The **Fa**ce **Wash**ing Methods (FAWASH) trial: an open, parallel-group randomized controlled trial comparing face washing methods for the removal of *Chlamydia trachomatis*.

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List of Acronyms

Ct – *Chlamydia trachomatis*
FPC - (follicles, papillary hypertrophy and diffuse infiltration, conjunctival scarring)
TF - trachomatous inflammation—follicular
PCR – polymerase chain reaction (test)
WASH – water, sanitation and hygiene
WHO – World Health Organization

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Summary

Trachoma, a Neglected Tropical Disease (NTD), is the commonest infectious cause of blindness globally, affecting some of the world's poorest communities (1). Trachoma elimination requires implementation of the World Health Organization (WHO)-endorsed SAFE strategy: **S**urgery for trichiasis; **A**ntibiotics to treat infection; **F**acial cleanliness and **E**nvironmental improvement to reduce transmission. Improving the evidence base for the "F" component of the SAFE strategy for trachoma elimination is highlighted as a critical action to reach 2030 targets in the WHO NTD Roadmap 2021–2030 (2); the proposed research directly addresses that critical action.

We will conduct a study to assess the effectiveness of different face cleansing protocols at removing *Chlamydia trachomatis (Ct)* bacteria and oculo-nasal secretions from the faces of children with active trachoma. We will also assess how long it takes for *Ct* to build up again on children's faces after they are washed. The study will be carried out in one zone in Oromia, Ethiopia with high trachomatous inflammation—follicular (TF) prevalence. A total of 470 participants will be selected purposively following a screening process. Children aged 1−7 years with severe follicular and/or papillary inflammation will be eligible to participate in the study. Once parental consent has been obtained, we will i) take a conjunctival swab to test for *Ct* infection, ii) swab each child's face and hands for *Ct* and iii) assess facial cleanliness using both qualitative and quantitative metrics. Recruited children will be randomised into three equal groups: face washing with water only, face washing with water and soap and face washing with a SuperTowel. Following face washing, each child's face and hands will be swabbed again for *Ct.* Swabbing will be repeated at regular intervals up to 8 hours post-protocol.

There is currently a lot of international momentum to better understand the "F" component of the SAFE strategy to improve both resource allocation and intervention effectiveness. This study is the first of its kind to explore whether and how face washing can remove *Ct* from children's faces. This study will have the opportunity to directly improve trachoma elimination. The proposed study leverages collaborations formed during the Stronger-SAFE trial and builds on published pilot work conducted in Ethiopia in 2018 (3).

Introduction

Trachoma, a Neglected Tropical Disease (NTD), is the commonest infectious cause of blindness globally, affecting some of the world's poorest communities [1]. Trachoma is caused by repeated ocular infection with the bacterium *Chlamydia* trachomatis (*C*t). Active trachoma begins in childhood with recurrent episodes of follicular conjunctivitis (TF). Chronic inflammation results in immunologically mediated conjunctival scarring and in-turned eyelashes scratching the eye: trichiasis. Eventually sight is lost from irreversible corneal opacification [1].

Trachoma is currently endemic in 42 countries. The latest estimates from the Global Trachoma Mapping Project (GTMP) suggest that 180 million people live in trachoma endemic areas and 3.2 million people have trachomatous trichiasis [2]. Around 2.2 million people are visually impaired, of whom 1.2 million are blind [3]. More than 80% of the burden of active trachoma is concentrated in 14 countries, mainly in the Sahel of West Africa and savannahs of East and Central Africa, where water supplies are often scarce [2].

Trachoma control requires community-wide measures. The World Health Organization (WHO) Alliance for the Global Elimination of Trachoma by 2020 (GET2020) recommends the SAFE Strategy: **S**urgery for trichiasis, **A**ntibiotic to treat *Ct* infection, **F**acial cleanliness and **E**nvironmental improvements to suppress transmission [1]. Many endemic countries are implementing SAFE, and there has been a major effort to scale up activities, aiming to eliminate trachoma by 2020 [2].

Currently, the antibiotic component involves mass drug administration (MDA) with oral azithromycin to all community members older than six months. This is given as a single, annual dose, initially for 1-5 years, before reassessing the district-level TF prevalence in 1-9 year olds and deciding whether MDA can be discontinued [4]. The F&E components are much more variable in content and application. If F&E are implemented at all, it usually involves improving water access, sanitation and hygiene (WASH) and fly-control [1].

Unfortunately, there is now growing evidence, particularly from hyperendemic regions (>20% TF), that current approaches are not having the anticipated impact on infection and disease [5-8]. This is a significant threat to the timely elimination of trachoma. Over 44 million live in districts with >30% TF (GTMP data). In hyperendemic areas, current antibiotic schedules appear insufficient to reliably achieve long-term control after treatment completion. For example, in Ethiopia, which has the greatest trachoma burden, despite seven years of annual or biannual high-coverage MDA, the prevalence of TF remains well above threshold for continuing MDA [5]. Data on *Ct* after repeated MDA rounds in hyperendemic settings indicates that reliable long-term control is not consistently achieved, with re-emergence of infection being typical [6, 8].

Moreover, our understanding of how *Ct* is transmitted within endemic communities is largely based on supposition. We believe that endemic trachoma is sustained by ongoing person-to-person *Ct* transmission, probably through a combination of direct contact and indirect transmission on fomites and flies (*Musca sorbens*). However, detailed studies investigating potential transmission routes and their relative importance have never been conducted. Therefore, we do not currently have a clear, evidence-based understanding of transmission biology or its socio-behavioural determinants, on which to base rational decisions about public health F&E interventions to eliminate trachoma.

Facial hygiene interventions

The face washing component of the SAFE strategy aims to maintain clean faces in the community in order to reduce eye-seeking flies and person-to-person transmission of the trachoma organism.

However, programmatic recommendations with regards to face washing have been indecisive, due to the uncertainty around whether or not face washing can limit transmission [9].

The trachoma literature is replete with cross-sectional studies (including several conducted by the applicants) which report associations between active trachoma and/or *Ct* infection and clean faces (absence of ocular or nasal discharge outside of the eye/nostril area), and between active trachoma/infection and the frequency of face washing [10-15]. However, these studies demonstrate associations, rather than causal relationships. A systematic review conducted by Stocks et al., suggested that," Having a clean face was significantly associated with reduced odds of TF/TI" [16]. The problem with that interpretation is that active trachoma results in the production of mucosal discharge, therefore faces are more likely to be clean in the absence of active disease (one cannot simply infer from these cross sectional studies that cleaning faces reduces the risk of trachoma).

