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Health and development effectiveness of integrated home-based interventions in rural Andean communities: a randomised trial

Submission date
30/11/2017

Recruitment status
No longer recruiting

Registration date
15/01/2018

Overall study status
Completed

Last Edited
07/06/2022

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims

Children and women in low- and middle-income countries are frequently exposed to accumulating health and developmental risks often rooted in unhealthy environments. Nearly 3 billion people worldwide use solid fuels, which are a major source of household air pollution (HAP). Exposure to HAP drastically increases the risk of acute respiratory infections and cognitive deficits in children. In addition, a considerable fraction of the world population lacks access to secure drinking water sources (11%) or adequate sanitation (36%). Exposure to unsafe drinking water, sanitation and inadequate personal hygiene (WASH) increases the risk of several negative health outcomes such as diarrhoea, malnutrition or trachoma. In 2011, HAP and WASH accounted for 1.3 million child deaths, more than AIDS, malaria and measles combined. Early child development (ECD) is one of the main social determinants of health – opportunities that are provided to young children are crucial in shaping their lifelong health and development status. However, today 200 million children worldwide are not developing their full cognitive potential. This disparity has lifetime adverse consequences and impacts the wellbeing of future generations. Poor cognitive stimulation has been identified as one of the key risk factors hampering ECD in low-income countries. Poor health and development require integrated approaches to address underlying the risks and structural determinants. Many investigations have demonstrated that low-cost interventions addressing common health risk factors at the same time have a powerful combined effect, leading to significant health and social improvements. Health and ECD interventions have demonstrated to be effective alone, so integrating environmental, health and ECD interventions can create safe, stimulating and responsive homes where children can play and eat without being exposed to factors that threaten their health and development. Furthermore, this approach can reduce the use of resources and provide a more holistic approach towards prevention. Although Peru is now classified as upper-middle income country economic growth it maintains large inequalities between urban and rural areas with poverty and extreme poverty, infant mortality, chronic malnutrition and illiteracy. The home-based interventions proposed in this study can alleviate the negative effects of poverty on child health and development and thereby prevent the widening gap between the rich and the poor. This includes health and non-health benefits such as better nutritional status, empowerment of women or the community, capacity building,

increased security and time savings. The aim of this study is to assess the effectiveness of a package of home-environmental health and ECD interventions in rural Andean communities.

Who can participate?
Families with at least one child aged under 20 months, who use solid fuels as their main energy source for cooking/heating, have access to piped water in the yard or the community where the kitchen connections can be made, and do not plan to move within the next 24 months

What does the study involve?
Communities in two poor rural provinces of the Peruvian Andes are randomly allocated to one of four groups. Households in the three intervention groups receive either improved biomass cookstoves, kitchen sinks and hygiene education, the Peruvian national program on ECD, or both interventions combined. The control group do not receive any of the interventions during the study and follow-up period, but receive all the interventions (kitchen stove and sink) at the end of study. The researchers monitor the occurrence of acute respiratory infections, diarrhoea and changes in ECD in children under 36 months of age over one year through weekly visits and start and end of study comparisons. In addition, they study changes in exposure to air pollution in households and individuals in a small group of participants to assess cookstove efficiency, and also analyse the presence of E.coli (one of the main causes of diarrhoea) in drinking water of all the participants at the beginning and end of the study and regularly during the study in a small group of participants.

What are the possible benefits and risks of participating?
Households receive a cookstove, a kitchen sink and a piped water supply into the kitchen, which may improve health and development. The study will provide much needed evidence on health and non-health impacts and factors influencing the effectiveness of the interventions. There are no known risks of participating in this study. All study households receive all of the interventions at the end of the study.

Where is the study run from?
The study takes place in two Peruvian provinces (San Marcos and Cajabamba)

When is the study starting and how long is it expected to run for?
November 2014 to December 2017

Who is funding the study?
1. UBS Optimus Foundation (Switzerland)
2. Grand Challenges Canada (Canada)

Who is the main contact?
1. Stella Hartinger
2. Daniel Mausezahl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title
A 2x2 factorial 12-month randomised trial to evaluate the effectiveness of two integrated home-based interventions in environmental health and early child development for improving health and child development in children under 36 months living in rural Andean communities (IHIP-2)

Acronym
IHIP-2

Study objectives
Hypothesis 1: Improved biomass cookstoves and improvements in access to drinking-water and hygiene education lead to reductions of the morbidity of the most important diseases in children.
Hypothesis 2: Home-based early child stimulation leads to measurable improvements in major child development areas.
Hypothesis 3: Integration of environmental health and early child education interventions leads to synergistic effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Cayeteno Heredia University ethics review board, 02/11/2014

