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Implementation of a baby-friendly workplace support initiative and assessment of its feasibility and success in improving mother and child nutrition and health

Submission date
28/10/2016

Recruitment status
No longer recruiting

Registration date
21/12/2016

Overall study status
Completed

Last Edited
04/10/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Breastfeeding is the best way of providing newborns with the nutrients they need for healthy growth and development. Unfortunately, statistics show poor adherence to the WHO breastfeeding advice to feed the newborn only breast milk for six months (exclusive breastfeeding). Several studies have reported employment as an obstacle to breastfeeding, with reduced breastfeeding rates among employed mothers after returning to the workplace. Interventions that promote breastfeeding are important for child growth, development and survival, and the well being and productivity of mothers and their families, and therefore to achieving sustainable development. Workplace support for breastfeeding is key to sustainable development as it has an impact on the well being of the employees, their economic productivity, and the growth and development of their children through mothers practicing the best breastfeeding and care practices. The aim of this study is to test a model of workplace support for breastfeeding in a tea plantation in Kericho County, Kenya.

Who can participate?
Women of reproductive age (12-49) who are employees of the tea farm, and their children aged less than one year. Male employees, other community members including fathers and grandmothers of the children, community leaders, healthcare workers, policy and decision makers and employers, including managers and supervisors, also participate.

What does the study involve?
A survey is carried out before the intervention starts. A group of women are followed-up and monitored over 12 months. The data from the start and the end of the study are compared to assess any changes that might have resulted due to the intervention. Photos and videos are also taken by a group of women employees to describe their workplace and community environment and conditions and enable them to express their views on working and breastfeeding. The women have an opportunity to hold exhibitions to tell their stories and share their experiences and views to key decision makers like managers of the tea plantation, the Ministry of Health and

UNICEF. To determine whether the community is ready for the intervention, interviews are also conducted with community members/employees, employers, the county health management team, and the county government.

What are the possible benefits and risks of participating?
The participants do not receive any direct benefit for participating in the study but the information they give will be useful in informing policy and interventions that could benefit their community as a whole. No risks are anticipated. However, to minimize any unforeseeable risks or discomforts that might be posed to the participants the training of the data collectors will be key. The data collectors are made aware of the importance of minimizing participants' discomfort and of the absolute requirement of confidentiality. At the end of the interviews, participants are given the opportunity to speak to someone about any issues covered in the interviews. A letter of agreement with the tea estate is signed to ensure that the participants are protected from victimization by the management. The identifying details of the participants are collected in a different form from the survey questionnaire for anonymity. Therefore the researchers do not anticipate any risk or harm to the participants as a result of their participation in this study.

Where is the study run from?
The study is run by the African Population and Health Research Center and will take place in an identified tea estate in Kericho County, Kenya

When is the study starting and how long is it expected to run for?
January 2016 to December 2017

Who is funding the study?
UNICEF

Who is the main contact?
Dr Elizabeth Kimani
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HCS/2016/0095

Study information

Scientific Title
Evidence-based implementation of baby-friendly workplace support initiative and evaluation of its potential feasibility and effectiveness on improving maternal and child nutrition and health

Acronym
KBFWI

Study objectives
1. The workplace support initiative has no effect on the breastfeeding practices, nutritional status, health and well-being of mothers and their children
2. The workplace support initiative is not cost-effective from the employer's perspective

Ethics approval required
Old ethics approval format

Ethics approval(s)
AMREF Ethical Scientific and Research Committee, 19/05/2016, ref: P231_2016

Study design
Interventional single-center study that will use an evidence-based mixed method approach combining effectiveness-implementation hybrid trials and participatory action research methods

Primary study design
Interventional

Study type(s)
Quality of life

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

Interventions
The intervention aims to provide an enabling environment for mothers, working in a tea plantation in Kenya, to combine breastfeeding and work. The implementation design will be refined after a baseline formative study (qualitative, quantitative and participatory data collection) that will be conducted before the intervention begins. All pregnant women in the study community will be identified and recruited by peer educators at the community level before the beginning of the intervention. These women will be followed up after birth till the end of the implementation period. The implementation will be guided by the Baby-Friendly Community Initiative (BFCI) and the workplace support guidelines launched by the Ministry of Health (MoH) in 2015 and a bill of parliament passed in April 2016 that mandates employers to provide a breastfeeding friendly workplace through providing time, space and support for breastfeeding working mothers. The actual implementation design will be refined after the

baseline formative study that will be conducted at the beginning of the project before the implementation of the intervention begins.

The implementation phase will be for 12 months, this period will be adequate to have an effect on the duration of exclusive breastfeeding, and its potential effect on other outcomes including work participation and productivity and nutritional and health outcomes of the infants.

During the implementation phase, all pregnant women recruited during the pre-implementation phase will be followed up for the period of the implementation phase (12 months). During midline, qualitative and quantitative assessments will be conducted. Additionally, innovative participatory methods will be used to document changes and experiences. A detailed case-study of good practices in Kenya with extensive literature review will also take place.