Since Ct is found in ocular and nasal discharge from an infected person which escapes the eye and nose to reach a person's face, there is an assumption that promoting face washing could reduce trachoma transmission. There is a plausible theory of change for how this might happen:

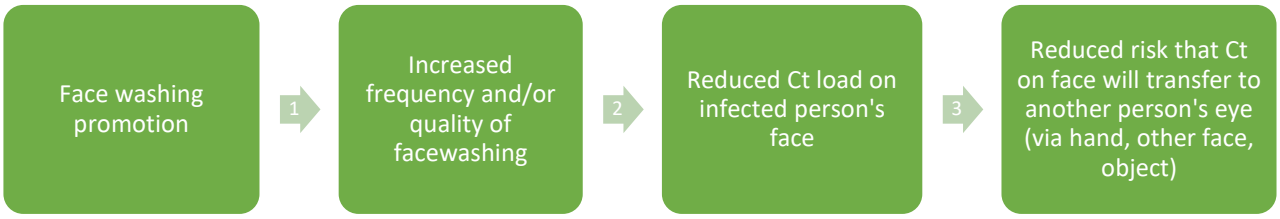


Figure 1: Theory of change for face washing promotion

However, there have been very few studies to investigate whether facial cleanliness programmes substantially reduce the prevalence of trachoma in communities. A recent Cochrane Review [17] found only two intervention trials, and concluded there is currently little or no evidence that face washing significantly impacts on trachoma. The best known of these was a community based randomized trial on the effect of face-washing on active trachoma in children was conducted in three pairs of Tanzanian villages by West et al., in 1995 [18]. This looked at the impact of a fairly intensive face washing promotion intervention on active trachoma in the intervention arm, in addition to mass treatment in both arms. There was no difference in the prevalence of TF and TI between intervention and control villages, but, being in the intervention group was associated with a lower prevalence of TI (more severe trachoma): OR 0.62 (0.40, 0.97), so the authors concluded that face washing could be protective for trachoma.

In addition to a lack of high quality studies of face washing interventions, there have also been few attempts to systematically investigate any of the assumed links in the theory of change, i.e. the arrows in Figure 1. There remain gaps in our understanding about how best to design interventions that lead to the desired behaviour change [19] (Arrow 1). It is possible that Ct on the face is not a common source of transmission, and that transmission is more likely by hands or objects that directly touch the surface of the eye (Arrow 3). This study focusses on unpacking the assumptions in Arrow 2: *That improved face washing will lead to reduction in Ct load on an infected person's face.*

There are gaps in understanding about how effective face washing is to reduce Ct load on faces. The small number of studies of face washing have only investigated the effect on ocular and nasal

discharge, rather than on Ct load. West et al. (same study as above) [18] found that children in the intervention villages had 1.61 times the odds (95% CI 0.94- 2.74= not statistically significant) to have a sustained clean face than those in the control villages, defined as a face free of ocular and nasal discharge on at least two of three post intervention surveys.

King et al. [20] argue that a 'dirty face' is not a good predictor of whether a face has been washed. They conducted a randomised trial of 424 children to receive a standardised face wash or none, and observed faces for ocular and nasal discharge, dust, food and flies at three time points through the day and at baseline. A significant difference was observed in the presence of ocular discharge ($P < 0.001$) and dry nasal discharge ($P < 0.001$) between the washed and unwashed groups, but two hours after washing, the presence of ocular discharge predicted face washing in only 63% of children, reducing to only 54% in four hours from washing.

In our own studies conducted in Phase 1 of Stronger SAFE (Ethics reference: 14325), we asked 34 children aged 1-9 with TF/TI to wash their faces with either water only or water and soap. Each child was given instructions about washing their face properly and was observed to follow these instructions. We found that washing with soap and water was more effective at removing ocular discharge than washing with water only (89% vs 27%, $p = 0.003$). In comparison, nasal discharge was not effectively removed by any method: discharge was removed from 27% of 11 children with nasal discharge at baseline by washing with soap, and 50% of 14 children by washing with water ($p=0.250$ for comparison with washing with soap). However, only two of these children enrolled (both randomly assigned to wash with water only) were positive for Ct by ocular swab, so we were unable to fully test our hypotheses that face washing would reduce Ct load on the face – the relevant agent for transmission of infection.

Facial hygiene measures and metrics

The current indicator used to assess facial cleanliness is that of having a 'clean face', most commonly defined as the absence of ocular and/or nasal discharge on the face. However, as the studies above show, this is not necessarily well associated with the exposure/behaviours of interest (face cleaning), or directly useful for programmes wanting data on whether their facial hygiene interventions are effective. Researchers at Emory University have therefore developed, piloted, and assessed the reliability of a novel, quantitative hygiene metric that can be used to assess facial cleanliness. This novel hygiene metric compares the "dirtiness" of a child's face or hands to a standardized colour scale. The "dirtiness" of the child's face (or hands) is assessed by using a pre-moistened, sterile gauze pad to trace the skin along a child's face (or hands/other body part) in a standardized manner. The colour of the darkest point within the darkest half-inch (i.e., roughly the size of a fingernail) of the gauze pad is then compared to a standardized colour scale. Using colour theory principles, this standardized 11-point brown scale depicts a continuum of colour along a specific red green blue (RGB) colour model array. The brown scale ranges from 10 (i.e., colourless control) to 0 (i.e., darkest decile along the colour scale), with each point (i.e., colour and accompanying number) along the continuum representing a 10% increase in the saturation of colour along the RGB colour model array. This tool has undergone reliability testing in Ethiopia, finding a very high inter-rater reliability.

LSHTM and Emory are now collaborating to employ this novel quantitative hygiene metric along with current facial cleanliness metrics (i.e., signs of ocular and nasal discharge) to investigate the relationship between dirty faces (as measured by each metric) and the facial hygiene behaviours trialled here.

Stronger-SAFE WASH Sub Study

Rationale

1. We lack studies to show the reduction of *Ct* load present on the face we can reasonably expect from improved face washing practices.
2. We need more robust evidence of whether washing with soap (or with other materials) is more effective than water at removing *Ct* from the face, and the role of fabrics (e.g. towels) used to wipe/wash faces in furthering transmission.
3. We lack studies investigating the *Ct* load of discharge that returns quickly after washing (and whether it is as high as discharge not triggered by washing).
4. We need new metrics of facial hygiene that are valid, reliable and useful.

Study Aim and Objectives

The primary aim is to find the optimal facial hygiene practice to reduce the likelihood of *Ct* being present on the faces of infected children in order to improve the design of interventions for trachoma control. We hypothesise face washing with soap will reduce the amount of *Ct* found on infected children's faces

Our primary objective is to assess the relative effectiveness of face washing with soap and water compared with face washing with water only on the removal of *Ct* from the faces of children with ocular trachoma infection.

Our secondary objectives are to:

- Assess the relative effectiveness of face wiping (with a product called the 'SuperTowel'®) compared with face washing with water and face washing with water and soap on removal of *Ct* from the faces of children with ocular trachoma infection.
- Assess the relative effectiveness of three facial cleanliness methods on removal of ocular and nasal discharge on the faces of children with ocular *Ct* infection
- Assess the relative effectiveness of three facial cleanliness methods on the mean reduction in *Ct* load on the faces of children with ocular trachoma infection
- Assess how long it takes for *Ct* to return to children's faces following face washing or wiping.
- Assess the effectiveness of the product called the 'SuperTowel'® to kill (reduce viability) of *Ct* transferred to it

Objectives related to the 'SuperTowel'® will be reviewed following an *in vitro* pilot to confirm the properties of the 'SuperTowel'® in relation to killing *Ct* bacteria on contact.

