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Protocol for a Cluster Randomised Stepped Wedge Trial Assessing the Impact of a Community-Level Hygiene Intervention and a Water Intervention Using Riverbank Filtration Technology on Diarrhoeal Prevalence in India

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Protocol for a cluster randomised stepped wedge trial assessing the impact of a community-level hygiene intervention and a water intervention using riverbank filtration technology on diarrhoeal prevalence in India

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ABSTRACT

Introduction: Diarrhoea is a leading cause of death globally, mostly occurring as a result of insufficient or unsafe water supplies, inadequate sanitation and poor hygiene. Our study aims to investigate the impact of a community-level hygiene education program and a water quality intervention using riverbank filtration (RBF) technology on diarrhoeal prevalence.

Methods and analysis: We have designed a stepped wedge cluster randomised trial to estimate the health impacts of our intervention in 4 rural villages in Karnataka, India. At baseline, surveys will be conducted in all villages, and householders will receive hygiene education. New pipelines, water storage tanks and taps will then be installed at accessible locations in each village and untreated piped river water will be supplied. A subsequent survey will evaluate the impact of hygiene education combined with improved access to greater water volumes for hygiene and drinking purposes (improved water quantity). Villages will then be randomly ordered and RBF-treated water (improved water quality) will be sequentially introduced into the 4 villages in a stepwise manner, with administration of surveys at each time point. The primary outcome is a 7-day period prevalence of self-reported diarrhoea. Secondary outcomes include self-reported respiratory and skin infections, and reported changes in hygiene practices, household water usage and water supply preference. River, tank and tap water from each village, and stored water from a subset of households, will be sampled to assess microbial and chemical quality.

Ethics and dissemination: Ethics approval was obtained from the Monash University Human Research Ethics Committee in Australia and The Energy and Resources Institute Institutional Ethics Committee in India. The results of the trial will be presented at conferences, published in peer-reviewed journals and disseminated to relevant stakeholders. This study is funded by an Australian National Health and Medical Research Council (NHMRC) project grant.

Strengths and limitations of this study

- This is the first randomised control trial (RCT) to assess the health impact of a community-level water intervention using riverbank filtration technology.
- This community-level study is novel as it considers the impact of interventions that target water access/quantity and improved water quality.
- The stepped wedge RCT design allows all participants to eventually receive the intervention, improving equity and acceptability; intervention effects are estimated from within-village differences while controlling for time trends.
- Collection of household stored water samples prior to health survey administration enables assessment of the relationship between microbiological quality of stored drinking water and diarrhoea.
- Incorporation of only four clusters (villages) in the trial may limit generalisability.

Trial registration number: ACTRN12616001286437; pre-results.

INTRODUCTION

Access to a safe, reliable and continuous supply of water for drinking, cooking and personal hygiene is an essential requirement for good health. The WHO estimates that around 10% of the total burden of disease worldwide could be prevented by improvements related to water, sanitation and hygiene.[1] A leading cause of death and disease globally is diarrhoea, and an estimated 90% of diarrhoea-related deaths

occur as a result of unsafe drinking water and sanitation.[2] [3] Global initiatives such as the Sustainable Development Goals have led to significant advances in access to improved water sources and improved sanitation;[4] however, progress has been uneven and large disparities remain between rural and urban areas. An estimated 663 million people worldwide still use unimproved water sources, and one-fifth of these people live in South Asia.[4]

India has the highest burden of child mortality and morbidity related to diarrhoea in Asia.[2] [5] Despite recent improvements in water sources and sanitation facilities for some of the population, many people in rural areas still cannot access improved water sources and gross disparities in coverage exist across the country.[3] [6] Technical water treatment solutions are out of the financial reach of most communities. Affordable water treatment systems that have beneficial human health effects and that can be maintained and sustained using local resources are needed.