Study design
Community-level controlled 2x2 factorial cluster randomised non-blinded trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Diarrhoea, acute respiratory infections and early child development

Interventions
The interventions will be implemented as a randomised controlled trial with a 2x2 full factorial design. This design applies two intervention packages individually and in combination:
1. An environmental health intervention comprised of improved biomass cookstoves, kitchen sinks and hygiene education (IHIP)
2. An early child development program applied by the Peruvian state (ECD)

This design leads to four potential experimental conditions with a 1:1:1:1 allocation ratio. Communities in two poor rural provinces of the Peruvian Andes will be randomly allocated to the three intervention and one control group:
1. IHIP + ECD
2. IHIP
3. ECD
4. Control: the control group did not receive any of the interventions during the trial and follow-up period. However, participants in the control group will receive all the interventions (kitchen stove and sink) at the end of study.

The four intervention arms are assessed simultaneously during 12 months for a primary endpoint of changes in ECD and health morbidity in children under 36 months of age.

Intervention Type
Mixed

Primary outcome measure

1. Diarrhoea incidence: cases recorded weekly during 12 months of follow-up with a paper-based questionnaire using the WHO protocol/definition of diarrhoea (at least three loose stools passed within 24 hours)
2. Age standardized mean score of psychomotoric assessment: cognitive, language and motor development will be assessed twice, at baseline and end of study in children <3 years of age. The assessment will be carried out by trained local fieldworkers and trained psychologists using nationally and internationally standardised validated and comparable tools. ECD status is measured with a Peruvian validated tool (ESDI) at the baseline and end of study and with an international validate tool (Bayley Scales of Infant Development) at the end of study.

Secondary outcome measures
1. Compliance to use the interventions, recorded weekly during 12 months of follow-up
2. Acute respiratory infections incidence during 12 months of follow-up: ARI cases are recorded weekly with a paper-based questionnaire using the WHO/IMCI protocol for diagnosis. ARI will be diagnosed in children <3 years of age by trained local fieldworkers using the IMCI protocol: presence of cough and fever and observable signs: difficult breathing (>60 breaths per minute and >50 breaths per minute in children < 1 years and > 1 year respectively), chest in-drawing, stridor or other danger signs (i.e. vomiting, being lethargic)
3. Incidence of severe cases of diarrhoea such as persistent diarrhoea (lasts 14 days or longer) and bloody diarrhoea
4. Household and personal exposure to carbon monoxide (CO) and particle matter (PM2.5) during 12 months of follow-up. Household Air Pollution (HAP) assessment is conducted at various time points (4 time points) in a sub-sample of participants (N=40)
5. Microbiological contamination (E.coli) in drinking water. This analysis is carried out by a trained biologist for all study participants at the baseline and end of study, and in a sub-sample of participants (N=40) at various time points over 12 months (4 measurements). The method used for the microbiological analysis is the membrane filtration method (delAgua)

Overall study start date
30/11/2014

Completion date
31/12/2017

Eligibility

Key inclusion criteria
Families eligible for the trial must comply with all of the following at recruitment:
1. Have at least one child <20 months living in the home
2. Use solid fuels as main energy source for cooking/heating
3. Have access to piped water in the yard or the community where the kitchen connections can be made
4. Do not plan to move within the next 24 months

Participant type(s)
Other

Age group
Mixed

Sex
Both

Target number of participants
40 clusters with approximately 320 participants

Total final enrolment
317

Key exclusion criteria
1. Participate in the Peruvian national programme on early child development (PNCM)
2. The child has any congenital or chronic disease
3. Refusal to participate

Date of first enrolment
02/07/2015

Date of final enrolment
24/02/2016

Locations

Countries of recruitment
Peru

Study participating centre
UPCH-SwissTPH San Marcos Research Station
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51

Sponsor information

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Research organisation

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Funder(s)

Funder type
Charity

Funder Name
UBS Optimus Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Funder Name

Grand Challenges Canada

Alternative Name(s)
Grands Défis Canada, GCC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
The first submission on the study protocol will be Jan/Feb 2018. The trialists plan to submit a baseline manuscript in Mar/Apr 2018.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Daniel Mausezahl and Stella Hartinger.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/04/2020	06/04/2020	Yes	No
Results article		06/06/2022	07/06/2022	Yes	No