A further aim is to evaluate the ability of a novel, quantitative metric to predict recent personal cleaning practices. The purpose of this study is to determine whether there are meaningful differences in the sensitivities of this novel metric vs current metrics (i.e. signs of ocular and nasal discharge) to detect differences in pre- and post-cleaning facial cleanliness, across different face cleaning practices.

We are also interested in learning whether spread of *Ct* through the gastrointestinal tract might be possible.

Outcome measures

Primary outcome

- Proportion of participants without *Ct* detected on faces immediately following face washing with soap and water, compared with the face washing with water only group *(i.e. To assess whether soap is needed to remove Ct from faces or whether water alone is sufficient).*

Secondary outcomes

- Proportion of participants without *Ct* detected on faces immediately following face wiping with the SuperTowel
- Proportion of participants without ocular or dry nasal discharge on faces immediately following washing/wiping protocol
- Mean $\log_{10}$ reduction in load of *Ct* on faces immediately following the washing/wiping protocol
- Proportion of participants without *Ct* / ocular and nasal discharge on faces at 1, 2, 4, 6 and 8 hours following the washing/wiping protocol
- Mean $\log_{10}$ increase in load of *Ct* on faces at 1, 2, 4, 6 and 8 hours following protocol
- Mean viable load of *Ct* found on the SuperTowel® samples after use.

The screening of such a large number of children offers an opportunity to conduct related analyses alongside our trial work. Some planned ancillary objectives are mentioned below.

- We will also compare the ability of a novel, quantitative metric vs current metrics (i.e. signs of ocular and nasal discharge), to predict recent personal cleaning practices, across the three methods.
- We will look for evidence of *Ct* in the stools of children with ocular infection, evidenced by PCR.
- We will evaluate the diagnostic ability of the rapid test used to screen for ocular infection as compared to ocular infection detected through PCR.

Methods

Study design

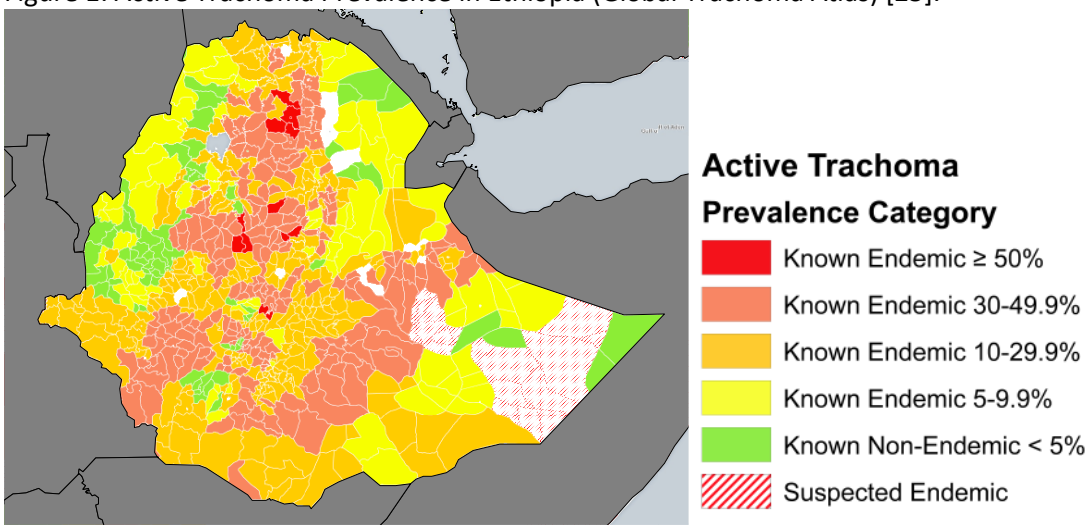
This is a three-arm, open, parallel-group randomised controlled trial.

Study setting and population

The study will be carried out in one *zone* in Oromia in districts with high TF prevalence in 1-9 year olds (TF1-9>40%) selected according to GTMP (Global Trachoma Mapping Project) data. We will confirm the *de facto* TF prevalence in 1-7 year olds (the eligible population for the study, see below) and the absence of recent - within the last 6 months; ideally as close to a year ago as possible -azithromycin mass drug administration (MDA) in selected *woredas* prior to commencing the study. The total population of the zone is estimated at 3.9 million . In some of the districts of this zone, trachoma surveillance survey (TSS) conducted in 2022, after five rounds of MDA, showed the TF prevalence is greater than 11% in children ages 1-9 years.

Ethiopia remains the country with the greatest trachoma burden [2]. It is estimated that 30% of Africa's trachoma burden is in Ethiopia. More than 80% of its population of 90 million live in rural areas and 37% live on less than a dollar a day [21]. Half the population travel significant distances to access safe drinking water and sanitation coverage is lower than expected [22]. A national survey conducted in Ethiopia in 2010 showed that access to water supply and sanitation was 52% and 63% respectively [23]. These environmental and living conditions are believed to create the ideal situation for trachoma to flourish. In Oromia, both active trachoma and trichiasis are significant public health problems. The most recent GTMP data published for this region shows an estimated overall prevalence of TF1-9 of 23.4% across 252 districts [24]. In 46% of surveyed districts, TF1-9 prevalence was >30% in 126 of 252 districts [25].

Figure 1: Active Trachoma Prevalence in Ethiopia (Global Trachoma Atlas) [25].



Sample size

During the pilot work for this study, 1/9 (11%) children with ocular discharge before washing still had discharge after washing with water and soap, whereas 11/15 (73%) children still had discharge after washing with water alone, an difference of 62% (Czerniewska *et al.*, 2020). We expect the reductions in facial *Ct* DNA to be more modest. Assuming 90% of children with facial *Ct* before washing still have facial *Ct* after washing in the water only arm and 60% of children with facial *Ct* before washing still have facial *Ct* after washing with water and soap, 47 children with *Ct* on their faces will be needed in each trial arm. This target will be inflated by 10% to account for people being lost to follow-up.

This sample size was calculated using the following formula:

$$n = (Z_{\alpha/2}+Z_{\beta})^2 * (p_1(1-p_1) + p_2(1-p_2)) / (p_1-p_2)^2$$

Where $Z_{\alpha/2}$ is the critical value at our pre-determined confidence level (95%) adjusted using Bonferroni's correction for multiple comparisons to accommodate our three-arm design (0.05/3=0.017, critical value for 0.017=2.573), Z_{β} is the critical value for the study power (80%), and p_1 and p_2 are the proportions of children with detectable *Ct* on their faces immediately after washing in each group.

Based on previous data from the Stronger SAFE project, we expect 50% of children with severe inflammation (F3 and/or P3) to have ocular infection and 60% of those children with ocular *Ct* infection to have *Ct* on their faces (Last *et al.*, 2020). Therefore, to recruit (3 x 47 =) 141 children with facial *Ct*, we need (141/0.6 =) 235 children with ocular *Ct*, for which we will need to enrol at least (235/0.5 =)

470 children with F3 and/or P3 to achieve our sample size. If 5% of our screened sample have F3/P3, we will need to screen 9,400 children to achieve this sample.

Participant eligibility and recruitment

Children aged 1-7 years will be the primary target population, as both active trachoma and the presence of ocular infection disproportionately affecting young children (18). In addition, as this age group is particularly affected by trachoma, it is children that need effective interventions to reduce *Ct* on faces.

A total of 470 participants will be selected purposively following a screening process. Following verbal parental consent, children aged 1-7 years will be assembled in a central point in each study *kebele* (community) and screened for clinical signs of TF or trachomatous inflammation—intense (TI) by a Tropical Data certified ophthalmic nurse with experience grading trachoma. Both simplified WHO grading and FPC (follicles, papillary hypertrophy and diffuse infiltration, conjunctival scarring) grading system will be performed. Children with severe TF (F3) or TI (P3) will be invited to take part in the study. A subsample may be tested for conjunctival *Ct* infection using a rapid diagnostic test (RDT), such as DjinniChip (19), as a quality assurance mechanism to determine whether the clinical screening is successfully identifying children with infection. Children who have clinical trachoma not meeting the criteria for enrolment (ie. mild TF, F2) will be treated for trachoma at this point based on clinical positivity.

We will identify high prevalence communities for recruitment through analysis of programmatic survey data and target those communities for recruitment. When a case of infection is identified, a snowball method will be used to recruit contacts, playmates and siblings. To recruit 470 individuals with severe inflammation, we plan to screen approximately 9,400 children aged 1-7 years . These estimates are based on prior experience in region from the Stronger SAFE study (20).

Children aged 1-7 years with severe conjunctival inflammation (F3, P3) will be eligible to participate in the study. Children will be recruited following receipt of parental written informed consent.

Inclusion criteria

- Parental consent to take part
- Participant assent to take part
- Severe conjunctival inflammation (F3 and/or P3)
- Aged 1-7 years residents of Oromia State, Ethiopia
- Availability for study period (8 hours)

Exclusion criteria

- Known allergy to study materials
- Significant facial and/or ocular injury or pathology

Study timescale and withdrawal from the study

Trial screening and recruitment will continue until the sample size has been recruited in all three arms. All participants will be asked to participate for the full 8-hour observation period. Participants who experience adverse reactions to the face washing protocols (for example, an allergic reaction to the soap used) and/or wipe/swab specimen collection procedures will be withdrawn from the trial. Participants experiencing illness or adverse events not related to the trial will also be withdrawn. Data collected up to the point of withdrawal will still be used unless the participants explicitly requests that it is not.

Where a participant is withdrawn >6 hours after face washing, they will not be replaced. Where a participant is withdrawn ≤6 hours after face washing they will replaced by recruitment of an additional participant from the ongoing screening process. Participants will be able to withdraw by speaking to any member of the study team during the visit, or by contacting the study team using the contact information on the information sheet.

Intervention allocation

Recruited children will be randomised into one of three equally sized groups of 47 in the field. We will use a randomisation method appropriate to the field setting. For example, we might ask them to select a wrapped sweet (without looking) from a bag containing an equal number of different colours of sweet wrapper each indicating a different protocol.

The face washing interventions will be allocated to the three groups as follows:

- Group 1 – (Protocol A) Face washing with water (control group)
- Group 2 – (Protocol B) Face washing with water and soap (primary comparison)
- Group 3 – (Protocol C) Face wiping with SuperTowel® (secondary comparison)

Protocol C - SuperTowel®

The SuperTowel® has been developed to be an alternative to soap and water in situations where soap and water are scarce. It is a microfibre cloth that has been treated so that it kills pathogens that it absorbs. The treatment is permanently bonded to the cloth, so it cannot come off onto skin, or be washed off. SuperTowel® has been shown to be effective as a tool for hand hygiene in water-scarce regions (21-23), but its use for face washing will be a novel application.

An overview of the trial design showing screening and intervention allocation in Rounds 1 and 2 is shown in Figure 1.

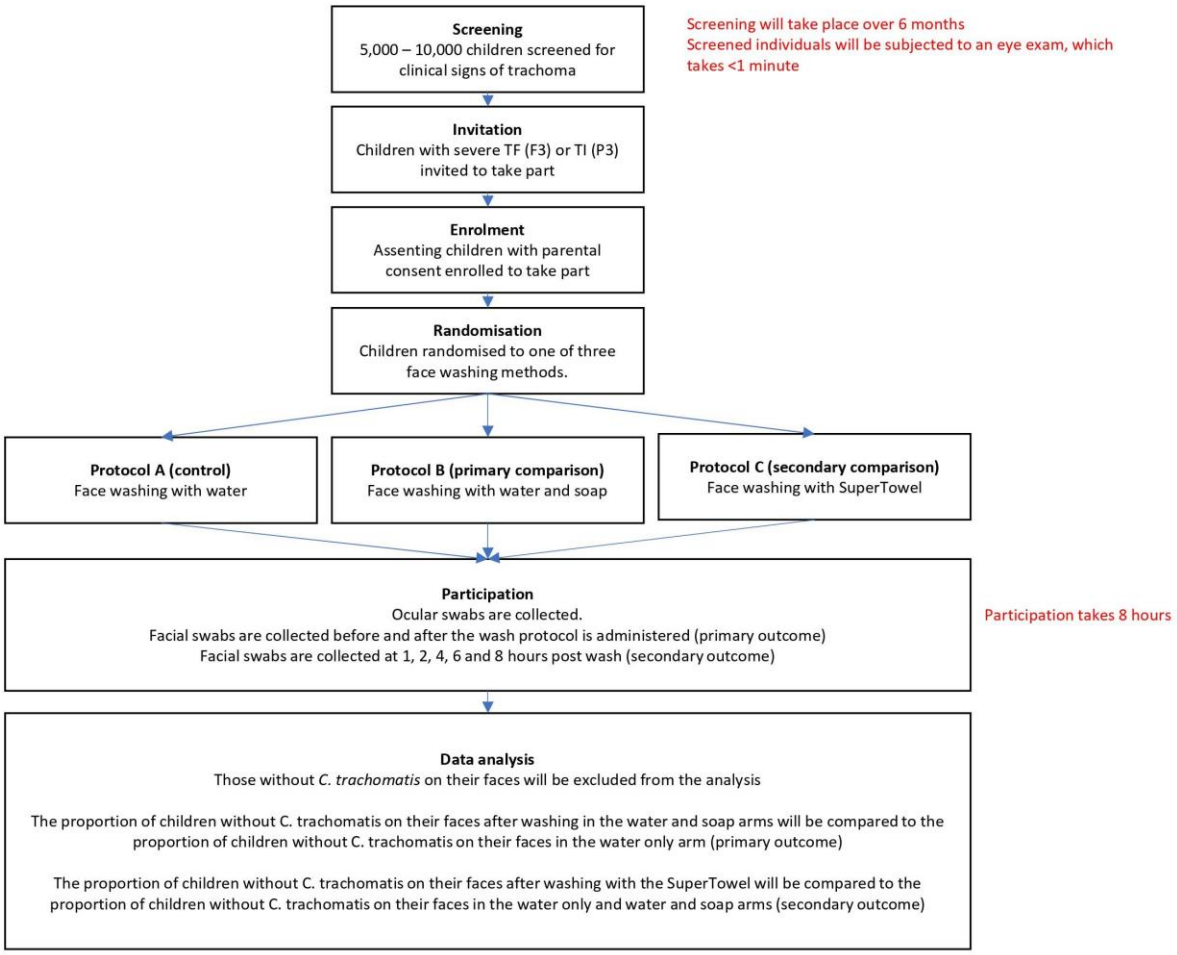


Figure 1. Overview of Trial design.

