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An mHealth Tool to improve community health agent performance for child development: a cluster-randomized controlled trial in Peru

Submission date
29/11/2018

Recruitment status
No longer recruiting

Registration date
04/12/2018

Overall study status
Completed

Last Edited
10/01/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Cultivating good child development creates long-term impact on the well-being of the individual and society. Peru has a high level of many risk factors that are associated with poor child development, including chronic malnutrition, anemia, and poor education opportunities. The use of 'community health agents' (CHA) can improve child developmental outcomes through health promotion and education, referral to health services, and surveillance. An effective CHA program can improve cognitive development, child nutrition, and prevention of diseases for populations in low-resource settings. The performance of CHAs can be enhanced by providing them information and communication technology (ICT) to use for their program activities. The current study will evaluate the impact of a tablet-based application (The Child Health Education and Surveillance Tool – The CHEST) that intends to improve the performance of CHAs during their home visits with children under 4.

Who can participate?
Study participants will include community health agents, the primary caregiver of a child below the age of 4, and children under the age of 4. All community health agents, caregivers, and children in the intervention communities will be invited to receive the intervention. The primary caregiver of the child must be over the age of 16 and speak Spanish. The child will be excluded from the study (but not the intervention) if they have a developmental disability.

What does the study involve?
The community health agents in the intervention group will receive a tablet pre-loaded with The CHEST Application that will guide them through the steps to execute an effective home visit and provide videos and images to help teach key health messages. The CHEST will organize their caseload and provide a mechanism to record and report child health indicators. The community health agents in the control group will not receive a tablet, and so will continue conducting their activities as community health agents as per the status que. The outcomes in the intervention group will be compared to the outcomes in the control group. The primary outcomes include early childhood development scores, prevalence of anemia, and prevalence of chronic malnutrition.

What are the possible benefits and risks of participating?
The children in the intervention group are expected to experience improved early childhood development outcomes and improved nutrition due to their caregiver becoming more knowledgeable of healthy child-rearing practices. There are no potential risks or side effects associated with the intervention. The children in the control group will receive the stand benefits from the community health agent program without the additional ICT tool.

Where is the study run from?
The study is being conducted in communities in the country of Peru, department of Loreto, province of Maynas, and districts of Mazan, Puchana, and Las Amazonas. The study is being administered by the Peruvian research organization, Elementos. The home office is located at Jiron Domeyer 105, Barranco, Lima, Peru.

When is the study starting and how long is it expected to run for?
Recruitment for the study will begin in March, 2019 and the intervention will be implemented in May, 2019. The intervention will operate in the communities for 12 months before the follow-up survey is conducted. The study is expected to be completed in June, 2020.

Who is funding the study?
The study is funded by the grant, Saving Brains, by Grand Challenges Canada.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15463-18

Study information

Scientific Title
An mHealth Tool to improve the performance of community health workers during home visits to improve child development and nutrition. A cluster-randomized controlled trial in Peru

Acronym
Chest Project

Study objectives
1. The digital health device will improve the performance of community health agents during their home visits with children, as measured by doses, content, and inter-personal relationships.
2. Improved performance by community health agents will increase knowledge acquisition and healthy child-rearing practices by care-givers.
3. Improved knowledge and healthy practices by caregivers will improve the health and development of the child that receive the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Ethics Committee of the National Hospital of Mother and Children “San Bartolome”, 08/11/2018, ref. 15463-18.

Study design
Quasi-experimental, cluster randomized controlled 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 the contact details below to request a participant information sheet.

Health condition(s) or problem(s) studied
Early childhood development

Interventions
The intervention group will receive a training workshop on how to use the digital health tool and each community health agent will receive an electronic tablet with the CHEST Application pre-loaded. The community health agents will utilize the tablet to guide them through their home visits with mothers of children less than 4 years old in their communities. The intervention group and control group will receive the baseline survey and follow-up survey, which includes early childhood development evaluations, anemia diagnostic, and a KAP survey. The control group will not receieve an intervention. The community health agents in the control group will continue to conduct home visits and other activities in their community, as per the status quo. One year after the implementation of the intervention, the follow-up surveys will be conducted. For the selection of the sample populations, communities will be treated as clusters and paired 1-1 based on propensity score matching. The propensity score will be determined by the size of the community, distance from the capitol, and type of health center in the community. One cluster in each pair will be randomly assigned to the intervention group and the other cluster to the control group. The randomization will be conducted by a random number generator.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
1. Child development scores will be measured using the Caregiver Reported Early Development Instrument (CREDI) at baseline and 12 weeks.
2. Anemia prevalence in children will be evaluated by the local health center using the Hemocue at baseline and 12 weeks.
3. Chronic malnutrition prevalence in children will be assed by the local health center during the children's growth monitoring check-ups, continuously throughout the study. The data will be gathered and analyzed at baseline and 12 weeks.

Secondary outcome measures
Caregivers:
1. Knowledge evaluation scores will be measured using a knowledge exam created by the study team, at baseline and 12 weeks.
2. The frequency of which caregivers bring their child to growth monitoring check-ups will be evaluated by data obtained from the local health center, at baseline and 12 weeks.

Community health agents:
1. The performance evaluation scores of community health agents will be measured using an observational checklist created by the author, at baselina and 12 weeks.
2. Self-efficacy scores of the community health agents will be measured using a qualitative questionnaire at baseline and 12 weeks.
3. The number of home visits made by community health agents will be measured using the CHEST Application consistently throughout the intervention.

Overall study start date
10/01/2018

Completion date
01/08/2020

Eligibility

Key inclusion criteria
Children:
1. Children aged 6 to 36 months.

Caregivers:
1. Primary caregiver of the child is older than 16 years.
2. The caregiver is willing to receive visits from the CHA.

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
698

Total final enrolment
500

Key exclusion criteria
Caregivers:
1. Families where the main caregiver or the child does not speak Spanish.

Children:
1. Children with mental or physical disabilities.

Date of first enrolment
01/02/2019

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
Peru

Study participating centre

Community
Maynas, Loreto, Peru
Iquitos
Peru
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Sponsor information

Organisation
Elementos

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Sponsor type
Research organisation

Website
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Funder(s)

Funder type
Government

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
Following the study will be publication of the impact evaluation of the intervention. The results will be published in an international peer reviewed journal.

Intention to publish date
01/08/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in the publically available repository, figshare (https://figshare.com/). De-identified participant data, including early childhood development evaluation scores, anemia results, chronic malnutrition results, KAP survey results, and CHA performance evaluations, will be stored in the repository. The data will be available through the repository for 10 years. Data from participants will only be made available if consent was provided by the participant through the informed consent process.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/11/2019	15/01/2021	Yes	No
Results article		22/09/2022	10/01/2024	Yes	No