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Pilot study in rural setting in Kenya to determine whether the baby friendly community initiative (BFCI) will work

Submission date
07/08/2014

Recruitment status
No longer recruiting

Registration date
24/09/2014

Overall study status
Completed

Last Edited
14/01/2020

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Nutrition in the first 1000 days of life (during pregnancy and in the first two years of life) is critical for child growth, well-being and survival. Malnutrition during this period is a major cause of poor health, and is associated with a large number of deaths. It is also related to poor performance in school and other diseases later in life such as diabetes. Proper breastfeeding and feeding in young children is known to reduce the levels of malnutrition in children. Poor breastfeeding and child feeding practices are widely seen in Kenya, like in other low income countries, with potential unfavourable effects on child growth, health and survival. To address the poor feeding practices, the government of Kenya has planned to implement the Baby Friendly Community Initiative (BFCI), a global initiative that aims at providing counselling and support on breastfeeding and other feeding practices at the community level. This is very important especially in low income countries like Kenya where access to healthcare facilities and counselling and support for breastfeeding is poor. However, there is no evidence that implementing such an initiative is possible and we do not know whether such an initiative would work effectively to improve breastfeeding and other feeding practices, and eventually childs nutrition and overall health in Kenya. This study aims to put the BFCI practice to test and find out whether it is possible and effective.

Who can participate?
All pregnant women aged between 15-49 years old in Koibatek sub-county, Baringo county, Kenya, and their respective children (when born).

What does the study involve?
A total of 12 community units (usually equating a village with a population of about 5,000 people) are involved in the study. The community units are randomly allocated to either the intervention group or the control group. The intervention group receive counselling and support on maternal and child nutrition by community health workers and healthcare professionals at health facilities within the community. The control group receive the usual care offered by the government, which include visits by community health workers on general health and information materials on maternal and child nutrition. The mother-child pairs in both groups are

followed up from recruitment (during pregnancy) until the child is 6 months old. During this period information is collected including breastfeeding and infant feeding knowledge, attitudes and practices; information on child health, and body measurements of both the mother and the child including height, weight and mid-upper arm circumference. Interviews are also conducted with their family, community leaders and healthcare workers to find out about the knowledge, attitudes and practices regarding maternal nutrition, breastfeeding and other child feeding practices, and establish the local contexts and cultural factors that contribute towards maternal and child nutrition in the study areas.

What are the possible benefits and risks of participating?
It is expected that the intervention (if effective) will improve maternal and child nutrition behaviours and eventually the nutritional and health status of the children and their mothers. Those in the control group will benefit from counselling on general health from community health workers and will receive information materials on maternal and child nutrition. A proportion of the children in the study may be severely malnourished and will be referred for treatment and support at appropriate health facilities. The findings of the study will be useful in informing policy and taking steps to benefit the community as a whole. There are minimal risks and discomfort associated with taking part in the study which may include the time spent. The study team will try to minimize these as much as possible.

Where is the study run from?
The study takes place in Koibatek sub-county and Baringo County (Kenya)

When is study starting and how long is it expected to run for?
November 2014 to June 2016

Who is funding the study?
1. National Institutes of Health (NIH) (USA)
2. United States Agency for International Development (USAID) (USA)

Who is the main contact?
Prof. Judith Kimiywe
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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
N/A

Study information

Scientific Title
Feasibility and effectiveness of the baby friendly community initiative in Kenya: a pilot community trial in a rural setting

Study objectives
Implementation of the baby friendly community initiative will improve access to professional counseling and support on maternal, infant and young child nutrition to mothers in Koibatek sub-County, Baringo County, hence leading to greater knowledge and self-efficacy in breastfeeding and other infant and young child feeding practices, thereby resulting in adherence to WHO guidelines for breastfeeding and complementary feeding. This is expected to lead to improved rates of exclusive breastfeeding for 6 months and other optimal breastfeeding and complementary feeding practices. Eventually, improved practices are expected to impact on child nutritional and health outcomes in the community.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kenya Medical Research Institute, 04/08/2014, Reference: KEMRI/RES/7/3/1 - NON - SSC protocol No. 443

Study design
Prospective cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Nutrition

Interventions
The intervention will involve personalized, home-based counselling and support of pregnant and lactating women on maternal, infant and young child nutrition and also counselling and support by healthcare professionals at basic health facilities in the community. Pregnant women in the treatment group will be visited by community health workers on a regular basis throughout pregnancy and until the child is 6 months old. During these visits, the women will be given one-on-one counselling on their own nutrition and also on proper breastfeeding and infant and young child feeding practices. Additionally, pregnant women in the treatment group will receive information materials regarding maternal, infant and young child nutrition. Health professionals in the facilities in the intervention community units will be sensitized on the baby friendly community initiative so to counsel and support mothers effectively. Further, mother support groups involving mothers will be formed under which mothers will educate and support each other on breastfeeding and other child care practices.

