Reducing childhood illness – Fostering growth
An integrated home-based intervention package (IHIP) to improve indoor-air pollution, drinking water quality and child nutrition

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EXECUTIVE SUMMARY

Child mortality attributable to pneumonia, diarrhoea and malnutrition accounts globally for the majority of 8.8 million annual deaths. More than half of these deaths are preventable. Available and effective interventions include safe water supply, household water treatment, improved chimney stoves and personal- and home-hygiene and -health messages. In Peru, the current health services reform is focused on shifting responsibilities to peripheral levels, i.e., the Regions (secondary geopolitical division in the country); thus, empowering community organisations to manage primary health care services, including health promotion and preventive measures at household level. This government decision is in line with Peru's efforts (of the past two decades) in poverty alleviation, by increasing the quality and quantity of employment, focusing on education and health, and consolidating democracy and the rule of law. This current political situation and policy framework to integrate effective preventive interventions that can be delivered by local institutions and programmes at family level, prompted us to test the efficacy of a package of proven effective health interventions to reduce childhood illness burden at rural household level of diarrhoea, pneumonia and under-nutrition.

The goal of this PhD thesis was to assess the efficacy of an Integrated environmental Home-based-Intervention Package (IHIP), comprising improved chimney stoves, access to safe drinking water from solar radiation based household water treatment (SODIS), and hygiene education interventions, to reduce morbidity of acute respiratory infections, diarrhoea and poor growth of rural Peruvian children under three years of age.

We implemented a community-randomised control field trial (cRCT) in 51 communities clusters to evaluate the IHIP-project in reducing the rate of acute diarrhoea illness, acute lower respiratory infection (ALRI) and promoting child growth in children aged 6 to 35 months in rural communities of the San Marcos Province, Cajamarca Region, Peru. The cRCT was divided into stages:

- Set-up, community selection and participatory intervention development: The project site was selected and agreements were signed with local authorities. Additionally, a pilot

phase was carried out for the selection of the IHIP interventions and the adaptation of these to local customs, preferences and beliefs. This participatory phase is described in detail in Chapters 4 & 5.

- Randomization and Enrolment: The 51 community were randomised into the IHIP and control groups, using covariate-based constrained randomisation as proposed by Moulton.
- Baseline Data Collection: We collected socio-economic and demographic household attributes, microbiological data and anthropometric measurements. Chapter 6 describes the randomisation, enrolment and baseline in detail.
- Carbon monoxide (CO) and Particulate Matter ($PM_{2.5}$) household air quality assessment: Chapter 7 & 8 describe the efficacy of the OPTIMA-improved stove in improving household air quality in comparison to traditional open fire stoves and other stove models locally available and used.
- Morbidity surveillance and field data acquisition: Trained field workers visited each household weekly and collected morbidity data from mothers regarding the daily occurrence of signs and symptoms diarrhoea and respiratory illnesses of their children. Anthropometric measurements were taken every two months and microbial sampling fom mothers' hands, kitchen wipes and drinking water was collected every 6 months, at baseline construction phase, at mid-term and at end-of-study. Chapter 9 describes the IHIP impact on morbidity reduction.
- Workshops for a community-driven sustainable roll-out of the IHIP interventions: The workshops were organised in the community's elementary school; community members, district and municipal health professionals, teachers and local authorities took part. As part of the roll-out phase, evaluations and compliance surveys were carried out three and twelve months after the the roll-out capacity building workshops. Chapter 10 describes the processes and dynamics at individual, household, community and institutional level applying a socio-ecological framework for analysis. It describes the achievement of the community-driven auto-dessemination and level of replication of the IHIP intervention package.

Our community-randomised control trial demonstrated that IHIP reduced 22% per year of child diarrhoea (RR 0.78, 95% CI: 0.49-1.05) and found an odds ratio of 0.71 for diarrhoea prevalence (OR 0.71, 95%, CI: 0.47, 1.06). No effects on the frequency of acute lower respiratory infections (RR 0.99, 95% CI: 0.59, 1.65) or child's growth rates were found when comparing study arms. We identified three reasons for this moderate diarrhoea reduction: i) hand-washing promotion was universally found in our setting, since it is being promoted by the health care centre; ii) SODIS compliance was moderate: only one third of the beneficiaries were using the method regularly; and iii) the increased awareness for the child's needs linked to the control intervention, could induce improved child care behaviour. The lack of effect on ALRI, could be linked to insufficient reduction in exposure to household air pollutants and high health service utilisation due to cultural beliefs and health seeking customs. The household air pollution assessment study revealed only moderate reductions of 45% and 27% reduction of $PM_{2.5}$ and CO, respectively for mothers' personal exposure. This result was achieved in the best working stoves only. This may most likely not be sufficient to reduce impact on physician-diagnosed pneumonia.

Community participatory meetings and surveys (carried out at the meetings) revealed that people's decisions on adopting household-level environmental and hygiene interventions, was not only based on individual perceptions of their potential gains, but also depended on peer pressure, social network relations and how technical construction knowledge was communicated, applied and spread within the community. In addition, individual perceptions regarding pollution levels of water and household air (transparent, odourless water *vs* dirty air environments) influenced perceived gains and the adoption of certain interventions; especially in relation to the improved chimney stoves. Access to information on how to build a stove also accelerated roll-out activities. Adoption was further enhanced when health-care providers and programme implementers - including civil social organisations - encouraged the use of interventions, especially when in line with governmental policies.

The IHIP had several additional benefits beyond health outcomes. Households stated that the stoves reduced cooking time and effects related from open fire and indoor smoke emissions reduced wood consumption, which resulted in reduced household expenses for firewood, other costs for cooking, and substantial time savings during preparation of food and cooking, included being able to perform other task while cooking, which was a new possibility. Additionally, mothers reported on the benefits of the kitchen sink, stating that it facilitated handwashing, and washing of utensils with detergent, generating a cleaner kitchen environment and fostered home and food hygiene in general. The IHIP package motivated families to improve the kitchen living area in general. The overwhelming acceptance and sustained use was not only observed in the IHIP families but also in non-participating families, that had copied the OPTIMA-improved stove after the community engagement in the roll-out activities, and were using it daily, even 16 months after the first stoves had been built. We conclude that the IHIP package added to the family status within the community, improved quality of life and impacted on their livelihoods, by empowering the beneficiary families.

In conclusion, through this project we envisaged to demonstrate how an integrated package with already available effective interventions can be implemented at the household level in rural areas of the country. IHIP interventions have additive effects. However, behaviour change for intervention adoption is necessary to achieve compliance, replication and sustainability. We have provided a unique view on how to deliver interventions, and innovative deliveries are the kind of evidence needed to fortify existing initiatives. Achieving the incorporation of a new intervention in the target population is a complex dynamic that goes beyond the acceptance and initial use. It depends not only on the sustained support from the policy levels down to community development actors and institutions present in the field. It also depends on the characteristics of the users, the intervention at hand, the perceived benefits and the degree in which the users are willing to incorporate the intervention in their way of life.

RESUMEN EJECUTIVO

La mortalidad infantil atribuida a neumonía, diarrea y malnutrición es responsable de la mayor parte de las 8.8 millones de muertes anuales (Black et. al. 2010). Mas de la mitad de estas muertes son prevenibles si se utilizaran las intervenciones adecuadas (Rehfuess et al. 2009; Bruce et al. 2007). Para poder proveer este tipo de intervenciones, sistemas de agua potable, tratamiento de agua al nivel del hogar, cocinas mejoradas y mensajes de higiene, tenemos que mejorar los mecanismos de difusión en diferentes niveles, sistemas de salud, actores locales y al nivel del hogar. En el Perú, la reestructuración los servicios de salud a nivel regional (segunda división geopolítica del país), se han echo para mejorar su manejar, empoderar a las organizaciones locales y mejorar los sistemas primarios de salud, incluyendo la promoción y prevención de enfermedades al nivel del hogar (PCM, 2011). El estado Peruano –en las ultimas dos décadas- se ha dedicado a batallar la pobreza, incrementando la calidad y cantidad de trabajo, enfocándose y mejorando la educación y salud y consolidando la democracia y ley del estado (EC, 2007). Esta situación política, ha echo posible integrar intervenciones preventivas en salud que puedan ser llevadas acabo por instituciones locales y por programas que se centren a nivel del hogar. Esto nos llevo a evaluar la eficacia de un paquete de intervenciones, el cual se enfoca en las tres principales causas de morbilidad infantil en el Perú y el mundo: diarrea, neumonía y malnutrición infantil. A través de este proyecto queremos demostrar como un paquete integral con intervenciones previamente demostradas puede ser implementado a nivel del hogar en las zonas más pobres del país.

El objetivo del estudio es reducir la morbilidad de enfermedades respiratorias, diarrea y mejorar la nutrición en niños menores de 5 años por un 20% o mas en el grupo de intervención. Para lograr este objetivo, implementamos un Paquete Integral de Intervenciones a Nivel del Hogar (IHIP), el cual comprende una cocina mejorada, un lavatorio en la cocina, acceso a agua limpia a través de un método de tratamiento a nivel del hogar y dos intervenciones sobre higiene personal en el hogar.

Implementamos un estudio randomizado a nivel del hogar (cRCT) en 51 comunidades, para evaluar la efectividad del paquete de intervenciones para en reducir enfermedades diarreicas

agudas, las infecciones respiratorias agudas bajas (ALRI) y promover el crecimiento en niños entre 6 y 36 meses de edad en comunidades rurales de la provincia de San Marcos, Cajamarca, Perú. El cRCT fue dividido en etapas, cada una con sus objetivos específicos:

- Selección de comunidades y desarrollo de las intervenciones: se selecciono la ubicación donde se llevo a acabo el proyecto y se firmaron los acuerdos con las autoridades localidades. Adicionalmente llevamos acabo un estudio piloto donde seleccionamos las intervenciones junto con las poblaciones y adaptamos las intervenciones a las creencias locales para asegurar su utilización durante el estudio. La fase se describe en mayor detalle en los Capítulos 4 y 5.
- Randomizacion y enrolamiento: Durante esta fase las 51 comunidades fueron randomizadas a los grupos IHIP y control.
- Información de Línea de Base: Colectamos información socio-económica y demográfica de las viviendas, muestras microbiológica e hicimos mediciones antropométricas de talla y peso para evaluar el estado nutricional en los niños. El Capítulos 6 describe la randomizacion, enrolamiento e información de línea de base en mayor detalle.
- Mediciones de CO y PM2.5: Los capítulos 7 y 8 describen la eficiencia de la cocina mejorada “OPTIMA-improved stove” para mejorar la calidad de aire de interiores comparando los resultados con las cocinas tradiciones y fogones abiertos encontrados en las casas control.
- Monitoreo de morbilidad y adquisición de la información: Los trabajadores de campo entrenados visitaron las viviendas semanalmente para recolectar la data de morbilidad en la ocurrencia de signos y síntomas de las enfermedades respiratorias y diarrea. Se tomaron mediciones antropométricas cada dos meses y colectamos información microbiológica a la mitad y al final de estudio. Estos resultados se describe en detalla en el Capitulo 9 del presente documento.
- Talleres de desimanación: Talleres finales fueron organizados en las escuelas, se invitaron a los miembros de las comunidades, profesiones de salud, profesores y autoridades locales. Como parte de la fase de diseminación, evaluamos la extensión de la desimanación tres y doce meses después de haber llevado a cabo los talleres. El capitulo 10 describe a detalle los niveles de replicación del paquete de intervenciones.

Nuestro estudio demostró que en las familias que utilizaron este paquete de intervenciones IHIP, sus niños tuvieron una reducción las enfermedades diarreicas en un 22% por año (RR 0.78, 95% CI: 0.49-1.05) y una reducion de 0.71 fue encontrada en la razon de momions para diarrea longitudinal (OR 0.71, 95%, CI: 0.47, 1.06). No se observaron reducciones en la frecuencia de enfermedades respiratorias agudas bajas, ni en el crecimiento de los niños al comparar ambos grupos del estudio. Identificamos tres razones para explicar la moderada reducción en diarrea: i) la promoción del lavado de manos por parte del centro de salud es encontrado universalmente en las comunidades, ii) la utilización de SODIS fue baja, solamente observando un tercio de las familias que utilizaban el método y iii) suponemos que las intervenciones del grupo control pudo haber generado un cambio en el comportamiento de las madres sobre la salud de los niños en el grupo control. Para ALRI encontramos que no tuvimos una reducción significativa en CO y $PM_{2.5}$ a nivel del hogar y a nivel personal (Capítulos 7 & 8). La segunda razón puede deberse al comportamiento para buscar ayuda en los establecimientos de salud (Capitulo 9). Adicionalmente un estudio determinó que se necesita una reducción del 50% de CO para poder observar in impacto en neumonía diagnosticada por un médico (Smith et al. 2011).

Para determinar si las intervenciones IHIP pueden ser auto-diseminadas realizamos un taller final donde presentamos los resultados de las intervenciones y fomentamos su uso a través de sesiones demostrativas. Estas sesiones y las subsiguientes encuestas que realizamos reveló que las decisiones que lleva a las personas a utilizar las intervenciones no solamente se basan en percepciones individuales, pero también dependen de presiones ejercidas por los grupos sociales, las relaciones interpersonales en estos grupos y el acceso de la información, por ejemplo saber como construir una cocinas. Adicionalmente, las percepciones individuales referentes a la contaminación del aire o el agua en le hogar (aire sucio vs. agua transparente y limpia) influencia su percepción de cual intervención les conviene adoptar, en este caso las cocinas mejoradas. Acceso a la información de como construir una cocina también acelera el proceso de diseminación especialmente cuando los implementadotes del programme fomentan el uso de estas y aun mas cuando estas están en línea con políticas nacionales.

Las intervenciones del IHIP tienen otros beneficies aparte de los ligados a salud. Las viviendas que tuvieron las intervenciones nos informaron que las cocinas reducen el tiempo para terminar una comida, las secuelas ligadas al humo (ojos irritados y toser) ya no son persibidas y ya no no gastan tanto en colectar o compara leña semanalmente. Adicionalmente las madres reportaron los beneficios que los lavatorios les brindan. La posibilidad de tener agua corriendo en el ambiente de la cocina es un beneficio increíble cuando tienen que lavar los utensilios de la cocina, lavarse las manos y mejorar la higiene de sus cocinas en general. El paquete de intervenciones motivo a las madres a mejorar le ambiente de las cocinas en general. Por último la aceptación universal del paquete de intervenciones fue sorprendente, con nuestras madres participantes y con familias que se copiaron las intervenciones después de los talleres de diseminación. Creemos que el paquete de intervenciones también mejora el estatus de las familias, mejora la calidad de vida, sus capitales y empodera a las familias.

En conclusión es posible que el paquete de intervenciones IHIP pueda tener un efecto mayor sobre la salud en los niños, pero al introducir varios mensajes simultáneamente, las familias pueden haberse abrumado, haciendo que no se utilicen de la manera mas optima. Adicionalmente, el cambio en el comportamiento que se necesita para la adopción de una intervención y que esta sea utilizada, replicada y sostenida en el tiempo es enorme. Sin embargo, hemos proporcionado una visión única de como entregar un paquete de intervenciones de una manera innovadora y hemos generado la evidencia necesaria para fortificar las intervenciones existentes. Sabemos que para hacer que una población adopte una intervenciones es un proceso complicado que se base en complejas dinámicas, las cuales van mas allá de solamente aceptar el paquete. Depende de la característica de los usuarios, la intervención que deben utilizar, y los beneficios percibidos. Es por eso que consideramos que este paquiete de intervenciones es el primer paso para lograr intervencioens sostenibles que tengan un impacto sobre la salud.

ABBREVIATIONS

AGRORURAL	Rural Productive Agrarian Development Programme
AGROBANCO	Agricultural Bank
ALRI	Acute Lower Respiratory Infections
ANA	National Water Authority
APCI	Peruvian International Cooperation Agency
ARI	Acute Respiratory Infections
BMF	Biomass Fuel
CCT	Controlled Cooking Test
CENAN	National Center for Feeding and Nutrition
CFU	Colony Forming Units
CHERG	Child Health Epidemiology Research Group
CNISP	Chinese National Improved Stove Program
CO	Carbon Monoxide
COPD	Chronic Obstructive Pulmonary Disease
cRCT	Community Randomised Control Trial
CRECER	National Strategy for Poverty Reduction and Chronic Malnutrition
DAEC	Diffuse-adherent *E. coli*
DALY	Disability Adjusted Life Years
EID	Enteric infectious disease
EAEC	Enteroaggregative *E. coli*
EIEC	Enteroinvasive *E. coli*
EKBB	Ethikkommission Beider Basel
EPA	Environmental Protection Agency
EPEC	Enteropathogenic *E. coli*
ETEC	Enterotoxigenic *E. coli*
EU	European Union
FONCODES	National fund for Cooperation and Social Development
GACC	Global Alliance for Clean Cookstoves
GDP	Gross Domestic Product
GEE	Generalized Estimating Equations
HAP	Household Air Pollution
HAZ	Height-for-age
HWT	Household Water Treatment
IDR	Incidence Density Ratios
IDS	Institute of Development Studies
IHIP	Integrated Home-based Intervention Package
IIN	Nutritional Research Institute
INABIF	National Programme for Family Wellbeing
INDECI	National Institute of Civil Defence
INEI	National Institute of Statistics and Informatics’
INS	National Health Institute
IRR	Incidence Rate Ratio
JUNTOS	National Programme - Direct Support for the Most Poor

KPT	Kitchen Performance Test
MDG	Millennium Development Goals
NBI	National poverty indictors
NGO	Non Governmental Organizations
NIOSH	National Institute for Occupational Safety and Health
NO	Nitrogen Dioxide
NPIC	Indian National Programme on Improved Chulhas
OBEC	Scholarship and Educational Credit Offices
OR	Odds Ratio
OSHA	Occupational Safety and Health Administration
PCM	Presidency of the Ministry Council
PCR	Polimerase Chain reaction
PET	Polyethylene Terephthalate Bottles
PM	Particulate Matter
PRONAA	Integrated Nutritional Programme
PRONAMA	National Programme for Alphabetization
PRONASAR	National Rural Water and Sanitation Programme
PRONIED	National Programme for Education Infrastructure
PRONOEI	Early Child School Programme
PNCVPS	National Programme again Sexual and Family Violence
PSI	Sectorial Irrigation Programme
RESPIRE	Randomised Exposure Study of Pollution Indoor & Respiratory Effects
RR	Relative Rate
RSV	Respiratory Syscytial Virus
SENASA	National Service of Agrarian Sanitation
SIS	Integrated Health Insurance
SODIS	Solar Disinfection
STEC	Shiga-toxin producing *E. coli*
ST-CIAS	Technical Secretarial Inter-ministerial Commission of Social Affairs
TEPSI	Psychomotor Development Test
UN	United Nations
UNICEF	United Nations Children's Fund
WHO	World Health organization
WAZ	Weight -for-age

PART I: INTRODUCTION, BACKGROUND, OBJECTIVES AND METHODOLOGICAL OVERVIEW OF THE INTEGRATED-HOMES BASED PACKAGE (IHIP)

1.0 INTRODUCTION

1.1 Population and Disease - childhood diseases at household level

The world changed in the last centuries; global population has gone from proximately 1.6 billion around 1900 to over 7 billion, and more than half migrated to urban areas seeking better conditions and opportunities (UN, 2010). Still, nearly 1 billion people do not have access to improved drinking water sources, 2.6 billion do not have access to improved sanitation and about half of the world's population still relies on biomass fuels for cooking, heating and lighting (Rehfuess et al. 2006). Furthermore worldwide, approximately 8.8 million children under five die each year, due to two main causes: pneumonia (18%) and diarrhoea (15%), which accounted for 2.9 million deaths in 2008 (Black et al. 2010). Half of these deaths can be attributed to environmental risk factors, such as household air pollution, (Rehfuess et al. 2009; Bruce et al. 2007, Prüss-Ustun and Corvalan, 2006), unsafe drinking water, inadequate sanitation and insufficient hygiene; thus, being preventable with solid environmental interventions (WHO, 2008). The environmental conditions in which these children live (lack of water supply, insufficient sanitation, no access to clean household air and lack of hygiene) generate household conditions in which disease transmission pathways - via faeces or air pollution- are not only possible but rather likely to occur.

In recent years, water quantity and quality has been the subject of considerable attention in the quest to improve community and child health. The United Nations Millennium Development Goals (MDGs) encapsulated a global agreement to tackle the persistent health, social and economic effects of poverty. The MDGs included a target for access to safe drinking water, Target 7c stating that it is necessary to reduce by half, between 1990 and 2015, "the proportion of the population without sustainable access to safe drinking-water and basic sanitation" (UN, 2010). Many governmental and non-governmental organizations have focused their efforts in installing water supply systems and introducing household water treatments to improve water quality at point of use. Nevertheless, public infrastructure can only be fully effective if employed in conjunction with safe hygiene practices at home (Curtis et. el. 2000). According to Curtis (Curtis et. al. 2011), promotion of hygiene might be the single most cost-effective way of reducing the global burden of infectious disease (diarrhoeal and respiratory diseases) and others have shown that handwashing for example may have a dual effect on the reduction of child diarrhoea and respiratory infections (Cairncross 2003) However, funding for hygiene interventions such as hand washing with soap, safe food handling and the removal of animal faeces have been neglected until recently (www.globalhandwashing.org/). It has only been recently that governments, funding agencies and policy makers have accepted that hygiene promotion needs to play a mayor role in achieving health benefits at personal and community levels.

Household air pollution has also mainly been considered in isolation and as an environmental problem by itself. Exposure to household air pollution from the use of biomass fuels was recently considered a public health problem affecting around 50% of the world's population (Smith & Mehta, 2003). Previously, research, guidelines and policies had only focused on and addressed the health effects of ambient air pollution. The recent shift towards the home environment, has also stimulated recent global initiatives to consider improved chimney stoves as the most cost-effective response to household air pollution (Global Alliance for Clean Cookstoves), and in the Peruvian context the national initiative "Half a Million Improved Stoves for a Smokeless Peru" was launched in 2009 (Bodereau, 2011). However, these initiative will have only lasting health impacts if smoke reduction devices are adequately designed to reduce air pollutants below health hazardous concentrations, are installed, maintained, and used appropriately (Naeher, 2007, Ruiz-Mercado, Masera et al. 2011)). Additionally, a reduction in the proportion of population that relies on solid fuels can also help achieve the MDG 7a, "Ensure Environmental Sustainability". In Peru alone, if we estimate that each family consumes around 9 kg of wood per day (Hartinger, et. al. 2012), which translates to 18 million kg of wood burned daily, just for a family to meet basic energy needs for cooking, boiling water, and lighting, this creates a considerable ecological pressure on forests, particularly in areas where biomass is scarce and the demand for wood outweighs natural re-growth (Rehfuess et al. 2006).

The improvement of community and child health relies on the successful development, validation and application of effective interventions, and perhaps more importantly, their successful adoption, compliance and future replication. This process is complex.

Incorporating a new effective intervention follows a complex dynamic that goes beyond the acceptance and initial use. It depends among other factors, on the characteristics of the users, the intervention options available, the perceived benefits by the end users, their social networks and the access to information, on how the interventions and their effects/impacts are communicated and spread within the community (Rogers, 2005). On a global scale, steps have been taken to improve decision-making by governmental and public health planners with regard to environmental health issues and -interventions. Research generating evidence for development processes can produce necessary and valid tools and approaches to map, measure and understand the community dynamics to address mitigating actions.

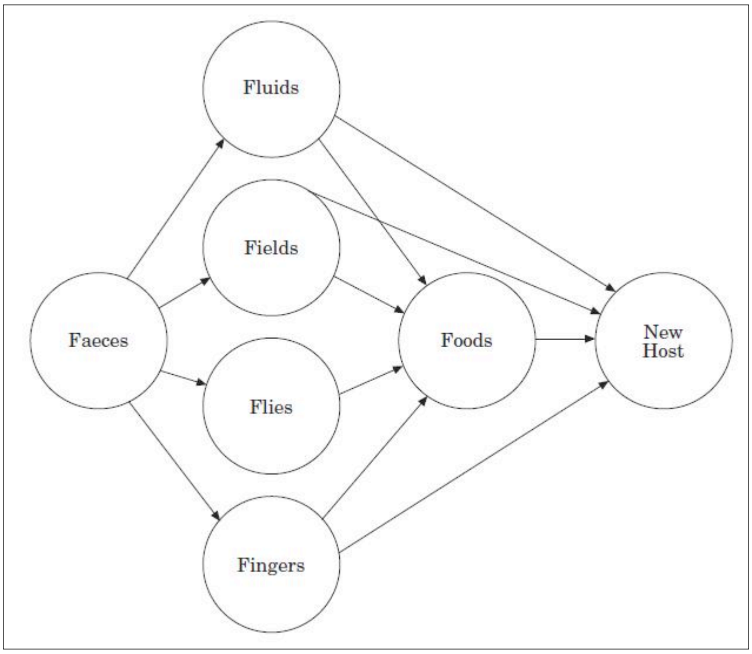
1.1.1 Water related disease and pathways of transmission

Diarrhoeal diseases are the leading cause of death and malnutrition in children under five years of age; responsible for 1.5 million deaths per year (Black et al. 2010). About 80% of the deaths due to diarrhoea occur in the first two years of life, with an incidence of 3 episodes per child per year (Kosek et al. 2003). The main cause of death from acute diarrhoea is dehydration, which results from the loss of fluids and electrolytes. Persistent diarrhoea, can also lead to under nutrition, poor growth, decreased immunocompetence and death (Lanata & Black 2008, Boschi-Pinto et al. 2009).

The mayor diarrhoea-causing pathogens have been identified in community and hospital based studies (Oyejide & Fagbami 1988, Yang et al. 1990, Al-Jurayyan et al. 1994, Biswas et al. 1996, Qadri et al. 2005, Cama et al. 1999, Biswas et al. 1996); however, community-based studies are more representative of the overall occurrence of disease, since their findings are not related to severity or health seeking behaviours. According to a recent review published by CHERG (Boshi-Pinto C et. al., 2009), the organism most frequently isolated were enterotoxigenic *Escherichia coli* (14% of all episodes), followed by *Giardia lamblia*, *enteropathogenic E. coli* and rotavirus, with a prevalence ranging between 8 and 10%. Other pathogens that have been identified to a lesser extent which are *Campylobacter, Shigella, Cryptosporidium parvum* and *Entamoeba histolytica*.

Diarrhoeal pathogens are transmitted through the faecal-oral route (Curtis et al. 2000), through ingestion of food or ingestion of faecal-matter, contaminated water, person to-person contact, or direct contact with infected faeces (Black 1989). The F-diagram (figure 1-1) Wagner & Lanoix (1958) indicates that contamination with diarrhoeal pathogens originate in stools, and suggests that if primary barriers (disposal of stools in a safe way, removal of traces of faecal material from hands after contact with excreta and prevention of contamination of water with faeces) were in place, then secondary barriers (HWT, hand washing linked to handling foods) would be less important. It is essential to consider that since there are multiple routes of infection, an intervention that improves only one type of hygiene behaviour may be useless if children still receive infective doses of pathogens through one or more of the other routes.

Figure 1-1: The "F-Diagram" of the Transmission of Disease from Excreta from Wagner & Lanoix (1958).



Prevention of diarrhoea focuses on the placement of barriers and the interruption of the transmission pathways. According to WHO, preventive strategies involve providing access to safe drinking water (quantity and quality) and improving sanitation systems (latrines and proper disposal of human waste). Other preventive strategies, linked to behaviour are to encourage exclusive breastfeeding for the first six months of life and improve weaning practices, promote hygiene education and hand washing, improving nutritional status of children (zinc, vitamin A, dietary supplementation with nucleotides) and promoting immunisations (measles and rotavirus).

Epidemiological evidence shows that the most important risk factors are linked to behaviours that encourage human contact with faecal matter. Improper disposal of faeces, lack of hand washing after defecation (Han 1986), handling faeces when cleaning children after defecation, and before handling food (Huttly et al. 1997, Curtis et al. 1997, Mahalanabis et al. 1991, Plate et al. 2004, Curtis 1995; Lanata 1998). The inappropriate sanitation infrastructure for excreta disposal (latrines) is a known risk factor (Curtis 1995). In particular, hand contact with ready-to eat foods (i.e. food consumed without washing, cooking, or preparation by the consumer) represents a potentially important mechanism by which diarrhoea-causing pathogens are disseminated. The underlying consequence of malnutrition has also been identified as a risk factor which not only contributes to diarrhoeal episodes, but also increases the duration of the episode and the frequency of later episodes (Lanata & Black 2008). Non-breast-fed children can have up to a twofold increase in diarrhoeal duration and up to six fold increase risk of persistent diarrhoea compared with partially or fully breast-fed children (Victora et al. 1989, Huffman & Combest 1990). Table 1-1 below shows a list of know risk factors for diarrhoea disease.

Table 1-1: Main risk factors for diarrhoea illness

References	Risk Factors
Huttly et al. 1997 Fuchs et al. 1996 Motarjemi et al. 1993 Victora et al. 1989	Lack of breastfeeding • Early introduction to solid foods • Contamination of weaning foods
Gogia & Sachdev 2011 Nahar et al. 2010 Mahalanabis 1991	Malnutrition • Micronutrient Status • Vitamin A and zinc deficiency • Decreased immunity
Gewa & Yandell 2011 Oni 1996	Socio-economic factors • Low Maternal age • Low maternal education
Simiyu 2010 Gundry et al. 2004 Nanan et al. 2003 VanDerslice et al. 1994 Esrey et al. 1988 McCabe & Haines 1957	Environmental Factors • Limited access to clean drinking water • Inappropriate handling of water • Poor sanitation • Open defecation • Uncover water reservoirs
Luby et al. 2011 Luby et al. 2004 Iijima et al. 2001 Aziz et al. 1990 Han et. al. 1986 Khan 1982	Improper hygiene practices • Faecal contamination of hands • Contamination of kitchen utensils (plate, spoon, cloths) • Improper food storage or preparation • Contamination of baby bottles
Koster et.al.1981	Prior infections • Post measles attack

1.1.2 Household air pollution related diseases and main risk factors

According to WHO, household air pollution is responsible for about 1.6 million premature deaths per year due to exposure to incomplete biomass fuel (BMF) combustion (Smith et al. 2004), affecting mainly women and small children (Rehfuess et al. 2006; Díaz et al. 2007). They are continuously exposed to indoor health damaging pollutants, including several carcinogenic compounds, hazardous gases (CO and NOx) and fine particles (Naeher et al. 2007), which increases the risk of several respiratory illness, such as acute respiratory infections, chronic obstructive pulmonary diseases, asthma and tuberculosis (Siddiqui et al. 2008, Dix-Cooper, et al. 2011, Po et al. 2011, Smith and Mehta 2003, Saha et al. 2005, Díaz et al. 2007). This thesis will focus only on acute lower respiratory infections (ALRI), as one of the main trial outcomes.

Acute lower respiratory infection incidence in children under five is estimated to be 0.29 episodes per child-year in developing countries and 0.05 episodes per child-year in developed countries (Lanata et al. 2004). This corresponds to about 156 million new episodes each year worldwide, out of which, 151 million occur in developing countries (Rudan 2008). ALRI are defined by the International Classification of Disease (WHO, 2010) as those infections that affect the lower airways below the epiglottis and include acute manifestations of laryngitis, tracheitis, bronchitis, bronchiolitis, lung infections or any combination of these together with upper respiratory infections including influenza (Lanata & Black 2008). The viruses and bacteria that cause pneumonia are usually found within the nose or throat of the child and can easily infect the lungs if they are inhaled. They can also be spread via air-borne droplets from a cough or sneeze or through blood during and shortly after birth.

Studies identified the pathogens responsible for generating or facilitating the development of pneumonia. The most severe cases of pneumonia are caused by bacteria, of which the most significant is *Streptococcus pneumoniae* (pneumococcus) identified in 30-50% of all pneumonia cases. *Haemophilus influenzae* type b, with *Staphylococcus aureus* and *Klebsiela pneumoniae* prevalent in 10-30% of the cases ranks as second causing agent (Rudan 2008). Respiratory syncytial virus (RSV) was isolated in 11-37% of patients with pneumonia and interactions with bacteria are hypothesised and facilitating the development of bacterial pneumonia. Other important viruses are adenovirus, parainfluenza virus, and influenza virus.

Strategies for preventing acute lower respiratory infections are immunisations against measles, diphtheria, pertussis, haemophilus influenzae type b (Hib), pneumococcus, influenza and the pneumococcal conjugate vaccine (Roth et. al, 2008). In addition to immunisation, adequate nutrition interventions could help improve children's natural defences, for example exclusive breastfeeding for the first six months of life (Lanata & Black 2008). Environmental exposure to household air pollution and parental smoking and lack of hygiene also contribute to the incidence of pneumonia (WHO 2011).

ALRI risk factors vary between different settings and study populations. Factors such as socio-economic level, culture, geography, location, and weather, access to health care or awareness are just some of the behavioural risk factors that can influence studies between settings. (Lanata et al. 2004, Johnson & Aderele 1992) Among the most significant, we find low birth weight, accounting for an increase of 50% in the probability of getting pneumonia (Victora et al. 1988). Non-breastfed children were 17 times more likely to be hospitalised for pneumonia and infants under 3 months had an much higher increase in the risk of pneumonia (César et al. 1999). Malnutrition is also an important risk factor; children with Z-scores under -3 for weight-for-age had an increase risk of acute lower respiratory infections. Attendance to day care centres has also been strongly linked as a risk factor with a 5 to 12 greater risk of pneumonia (Louhiala et al. 1995). The exposure to indoor wood smoke from open fires has been shown to increase the risk of having severe pneumonia three fold in children under 18 months of age (Po et. al. 2012, Smith et al. 2011). Overcrowding, limited access to healthcare services, lack of immunizations, limited access to clean water and poor sanitation, are also potential risk factors (table 1-2).

Table 1-2: Main risk factors for acute lower respiratory infections

Studies	Risk Factors
Thompson et al. 2011 Dharmage et al. 1996 Victora et al. 1994	Low Birth weight (≤2500 g)
Khan et al. 2009 Rudan 2008 César et al. 1999 Fonseca et al. 1996	Lack of Breast feeding (during the first 6 months of life)
WHO 2011 Roth et.al.2009 Sripaipan et al. 2002 Bhutta et al. 1999 Muhe et al. 1997	Malnutrition • Micronutrient Status (Vitamin, A,C, D and selenium deficiency) • Zinc deficiency
Celedón et al. 2002 Johnson et al. 1992	Immunosuppression
Lanata et al. 2004 César et al. 1997 Dharmage et al. 1996 Louhiala et al. 1995 Johnson & Aderele 1992	Socio-economic factors • Attendance to day care centres • Age • Overcrowding • Gender (male) • Mother's education
Smith et al. 2011 Mengersen et al. 2011 Naeher et al. 2007 Kim et al. 1996 De Francisco et al. 1993 Armstrong & Campbell 1991	Environmental factors • Indoor air pollution • Outdoor air pollutants • Altitude • Season
Al-Delaimy et al. 2002 Gold et al. 1999 Jinot & Bayard 1996	Parental Smoking
Kaneko et al. 2002 Wang et al. 1995 Holberg et al. 1991	Prior respiratory diseases
Cattaneo 1994 Osterhaus & de Vries 1992	Lack of immunization • Measles immunization (within the first 12 months of life)
Davis et. al. 2008	HIV

1.2 Policies regarding water, hygiene, and household air pollution in the Peruvian context

According to the 2007 census, Peru had a population of 27,057,199 million people, with an annual growth rate estimated at 1.6%. Approximately, one third of the population (6.6 million) are low-income residents living in the poorest areas of the country. They have limited and deficient access to basic services such as drinking water, (30% relying on rivers, springs, canals or unprotected wells), electricity (30%), sanitation (30%) and use biomass fuels (carbon, wood and cow dung) for cooking and heating (93%). The regions with the highest rates of poverty and extreme poverty are located in the Central mountain ranges. Cajamarca located in the north is ranked in 8^{th} place (among regions), with a 56% poverty rate in 2009. Accordingly to the "unsatisfied basic needs indicator", our population had a substantially higher classification of "poor" households for rural populations than reflected in national figures (99.5% versus 49.5% respectively) (Hartinger, et.al.2011). The Cajamarca population is afflicted by high infant mortality rates; acute respiratory illnesses (14%) and diarrhoeal diseases (12%), being the first and second causes of post-neonatal infant mortality (INEI 2012).

In the past two decades the government of Peru has focused its efforts on mitigating poverty, through three priorities in its policy agenda: (i) increasing the quality and quantity of employment, (ii) fighting poverty through a special focus on education and health, and (3) consolidating democracy and the rule of law (EC, 2007). Since 2001, the government of Peru declared that policies would focus mainly on poverty eradication in the context of sustainable development and the Millennium Development Goals (APCI, 2007, EC, 2007). Under this context, the Peruvian International Cooperation Agency (APCI) -created in 2002 with the goal of programming, organizing, prioritizing and supervising, international cooperation funds- established four strategic areas where international cooperation's could (and can) invest and complement tasks carried out by the Peruvian state: i) human security, securing universal access to drinking water and sanitation, as well as eliminating all forms of exclusion and discrimination, ii) governance, contributing to a democratic, transparent, decentralized and efficient state, iii) human development, through universal access to education and improved health and nutrition, and iv) sustainable competitiveness, through the promotion of national competitiveness, appropriate work conditions and work opportunities, sustainable use of natural resources, protection of the environment, scientific and technological development and the integration of Peru in the world's economy (APCI, 2007).

In 2007, under the Technical Secretarial of the Inter-ministerial Commission of Social Affairs (ST-CIAS), a set of national policies was created, linked to social development. They were under the supervision of the Presidency of the Ministries Council (Presidencia del Consejo de Ministros - PCM) and the Ministry for Women and Social Development. They conceived four objectives i) democracy, ii) equity and social justice, iii) national competitiveness and iv) an efficient, transparent and decentralized state (table 1-3).

Under this agenda and focusing on Objective 2: *Equity and Social Justice*, in 2007, the executive branch of the Peruvian government, created the National Strategy for Poverty Reduction and Economic Opportunities (CRECER). The strategy was placed under the direct control of the Presidency of the Ministries Council (PCM). The political ownerships gave sufficient political leverage to get together ministries and necessary entities to undertake this task, focusing on inter-sectorial institutional-level collaboration. CRECER was conceptualized using a causal model for malnutrition, principally focusing on water and sanitation, nutritional practices and fighting infectious diseases (diarrhoea and respiratory illnesses). It has three operational axes: i) the development of human capabilities and respect of fundamental rights, ii) the promotion of opportunities and economic capacities and iii) the establishment of a social protection network (CIAS, 2011).

CRECER created a common action framework for the Ministry for Women and Social Development, the Ministry for Health, the Ministry for Education, the Ministry for Agriculture, the Ministry for Housing, and the Ministry for Employment, and operated through the regular budget of each sector and programme. It also incorporated the cash transfer National Programme JUNTOS (Direct Support for the Most Poor) (JUNTOS, 2010) that has played a key role for this initiative. CRECER target population includes 1 million children under five and 150 thousand pregnant women in the 880 districts of 21 regions of Peru. The following table (table 1-4) presents the different programmes (IDS, 2011).

Table 1-3: Objectives and governmental policies under the Technical Secretariat of the Inter-ministerial Commission of Social Affairs

Objectives	Governmental Policies
Objective 1: Democracy and Rights	• Fortification of the Democratic Regiment and State Right • Fortify Political Parties and Political Life • Reaffirmation of the National Identity and improve Institution Dialogue • Govern with Strategic Planning • National Prospective and Transparent Procedures • Exterior Policies for Peace, Democracy, Development and Social Integration • Violence irradiation • Decentralized Policies to improve Administration of Sustainable and Joint Development • National Security Policy
Objective 2: Equity and Social Justice	• Poverty Reduction • Equal Opportunity Promotion: Universal access to Public, Free and Good Quality Education • Universal access to Health Services and Social Security • Access to a Productive Job, that is Fulfilling and Dignified • Promotion of Food Security and Nutrition • Fortification of the Family Unit. Child and Adolescent Protection
Objective 3: National Competitiveness	• Affirmation of a Social Economic Market • Fortification of Economic Activities, Competitiveness and Productiveness • Sustainable Development and Environmental Management • Development of Science and Technology • Development of Infrastructure and Housing • Commerce and Market Expansion • Development towards Rural Agriculture
Objective 4: Transparent, Efficient and Decentralized Government	• Effective and Transparent Government • Reinforce the Role of the army in Serving Democracy • Promotion of Ethics, Transparency and Eradication of Corruption, Money Laundry, Tax Evasion and Contraband • Eradication of Illegal Drug Production, Trafficking and Drug Consumption • Access to justice, Uphold Human Rights and the Constitution • Access to Information, Liberty of Expression and Liberty of Press

Table 1-4: National policy, strategy, sectors involved and programmes by sector

National Policy	Strategy	Sectors Involved	Programmes
Objective 2: Equity and Social Justice	National Strategy for Poverty Reduction and Economic Opportunities - CRECER	Presidency of the Ministry Council	National Institute of Civil Defence - INDECI Direct Support for the Most Poor - JUNTOS.
		Ministry of Health	Integrated Health Insurance - SIS. National Center for Feeding and Nutrition - CENAN. General Direction for Health Promotion National Health Institute - INS Nutritional Integral Programme - PRONAA
		Ministry of Education	National Programme for Alphabetization - PRONAMA. Scholarship and Educational Credit Offices - OBEC National Programme for Education Infrastructure - PRONIED.
		Ministry of Women and Social Development*	National Programme for Family Wellbeing - INABIF. National Programme again sexual and family violence - PNCVPS. National fund for the Cooperation and Social Development - FONCODES Nutritional Integral Programme - PRONAA WawaWasi National Programme
		Ministry of Housing, Construction and Sanitation	Water for Everybody National Rural Water and Sanitation Programme - PRONASAR. Own House Programme
		Ministry of Agriculture	Rural Productive agrarian Development Programme - AGRORURAL. Subsection Irrigation Programme - PSI. National Service of Agrarian Sanitation - SENASA. Agricultural Bank - AGROBANCO. National Water Authority - ANA
		Other Institutions	Local and Regional Governments
		NGOs	Active participation of NGOs in study areas

The information was collected from the Presidency of the Ministry Council webpage: http://www.pcm.gob.pe/, ST-CIAS webpage: http://www.cias.gob.pe/cias/index.php#

* The Ministry of Women and Social Development was recently split into the Ministry of Development and Social Inclusion and the Ministry of Women and Vulnerable Populations

The government has created the perfect umbrella strategy with the National Strategy for Poverty Reduction and Economic Opportunities “CRECER” (PCM 2007), for research endeavours, thus providing the perfect setting for the development of the IHIP interventions.

1.3 A systemic approach - Rationale behind the home-based environmental intervention package (IHIP)

There is evidence that simple, acceptable, low-cost interventions at the household and community levels are capable of considerably decreasing the disease burden in the developing world (Clasen et. al. 2010, Fewtrell & Colford 2005, Gundry 2004, Curtis & Cairncross 2003). Improved acces to adequate water and sanitation facilities, household water treatment and hygiene education (i.e. hand-washing with soap and correct excreta disposal) are among the most actions identified to reduce the risks of diarrhoeal illness in a range from 25% - 45% (Fewtrell et. al. 2005, Esrey and Habicht 1986). Combination of interventions or multiple interventions have also been assessed and proven effective (Aziz et al. 1990; Hoque et al. 1996; Mertens et al. 1990; Messou et al. 1997a; Nanan et al. 2003; VanDerslice & Briscoe 1995), however no additive effects were observed (Fewtrell et al. 2005). Reasons to why additive effects are not observed may be the complexity of delivering multiple interventions in one environment, competing messages in the study site, lack of political influence regarding the interventions at hand or systemic factors that could be influencing compliance, and usage of the intervention.

In the current Peruvian political context of reducing poverty and child malnutrition, institutions are seeking interventions that can tackle several household problems simultaneously (air pollution, poor drinking water quality, morbidity, malnutrition) and provide tangible social benefits that lead to behavioural long lasting intrapersonal changes. However, a broader understanding of the systems capacity (policy, inter-sectorial articulation at institutional levels) in order to recognize the linkages, relationships, interactions and behaviours that characterize the system is essential (Kumar et al. 2011, Lonergan & Vansickle 1991); if the researchers and the development community want to design health interventions that are beneficial.

The idea behind the integrated home-based environmental intervention package was to create a package of interventions that could be delivered simultaneously, without competing with each other and jointly provide synergistic health gains (proximal effects on child health indicators) and at the same time improve long-term social status, household livelihoods and sustainability of the interventions (distal effects). We designed our IHIP package, considering factors at multiple levels, including the range from policy, institutional, community, household, intrapersonal and interpersonal levels as described by the socio-ecological model (McLauren & Hawe, 2005). This system context may affect the compliance and future up-take and sustainability of any new intervention.

The package was developed during an interactive phase using different participatory and in their process empowering approaches. The study personnel gained the trust and were regarded as equal partners in home-hygiene related communal actions ad deliberations. We identified and convened key stakeholders (e.i. community members, local authorities, teachers and chiefs) in an effort to gain insights into cultural beliefs and potential approaches, with the sole aim of laying the foundations to ensure adherence, compliance, sustainable use and replication of the interventions beyond the life of the project (Hartinger et al. 2012).

1.4 Testing Public Health Interventions

Randomised controlled trials (RCT) are the gold standard of clinical research for determining cause-effect relationships between treatment/intervention and outcomes as well as for the assessment of interventions' cost-effectiveness (Moher et. al. 2012). In the past decades several randomised trials have been developed in order to determine the relationship between diarrhoeal diseases and quality and quantity of water, household water treatment, hygiene and sanitation (Clasen et. al 2007). However, the first RCT involving household air pollution and ALRI was not published until 2011 from the RESPIRE trial in Guatemala (Smith et. al. 2011). Before this, evidence was only based on observational, clinical or community-based studies, which presented several limitations due to study design (Changappa et.al. 2007, Mengersen et.al. 2011).

1.4.1 Household water treatments and water supply

1.4.1.1 Household Water Treatment- Solar disinfection

There are a variety of household water treatment (HWT) technologies to improve water quality and reduce waterborne diseases in drinking water, currently in use in different parts of the world. We can divide them into two big groups of treatments: physical and chemical. The physical methods include boiling, filtering and exposure to UV radiation (solar disinfection). The chemical methods include coagulation-flocculation and precipitation, and chemical disinfection (i.e.: chlorine). The use, compliance, adherence and sustainability of the HWT depend on the setting and its conditions, cultural beliefs and the accessibility to the required products. For the purposed of this thesis the focus will be on solar disinfection (SODIS) as HWT only.

Solar disinfection is a simple, low-cost household water treatment. The method consists of exposing water at least during a six-hour period to direct sunlight in transparent polyethylene terephthalate bottles (PET) in order to accomplish purification (Berney et al. 2006; Dejung et al. 2007; Gómez-Couso et al. 2009). The solar radiation of UV-A, sunlight (wavelengths 320-450nm), and mild heat inactivates bacteria. Additionally, solar disinfection can also help avoid secondary water recontamination due to unsafe storage, since water is stored in narrow neck bottles minimizing contact with the external pathogens (Mintz et al. 1995).

