Appendix A: World Health Organization Trial Registration Data Set

DATA CATEGORY	INFORMATION
Primary registry and trial identifying number	Australian New Zealand Clinical Trials Registry ACTRN12616001286437
Date of registration in primary registry	13/09/2016
Secondary identifying numbers	U1111-1187-3423 (Universal Trial Number) NHMRC1083408 (Grant number from National Health and Medical Research Council Australia)
Source(s) of monetary or material support	National Health and Medical Research Council
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Public title	Evaluating the impact of hygiene and water interventions on diarrhoeal disease in India
Scientific title	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
Countries of recruitment	India

Health conditions(s) or problems(s)	Diarrhoea
studied	Respiratory infections
	Skin infections
Intervention(s)	Intervention: delivery of a community-level hygiene education program and delivery of riverbank filtration (RBF) treated water at a community level (improved water quality) Control: delivery of a community-level hygiene education program and improved access to untreated river water at a community level (improved water quantity)
Key inclusion and exclusion criteria	Ages eligible for study: all Sexes eligible for study: both Village inclusion criteria: rural villages in India currently using untreated river water as a primary source of drinking water, hydro-geologic conditions allowing construction of RBF systems, availability of suitable land for RBF system installation and community receptiveness to installation of RBF systems and commitment to ongoing operation and maintenance Village exclusion criteria: villages with less than 500 households, where untreated river water is not a primary source of drinking water for most households, and/or where hydro-geologic conditions are unsuitable or land not available for RBF installation
Study type	Type of study: Interventional Randomisation performed by statistician with order determined from computer generated uniform random numbers. Allocation sequence known to statistician and one other investigator. Other investigators and participants blinded to allocation sequence. Primary purpose: prevention
Date of first enrolment	25/02/2016
Target sample size	1720 households
Recruitment status	Recruiting
Primary outcome(s)	Self-reported diarrhoea (7 day period prevalence)
Key secondary outcomes	Self-reported respiratory infections (7 day period prevalence) Self-reported skin infections (7 day period prevalence) Self-reported hygiene practices Self-reported preferred/adopted domestic water supply and household water consumption