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

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1 Purpose and study design

This plan describes the analysis of child feeding and anthropometric data from the Mfangano microclinics nutrition study. The study used a non-randomized controlled before-and-after design. Mfangano East received six microclinics nutrition sessions over approximately three months; Mfangano North continued routine services as the comparison community. Caregiver-child pairs were assessed at baseline and approximately six months later. Each arm comprised one community, with no random allocation. The analysis will describe baseline characteristics, summarize the five outcomes by arm and assessment, and compare within-arm changes and between-arm differences. With one community per arm, community differences cannot be separated from intervention assignment.

2 Analysis populations and data preparation

The recruitment target was approximately 160 caregiver-child pairs, including anticipated attrition. The child will be the unit of analysis for nutritional outcomes. Participants will be classified by their original community regardless of session attendance. Assessment-specific summaries will use valid observations for each outcome; paired analyses will require valid, linked baseline and follow-up values.

Actual assessment dates will determine age and follow-up interval. Feeding indicators for children aged 6-23 months will use age at each assessment; children outside that range will be accounted for separately. Valid anthropometric measurements will remain available for cohort summaries, with age and measurement position recorded.

Data checks will cover identifier uniqueness, visit linkage, community assignment, dates, age, units, repeated measurements, duplicates, missingness and dietary consistency. Questionable values will be checked against source forms. Corrections and exclusions will be logged; extreme values will not be removed solely because they are unusual. Original data will be retained separately from analysis files.

3 Outcomes and derivation

3.1 Minimum dietary diversity

The preceding 24-hour recall will be coded into seven food 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 consumed group will contribute one point, giving a score of 0-7. Mixed-dish ingredients will be assigned to their groups, and repeated consumption within a group will count once. Minimum dietary diversity will mean consumption from at least four of the seven groups, using WHO 2008 definitions consistently at both assessments. The percentage will equal the number meeting the criterion divided by the evaluable denominator, multiplied by 100. Missing responses will not be coded as no consumption. Incomplete recalls will be classified only when known responses unambiguously determine the binary outcome; otherwise, it will be missing. The score will require complete group information.

3.2 Meal frequency

The study-defined indicator will be the percentage receiving at least three meals in the preceding 24 hours. Feeds will include solid, semi-solid or soft foods and milk feeds for non-breastfed children. Foods eaten together will count as one occasion; breastfeeding episodes will not count as complementary-food feeds. Incomplete histories that prevent classification will be missing. The uniform three-feed threshold will be distinguished from WHO age- and breastfeeding-specific minimum meal frequency.

3.3 Anthropometric outcomes

Weight, recumbent length and head circumference will be reported separately in kilograms, centimeters and centimeters, respectively. Child weight derived from caregiver-child weighing will equal combined weight minus caregiver weight. Valid repeated weight and head circumference readings within an assessment will be averaged after source checks. Measurements with no valid reading will be missing. Standing height will be identified separately rather than silently combined with recumbent length. No additional z-score endpoint or new primary/secondary outcome hierarchy is introduced.

4 Descriptive analyses

Participant flow will report documented numbers approached, eligible, enrolled, assessed and analyzed by arm, with reasons for non-participation or follow-up loss where available. Baseline caregiver, child and household characteristics will be

summarized using counts and percentages or means and standard deviations. Medians and interquartile ranges will describe markedly skewed variables. Every summary will state its non-missing denominator; baseline significance tests will not establish comparability.

For each feeding outcome, tables will show the numerator, evaluable denominator and percentage by arm and time point. Anthropometric tables will show sample size, mean and standard deviation. Dietary diversity scores and feeding counts will be summarized separately from the binary indicators.

5 Comparisons and statistical methods

5.1 Feeding outcomes

Percentage-point contrasts will be calculated as follows:

- Within-arm change: follow-up percentage minus baseline percentage.
- Between-arm difference: intervention minus comparison at each assessment.
- Descriptive difference between changes: intervention-arm change minus comparison-arm change.

Main contrasts will use assessment-specific available cases, with denominators displayed. A paired-cohort sensitivity analysis will repeat these contrasts among children with valid values at both assessments. Transition counts will describe changes in individual indicator status. These comparisons will remain descriptive, without confirmatory tests or causal difference-in-differences claims.

5.2 Anthropometric outcomes

For each measure, the analysis will report intervention-minus-comparison mean differences at baseline and follow-up. Within-child change will equal follow-up minus baseline; its mean and standard deviation will be reported by arm among linked valid pairs, followed by the difference between mean changes.

Exploratory comparisons between arms at each assessment will use Welch two-sample t-tests, allowing unequal variances. Reports will include mean differences, Welch 95% confidence intervals and two-sided p-values. Distributions, histograms, sample sizes and influential values will be examined. If the t-test approximation is unsuitable, comparisons will remain descriptive. Within-child changes will use linked observations rather than treating repeat assessments as independent samples.

5.3 Uncertainty and multiple comparisons

The exploratory tests assume independent children; correlation within communities or microclinics may invalidate this assumption. Their intervals and P values do not provide valid inference about a community-level intervention effect. Two communities do not support reliable cluster-adjusted intervention inference. All specified comparisons will be reported, with unadjusted P values and 0.05 used only as an exploratory reference. No confirmatory familywise claim will be made.

6 Missing data and sensitivity analyses

No imputation or last observation carried forward will be used. Missing outcomes will not be coded as failure or assumed unchanged. Available-case and paired-cohort analyses will be identified, with outcome-specific denominators. Loss to follow-up, age-related indicator ineligibility, incomplete recall and unusable measurements will be distinguished. Baseline characteristics of retained and non-retained participants will be described where numbers permit. Sensitivity reporting will compare available-case and paired-cohort feeding contrasts and document measurement exclusions.

7 Software reporting and interpretation

Analyses will use Stata, with the actual version recorded; Stata 13 was described for the historical analysis. Do-files, derivation rules and logs will be retained. Counts will be integers; percentages and percentage-point contrasts will generally

use one decimal place. Measurement summaries will reflect recorded precision. Exploratory p-values will use three decimal places or $p < .001$, with intervals labelled 95%. Public outputs will contain no direct participant identifiers.

Interpretation will consider non-random allocation, one community per arm, within-group correlation, maturation, seasonality, concurrent services, recall error and missing follow-up. Increases in raw child size will not automatically be attributed to improved nutrition. Any change in outcomes, definitions or methods will be dated, justified and reported as an amendment or additional exploratory analysis.

8 Supporting documents

Study protocol, version 3.0: *Assessment of the Effects of Microclinics Intervention on Nutritional Status of Children 6-23 Months Old in Mfangano Island, Western Kenya*.

WHO. Indicators for assessing infant and young child feeding practices. Part 1: Definitions. Geneva; 2008.