Microbiological studies showed the efficacy of solar disinfection on improving water quality, by inactivating waterborne pathogens such as *Escherichia coli, Vibrium cholera, Streptococcus faecalis,* enterococci and viruses such as lomyocarditis virus, rotavirus and bacteriophage f2 (Sommer et al. 1997, Berney et. al. 2006). Although, epidemiological studies provide evidence for the reduction of diarrhoeal disease on SODIS users, the impact of the reduction varies considerably between studies (Clasen et. al. 2007). Evidence for the effectiveness of SODIS is also coming from a limited number of randomised clinical trials only. The few trials published according to CONSORT guideline criteria (Mäusezahl, et. al 2009), or in the medical literature (Conroy et. al 1996, Conroy et. al 1999, Rose, 2006), are outnumbered by a multitude of observational studies, but only few studies providing data of sustainability after the trial end (Arnold et al. 2009).

Initial randomised trials developed by Conroy and colleagues reported a reduction 10% on the incidence of diarrhoea and 24% on severe diarrhoea after adjusting for confounders in children between 5- 16 years (Conroy et al. 1996). A subsequent study reported a moderate 16% reduction for severe diarrhoea in children under 6 years of age (Conroy et al. 1999).

More recently, a randomised controlled trial carried out in rural Bolivia in 2009, did not find a significant difference in diarrhoea episodes between study arms, observing a relative risk of 0.81 (Mäusezahl et al. 2009), congruent with the results found by Conroy. Other most recent RCTs by Du Preez and colleagues find similar results observing a difference in incidence of dysentery between study arms (Du Preez et al. 2010). However, the validity of the SODIS trials of duPreez in South Africa, Kenya and Cambodia (McGuigan, et. el. 2011) were not analysed per protocol, and reported findings not adhereing to the CONSORT principles for reporting RCTs and there validity were hence questioned (Arnold, et. al 2012, DuPreeze, et al. 2012, Hunter, 2012, DuPreez et.al 2012). However, there are trials that have observed and reported higher reduction levels among users. The highest reduction was found in a trial carried out in India, with an observed 75% reduction in diarrhoea prevalence eight weeks after implementation of SODIS among users (Rai et al. 2010). Rose and colleagues observed a 40% reduction in the risk of diarrhoea, despite the fact that 86% of the children were also drinking water from other sources, probably contaminated (Rose et. al. 2006). The latest study published by Du Preeze and colleagues in 2011, reported a 45% reduction on dysentery episodes and 27% reduction on non-dysentery episodes and an annual increase of 0.8cm in height for age in children that consumed SODIS (Du Preeze et.al. 2011). Another recent trial by the same group and authored by McGuigan reported a 50% reduced incidence of dysentery and a 63% reduction of non-dysentery episodes, with an almost universal compliance of the SODIS method (McGuigan, et. al. 2011) (table 1-5).

Diffusion of SODIS has been on-going for the last 25 years and currently unconfirmed sources report 2 million people worldwide use SODIS as a HWT. Several studies have tried to identify potential barriers for solar disinfection diffusion and sustainability. A SODIS cluster-randomised trial carried out in rural Bolivia, identified that individuals were more likely to use the method if they attended SODIS promotional events, were women, owned latrines, and had severally wasted children (Christen et al. 2011). Another study, also focusing on SODIS adoption, measured the different behaviours on SODIS “relapsers” (individual who fails to perform the introduced behaviour) comparing them with continuous users and observed that relapsers had significantly lower values than continuous users due to behavioural factors. They concluded that the relapsers personal behaviour did not support the fragile and often situation-dependent establishment of long-term habit changes and considered that future intervention should incorporate cues and remainders to engage in the new behaviours (Tamas & Mosler, 2011).

Table 1-5: Solar disinfection intervention studies and impact on health

Study	Design and setting (duration)	No participants (age)	Health Outcomes
Conroy et al. 1996	RCT among Maasai in rural Kenya (12 weeks FU)	206 (5-16 years)	Diarrhea incidence: 10% Severe diarrhea: 24%
Conroy et al. 1999	RCT among Maasai in rural Kenya (1 year FU)	349 (under 6 years)	Severe diarrhea: 16% reduction
Rose et al. 2006	RCT in urban slum in south India (6 months FU)	200 (under 5years)	IRR of diarrhea: 0.64 Risk if diarrhea reduced 40%
Mäusezahl et al. 2009	RCT in rural Boliva (12 months FU)	725 (under 5 years)	RR of diarrhea: 0.81
Rai et al. 2010	RCT in urban slum area of Mazegoan, Jorethang, south Sikkim (8weeks FU)	136 (under 5 years)	Diarrhea prevalence: 75% reduction
Du Preez et al. 2010	RCT in periurban communities of South Africa (12 months FU)	718 (under 5 years)	IRR diarrhoea: 0.64 IRR dysentery: 0.36
Du Preez et al. 2011	RCT in peri-urban and rural communities in Nakuru, Kenya (12 months FU)	1089 (under 5years)	IRR dysentery days: 0.56 IRR dysentery episodes: 0.55 HAZ: 0.8cm increase
McGuigan et al. 2011	RCT in rural communities of Cambodia (12 months FU)	928 (under 5 years)	IRR dysentery: 0.50 IRR nondysentery diarrhea: 0.37

IRR: incidence rate ratio

1.4.1.2 Water supply

Water supply can function as an enhancing factor for improvements on water quality, increased water availability, increased general sanitation and personal hygiene levels in the household, and finally a contribution to the perception of having clean water (smell, appearance and taste) that indirectly serves as an incentive for consumption (Wang et al. 1989, Esrey et al. 1985).

According to the Fewtrell review (Fewtrell and Colford 2005), water supply interventions (defined as interventions where new water sources have been introduced into a population, where a source has been protected, (stand post, borehole, spring or well) or -as in the case of our intervention-, an existent water connection was improved) the intervetnions can reduce diarrhoeal illness by a pooled estimate of 0.75; results congruent with those reported in the meta-analysis made by Clasen and colleagues in 2007 (Clasen et. al 2007). However, it is important to mention that Clasen's review considered water supply interventions delivered in combination with hygiene education and sanitation, so the reported results are in reality the outcomes of a composite of interventions.

One of the main limitations to provide adequate water supply systems is the initial investment cost during the first year of implementation and long lag period before any economic benefits are noticed. Developing countries have limited governmental resources to invest in social development and do not necessarily prioritize interventions with long-term benefits, even when cost-benefit analyses clearly demonstrate a direct benefit in prevention, early treatment and reduction in morbidity and mortality rates (Haller et al. 2007, Hunter et al. 2009). Additional health benefits that have been reported with the implementation of water supply interventions are, increase in productivity due to averted DALYs, savings within the health sector, patient treatment and travelling costs. Non-health benefits are linked to time reduction expenditure or time-saving (Pattanayak et al. 2010). Table 1-6 presents the most relevant studies on water supply and health effects.

Table 1-6: Water supply intervention and impact on health

Study	Design and setting (duration)	No participants (age)	Health Outcomes
Ryder et al. 1985	Observational in rural Panama	(under 60months)	No effect on diarrhoea
Esrey et al. 1988	Cross sectional collection. Rural Lesotho, southern Africa (3 CS for five week periods)	247 (under 60 months of age)	Increase in length and weight 0.236cm / 235g Diarrhoea pathogens were lower in intervention arm.
Alam et al. 1989*	QRCT among five political subunits of a village in rural Bangladesh (3 years FU)	623 (6-23 months)	Incidence of diarrhoea: 40% reduction
Wang et al. 1989	Cohort among 12 villages in rural China (4 months FU)	29,687 (all ages)	EID incidence reduction: 38.6% reduction
Aziz et al. 1990*	QRCT among two villages in rural	About 9600 (all ages)	Diarrhoea episodes: 25% reduction

	Bangladesh (3 years FU)		
Tonglet et al. 1992	QRCT among three villages in north Kivu Zaire (12 months FU)	1096 (under 4 years)	No effects observed.
Messou et al. 1997b*	QRCT among four villages in rural Ivory Coast; two underwent intervention, two were controls	985-1260, depending on study year (under 5years)	IR diarrhoea: 50% reduction Proportion of deaths: 85% reduction
Gasana et al. 2002	QRCT in rural Rwanda (12 months FU)	475 (under 5years)	Diarrhoea: 22% reduction
Opryszko et al. 2010	RCT among 32 villages in Wardak (12 months FU)	11085 (all ages)	IRR: 0.61
Majuru 2010	Cohort among three villages of the Limpopo Province, South Africa (13 months FU)	553 (all ages)	IRR: 0.43 57% reduction in diarrhoea

EID: Enteric infectious disease, IRR: Incidence Rate Ratio

*Interventions with additional hygiene components, such as hygiene education, hand washing, sanitation

1.4.2 Environmental Hygiene Interventions

Hygiene interventions in relation to diarrhoea are those actions and activities that seek to encourage a specific behaviour in order to reduce diarrhoeal illnesses. We can separate them into two broad categories: health and hygiene education, and hand washing. Hygiene education messages differ among studies, in their content, in the way they are delivered and in their frequency, recipient (mother) and measurement (child). On the other handwashing has specific guidelines regarding the adequate way to educate and promote handwashing behaviour (WHO 2012) and recommended moments when it should be applied (Luby et al. 2011). This thesis focuses on two hygiene interventions: hand-washing and the correct handling and disposal of animal excreta.

1.4.2.1 Hand-washing

Hand-washing with soap decontaminates hands and prevents cross contamination by eliminating pathogens that adhere to hand surfaces (Ejemot et al. 2008). The mechanical action removes pathogens, when hands are rubbed vigorously, and the soap chemically kills colonized flora on hands surfaces and skin crevices. However, the behavioural changes required to achieve the correct hand-washing behaviour are complex and can be limited by several factor such as: knowledge, availability of water and soap, and cultural beliefs. Curtis and Cairncross in 2003 suggested that hygienic behaviour could be motivated by several factor such as: desire to nurture a baby, desire to create an attractive environment, desire to tidy and order, desire to avoid things that are disgusting and a desire to create a good impression on other people (Curtis and Cairncross 2003). However, further studies are needed to identify ways to encourage people to wash there hands properly.

Several randomised control trials (Luby et al. 2004; Luby et al. 2006; Halder et al. 2010), case-control, cross sectional, observational and experimental studies (Burton et al. 2011, Schmidt et al. 2009) on hand-washing with soap, have reported a reduction in diarrhoeal illnesses, including shigellosis and severe intestinal infections (table 1-7). A review made by Curtis reported a 47% reduction of diarrhoeal episodes (Curtis and Cairncross 2003) and the one made by Fewtrell and Colford in 2005 a 44% reduction. However, the reviews were based on case-control and cross sectional studies. A later review done by Ejemont and colleagues in 2008 (Ejemont et. al 2008) based only on randomised controlled trials, confirmed diarrhoeal reduction, but with more moderate findings; observing a 39% risk reduction for institution-based trials and a 32% reduction for the community-based trials. The observed variation between trials was expected, due to the different settings, populations, cultural believes, compliance and the intensity of the hand-washing interventions. A commentary from Curtis in 2010 in response to the latest review done by Ejemont, reflected the uncertainly of handwashing interventions true impact on diarrhoeal reductions and expressed the urgent need for further research in this area (Curtis, 2010).

Additionally, recent studies, have also reported that handwashing with soap is associated with the reduction of acute respiratory infections in children (Cairncross 2003, Luby et. al. 2005), since diarrhoea pathogens can also cause ARI and have similar transmission pathways, such as contact with hands, surfaces and objects (Chin-Hai Fung 2006, Luby et al. 2009).

Table 1-7: Hygiene and handwashing interventions and impact on health

Study	Design and setting (duration)	No participants (age)	Health Outcomes
Khan 1982	RCT among urban Bangladesh (10 day FU)	1,196 (all ages)	Secondary infection rate: 67% reduction Secondary case rate: 84% reduction
Sircar et al. 1987	RCT among urban slum India (13months FU)	3,668 (all ages)	Incidence of Dysentery : 32 % reduction
Myo Han & Hlaing 1989	RCT among poor urban Myanmar (4 months FU)	494 (under 5 years)	Diarrhoea Incidence (IDR): 0.70 Dysentery Incidence (IDR): 0.58 (<2years)
Wilson et al. 1991	RCT among rural Indonesia (20 weeks FU)	445 (under 11 years)	Diarrhoea Episodes: 82% reduction
Shahid et al. 1996	RCT among periurabn slum in Dhaka city, Bangladesh (12 months FU)	1367 (all ages)	Diarrhoea incidence: 47-73% reduction
Hoque 2003	Case Control		
Luby et al. 2004	RCT among urban squatter settlements in Karachi, Pakistan (12months FU)	4691 (under 15 years)	Diarrhoea incidence: 53% reduction (children under 15 years old)
Luby et al. 2006	RCT among urban squatter settlements in Karachi, Pakistan (8months FU)	8949 (all ages)	Diarrhoea prevalence: 51-64% reduction depending on the delivered intervention.

IDR: Incidence Density Ratios

*Intervention with additional hygiene components, such as hygiene education

1.4.2.2 Disposal of animal excreta to reduce faecal contact

Humans have always lived in close relation to animals, which can be the cause of health-threatening diseases to humans. *Campylobacter, Escherichia coli, Salmonella, Shigella* species and *Trichinella* (Jarousha et al. 2011) are among pathogens commonly found in animals and humans. The idea of the intervention was to isolate animals living in the kitchen environment and dispose of their excreta to a safe location, thus reducing direct or indirect human contact with the excreta. However, these interventions are usually linked to other interventions, such as sanitation and water supply. Table 1-6 and 1-7 shows all the water supply studies and handwashing interventions that have been developed in conjunction with hygiene interventions.

1.4.3 Improved chimney stove interventions

Household air pollution (HAP) from domestic biomass combustion is a large health problem in developing countries (Smith & Mehta, 2004). Household air pollution is identified as the eighth most important risk factor and responsible for 2.7% of the global burden of diseases. Globally, household air pollution accounts for 1.6 million cases of premature mortality and 39 million disability-adjusted life years (DALYs) in the year 2000 (Rehfuess et al. 2006, WHO, 2002). The overall disease burden increases in developing countries to 3.7% making it the fourth most important risk factor for these countries. The exposure to household air pollution my double the risk of pneumonia and other acute lower respiratory infections contributing to more than 800,000 deaths in children under 5 (Bruce et. al. 2000).

A systematic review done by Dherani, concluded that household air pollution from incomplete combustion of biomass fuels is responsible for an increase in the risk of pneumonia in children under five by a factor of 1.8 (OR: 1.79; 95% CI: 1.26-2.21) (Dherani et al. 2008) and the one carried out by Po, determined that the overall pooled OR of biomass fuels with acute respiratory infections was of 3.5 (Po et al. 2011). However, both reviews were done with observational, hospital and community based and cross sectional studies (Cynthia et al. 2008; Dasgupta et al. 2006; Hutton, Rehfuess et al. 2007, Masera et al. 2007, McCracken et al. 2007, Smith et al. 1993, Díaz et al. 2007, Bruce et al. 2007, Ezzati & Kammen 2002,). One problem with these studies is their methodological limitations, which are susceptible to selection bias and probability of misclassification. The results from a recently published RESPIRA randomised controlled trial (Smith et. al 2012) showed that improved chimney stoves can reduced severe pneumonia by a third, but only if the stove efficacy achieves a 50% reduction in personal exposure.

Half of the world's population depends on biomass fuel for cooking, boiling water, lighting and heating (Rehfuess et al. 2006, Martin et al. 2011). Burning biomass fuels in un-vented stoves and closed rooms results in high levels of pollutants in the air (Fullerton et al. 2008; Smith et al. 2000), many hazardous to human health, such as carbon monoxide (CO), small particulate matter (PM_{10} and $PM_{2.5}$) including small soot or dust particles that can penetrate deep into the lungs, nitrous oxides (NOx) sulphur oxides (SOx) and a range of volatile organic compounds (VOCs), including formaldehyde, benzene and 1,3-butadiene and polycyclic aromatic compounds such as benzo-α- pyrene (Peabody et al 2005; Naeher, 2007). Continues exposure to these pollutants can cause mucous membrane irritation and respiratory diseases, reducing the resistance to infection and increasing the risk of cancer. It increases the risk of acquiring acute lower respiratory infections, chronic obstructive pulmonary disease (COPD) and lung cancer (from coal stoves) asthma, low birth weight and other adverse birth outcomes (Siddiqui et al. 2008), cardio-vascular and other inflammatory conditions (Po et al. 2011), eye diseases, such as cataracts and blindness (Smith and Mehta 2003; Saha et al. 2005) and headaches (Díaz et al. 2007).

1.4.3.1 Improved chimney stoves- a solution to the problem

In the last century, wood stoves have been adopted by middle- and upper-income families when petroleum based fuels became scarce. The motivation for implementing and later disseminating biomass combustion stoves, was not linked to health related problems, but rather linked to the goal of tackling the eminent pressure on natural resources, which can lead to fuel shortage, impoverishment of forest lands and loss of soil fertility (Barnes et al. 1994).

The first improved stove programmes were implemented in China and India in the 1950s and 1960s, without great dissemination success. However, in the early 1980s, the Chinese government financed the Chinese National Improved Stove Program (CNISP). This initiative focused on providing rural households throughout the country with more efficient biomass stoves for cooking and heating (Peabody et al. 2005). Between 1982 and 1992 the programme installed 129 million improved stoves in rural households (Smith et al. 1993). The costs were about USD $9.0 per stove. Regarding India, the Indian National Programme on Improved Chulhas (NPIC) was launched in 1983. By September 2000, 32 million stoves of various types had been promoted. Since the mid-1970s, an “Appropriate Technology” movement began in Latin America. Mexico developed a number of improved chimney stove models (Lorena, Rocket and Justa) that included a combustion chamber and chimney (Troncoso et al. 2007, Masera et al. 2005). In Guatemala, the Lorena improved stove was introduced in 1976 and by 1980 it was part of a large-scale production. However, in 1993 the improved stove model was changed to the “plancha-armada” prototype and was used for testing the causal-effect pathways of improved stoves and ALRI reduction (Smith et. al. 2011). In Peru the first improved stoves were introduced as part of other NGO programmes, since the mid 1990s.

1.4.3.2 The future of improved chimney stoves

After several studies pinpointed the disease burden related to biomass fuel cooking, a global alliance was formed, promoted by several private, public and non-profit partners. The Global Alliance for Clean Cookstoves seeks to improve livelihoods, empower women and combat climate change by using clean and efficient household cooking solutions. They have developed a platform where different entities can converge into a common goal: 100 million households adopting clean and efficient cook stoves and fuels by 2020 (United Nations Foundation, 2012). In Peru several organisations contribute to the Global Alliance's goal and have embraced the task by developing a campaign called the "Half Million Improved Stoves for a Smokeless Peru" (Medio Millon de Cocinas para un Peru sin Humo). The goal is to install half a million stoves by December 2011 (Bodereau 2011). By October 2011 they had installed 216,537 improved stoves, a little bit below 50% of the overall goal; however, efforts are still on their way.

1.5 Key issues for impact - compliance, behaviour change and sustainability

Intervention studies in developing countries are always looking for simple, low-cost, behaviour based interventions in order to interrupt disease transmission and improve child health, with the ultimate goal of generating an easily adopted and sustainable programme over time. However, the process of incorporating a new intervention in the target population follows complex dynamics that go beyond acceptance and initial use. Compliance depends on several factors such as the characteristics of the users, the intervention in itself and the degree to which the users are willing to incorporate the intervention in their way of live (or even if these are compatible).

According to Vanden Den Ban and Hawkins, in order for an intervention to be adopted, used and maintained, it must represent a clearly-definable advantage, be more useful than the interventions it is substituting and be compatible with the attitudes, values, beliefs and needs of the users. Interventions must be easy to understand and implement, and benefits must be tangible (Van den Ban and Hawkins, 1996, Hartinger et. al. 2012).

An important issue is that current implementers and researchers do not consider that there are learning periods needed to incorporate and assimilate the interventions to have people become users (Ruiz-Mercado, et. al. 2011). Most studies document treatment effects on short follow-up periods, and typically under weekly or bi-weekly behavioural reinforcement (Arnold et al. 2009), showing only the efficacy at early stages of the study and early use. Arnold's and colleagues were one of the first to follow-up six months after the conclusion of a three-year hand-washing and water treatment intervention in rural Guatemala. Results revealed a lack of impact on child health, consistent with an unsustained behaviour adoption (Arnold et al. 2009). Other authors have also recognized these issues. Fewtrell and colleagues (Fewtrell et al. 2005), argued that there is little information on the longevity of health-related effects and behavioural changes beyond immediate follow-up periods after trials are concluded. More recently, Ejemont presented three conclusions: i) trials had short-term follow-up phases, ii) most of them are efficacy and not effectiveness trials due to intensive monitoring; and iii) sustainability of trials is unclear (Ejemont et. al. 2008). Hunter in 2010 discussed that HWT trials have been conducted over short follow-up periods, with a median duration 26 weeks (Hunter et. al. 2010), thus results only focus on the early stages of the trial. Finally Schmidt and Cairncross in 2009 argued the possibility that many of the HWT interventions were not truly reflecting the reported health effects, but were biased due to subjective measurements and non-blinding designs (Schmidt and Cairncross 2009, Hunter 2010).

1.5.1 Critical Issues for Sustainability

There are several theories on how populations behave when an intervention is provided. According to Rogers (Rogers 1995) and Van den Ban and Hawkins (Van den Ban and Hawkins 1996), whenever an intervention is offered to a rural community, the population splits into four categories. The first group are early adopters (enthusiastic people ready to accept innovations); a second group will adopt the technology fairly fast; the third group is composed of sceptics, who see any new intervention with caution and will accept it only under economic or social pressure; and finally those who linger in past experiences and will take a very long time to adopt the intervention. In another study carried out by Ruiz-Mercado in 2011 -in the adoption and sustained use of improved stoves- he used diffusion of innovations theory proposed by Roger in 2003 and concluded that there is a time period needed for the individuals to receive the information about the intervention, evaluate its usefulness, incorporate it, combine it with there own existing practices, to finally come to the decision to use it (or not) (Ruiz-Mercado 2011). He divided the proposing time period into three stages: i) learning-adjustment, ii) stabilization sustained, use and iii) dissadoption. If time is required to achieve behavioural change for compliance, adoption and sustained use, is it save to say that interventions must measure proximal effects for longer periods of time.

Recent research is focusing on returning to the field after concluding the study and measuring adherence and sustainability of their interventions. The results have been diverse. An example is the CARE/Madagascar Safe Water System (SWS) campaign. Ram in 2007 returned to the field 18 months after the intervention concluded to measure chlorine users. He found that 54% of the household's water supply had traces of free chlorine (Ram et al. 2007). Luby and colleagues (Luby et al. 2008), only found that 5% of households regularly treated their water with a flocculants disinfectant six months after the conclusion of their trial. And Arnolds and colleagues (Arnolds et al 2009) found 9% confirmed water treatment adoption in a SODIS intervention six months after conclusion. According to Curtis and colleagues, two potential scenarios could be explaining these phenomena, i) the intervention was successfully adopted and increased the health gain, but the new behaviours were not sustained after intervention completion, or ii) the intervention never led to behavioural changes (Curtis et al. 2011).

2.0 GOAL AND OBJECTIVES

To reduce morbidity of acute respiratory infections, diarrhoea (maternal report of diarrhoea or infection with enteric pathogens as proxy indicator) and poor growth of children under 5 by about 20% or more in the intervention arm.

Main Objective:

To implement a community-randomised trial among 51 communities to evaluate the impact of delivering an Integrated Environmental Home-based-Intervention Package (IHIP) to reduce acute respiratory infections through improved stoves reducing household air pollution, diarrhoeal diseases burden through access to safe drinking water based on point-of-use treatment options, and to reduce contamination of child- and weaning food through hygiene education proven to be effective.

Secondary Objectives

- Identify potential exposures at household level that are associated with the contamination of food, drinking water, kitchens utensils and surfaces, and caregivers and children's hands.
- Develop, evaluate and test an effective low-cost, home-based intervention package (IHIP) which would reduce the household burden of disease.
- Describe the design and baseline characteristics of a community-randomised controlled intervention trial to evaluate the effectiveness of an IHIP.
- Describe household indoor air pollution concentration levels of PM2.5 and CO in the kitchen environment and personal exposures of mothers on intervention and control households.
- Determine the level of, achievements of a post-intervention community roll-out of the IHIP and levels of sustainability.

3.0 METHODOLOGY

This thesis deals with the relationship between environmental factors and how efficient –and yet simple- interventions, delivered in an integrated manner can produce synergistic effects to reduce the burden of disease of childhood diarrhoea and ARI diseases and impact on child growth. This thesis begins with describing the selection and cultutral adaption of the IHIP interventions, identifing environmental indicators, collecting baseline information and evaluating the household indoor pollution and personal exposure. The study continued with the morbidity surveillance evaluation and the level of self replication after our community driven roll out activites.

3.1 Summary of the Research Approaches

We implemented a community-randomised controlled field trial (cRCT) in 51 community-clusters to evaluate the efficacy of the home-based intervention package (IHIP) interventions on reducing the rate of acute diarrhoeal illness, acute lower respiratory infection and child growth in children aged 6 to 35 months in rural communities of San Marcos, Cajamarca, Peru. The cRCT was divided into six different phases, each with its specific objectives:

1. **Set-up, community selection and participatory intervention development:** The selection of the Province of San Marcos as site for the study took place December 2007. Agreements were signed with local authorities and with community leaders on July 2008, after the screening activities and household information census was carried out. The selection of suitable intervention components and activities and identification of microbiological indicators was carried during a preliminary exploration among 7 communities not participating in the trial, between May and August 2008.
2. **Randomization and Enrolment**: The 51 community-clusters were randomised into the IHIP and control groups. Enrolment took place between September 2008 and January 2009. The field personnel were responsible for enrolling 20 to 25 households daily in order to comply with the proposed timeframe. Each household that had a child below 36 months of age complied with the inclusion criteria and agreed to consent was enrolled.

3. **Baseline Data Collection**: We conducted a baseline survey between October 2008 and January 2009 collecting socio-economic and demographic household characteristics. Additionally we collected microbiological data (faecal contamination and diarrhoegenic *E. coli*) on kitchen utensils, mothers' and children's hands, drinking water and collected stool specimens from diarrhoea-symptomatic and asymptomatic children. Anthropometric measurements of children were also obtained. Childhood psychomotor development indicators were also assessed in all children in our study at baseline providing specific baseline information for the evaluation of the psychomotor intervention in the control arm of the trial.
4. **Implementation of Interventions**: The OPTIMA-improved stove and kitchen sinks were installed between October 2008 and January 2009. Solar disinfection as a HWT and hygiene messages, i.e. hand-washing and the elimination of animal excreta and isolation of animals from the kitchen environment, were repeatedly promoted once a month until December 2009. In the control study arm, a psychomotor stimulation intervention focusing on early child development was adapted from the government WawaWasi National Programme.
5. **Morbidity surveillance and field data acquisition**: The surveillance took place during February 2009 - January 2010. Trained field workers visited each household weekly and collected morbidity data from the mother about the daily occurrence of signs and symptoms of child diarrhoea and respiratory illnesses. Anthropometric measurements were collected every two months and microbial quality of the drinking water, hands and kitchen utensils as well as stool samples were collected at baseline, mid-term and at the end of the surveillance period. Additionally, CO and $PM_{2.5}$ kitchen and personal exposure measurements were collect between June-August 2009.
6. **Workshops for a self driven roll out of the IHIP interventions:** to support a process of community driven roll-out of the IHIP-intervention, twenty-four handover workshops were carried out during March-June 2010. The workshops were organized in the community's elementary school and local participating

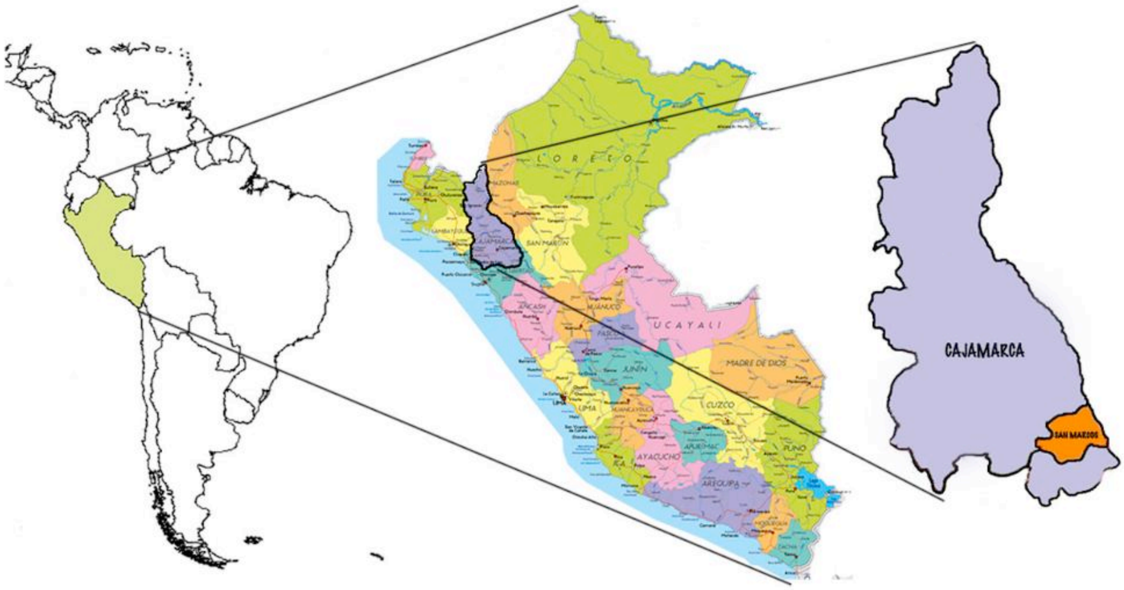
and non-participating families, health professionals (promoters and health centre staff), teachers and local authorities were invited. End of roll out evaluations and compliance surveys were carried out three and twelve months after the workshops were concluded corresponding to 6 and 15 months after the formal intervention trial ended.

3.2 Set-up, community selection and development of interventions

3.2.1 Set-up and site selection

Cajarmarca, region located on the North-eastern highlands of Peru, was identified as the potential region due to its high proportion of rural population, access year round and Spanish as the predominant language. Cajamarca had a strong health systems network set up in their rural communities, which enables us to work jointly with them. After deliberations with the local health authorities, the areas of Celendin, Baños del Inca and San Marcos were considered. The selection criteria were 1) not taking part in another intervention programme, 2) have a sufficient number of rural communities that were not too distant from each other, 3) to be accessible year round, and 4) to have an urban town with access to communication systems (telephone and internet). The San Marcos Health Network was found eligible and supportive of the study. Based on these findings, San Marcos was selected as the study site at the end of 2007. In January 2008, we establish our field operation facilities, located in downtown San Marcos (50,000 inhabitants).

Figure 3-1: Location of study site



3.2.2 Community and household selection

The eligible rural communities were selected with an initial house-to-house census. During the months March and June 2008 we identified initially 56 potential rural communities that complied with the following criteria: i) no access to potable water and sewage systems, ii) use of wood as energy source for cooking and heating, and iii) were located a maximum of a 90-minute drive away from the project office.

In order to get all families in the study area who had children in the required age range (6-35mo), we jointly worked with the Health Centres (Growth and Development Programme and PRONOI) and "Vaso de Leche" mothers group of the area. Each institution managed their own list of children under five who participated with them. We visited all families in the area and screened a total of 865 households for eligibility.

The census was complemented with a short socio-economic survey that collected general information on the child (sex, age), parents' education, tenancy, household characteristics and asset, main activity of the family head and tried to identify potential stakeholders in the study area (NGO's, mother groups, water board).

3.2.3 Development of the integrated Invention

To develop the interventions we carried out a preliminary study in seven communities in the San Marcos Province, from May to September 2008, with the aim to selected appropriate technologies for drinking water treatment, stove improvements to reduce indoor air pollution, and improvements in household hygiene that would be culturally acceptable by the local population and to select microbiological indicator to use as objective outcomes measurements. The process was entirely community-led with involvements of mothers, beneficiaries, household heads, local builders and technicians and community leaders (Hartinger *et al*., 2012).

3.2.3.1 Improved Stoves

The OPTIMA-improved stove was selected after assessing the efficiency of three existing stove designs called Tulpia, Traditional and SEMBRANDO stoves and the two newly developed stove models the OPTIMA-I and OPTIMA-II which were built by a local entrepreneur. We used two standard protocols to test the stove performance: the controlled cooking test (CCT) and a kitchen performance test (KPT) (VITA 1985).

3.2.3.2 Household Water Treatment - Solar disinfection (SODIS)

Solar disinfection was selected as home based water treatment method, because it would complement the actively promoted method of boiling by the Ministry of Health. Since piped and gravity-based water home connections (from unimproved water sources) are common householders considered the SODIS water treatment specifically suitable. During our preliminary work we tested the efficacy of the solar disinfection method in our setting and acceptability and usages of the method with our mother. Each of the 12 family was provided with four 2L PET bottles (cost per bottle US$ 0.20). Mother/caretakers were trained in the general application of the method in daily practice according to standard procedures (www.sodis.ch). The mother had to fill the PET bottles with water to the top, without allowing air pockets to form and then close the cap. The bottles are exposed to direct sunlight for at least six hours or for two days under cloudy conditions or rain. Once the bottles are collected, the mother must store the water in the same SODIS bottle until consumed. General applications of the SODIS method in daily practice were done according to standard procedures (www.sodis.ch).

3.2.3.3 Kitchen Sink

The decision to include kitchen sinks as part of the intervention package was done after focus group discussion. Study mothers were interested in i) improving their water supply, ii) have access to running water at all times, minimizing recontamination in the household by storage of water; iii) time saving in washing food and utensils and, iv) running water for hand washing.

3.2.3.4 Hygiene Messages

The selection of our hygiene messages was in concordance with the existing guidelines of the Ministry of Health's hygiene policies. We intended to reinforce official health promotion messages regarding hand washing and hygiene in the households. Mother were instructed to wash their hands and children's hands after defecation, after changing diapers, before food preparation, before eating and before feeding infants and small children - ideally with soap or detergent (ayudin), which were universally available in local homes. The eliminate animal excreta from the kitchen environment and isolate household animals from the kitchen area was the second hygiene message As part of our hygiene message we taught the mother in the importance of keeping the kitchen environment clean and animals separated in the kitchen or in a different environment.

3.2.3.5 Psychomotor Stimulation Intervention in the Control Arm

We selected an intervention that was unrelated to the IHIP and that could help to reduce potential dropout and non-blinding bias in the control study arm. After intensive search we decided to use and adapted the government-based WawaWasi National Programme, which provided early age stimulation to children under four-years of age at day-care centres. Together with the WawaWasi personnel in Cajamarca city, we adapted the intervention to be used at household level and designed a package of toys that are necessary for the child's development at different age groups. Each child received six set of toys throughout the 12 month surveillance period, approximately every two months. When a set of toys was delivered the mothers were trained and instructed in the use of the early stimulation toys and materials. They were instructed to play and encourage their children at least 30 minutes every day. We used to evaluation tools the WawaWasi programme “Lista de Cotejo” and the TEPSI (a set of validated child development indicators used in the national programme) from the Ministry of Health.

3.2.4 Microbiological Indicators

We selected a set of microbiological indicators to use as objective outcome measurements of kitchen hygiene and water quality. We selected the most contaminated kitchen utensils (kitchen wipes, plates and spoon), mother and child’s hands samples, and the child’s drinking water. Ones the microbiology indicators were determined; we collected them in three points in time, at baseline, mid-term and at the end of the surveillance period, to cover data collection during dry and wet season (Chapter 5).

3.2.5 Qualitative assessments of cultural acceptability and performance

We carried out anthropological work; i) to assemble general knowledge regarding health (diarrhoea, pneumonia, nutrition, health seeking practices) and hygiene, ii) to determine the perceptions of the intervention package after one month of introduction in the pilot households, iii) for gathering general perception of the community’s main stakeholders of the San Marcos Province in order to obtain a better understanding of the local framework conditions for a potential scaling up activities, and iv) to assess after one year the experiences and perceptions of the improved stoves, sinks, water treatment and hygiene messages in the pilot households (Chapter 4).

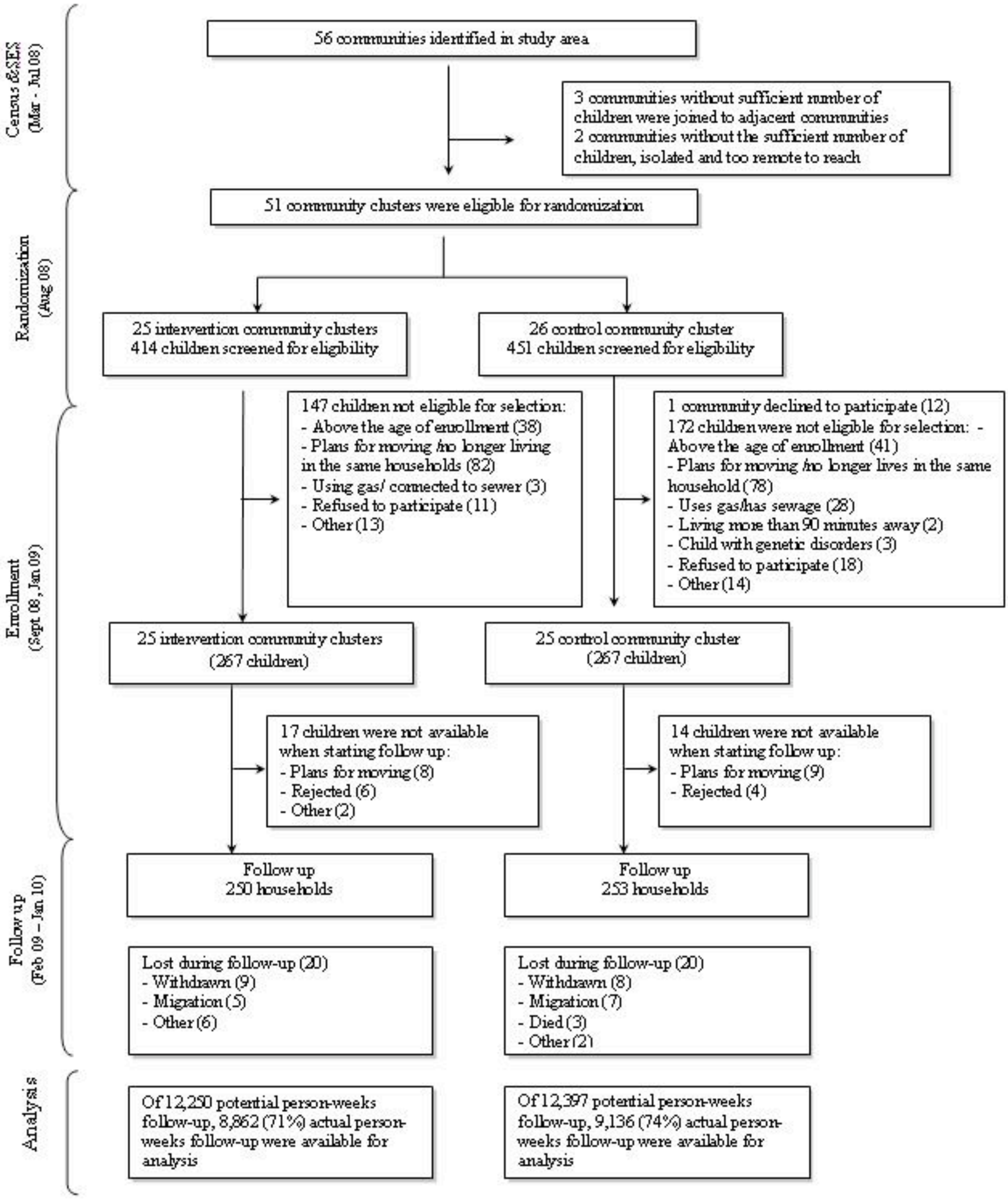
The analysis of the data was done according to the methods described in Dawson, et al. (1993) (Dawson et al. 1993) for focus group discussion and standard content analysis of interview data by grouping themes after coding the transcripts and selecting appropriate quotes to illustrate findings.

3.3 Study Design

(Hartinger et al. 2011/Art. 3) The study was designed as a community-randomised controlled field trial to evaluate the IHIP interventions on reducing the rate of acute diarrhoeal illness, acute lower respiratory infection and improving child growth in children aged 6 to 35 months at enrolment over a 12 month surveillance period. 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, d) tenants planning to stay in their home for the next 12 months. Due to the nature of the intervention, blinding was not possible.

Sample size was calculated using the method of Hayes and Bennett (Hayes & Bennett 1999). We initially aimed at detecting a 33% absolute reduction in the annual diarrhoeal and ALRI incidence rate in children with an 80% power at a 5% level of significance. However, the number of children in each community was lower than expected. From the 56 communities originally identified, three had less than three households with children in the required age and were annexed to their nearest neighbouring community for randomisation. Furthermore two communities were too remote to reach and were excluded. Hence, 51 communities remained eligible for randomisation (Fig. 3-2). An updated sample size calculation revealed that the new number of clusters would be sufficient to detect a reduction of 22% incidence reduction assuming a minimum of 5 person-years of observation in each cluster keeping all other parameters constant. We randomised 51 communities using the covariate-based constrained randomization as proposed by Moulton (Moulton 2004). After the randomization, enrolment and baseline collection took place between September 2008 and January 2009. If we found more than one eligible child per household, we selected the younger child.

Figure 3-2: Participants and Community Flow Chart



3.3.1 Data Collection

The surveillance team visited each household weekly and collected morbidity data from the mother/caretaker on the daily occurrence of signs and symptoms of child diarrhoea and respiratory illnesses. The mother was asked a set of screening questions to detected diarrhoea and respiratory infections. If the child had three or more liquid or semi-liquid stools in the last 24h or blood in the stool, additional questions (sunken eyes, child drinks avidity, dry mouth, tongue and mucous membranes) were asked to determine the severity of the episode. If the child had cough and/or fever the day of the exam or in the last 48h, additional questions on diagnostical (noisy breathing, rhonchus/wheezing, fast breathing rates, malaise, lack of appetite, lower chest indraw) were answered. Severely ill subjects were seen by the study physician on the same day and, if required, referred to local healthcare services, where the child was re-evaluated by the physician at the health centre.

Anthropometric measurements were collected every two months. Two trained field workers took Lengths/heights and weights of children during home visits, using digital scales (Robusta 813 SECA) sensitive to 0.1 Kg and portable wood length boards (1cm scale with mm increments). All measurements were taken three times, using the arithmetic mean for analysis. We placed the scales on a flat wooden board levelled for horizontal position.

Environmental samples from the mother's hands, kitchen cloths and drinking water were collected at baseline, midterm and at the end of the surveillance period. All analysis was done in accordance to standard methods. We also collected stool samples from diarrhoea-symptomatic and asymptomatic children. Both stool and environmental samples were analysed to detect diarrhoeagenic *E. coli* using real time PCR multiplex system.

Supervisors revisited study homes each month. Discrepancies between the supervisor and field worker were clarified during joint visits to the households.

Compliance data was collected weekly during surveillance, by spot check observations and monthly by the educator's team, when promoting and re-enforcing the interventions.

3.3.2 Outcome Measures

Primary Outcomes

Diarrhoea: was defined as the passage of three or more liquid or semi-liquid stools in a 24-hour period or the passage of at least one liquid or semi-liquid stool with blood or mucus (Morris et al. 1994; Wright et al. 2006; Baqui et al. 1991). A diarrhoeal episode was defined to begin on the first day of diarrhoea and ended the last day of diarrhoea followed with at least two consecutive non-diarrhoeal days.

Acute lower respiratory infections (ALRI): a child presenting with cough or difficulties breathing with a raised respiratory rate (≥50 per min in children aged 6-11 months and ≥40 per min in children aged 12 months and older) on two consecutive measurements (Gove 1997; Lanata et al. 2004). Additional clinical symptoms were also considered as risk factors (noisy breathing, rhonchus/wheezing, fast breathing rates, malaise, lack of appetite, lower chest indrawn). An ALRI episode was defined beginning and ending on the first and last day when the ALRI definition was met followed by at least 14 days without ALRI. The study physician verified ALRI episodes on the follow-up visit.

Anthropometric measures: Stunting, wasting and underweight were defined as below -2 Z-scores of the WHO growth standards curves.

Secondary Outcomes

Microbial contamination: Total coliforms and E. coli were analysed in drinking water, mother's hands and kitchen cloths/sponges. Mothers' hands and kitchen cloths/sponges were analyzed for total coliforms and *E.coli* using PetrifilmTM EC plates applying standard methods (WHO 2008). Results for kitchen cloths/sponges were expressed as colony-forming units per cm2 (CFU/cm2). Water samples were analyzed for thermo-tolerant (faecal) coliforms using a membrane filtration method OXFAM-DELAGUA. Results were expressed as colony-forming units per 100ml of water (CFU/100ml). All samples were double-read by the microbiologist, if the reading had more than 10% difference in counts a third microbiologist was consulted for a final decision.

For the detection of diarrhoeagenic E. coli, five colonies per sample were saved in peptone media vials for further characterization. From the Petrifilm™ EC plate priority was given to save typical *E. coli*-like colonies (blue colonies with gas) (AOAC 2000). However, if less than five or none typical colonies were present, other coliforms were saved to arrive to five colonies per sample. The samples were analysed using a real time PCR multiplex system, (Guion et.al., 2008) which detects virulence genes of enterotoxigenic *E. coli* (ETEC), enteroinvasive *E. coli* (EIEC), enteropathogenic *E. coli* (EPEC), Shiga-toxin producing *E. coli* (STEC), enteroaggregative *E. coli* (EAEC) and diffuse-adherent *E. coli* (DAEC). The multiplex PCR was done in a five-colony pool per sample (Barletta et al., 2009).

Stool specimens: Samples from diarrhoea -symptomatic and asymptomatic- children were screened to detect diarrhoeagenic *E. coli*. The same method as described above was used for detecting *E. coli* virulence genes.

3.4 Ethical Considerations

The Nutritional Research Institute (IIN) Ethical Review Board and the cantonal ethical review board of University of Basel, Switzerland (Ethikkommission Beider Basel, EKBB) approved the study. The Cajamarca Regional Health Authority and the Peruvian National Institute of Health (INS) also approved the trial, which was nationally registered with INS. The trial was registered at ISRCTN (ISRCTN28191222). Community leaders and local authorities from the study area signed a collaborative agreement with the IIN and Swiss TPH before the beginning of the study activities. The mother/caretaker or father of each study child signed a written informed consent. The study nurse 'or' physician evaluated ill children or they were referred by the field staff to the local health centre in San Marcos or to the clinic in Cajamarca. The project provided transport and treatment costs for those patients.

PART II: DEVELOPING AN INTEGRATED INTERVENTION PACKAGE IN THE RURAL PERUVIAN ENVIRONMENTAL HEALTH CONTEXT

CHAPTER 4

COMBINING INTERVENTIONS: IMPROVED CHIMNEY STOVES, KITCHEN SINKS AND SOLAR DISINFECTION OF DRINKING WATER AND KITCHEN CLOTHES TO IMPROVE HOME HYGIENE IN RURAL PERU

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FACTS Reports

Combining interventions: improved chimney stoves, kitchen sinks and solar disinfection of drinking water and kitchen clothes to improve home hygiene in rural Peru.