Pilot study

We will carry out two small pilot studies as follows:

1. *In vitro* lab study to assess the ability of the *SuperTowel*® to kill *Ct* on contact.
2. Pilot study to test and refine trial screening and data collection procedures. To help set a cut-off time to ensure that included children still have infection (indicated by *Ct* on their faces) from the time of screening until the completion of all protocols, we will also follow up to 20 ocular positive children included in the pilot for 7 – 10 days. Each day we will swab their faces (only) to test for *Ct* presence.

Procedure

On a rolling basis after screening, in households with eligible children recruited into the study:

1. Inform the female primary caregiver of children aged 1-7 years about the WASH sub studies and consent. Agree a convenient time to return to conduct the study. Request that the child's face is not cleaned or washed in the morning before your visit unless the child is particularly uncomfortable.
2. Set up examination station, and ask other HH members to stay at least 5 meters away from this
3. Use ODK form to capture all data (see Appendix 2 for indication of the contents of ODK form)
4. Examine children's eyes and assign a WHO grade and FPC grade to each conjunctiva

5. Take a conjunctival swab from the participant, according to a standardised swabbing protocol (Appendix 3). This swab will be used to confirm ocular *Ct* infection by polymerase chain reaction (PCR).
6. Take an air swab following standardised protocol.
7. Photograph and record current facial cleanliness, per qualitative cleanliness metrics (presence of ocular and nasal discharge, and flies) and any reported face and handwashing that has taken place that morning
8. Wipe the skin of the child's forehead using a moist, sterile gauze pad. Use a standardized, 11-point brown colour scale to score the colour of the darkest point within the darkest half-square inch (i.e., thumb-nail sized area) of each gauze pad. After scoring, photograph each wipe along with the colour scale and negative control (i.e., unused wipe).
9. Swab the child's face (under eye, across the cheek, and under the nostril) and both hands (fingers, palms and backs of both hands) according to a standardised swabbing protocol (Appendix 3). Swab caregivers' hands too as they will be washing the child's face. Record data.
10. Round 1: For Protocols A-C: Instruct caregivers to wash the child's face with water only (Protocol A), with water and soap (Protocol B), or to wipe the child's face with the *SuperTowel* (Protocol C) following a standardised protocol according to intervention allocation. Ask a household member to bring water for face washing in the vessel they would normally use. The face should be washed using two hands and should last about 30 seconds. All parts of the face should be washed carefully, including around the eyes and nose. Provide ordinary non-medicated soap for Protocol B. The face and hands should not be dried and should not touch anything until the next swab is taken.
11. Wait 5 minutes for child's hands and face (and the caregivers' hands) to air dry if Protocols A or B have been followed, photograph the face and record whether the wash removed existing ocular and nasal discharge
12. Immediately repeat swabbing of the child's face and hands and caregivers' hands Record.
13. Request that the child's face is not washed or wiped again until the end of the study if possible, unless the child is particularly uncomfortable.
14. Ask the caregiver to wash their hands with soap and swab hands again.
15. Swab child's face and hands of children and carers 1, 2, 4, 6 and 8 hours after face washing. At each time point photograph and record facial cleanliness (presence of ocular and nasal discharge, and flies) and record reported face or handwashing since the last swab was taken.
16. Wipe the skin of the child's forehead using a moist, sterile gauze pad. Use a standardized, 11-point brown colour scale to score the colour of the darkest point within the darkest half-square inch (i.e., thumb-nail sized area) of each gauze pad. After scoring, photograph each wipe along with the colour scale and negative control (i.e., unused wipe).
17. Ask the child to wash their face with soap and water to complete the study. Provide Soap for this purpose.
18. Complete a brief risk factor survey.
19. Before leaving, thank the female primary caregiver and child(ren) and answer any outstanding questions
20. Collect stool sample from child.
21. Treat children for trachoma at end of the study.
22. Due consideration will also be given to the current COVID-19 pandemic by adhering to the national Standard Operating Procedures (SOP).

NB: We might also ask participants to allow us to video the face washing procedure and/or our team members completing the wipes and swabs. The purpose of these videos is for internal fidelity checks, and also to get a sense of the way that people typically wash faces in this setting.

Sample storage and management

All swab samples will be stored in 500µL 2SP transport medium and stored on ice packs in the field. Stool samples will be stored on ice.

All used SuperTowel® samples will be sealed in a biohazard bag (or in a 2SP transport medium inside 50ml falcon tubes, if feasible) immediately after use, and will not be reused on other participants.

About the SuperTowel®

The SuperTowel® is a product developed by RealRelief. It has been designed as a soap alternative product for emergency situations but also has potential for use in other water-scarce areas. 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 skin 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 4). The anti-microbial technology is achieved by long chains of carbon atoms attached to positively charged nitrogen atoms bonded to a silica layer on to the fabric. Each of these three elements have a specific function. The silica-based group functions as the antimicrobials anchor. The silica group is anchored through covalent bonds which are formed through standard hydrolysis reactions that allows the antimicrobial to be bond to almost any surface while allowing cross linking and polymerisation with other molecules. The positively charged nitrogen atom attracts negatively charged microbes including bacteria and fungi. The long chains of carbon atoms function as a needle that pierces the cell membrane of a microbe while it gets attracted towards to positively charged nitrogen atom causing membrane disruption. This membrane disruption results in leakage of cytoplasmic materials killing the microbe. When the negatively charged microbe gets drawn further on to the carbon atom chains it will eventually come in contact with the positive nitrogen atoms. This contact causes the electric balance to be disturbed and can cause the microbe to explode under its own osmotic pressure. The technology can offer complete protection against most pathogens, thereby giving a clean and microbe free hand. If the water is contaminated (e.g. grey water), the technology could remove the pathogens in the water absorbed by the towel. As the bonding is permanent the fabric does not call for replacement until it is damaged or lost. The SuperTowel® will reduce the amount of water needed for hand and face washing, reduce drainage problems that are often seen around hand washing facilities, and negate the need for soap.

The basis of the antimicrobial treatment is Quaternary Ammonium Compounds, known as QAC or Quats. They are used in a dissolved liquid form and proven effective to disinfect patient care supplies or equipment such as cystoscopes or cardiac catheters in hospitals. Besides its clinical use QAC are also commonly used in ordinary environmental sanitation of surfaces such as floors, furniture, and walls. The problem with QAC is that they are water soluble and therefore end up in the environment and there is a lot of discussion about these compounds. What is used on SuperTowel® is a derivative of QAC, sometimes called QAS, which stands for Quaternary Ammonium Silane. The mode of action is the same, but the decisive difference is that QAS are bonded permanently to the surface they have been attached to, in this case a microfiber cloth. So the QAS does not leave the towel, and it only kills bacteria that lands on the towel. The Material Safety Data Sheet is provided in Appendix 5.

