ISRCTN38407248 https://doi.org/10.1186/ISRCTN38407248

Effect of pumpkin pulp-seed intake on children's nutritional status

Submission date
27/03/2023

Recruitment status
No longer recruiting

Registration date
12/04/2023

Overall study status
Completed

Last Edited
14/04/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Globally, malnutrition accounts for 45% of deaths of < 5-year-old children annually. Africa is the most affected with 48 million undernourished children. In Kenya, 26% of children are stunted, 4% are wasted, 11% are underweight, 19.5% are vitamin A deficient and 24.2% are iron deficient. Kitui County (ASAL) has a high prevalence of childhood malnutrition, with high poverty (47%) and high food insecurity (69%). The nutritional status of preschool children in Kitui County is a public health concern, with 46% stunting, 3.4% wasting, 19.7% underweight, 35.1% vitamin A deficiency and 29.5% iron deficiency. The high prevalence of malnutrition is due to sub-optimal diets of children that are inadequate, deficient in essential nutrients and lack diversity. It is costly to treat malnutrition. Strategies to address malnutrition, including supplementation and mass fortification have been adopted, among other strategies, however, the prevalence of malnutrition among children is still high. Formulation of food products using locally available nutrient-rich foods, such as pumpkin (neglected and underutilized), to enrich staple foods, such as sorghum, has the potential to address nutritional inadequacies. There is a need for evidence on the effect of nutritional interventions that use locally available foods in the prevention /management of malnutrition. Few efficacy trials have been performed in Kenya using a flour blend of sorghum and pumpkin pulp and seeds for the improvement of the nutritional status of children. The trial objectives are to; evaluate the nutrient content of pumpkin, white and red sorghum grains, formulate and evaluate the nutrient content, sensory acceptability and microbial properties of sorghum-pumpkin flour blends, determine the characteristics of children caregivers in Kitui County, evaluate the water hygiene and sanitation practices of children caregivers in Kitui County and to assess the effect of sorghum-pumpkin flour blend porridge intake on vitamin A status, iron and wasting status of 36-47-month-old children in Kitui County.

Who can participate?
Child-caregiver pairs. Caregivers should be above 18 years of age, while children should be between 36-47-months old. Both healthy and moderately malnourished children can participate in the study.

What does the study involve?
The study involves providing porridge to children and feeding the same to them on a daily basis. The children in the control group receive porridge prepared from sorghum flour while those in

the intervention group receive a pumpkin-sorghum flour blend porridge. Assessment of dietary practices will occur on a monthly basis. The morbidity patterns of the child will be recorded every two weeks. Anthropometry measures of weight and height are recorded on monthly basis. Micronutrient status of the children including hemoglobin, vitamin A and iron levels are determined both at the beginning and end of the study.

What are the possible benefits and risks of participating?
The benefits of participation include the improvement of nutrient intake and nutritional status of children due to porridge consumption made of enriched sorghum flour. The study results will be of benefit to society since they may provide information on measures that may improve nutrient intake and help in reducing risk/managing malnutrition. The risks of participation include the discomforts that may occur during the blood drawing process however, trained medical personnel were engaged to undertake that task. Other discomforts may be experienced including allergic reactions to porridge consumption. However, no allergic reactions have been recorded.

Where is the study run from?
Jomo Kenyatta University of Agriculture and Technology (Kenya)

When is the study starting and how long is it expected to run for?
February 2019 to June 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Jane Gatwiri Mbijiwe, Janembijiwe@rpe.jkuat.ac.ke (Kenya)

Contact information

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Additional identifiers

Protocol serial number
PSP 1

Study information

Scientific Title
Impact of intake of pumpkin-sorghum grain flour blend porridge on nutrient intake, vitamin A and iron status of children aged 36-47 months in Kitui County, Kenya

