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Evaluation of the feasibility and effectiveness of a health facility-based combined with home-based early childhood development (ECD) intervention in Siaya County, Kenya

Submission date
13/06/2018

Recruitment status
No longer recruiting

Registration date
03/07/2018

Overall study status
Completed

Last Edited
23/08/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
About 250 million (43%) children aged under five years in low- and middle-income countries are at risk of not reaching their developmental potential. Sub-Saharan Africa has the highest percentage at 67% due to exposure to multiple risks, including poverty, malnutrition, poor health, and inadequate stimulation at home. In order to promote early childhood development (ECD), PATH is supporting the Ministry of Health in Siaya County to integrate ECD counselling and screening into routine facility-based health services and facilitate playbox sessions in health facility waiting areas, and further integrate parental counselling on early stimulation into home-based visits by community health workers. The aim of this study is to evaluate the feasibility and effectiveness of a healthcare system-integrated ECD intervention in terms of improvements in mother/caregiver ECD knowledge, attitudes and practices, as well as child growth and developmental outcomes. Furthermore, the study will also estimate the cost and cost-effectiveness of the intervention from the provider's perspective.

Who can participate?
Pregnant women aged 15+ years who are in their third trimester, using the ANC services in the selected facilities

What does the study involve?
Participants are randomly allocated into one of three groups. In group 1, mothers and children receive the health facility-based ECD intervention integrated into the routine facility-based Ministry of Health service touch-points. In addition, they receive home visits from Community Health Volunteers (CHVs) per the Ministry of Health-mandated schedule, but these home visits do not include any ECD content. In group 2, mothers and children dyads receive the health facility-based ECD intervention combined with the home-based ECD intervention integrated into routine CHV home visits. In group 3, mothers and children receive the current Ministry of Health standard care only, which includes routine immunization and supplementation services and CHV home visits that do not include ECD content. The mothers' knowledge, attitudes and practices

regarding ECD (stimulation and responsive caregiving) is assessed using a structured questionnaire at the last trimester of pregnancy and at child age 2 months, 10 months, 18 months and 27 months.

What are the possible benefits and risks of participating?
The participants do not receive any direct benefit for participating in the study. However, the information they provide will be useful in informing policy and interventions that would benefit children and their community as a whole. The researchers do not anticipate any risk or harm to the participants as a result of this study beyond what they experience in their day to day activities.

Where is the study run from?
Bondo Sub-County (Kenya)

When is the study starting and how long is it expected to run for?
May 2018 to October 2021

Who is funding the study?
ELMA Foundation (South Africa)

Who is the main contact?
Dr Elizabeth Kimani

Contact information

Type(s)
Scientific

Contact name
Dr Elizabeth Kimani

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HCS/2016/14

Study information

Scientific Title
Evaluation of the feasibility and effectiveness of a health facility-based combined with home-based early childhood development (ECD) intervention in Siaya County, Kenya

Study objectives
1. The health facility-based and health facility-based plus home-based ECD intervention will result in high scores in terms of mother/caregiver ECD knowledge, attitudes and practices
2. The health facility-based and health facility-based plus home-based ECD intervention will result in a higher proportion of children aged 0-3 years achieving their developmental milestones, compared to those in the control group
3. The health facility-based and health facility-based plus home-based ECD intervention are operationally feasible in Kenya.
4. The health facility-based and home-based ECD interventions are cost-effective in Kenya
5. There is an incremental advantage of the health facility-based plus home-based ECD intervention over the health facility based only intervention in terms of effect on caregiving practices and child growth and developmental outcomes for children aged 0-3 years

Ethics approval required
Old ethics approval format

Ethics approval(s)
Amref Health Africa Ethics and Scientific Review Committee, 16/03/2017, ref: P314/2017

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Child growth development

Interventions
Method of randomization: matched pairs design randomization.

Arm 1: mother/caregiver-child dyads will receive the health facility-based ECD intervention that will be integrated into the routine facility-based MOH service touch-points previously indicated. In addition, they will receive home visits from CHVs per the MOH-mandated schedule, but these home visits will not integrate any ECD content.
Arm 2: mother/caregiver-child dyads will receive the health facility-based ECD intervention combined with the home-based ECD intervention that will be integrated into routine CHV home visits.
Arm 3: mother/caregiver-child dyads will receive the current Ministry of Health's standard care only, which includes routine immunization and supplementation services mentioned previously and CHV home visits that do not integrate ECD content.

