

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

<b>Submission date</b> 21/03/2025	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/03/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/06/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 November 2025

Who is funding the study?

The European Union HORIZON EUROPE programme grant: Healthy Diets 4 Africa.

Who is the main contact?

Dr Juliana Kiio, [kiio.juliana@ku.ac.ke](mailto:kiio.juliana@ku.ac.ke)

## Contact information

### Type(s)

Public, Principal Investigator

### Contact name

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Scientific

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Cluster randomised trial

**Study setting(s)**

Community

**Study type(s)**

Prevention

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

**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 measure**

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

**Secondary outcome measures**

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/cm<sup>2</sup>), fat mass index (kg/cm<sup>2</sup>)) 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

**Overall study start date**

01/08/2024

**Completion date**

30/11/2025

## **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

**Age group**

Child

**Lower age limit**

6 Months

**Upper age limit**

18 Months

**Sex**

Both

**Target number of participants**

240

**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

### **Sponsor details**

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### **Sponsor type**

University/education

### **Website**

<https://medicine.ku.ac.ke/food-nutrition-and-dietetics>

### **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**

### **Publication and dissemination plan**

Planned publication in peer-reviewed journals

### **Intention to publish date**

31/12/2026

### **Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a later date

### **IPD sharing plan summary**

Data sharing statement to be made available at a later date