A Feasibility Study of Delivering Adolescent Nutrition Interventions through School-Based Platforms in Ethiopia: A Cluster-Randomized Evaluation

Study Protocol

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I. Introduction

1.1 Background and rationale

Adolescence is a critical period of physical and psychological development and for achieving human potential. Rapid physical, psychosocial and cognitive growth and development is coupled with increased energy and nutrient requirements (Das et al., 2017; Spear 2002). Poor nutrition during adolescence can have adverse consequences impacting health in adulthood. The significance of nutrition during adolescence is especially important for girls, as poor nutrition can affect their well-being as well as the survival, health and well-being of their children (Das et al. 2017). Data and evidence on the nutritional status of adolescents in low- and middle-income countries is scarce, even though they represent some 1.8 billion individuals. Globally, the health and nutrition status of adolescents have only modestly improved over the last 50 years (Akseer et al. 2017).

In Ethiopia, where the population is very young with 40 percent under the age of 15 years (UNDP 2017), evidence on the nutrition of adolescent girls and their determinants is limited as literature tends to focus on issues of child marriage, education, economic empowerment, and sexual and reproductive health (Stavropoulou and Gupta-Archer 2017). There is, however, growing recognition of the importance of adolescent health and well-being (Patton et al. 2016). In 2015, the UN Secretary-General's Global Strategy for Women's, Children's, and Adolescents' Health was launched, in part, to include adolescents as a focus of the new Sustainable Development Goals. The federal government of Ethiopia has adopted a package of adolescent nutrition interventions into national guidelines (see Ethiopia's Federal Ministry of Health (FMOH) *National Guideline on Adolescent, Maternal, Infant and Young Child Nutrition*).

Alive & 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. 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, Adolescent, 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 level for achieving large scale and sustainability, and strengthening the evidence base for programs and policies.

In Ethiopia, A&T will test the feasibility of implementing a package of locally tailored adolescent nutrition interventions through school-based (in-class curriculum, extracurricular activities, parent-teacher associations and activities) and community platforms. The impacts of these nutrition-focused interventions will be compared with standard school and community activities in control areas.

1.2 Objectives

To evaluate the feasibility and impact of delivering nutrition interventions through school-based platforms on diet quality among adolescent girls.

Research questions for the evaluation include:

1) Is it **feasible** to integrate locally relevant adolescent nutrition interventions through schoolbased platforms?

- 2) What are the **barriers and opportunities** for strengthening school-based nutrition interventions for adolescents?
- 3) What are the impacts of interventions on the **quality of diets** (dietary diversity and less consumption of unhealthy snacks) among adolescent girls?

1.3 Trial design

The evaluation will use a two-arm cluster-randomized, non-masked trial design, consisting of two crosssectional surveys at baseline and endline. The unit of randomization is the primary school which includes grades 1-8. The baseline survey will take place in October-November 2019 (when the school year begins), and the endline survey will place in March-April 2021 (following the end of first semester classes). Program implementation was halted from March to October 2020 due to the COVID-19 pandemic, thus the endline survey was postponed to the following school year after implementation was reinitiated. The study design will allow us to assess the impact of adolescent nutrition interventions delivered through school on adolescent girls aged 10-14 years enrolled in grades 4-8.

II. Methods: Participants, Interventions and Outcomes

2.1 Study setting

Implementation of the adolescent 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 at the request of the Government of Ethiopia, so that adolescent 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. 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 the primary school system are standardized nationwide, providing further incentive to include diverse areas for study implementation.

Figure 1. Study regions



Net primary school attendance is moderate nationwide, but lower in the Somali region: the net attendance ratio (percentage of official primary school-age population that attends primary school) is 73.8 in SNNPR and 59.2 in Somali (compared to 71.3 nationwide) (see **Table 1**). While there is gender parity in primary school attendance in SNNPR, the net attendance ratio for girls is 5.9 percentage points lower than the ratio for boys in Somali. Though not ideal, primary schools offer one of the few opportunities for the government to reach a substantial number of adolescent girls in the 10 to 14-year age group through nationally scaled up programs.