Intervention Type
Behavioural

Primary outcome measure
Caregiver's knowledge, attitudes and practices regarding early child development (stimulation and responsive caregiving), assessed using structured questionnaire at:
T0 (Pre-birth) last trimester of pregnancy
T1 (Month 1-2) at child age 2 months
T2 (Month 9-10) at child age 10 months
T3 (Month 17-18) at child age 18 months
T4 (Month 25-28) at child age 27 months

Secondary outcome measures
1. Child growth and developmental outcomes, assessed using Ages and Stages Questionnaire Version 3 (ASQ-3)
2. Caregiver practice, assessed using Multiple Indicator Cluster Survey (MICS)
3. Operational feasibility and cost and cost-effectiveness of the health facility-based plus home-based ECD intervention

Measured at:
T0 (Pre-birth) last trimester of pregnancy
T1 (Month 1-2) at child age 2 months
T2 (Month 9-10) at child age 10 months
T3 (Month 17-18) at child age 18 months
T4 (Month 25-28) at child age 27 months

Overall study start date
17/05/2018

Completion date
10/10/2021

Eligibility

Key inclusion criteria
1. Pregnant women aged 15+ years who are in their third trimester
2. Using the ANC services in the selected facilities
3. Provide consent to participate in the study
4. All the children will be recruited shortly after birth - this will include children with any form of disability as the intervention also targets such children

Participant type(s)
Mixed

Age group
Mixed

Sex
Female

Target number of participants
699

Key exclusion criteria
Caregivers with mental impairment

Date of first enrolment
17/05/2018

Date of final enrolment
08/08/2018

Locations

Countries of recruitment
Kenya

Study participating centre
Bondo Sub-County
Kenya
40601

Sponsor information

Organisation
African Population and Health Research Center

Sponsor details
PO Box 10787
Nairobi
Kenya
00100

Sponsor type
Research organisation

Website
www.aphrc.org

ROR
https://ror.org/032ztsj35

Funder(s)

Funder type
Charity

Funder Name
ELMA Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
South Africa

Results and Publications

Publication and dissemination plan
The trialists expect to submit the protocol for publication after the registration process is complete. To communicate the study findings, they have set plans to publish at least three articles in Open Access peer-reviewed scientific journals. One article will be published soon after baseline analysis in December 2018. The remaining articles will be published after the midline and endline data analysis at least one year after the end of the intervention.

Intention to publish date
10/10/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Elizabeth Kimani-Murage (info@aphrc.org). The study will use a mixed methods approach combining both quantitative and qualitative data collection methods, records review, checklists, and direct measurements. In line with APHRC's data sharing policies and with approval of the partners (funding agency) the primary data will be made available in a timely manner and in an anonymized, user-friendly format to external users through the online APHRC Microdata Portal. The data will be released to the public domain two years after the release of

analytical data sets (i.e. after finalization of data cleaning). The 24-month embargo will enable the research team to finalize publications addressing core study objectives and allow other interested host organization staff to use the data. Graduate students seeking to use the data for writing their theses and dissertations before the embargo can be given permission to use such data if they are supervised by collaborative partners or if they are former employees of APHRC. Difference-in-Differences (DID) will be used as the main analytical method of the data since the study design is a cluster randomised controlled trial with before and after measurement on the same individuals. The DID will be used to estimate the average difference between outcome values for the two groups (intervention and control groups) at baseline and during the follow up periods. For the qualitative data, the trialists will develop codes and identify emerging themes. They have an informed consent document which comprises an information sheet and consent certificate. Participants' consent is sought during the recruitment process, and will be sought at future contact periods when data is being collected. The trialists have already obtained scientific approval from the internal scientific review committee at the African Population and Health Research Center (APHRC). Ethical approval was sought and obtained from the Amref Health Africa's Ethical and Scientific Review Committee (ESRC).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/03/2022	23/08/2023	Yes	No