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Determination of whether one-on-one counselling of mothers in their houses improves their infant feeding practices and eventually nutritional and health status of the child in two slums in Nairobi - Maternal Infant and Young Child Nutrition study (MIYCN)

Submission date
26/11/2012

Recruitment status
No longer recruiting

Registration date
28/11/2012

Overall study status
Completed

Last Edited
11/05/2020

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims:
Under nutrition is a major contributor to poor health, and is associated with a large number of child deaths. It is also related to poor performance in school and other diseases e.g. diabetes later in life. Proper breastfeeding with babies and feeding in young children is known to reduce the levels of under nutrition in children. However, poor breastfeeding and young child feeding practices are common in Kenya, and particularly so in the urban slums. The aim of this study is to determine whether counselling of mothers on one-on-one basis at their houses by community health workers will improve their breast feeding and infant and young child feeding practices and eventually whether this will improve nutritional and health status of their children.

Who can participate?
All pregnant women aged between 12-49 years old in Korogocho and Viwandani, and their children (when born)

What does the study involve?
The villages in each slum will be randomly allocated to receive either the one-on-one counselling sessions or usual counselling. The mother-child pairs in both one-on-one counselling sessions and usual counselling groups will be followed up from recruitment (during pregnancy) till the child is one year. During the follow-up period, data will be collected from the mother child-pair including information on breastfeeding and infant feeding knowledge, attitudes and practices; information on child morbidity status; anthropometric measurements of both the mother and the child including height, weight and mid-upper arm circumference; and body composition measurements to determine the fat percentage of the mother and the child; and blood pressure among the mothers.

What are the possible benefits and risks of participating?
It is expected that the counselling sessions (if effective) will improve the nutritional status of the mother, infant feeding practices and eventually the nutritional and health status of the child. Those receiving normal counselling will benefit from obtaining information materials on maternal, infant and young child nutrition. A proportion of the children in the study will be severely malnourished, so we plan to support rehabilitation centres in the study sites where we hope to refer severally malnourished children for nutritional support. 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. The study will use DXA (Dual energy x-ray absorptiometry) equipment to measure for body fat. This has some radiation emissions, but this is extremely low, and is not known to cause harm to human beings.

Where is the study run from?
African Population and Health Research Center (APHRC) (Kenya)

Where does the study take place?
In two slums of Nairobi, Kenya: Korogocho and Viwandani.

When is the study starting and how long is it expected to run for?
Recruitment of participants began in September 2012 and will continue for a period of 6 - 9 months. Follow-up of the participants will run until around August 2014. It is hoped that an additional grant will be awarded to allow the follow up to continue until the children are 5 years old (until 2018).

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Dr Elizabeth Kimani
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Effectiveness of personalized home-based nutritional counselling of pregnant and lactating mothers on infant feeding practices, morbidity and nutritional status of infants in Nairobi slums: a cluster randomized controlled trial

Acronym
MIYCN

Study objectives
Personalized home-based counselling of mothers in Nairobi slums by community health workers on their own nutrition, breastfeeding and infant and young child feeding will improve their nutritional status, breastfeeding and complementary feeding practices. This will in turn improve the childs nutritional status and reduce their morbidity from common childhood illnesses particularly diarrhoea.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kenya Medical Research Institute (KEMRI), Nairobi, 22/03/2012; ref: KEMRI/RES/7/3/1

Primary study design
Interventional

Study design
Prospective cluster randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Nutritional status

Interventions
The intervention will involve personalised, home-based counselling of pregnant and lactating women on maternal, infant and young child nutrition. Pregnant women in the treatment group will be visited by community health workers on a regular basis throughout pregnancy and until the child is one year. 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. Pregnant women in the control group will only receive information materials on maternal, infant and young child nutrition. They will also be visited by community health workers to be advised regarding their pregnancy including on antenatal clinics and necessary tests during pregnancy and importance of health facility as part of the standard care in the Kenyan health care system. The mother-child pair in both the treatment and control groups will be followed-up from pregnancy till the child is one

year old (with the current grant), but it is anticipated that an extension grant will be sought to allow follow-up until the child is five years old.

Intervention Type
Behavioural

Primary outcome(s)
1. Knowledge, attitudes and practices regarding breastfeeding, infant and young child feeding; measured using questionnaire administered to the mother. Data will be collected every two months during pregnancy and every month during the childs first year of life
2. Child morbidity from diarrhoea; 14-day recall by the mother /caregiver using a questionnaire; Data will be collected every month during the childs first year of life
3. Child nutritional status; determined using data on anthropometric measurements (height, weight, mid-upper-arm circumference) and body composition determined using DXA machine. Anthropometric measurements will be taken every month during infancy while body composition assessment will be done at three months and at the end of infancy

Key secondary outcome(s)
1. Maternal nutritional status; determined using data on anthropometric measurements (height, weight, mid-upper-arm circumference) and body composition determined using stable isotope technique. Anthropometric measurements will be taken every two months during pregnancy and during the first year of the childs life, while body composition assessment will be done at recruitment and in the third pregnancy trimester on a 10% sample of women
2. Child motor development; self-reported by the mother/caregiver using questionnaire and direct observation every month during the childs first year of life
3. Morbidity from other childhood illnesses other than diarrhoea e.g. respiratory illnesses; 14-day recall by the mother /caregiver using a questionnaire; Data will be collected every month during the childs first year of life
4. Cost-effectiveness

Completion date
31/08/2014

Eligibility

Key inclusion criteria
1. Pregnant women who consent to participate in the study
2. Aged between 12 - 49 years old in Korogocho and Viwandani, Nairobi
3. Members of the NUHDSS and their respective children (when born)

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex

Female

Total final enrolment
1001

Key exclusion criteria
Women who are recruited but give birth before receiving the first (counselling) visit by the community health worker

Date of first enrolment
01/09/2012

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
Kenya

Study participating centre
African Population & Health Research Center (APHRC)
Nairobi
Kenya
00100

Sponsor information

Organisation
African Population & Health Research Center [APHRC] (Kenya)

ROR
https://ror.org/032ztsj35

Funder(s)

Funder type
Research organisation

Funder Name
Wellcome Trust (UK) ref: 097146/Z/11/Z

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

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?
Results article	results	19/12/2017		Yes	No
Results article	results	01/04/2019	11/05/2020	Yes	No
Protocol article	protocol	27/12/2013		Yes	No