ASSESSMENT OF THE EFFECTS OF MICROCLINICS INTERVENTION ON NUTRITIONAL STATUS OF CHILDREN 6-23 MONTHS OLD IN MFANGANO ISLAND, WESTERN KENYA

Principal investigator
Ouma Dan Omollo, MPH
School of Public Health and Community Development
Maseno University, Kenya

Co-investigators/ Academic Supervisors
1. Dr. Louisa Ndunyu
   Department of Public Health and Community Development
   School of Public Health and Community Development
   Maseno University, Kenya

2. Prof. Collins Ouma
   Department of Biomedical Sciences
   School of Public Health and Community Development
   Maseno University, Kenya

Academic context
Master of Public Health in Epidemiology and Population Health
Thesis registration number PG/MPH/06027/12
Thesis submitted in 2021

Study implementation setting
Mfangano East and Mfangano North, Homa Bay County, Kenya
Ekialo Kiona Centre, Mfangano Island

Document version 3.0
Original protocol date: 3 September 2014
Revision date: 2 September 2015

1 Protocol summary

The study will evaluate a community health volunteer facilitated microclinics nutrition intervention in Mfangano East, with Mfangano North serving as the comparison community. A nonrandomized controlled before-and-after design will assess caregiver and child pairs at baseline and approximately six months later. The evaluation will assess dietary diversity, meal frequency, child weight, recumbent length and head circumference.

Item	Study specification
Design	Two community quasi experimental controlled before and after evaluation; no random allocation
Intervention community	Mfangano East
Comparison community	Mfangano North; routine Ministry of Health services
Participants	Adult mothers or caregivers and children from fishing dependent households
Recruitment target	Approximately 160 caregiver and child pairs, allowing for 10% anticipated attrition
Assessment period	Baseline October to November 2014; follow-up April to May 2015
Intervention exposure	Six sessions approximately every two weeks over three months
Assessment schedule	Baseline before intervention and approximately six months after baseline
Measurement domains	Dietary diversity, feeding frequency, child weight, recumbent length and head circumference

2 Background and objectives

The complementary feeding period places increasing nutritional demands on children while household access to diverse foods may be constrained. In fishing dependent communities on Mfangano Island, food access is shaped by livelihoods, household resources and social relationships. Feeding education alone may be insufficient when caregivers lack practical support or resources to implement recommendations. Dietary diversity offers a feasible measure of the variety of foods consumed, although it does not establish adequate energy or nutrient intake [1,2].

Microclinics will bring together people connected through existing social relationships to learn, discuss health practices and undertake shared activities. The nutrition intervention will combine facilitated education with cooking activities, role plays, group action plans and activities intended to improve food access. The evaluation will assess the intervention package as a whole.

The comparison community will provide observations over the same period [3] among households continuing routine services. Community selection will be nonrandomized, and each arm will comprise one community. The analysis will describe changes over time and between-arm differences, while accounting in its interpretation for the limitations of the community comparison [4-6].

General objective

To assess the effects of a microclinics nutrition intervention on nutritional status and feeding practices among children aged 6 to 23 months in Mfangano Island, western Kenya.

Specific objectives

- To assess child anthropometric measurements in the intervention and comparison communities at baseline and six-month follow-up.
- To assess minimum dietary diversity using the four-of-seven-food-group definition in the two communities.
- To assess child feeding frequency using caregiver-reported feeding occasions during the preceding 24 hours.

3 Study design population and recruitment

Design and setting

The study will use baseline and repeat assessments of the same caregiver and child pairs approximately six months apart. Mfangano East will receive the intervention and Mfangano North will serve as the comparison community. Mfangano East will be selected for implementation by convenience. Mfangano North will be selected for demographic and cultural similarity and shared reliance on fishing, without formal matching. Neither communities nor individuals will be randomly allocated.

The evaluation will be nested within Research on Environmental and Community Health (RECH), an existing cohort examining fisheries resources, household livelihoods, food security, fish consumption and child health. Recruitment will be drawn from eligible members of that cohort in Mfangano East and North.

Eligibility

Mothers or caregivers will be eligible if they are aged at least 18 years, reside in Mfangano East or North, report fishing as the main household livelihood, do not plan to relocate during follow-up and can provide informed consent. Children aged 6 to 23 months will be eligible. Caregivers in the intervention community will also be willing to join a microclinic. No upper caregiver age limit will apply.