Most previous studies of water quality interventions in developing settings have focused on household based 'point-of-use' (POU) interventions, which can be delivered to and randomised at the level of single households.[7] Systematic reviews of these studies have demonstrated a reduction in diarrhoeal disease associated with the use of such devices; however, effect sizes are heterogeneous.[8–10] Additionally, POU interventions are frequently limited by poor uptake and lack of sustained use, and may have low acceptability to the population.[7–9] Community-level interventions are an alternative approach to water quality improvement, where improved water supplies (eg, filtered water) are piped to communal tanks or directly to households. These interventions may have broader uptake and coverage, and may have additional health benefits due to increased water availability for personal hygiene and household use. Unfortunately, such interventions are often limited by cost, and there is currently insufficient evidence to know if they consistently reduce diarrhoeal rates.[8]

An inexpensive community-level intervention approach is riverbank filtration (RBF), a water treatment technique used in Europe for over 100 years that can remove contaminants from water to improve water quality.[11] [12] RBF wells can be installed in the immediate proximity of polluted rivers (figure 1). When an RBF well is pumped, river water is induced to flow through porous riverbed sediments and in the process bacterial pathogen removal efficiencies of three to four log can be achieved[13] and heavy metal and organic pollutant concentrations are reduced. Pilot studies have demonstrated the feasibility of using RBF technology for water treatment in rural communities in India, and the ability of such technology to supply quantities of water sufficient to ensure all personal hygiene, food hygiene, laundry and bathing needs are met.[12] [14] RBF uses auto-regenerative, natural treatment processes, so properly engineered systems can remain effective indefinitely.
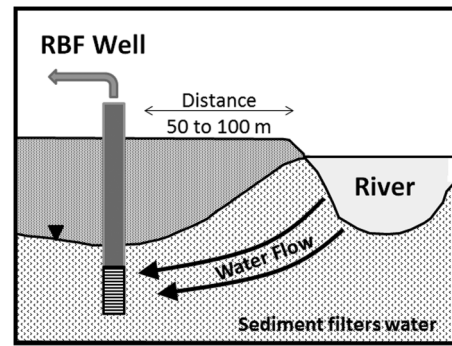

Figure 1 Schematic of a riverbank filtration system.

Unlike other community-level interventions, such as high-capacity reverse osmosis filtration systems, RBF systems are technologically non-complex and comparatively inexpensive; required maintenance is limited to disinfection of the well(s) and/or pipeline and storage tanks, if indicated by the presence of faecal indicator bacteria in routinely collected water samples. An RBF system consists of one or more RBF wells, electric submersible pump(s), water storage tank(s) and pipeline(s) fitted with taps at designated water distribution points. While RBF operators require minimal training and can therefore be recruited from local communities, the placing and design of RBF wells and water supply infrastructure requires input from hydrogeologists and engineers.

We have designed a stepped wedge cluster randomised control trial (RCT) of a community-level hygiene education intervention and a source-based improvement in community water supply using RBF in four rural Indian communities. We plan to address the following objectives:

- *Primary objective:* to measure the effect of hygiene education and provision of RBF-treated water on the prevalence of diarrhoea in four rural India communities.
  - Specific research question: in communities receiving hygiene education, does supply of piped RBF-treated water reduce the (7-day period) prevalence of reported diarrhoeal disease in comparison to piped unfiltered river water?
- Secondary objectives
  - To measure the effect of hygiene education and provision of RBF-treated water on the (7-day period) prevalence of other hygiene-related illnesses, including respiratory and skin infections;
  - To determine whether hygiene education and provision of RBF-treated water leads to changes in hygiene practices, preferred domestic water supply or household water consumption;
  - To determine whether installation of RBF systems leads to effective and sustainable removal of bacterial faecal indicators, turbidity reduction and chemical removal;

– To evaluate the cost-effectiveness of installing RBF systems in India;
– To confirm the feasibility of transferring RBF system maintenance to local communities;
– To document household water storage practices and to compare the microbiological quality of piped and stored household water;
– To investigate the temporal association between the microbiological quality of stored household water and the prevalence of reported diarrhoea.

METHODS AND ANALYSIS
Study design
This study will use a closed cohort stepped wedge cluster randomised design (figure 2), which involves a sequential crossover of clusters from the control to the intervention arm, so that every cluster begins in the control condition and eventually receives the intervention, with the order of crossover randomly determined.

The study will be conducted in four rural villages, currently using untreated river water as their primary source of water for drinking and hygiene. At the start of the study period, baseline (T0) demographic and health data will be collected from each consenting household and baseline hygiene education will be provided. Following this, new pipes, water storage tanks and taps will be installed in accessible locations throughout all villages. Once completed, simultaneous supply of piped untreated river water to all villages (control arm) will be provided (start of T1). This will increase the quantity of water available and ensure that all households in the villages have improved spatial and temporal (seasonal) access to greater volumes of untreated river water for hygiene and drinking purposes (improved water quantity). The second (T1) health survey will start 4 weeks after the initiation of piped untreated river water supply to evaluate the impact of hygiene education combined with improved water quantity compared with baseline (T0). RBF-treated water (intervention arm) will then be sequentially introduced to each village in random order at 12-week intervals (T2–T5), with health surveys performed 4 weeks after the implementation of the intervention to assess the additional effects of improved water quality. RBF systems will be built during the construction phase but will remain disconnected until the relevant village is randomised to receive the intervention. River, tank and tap water from each village will be sampled to assess microbial and chemical quality, and microbiological analysis will be performed on stored water from a subset of households.

The stepped wedge cluster RCT is a pragmatic study design in which all villages within the study eventually receive the intervention, thereby improving equity and acceptability. Comparisons between intervention and control are made within each cluster, maximising statistical power, particularly when cluster sizes are large. Between-cluster variation and seasonal effects are accommodated in the statistical analysis model.

This study is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616 001286437) and the WHO Trial Registration Data Set for this study is included in online supplementary appendix A. Study registration was delayed until after recruitment due to human resource constraints; however, protocols developed prior to data collection were strictly followed. At the time of registration, only baseline demographic and health data had been collected; water supply systems, representing the control condition for the stepped wedge study design, had not yet been implemented. The study is expected to end in January 2018.
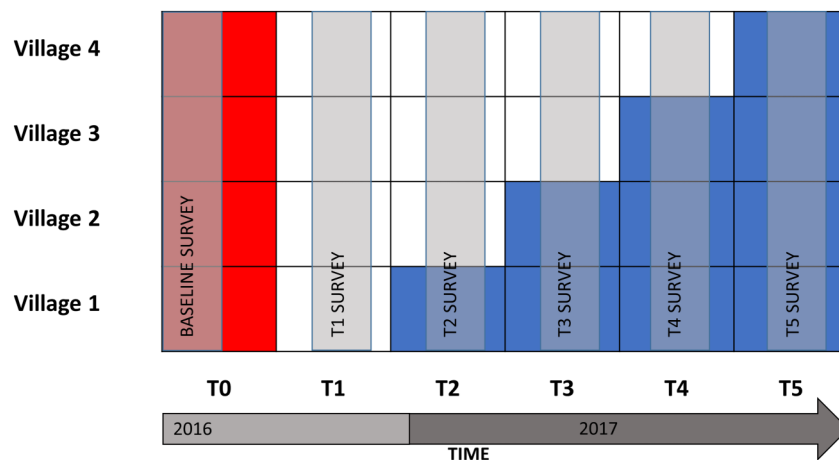

Figure 2 Stepped wedge schematic for the study. Each cell represents a data collection point. Each 'step' from T1 to T5 will be ~12 weeks in length. Shaded red cells represent the prepipe augmentation stage and the baseline (T0) survey will be performed during this stage. Once the augmented pipework has been completed in all four villages, piped untreated river water will be delivered to all villages (unshaded cells, pre-riverbank filtration (RBF) intervention). The RBF intervention (shaded blue cells) will then be sequentially introduced to the villages in random order. The T1–T5 household surveys will start in week 5 of each step.

Setting

The study will be conducted in four similarly sized villages of ~3000 people situated along the Krishna River in the Belgaum district of the state of Karnataka, India. The Krishna River is India's fourth largest river basin, receiving effluent and wastewater from large cities, including Hyderabad, Pune, Kolhapur, Satara and Kurnool.[15] Local sewage treatment plants are typically working beyond capacity, so most wastewater is discharged into the river untreated.