Intervention Type
Behavioural

Primary outcome(s)
Duration of exclusive breastfeeding, measured using surveys at baseline and end-line using 24 hour recall

Key secondary outcome(s))
1. Nutritional status of infants, determined using anthropometric measurements (height and weight, mid-upper arm circumference) at baseline and endline. It will also be collected from postpartum women (recruited at baseline while pregnant to be part of a cohort) within the 1st month post-delivery and thereafter monthly during the implementation period.
2. Breastfeeding practices, including continued breastfeeding with complementary feeding, measured at baseline and endline. It will also be collected from postpartum women (recruited at baseline while pregnant to be part of a cohort) within the 1st month post-delivery and thereafter monthly during the implementation period.
3. Morbidity of children using 14 days recall, measured at baseline and endline from all mothers with children under 1 year. It will also be collected from the cohort follow-up women (pregnant women recruited at baseline) within the 1st month post-delivery and thereafter monthly during the implementation period.
4. Work participation and productivity of women working in tea plantations, assessed using a presenteeism and absenteeism scoring method at baseline and endline using a mixed method approach (qualitative and quantitative methods). Qualitatively the trialists will seek to answer questions regarding current workplace conditions and the perceived effects on health, wellbeing, work participation and productivity of the workers. In addition, process evaluation during the implementation phase will be conducted. This will be through observations for changes in community workplace conditions and support, references to guidelines, using checklists, and obtaining monthly records on work participation and productivity for breastfeeding women. At mid-term, in-depth interviews and focus group discussions will be conducted with women and men on their experiences with community workplace support and their satisfaction and potential areas of improvement.
5. Cost effectiveness of the intervention from the employer and societal perspectives:
5.1. The return on investment, considering the costs to the business of implementing the intervention and using the data captured in the surveys (at baseline, mid and endline) on worker absenteeism and productivity. Average differences in productivity and days in work will be estimated. The effects of changes in the labour force such as retention of high performing staff, maintenance of a skilled workforce, improved morale and hence motivation and reputation benefit will be estimated from the quantitative interviews. Healthcare utilization will also be

accounted for as this is provided by the employer.
5.2. The health cost-effectiveness of the intervention in terms of a cost per DALY (Disability Adjusted Life Years). Healthcare costs and utilization and the DALYs associated with the observed change in breastfeeding rates will be identified from the literature.

Completion date
30/09/2018

Eligibility

Key inclusion criteria
1. The primary participants are women of reproductive age (12-49) who are employees of a tea farm in Kericho County, Kenya, and their children aged less than one year
2. Other participants include their employers including managers at the tea farm, male employees and other community members including fathers, and grandmothers (of the children), community leaders, health care workers, policy and decision makers

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
832

Key exclusion criteria
The intervention/trial will not exclude anyone. However, the research will exclude eligible participants who have physical or intellectual impairment that could hinder clear communication e.g. deaf or dumb participants

Date of first enrolment
19/09/2016

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
Kenya

Study participating centre

Tea farm in Kericho County
Kenya
-

Sponsor information

Organisation
African Population and Health Research Center

ROR
https://ror.org/032ztsj35

Funder(s)

Funder type
Charity

Funder Name
UNICEF

Alternative Name(s)
United Nations Children's Fund, United Nations Children's Emergency Fund, United Nations International Children's Emergency Fund, Fonds des Nations Unies pour l'enfance, Fondo de las Naciones Unidas para la Infancia, ,

Funding Body Type
Government organisation

Funding Body Subtype
International organizations

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The qualitative and quantitative datasets generated during and/or analysed during the current study will be stored in the APHRC Microdata Portal (microdata.aphrc.org or http://aphrc.org /catalog/microdata/index.php/catalog). External users (non-APHRC staff) and collaborative partners will fill an online request form and commit to abide by the guidelines for data use specified on the form. Authorization will be granted by the Director or Research, in consultation

with the concerned Principal Investigator and Program Leader. The data will be made available to users through the APHRC Microdata Portal. While decisions to grant authorization will be made on a case by case basis, the APHRC data sharing guidelines will apply in considering such applications. Data requests will be processed within five working days. After the request is submitted, a confirmation email will be sent to the applicant. Once the data request processed, a notification email will be sent to the applicant. In case of approval, the email will provide instructions for free download of the requested datasets. All datasets shared through the APHRC Microdata Portal are fully anonymized with all individual identifiers removed and noise added on sensitive variables (i.e., longitudinal datasets). The following restrictions apply:
1. APHRC and the relevant funding agencies bear no responsibility for use of the data or for interpretations or inferences based upon such uses.
2. The data access agreement will come into force on the date the approval is given for access to the data sets and remains in force until the completion date of the project or an earlier date if the project is completed ahead of time.
3. If there are any changes to the project specification, security arrangements, personnel or organization detailed in this application form, it is the responsibility of the Applicant to seek the agreement of the APHRC Director of Research to these changes. Where there is a change to the Applicant's organization this will involve a new application being made and termination of the original project.
4. Breaches of the agreement will be taken seriously and APHRC will take action against those responsible for the lapse if willful or accidental. Failure to comply with APHRC's directions will be deemed to be a major breach of the agreement and may involve recourse to legal proceedings. APHRC will maintain and share with relevant authorities/partners a register of those individuals and organizations which are responsible for breaching the terms of the Data Access Agreement and will impose sanctions on release of future data to these parties.

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/04/2021	04/10/2021	Yes	No
Protocol article		01/01/2021	04/10/2021	Yes	No