Supertowel

Improving the Supertowel: An Alternative Hand Cleaning Product for Emergencies

Version 15/11/2019

<Amendments and previously approved versions>

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Protocol authorised by:

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TrialManagement Group

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Trial Coordination Centre

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Clinical Queries
Clinical queries should be directed to Belen Torondel who will direct the query to the appropriate person (Dr.Rummana Khan).

Sponsor

London School of Hygiene & Tropical Medicine is the main research sponsor for this study. For further information regarding the sponsorship conditions, please contact the Research Governance and Integrity Office:

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Funder
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SCOPE:

This protocol describes the Supertowel study and provides information about procedures for entering participants. The protocol should not be used as a guide for the treatment of other participants; every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study, but centres entering participants for the first time are advised to contact the trials centre to confirm they have the most recent version.

Problems relating to this trial should be referred, in the first instance, to the study coordination centre.

This trial will adhere to the principles outlined in the International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines, protocol and all applicable local regulations.

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GLOSSARY OF ABBREVIATIONS

WASH	Water, Sanitation and Hygiene
EN 1499	European Committee for Standardization
WHO	World Health Organization
E.Coli	*Escherichia Coli*
cfu/ml	Colony formed unit/mililiter

KEYWORDS
Supertowel, handwashing, hand-cleaning, in vivo test

STUDY SUMMARY

TITLE Improving the Supertowel: An alternative hand cleaning product for emergencies

DESIGN Protocol of the European Committee for Standardization (EN 1499) (Cross-over Design)

AIMS Test the efficacy of the Supertowel as a hand-cleaning product using simulations of 'real-world' hand cleaning conditions and using an in vivo design with healthy male volunteers.

OUTCOME MEASURES Log_{10} reduction of bacteria (Non pathogenic Escherichia Coli (ACTC 11229) in pre-contaminated volunteer hands after using reference and test product.

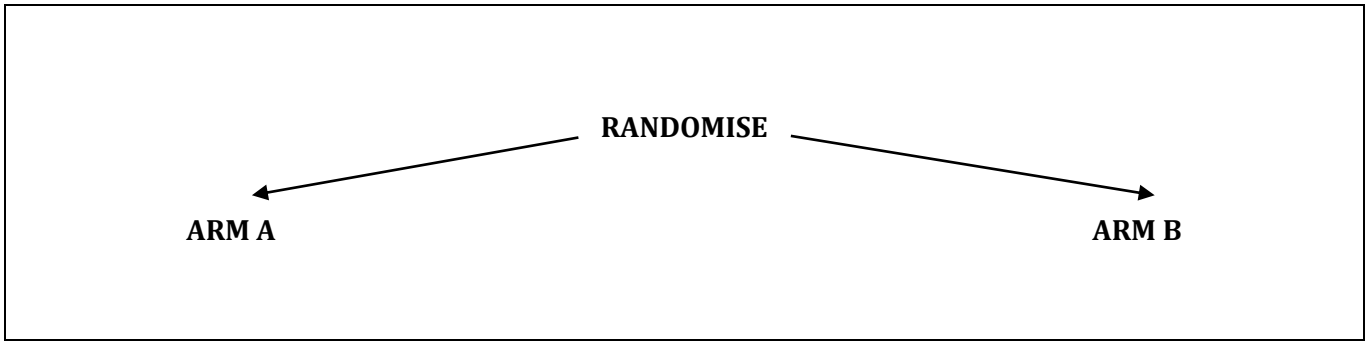
POPULATION Healthy adult volunteers from India

ELIGIBILITY Healthy adult volunteers from India

TREATMENT Supertowel or soap

DURATION 8 weeks for the total study (each volunteer will test the different products only once, each participant will be required to be present at the laboratory for 2 days only)