This region is appropriate for this study for several reasons: (1) prior pilot work has established excellent working relationships with local NGOs and community representatives, (2) many of the villages in the area do not currently have access to improved water sources, and (3) since the Krishna River is one of India's most polluted rivers, the capacity of RBF to reduce turbidity, remove heavy metals and remove *Escherichia coli* (the latter measure indicative of bacterial faecal pathogen removal) will be quantifiable.

Site selection

More than 20 villages along the Krishna River were visited by study investigators and evaluated for inclusion in the study. Features assessed included village demographics, current water usage and sources, hydrogeological conditions, availability of suitable land for RBF infrastructure, community receptiveness to installation of RBF systems and commitment to ongoing operation and maintenance of RBF infrastructure. Villages were excluded if: (1) there were an insufficient number of households, (2) untreated river water was not the primary source of drinking water for most households and/or (3) necessary water supply works were unlikely to be feasible due to cost, logistics or community participation. Following application of exclusion criteria, four villages remained that fulfilled the study requirements.

Among selected villages, there is substantial seasonal variation in water availability and accessibility. During the wet season, river levels are high and villagers can collect water from nearby sections of the river. During the dry season, some villagers travel up to 8 km to collect water from the river. A small subset of households have access to alternative water supplies, such as privately piped unfiltered river water, or private bore water.

Engagement

Relevant local information was obtained via meetings between researchers, members of the local government body (Gram Panchayat) and village elders in each of the candidate villages. A participatory community model was used to gather information about existing water supply systems, sanitation facilities, electricity supply, up-to-date population and household statistics and to gauge interest in the project. The planned study design was discussed and village representatives were advised that the RBF intervention would be allocated in a random order.

The Gram Panchayat were asked about barriers, if any, to village participation. Discussions were conducted in the local language, Kannada. Bore wells, pipework, community tanks and village standpipes were marked on a Google map image of each village. Stickers representing pumps, valves, storage tanks and other water supply features (sourced from an Australian Community Water Planner field guide)[16] were then employed to assist in mapping out proposed water supply works with village representatives.

Following identification of four villages that met inclusion criteria and agreed to participation, relevant approvals were sought from the Indian government at a ministerial level (Belgaum District Chief Engineer) and from each Gram Panchayat.

Intervention

The intervention will incorporate a hygiene education program primarily focusing on hand hygiene and safe storage of household water supplies, and a community-level water quality intervention using RBF technology. Educational materials have been developed from open content resources produced by the Centre for Affordable Water and Sanitation Technology (CAWST) and HydrAid, licensed under the Creative Commons Attribution 2.5 Canada Licence. Education will be structured around two posters (see online supplementary figures 1 and 2) which have been translated into the local language, Kannada. Following enrolment, members of each consenting household will be provided with hygiene education by trained fieldworkers, and laminated copies of educational materials will be supplied to each household. A poster focusing on reducing contamination of food and utensils by improving hand hygiene will be provided for display near each household's handwashing station, and a poster focusing on reducing the risk of contamination of stored water by promoting covering drinking water containers and safely accessing drinking water will be provided for display near water storage containers. At each subsequent household visit, the presence and location of these posters will be assessed, and any missing posters replaced. Posters will also be displayed on project tanks and in public spaces in each village.

The water quality intervention will use RBF technology. At each RBF site, one or more wells will be installed in a location at least 50 m away from the river. PVC pipes with a diameter of 15 cm will be used, with vertical slots of ~15 cm length cut into the pipe. If possible, an outer steel casing and a bentonite seal will be installed to protect the PVC well casing. If this is not possible, the uppermost 1 m around the PVC pipe will be excavated and back-filled with concrete. Above the surface, the well heads will be encased in a 1 by 1 m concrete slab for additional protection. The well head will be covered by a steel cap and further protected by a locked steel cage (figure 3). A pump submerged into each well will induce water to flow through porous riverbed (alluvial)

sediments, facilitating removal of pathogens and dissolved/suspended contaminants via a combination of physical, chemical and biological processes.[17] The pump in the RBF well will be sized to provide sufficient pressure to move water from the well to storage tanks. Prior to use, all wells will be sanitised with a solution of one part 5% sodium hypochlorite (NaOCl) bleach to three parts water. Each RBF well will be fitted with a calibrated water meter to gauge volumes of water produced, and a pressure head logger will be installed at each well field to automatically monitor the well's water level.

