ALIVE & THRIVE BURKINA FASO (A&T-BFA)
MATERNAL NUTRITION IMPLEMENTATION RESEARCH (MNIR)

Assessing the Feasibility of Integrating a Package of Maternal Nutrition Interventions into Antenatal Care Services in Burkina Faso: A Cluster-Randomized Evaluation

Data Analysis Plan

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I. Study Background and Approach

In Burkina Faso, Alive & Thrive (A&T) has integrated a package of maternal nutrition interventions as part of the antenatal care (ANC) services provided by the government health system through system strengthening and social and behavior change communication (SBCC) approaches. Interventions are implemented in four health districts (two districts per region) in two regions – Boucle du Mouhoun (2 health districts) and Hauts Bassins (2 health districts). Key interventions include (1) maternal nutrition counseling (diet quality and quantity), (2) iron and folic acid (IFA) supplementation (adequate supply and counseling), (3) weight gain monitoring (measurement and interpretation), and (4) counseling on early initiation and exclusive breastfeeding practices. As per the 2016 WHO ANC guidelines (World Health Organization, 2016), A&T also promoted 8 ANC contacts during pregnancy, i.e., at least 4 visits at health facilities and 4 contacts in the community.

1.1 Research questions

The implementation research study addresses three research questions:

Research question 1 (RQ1)	What are the program **impacts on maternal practices**: (1) consumption of diversified foods and adequate intake of micronutrients, protein and energy compared to recommended intakes; (2) consumption of IFA supplements during pregnancy; and (3) early breastfeeding practices?
Research question 2 (RQ2)	Can the **coverage and utilization** of key maternal nutrition interventions (named above) and number of ANC contacts be improved through system strengthening and SBCC approaches?
Research question 3 (RQ3)	What **factors influenced** integration and strengthening of maternal nutrition interventions into the government ANC service delivery platform?

1.2 Impact evaluation study design

The impact evaluation of A&T's interventions used a cluster-randomized design with repeated cross-sectional surveys at baseline and endline. We applied stratified random allocation to 80 health centers (CSPS, Centre de Santé et de Promotion Social) within four health districts (Boromo, Toma, Dande, and Lena), which were assigned to either the A&T intervention (40 CSPS) or control areas (40 CSPS). The baseline survey was conducted in November-December 2019 and the endline survey was conducted in January-March 2021 in the same 80 CSPS catchment areas, thereby creating panel data at the CSPS level (not at individual level). Program implementation duration was approximately 12 months, with a couple of months of interruption due to the COVID-19 pandemic in March-April 2020.

1.3 Study sample

The two main study sample groups are: 1) pregnant women (PW), as this sample allows the assessment of dietary diversity and adequacy of micronutrient, protein and energy intake during pregnancy; and 2) recently delivered women (RDW) who have children less than 6 months of age, as this sample provides the best opportunity to assess the primary outcomes related to intervention exposure throughout pregnancy. PW and RDW were sampled separately but within the same CSPS catchment areas.
For PW, we estimated a total sample size of 960 women (480 per arm) to detect a difference of 0.37 food groups in the mean dietary diversity score. For RDW, we estimated a total sample of 1920 women (960 per arm) to detect a difference of 15 tablets in the mean IFA tablets consumed after intervention.

Additionally, we included all husbands of RDW present at the time of the survey. Outside of the two main sample groups, nurses-midwives (N-M, 1 per CSPS) and community health workers (ASBC, within

1-3 villages per CSPS) were interviewed. Direct observations of ANC visits (2 per CSPS) to assess service quality, followed by exit interviews to assess service recall and client satisfaction, were conducted among pregnant women attending ANC at the time of the survey.

Table 1: Sample sizes

		Baseline 2019		Endline 2020	
Survey respondent type		**Intervention**	**Control**	**Intervention**	**Control**
Household survey:					
1	Pregnant women + 24h dietary recall	480	480	480	480
2	Recently delivered women with children <6 months	960	960	960	960
3	Husbands of RDW with children <6 months	960	960	960	960
Service provider survey:					
4	Nurses-midwives	40	40	40	40
5	Community health worker (ASBCs)	120	120	120	120
Observations:					
6	ANC observation + exit interview	80	80	80	80
	Total:	2,640	2,640	2,640	2,640

II. Outcome Measures and Indicators

Outcome measures corresponding to the three research questions are presented below. Only some outcome measures under RQ 1 pertain to the primary outcomes of the evaluation (i.e., used to test study hypotheses and arrive at a decision on overall study impact and to serve as basis to calculate the sample size); RQs 2 and 3 focus on secondary outcomes.

2.1. Research question 1 (impact on maternal nutrition practices)

For impact estimates, outcome measures related to maternal diet will be used from the PW datasets, and outcomes to IFA consumption and early breastfeeding practices will be used from the RDW data.

Table 2: Outcome measures for RQ1

Outcome	Indicator	Data source
Maternal dietary diversity and adequate intake	*Primary outcome:* - Dietary diversity score (# of food groups) *Secondary outcomes:* - % PW consumed at least 5 food groups (minimum dietary diversity) - Mean probability of adequacy of micronutrients - % PW consumed and quantity of each food group - Energy, carbohydrate, protein and fat consumption	PW survey PW 24h dietary recall
IFA consumption	*Primary outcome:* - # of IFA tablets consumed *Secondary outcomes:* - % RDW consumed 180+ IFA tablets - # of IFA tablets received	RDW survey
Early breastfeeding practices	*Secondary outcomes:* - % infants <6 months breastfed within 1h of birth - % infants <6 months with no pre-lacteals fed - % infants <6 months exclusively breastfed	RDW survey

2.2 Research question 2 (coverage and utilization)

For effects on coverage and utilization of interventions during ANC visits, outcome measures will be used from the RDW survey data. In the context of the overall evaluation, outcomes under this research question are considered as secondary outcomes.

Table 3: Outcome measures for RQ2

Outcome	Indicator	Data source
ANC visits and contacts	- # of ANC visits (at health facility) - Total # of ANC contacts - % RDW with at least 4 ANC visits - % RDW with at least 8 ANC contacts - % RDW received ANC visit in first trimester of pregnancy - # of contacts outside of health facility (home visits and GASPAs)	RDW survey
Counseling on dietary diversity and adequate intake	During ANC visits and other ANC contacts: - % RDW received counseling on maternal nutrition - % RDW received counseling on dietary diversity - % RDW received counseling on consuming adequate quantity of food	RDW survey
Counseling on IFA supplementation	During ANC visits and other ANC contacts: - % RDW received counseling on importance of IFA - % RDW received counseling on how/reminders to take IFA - % RDW received counseling on managing IFA side effects	RDW survey
Weight gain monitoring and counseling	During ANC visits and other ANC contacts: - # times weighed - % RDW weighted at least 4+ times/at each ANC visit - % RDW received counseling about weight gain during pregnancy	RDW survey
Counseling on early breastfeeding practices	During ANC visits and other ANC contacts: - % RDW received counseling on breastfeeding practices - % RDW received counseling on early initiation of breastfeeding - % RDW received counseling on not feeding pre-lacteals - % RDW received counseling on exclusive breastfeeding	RDW survey

2.3 Research question 3 (health system factors)

For assessing factors related to strengthening service delivery, measures will be used from the CSPS checklist and N-M and ASBC survey datasets. In the context of the overall evaluation, outcomes under this RQ3 count as secondary outcomes.

Table 4: Outcome measures for RQ3

Outcome	Indicator	Data source
Equipment and materials to support maternal nutrition services	- % CSPS with maternal nutrition counseling job aids - % CSPS with IFA supplementation job aid - % CSPS with breastfeeding counseling job aids - % CSPS with functional weighing scale - % CSPS with currently stocked with IFA tablets - % CSPS with register to monitor IFA stocks - % CSPS reporting stock-out of IFA in past 6 months	CSPS checklist
Service providers' training and supportive supervision	- % NM received maternal nutrition training - % ASBC received maternal nutrition training	N-M survey ASBC survey

	- % NM/ASBC by training content - % NM/ASBC received supervision - % NM/ASBC by supervision content	
Service providers' knowledge	- Knowledge scores for dietary diversity, adequate intake, IFA, and weight gain monitoring - Knowledge scores for breastfeeding	N-M survey ASBC survey
Service providers' work tasks and workload perceptions	- % NM/ASBC record-keeping on ANC services - % NM/ASBC by content of record-keeping - % NM/ASBC with increased workload in past 1y due to ANC services	N-M survey ASBC survey
Service providers' provision of services	- % NM/ASBC provided maternal nutrition interventions - % NM/ASBC by counseling messages provided (on dietary diversity, IFA, weight gain monitoring, and breastfeeding) - % NM/ASBC used job aids for maternal nutrition counseling - % ASBC provided home visits to PW/number of visits in last 30 days - % ASBC conducted GASPA for PW/number of meetings in last 30 days	N-M survey ASBC survey

III. Statistical Analysis Plan

3.1 General principles and methods

Data analyses will be performed using STATA version 16.0 (StataCorp LLC). All applicable statistical tests will be two-sided to allow potential findings of unexpected effects. Statistical significance will be presented at levels of $p<0.05$, $p<0.01$, and $p<0.001$.

A diagram presenting the flow of clusters and individuals through the trial, based on the Consolidation Standard of Reporting Trials (CONSORT) statement: extension to cluster randomized trials (Campbell et al., 2012; Eldridge et al., 2016), is shown as follows.

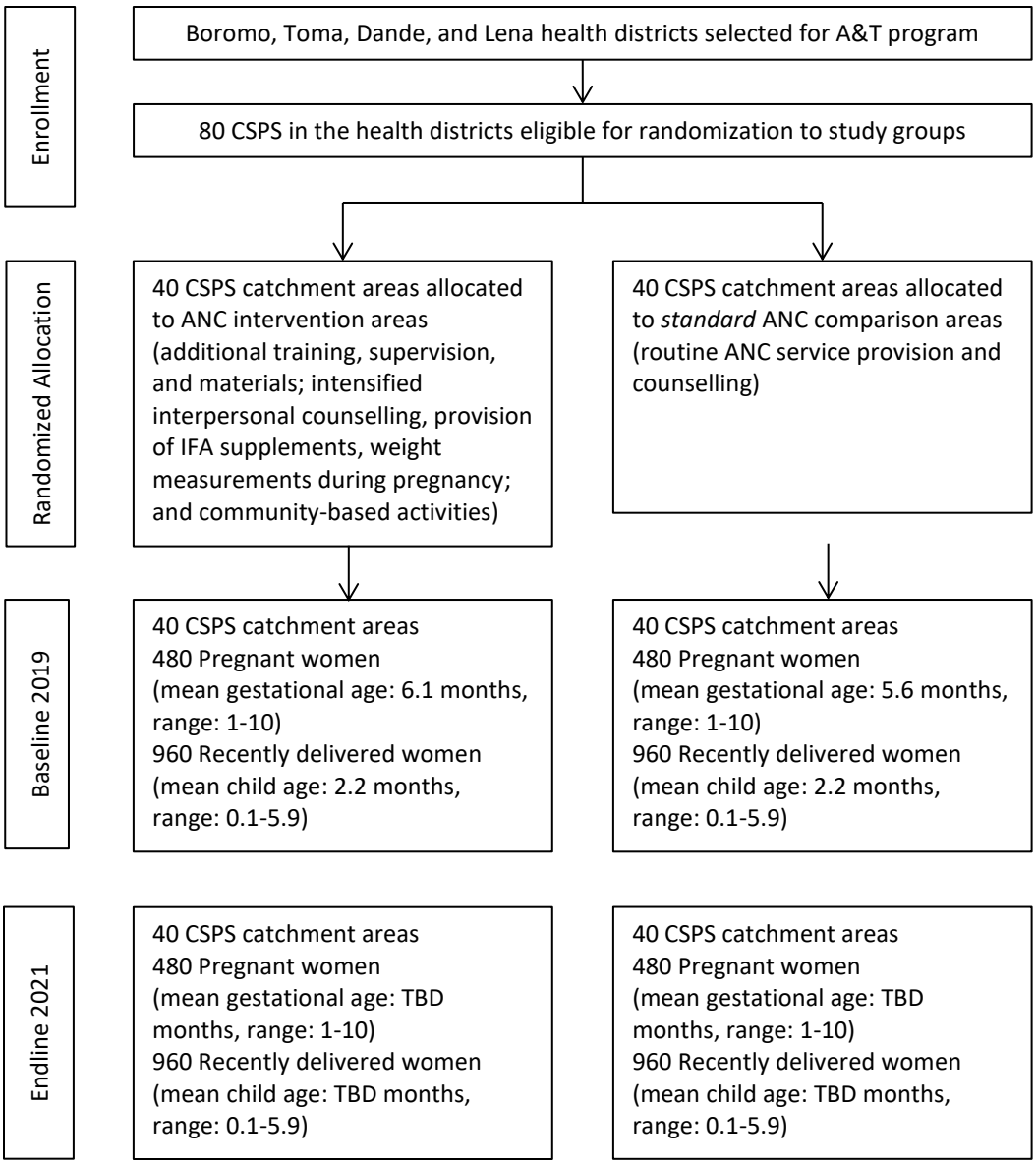

Figure 1. CONSORT flow diagram for repeated cross-sectional surveys

3.2 Sample characteristics

Baseline and endline characteristics will be reported between randomized program groups (A&T and control). For household samples, indicators of maternal characteristics (age, marital status, education, occupation, and religion), obstetric history (age of marriage, age at first birth, gravida, parity, number of living children, and trimester of pregnancy,), household composition (size, number of adults and children, and household head) and other household characteristics (household food security, livelihood, and socioeconomic status) will be reported. Binary variables will be summarized as proportions, and continuous variables will be summarized as mean values with standard deviations (when normally distributed) or as median with interquartile range (for non-normal distribution variables). The Shapiro-Wilks test will be used to test for normality of data distribution. T-test will be used to compare and infer significant difference between the program groups.

Table 5: Dummy table for sample characteristics

Indicator	Baseline		Endline	
	A&T (N=)	Control (N=)	A&T (N=)	Control (N=)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Age of respondent (years)				
	Percent	Percent	Percent	Percent
Marital status Education level Occupation Religion				

3.3 Impact estimates

The main analysis of impacts will be performed using intent-to-treat (ITT) specifications, wherein all study participants in the originally assigned program group at baseline are included in the statistical analysis and analyzed according to their program group, regardless of whether they received interventions or not. Women who refused or withdrew consent or those who are ineligible according to study protocol are excluded from ITT analysis.

The main impacts of the interventions will be estimated for: (1) maternal diet during pregnancy, (2) consumption of IFA supplements, and (3) early breastfeeding practices; secondarily, impact will be estimated for exposure to key interventions: (4) maternal nutrition counseling, (5) counseling on IFA supplementation, (6) weight gain monitoring and counseling, (7) breastfeeding counseling. The impact on dietary diversity will assessed among PW, and impact on all the remaining outcomes will be assessed among RDW.

The difference-in-difference (DID) method will be used to estimate impacts by comparing the changes in outcomes over time (baseline vs. endline) between study arms (intervention vs. control). Point estimates and changes in the outcomes will be reported. For the analysis, the Stata *diff* command will be used, accounting for clustering at the CSPS level with a cluster version of Huber-White robust estimator of standard errors and using degrees of freedom appropriate for the number of CSPS (Hayes & Moulton, 2017). The fixed effects in the two-level regression models will be study arm, survey time, and arm times survey; the latter estimates the difference between arms in changes over surveys. We will conduct ITT analyses based on the original evaluation design, as well as the adjusted ITT analyses using the ITT groups but adjusting for gestational age (for PW only), maternal characteristics, child age and sex (for RDW only), and other variables that may be different between study arms.

Table 6: Dummy table for impact estimates

Indicator	Baseline		Endline			
	A&T (N=)	Control (N=)	A&T (N=)	Control (N=)	Unadjusted DID	Adjusted DID
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	pp	pp
Dietary diversity score (number of food groups) Number of IFA tablets consumed						

	Percent	**Percent**	**Percent**	**Percent**		
Minimum dietary diversity (≥5 food groups) Consumed 180+ IFA tablets						

3.4 Plausibility analysis

In addition to the estimation of impacts, we will conduct plausibility analyses by two methods, to provide further evidence for the likelihood or strength of our impact estimates. First, we will assess whether social desirability bias may have influenced reported outcomes. Second, we will examine the intermediate outcome indicators along the program impact pathways (from service delivery to exposure and behavioral determinants) to determine whether the program resulted to the outcomes as intended by design.

3.4.1 Testing for social desirability bias

For outcome measures based on individual report, social desirability bias may play a potential role in influencing response. We applied a 13-item social desirability index, adapted from Reynolds and Gerbasi (Reynolds, 1982), to determine the extent to which respondents were likely to report behaviors based on their desire to please others, present oneself to others in a favorable way, or for social approval, i.e., "social desirability":

No.	Question item	
1	Is it sometimes hard for you to go on with your work if you are not encouraged?	NOO=1
2	Do you sometimes feel resentful when you don't get your way?	NO=1
3	Do you occasionally give up doing something because you don't think you have the ability?	NO=1
4	Do you occasionally feel like not listening to people event though you know they were right?	NO=1
5	No matter who you're talking to, are you always a good listener?	YES=1
6	Have there been occasions when you took advantage of someone?	NO=1
7	Are you always willing to admit it when you make a mistake?	YES=1
8	Do you sometimes try to get even, rather than forgive and forget?	NO=1
9	Are you always courteous, even to people who are disagreeable?	YES=1
10	Have you ever been irritated when people expressed ideas very different from your own?	NO=1
11	Have there been times when you were jealous of the good fortune of others?	NO=1
12	Are you sometimes irritated by people who ask favors of you?	NO=1
13	Have you ever deliberately said something that hurt someone's feelings?	NO=1
	Total score	13

The social desirability score (SDS) will be created by adding up the number of socially desirable answers, out of the total 13 question items. We will conduct three analyses using this score: (1) estimation of mean SDS by program group to compare differences in the level of social desirability bias between the intervention and control groups; (2) tabulation of key outcomes by SDS to assess whether the reported outcomes varied by SDS levels; and (3) regressions with each of the outcomes as dependent variables to test the interaction between SDS and intervention group, to determine whether or not social desirability bias differentially affected the impact of the A&T interventions on key outcomes.

3.4.2. Analysis of program impact pathways

The program impact pathway (PIP) was developed in collaboration with the A&T program team to map out the mechanisms through which the interventions were expected to achieve impact. The purpose of

the PIP analysis is to lay out the theoretical causal links between program activities, outcomes, and impacts. We will examine key indicators along the components of pathways (addressed in part by RQ2 and RQ3), to interpret and support the impact evaluation results. We will compare differences between program groups for indicators along the pathway matched to the relevant outcomes (dietary diversity, IFA consumption, and breastfeeding practices), using mixed-effects regression models, accounting for geographic clustering. Additional path analyses will be considered based on the results of the above analyses.

Table 7: Measures for program impact pathways

Outcome	Key Indicators	Data source
Service providers' capacity-building and service provision:		
Training and supervision (**RQ3**)	- % NM received maternal nutrition training - % ASBC received maternal nutrition training - % NM/ASBC by training content - % NM/ASBC received supervision - % NM/ASBC by supervision content	N-M survey ASBC survey
Service providers' knowledge (**RQ3**)	- Knowledge scores for dietary diversity, adequate intake, IFA, and weight gain monitoring - Knowledge scores for breastfeeding	N-M survey ASBC survey
Service provision (**RQ3**)	- % NM/ASBC provided maternal nutrition interventions - % NM/ASBC by counseling messages provided (on dietary diversity, IFA, weight gain monitoring, and breastfeeding) - % NM/ASBC used job aids for maternal nutrition counseling - % ASBC provided home visits to PW/number of visits in last 30 days - % ASBC conducted GASPA for PW/number of meetings in last 30 days	N-M survey ASBC survey
Beneficiaries' exposure and behavioral determinants:		
ANC visits and contacts (**RQ2**)	- # of ANC visits (at health facility) - Total # of ANC contacts - % RDW with at least 4 ANC visits - % RDW with at least 8 ANC contacts - % RDW received ANC visit in first trimester of pregnancy - # of contacts outside of health facility (home visits and GASPAs)	PW survey RDW survey
Counseling on dietary diversity and adequate intake (**RQ2**)	During ANC visits and other ANC contacts: - % RDW received counseling on maternal nutrition - % RDW received counseling on dietary diversity - % RDW received counseling on consuming adequate quantity of food	PW survey RDW survey
Counseling on IFA supplementation (**RQ2**)	During ANC visits and other ANC contacts: - % RDW received counseling on importance of IFA - % RDW received counseling on how/reminders to take IFA - % RDW received counseling on managing IFA side effects	PW survey RDW survey
Weight gain monitoring and counseling (**RQ2**)	During ANC visits and other ANC contacts: - # times weighed - % RDW weighted at least 4+ times/ at each ANC visit - % RDW received counseling about weight gain during pregnancy	PW survey RDW survey
Counseling on early breastfeeding practices (**RQ2**)	During ANC visits and other ANC contacts: - % RDW received counseling on breastfeeding practices - % RDW received counseling on early initiation of breastfeeding - % RDW received counseling on not feeding pre-lacteals	PW survey RDW survey

	- % RDW received counseling on exclusive breastfeeding	
Beneficiaries' knowledge and perceptions	- Knowledge scores for dietary diversity, adequate intake, IFA, and weight gain monitoring - Knowledge scores for breastfeeding - Beliefs, self-efficacy, and social norms score	PW survey RDW survey

Table 8: Dummy table for program impact pathways analysis

Indicator	Baseline		Endline	
	A&T (N=)	Control	A&T	Control
	Mean (SD)			
(see indicators in Table 7)				
	Percent			

IV. References

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