REFERENCE DIAGRAM



1. INTRODUCTION

1.1 WHY HANDWASHING

Diarrhoeal diseases are a common cause of morbidity and the leading cause of death among children under five, accounting for 19% of mortality in this age group [1]. Most of all diarrhoeal deaths of children under five years are in Africa and South East Asia [2]. The vast majority of diarrhoeal diseases are caused by bacteria, viruses and protozoa, mainly found in human faeces which are spread from the stool of one person to the mouth of another. Hands can act as a vector for transmission of faecal pathogens, either via direct person-to-person transmission or by contaminating food that is later consumed [3]. Hand washing with soap after defecation and before handling food is the most effective mechanism for interrupting diarrhoeal disease transmission, with the potential to reduce it by 23% to 48% [4-6]. Hands are also transmission vectors for respiratory infections, and handwashing with soap can also reduce respiratory illnesses by an average 21%, [7].

Handwashing rates are sub-optimal globally [8], but this is of particular concern in humanitarian emergencies when faecal-oral disease risk increases [9-10], and is often a leading cause of morbidity and mortality. Access to hand washing facilities, water and soap in humanitarian emergencies is limited. Those affected by emergencies typically rely on non-government organisations (NGOs) to distribute soap and water. However this approach alone has not been found to increase handwashing rates. Partly this is because when water and soap are scarce they are prioritised for tasks other than handwashing. Secondly it is often difficult for NGOs to meet the demand of beneficiaries – particularly in protracted crises. The Sphere Standards [11] recommend that in an emergency one person should have one 250g bathing soap per month and at least 6 litres of water per day. But in 2016, there were 65.6 million people displaced [12] from their homes due to conflict, persecution and crises and therefore meeting the needs of all these people is a mammoth logistical task. In many camp settings toilets and associated handwashing facilities (if present) are shared. Invariably the soap that NGOs provide is rarely placed at the handwashing facility as people worry about it being stolen and used by others. As such individuals are required to walk to the toilet carrying their own bar of soap. When they use the shared (and often unclean) toilet there is nowhere to store the soap hygienically. Then after washing their hands with the soap the individual has to walk back to their shelter with the slimy bar of soap, meaning that their hands are still covered with soap at the end of the process. Of course in practice this is far too inconvenient and so hands are normally just rinsed with water, if at all.

1.2 THE SUPERTOWEL

The Supertowel has been designed as a soap alternative for these types of emergency situations. The Supertowel is a durable fabric with a permanent anti-microbial bonding. The treated fabric must be dipped in water and then rubbed against the hands so that pathogens will be transferred to the fabric where they will be killed. Several laboratory test have demonstrated the bactericidal effect of the fabric against different bacteria (Appendix 1). The anti-microbial technology is achieved by long chains of carbon atoms attached to positively charged nitrogen atoms bonded to a silica layer of the fabric. The positively charged layer attracts negatively charged microbes including bacteria and fungi causing membrane disruption of the microbes. The Supertowel will kill microbes efficiently and within seconds once the microbe is on the towel. As the bonding is permanent the fabric does not call for replacement until it is damaged or lost. The Supertowel provides an alternative to large-scale soap distribution. It could be beneficial to emergency responders as it will be easier (smaller and lighter) to distribute and last longer than soap, negating the need for frequent distributions. The Supertowel will reduce water wastage associated with hand washing and reduce drainage problems that are often seen around hand washing facilities. The Supertowel will also be beneficial to those effected by emergencies as it can easily be carried by users all the time, making hand cleaning more convenient.

1.3. RESEARCH TO DATE

Over the last two years our consortium has been able to prove, under controlled laboratory conditions, that hand cleaning with the Supertowel is more efficacious than handwashing soap and water [13]. Our subsequent field study in a refugee camp in Northern Ethiopia indicated that the Supertowel is an acceptable and desirable product among crisis-affected populations and is likely to result in more frequent handwashing in these difficult circumstances [14].

The aim of this study is to develop greater evidence on whether the Supertowel remains is as efficacious when used under conditions which mimic "real-world hand cleaning conditions". This will be tested through a set of controlled laboratory experiments with healthy volunteers in India.