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Abstract. Home based interventions are advocated in rural areas against a variety of diseases. The combination of different interventions might have synergistic effects in terms of health improvement and cost effectiveness. However, it is crucial to ensure cultural acceptance. The aim of the study was to develop an effective and culturally accepted home-based intervention package to reduce diarrhoea and lower respiratory illnesses in children. In two rural Peruvian communities we evaluated the performance and acceptance of cooking devices, household water treatments (HWT) and home–hygiene interventions, with qualitative and quantitative methods. New ventilated stove designs reduced wood consumption by 16%. The majority of participants selected solar water disinfection as HWT in a blind tasting. In-depth interviews on hygiene improvement further revealed a high demand for kitchen sinks. After one year of installation the improved chimney stoves and kitchen sinks were all in use. The intervention package was successfully adapted to local customs, kitchen-, home–and hygiene management. High user satisfaction was primarily driven by convenience gains due to the technical improvements and only secondarily by perceived health benefits.

Keywords. Solar water disinfection, improved chimney stoves, home-hygiene interventions, household water treatment, Peru.

1 Introduction

Globally, more than 2.5 million children under five years of age die annually from diarrhoea and acute lower respiratory-tract infections (Black, *et al*., 2010). In Peru, recent national mortality statistics indicate 14% of deaths in children <5 years of age were attributable to acute lower respiratory-tract infections and 12% to diarrhoeal diseases (INIE, 2007, WHO, 2008).

Several studies demonstrated that simple, efficient and effective interventions at household level including improved sanitation, personal hygiene and improved water supply are cost-beneficial and cost-effective approaches in reducing the diarrhoeal disease burden (Mäusezahl *et al*., 2009, Clasen *et al*,. 2007, Clasen *et al*., 2008, Ejemont *et al*., 2008, Hunter *et al*., 2008). A recent systematic review estimated that hand washing with soap reduced diarrhoea by 43% and household water treatment by 17% (Cairncross *et al*., 2010). This is especially important for populations with access to sufficient quantities of water of inadequate microbiological quality (Esrey *et al*., 1985). A further type of intervention that can reduce the burden of childhood disease is the provision of improved chimney stoves. A recent meta-analysis on the impact of household air pollution demonstrated a nearly two fold increase in the odds of suffering from childhood pneumonia if the child was exposed to smoke from incomplete combustion of household fuels (Dherani *et al*., 2008). Changing from open fires to improved ventilated stoves has been demonstrated to improve indoor air quality and reduce severe acute lower respiratory infections among infants (Smith *et al*., 2011).

We carried out a study in Peru to provide a basis for designing a "package" of several interventions to tackle both, the problem of childhood diarrhoea and respiratory infections in a rural area in Peru. This was a pilot study for a planned larger programme of interventions carried out in a

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randomised controlled trial (Hartinger *et al*., 2011). Though single interventions can bring benefits, a package can bring greater advantages because of synergistic effects. An integrated package of home-based health interventions on priority child diseases will enhance health gains through synergistic effects. Synergy effects can be expected because children infected with one infectious disease become more susceptible to other diseases and multiple interventions are able to interrupt multiple transmission cycles at the same time. Furthermore, interventions addressing several health hazards simultaneously are more likely to address the caretakers' perceived benefits leading to more sustainable compliance. Finally, the associated costs, especially management costs, are lower if multiple interventions are being implemented jointly. However, interventions can only bring real benefit if they are sustainable. This will only be the case if the interventions are culturally acceptable to the beneficiaries, and they need to be involved in planning and implementation.

We describe the approach and the initial testing of an effective low-cost, home-based intervention package (IHIP) which would reduce the household burden of disease (acute lower respiratory infections (ALRI) and diarrhoea in children) in rural communities in the Cajamarca region of Peru. The package included the development and evaluation of an improved ventilated cooking stove together with a kitchen sink, the promotion of a home-based drinking water treatment technique combined with hand washing and hygiene education. Potential beneficiaries were consulted about their needs and preferences before the project started, and asked about their perceptions of the project after a year of implementation. The findings of the randomised controlled trial are published in subsequent papers. (Trial registry ISRCTN: 28191222).

2 Methods

2.1 Study site

The study was carried out in seven communities in San Marcos Province, Cajamarca Region in the northern Andes of Peru from May to September 2008.

The majority of the population relies on traditional open fire stoves inside the house called *Tulpias* for cooking (Figure 1). Wood for cooking is gathered or bought for an equivalent of US$ 2.5 per 20kg. The firewood usually lasts for three to four days with daily use for about six hours in a typical family of five members. Water supply systems consist of natural spring–or stream water led into reservoirs and piped to each rural household court yard. These systems are managed by small water boards belonging to each community, consisting of community members selected every two years. The boards are responsible for organizing and maintaining the use of the water supply systems, including chlorination. They collect monthly payments from each household, equivalent to US$0.35 to cover expenses for repair materials. Boards also designate work brigades for draining, cleaning and repairing the reservoirs and pipes, especially during the rainy season. The reservoir water is restricted to household water use (drinking, washing); other uses such as irrigation are prohibited and misuse is fined.

2.2 Intervention development

There were five steps to selected appropriate technologies for drinking water treatment, stove improvements to reduce household air pollution, and improvements in household hygiene that would be culturally acceptable; i) We consulted local authorities and community members twice about appropriate designs and options, ii) We selected households to install and test the new devices, iii) we assessed the needs and concerns of user families, the general population and other stakeholders one month after the interventions were set up (August 2009), iv) we validated our surveillance instruments and tested our hygiene messages, and, v) we evaluated current use, determinants of adoption, rejections or discontinuation of using the stoves, sinks and water treatment and recorded users and non-users' experiences and general perceptions about the different home-hygiene improvements 12 months after the IHIP had been implemented.

2.3 Study sample

A total of 115 households were purposively selected. In 46 of these households we collected water samples to test solar disinfection and chlorine residue; in 58 households we carried out our control cooking and kitchen performance tests and in an additional 11 households open interviews and 3 focus group discussions were conducted. We selected communities that were currently not receiving any governmental or non-governmental aid or services except for the national conditional cash transfer programme *JUNTOS* (JUNTOS, 2010) and the Ministry of Health routine health programmes. The households had to fulfilled the following criteria: i) use of firewood, charcoal or dung as heating material for cooking, and ii) have at least one child aged between six and 35 months living at home, and iii) the households had to have easy access and be close to the city of San Marcos. Informed consent was obtained from all households willing to participate.

2.4 Qualitative assessments of cultural acceptability and performance

We carried out anthropological work; i) to assemble general knowledge regarding health (diarrhoea, pneumonia, nutrition, health seeking practices) and hygiene, ii) to determine the perceptions of the intervention package after one month of introduction in the pilot households, iii) for gathering general perception of the community's main stakeholders of the San Marcos Province in order to obtain a better understanding of the local framework conditions for a potential scaling up activities, and iv) to assess after one year the experiences and perceptions of the improved chimney stoves, sinks, water treatment and hygiene messages in the pilot households.

The analysis of the data was done according to the methods described in Dawson, Manderson and Tallo (Dawson *et al*., 1993) for focus group discussion and standard content analysis of interview data by grouping themes after coding the transcripts and selecting appropriate quotes to illustrate findings.

Figure 1. Type of stoves found in the Province of San Marcos and the OPTIMA-II improved chimney stove model. a: Open fire "Tulpia"; b: "Traditional" stove; c: government design "SEMBRANDO" stove; d: OPTIMA-II stove.

2.5 Selection, implementation and quantitative assessment of improvements

The selection of the intervention was done in a truly participatory manner over a month interactive phase, were the study personnel become trustworthy and equal partners with the community. Thus this approach enable us to gain insights into cultural beliefs and potential approaches, this the sole aim of ensuring adherence, compliance and sustainable use of the interventions beyond the life of the project.

2.5.1 Improved Chimney Stoves

We modified an existing and culturally well-accepted stove type to improve its performance. We assessed the efficiency of three existing stove designs called *Tulpia*, *Tradicional* and *SEMBRANDO* stoves and two newly developed stove models the *OPTIMA-I* and *OPTIMA-II* which were built based on out consultations with the communities. In 58 households, we purposely selected 16 households to built OPTIMA-I (N=4), OPTIMA-II (N=8) and SEMRBANDO (N=4) stoves, to carry out control cooking tests (CCT). In the remaining 42 households our kitchen performance tests (KPT) were conducted.

The *Tulpia* open fire stove consists of three stones placed in a triangle holding one pot at a time (Figure 1a). The design of the traditional stove (*Tradicional)* varies, but usually consists of two to three potholders built on two piles of mud bricks crossed by a metal rod acting as support for the pots (Figure 1b). Traditional stoves neither have a combustion chamber nor a smoke removal system. The third model, *SEMBRANDO*, was promoted in a national governmental programme. The *SEMBRANDO* stove consists of an L-shaped combustion chamber made from a refractory material with two potholes and a flue/chimney (Figure 1c). The fourth and fifth models (*OPTIMA-I and -II*) were newly designed by a local manufacturer and built from red burnt bricks, plastered with a mixture of mud, straw and donkey manure (Figure 1d). Both models had three pot holders, a closed combustion chamber, a metal chimney with a regulatory valve, a hood, and metal rods that provided structure for the stove. The two stoves differed only in the number of red burnt bricks used for additional support within the combustion chamber (*OPTIMA-I*: 50 bricks. *OPTIMA-II*: 100 bricks). The research costs of the *OPTIMA-II* stove were US $57, including materials and labour which took four hours to build. Commercial mass production could substantially lower purchasing costs in the future. The use of local building materials was an essential precondition for facilitating future large-scale self-dissemination, manufacturing and repair.

Quantitative and qualitative measures were used to assess the stoves performance and the preferences of the local population in order to choose a model for the intervention package to be tested in the forthcoming community randomised evaluation trial.

We conducted stove performance tests using two standard protocols in the family homes: the controlled cooking test (CCT) and a kitchen performance test (KPT) (Bailis *et al.*, 2007, VITA, 2004). We deviated from the CCT-standard protocol in repeating the test twice, instead of three times. In each household we applied the protocol to the existing stove and the newly constructed *OPTIMA* stove using the most common wood type *Hualango* (*Duranta cajamarcensis* Moldenke) (Hartinger *et al.*, *submitted*). Data was gathered once for a 24-hour period for the KPT.

Figure 2. Solar disinfection and study kitchen sinks.
a: Solar disinfection of drinking water and kitchen cloths; b: Study-built kitchen sink.

Testing tools and hardware included local mud pots, timers, two spring scales with a 20kg range (precision +/- 0.1kg) to measure remaining unburned wood, charcoal and ashes.

Outcome measures for the CCT included a food-to-fuel ratio calculated as the ratio of fuel used by the amount of food for a standard cooked meal. Our standard meal consisted of 500g of unpeeled potatoes, 500g of rice and 1L of water. In order to simulate a normal cooking process, we placed pots with water in the other potholes.

Outcome measures of the KPT were daily fuel use (measured as the total amount of fuel used in 24 hours), daily energy use (multiplying by the calorific value), fuel use per capita (kg/person) and energy use per capita (MJ/person). These measures were normalized by the age-corrected number of people served at the meal. Person-meals were calculated as number of adult male (15 – 59 years) equivalents. Children under 14 years were weighted by a factor of 0.5, adult females and males over 59 years by factor 0.8. We used the "Shell Foundation HEH Project Kitchen Performance Test: Data and Calculation Form" (Bailis *et al.*, 2007) to calculate the calorific value of wood (18 MJ/kg).

Study funding unfortunately did not allow for to measuring indoor household air pollutant levels. Additional funding allowed us to assess carbon monoxide (CO) and particulate matter of less than 2.5 microns (PM2.5) only seven months into the main trial (Hartinger *et al.*, *submitted*).

2.5.2 Household water treatment (HWT)

We collected a total of 46 water samples. All samples were used to analyze solar disinfection; out of these, 26 samples were analyzed for free chlorine and turbidity.

Initially, various options for household drinking water treatment that would complement boiling–method officially promoted by the Ministry of Health–were discussed (chlorination, solar water disinfection (SODIS) and ceramic filters). Twenty three family members completed a blind tasting of differently treated waters. SODIS had the highest acceptance. The SODIS method is a low-cost HWT; requiring water in polyethylene terephthalate bottles (PET) to be exposed to direct sunlight for at least six hours in order to accomplish purification (Berney *et al.*, 2006, Sommer *et al.*, 2997). To test the acceptability and usages of the method, we provided four 2L PET bottles (cost per bottle US$ 0.20) to 12 households. Mother/caretakers were trained in the general application of the method in daily practice according to standard procedures (www.sodis.ch, Figure 2a).

There is considerable literature on the efficacy of solar disinfection (Sommer *et al.*, 1997), however we decided to analysed the purifying effects of UV-light on drinking water in our setting, which is characterized by an intensive UV radiation, high altitudes and mild to cold temperatures. Samples that were collected from household drinking water supplies were placed in 2L bottles exposed to direct sunlight, and tested for bacterial load after 0, 2, 4, 6, 8, 24, 48 and 72 hours. Control samples were collected from the same drinking water source, placed in 2L bottles and kept in the shade for the same time intervals.

Water samples were analysed for thermotolerant (faecal) coliforms using a standard membrane filtration method in the Oxfam DelAgua® field kit for water testing. This generated countable colonies. Samples were analyzed for the occurrence of thermotolerant coliforms and coliforms following standard procedures from the 2002 WHO guidelines for drinking water quality (WHO, 2008). Results were expressed as colony-forming units per 100ml of water (CFU/100ml).

We also analyzed free chlorine residues and turbidity (Nephelometric Turbidity Units) in water samples applying standard testing provided in the DelAgua water test kit. These tests were done to evaluate whether the water quality, of different community drinking water sources (reservoirs), had chlorine residue, and, thus, determine if they have been chlorinated according to local water quality guidelines.

2.5.3 Kitchen sinks and cloths, hand washing, and kitchen environment

During our preliminary studies we found a high contamination rate of total and faecal coliforms on mothers' and children's hands (Gil *et al.*, *submitted*). Our aim was to reinforce official health promotion messages regarding hand-washing, by providing a continuous and abundant flow of water in the kitchen area to lower barriers for hand washing at home. We installed kitchen sinks with pipes connected to the outside tap at US $68 (research costs) (Figure 2b). The price included materials (cement, bricks, tubing) and labour. Field workers encouraged participants to practice hand-washing according to the following procedure: wet both hands, lather them completely with soap or detergent, rub them for at least 45 seconds, rinse them with water and then dry. Mothers were instructed to wash their hands and children's hands after defecation, after changing diapers, before food preparation, before eating and before feeding infants and small children– ideally with soap or detergent, which were universally available in local homes.

The second hygiene message was to eliminate animal excreta from the kitchen environment and isolate household animals from the kitchen area. This was of particularly importance, because families in rural Andes areas maintain a close relationship with their domestic animals mainly guinea pigs, chickens and dogs, allowing them to roam freely within the house and the kitchen. Small children are particularly exposed to infection from animal excreta because they inevitably spend a lot of time in the kitchen with their mothers. Compliance was not formally assessed during our evaluation.

Kitchen utensils and kitchen cloths are an additional potential source of contamination in the kitchens environment. In our study households, the kitchen cloths, called *Mallas,* were identified as the most contaminated utensil in the kitchen.

2.6 Ethics

This study was approved by the Nutrition Research Institute (IIN) Ethical Review Board and the Cantonal Ethical Review Board of Basel, Switzerland (EKBB). All participating families provided written informed consent.

3 RESULTS

3.1 Qualitative assessment

Several health topics were addressed during personal interviews and focus groups. Our aim was to understand the concerns and perceptions of the families with respect to respiratory infections, diarrhoea and nutrition and how the interventions were initially perceived also regarding potential benefits and obstacles for sustainable use.

3.1.1 General perception about health and hygiene

In general, mothers considered respiratory infections being caused by cold weather and changing seasons. To prevent children from getting sick, mothers thought that they should dress children in warmer clothes. *"They usually get the flu from the cold and the change of the weather, from that they get the flu. Sometimes they get fever and a little bit of diarrhoea"* (*Chuquipuquio* Community, mother, 39 years). A father from *Manzanilla*, also commented that *"up until now my child has been sick of the flu, no other disease. The children in Manzanilla get the flu and diarrhoea. The flu occurs because of lack of cleanliness and cold weather. When the mother is sick, the child will get sick through the breast milk and that causes disease… for them not to get sick the mother has to wrap up the child and herself with lots of cloths (Manzanilla* Community, father, 24 years*).* For some families it was evident that wood smoke caused health problems in children and in grown-ups, causing eye irritation, problems in the lungs and asthma: "*the smoke affects the lung" (Chuquipuquio* Community, mother 39 years). *"The smoke irritates the child, the child goes in the kitchen and starts crying and they can't breath. They can get a disease if they absorb the smoke" (Pomabamba* Community, father, 20 years). In contrast, older women seemed to be accustomed to the exposure of smoke. They were also more concerned about collecting heavy loads of firewood, back pains from this activity, and the time spend for collecting wood, a resource they perceived as becoming increasingly scarce.

In almost all in-depth interviews contact with dirty floors and children putting dirty hands in their mouths or eating with dirty hands were the three exclusively mentioned causes for child diarrhoeal illness. Respondents were not aware that other family members could also be a source for contaminating the child while cooking or handling. However, when asked about hygiene and hand washing, family members responded always washing their hands and also reported the appropriate times for it: *"I wash my hands before I eat my food and after I go to the bathroom. We are in contact with the dirt, because we work in the fields." (Chuquipuquio* Community, mother, 39 years). *"I wash my hands with water and soap. I wash my hands when I sit down for lunch and to go for a walk. My daughter does not wash her hands, her mother washes them for her with warm water, but without soap because her hands are clean, they don't get dirty she can only sit down, she can not crawl" (Pomabamba* Community, father, 20 years).

Water was not considered on a causal pathway for acquiring child diarrhoea. Water was perceived as clean and many families drunk it directly from the outside water faucets. Only few said that they boiled water for drinking, but only for the child. As described earlier, natural water source were lead into reservoirs, and in theory they were chlorinated. However we could not find traces of free chlorine in any of the water samples taken directly from the faucets (Gil *et al*., *submitted*). We later learned that reservoirs were only cleaned once a month with chlorine. When we asked community members about the mandatory chlorination of their reservoirs all of them expressed that they disliking it due to the taste and fear of acquiring disease, such as cancer.

Mothers did not mention nutrition as a health problem, either because of denial or because of not being able to recognize under-nourishment in children. A mother said *"they* [health staff] *have told me that my daughter is undernourished, because she is now one year and a half and does not gain weight. I don't think she is undernourished because we feed her and she eats fine. Why would she be undernourished? None of my other children ever were." (Socchagon* Community, mother, 35 years). *"I have not seen an under nourished child. They are skinny and do not grow." (Sicsibamba,* Community, mother 32 years*).*

Table 1. Results from the Control Cooking Test: Total Cooking Time, and Ratio Food to Fuel.

Stove type		**Total Cooking Time**					**Ratio Food to fuel**		
	n	Mean (minutes)*	SD	Reduction %	pa	Mean (kg/g)**	SD	Reduction %	pa
Open Fire	16	78	16		reference	0.49	0.15		reference
SEMBRANDO	8	95	21	-18	0.07	0.45	0.09	7	0.95
OPTIMA-I	8	52	7	33	<0.0001	0.42	0.08	14	0.46
OPTIMA-II	16	64	14	18	0.006	0.41	0.13	16	0.13

a: Mann Whitney pair wise comparisons, open fires were used as reference group.
* Time required to start the fire and cook the test meal in the main furnace.
** Grams of wood required to cook a Kg of typical noon meal for a family.

Table 2. Results of the Kitchen Performance Test: Comparison of two stoves types under normal household conditions during 24 h in terms of total and per capita fuel used and energy consumption.

Stove type		**Daily fuel use (kg)**		**Fuel use per capita (kg/ person)**				**Daily energy use (MJ)**		**Energy use per capita (MJ/ person)**			
	N	Mean	SD	Mean	SD	Reduction %	pa	Mean	SD	Mean	SD	Reduction %	p
Open Fire	23	9.3	3.3	2.8	1.1			167	59	51	29		
OPTIMA-II	35	7.8	1.5	2.4	0.7	15	0.08	141	29	43	14	16	0.18

a: Mann Whitney

3.1.2 Perception after one month of implementation

Initial impressions from participating families were important to recognize potential problems. Families from one community partly misinterpreted instructions on how to apply the SODIS method: a mother exposed water bottles (and her potatoes) only during the night–because of the purifying effects of moonlight.

Faster cooking and resulting time saving allowed mothers/caretakers to do a variety of other activities e.g. washing utensils, cleaning and tending their animals. This was recognized as one of the most important benefit of the improved chimney stoves: *"There is less smoke in the kitchen environment, and my son is exposed to less smoke. We can cook faster and the food remains warm for a much longer time.* (Manzanilla, Community father, 34 years) Additionally, the same father reported that he acquired the skills to build improved chimney stoves and would be ready to assist others when ever they build a new stove. Kitchen sinks, provided running water inside the household and were considered the most important benefit of the IHI package and at large. Repeatedly during those initial assessments participating mothers remarked that they were initially anxious to participate as they strongly feared that foreign organizations and mining companies (common in the area) come to the region to try and steal their children. Those experiences were essential for strategizing our approach in the project implementation.

3.1.3 Perceptions after one year

All improved chimney stoves and kitchen sinks were being used on a daily basis after one year. Sixty six percent of households claimed that the stoves were in excellent conditions and that no repairs were needed. However, three households mentioned that they had to repair their stoves twice since the installation. All kitchen sinks were in good condition and no negative remarks or disadvantages were recorded. The amenity of the sinks was highly valued, not only due to the increase availability of water but also for facilitating a much more time-efficient cleaning of the kitchen environment: "*Before I had to carry the water from outside and did not use Ayudin* [type of detergent] *because I needed a lot of water,–now I wash everyday with Ayudin" (Manzanilla* Community, mother, 32 years*)*.

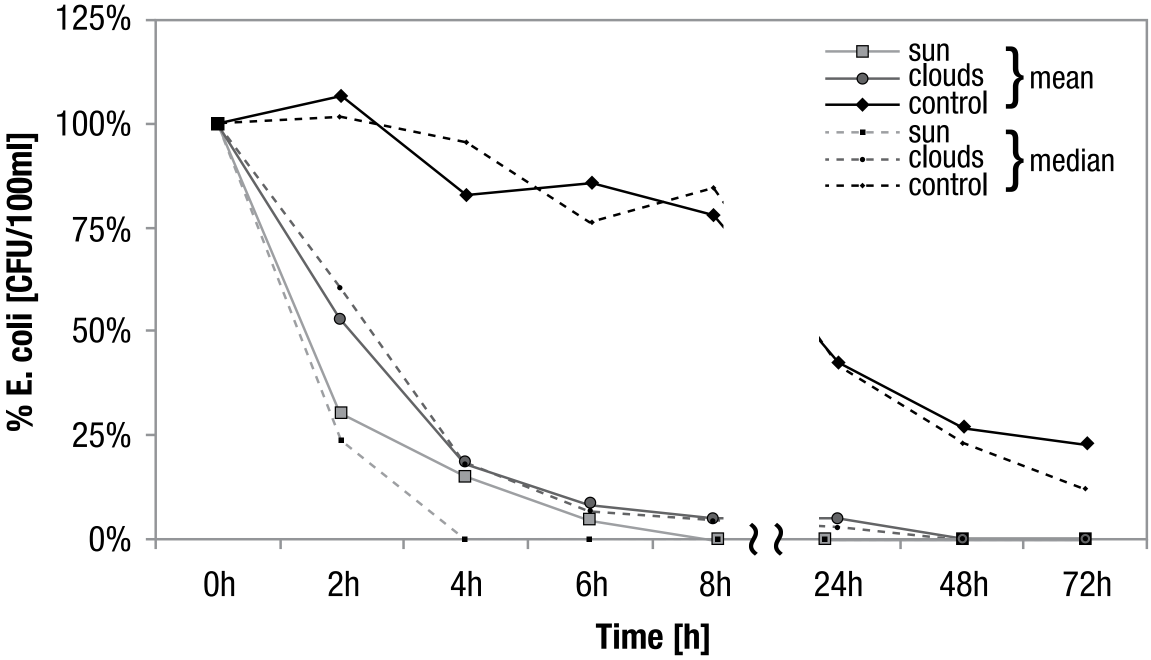

Figure 3. Thermotolerent coliforms concentration in water samples after exposure to sunlight in normal sunny days. Sunny days (n = 22, light grey line); cloudy days (n = 3, dark grey line) and control bottles not exposed to sunlight (n = 9, black line).

Mothers confirmed initial impressions that a key advantage of the improved chimney stove installed in their kitchen was the additional time freed from supervising the cooking,–time they used for other household chores. Consistently they reported less eye irritation among their children and among themselves, better health in general and well-being and significantly less wood consumption "*I cook faster using the three pot-holders at the same time. I start to cook at 9:00 to 10:00am and the food keeps warm until 12:00pm. I can knit while cooking" (Manzanilla* Community, mother*, 29* years*).*

In contrast to the enthusiastic uptake of the indoor air and kitchen hygiene devices the SODIS HWT was adopted and continued to be used by 30% of the households after being instructed on how to apply the method only once on a single household visit at the beginning of the study. To apply a household water treatment method (boiling, chlorine) was not perceived as necessary; families believed that by cleaning the reservoir once a month with chlorine the water supply would remain clean. The rainy season was also considered an inappropriate time to use SODIS: *"We don't have the bottles out, because it started to rain and the water turned green, rain, rain and rain, we did not change the bottles any more. During the summer yes … the bottles helped…we all drink from them…but we did not get used to them when there was no sun" (Manzanilla* Community, mother, 35 years*).*

3.2 Control cooking test and kitchen performance test

Table 1 summarizes the CCT results. Data showed that both *OPTIMA* models had a significantly shorter cooking time compared to the open fires. Similarly, the *OPTIMA* stoves had a 15% lower ratio of food-to-fuel compared to the open fires; however, this difference was not statistically significant. The performance of the *SEMBRANDO* stove was always below that of the *OPTIMA* designs.

Table 2 summarizes the KTP results. Overall the *OPTIMA-II* stove showed a better performance compared to the open fire stove, showing a 15% reduction in daily fuel and energy use and 16% reduction in fuel and energy use per capita. However, there was considerable variation and the improvements were not statistically significant.

Despite the fact that the *OPTIMA-I* model exhibited a better performance in the food-to-fuel ratio, we selected the *OPTIMA-II* to be implemented as part of the intervention package, since additional bricks within the combustion chamber could provide a longer lifespan and sturdiness.

3.3 Solar disinfection

To evaluate the perception regarding home-based water treatment techniques we carried out a blind tasting test, were 23 household members participated. We poured five glasses of differently treated drinking water (boiled, solar-disinfected, chlorinated, commercially bottled water and untreated tap water) in numbered glasses offered to the blindfolded participants. About half of the participants preferred the solar disinfected water and only 9% favoured the chlorinated water.

To test the efficacy of SODIS, we collected a total of 46 water samples from different sources, 10 samples were initially uncontaminated and further two had contamination levels above the detection limit and, therefore, were not included for the analysis. From the remaining 34 samples, nine samples were used as controls and 25 samples were exposed to sunlight. Three of those 25 samples were exposed during cloudy conditions and were analyzed separately. As seen in Figure 3, water bottles exposed to direct sunlight, reached on average zero thermotolerant coliform counts after eight hours. If the weather was cloudy the bottles reached zero thermotolerant coliform, counts after 48h of exposure, although the counts were already remarkably lower at 8h of exposure. The turbidity ranged between 5 to 30 NTU, only one sample had a turbidity of 50 NTU and was filtered before exposed to sunlight.

4 Discussion

The aim of the study was to exploit in a participatory approach options for an integrated home-based environmental intervention package that would address local needs regarding kitchen hygiene and cooking preferences and result in well-perceived convenience gains that would not only lead to a higher compliance, but also to reduced households burden of disease in a forth coming evaluation trail. The locally made *OPTIMA-II* stove was selected as the best improved chimney stove model from several options. Families of two test communities chose the *OPTIMA-II* stove for scale-up in the subsequent community-randomised evaluation of a home-based environmental intervention package to improve indoor air quality, drinking water quality and home-hygiene.

Selection criteria were based on a CCT, where the *OPTIMA-II* model had the shortest total cooking time, and smallest food-to-fuel ratio. The KPT revealed that *OPTIMA-II* stoves used less daily fuel and energy than other locally available alternatives. Mothers' overwhelming acceptance, sustained use and the general perception of a massive convenience gain, including substantial time saved were also important selection criteria.

The installation of the kitchen sink facilitated hand washing with soap, and washing of utensils with detergent, generated a cleaner kitchen environment and fostered home hygiene in general. Since water was available all the time–with exceptions during the dry season–they were not restricted in using the kitchen sinks. We did not measure the increase in water utilization, but it is known that water availability is crucial and as important as water quality for hygiene improvements (Esrey *et al*., 1985 Fewtrell *et al*., 2005). We plan to evaluate the increase of water consumption in the forthcoming trial in order to distinguish also potential effects of increased water quantity on health (Fewtrell *et al*., 2005). Solar disinfection was selected as the HWT by the communities in a participatory manner. The other two options–chlorination and filtration–rendered unfeasible. Chlorination was universally rejected, based on bad flavour and a popular belief that chlorine could be dangerous for the health of children. We searched for ceramic filters as reliable HWT alternative for this population but could not find any local suppliers. Therefore, SODIS was chosen to be promoted as water purification technique in the intervention package**.** Some authors voiced concerns regarding potentially hazardous agents being released from PET bottles when exposed to sunlight (Shotyk *et al*., 2006, Sax, 2009). Recent respective evaluations, however, indicated no negative effects (Ubomba-Jaswa *et al*., 2010) and reported comparable levels of contaminants among commercially bottled water (Schmid *et al*., 2008). To address potential negative adherence, our SODIS education campaign will address this issues. Additionally, our study confirmed that water was disinfected after eight hours of solar exposure as indicated by zero thermotolerant coliform, growth. Thermotolerant coliforms counts remained high in control samples unexposed to sunlight. These, findings are in concordance with evaluations in similar mountainous high altitude settings (Boyle *et al*., 2008). However, the educational messages of the SODIS method had to be adapted to local beliefs; mothers thought that exposing water to direct sun could cause health problems, by bloating their stomach and, hence, they were reluctant to consume it at first. However, it should be noted that in this small scale pilot setting the SODIS HWT was not implemented with the intensity as indicated in the published guidelines (www.sodis.ch) or when going to scale (Mäusezahl *et al*., 2009).When mothers were told the bottles had to be exposed for one day, they agreed to consume the water, because this meant leaving the bottles exposed to the purifying effects of the moonlight i.e. now being fully compatible with local believes that moonlight has curative effects on humans and environment.

A general misconception regarding chlorination of the reservoir was identified. Cleaning and maintenance with chlorine do not equate chlorination. No chlorine dispenser or any other chlorination method was found indicating neither current nor passed use. This is consistent with other observations of chlorination used in Latin America (Arnold & Colford, 2007, Rufener, *et al*., 2010). Similar results were found when testing the San Marcos and Cajamarca city water supplies. No trace of residual free chlorine was found, indicating a regional and not just a local problem. In the study area, peoples dislike for the taste and smell and fear of potential health problems were identified as barriers for the adoption of chlorination as a HWT. There is a need to develop a specific intervention to bring chlorination to its full use both; in cities in the Cajamarca Region as well as in rural water supply systems given that an ubiquitous piped water system is the ultimate aim of the national water supply programme.

Our microbiological studies indicated that kitchen cloths were heavily contaminated[21]. Many studies in developed and developing countries identified kitchen sponges or dishcloths as a source of contamination of food and hands (Sharma *et al*., 2009, Hilton & Austin, 2000). Effective interventions like the use of disinfectants, hand washing or more sophisticated treatment options have been developed and globally promoted (WSSCC, 2010, Luby *et al*., 2004). We applied solar disinfection based on UV radiation, to disinfect successfully and at no cost the *malla*'s used in our study area as kitchen cloths.

There are limitations to the study. The sample size used in this exploratory study was small. The selected families may hence not fully represent the population of the study area, although they lived in the same area and under conditions similar to the communities envisaged to participate in the forthcoming evaluation trail. In the selection of the improved chimney stove, we did not include any evaluation regarding the reduction of indoor air emissions, due to budget constraints. Air quality measurements were taken in a subsequent study.

In conclusion, this study identified three promising, home-based interventions that could be implemented in concert as a package and at larger scale. We will evaluate in a community-based cluster randomised trial the efficacy of an integrated home-based intervention package (IHIP) in reducing child diarrhoea, ALRI and improving child growth combing an improved chimney stove, a kitchen sink with running water and solar drinking water disinfection and kitchen–and food hygiene education on child diarrhoea, acute respiratory illnesses and growth in 51 rural communities in Peru.

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CHAPTER 5

FAECAL CONTAMINATION OF FOOD, WATER, HANDS AND KITCHEN UTENSILS AT HOUSEHOLD LEVEL IN RURAL AREAS OF PERU

INTERNATIONAL PERSPECTIVES

Although most of the information presented in the Journal refers to situations within the United States, environmental health and protection know no boundaries. The Journal periodically runs International Perspectives to ensure that issues relevant to our international membership, representing over 20 countries worldwide, are addressed. Our goal is to raise diverse issues of interest to all our readers, irrespective of origin.

Fecal Contamination of Food, Water, Hands, and Kitchen Utensils at the Household Level in Rural Areas of Peru

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Abstract **The study described in this article evaluated sources of contamination of children's food and drinking water in rural households in the highlands of Peru. Samples from children's meals, drinking water, kitchen utensils, and caregivers' and children's hands were analyzed for total coliforms and *E. coli* counts using Petrifilm EC. Thermotolerant coliforms in water were measured using DelAgua test kits while diarrheagenic *E. coli* was identified using polymerase chain reaction methods (PCR). Thermotolerant coliforms were found in 48% of all water samples. *E. coli* was found on 23% of hands, 16% of utensils, and 4% of meals. Kitchen cloths were the item most frequently contaminated with total coliforms (89%) and *E. coli* (42%). Diarrheagenic *E. coli* was found in 33% of drinking water, 27% of meals, and on 23% of kitchen utensils. These findings indicate a need to develop hygiene interventions that focus on specific kitchen utensils and hand washing practices, to reduce the contamination of food, water, and the kitchen environment in these rural settings.**

Introduction

Diarrheal diseases are among the leading causes of childhood illness and death in developing countries, killing an estimated 1.3 million children less than five years of age annually (Black et al., 2010).

The World Health Organization outlines several aspects critical to the prevention of diarrhea. They include improved drinking water systems and sanitation facilities, improved nutrition (through breast-feeding and better weaning practices), and good personal and domestic hygiene, among others (United Nations Children's Fund/World Health Organization [WHO], 2009). Several studies have demonstrated a high prevalence of bacterial contamination of water and foods within households (Black et al., 1989; Lanata, 2003; Wright et al., 2004), which is likely associated with incidence of infections in susceptible individuals, especially children.

A need exists for effective interventions in developing countries that can minimize food and water contamination at the household level and therefore reduce the rate of diarrhea in these environments (Hunter, 2009; Lanata, 2003). By measuring risky practices and behaviors and identifying kitchen sites, niches, and surfaces that harbor pathogenic microorganisms, we can provide a basis from which to develop effective interventions. The aim of our study was to identify those potential exposures at the household level, specifically those associated with contamination of food, drinking water, kitchen utensils and surfaces, and caregivers' and children's hands. Our study was conducted to inform a subsequent randomized trial that evaluated the health effects of an integrated home-based intervention package in a rural area of Peru. In addition, we tested for the presence of diarrheagenic *E. coli* (Nataro & Kaper, 1998) as an indicator of pathogenic *E. coli* in this setting.

Materials and Methods

Study Site

Our study was conducted in rural communities of San Marcos Province, Cajamarca, situated at 2,200 to 3,900 m above sea level in the highlands of Peru. Daily temperatures ranged from 7.6°C–25.0°C during the study period and relative humidity was between 59% and 73%. Agriculture and subsistence farming are the major economic activities in this area. Houses are mud brick structures with clay tile roofs supported by tree rods, earthen floors, and few open windows. A typical house consists of three rooms: a kitchen and dining room, a living and sleeping room, and a storage area. Water supply for about 61% of rural homes in San Marcos comes from a piped gravity system that transports untreated water captured from springs through individual or small-scale collective plastic piping to a tap in the courtyard. Only 9% of households have electricity, 2% have a closed sewage system, and 75% have access to a pit latrine (Instituto Nacional de Estadística e Informática, 2007).

Meals are based mainly on potatoes and other tubers and legumes, eaten with rice or boiled in a soup or a stew. Red meat and chicken are seldom consumed due to their high cost. Animals like dogs, guinea pigs, and chickens roam free in kitchens and households. The latter two are bred at home for sale or reserved for festive meals. Meals are prepared three to four times a day and eaten by adults and children alike. Leftover food is not consumed but discarded or fed to the animals. No time is set at which to start cooking the midday meal. Mothers start cooking anywhere from 8:00 a.m. to 12:00 p.m. and keep the food on the fire until lunch. Meals are served directly from pots to plates using wooden ladles. Kitchen utensils are washed with water brought from an outside faucet in a plastic basin, and a *malla*, a local kitchen cloth, also is used to clean dirty surfaces and caregivers' hands while cooking. The *malla* is kept wet after rinsing in the same washing up water, which is not changed very often.

Most households have access to tap water from a faucet installed in the yard. The gravity-based piped water supply system provides spring water to each household. The water is unfiltered, untreated, and chlorination is uncommon. Drinking water is either consumed directly from the faucet or boiled with herbs for children's consumption only. Hygiene practices include hand washing with water only; soap and detergent are rarely used.

Study Design

Households were identified in 32 communities based on home visits and enrolled by a trained field worker between April and September 2008 if they had a child aged 6 to 35 months. Field workers visited each participating household (N = 64) once, mostly at noon, to sample food, water, and kitchen environments.

Sample Collection

In each household approximately 20 g of each food served to the child was collected. If the child had already eaten, samples were taken from the pot. Between 50 and 100 mL of the child's drinking water and one sample from each of the available kitchen utensils (i.e., dish, cup, pot, cutlery, cutting board, and kitchen cloth) were also collected. For both the child and the caregiver, one hand was rinsed in buffer solution for microbiological testing. Samples were collected following standard procedures (Swanson, Busta, Peterson, & Johnson, 1992; WHO, 1997).

For kitchen surfaces, a 10 x 10 cm area of the cutting board or table and the surface of the utensil that was in contact with the child's food or drink was wiped using a cotton swab moistened with Butterfield's phosphate buffer (BPB) and then placed into a tube containing 10 mL of BPB. Kitchen cloths were collected in a new resealable plastic bag and a 10-cm^2 portion was cut and placed in a sterile plastic bag filled with 100 mL of BPB. To obtain samples from hands, caregivers and children placed one hand into a sterile plastic bag filled with 100 mL of BPB. The hand was massaged for 60 seconds, with emphasis on rubbing between fingers, around the fingernails, and the palm of the hand. All samples were kept in a Styrofoam box with cold packs for transport to the project laboratory in San Marcos City and stored at 8°C until processing the same day.

Sample Analyses

Food, utensils, and hand samples were analyzed for total coliforms and *E. coli* using Petrifilm *E. coli*/coliform count plates, following standard procedures (Association of Analytical Communities [AOAC], 2000). A 1-mL aliquot of 10-fold dilutions was plated onto a Petrifilm EC plate. The plates were incubated at 35°C ± 1°C for 24 hours ± 2 hours to enumerate total coliforms and 48 hours ± 2 hours to enumerate *E. coli*. Water samples were analyzed for thermotolerant (fecal) coliforms using a membrane-filtration method, i.e., the Oxfam DelAgua water testing kit, and results were recorded as *E. coli* (CFU/100mL of water), an indicator for thermotolerant coliforms.

Colony counts were recorded by the on-duty lab microbiologist. Cultures were reread by a second microbiologist. Digital pictures taken from each sample were read by a third microbiologist to decide on a final result in case of discrepancies (more than 10% difference) between the first two counts.

For the detection of diarrheagenic *E. coli*, five colonies per sample were saved in peptone media vials for further characterization. From the Petrifilm EC plate, priority was given to typical *E. coli*-like colonies (blue colonies with gas) (AOAC, 2000); however, other coliforms were saved if less than five typical *E. coli*-like colonies were present. The peptone media vials were transported to the Enteric Diseases and Nutrition Laboratory at the Tropical Medicine Institute, Cayetano Heredia University, Lima, for analysis using a real-time polymerase chain reaction (PCR) multiplex system (Guion, Ochoa, Walker, Barletta, & Cleary, 2008), which detects virulence genes of enterotoxigenic *E. coli* (ETEC), enteroinvasive *E. coli* (EIEC), enteropathogenic *E. coli* (EPEC), Shiga-toxin–producing *E. coli* (STEC), enteroaggregative *E. coli* (EAEC) and diffuse-adherent *E. coli* (DAEC). The multiplex PCR was done in a five-colony pool per sample (Barletta et al., 2009).

Data Analysis

Geometric means of the colony counts (total coliforms and *E. coli*) for each type of sample were calculated. A value of 0.5 was assigned to all samples with zero colony counts to allow for calculations. Proportional differences were analyzed by Chi-square tests with Yates's correction or by two-tailed Fisher's exact test using Epi Info version 6 statistical package.

Results

A total of 275 samples (134 from kitchen utensils, 77 from children's meals, 43 from hands, and 21 from children's drinking water) from 64 households were analyzed. The frequency of contamination with total coliforms and *E. coli* by type of sample is

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TABLE **1**

Total Coliforms and *E. coli* in Food, Water, Utensils, and Hands From Rural Households of Peru

Sample Type	Total Coliforms			*E. coli*		
	% (*n/N*)	Geometric Mean	Ranges	% (*n/N*)	Geometric Mean	Ranges
Child meals		CFU/g	CFU/g		CFU/g	CFU/g
Salad	67 (2/3)	4.4 x 10	10^2	0 (0/3)		0
Dairy	44 (4/9)	8.1 x 10	10^2–10^9	22 (2/9)	4.2	10^0–10^7
Tuber cooked/fried	21 (3/14)	1.6	10^1–10^2	0 (0/14)		0
Rice	18 (2/11)	1.2	10^1–10^2	0 (0/11)		0
Soup	17 (2/12)	1.7	10^2–10^3	8 (1/12)	1.0	10^3
Toasted bread	11 (1/9)	0.8	10^1	0 (0/9)		0
Oat	9 (1/11)	1.4	10^4	0 (0/11)		0
Stew	0 (0/8)		0	0 (0/8)		0
All child meals	19 (15/77)		0–10^9	4 (3/77)		0 –10^7
Drinking water	N/A	N/A	N/A	48 (10/21)	2.6*	10^0 –10^2*
Kitchen utensils		CFU/utensil†	CFU/utensil†		CFU/utensil†	CFU/utensil†
Kitchen cloth	89 (17/19)	1.2 x 10^4‡	10^0–10^7‡	42 (8/19)	1.2 x 10‡	10^0–10^5‡
Washing basin	70 (7/10)	2.1 x 10	10^1–10^3	10 (1/10)	1.0	10^2
Water jar	69 (9/13)	1.3 x 10^2	10^1–10^9	15 (2/13)	1.2	10^1–10^2
Pot	64 (7/11)	6.3 x 10^2	10^1–10^9	18 (2/11)	1.4	10^0–10^3
Spoon	64 (9/14)	2.9 x 10	10^1–10^3	21 (3/14)	1.3	10^1–10^2
Dish	58 (7/12)	1.2 x 10^2	10^1–10^9	8 (1/12)	0.6	10^1
Cup	50 (6/12)	2.5 x 10	10^0–10^7	8 (1/12)	0.5	10^0
Bottle's nipple	45 (5/11)	2.4 x 10	10^1–10^9	9 (1/11)	1.1	10^3
Cutting board	43 (6/14)	2.0 x 10‡	10^0–10^5	14 (2/14)	0.8‡	10^0‡
Ladle	28 (5/18)	2.2	10^1–10^3	6 (1/18)	0.6	10^1
All kitchen utensils	58 (78/13)		10^0–10^9	16 (22/134)		10^0–10^5
Hands		CFU/hands	CFU/hands		CFU/hands	CFU/hands
Caregiver	76 (16/21)	2.8 x 10^2	10^1–10^5	29 (6/21)	4.8	10^1–10^4
Child	55 (12/22)	2.2 x 10	10^1–10^4	18 (4/22)	1.4	10^1–10^3
All hands	65 (28/43)		10^1–10^5	23 (10/43)		10^1–10^4

*Thermotolerant (fecal) coliform CFU/100 mL.
†Area of utensil in contact with food/drink.
‡CFU/100 cm^2.

presented in Table 1. Total coliforms were significantly more present on hands (65%) and on kitchen utensils (58%) than in children's meals (19%); $p < .01$. Kitchen cloths (89%, 17/19) and caregivers' hands (76%, 17/19) were the individual samples most frequently contaminated with total coliforms. The frequency of *E. coli* in drinking water (48%) was significantly higher than that of kitchen utensils (16%, $p = .002$) and children's meals (4%, $p < .0001$). No statistical difference was observed, however, when comparing drinking water and all hands ($p = .09$). Kitchen cloths were most frequently contaminated with *E. coli* (42%), with a geometric mean of 1.2 x 10^4 CFU/100 cm^2.

A total of 108 samples were tested for diarrheagenic *E. coli*. DAEC was the most frequent type identified (9/108), followed by ETEC (8/108), EIEC (4/108), STEC (3/108), and EAEC (1/108). Overall, at least one type of diarrheagenic *E coli* was detected in 20% of all tested samples, including in 33% (2/6) of children's drinking water, 27% (3/11) of children's meals, 23% (14/60) of kitchen utensils, and 10% (3/31) of hands.

Discussion

Our study describes the high frequency of microbiological contamination of water and food consumed by children in parts of rural Peru, and indicates an important potential cause of diarrhea. A high percentage (48%) of the water consumed by children was often boiled with herbs and subsequently kept in jars or pots, but contained thermotolerant coliforms. Dairy products and boiled soups also had remarkably high *E. coli* counts (up to 10^7 CFU/mL in dairy). The source of these contaminants likely originates from contaminated kitchen utensils including plates, spoons, pots, or jars, as well as *mallas*, the local kitchen cloths. Children's and caregivers' hands were also contaminated with *E. coli* due to poor hygiene practices.

Our study had some limitations. Sampling was conducted during the dry season (April to September), and not during the rainy season (December through March). Hence, seasonal variations in water and food contamination were not captured. Study conditions allowed for only a small number of convenience samples from each type of food or kitchen utensil, which is sufficient for descriptive purposes, but limited for giving precise estimates. Sampling centered on the midday meal for logistical reasons. It is possible that meals prepared in the early morning or in the evening may have had different levels of contamination, influenced by cooler temperatures at those times. Future studies would need to sample children's meals over a 24-hour period and ideally, repeatedly, in order to fully describe the level and variability of food contamination in these households. Study conditions did not allow for serial sample collection before and after food preparation and at the time of serving to children, which would have allowed us to identify the critical control points to minimize or eliminate the risk of contamination in a hazard analysis and critical control point system (Bryan, 1981).

