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# A community randomised controlled trial evaluating a home-based environmental intervention package of improved stoves, solar water disinfection and kitchen sinks in rural Peru: Rationale, trial design and baseline findings ☆

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ABSTRACT

*Introduction:* Pneumonia and diarrhoea are leading causes of death in children. There is a need to develop effective interventions.
*Objective:* We present the design and baseline findings of a community-randomised controlled trial in rural Peru to evaluate the health impact of an Integrated Home-based Intervention Package in children aged 6 to 35 months.
*Methods:* We randomised 51 communities. The intervention was developed through a community-participatory approach prior to the trial. They comprised the construction of improved stoves and kitchen sinks, the promotion of hand washing, and solar drinking water disinfection (SODIS). To reduce the potential impact of non-blinding bias, a psychomotor stimulation intervention was implemented in the control arm. The baseline survey included anthropometric and socio-economic characteristics. In a sub-sample we determined the level of faecal contamination of drinking water, hands and kitchen utensils and the prevalence of diarrhoegenic *Escherichia coli* in stool specimen.
*Results:* We enrolled 534 children. At baseline all households used open fires and 77% had access to piped water supplies. *E. coli* was found in drinking water in 68% and 64% of the intervention and control households. Diarrhoegenic *E. coli* strains were isolated from 45/139 stool samples. The proportion of stunted children was 54%.
*Conclusions:* Randomization resulted in comparable study arms. Recently, several critical reviews raised major concerns on the reliability of open health intervention trials, because of uncertain sustainability and non-blinding bias. In this regard, the presented trial featuring objective outcome measures, a simultaneous intervention in the control communities and a 12-month follow up period will provide valuable evidence.


☆ Trial registry: http://www.controlled-trials.com/ ISRCTN28191222.

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## 1. Introduction

Acute respiratory infections and diarrhoea are leading causes of child mortality worldwide [1]. It was estimated that half of the annual deaths due to lower respiratory infections and 80% of the diarrhoea attributable mortality are linked to environmental risk factors, such as indoor air pollution due to incomplete combustion [1,2] and inadequate access to safe water supply, sanitation facilities and hygiene [3]. Air pollution due to incomplete combustion of biomass fuels account for 2.9% of worldwide deaths per year, and for 3.7% of the overall disease burden in developing countries [4]. Similarly, unsafe water and sanitation account for 9% and under nutrition is the estimated underlying cause for one third of under-five mortality [5].

Under-five child mortality due to preventable conditions, such as improving water, sanitation and hygiene, and indoor and outdoor air pollution became a global priority [6]. Several low cost, efficient and effective interventions, such as providing running water within the kitchen area, improving water quality through household water treatment and washing hands using soap are acceptable interventions in most communities. They contribute effectively to the prevention of diarrhoeal diseases and the transmission of acute lower respiratory infection (ALRI) [7–10]. A recent systematic review provided evidence that hand washing with soap can reduce child diarrhoea by 48%, and the risk to acquire a diarrhoeal illness can be reduced by 17% and 36% through adequate household water treatments (HWT) and improved sanitation [11]. Similarly it has been shown that simple indoor air quality interventions reduce disease burden for ALRI [4]. Biomass fuel smoke contains a large range of health-damaging pollutants that can cause mucous membrane irritation and aggravate respiratory diseases by reducing the resistance to infection [12,13]. A recent meta-analysis determined a pooled odds of disease of 1.8 for children exposed to cooking with solid fuels [14,15].

According to the WHO country profile, 19% of Peru's environmental burden could be prevented by environmental improvements [16]. Several “improved stoves” programmes of government and NGO were developed to reduce indoor air pollution as environmental health hazard [17,18]. However, stoves come in a variety of designs and their efficiency in reducing children's respiratory problems has not always been evaluated [19]. In addition to the national stove improvement programme, several large scale programmes were implemented to increase piped water and sanitation in rural Peruvian populations [17,20].

We developed an Integrated Home-based Intervention Package (IHIP) to improve unsafe drinking water and hygienic conditions and indoor air pollution from biomass fuel combustion. In an extended community participatory approach we developed a home-based environmental intervention package comprising an improved, ventilated stove to reduce indoor air pollution; a kitchen sink to increase water and kitchen hygiene and a solar disinfection home-based water treatment (HWT) to improve drinking water quality [21]. The hardware interventions were complemented with a hand washing-with-soap and kitchen hygiene educational component to enhance potential effects to reduce acute child diarrhoeal and respiratory infections diseases and their effects on child growth. We describe the design and baseline characteristics of a community-randomised controlled intervention trial to evaluate the effectiveness of an IHIP.

## 2. Methods

### 2.1. Study area and population

The study was conducted in the San Marcos Province, Cajamarca region, northern Peru. We selected this area for its number of well separated accessible rural communities, and because no health related intervention programmes were currently being implemented. Most of the local residents were small-scale farmers, living in small houses with earthen floors and adobe walls, with three or more persons sleeping in the same room and with traditional stove or open fire for cooking. To identify eligible rural communities and households with children aged 6–35 months, trained field worker conducted a house-to-house preliminary screening between March and June 2008 and identified an initial group of 56 rural communities complying to the following criteria: i) no access to potable water and sewage systems, ii) the majority of the population used biomass fuel for cooking and heating, and iii) were located in a 90-minute drive range away from the project office in San Marcos town.

### 2.2. Trial design

We implemented a community-randomised controlled field trial to evaluate the efficacy of the IHIP interventions on reducing the rate of acute diarrhoeal illness, acute lower respiratory infection and child growth in children aged 6 to 35 months at enrolment over a 12 month surveillance period. Morbidity surveillance started after all IHIP-interventions were in place (February 2009).

Due to the nature of the intervention, blinding was not possible. As a strategy to reduce non-blinding bias, a child psychomotor development intervention was implemented in the control arm as an equivalent to the IHIP in the intervention arm. Psychomotor development of children in both arms was evaluated using a standardised and validated assessment tool used by national authorities. For balancing the intensity of the contact at the household level over the 12-month surveillance period motivational and monitoring follow-up procedures including morbidity, anthropometric and psychomotor evaluations were done in both study arms at similar a rate of recurrence.

A household was considered eligible for the study if the following criteria were met: a) at least one child aged 6 to 35 months living in the home, b) using wood or solid fuel as main energy source for cooking, c) not being connected to public sewage, and d) tenants planning to stay in their home for the next 12 months. A household was excluded if a) the child had any congenital abnormalities or suffered from a chronic debilitating illness, and b) families that had two or more households in different geographical areas with migration within sites that lasted more than 6 months during the year (mainly for migratory agriculture practices).