Pregnant women in the control group will receive standard care that will involve visits by community health workers and counselling on general health including antenatal and postnatal care, necessary tests during pregnancy and the importance of health facility delivery. They will also receive information materials on maternal and child nutrition.

Joint/scientific contact details:
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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary outcome measure is the proportion of exclusive breastfeeding for the first 6 months. This will involve determining the impact of the BFCI intervention on the level or proportion of exclusive breastfeeding for the first 6 months. Data on breastfeeding practices will be collected longitudinally from birth every 2 months through an interviewer-administered questionnaire to the mother (24-hour recall at 2, 4, 6 months) with probes on the age at introduction of foods or liquids (if appropriate). Analyses will focus on the differences between the two study arms in the proportion of infants being exclusively breastfed at 6 months, as well as at the two earlier times of 2 and 4 months postpartum.

Secondary outcome measures
Qualitative
1. Norms and cultural factors that influence breastfeeding and other maternal, infant and young child feeding practices. Data will be collected through qualitative interviews with mothers, fathers, community leaders, TBAs, community health workers, other community members, and healthcare providers.
2. Enabling factors and barriers. Data will be collected through qualitative interviews with

mothers, fathers, community leaders, TBAs, community health workers, other community members, and healthcare providers to identify key players and structures in the community that would facilitate implementation of BFCI; factors that influence uptake of interventions in the community; and any potential hindrances to the success of the intervention (e.g., myths, beliefs)

Quantitative
3. MIYCN knowledge, attitudes and practices according to WHO recommendations. Data will be collected through self-reports by mothers using an interviewer-administered questionnaire at recruitment and every 2 months during the follow-up period to determine change in knowledge, attitudes and practices with the intervention.
4. Timing of initiation of breastfeeding. Data will be collected through self-reports by mothers using an interviewer-administered questionnaire within the first 2 months of birth.
5. Nutritional status: stunting, underweight, wasting within the first 6 months. This will be done through anthropometric measurements (weight, height and mid-upper arm circumference) every 2 months after birth till 6 months.
6. Diarrhea morbidity: evidence indicates that breastfeeding is preventive against infections such as rotaviral diarrhea. It is therefore expected that promotion of exclusive breastfeeding would impact on the rate of diarrhea morbidity. Data on diarrhea morbidity in the last 2 weeks for the child will be collected longitudinally through an interviewer-administered questionnaire to the mother every 2 months.
7. Satisfaction with the intervention, facilitating and limiting factors. Data will be collected through a self-administered questionnaire to the mother. Additionally, qualitative interviews will be conducted with the mothers and community members including community health workers on experiences with the intervention.

Overall study start date
01/11/2014

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Pregnant women who consent to participate in the study
2. Aged between 15 - 49 years old in Koibatek sub-county, Baringo County, Kenya

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
800

Key exclusion criteria

1. Women of reproductive age who will have given birth before receiving at least one counselling session particularly regarding exclusive breastfeeding.
2. Women who lose the pregnancy and/or have a still-birth
3. Women who are lost to follow-up during pregnancy
4. Mother-child pairs of children with a disability that makes delivery of the intervention difficult e.g. hearing or sight problem, or mental handicap

Date of first enrolment
01/11/2014

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
Kenya

Study participating centre
PO Box 43844
Nairobi
Kenya
00100

Sponsor information

Organisation
National Academy of Sciences (NAS) (USA)

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Sponsor type
Research organisation

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ROR
https://ror.org/038mfx688

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health (NIH) (USA)

Alternative Name(s)
Institutos Nacionales de la Salud, US National Institutes of Health, NIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Funder Name
United States Agency for International Development (USAID) (USA)

Alternative Name(s)
U.S. Agency for International Development, Agency for International Development, USAID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Funder Name
Through the Partnership for Enhanced Engagement in Research (PEER) Health Program, through the National Academies of Science (NAS) (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/09/2015		Yes	No
Results article	results	08/05/2018		Yes	No