Few studies (Adachi, Mathewson, Jiang, Ericsson, & DuPont, 2002; Vigil et al., 2009) have attempted to identify diarrheagenic *E. coli*—the strains of *E. coli*—in environmental samples (food, water, and utensils), using molecular and specific PCR methods. We tested for these groups of pathogens by PCR, based on a presumptive identification of *E. coli*-like colonies and coliforms. We found only a small number of colonies with diarrheagenic *E. coli* strains. It is unclear whether the lower isolation rates found are real or are due to low sensitivity in our selection of *E. coli*-like colonies. These results suggest that risk estimates based on total coliform or *E. coli* counts overestimated the true risk of diarrheal diseases from food and water due to pathogenic *E. coli*.

Despite these limitations, the results of our study are comparable to others from developing country settings, where weaning food and water in households were frequently found to be contaminated with fecal matter (Clasen et al., 2003; Kung'u et al., 2009; Rufener, Mäusezahl, Mosler, & Weingartner, 2010). In a study conducted in peri-urban Lima, Peru (Black et al., 1989), weaning food was found to be contaminated with *Salmonella* spp., *Vibrio cholerae* non-O1, and ETEC originating from secondary contamination of kitchen utensils after food preparation. Foodborne illnesses are associated with food preparation too far in advance of consumption (allowing growth of pathogens present in the food to levels exceeding the minimal infectious dose), improper cooling, and inadequate reheating (Lanata, 2003). In our study communities, food stuffs and leftovers were not stored for second servings, since cooking was done three to four times per day; however, food samples collected at eating time directly after cooking were found to be contaminated. This could be explained by the high frequency of contamination found on kitchen surfaces and utensils, most likely due to the washing up process: washing up in a plastic basin with untreated and unchanged water leaves food residuals behind as a source for bacterial growth. Other studies have shown how common cross contamination is in the kitchen through contaminated water used to clean dishes (Beumer & Kusumaningrum, 2003).

Our study indicates that kitchen cloths may present a significant yet underrecognized source of contamination of kitchen utensils, since cloths are used all over the kitchen to wipe dirty surfaces as well as hands and remain wet after rinsing in the same washing-up water. In other settings, kitchen cloths were identified as vehicles for pathogens that were able to survive for extended periods of time (Kusumaningrum, van Putten, Rombouts, & Beumer, 2002; Mattick et al., 2003). Food safety interventions in these communities should focus on kitchen hygiene practices, hand washing, safe food preparation, and safe handling of cooked food.

Conclusion

The prevalence of fecal contamination of food and drinking water given to children highlights the need for improving domestic hygienic practices, like hand washing and cleaning kitchen utensils, to prevent diarrheal diseases transmitted through the fecal-oral route. Effective interventions to reduce contamination of the kitchen environment should be developed. Further studies are needed on the correlation between diarrheagenic *E coli* identification as detected by PCR and the traditional culture method for detecting fecal coliforms in food and water. In a related study, we will evaluate the impact on the rate of diarrheal diseases in young children of an intervention designed to improve water availability in the kitchen environment through kitchen sink installation, using point-of-use water disinfection by solar exposure. Further effects of promoting hand washing with soap or detergent and improving hygiene practices in the kitchen will also be studied.

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PART III: BASELINE INFORMATION AND INDOOR AIR EVALUATIONS

CHAPTER 6

A COMMUNITY RANDOMISED CONTROLLED TRIAL EVALUATING A HOME-BASED ENVIRONMENTAL INTERVENTION PACKAGE OF IMPROVED STOVES, SOLAR WATER DISINFECTION AND KITCHEN SINKS IN RURAL PERU: RATIONAL, TRIAL DESIGN AND BASELINE FINDINGS

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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.
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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).

2.3. Sample size

Sample size was calculated using the method of Hayes and Bennett [22]. Given that national sources indicated similar disease rates for child diarrhoea and ALRI of 5 episodes per child per year [23], we aimed of detecting a 33% absolute reduction in the annual diarrhoeal and ALRI incidence rate in children (from 5 to 3.33 episodes per child, intervention compared to control study arm) with an 80% power at a 5% level of significance. This required a minimum of 10 person-years of observation in each cluster. Considering a coefficient of between-cluster variation (k) of 0.2 we needed 9 villages each in the intervention and control arm. To adjust for loss to follow up of individual households, incomplete longitudinal data and a dropout rate of up to two villages per study arm, we arrived at a final sample size of 22 communities (11 in each arm) with 30 children each. The census identified 56 eligible communities. Three communities had less than three households with children in the required age range. These communities were annexed to their nearest neighbouring

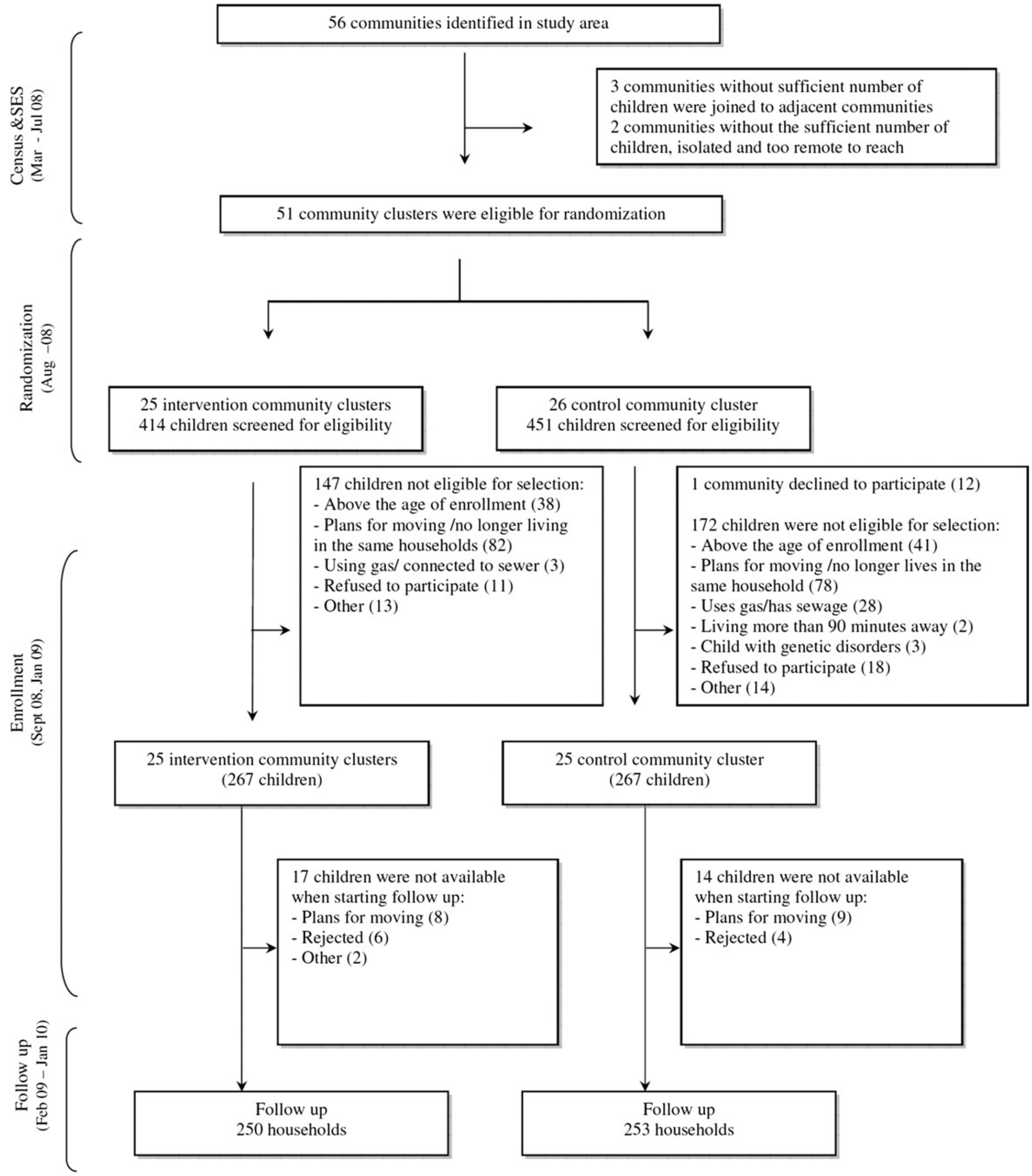

Fig. 1. Flow diagram of a community randomised controlled trial of a home based indoor air, drinking water and hygiene intervention package in rural Peru.

community for randomisation. Two communities had insufficient number of children and were too remote to reach and were, thus, excluded. Hence, 51 communities remained eligible for randomisation (Fig. 1).

The number of eligible households per community was much lower than expected (Fig. 1). We decided to randomise all communities and to enrol all eligible and consenting households with eligible children. The minimum cluster size was defined as four children per cluster. The number of children in the 51 community clusters available for randomization ranged from four to 29 children per cluster. An updated sample size calculation revealed that the new number of clusters would be sufficient to detect a reduction of 22% incidence reduction assuming a minimum of 5 person-years of observation in each cluster keeping all other parameters constant.

2.4. Randomization

We allocated the 51 communities to the intervention arms by using covariate-based constrained randomization as proposed by Moulton [24]. Prior to randomization the communities were stratified by terciles of median land surface owned by eligible households. Out of the 1.4×10^{14} possible allocation sequences we identified those who satisfied the following restriction criteria: a) the difference between the number of participating children in the intervention and the control arm should be less than two in each stratum, b) the median of the caretakers' total years of schooling in each community should not differ by more than one year in each stratum. The difference in the proportion of households within each village that c) are Catholics, d) have electric supply and e) are farmers should be less than 20 percentage points in each stratum. From the 4.7×10^{11} combinations that fulfilled these criteria, one was randomly selected as final allocation sequence. Subsequently, we randomly selected 400 additional restricted sequences, to examine how often two specific villages appeared together in the same study arm to ensure that all villages were independent of each other. We chose relaxed constraints (i.e. differences) to ensure a proper randomization process where all experimental units would be truly independent from each other. The restriction variables were chosen as they were likely to be linked to the socio-economic status and were expected to show heterogeneity among the 51 communities.

2.5. Enrolment

Upon the randomization of the communities, participants were enrolled between September 2008 and January 2009 after updating our census database with the information on new eligible children that had come to age. We included new households that currently had children 6 to 35 months of age living permanently in the house. If more than one eligible child was found in a household, we randomly selected one for study participation. One parent, usually the mother, signed a written informed consent after trained field workers explained the study in detail.

2.6. Morbidity surveillance and field data acquisition

2.6.1. Health outcomes

Primary outcomes are diarrhoea, defined as the passage of three or more liquid or semi-liquid stools in a 24-hour period or the passage of at least one liquid or semi-liquid stool with blood or mucus [25], acute lower respiratory infections defined as a child presenting with cough or difficulties with breathing with a raised respiratory rate on two consecutive measurement [26]; and stunting, wasting and underweight defined as below -2 Z-scores of the WHO growth standards curves.

We also assessed the frequency of reported symptoms of child cough, fever medical treatment seeking and compliance using the interventions. In a sub-sample of subjects in both arms we investigated the total coliforms and *E. coli* analysed from drinking water, mother's hands and kitchen cloths/sponges and stool samples collected from diarrhoea-symptomatic and -asymptomatic children.

2.6.2. Measuring health outcomes

Trained field workers visited each household weekly and collected morbidity data from the mother or caretaker about the daily occurrence of signs and symptoms of child diarrhoea and respiratory illnesses. In order to detect respiratory infections, the mother was asked a set of screening questions. If the child had cough and/or fever the day of the exam or in the last 48 h, additional diagnose questions linked to severity symptoms (noisy breathing, rhonchus/wheezing, fast breathing rates, malaise, lack of appetite, lower chest in-draw) were asked. Field worker were instructed to obtain two measurements of respiratory rates, which increase the specificity for a diagnosis of pneumonia without a loss of sensitivity [27].

Severely ill children with diarrhoea, cough and/or fever and with elevated respiratory rates and any other signs of severity for those conditions, were referred to the local health care centre for free evaluation and treatment.

Anthropometric measurements were collected every two months. Lengths/heights and weights of children were taken by two trained field workers during home visits, using digital scales (Robusta 813 SECA) sensitive to 0.1 kg and portable wood length boards (1 cm scale with mm increments). All measurements were taken three times, using the arithmetic mean for analysis. We placed the scales on a flat wooden board levelled for horizontal position.

2.6.3. Socioeconomic survey

Field workers implemented a baseline socio-demographic survey to obtain information on household demographics, education, family composition, economic characteristics and general home-, kitchen- and water management. The information was used to classify study households according to national poverty indicators called "unsatisfied basic need indicators" of the national statistical office [28]. Five basic need components were assessed: 1) inappropriate infrastructural characteristics (dirt floors or mud/stone walls); 2) crowding; 3) lack of access to basic sanitation; 4) having at least one child in school age not attending school; and 5) family head with incomplete elementary school level education and with at least three dependants. Applying the national poverty classification indicators, any household that had one unsatisfied basic need was considered "poor". The lack of more than one basic need determines the level of poverty [28].

2.6.4. Environmental exposure measurements

In order to evaluate the microbial quality of the drinking water, hands and kitchen utensils, trained field workers collected samples at baseline, midterm and at the end of the surveillance period, thus covering data collection during dry and wet season. All samples were collected between 7am and 12pm and were carried in a cooled, insulated envelope to the project laboratory. Samples were stored at 4 to 8 °C and processed on the day of collection. Mothers' hands and kitchen cloths/sponges were analyzed for total coliforms and *E. coli* using PetrifilmTM EC plates applying standard methods [29]. Results for kitchen cloths/sponges were expressed as colony-forming units per cm^2 (CFU/cm^2). Water samples were analyzed for thermo-tolerant (faecal) coliforms using a membrane filtration method OXFAM-DELAGUA. Results were expressed as colony-forming units per 100 ml of water (CFU/100 ml). All samples were double-read by two microbiologists, if the reading had more than 10% difference in counts a third microbiologist was consulted for a final decision.

2.6.5. Stool specimen tests

Stool samples from diarrhoea-symptomatic and asymptomatic children were collected. All diarrhoea-symptomatic stool specimens were collected from children that presented signs and symptoms of diarrhoea during the day of the weekly visit. Additionally, we collected stool specimens from 100 randomly selected healthy children, 50% in each intervention arm at baseline, midterm and at the end of the surveillance period. Field workers were instructed to collect the samples and place them in sterile plastic containers and transport them in a cooled envelope to the field laboratory the same day. Stool specimens were stored in Cary Blair transport media and refrigerated at −20 °C. Stool and environmental samples were analyzed to detect diarrhoeagenic *E. coli*. Every three weeks all Carry Blair tubes were transported to the Nutritional Research Institute (IIN) laboratory in Lima. Samples were inoculated onto MacConkey agar plates and after incubation *E. coli*-like colonies were isolated for further testing. Five colonies per sample for either coliforms or *E. coli* were saved in peptone media vials, and later transported to a specialised laboratory for analysis using real time PCR multiplex system [30]. The PCR method detected virulence genes of enterotoxigenic (ETEC), enteroinvasive (EIEC), enteropathogenic (EPEC), Shigatoxin producing (STEC), entero-adherent (EAEC) and diffusely-adherent *E. coli* (DAEC) [30].

2.6.6. Spot check observations

To reinforce the intervention messages and gather compliance data, two additional groups of field workers visited the study households monthly. They conducted spot observations about the usage of improved stove, hand washing, application of SODIS, kitchen hygiene and environment, the use of the psychomotor stimulation tools in the control arm and compliance overall.

2.7. Design and implementation of the main interventions

2.7.1. The IHIP home-based intervention package

To develop the intervention package, we conducted a series of qualitative and quantitative explorations on people's needs and preferences for specific smoke reduction and drinking water treatment devices [21]. We also tested personal (hands, stool specimen) and kitchen-environmental samples for faecal contaminations in an exploratory study carried out in adjacent communities to the study site [31]. Those studies led to the development of a new stove *OPTIMA*, combined with a kitchen sink and solar disinfection as a HWT and the development of kitchen hygiene education [32]. As part of the hygiene messages we promoted hand-washing and the elimination of animal excreta and isolation of animals from the kitchen environment.

Education messages were re-enforced monthly by field workers in both study arms. Mothers in the IHIP group were instructed to keep their kitchen environment clean, to wash their hands and children's hands ideally with soap or detergent after defecation, after changing diapers, before food preparation, before eating and before feeding infants and small children and. Additionally, mothers were instructed in the correct use of the improved stoves including cleaning and removing ashes and wood residues that could obstruct the ventilation. The correct application of the SODIS-method was also encouraged. Mothers from the control arm were trained in the correct use of the early stimulation toys and were urged to engage their children at least 30 min every day.

2.7.2. Intervention in the control arm

To counteract potential dropout and non-blinding bias in the control study arm, a psychomotor stimulation intervention focusing on early child development, – hence unrelated to the IHIP– was selected. This intervention was adapted from the government-based WawaWasi National Programme, which provides early age stimulation to children under four-years of age at day-care centres [33]. Together with WawaWasi experts, we adapted the intervention to be used at household level. Mothers were trained in the use of the early stimulation toys and materials. They were instructed to play and encourage their children at least 30 min every day. The baseline and end of study evaluation were done using the psychomotor development evaluation tool from the WawaWasi programme. This evaluation was conducted with children from both study arms and lasted about 30–45 min testing seven levels of child development: basic habits, personal and social development, gross and fine motor skills, relationship between objects, space and time and communication. Each area was assessed with a different set of interactive toys and materials.

2.8. Baseline assessment

We conducted a baseline survey between May and August 2008 collecting socio-economic and demographic household characteristics. To understand the occurrence of faecal contamination and the presence of diarrhoegenic *E. coli* strains at the outset, we tested kitchen utensils, mothers' and children's hands, drinking water and collected stool specimens from diarrhoea-symptomatic and asymptomatic children. Additionally anthropometric measurements of children in our study were obtained. Childhood psychomotor development was also assessed in all children in our study at baseline (data not presented).

2.9. Ethics

The study was approved by the Nutritional Research Institute Ethical Review Board and the cantonal ethical review board of University of Basel, Switzerland (Ethikkommission Beider Basel, EKBB). The Cajamarca Regional Health Authority and the Peruvian National Institute of Health (INS) also approved the trial which was nationally registered with INS and with the ISRCTN (ISRCTN28191222). Community leaders and local authorities from the study area signed a collaborative agreement with the IIN before study implementation. The mother/caretaker or father of each study child signed a written informed consent form.

3. Results

3.1. Recruitment

A total of 865 households (414 intervention- and 451 control arm) from 51 communities were screened for eligibility (Fig. 1). Of those 38% (147 households in the intervention, 184 in the control arm) did not meet all inclusion criteria or refused to participate. Additionally, one community randomised to the control arm refused to participate. In total, we enrolled 534 households of 50 community clusters into the study; 267 households in 25 clusters per study arm. Between enrolment and the start of the evaluation study period, i.e. the follow-up phase (Feb 2009), 31 households were lost (17 and 14 in the intervention and control arms). A total of 503 households, 250 in the intervention and 253 in the control arm started the follow-up phase.

3.2. Baseline characteristics

We obtained demographic and socio-economic household characteristics information from 534 households, 261 (97%) of the intervention arm and 251 (94%) control households. Both study arms were balanced according to these characteristics (Table 1). The mean number of persons living in each household was five for the intervention arm and 4.6 for the control arm. Caretakers mean age was 30 years in the intervention arm and 29 years in the control arm. The educational level for mothers and household heads for both study arms was similar. Some 73% and 81% of the households in the intervention and control arm had a piped water system with a faucet available in the household's yard; the others collected their water from open wells or unprotected water sources. The proportion of stunted children was 54%, underweight 6%. Wasting was rarely observed (Table 1).

3.3. Household microbial contamination

A total of 870 samples of drinking water, kitchen utensils and mother's hands were collected, 414 in the intervention and 456 in the control arm. The frequency of contamination with total coliforms and *E. coli* was similar between study arms (Table 2). Kitchen cloths/sponges were the most frequently contaminated kitchen utensils. About two third of all drinking water samples were found positive for *E. coli*. Seventy two percent of all samples grew coliforms and were further tested for diarrhoegenic *E. coli*. Drinking water, kitchen wipes and mother's hands, were contaminated with no difference between study arms (Table 3). The most common type of diarrhoegenic *E. coli* were EPEC (2%) and EAEC (2%) in all samples tested.

3.4. Stool samples

A total of 46 diarrhoeal specimens were collected, 24 in the intervention and 22 in the control arm (Table 4). A total of 93 specimens from healthy children were obtained. Overall the most frequent type of diarrhoegenic *E. coli* found was EPEC (11%), followed by EAEC (9%) and ETEC (9%). The proportion of diarrhoegenic *E. coli* infection was 39% in the intervention arm and 25% in the control arm. Diarrhoegenic *E. coli* was more frequently isolated in diarrhoeic specimens than in stools samples of healthy children in both study arms.

Table 1
Demographic and socio-economic characteristics of 534 households in rural Peru.

Characteristics	Intervention arm			Control arm		
	N	Mean or %	SD	N	Mean or %	SD
Demography						
Child sex (female)	267	47%		266	49%	
Child age	266	2.0	0.7	266	2.0	0.7
Children <1 year	266	9%		266	9%	
Female headed households	261	3%		263	7%	
Age of caretaker	217	30	7.8	223	29	7.7
Maternal education						
None	261	9%		251	4%	
Primary level	261	25%		251	30%	
Secondary level	261	4%		251	8%	
Higher degrees	261	2%		251	0.4%	
Years of education	227	4	1.7	228	4.1	1.7
Agriculture as main activity of family head	261	81%		251	69%	
Household assets						
Motorcycle	261	2%		251	0.4%	
Vehicle (tractor, car)	261	0.7%		251	0.4%	
Radio	261	86%		251	90%	
Bicycle	261	18%		251	19%	
Television	261	17%		251	24%	
Cell phone	261	14%		251	19%	
Household characteristics						
Household with latrines	261	80%		251	83%	
Piped water supply	261	73%		251	81%	
Water from well or stream	261	19%		251	12%	
Electricity	261	15%		251	18%	
Anthropometry						
Stunting[a]	196	56%		194	52%	
Wasting[a]	182	1%		183	0%	
Underweight[a]	201	5%		202	6%	

[a] Below -2 Z-scores of the median WHO growth standards.

Table 2
Total coliforms and *E. coli* contamination of drinking water and main kitchen hygiene indicators (percentages [%] and geometric means [GM]).

Sample type	Total coliforms		Concentration of total coliforms		*E. coli*		Concentration of *E. coli*	
	% (N)		GM		% (N)		GM	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
Drinking water[a]	NA	NA	NA	NA	68 (88)	64 (94)	0.9	1.2
Mother's hand[b]	81 (95)	86 (109)	15.2	20.9	27 (95)	22 (109)	1.4	1.3
Kitchen cloth[c]	95 (45)	100 (38)	48.8	55.8	31 (45)	31 (38)	1.2	1.1
Kitchen sponge[c]	82 (11)	82 (11)	4.2	61.4	36 (11)	9 (9)	1.2	0.6
Spoon[d]	40 (77)	61 (80)	1.4	2.1	1 (77)	10 (80)	0.5	0.6
Plate[d]	37 (97)	56 (121)	1.3	2.6	3 (97)	8 (121)	0.5	0.6
Bottle nipple[d]	100 (1)	100 (3)	NA	NA	0 (1)	0 (3)	NA	NA

[a] Colony forming units (CFU)/100 ml.
[b] CFU/hands.
[c] CFU/10 × 10 cm sampling surface.
[d] CFU/area in contact with food or drink.

4. Discussion

Cluster randomised trials are considered the gold standard to determine the effect of health interventions. We selected a cluster randomization instead of an individual randomization of households, to avoid problems of cross-contamination between neighbouring households assigned to different study arms in an open trial. Non-blinded trials have the advantage that community level dynamics for adoption allow for a natural diffusion. Only households that complied with the enrolment criteria received the intervention, but, scaling up activities and handover workshops will approach stakeholders and stimulate families to replicate the IHIP at the end of the study.

Recent reviews, meta-analyses and discussions identified non blinding, sustainability and subjective outcomes as critical issues [34–36]. Non-blinding bias might be a serious problem in intervention and in control communities. Field workers who collected the data will be aware of the interventions and could possible introduce courtesy bias. Only few blinded placebo controlled trials on home based drinking water treatment in resource limited settings are published in the peer reviewed literature [37–39], all of them found no or only small health effects. Unfortunately, the current debate [36,40] remains silent about the fact that a placebo controlled trial will underestimate the true effect of the intervention, because blinding would negatively affect compliance and inhibit the community dynamics, both of which are known to play a significant role in the process of

Table 3
Frequency of isolated diarrhoegenic *E. coli* of drinking water and main kitchen hygiene indicators.

Intervention	N	EPEC	STEC	EIEC	EAEC	ETEC	DAEC	All positives
Drinking water	60	4	0	0	3	0	0	12%
Mother's hand[a]	87	2	3	0	0	0	0	6%
Kitchen cloth	39	1	0	2	0	0	0	8%
Kitchen sponge	12	0	0	0	0	0	0	0%
Spoon	37	0	0	0	0	1	0	3%
Plate	49	0	0	0	0	2	1	6%
Bottle nipple	2	0	0	0	0	0	0	0%
Control	**N**	**EPEC**	**STEC**	**EIEC**	**EAEC**	**ETEC**	**DAEC**	**All positives**
Drinking water	63	4	0	0	2	0	0	10%
Mother's hand	106	0	1	1	5	1	0	8%
Kitchen cloth	19	1	0	0	0	1	0	11%
Kitchen sponge	8	0	0	0	0	0	0	0%
Spoon	52	0	0	2	0	0	0	4%
Plate	75	0	1	0	1	0	0	3%
Bottle nipple	0	0	0	0	0	0	0	0%

EPEC = Enteropathogenic *E. coli.*
STEC = Shiga toxin-producing *E. coli.*
EIEC = Enteroinvasive *E. coli.*
EAEC = Enteroaggregative *E. coli.*
ETEC = Enterotoxigenic *E. coli.*
DAEC = Diffusely adherent *E. coli.*
[a] One sample with mixed contamination EAEC and ETEC.

Table 4
Diarrhoegenic *E. coli* isolated from stool samples of children between 6 and 36 months of age.

Intervention	N	EPEC	STEC	EIEC	EAEC	ETEC	DAEC	All positives
Healthy children	47	6	1	2	3	5	0	36%
Ill children	24	2	0	1	5	3	0	45%
Control	**N**	**EPEC**	**STEC**	**EIEC**	**EAEC**	**ETEC**	**DAEC**	**All Positives**
Healthy children	46	2	0	0	3	3	1	19%
Ill children[a]	22	4	0	1	2	2	0	36%

EPEC = Enteropathogenic *E. coli.*
STEC = Shiga toxin-producing *E. coli.*
EIEC = Enteroinvasive *E. coli.*
EAEC = Enteroaggregative *E. coli.*
ETEC = Enterotoxigenic *E. coli.*
DAEC = Diffusely adherent *E. coli.*
[a] One sample with mixed contamination EPEC and ETEC.

adaptation of new methods [41]. Recently, Boisson et al. [39] published the results of a double-blinded placebo controlled trial to assess the effect of water filter devices in the field. After eight months almost none of the participants drank filtered water exclusively. We believe that the true impact lies between the estimates of blinded and open trials.

Consequently, we choose an open design and tried to minimise non-blinding bias. All data collection instruments were standardised, all study workers were thoroughly trained and data collection was done by an independent team of field workers, which was not part of the initial education and re-enforcement of the interventions during the follow-up period. Furthermore, the selection of a psychomotor stimulation package in the control arm was fully based on a strongly expressed felt need, – like the IHIP intervention –, and aimed at reducing non-blinding bias and drop-out rates in this trial arm. However, financial and logistical reasons allowed implementing the psychomotor package only in the intervention arm. It would have been ideal to test the IHIP intervention against a psychomotor stimulation intervention in both trial arms to make the control intervention a true counterfactual. On the other hand we are also convinced that the participants in the intervention arm would have been overstrained with too many different messages and activities. Falling short introducing the control intervention in both trial arms the potential impact of the psychomotor stimulation on the primary outcomes would underestimate a potential effect of the IHIP-intervention.

Trials using only subjective outcomes are more susceptible to bias. Thus, and to reduce potential bias due to the lack of blinding, we collected data on a variety of objective outcomes including respiratory rates, weight gain, child growth, environmental samples (water, mothers' hands and kitchen cloths), stool samples from ill and healthy children in addition to subjective outcome measures such as mother/caretakers' assessment of illness and disease.

The use of longitudinal prevalence measures for diarrhoeal or respiratory infections has recently been argued for [36]. We chose incidence rather than longitudinal prevalence (LP) as outcome measure in order to best deal with large variations of episode duration – a key constraint to use LP–, and with the recurrent character of our two primary outcomes. The use of LP and monthly outcome measurements is further constraint as the authors illustrate the need to considerably increase sample size maintaining the same power of the study [36]. We concur with Zwane and colleagues that frequent contacts and measurements may influence illness reporting and, thus, potentially bias intervention effects [42]. However, given the features of our interventions and household surveillance in both study arms we believe that any potentially resulting bias will be balanced.

The one-year follow-up surveillance period in our study is substantially longer compared to the median follow-up period of about 6 months in other studies [35]. Studies with shorter follow-up periods indicated higher health impacts and higher compliance levels, which is consistent with the evidence that the effectiveness of the interventions clearly declines with the duration of the follow-up [35]. Possible reasons for this decline are that participants stop using the interventions; the interventions start to fail for technical or other reasons, or reporting fatigue in long follow-up studies especially for reporting of subjective outcomes. Thus, sustainability and adherence are key factors for the intervention. We learned in our community work and in other studies [21,43,44], that good health is not always the convincing entry point and motivation to foster and strengthen adoption at the home level, e.g. time gain, social status and cost reduction, are other important perceived improvements and, hence, drivers for adoption. Thus, and in discussing those issues all interventions in this trial were selected in a community participatory approach, to ensure compliance [21]. Preliminary work revealed several key components necessary for adherence e.g. the availability of water in the kitchen environment was suggested by the participants – they considered that it would help improve hand-washing and home hygiene – thus it was included as part of the IHIP.

There are several limitations to the study. First, the interventions were delivered in a package format and hence, there is no clear way to differentiate the impact of each individual intervention on the decrease of diarrhoea episodes and prevalence due to household water treatment (solar disinfection of drinking water and kitchen cloths), water availability (kitchen sinks), and hand washing health education messages. Time- and financial constraints did not allow adopting a factorial design to adequately estimate the synergies, and sample size would have needed to be substantially increased to detect significant interactions.

The combined household burden of disease from indoor air pollution, contaminated drinking water and from poor food- and kitchen hygiene in rural Peru is particularly high. The characteristics of the study households are typical of rural households in Peru. However, some differences were found when comparing our data to the national census [28] and the national Demographic and Family Health Survey [45]. The proportion of households with piped water system in the yard was remarkably higher than the proportion reported from rural Peru (71% *versus* 22%). We also found a higher percentage of latrines (87% *versus* 47%) and the use of wood as a main fuel source for cooking (99% *versus* 77%) comparing study households to overall rural Peru rates. These differences are due to a more successful implementation of these national programmes in the Cajamarca region. Anthropometric measurements indicate show no significant differences between stunting, wasting and under nutrition between study arms, and showed that our results were comparable to national statistics [45].

Considering the national poverty criteria based on the “unsatisfied basic needs indicator”, our population had a substantially higher classification of “poor” households for rural populations than reflected in national figures (99.5% *versus* 49.5% respectively) [28]. Because this national poverty classification gives special importance to structural components and has equal weight for all components, our population, was more frequently allocated to the “poor” category in that classification system due to the lack of adequate household infrastructure and education. Additionally the “poor” category varies depending on the geographical regional: 46.2% of the rural coastal area of Peru mainly composed of peri-urban slums populations is considered poor, compared to 43.5% of the Andean region (our study site), and 70.7% of the rain forest region.

This community-randomised control trial including 51 communities is one of the few trials that combine well documented effective interventions into a single package. We have demonstrated that the IHIP-combined intervention package meets significant local needs and is a feasible intervention in the Peruvian Andes; our next challenge will be to determine its effectiveness in reducing childhood illnesses.

Author contributions

The principal investigators: Drs Mäusezahl and Lanata had full access to the data and take responsibility for the integrity of the data and accuracy of the data analysis.

Study concept and design: Mäusezahl, Lanata

Obtained funding: Mäusezahl, Lanata

Acquisition of data: Hartinger, Lanata, Gil, Verastegui

Implementation of public health interventions: Hartinger, Lanata, Gil, Verastegui

Analysis and interpretation of data: Hartinger, Lanata, Hattendorf, Gil, Verastegui, Ochoa, Mäusezahl.

Drafting of the manuscript: Hartinger, Mäusezahl, Lanata, Hattendorf

Critical revision of the manuscript for important intellectual content: Gil, Verastegui

Statistical analysis: Hartinger, Hattendorf, Verastegui

Potential conflicts of interest of the authors

None declared.

Role of the sponsor

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CHAPTER 7

CHIMNEY STOVES MODESTLY IMPROVE INDOOR AIR QUALITY MEASUREMENTS COMPARED WITH TRADITIONAL OPEN FIRE STOVES: RESULTS FROM A SMALL-SCALE INTERVENTION STUDY IN RURAL PERU

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Chimney stoves modestly improved Indoor Air Quality measurements compared with traditional open fire stoves: results from a small-scale intervention study in rural Peru

Abstract Nearly half of the world's population depends on biomass fuels to meet domestic energy needs, producing high levels of pollutants responsible for substantial morbidity and mortality. We compare carbon monoxide (CO) and particulate matter ($PM_{2.5}$) exposures and kitchen concentrations in households with study-promoted intervention (OPTIMA-improved stoves and control stoves) in San Marcos Province, Cajamarca Region, Peru. We determined 48-h indoor air concentration levels of CO and $PM_{2.5}$ in 93 kitchen environments and personal exposure, after OPTIMA-improved stoves had been installed for an average of 7 months. $PM_{2.5}$ and CO measurements did not differ significantly between OPTIMA-improved stoves and control stoves. Although not statistically significant, a *post hoc* stratification of OPTIMA-improved stoves by level of performance revealed mean $PM_{2.5}$ and CO levels of fully functional OPTIMA-improved stoves were 28% lower (n = 20, $PM_{2.5,}$ 136 μg/m^3 95% CI 54–217) and 45% lower (n = 25, CO, 3.2 ppm, 95% CI 1.5–4.9) in the kitchen environment compared with the control stoves (n = 34, $PM_{2.5}$, 189 μg/m^3, 95% CI 116–261; n = 44, CO, 5.8 ppm, 95% CI 3.3–8.2). Likewise, although not statistically significant, personal exposures for OPTIMA-improved stoves were 43% and 17% lower for $PM_{2.5}$ (n = 23) and CO (n = 25), respectively. Stove maintenance and functionality level are factors worthy of consideration for future evaluations of stove interventions.

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Key words: Household air pollution; Carbon monoxide; Particulate matter; Improved chimney stoves; Peru.

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Practical Implications

The use of improved chimney stoves did not result in significantly lower levels of personal exposure to products of incomplete combustion from biomass fuels when compared with control stoves. However, stove performance may vary among stove types, and it is usually linked to operation and maintenance, perception, user satisfaction, and sustainability of these stoves. Thus, stove maintenance levels should be used as proper indicators of efficacy and performance and not only stove type. Additionally, long-term benefits and sustainability of programs are harnessed through education of all household members, focusing mainly on awareness, importance of household air quality, and sustained stove functioning. Therefore, stove program implementers and evaluators should not only need to look at achieving air pollution thresholds, but convenience gains and social impact on families.

Introduction

Approximately half of the world's population continues to depend on biomass fuels in order to meet their basic energy needs for cooking, boiling water, lighting, and heating (Martin et al., 2011; Rehfuess et al., 2006). Burning biomass fuels in unvented stoves and closed rooms produces high levels of pollutants

(Fullerton et al., 2008; Smith et al., 2000) beyond the USEPA National Ambient Air Quality Standards (USEPA, 2005a). Household air pollution (HAP) from solid fuels ranks 5th in the global burden of disease estimate in 2010, with annual cause-specific deaths exceeding 3.5 million cases (Lozano et al., 2013). This large burden affects mainly women and small children (Díaz et al., 2007; Rehfuess et al., 2006) due to their continuous indoor exposure to health-damaging pollutants, including several carcinogenic compounds, hazardous gases (CO and NOx), and fine particles while cooking (Naeher et al., 2007). These pollutants increase the risk of acute lower respiratory infections and chronic obstructive pulmonary disease and may cause lung cancer (from coal stoves), asthma, low birth weight and other adverse birth outcomes (Po et al., 2011; Siddiqui et al., 2008; Tielsch et al., 2009), neurodevelopment impairments (Dix-Cooper et al., 2012), cardiovascular and other inflammatory condition (Baumgartner et al., 2011; Clark et al., 2010; McCracken et al., 2011), eye diseases, such as cataract and blindness (Saha et al., 2005; Smith and Mehta, 2003), and headaches (Díaz et al., 2007).

In Peru, almost 93% of the rural population relies on biomass fuels for cooking and heating (INEI, 2007). Exposure–response analysis shows the relationship between combustion particles and respiratory illnesses and the need to reach low levels of HAP from biomass fuel use to successfully reduce adverse health effects including pneumonia (Smith and Peel, 2010; Smith et al., 2011). One of the most cost-effective HAP control measures is the use of improved chimney stoves (Naeher, 2009), given that they are adequately designed, installed, maintained, and continuously used. A recent randomized controlled trial found significant reductions in severe pneumonia cases for children less than 18 months after receiving a woodstove with chimney (Smith et al., 2011).

The Global Alliance for Clean Cookstoves (GACC) initiative launched on September 2010 (GACC, 2011) has provided a platform where different entities can converge into a common goal of deploying 100 million clean and efficient cookstoves by 2020. The GACC is supported by private, public, and nonprofit partners, which aim to overcome the market barriers and achieve the established goal. In Peru, 2 years prior to this initiative, several organizations aimed to install/deploy 500,000 certified biomass improved chimney stoves by 2011 (Bodereau, 2011); by the end of 2011, around 300,000 improved stoves were built. However, in many cases, the success of these HAP mitigation programs, like the Peru national stove program, is often measured by the number of installed stoves rather than adoption, continuous utilization, and maintenance by the users over time (Armendáriz-Arnez et al., 2010; Bodereau, 2011).

As part of a community cluster-randomized controlled field trial carried out in the Cajamarca region of Peru, we installed 250 improved chimney stoves (called OPTIMA-improved stoves), to determine their impact in reducing acute lower respiratory infections (ALRI) in children between the ages of six and 36 months when compared with 253 households with control stoves (Hartinger et al., 2011). The current study describes household air pollution levels of $PM_{2.5}$ and CO in 93 of the 503 kitchen environments, and personal exposures of mothers at a median of 7 months after the OPTIMA-improved stoves were installed. The effectiveness of the OPTIMA-improved stoves of improving air quality is compared with air pollution levels in control household using a number of stoves including traditional stoves.

Methods

Setting

The study was carried out in the northern highlands of Peru (Province of San Marcos, Cajamarca Region), between the months of June and August 2009 (dry season). The altitude ranges between 2200 and 3900 meters above sea level, with temperatures fluctuating between 7 and 25°C and relative humidity between 59 and 73% as measured during the study period.

The population comprised mostly of farmers, typically living in small houses made out of earthen floors and adobe walls, with three or more people sleeping together in the same room. The majority of the population relied on firewood for cooking and heating. The wood was usually gathered from nearby shrubs and parcels of land or bought from the town or from local landowners. The cost of one load of wood (approx. 20 kg) was about US$ 2.5 in local currency and usually lasted 3–4 days for cooking. Traditional stoves or open fires are usually located inside the house in an unventilated kitchen area (Hartinger et al., 2011). There were no relevant sources of outdoor or of indoor pollution (other than from open fire cooking) in study homes and in the community.

Study design and enrollment

We conducted a cross-sectional HAP exposure assessment within the framework of a community-randomized controlled trial (c-RCT, parent study) of 51 communities in the San Marcos Province (Hartinger et al., 2011, 2012). The aim of the parent study was to evaluate an integrated home-based environmental intervention package (IHIP) against childhood diarrhea and respiratory infections. The interventions comprised of an improved chimney stove—called OPTIMA and a kitchen sink, complemented by the promotion of a solar disinfection method as a home-based water treatment (HWT), hand washing and kitchen hygiene. In an effort to increase the desire to use the stove and foster sustained user compliance for future users and recipients of the interventions during the trial, we conducted a pilot study in seven communities outside the study area. For this pilot study, we tested several potential designs and consulted on cooking habits and preferences to provide a user-friendly stove design, which met their household and cooking needs. The families, thus, commented on operation and maintenance issues, size of the mouth of the stove, number of furnaces, and heat emission needs per furnace (Hartinger et al., 2012).

All OPTIMA-improved stoves were installed between October 2008 and January 2009 and evaluated for this study 6 and 8 months later (median 7.4 IQR = 6.6–8.1 months). All households from the parent study were eligible to participate, if they complied with the following criteria: (i) the stoves had to be located in a in-house kitchen environment (at least three full walls and a roof over the kitchen); (ii) the households had to be within a half-hour walking distance from a road in order to transport the air sampling equipment; and (iii) the mother or caretaker had to agree to wear the equipment to measure air quality and comply with the project instructions for the duration of the study (48 h) and agree to sign the informed consent forms.

In the current study, households were conveniently selected from participating households of the parent study. Because we had a limited number of air quality equipment, we stopped the enrollment in each of the 51 communities after two households consented to participate. We enrolled a total of 93 households: 43 households had an OPTIMA-improved stove installed, 48 belonged to the control group of households using diverse cooking stoves (open fires $N = 35$, self-improved stoves $N = 7$, supplied by NGO $N = 6$) and two household belonged to a neighboring community where the NGO *Sembrando* had implemented an improved stove program. We selected the two NGO households for comparison reasons and sampled them using the same selection criteria as described above. The selected households compared well to the general cohort ($N = 503$). We found that 15% of our selected households and 9% of the nonselected households had a person who smoked; 45% of our selected households and 49% of the nonselected households have a completely closed kitchen environment. Cooking practices were similar among mothers in the study; our selected mother reported spending a mean of 189 min (s.d. ± 73) and our nonselected households a mean of 169 (s.d. ± 42) for cooking in a day.

Given that the control arm of the parent study included a diversity of stove types, the control households we selected for the current study also reflect this heterogeneity. This heterogeneity comprised the following stove types: 'open fire', 'self-improved by household', and 'supplied by NGO'. The 'open fires' included the 'Tulpia' stove, the most common traditional three-stone fire stove type in this area. The 'self-improved by household' type includes all households, which constructed a stove without support or advice from any organizations or institution. The 'supplied by NGO' type included stoves provided by the national program *JUNTOS* or independent NGOs such as *ADI-AR*. These stoves were originally enrolled into the control arm of the RCT as control stoves, which were improved by an NGO by the time enrollment for this study took place.

After the HAP exposure assessment (CO and $PM_{2.5}$ measurements), we decided to classify *post hoc* all OPTIMA-improved stoves. The stoves were then stratified into two functionality levels: FL-I stoves that were at the time of the assessment in good running conditions (plastered stove and no visible leaks when in use) and FL-II stoves were in the need of repairs (replastering, filling small cracks, cleaning the chimney, chimney valve replacement, etc.). Among all OPTIMA-improved stoves, 159 of 250 (64%) were classified as FL-I and 91 of 250 (36%) as FL-II. Among household participating in this study, 28 of 43 (66%) were classified as FL-I and 15 of 43 (35%) as FL-II. All OPTIMA-improved stoves were revisited 9 months (median 9.3 IQR = 9.0–9.7 month) after installation and repaired as needed by the original stove builders.

Household air pollution measurements

Personal exposure sampling. Personal air sampling equipment was placed in vests worn in the breathing zones of mother/caretakers (hereafter mothers) for 48 h. These vests held real-time CO monitors and 48-h time-integrated $PM_{2.5}$ samplers. The sampling inlets were placed on the chest halfway between the throat and the diaphragm. Subjects were instructed to keep the vests on at all times except when sleeping or washing clothes, in which case the equipment was placed next to them. They were instructed to place vests on a nightstand next to their bed during the night. To measure real-time CO exposure, each vest held a Draeger Pac III datalogger and a CO-specific sensor (Draeger Safety Inc., Pittsburgh, PA, USA), set to record concentration levels at 30-s intervals. Forty-eight-hour time-integrated $PM_{2.5}$ samples were collected using particle-size-selective Triplex Cyclones (Model SCC 1.062; BGI Inc., Waltham, MA, USA) and SKC universal sampling pumps (Aircheck® XR5000; SKC Inc., Eighty Four, PA, USA), set to pull air at 1.5 l per minute. Preflows and postflows were taken for each pump, and all equipment was calibrated and cleaned per manufacturer protocol. After 48 h, the vests were retrieved; starting and completion times (run-time) were recorded at the household for each piece of equipment, and air sampling calculated thereof. Filters for each sampling day were placed in individual cassettes and stored in Ziploc bags in a −20°C freezer at the study site.

Kitchen environment air pollutant sampling. A stationary sampling box was placed indoors and at approximate breathing height (1.5 m) adjacent to where the mother/caretaker stands for cooking. Each box contained a sampling pump (Aircheck® 2000; SKC Inc.), a 12-V battery, a filter/cyclone sampling train attached to Tygon® tubing, and a Pac III CO monitor (Draeger Safety Inc.). The same protocol as for the personal filters was used. After 48 h, the equipment and sampling box were retrieved; run-times were recorded at the household for each piece of equipment, and sampled filters were transported in a cooler from the household and stored in the laboratory freezer at −20°C.

Community air pollutant sampling. A central outdoor location was selected in San Marcos town to serve as a fixed sampling site, providing background levels of both CO (real-time) and $PM_{2.5}$ (48-h time-integrated) concentrations. A sampling scheme similar to that used in the study homes was set up outside a window at this stationary outdoor site. To measure real-time CO, a Langan CO monitor (model T15n; Langan Products Inc., Elmwood Park, NJ, USA) was used. Forty-eight-hour time-integrated $PM_{2.5}$ was measured using a SKC Air Check Pump with a BGI Triplex Cyclone and Teflon-coated glass fiber filter.

Laboratory, field, and open blanks. Two laboratory filter blanks were collected at the time of the pre- and postweighing. During each sampling week, field blanks were collected to adjust for background noise in the equipment, and the open blanks were collected to account for noise in the filter media. There were a total of 44 field and open blanks (mean ± s.e.): 28 field blanks (0.013 ± 0.002 mg) and 16 open blanks (0.004 ± 0.001 mg). There were approximately one field blank for each sampling day and an open blank for every other sampling day. Final particulate mass values for study samples have been adjusted for field filter blank values by subtracting the average of the field blank (13 μg) from the postweights. The difference of the pre- and adjusted postweights together with the average volume of air sampled over the 48-h period was used to calculate mass concentrations. All mass concentrations are presented in $\mu g/m^3$.