Caregivers with a mental or physical health condition preventing adequate participation will be excluded. Children born with congenital abnormalities affecting anthropometric assessment will be excluded from those measurements.

Recruitment and consent

Trained research assistants will approach potentially eligible caregivers over approximately two months, explain the evaluation and invite voluntary participation. In Mfangano East, consenting caregivers willing to join will be linked to a community health volunteer and microclinic. Eligible caregivers in Mfangano North will be invited to the comparison arm. Written informed consent will cover caregiver participation and parental or guardian permission for child participation. Declining or withdrawing will not affect access to routine health services.

Sample size

The study will target approximately 160 caregiver and child pairs, including an allowance for 10% anticipated attrition. This target will support the broader nutritional evaluation, including anthropometry, dietary diversity and meal frequency. Participants will be recruited from eligible members of the existing cohort in the two communities. Allocation will reflect the nonrandomized community design.

4 Intervention and comparison procedures

Microclinic formation and facilitation

Caregivers in Mfangano East will form small groups of approximately 5 to 10 people, including friends, relatives and members of existing social networks. Groups will be known locally as Kanyaklas. Each group will select a community health volunteer to facilitate activities. Facilitators will receive curriculum training approximately every other Monday and will facilitate group sessions at locally convenient times and places. They will receive mentorship, stipends and transport support.

Curriculum and practical activities

The curriculum will comprise six sessions delivered approximately every two weeks over three months. Topics will include family planning; prenatal nutrition and safe delivery; breastfeeding; complementary feeding; malnutrition and feeding during illness; and family food security.

Sessions will combine nutrition information, discussion, role plays, practical cooking and group action plans. Cooking activities will include preparation of nutritious porridge for young children. Household food access activities will include kitchen gardens and demonstration-farm participation. Groups will earn points for completing agreed actions. Participants will be encouraged to support one another between sessions.

Delivery monitoring

Community health volunteers will record attendance and arrange make-up sessions for members missing scheduled meetings. The principal investigator will supervise field procedures. Attendance records and completed group activities will support delivery monitoring, while child outcome assessments will be conducted separately.

Comparison condition

Caregivers in Mfangano North will not participate in the microclinics nutrition program during the evaluation period. They will continue to access routine Ministry of Health services through the community health strategy. Routine services will also remain available to intervention community participants.

Participant contact schedule

Stage	Activities
Baseline	Participants will complete eligibility confirmation and consent; caregiver and household questionnaire; child 24-hour food recall; anthropometry.
Program period	Six facilitated sessions over approximately three months in the intervention community; attendance and make-up sessions
After curriculum completion	Continued usual household practices and routine services during the remaining observation period
Six-month assessment	Participants will complete repeat dietary recall and anthropometry using the same assessment approach in both communities.

5 Dietary and feeding outcome measurements

Caregiver reported dietary recall

Trained research assistants will administer a structured 24-Hour Food Recall Form asking what, when, where and how much the target child consumed during the preceding day, including foods consumed away from home. Mixed dishes will be recorded with their ingredients. The form will capture four named meal sections, other meals or snacks, unusual intake, illness, appetite and medication. Household utensils will support description of quantities. Dietary recalls will be conducted at baseline and approximately six months after baseline.

Percentage of children achieving minimum dietary diversity

Foods will be classified using the study Dietary Diversity Coding Tool into seven groups: grains, roots and tubers; legumes and nuts; dairy products; flesh foods; eggs; vitamin A-rich fruits and vegetables; and other fruits and vegetables. Each group consumed will contribute one point, giving a food-group count of 0 to 7. Ingredients from mixed dishes will be assigned to their respective groups; repeated consumption within a group will not increase its contribution.

Minimum dietary diversity will be defined as consumption from at least four of the seven food groups during the preceding 24 hours, using the WHO 2008 indicator [1]. The arm-specific outcome will be the number meeting this criterion divided by the number with an evaluable recall, multiplied by 100. The unit will be percentage of children. A higher percentage will indicate more children meeting the criterion. The same definition will be applied at both assessments.

Percentage of children receiving at least three feeds in 24 hours

The reported timing and content of feeding occasions will be used to derive feeding frequency. The study threshold will be consumption of solid, semi-solid or soft foods at least three times in the preceding 24 hours, including milk feeds for non-breastfed children. The outcome will be the number meeting this threshold divided by the number with an evaluable recall, multiplied by 100. The unit will be percentage of children. A higher percentage will indicate more children meeting the study-defined threshold.