Covered storage tanks (2000–3000 L), pipes and taps will be installed in all villages during the project's baseline (T0) stage. At least one storage tank will be placed at the topographic highest point in the village to enable gravity flow to tanks and taps, but if gravitational pressure is insufficient, transfer pumps will be installed. If needed, sediment filters will be installed at the RBF well head to remove suspended solids. During the T1 stage, unfiltered river water will be pumped from the river to the storage tanks. Since each village is allocated to RBF, the pipework for that village will be connected to the RBF field by a buried 5 cm plastic pipe.

Depending on the distance from the river, the size of the village and the exact routing of the water distribution system in each village, the length of the pipeline and the number of storage tanks and taps will vary from site to site, that is, the pipeline length will range from about 2000 to 3900 m and the number of storage tanks will be ~12 to 17 per village. For cost reasons, individual tap connections will be installed in appropriate communal locations rather than to each household.

RBF system maintenance will be conducted as required throughout the study. Maintenance will consist of disinfection of the well(s) and/or the pipeline and storage tanks, if indicated by the presence of faecal indicator bacteria in routinely collected water samples. A sodium hypochlorite solution will be prepared, added to the well(s) and pumped through the distribution system. During these maintenance periods, lasting ~24 hours, access to the water distribution system will be prohibited.

Recruitment

All households from each village will be approached. Each household approached will be allocated a unique number irrespective of whether the household consents to participation. Twelve pairs of surveyors (three for each village) who are fluent in English and Kannada will provide an explanatory statement describing the study (see online supplementary appendix B) to a self-nominated adult household representative. The household representative will then be invited to participate in the study and provide consent on behalf of their household. All household members will be eligible for inclusion in the study, regardless of age. At the time of recruitment, householders will also be given the option to provide written informed consent to: (1) participation in future interviews, (2) collection of stored water samples and/or (3) photography of household water storage containers and handwashing area(s). Each household will have the option to participate in up to five subsequent surveys.

Data collection

Health surveys

Twelve pairs of surveyors will be trained to conduct household surveys. In consenting households, each household member will be allocated a person identifier number and identifiable information will be collected (age, first name, gender, relationship to head of household, marital status, educational attainment and main occupation/activity) and entered onto a standardised paper registration form, which will be stored in a secure location (locked filing cabinet with restricted access). All subsequent survey data will be deidentified (using unique household and person identifier numbers only) and collected using an electronic data collection form on handheld electronic tablet devices, designed using Magpi's data collection platform (http://home.magpi.com/). Magpi is a real-time, configurable, cloud-based mobile collection and communication tool with global positioning system coordinates and time stamping. Questionnaires will be written in English, and imported onto tablet devices for onsite data entry. Validation rules and range limits will be used to ensure precise data entry. Following survey completion, deidentified data will be transmitted to a central database via the cloud. During each survey period, study investigators will inspect data on at least a weekly basis to verify data upload, assess completeness of data entry and identify missing data fields and duplicate records. Where required, appropriate remedial action (eg, refresher training of health surveyors) will be undertaken.

Surveys will be administered in Kannada and will include questions on household water sources, storage, treatment and usage, household handwashing facilities and practices, and sanitation facilities and practices. Surveys will also collect information on the health of each household member and on socioeconomic indicators. Specific questions will focus on diarrhoeal, skin and respiratory symptoms, health-seeking behaviour and consumption of water outside of the household setting.

Specimen collection and analysis

River water, RBF tank water and tap water from each village will be sampled at each stage of the study to assess bacteria (E. coli), organoleptic (smell, taste) and physico-chemical (pH, temperature, electrical conductivity, turbidity and dissolved oxygen) parameters using calibrated digital field meters and specialised laboratory equipment. Approximately 6000 water samples will be collected over the entire study period (up to 184 samples per week).