School dropout is a serious concern; in 2014, 61.8 percent of students who started primary school dropped out between the first and last grade (World Bank EdStats, 2019). Dropout rates are roughly the same for boys (62.7 percent) and girls (60.7 percent). Primary school-life expectancy is 6.2 years (6.4 for boys and 5.9 for girls). In 2015, there were more than 2.2 million children of primary school age who were not in school, 60.8 percent of which were girls (World Bank EdStats, 2019). The desirability of sending girls to school may be improved through additional services such as adolescent nutrition-related activities.

Information on dietary diversity among adolescent girls and boys 10-14 years of age is unavailable in the 2016 EDHS. However, body mass index (BMI) indicators are available for boys and girls ages 15-19 years of age. A low BMI can indicate eating too little or having an unbalanced diet that lacks adequate nutrients. Roughly 45 percent of adolescent girls in Somali and 17.4 percent of adolescent girls in SNNPR are thin (BMI <18.5 kg/m2). Thinness is more common among adolescent boys: 78.1 percent are thin in Somali and 45.2 percent are thin in SNNPR.

Information on dietary intake is critical for appropriate planning of interventions that can effectively improve the diets and nutritional status of adolescents. But few studies have assessed dietary diversity among adolescents and school-aged children in Ethiopia. Those that have are limited to specific regions and towns across the country. Of the studies reviewed by a recent A&T landscape analysis of adolescent health and nutrition in Ethiopia, mean dietary diversity scores ranged from 3 food groups (Herrador et al. 2014) to 7 (Gali et al. 2017), with the average scores across studies being 4.5 food groups (Truebwasser 2017). Knowledge of healthy food choices among adolescents may also be limited. A Knowledge, Attitudes and Practice (KAP) survey conducted in several regions (including SNNPR and

Somali) of Ethiopia found that only two thirds of adolescent girls reported hearing about balanced diets. In Somali, 85 percent had not heard about balanced diets (FMOH and UNICEF, 2016).

Across SNNPR and Somali regions, A&T selected seven woredas (districts) as potential intervention areas on the basis of having adequate school access and infrastructure. Four woredas were selected in SNNPR and three woredas in Somali region. In Somali, woredas with more settled communities and less security issues were selected; fewer woredas were also selected, compared with SNNPR, as the communities are more homogenous. The list of study woredas and their corresponding total numbers of primary schools with grades 1-8 are presented in **Table 1**.

No.	Region	Zone	Woreda	Population	Kebeles	Primary Schools with grades 1-8
1		Fafan	Gursum	37,425	15	11
2	Somali	Fafan	Harawa	32,034	16	9
3		Fafan	Keberi Beyah	165,518	29	15
4		Gurage	Sodo	175,400	54	32
5	CNINDD	Gurage	Muhor Na Aklil	119,137	29	34
6	SININPR	Silti	Dalocha	89,807	18	19
7		Kembata Tembaro	Doyo Gena	78,634	18	23

Table 1. Study woredas and total number of primary schools available

2.2 Eligibility criteria

To be eligible for inclusion in the study, adolescent girls must be enrolled in the study primary school, be between 10 to 14 years of age (grades 4-8) and have received parental consent and given assent to participate in the study. Adolescent girls will be excluded if they or their parent/guardian are unwilling to participate in any part of the baseline or endline surveys.

At the school level, the principal and science teacher, and health extension workers (HEW) responsible for providing nutrition education or facilitating other related activities/interventions and have given informed consent will be interviewed.

2.3 Interventions

The package of locally tailored adolescent nutrition interventions will include in-school education about nutrition and healthy food choices, mentoring and peer group activities related to nutrition, and parent education on adolescent nutrition during school and community meetings. Intervention components are presented in **Table 2**.

CORE INTERVENTIONS	INTERVENTION PRIMARY SCHOOLS	CONTROL PRIMARY SCHOOLS
At school:		
 Classroom education about healthy diet and nutrition 	Classroom lessons related to nutrition, dietary diversity, healthy food choices and hand washing	Standard health education
 Flag events or assemblies about healthy diet and nutrition 	Flag events or school assemblies led by principals to provide messages on nutrition, dietary diversity, healthy food choices and hand washing	Standard flag ceremonies or assemblies

Table 2. Description of interventions for treatment and control primary schools

 Peer group mentoring on healthy diets and nutrition 	Selected adolescent girls are mentored by science teachers as peer mentors and hold weekly group discussions with other girls to discuss nutrition, dietary diversity, healthy food choices and handwashing	None
 BMI measurement and counseling 	Trained science teachers take anthropometric measurements of adolescent girls to calculate BMI and provide nutrition counseling	None
Parent-teacher meetings	Parent-teacher meetings to inform and encourage parents about adolescent nutrition, dietary diversity, healthy snacks, and handwashing	Parent-teacher associations focused on school performance and management
Home visits by health workers	Home visits by HEWs and/or community volunteers to discuss with parents about adolescent nutrition, dietary diversity, i healthy food choices, and handwashing	Home visits for routine health services
Community gatherings to discuss adolescent nutrition	Community gatherings by HEWs and meetings with religious leaders to discuss with parents about adolescent nutrition, dietary diversity, healthy food choices, and handwashing	None
Training for school staff and other actors	Workshop on the adolescent nutrition interventions above for school principals, science teachers, HEWs, supervisors, and woreda officers	Standard education training
Supportive supervision for school staff and other actors	Biweekly supportive supervision on adolescent nutrition activities for schools and HEWs by school supervisors or woreda health/education office	Standard school supervision

2.4 Outcomes

The primary outcome of the study focuses on diet quality measures:

1) Dietary diversity among adolescent girls

- i. Mean number of food groups consumed by adolescent girls
- ii. Proportion of adolescent girls who achieve minimum dietary diversity (at least 5 food groups)

The secondary outcomes relate to exposure to and utilization of key nutrition interventions, as well as service provider capacities. These include:

- 2) Meal frequency and healthy food choices among adolescent girls (less consumption of sugary drinks and salty/fatty processed foods)
- 3) Exposure to nutrition interventions at school and to nutrition information from school, health workers, and other sources among adolescent girls and their parents
- 4) Nutrition knowledge and handwashing knowledge and practices among adolescent girls and their parents

- 5) School teacher, principal and HEW knowledge on benefits and intervention content for dietary diversity and healthy foods/snacks, and handwashing
- 6) Availability of resources (educational materials, healthy food environments, and training and supportive supervision for teachers/staff)

2.5 Participant timeline

Enrollment of adolescent girls will take place in October 2019, at the time of baseline survey. Interventions were planned to be implemented for a single school year (approximately 7 months), from October 2019 (when the school year/regular school classes begin) to May-June 2020 (when the regular school classes end for the school year).

In March 2020, the World Health Organization declared COVID-19 a pandemic. School closures and disruptions to work and field conditions in Ethiopia resulted in program implementation being halted in March 2020. Trainings for school principals, teachers and HEWs re-initiated in November 2020, and interventions will be implemented through the first school semester. Adolescent girls will be assessed at endline in March-April 2021.

2.6 Sample Size

The primary study sample is adolescent girls enrolled in primary school and aged 10-14 years (grades 4-8). The sample size was estimated based on current prevalence of the primary outcome, 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 (54 clusters) rather than the individual level, cluster effect was considered for sample size calculation.

We used the number of food groups from the A&T Phase 1 endline survey for SNNPR (mean: 3.26, SD: 1.40, categorized as 9 food groups; Arimond et al., 2010), assuming an intra-cluster correlation (ICC) of 0.18. We calculated that a minimum sample of 189 girls per group will be able to detect a minimum of 0.6 food group consumption increase. The sample size at endline will be rounded to 270 girls per group so that 10 girls per school (2 per grade) will be sampled. Based on baseline data, we observed a mean of 3.69, SD: 1.56, categorized as 10 food groups. Assuming an ICC of 0.015, we estimated that this sample size will detect a minimum difference of 0.5 food groups.

School principals, science teachers and HEWs responsible for providing nutrition education or facilitating other related activities/interventions will also be included in both baseline and endline surveys.

At baseline, a light data collection at schools and subsamples of adolescent girls and their parents will be conducted to assess comparability between study arms. At endline, the full samples of adolescent girls and their parents will be surveyed (including those who participated at baseline).

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

Table 3. Sample sizes

	Baseline 2019		Endline 2021		
	Intervention Control		Intervention	Control	
Adolescent girls	81	81	270	270	
Parents of adolescents	81	81	270	270	
Principals (1 per school)	27	27	27	27	

Science teachers (1 per school)	27	27	27	27
HEWs (1 per school)	27	27	27	27
Total	243	243	621	621

2.7 Recruitment

Study participants will be sampled using a school-based sampling strategy. Lists of eligible adolescent girls will be taken from primary school enrollment registries. Enrollment typically begins in late September and continues for roughly two weeks after school begins to accommodate for any delays. Enrollment records (available at the time of the survey) will be used to verify the birthdate/age of eligible students, which may be recorded from birth certificates or self-reported. Then, adolescent girls will be randomly selected by simple random sampling until the required sample size is reached and visited at home to be recruited and interviewed.

III. Methods: Assignment of Interventions

3.1 Allocation

A cluster is defined as the primary school that includes grades 1-8. Four woredas in SNNPR (with 31 schools) and three woredas in Somali region (with 23 schools), i.e., one school under each woreda school supervisor, were selected as potential intervention areas (see **Figure 3**). (Within woredas, there are designated supervisors at the education office who are responsible for supervising 1-7 schools. Supervisors are responsible for visiting schools one day per week (less frequently in the Somali region) and are provided with a checklist to ensure that schools are operating effectively. As feasible, we tried to select one school under the responsibility of a (unique) supervisor, to avoid study contamination and confusion among supervisors in conducting their duties.) The samples across the two regions will be pooled to estimate effects at program level. We will use stratified randomization within woreda to try to balance potential co-interventions and confounders. Then 27 schools will be allocated to the intervention arm and 27 schools 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. Adolescents in the intervention areas will not be informed about the results of the randomization. However, there will be no blinding of the interventions at schools or other points of service delivery.

IV. Methods: Data Collection, Management and Analysis

4.1 Data collection methods

Data will be collected at the primary school and household levels, using pretested questionnaires. The following set of tools will be translated from English to Ahmaric and used during the baseline and endline surveys:

- i. Primary school observation checklist
- ii. Teacher/Principal questionnaire
- iii. Health Extension Worker (HEW) questionnaire
- iv. Adolescent girl questionnaire

v. Parents questionnaire

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

Figure 2. Trial flow



Note: The baseline and endline surveys will include cross-sectional interviews of adolescent girls, as well as their parents, school principals, science teachers, and HEWs.

Data collection method	Topics included
Primary school	Infrastructure, WASH, supplies, food environment, and nutrition education
observation checklist	materials (e.g. posters) and displays
Teacher/Principal	Teacher/principal background, school role, nutrition-related activities/
questionnaire	interventions, perceptions/beliefs, nutrition knowledge
LIEW questienneire	HEW background, school and community role, nutrition-related activities,
new questionnaire	perceptions/beliefs, nutrition knowledge
	Adolescent background, school attendance, meal and snacking patterns,
Adoloscont girl	home food environment, nutrition knowledge, WASH practices, social
Audiescent gin	desirability, parental interaction and other influencers (including sharing
questionnaire	education messages and materials), gender and marriage beliefs and decision-
	making power
	Household roster, social involvement, exposure to nutrition information,
Devent evention noire	dietary diversity, nutrition knowledge, gender and marriage beliefs and
Parent questionnaire	decision-making power, social desirability, home food environment, food
	security, dwelling and assets

Table 4. Data collection methods and topics

4.1.1 Primary school observation checklist

A school observation checklist will be included to obtain information on the infrastructure of the school, supplies and materials, food environment and student enrollment.

Module	Торіс	Description	Respondent
1	School identification	Location and school supervisor	Enumerator
2	Infrastructure	School amenities and condition	Enumerator (direct
			observation)
3	Supplies, materials	Availability of desks, books, textbooks,	Enumerator (direct
	and records	pens/pencils, computer, nutrition	observation and
		materials, etc. and records of nutrition	taken from school
		activities, PTA meetings and	records)
		community events	
4	Food environment	School canteen, availability of food	Enumerator (direct
		items, food points off school grounds	observation)
5	School hours and size	School hours, break times, and	Enumerator (taken
		number of students and teachers	from school records)
6	Student enrollment	Attendance and school records of	Enumerator (taken
	and attendance	adolescent girls participating in the	from school records)
		study	

Table 5. Description	of topics to b	be included i	n the primary	school	observation	checklist

4.1.2 Teacher/Principal questionnaire

Interviews with principals and science teachers at the primary schools will gather information on the individual's role at the school, nutrition-related activities/interventions, nutrition knowledge, exposure to training, and supervision.

Module	Торіс	Description	Respondent
1	Identification	School and respondent type	Enumerator
2	Demographic	Age, gender, education, language,	Teacher/Principal
	characteristics	years of experience	
3	School role	Position, years worked at the school,	Teacher/Principal
		class(es)/grade(s) taught, subjects	
		taught	
4	School management	PTA meetings, number of students,	Teacher/Principal
		number of teachers, school meal	
		programs, extracurricular activities	
5	Perceptions and	Important subjects, student	Teacher/Principal
	beliefs about	attendance, student nutrition/diet,	
	adolescent issues	WASH, teacher support	
6	Nutrition activities in	Involvement with nutrition-related	Teacher/Principal
	school	activities/interventions	
7	Health and nutrition	Nutrition knowledge, WASH	Teacher/Principal
	knowledge	knowledge	
8	Training exposure	Exposure to and training received on	Teacher/Principal
		adolescent nutrition	
9	Supervision	Supervision received from superiors,	Teacher/Principal
		woreda school supervisors, etc.	

Table 6. Description of modules in the teacher/principal questionnaire

4.1.3 HEW questionnaire

Interviews with HEWs at the primary schools will gather information on the individual's role at the school and in communities, nutrition-related activities, nutrition knowledge, exposure to training, and supervision.

Module	Торіс	Description	Respondent
1	Identification	Location, health post	Enumerator
2	Demographic	Age, education, years of experience	HEW
	characteristics	and other characteristics of the HEW	
3	Time commitments	Types and frequency of activities or	HEW
	and workload	interactions with school and parent-	
		teacher association, content/topics	
		discussed	
5	Health and nutrition	Knowledge and importance of proper	HEW
	knowledge	nutrition for adolescent girls	

Table 7. Description of modules in the HEW questionnaire

7	Perceptions and	Perceptions and beliefs about	HEW
	beliefs about	adolescent issues (e.g. health,	
	adolescent issues	nutrition, WASH) in the kebele	
8	Training exposure	Exposure to and training received on	HEW
		adolescent nutrition	
9	Supervision and	Frequency and content of supervision	HEW
	contact with other	on adolescent nutrition	
	actors	services/activities	

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

4.1.4 Adolescent girl questionnaire

Interviews with adolescent girls will be conducted at baseline and endline and gather information on school attendance, exposure to nutrition information, dietary diversity, meal and snacking habits, WASH practices, health and health seeking behaviors, health and nutrition knowledge, food security, home food environment, parental interactions, social desirability, gender and marriage beliefs and decision-making power, and anthropometry.

Module	Торіс	Description	Respondent				
1	Identification	School and grade of adolescent	Enumerator				
2	Adolescent and family	Age, DOB, grade level, language,	Adolescent				
	background	characteristics of mother/father					
3	School attendance	Attendance, reasons for absences,	Adolescent				
		extracurricular activities, class					
		performance					
4	Exposure to nutrition	Exposure to adolescent nutrition	Adolescent				
	information	and/or WASH information at school					
		and outside of school, and exposure to					
		media and food/drink advertisements					
5	Dietary diversity	Dietary diversity of the adolescent in	Adolescent				
		the past 24 hours					
6	Meal and snacking	Meals/snacks taken during school	Adolescent				
	habits	days, foods consumed before and					
		during school, access to food vendors					
		near school grounds					
7	WASH practices	Handwashing, drinking water, food	Adolescent				
		hygiene, menstruation					
8	Health and health	Illness, health seeking behaviors,	Adolescent				
	seeking behaviors	weight and body image					
9	Health and nutrition	General knowledge of health and	Adolescent				
	knowledge	nutrition, including WASH and					
		importance of various macro and					
		micronutrients					
10	Home food	Availability of foods at home	Adolescent				
	environment						

Table 8. Description of modules in the adolescent girl questionnaire

11	Food security	Prevalence of household hunger using the FANTA household food insecurity	Adolescent
12	Parent-adolescent interactions	access scale (HFIAS) Relationship and interactions with parents, and perceptions of parents' monitoring of food and eating habits	Adolescent
13	Social desirability	Desire for social approval	Adolescent
14	Gender, marriage beliefs and decision- making power	Opinions about girls' and boys' education, marriage and household roles, and decision-making power in the household	Adolescent
15	Anthropometry	Weight and height measurements	Adolescent

4.1.5 Parent questionnaire

Interviews with parents of adolescent girls will be conducted at baseline and endline and gather information on school involvement, exposure to nutrition information, dietary diversity, health and nutrition knowledge, food security, home food environment, social desirability, gender and marriage beliefs and decision-making power, dwelling and assets.

Module	Торіс	Description	Respondent			
1	Identification	School and respondent type	Enumerator			
2	Household roster	Information on 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 adolescent girl, and the highest educational level attained and activity/employment in the past month of all household members at least 15 years of age	Parent			
3	School involvement	School fees, and participation in parent-teacher association, school management committee and teacher meetings	Parent			
4	Exposure to nutrition information	Exposure to adolescent nutrition and/or WASH information, and exposure to media and food/drink advertisements	Parent			
5	Dietary diversity	Dietary diversity of the adolescent and household in the past 24 hours	Parent			
6	Home food environment	Availability of foods at home	Parent			
7	Health and nutrition knowledge	General knowledge of health and nutrition, including WASH and	Parent			

Table 9. Description of modules in the adolescent girls' parents' questionnaire

		importance of various macro and	
		micronutrients	
8	Parent-adolescent	Relationship and interactions with	Parent
	interactions	adolescent, monitoring of food and	
		eating habits, adolescent weight and	
		body image	
9	Social desirability	Desire for social approval	Parent
10	Gender, marriage	Opinions about girls' and boys'	Parent
	beliefs and decision-	education, marriage and household	
	making power	roles, and decision-making power in	
		the household	
11	Food security	Prevalence of household hunger using	Parent
		the FANTA household food insecurity	
		access scale (HFIAS)	
12	Dwelling	House construction (materials used for	Parent
		floor, walls, and roof), availability of	
		water and electricity, sources of	
		fuel/energy for cooking, WASH	
		facilities	
13	Assets	Ownership of durable household	Parent
		goods (in working condition), including	
		tools for agricultural production	

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.

All survey staff will be assessed for COVID-19-related symptoms 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 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 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

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 schools.