Analysis of pumps and filters

To better describe daily variability in our exposure measurements, the homes were sampled for a 48-h period. The $PM_{2.5}$ measurements were only considered valid if the equipment ran for at least 2160 min. Filters were collected, stored at the site laboratory, and transported on cold packs to the University of Georgia for gravimetric analysis. The filters were desiccated in climate-controlled conditions (21 ± 0.1°C; 40.9 ± 1.5% relative humidity) for 48 h prior weighing. Following the USEPA's Quality Assurance Guidance Document (USEPA, 2005b), each filter was weighed twice before and after sampling using a Cahn C-35 microbalance with a sensitivity of ±1 μg. $PM_{2.5}$ concentrations (weight/cubic meter air sampled) were derived by dividing the average mass of each filter weight by the intake volume of sampled air.

Compliance and observational data

We measured compliance and maternal cooking behavior using questionnaires, conducting participatory observations and assessing compliance during monthly training visits as part of the c-RCT parent study. Questionnaires were administered on the second day of the indoor air sampling scheme. They were used to assess personal exposure to air pollution, behavioral habits (household chores, child care), mobility (including activities in and around the home, attending the fields, and commuting), cooking, cleaning, and personal and household characteristics. We measured the kitchen volume and took window and door measurements (in cm).

Participatory observational data were collected as part of the c-RCT parent study in 236 (108 intervention and 128 controls) of the 503 participating households. Such observational data were available for 18 of 43 households with OPTIMA-improved stoves and 25 of the 48 control households in the present study. The mother's behavior was observed during the preparation of a lunch meal (9 am–1 pm) and recorded. Field workers remained at the household between 3 and 4 h. This information provided input on the mother's cooking practices and usage of the stove. Additionally, we measured compliance in all OPTIMA-improved stove homes ($N = 43$), routinely monitored actual usage, maintenance, and problems with the stoves, with the aim of determining daily use and the mothers perception of the maintenance level of their stoves.

Statistical analysis

Data were analyzed using STATA 10.0. Personal and kitchen $PM_{2.5}$ and CO means, standard deviations, confidence intervals, and medians were calculated by stove type. Skewed data were log-transformed where appropriate. Scheffe's multiple comparison tests were used to calculate significant levels between stove types. Results were considered to be statistically significant at $P < 0.05$.

Spearman correlation coefficients were calculated for air quality measurements, between kitchen $PM_{2.5}$ and

CO measurements and between kitchen and personal $PM_{2.5}$ and CO measurements. Linear regression models were created to determine potential covariates that could explain the variation in air quality measurements in the kitchen environment and personal exposure. CO and $PM_{2.5}$ measurements were log-transformed for the bivariate and multivariable regressions. The variables with P values less than 0.25 in the bivariate model were included in the multivariable model.

Ethics

The study was approved by the Nutrition Research Institute (IIN) Ethical Review Board, the Institutional Review Boards at the University of Georgia and Emory University, and the ethical review board at the Cayetano Heredia University. Written informed consent for this study was obtained from each study participant. The demographic and socio-economic data had previously been collected in the parent study (ClinicalTrials.gov Identifier: NCT00731497), which had received clearance from the independent ethics committees of IIN and the ethical review board of University of Basel, Switzerland (Ethikkommission Beider Basel, EKBB). The participant information provided and the informed consent obtained for the current study included the information that previously collected data would be used and asked for the respective permission.

Results

We enrolled a total of 93 households. Forty-three households had an OPTIMA-improved stove installed, 48 belonged to control stove households, and two belonged to a neighboring community with *Sembrando* stoves. The total '*N*' for the analysis of each group varies due to measurement errors and equipment failure. In total, we exclude 27 $PM_{2.5}$ kitchen measurements (14 controls and 13 intervention), 14 personal $PM_{2.5}$ measurements, (six intervention and eight control), eight CO kitchen measurements (four intervention and four control), and seven CO personal measurements (four intervention and three control).

The study groups were comparable with respect to their socio-demographic and kitchen characteristics (Table 1): 86% of the kitchens had four walls, and 43% had no windows in the kitchen area. Both groups used *Eucalyptus sp.* as the main source of firewood for cooking (Table 1). Community air pollution sampling showed that the average background outdoor $PM_{2.5}$ level during the study period was 13 $\mu g/m^3$ for $PM_{2.5}$ and 0.6 ppm for CO.

Arithmetic mean and median kitchen and personal exposure to air pollutants are presented in Figure 1 and Table 2. Overall, $PM_{2.5}$ mean values for OPTIMA-improved stoves (148 $\mu g/m^3$ 95% CI 88–208, N = 30) in the kitchen environment were 22% lower compared with control stoves (189 $\mu g/m^3$ 95% CI 116–261, N = 34); however, the differences were not statistically significant. Similarly, for CO in the kitchen environment, the overall difference was 19% (4.7 ppm 95% CI 2.8–6.6 ppm, N = 39 vs. 5.8 ppm 95% CI 3.3–8.2 ppm, N = 44), which was not statistically significant. At the personal level, we did not observe a statistically significant difference in CO levels between users cooking with an OPTIMA-improved stove and in the control stove (35 open fires, seven self-improved stoves, six supplied by NGO). However, $PM_{2.5}$ at personal levels was 20% lower among OPTIMA stove users (Table 2) compared to the control group, but this difference was also not statistically significant. In table 2, for 95% CI where the lower confidence interval value is "0", the actual values were all negative numbers and since negative concentrations and exposures are not helpful in this context, a value of "0" has been substituted in each case.

Table 1 Basic socio-demographic and kitchen characteristics from the study participants of the San Marcos province. Data are means (s.d.) or numbers (%)

	Optima-improved stove (N = 43)	Control stoves (N = 48)
Socio-demographic characteristics		
Number of family members[a]	4.7 (1.2)	4.7 (1.3)
Housewife as main activity of mother	39 (91%)	45 (94%)
Farming as main activity of the family head	34 (79%)	40 (83%)
Family members that smoke cigarettes	4 (9%)	10 (21%)
Kitchen characteristics		
Kitchen volume (m^3)[b]	29 (18.6)	37.2 (25.7)
Type of wood used for cooking[c]		
Eucalipto (*Eucalyptus sp.*)	18 (42%)	21(45%)
Acacia *(Acacia macrantha)*	8 (19%)	9 (19%)
Chamana (type of wood)	3 (7%)	6 (13%)
Other	14 (33%)	11 (23%)
Kitchen windows[c]		
Completely closed–No windows	20 (47%)	20 (43%)
One window	20 (47%)	20 (43%)
More than one window or door opening	3 (7%)	7 (15%)
Number of kitchen walls[c]		
Four walls	40 (93%)	40 (85%)

[a]N = 42 for traditional stove arm.
[b]N = 42 for Optima stove arm.
[c]N = 47 for traditional stove arm.

Larger differences in pollution concentrations were observed within the OPTIMA-improved stove functionality levels (Figure 2 and Table 2). FL-I stoves had 28% lower $PM_{2.5}$ (136 $\mu g/m^3$ 95% CI 54–216, N = 20) and 45% lower CO (3.2 ppm 95% CI 1.5–4.9, N = 25) in the kitchen environment measurements compared with control stoves; however, statistical significance was not reached (Table 2). Similarly, personal exposure to PM and CO was 43% and 17% lower, respectively, with no statistical significance observed compared to control stoves.

Particulate $matter_{2.5}$ and CO concentrations were moderately correlated in simultaneous measurements

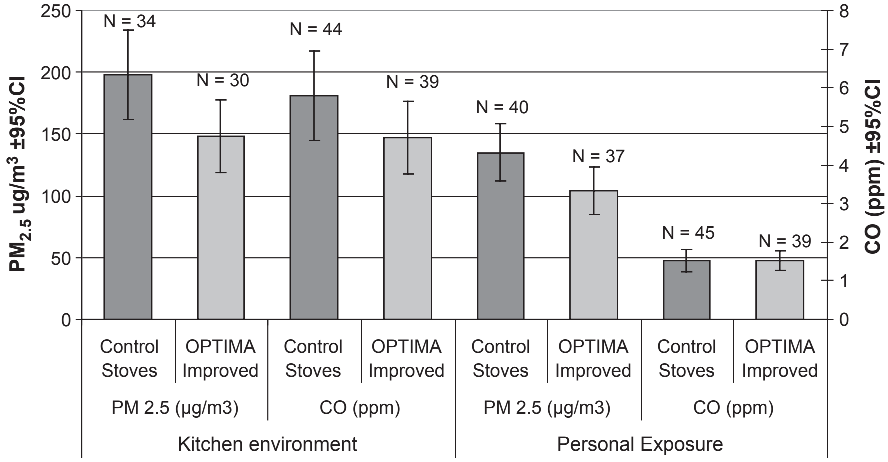

Fig. 1 Forty eight hours $PM_{2.5}$ and CO mean concentrations between traditional and OPTIMA-improved stove for kitchen environment and personal exposure. Control stoves include all control households, (open fires, self-improved by household, and NGO). OPTIMA-improved stoves include all OPTIMA-improved stoves functionality levels (FL-I and FL-II)

Table 2 Air quality measured for 48-h CO and PM_2 in the kitchen and at personal level in relation to stove type and functionality levels in rural Peru

Sampling location	Measurement	Stove type	*N*	Mean	95% CI	Median	% difference	*P*-values[c]
Kitchen environment	PM 2.5 (μg/m^3)	Control stoves[a]	34	189	116–261	116	Reference	
		Open Fire	24	211	116–305	139		
		Self-improved by household	6	117	3.7–230	93		
		NGO	4	166	0–559	50		
		OPTIMA-improved stove[b]	30	148	88–208	102	22%	0.87
		FL-I	20	136	54–217	77	28%	0.36
		FL-II	10	173	72–273	123	8%	0.98
	CO (ppm)	Control stoves	44	5.8	3.3–8.2	2.4	Reference	
		Open Fire	32	5.2	2.8–7.5	2.4		
		Self-improved by household	7	7.2	0–17.8	3.1		
		NGO	5	7.5	0–23.1	2		
		OPTIMA-improved stove	39	4.7	2.8–6.6	2.9	19%	0.39
		FL-I	25	3.2	1.5–4.9	2.1	45%	0.60
		FL-II	14	7.5	3.2–11.7	5.5	−28%	0.29
Personal exposure	PM 2.5 (μg/m^3)	Control stoves	40	129	82–176	94	Reference	
		Open Fire	28	145	90–200	116		
		Self-improved by household	7	135	0–320	59		
		NGO	5	35	0–72	40		
		OPTIMA-improved stove	37	104	64–144	55	20%	0.55
		FL-I	23	74	38–109	40	43%	0.12
		FL-II	14	154	65–244	76	−19%	0.99
	CO (ppm)	Control stoves	45	1.4	0.8–2.0	0.6	Reference	
		Open Fire	32	1.5	0.8–2.1	0.7		
		Self-improved by household	7	1.8	0.0–5.0	0.5		
		NGO	6	0.5	0.1–0.8	0.4		
		OPTIMA-improved Stove	39	1.5	1–2	1	−6%	0.59
		FL-I	25	1.2	0.7–1.7	0.8	17%	0.74
		FL-II	14	1.9	0.9–3.2	1.2	−39%	0.32

Mean refers to arithmetic mean. For 95% CI where the lower confidence interval value is "0", the actual values were all negative numbers and since negative concentrations and exposures are not helpful in this context, a value of "0" has been substituted in each case.

[a]Control stoves include all control households (open fires, self-improved by household, and NGO). NGO: stoves build by nongovernmental organization.

[b]OPTIMA-improved stoves include all OPTIMA-improved stoves functionality levels (FL-I and FL-II). FL-I: stoves in good running conditions (plastered stove and no visible leaks when in use. FL-II: stove in need of repairs (replastering, filling cracks).

[c]Scheffe's multiple comparison test was used.

in the kitchen environments (Spearman's rank correlation coefficient $r_s = 0.63$, $n = 61$, $P < 0.0001$). A significant correlation between $PM_{2.5}$ and CO was also found when we stratified the data by study group (OPTIMA-improved stove: $r_s = 0.70$, $n = 27$, $P < 0.0001$; control: $r_s = 0.65$, $n = 32$, $P < 0.0001$). Likewise, statistically significant correlations were found between kitchen and personal $PM_{2.5}$ ($PM_{2.5}$:

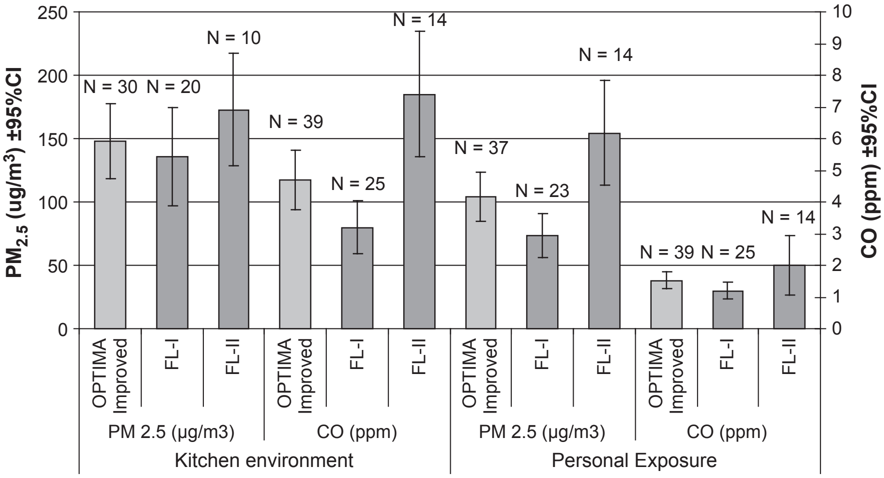

Fig. 2 Forty eight hours $PM_{2.5}$ and CO concentrations in OPTIMA-improved households separated into functionality levels. OPTIMA-improved stoves include all OPTIMA-improved stoves functionality levels (FL-I and FL-II). FL-I: stoves in good running conditions (plastered stove and no visible leaks when in use). FL-II: stove in need of repairs (replastering, filling cracks)

$r_s = 0.52$, $n = 59$, $P < 0.0001$) and kitchen and personal CO concentrations (CO: $r_s = 0.64$, $P < 0.0001$, $n = 84$).

A bivariate analysis (Table 3) showed that Acacia, a type of firewood (coefficient 1.0 95% CI 0.1; 1.9), was a significant determinant for predicting $PM_{2.5}$ concentrations in the kitchen environment. However, we did not observe any other predictor values for kitchen CO concentrations or for personal exposure levels of CO or $PM_{2.5}$. The multivariable analysis did not reveal any significant predictors for any of the personal or kitchen measurements of CO and $PM_{2.5}$. The R values were low, indicating that the predicting factors could only explain a low proportion of the overall variance.

Findings from the participatory observational surveys ($n = 236$) revealed a reported 90% (212 of 236) daily use of the OPTIMA-improved stove and an observed lower lunch-cooking times (50 min vs. 66 min; $P < 0.0001$) compared with those using other cooking stoves. Additionally, 96% of the mothers using the OPTIMA-improved stove ($n = 43$) reported performing other activities while cooking, such as washing cloths, feeding the animals, cleaning, tending their children, or visiting a neighbor. Finally, mothers from the control households perceived stove-related smoke exposure more strongly as a nuisance than mothers using the OPTIMA-improved stove (Table 4).

Discussion

We investigated the effectiveness of a beneficiary-designed improved stove in reducing exposure to household air pollution within the framework of a community-randomized trial. About 7 months after initial introduction of the OPTIMA-improved stoves, $PM_{2.5}$ and CO concentrations were measured as household air pollution and compared with control stove households, which comprised of three-stone open fire stoves, self-improved by household stoves, or supplied by NGOs

Overall $PM_{2.5}$ and CO arithmetic mean values for the kitchen environment and personal exposure were lower in the improved stoves group, but the difference lacked statistical significance. Also, despite a limited sample size and lack of statistical significance, when OPTIMA-improved stoves were stratified by functionality levels, fully functional improved stoves appeared to have lower $PM_{2.5}$ and CO values in both kitchen and personal measurements compared with OPTIMA-improved stoves in need of repair. On the other hand, faster cooking times and the possibility of performing other activities while cooking were much welcomed benefits derived from the improved stove confirming our findings from the exploratory pilot phase developing the parent trial (Hartinger et al., 2012).

Previous studies have yielded inconsistent evidence. In two randomized controlled field trials, Smith and colleagues found in Guatemala up to 90% lower CO concentrations in the intervention group (Smith et al., 2011), whereas Burwen and Levine found no noteworthy reduction in rural Ghana (Burwen and Levine, 2012). In two before and after stove installation studies, reductions between one-third and two-thirds were observed (Dutta et al., 2007; Fitzgerald et al., 2012; Masera et al., 2007)

We captured ambient air CO and $PM_{2.5}$ levels as a background against which to compare changes in indoor levels in control and intervention households. The purpose for community air pollution measures was to report the general ambient air levels in San Marcos in order to observe any changes throughout the study period, which may have impacted our results. No such trends during the study period were observed.

Table 3 Bivariate and multivariable regression analysis of covariates for 48-h log-transformed CO and $PM_{2.5}$ levels of kitchen and personal exposure

Variable	Carbon monoxide (CO) *n*	Bivariate Coef (95% CI)	Multivariable[a] Coef (95% CI)	Particulate matter ($PM_{2.5}$) *n*	Bivariate Coef (95% CI)	Multivariable[b] Coef (95% CI)
Kitchen						
Stove type	83			64		
Control (reference)						
FL-I		−0.3 (−0.9; 0.3)	−0.3 (−0.9; 0.2)		−0.7 (−1.4; 0.1)	−0.7 (−1.4; 0.1)
FL-II		0.6 (−0.1; 1.3)	0.6 (−0.1; 1.3)		−0.0 (−1.1; 1.1)	−0.4 (−1.4; 0.6)
Kitchen volume (100 m^3)	79	−0.2 (−1.4; 1.0)	–	61	−1.6 (−3.2; −0.0)	−1.5 (−3.2; 0.2)
Wood used for cooking	85			65		
Eucalipto (reference)						
Acacia		−0.4 (−1.1; 0.4)			**1.0 (0.1; 1.9)**[c]	0.6 (−0.5; 1.7)
Other wood types		−0.1 (−0.7; 0.4)	–		0.4 (−0.4; 1.1)	0.2 (−0.6; 1.0)
Kitchen windows	82			63		
No windows (reference)						
One or more windows		−0.3 (−0.9; 0.2)	−0.5 (−1.0; 0.1)		−0.2 (−0.9; 0.5)	–
Number of kitchen walls	82			63		
Four walls (reference)						
Less than four walls		−0.0 (−0.8; 0.8)	–		0.3 (−0.8; 1.4)	–
Personal exposure						
Stove type	85			77		
Control (reference)						
FL-I		−0.2 (−0.8; 0.3)	−0.2 (−0.8; 0.3)		−0.6 (−1.2; 0.1)	−0.4 (−1.1; 0.3)
FL-II		0.5 (−0.2; 1.2)	0.6 (−0.1; 1.2)		0.3 (−0.6; 1.1)	0.4 (−0.5; 1.2)
Kitchen volume (100 m^3)	79	0.3 (−0.9; 1.5)	–	74	−0.4 (−1.9; 1.1)	–
Time spent cooking (h)	81	−0.1 (−0.6; 0.4)		75	−0.4 (−1.1; 0.2)	−0.4 (−1.0; 0.3)
Does the mother perform other activities while cooking? (no = reference)	85	0.1 (−0.6; 0.7)		78	−0.1 (−0.9; 0.8)	–
Wood used for cooking	85			78		
Eucalipto (reference)						
Acacia		−0.5 (−1.2; 0.2)	−0.6 (−1.2; 0.08)		−0.1 (−1.0; 0.8)	–
Other wood types		−0.3 (−0.8; 0.3)	−0.4 (−0.9; 0.2)		0.1 (−0.6; 0.8)	–
Kitchen windows	82			76		
No windows (reference)						
One or more windows		0.1 (−0.4; 0.6)	–		0.3 (−0.4; 0.9)	–
Number of kitchen walls	82			74		
Four walls (reference)						
Less than four walls		−0.1 (−0.9; 0.7)	–		0.3 (−0.7; 1.3)	–

[a]Kitchen: $n = 82$, $R^2 = 0.09$; Personal: $n = 82$, $R^2 = 0.09$.
[b]Kitchen: $n = 61$, $R^2 = 0.14$; Personal: $n = 75$, $R^2 = 0.06$.
[c]Asterisks indicate statistically significance ($P < 0.05$).
–, refers to variables not included in the multivariate models.
Bivariate regression analysis refers to linear models that include the outcome variable and only one predictor variable. Multivariable regression analysis refers to linear models that include the outcome variable and all predictor variables listed in the table.

To understand the variation in $PM_{2.5}$ and CO concentrations of our improved stove, we classified them *post hoc* into FL-I and FL-II and observed a trend of increasing pollutant concentrations with declining stove performance due to structural damages from use. These included observed cracks or leaks of the general structure of the stove and around the potholders, the broken parts of the internal combustion chamber, or the chimney structure as well as the malfunction of the chimney valve. In categorizing the improved stoves, the $PM_{2.5}$ and CO exposures at kitchen and personal levels could be better predicted compared with using a less sensitive dichotomous categorization of stove type (OPTIMA vs. control). This indicates the importance of presenting stove performance in terms of reduction of $PM_{2.5}$ and CO in relation to current stove conditions or levels of operation and maintenance needs.

Although the use of local materials and monthly training on the importance of repairs facilitated the self-maintenance of the stoves, OPTIMA-improved stoves were partly well kept with *post hoc* repairs revealing that 36% (91 of 250) of the stoves were not properly maintained. Further assessment of our compliance data revealed a gap between the mother's perception of appropriate maintenance and the actual repairs needed for the stove. The use of stove type to assign or determine exposure may be flawed given the varying HAP concentrations among households in our study, which employed the same stove type. Clark et al. (2010) suggest the utility of stove levels may be

Table 4 Mothers' cooking behavior and smoke exposure perceptions of 93 study participants in rural Peru. Data are means (s.d.) or numbers (%)

	Optima-improved stove N = 43	Control stoves N = 47
Mothers' behavior and perceptions		
Mother performs other activities while cooking[a]	38 (96%)	21 (56%)
Hours the stove was lit[b]	9.1 (4.0)	9.2 (3.8)
Mother's self-report of minutes spent cooking per day	187 (75)	201 (84)
Perceived exposure to smoke from motor vehicles		
Low	29 (67%)	34 (72%)
Medium	2 (5%)	5 (11%)
High	2 (5%)	6 (13%)
Does not know	10 (23%)	2 (4%)
Perceived exposure to smoke from kitchen stoves		
Low	26 (60%)	11 (24%)
Medium	7 (16%)	15 (32%)
High	5 (12%)	19 (40%)
Does not know	5 (12%)	2 (4%)

[a]N = 38 for optima stove and 37 for traditional stove arm.
[b]N = 38 for optima stove arm and 45 for traditional stove.

more representative of HAP exposures and indoor levels. They note the importance of assessing the condition of the stoves rather than a mere comparison between traditional and improve stove type (Clark et al., 2010).

Improved stove adherence could also prove to be a challenge. Our reported high daily use was due to the perceived convenience gains (shorter cooking times, reduced wood consumption, and limited supervision) and matched traditional cooking practices (Hartinger et al., 2012). In Central Mexico, the Patsari wood cookstove reported a 50% adherence after 10 months (Romieu et al., 2009; Ruiz-Mercado et al., 2011). We expect adherence to OPTIMA-improved stove use to be higher given that after a median of 7.4 months (IQR: 6.6–8.1), OPTIMA-improved stove usage ranged at 90% although we cannot exclude dual use of open fire stoves during the study period. In Bangladesh, of 105 biofuel-using households that had considered improved stoves, nine (8.5%) decided to use them, while the rest did not adopt improved stoves due to the large initial investment, inconvenience of the stoves, or other reasons (Dasgupta et al., 2009). Our results suggest that stove repair and maintenance are important in the success of any HAP mitigation program. Moreover, the metric of success needs to include the number of stoves that are adequately designed, as well as continually and exclusively used (Clark et al., 2010; Dutta et al., 2007; Naeher, 2009; Smith et al., 2011).

The type of wood used for cooking was associated with $PM_{2.5}$ concentrations in the kitchen in the bivariate analysis only. This underscores the importance of combining new types of clean fuels together with new clean cookstove designs in the control of HAP. Mothers using improved stoves reported spending less time cooking a lunch meal while performing unrelated cooking activities, inside and outside the kitchen environment. Subjects performing other tasks in and around the kitchen may experience exposures, which outweigh potential exposure risk reductions due to shorter cooking times (Künzli, 2011).

Our study experienced some equipment failure of the $PM_{2.5}$ pumps that were occasionally not recording measurements for the full 48-h battery lifetime due to insufficient charging of batteries caused by power fluctuations at the field site. Further, the study had no means to validate the correct and uninterrupted wearing of the mother's equipment vest during the 48-h collection periods. Nonetheless, consistent with another study, we found moderate correlations between personal and kitchen $PM_{2.5}$ and CO measurements (Bruce et al., 2004). Finally and because this study commenced after installing the OPTIMA-improved stoves, no data of baseline emissions of pollutants were available for before and after comparisons.

Consistent with findings from an HAP study in Mexico, the mothers in our study clearly identified perceptible smoke as a daily nuisance mentioning frequent eye irritations as a key sequel (Romieu et al., 2009). Mothers perceived smoke reduction from the OPTIMA-improved stove, which ranged along a 45% reduction in $PM_{2.5}$ particles of the personal exposure for well-maintained stoves after being in daily use for an average of 7 months and a 17% reduction in CO, although these reductions were statistically insignificant. However, future impact evaluations of household air pollutions interventions should consider assessing both outdoor and indoor determinants of air pollution risk exposures, because improved chimney stoves remove household air pollutants into the community environment, which may cause significant human exposure outdoors particularly in densely populated areas (Künzli, 2011).

Overall, the reductions in indoor air $PM_{2.5}$ and CO concentrations from the OPTIMA-improved stove were lower than expected. At the overall mean concentrations measured in the intervention group ($PM_{2.5:}$ 148 $\mu g/m^3$ and CO: 4.7 ppm), the reduction in HAP is not expected to result in significant health improvements (Smith et al., 2011). In their analysis of outdoor air pollution, tobacco smoke, and active smoking studies, Smith and Pillarisetti (2012) demonstrate that at about 150 $\mu g/m^3$ average annual $PM_{2.5}$ exposures for example, the CVD risk slowly increases to the level experienced by active smokers. In our study, kitchens with intervention stoves had overall mean $PM_{2.5}$ concentrations of 148 $\mu g/m^3$, while control kitchens had a mean of 189 $\mu g/m^3$. Hence, the risk is essentially the same at these two mean $PM_{2.5}$ levels although the mean concentration measured in intervention kitchens appears to be lower compared with control kitchens. Given the large global population that experiences exposures between second-hand smoke and active tobacco smoke exposure levels, lower HAP levels must be achieved and sustained to yield greater public health benefits (Smith and Peel, 2010; Smith et al., 2011).

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CHAPTER 8

CARBON MONOXIDE EXPOSURES AND KITCHEN CONCENTRATIONS FROM COOKSTOVE RELATED WOODSMOKE IN THE HOUSEHOLD INDOOR ENVIRONMENT IN SAN MARCOS, PERU

Carbon monoxide exposures and kitchen concentrations from cookstove-related woodsmoke in San Marcos, Peru

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Background: Nearly half of the world's population is exposed to household air pollution (HAP) due to long hours spent in close proximity to biomass-fueled fires.
Objective: We compare CO exposures and concentrations among study promoted intervention stove users and control stove users in San Marcos Province, Cajamarca region, Peru.
Methods: Passive CO diffusion tubes were deployed over a 48-hour sampling period to measure kitchen CO concentrations and personal mother and child CO exposures in 197 control and 182 intervention households.
Results: Geometric means (95% CI) for child, mother, and kitchen measurements were 1.1 (0.9–1.2), 1.4 (1.3–1.6), and 7.3 (6.4–8.3) ppm in control households, and 1.0 (0.9–1.1), 1.4 (1.3–1.6), and 7.3 (6.4–8.2) ppm among intervention households, respectively.
Conclusion: With no significant differences between control and intervention CO measurements, results suggest that intervention stove maintenance may be necessary for long-term reductions in CO exposures.

Keywords: Carbon monoxide, Children, Cookstove, Exposure assessment, Household air pollution, Peru, Women, Woodsmoke

Introduction

It is estimated that nearly half of the world's population burns biomass, mostly as fuel for cooking,[1,2] resulting in household air pollution (HAP). Women and young children bear the brunt of high HAP exposures due to the long hours spent in close proximity to cooking fires.[3,4] Household stoves typically used for cooking and heating in the developing world do not burn fuel cleanly leading to incomplete combustion in the domestic environment.[1,4,5] Smoke from incomplete biomass combustion contains health-damaging pollutants,[6,7] of which carbon monoxide (CO) and particulate matter with an aerodynamic diameter of ≤2.5 μm ($PM_{2.5}$) are major constituents.[5,8]

HAP exposure, from cooking with solid fuels, is responsible for approximately 3% of the global burden of disease.[2,9–11] HAP levels may vary depending on factors such as the time spent cooking, fuel type, cooking environment, and household ventilation.[12–14] Concentrations of CO and PM also vary over short (less than 1 day) time periods.[15] As such, it is essential to capture high-intensity exposures and emissions over an extended period of time. Adequate characterization of exposure to residential biomass combustion is crucial in vulnerable populations such as in rural communities in Peru where biomass fuels are used on a daily basis for cooking and heating.[16]

Personal exposures and kitchen concentrations of HAP can be estimated using questionnaires and exposure modeling, measured directly with air pollution monitors and to a limited extent, biomarkers can also be used to estimate internal dose from HAP exposures.[5,17–21] CO can be used as a proxy for $PM_{2.5}$ when both pollutants are from the same source and air pollution levels are high as observed in indoor cooking conditions.[22] A few studies in the past decade have successfully demonstrated the use of inexpensive passive diffusion tubes in quantifying exposure to HAP as well as ambient concentrations.[8,22–25]

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We report a cross-sectional study conducted within the framework of a community-randomized controlled trial (c-RCT, parent study) by the Instituto de Investigación Nutricional (IIN) and the Swiss Tropical and Public Health Institute.[26,27] Our primary objective was to compare CO exposures and concentrations among study promoted intervention stove users and control stove users in San Marcos Province, Cajamarca region, Peru. We also investigated factors that are associated with CO exposures and kitchen concentrations among study subjects. Finally, we examined correlations in CO measurements between personal mothers' and children's exposures and between personal exposures and kitchen concentrations in this population.

Methods

Study design and study homes

Measurements presented in this paper occurred between June and August 2009. The May–August period in the study region is characterized by dry conditions and cold nights. All measurements were taken during this season, no follow-up measurements occurred during the rainy season. The altitude in the region ranges between 2200 and 3900 m above sea level. Mean altitudes $\pm$SD for intervention and control households are 2684$\pm$284 and 2727$\pm$438 m above sea level, respectively. For this cross-sectional study, control and intervention households were from participating households in the parent c-RCT (n=250 and 253 for intervention and control homes, respectively). The c-RCT involved 51 community clusters who used solid fuels in the Province of San Marcos, Cajamarca region, Peru.[26,27] The intervention was randomized at the community level, with the 51 community clusters allocated into the intervention arms by using covariate-based constrained randomization.[26] Field workers for the c-RCT visited all study homes during this 3-month period; however, subjects' availability, willingness to participate, as well as time and budget constraints, limited the total sample size of the present study.

The aim of the parent study was to evaluate an integrated home-based environmental intervention package against childhood diarrhea and respiratory infections. A pilot study was conducted in seven communities outside the study area, where several potential stove designs were tested, and subjects were consulted on cooking habits and preferences to provide a user-friendly stove design which met their household and cooking needs.[27] The final stove model for the c-RCT was called the OPTIMA-improved stove (hereafter OPTIMA stove). Kitchen performance tests of the OPTIMA stoves revealed a 15% reduction in daily fuel and energy use and a 16% reduction in fuel and energy use per capita compared with the traditional open fire stoves, although there was wide variability.[26,27] The OPTIMA stove was built with red burnt bricks plastered with a mixture of mud, straw, and donkey manure.[27] It has three pot holes for cooking, a closed combustion chamber, metal chimney with a regulatory valve, a hood, and metal rods for support.

OPTIMA stoves were installed between October 2008 and January 2009 in 250 households (hereafter intervention households). There were no emissions tests or HAP exposure assessment before installation of the intervention stoves. The current study reports the only exposure assessment conducted for these stoves 6–8 months after installation (median: 7.4; IQR=6.6–8.1 months).[28] OPTIMA stoves were later stratified (after exposure assessment had occurred) into two categories based on their levels of functionality (FL). FL-I stoves were in good running conditions at the time of the assessment (plastered stove and no visible leaks when in use) and FL-II stoves were in need of repairs (re-plastering, filling small cracks, cleaning the chimney, chimney valve replacement). Field workers, during monthly visits, instructed OPTIMA stove users in the correct use of the stoves including cleaning and removing ashes and wood residues. Although surveillance occurred in all study homes, stove repair and maintenance were not addressed during home visits until after air quality monitoring had occurred. Households with OPTIMA-improved stoves were re-visited 9 months (median: 9.3; IQR=9.0–9.7 months) after installation and repaired as needed by the original stove builders.[28]

The control arm of the c-RCT included households with a diversity of stove types.[27] As such control households in this study had a wide range of stove types including (1) chimney stoves whose raw materials were provided by non-governmental organizations (hereafter referred to as NGO; n=30); (2) chimney stoves built by the households themselves (hereafter referred to as self-improved by household; n=34); (3) gas stoves (n=4); and (4) non-vented stoves with pot holes for cooking including the common three-stone open fire stove (hereafter referred to as traditional; n=129). At the time of sampling, control households had stoves which had been in use between 4 months and over 10 years. Lastly, households in each arm of the intervention were classified according to the primary stove in use and it is possible that some chimney stoves were used together with traditional stoves in some households, particularly for cooking animal feed or other meals which required substantial cooking times.

Sample size

Mothers/primary caregivers (hereafter referred to as mothers) were sampled from 182 intervention households (final $n=161$) and 197 control households (final $n=154$) (Table 1). Some households were sampled two or three times during the study period (13 intervention households and 12 control households) and in eight control households, two tubes were used on the same day. In each case, the multiple measurements (pseudo-replicates) were averaged to get a single value for data analysis per subject. Losses in sample size were similar except for the number of broken tubes [$n=5/182$ (3%) among intervention and $n=18/197$ (9%) among control households]. We are unsure as to why there was a higher breakage rate among control households, but we do not expect this to influence our study findings. Measurements were not reattempted in households with lost or broken tubes.

During the first month of sampling, kitchen tubes were taped directly above stove openings in study kitchens at ~1.5 m. These tubes, representing 29% of the data, have been excluded from all analysis to avoid inflating the values of the kitchen measurements (Table 1). There were a total of 40 tubes [$n=11/182$ (6%) from intervention households and $n=29/197$ (14%) from control households] that had yellow and/or white stains. Like Smith *et al.* in 2010, these tubes were excluded from the final data set as the stains may be due to other gases that entered the tube along with CO during sampling. Duplicate same day measurements in a small subset of households were collected to check for reliability in tube measurement. All collocated tubes had stain length measurements within 1.5 mm of each other (10 ppm-hour). Owing to field workers monitoring previously sampled community clusters, certain households were sampled more than once during the 3-month exposure assessment.

Exposure assessment

Time integrated CO measurements were taken using Dräger Diffusion Tube for Carbon Monoxide, with a range of 6–600 ppm-hour (parts per million-hour). All tubes were from the same manufacturing lot. The sampler uses principles of diffusion and colorimetry where CO passively diffuses into the tube and causes the reduction of sodium palladosulfite to palladium metal.[29] The result is a grayish stain inside the tube, which corresponds to a cumulative dose of CO.

Three CO passive diffusion samplers were set up and left in place for 48 hours in each household to measure exposures to CO. Two tubes were for personal sampling: one worn in the breathing zone of the mother and one worn by a child under the age of 5 years who was enrolled in the parent c-RCT. The third tube was set up in the kitchen, at the breathing height (approximately 1.5 m) of the mother and close to where she stands during cooking. The times of tube breakage and capping, which marked the beginning and termination of sampling, respectively, were recorded on data sheets.

For all but 93 study subjects, tubes were placed in cloth coverings with an attached string for hanging around the neck, and pinned in the subject's breathing zones. The cloth covering was for comfort, protection of tubes from direct sunlight,[25] and has been shown to not affect CO measurements.[30] For 93 of the mothers (50 control and 43 intervention stove users) in this study, CO tubes were placed in vests worn in the breathing zones of subjects. These vests held real-time CO monitors and 48-hour time integrated $PM_{2.5}$ samplers for personal air sampling and the data for these measurements are presented elsewhere.[28] CO tubes from these 93 mothers are included in the final data set of this study. Subjects were instructed to keep the tubes on at all times and to place them by their bedside at night.

Upon return to the field station, tubes were stored in a $+4°C$ refrigerator before and after reading. Tubes were read by two of the authors (AAC and SMH) and an arithmetic mean was taken. Reading took place in a white, bright fluorescent tube lit laboratory room at a table with a white surface. The least squares regression technique developed by Smith *et al.*[25] for Randomized Exposure Study of Pollution Indoors and Respiratory Effects (RESPIRE) was employed. In brief, the length of stain was measured for each tube and converted to a cumulative exposure in ppm-hour. ppm-hour was subsequently divided by the total sampling time to

Table 1 Description of passive diffusion CO tubes deployed in intervention and control households during household air pollution exposure assessment in rural Peru

	Intervention homes			Control homes		
	Child	Mother	Kitchen	Child	Mother	Kitchen
Total number of tubes	172	182	182	173	197	197
Broken	9	5	0	10	18	2
Lost	5	14	1	11	17	0
Unavailable during pick-up	4	2	2	4	8	4
Sampling error	0	0	55	0	0	42
Tubes with stains	0	0	11	0	0	29
Final sample size	154	161	113	148	154	120

obtain CO personal exposures and kitchen levels. Questionnaires were administered on the second day of air sampling to obtain data on household air pollution, respiratory health-related symptoms, demographics, daily activities, and commuting habits.[28]

Human subjects and ethical issues statement

This study was approved by the Internal Review Boards at University of Georgia, the Centers for Disease Control and Prevention of the United States, and by the ethical committee of the IIN and the ethical review board at the Cayetano Heredia University in Peru. The demographic and socio-economic data had previously been collected in the parent study (ClinicalTrials.gov Identifier: NCT00731497) which had received clearance from the independent ethics committees of IIN and the ethical review board of University of Basel, Switzerland (Ethikkommission Beider Basel). Signed consent forms were obtained from all participating households. During May 2010, workshops were held to present study results and hold discussions with the communities.

Statistical Analysis

SAS version 9.1 (SAS Institute, Cary, NC, USA) was used for all data analysis. Sampling duration ranged from 2399 (40 hour) to 3442 (57 hour) minutes, with a mean of 2860 minutes (48 hours). All CO data were natural log transformed for regression analyses. SAS PROC GLM was used to fit general linear models which assess the impact of select variables on personal mother and child CO exposures as seen in equation (1):

$$y_{ij} = \mu_j + \beta_1 X_{1ij} + \ldots + \beta_p X_{pij} + \varepsilon_{ij} \quad (1)$$

Here y_{ij} is the log CO exposure/concentration measured on the ith subject/kitchen with the jth stove type; μ_j is the population mean log CO for the jth stove type at the average value of the covariate; β_p is the effect of X_p, the covariate under consideration and ε_{ij} is a mean zero, constant variance error term assumed to follow a normal distribution.

The passive CO tubes placed in kitchens were found to have reached the 600 ppm-hour upper limit after 48 hours for 46/113 intervention households and 59/120 control households. Hence for kitchen concentrations only, due to right censoring of approximately 47% of the data, PROC LIFEREG was used to fit linear models to the kitchen data. These models explain the linear relationship between kitchen CO concentrations and select variables in the form given in equation (1). The LIFEREG procedure implements maximum likelihood estimation and inference in the presence of censored data. Ignoring the censoring (e.g. by fitting the model via least squares as in PROC GLM) would result in biased parameter estimates, incorrect standard errors, and invalid statistical inference.

Information on covariates was obtained from the administered questionnaires on the second day of HAP sampling. Covariates were included in GLM models individually to test for significant associations with personal or kitchen CO. The final group of covariates considered for inclusion in the full models include mother's age, time spent playing with child, cooking time, number of people in household, presence of smokers in household, age of stove, wood type used in cooking, kitchen environment, mother's frequency of cleaning ashes from stove, distance of household to road, and stove type (Table 4). Backward elimination was the process used for model selection. Starting with all candidate variables, we removed non-significant variables other than stove type using a chosen model comparison criterion ($P=0.2$). Variables were deleted one at a time if the P values for their corresponding regression coefficients were higher than 0.2. This process was repeated until only variables that were statistically significant remained in the model. The effect of stove type was retained in all models to allow comparison of CO exposures and concentrations across stove type.

Kitchen environment refers to the nature of the cooking area which was categorized as enclosed (four full walls and a roof) or open (less than four walls, or open to the outside). Wood type refers to the most common wood type cooked with by the various wood stove users in this study. Cooking time refers to the estimated amount of time mothers spent cooking a meal on a typical day and it is a way to estimate proximity to the cooking fire. The time mothers spent in playing with their children during the day was also assessed to determine whether this affected their respective exposures. This variable was chosen as a proxy for how often the mother and child are together on any given day. This variable was considered to be potentially important because if playing time did not overlap with cooking time, it could impact personal exposures.

Stove type was retained in all models in order to compare personal exposures and kitchen log CO concentrations across stove types (first by control and intervention stoves and then by specific stove types). Comparisons were done with an F test for equal means across all stove types for all models. Then for personal mother and child exposures, Dunnett's test for pairwise comparisons of each stove type with OPTIMA FL-I as the reference stove was performed. Cooking time and time mothers spent playing with their children were centered at their respective means across households in all regression models. Finally, to examine how well the tubes predict personal and kitchen area measurements, Spearman correlation coefficients (r) between personal mother and child CO exposures and between personal (mother and child) and kitchen CO measurements were calculated separately by stove type.

Results

Household characteristics

Demographic and household information for households using various stove types are presented in Table 2. Except for differences in television ownership and the number of smokers present in households, the study population was comparable with respect to their socio-demographic and kitchen characteristics (Table 2). Households with NGO stoves and self-improved by household stoves owned fewer television sets: 5% and 6% respectively compared to 17%, 29%, and 30% for the OPTIMA FL-II, FL-I, and traditional stoves, respectively (Table 2). Households with self-improved stoves had 19% of family members who smoked, compared to 7–8% of smokers in households with other stove types (Table 2). All variables mentioned above are comparable among control and intervention households in the entire c-RCT population[26] and were not statistically significant during subsequent regression analysis. *Eucalypto* (eucalyptus) was the most common wood type used for cooking by 34% (n=32 OPTIMA FL-I stoves) to 65% (n=13 self-improved by household stoves) of the women in this study (Table 2).

CO Exposures and Concentrations

Summary statistics of unadjusted CO exposures and kitchen concentrations in intervention and control households and across stove type are presented in Table 3. It must be noted that our study population included mothers who used gas stoves (n=4), and these have been excluded from subsequent analysis.

Regression analysis: control and intervention households

There were no statistically significant differences between intervention and control households for any of personal CO exposures: mother (F=0.02; df=1, 288; P=0.89) and child (F=0.49; df=1, 287; P=0.48). Likewise, for kitchen concentrations, the model revealed no differences in kitchen CO concentrations in intervention and control households (Chi-square=0.28; df=1; P=0.59). Owing to the lack of statistical significant differences between control and intervention measurements, for the remainder of the results, we analyze data by stove type: OPTIMA FL-I, OPTIMA FL-II, NGO, and traditional and stoves which were self-improved by the households.

Table 2 Demographic and household information by stove type for study households in rural Peru

Characteristic	Stove type* OPTIMA FL-I† (n=92)	OPTIMA FL-II† (n=64)	NGO‡ (n=25)	Self-improved by household (n=21)	Traditional (n=96)
Mothers' characteristics					
Mean age (SD), years	30 (7.1)	31 (9.3)	31 (8.0)	27 (7.4)	29 (6.6)
Mean time spent playing with child (SD), hours	0.9 (0.8)	0.8 (0.6)	0.7 (0.4)	0.7 (0.5)	0.8 (0.6)
Mean cooking time (SD), hours	3 (1.0)	3 (0.9)	3 (0.6)	3 (1.0)	3 (1.1)
Household characteristics					
Mean number of people in household (SD)	5 (1.5)	5 (1.8)	5 (1.4)	4 (1.3)	5 (1.5)
Number of households with smokers, n (%)	6 (7%)	4 (7%)	2 (8%)	4 (19%)	8 (8%)
Own a television set, n (%)	22 (29%)	7 (17%)	1 (5%)	1 (6%)	25 (30%)
Kitchen characteristics					
Length of stove use n (%)					
<1 year	92 (100%)	64 (100%)	9 (53%)	11 (69%)	16 (21%)
1–2 years	0	0	5 (29%)	1 (6%)	15 (20%)
3–5 years	0	0	2 (12%)	3 (19%)	16 (21%)
>5 years	0	0	1 (6%)	1 (6%)	29 (38%)
Most common wood type, n (%)					
Eucalypto	32 (34%)	24 (41%)	9 (39%)	13 (65%)	38 (40%)
Kitchen environment: number of kitchen walls, n (%)					
Four walls	69 (75%)	40 (63%)	18 (72%)	17 (85%)	77 (88%)

Note: *Total sample sizes for number of people in the household, mother's age, cooking time, and time spent playing with child for the various stove types are as follows: OPTIMA FL-I (n=92), OPTIMA FL-II (n=64), NGO (n=25), self-improved by household (n=21), and traditional (n=96). For all other variables, the sample sizes and percentages reflect the total number of responders for each stove category.

†Functionality level (FL) I refers to an OPTIMA-improved stove in good conditions, and FL-II refers to an OPTIMA-improved stove in need of repairs (e.g. re-plastering).

‡NGO: three main NGOs had improved stoves; JUNTOS-National cash transfer program. Part of the requirements is that families must build an improved stove with a chimney; SEMBRANDO and ADIAR are NGOs that work in nearby communities.