1.4 RATIONALE FOR CURRENT STUDY

To test the efficacy of the Supertowel as a hand-cleaning product under different "real-world" conditions.

2. STUDY OBJECTIVES

Test the efficacy of the Supertowel as a hand-cleaning product using simulations of 'real-world' hand cleaning conditions. This will be achieved by using an in vivo design with healthy volunteers in India and a protocol adapted from the European Committee for Standardization protocol (EN 1499) [15].

Tests will be designed to explore the following objectives:

- Is the Supertowel as efficacious as soap if used for hand-cleaning for a short period of time (ie. 15 seconds)?
- Is the Supertowel as efficacious as soap if used for hand-cleaning when moist rather than soaking wet?
- Is the Supertowel efficacious for hand-cleaning if soiled and oily?
- Is a Supertowel soaked in contaminated water and then used for hand cleaning more efficacious than handwashing with soap and contaminated water?

3. STUDY DESIGN

To test the efficacy of the Supertowel under the different conditions, we will use a crossover controlled study based and adapted on the protocol of the European Committee for Standardization (EN 1499) which is designed to evaluate the ability of hand-wash agents to eliminate transient pathogens from volunteers' hands without regard to resident microorganisms. This procedure is based on the "post-contamination treatment" of hands and involves the placement of the test organism (E. coli [ATCC 11229]) on the hands of test subjects, followed by exposure of the test product.

The study will be organized in two rounds of tests. 32 healthy volunteers will be selected for the study. 16 volunteers will be invited for the first round and 16 more for the second round. Each volunteer will receive treatment with all the different procedures the same day of visit to the laboratory.

This is a single centre study conducted in KET's Scientific Research Centre, Mumbai (India). The recruitment and performance of tests will be done at KET's Scientific Research Centre, Mumbai (India) Laboratory of India.

3.1 STUDY OUTCOME MEASURES

Reduction of bacteria in pre-contaminated hands of volunteers after using the different test conditions.

3.2 RISKS AND BENEFITS

There are no foreseeable discomforts, distresses, or hazards to which research participants will be exposed. The fabric has been tested previously and the data in the Material Safety Data Sheet (MSDS)(Appendix 2) confirms that material is safe and in previous tests there were no adverse reactions.

The test will be done with non-pathogenic E.coli. After the study is finished, the participants will be asked to wash their hands with medicated soap.

The volunteers will be compensated with a small amount of money (to cover transport cost to the laboratory and subsistence expenses) to participate in the study. There is no other compensation for taking part in this study, but they will be informed that they are contributing to research that could help many others in the future.

4. SELECTION AND WITHDRAWAL OF PARTICIPANTS

4.1 PRE-RANDOMISATION OR PRE-REGISTRATION EVALUATIONS

No diagnostic test needs to be carried out to select the male participants.

4.2 INCLUSION CRITERIA

Volunteers will be recruited by using poster advertisements (Appendix 3) which will be placed within the institution which the laboratory is a part of.
To be eligible volunteers must:

- Be male and older than 18 years old.
- Be physically examined to ensure they are healthy and with healthy skin (without skin disorders like eczema, paronychia, scabies, abrasions, lacerations or skin allergy).
- Have short fingernails with no artificial nails.
- Have no history of drug allergy.
- Nothave taken any systemic antibiotic in the two weeks prior to the study, which could otherwise impair the efficacy of the product being tested.
- Remove all forms of jewellery from their hands prior to hand washing, since it has the potential of retain some bacteria, which could affect the recovery pre and post values of the test.

4.3 EXCLUSION CRITERIA

Unhealthy volunteers and volunteers with unhealthy skin, history of drug allergy, taken systemic antibiotics in the previous two weeks of the study will be excluded from the study.

4.4 WITHDRAWAL CRITERIA

Volunteers will be read an information sheet (Appendix 4) where the full study will be explained and where all the procedures for withdrawing from the study will be described. After agreeing to participate in the study, participants will be asked to sign a consent form (Appendix 5).

Participants can withdraw at any time without giving a reason and without having any repercussion. If this is the case, a new volunteer will be recruited and all the data from the withdrawn volunteer will be destroyed.

In the case that a volunteer feels sick or suffers any injury or has a reaction to the product, the participant will be asked to withdraw from the study and appropriate support will be given in the laboratory by Dr.Rummana Khan. First aid and management of minor health issues will be provided at the laboratory but any more serious health issues will be referred toa nearby health centre. A new volunteer will be recruited and data from withdrawn participant will be destroyed.

5. RANDOMISATION AND ENROLMENT PROCEDURE

5.1 RANDOMISATION OR REGISTRATION PRACTICALITIES

All the participants from each round will receive all the treatments/procedures in a randomised sequence order (using a cross-over design) that will be pre-organized by the researchers.

5.2 UNBLINDING (IF APPLICABLE)

All the participants will know which type of treatment they will be receiving throughout the testing process.

6. TRIAL TREATMENT

6.1 Name and description of investigational treatment product(s)

Supertowel:

The Supertowel is a durable fabric with a permanent anti-microbial treatment. The treated fabric must be dipped in water and then rubbed against the hands so that pathogens will be transferred to the fabric where they will be killed.

Soap:

Non-antimicrobial bar soap will be used as a reference product for three of the experiments.

6.2 Treatment of participants.

6.2.1.Contamination procedure:

The hands of each volunteer will be washed with a non-medicated soap, dried and fingers (up to the proximal interphalangeal joints) will be immersed for 5 seconds in a contamination fluid which contained non-pathogenic *Escherichia coli (ACTC 11229)* $8.3x10^8$cfu/ml. Excess of fluid will be drained off and hands will be air-dried for 3 min.

Pre value. Bacteria will be recovered for the initial pre value by kneading the fingertips of each hand separately for 60 seconds in 10 ml of tryptone soya broth (TSB) without neutralizers. The pre values will be estimated using the Miles *et al*. technique [16].

6.2.2. Hygienic hand-washing procedures/treatments:

Each volunteer will receive the following procedures/treatment in a pre-stablished random order over the course of one day.

Procedure 1.

- Treatment: Hand cleaning with the Supertowel for 15 seconds.

  The Supertowel will be soaked in water by submersing it completely in a bucket filled with tap water. The amount of water absorbed by the ST will be recorded by means of weighing the towel before and after soaking. The volunteers will use the soaked Supertowel for 15 seconds to clean their pre-contaminated hands.

- Control: Hand washing with bar soap and water for 15 seconds.

  The control group will wash their pre-contaminated hands with normal bar soap and water for 15 seconds. Hands from volunteers washed with soap will be allowed to dry for 3 minutes.

  Prior to doing either of the conditions above, a laboratory technician will demonstrate to the volunteer how to use either the Supertowel or the bar soap for the required time. 15 sec, e.g. wetting hands for 5 seconds, lathering soap for 5 seconds and rinsing hands for 5 seconds).

Procedure 2.

- Treatment: Hand cleaning with a Supertowel that is damp for 60 seconds

  The Supertowel will be soaked in water by submersing it completely in a bucket filled with tap water. The water on the Supertowel will then be squeezed out so that it is not dripping. The Supertowel will be weighed before soaking and after squeezing. Volunteers will clean their pre-contaminated hands with the damp Supertowel for 60 seconds.

- Control: Handwashing with bar soap and water for 60 seconds

  The control group will wash their pre-contaminated hands with normal bar soap and water for 60 seconds by following the "WHO guidelines for handwashing when hands are visibly soiled" (a diagram of the steps was given to them, appendix). After handwashing, hands will be allowed to dry for 3 minutes.

Procedure 3.

