and suggestions for improvement), and participants' opinions and suggestions regarding the interventions. Data were transcribed using Microsoft Word, at the end of each data collection day. Data were analysed, using content analysis, and while data collection was on-going. Preliminary codes emerged from reading the first few transcripts. These were then used as coding schemes to code the remaining transcripts [178, 179].

From the codes, categories that were mutually exclusive were created. These were used to organise the coded data, with similar concepts grouped together and counted [178-181]. For instance, regarding qualitative data around participants suggestions to improve the HWS, one of the coding categories which emerged was 'HWS design improvement'. Under this code, 'HWS stands improvement' and 'water evacuation system improvement' were some of the subcategories which emerged. When needed, new codes and categories were created, when the data did not fit into the existing ones [178]. Data within each coding category were then examined, to assess whether the data could be further classified [178, 179].

## 8. Quality assurance and control

The PhD candidate and fieldwork assistants were in charge of quality assurance and control. The trial and all data were also available for auditing by LSHTM Quality Assurance Manager.

### 8.1. Trial data collected by the fieldworkers

60% of fieldworker data collection visits were monitored. This was done to ensure that fieldworkers were in their compound at the expected times, and collecting data as intended. For structured observations, we visited compounds unannounced and observed how fieldworkers were collecting data, and whether they were missing any relevant events that were taking place whilst we were there. For the interviews, we monitored part of each fieldworker's interview.

Each data collection session was immediately followed by a debriefing session with all the fieldworkers present. The PhD candidate and fieldwork assistants double checked the data collected by each fieldworker. For the questionnaire, when there was missing data and depending on the type of data missing, fieldworkers were asked to revisit respondents as soon as possible (i.e. on the same day, if it was not too late; or the next day) to collect the missing information, unless the respondent had refused to answer the question. If the data were missing on scale items, fieldworkers could not go back to collect the information again, as this would have brought the respondent's attention on handwashing. There were no missing data for the structured observations. Debriefing sessions were also an opportunity for fieldworkers to discuss any issues they had encountered during data collection, and noted in their notebooks.

### 8.2. Trial data collected by the intervention providers

As mentioned in Chapter 8, we could not monitor the interventions' delivery for masking reasons. A recorder was given to each intervention provider, and they were instructed to record each of their intervention delivery sessions. The PhD candidate, then listened to the recorded sessions, and discussed with intervention providers if there were any issues with the way they were implementing the interventions (e.g. issues with the type of answers they provided to residents, how convincing they sounded).

At the end of each intervention delivery day, a debriefing session took place, during which the PhD candidate and fieldwork assistants doubled checked the data collected by the intervention providers. If there were mistakes, we either explained to them or had them explain to us why these were mistakes, and how to correct the mistakes. Corrections were made directly on the data collection tools, and initialled. When, rarely, there were missing data in the data collection tools, intervention providers were able to remember the missing information, using the collected data. Debriefing sessions were also an opportunity for the intervention providers to discuss any issues they had encountered during intervention delivery. When necessary (see Section 3.4.1), the PhD candidate amended the intervention delivery protocol, based on feedback from the intervention providers.

## 9. Data management

### 9.1. Confidentiality

All hard copies of the data collected were kept in a locked cabinet, at the PhD candidate's residence in Abidjan. The PhD candidate was the only person who had access to the cabinet. All forms were anonymous, as respondents' names were not recorded.

### 9.2. Data entry

Data were double entered by two data entry clerks in Abidjan, as the trial was on-going, using EpiInfo 7. Two computers were purchased for the purpose of the trial, and were password-protected. Data was backed up on the PhD candidate's external drive and the LSHTM network drive, both password

protected. The PhD candidate performed data entry checks of all the data entered, every two weeks, throughout the trial.

## 10. Financing and Insurance

This trial was self-funded and insured by LSHTM.

## 11. Publication Policy

Papers reporting the trial findings will be written for publication by the PhD candidate and in collaboration with her supervisory committe