Table 3 Forty-eight-hour Unadjusted personal CO exposures and kitchen CO concentrations measured in all control and intervention homes

Stove type	Statistics	Child	Mother	Kitchen
Intervention	GM[§] (95% CI) ppm	1.0 (0.9–1.1)	1.4 (1.3–1.6)	7.3 (6.4–8.2)
	n	154	161	113
OPTIMA FL-I*	GM (95% CI) ppm	1.0 (0.6–1.4)	1.5 (1.1–1.9)	7.2 (6.6–7.8)
	n	93	97	67
OPTIMA FL-II*	GM (95% CI) ppm	1.1 (0.8–1.5)	1.5 (1.1–2.0)	7.4 (6.2–8.9)
	n	61	64	46
Control[†]	GM (95% CI) ppm	1.1 (0.9–1.2)	1.4 (1.3–1.6)	7.3 (6.4–8.3)
	n	148	154	120
NGO[‡]	GM (95% CI) ppm	1.1 (0.3–1.9)	1.5 (0.7–2.3)	6.3 (5.3–7.3)
	n	25	25	18
Gas	GM (95% CI) ppm	0.8 (0–3.5)	0.9 (0–3.8)	4.0 (0–9.4)
	n	4	4	4
Self-improved by household	GM (95% CI) ppm	0.7 (0–1.7)	1.2 (0.3–2.1)	7.0 (5.8–8.2)
	n	21	23	17
Traditional	GM (95% CI) ppm	1.1 (0.7–1.5)	1.5 (1.1–1.9)	7.6 (7.1–8.1)
	n	98	102	81

Note: *Functionality level (FL) I refers to an OPTIMA-improved stove in good conditions, and FL-II refers to an OPTIMA-improved stove in need of repairs (e.g. re-plastering).
[†]Geometric mean for all control stoves does not include gas stoves.
[‡]NGO: three main NGOs had improved stoves; JUNTOS-National cash transfer program. Part of the requirements is that families must build an improved stove with a chimney; SEMBRANDO and ADIAR are NGOs that work in nearby communities.
[§]GM refers to geometric mean.
Sample sizes represent the total number of subjects from whom CO measurements were taken. For mothers $n=154$ and 161, and for children, $n=148$ and 154 in control and intervention homes, respectively.

Regression analysis: specific stove types

Personal CO exposures: mothers

Summary statistics for covariates included in our models are presented according to stove type (Table 4). The regression model for mothers in this study revealed that personal CO exposures did not differ significantly across stove types (overall F test statistic=0.24, $P=0.92$, Table 5A). All other variables were found to be statistically insignificant using backward elimination. Dunnett's test revealed no significant difference between mean mother personal log CO exposures using the OPTIMA FL-I stove ($n=92$) and any other stove type [$P=1.00$, 1.00, 0.85, and 1.00 for OPTIMA FL-II ($n=59$), NGO ($n=23$), self-improved by household ($n=20$), and traditional ($n=96$) stoves, respectively, Table 5A].

Personal CO exposures: children

Although not found to be statistically significant, children's CO exposures were lower in households with self-improved stoves and higher for all other stove types (overall F test statistic=1.67, $P=0.16$, Table 5B). Dunnett's test revealed no significant differences in mean child personal CO exposures between OPTIMA FL-I ($n=92$) and other stove types [$P=1.00$, 0.79, 0.34, and 0.56 for OPTIMA FL-II ($n=59$), NGO ($n=22$), self-improved by household ($n=19$), and traditional ($n=95$) stoves, respectively, Table 5B].

For children in this study, the regression model showed that time mothers spent cooking during the sampling period was marginally associated ($P=0.0504$) with their CO exposures (Table 5B). The model estimated a decrease of 0.11 ppm (SE=0.056)

Table 4 Effects of all variables in the full model for each sample type. Test statistics and *P* values for modeled effects are provided for personal exposures and kitchen concentrations of log CO. All covariates listed in the table were included in an initial model and then backward elimination was used to arrive at the final model for each sample type

	Child		Mother		Kitchen	
Variable	*F* test statistic	*P* value	*F* test statistic	*P* value	Chi-square statistic	*P* value
Mother's age	0.70	0.41	1.22	0.27	0.05	0.82
Time spent playing with child	1.50	0.22	0.26	0.61	0.43	0.51
Cooking time	4.57	**0.03**	6.04	**0.02**	3.82	**0.05**
Number of people in household	0.22	0.64	0.84	0.36	1.39	0.24
Presence of smoker in household	0.02	0.90	0.07	0.80	0.10	0.75
Age of stove	0.06	0.81	2.06	0.15	0.03	0.86
Wood type	0.26	0.77	0.34	0.71	1.83	0.40
Kitchen environment	1.54	0.22	2.31	**0.04**	9.26	0.16
Mother's frequency of cleaning ashes from stove	0.55	0.70	0.76	0.55	1.82	0.77
Distance of household to road	0.33	0.92	1.26	0.28	1.91	0.93
Stove type	0.57	0.68	0.70	0.60	2.75	0.60

in children's personal CO exposures for every additional hour spent cooking by their mothers. Children's age in years was centered at its mean across households to investigate the effect of age, and possible interactions between child's age and mother's time spent cooking. However, neither of these effects were statistically significant (P=0.7363 and 0.1943), for the main and interaction effects, respectively. The interaction between cooking time and the time mothers spent playing with children also did not reach statistical significance (F test statistic=0.94, P=0.33).

Kitchen CO concentrations

Kitchen CO concentrations were marginally associated with the type of wood used for cooking (Chi-square=5.52, df=2, P=0.06, Table 5C). Study

Table 5 Model derived analysis of variance and geometric means (with 95% confidence intervals) for 48-hour time integrated personal CO exposures and kitchen concentrations

A		Mothers' personal CO exposures		
Variable		Num DF, Dem Df[§]	F test statistic	P value
Stove type		4, 285	0.24	0.92
Variable	n	Mean CO (ppm)	95% CI (ppm)	Ho: mean=OPTIMA Fl-I[¶]
OPTIMA FL-I*	92	1.5	1.3, 1.7	–
OPTIMA FL-II*	59	1.5	1.2, 1.8	1.00
NGO[†]	23	1.5	1.1, 2.0	1.00
Self-improved by household	20	1.3	0.9, 1.7	0.85
Traditional	96	1.5	1.3, 1.7	1.00
B		**Children's personal CO exposures**		
Variable		Num DF, Dem Df	F test statistic	P value
Stove type		4, 281	1.67	0.16
Cooking time[‡]		1, 281	3.86	0.05
Variable	n	Mean CO (ppm)	95% CI (ppm)	Ho: mean=OPTIMA FL-I
OPTIMA FL-I*	92	1.0	0.9, 1.2	–
OPTIMA FL-II*	59	1.0	0.8, 1.2	1.00
NGO[†]	22	1.2	0.9, 1.6	0.79
Self-improved by household	19	0.7	0.5, 1.0	0.34
Traditional	95	1.2	1.0, 1.3	0.56
C		**Kitchen CO concentrations**		
Variable		Df[§]	Chi-square	P value
Stove type		4	1.68	0.79
Wood type		2	5.52	0.06
Variable	n	Mean CO (ppm)[¶]	95% CI (ppm)	P value
Stove (reference=OPTIMA FL-I*)	67	7.2	6.1, 8.5	–
OPTIMA FL-II*	46	7.4	6.2, 8.9	0.81
NGO[†]	18	6.3	4.7, 8.5	0.55
Self-improved by household	17	7.0	4.9, 10.2	0.53
Traditional	81	7.6	6.5, 8.9	0.43
Wood type (reference=other types of wood[‡])	77	6.7	5.6, 7.8	–
Eucalypto (Eucalyptus sp)	82	7.4	6.4, 8.6	0.22
Hualango (Acacia sp)	68	8.4	7.2, 9.8	0.02

Note: *Functionality level (FL) I refers to an OPTIMA-improved stove in good conditions, and FL-II refers to an OPTIMA-improved stove in need of repairs (e.g. re-plastering).

[†]NGO: three main NGOs had improved stoves; JUNTOS-National cash transfer program. Part of the requirements is that families must build an improved stove with a chimney; SEMBRANDO and ADIAR are NGOs that work in nearby communities.

[‡]Cooking time refers to the estimated cooking time of mothers in study region that have been centered by subtracting the mean cooking time from individual cooking times.

[§]Num DF and Dem DF refer to numerator and denominator degrees of freedom, respectively. DF in part c refers to the degree of freedom for the model.

[¶]Ho: mean=OPTIMA FL-I refers to the probability of the mean personal CO exposure from other stove type=OPTIMA FL-I stove users mean CO exposure using Dunnett's test.

— denotes non-applicable results

Sample size represents subjects who had complete questionnaire information on wood type and stove type only rather than the total number of subjects from whom CO measurements were taken. For mothers, n=151 and 139, and for children, n=151 and 136 in control and intervention homes, respectively.

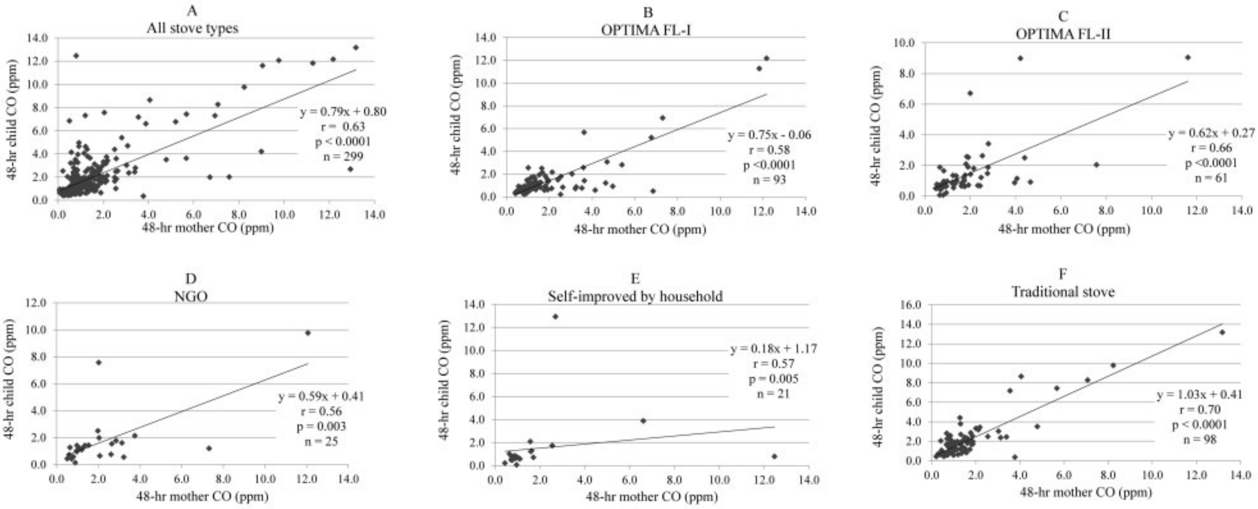

Figure 1 Spearman correlation coefficients (*r*) between personal mother and child CO exposures for all intervention and control households (A). Then separate plots are presented by stove type: OPTIMA FL-I (B), OPTIMA FL-II (C), NGO (D), self-improved by household (E), and traditional (F) stoves.

subjects used different types of wood as fuel including pine, *eucalypto* (eucalyptus), cypress, *talla*, *huayo*, and *hualango*. After preliminary analysis, firewood types were grouped into *eucalypto* (n=82), *hualango* (n=68) and other wood types (n=77). Households that used *hualango* had higher and statistically significant (P=0.02) kitchen CO, whereas households that used *eucalypto* did not (P=0.22) when compared to other wood types (Table 5C). There was no difference in kitchen CO between households that used *eucalypto* compared to *hualango* (P=0.19). Households using *hualango* had 8.4 (7.2–9.8) ppm (mean with 95% CI), those using *eucalypto* had 7.4 (6.4–8.6) ppm and those using other wood types had 6.7 (5.6–7.8) ppm of CO in the kitchen (Table 5C).

Passive tube correlations

Spearman correlation coefficients (r) between personal CO exposures and kitchen CO levels are presented by stove type used in households in Fig. 1. All mother and child measurements were correlated (r=0.63, P<0.0001, n=299; Fig. 1A). The correlation coefficient value between mother and child personal samples was larger for all control stoves when compared with all intervention stoves (control: r=0.67, P<0.0001, n=145; intervention: r=0.60, P<0.0001, n=154).

Among intervention households, correlations between personal mother and child CO exposures were moderate to low (Fig. 1B and C), with the strength of the correlation slightly increasing with decreasing stove quality (r=0.58, P<0.0001, n=93 for OPTIMA FL-I compared to r=0.66, P<0.0001, n=61 for OPTIMA FL-II). Personal mother and kitchen samples were moderately to weakly correlated (r=0.23, P<0.03, n=67 for OPTIMA FL-I compared to r=0.29, P=0.02, n=46 for OPTIMA FL-II). Child and kitchen samples had a weak correlation (r=0.38, P=0.0002, n=67) for households with OPTIMA FL-I and a marginal statistically significant correlation for OPTIMA FL-II households (r=0.23, P=0.08, n=46).

For personal mother and child's correlation in the control arm of the intervention, households using traditional stoves (Fig. 1F) had a larger correlation (r=0.70, P<0.0001, n=98) than households using NGO (Fig. 1D) and self-improved by household (Fig. 1E) stoves (r=0.56, P=0.003, n=25 and r=0.57, P=0.005, n=21, respectively). Kitchen CO levels were marginally correlated with mothers' personal exposures (r=0.47, P=0.06, n=17) and significantly correlated with children's exposures when stoves were self-improved by household (r=0.51, P=0.04, n=17).

Discussion

Carbon monoxide measurements in this study did not demonstrate statistically significant differences across the various stove types in both arms of the intervention. The lack of differences in CO exposures between control and intervention households seems contrary to results reported in other chimney stove intervention studies.[14,25,31–34] While some of the intervention studies mentioned above assessed HAP exposures before and soon after stove installation, other stoves were monitored frequently and stoves were routinely fixed. In this cross-sectional study, we present data on HAP measurements of chimney stoves referred to as OPTIMA stoves that had been in use, on average, for several months. Some of these stoves had not been maintained, and may have been improperly used. Our results have potential implications for intervention studies in the developing world aiming to answer the question of stove performance months after installation and use.

Findings from RESPIRE demonstrate that a well-maintained stove decreased CO exposures by 50%

and kitchen concentrations by 90% with a corresponding 22% decrease in physician diagnosed pneumonia in children.[35] It must be noted that these households had stoves that had been installed for on average of 18 months, with weekly visits where repairs and maintenance were provided as needed.[35] An ideal stove must be affordable and simultaneously have high heating efficiency and low, non-health-damaging emissions.[4,36] Lessons from current global stove intervention studies point to the fact that cookstove related woodsmoke exposures can be reduced; however, these reductions need to be larger and must be sustained for several years to yield greater public health benefits.[35,37]

One goal of the c-RCT was to determine impact of the OPTIMA stoves in reducing acute lower respiratory infections in children between the ages of 6 and 36 months. Children in homes with OPTIMA FL-II stoves had CO exposures of 1.0 (0.9–1.2) ppm. In the Gambia, a study of 1115 children reported a mean CO exposure of 1.04 ± 1.45 ppm ($\pm$SD).[23] Children in households using the plancha chimney stoves in the RESPIRE study had a geometric mean of 1.0 (2.4) ppm (SD).[25] These CO tube measurements from children in the above mentioned studies are similar to results in the current study; however, the levels of HAP experienced by OPTIMA stove users may not result in significant health improvements compared to control stove users due to two main reasons. First, there were no significant differences between control and intervention household measurements; hence, health impacts between the two groups are expected to be similar. Second, findings from an exposure-response analysis from the RESPIRE study suggest that larger HAP exposure reduction is needed to observe reductions in child mortality from acute lower respiratory infections.

Our results also suggest children's CO exposures decreased (marginally) with increasing time mothers' spent during cooking. This finding could be spurious although possible reasons could be due to decreased CO emissions from the fire presumably after cooking has occurred or after cooking, children were further away from the cookstoves. A third reason for decreased child exposure with increased cooking time could be due to maternal mis-reporting, that children were further away from cookstoves during cooking events. However, we do not have data from time activity diaries of subjects to corroborate these possible explanations.

All personal mother and child CO exposures were correlated amongst our study population. This agrees with the literature that suggests that when children data are unavailable, data from their mothers can be used to estimate exposures of the children especially in a high HAP setting.[22] As expected, kitchen CO measurements were higher compared to personal measurements; and mothers' personal exposures were higher compared to children's. Also as seen from our results, kitchen measurements need to be used with caution where personal measurements are unavailable, since kitchen levels can inform but can overestimate personal exposures.[8,13,25]

Aside from the significant correlation between personal exposures, our results showed an increase in the value of the correlation coefficient with a corresponding increase in stove deterioration. For example, among intervention stove users, the correlation between personal mother and child exposures among OPTIMA FL-II stove users had a slightly higher value compared to OPTIMA FL-I. Also among control stove users, the correlation among traditional stove users had a higher value compared to households with chimney stoves. This suggests stronger correlation between personal exposures with increasing HAP levels,[22] and is a finding which needs to be corroborated by other studies.

A number of reasons may have led to high HAP levels in intervention households in our study. Adequate stove design, manner of stove use (i.e. whether it is used continuously, properly and exclusively), as well as maintenance over time, are key factors in HAP mitigation. Design and construction of efficient cookstoves is also key to reducing and sustaining low exposure levels.[35] It must be noted that cookstoves, with use, are expected to degrade with time even with adequate maintenance.[38] Hence, there is the need to design and construct cookstoves where factor in the high temperatures and pressure factors will impact its degradation. Additionally, it is important to recognize the effect, if any, of altitude on the combustion efficiency of cookstoves.

Improper stove use is another important factor. If fitted pots are not placed in tightly sealed pot holes on the stove top during cooking, combustion emissions can leak into the indoor environment. The same is true for openings designed for fuel insertion. Any uncovered chimney stove opening may introduce into the household environment emissions akin to an open fire. Conversely, although OPTIMA stove users were not specifically asked whether they had used open fires during the sampling period, this is a possibility given that even gas stove users in this study reported the use of firewood during the sampling period. Findings from participatory observational surveys revealed a reported 90% (212/236) daily use of the OPTIMA-improved stove after about 7 months (median 7.4, IQR=6.6–8.1 month).[28] However, there is the possibility these households used open fire stoves throughout that period. Lack of exclusive and continuous stove usage can introduce more HAP into the kitchen environment and needs to be addressed if an intervention program is to be successful and sustained over time.

It has been documented that intervention stoves can improve health when properly used.[12,35,39] It is important then to determine the stove's performance at the time of installation[31] and also months and years after installation, as the intervention stove may possibly introduce greater HAP if improperly maintained and used. Also the importance of functionality levels within stove type is important in HAP exposure assessment. Clark *et al.*[40] suggest the utility of stove functionality levels to be more representative of HAP exposures and indoor levels. They note the importance of assessing the condition of the stoves rather than a mere comparison between traditional and improve stove type.[40] Our results indicate that after an average of 7 months of use, OPTIMA stoves (whether they were in need of repairs or not) did result in significantly lower personal CO exposures and kitchen levels when compared to control stoves. Hence, stove maintenance and functionality are both essential in understanding HAP exposures.[36]

Results from our study seem to suggest that stoves which were self-improved by households had lower HAP measurements, almost akin to gas stove measurements, although this was not statistically significant. We do not know the reason for this finding. However, we can surmise that these stoves may have had better durability, lower emissions or perhaps the subjects took more responsibility for the maintenance of these personally constructed stoves. The qualities of any control stove type must also be assessed in future studies as they could provide insight on potential stove designs in local communities.

Firewood type is another important factor in the quest to reduce HAP.[41] In our study, households using *hualango* (Acacia sp.) as firewood had higher mean kitchen CO compared to other wood types used. High biomass combustion by-products such as PM and CO are associated with biomass fuel use;[1,42] hence, this finding is expected. With the move to decrease HAP on the international horizon, the need for utilizing cleaner energy (from wood to eventually using gas and electricity) should be considered in conjunction with the design of cookstoves.

This study is timely even as The Global Alliance for Clean Cookstoves (GACC) continues to build momentum in the effort to reduce HAP and the adverse health effects associated with it. The GACC, led by the United Nations Foundation, has the goal of 100 million households adopting clean and efficient cookstoves by the year 2020.[43] The success of household air pollution mitigation programs will depend not just on the number of disseminated stoves, but on the number of stoves that are adequately designed, continually, exclusively and properly used, as well as maintained over time.[12–14]

Limitations

Although valuable lessons can be gleaned from our study, single 48-hour measurements limit our ability to detect the temporal and within household variability in exposure.[23,44,45] This is important for a site such as San Marcos, which is subject to considerable seasonal climate changes that may impact the combustion efficiency of cookstoves, and the types of available cooking fuel. Future studies should consider taking repeated measurements over time.[23,25] Also information from time activity diaries may help future studies to derive better estimates of exposure.

It is also essential to be able to make population inferences based on larger sample sizes for each stove type. Control groups in this study, by design of the parent study, consisted of a diverse range of stoves with varying air pollution levels. Future studies with the primary aim of assessing HAP exposure need to limit the number of control groups or ensure adequate sample sizes in each stove category.

Another limitation is the timing of the HAP exposure assessment. Study households were not sampled before and immediately after chimney stove installation and this prevented evaluation of the effectiveness of the OPTIMA stoves soon after installation. Additionally, a change in kitchen sampling procedure led to the loss of nearly 30% of kitchen samples and demonstrated the importance of accurately quantifying exposure.

Finally, air pollution levels in some study households may have contributed to some tubes reaching maximum stain length. Ideally, the tubes should be monitored after deployment to detect any high levels of exposure or other sampling problems[23] and replaced if the upper limit of detection is reached. However, this was a hard feat to accomplish given substantial traveling distances to study households in the 51 community clusters.

Conclusion

After installation of study promoted chimney stoves in San Marcos, Cajamarca region, Peru, personal CO exposures and kitchen levels measured with passive diffusion tubes did not differ significantly between intervention and control households. Personal mother CO exposures were correlated with children's exposures. These results point to the fact that where data are unavailable, mothers' exposures can be used to predict children's exposures especially in high-pollution settings. Results suggest that proper and exclusive chimney stove use, maintenance of stoves as well as changes to fuel types may be necessary in reducing CO and more generally, HAP exposures.

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Disclosure

The authors declare no conflicts of interest.

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PART IV: THE IHIP-PERU TRIAL: EVALUATING AN INTEGRATED ENVIRONMENTAL HOME-BASED INTERVENTION PACKAGE

CHAPTER 9

AN INTEGRATED HOME-BASED INTERVENTION PACKAGE (IHIP): IMPROVING INDOOR-AIR POLLUTION, DRINKING WATER QUALITY AND CHILD NUTRITION IN RURAL PERU: A COMMUNITY RANDOMISED CONTROLLED TRIAL

Title: Improving household air pollution, drinking water quality and hygiene in rural Peru: A community randomised controlled trial of an environmental, home-based intervention package.

Running title: Integrated home-based package to reduce childhood illnesses

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

Abstract

Background: Diarrhoea and acute lower respiratory infections are leading causes of childhood mortality. Simple low-cost interventions have proven efficient and effective in reducing diarrhoea and severe pneumonia episodes; however, an integrated intervention package can be more beneficial in addressing multiple health burdens simultaneously.

Methods and Findings: We conducted a community-randomised controlled field trial in 51 rural communities in Peru to evaluate the effects of an environmental home-based intervention package (IHIP), in reducing lower respiratory infections, diarrhoeal disease and improving growth in children under 36 months of age. In the intervention arm 250 households received and were trained in the correct use and proper maintenances of an improved stove, kitchen sink, solar disinfection of drinking water and a handwashing promotion. The control group received a psychomotor stimulation programme. We recorded 24,647 child-days of observation in a 12 months period after the interventions were implemented. The mean incidence of diarrhoea was 2.8 episodes compared to 3.1 episodes per child year in the intervention and control arms. An adjusted relative risk of 0.78 (95%CI: 0.58-1.05) was found for diarrhoea incidence and an Odds Ratio (OR) of 0.71 (95% CI: 0.47-1.06) for diarrhoea prevalence. No noteworthy effects on acute lower respiratory infections or child's growth rates were observed.

Conclusions: Combined air quality, drinking water and home-hygiene interventions reduce diarrhoea in children below age three within 12 months. No further intervention effects on child growth- and respiratory outcomes were observed, despite high compliance of using kitchen sinks and improved stoves. It is likely that the IHIP-interventions have an additive effect in improving multiple health outcomes. However, time needed to achieve attitudinal and behaviour change among beneficiaries when providing composite interventions may have been underestimated and an effect on respiratory infections obscured by insufficient household air quality improvement of the popular OPTIMA-improved stove.

Key words: community randomised control trial, diarrhoea, acute lower respiratory infections, improve stove, water treatment, child growth, SODIS, Peru

Introduction

Diarrhoea and acute lower respiratory infections remain as leading causes of childhood mortality with an estimate of 1.3 and 0.7 million deaths per year respectively (1). Unsafe drinking water, poor sanitation, lack of hygiene and poor household air quality are considered to be among the most important risk factors responsible for the high burden of disease (2, 3).

Systematic reviews on water, sanitation and hygiene in developing countries suggest that improved drinking water and hand washing with soap could help prevent between 20% - 35% of the global burden of diarrhoea disease annually (4-6); Randomized control trials on household water treatment and hand washing consistently provide evidence of the impact of these interventions on diarrhoeal disease reductions in children under five (7, 8). Similarly, a meta-analysis on household air pollution (HAP) showed that children were three times more likely to develop acute respiratory infections (ARI) when exposed to biomass fuel smoke (9) and the only published randomized trial, observed a reduction on 30% on severe pneumonia cases with the introduction of chimney stoves (10).

The idea of a composite intervention to tackle several household burdens simultaneously has been described previously and proven efficient especially in the water and sanitation sector (11-13). The interventions for this study were developed using a participatory approached during a six-months pilot phase (14-16). We identified and convened main stakeholders and beneficiaries to develop an intervention package that is adapted to local beliefs and cultural views. Additionally, the control group received a control intervention on early child development to reduce non-blinding and reporting bias originated from open trial designs (17-19).

The main objective of the study was to reduce respiratory infections and diarrhoeal disease and improve growth in children less than 36 months of age by implementing an environmental home-based intervention package (IHIP), comprised of the construction of an improved stove and a kitchen sink, promotion of solar disinfection as household water treatment method and hand washing promotion as hygiene components.

Methods

Ethics

The Nutritional Research Institute (IIN) Ethical Review Board and the cantonal ethical review board of University of Basel, Switzerland (Ethikkommission Beider Basel, EKBB) approved the study. The Cajamarca Regional Health Authority and the Peruvian National Institute of Health (INS) also approved the trial, which is nationally registered with INS. The trial was registered at ISRCTN (ISRCTN28191222). Community leaders and local authorities from the study area signed a collaborative agreement with the IIN and Swiss TPH after initial screening for community eligibility and before randomisation. The mother/caretaker or father of each study child signed a written informed consent before study implementation. Sick children found during the follow-up period were evaluated by the study nurse/physician or were referred to the local health centre in San Marcos or to the clinic in Cajamarca. The project provided transport and treatment costs for those patients.

Site and Population

The study was conducted from September 2008 to January 2010 in the San Marcos Province, located 60 km north of Cajamarca city, in the northern region of Peru. San Marcos is located between 2200 and 3900 meters above sea level.

Most of the population are small-scale farmers, living in small houses with earthen floors and adobe walls, with three or more persons sleeping in the same room and used an unventilated traditional stove or open fire for cooking and heating. About 80% of the population has a piped water system with a faucet available in the household's yard and 65% of water samples were contaminated with faecal coliforms and 10% of them with diarrhoeagenic *E.coli* (20).

Study design

We implemented a community-randomised controlled field trial to evaluate the IHIP interventions on reducing the rate of acute diarrhoeal illness, acute lower respiratory infection (ALRI) and improving child growth in children aged 6 to 35 months at enrolment over a 12 month surveillance period. Sample size determination, screening, randomisation and enrolment have been previously described in detail (19). In brief, 56 rural communities were identified by an initial house-to-house census and screened for eligibility. One child aged 6 to 35 months was randomly selected from each eligible household willing to participate. Eligibility criteria on household level included use of solid fuels, no public sewage connection and no intention to move away during the study period. Due to the nature of the intervention, blinding was not possible (19). To counteract potential unbalance of dropouts between study arms and non-blinding bias, a psychomotor stimulation intervention, which is unlikely to have an impact on diarrhoea and respiratory infections, was implemented simultaneously in the control study arm.

The trial was powered to detect an incidence rate reduction of 22% with 80% power at a 5% level of significance, assuming 5 episodes of ARI per child-year of observation and a coefficient of variation of $k = 0.2$. All 51 communities fulfilling the eligibility criteria were randomized using covariate-based constrained randomisation as proposed by Moulton (21).

Randomisation, enrolment and baseline data collection took place between September 2008 and January 2009 (figure 1).

Development of Interventions

The components of the environmental home-based intervention package (IHIP) were selected in a participatory manner. We investigated efficacy and acceptability of potential hard- and software interventions in communities located in a neighbouring area. With the community member's involvement a new stove called "OPTIMA-improved stove" and a kitchen sink were developed. Approaches to stimulate behavioural change included the promotion of solar drinking water disinfection and kitchen hygiene (hand-washing with soap and elimination of animal excreta).

The stoves were built with local materials to enable self-maintenance and repair. Nine months after installation all stoves were re-visited and repaired as needed by the original stove builders. Mother/caretakers were also trained in the general application of the solar disinfection method SODIS method in daily practice according to standard procedures (www.sodis.ch) (18). Mothers were instructed to wash their hands and children's hands with soap or detergent after defecation, after changing diapers, before food preparation, before eating and before feeding infants and small children. Finally, mothers were told to separate the animals from the kitchen environment by removing them or confining them to a specific area and to remove the excreta and eliminated it in the latrines. Further details on the development of the intervention package – including stove performance, assessing the microbiological efficacy of solar drinking water disinfection and qualitative assessment of perception – are described elsewhere (19).

The intervention in the control communities was based on the National WawaWasi early child development (ECD) programme, which provides psychomotor and cognitive stimulation in children under four-years of age at day-care centres (22). Together with WawaWasi experts, we adapted the intervention to be used at household level and trained field staff under their supervision. Mothers were trained in the use of the ECD toys and materials and instructed to play with their children at least 30 minutes every day. Families received a new set of toy every two months depending on the child progress and age (19).

Training of field staff

Four different teams were trained for intervention delivery and data collection. Each team received extensive training in their respective tasks. Field workers were responsible for collecting morbidity data and were trained in interviewing techniques, data recoding, the identification of signs and symptoms of child diarrhoea and ALRI severity symptoms, as well as for measuring respiratory rates. Additionally, the team was responsible for collecting spot check observations on household hygiene and environmental health condition. The anthropometric team was trained and standardised in measuring child weight and height. The health promoters' team was locally hired elementary school teachers. They promoted regular use of both interventions (IHIP and ECD) and collected compliance data on a monthly basis. They were trained to re-enforce the IHIP and ECD intervention messages and to encourage correct use. The environmental team was responsible for collecting environmental samples to test for faecal contamination of mothers' hands, drinking water, and kitchen cloths. They were trained in collection and handling of samples to avoid cross contamination.

Implementation

The IHIP interventions (OPTIMA-stove and kitchen sinks) were installed between October 2008 and January 2009. Solar disinfection as a HWT and hygiene messages on hand-washing and the elimination of animal excreta, were reinforced once monthly during the 12 months follow-up period. Each child in the control group received six sets of toys approximately every two months during the year of follow-up. The health promoters' team was responsible for the initial implementation and repeated promotion of the interventions. The promotion was done with the same intensity (monthly) in both study groups.

Data collection

The surveillance period took place from February 2009 to January 2010. Field workers visited each household weekly and collected morbidity data from the mother/caretaker on daily occurrence of signs and symptoms of child diarrhoea and respiratory illnesses. If diarrhoea was observed additional information on the severity and occurrence of the episode was collected (sunken eyes, dry mouth, tongue and mucous membranes and thirstiness). If a child had cough or fever on the day of the household visit or a day prior, we looked for danger signs (23) to assess the severity of the respiratory illness by recording noisy and/or fast breathing, rhonchus/wheezing, lower chest indraw, malaise and lack of appetite. If any of the severity signs were present the child was seen and treated by our study physician on the same day or referred to local healthcare services. General questions were asked to the mothers/caretakers to determine the child's health at the moment of the weekly home visit, including questions related to health seeking behaviour (seeking outpatient care, hospitalisation and type of medical treatment).

Anthropometric measurements were collected every two months. Two trained field workers took Lengths/heights and weights of children during home visits (24).

Environmental samples from the mother's hands, kitchen cloths and water for drinking were collected at baseline, mid term and at the end of the surveillance period. In total we collected 1833 samples. All analyses were done in accordance to standard methods (15, 20).

Outcome Measurements

We had three primary health outcomes, diarrhoea, acute respiratory infections and child growth.

Diarrhoea was defined as the passage of three or more liquid or semi-liquid stools in a 24-hour period or the passage of at least one liquid or semi-liquid stool with blood and/or mucus (25–27). An episode was defined to begin on the first day of diarrhoea and ended the last day of diarrhoea followed with at least two consecutive non-diarrhoeal days.

Acute respiratory infections (ARI) were defined as a child presenting cough and/or difficulties to breath. For children with cough or fever at the time of the household visit or within the preceding 24 hours, ALRI was assessed. ALRI was defined as a child presenting with cough or difficulties with breathing with a raised respiratory rate (>50 per min in children aged 6-11 months and >40 per min in children aged 12 months and older) on two consecutive measurements (23,28). An episode was defined to begin on the first day of cough or difficulties to breathe and ends with the last day of the same combination followed by at least 7 days without those symptoms (28).

Three indicators were used to evaluate the nutritional status of the study children: stunting, wasting and underweight as defined by WHO using the WHO reference population (24).

Statistical Analysis

We applied an intention-to-treat analysis comparing the incidence rates (IR) of diarrhoea and respiratory infection per child year in intervention versus control communities. Longitudinal prevalence's (PR) were calculated as the number of days ill per days under observation. All children with at least one day of follow up were included in the analysis. Generalized estimating equations (GEE) models were fitted to adjust for correlation within villages (29). The unadjusted model included only the design factors and the intervention effect. Further models adjusted for child's age and sex.

The statistical models included the log link function for negative binomial (IR) and logit for Bernoulli distributed data (PR). The logarithm of days under observation was included as offset variable (IR). The statistical analyses were performed using SAS software v9.3 (PROC GENMOD, SAS Institute Inc.). Data management and descriptive analysis were done with R V3.0.0 (R development core team). The coefficient of variation (k) and the 95% credible interval was estimated via Bayesian generalized random effects models using WinBUGS 1.4.

Results

Of the 51 communities, 25 communities (267 households) were randomised to the intervention and 26 (267 households) to the control arm (Fig 1). One community in the control declined to participate. Further details on participant flow before start of follow up are found in Hartinger et. al 2011 (19). The final analysis included 248 children from the intervention arm and 251 children from control communities. Information on morbidity was collected for about 18,000 person-weeks representing 71% and 74% of the total possible observation time in intervention and control arms.

Baseline characteristics were balanced between study arms with the exception of the coverage of piped water supply (table 1). Both study populations were classified as "poor" according to national standards. Basic sanitary facilities were found among 80% of the households. Despite the coverage of piped water supply about three quarter of the drinking water supply was contaminated with E. coli in both study arms (65%). Further socio-demographic, household and environmental baseline context is described elsewhere (19).

Diarrhoea morbidity

Children in the intervention arm reported a total of 301 diarrhoea episodes which corresponds to a mean of 1.8 episodes per child year. In the control arm 375 episodes and a mean of 2.2 episodes per child year occurred. The mean episode length of 2.8 days was shorter in the intervention arm compared to 3.1 days in the control arm (table 2). The statistical analysis estimated that children in the intervention communities had 22% fewer diarrhoea episodes per year compared to the children in the control communities (relative rate (RR): 0.78, 95%CI: 0.58-1.05). A similar result was found for the longitudinal prevalence with an odds ratio (OR) of 0.71 (95% CI: 0.47-1.06). However, both results were of border line significance with p-values < 0.10 and p-value <0.09 respectively (table 3). The clustering coefficient k was 0.39 (95% confidence interval: 0.25-0.57). The weekly prevalence of child diarrhoea indicated no evident temporal effect throughout the follow-up period (figure 2). To confirm that the findings were not sensitive to the choice of covariates, we rerun the analysis including piped water supply and/or latrine ownership in the model. None of the models yielded meaningful changes in the point estimates of confidence intervals.

Respiratory infections

The total number of ARI episodes was 831 in the intervention group and 877 in the control group, out of these we achieved 68% and 63% of respiratory rate measurements in the intervention and control groups respectively, corresponding to 554 and 563 ARI episodes. Out of these, 255 intervention and 218 controls had received medical treatment before the weekly surveillance, which may have affected respiration. The total number of ALRI episodes was 25 in the intervention and 10 in the control group (table 2). The relative rate for ARI episodes was 0.95 (0.39, 1.65; p-value 0.53) and 2.45 (95% CI: 0.82 to 7.39; p-value 0.11) for ALRI. The corresponding odds- or rate ratios were close to 1 (zero effect (table 3). Weekly prevalence of the indicators are illustrated in figure 3.

Anthropometric measurements

At baseline children of both study arms had similar frequencies of stunting (median of -2.2 and -2.0 z-scores below average WHO growth standards in intervention and control arm) and underweight (median -0.8 and -0.7). At end-of-follow-up measurements in month 12 no median difference in anthropometrics was observed between intervention and control arms for stunting (-2.1 and -1.9 z-score respectively) or underweight (-0.6 and -0.7 respectively).

Microbiological Samples

A total of 1994 samples of drinking water, kitchen cloths and mother's hands were collected throughout the study (477 at baseline, 675 at midterm and 842 for the end-of-study). The proportion of E.coli concentration for all indicators was similar at baseline between groups. E.coli concentration in drinking water was reduced from 67% at baseline to 42% (p-value = 0.052) at the mid study evaluation; however this difference was not maintained at the end of study (53%; p-value: 0.111) (Figure 4). We observed an E.coli geometric mean of CFU/100ml of 9 (CI 95% 3.6-22.4) for drinking water samples at baseline, 6.1 (CI 95% 0.7-48.2) at mid study- and 2.9 (CI 95% 1.9 - 4.5) at end of study evaluations. A similar decline in E.coli geometric mean was observed for control households.

Compliance

Indicators and methods of measuring compliance in this trial are detailed in the Appendix. Field workers that carried out weekly spot check observation of compliance observed an initial prevalence of SODIS use of 60% with a steady declined throughout the follow-up period, until it reached 10% at the end of the study. During the monthly training sessions health promoters reported constantly around 55% of SODIS; and mothers reported compliant SODIS use at 75% throughout the study (S1). Compliance of the OPTIMA-improved stove and kitchen sink use is based on monthly maternal reporting. 90% of all mothers reported using the OPTIMA-improved stove daily (S2), and two thirds reported using the kitchen sink for washing utensils and children's hands daily (S3). Continuous water flow based on seasonal water availability and connection to a water supply system were two limitations for use.

Discussion

Our community-randomised control trial in 51 rural Peruvian communities showed that households using the interventions from an environmental home-based intervention package (IHIP) consisting of a chimney improved stove, a kitchen sink and SODIS as HWT, can reduce child diarrhoea episodes by 22% (RR 0.78, 95% CI: 0.49-1.05) and diarrhoea prevalence (OR 0.71, 95%, CI: 0.47, 1.06). No noteworthy effects on acute respiratory or acute lower respiratory infections episodes or child's growth rates were found when comparing study arms.

We observed a moderate reduction in diarrhoeal episodes and prevalence. Although the confidence intervals indicated borderline significance only, there are some indications that the estimate might be close to the true parameters; - The observed effect is very consistent among all indicators in terms of incidence, length of episodes, number of persistent episodes, and episodes with blood in stool. Objective environmental indicators such as drinking water also corroborate the observed reduction on diarrhoea. Number of episodes with medication and visits to health facilities were lower in the intervention arm (data not shown).

Our moderate reduction could be due to, insufficient power or frequency of monitoring. Firstly, our study was sufficiently powered to detect a 22% reduction of diarrhoea episodes assuming 5 episodes per person-years of observation. However, we observed a mean diarrhoea episode of 2 in this population. Secondly, we used a 7-day recall to collect diarrhoea sings and symptoms. A smaller period could reduce subjectivity and bias in un-blinded trials (30), however shorter recall periods usually required larger sample sizes that are many times not feasible (31). To counteract this we collected objective environmental indicators: drinking water, kitchen cloths and mother hands. We observed a reduction in the *E.coli* concentration for drinking water between baseline and mid study evaluations; however this was not sustained in the end of study evaluation.

Despite our limitations the reduction in child diarrhoea observed compares well with those reported in water supply intervention trials (32-34), were up to 25% diarrhoea episodes reductions were observed. Water supply interventions are often accompanied by other environmental interventions intended to prevent faecal-oral transmission, including basic hygiene education, improved sanitation and improved in-home water storage (6), thus making it difficult to interpret whether the improvements to a water supply have improved quality or quantity, or both (34).

The reduction was also consistent with results found in four SODIS trials. Two trials carried out in the Maasai cultural settings reported a 10% reduction on the incidence of diarrhoea and 24% on severe diarrhoea in children between 5- 16 years (35), and report a 16% reduction for severe diarrhoea in children under 6 years of age (36). A third trial in a rural Bolivian setting found a 19% reduction of diarrhoeal episodes in children under 5 years old (37). However, other SODIS trials have observed and reported higher reductions in diarrhoea among users (38); and Du Preeze and colleagues recently reported a 45% reduction on dysentery episodes and 27% reduction of non-dysentery episodes and observed an increase of 0.8cm in height for age (39), although the anthropometric outcome have been criticised as biologically implausible (40) and potentially biased (41). A more recent trial by the same group reported a 50% reduced incidence of dysentery and a 63% reduction of non-dysentery episodes, with an almost universal compliance of the SODIS method (42). Although, both trial were registered together in the trial registry and followed the same protocol they were analysed and presented in different ways, which makes the interpretation of the results difficult (clinicaltrials.gov/ct2/show/NCT01306383).

A recent meta-analysis on hand washing with soap interventions trials reported a 39% reduction in diarrhoea episodes in children in institutions in high-income countries and a 32% reduction in episodes in children living in communities in low- or middle-income countries (43). We believe that we did not observe a reduction in this magnitude, due to the universal hand washing promotion carried out throughout our setting (implying that control household had also been instructed in the correct use of hand washing practices)

We did not observe a reduction in acute respiratory infections, or ALRI episodes in the sub-analysis. The potential reasons for no effect could be attributable to four factors: insufficient power of the study to detect reduction in ARI and ALRI, our OPTIMA stove lawering air pollution (44) but not to respiratory health relevant threshold (WHO-Household Air pollution guidelines 2014), our limited capacity to produce objective measurements of ARI severity from examining children with cough or difficulty breathing only once per week, and the studies limits to clinically diagnose ALRI.

The results from the RESPIRE trial yet unknown when our study was planned we powered the study to sufficiently detect a 22% reduction of ARI episodes assuming 5 episodes per person-years of observation. ALRI was analysed as a secondary analysis. Despite focussing on ALRI as a primary endpoint the RESPIRE trial found a significant reduction only in severe pneumonia in a secondary and imputation-based analysis (10). The second limitation was the insufficient exposure reduction. The minimal reduction needed to achieve impact on physician-diagnosed pneumonia is a mean CO exposure reduction of 50% (10). In our study we found a small reduction of CO and PM2.5 pollutants, with broad and overlapping confident intervals between study groups that was more pronounced in stoves that were better maintained. Our exposure data was taken only once, seven months after the implementation of the OPTIMA-improved stoves (44,45) as our trial never intended to routinely measure CO or PM2.5 concentrations to determine levels of exposure. Best functioning stoves achieved a 45% and 27% reduction of PM2.5 and CO respectively in mothers' personal exposure (46). Additionally, chimney-improved biomass stoves are not necessarily reducing emissions from incomplete combustion. Rather, they are venting smoke to the immediate outdoors allowing for perceivably less smoke indoors but contaminating the immediate and neighbouring outdoor - and indoor environments from re-entering (46). Additionally, the new behaviour patterns developed from the acquisition of a new stove in our subjects, could change the time spend in the kitchen environment thus increasing exposure to HAP pollutants, since most stoves do not reach WHO guidelines. We currently can only speculate that time saved from attending the cooking and wood collection is re-invested in other inside kitchen tasks, cleaning or even could shift the household focal point to the kitchen that is now a more comfortable environment, (observational evidence). In our setting OPTIMA-improved stoves were universally in use among beneficiaries in the intervention arm and were valued through the entire study setting. Our assessment of compliance indicated that 90% of the OPTIMA-improved stoves were used daily, throughout the 12 months study period. Two year after the end of study, an evaluation showed that around 85% of the stoves were still in use. However, in order to keep the stove functioning at proper levels, external sources (engineers) are needed, which could be a limiting factor for effectiveness. Our monthly reminders on maintenance and correct use of the stoves, and the initial premises that the use of local materials would facilitate local operation and maintenance proper levels were not fully achieved. Project-initiated repairs were carried out once nine months after the stoves were implemented. At this point 35% of our stoves needed minor repairs, (e.g. replastering) and 1% needed mayor repairs (e.g. a broken chimney valve).

A third limitation was the monitoring frequency for ARI and ALRI. Our study population had easy access to health facilities and a prominent health seeking behaviour, which was a determinant for correct diagnose of ARI and ALRI. A significant number of ARI and ALRI cases (~80%) had attended a health centre and/or received treatment for at least 2 days at the time of the household visit. Despite the mothers report on cough, fever and difficulties to breath, the respiratory rates were found normal, invalidating the application of the standard WHO-IMCI criteria to define and diagnose an ALRI episode. Several studies report that the ideal frequency of monitoring should be at least once a week (28), we believe that an increase in the frequency of monitoring could provide better outcomes, since we could capture the beginning of the episodes. The fourth limitation is the diagnosis of ALRI. For this study we used the WHO-IMCI field diagnostic criteria for ARI/ALRI. We should have used a more objective way of defining ALRI, through pulse oximetry and/or chest x-rays for a radiological recognition of ALRI (28).

As mentioned the study had several limitations, insufficient power, insufficient exposure reduction, or insufficient frequency on data collection, no clinical diagnosis of ALRI or IHIP compliance. Each of them addressed above. A final limitation was the study design. No designed would allow for double blinding at community level. This could lead to non-blinding bias and reporting bias. However, open trial design benefit from and harness the community dynamics generating interest and motivating for a demand-driven replication. Furthermore, the selection of an equally attractive intervention in the control arm (a child psychomotor and cognitive stimulation package) reduced non-blinding bias, drop-out rates and reporting bias and by using standardised data collection tools, independent data collection teams and objective measurements (19)(20) we ensured the quality of data collection in the study.

Finally, future study focusing on household air pollution should focus on how to design interventions (chimney stoves) that can achieve large and sustainable HAP reductions, ensure high adoption rate and collect frequent environmental measurements to ensure sustained reductions throughout the life of the study (47).

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Abbreviations: IHIP: Integrated home-based intervention package; CI: confidence interval; IQR, interquartile range; IR, incidence rate; NGO, nongovernmental organisation; OR, odds ratio; RR, relative rate; SODIS, Solar drinking water disinfection; HAP: household air pollution; ARI: acute respiratory infections; ALRI: Acute lower respiratory infections; PR: Longitudinal prevalence; GEE: generalized estimating equations.

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Table 9-1: Demographics and socio-economic characteristics of 503 households in rural Peru

		Intervention Arm		Control Arm
Characteristics	**N**	**Mean (SD) or %**	**N**	**Mean (SD) or %**
Demography				
Number of household members	226	5.0 (1.6)	234	4.6 (1.5)
Age in years of enrolled children	250	2.1 (0.7)	253	2.1 (0.7)
Female children	250	50%	253	50%
National poverty indicators [a]				
1 unsatisfied basic need	224	17 %	231	23 %
2 unsatisfied basic need	224	25 %	231	28 %
3 unsatisfied basic need	224	40 %	231	35 %
4 unsatisfied basic need	224	14 %	231	10%
Household Characteristics				
Household with latrines	245	80%	239	84%
Piped water supply	245	74%	239	82%
Microbiological Indicators (*E.coli*)				
Drinking water	88	68%	94	64%
Kitchen wipes	56	34%	35	25%
Mother hands	95	27%	109	22%
Anthropometrics				
Stunting (Median (IQR))	196	-2.2 (-2.7, -1.4)	194	-2.0 (-2.5, -1.4)
Underweight (Median (IQR))	201	-0.8 (-1.2, -0.2)	202	-0.7 (-1.2, -0.1)

[a] National Poverty Indicators: five parameters comprises this indicator: 1) inappropriate infrastructural characteristics; 2) crowding; 3) lack of access to basic sanitation; 4) having at least one child in school age not attending school; and 5) family head with incomplete primary level education with at least three dependants. A household is considered “poor” if they have one unsatisfied basic need (Hartinger et. al. 2011).

Table 9-2: Descriptive statistics of main diarrhoeal and respiratory health outcomes: episodes, duration and days ill of illness and anthropometric measurements

Health Conditions	Class or parameter	Intervention (N=248)	Control (N=251)
Days under observation	Median (IQR)	265 (225-293)	276 (235-297)
Day under observation	Total	62031	63952
Diarrhoeal illness			
Number of episodes	Median (IQR)	1 (0-2)	1 (0-2)
Days with diarrhoea	Median (IQR)	2 (0-4)	2 (0-6)
Total number days with diarrhoea	Total	827	1125
Total number of episodes	Total	301	375
Total number of persistent episodes (>14 days duration)	Total	0	4
Mean length of episode (days)		2.8	3.1
Diarrhoea Incidence (Number episodes / child year)	Mean	1.8	2.2
Diarrhoea Prevalence (Number diarrhoeal days / child year)	Mean	4.9	6.6
Number of diarrhoeal episodes with blood	Total	17	24
Number of diarrhoeal episodes with vomiting	Total	51	54
Respiratory infections			
Days with cough or difficulties breathing	Median (IQR)	17 (8-25)	14 (8-26)
Total number of days with cough or difficulties breathing	Total	4534	4635
Total number of days with cough or difficulties breathing and fever	Total	951	1034
Total number of ARI episodes [a]	Total	831	877
Percentage of ARI episodes seen with respiratory rate measurements [b]	%	68% (554)	63% (563)
Number of ALRI episodes that received with medical treatment before the household visit		255/554	218/563
Total number of ALRI episodes [b]	Total	25/554[c]	10/563[d]
Number of children with at least one ALRI episode	Total	17	10
Anthropometrics overview			
Stunting (Height/length-for-age)	Median (IQR)	-2.1 (-2.7/-1.3)	-1.9 (-2.5/-1.4)
Underweight (Weight-for-age)	Median (IQR)	-0.6 (-1.1/-0.2)	-0.7 (-1.2/-0.2)

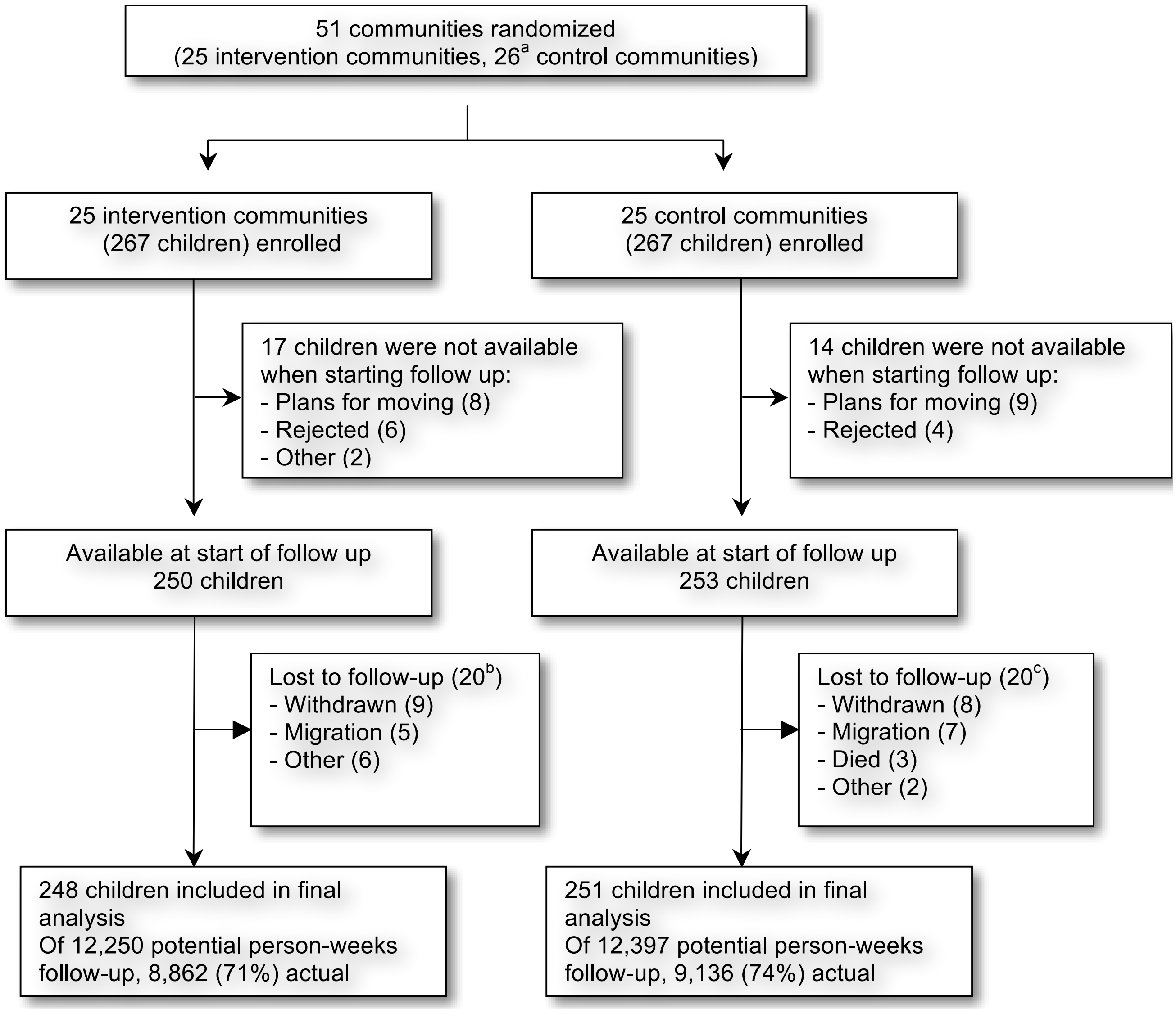
[a] cough or difficulties breathing;
[b] ALRI: Child ill with cough or difficult breathing combined with high respiratory rates or subcostal retraction.
[c] in 255/554 episodes the mother started medical treatment before the visit of the field worker
[d] in 218/563 episodes the mother started medical treatment before the visit of the field worker

Table 9-3: Effect of the intervention on diarrhoea and acute respiratory infections

Outcome	Crude model [a]			Age sex model [b]			Age sex piped			Age sex piped latrine		
(n=499)	RR/ OR	95% CI	p value	RR/ OR	95% CI	p value b)	RR/ OR	95% CI	p value c)	RR/ OR	95% CI	p value d)
Nr of diarrhoea episodes e) (RR)	0.78	0.58, 1.05	0.10	0.79	0.60, 1.03	0.09	0.79	0.61, 1.04	0.09	0.79		0.09
Diarrhoea prevalence (OR)	0.71	0.47, 1.06	0.09	0.72	0.49, 1.05	0.09	0.72	0.48, 1.05	0.09	0.71		0.08
Episodes with blood (OR)	0.80	0.39, 1.65	0.55	0.80	0.39, 1.65	0.54	0.80		0.46	0.77		0.46
Nr of ARI episodes (RR)	0.95	0.82, 1.10	0.53	0.95	0.82, 1.10	0.51	0.95		0.50	0.95		0.50
Nr of ALRI episodes (RR)	2.45	0.82, 7.39	0.11	2.47	0.84, 7.29	0.10	2.40		0.10	2.48		0.10
Cough or difficult breath prevalence (OR)	0.97	0.79, 1.19	0.80	0.97	0.79, 1.19	0.79						
Cough or difficult breath & fever prevalence (OR)	0.89	0.71, 1.12	0.33	0.89	0.71, 1.12	0.33						

Nr of episodes: Number of episodes per child year
Prevalence: Number of days ill per days under observation
Episodes with blood: Children with at least one bloody diarrhoea episode
ARI: reported cough or difficulties to breath
ALRI: reported cough or difficulties to breath and age specific tachypnea
a) Adjusted for design factors (intra village correlation)
b) Adjusted for child's age and sex and for design factors (intra village correlation).
c) Adjusted for child's age and sex and for design factors (intra village correlation).
d) Adjusted for child's age and sex and for design factors (intra village correlation).
c) Clustering coefficient k = 0.39

Figure 9-1: Flow of participants from randomisation through to the final analysis



[a] One community (12 children) declined to participate during enrolment
[b] Two children without any follow up data excluded from final analysis
[c] Two children without any follow up data excluded from final analysis

Figure 9-2 Weekly prevalence of child diarrhoeal illness

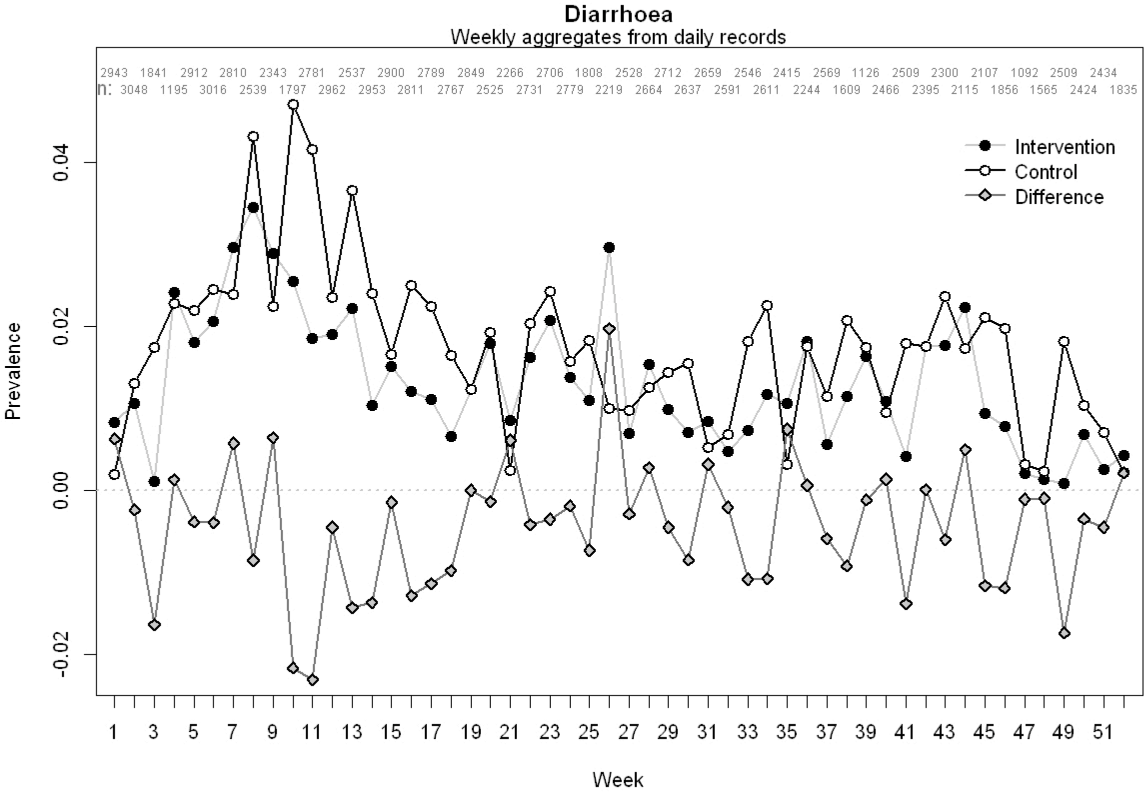
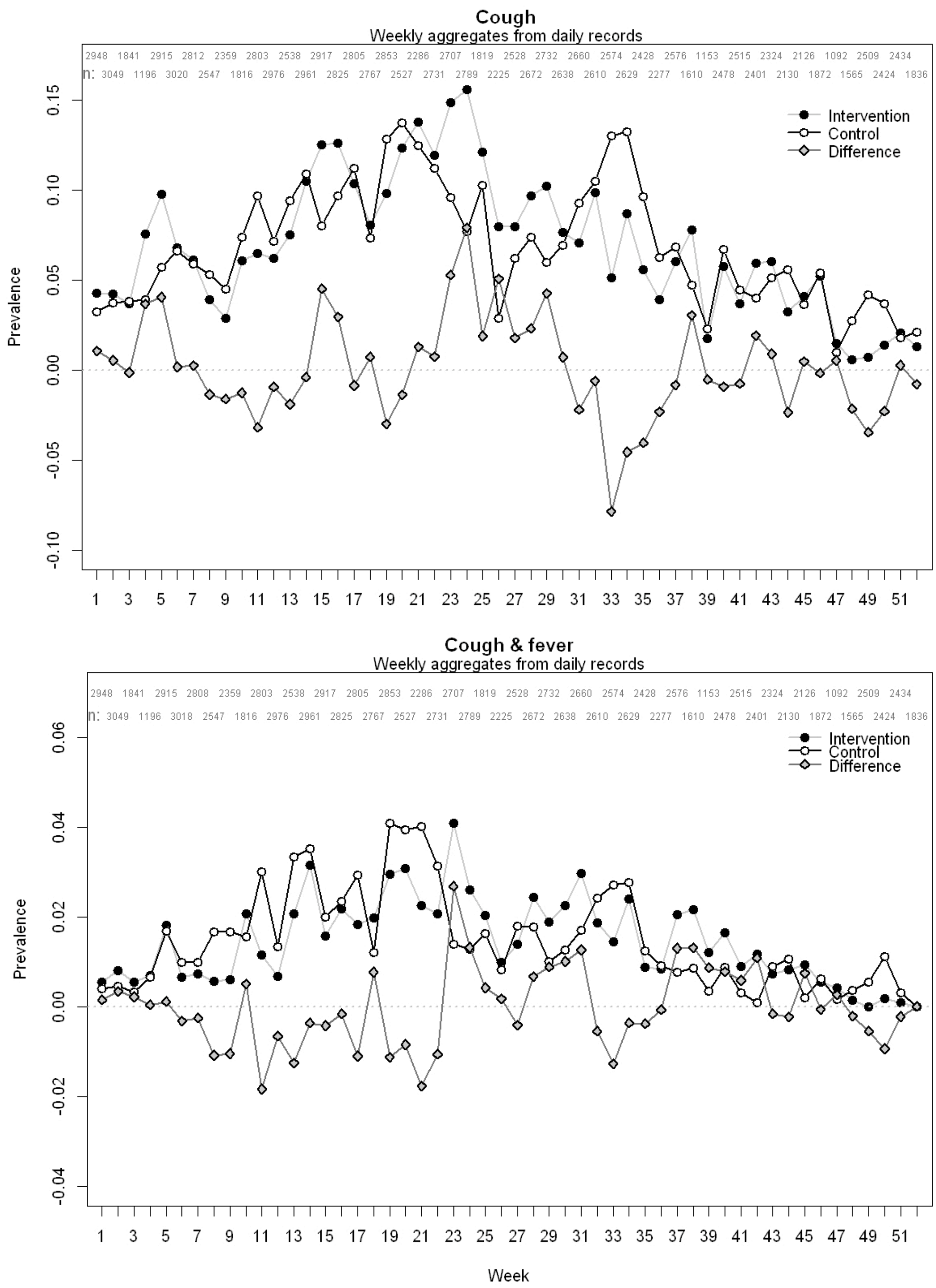


Figure 9-3: Weekly prevalence of child cough and cough and fever



Supplementary Material - Compliance Assessment

Background:

Community and child health improvement rely ultimately on the successful development, and application of effective interventions. Longterm impact, though, depends then more on their successful adoption, compliance and sustained correct use and maintainance. Apart from externalities of market forces at supply and demand sides, regulatory and policy mechanisms, community- and household dynamics for uptake are complex.

The dynamic process from short term adoption of any intervention (including our environmental IHIP) to sustained, long-term use depends on social and ecological factors that include knowledge, perceptions and individual behaviours, available options and technical characteristics, perceived benefits from the intervention, household economics as well as social networks and the access to information, to name a few.

To selected the appropriate technologies for our package of environmental interventions that would be culturally accepted we underwent several steps in a preliminary exploratory study, We i) consulted local authorities and community members about appropriate designs and options; ii) tested the new devices *insitu* using qualitative and quantitative methods; iii) collected and assessed the needs of user families, the general population and other stakeholders to modify the interventions accordenly and iv) evaluated determinants of adoption, discontinuation of use and general perceptions about the different home-hygiene improvements (1). Upon complition we randomized our communities and participantes were enrolled between September 2008 and January 2009. During this period we collected our baseline data and implemented the interventions.

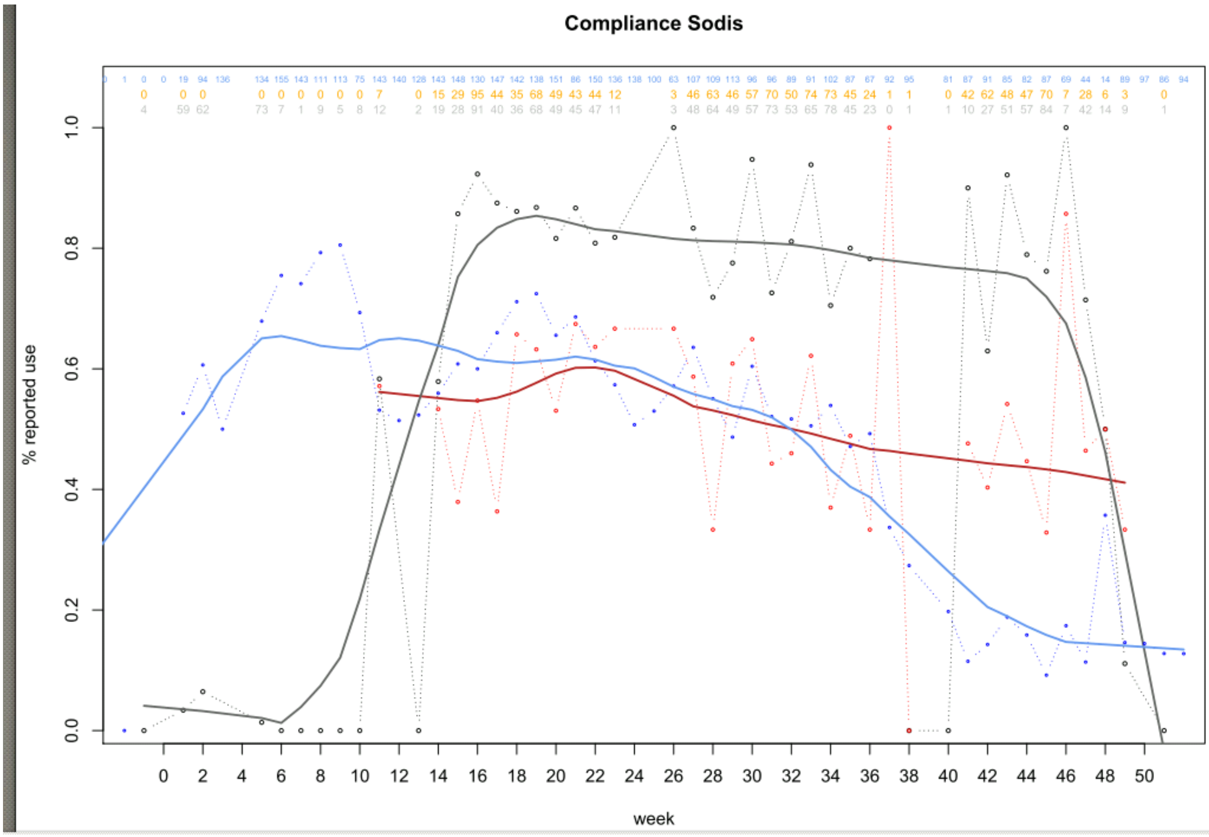
The compliance assessment for our IHIP–trial combining an improved stove, solar drinking water disinfection, a kitchen sink and handwashing promotion was carried out by two independent field staff team and started 2 month after the follow-up period began. Briefly we describe the field's team responsibilities: i) field workers were responsible for collecting morbidity data and for collecting spot check observations on household hygiene and environmental health condition and the ii) health promoters' team is responsible for promoting regular use of the interventions and collecting compliance data on a monthly basis, through spot check observations and mother self-report.

Findings & Discussion:

The solar water disinfection compliance data was obtained from weekly spot check observation and during monthly training sessions by the health promoters' team and self reported use by the mothers. The SODIS compliance data differed according to the valuation source: self report use by mother was around 75% throughout the follow-up study period, weekly spot check observation by the field workers generated 60% compliance at baseline and declined to 20% by the end of the study. Health promoters observed about 60% compliance at start with a decline to 40% at the end. Data from the two independent (surveillance and health promoter teams) evaluation sources show a coherent declining trend that could be due of a potential courtesy bias. We believe that the real SODIS compliance is around 30%. (S1).

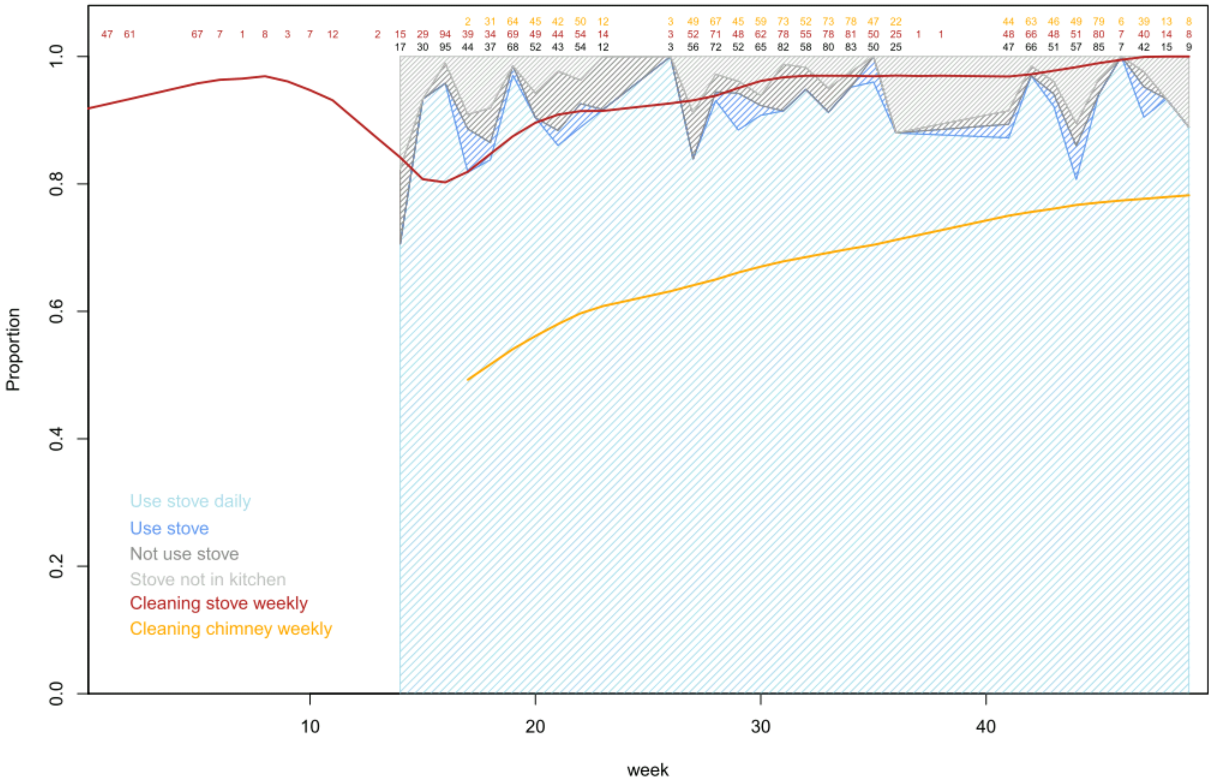
The OPTIMA-improved stove (S2) and kitchen sink (S3) compliance information was obtained monthly by the Health promoters, however this information was self-report. (S2) 90% of all mothers reported using the OPTIMA-improved daily. A similar proportion was reported for stove maintanece (combustion chamber and chimney). Toward the end of the study -probably after recognising the importance to regularly unclogg the chimney from agglutinating soot- around 80% reported weekly cleaning their stove chimneys. (S3) Two thirds of the mothers reported using the kitchen sink for washing utensils and children's hands. Continuous water flow based on seasonal water availability and connection to a water supply system were two reported key limitations for use. Additionally, two thirds of the mothers reported using the kitchen sink for washing utensils and children's hands.

Supplementary figure S1: Weekly compliance of the solar water disinfection method (SODIS).



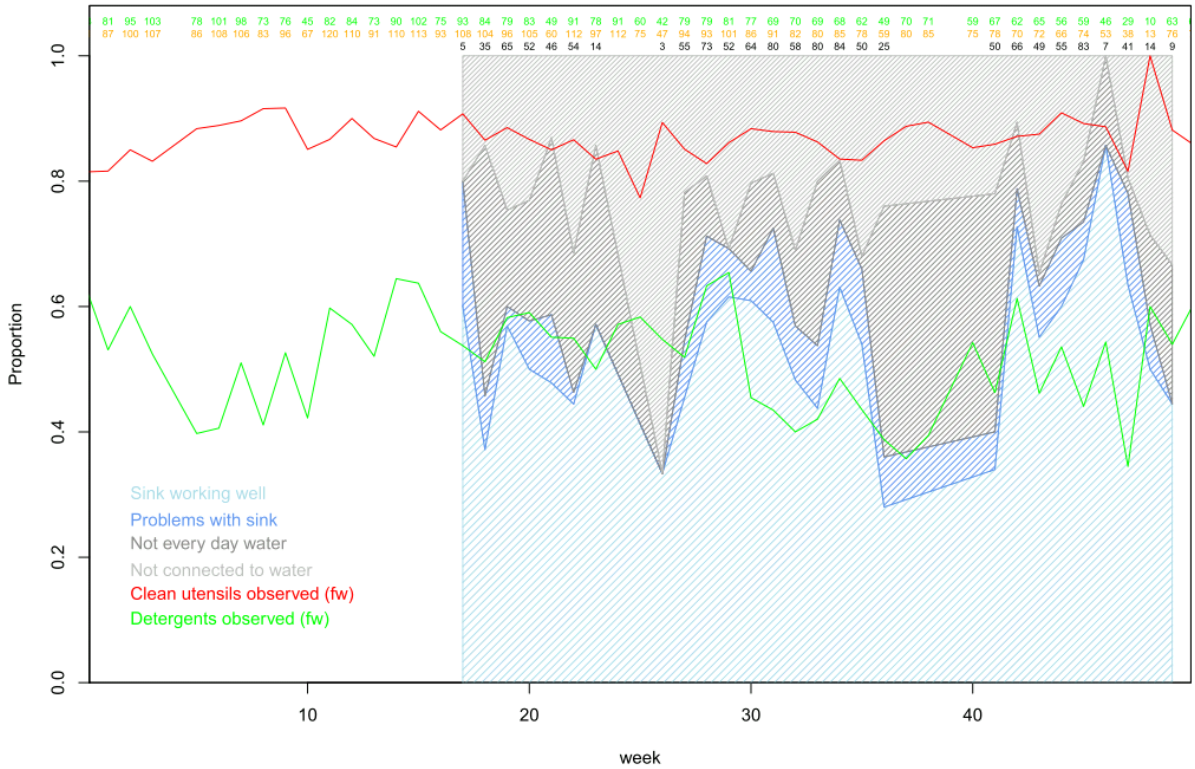
In this graph we depict the reported averaged weekly compliance of solar water disinfection, starting at 12 weeks after implementation of the SODIS intervention. We report the compliance measured by three different assessors: the grey line corresponds to the mother's self reported use ("Do you use SODIS") as obtained from health promoters' records; the red line corresponds to the health promoters' assessment of SODIS use, through direct observation of SODIS-bottles exposed to sun at the time of the household visit; and the blue line corresponds to the surveillance team's independent assessment of SODIS-bottles exposed to sun during the household visit.

S2: Weekly reported compliance of using the stove for cooking generally, and specified daily use, of stove use outside the kitchen and weekly cleaning of stove and chimney.



In this graph we illustrate the high compliance of the OPTIMA-improved stove use as reported by the study mothers. Dark blue line: the area below the line (dark plus light blue shading) represents reported principle use of the stove for cooking during the week. The light blue shaded area specifies the level of daily stove use. The red and yellow lines report on the proportion of mothers cleaning weekly stove and chimney. The shaded light grey reports on stoves that are not located in the kitchen environment and the darker grey area on stoves that are not in use.

S3: Weekly compliance of kitchen sink use.



In this graph we illustrate the compliance of the kitchen sink use as reported by the study mothers. The light blue shaded area specifies the sinks that were working properly. The shaded dark and light grey represent the sinks that do not have water everyday or are no longer connected to a water source. The dark blue shaded area are self-reported problems with the sink; and the shaded light grey reports on sinks that are in use and work properly. The red and green lines report on the proportion of clean utensils and detergent observed by the field worker.

PART V: COMMUNITY DRIVEN ROLL-OUT OF THE IHIP INTERVENTION PACKAGE

CHAPTER 10

COMMUNITY-DRIVEN ROLL-OUT OF AN ENVIRONMENTAL HOME-HYGIENE INTERVENTION PACKAGE ON HOUSEHOLD AIR POLLUTION, DRINKING WATER QUALITY AND HYGIENE EDUCATION IN RURAL PERU

Community-driven roll-out of an environmental home-hygiene intervention package on household air pollution, drinking water quality and hygiene education in rural Peru

Experiences from a post-intervention phase of the IHIP-Peru community randomised intervention trial.

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Working paper

Abstract

Effective community health and social development relies in essence on the successful development, validation and application of effective interventions and their successful roll-out in large scale programme frameworks. We applied the SEM to describe behavioural change, population dynamics observed during our roll-out activities were local actors were convene and during our auto-dissemination surveys. To aimed to determine the level of replication of the IHIP intervention package three and twelve months after the conclusion of the roll-out activities. The SEM revealed that people's decision on adopting home-environmental and hygiene intervention is not only based on individual perceptions of their potential gains, but depends on peer pressure, social network relations and how technical construction knowledge is communicated, applied and spread within the community. Individual perceptions regarding pollution levels of water and household air (transparent, odourless water *vs* dirty air environments) influenced adoption of certain interventions based on perceived convenience gains (i.e. improved chimney stoves). Information regarding how to manually build a stove accelerated roll-out activities and was enhanced when health care providers and programme implementers including civil social organisations encouraged the use of interventions. When designing community health based intervention, it is important to consider the household in a wider system's context to create environmental sound interventions that support and promote effective and sustainable behaviour change.

Key words
Community roll-out, auto-dissemination, IHIP, socio-ecological model, Peru

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Introduction

Effective community health and social development relies in essence on the successful development, validation and application of effective interventions and their successful roll-out in large scale programme frameworks (Arnold et al. 2009). The challenges for such programmes to be successful with regard to improving community health and livelihoods are manifold; they need be easily delivered, adopted, disseminated and sustained, and supported by a strong institutional base and policy framework. However, all challenges mastered, the central decisive factor is to achieve attitudinal and behavioural change. The process of incorporating a new intervention in the target population is a complex dynamic that goes beyond the acceptance and initial use. It depends on the characteristics of the users, the intervention in hand, the perceived benefits and the degree on which the users is willing to incorporate the intervention to their way of life.

Several theories tried to understand how community dynamics occur. The diffusion of innovation theory describes how diffusion occurs within communities, by separating the process into stages and categorizing the population into levels of adoption (Roger et.al.1995). This dynamic implies that successful diffusion depends on how an organisation or social network deals with its innovators, early adopters, and the interface between early adopters and the early majority (Berwick 2003). From a systems thinking perspective the framework provides a deliberate and comprehensive set of tools and approaches to better understand, design, measure and evaluate interventions that will operate more successfully and effectively in complex, real world settings (WHO 2009). While the socio-ecological model describes and identifies determinants of health behaviours at different system levels and helps articulate the complexities between and among them (Green et al. 1996). All theories and models try to predict how the system (individuals, social network, community, institutions and policies) will react in response to new interventions (or technologies or innovations) and aim to identify the synergies that can be harnessed.

According to (Batterman et al. 2009), an important reason why interventions are not sustained and disseminated is that scientific enquiries tend to focus on short-term immediate, i.e. proximal outcomes (e.g disease or illness reduction or short-term income) and not on distal factors that involve social and ecological processes (social network and environmental factors), systemic impacts that usually requires a system-wide thinking (WHO 2009, Ruiz-Mercado et al. 2011, Van den Ban and Hawkins, 1996, & Roger et. al. 2005). Additionally, the lack of evaluating interventions' potential composite effects on households and their livelihoods is striking given well-established associations between household-/child health, wealth, education and child development outcomes (Hatt & Waters 2006).

An integrated home-based intervention package (IHIP), focusing on environmental home hygiene was designed with the aim to integrate effective low-cost household-level interventions that could be easy adopted and delivered in concert providing synergic effects to obtain high impact on household health on proximal outcomes and at the same time improve long-term social status, livelihoods and sustainability (distal outcomes). The idea of a composite intervention has been descried previously and proven efficient especially at water and sanitation sector (K. M. A. Aziz et al. 1990; B A Hoque et al. 1996; Mertens et al. 1990; Messou et al. 1997; Nanan et al. 2003; VanDerslice & Briscoe 1995); however, most integrated approaches focused only on health outcomes and not on distal effects.

The Peruvian IHIP intervention package was developed using a participatory approached over an interactive phase, were the study personnel become trustworthy to the villagers and partners on equal footing with the community. We identified and convened main stakeholders (i.e. community members, local authorities) in an effort to gain insights into cultural beliefs and potential approaches, with the sole aim of laying the foundations to ensure adherence, compliance, sustainable use and auto-dissemination of the interventions beyond the life of the project.

In this context we applied the social-ecological model (SEM) to consider individual use behaviour of the IHIP intervention in the context of and between the multiple levels building the systems context around the individual and the household, namely, the levels from intra to interpersonal, community, institutional, and policy levels (Kumar et al. 2011), (Lonergan & Vansickle 1991). We applied the SEM to describe behavioural change, population dynamics observed during our roll-out activities were local actors were convene and during our auto-dissemination surveys. We discuss the level of replication of the IHIP intervention package three and twelve months after the conclusion of the roll-out activities. In addition we will use the socio-economical model to explore the factors for auto-dissemination of IHIP and finally discuss recommendations for future hygiene, and environmental home-based interventions.

Methods

Study site

The study was conducted in 51 communities on the northern highlands of Peru, in the Cajamarca Region, San Marcos Province, between February 2010 and June 2011. The social community structure is comprised specifically of local authorities (mayor, governor, judge), community organisations, e.g. water board, mother groups ("Vaso de leche", community kitchens) civil watch ("ronderos"), parents associations (APAFA) and governmental institutions (i.e. schools and local health centers). Several civil society organizations and local non-governmental organizations such as PLAN, ADIAR, IDEAS, JICA, and research institutions (IIN-SwissTPH) were currently or in the recent past, present in the study area.

We conducted a community-randomised control trial to determine the efficacy of the IHIP interventions in reducing of acute diarrhoeal illness, acute lower respiratory infection and impacting child growth in children aged 6 to 35 months. A total of 503 households (250 interventions and 253 controls) were followed for 12 months. The study population was separated into two groups: one receiving the IHIP interventions, specifically the OPTIMA-improved stove, a kitchen sink with running water, solar water disinfection (SODIS) as a home-based drinking water treatment (HWT), hand-washing as the hygiene component. The control group received an alternative early child stimulation (psychomotor) intervention serving as a control group in the main trial (Hartinger et. al. 2012).

Socio-economics data revealed that on average five people lived in each household, with the mother's mean age of 30 years. Some 78% of the study populations had a piped water supply with a faucet available in the household yard, 50% of the households had garbage visible on the kitchen floor and 27% had animal faeces on the kitchen floor (Hartinger et al. 2011).

Approaches to Scaling up IHIP interventions

We undertook three steps to generate community driven roll-out and auto-dissemination. We first conducted demonstrative workshop were we presented the IHIP study results in a community roll-out sessions, we then evaluated the roll-out activities and determined the level of replication of the interventions within the study communities, and finally we determined replication factors using the socio-ecological model.

Roll-out activities

Roll-out activities took place between March-June 2010; two months after the IHIP intervention study concluded (table 1). Community roll-out activities were carried out through 24 community workshops organized in the community primary schools. Community members, regardless if they had already participated as intervention IHIP households or were living in the households of the study communities that had not received the interventions, were invited. Health professionals (promoters and health centre providers), teachers and local authorities were also invited. Primary schools were selected to increase community attendance and benefit the community by leaving the interventions implemented during our demonstrative workshops.

The workshops were organised in three consecutive sessions; i) the first session was structured as an oral presentation the final results of the IHIP intervention study were presented, ii) the second session was an interactive dialogue between all participants, researcher and builders. The workshop participants where actively involved in the discussions for generating joint ideas of how such an intervention could be adopted by community members and scaled-up through community led processes; and iii) finally a session demonstrating "how to use, maintain and build" the OPTIMA-improved stove.

All sessions were recorded and transcribed. Data from those sessions were analysed using standard qualitative analytical methods including standard content analysis of data obtained from the transcripts (Miles & Michael 1994, Dawson et al. 1993).

Replication Assessment

We conducted two surveys to determine the level of replications of the IHIP package in the study communities. The first survey was carried out three months after the scaling up activities concluded (August-November 2010) and the second 12 months (April-June 2011) (table 1). We created a set of criteria to determine the extend of the auto-dissemination as a consequence of the roll-out activities in the community and the quality of the self-made replicas of the OPTIMA- improved stoves, kitchen sinks and SODIS as HWT method.

An OPTIMA-replica qualified as a correct replica if i) the stove had a chimney with a regulatory valve and a hood, and had a ii) small rims inside the combustion chamber ("trampas") and iii) a metal cover for the mouth of the stove.

A proper replica of the kitchen sink exited if, i) the sink was located in the inside kitchen environment, ii) was connected to a piped water supply and iii) was fitted with a functioning faucet and drainage system.

SODIS as the appropriate household water treatment qualified as being used properly if i) the field worker observed the transparent plastic PET bottles placed horizontally exposed to sunlight or ii) he observed the SODIS bottles in the kitchen environment being in use.

Data Analysis -using the social-ecological model as an analytical framework

We collected quantitative and qualitative data to describe determinants of adoption. For the purpose of a systematic analysis of these data sets the socio-ecological framework was adopted (Green et al. 1996) to properly structure the presentation of the determinants that lead to auto-dissemination by applying a systematic view on the dynamics observed. We categorised the determinants accordingly to their potential sphere of influence: i) at intrapersonal level, e.g. with issues related to knowledge and skills, ii) at interpersonal level e.g. factors influencing the social network or the interaction between community members, and family, iii) at community level, e.g. information available at a health care level or from programme promoters, iv) at institutional level, e.g. availability of actors and programmes and delivered interventions in the study area and v) at policy level factors, e.g. general mandates or governmental sectorial policies. Each level has specific indicators explaining processes leading to the auto-dissemination of the interventions in the communities.

- *Intrapersonal level*: Determined beliefs, attitude, and determine perceived barriers for factor uptake and benefits of the home-based interventions including i) knowledge (how to build the interventions), ii) technology transfer (access to technological designs details) and iii) access to materials. Additionally, gaining confidence in and trusting new comers (programme and NGO implementers) to the community is essential for intervention to be disseminated and adopted. We tried to gain insight of this component during roll-out sessions.
- *Interpersonal level*: Interpersonal relationships have mayor influence on personal behaviours, especially when dealing with health behaviours, referring specifically to the social influence of friends, family and social networks at large (Mosler et.al. 2012). The selected indicators were i) technology transfer and translation of stove and sink construction knowledge to family member and neighbours, ii) peer pressure, iii) perceived benefits of the intervention by family members or neighbours, and iv) number of family members that had implemented the interventions at the community.
- *Community level*: To determine the level of information available in the study area regarding health and hygiene in general and IHIP interventions, and determine the individual's awareness of such existing information. We determined which stakeholders were more commonly known (health care staff, teachers, local authorities, community leaders, IHIP programme implementers) and entrusted to provide the most reliable information regarding health education and environmental hygiene interventions in the study area.

- *Institutional level*: refers to the social influence regarding the presence of institutions and key actors of interventions and programmes in the area. The influence could be positive if the interventions complement the array of existing community development messages, e.g. from Peru
- *Policy level*: At this level, we analyse if the community members were aware of any policies and of institutions responsible for delivering them. In the Peruvian contemporary context, the government is committed through a national strategy to reduce poverty and enhance economic opportunities, through sectorial programmes at national level (Supplementary table 1).

We qualitatively classified the degree in which the roll-out activities influenced the decision of householders of adopting IHIP intervention. The classification was done on community, institution and political levels only, since intra and interpersonal levels mostly refer to beliefs, and basic knowledge of the interventions. We classified them according to a qualitative classification: referring to interventions that were only mentioned during our roll-out sessions or auto dissemination questionnaires (+/-), referred to interventions that presented the lowest level influence (+), referred to a moderate level of influence (++) and referred to the highest level of influence (+++).

Ethics

The study was approved by the Nutritional Research Institute Ethical Review Board and the cantonal ethical review board of University of Basel, Switzerland (Ethikkommission Beider Basel, EKBB). For this study the family head provided gave verbal consent.

Results

Overall 24 community workshops were conducted during the roll-out activities of the IHIP study. In total 631 community members, 119 teachers and 110 local authorities and mayor stakeholders participated in these activities. The main issues that arose during the interactive session were the motivating relationship between the IHIP field staff, participating families and local authorities, imparting a feeling of familiarity and trust within community members. The realisation that the IHIP project fully complied with providing intervention and services as stipulated in the protocol. Authorities and families valued much that "promises" made at the outset and during our public hearings in the enrolment phase by the IHIP project staff were kept. The household environmental quality (water and air) and hygiene; and the IHIP intervention package benefits and disadvantages were also discussed (table 1). Regarding the IHIP environmental components, community members and local authorities were unaware and surprised about of the high levels of contamination in their drinking water supply. Those who were aware, two local authorities, admitted they purposely did not chlorinate the water supply, because community members disliked the taste. Teachers, on the other hand, were suspicious about the local drinking water quality and thus, encouraged students to bring clean water in plastic containers. They also realised the potential of applying these hygiene and household water treatment interventions in their schools and were keen to copy the interventions. Schools were recognised as excellent platforms to disseminate hygiene and solar disinfection methods, by incorporating IHIP messages as part of the schools curricula (table 1). For this reason we returned to all primary schools located in the study area three months after the completion of the roll-out sessions to determine the level of replication of the IHIP interventions. We measured all primary schools found in the study area (N=45). We found that 36 schools had an improved-chimney stove; 24 were built during our roll-out demonstrative sessions, two were built by IHIP personnel as requested by the schools directors who had attended the roll-out sessions. They proactively gathered their materials, hired local labour and requested supervision from the project. Of the remaining 10 schools, four stoves were built by another NGO and six were built by the parents and teacher as a consequence of roll-out session. However, only two stoves fully complied with our criteria to be considered an OPTIMA-replica. Additionally, 10 (22%) schools had copied SODIS intervention and 2 (29%) schools had copied the kitchen sinks with piped running water (table 2).

Three and 12 months after the roll-out activities concluded the situation in the communities presented differently: A total of 864 household had been actively working to improve their home environment based on the recommendations and insights gained from the community workshop sessions. Those household either lived in the original intervention communities, but were not considered to receive the IHIP intervention as a result of the randomisation process (439 households), or belonged to the original study's control communities that had received the psychomotor control intervention at (425 household) (table 3).

Out of all the IHIP interventions, improved-chimney stoves were the most frequent replicated. We found that 27% (230/864) of the households had acquired an improved stove in the last 12 months and 33% of them (75/230) qualified as a proper OPTIMA-replica. Solar disinfection was found in a limited number of households. After twelve months only 10 households had copied and used the method correctly. Kitchen sinks were a desired commodity in our communities. However, the expensive materials and difficulty of the design made the replication limited. In total we found that 62 (7%) households had installed a sink in the inside the kitchen environment or household yard in the last 12 months, however out of these only four had done it inside the kitchen environment (table 3).

To establish the factors that stimulate adoption at the different socio-ecological level we grouped auto-dissemination questionnaires and roll-out session to reflect the level of the socio-ecological system level on which the information was provided to the individuals (table 4). At intrapersonal level the main factors that encourage adoption of the IHIP intervention were i) a personal interest toward having the intervention at household level (20%), ii) the availability of the design features to copy from within the community (45-63%) and iii) the knowledge on how to manually build the interventions using their own technical and labour resources (52-60%). Additionally, recurrent issues mentioned in all discussions during the self driven roll-out related to cash resources available for investment at household level, trust that the IHIP interventions would provide benefits and the utility perceived for the interventions, specifically linking room ventilation and smoke reduction to improve health (eye irritation, and cough) and conveniences gain linked to faster cooking and wood savings. At the interpersonal level, the knowledge from family members or of neighbours about how to build and use the IHIP interventions was a main determinant (table 4). This was congruent with the information obtained during the roll-out sessions, which also generated peer pressure and social status as crucial factors for trusting in, for adopting and for maintaining the IHIP interventions (table 1). At the community level, the main factors supporting adoption was a well-functioning interaction between the individual and the field officers from the national cash transfer programme JUNTOS and the IHIP motivating roll-out sessions (figure 2). However, individuals felt that the best source for improving one's knowledge regarding better home-hygiene, family and health education came from the health centre promoters.

At the institutional level, the number of existing IHIP interventions in the study area was not an important factor for higher self-adoption. However, the presence of the national cash transfer programme JUNTOS was an important factor at this level (figure 2). Other NGOs (i.e. PLAN, ADIAR, and SEMBRANDO) were only mentioned during our roll-out sessions and did not exemplify any level of influence.

Discussion with community members, teachers, local authorities and main stakeholders elucidated that they were unaware of any governmental, regional or local policy regarding health, water and sanitation, home-hygiene or air pollution. However, they did mention that Ministry of Health field staff (health centre promoters) provided information regarding these topics (figure 2).

