A Feasibility Study of Integrating Maternal Nutrition Interventions into Antenatal Care Services in Ethiopia: A Cluster-Randomized Evaluation

Study Protocol

International Food Policy Research Institute

June 2, 2021

VERSION: 2

Clinicaltrials.gov: NCT04125368

Funding: We acknowledge funding support from the Bill & Melinda Gates Foundation (grant no. OPP1171874), through Alive & Thrive, managed by FHI Solutions LLC. Additional financial support was provided by CGIAR Research Program on Agriculture for Nutrition and Health (A4NH), led by the International Food Policy Research Institute.

Roles and responsibilities:

Co-Investigators:

Dr. Sunny S. Kim
Research Fellow
Poverty, Health and Nutrition Division
International Food Policy Research Institute
1201 I St. NW
Washington, DC 20005-3915
USA
Phone: +1 202-862-4611
Email: sunny.kim@cgiar.org

Dr. Purnima Menon
Senior Research Fellow
Poverty, Health and Nutrition Division
International Food Policy Research Institute
9th Floor, Aggarwal Corporate Tower
Govind Lal Sikka Marg, Rajendra Place
New Delhi 110008
India
Phone: +91 11-66219-276
Email: p.menon@cgiar.org

Dr. Amare Worku Tadesse
Associate Professor of Nutrition and Public Health
Head, Department of Public Health Sciences
Addis Continental Institute of Public Health (ACIPH)
Yeka Sub City, Woreda 13, House No. B227
P.O. Box: 26751/1000
Addis Ababa
Ethiopia
Phone: +251 116-390018
Email: amarewaciph@gmail.com

Protocol contributors: Sunny Kim (Principal Investigator), Celeste Sununtnasuk (Project Manager), Amare Worku (Co-Principal Investigator), Yemane Berhane (ACIPH Director, Technical Advisor), Hanna Y. Berhane (ACIPH Deputy Director for Research and Community Services, Technical Advisor), Phuong Nguyen (Research Fellow), Purnima Menon (Co-Principal Investigator)

Sponsor: International Food Policy Research Institute (IFPRI)
1201 I St. NW
Washington, DC 20005-3915
USA
Phone: +1 202-862-3915

Contents

List of Tables

List of Figures

I. Introduction

1.1 Background and rationale

Poor maternal nutrition is a major public health concern and has adverse consequences on fetal and early childhood growth, infant morbidity and mortality, and health and productivity in adulthood (Black et al. 2013). Despite the availability of promising and affordable interventions for improving maternal nutrition in developing countries, many women do not receive proven maternal nutrition services during pregnancy. In Ethiopia, 62 percent of women receive antenatal care (ANC) from a skilled provider and just two-thirds of women who attend ANC receive nutrition counseling; nearly 60 percent of women do not consume any IFA tablets during pregnancy (CSA & ICF, 2016).

There is wide recognition of the importance of integrating maternal nutrition interventions in ANC to improve maternal and child health (Bhutta et al. 2013). In 2016, World Health Organization (WHO) ANC guidelines were updated to place a high priority on nutrition interventions during pregnancy to improve perinatal outcomes and women's experience of care. In Ethiopia, the government has adopted a package of maternal nutrition interventions into national guidelines (see Ethiopia's Federal Ministry of Health (FMOH) *National Guideline on Adolescent, Maternal, Infant and Young Child Nutrition*). Despite these efforts, the coverage and quality of maternal nutrition interventions remains low. Alive & Thrive (A&T) is interested in improving nutrition coverage among users of government ANC services.

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. In October 2017, A&T was awarded by the Bill & Melinda Gates Foundation's Ethiopia Office a new five-year agreement to Accelerate Improvements in Maternal, Infant and Young Child Nutrition in Ethiopia. The A&T Ethiopia 3.0 investment (2018–2022) will support the government of Ethiopia to achieve targets set out in the national nutrition program (NNP II) and the National Nutrition Sensitive Agriculture Strategy (NNSAS). A&T will focus its role on strengthening systems at the national and regional levels for achieving large scale and sustainability, and strengthening the evidence base for programs and policies.

In Ethiopia, 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 (WHO, 2016) and the NNP II. These include interpersonal counseling on diet quality during pregnancy, counseling on iron-folic acid (IFA) supplementation, adequate weight-gain monitoring, counseling on early breastfeeding practices, and systems strengthening through training and supportive supervision. The impacts of these intensive interventions in users of government ANC services will be compared with standard ANC services.

1.2 Objectives

A cluster randomized evaluation trial will be conducted to determine 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, and breastfeeding counseling) be improved by integrating nutrition-focused behavior change interventions and health systems strengthening approaches into existing ANC services?

3) Can the **quality of diets** (dietary diversity and meal frequency) among pregnant women be improved by integrating nutrition-focused behavior change interventions and health systems strengthening approaches into existing ANC services?

1.3 Trial design

The evaluation will use a two-arm cluster-randomized, non-masked trial design, consisting of two cross-sectional surveys at baseline and endline. The unit of randomization is the health center and associated health posts in the catchment area. The baseline survey will take place in October-November 2019, and the endline survey will take place in July-September 2021. Program implementation was interrupted between April and July 2020 due to the COVID-19 pandemic. The endline survey was postponed to July-September 2021 to maximize implementation duration. The repeated cross-sectional study design will allow us to assess the impact of the maternal nutrition interventions delivered at health facilities on currently pregnant and recently delivered women who attend government ANC services.

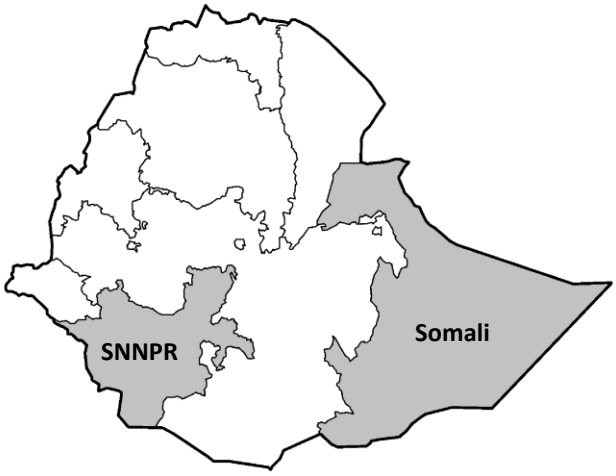
II. Methods: Participants, Interventions and Outcomes

2.1 Study setting

Implementation of the maternal nutrition study will take place in two regions: Southern Nations Nationalities and People's Region (SNNPR), a primarily agrarian region, and Somali, a region with a high population of pastoralists (see **Figure 1**). The Somali region is among the poorest of Ethiopia's nine administrative regions, predominantly rural, and relatively ethnically homogeneous. According to the most recent Ethiopian census in 2007, 38 percent of the population in Somali is pastoral compared with less than one percent in SNNPR (CSA 2007). SNNPR is one of the most populous regions in Ethiopia as well as the most diverse; more than 80 ethnic groups reside in the region.

Study regions were selected by the Government of Ethiopia, so that maternal nutrition intervention packages be tested in both agrarian and pastoral settings. Pastoralists—agriculturalists who rely primarily on their livestock for their food and income—and the regions they live have had few opportunities to be studied in the past, as their migratory nature makes it particularly difficult to track them through surveys. Policymakers are requesting programmatic experience across regions so that results and interventions can be used for the scale-up of nationally accepted guidelines and targets. Current guidelines for ANC services are standardized nationwide, providing further incentive to include diverse areas for study implementation.

Figure 1. Study regions



While there has been an increasing trend in coverage of services during pregnancy and early infancy, major gaps in coverage persist nationwide and in study regions (see **Figure 2**). Current ANC service utilization is low in the study regions and nationwide: only 11.8 percent of women in Somali and 38.2 percent of women in SNNPR achieved the WHO-recommended four or more ANC visits during pregnancy (compared to 31.8 percent nationally) (CSA & ICF, 2016). Among women who had at least one ANC visit, 48 percent in Somali and 62.3 percent in SNNPR received nutrition counseling. More than half (56 percent) of women in Somali and nearly a third (30.4 percent) of women in SNNPR did not attend ANC during their pregnancy.

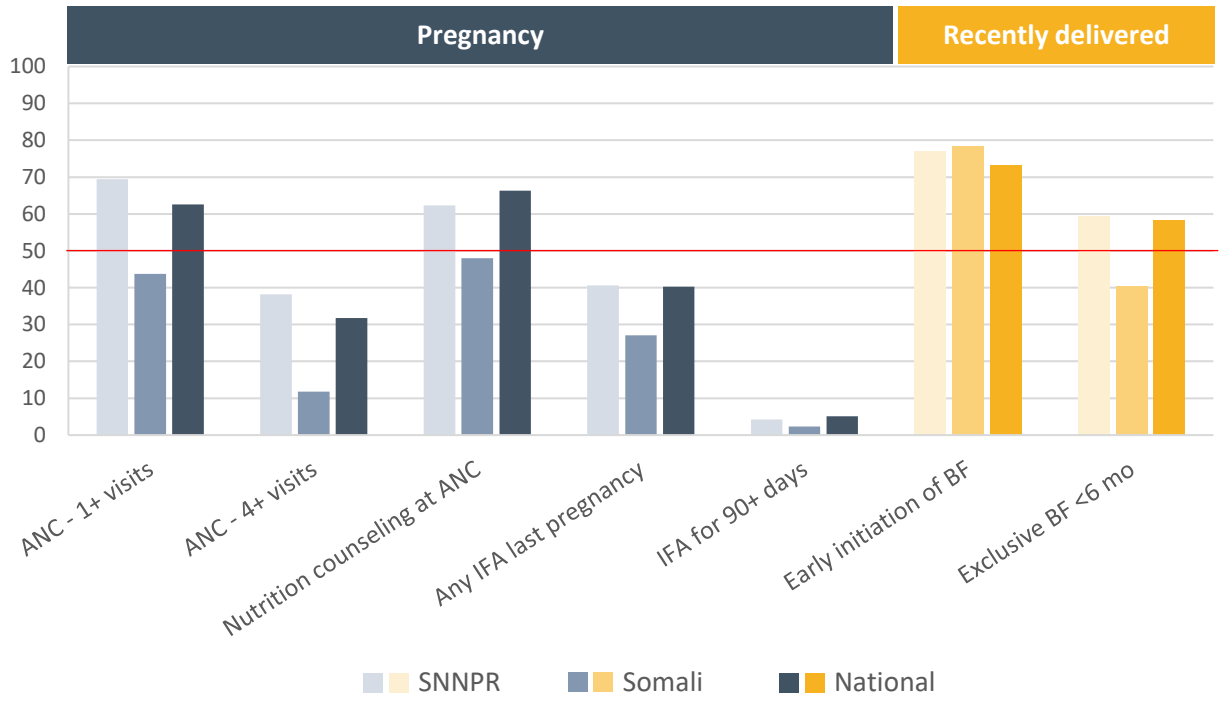
IFA consumption during pregnancy is also low in Ethiopia. Current WHO guidelines recommend daily IFA supplementation for women throughout pregnancy, beginning as early as possible. Ideally, women should receive IFA tablets no later than the first trimester, corresponding to 6 months (180 days) of supplementation. Very few women (4.2 percent in SNNPR and 2.3 percent in Somali) achieve at least 90 days of IFA supplementation before delivery (CSA & ICF, 2016). Seventy-two percent of women in Somali and 59 percent of women in SNNPR did not consume any IFA tablets during their most recent pregnancy.

Notwithstanding the critical nutritional needs of pregnant women, who must meet the additional energy and micronutrient requirements for fetal development and to protect their health through pregnancy and delivery, evidence on the dietary intake of pregnant women in Ethiopia is scarce. One study conducted in rural SNNPR found that while nearly all pregnant women reported the need for dietary improvements during pregnancy, only a quarter of women reported increased food intake and no significant differences were found between the dietary intakes of pregnant and non-pregnant women (Asayehu et al. 2017). Moreover, even among those pregnant women who claimed improved food intake, energy and most micronutrient intakes were inadequate.

Misconceptions about weight gain during pregnancy and food taboos also persist in some areas of Ethiopia. Many rural women in the Oromia region were found to oppose gaining weight during pregnancy, out of fear of delivery complications associated with the birth of a large baby (Zerfu et al. 2016). Limited weight gain, before and during pregnancy, can result in inadequate birthweight and fetal growth (Frederick et al. 2008; Siega-Riz et al. 2009).

Regarding early breastfeeding practices, nearly all women in Ethiopia have ever breastfed their children, with nearly 80 percent of women in SNNPR and Somali reporting early initiation of breastfeeding (within one hour of birth) (CSA & ICF, 2016). Exclusive breastfeeding among children during the first 6 months is less prevalent; only 40 percent of infants in Somali and roughly 60 percent of infants in SNNPR are exclusively breastfed.

Figure 2. ANC and breastfeeding indicators among Ethiopian women of reproductive age



Source: 2016 Ethiopia Demographic and Health Survey

Across SNNPR and Somali regions, A&T selected seven woredas (districts) as potential intervention areas on the basis of having adequate health facility access and infrastructure. Four woredas were selected in SNNPR and three woredas in Somali region. Fewer woredas were selected in Somali as the communities are more homogenous, and those with less security issues were identified. The list of study woredas and their corresponding numbers of health centers and posts are presented in **Table 1.**

Table 1. Study woredas and total number of available health centers and health posts

No.	Region	Zone	Woreda	Population	Kebeles	Health Centers	Health Posts
1	Somali	Fafan	Gursum	37,425	15	3	18
2		Fafan	Harawa	32,034	16	2	15
3		Fafan	Keberi Beyah	165,518	29	5	34
4	SNNPR	Gurage	Sodo	175,400	54	7	39
5		Gurage	Muhor Na Aklil	119,137	29	5	30
6		Silti	Dalocha	89,807	18	4	18
7		Kembata Tembaro	Doyo Gena	78,634	18	4	19

2.2 Eligibility criteria

Women of reproductive age (15 to 49 years old) are eligible for inclusion in the baseline and endline surveys if: 1) they are registered at the government health center as currently pregnant and have attended at least 1 ANC visit at the government health center/post, or have a child under 6 months of age (recently delivered) at the time of the survey and attended at least 1 ANC visit at the selected health center/post, 2) reside within sample kebeles in the health center catchment area, and 3) have given informed consent. Recently delivered women must have had a live birth within 6 months preceding either of the two surveys and the infant must still be alive and living with them.

At the health center level, the nurse-midwife responsible for providing ANC, available at the time of the survey, and has given informed consent will be interviewed. At the health post level, the health extension worker (HEW) available at the time of the survey and has given informed consent will be interviewed. If more than one health worker/extension worker are eligible, the person primarily responsible for ANC or with the most experience in providing ANC (determined as the individual who has worked the most years in the current position) at the study health facility will be invited to participate.

2.3 Interventions

The package of maternal nutrition interventions will include interpersonal counseling on diet quality during pregnancy, counseling on IFA supplements, adequate weight-gain monitoring, counseling on early breastfeeding practices, and systems strengthening through improving the IFA supply chain, training and supportive supervision. Intervention components are presented in **Table 2**.

Table 2. Overview of interventions in intensive and non-intensive intervention areas

CORE INTERVENTIONS	INTERVENTION	CONTROL
At health facilities:		
• Counselling on diet quality during pregnancy	Intensified counselling on dietary diversity and increased meal frequency during pregnancy	Standard counseling at health facilities
• Strengthening distribution and promotion of IFA supplementation	Strengthened government distribution of supply of IFA with counseling about its importance, managing side effects, and reminder about subsequent supplies	Current practice of supply and distribution of IFA tablets at health facilities
• Weight-gain monitoring	Weight-gain monitoring with messaging to mothers about healthy diet and adequate rest; excess weight gain as a danger sign	Current practice of weight-gain monitoring at health facilities
• Counseling on early breastfeeding practices	Intensified counseling on importance, benefits, and how-tos of early initiation of breastfeeding and exclusive breastfeeding	Standard breastfeeding messages at health facilities
Home visits by HEWs	Home visits to pregnant women by HEWs to discuss maternal nutrition (dietary diversity, adequate food intake, IFA supplementation, and weight gain), early breastfeeding practices, provide ANC and Pregnant Women Conference referrals, and engage husbands	Home visits for routine health services
Pregnant Women Conferences/ Mother Support Groups	HEWs use A&T intervention tools (e.g. posters and maternal nutrition follow-up card) to reinforce maternal nutrition messages,	Standard meetings

	encourage ANC attendance, distribute IFA tablets, measure and track weight gain, promote early breastfeeding practices, and encourage husband participation	
Kebele and community meetings	HEWs and community volunteers (Women's Development Army (WDA), imams, etc.) deliver maternal nutrition messages and encourage ANC visits	Standard meetings
Training for health staff and other actors	Trainings on the maternal nutrition interventions above for health center heads, nurse-midwives, HEWs, community volunteers (WDA, imams, etc.), woreda health officers, and other key actors	Standard health training
Supportive supervision for health staff and other actors	Supportive supervision of maternal nutrition activities conducted by woreda nutrition officers, woreda health officers, TDA or A&T	Standard health facility supervision

2.4 Outcomes

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

1) **Maternal dietary diversity and quality of diets among pregnant women**
    i. Mean number of food groups consumed by pregnant women
    ii. Proportion of pregnant women who achieve minimum dietary diversity
2) **Use of iron-folic acid (IFA) supplements**
    i. Mean number of IFA tablets consumed during pregnancy
    ii. Proportion of women who received 90+ IFA supplements during pregnancy

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

3) Early initiation of breastfeeding
4) Use of ANC services (total number of ANC visits and timing of the first ANC visit)
5) 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)
6) Exposure to nutrition information from ANC and other sources
7) Women's knowledge and perceptions about maternal nutrition and breastfeeding
8) Health worker knowledge on benefits and service provision for IFA supplementation, dietary diversity counselling, weight gain monitoring, and breastfeeding counselling
9) Availability of service supports (IFA supplies, records/registers and regular review of nutrition intervention coverage and IFA supply data, weight measurement equipment, counseling materials, and training and supervision for health workers)

2.5 Participant timeline

Enrollment of pregnant and recently delivered women will begin in October 2019, at the time of baseline survey. Interventions were planned to be implemented for up to one year, following the baseline survey. Then, pregnant and recently delivered women would be assessed at endline, exactly one year after baseline.

In March 2020, the World Health Organization declared COVID-19 a pandemic. Disruptions to work and field conditions in Ethiopia resulted in program implementation being halted in April 2020 when the Government of Ethiopia declared a state of emergency. A&T began providing supportive supervision in July 2020 and refresher trainings for nurse-midwives and HEWs were held in November 2020. Interventions will be implemented through July 2021.Pregnant and recently delivered women will be assessed at endline in July-September 2021.

2.6 Sample Size

The two main survey samples for the primary outcomes will be: 1) pregnant women who attended at least 1 ANC at the sampled health center or associated health post, as this sample allows the assessment of diet quality during pregnancy; and 2) recently delivered women who attended at least 1 ANC at the sampled health center or associated health post and who have children <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). Sample sizes were estimated based on current known prevalence of the primary outcomes among women who attended ANC, the expected change after intervention, power to detect those differences (80%), and level of significance (α=0.05) As the intervention was randomized at the cluster level (30 clusters) rather than the individual level, cluster effects were considered for sample size calculations.

For the sample size for pregnant women, we used the number of food groups from the A&T Phase 1 endline survey for SNNPR (mean: 3.04, SD: 1.39, categorized as 9 food groups; Arimond et al., 2010), assuming an intra-cluster correlation (ICC) of 0.21. We calculated that a sample of 270 pregnant women per group will be able to detect a minimum of 0.75 food group consumption increase. Using baseline data, we observed a mean food group consumption of 3.50 (SD: 1.49) out of 10 food groups. Assuming an ICC of 0.096, we estimated that this sample size will detect a minimum difference of 0.61 food groups.

For the sample size for recently delivered women, we used the number of IFA tablets consumed from the DHS 2016 data for SNNPR (mean: 33.19, SD: 30.36), assuming an ICC of 0.15. We calculated that a sample of 945 recently delivered women per group will be able to detect a difference of 13 tablets consumed. For the proportion of women who consumed 90+ IFA tablets, we calculated that a sample of 450 recently delivered women will be able to detect a minimum of 15% increase in women consuming 90+ IFA tablets. At baseline, an error in the final Computer-Assisted Personal Interviews (CAPI) form for recently delivered women led to missing data values for the outcome variable on total IFA tablets consumed. We instead used the percentage of recently delivered women at baseline who ever consumed IFA tablets (84.3 %) and assumed an ICC of 0.150. We estimate that the sample size will detect a 12.3% increase in women who ever consumed IFA tablets. If husbands of recently delivered women are present at the time of the endline survey, they will also be interviewed briefly about their exposure to interventions, health and nutrition knowledge and any support provided during pregnancy.