This outcome will use a uniform study-defined three-feed threshold. It will be distinguished from the WHO minimum meal frequency indicator, which will require age- and breastfeeding-specific thresholds [1].

Assessment endpoints and contrasts

The five measurement-specific endpoints will be assessed at six-month follow-up. Corresponding baseline measurements will describe initial status and support within-arm and between-arm descriptive change calculations. Dietary and feeding contrasts will be expressed in percentage points, while anthropometric summaries will use kilograms or centimeters as appropriate.

6 Anthropometry and field quality assurance

Mean child body weight

Trained research assistants will measure weight using calibrated weighing scales and record readings on the Child Anthropometry Form. Children able to stand independently will be weighed directly. For children unable to stand, child weight will be derived by subtracting caregiver weight from combined caregiver and child weight. Two measurements will be obtained, with a third when the first two differ by at least 0.5 kg. Mean body weight will be summarized by study arm at baseline and six months. The unit will be kilograms.

Mean child recumbent length

Research assistants will measure recumbent length using an infantometer and record it in centimeters. Children younger than 24 months will be measured in the recumbent position even if they can stand independently. Mean length will be summarized by arm at baseline and six-month follow-up. Standing height will be measured using a stadiometer when age appropriate and will be distinguished from recumbent length. The unit will be centimeters.

Mean child head circumference

Research assistants will measure head circumference using a head circumference measuring tape and record three readings in the designated fields on the Child Anthropometry Form. Mean head circumference will be summarized by study arm at baseline and six months. The unit will be centimeters.

Anthropometric recording

Repeated weight and head circumference readings will be retained on the Child Anthropometry Form for quality review. Measurements will be checked for completeness and consistency before analysis. Weight, length and head circumference will be reported separately in their original measurement units.

Training and quality assurance

Research assistants will receive training in interviewing, anthropometry, questionnaire completion, ethics and confidentiality. Supervised mock interviews will support familiarization with the tools. Instruments will be piloted among caregivers outside the study sample. Completed forms will be reviewed daily for completeness, accuracy and logical consistency. Queries will be resolved using source forms, and the principal investigator will supervise data collection. Calibrated equipment will be used for anthropometric assessments.

The same assessment approach will be used in both arms. Interpretation will consider recall and social desirability bias associated with caregiver report and the limited ability of a single 24-hour recall to represent usual intake. Participants and facilitators will be aware of intervention participation.

7 Data management analysis and ethics

Data management

Reviewed source forms will be entered into a secure Microsoft Access database. Categorical responses will be coded and labelled, and subsequent checks will examine missingness, completeness and response consistency. Access to paper and electronic records will be restricted to authorized research personnel. The database will be password protected.

Statistical analysis

Data will be analyzed using Stata version 13. Categorical measures will be summarized using frequencies and percentages, while continuous measures will be summarized using means and standard deviations. Study outcomes will be presented separately by arm and assessment period.

Dietary diversity will be summarized by arm and time point. Within-arm percentage-point change will equal the six-month percentage minus the baseline percentage. Between-arm difference will equal intervention minus comparison at each assessment. A descriptive difference-in-differences contrast will subtract the comparison-arm change from the intervention-arm change. These comparisons will remain descriptive, without an adjusted intervention-effect model or formal causal difference-in-differences model.

Feeding frequency and anthropometry will be summarized separately using their stated units. Exploratory between-arm comparisons of continuous anthropometric measurements will use two-sample t-tests with a two-sided significance level of 5%. Interpretation will take account of the unreplicated allocation of one community per arm.

Missing data and design limitations

Assessment-specific denominators will accompany dietary and feeding percentages. Missing outcomes will not automatically be treated as failure to meet a threshold. Follow-up loss will be reported separately, and no imputation will be applied to descriptive summaries. Interpretation will consider community-level confounding, nonrandom recruitment, possible within-group correlation, seasonality and concurrent changes. The analysis will not separate community effects from intervention allocation.

Ethics and participant protection

The study will be conducted under Maseno University Ethics Review Committee approval reference MSU/DRPI/MUERC/00217/14, dated 25 September 2014. Local permission will be obtained through the sub-county Ministry of Health office. Recruitment and baseline assessment will commence after the required approvals and permissions.

