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Piloting integrated nutritional, early childhood development and water, sanitation hygiene interventions

Submission date
31/10/2016

Recruitment status
No longer recruiting

Registration date
08/05/2017

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
More than 200 million children under age 5 years are failing to reach their full potential of cognitive development (development of thinking, learning and memory skills). Traditional vertical programs typically only focus on only one area, such as maternal nutrition, child nutrition, water, sanitation, hygiene, community stimulation or reducing environmental lead exposure. Integrating these programs together however could be the most effective way of helping high risk mothers' to facilitate their childrens' development. The aim of this study is to develop a program which combines maternal nutrition, early childhood stimulation, water, sanitation, hygiene, infant and young child nutrition and lead exposure prevention delivered by local community promoters.

Who can participate?
Pregnant mothers and mothers of children under two years of age in select villages in Khishoreganj district (Bangladesh)

What does the study involve?
This study consists of two phases. In the development phase, community members who consent to participate are involved in group discussions, interviews, and participate in test versions of the main intervention in order to assess how feasible and acceptable it is. The resulting programme has four main components: water, hygiene and sanitation, nutrition, lead poisoning prevention and child stimulation. A different sample of community members who consent to participate are allocated to one of three groups. Those in the first group are encouraged to attend courtyard group meetings twice a month. Those in the second group receive a visit from community health promoters once a month in their home and are also encouraged to attend the monthly courtyard meetings in betwen their monthly home visits. The meetings/home visits are conducted by community health promoters and discuss the four intervention components. Those in the last group continue as normal and do not not attend any meetings or have home visits. Participants are followed up by community promoters at the beginning and end of the study to assess the feasibility, acceptability and uptake of this integrated interventions.

What are the possible benefits and risks of participating?
Participants may benefit from improved health. There are no notable risks with participating.

Where is the study run from?
The study is run from International Centre for Diarrhoeal Disease Research (Bangladesh) and takes place in villages in Khishoreganj district (Bangladesh)

When is the study starting and how long is it expected to run for?
July 2016 to August 2018

Who is funding the study?
Bill and Melinda Gates Foundation (USA)

Who is the main contact?
Professor Steve Luby

Contact information

Type(s)
Scientific

Contact name
Prof Steve Luby

ORCID ID
http://orcid.org/0000-0001-5385-899X

Contact details
Stanford University
Y2E2, MC 4205
473 Via Ortega
Stanford
United States of America
94305

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PR-16037

Study information

Scientific Title

Piloting scalable nutritional, psychosocial and environmental interventions for child growth and development

Acronym
RINEW Pilot

Study objectives
The aim of this study is to develop and pilot an intervention package integrating maternal nutrition, early childhood stimulation, water, sanitation, hygiene, infant and young child nutrition and lead exposure prevention delivered by local community promoters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
International Centre for Diarrhoeal Disease Research ICDDR, B Ethical Review Committee, 15/06/2016, ref: PR-16037

Study design
Stage one: Formative study
Stage two: Pilot community randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled 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 patient information sheet

Health condition(s) or problem(s) studied
Sub-optimal child development

Interventions
Current interventions as of 16/09/2019:
Formative Research stage:
This study includes an initial period of formative research on each of the intervention components to make sure that the interventions are evidence based, feasible and acceptable within the community. During this phase the integrated WASH, nutrition, lead poisoning and stimulation curriculum is developed. Community members are involved in focus group discussions, interviews, and participate in initial versions of group and home sessions to gather feedback and asses areas for improvement.

Pilot study:
Following the formative research phase, eligible community members who consent to participate are enrolled in the nine month pilot study, with interventions based on the initial formative research period. The interventions are conducted by community health promoters. This includes promoting maternal nutrition (i.e. promoting a diverse diet of nutrient-dense food), child nutrition (i.e. encouraging breastfeeding and high nutrient diets), increasing psychosocial stimulation (i.e. providing coaching to mothers on how to engage with their children), reducing lead exposure (i.e. teaching about pathways to exposure) and improving water, sanitation and hygiene (i.e. encourage handwashing, improving latrines, improving cooking methods).

Villages are randomly allocated to three different groups. Those in the first group (participants in 8 villages) are encouraged to attend fortnightly courtyard group meetings, those in an equally sized second group are visited by community health promoters once a month in their home as well as receive encouragement to attend monthly courtyard group meetings in between the monthly home visits. The last group (15 villages) act as the control group and they do not receive any intervention.

Mothers are visited at baseline and endline by study evaluators to assess the feasibility, acceptability and uptake of the integrated intervention.

Previous interventions:
Formative Research stage:
This study includes an initial period of formative research on each of the intervention components to make sure that the interventions are evidence based, feasible and acceptable within the community. During this phase the integrated WASH, nutrition, lead poisoning and stimulation curriculum is developed. Community members are involved in focus group discussions, interviews, and participate in initial versions of group and home sessions to gather feedback and asses areas for improvement.

Pilot study:
Following the formative research phase, eligible community members who consent to participate are enrolled in the nine month pilot study, with interventions based on the initial formative research period. The interventions are conducted by community health promoters. This includes promoting maternal nutrition (i.e. promoting a diverse diet of nutrient-dense food), child nutrition (i.e. encouraging breastfeeding and high nutrient diets), increasing psychosocial stimulation (i.e. providing coaching to mothers on how to engage with their children), reducing lead exposure (i.e. teaching about pathways to exposure) and improving water, sanitation and hygiene (i.e. encourage handwashing, improving latrines, improving cooking methods).

Participants are randomly allocated to three different groups. Those in the first group (one-third of the mothers) are encouraged to attend fortnightly courtyard group meetings, those in the second group (one-third of the mothers) are visited by community health promoters once a month in their home as well as receive encouragement to attend monthly courtyard group meetings in between the monthly home visits. The last group act as the control group and they do not receive any intervention.

Mothers are visited at baseline and endline by study evaluators to assess the feasibility, acceptability and uptake of the integrated intervention.

Intervention Type
Behavioural

Primary outcome measure
1. Feasibility and acceptability of the interventions as assessed by qualitative feedback from the study population and study implementers occurs continuously throughout the study (both formative stage and pilot intervention)
2. Adoption of behavior change recommendations as assessed by surveys (through use of the Family Care Indicators (FCIs) as well as additional items from the Home Observation Measurement of the Environment (HOME) scale), spot checks, and structured observations at baseline and endline of the pilot intervention.

Secondary outcome measures
Child development is measured using the Ages and Stages Questionnaire (ASQ) at baseline and endline of the pilot intervention.

Overall study start date
01/07/2016

Completion date
31/08/2018

Eligibility

Key inclusion criteria
Pregnant mothers and mothers of children <2 years of age in select villages in Khishoreganj district.

Participant type(s)
All

Age group
Mixed

Sex
Both

Target number of participants
360

Total final enrolment
621

Key exclusion criteria
Families planning to move.

Date of first enrolment
01/06/2017

Date of final enrolment

01/08/2017

Locations

Countries of recruitment
Bangladesh

Study participating centre
International Centre for Diarrhoeal Disease Research
68, Shaheed Tajuddin Ahmed Sarani
Mohakhali
Dhaka
Bangladesh
1000

Sponsor information

Organisation
Bill and Melinda Gates Foundation

Sponsor details
500 Fifth Avenue North
Seattle
United States of America
98109

Sponsor type
Charity

Website
www.gatesfoundation.org

ROR
https://ror.org/0456r8d26

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation

Results and Publications

Publication and dissemination plan
Planned publication of the outcomes of the study in one or more manuscripts in peer-reviewed journals within 24 months of conclusion of data collection.

Intention to publish date
31/08/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2021	23/04/2021	Yes	No
Results article		07/05/2021	14/06/2023	Yes	No