

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	☐ Prospectively registered ☐ Protocol
Registration date 03/07/2018	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 23/08/2023	Condition category Other	☐ 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

Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Cluster randomized controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

Female

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

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

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