The randomized study design allows for the identification of causal effects of the adolescent nutrition intervention through comparisons of mean outcomes between the treatment and control groups. Key indicators will include dietary diversity. Impact 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. Monitoring

5.1 Data monitoring

Data collection (including observational, adolescent girl, and principal/science teacher/HEW 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

The nutrition interventions will primarily focus on behavior change related to healthy diets, and we do not anticipate any harms from the study. Any adverse events or unintended effects during provision of interventions will be recorded and monitored, and subjects will be referred to their nearest health provider as appropriate.

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 obtained from the Addis Continental Institute of Public Health 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-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 and the parent/guardian of the participant. 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 nutrition education in schools 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 results 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

	2019											
Deliverable/Activities		Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1. Study protocol												
Discuss study and evaluation design with A&T	х	х	х									
Prepare study protocol			х	х	х	Х						
2. Baseline data collection tools												
Develop questionnaires/data collection tools				х	х	х						
Select and contract survey firm						Х	х					
Translate questionnaire							х					
Program CAPI questionnaire							х	х				
3. Local and US-based IRB approvals												
IRB application at IFPRI								х				
IRB application in Ethiopia							х					
4. Baseline survey implementation												
Pretest, revise and finalize questionnaire								х				
Enumerator training									х			
Data collection										х	х	
5. Data cleaning and analyses												
Data cleaning											х	х
Data analyses												х

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

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

References

Akseer, Nadia, Sara Al-Gashm, Seema Mehta, Ali A. Mokdad, and Zulfiqar A. Bhutta. 2017. Global and regional trends in the nutritional status of young people: A critical and neglected age group. *Annals of the New York Academy of Sciences*, 1393(1): 3-20. <u>https://doi.org/10.1111/nyas.13336</u>

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

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.

Das, Jai K., Rehana A. Salam, Kent Thornburg, Andrew M. Prentice, Susan Campisi, Zohra S. Lassi, Berthold Koletzko, and Zulfiqar A. Bhutta. 2017. Nutrition in adolescents: physiology, metabolism, and nutritional needs. *Annals of the New York Academy of Sciences*, 1393(1): 21-33. https://doi.org/10.1111/nyas.13330

Patton, George C., Susan M. Sawyer, John S. Santelli, David A. Ross, Rima Afifi , Nicholas B. Allen, Monika Arora, Peter Azzopardi, Wendy Baldwin, Christopher Bonell, Ritsuko Kakuma, Elissa Kennedy, Jaqueline Mahon, Terry McGovern, Ali H. Mokdad, Vikram Patel, Suzanne Petroni, Nicola Reavley, Kikelomo Taiwo, Jane Waldfogel, Dakshitha Wickremarathne, Carmen Barroso, Zulfiqar Bhutta, Adesegun O. Fatusi, Amitabh Mattoo, Judith Diers, Jing Fang, Jane Ferguson, Frederick Ssewamala, and Russell M. Vine. 2016. Our future: a Lancet commission on adolescent health and wellbeing. *The Lancet*, 387(10036): 2423-2478. https://doi.org/10.1016/S0140-6736(16)00579-1

Patton, George C., Carolyn Coffey, Claudia Cappa, Dorothy Currie, Leanne Riley, Fiona Gore, Louisa Degenhardt, Dominic Richardson, Nan Astone, Adesola O. Sangowawa, Ali Mokdad, and Jane Ferguson. 2012. Health of the world's adolescents: A synthesis of internationally comparable data. *The Lancet*, 379(9826): 1665-1675. <u>https://doi.org/10.1016/S0140-6736(12)60203-7</u>

Spear, Bonnie A. 2002. Adolescent growth and development. 2002. *Journal of the American Dietetic Association*, 102(3 Suppl.): S23-S29. <u>https://doi.org/10.1016/S0002-8223(02)90418-9</u>

Stavropoulou, Maria, and Nandini Gupta-Archer. 2017. *Adolescent girls' capabilities in Ethiopia: The state of the evidence.* London: Gender & Adolescence: Global Evidence (GAGE).