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The impact of diverse complementary foods on improving children's nutrition in Makueni County, Kenya

Submission date
21/03/2025

Recruitment status
No longer recruiting

Registration date
24/03/2025

Overall study status
Completed

Last Edited
06/02/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Malnutrition is still widespread in low-income settings. According to the 2022 Kenya Demographic and Health Survey, the prevalences of stunting, underweight and wasting were 17.6%, 10.1% and 4.9%, respectively. In addition, the prevalence of micronutrient deficiencies is high in sub-Saharan Africa with more than half of the global micronutrient malnutrition cases. One of the affected counties is Makueni, where the malnutrition levels are at or above the average. Optimal complementary feeding practices are important to prevent malnutrition. In Kenya, only 31% of 6-23-month-old children receive a minimum acceptable diet (MAD). There is, therefore, a need to develop sustainable strategies that families can use to improve the health and nutrition status of their children. Kenya has made considerable efforts to address its nutrition gap by developing National Food Recipes. However, the developed recipes target the general population with little or no attention to complementary feeding. In addition, the country has a wide range of cultures, diverse diets and methods of food preparation. This points to the need to develop complementary feeding recipes specific to the different community groups. Furthermore, community involvement in the development of recipes has the potential to enhance recipe acceptability and the use of behaviour change strategies may further improve child nutrition and household dietary intake. The current trial will assess the effect of a diversified complementary food intervention based on co-created recipes combined with behaviour change strategies on the diet quality and nutritional status of young children in Makueni County, Kenya.

Who can participate?
Children aged 6-18 months old whose family intends to stay in the catchment area. Children with severe acute malnutrition or known critical or chronic conditions that may affect the nutrition status of the child are excluded from the study.

What does the study involve?
This is a community-based controlled trial that tests the effectiveness of a diversified complementary food intervention on the diet quality and nutritional status of young children. Children will be enrolled at 4 study sites and followed for a period of 6 months. At two

intervention sites, caregivers will receive nutrition counselling according to national guidelines as well as training in the use of kitchen gardens and drying vegetables to bridge the seasonal gap in vegetable availability. They will also have demonstration cooking, and tasting sessions and receive thorough training in the preparation of healthy diversified complementary food according to recipes prepared through a co-creation recipe development process. Recipe booklets will be given to primary caregivers with further support on home preparation to help improve their child feeding practices. The primary caregivers will be encouraged to prepare and feed their children using the developed recipes. At two control sites, caregivers will receive nutrition counselling according to national guidelines as well as training in the use of kitchen gardens and drying vegetables to bridge the seasonal gap in vegetable availability.

What are the possible benefits and risks of participating?
Children in the study will benefit from the close monitoring by nutritionists and health personnel. Training of community health promoters, community staff and caregivers will build capacity and enhance awareness of child malnutrition and early nutrition counseling.
The intervention uses local market food and homegrown food items. Risks included spoiled food or unknown allergies, but caregivers will be trained in good food hygiene. Blood samples will be collected by trained nurses, but may cause temporary discomfort to the children. The study team will ensure children's safety throughout the study. Only child-friendly, competent staff and researchers will be involved, minimizing risks and addressing any safety concerns. Measures will be in place to protect children, mothers, families and communities during the study and dissemination of findings.

Where is the study run from?
The study is conducted at four health centres in Makueni County, Kenya: Kathonzweni, Mbuvo, Kitise, Kanzokea

When is the study starting and how long is it expected to run for?
August 2024 to December 2025

Who is funding the study?
The European Union HORIZON EUROPE programme grant: Healthy Diets 4 Africa.

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effectiveness of diversified complementary food on diet quality and nutritional status among children 6-18 months old: A cluster randomized controlled trial in Makueni County, Kenya

Acronym
HD4A-RCT-KE

Study objectives
A diversified complementary food intervention based on recipe co-creation increases the diet quality and the nutritional status (anthropometry, body composition, serum vitamin A and iron status) of children aged 6-24 months

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/01/2025, Kenyatta University Ethics Review Committee (Kenyatta University, Nairobi, PO Box 43844, Kenya; +240 8710901/12; chairman.kuerc@ku.ac.ke), ref: PKU/3098/I3022

Study design
Cluster randomized community-based controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of malnutrition in 6-24 month-old children

Interventions
This is a cluster randomized, community-based controlled trial, which tests the effectiveness of a diversified complementary food intervention on diet quality and nutritional status of young children. Children will be enrolled at 6-18 months of age and followed for 6 months.

The intervention group will receive nutrition counselling according to national guidelines as well as training in the use of kitchen gardens and drying vegetables to bridge the seasonal gap in vegetable availability. They will also have demonstration cooking, and tasting sessions and receive thorough training in the preparation of healthy diversified complementary food according to recipes prepared through a co-creation recipe development process. Recipe booklets will be given to primary caregivers with further support on home preparation to help improve their child feeding practices. The primary caregivers will be encouraged to prepare and feed their children using the developed recipes. To promote long-term behaviour change, specific strategies developed through the Capability, Opportunity, Motivation - Behaviour (COM-B) change model will be implemented alongside the recipe demonstration and training.