In a subset of consenting households (~160 per village), household stored water samples will be collected alongside the T1–T5 health surveys using
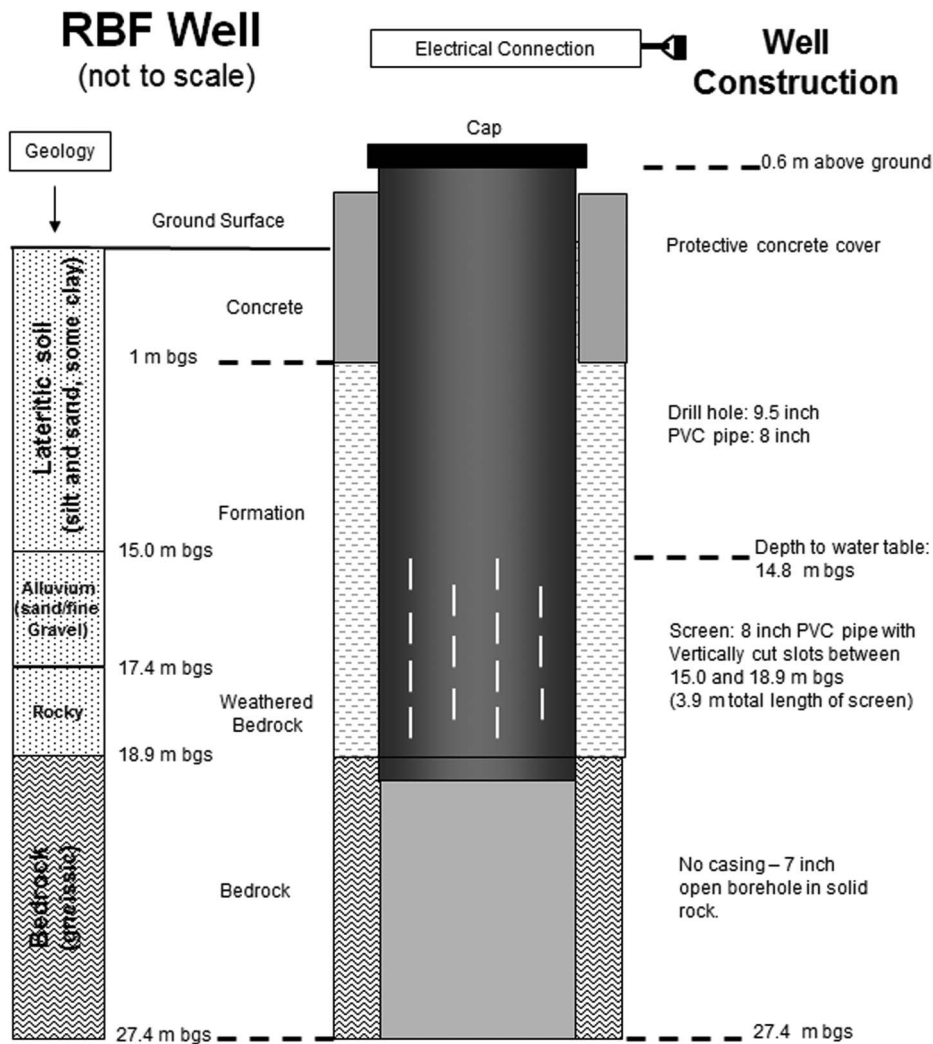
Figure 3   Schematic of a riverbank filtration well.

sterile sample containers and aseptic technique. Results will be compared with samples taken from piped water systems to assess for contamination of drinking water associated with unsafe storage or poor hygienic practices. Stored water samples will be collected 1 week prior to administration of health surveys to enable assessment of temporal associations between contaminated stored household water and reported diarrhoea.

Samples for microbiological testing will be analysed within hours of sample collection by a trained local technician at a purpose-built local laboratory. *Escherichia coli* bacteria will be analysed as most probable number using the US Environmental Protection Agency (US EPA) approved Colilert method (IDEXX Laboratories). Following the Bureau of Indian Standards (BIS) water quality guidelines,[18] a subset of samples will be analysed by an independent laboratory for chemical quality (anions and cations, heavy metals and organic pollutants). RBF system electricity consumption and water output will be recorded in a field journal and/or tablet device.