- Treatment: Hand cleaning for 60 seconds with a Supertowel that has been soaked in contaminated water.

  A Supertowel will be soaked in water which has artificially contaminated with non-pathogenic E.coli. The water will be designed to mimic highly contaminated grey water so it will be contaminated at 2,000 cfu/100 ml which is double the acceptable level of contamination for handwashing. Volunteers will clean their pre-contaminated hands with the contaminated Supertowel for 60 seconds.

  Control: Handwashing with bar soap and water for 60 seconds.

  Water which is contaminated with non-pathogenic E.coli. at 2,000 cfu/100ml will be stored in a bucket which has a tap at the base. The control group volunteers will wash their hands with the contaminated water and bar soap for 60 seconds. They will follow the "WHO guidelines for handwashing when hands are visibly soiled" (a diagram of the steps will be given to them). After handwashing, hands will be allowed to dry for 3 minutes.

Procedure 4.

- Treatment: Hand cleaning for 60 seconds with a Supertowel that is visibly dirty and oily.

  The Supertowel will be made visibly dirty and oily for example, by immersing it in a mix of 5 grams of sterile soil (previously autoclaved), 5 ml of clean cooking oil and 100 ml of water (we will play in advance, to find out the most appropriate amounts of these products).The Supertowel will be rubbed against itself to ensure the soil and oil are spread out across the surface of the Supertowel. Volunteers will clean their pre-contaminated hands with the dirty Supertowel for 60 seconds.

- Control: Hand cleaning for 60 seconds with a clean Supertowel.

  The Supertowel will be soaked in water by submersing it completely in a bucket filled with tap water. The amount of water absorbed by the ST will be recordedby means of weighing the Supertowel before and after soaking. The control group will clean their pre-contaminated hands of with thesoaked Supertowel for 60 seconds.

Procedure 5.

Testing the Supertowel under a mix of aforementioned conditions. The exact design of this study will be determined after results of procedures 1-4 are obtained. For example, a possible test might be to assess whether a damp Supertowel is still efficacious when used for 15 seconds (combining procedure 1 and 2).

6.2.3.Post values. After drying of the hands, the thumbs and fingers of both left and right hands will be rubbed in separate petri dishes containing 10 ml of TSB for 60 seconds. Post values will be determined using the method of Miles *et al*. [16]. After the procedure, the volunteers will be given medicated soap to wash their hands before going home.

6.3 Dosage schedules/modifications

We will use two rounds of experiments, in round 1 we will test all the procedures 1 to 4 of previous section and in round 2 we will test experiments from procedure 5. For each round we will recruit 16 volunteers and in both rounds we will use a cross-over design.

- For round 1 each volunteer will receive 8 procedures; we will use a Latin square design where 16 different sequences of the seven procedures will be created beforehand. The sequences will be allotted to individual volunteers by means of a number draw. This process means that each volunteer will use all of the hand-washing procedures once and will do so in the order prescribed by the randomly selected sequence.
- For round 2, we will use a cross-over design in which the 16 volunteerswill be allotted randomly to two groups of the same size. One group will apply the new generated conditions (which will be designed after having results from previous round) and the other will test the control procedure that will be designed to be an appropriate reference condition for the new procedure. In a consecutive run, the two groups will reverse roles (crossover design). At the end of the whole series of runs, every subject will have used each hand-washing procedure once.

7(II). SAFETY REPORTING FOR NON-DRUG TRIALS

7.1 DEFINITIONS

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 death Is life-threatening Requires inpatient hospitalisation or prolongation of existing hospitalisation Results in persistent or significant disability/incapacity Consists of a congenital anomaly or birth defect Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

7.2 REPORTING PROCEDURES

Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

The Supertowel has been tested previously and is been considered safe (Appendix 2). There have been no prior adverse events. Therefore, based on this experience no safety issues are anticipated. We don't anticipate that the bar of soap or the sterile oil and soil (used in procedure 4) will produce any adverse effect among participants, as these products are safe and non-pathogenic. For the purpose of this study we use the following definitions for safety reporting:

Definitions used:

Adverse Event (AE): any untoward medical occurrence in a clinical study subject. This includes any incidental findings that may be discovered as a result of the study.
Serious Adverse Event(SAE): any untoward and unexpected medical occurrence or effect that:

- Results in death

- Is life-threatening – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*
- Requires hospitalisation, or prolongation of existing in patients' hospitalisation
- Results in persistent or significant disability or incapacity
- Is a congenital anomaly or birth defect

Medical judgement should be exercised in deciding whether an AE is serious. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

Recording and reporting of procedures:
All adverse events will be recorded and appropriate treatment or referral be provided. For any serious events, the appropriate SAE form should be completed and submitted to the Chief Investigator within 24 hours.

All SAEs will be reported within 24 hours to the Head, Microbiology department from KET's Research Centre/ LSHTM Ethics Committees where in the opinion of the Principal Investigator; the event was thought to be 'related', i.e. resulted from the administration of any of the research procedures.

Contact details for reporting SAEs
Fax:+91-22-,21635404 attention to Dr.Rummana Khan
Please send SAE forms to: Dr.Rummana Khan
Tel: + (Mon to Fri 09.00 – 17.00)

8. ASSESSMENT AND FOLLOW-UP

The assessment will happen in real-time, then there will be not further follow up of participants. However, participants will be given contact details of the trial manager in case they have further questions.

8.1 LOSS TO FOLLOW-UP

As the experiments will be done with each volunteer at the same day, loss to follow up is not considered in this study. If for whatever reason a volunteer does not complete all the tests, a new volunteer will be recruited and data from the volunteer not completing all tests will not be considered and will be destroyed.

8.2 TRIAL CLOSURE

The trial will close once all the planned tests are done with the 32 volunteers.

9. STATISTICS AND DATA ANALYSIS

For all the procedures, log counts from the left and right hands of each subject will be averaged separately, for both pre and post values. The arithmetic means of all individual $\log_{10}$ reduction values will be calculated. Statistical analysis will be performed with the Statistical Package STATA version 13.0. Wilcoxon matched-pair signed ranks test will be used to test for differences between each *Supertowel procedure* and their reference condition. The new procedure (*Supertowel under different conditions)* will be considered as effective as the reference product (soap) if the mean $\log_{10}$ reduction factor is not significantly smaller for the former than for the latter. Because of the confirmative nature of the test on this application, the level of significance is set at p = 0.1. The test is to be used one-sided. The

discrimination efficiency of the test procedure described has been set to detect a difference between the two mean log reduction factors of approximately 0.6 log at a power of 95%. Data and all appropriate documentation will be stored for a minimum of 5 years after the completion of the study.

10. MONITORING

10.1 RISK ASSESSMENT

We considered that the tests planned present a low risk as our product is considered safe, the tests are expected to cause no harm for participants (the pre-contamination of hands are done with non-pathogenic *E.coli*, and the type of tests do not involve invasive tests). We do not anticipate further risks in this type of study.

10.2 MONITORING AT STUDY COORDINATION CENTRE

The trial manager will be in charge of providing training about all the SOP and will work very closely with the UK co-investigator Belen Torondel to ensure the laboratory standards of the KET's Research Centre are maintained.

Data management:

Once enrolled, subjects will be allocated an individual study identification number (ID). These unique ID number will be used on all samples and data forms generated during the course of the study. Linkage of the ID back to the study subject will not be possible without a lookup table, which will only be held by key study personnel during the course of the study. Once data is collected, soft copy of the data will be password protected and data encrypted, with all identifiable information removed. This will be done to preserve privacy and confidentiality of participants. Anonymity will be preserved through use of participant's study ID. Analysis will be performed on an anonymised copy of the data. At all stages, staff/collaborators responsible for sample analysis will be blinded as to the subject's identification. Together, these processes will ensure complete confidentially of the data gathered.

Once data collection is complete, the trial manager will be responsible of the custody of the consent forms and any other data collection form. The trial manager will maintain safe custody of all research records for the recruited participants in lockable cabinets and cupboards with access limited to authorised users only. Soft copy of the data will be password protected and data encrypted, with all identifiable information removed. All documents will be brought to LSHTM. Hard copies of data will be stored for up to 10 years, in case data needs for verification purposes later, after which they will be safely destroyed. Soft copy data will be stored on an encrypted flash drive for an extended period of time. All data will be stored on an encrypted flash drive.

11. REGULATORY ISSUES

11.1 ETHICS APPROVAL

The Study Coordination Centre has applied for ethical approval from the LSHTM Research Ethics Committee, as well as from KET's Institutional Scientific and Ethics Committee.

11.2 CONSENT

Informed consent must be obtained prior to the participant undergoing the procedures.

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Participant consent will be written in the form of a signature. Participants will be asked permission for video recording in accordance with local ethical regulations. These videos will not be made public and will only be viewed by the researchers involved with this study and by ethical committees if requested.

The right of the participant to refuse to participate without giving reasons must be respected.

All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

The PI is responsible for ensuring that all vulnerable participants are protected and participate voluntarily in an environment free from coercion or undue influence.

11.3 CONFIDENTIALITY

Any participants' identifiable data collected by the Study Coordination Centre will be stored securely and their confidentiality protected in accordance with the Data Protection Act 1998.

Once enrolled, subjects will be allocated an individual study identification number (ID). These unique ID number will be used on all samples and data forms generated during the course of the study. Linkage of the ID back to the study subject will not be possible without a lookup table, which will only be held by key study personnel during the course of the study.

Once data is collected, soft copy of the data will be password protected and data encrypted, with all identifiable information removed. This will be done to preserve privacy and confidentiality of participants. Anonymity will be preserved through use of participant's study ID. Analysis will be performed on an anonymised copy of the data.
At all stages, staff/collaborators responsible for sample analysis will be blinded as to the subject's identification. Together, these processes will ensure complete confidentially of the data gathered.

11.4 INDEMNITY

London School of Hygiene & Tropical Medicine holds Public Liability ("negligent harm") and Clinical Trial ("non-negligent harm") insurance policies which apply to this trial.

11.5 SPONSOR

London School of Hygiene & Tropical Medicinewill act as the main sponsor for this study. Delegated responsibilities will be assigned locally.

11.6 FUNDING

This study is funded by the Office of U.S. Foreign Disaster Assistance (OFDA).

11.7 AUDITS AND INSPECTIONS

The study may be subject audit by the London School of Hygiene & Tropical Medicine under their remit as sponsor, the Study Coordination Centre and other regulatory bodies to ensure adherence to GCP.

12. TRIAL MANAGEMENT

A Trial Management Group (TMG) will be appointed and will be responsible for overseeing the progress of the trial. The day-to-day management of the trial will be co-ordinated through the KET's Research Centre. A Trial Management Group (TMG) will be composed by Dr.Belen Torondel, Dr.Rummana Khan,Torben Holm Larsen and Sian White.

13. PUBLICATION POLICY

We will seek to publish the findings of all the studies outlined in this protocol in an open-access, peer-reviewed journal irrespective of the outcome of the tests. We anticipate that the following members of the

trial management group will be authors: Belen Torondel, Rummana Khan, Torben Holm Larsen and Sian White. We will acknowledge in this publication the source of funding and declare conflicts of interest.

14. REFERENCES

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15. APPENDIX LIST

Appendix 1: Previous experiments done to test efficacy of the fabric to kill bacteria.
Appendix 2: Safety information: Material Safety Data Sheet (MSDS).
Appendix 3: Recruitment poster
Appendix 4: Information sheet
Appendix 5: Consent form