Nurse-midwives and HEWs providing ANC in the study areas will also be included in both baseline and endline surveys. Three kebeles/health posts (where HEWs fall under the supervision of corresponding health centers) will be sampled per health center catchment area. Government guidelines advise that pregnant women should receive their first and last ANC visits at the health center, and other ANC visits may be provided at health posts. Direct observations of ANC visits (two per health center and one per health post) to assess service quality, followed by exit interviews to assess client satisfaction, will be conducted at endline among a subgroup of pregnant women attending ANC at the time of the survey.

At baseline, a light data collection at all facility levels (health centers and health posts) and subsamples of pregnant and recently delivered women will be conducted to assess comparability between study arms. At endline, the full samples of pregnant and recently delivered women will be surveyed.

Thus, the overall study samples sizes are presented in **Table 3**.

Table 3. Sample sizes

	Baseline 2019		**Endline 2020**	
	Intervention	**Control**	**Intervention**	**Control**
Pregnant women	90	90	270	270
Recently delivered women/Husbands	180	180	945	945
Nurse-midwives (1 per health center)	15	15	15	15
HEW (1 per health post)	45	45	45	45
Facility assessments (1 per health center/post)	60	60	60	60
ANC observation and exit interview (2 per health center, 1 per health post)	0	0	75	75
Total (*excluding* facility assessment)	330	330	1,350	1,350

2.7 Recruitment

Health center and health post registries will be reviewed to identify eligible pregnant and recently delivered women from the selected study areas for the interview. We will select 3 kebeles per cluster (health center catchment area) to recruit 2 pregnant women per kebele at baseline (6 at endline) and 4 recently delivered women from each kebele at baseline (21 at endline) (to balance achieving a geographical spread across the cluster with logistical feasibility). Program monitoring data indicate that achieving the sufficient endline sample sizes of pregnant and recently delivered women from 3 kebeles per cluster may be difficult. If the required sample sizes cannot be reached from the 3 kebeles alone, 10 recently delivered women will be sampled from each kebele and 33 will be sampled from each health center catchment area and any additional pregnant women needed to reach the sample size can be taken from the health center catchment area. Pregnant women will be asked whether they currently attend ANC at the selected government health center and/or health post. Recently delivered women will be asked whether they attended any ANC at the selected government health center and/or health post during pregnancy. From the two separate lists (for pregnant women and for recently delivered women), women will be randomly selected by simple random sampling until the required sample sizes are reached.

III. Methods: Assignment of Interventions

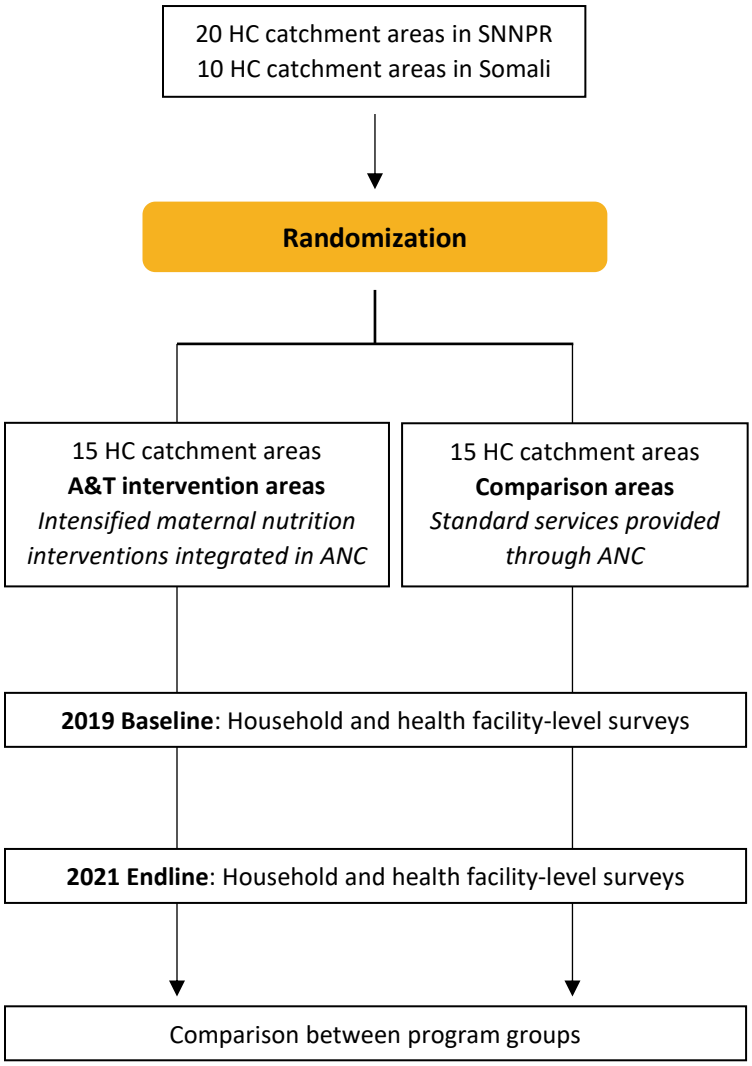
3.1 Allocation

A cluster is defined as the health center catchment area. Four woredas in SNNPR (with 18 health centers and 2 hospitals) and two woredas in Somali region (with 10 health centers) were selected as intervention areas (see **Figure 3**). The samples across the two regions will be pooled to estimate effects at program level. We will use stratified randomization to try to balance potential co-interventions and confounders. Where there are odd numbers of health centers within woredas, the remaining health centers will be randomized within the same region. Then, 15 clusters will be allocated to the intervention arm and 15 clusters will be allocated to the control arm by use of computer generated pseudo-random numbers.

3.2 Blinding (masking)

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.

Figure 3. Trial flow



Note: HC: health center. The baseline and endline surveys will include cross-sectional interviews of pregnant and recently delivered women, as well as providers of ANC services at government health facilities.

IV. Methods: Data Collection, Management and Analysis

4.1 Data collection methods

Data will be collected at the health facility and household levels, using pretested questionnaires. The following set of tools will be translated from English to Amharic 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. Health Extension Worker (HEW) questionnaire

v. Pregnant women questionnaire
vi. Recently delivered women/Husband questionnaire

Topics included in each of the data collection methods and sample sizes are presented in **Table 4**.

Table 4. Data collection methods and samples

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 and exit interview	Direct observation checklist of ANC session to document services provided, perceptions of counseling received, and patient satisfaction
Nurse-midwife questionnaire	Nurse-midwife's responsibilities, time commitments and workload, capacity, knowledge, motivation, supervision, and ANC service provision at the *health center*
Health extension worker (HEW) questionnaire	HEW's responsibilities, time commitments and workload, capacity, knowledge, motivation, supervision, and ANC service provision at the *health post*
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/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 and other family members during pregnancy

4.1.1 Health facility observation checklist

A facility observation checklist will be included to obtain information on the presence and condition of infrastructure, facility and staff characteristics, ANC equipment and services, patient caseload and monitoring of ANC patients. Checklists will be the same for health centers and health posts.

Table 5. Description of topics to be included in the health facility observation checklist

Module	Topic	Description	Respondent
1	Facility 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	Enumerator (direct observation)
4	ANC equipment and materials	Availability of functioning ANC equipment and counseling materials	Enumerator (direct observation)

5	ANC services provided	Services provided in-facility, IFA stocks and records	Enumerator (registers, inquire with health worker)
6	Patient caseload	Health facility catchment population, caseload for ANC, referrals, and counselling	Enumerator (registers, inquire with health worker)
7	Monitoring system	Monitoring and tracking of ANC clients, and records of ANC services, community activities, training, and supervision	Enumerator (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.

Table 6: 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.

Table 7. Description of modules in the nurse-midwife questionnaire

Module	Topic	Description	Respondent
1	Identification	Location, health center	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, time commitments, number of consultations and patients, monitoring and tracking of ANC clients, and records of ANC services provided	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 child feeding knowledge	Knowledge of the importance of early initiation of breastfeeding and exclusive breastfeeding	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 Health Extension Worker (HEW) questionnaire

Interviews with HEWs who provide ANC services at health posts 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 8. Description of modules in the HEW questionnaire

Module	Topic	Description	Respondent
1	Identification	Location, health post	Enumerator
2	Demographic characteristics	Age, education, years of experience and other characteristics of the HEW	HEW
3	Time commitments and workload	Workload of the HEW, including responsibilities, time commitments, number of consultations and patients, and records of ANC services and community activities provided	HEW
4	Nutrition counseling information	Topics/messages provided as part of nutrition counseling during ANC	HEW
5	Health and nutrition knowledge	General knowledge on health and nutrition, WASH, nutrition during pregnancy, anemia, and IFA supplementation	HEW
6	Breastfeeding and child feeding knowledge	Knowledge of the importance of early initiation of breastfeeding and exclusive breastfeeding	HEW

7	Training exposure	Exposure to and training received on maternal nutrition	HEW
8	Supervision and contact with other actors	Frequency and content of supervision received from superiors, and contact with other actors (e.g. kebele leaders)	HEW

Note: At baseline, the HEW interview for the Maternal Nutrition study will be conducted at the same time as the HEW interview for the Alive & Thrive Ethiopia 3.0 Adolescent Nutrition study. There is one questionnaire for both studies, therefore only the modules relevant to the Maternal Nutrition study are included above.

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, maternal nutrition and breastfeeding knowledge, use of ANC, IFA consumption, social desirability, women's decision-making power, and mental health will be collected.

Table 9. Description of modules in the pregnant women'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 in the past month of all household members at least 15 years of age	Pregnant woman
3	Obstetric history	Marriage, pregnancy, and childbirth history	Pregnant woman
4	Use of antenatal care (facility-based)	Frequency, location, provider, and timing of ANC use; services/messages received during ANC	Pregnant woman
5	Exposure to maternal nutrition information interventions in the community	Frequency and exposure to maternal nutrition information during home visits, pregnant women's conferences/meetings, and other community meetings or gatherings	Pregnant woman
6	Consumption of IFA supplements	Current consumption of IFA tablets, receipt/purchase of IFA tablets, tracking of IFA consumption, observation of tablets/strips/bottles of IFA	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, WASH, nutrition during pregnancy, anemia, and IFA supplementation, early initiation and exclusive breastfeeding	Pregnant woman
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 role and 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 and husband questionnaire

Detailed interviews with recently delivered 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, maternal nutrition and breastfeeding knowledge, use of ANC and postnatal services, IFA consumption during pregnancy, breastfeeding and child feeding practices, social desirability, women's decision-making power, mental health, postnatal functional disability and anthropometry will be collected. If husbands of recently delivered women are present at the time of the endline survey, they will also be interviewed briefly about their health and nutrition knowledge and any support provided during pregnancy.

Table 10. Description of modules in the recently delivered women'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 in the past 12 months of all household members at least 15 years of age	Recently delivered woman

3	Obstetric history	Marriage, pregnancy, and childbirth history	Recently delivered woman
4	Use of ANC and postnatal care (PNC) services	Frequency, location, provider and timing of ANC/PNC use, services/messages received during ANC/PNC	Recently delivered woman
5	Exposure to maternal nutrition interventions in the community	Frequency and exposure to maternal nutrition information during home visits, pregnant women's conferences/meetings, and other community meetings or gatherings	Recently delivered woman
6	Consumption of IFA supplements	Consumption of IFA tablets during pregnancy, receipt/purchase of IFA tablets, tracking of IFA consumption	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 and perceptions on health and nutrition, WASH, nutrition during pregnancy, anemia, and IFA supplementation	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 of recently delivered woman and index child <6 months of age	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, WASH, 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 and other family members	Husband

4.2 COVID-19 precautionary measures

Since early 2020, close-range contacts between enumerators and study participants during data collection activities present a particular risk for spreading COVID-19 in communities with vulnerable populations. The collaborating survey firm, Addis Continental Institute of Public Health (ACIPH), has developed formal fieldwork guidelines based on directives for the prevention and control of the COVID-19 pandemic by the Ministry of Health (MOH) and Ethiopian Public Health Institute, and UNICEF recommendations for surveilling and monitoring nutrition in the context of COVID-19. As part of the guidelines, all enumerators and study participants will wear masks (provided to them) and wash or sanitize their hands before and after each interview. Interviews will be conducted outside or in a well-ventilated space and enumerators will maintain two meters of distance from the interviewee and other household members. Measuring boards and scales will be sanitized after every anthropometric measurement. Any study staff with COVID-19-related symptoms (fever, dry cough, extreme fatigue, respiratory problems, or any unusual illness) will be immediately excluded from fieldwork and remain isolated as per MOH guidelines. Any study participants with COVID-19-related symptoms will be excluded from the study and advised to remain isolated and seek appropriate services according to MOH and any local guidelines.

Before enumerator training begins, all study staff will be tested for COVID-19. Any individual who tests positive will be advised to isolate and seek appropriate health services as described above. Study staff will also be assessed for COVID-19-related symptoms before each day of enumerator training begins. While in the field, field supervisors will assess enumerators each day before starting data collection using a COVID-19 symptom monitoring chart. In addition, Co- and Principal Investigators of the project will be in daily contact with ACIPH 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 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

Data analysis will use econometric analysis to control for (any) differences at baseline and between intervention and comparison groups for all relevant variables of interest. Statistical testing for 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 and/or analysis of covariance (ANCOVA) controlling for covariates. Data management, data cleaning and statistical analyses will be conducted using Stata version 16 (Statacorp, USA). The statistical significance for tests will be set at 5% for main effects or 10% in case of interactions. All statistical tests will be one-sided.

V. Methods: Monitoring

5.1 Data monitoring

Data collection (including observational, women, and health worker data collection) will be undertaken 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, project manager, and principal and co-principal investigators of the survey firm and IFPRI will closely monitor enumerators and the quality of data collected to ensure the integrity of the data during data collection.

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 submitted for ethical clearance from the Institutional Review Boards (IRB) of FHI 360 and the International Food Policy Research Institute in Washington, DC. In Ethiopia, ethical clearance will be sought from the ACIPH IRB.

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-Principal Investigators and ACIPH Co-Investigator) to and agreed upon with Alive & Thrive. Substantive changes to the protocol that may impact the safety of participants or the scientific validity, scope, or ethical rigor of the study will be reviewed by the IFPRI 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 or assent

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 or program staff.

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 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.

6.5 Declaration of interests

The authors declare that they have no competing interests.

6.6 Access to data

All Co- and Principal Investigators of the project (based in the US and in Ethiopia) 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.

6.7 Ancillary and post-trial care

Not applicable.

6.8 Dissemination policy

Close engagement with the government of Ethiopia is of primary importance to the project. The A&T Ethiopia 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											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1. Study protocol												
Discuss study design with A&T	x	x	x									
Prepare study protocol			x	x	x	x						
2. Baseline data collection tools												
Develop questionnaires/data collection tools				x	x	x						
Select and contract survey firm					x	x						
Translate questionnaire							x					
Program CAPI questionnaire							x	x				
3. Local and US-based IRB approvals												
IRB application at IFPRI								x				
IRB application in Ethiopia							x					
4. Baseline survey implementation												
Pretest, revise and finalize questionnaire								x				
Enumerator training									x			
Data collection										x	x	
5. Data cleaning and analyses												
Data cleaning											x	x
Data analyses												x

Deliverables/Activities	2020											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Data analyses	x	x										
6. Baseline results tables and datasets												
Draft and finalize baseline results			x	x	x	x						
Prepare clean datasets							x					

Deliverables/Activities	2021											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
7. Endline data collection tools												
Develop questionnaires/data collection tools				x	x							
Translate questionnaire						x						
Program CAPI questionnaire						x	x					
8. Local and US-based IRB approvals												
Obtain IFPRI IRB approvals to conduct fieldwork							x					
Obtain local IRB approvals to conduct fieldwork							x					
8. Endline survey implementation												
Pretest, revise and finalize questionnaire							x					
Enumerator training							x					
Data collection							x	x	x			
9. Data cleaning and analysis												
Data cleaning									x	x		
Data analyses										x	x	x
10. Endline results tables and datasets												
Draft endline results											x	x
Finalize endline report and findings												
Prepare clean datasets												

Deliverables/Activities	2022											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
9. Data cleaning and analysis												
Data cleaning												
Data analyses	x	x										
10. Endline results tables and datasets												
Draft endline results												
Finalize endline report and findings	x	x	x									
Prepare clean datasets				x								

References

Alemayehu, Alemayehu A., Yewelsew Abebe, and Rosalind S. Gibson. 2011. "A 24-h recall does not provide a valid estimate of absolute nutrient intakes for rural women in southern Ethiopia." *Nutrition*, 27(9): 919-924. https://doi.org/10.1016/j.nut.2010.10.015

Arimond, Mary, Doris Wiesmann, Elodie Becquey, Alicia Carriquiry, Melissa C. Daniels, Megan Deitchler, Nadia Fanou-Fogny, Maria L. Joseph, Gina Kennedy, Yves Martin-Prevel, and Liv Elin Torheim. 2010. "Simple food group diversity indicators predict micronutrient adequacy of women's diets in 5 diverse, resource-poor settings." *Journal of Nutrition*, 140(11): 2059S-2069S. https://doi.org/10.3945/jn.110.123414

Asayehu, Tamene Taye, Carl Lachat, Stefaan De Henauw, and Seifu Hagos Gebreyesus. 2017. Dietary behaviour, food and nutrient intake of women do not change during pregnancy in Southern Ethiopia. *Maternal & Child Nutrition*, 13(e12343). https://doi.org/10.1111/mcn.12343

Bhutta, Zulfiqar A., Jai K Das, Arjumand Rizvi, Michelle F. Gaffey, Neff Walker, Susan Horton, Patrick Webb, Anna Lartey, and Robert E. Black. 2013. "Evidence-based interventions for improvement of maternal and child nutrition: what can be done and at what cost?" *Lancet*, 382(9890): 452-477. https://doi.org/10.1016/S0140-6736(13)60996-4

Black, Robert E., Cesar G. Victora, Susan P. Walker, Zulfiqar A. Bhutta, Parul Christian, Mercedes de Onis, Majid Ezzati, Sally Grantham-McGregor, Joanne Katz, Reynaldo Martorell, and Ricardo Uauy. 2013. "Maternal and child undernutrition and overweight in low-income and middle-income countries." *Lancet*, 382(9890): 427-451. https://doi.org/10.1016/S0140-6736(13)60937-X

Central Statistical Agency (CSA) [Ethiopia] and ICF. 2016. *Ethiopia Demographic and Health Survey 2016*. Addis Ababa, Ethiopia, and Rockville, Maryland, USA: CSA and ICF.

Central Statistical Agency (CSA) [Ethiopia]. 2007. *Population and Housing Census*. Addis Ababa, Ethiopia.

Federal Democratic Republic of Ethiopia Ministry of Health (FMOH). 2016. *National Guideline on Adolescent, Maternal, Infant and Young Child Nutrition*. Addis Ababa, Ethiopia: FMOH.

Frederick, Ihunnaya O., Michelle A. Williams, Anne E. Sales, Diane P. Martin, and Marcia Killien. 2008. Pre-pregnancy Body Mass Index, Gestational Weight Gain, and Other Maternal Characteristics in Relation to Infant Birth Weight. *Maternal and Child Health*, 12(5): 557-567. https://doi.org/10.1007/s10995-007-0276-2

Siega-Riz, Anna Maria, Meera Viswanathan, Merry-K Moos, Andrea Deierlein, Sunni Mumford, Julie Knaack, Patricia Thieda, Linda J. Lux, and Kathleen N. Lohr. 2009. A systematic review of outcomes of maternal weight gain according to the Institute of Medicine recommendations: birthweight, fetal growth, and postpartum weight retention. *American Journal of Obstetrics and Gynecology*, 201(4): 339.e1-339.e14. https://doi.org/10.1016/j.ajog.2009.07.002

World Health Organization (WHO). 2016. *WHO recommendations on antenatal care for a positive pregnancy experience*. Geneva, Switzerland: World Health Organization.

Zerfu, Taddese Alemu, Melaku Umeta, and Kaleab Baye. 2016. Dietary habits, food taboos, and perceptions towards weight gain during pregnancy in Arsi, rural central Ethiopia: a qualitative cross-sectional study. *Journal of Health, Population and Nutrition*, 35(22). https://doi.org/10.1186/s41043-016-0059-8