Written informed consent will be obtained in the caregiver’s preferred language, Dholuo, Swahili or English. Parents or guardians will provide permission for child participation. Child assent will not be sought given the children’s developmental stage. Participation will be voluntary, withdrawal will not affect routine services, and confidentiality will be maintained. Participants will be reimbursed KES 200 at each baseline and follow-up assessment for their time and transport.

8 Study timeline and estimated budget

Study timeline

Study preparation and field activities will run from September 2014 to May 2015. Recruitment and baseline assessments will take place in October to November 2014. Follow-up will occur in April to May 2015, approximately six months after each participant's baseline assessment. Each microclinic will complete six fortnightly sessions over approximately three months. Delivery across groups will be staggered from November 2014 to February 2015. Analysis and dissemination will follow completion of fieldwork.

Activity	Sep 2014	Oct 2014	Nov 2014	Dec 2014	Jan 2015	Feb 2015	Mar 2015	Apr 2015	May 2015	Jun 2015
Approvals and community entry	■									
Staff training and piloting	■	■								
Recruitment and baseline		■	■							
CHV training and mentorship			■	■	■	■				
Six session curriculum delivery			■	■	■	■				
Post-curriculum observation						■	■	■	■	
Six-month follow-up								■	■	
Data review and entry		■	■	■	■	■	■	■	■	
Final cleaning and analysis									■	■
Report and dissemination										■

Shaded cells indicate scheduled activity months. The four-month curriculum window will accommodate staggered group starts; each group will receive approximately three months of sessions. Participant follow-up will remain anchored to the individual baseline date.

Key milestones

Milestone	Scheduled completion
Ethics and local permissions	September 2014
Baseline assessment	November 2014
Six sessions per intervention group	February 2015
Six-month outcome assessment	May 2015
Analysis and study reporting	June 2015

Estimated study budget

The estimated budget will total KES 556600. It will cover recruitment, baseline and follow-up assessment, intervention delivery, anthropometric equipment, data management and dissemination. Costing will use 160 caregiver and child pairs for two assessment visits. Ten community health volunteers will be included in the facilitation cost estimates.

Budget item	Quantity	Unit cost KES	Total KES
Participant time and transport	320	200	64,000
Research assistant field days	80	1,500	120,000
Field supervision days	20	2,500	50,000
CHV session facilitation	60	500	30,000
CHV training and transport	60	300	18,000
Field transport days	30	1,500	45,000
Calibrated weighing scales	2	10,000	20,000
Infantometers	2	12,000	24,000
Head circumference tapes	4	500	2,000
Curriculum materials by session	6	3,000	18,000
Cooking demonstration rounds	6	4,000	24,000
Kitchen garden and farm support	10	2,000	20,000
Data entry and cleaning days	20	1,500	30,000
Questionnaires and printing packs	160	100	16,000
Dissemination meeting	1	15,000	15,000
Communication and administration	1	10,000	10,000
Subtotal			506,000
Contingency 10 percent			50,600
Total estimated budget			556,600

Budget basis

The 320 participant assessment payments will comprise 160 baseline and 160 follow-up visits at KES 200 each. Research assistant costs will comprise four assistants working for an estimated 20 days each across preparation and assessment rounds. Facilitation and training will be costed for ten volunteers over six curriculum rounds. Equipment will support parallel assessment teams. The contingency will provide for operational cost variation and additional follow-up needs.

9 References

1. World Health Organization. Indicators for assessing infant and young child feeding practices. Part 1 Definitions. Conclusions of a consensus meeting held 6 to 8 November 2007 in Washington DC, USA. Geneva: WHO; 2008.

2. Ruel MT. Operationalizing dietary diversity: a review of measurement issues and research priorities. Journal of Nutrition. 2003;133(11 Suppl 2):3911S-3926S. doi:10.1093/jn/133.11.3911S.

3. Omollo OD. Assessment of the Effects of Microclinics Intervention on Nutritional Status of Children Below Two Years in Mfangano Island, Western Kenya. Master of Public Health thesis. Maseno University; 2021.

4. Omollo D. Dietary diversity manuscript. Working copy titled More Diverse Diets among children 6-23 months in Mfangano Island, western Kenya: effects of a Microclinics program for mothers and caregivers. Available file Dietary diversity paper (3).docx; 2026. Unpublished manuscript.

5. Kasiulevicius V, Sapoka V, Filipaviciute R. Sample size calculation in epidemiological studies. Gerontologija. 2006;7(4):225-231.