Water quality, microbiological and chemical testing results for RBF-treated water samples will be assessed according to Indian drinking water quality guidelines.[18] If RBF-treated samples do not meet national standards, the RBF operation will be reviewed and optimised, and/or additional water treatment measures (eg, chlorination) will be considered.

Study outcomes

The primary outcome of the study is a 7-day period prevalence of diarrhoea among villagers of all ages. Secondary outcomes include a 7-day period prevalence of other hygiene-related illnesses (respiratory and skin infections), reported changes in hygiene practices, household water usage and water supply preference. Outcomes will be measured at each of the six survey visits.

Sample size

Sample size estimations for the primary outcome were based on detecting a relative reduction in the prevalence of diarrhoea in the past 7 days with 80% power

and α=0.05. Calculations were based on a two-level hierarchy stepped wedge design structure of individuals nested within villages. We obtained estimates of diarrhoeal prevalence and household size from pilot work conducted in Karnataka, India, that included a survey of 7 villages (110 households).[19] We used a within-village correlation of a 7-day diarrhoea period prevalence of 0.02, which is conservative relative to the value of 0.01 obtained from a large cluster randomised trial in India[20] and estimated a 50% increase in prevalence during the wet season (June–October). On the basis of results of systematic reviews of other water and hygiene interventions,[9] [10] [21] we assumed that our intervention would lead to a ~35% relative reduction in self-reported diarrhoea. The required sample size was obtained using numerical simulation. Hypothetical trial data were simulated from a binary random effects model with a logarithmic link and with the desired within-cluster correlation,[22] followed by an analysis aggregating the data to prevalences for each village at each time point and fitting a linear regression model with the logarithm of the prevalence as the dependent variable, controlling for seasonal effects and with fixed effects for villages. Using this approach, we estimated that 430 households (with an average household size of 5 persons) will need to be recruited from each of the 4 villages to detect a 35% reduction from a baseline diarrhoeal prevalence of 3% with 80% power. Estimated power with a within-village correlation of 0.01 (rather than 0.02) is 87%. We also verified that the type I error rate of 5% was preserved with this procedure with only four villages (clusters). To allow for attrition across the five repeat surveys, we plan to recruit all available consenting households to ensure that adequate power is retained for analysis of the primary outcome.

Randomisation and blinding
Randomisation will be performed by the study statistician (ABF); random ordering of the allocation sequence will be determined from computer-generated uniform random numbers. The allocation sequence will only be made available to two study investigators (ABF and MS). Indian study investigators will be blinded to the allocation sequence with only the next village randomised for rollout being revealed at each intervention implementation time point. Study participants will be blinded to the allocation sequence and those not yet receiving the intervention will not be aware of the time at which they will have the intervention implemented. Blinding to the intervention (ie, the type of water being received) is not possible due to potential differences in turbidity of untreated and RBF-treated river water.

Statistical analysis
The primary outcome (diarrhoeal prevalence) will be calculated for each cell in the stepped wedge design by aggregating over all individuals surveyed in each village during each time period. Estimation of intervention effects will be obtained from a linear regression of the logarithm of the village-aggregated prevalence adjusting for seasonal effects and incorporating village as a fixed effect. The intervention effect coefficient will be exponentiated to produce an estimated relative reduction (with 95% CIs) in the overall prevalence of diarrhoea in the intervention periods (post-RBF) compared with control periods (piped but unfiltered water). This analysis model controls for both clustering of individuals within villages and for repeated assessments of villages over time. Analyses of secondary outcomes will be made using the same methods as above for prevalence outcomes, and using linear regression models of village-time averages without log transformation for continuous outcomes. We will use multiple imputation to impute missing outcomes at the individual person level which will then be aggregated for the village-level analyses. We will perform post hoc sensitivity analyses adjusting for aggregates at the village level of variables that are observed to change over time. We will perform limited subgroup analyses assessing intervention effects in children under 5 years of age and in adults aged over 65 years, although such analyses will have limited power.

