ISRCTN34314544 https://doi.org/10.1186/ISRCTN34314544

Effects of structured nutrition education on maternal perceptions, and exclusive breastfeeding duration in Kiandutu health centre, Thika - Kenya

Submission date
02/02/2017

Recruitment status
No longer recruiting

Registration date
21/04/2017

Overall study status
Completed

Last Edited
06/06/2023

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Background and study aims
Breastfeeding has been shown to be important for the health, nutrition and survival of children. This is especially the case in developing countries, where there are high rates of infectious diseases and a lack of good nutrition. Despite this, exclusive breastfeeding rates in Kenya are low, particularly in city slums. This study is looking at a personalized nutrition education program that encourages exclusive breast feeding (EBF) for the first six months and is tailored to improve mothers' breastfeeding self-efficacy. The aim of this study is to look at the effectiveness of this program at improving EBF rates and breast feeding self-efficiency.

Who can participate?
Healthy pregnant women.

What does the study involve?
Participating villages are randomly allocated to one of two groups. Those in the first group take part in the education program. This involves listening to a talk at the health centre about the importance of a proper diet during pregnancy and while breast feeding, and information about the value of breastfeeding to children's health. Those in the second group continue as normal for the duration of the study. Participants in both groups are followed up twice during pregnancy and once a month after they have given birth for six months to find out how many women are exclusively breastfeeding their babies and their views about breastfeeding.

What are the possible benefits and risks of participating?
Participants who take part in the education program benefit from learning about the importance of a good diet and breastfeeding, which could encourage them to eat more healthily and to breastfeed their baby. There are no direct risks involved with participating.

Where is the study run from?
1. Kianhutu Health Centre (Kenya)
2. Makongeni Health Centre (Kenya)

When is the study starting and how long is it expected to run for?
February 2012 to October 2014

Who is funding the study?
National Commission of Science Technology and Innovation (Kenya)

Who is the main contact?
Ms Dorothy Mituki

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EU/DVRE/028

Study information

Scientific Title
Effects of structured nutrition education on maternal perceptions, and exclusive breastfeeding duration in Kiandutu health centre, Thika - Kenya: A cluster randomized controlled study

Study objectives
Null hypotheses:
1. There is no significant difference in socio-economic, household food security and post-partum

factors between mothers in the structured nutrition education group and the comparison group
2. There is no significant difference in BSE and breastfeeding perceptions for mothers in the two groups at baseline
3. There is no significant difference in BSE and breastfeeding perceptions for mothers in the two groups before and after the intervention
4. There is no significant difference in BSE and breastfeeding perceptions for mothers in the intervention and those in the comparison groups after the intervention
5. There is no significant relationship between socio-economic, household food security post-partum factors, BSE, breastfeeding perceptions and EBF duration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Egerton University Ethics Committee, 07/06/2013, ref: EU/DVRE/028

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

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
Breastfeeding

Interventions
The participating villages are randomized to one of two groups in a 1 :1 ratio using the Microsoft excel function.

Intervention group: Participants receive personalized nutrition education at the health facility. This involves a talk on the importance of proper diet during pregnancy and lactation, including dietary diversity, the value of exclusive breastfeeding and the fact that all women can practice EBF with a positive mind set. It will also involve giving them information on how to deal with issues relating to breastfeeding. The content is developed from the Kenyan maternal infant and young child guidelines (which is developed from the UNICEF/WHO maternal infant and young child guidelines). Participants are followed up in their homes by Community Health Workers (CHWs) for 2 times during pregnancy at ≤ 28 and 37 weeks gestation and every month after delivery up to six months post-partum.

Comparison group: Participants receive standard care for the duration of the study. This involves group nutrition education and general health issues done by the health care workers at the facility

Follow up for all participants involves taking their 24 hour recall and weight data at 1, 6, 10 and 14 weeks and 6 months at the study facility.

Intervention Type
Behavioural

Primary outcome measure
Exclusive breastfeeding rate is measured using the 24 hour recall at 1, 6, 10 and 14 weeks and 6 months.

Secondary outcome measures
1. Breastfeeding self-efficacy is measured using the breast feeding self efficacy scale (short form) (BSES-SF) at baseline (34 weeks) at mid (37 weeks) and at end of intervention (6 months)
2. Perceptions towards exclusive breastfeeding is measured using the Deborah McCarter-Spaulding perceptions scale at baseline (34 weeks) at mid (37 weeks) and at end of intervention (6 months)

Overall study start date
12/02/2012

Completion date
05/10/2014

Eligibility

Key inclusion criteria
1. Women who are less than six months gestation
2. No history of chronic disorders such as hypertension, diabetes, HIV and tuberculosis
3. Aged 18 years and over

Participant type(s)
Other

Age group
Other

Lower age limit
18 Years

Sex
Female

Target number of participants
Healthy pregnant owmen, 157 mothers per arm

Total final enrolment

526

Key exclusion criteria
1. Preterm delivery and Infants delivered less than 37 weeks gestation
2. Multiple births, only mothers with singletons continued in the study
3. Low birth weight (below 2500gms)
4. Those who give bitch to children born with congenital disorders

Date of first enrolment
03/09/2013

Date of final enrolment
02/10/2014

Locations

Countries of recruitment
Kenya

Study participating centre
Kianhutu Health Centre
Thika-Garissa Highway
Off Broadways Primary School
P.O BOX 3,304
Madaraka Thika
Kenya
01002

Study participating centre
Makongeni Health Centre
Thika-Garissa Highway
P.O BOX 1,747
Madaraka Thika
Kenya
01002

Sponsor information

Organisation
National Commission of Science Technology and Innovation

Sponsor details

8th -9th Floor, Utalii House
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Sponsor type
Research council

Website
http://www.nacosti.go.ke

ROR
https://ror.org/03wzc0b85

Funder(s)

Funder type
Government

Funder Name
National Commission of Science Technology and Innovation

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
30/05/2017

Individual participant data (IPD) sharing plan

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		28/04/2020	06/06/2023	Yes	No