Prior studies using SuperTowel

In December 2017 the manufacturer partnered with LSHTM to determine in whether the SuperTowel® was as efficacious as soap for removing non-pathogenic *E.coli* from artificially contaminated hands in laboratory conditions. These tests were carried out following a protocol in line with European standards. The tests used a cross-over design whereby all study participants were asked to clean their hands with both the SuperTowel® and by handwashing with soap. This first test used a standard piece of polyester fabric treated with the permanent anti-microbial bonding. The full protocol for this was previously submitted and approved to the ethics committee at LSHTM (submission code: 14464). The outcome of this initial trial was that, in its current form, the SuperTowel® proved to be less efficacious than handwashing with soap at removing *E.coli* from hands. However, 38% of participants actually managed to attain cleaner hands by using the SuperTowel® than they did with soap. As per the research protocol we then held a creative workshop with a group of textile designers to improve the form and shape of the SuperTowel® in the hope that its efficacy could be improved. Three new micro-fibre materials were identified through this workshop, treated with the anti-microbial bonding and tested in a second round of laboratory tests in India in March 2018 [27]. The outcome of these tests were that all three of the new fabrics were more efficacious than soap at removing non-pathogenic *E.coli* from hands. The three SuperTowel® products were respectively able to achieve a mean log reduction factor of 4.11 (SD 0.47, p-value 0.0005), 3.84 (SD 0.61, p-value 0.0019) and 3.71 (SD 0.67, p-value 0.0052) compared to the reference soap which achieved a mean log reduction factor of 3.01 (SD 0.63).

Use of SuperTowel in Ethiopia

The acceptability of the SuperTowel® was tested in two refugee camps in the Tigray Region of Ethiopia in September 2018 [28]. The full protocol for this was approved to the ethics committee at LSHTM (reference 15093) and in Ethiopia. Through behaviour trials, focus groups and interviews with humanitarian actors, colleagues showed the product was considered acceptable to crisis-affected populations and humanitarian actors, and feasible to deliver [28].

Data analysis

Laboratory Procedures

Swabs and stool samples: Chlamydia trachomatis detection by quantitative PCR

Samples will be kept on ice-packs in the field and transferred to a -20^{0}C freezer within eight hours. Samples will be transferred each week to the ORHB Public Health Laboratory in Adama where DNA extraction and amplification tests for *Ct* will be performed. Upon receipt in the laboratory, each sample will checked against the sample log sheets. Any missing samples or samples not suitable for analysis will be reported to the study coordinator, along with a daily report on sample submission. Samples will be stored in a -80^{0}C freezer.

In the Adama laboratory, DNA will be extracted from the swabs and stool samples using a commercially available kit. The DNA extract will then be tested using a previously described three-plex real-time quantitative PCR assay.[29] This simultaneously tests for: (1) a human DNA target (Internal Control to confirm adequacy of sample collection, extraction and PCR reaction); (2) a *C. trachomatis* chromosomal DNA target; (3) a *C. trachomatis* plasmid DNA target. To assess the potential viability of the *Ct* detected in the non-ocular samples, we will pre-treat swab samples before extraction using PMA and light.[30]

SuperTowel®: Chlamydia trachomatis detection by quantitative PCR

SuperTowel® samples will be kept on ice-packs in the field and transferred to a -20^{0}C freezer within eight hours. Samples will be transferred each week to the ORHB Public Health Laboratory in Adama where they are stored in a -80^{0}C freezer. Upon receipt in the laboratory, each sample will be checked against the sample log sheets. Any missing samples will be reported to the study coordinator.

In the Adama laboratory, the SuperTowel® will be rinsed with PBS before vacuum filtration using a 0.2 micron pore diameter filter. DNA (untreated and treaded with PMA) will be extracted from the filters using a commercially available kit. The DNA extract will then be tested using the quantitative PCR assay described above. The vacuum filtration process will be piloted in the laboratory to ensure validity prior to this study.

Statistical Analysis

CONSORT guidelines for analysing and reporting clinical trials will be followed. A flowchart will show all potentially eligible and ineligible participants for the trial, and reasons for exclusion. The number of participants enrolled per protocol will be shown, along with number with outcome data. The baseline characteristics of participants will be summarised by arm.

Analyses will be 'per-protocol' so efficacy can be assessed, but will be restricted to children with *Ct* on their face at baseline as determined by PCR. Participants will be analysed according to the protocol they performed. Primary comparisons will be between Protocols A and B and will compare the proportion of participants without *Ct* detected on faces immediately following face washing according to each protocol. In secondary analysis we will look at *Ct* removal following Protocol C, removal of oculo-nasal discharge following Protocols A-C and mean $\log_{10}$ reduction in load of *Ct* on faces immediately following each Protocol. A further secondary analysis will compare how quickly the load of Ct builds up on the faces of infected children, following removal by each of these four methods. Regression analyses will be performed to evaluate the relative efficacy of the various cleaning methods for removing Ct from faces using 'washing with water' as the comparison. Another secondary analysis will assess the viable load of Ct found on the SuperTowel® samples after use, to give an indication of their potential role as fomites in transmission.

We will also compare the ability of a novel, quantitative metric vs current metrics (i.e. signs of ocular and nasal discharge), to predict recent personal cleaning practices, across the four methods.

We will look for presence of *Ct* in stool as determined by PCR.

As ocular infection is assessed through both rapid test and PCR, we also have the opportunity to compare the results to evaluate the diagnostic ability of the rapid test.

Data management

Data from the study will be jointly managed by the LSHTM and FHF team in Ethiopia, coordinated by the Ethiopian Project Manager and the PI. Data will be entered at the time of collection via electronic data capture on password protected Android Devices using the Open Data Kit (ODK) secure data capture system provided by LSHTM http://opendatakit.lshtm.ac.uk/. All data is automatically encrypted on the Android devices when the ODK form on the Android devices is filled and finalised. The ODK Collect app uses the public encryption key along with an encryption algorithm to convert the data in to an encoded (encrypted) form. Once the form is finalised, the data cannot be reopened or

read on the device (e.g. in the case of loss or theft of the tablet). Any photographs, audio/video recordings and other attachments are also encrypted. Encrypted data will be sent over the internet from the Android devices to a secure server at LSHTM for secure storage and backup. Only the encrypted forms of the data will be stored on the servers**, so** no person could view any data on any server through the web, even if they have a copy of the admin username and password. In the case that WiFi is unavailable in the study area for several days, we will back up encrypted forms to the password protected laptop of the local PI.

Data will be downloaded from the ODK server and then decrypted offline using a piece of software called ODK Briefcase**.** This will only be done by the study investigator and co-investigators who have access to the decryption key, saved on personal usb drives kept securely in locked cabinets and offices, meaning that only a small number of individuals can ultimately see the human readable form of the data. All decrypted data containing any personal identifiers will be stored on a secure server at LSHTM and in no other place. Paper records (consent forms) will be managed and stored in the secure/locked project office in locked cabinets.