Cost-effectiveness and cost–benefit analysis
Economic evaluation of RBF will be performed at the conclusion of the study. Cost-effectiveness of RBF for prevention of illness, especially diarrhoea, will be measured and reported as cost per event prevented and cost per disability-adjusted life year averted. Benefits including productivity gains will be quantified, cost-effectiveness ratios and a cost-benefit analysis will be evaluated and extensive sensitivity analysis will be performed to assess the impact of cost drivers and uncertain variables.

Strengths
This is the first randomised controlled study to assess the health impact of a community-level water intervention using RBF technology. This community-level study is also novel as it considers the impact of interventions that target increased water access and improved water quality. The stepped wedge RCT design allows all participants to eventually receive the intervention, improving equity and acceptability. While waterborne and hygiene-related illnesses vary with temporal factors such as season, we are able to control for temporal effects in the model because these factors apply to all villages together and the stepped wedge model includes a time factor variable. Factors that remain constant over time (eg, demographic factors such as age and gender) will be controlled for in the statistical analyses involving within-village comparisons.

Limitations
The incorporation of only four clusters (villages) in the trial may limit the generalisability of results. While characteristics of study villages (eg, literacy, employment and household sizes) are comparable to Karnataka state

averages, they may not be generalisable to the rest of India. Baseline imbalances (eg, the proportion of persons from Scheduled Castes, the proportion of children aged under 5 years and open defecation rates) will be dealt with using fixed village effects. Our analyses are purely within-village comparisons; hence, village-level factors that differ across villages at baseline but remain constant over time are automatically controlled for in these analyses.

While the allocation sequence will not be revealed to participants, we expect that participants will become aware that they are receiving the intervention (RBF-treated water) due to potential differences in turbidity and taste of untreated river water and RBF-treated water. Since water usage and health symptoms will be self-reported and blinding is difficult, any preconceived ideas about the value of increased water quantity or water treatment could bias symptom reporting. This so-called 'courtesy bias' (a degree of minimisation of symptoms) might occur when piped water is initially delivered (T1), or when RBF is supplied (T2–5). To detect courtesy bias and assess the validity of self-reporting, we have included falsification symptoms in health surveys (such as the presence of scrapes or bruises or urinary tract symptoms). These fairly common symptoms have been deliberately chosen as they might be prone to courtesy bias, but would not be expected to be affected by the RBF intervention.

Contamination of stored water within the household may bias the effect of consuming RBF-treated water; however, collection of household stored water samples prior to health surveys in a subset of households will allow an assessment of the likelihood of contamination and the relationship between the microbiological quality of stored drinking water and diarrhoea.

Our primary research question is based on the provision of RBF-treated water rather than adherence to the intervention, as indicated by our use of an intention-to-treat analysis. However, we expect that adherence to RBF-treated water will be imperfect, as alternative drinking water sources are available to study participants. Each survey will collect information on preferred household drinking water sources, and this information will be reported, as the use of alternative water sources may be a limitation of the intervention.

Safety and data monitoring

This is a low-risk study, and there are no foreseeable risks to participants from the intervention. Therefore, a data monitoring committee is not required and no interim analysis is planned.

DISSEMINATION

Surveyors will provide householders with a written explanatory statement and will verbally explain the broad aims of the study before providing householders with an opportunity to ask questions. Participants will be advised at the time of recruitment that participation in the study is voluntary and that they may withdraw from the study at any time. Written signed consent will be obtained from an adult householder (aged ≥18 years). For illiterate participants, an ink thumb-print will be used in lieu of a signature.

Any modifications to the protocol which may impact on the conduct of the study (eg, changes to eligibility criteria, outcomes, analyses) will be approved by ethics committees in Australia and India prior to implementation, and communicated to participants and other relevant stakeholders via written correspondence. Protocol changes will also be formally documented on the ANZCTR website.

Results of the study will be published in peer-reviewed journals, presented at national and international conferences, and discussed with project partners. Participants will have access to results via access to The Energy and Resources Institute (TERI) and Monash University websites, which will contain a summary of the study findings. In addition, summary results will be sent to village elders for their dissemination to the community.

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