Acronym
PSP

Study objectives
H01: The addition of pumpkin into sorghum grain has no significant influence on the nutrient content of the resulting flour blend.
H02: Sorghum grain & pumpkin flour blend is not acceptable to consumers.
H03: Consumption of sorghum grain-pumpkin flour blend porridge has no significant effect on the nutritional status of preschool children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 17/03/2020, Mount Kenya University Ethical Review Committee (P.O. Box 342-0100 Thika, Kenya; +254709153000; info@mku.ac.ke), ref: MKU/ERC/1550
2. Approved (Renewal of approval) 21/01/2021, Mount Kenya University Ethical Review Committee, ref: MKU/ERC/1750

Primary study design
Interventional

Study design
Interventional cluster-randomized two-group study design

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of malnutrition among children aged under 5 years

Interventions
The study design is a cluster randomised trial. The study site Kitui County was purposely selected because it had the highest prevalence (46%) of malnutrition among under-five-year-old children in Kenya. Study sites Itoloni and Nzeluni were selected using simple random sampling. Study participants were recruited based on the following inclusion criteria; those that understood the study objectives and gave informed consent, and children who were normal or with moderate malnutrition. Those that had severe malnutrition were excluded from the study. Those that had not lived in the area for a period of more than 6 months were also excluded. The local administration, community health workers, researchers and research assistants were engaged in the recruitment of study participants.

The study comprises a study control and an experimental group. Feeding centres were randomized to avoid contamination of participants in the experimental group sharing information with those in the control group. The feeding centres were randomized into an intervention group and a control group by a biostatistician at a ratio of 1:1 using Microsoft excel. Each study group had one feeding centre. Children were assigned to the study group based on sex.

Allocation and Masking: The study was carried out at two study sites, each site exclusively for the experimental group and the other for the control group which allowed blinding/masking. The study monitored participants every month for six months of the study. Further, the participants, enumerators and biostatisticians were also blinded to the study hypothesis.

The children in the control received porridge made of sorghum flour while those in the intervention group were fed porridge prepared from a sorghum-pumpkin flour blend. The children received 250 ml of porridge each day for 6 months of study. Porridge was prepared by the researcher and trained research assistants. In the study the following parameters were monitored each month: food consumption, nutrient intake and anthropometric measures, this was in accordance with FAO and WHO provisions. Biochemical measures of haemoglobin, serum ferritin and serum retinol levels were monitored at baseline and endline, and the WHO standard procedures in blood collection and analysis were adhered to. Also, morbidity patterns of the children were monitored at baseline and every two weeks for the 6 months of study. At the beginning of the study, the children in both the control and experimental group were dewormed.

Intervention Type
Other

Primary outcome(s)
Nutritional status of children fed either sorghum flour or sorghum grain-pumpkin flour blend porridge measured using biochemical methods baseline and endline (6 months)

Key secondary outcome(s)
1. Anthropometric indices measures included height, weight, age and sex, defined by WHO child growth standards (WHO, 2008), measured using participant's actual body measures at baseline and months 1, 2, 3, 4, 5 and 6
2. Dietary intake data measured using a participant self-reported 7-day food frequency questionnaire, 24-hour dietary recall questionnaire and dietary diversity questionnaire following

the Food and Agriculture Organization (FAO 2015) guidelines at baseline and months 1, 2, 3, 4, 5 and 6
3. Morbidity measured using morbidity study questionnaires (interviews) at baseline and every two weeks until the end of the study at 6 months

Completion date
29/06/2021

Eligibility

Key inclusion criteria
1. Give informed consent and assent from the children
2. Moderately malnourished or healthy children
3. Caregivers allowing periodic home visits
4. Those with no plans of relocating from the study area during the six months of study and also those who had lived in the study location for more than 6 months

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
108

Key exclusion criteria
1. Those with severe malnutrition
2. Visibly very sick children
3. No consent from caregivers
4. Those on other nutritional support programs

Date of first enrolment
01/06/2020

Date of final enrolment
01/11/2020

Locations

Countries of recruitment
Kenya

Study participating centre
Kitui County
Box 460
Kitui
Kenya
90200

Sponsor information

Organisation
Jomo Kenyatta University of Agriculture and Technology

ROR
https://ror.org/015h5sy57

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			28/03/2023	No	No