The control group will receive nutrition counselling according to national guidelines as well as training in the use of kitchen gardens and drying of vegetables to bridge the seasonal gap in vegetable availability.

Intervention Type
Behavioural

Primary outcome(s)
The number of food groups consumed measured using the Minimum Dietary Diversity (MDD) questionnaire at baseline, 1, 2, 3, 4, 5, and 6 months

Key secondary outcome(s))
1. Proportion meeting minimum dietary diversity score measured using the MDD questionnaire at baseline, 1, 2, 3, 4, 5, and 6 months
2. Proportion meeting minimum acceptable diet measured using the MDD questionnaire + minimum meal/milk frequency at baseline, 1, 2, 3, 4, 5, and 6 months
3. Weight gain (g) measured using a standard paediatric weighing scale to the nearest 100 g at baseline, 1, 2, 3, 4, 5, and 6 months
4. Mid-upper arm circumference (cm) (MUAC) measured using a non-elastic MUAC tape at baseline, 1, 2, 3, 4, 5, and 6 months
5. Length (cm) measured using a Seca length board to the nearest 0.1 cm at baseline, 1, 2, 3, 4, 5, and 6 months
6. Length-for-age z-score calculated using AnthroPlus software at baseline, 1, 2, 3, 4, 5, and 6 months
7. Weight-for-length z-score calculated using AnthroPlus software at baseline, 1, 2, 3, 4, 5, and 6 months

8. Weight-for-age z-score calculated using AnthroPlus software at baseline, 1, 2, 3, 4, 5, and 6 months
9. Body composition (fat-free mass (kg), fat mass (kg), fat-free mass index (kg/cm2), fat mass index (kg/cm2)) measured using bioelectrical impedance analysis at baseline and 6 months
10. Haemoglobin (g/L) measured using Hemocue at baseline and 6 months
11. Inflammation-corrected serum ferritin (ug/L) measured using high throughput ELISA at baseline and 6 months
12. Serum soluble transferrin receptor (mg/L) measured using high throughput ELISA at baseline and 6 months
13. Serum C-reactive protein (mg/L) measured using high throughput ELISA at baseline and 6 months
14. Serum alpha-1-acid glycoprotein (g/L) measured using high throughput ELISA at baseline and 6 months
15. Inflammation-corrected retinol-binding protein measured using high throughput ELISA at baseline and 6 months
16. Insulin-like growth factor-1 measured using Cobas instrument at baseline and 6 months
17. Adverse events measured using study records at 1, 2, 3, 4, 5, and 6 months
18. Care-giver reported morbidity measured using caregiver recall (the last 2 weeks) at baseline, 1, 2, 3, 4, 5, and 6 months
19. Proportion lost to follow-up, measured using study records, calculated as the number of children/caregivers who do not come for a follow-up visit within a visit window of 14 days/total number of children enrolled at baseline, 1, 2, 3, 4, 5, and 6 months
20. Percentage of caregivers using the prepared recipes to feed their children measured using study records, calculated as the number of caregivers that use one or more recipes to feed their child/total number of children/caregivers enrolled, at 1, 2, 3, 4, 5, and 6 months
21. Amount of Kenyan shillings that caregivers are willing to pay for the dishes from the co-created recipes measured using contingent valuation methods at baseline and 6 months

Completion date
19/12/2025

Eligibility

Key inclusion criteria
1. Aged 6-18 months
2. Living within the catchment area
3. Lived in the study area for 6 months before the trial
4. Caregiver able and willing to participate in both clinic and home visits
5. Written informed consent given by parent/caregiver

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 months

Upper age limit
18 months

Sex
All

Total final enrolment
240

Key exclusion criteria
1. Severe acute malnutrition; measured as mid-upper arm circumference (MUAC) < 115 mm or weight-for-length z-score (WLZ) < -3 or bilateral pitting oedema
2. Known critical or chronic condition which may affect the nutrition status of the child
3. Participation in another study or program which impacts this study or previously enrolled in this study
4. Family plans to move away from the catchment area in the next 6 months

Date of first enrolment
26/03/2025

Date of final enrolment
25/04/2025

Locations

Countries of recruitment
Kenya

Study participating centre
Health centers in Makueni county
Kathonzweni, Mbuvo, Kitise, Kanzokea
Makueni County
Kenya
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Sponsor information

Organisation
Kenyatta University

ROR
https://ror.org/05p2z3x69

Funder(s)

Funder type
Government

Funder Name
HORIZON EUROPE Framework Programme

Alternative Name(s)
Horizon Europe, Horizon Europe Programme, Framework Programme, Horizon Europe, EU Framework Programme, Horizon

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes