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

Study Protocol[1]

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I. Introduction

1.1 Background and rationale

Adequate maternal nutrition is important for maternal health and wellness and is a major determinant of pregnancy outcomes [1]. In low-and middle-income countries (LMICs), maternal and child malnutrition is a public health concern resulting in increases of morbidity and mortality [2]. Poor maternal nutrition is associated with adverse pregnancy outcomes such as low birth weight (LBW), preterm birth, large- and small-for-gestational age, intrauterine growth restriction, cesarean delivery and gestational diabetes mellitus [1, 2]. In the long term, maternal undernutrition is associated with chronic diseases (e.g., glucose intolerance, coronary heart disease, obesity, and increased risk of breast cancer), less schooling and reduced economic productivity in offspring exposed to undernutrition during fetal life [1-3].

Routine antenatal care (ANC) offers opportunities to receive a broad range of health promotion and prevention services including support for adequate nutritional care for pregnant women and their newborns, and any required medical treatment [4]. However, it has been shown that in LMICs half of women did not receive the four ANC visits (recommended until 2016) and the quality of ANC was suboptimal for those who met the recommendation [5, 6]. In 2016, World Health Organization (WHO) updated its guidelines on ANC with a high priority placed on nutrition interventions. These new guidelines recommended increasing the number of ANC from four to at least eight contacts to improve women's positive experience of care and to reduce perinatal morbidity and mortality [7]. Following these new recommendations, the government of Burkina Faso is working with WHO and other partners to revise the national guidelines on ANC and eventually test elements of the essential core package of routine ANC needed by women throughout pregnancy.

In Burkina Faso, despite continued improvement, the adjusted maternal mortality ratio (371 deaths per 100,000 live births) [8] and the neonatal mortality rate (25 deaths per 1,000 live births) remain high [9]. Anemia and severe acute malnutrition are among the ten principal causes of death among children under five years, in health facilities [10]. According to the findings from the 2017 Performance Monitoring and Accountability (PMA) 2020 nutrition survey, among women age 10-49 years who had a live birth in the last two years, 83% visited a qualified ANC provider. Among those who sought prenatal care, 70% of women reported attending at least four visits [11]. However, information on nutritional status shows that undernutrition is highly prevalent among women and children. According to the 2010 DHS, 16% of women of child-bearing age were undernourished (BMI <18.5kg/m2), and 58% of pregnant women were anemic [12]. There is still a high prevalence of LBW (14%) and stunting among under five years of age (33%) [8]. All this suggests the need to reinforce nutrition interventions provided during pregnancy and enhance coverage and utilization of ANC services.

Alive and Thrive (A&T) is an initiative that supports the scaling up of nutrition interventions to save lives, prevent illnesses, and contribute to healthy growth and development through improved maternal nutrition, breastfeeding and complementary feeding practices in several countries. Since 2014, A&T has worked with the Burkina Faso Ministry of Health (MOH) to scale up breastfeeding nationally and is now working to support the MOH and various international and local partners to scale up interventions to address a full range of maternal, infant, and young child nutrition (MIYCN) practices.

In Burkina Faso, A&T will develop and test the integration of an intensive package of maternal nutrition interventions into existing ANC services delivered through government health facilities that will align with the latest global evidence [7]. These include intensified counseling and support on dietary diversity and quality during pregnancy, iron-folic acid (IFA) supplements consumption, importance of ANC and increasing the number of visits, adequate weight-gain monitoring, and early initiation of and exclusive breastfeeding. The International Food Policy Research Institute (IFPRI) will carry out a research study to assess the feasibility of integrating this package of maternal interventions into existing ANC services and to identify enabling factors and challenges. The findings of this evaluation study will provide the MOH and its partners with important information needed to scale up interventions to achieve the new ANC recommendations.

1.2 Objectives

The overall study objective is to evaluate the feasibility and impact of integrating locally relevant maternal nutrition interventions into existing ANC services on diet quality and utilization of nutrition interventions during pregnancy.

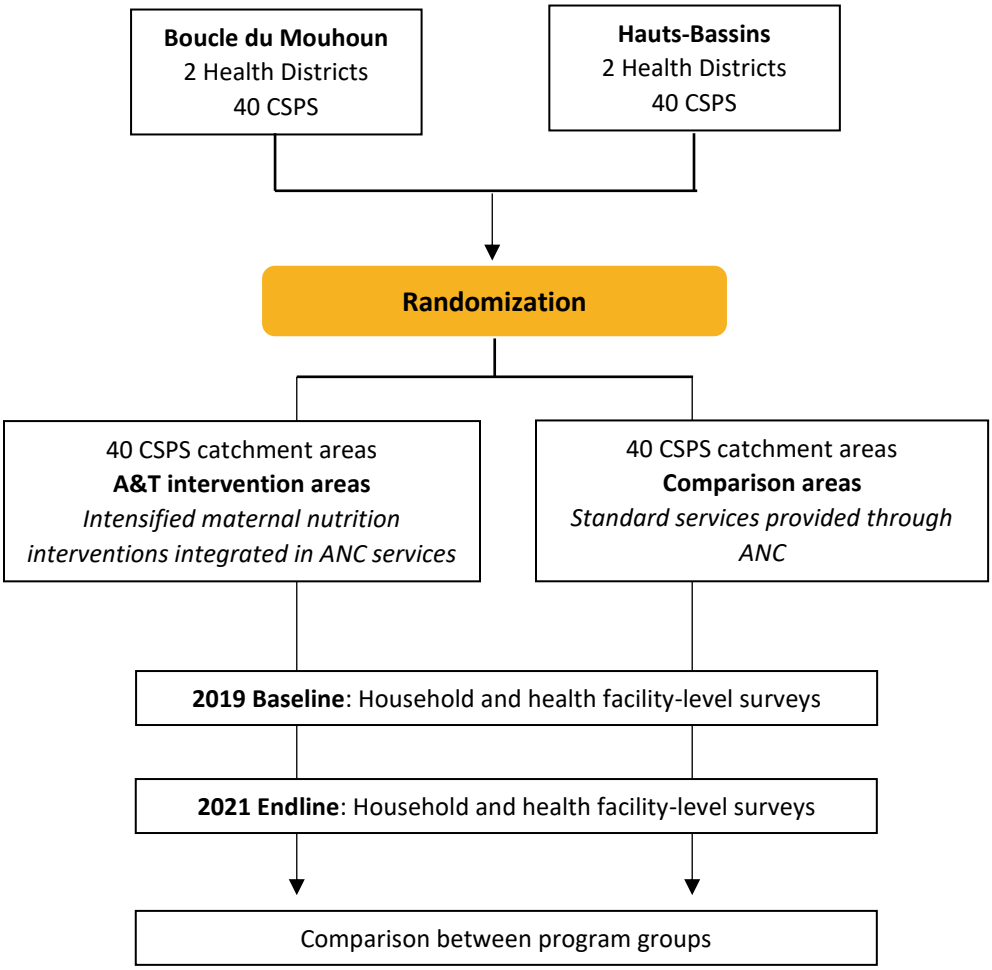
Research questions for the evaluation include:

1) Is it **feasible** to integrate locally relevant maternal nutrition interventions based on the WHO ANC guidelines into existing ANC services delivered through government health facilities?
2) Can the **coverage and utilization** of key nutrition interventions (nutrition counseling, weight gain monitoring, IFA supplement consumption) be improved by integrating nutrition-focused social and behavior change communication (SBCC; community mobilization and interpersonal communication) and systems strengthening approaches into existing ANC services?
3) Can the **quality of diets** (dietary diversity and adequate intake of micronutrients, protein, and energy) among pregnant women and early breastfeeding practices (early initiation of and exclusive breastfeeding) be improved by the nutrition-focused SBCC interventions?
4) What are the **barriers and opportunities** for completing 8 ANC contacts?

1.3 Trial design

The present study is designed as a two-arm cluster-randomized, non-masked trial, consisting of two cross-sectional surveys at baseline and endline. The unit of randomization is the health and social promotion center (CSPS) catchment area. The study is designed to have sufficient power to estimate differences between study groups across regions (**Figure 1**). A baseline cluster/facility-level and household survey will take place in November-December 2019. As soon as the baseline survey is completed, the intervention will be implemented at the CSPS and in the villages of the intervention group for up to 12 months. The endline survey will take place approximately one year later in January-February 2021. The repeated cross-sectional study design will allow us to assess the impact of the maternal nutrition interventions on currently pregnant and recently delivered women.

Figure 1. Trial flow



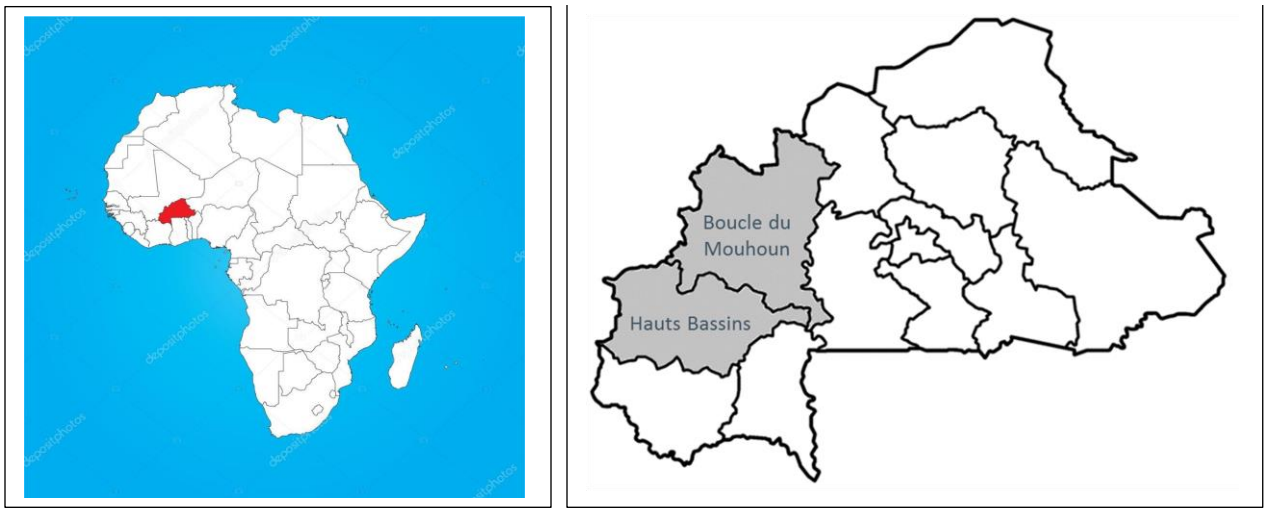
Note: CSPS: Centre de Santé et de Promotion Social. The baseline and endline surveys will include cross-sectional interviews of pregnant, and recently delivered women and their husbands, as well as providers of ANC services.

II. Methods: Participants, Interventions and Outcomes

2.1 Study setting

The study will be conducted in Boucle du Mouhoun and Hauts-Bassins, two of the 13 regions of Burkina Faso (**Figure 2**), often referred to as the country's breadbasket. Their capital cities are located 273 km and 360 km respectively, from Ouagadougou (the capital of the country). The regions were selected with the Government of Burkina Faso based on regional-level engagement and ownership, presence of community health workers and functioning community-women's groups known as Groupes d'Apprentissage et de Suivi des Pratiques Optimales d'Alimentation du Nourrisson et du Jeune Enfant (GASPA), size of the region, ANC attendance and security concerns.

Figure 1: Study regions



In Burkina Faso, the health care system is organized into three administrative levels: central, intermediate and peripheral [10]. Health facilities are also organized in three levels as follows: the first level known as health district includes medical centers with surgical services (CMA), health and social promotion centers (CSPS) and isolated maternity units; the second level with regional hospitals (CHR); and the third level includes university/national hospitals (CHU). At the district level, CMA represents the referral center for health centers of the first level. In Boucle du Mouhoun, two out of six health districts and two out of eight in Hauts-Bassin were selected as part of the study.

ANC coverage with at least one ANC visit is very high in Burkina Faso. About 97% of recently-pregnant women reported attending ANC at least once during their last pregnancy in 2017 [13]. The majority of women who received ANC also received it from a skilled provider, mostly from a midwife (71.3% in Boucle du Mouhoun, 85.8% in Hauts-Bassins) or nurse (19.1% in Boucle du Mouhoun, 17.9% in Hauts-Bassins) [13]. Most women attended ANC at least twice during their pregnancy, and roughly one-third of women in Boucle du Mouhoun and half of women in Hauts-Bassins are within their first trimester at the time of their first ANC visit. At national and regional levels, approximatively one-third of women attended at least four ANC visits (as recommended until 2016) during pregnancy [12].

IFA consumption is nearly universal in Burkina Faso [13]. Current WHO guidelines recommend daily IFA supplementation (30-60 mg elemental iron and 400 mcg folic acid) for women during pregnancy,

beginning as early as possible to prevent maternal anemia, puerperal sepsis, low birth weight, preterm birth, maternal anemia and iron deficiency [14]. Ideally, pregnant women should receive IFA tablets no later than the first trimester, corresponding to 6 months (180 days) of supplementation. Ninety-seven percent of women in Boucle du Mouhoun and Hauts-Bassins reported taking at least one IFA or iron tablet during their most recent pregnancy, with 70.6% and 86.0% of women taking at least 90 tablets, respectively [13].

According to the 2017 PMA2020 nutrition survey, calcium supplementation is not common [13]. WHO currently recommends daily calcium supplementation (1.5-2.0 g oral elemental calcium) in populations with low dietary calcium intake to reduce the risk of pre-eclampsia. However, in Burkina Faso calcium supplementation during pregnancy is not yet recommended until further evidence becomes available.

Women's dietary diversity is poor. The mean dietary diversity score (out of 10 food groups) among recently-pregnant women is 3.9 in both regions, slightly higher than the national average of 3.4 [13]. Health providers are nearly twice as likely to provide women information on the importance of diet quality (such as eating a variety of foods and high iron foods) during pregnancy than the importance of quantity (i.e. eating extra food) during ANC services [13].

ANC services are provided in nearly all health facilities, and ANC services are offered, on average, 5-6 days per week [11]. Weighing, nutrition counseling, and IFA supplementation are routine ANC services. Weight gain monitoring during pregnancy is important as body mass index and gestational weight gain are indicators of maternal nutrition and are associated with pregnancy outcomes. Among women who attended ANC during their most recent pregnancy during the past two years, nearly all of them were weighed at least once. However, among them, only 62% of women reported receiving information about their weight gain. This proportion was 72.7% in Hauts-Bassin, higher than in Boucle du Mouhoun. [13]. Roughly half of all facilities support community health workers to provide nutrition services.

Breastfeeding is a common practice: in 2017, 97.4% of Burkinabe women have ever breastfed [13]. Early initiation breastfeeding (within one hour) was 60.2 % in Boucle du Mouhoun and 60.3 % in Hauts-Bassins. About 91% and 74% of women reported receiving information on breastfeeding immediately after birth in Boucle du Mouhoun and Hauts-Bassins, respectively. Among those who received information about breastfeeding their newborn, 59% reported breastfeeding within one hour of birth, and 55% of women reported exclusively breastfeeding their baby.

In the two health districts in Boucle du Mouhoun and two in Hauts-Bassin selected as potential intervention areas, an exhaustive list of all CSPS was prepared (total of 223 CSPS in Boucle du Mouhoun and 182 CSPS in Hauts-Bassins). Areas with high security risk, physical inaccessiblity, and presence of similar intervention programs were excluded from the study. The final list of 80 CSPS catchment areas included in the study is provided in **Appendix 1.**

2.2 Eligibility criteria

The study includes two main samples: pregnant women (PW) and recently delivered women (RDW), to assess diet during pregnancy (among PW) and intervention exposure throughout pregnancy (among RDW).

Inclusion criteria:

1) Women of reproductive age (15 to 49 years old)

2) Currently pregnant or having a living child under 6 months of age (recently delivered) at the time of the survey
3) Residency in the health center catchment area
4) Informed consent

Exclusion criteria:

1) Severe illness (e.g., any severe illness symptoms mentioned/identified by the woman, a relative or the enumerator) in woman and/or child requiring immediate hospital referral
2) Chronic or congenital illness (e.g., any health condition mentioned/identified by the woman, a relative or the enumerator) in women and/or child interfering with dietary intake

At the health center level, health staff particularly the nurse-midwife responsible for providing ANC, and community health workers are eligible to participate in one-to-one interviews after providing informed consent.

2.3 Interventions

The package of maternal nutrition interventions will include intensified counseling on diet quality during pregnancy, distribution of and counseling on IFA supplements for better adherence, counseling on early initiation of and exclusive breastfeeding, weight-gain monitoring, systems strengthening through training and supportive supervision, as well as community mobilization. Intervention components are presented **in Table 1**.

Table 1: Description of interventions for intervention and control areas

CORE INTERVENTIONS	INTERVENTION AREAS	CONTROL AREAS
HEALTH FACILITY LEVEL:		
Counseling on diet quality	• Intensified counseling on dietary diversity and quality using job aids	• Standard nutrition counseling
Distribution and promotion of IFA supplementation	• Intensified counseling on purpose of IFA supplements, managing side effects, and importance on adherence to daily consumption • Distribution/prescription of sufficient IFA supplements at each ANC visit/contact • Use of reminders for women and their spouses • Monthly stock monitoring to assure sufficient supplies	• Standard counseling on consumption of IFA and how to manage side effects • Distribution/prescription of IFA at each ANC visit • Routine stock monitoring
Weight-gain monitoring	• Measurement of weight gain during each ANC visit and advise on healthy weight gain • Use of monitoring sheets	• Standard weight measurement
Counseling on early breastfeeding practices	• Intensified counseling on early initiation of breastfeeding and exclusive breastfeeding using job aids	• Standard breastfeeding counseling

Reminders on ANC attendance	• Reminder on importance of early ANC attendance and 8 visits/contacts (at least 4 visits at health facility)	• Standard reminder
COMMUNITY LEVEL:		
Community mobilization	• Orientation sessions for community leaders (traditional and religious leaders, local associations, etc.) about ANC • Gatherings among mothers-in-law, husbands, and other influencers about ANC and their roles • Promotion of ANC service utilisation and the importance of early ANC visit during the first trimester. • Identification of pregnant women for early ANC	• Standard ASBC activities
Interpersonal communication in GASPA (women's groups) and during home visits	• Focused discussions during GASPA meetings • 2-3 home visits per pregnant woman by ASBCs (Counseling on diet quality, breastfeeding, importance on adherence to daily IFA consumption and side effect management, etc.)	• Standard GASPA meetings • Standard ASBC activities
SYSTEM SUPPORTS:		
Training/refreshers	• Training on nutrition interventions during ANC for all ANC providers and community health workers	• Standard government training
Supervision	• Semi-annual supervision by DRS • Quarterly supportive supervision of health facility staff by the health district management team • Monthly supportive supervision of ASBC	• Quarterly integrated supervision for all care providers • Standard supervision of ASBC every 2 months
Progress review	• Monthly review between health facilities and ASBC	• None
Data recording and monitoring	• Training and recording of up to 8 ANC visits and nutrition services on registers • Training on data utilization to improve service coverage and quality	• Routine data recording and monitoring

2.4 Outcomes

The primary outcome indicators of the study are focused on diet quality and IFA supplementation. These include:

1) **Maternal dietary diversity among pregnant women**
    i. Mean number of food groups consumed by pregnant women
2) **Use of iron-folic acid (IFA) supplements among RDW**
    i. Mean number of IFA tablets consumed during pregnancy

The secondary outcomes relate to exposure to and utilization of key maternal nutrition, weight gain monitoring, and early breastfeeding interventions, as well as health worker knowledge and capacities at the points of service delivery. These include:

3) Maternal diet quality: proportion of pregnant women who achieve minimum dietary diversity; and micronutrient, protein and energy adequacy among pregnant women compared to the recommended dietary intake
4) Proportion of women who received 90+ IFA supplements during pregnancy
5) Early initiation of breastfeeding and exclusive breastfeeding practices of children
6) Use of ANC services (total number of ANC visits/contacts at facility and community levels and timing of the first ANC visit)
7) Exposure to nutrition interventions during ANC, including weight gain monitoring (proportion of women who are weighed and counselled about adequate weight gain, total number of times women are weighed during pregnancy)
8) Exposure to nutrition information from community health workers (proportion of women who were visited at home during pregnancy, total number of times visited), community groups, and other sources
9) Health worker knowledge on benefits and service provision for IFA supplementation, dietary diversity counselling, weight gain monitoring, and breastfeeding counselling
10) Availability of service supports (IFA supplies, records/registers, weight measurement equipment, counseling materials, and training and supervision for health workers)

2.5 Sample size

The two main samples for the primary outcomes are: 1) pregnant women (PW) as this sample allows the assessment of diet quality during pregnancy; and 2) recently delivered women (RDW) who have children under 6 months of age, as this sample provides the best opportunity to assess the primary outcome related to intervention exposure throughout pregnancy (i.e., IFA consumption). Based on an initial mean dietary diversity score of 3.52 food groups across both regions and intra-cluster correlation of 0.110 from the 2019 baseline data (Kim et al., 2020) , a significance level of 5% and power of 80%, the sample size of 480 PW per arm is estimated to detect a difference of 0.37 in the mean dietary diversity score after intervention.

For RDW, using an initial mean of 108.64 IFA tablets consumed across both regions and intra-cluster correction of 0.206 at baseline (Kim et al., 2020) and the same assumptions above for statistical significance, the sample size of 960 RDW per arm is estimated to detect a difference of 15 tablets in the mean IFA tablets consumed after intervention. If husbands of RDW are present at the time of the survey, they will also be interviewed briefly about their health and nutrition knowledge and any support provided during pregnancy. Approximately half of the expected sample size of husbands was available at baseline.

Outside of these two main samples, nurses-midwives (1 per CSPS) and community health workers (within 3 villages per CSPS) will be interviewed. In addition, direct observations of ANC visits (2 per CSPS) to assess service quality, followed by exit interviews to assess client satisfaction, will be conducted among a subgroup of pregnant women attending ANC at the time of survey.

The overall study samples sizes are presented in **Table 2**.

Table 2: Estimated sample sizes

	Baseline 2019		**Endline 2020**	
	Intervention	**Control**	**Intervention**	**Control**
Pregnant women	480	480	480	480
Women with children 0-5 months old	960	960	960	960
Husbands of women with children 0-5 months old	960	960	960	960
Nurses-midwives	40	40	40	40
Community health worker (ASBCs)	120	120	120	120
ANC observation & exit interview	80	80	80	80
Total	2,640	2,640	2,640	2,640

2.6 Recruitment

In the catchment area of the pre-selected CSPS, a census will be conducted in three randomly selected villages representing the CSPS catchment area to identify PW and RDW. From two separate lists (for PW and RDW), women will be randomly selected by simple random sampling until the required sample sizes are reached. At least 10 and 24 households per cluster need to be visited in the villages to identify PW and RDW, respectively.

At each CSPS, the nurse-midwife mainly responsible for providing ANC services will be invited participate in the study. In each surveyed village, the community health worker (ASBC) mainly responsible for ANC/care for pregnant women or, in the case that more than one ASBC is responsible, with the longest duration in that position will be invited to participate in the study. In addition, at each CSPS, two ANC sessions that take place during the time of the survey will be observed, with prior permission and consent for observation and post-observation exit interview.

III. Methods: Assignment of interventions

3.1 Allocation

We applied stratified random allocation to obtain a more balanced distribution of cluster-level covariates between study arms. First, we divided clusters/CSPS by health districts. Then we stratified clusters into 2 strata using available data on a set of criteria:

- Type of catchment area
- Number of villages covered
- Total population size
- Total number of pregnant women and total number of children <6 months
- Number of ANC admissions and proportion of ANC attended
- Distance between CSPS and district hospital

Then we used Stata to assign unique computer-generated random numbers to each cluster, sort numbers, and allocate each cluster in order to one of two study arms (intervention or control).

3.2 Blinding

This evaluation study will be unblinded. Women in the intervention areas will not be informed about the results of the randomization. However, there will be no blinding of the interventions at the level of service delivery.

IV. Methods: Data collection, management, and analysis

4.1. Data collection methods

Data will be collected at the health facility and household levels by trained field staff, using pretested questionnaires. The following set of tools will be translated from English to French and most spoken local languages and used during the baseline and endline surveys:

i. Health facility observation checklist
ii. ANC observation checklist and exit interview
iii. Nurse-midwife questionnaire
iv. Community Health Worker (ASBC) questionnaire
v. Pregnant women questionnaire
vi. Recently delivered women and Husband questionnaire
vii. Multi-pass 24-hour recall (for pregnant women only)

Topics included in each of the data collection methods are presented in **Table 3**.

Table 3: Data collection methods

Data collection method	Topics included
Health facility observation checklist	Condition of the facility infrastructure, service readiness, services provided by the facility, human resources, and ANC monitoring system
ANC observation checklist with exit interview	Direct observation checklist of ANC session to document services provided, perceptions of counseling received, patient satisfaction
Nurse-midwife questionnaire	Nurse-midwife 's responsibilities, capacity, knowledge, motivation, and ANC service provision at the health center
Community health worker (ASBC) questionnaire	ASBC's responsibilities, capacity, knowledge, motivation, and ANC service provision in the community
Pregnant women questionnaire	Household composition, household socioeconomic status, obstetric history, use of ANC, exposure to ANC, maternal nutrition and breastfeeding knowledge, household food security, social desirability, decision-making power, and mental health
Recently delivered women and husband questionnaire	Household composition, household socioeconomic status, obstetric history, use of ANC, exposure to ANC, maternal nutrition and breastfeeding knowledge and practices, pregnancy and postnatal care, household food security, social desirability, decision-making power, mental health, anthropometry, husband's health and nutrition knowledge, and husband's perceptions of maternal nutrition and roles of husbands, other family members and community/village during pregnancy
Multi-pass 24-hour recall (pregnant women)	Food intake over the previous 24-hours, recipes of prepared dishes

4.1.1 Health facility observation checklist

A facility observation checklist will be included to obtain information on facility characteristics, the presence and condition of infrastructure, service readiness, services provided, caseload, human resources, and ANC monitoring system at the facility. Checklists will be the same for all the CSPS as presented in **Table 4**.

Table 4: Description of topics in the health facility checklist

Module	Topic	Description	Respondent
1	Identification	Location, type of facility	Enumerator (direct observation)
2	Infrastructure	Building amenities and condition	Enumerator (direct observation)
3	Facility and staff characteristics	Hours of operation, type and number of staff, catchment population	Enumerator (direct observation)
4	ANC equipment, materials and medications	Availability of functioning ANC equipment, counseling materials and medications	Enumerator (direct observation)

5	ANC services provided	Services provided in-facility or through out-patient care, including ANC, nutrition counseling, provision of IFA, breastfeeding counseling	Enumerator (ANC registers, inquire with health worker)
6	Patient caseload	Caseload for ANC, referrals and counselling	Enumerator (ANC registers, inquire with health worker)
7	Monitoring system	Monitoring and tracking of ANC clients, data registers	Enumerator (pharmacy and ANC registers, inquire with health worker)

4.1.2 ANC observation checklist and exit interview with pregnant women

Direct observation of ANC sessions will be conducted by the enumerators to document the ANC process. In addition, post-observation exit interviews with pregnant women will be conducted immediately after observation to assess their satisfaction regarding the services received. The modules in the checklist are presented in **Table 5.**

Table 5: Description of modules in the ANC observation checklist and exit interview

Module	Topic	Description	Respondent
1	Identification	Location, type of facility, and type of service provider	Enumerator (direct observation)
2	Identification	Pregnant woman's name, birthdate, age, and antenatal care visit number	Enumerator (direct observation or pregnant woman)
3	Observation of antenatal care session	Provision and coverage of services such as medical history, danger signs of current pregnancy, physical examination, routine tests, IFA and other prophylaxis, and counseling/advice about nutrition	Enumerator (direct observation)
4	Exit interview	Services and messages received from the provider, and satisfaction with services received	Pregnant woman

4.1.3 Nurse-midwife questionnaire

Interviews with nurse-midwives who provide ANC services at health centers will be conducted at baseline and endline and will gather information on workload and time commitments, ANC service provision, knowledge of maternal nutrition and optimal breastfeeding practices, exposure to nutrition training, and supervision. The modules in the questionnaire are presented in **Table 6**.

Table 6: Description of modules in the nurse-midwife questionnaire

Module	Topic	Description	Respondent
1	Identification	Facility identification, nurse-midwife 's name	Enumerator

2	Demographic characteristics	Age, education, years of experience and other characteristics of the nurse-midwife	Nurse-midwife
3	Time commitments and workload	Workload of the nurse-midwife, including responsibilities, supervision provided to ASBCs, time commitments, number of consultations, and number of patients	Nurse-midwife
4	Nutrition counseling information	Topics/messages provided as part of nutrition counseling during ANC	Nurse-midwife
5	Maternal health and nutrition knowledge	General knowledge on health and nutrition, nutrition during pregnancy, anemia, and IFA supplementation	Nurse-midwife
6	Breastfeeding and feeding knowledge	Knowledge of the importance of early initiation of breastfeeding, exclusive breastfeeding, and timing of the introduction of other liquids foods	Nurse-midwife
7	Training exposure	Exposure to and training received on maternal nutrition	Nurse-midwife
8	Supervision and contact with other health workers	Frequency and content of supervision received from superiors, and contact with other health workers	Nurse-midwife

4.1.4 Interviews with ASBCs

Interviews with community health workers who provide ANC services (ASBCs) in the communities will be conducted at baseline and endline and will gather information on workload and time commitments, ANC service provision, knowledge of maternal nutrition and optimal breastfeeding practices, exposure to nutrition training, and supervision. **Table 7** presents the modules in ASBC questionnaire.

Table 7: Description of modules in the community health worker questionnaire

Module	Topic	Description	Respondent
1	Identification	Location, health facility, ASBC's name	Enumerator
2	Demographic characteristics	Age, education, years of experience and other characteristics of the ASBC	ASBC
3	Time commitments and workload	Workload of the ASBC, including responsibilities, time commitments, number of consultations, and number of patients	ASBC
4	Nutrition counseling information	Topics/messages provided as part of nutrition counseling during ANC	ASBC
5	Maternal health and nutrition knowledge	General knowledge on health and nutrition, nutrition during pregnancy, anemia, and IFA supplementation	ASBC
6	Breastfeeding and feeding knowledge	Knowledge of the importance of early initiation of breastfeeding, exclusive breastfeeding, and timing of the introduction of other liquids foods	ASBC

7	Training exposure	Exposure to and training received on maternal nutrition	ASBC
8	Supervision and contact with other actors	Frequency and content of supervision received from superiors, and contact with village elders	ASBC

4.1.5 Pregnant women questionnaire

Detailed interviews with pregnant women will be conducted in their homes at baseline and endline. Information on household composition, household socioeconomic status, household food security, dietary diversity, obstetric history, use of ANC, social desirability, and maternal nutrition and breastfeeding knowledge will be collected. The modules in questionnaire are presented in **Table 8.**

Table 8: Description of modules in pregnant women questionnaire

Module	Topic	Description	Respondent
1	Identification	Name, ethnicity, religion, phone number	Enumerator
2	Household roster	Information on the composition of the household, including designation of the head of household, a list of all household members, their ages and sex, and their relationship to the pregnant woman, and the highest educational level attained and activity/employment	Pregnant woman
3	Obstetric history	Age at first marriage, last menstrual period, gestational age, number of pregnancies, number of living children, date of last birth	Pregnant woman
4	Use of antenatal care (facility-based)	Frequency and timing of ANC use and exposure to nutrition counseling and messages during facility-based ANC contacts	Pregnant woman
5	Exposure to maternal nutrition interventions in the community	Exposure to maternal nutrition counseling and messages during home visits and community meetings and gatherings	Pregnant woman
6	Consumption of IFA	Current consumption of IFA tablets, receipt/purchase of IFA tablets; observation of IFA tablets/packs/bottles	Pregnant woman
7	Dietary diversity	Dietary diversity of the pregnant woman and household in the past 24 hours	Pregnant woman
8	Maternal health and nutrition knowledge and perceptions	General knowledge on health and nutrition, nutrition during pregnancy, anemia, and IFA supplementation; perceptions about maternal nutrition	Pregnant woman

		and roles of husbands, other family members and community/village	
9	Food security	Prevalence of household hunger using the FANTA household food insecurity access scale (HFIAS)	Pregnant woman
10	Dwelling	House construction (materials used for floor, walls, and roof), availability of water and electricity, sources of fuel/energy for cooking, WASH facilities	Pregnant woman
11	Assets	Ownership of durable household goods (in working condition), including tools for agricultural production	Pregnant woman
12	Social desirability	Desire for social approval	Pregnant woman
13	Women's decision-making power	Perceptions on women's role in the household, ownership of productive assets and decision-making power	Pregnant woman
14	Mental health	Mental health status over the past month	Pregnant woman

4.1.6 Recently delivered women

Detailed interviews with RDW will be conducted in their homes at baseline and endline. Information on household composition, household socioeconomic status, household food security, exposure to ANC and delivery and postnatal care, dietary diversity, social desirability, maternal nutrition knowledge, and breastfeeding practices and knowledge will be collected. If husbands of RDW are present at the time of the survey, they will also be interviewed briefly about their health and nutrition knowledge and any support provided during pregnancy. The description of modules in RDW is presented in **Table 9**.

Table 9: Description of modules in RDW's questionnaire

Module	Topic	Description	Respondent
1	Identification	Location, household	Enumerator
2	Household roster	Information on the composition of the household, including designation of the head of household, a list of all household members, their ages and sex, and their relationship to the pregnant woman, and the highest educational level attained and activity/employment	Recently delivered woman
3	Obstetric history	Marriage, pregnancy and childbirth history	Recently delivered woman
4	Use of antenatal and postnatal care services	Frequency and timing of ANC use at health facility and/or in the community), services/messages received during ANC	Recently delivered woman

5	Exposure to maternal nutrition interventions in the community	Exposure to maternal nutrition information outside of ANC services	Recently delivered woman
6	Consumption of IFA supplements	Current consumption of IFA tablets, receipt/purchase of IFA tablets	Recently delivered woman
7	Dietary diversity	Dietary diversity of the pregnant woman and household in the past 24 hours	Recently delivered woman
8	Breastfeeding and child feeding practices	Early initiation and exclusive breastfeeding practices	Recently delivered woman
9	Maternal health and nutrition knowledge and perceptions	General knowledge on health and nutrition, nutrition during pregnancy, anemia, and IFA supplementation; perceptions about maternal nutrition and roles of husbands, other family members and community/village	Recently delivered woman
10	Breastfeeding and child feeding knowledge	Knowledge, beliefs and attitudes toward early initiation of breastfeeding, exclusive breastfeeding, and continued breastfeeding	Recently delivered woman
11	Food security	Prevalence of household hunger using the FANTA household food insecurity access scale (HFIAS)	Recently delivered woman
12	Dwelling	House construction (materials used for floor, walls, and roof), availability of water and electricity, sources of fuel/energy for cooking, WASH facilities	Recently delivered woman
13	Assets	Ownership of durable household goods (in working condition), including tools for agricultural production	Recently delivered woman
14	Social desirability	Desire for social approval	Recently delivered woman
15	Women's role and decision-making power	Perceptions on women's role in the household, ownership of productive assets and decision-making power	Recently delivered woman
16	Mental health	Mental health status over the past month	Recently delivered woman
17	Postnatal functional disability	Ability to perform physical tasks and activities following birth	Recently delivered woman
18	Anthropometry	Weight and height measurements	Recently delivered woman
19	Husband's support during pregnancy	Support provided during pregnancy	Husband
20	Husband's exposure to maternal nutrition information	Exposure to maternal nutrition messages and method of receipt	Husband

21	Husband's knowledge about maternal nutrition	General knowledge on health and nutrition, nutrition during pregnancy, anemia, and IFA supplementation	Husband
22	Husband's perceptions about maternal nutrition	Husband's perceptions on maternal nutrition and roles of husbands, other family members and community/village	Husband

4.1.7 Multi-pass 24h-recall

Dietary intake data of pregnant women will be collected in women's homes using multi-pass 24-hour recall interviews (Gibson and Ferguson 2008), which have been validated in many low-income countries (Gibson et al. 2017). Standardized quality-control procedures will be implemented to mitigate potential underreporting of energy and nutrient intake and other reporting errors (Alemayehu et al. 2011).

The multi-pass 24-hour recall approach uses a special method to help individuals remember what they consumed. Enumerators will review the pregnant woman's food and drink taken over the past 24-hours several times. Each time, or "pass", more detailed information is collected, thus reducing the probability that foods and drinks are omitted. To help estimate portion sizes, respondents will be visited prior to the 24-hour recall and provided with standardized dishes (e.g. cups, bowls and spoons) to use for consuming and preparing food the following day (the anticipated day of recall). Descriptions of each pass are presented in **Table 10**.

Table 10: Description of the four passes for the multi-pass 24-h recall

Pass	Description
1	Obtain a list of all foods and beverages and indicate the time period when they were consumed.
2	Use probing questions to get more details about each food item or beverage, such as whether the food was cooked or raw when consumed.
3	Estimate the amounts of each food, beverage and dish consumed.
4	Verify the list of foods, beverages, and dishes from the first pass to capture any missed items.

In addition to the amounts of foods and beverages, enumerators will collect information on recipes of mixed dishes consumed. Weights of each ingredient and the total cooked weight of dishes will be collected. If the pregnant woman is not the individual in charge of food preparation, effort will be made to interview the food preparer.

4.2 COVID-19 precautionary measures

Since early 2020, close-range contacts between enumerators and household members present a particular risk for spreading COVID-19 in communities with vulnerable populations. The collaborating survey firm, AFRICSanté, has developed a formal standard operating procedure (SOP) on improved hygiene that enumerator staff will be trained on during survey training and must sign as part of a contract amendment. As part of the SOP, all enumerators and study participants will wear masks (provided to them) and wash or sanitize their hands before and after each interview. Enumerators will maintain two meters of distance between themselves and respondents during the interview. When

conducting anthropometric measurements, enumerators will use additional protective equipment including disposable gloves and overalls which will be disposed of after each survey. Measuring boards will be sanitized after every measurement. Before the interview begins, respondents will be asked if they have had any symptoms of illness in the past two weeks. If respondents have had at least three symptoms, they will be considered high risk and additional precautions will be observed.

Testing enumerators for COVID-19 before starting data collection is unlikely given the scant resources available for testing in Burkina Faso. However, all survey staff will be assessed for COVID-19-related symptoms (including fever, dry cough, extreme fatigue, body aches, sore throat, etc.) each day before enumerator training begins, and field supervisors will assess enumerators each day before starting data collection. In addition, Co- and Principal Investigators of the project will be in daily contact with AFRICSanté and in-country partners during data collection to assess the changing risks and government measures.

4.3 Data management

A secure data file structure will be established in an IFPRI-server-based Dropbox Professional folder for use by the IFPRI research team and potential collaborators. Original, sensitive (non-anonymized) data files and documents will be stored in a folder with access restricted to senior IFPRI researchers. A do file will be written to anonymize survey data files and export the anonymized data to a shared Dropbox folder for data cleaning and analysis by research support staff and other project team members.

All changes to the raw data output files from the Computer-Assisted Personal Interviews (CAPI) software will be recorded. Formatting, reshaping, and labeling of data will be documented using detailed and well-annotated do files.

4.4 Statistical methods

Descriptive analyses will be used to describe characteristics of the two groups. Testing of differences between the two groups will be done using a random effects regression, accounting for the clustering of errors within and across health center catchment areas.

The randomized study design allows for the identification of causal effects of the maternal nutrition intervention through comparisons of mean outcomes between the treatment and control groups. Key indicators will include dietary diversity (among pregnant women), IFA consumption, weight gain monitoring, and breastfeeding practices (early initiation and exclusive breastfeeding). Impacts will be assessed using difference-in-difference (DID) estimation. Data management, data cleaning and statistical analyses will be conducted using Stata version 15 (Statacorp, USA).

V. Methods: Monitoring

5.1 Data monitoring and storage

All data collection will be done using electronic tablets. Checks will be built into the CAPI software and applied at the time of data entry. These will include logic checks, valid values, skip patterns, and range checks among others to ensure efficiency and high data quality. In addition, enumerator monitoring will be incorporated into the CAPI software including recording the duration of interviews and GPS location of enumerators during data collection.

Field supervisors will closely monitor enumerators and the quality of data collected to ensure the integrity of the data during data collection. Project manager, principal and co-principal investigators of the survey firm and IFPRI will also closely monitor the quality of data collected.

5.2 Harms

Given that the nutrition interventions during ANC are provided according to government guidelines for standard health service, we do not anticipate any harms from the study. Any adverse events or unintended effects during provision of ANC will be handled according to standard care practices.

5.3 Auditing

Not applicable.

VI. Ethics and dissemination

6.1 Research ethics approval

This protocol, informed consent forms, and study questionnaires will be reviewed and approved by the IFPRI Institutional Review Board (IRB) based in Washington, DC. In Burkina Faso, ethical clearance will be obtained from a local IRB, Centre Muraz in Bobo-Dioulasso.

A COVID-19 country risk assessment system was developed by IFPRI to help researchers and IFPRI's IRB assess COVID-19 risk in countries where fieldwork is planned. In function of the level of COVID-19 risk identified in country, data collection methods will be adapted to minimize the transmission risk of COVID-19. Justification for resuming fieldwork with in-person contacts will be provided and accepted by the IRB.

6.2 Protocol amendments

All amendments to the protocol will be reported (by IFPRI Co-Investigators) to and agreed upon with Alive & Thrive. Any modifications to the protocol which may impact the safety of participants or the scientific validity including changes of study objectives, study design, participants, sample sizes, and study procedures will be reviewed by the IFPRI IRB and the local IRB.

Version control using protocol version identifiers and dates will be used to track the history of amendments and identify the most recent protocol version.

6.3 Consent

After explaining the study's objectives and procedures, enumerators will seek and obtain written informed consent from eligible study participants. Participation in the study is completely voluntary. Participants are free to withdraw at any time by informing survey team and it will not be held against them.

All COVID-19 transmission risks to study participants (including close contact required for taking anthropometric measurements) and the precautionary measures that will be followed during data collection to limit the risk of transmission will be included in the informed consent.

6.4 Risks and benefits

Close-range contacts between enumerators and household members present a particular risk for transmission of COVID-19 in communities with vulnerable populations. Precautionary measures to mitigate this risk are outlined in section 4.2.

For their time spent being interviewed, survey respondents will receive a monetary compensation. Pregnant women, recently delivered women, husbands of recently delivered women, nurse-midwives, ASBCs, and the heads of CSPS (who assist with the health facility observation checklist) will receive 1,000 CFA francs. Pregnant women who participate in the ANC observation and exit interview will receive 500 CFA francs.

6.5 Confidentiality

Precautions will be taken to ensure data confidentiality. Immediately after data collection, all data will be uploaded and stored securely in an IFPRI-server-based Dropbox Professional folder. To protect respondent confidentiality, only senior IFPRI researchers will have access to data and documents containing personally identifiable information. Research support staff and other project team members will have access to depersonalized data—located in a separate IFPRI-server-based Dropbox Professional folder—where direct identifiers have been replaced by randomly generated numeric IDs.

Data that is made publicly available will be carefully screened to remove any indirect and geographic identifiers which may breach the confidentiality of respondents.

6.6 Declaration of interests

The authors declare that they have no competing interests.

6.7 Access to data

All Co- and Principal Investigators of the project will have full access to the cleaned data. Other project team members will have access to data that has had all personally identifiable information removed.

In compliance with donor (Bill & Melinda Gates Foundation) open access policy requirements, fully anonymized datasets will be made publicly available one year after the end of the project. Metadata and other documentation of data collection procedures (such as the codebook, data collection instruments and interviewer guides/protocols) will also be made publicly available.

6.8 Ancillary and post-trial care

Not applicable.

6.9 Dissemination policy

Close engagement with the government of Burkina Faso is of high importance to the project. The A&T Burkina Faso team will be working in close partnership with government entities on strengthening maternal health systems at the national and regional levels throughout the duration of the project. Findings will be disseminated through in-country events, presentations, and conferences.

Within the research community, we aim to have the research peer-reviewed and published in high quality journals. Preliminary research findings may be presented at international conferences and internal IFPRI seminars.

VII. Timeline

7.1 Study timeline

Deliverables/Activities	2019												2020					
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
1. Study protocol																		
Discuss study design with A&T	x	x	x	x														
Prepare study protocol					x	x												
2. Baseline data collection tools																		
Develop questionnaires/data collection tools						x	x											
Select and contract survey firm						x	x											
Translate questionnaire							x	x										
Program CAPI questionnaire								x	x									
8. Dietary assessment formative work																		
Review programming and conduct focus groups as needed									x									
Refine tools and questionnaires									x	x								
3. Local and US-based IRB approvals																		
IRB application at IFPRI							x											
IRB application in Burkina Faso							x											
4. Baseline survey implementation																		
Pretest, revise and finalize questionnaire									x	x								
Enumerator training										x								
Data collection											x	x						
5. Data cleaning and analyses																		
Data cleaning												x	x					
Data analyses													x	x	x	x	x	x
6. Baseline results																		
Prepare preliminary results														x	x			
Draft and finalize baseline results																x	x	
Prepare clean datasets																	x	

Deliverable/Activities	2020						2021						
	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
7. Study protocol													
Review study protocol				x									
8. Endline data collection tools													
Develop questionnaires/data collection tools				x	x								
Translate questionnaire					x								
Program CAPI questionnaire		x	x		x	x							
9. Local and US-based IRB approvals													
Obtain IRB approvals at IFPRI					x								
Obtain IRB approvals in Burkina Faso					x								
10. Endline survey implementation													
Pretest, revise and finalize questionnaire							x						
Enumerator training							x						
Data collection							x	x					
11. Data cleaning and analysis													
Data cleaning								x	x				
Data analyses									x	x	x	x	x
12. Endline results tables and datasets													
Draft endline results										x	x		
Finalize endline report and findings												x	x
Prepare clean datasets													x

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