Discussion

Considering individuals and households embedded within social networks, which them selves are embedded within communities and influenced by institutions and policies is important and forms the theoretical basis for the socio-ecological model (SEM) (Kumar et al. 2011). Appling a SEM perspective to our study showed the interaction between underlying determinants for adoption of an environmental home based intervention package interact. Quantitative and qualitative data assessments and open discussions during community participatory meetings to support roll-out, revealed that people's decisions on adopting home-environmental and hygiene interventions was not only based on individual perceptions of their potential gains. The decisions also depended on peer pressure, social network relations and how technical construction knowledge was communicated, applied and spread within the community. In addition, individual perceptions regarding pollution levels of water and household air (transparent, odourless water *vs* dirty air environments) influenced perceived convenience gains and the adoption of certain interventions; especially in relation to the improved chimney stoves. Furthermore, access to information regarding how to manually build a stove accelerated roll-out activities and was enhanced when health-care providers and programme implementers -including civil social organisations- encouraged the use of interventions, especially when in line with governmental policies.

The interactions between the various levels of the SEM can help identify the impacts on health behaviour at different levels over time (Burke et al. 2009). A good example of this function can be observed in the design of our IHIP interventions (Hartinger et. al. 2012). The interventions were designed using a participatory approach over an interactive phase, enabling us to gain insights into potential approaches, for compliance and future replication. As part of the IHIP project, we planed to reinforce official health promotion messages regarding hand washing (Hartinger et al. 2011), however, mothers recognised that effective hand washing would not be possible if water taps were located outside the houses, in the yards. This simple comment helped us redesign the intervention and install kitchen sinks in the kitchen environment, using pipes connected from the outside tap; thus, lowering barriers for hand-washing and fostering hygiene at home. A similar situation was described during the roll-out session. An unnamed organisation had piped the water supply and provided the necessary tubing and materials for building water taps in the yards. Mothers recognised the benefits of having running water, but argued that carrying the utensils to the yard was cumbersome and that they would continue using filled plastic basins for washing utensils within the kitchen environment. As a result, the intervention did provide running water, but fell short on improving home-hygiene. The lesson to learn was encouraging local institutions targeting multiple levels of the SEM when developing environmentally sustainable, community-based interventions to improve health and also by involving the community members and main stakeholders from the beginning also to create ownership of the interventions as one of the key requisites to achieve sustained use.

We examined multilevel factors for dissemination using the SEM. According to the existing literature, intrapersonal and interpersonal levels are usually strongly linked, their relation well understood and mainly described as barriers for adoption. A SODIS cluster-randomised trial carried out in rural Bolivia, identified household level determinants for SODIS adoption. Individuals that attended SODIS promotional events, owned latrines, were women and had severally wasted children were most likely to use the method (Christen et al. 2011). Another study carried out by Tamas and Mosler (Tamas & Mosler 2011), also focusing on SODIS adoption, measured the different behaviours on SODIS relapsers (people who discontinued SODIS use) comparing them with continuous users. They observed that relapsers had significantly lower values than continuous users for behavioural factors, concluding that relapsers' personal behaviour did not support the fragile and often situation-dependent establishment of long-term habit changes. Summarising experiences made in the Guatemala RESPIRE work Ruiz-Mercado and colleagues delineate why individuals adopted cleaner fuels and cook stoves, but again the results mainly focused on household level determinants (income, education, gender and location) and only mentioned social structure as a potential factor (Ruiz-Mercado et al. 2011). The likelihood that beliefs and attitudes -which are the target of most interventions focused on achieving behaviour change- at the intrapersonal level, could be more amenable to change, when targeted by a known person from the social network (friends, family, health care providers and peers) is well understood (Kumar et al. 2011). If combined with increased information exchange and flow at the community and institutional levels and support at the policy level, the influence on auto-dissemination would increase (Coady et al. 2008).

The policy-level factors were the least understood in our setting; thus explaining very little of the auto-dissemination process within the study population. Despite the fact that the government had created the perfect umbrella strategy with the National Strategy for Poverty Reduction and Economic Opportunities "CRECER" (PCM 2007), very little was known and understood of this policy framework at lower levels (i.e. community and intra-and interpersonal levels) (Supplementary table 1). The most important aspect of this strategy was that it was conceptualised and generated using a causal model for diminishing malnutrition, principally focusing on water and sanitation, nutritional practices and fighting infectious diseases (diarrhoea and respiratory illnesses) (CIAS, 2011). This was the first initiative that involved different Ministerial sectors (Ministry of Health, Ministry of Education, Ministry of Housing Construction and Sanitation, among others) existing national programmes within each sector and governmental and non-governmental institutions. In theory the setting was perfect. However, local governments, and local stakeholders remain unaware of these interventions being carried out under a multilevel, integrated approach. Two perfect examples were observed during our roll-out sessions. The first was the lack of awareness by local authorities of the given rights they had that could help them attain existing funds specifically provided to them by the central government. Yearly, these funds are transferred to the province authority for distribution; distribution that did not necessarily occur. The few community authorities that were aware of these funds pointed out the lack of governance that existed at this level, which made the "Mayor" (Province authority) neither accountable nor transparent regarding community funds. The second example is the globally known national cash transfer programme "JUNTOS". This programme was incorporated as part of the CRECER initiative and provided 33$US to its beneficiaries after fulfilling certain requirements (Hartinger et. al. 2012). Families were keen to comply with the programme and receive the monthly stipend, but it remained unclear whether the health, education and socio-economic benefits that were part of the programme were fully understood. In the field we observed leaking chimney stoves, which in some cases were seemingly polluting the household air more strongly than the original open-fire "Tulpias" (Hartinger et al. *submitted*). Latrines were found used as storage facilities and in several unrecorded instances the cash benefits of the JUNTOS cash transfer programme had lead mothers into unwanted pregnancies. However, the programme remains an excellent platform for achieving coordinated actions among institutions and other programmes and had the highest incentive for auto-dissemination observed in the study setting. If interventions use this platform to fortify the existing interventions and include new approaches for health education, dissemination would be optimized.

Community response toward the IHIP intervention package amongst the study group and neighbouring community members was high. Both beneficiaries and project staff found the integration of health interventions to be efficient and effective. Additionally, a significantly enhanced awareness of the project and general health was reported even 16 months after the surveillance period of the study had concluded. Although we reported only moderate reductions in health impacts during the roll-out sessions (22% episode diarrhoea reduction and 29% on diarrhoea prevalence) (Hartinger et. al. *working manuscript*), general perceptions of a reduction in diarrhoeal disease and smoke-related conditions (eye irritation, cough, irritated respiratory tract) were manifested among the community members and IHIP-users.

Replication was observed in the study communities; however, IHIP roll-out sessions fell short on providing additional momentum for local adoption. As discussed above, motivation to support the higher uptake of improved chimney stoves had its origin in perceived benefits such as efficient fuel use, cleaner cooking environments and visible smoke reduction. Additionally, materials needed for the construction of chimney stoves could be locally made or purchased (chimney with valve) for relative cheap prices in the town of San Marcos. However, there were no chimney stove manufactures in our setting. Materials for kitchen sinks were more expensive and the building process was more complex. On the other hand, household water treatment seemed more linked to a health and hygiene behaviour change, thus the lower dissemination levels.

The very nature of the IHIP design (community randomised control trial), limited dissemination during the surveillance period of the study and was only after the study concluded and during roll-out sessions that we encouraged use. A second obstacle for IHIP dissemination was that we did not include local stakeholder and NGO's during the study follow-up period and only convened them during the pilot phase for the selection of the IHIP interventions and at the end during the roll-out workshops.

In conclusion there are important priorities to encourage community-driven roll-out of environmental home and hygiene interventions. The first is to clearly define the scope of particular integrated interventions and their components, that is, analysing the optimal number and types of interventions appropriate for given settings. The second is to develop frameworks for scaling up household- and community-level projects, by supporting local community workers and local businesses. Thirdly, interventions should be designed embracing a health-systems approach, ensuring multilevel interactions and links between the community members, their immediate environment (community), institutions and policies, in order to fortify the delivery and replication of interventions. The complexity lies in the fact that all these interventions are at the household, point-of-use level.

Table 10-1 Community members, teachers, local authorities and local stockholder's perceptions regarding the IHIP intervention package during the roll-out sessions at different communities in the province of San Marcos, Cajamarca.

Domain of Inquiry/ Stakeholders	**Community Member (N=631)**	**Teachers (N=119)**	**Local Authority /Mother groups (N=110)**
Relationship with project field staff	• Confidence and trust: Families recognized that trust, on the IHIP field staff and IHIP interventions was the first step towards working with us.		• Local authorities were aware of our presence in the field and found our promising.
General comments and observations during the scaling-up activities	• The mothers were keen to know if the study will continue working in the area. • Participating families agreed that we had complied with the study protocol as explained during enrolment. .	• Teachers want to apply the interventions in their schools and were interested to know if we will continue providing informative workshops.	• Local authorities wanted to know why the study was not going to continue and why not all the families received the interventions. • Local authorities also recognized we finalized the study as per the study protocol.
General comments about water quality, air quality and hygiene	• They were not aware of the high levels of contamination on their drinking water supply. • They recognize their household air pollution situation, and recognize the problems it can cause to their children health.	• Teacher recognizes that the water is not clean and asks the students do bring treated water for their personal consumption during school hours.	• In general, authorities were not aware of the levels of contamination on their drinking water. Only 2 authorities were aware that the water is not potable. • They do not chlorinate their drinking water supply because they dislike the taste. • Health authorities are responsible for supervising chlorination in the community water supply.
General comments about the OPTIMA-Improved stove	• Participating fathers were keen to know how to build the improved stoves (type of materials, number of furnaces, and type of bricks). • The mayor problem in the communities is wood collection and price.	• Primary schools have a governmental feeding programme (PRONAA). • Before we installed the OPTIMA-stoves the mother cooked on open fires.	• In general authorities recognized the importance of the stoves and encourage use.

Benefits	• Less cooking time and less wood consumption • Perform other tasks while cooking • Black smoke reduction in the kitchen environment.		
Disadvantages	• The stove must be cleaned regularly or the chimney will get clogged. • The mud plaster breaks easily.		
General comments about the Kitchen Sink	• Mothers use plastic basins for washing, that they fill form their outdoor tap.	• Increases hand washing behaviour in children.	• In the future they will encourage organizations to provide piped water into the kitchen environment and not leave the tap in the yard.
Benefits	• Easier to keep the utensils and kitchen environment clean • They can use detergent “ayudin” for washing utensils.		
Disadvantages	• Not all communities had a piped water supply system. • Difficult to build without assistance. • More expensive than the improved stove.	• More difficult to build and more expensive.	
General comments about Solar disinfection	• They were aware of the method and how to use it.	• Teachers showed interests about the method and will apply it in the school.	
Benefits	• Mother did not mention any benefit regarding SODIS.	• Easy to apply and will work well with the students.	
Disadvantages	• Mother do not trust the method, they were reluctance about exposing water directly to sunlight.		
Other national programmes and NGOs in the area of study	• *JUNTO only reaches* certain districts of the Province. • They recognize that they had heard about *SEMRBANDO* stoves and *PLAN*, but were not sure what they did. • They know that *JICA* gives guinea pigs farms.	• Teachers know that *PLAN* works providing libraries for schools and that *SEMBRANDO* is an NGO that provides stoves.	• Authorities reinforced that *JUNTOS* does not come to all communities. • *PLAN* wants to build water reservoirs, however the projects are stalled because the district and regional authorities will not provide the remaining funds.

Potential funds sources	• Families were not aware of any funds sources in their communities.	• Teachers were aware of the Participatory Budget*. They must present a project and the province authorities should transfer the funds. However, they did not know if the funds were only available for infrastructural projects, or household interventions also applied.	• Around half of the authorities were aware of the Participatory Budget*. • They acknowledge that they had not presented any project. However, when they asked the province authorities about the funds, they replayed that all funds were spent for the San Marcos market place.

* Participatory Budget: Funds available at community level for local projects. The number of community members and the political status of the community are used to calculate the amount.

Table 10-2 Replication of the IHIP interventions in 45 primary schools three months after the roll-out sessions

	N	**n (%)**
School that have an improved chimney stove	45	36 (80%)
Schools that have an OPTIMA-replica	45	27 (53%)
School using SODIS as a HWT method	45	10 (22%)
School that have a kitchen sink	45	2 (29%)

Table 10-3 Auto-dissemination surveys evaluation 3 and 12 months after the community workshops roll.out activities

	Communities with IHIP interventions			**Communities without IHIP interventions**			**Total (N=864)**
Households using an…	**3 months (N=266)**	**12 months (N=173)**	**Total (N=439)**	**3 months (N=272)**	**12months (N=153)**	**Total (N= 425)**	
	n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Improved stove (self-made, NGO, improved-chimney stoves, gas)	64 (24%)	43 (25%)	107 (24%)	74 (27%)	49 (32%)	123 (29%)	230 (27%)
OPTIMA-replica	28 (11%)	13 (8%)	41 (9%)	24 (9%)	10 (7%)	34 (8%)	75 (9%)
SODIS as a HWT method	4 (1.5%)	1 (1%)	5 (1%)	4 (2%)	1 (1%)	5 (1%)	10 (1%)
Kitchen sinks in the inside kitchen environment or HH yard	21 (8%)	18 (10%)	39 (9%)	17 (6%)	6 (4%)	23 (5%)	62 (7%)
Kitchen sink in the inside kitchen environment only	0 (0%)	2 (1%)	2 (0.5%)	0 (0%)	2 (1%)	2 (0.5%)	4 (0.3%)

Table 10-4: Questions used to determine auto-dissemination factors using the socio-ecological model

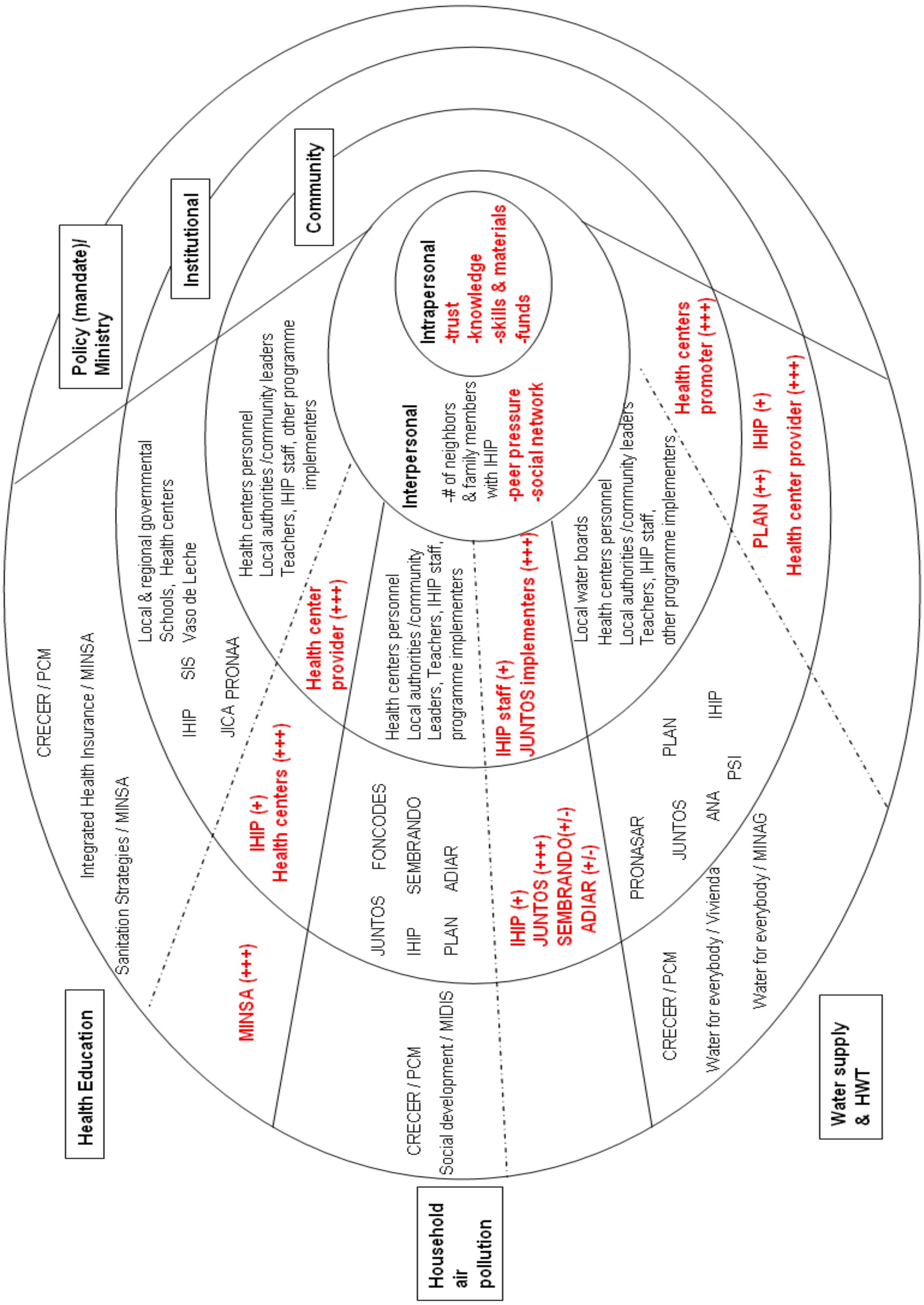
Survey Question	Communities without IHIP interventions		Communities with IHIP interventions	
Intra-personal level	**N**	**n (%)**	**N**	**n (%)**
Why did you decide to build your improved-chimney stove?	123		107	
I decided to build it on my own		26 (21%)		21 (20%)
In order to participate in the national cash transfer programme I had to have an improved stove		20 (16%)		7 (7%)
My other families or my neighbour has one		4 (3%)		1 (1%)
Other NGOs told me I should have one		4 (3%)		2 (2%)
After the roll-out session I decided I should have one		5 (4%)		5 (5%)
Where did you get the technical details for building an improved chimney stove?	113		92	
I copied the stove model from a neighbour		71 (63%)		45 (49%)
An NGO gave me building details		11 (10%)		7 (8%)
I learned how to build the stove after the roll-out sessions and copied the model built at the school		8 (7%)		4 (4%)
It was my own design		7 (6%)		4 (4%)
Other		5 (4%)		9 (10%)
Where did you get the materials for your improved chimney stove?	113		92	
I bought the materials		23 (20%)		11 (12%)
I made the bricks and bought the rest		28 (25%)		22 (24%)
I already had the materials		45 (40%)		30 (33%)
They (NGO, family) gave them to me as a present		11 (10%)		18 (20%)
Other		4 (4%)		6 (7%)
Why did you decide to build a kitchen sink (kitchen or yard)?	12		22	
Because I heard it at the IHIP roll-out session		3 (25%)		2 (9%)
A programme was installing sinks in my community		2 (17%)		1 (5%)
It increases hygiene in the kitchen environment		4 (33%)		4 (18%)
Another NGO told me to install a sink		2 (17%)		1 (5%)
Why do you not use solar disinfection as a water treatment method?	77		109	
I don't have SODIS bottles		9 (12%)		16 (15%)
I plan to start using SODIS soon		10 (13%)		18 (17%)
No body at home wants to be in charge of managing the bottle regularly / they don’t have time or forget		3 (4%)		6 (7%)

I don't like drinking water that has been exposed to the sun		2 (3%)		3 (3%)
I don't believe the method works		1 (1%)		4 (4%)
I use another HWT method		28 (36%)		27 (25%)
I Belief it is dangerous for my health		13 (17%)		22 (20%)
The water is already comes clean from the faucet		2 (3%)		2 (2%)
I do not know how to use the SODIS method		0 (0%)		5 (5%)
Inter-personal level				
Who helped you build your stove?	113		92	
An NGO helped me build my stove		7 (6%)		7 (8%)
I built it out of my own interest		68 (60%)		48 (52%)
A family member / neighbour /teacher helped me to build		28 (25%)		26 (28%)
Other		3 (3%)		3 (3%)
Where did you learn about drinking water household water treatment methods?	185		176	
I have always used it		15 (8%)		29 (16%)
Ministry of Health		154 (83%)		138 (78%)
IHIP roll-out sessions		5 (3%)		4 (2%)
From a family member or neighbour		21 (11%)		19 (10%)
My child learned about the method at school		4 (2%)		4 (2%)
Other		9 (5%)		7 (4%)
Where did you learn about solar disinfection as a HWT method?	77		109	
I have always used it		7 (10%)		8 (7%)
Ministry of Health		3 (4%)		5 (5%)
IHIP roll-out sessions		34 (44%)		54 (50%)
From a family member or neighbour		7 (10%)		14 (13%)
My child learned about the method in school		2 (3%)		2 (2%)
Community Level				
Have you seen or heard someone taking about improved stoves in your community?	425	144 (34%)	439	145 (33%)
Have you seen or heard someone talking about solar disinfection in your community?	425	77 (18%)	439	109 (25%)
Did you participate in the roll-out sessions?	425	51 (12%)	439	61 (14%)
Do you know someone who did participate in the roll-out sessions and new how to build, use and maintain the IHIP interventions?	425	111 (26%)	439	118 (27%)

Table 10-5: Timeline and activities

Timeframe	Activities	Summary
Jan - Jul 2008	Community Selection, preliminary screening and intervention selection	We signed agreements with local authorities and with community leaders, after the screening activities and household information census was carried out.
Jul - Sept 2008	Pilot Study	The selection of suitable intervention components and activities and identification of microbiological indicators was carried during this preliminary study
Sept - Dec 2008	Randomization, enrolment, Baseline data collection	The 51 community-clusters were randomised into the IHIP and control groups. Each household that had a child below 36 months, complied with the inclusion criteria and agreed to consent was enrolled. We conducted a baseline survey and collecting socio-economic and demographic household characteristics, microbiological data (*E.coli* and *diarrhoegenic E. coli*) on kitchen utensils, mothers' and children's hands, drinking water
Oct 2008 – Jan 2009	Intervention Implementation	The OPTIMA-improved stove and kitchen sinks were installed, with the implementation of solar disinfection as a HWT and hygiene messages, i.e. hand-washing and the elimination of animal excreta and isolation of animals from the kitchen environment.
Feb 2009 – Jan 2010:	12 month surveillance	Trained field workers visited each household weekly and collected morbidity data from the mother about the daily occurrence of signs and symptoms of child diarrhoea and respiratory illnesses. Anthropometric measurements were collected every two months and microbial quality of the drinking water, hands and kitchen utensils were collected at baseline, mid-term and at the end of the surveillance period
Mar – Jun 2010	Roll-out sessions	To support a process of scaling up and community driven roll-out of the IHIP-intervention (component of part-III of the research plan), twenty-four handover workshops were carried out. Auto-dissemination and compliance surveys were carried out three (Aug Nov- 2010) and twelve (Apr- Jun 2011) months after the workshops were carried out.

Figure 10-1: Communitiy driven roll-out and determinants for IHIP replication using the Socio-ecological model



Ministries: Vivienda: Ministry of Housing, Construction and Sanitation
MINSA: Ministry of Health
PCM: Presidency of the Ministry Council
MIDIS: Ministry of Development and Social Inclusion
MINAG: Ministry of Agriculture

JUNTOS: Cash Transfer Programme direct support for the poor
PRONASAR: National Rural Water & Sanitation Programme
CRECER: National strategy of articulated intervention to fight poverty and exclusions
SIS: Integrated Health Insurance
PRONAA Nutritional Integral Programme
FONCODES National fund for the Cooperation and Social Development
ANA: National water authority
PSI: Subsection Irrigation Programme
APAFA: parents school programme
Vaso de Leche: Mother group
Qualitative classification of decision influence: +/-: mentioned; +: low influence; ++: moderate influence; +++: high influence

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Supplementary table 10-1: Peruvian Policies, National Strategy and Governmental Institutions Programmes

Policy	National Strategy	Sectors Involved	Programmes
Objective 2: Equity and Social Justice	National Strategy for Poverty Reduction and Economic Opportunities - CRECER	Presidency of the Ministry Council	National Institute of Civil Defence - INDECI Direct Support for the Most Poor - JUNTOS.
		Ministry of Health	Integrated Health Insurance - SIS. National Center for Feeding and Nutrition - CENAN. General Direction for Health Promotion National Health Institute - INS Nutritional Integral Programme - PRONAA
		Ministry of Education	National Programme for Alphabetization - PRONAMA. Scholarship and Educational Credit Offices - OBEC National Programme for Education Infrastructure - PRONIED.
		Ministry of Women and Social Development*	National Programme for Family Wellbeing - INABIF. National Programme again sexual and family violence - PNCVPS. National fund for the Cooperation and Social Development - FONCODES Nutritional Integral Programme - PRONAA WawaWasi National Programme
		Ministry of Housing, Construction and Sanitation	Water for Everybody National Rural Water and Sanitation Programme - PRONASAR. Own House Programme
		Ministry of Agriculture	Rural Productive agrarian Development Programme - AGRORURAL. Subsection Irrigation Programme - PSI. National Service of Agrarian Sanitation - SENASA. Agricultural Bank - AGROBANCO. National Water Authority - ANA
		Other Institutions	Local and Regional Governments
		NGOs	Active participation of NGOs in study areas

*The information was collected from the Presidency of the Ministry Council webpage: http://www.pcm.gob.pe/

PART VI: DISCUSSION AND CONCLUSIONS

11.0 DISCUSSION

Using a strong scientific design and innovation regarding interventions delivery, this study addresses some priority health issues for rural Peru. This chapter focuses in the development of a home-based integrated environmental intervention package, termed IHIP. It starts with the current water hygiene, and household air pollution scenario in contemporary Peru. The chapter proceeds exploring the potentials of a household integrated approach like IHIP toward achieving the Millennium Development Goals (MDG) and poverty reduction in Peru, with emphasis on water, hygiene and household air pollution, followed by a review of the methods and strengths of the design, used to select and assess the health impact of the IHIP interventions in the study populations. Finally this chapter puts forward some recommendations and needs for future research.

11.1 Water, hygiene and household air pollution in Peru and their implications for the Millennium Development Goals

Peru has the highest growing economy in Latin America. The GDP has had a steady annual growth since 2007, resulting in a reclassification of the country as an Upper Middle Income country (World Bank 2010). As a whole, the country has seen several improvements in poverty reduction, health, education, infrastructure and an increasing sensation of a steady economy, but great disparities still exist. The contrast between the coastal cities and the rural Andean and Amazon basin populations are as big as ever. The GINI index[1] for Peru is 48 and 31% of the Peruvians still live below the national poverty line.

In the past two decades several initiatives and developmental programmes were created in an effort to reduce poverty and social and environmental inequalities in the context of the MDG. It became evident with the creation of the National Strategy for Poverty Reduction and Economic Opportunities ("CRECER"), conceptualized and generated using a causal model for malnutrition, which focused on water and sanitation, nutritional practices and fighting infectious diseases (diarrhoea and respiratory illnesses).

[1] The Gini index measures the inequality among values, in this case wealth. A coefficient of zero expresses perfect equality and a coefficient of one (100 on percentile scale) expresses maximal inequality among values.

The IHIP study has distinctive implications for national policy and for most of the Millennium Development Goals, notably MDGs 4, 5 and 7[2]. There is evidence that simple, acceptable, low-cost environmental interventions at the household and community levels are capable of dramatically decreasing the disease burden in the developing world (Clasen et. al. 2010, Fewtrell & Colford 2005, Gundry 2004, Curtis & Cairncross 2003). Water and sanitation, household water treatment and hygiene (i.e. hand-washing with soap and correct excreta disposal) are among the most used interventions and found to reduce the risks of diarrhoeal illness in a range from 25% to 45% (Fewtrell et. al. 2005). Regarding household air pollution, the widespread use of solid fuels to meet basic energy needs represents a major public health concern. Cooking and heating with solid fuels on open fires or traditional stoves in poorly ventilated environments leads to high levels of indoor air pollutants (Naeher et al. 2007) that can cause many health damaging illnesses such as increasing the risk of acute lower respiratory infections (ARLI), chronic obstructive pulmonary disease (COPD), and may cause lung cancer (from coal stoves) asthma, low birth weight and other adverse birth outcomes (Siddiqui et al. 2008), cardio-vascular and other inflammatory conditions (Po et al. 2011), eye diseases, such as cataracts and blindness (Smith and Mehta 2003; Saha et al. 2005) and headaches (Díaz et al. 2007). Indoor air pollution was been identified as the eighth most important risk factor and is responsible for 2.7% of the global burden of disease (Rehfuess et al. 2006). Globally, household air pollution accounted for 1.6 million deaths and 39 million DALYs in the year 2000 (Smith et. al. 2004). The latest meta-analysis showed that children were three times more likely to develop acute respiratory infections (ARI) if exposed to biomass fuels (Po et. al. 2011) and a recent randomised trial showed that the introduction of chimney stoves could reduce 30% of the severe pneumonia cases (Smith et. al. 2011).

11.2 Methodological issues and strength of the study

Research reported in this study demonstrates the value of applying complementary methodologies –especially using qualitative methods- leading to better development, delivery and adoption of health interventions that intend to change daily lives of householders. In

[2] MDG 4: reduce child mortality; MDG5: improve maternal health, MDG7: ensure environmental sustainability

concert with quantitative methods in this cRCT this allowed in addition to quantify the impact of the IHIP intervention package harnessing most important context information that otherwise would not be know in the required level of detail. There are several distinctive features and strengths of the IHIP intervention package that merit to be mentioned.

A first feature is the innovative approach of tackling several household problems and childhood diseases simultaneously and, packaging them in a new and coherent manner for intervention delivery (Chapter 4, 6). With national policies specifically focusing on poverty reduction, our intervention comes in a timely fashion. The overwhelming positive community response toward the IHIP intervention package amongst the study groups and neighbouring community members was unexpected for beneficiaries, local authorities and project staff alike and all stakeholders, also at municipal health care level found that the integration of the health messages together with the breadth of hardware in the kitchen environment was an efficient and effective way to blend delivery and adoption processes associated with the interventions. There is a strong potential in centring improving household environmental health on the kitchen environment in dealing with and focussing the attention of potential beneficiaries (Chapter 10).

Secondly, the participatory and intensive interactive pilot phase helped to identify critical pathways of contamination of child's food and drinking water (Chapter 5). The finding of faecal contamination emphasised the importance of improving domestic hygiene practices – like hand washing and cleaning of kitchen utensils- in order to prevent diarrhoeal diseases' transmission addressing and interfering several faecal-oral transmission pathways simultaneously. Additionally, by including the community -through open interviews and focus group discussions- we gained insight into the cultural beliefs and were able to develop potential approaches to ensure adherence and compliance of IHIP interventions.

Thirdly, a cluster randomised control study design was selected to avoid problems of cross contamination between neighbouring households assigned to different study arms and for allowing community dynamics to take place for the IHIP interventions which will typically be rolled out in potential programme through community rather than household level promotion. A cRCT design generates effectiveness measures considering such settings. However, our study could not be blinded at household level. To counteract non-blinding bias we collected a variety of objective outcomes: respiratory rates, weight gain, child growth, environmental samples (water, mothers' hands and kitchen cloths), stool samples from ill and healthy children, in addition to subjective outcome measures of diarrhoea and acute respiratory illness. Additionally, we ensured that our data collection instruments were standardised, that field workers had been thoroughly trained and that data collection was cross-referenced and carried out by independent teams (Chapter 6). We went a step further and selected an equally attractive and desired intervention for the control arm by design with the intention to counteracting dropout rates due to lack of motivation and for addressing ethical concerns associated with a non-intervention control group. The nature of the intervention –a psychomotor stimulation intervention focusing on early child development- was, - to our best knowledge-, unrelated to our IHIP health outcomes. However, we acknowledge the potential risk that additional indirect health effects could result in an increased awareness of children's needs by the parents.

A fourth strength was our data management and training of field staff.. Field staff was thoroughly trained, and closely supervised until they were capable of working independently and in a best possible standardised manner when approaching and questioning villagers as well as recording and entering data (Chapter 4). Copies of all data forms were obtained, and reviewed. Data entry was duplicated for approximately 10% of the data for the purposes of validating data entry. This was repeated until the error rate dropped below 1/1000.

11.3 Overview of IHIP main outcomes

The impact of the IHIP trial needs to be attributed to the entire intervention package, since an integrated delivery was intended. The main objective of the study was to reduce respiratory infections and diarrhoeal disease by 20% (as per research plan). In an effort to understand the reasons for not showing additive or no effects each intervention component was addressed separately: water quality and quantity, hygiene and household air pollution (Chapter 9).

Primary outcomes

The hygiene and household water treatment components of the IHIP achieved the main goal of the study. We observed 22% (RR 0.78: 95% CI: 0.49-1.05) fewer cases of diarrhoea episodes per child-year in the intervention arm and a similar result was found for the longitudinal prevalence with an odds ratio of 0.71 (95% CI: 0.47-1.06). Despite borderline significance, these findings may be indicative for a potential impact of the IHIP intervention on environmental health outcomes. We identified three reasons for this moderate outcome. First hand-washing promotion was universally found in our setting, since it was part of the regular communication efforts by the local health care centre; the second was that SODIS compliance was low: only one third of the beneficiaries regularly used the method; and thirdly, the increased awareness for the child's needs linked to the control intervention, could induce an increase in child care behaviour.

No substantial reduction in respiratory morbidity (cough or cough and fever) or acute lower respiratory infections (mainly pneumonia) was observed, although it was an expected direct health impact from the introduction of the OPTIMA-improved. However, a reduction in the direct symptoms from massive indoor smoke emissions such as red, watery and sore eyes, or the perceived lack of breathing air, were all perceived by beneficiaries and were found to result in a statistically significant reduction in the IHIP-intervention group. We identified two potential explanations for why we did not observe an impact on ALRI: (i) Insufficient exposure reduction of household air pollutants (Chapter 7 & 8) and (ii) beliefs regarding health-seeking behaviour (Chapter 9). The household air pollution assessment study revealed only small reductions of CO and PM2.5 pollutants in the kitchen environment, achieving a maximum reduction of 45% and 27% for PM2.5 and CO respectively for mothers' personal exposure with our best working stoves. Unfortunately, our 48hr PM2.5 and CO concentrations for the kitchen environment compare well with reports of evaluation of other stove types (Masera et al. 2007, Cynthia et al. 2008, Bruce et al. 2004), revealing that the current reduction levels of improved stoves are not optimal enough to be able to observe improvements in child health. A recent trial showed that a mean CO exposure reduction of 50% is the minimum needed to observe an impact on physician-diagnosable pneumonia (Smith et al. 2011). Another possible explanation is that, biomass chimney stoves are not reducing emissions but merely venting smoke to the immediate outdoors -some of which re-enters the homes- contaminating both outdoor and indoor environments (Künzli, 2011). Additionally, children's exposure to biomass smoke is not only occurring at home, but also during outside household visits. We observed that for 48hr CO passive tube assessment children exposure was moderately correlated to that of their mother's personal exposures ($r=0.50$ $p<0.0001$ $n=67$) and showed a weak correlation with the kitchen environment ($r=0.32$ $p=0.008$ $n=67$).

OPTIMA-improved stoves were highly in use and valued in our study setting. According to compliance data, 90% of the OPTIMA-improved stoves were used daily, throughout the projects life. Improved stoves can be one of the most cost-effective household air pollution (HAP) control measures (Naeher, 2009), if they are adequately designed, installed, maintained and continuously used. In our setting, we failed to reach proper levels of maintenance for the OPTIMA-improved stoves, despite the use of local materials to maximize maintenance. In a later assessment, around 35% of our stoves needed repairs after 9 months of having been installed.

In relation to this, it is important to mention that global large-scale dissemination schemes are currently being developed. The Global Alliance for Clean Cookstoves (GACC) initiative has provided a platform where different entities can converge onto a common goal: 100 million households adopting clean and efficient cookstoves and fuels by 2020. The alliance is supported by private, public and non-profit partners who aim to overcome the market barriers and achieve the established goal. In partnership with the GACC, several organizations in Peru have aimed to install/deploy 500'000 certified biomass improved chimney stoves by 2011 (Bodereau, 2011); by October 2011 they had installed 216,537 improved stoves, under 50% of the overall goal. The problem is that at least in Peru, the success of these household indoor air pollution mitigation programmes is often measured by the number of installed stoves rather than adoption, continuous utilization and maintenance by the users over time (Armendáriz-Arnez et al. 2010, Bodereau, 2011). Our study brings light to these key issues (maintenance, adoption), that must be considered when implementing stove interventions and in the general development of actions towards the goals set by the GACC. It is not enough to have the stoves installed, they must be accepted, used and maintained, that is, the initiative must seek sustainability.

Regarding cultural beliefs in relation to health-seeking behaviour, this could be linked to the perceived quality of the health care and access to health facilities (Lanata et. al. 2004). In our study health seeking behaviour was a determinant for correctly diagnosing ALRI. It revealed that both study groups had similar hospitalization rates; however the control group subjects visited the health facility with a higher frequency. It appears that the early detection and knowledge of the disease and health maintenance approaches could be playing an important role in health seeking behaviour and treatment in our setting. This affected our respiratory results, since a significant number of acute respiratory infections and ALRI cases had attended a health centre and/or received treatment. More than 80% (26/34) of the children with ALRI had already received treatment for at least 2 days at the time of the household visit and respiratory rates were found normal, invalidating the application of the standard WHO criteria defining an ALRI in our study. We originally defined ALRI according to the IMCI algorithm (as per study protocol): a child presenting cough and difficulties to breathe with a raised respiratory rate according to age on two consecutive measurements (Gove, 1997, Lanata et.al. 2004). However, due to our reduced number of measurements of respiratory rates and ALRI episodes, we deviated from our original definition and used the following: a child presenting cough, fever and difficulties breathing.

Finally, the deficient reduction of child's morbidity could explain the lack of a measurable effect on nutrition.

Secondary outcomes

The frequency of contamination was similar at baseline for both study arms. The mid-study evaluation revealed a 34% decrease in water for drinking *E.coli* contamination in the intervention arm. However, this decrease in faecal contamination was not statistically significant (p= 0.116), and the difference was not sustained in the end-of-study evaluation. Water for drinking was the most contaminated indicator throughout the study, which is consistant with the moderate solar water disinfection compliance observed throughtout the study. Only one third of the mothers were reported using the method regularly. Our results were consistent with those published by (Mäusezahl et. al. 2009), observing a mean SODIS-user rate of 32.1%.

11.4 Community driven roll-out of IHIP interventions

Chapter 10 describes the study roll-out and dissemination of IHIP interventions, using an innovative approach to identify potential factors and barriers of adoption at different levels. As mentioned before, adoption is an important factor when considering the impact that interventions have on people, communities and their development. Other studies have identified and reported on adoption and dissemination factors. A SODIS cluster-randomised trial carried out in rural Bolivia, identified that at the household level individuals that attended SODIS promotional events, owned latrines, were women and had severally wasted children were most likely to use the method (Christen et al. 2011). Another study carried out by Tamas and Mosler (Tamas & Mosler 2011), also focusing on SODIS adoption, observed that relapsers (people who discontinued SODIS use) had significantly lower values than continuous users for behavioural factors, concluding that relapsers' personal behaviour did not support the fragile and often situation-dependent establishment of long-term habit changes.

In relation to our study, community response toward the IHIP intervention package amongst the study group and neighbouring community members was high. Both beneficiaries and project staff found the integration of health interventions to be efficient and effective. Additionally, a significantly raised awareness of the project and general health was reported even 16 months after the surveillance period of the study concluded. During roll-out sessions the general perception regarding reduction of diarrhoeal disease and smoke-related conditions (eye irritation, cough, and irritated respiratory tract) was manifested among the community members.

We did observe replication in the study communities, however, IHIP roll-out sessions felt short on providing additional momentum for local adoption. As discussed, motivation to support the higher uptake of improved chimney stoves had its origin in perceived benefits such as efficient fuel use, cleaner cooking environments and visible smoke reduction. Additionally, materials needed for the construction of chimney stoves were able to me made locally made or purchased (chimney with valve) cheaply at the city of San Marcos. However, chimney stove manufactures did no exist in our setting. In other settings, there are several institutions such as International Research Group in Haiti or the Guatemala Stove Project that not only seek to install but, to expand local industry for improved household cookstoves. This is essential if we want to achieve sustained use. Materials for kitchen sinks were more expensive and the building process in itself was more complex. Additionally, the very nature of the IHIP design limited dissemination during the study surveillance phase. It was design to limit cross-contamination and not promote health messages outside of the participating households. However, future studies might consider implementing the interventions in the entire communities; this will not benefit compliance, sustainable use, but also provide the effectiveness of the interventions under real life settings.

With regards to scaling-up activities, community involvement could be increased by training up participating mothers to promote the project to those communities that are not yet involved (a peer-to-peer education approach). It would also be useful to encourage an exchange of experiences between communities with regard to stove building. One of the advantages that the project team had regarding this issue, was the fact that they had already built trustful relationships with the communities they were working with, being this trust an important factor for the success of any sustainability exercise.

As we described in Chapter 10, there is a gap between governmental policies and local stakeholders' knowledge regarding these policies and the appropriate development of these programmes. It also became evident that if policies were not linked to evidence-based research, the interventions could fall short and provide little benefit to the population.

11.5 Beyond health impacts of IHIP interventions

The installation of the OPTIMA-improved stoves and the kitchen sinks were the benefits that were most perceived and appreciated by the participating families. It met a strong local demand to reduce wood consumption and reduce wood costs, to shorten cooking time and to reduce indoor smoke emissions from open fire cooking. It is noteworthy that in a number of homes that received the intervention, the combined benefits of the stove and the sink seemed to have generated additional benefits, often encouraging families to improve the kitchen living area in general. Those main benefits perceived by householders of the OPTIMA-improved stove do have in common that they describe substantial convenience gains that are hardly linked to improved health (with the exception of reduced suffering from red, burning and tearing eyes and partly less coughing as consequence of heavy smoke reduction). The overwhelming acceptance and sustained use was not only observed in the IHIP families but also in non-participating families, that had copied the OPTIMA-improved stove after the community engagement in the roll-out activities, and were using it daily. This was fortified with data collected to address sustainability 16 months after the end of the follow-up phase. Similar to the perceived benefits of the chimney stove intervention community members reported on the benefits of the kitchen sink, stating that it facilitated handwashing with soap, and washing of utensils with detergent, generating a cleaner kitchen environment and fostered home and food hygiene in general[3]. In summary the cook stove and kitchen sink with running water interventions are seen as a commodity to improve quality of life, by improving daily life chores and necessarily motivated by health improvements only.

Community dynamics among community families was observed among families that had the interventions. Families considered themselves better-off and more advanced with regard to

[3] This information was obtained during follow-up surveys carried out 16 months after the completion of the RCT. The information will lead to a future publication on sustained use of IHIP interventions.

their newly acquired commodities for improving their kitchen environment than their neighbours. Social status, status change and pride linked to the IHIP (observable even in the 16 months post intervention evaluation) can be strong motivational drivers for sustainability.

Additionally, the population benefited greatly from the IHIP educational messages on home and kitchen hygiene, hand-washing behaviour, water quality and stove maintenance and manufacture. We added to the family status and livelihood impact, empowering families and communities through this mutual learning process.

11.6 Conclusion

This study identified five promising, home-based interventions that could be implemented in concert as a package and scaled-up to meet a broader set of demands: (1) an improved chimney cooking stove, (2) a kitchen sink with running water, (3) a solar drinking water disinfection, (4) handwashing and (5) animal excreta removal (Chapter 4 & 5). Thus, shifting actions towards an integrated household centred approach that not only focuses on proximal health outcomes, but also on longer-term household/livelihood impacts, ie sustainability impacts (distal outcomes) such as improved household economies, time savers, improved child care. We demonstrated that the IHIP-combined intervention package meets significant local commodity and convenience needs and is a feasible initiative that can be carried by the communities themselves in the Peruvian Andes (Chapter 6). Chapter 7 and 8, apart from presenting the household air pollution measurements, underscored the importance of not only measuring success of intervention programmes by the number of installed components (i.e. chimney stoves, sinks, solar disinfection users), but rather by also assessing the quality, compliance and maintenance of the devices, adoption and continuous use over time, that is, the sustainability of the intervention.

In order for self-driven replications and roll-out to take place, interventions must first develop a framework for scaling-up household- and community-level projects, by supporting local community workers and local businesses. Interventions should be designed embracing a health-systems approach, ensuring multilevel interactions and links between the community members, their immediate environment (community), institutions and policies, thus fortifying the delivery, replication, uptake and ultimately the sustainability of interventions (Chapter 10).

Additionally, other design methodologies could be explored for an adequate implementation of interventions (such as step-wedge designs). Understanding community dynamics from the start is necessary to make and sustain health behaviours, which can be both profound and challenging.

The potential of IHIP interventions for large scale dissemination with regard to their social, economic and health impacts should be further explored. Assessing severe child health outcomes including pneumonia and ARI-related mortality, identification of possible synergies among interventions, as well as the right combination of deliverable and packaged interventions, would provide very interesting insight for future research development. Especially in the light of current Global and Peruvian national endeavours to provide methodologies and interventions that can help reduce poverty in a sustainable way.

Recommendations

The experiences from the IHIP-Peru project, which - at large - can be viewed as a community-randomised participatory action-research endeavour humbly generates recommendations for programme planners, development actors, policy decision makers and researchers alike:

For policy makers:

- The contemporary Peruvian policy frameworks and stakeholder engagement at the health development sectors merits to more formally engage in a evidence for policy processes. Policy makers should become aware of ongoing research by local organisations or research institutions to harness the opportunities at hand or request for information to make evidence based dessition making for environmental health development.

For programme planners:

- IHIP-Peru was set out to have a multi-stakeholder involvement and make use at the evaluation phase of the empowerment achieved using a participatory approach when designing interventions in the initial phase. Prolonged participatory project preparation phases need to be planned and negotiated for with donors to generate ownership, assure continued knowledge exchange and mutual learning throughout the study and ensure sustainable intervention uptake.

- The intervention package comprising IHIP may eventually be an intervention within a community development framework (further evidence for its effectiveness provided). In that context evaluative implementation research should adopt a systemic viewpoint. This would better reflect on and allow us to understand underlying determinants for processes leading to improved household and community health outcomes of home-environmental health interventions.
- Health interventions must be aligned with government policies. Presently we can observe several actors (governmental and non-governmental organizations) providing different strategies that at some point are no longer sustained, forgotten (by a new establishment), interrupted or even duplicated. Duplication, mixed messages and distrust, puts greater strains on fortifying existing programmes and building upon the results of prior programmes.

For researchers:

- Explore other design methodologies to increase adequate intervention uptake, such as step-wedge designs. Step wedged designs would allow sequential roll-out of an intervention to participants over a number of time periods. This design would allow the measurement of additive effects of the integrated interventions and attributed effects to each.
- Research for development and research embedded in health development contexts (IHIP) should harness the potential to assess both the term immediate proximal outcomes (eg reduction of acute respiratory conditions, pneumonia) and the long-term social and livelihood impacts.
- To determine lasting effects of the interventions, researchers should consider measuring compliance, adoption and sustainability, 6 to 12 months after the last intervention, to assess the degree of change and to judge potential of sustainabilabe impacts.

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