Photographs of faces will be used for independent grading by blinded assessors within the LSHTM Stronger SAFE team (not involved in the data collection for this part of the study). Photographs of each wipe will be graded off-site using computer-automated densitometry scoring.

Laboratory data will be managed through an MS Access database. The laboratory will verify the samples received from the field, noting any errors, deficiencies or missing samples. After testing, the laboratory will submit results to the PI.

The Ethiopian Project Manager and the PI will be responsible for ensuring a secure and appropriate location for storage of study related documentation present at the study site, as well as for ensuring that only members of site staff who are authorised have access to the files. The site Investigator File will be held at the project office. The Investigator File will at all times remain available for internal audits and/or inspections of regulatory authorities, including after completion of the project.

After study completion, all the relevant study documentation will be retained in accordance with the local legislation, for a minimum period of 10 years after completion of the study. Laboratory specimens will be stored indefinitely for the participants who have given consent for long-term storage of their samples. Any processing of samples after long-term storage will be subject to an assessment of the integrity and quality of the samples. In our experience over the last 20 years, ocular samples frozen at -20^{0}C have readily detectable *Ct* DNA. The final dataset will be archived and maintained by FHF (Ethiopia) and at LSHTM.

Anonymised data sets will be made publicly available after publication, to ensure the data are available for other investigators to explore. Specific permission for this is requested in the consent form.

Data confidentiality

The data collection tools include personal identifiers (name, age and GPS location), which are used by project staff to identify participants for the purpose of follow-up. To safe guard identifiable information, all paper records will be kept in locked cabinets in the secure (locked) project office in Shashamane. Electronic data (collected via electronic data capture on password protected Android Devices using the Open Data Kit (ODK) secure data capture system provided by LSHTM http://opendatakit.lshtm.ac.uk/) will be kept in an encrypted form on password-protected computers in the project office and on a secure server at LSHTM. All decrypted data containing any personal identifiers will be stored on a secure server at LSHTM and in no other place.

Participants are asked separately whether they consent to photos being taken and they can select where and how these photos are used in reports and other communications when they provide consent. Photographs will be stored with the photo number only, not with names, ID number or identifiable data. As we will be interested in the ocular and nasal discharge present on the face, photographs will be cropped (or blurred in facial sections irrelevant to the study protocol) to focus on this element and individuals will not necessarily be recognisable from these photos.

Ethical considerations

Approval will be sought from the Federal Ministry of Innovation and Technology, the Oromia Regional Health Bureau (ORHB) Ethics Committee and the London School of Hygiene & Tropical Medicine Ethics Committee. The research will adhere to the tenets of The Declaration of Helsinki.

We will obtain written informed consent for children to take part in the study from a parent or guardian. As all participants will be younger than 12 years of age (the recommended age for assent) we will not obtain additional informed assent from our participants.

Informed consent

Prior to approaching members of the communities there will be initial dialogues with the community leaders and local health officials to introduce the purpose and nature of the research project.

Clinical screening: a large number of children will be assembled and screened by nurses for clinical signs of trachoma. This eye examination is standard and will be performed following verbal consent provided by parents/guardians.

Eye swab for rapid test (prior to study enrolment): As eye swabs will be taken from children identified during the screening to have clinical signs of trachoma, parents/guardians will be provided with information sheets and informed consent forms (Appendices 1A and 1B). Information will be provided in *Afaan Oromo*, the regional language, and will be read out loud to those unable to read. After verbal explanation of the relevant sections of the participant information sheet (Section 1. Screening) and having the opportunity to ask questions, informed consent will be gained and evidenced by a signature or thumbprint signature (deemed acceptable locally due to high rates of illiteracy), in the presence of the study team and independent witness.

Main study: Participants' parents/guardians will be again provided with information sheets and informed consent forms (Appendices 1A and 1B). Information will be provided in *Afaan Oromo*, the regional language, and will be read out loud to those unable to read. After verbal explanation of the relevant sections of the participant information sheet and having the opportunity to ask questions, informed consent will be gained and evidenced by a signature or thumbprint signature (deemed acceptable locally due to high rates of illiteracy), in the presence of the study team and independent witness.

Parents and guardians will be asked to provide consent.

The research described in this protocol does not pose risk to potential participants. Reasonable effort has been made to ensure the following:

1. **No harm** will be done.
2. **Respect**. The fundamental ethical principle will be adhered to by respecting individuals' decisions. Written Informed consent will be sought as a means to document willingness of the potential participants. No penalties whatsoever will be suffered should any potential participant refuse to participate. Further, participants will be informed that they are free to discontinue participation even without any reasons explained. Privacy will be respected at all

times; for example, if photos are taken they will be taken by family members with their full consent and the understanding that they may withdraw their consent at any time. The BMJ guidelines (British Medical Journal, 1998, 316, 1009-1011.) have been read and are adhered to.

3. **Confidentiality.** The data collection tools include personal identifiers (name, age and GPS location), which are used by project staff to identify participants for the purpose of follow-up. To safe guard identifiable information all paper records will be kept in locked cabinets in the secure (locked) project office in Shashamane. Electronic data will be kept in an encrypted form on password protected computers in the project office and on a secure server at LSHTM.
4. **Trained Field Workers.** All field workers will be trained in data collection and ethical considerations to ensure non-violation of ethics.
5. **Compensation for Participants.** We do not pay individuals to participate in research studies.

Treatment of trachoma

All children identified with trachoma infection will be offered Tetracycline Eye Ointment (TEO). All study participants will be treated for trachoma following the completion of Round 2. All children with clinical signs of trachoma who had a negative rapid test and were not included in the trial will be treated following screening. Mass drug administration occurs annually in these high prevalence communities, but treating again poses no harm, and is beneficial as we cannot assume all children are reached by MDA.

Safety considerations

The safety and wellbeing of the participants will be monitored and any adverse events managed/reported as appropriate.

Potential discomfort

The collection of the eye swabs might cause a few seconds of mild discomfort, but will not harm eyes in any way. The examination takes only a few moments to complete. This examination has been carried out in many countries including Ethiopia without problem. Collecting swabs from hands and faces is not uncomfortable and does not cause any pain. However, we are aware that some of the children we are collecting data from are very young and might find this experience overwhelming or very distressing.

The SuperTowel® has been developed to be an alternative to soap and water in situations where soap and water are scarce. It is like a normal cloth that you might use for cleaning, but it has been treated so that it kills many germs that land on it. The treatment is permanently bonded to the cloth, so it cannot come off on to skin, or be washed off.

While we do not envisage psychological distress resulting from any of our procedures, it is possible that participants could experience some minor psychological discomfort as a result of being questioned on their behaviour or being asked to demonstrate face washing practices for us.

Safety precautions

Eye examinations will be conducted by a fully trained ophthalmic nurse with previous experience and training with the project. Swabbing and wiping procedures will be conducted by the nurse and/or other members of the Stronger SAFE research team who have already received training in swab

collection and study methods, and have had ample practice and supervision in conducting similar protocols. Eye examinations and each swab collection takes 1-2 minutes.

We will train and sensitise our field workers to respect participants' emotions and make sure that our staff are aware that the purpose of the research is understanding and documenting behaviour; not judging participants or their families. Participants will be informed in advance that they do not need to answer any questions they are not comfortable with and they are free to stop participating at any time. We will immediately stop the study with a particular child if they show signs of undue distress.

We will use a new, clean SuperTowel® or a new bar of soap (as applicable) for every participant, so there is no risk of infection from previous people using it, and dispose of the SuperTowel® after each use, to ensure there is no potential for onward transmission. All soap used in the trial will be sourced in Ethiopia from licensed manufacturers.

In the event of minor adverse reactions such as localised skin redness and swelling or minor eye irritation, the Stronger-SAFE team field ophthalmic nurses, amongst whom Mr Muluadam Abraham will be given specific extended training in adverse event management, will advise participants. A jerry can of clean water will be available in the team car at all times for rinsing the face/eyes in the event of a minor reaction. Additionally, specific medication for treating allergic reactions in the field will be available in the field medical kit to be administered by the nurses if clinically indicated.

In the case of a severe reaction such as anaphylaxis or a severe skin reaction, or should further care be required, the person will immediately be escorted to Feya hospital (the best hospital in Shashmene). The field team will always include one ophthalmic nurse who can provide interim care until the car reaches the hospital. In addition, contact with the clinicians Dr Esmael Ali (based in Ethiopia), or the clinical team in London (Prof. Matthew Burton or Dr Anna Last) will be available by telephone while fieldwork is being conducted.

Safety and field study monitoring

The Lead Investigator and the local PI will review reports of minor or serious adverse effects daily, and stop the trial immediately if any product appears to have caused a serious adverse reaction in any participant.

We will appoint an independent field study monitor, in accordance with the Guidelines issued by the Drug administration and control Authority (DACA) (formerly Ethiopian Food, Medicine and Healthcare Administration and Control Authority /EFMHACA).

The field study monitor will be responsible for observing the responsibilities of all parties and reporting to the sponsor (LSHTM). The monitor will verify that the rights and well-being of the study participants are protected, that the data are accurate, complete and verifiable from source, and that the trial is conducted in compliance with GCP and local (DACA) regulations. The field study monitor will be familiar with, and have experience with, local regulations. They will be appropriately trained and have relevant scientific knowledge to properly understand and monitor the trial.

The monitor will be thoroughly familiar with, and they will verify adherence to protocol, information and consent sheets, and SOPs (including version/document control, currently approved versions). They will verify the qualifications of the research team, enrollment of only eligible participants, correct document record keeping, production of reports, and the accuracy and completeness of the case record form.

Monitoring plan

As this is a small-scale trial that does not involve an invasive investigational product (only locally-available soap, and the use of a microfiber towel), a visiting schedule of before, during and after the clinical phase will be sufficient. The monitoring visits will be documented, and notification will immediately be given to the relevant party (i.e. co-PIs, CI, or sponsor) regarding any issue raised during these visits. A full list of the duties conducted at each of these time points is given in the table below.

Outline of monitor duties at before, during and after clinical phase visits.

Item for monitoring	**Frequency**			
	Before	**During**	**After**	**Throughout**
Communicating with investigators (PI/CI)				x
Ensuring that receipt, use and return of the SuperTowel product is controlled and documented				x
Ensure investigator and staff are informed about the trial so they can carry out all of the processes correctly				x
Verify that essential documents are properly filed and maintained				x
Verify that the investigator provides all the required reports, notifications, applications and submissions, and that these documents are accurate, complete, timely, legible, dated, and identify the trial				x
Communicating deviations from the protocol, SOP, GCP, and the applicable regulatory requirements to the investigator and taking appropriate action designed to prevent recurrence of the detected deviations				x
Verify that all protocol amendments are distributed to site				x
Verifying that all regulatory/institutional approvals are in place prior to IP (soap and SuperTowel products) arriving on site	x			
Checking that storage facilities are suitable for IP and all study materials	x			
Checking facilities to ensure adequacy	x			
Ensure investigator receives current IB	x			
Verifying investigator has adequate qualifications	x	x		
Verifying that staff are adequately trained in protocol	x	x		
Verify that all protocol amendments are receive regulatory/institutional approval	x	x		
Ensure investigator receives all documents and supplies required to conduct trial	x	x		
Verify people carrying out tasks and processes have been officially delegated these tasks	x	x		
Monitoring suitability of facilities		x		
Checking that participants are provided with proper instructions on IP use		x		
Verify investigator is following protocol and protocol amendments		x		
Verify that written consent has been granted prior to participants entry into the trial		x		
Verify the investigator recruits only eligible participants		x		
Checking the accuracy and completeness of the Case Report Form/ data collection tool entries, source documents and other reports		x		
Ensuring that IP is disposed of in accordance with local regulations/sponsor rules		x	x	
Verify that source documents are accurate, up-to-date and maintained		x	x	
Informing the investigator of any errors, illegibility, omissions or inconsistencies in the Case Report Form/ data collection tools		x	x	
Determining that ALL adverse events are appropriately reported		x	x	

We will not institute an additional Data Safety Monitoring Board (DSMB) because of the low-risk nature of this behavioural trial and the fact that interventions are already readily available to the study

population. We also assume that data will accrue too quickly to make it useful for feasible for a DSMB to conduct interim analyses.

Anticipated outputs

There is currently a lot of international momentum about better understanding the 'F' component of the SAFE strategy, and there will be ample opportunity to share our findings with a broad audience. The Stronger SAFE investigator group is well placed to conduct conversations about the intervention at the right levels as it involves leaders within Ethiopia at the national and regional level, WHO and a leading implementing NGO, as well as at LSHTM. Many of the investigators are involved in the WHO GET2020 Alliance for the elimination of Trachoma.

We will inform the Ethiopian regional and Federal health authority and the community about the results via a written report and direct verbal communication. This information will be shared directly with the communities that participated in intervention development through public meetings. Formal reports will be written for the Ethiopian Federal and Regional health authority and the Federal Ministry of Science and Technology (FMOST). Reports will also be prepared for the Wellcome Trust and The Fred Hollows Foundation (Ethiopia and UK).

To ensure operational uptake of the findings of the studies, we intend to present these data at the annual National Trachoma Task Force and NTD Research Symposium (Ethiopia). Additionally, we will present this research (the process by which the intervention has been developed) at the annual Trachoma Scientific Informal Workshop prior to the WHO GET2020 Alliance meeting. Scientific results will be published in Open Access in peer-reviewed journals and presented at relevant international conferences.

Trial Sponsor

London School of Hygiene & Tropical Medicine will act as the trial sponsor. Delegated responsibilities will be assigned locally.

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.

Funding

The Wellcome Trust, London, UK, is funding this study.

Indemnity

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

Trial Registration

The trial will be registered on the Pan-African Clinical Trials Registry, after it has received ethical and regulatory approval.

Appendices

1A Participant Information Sheet
1B Participant Consent Form
2 Data Collection Form
3 Swabbing SOP
4 SuperTowel®: Efficacy Data
5 SuperTowel®: Material Safety Data Sheet
6 Adverse Event Documentation Log
7 Serious Adverse Event Documentation Log

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