ALIVE & THRIVE ETHIOPIA (A&T-ETHIOPIA)
ADOLESCENT NUTRITION IMPLEMENTATION RESEARCH (ANIR)

Data Analysis Plan, July 31, 2021

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Study protocol: Impact evaluation study protocol, version 2, dated January 15, 2021.

I. Study Background and Approach

In Ethiopia, Alive & Thrive (A&T) has developed a package of adolescent nutrition interventions implemented through school-based and community platforms. Interventions are implemented in one-half of the 54 primary schools across two regions – SNNP (31 schools) and Somali (23 schools). Core interventions include: (1) classroom lessons about adolescent nutrition and healthy diets, (2) flag ceremonies/ assemblies to remind about key healthy eating messages, (3) adolescent girls club/student peer mentoring on adolescent nutrition, and (4) parent-teacher meetings to educate parents about adolescent nutrition and healthy diets. Other interventions include body mass index (BMI) measurement and counseling for adolescent girls, home visits by health extension workers (HEW) to advise parents of adolescent girls, and community gatherings to build awareness about adolescent nutrition. The key behaviors promoted by these interventions were dietary diversity (at least 5 food groups daily, with locally available foods), eating breakfast before school and healthy snacks daily, and avoiding unhealthy/junk foods.

1.1 Research questions

The implementation research study addressed three research questions:

Research question 1 (RQ1)	What are the program **impacts on diet of adolescent girls:** (1) dietary diversity, (2) less consumption of unhealthy snacks, and (3) meal frequency? [*impact of integrating interventions into school-based platforms*]
Research question 2 (RQ2)	What is the **coverage and utilization** of key adolescent nutrition interventions (classroom nutrition education, flag events/assemblies on nutrition, peer group mentoring, and Parent-Teacher meetings)? [*outcome of integrating interventions into school-based platforms*]
Research question 3 (RQ3)	What **factors influenced** the integration of adolescent nutrition interventions into school-based platforms and their outcomes and impacts? [*pathway from integration of interventions to impact*]

1.2 Impact evaluation study design

The impact evaluation of A&T's interventions used a cluster-randomized design with repeated cross-sectional surveys at baseline and endline. We applied stratified random allocation to 54 primary schools within 7 districts (*woredas*) across two regions (SNNP and Somali), which were assigned to either the A&T intervention schools (27 schools) or control schools (27 schools). A small baseline survey was conducted in October-November 2019, and the endline survey was conducted in March-May 2021 in the same 54 schools, thereby creating panel data at the school level (not at individual level). Program implementation duration was approximately 4 months (1 school semester); implementation faced major disruptions due to the COVID-19 pandemic throughout most of 2020, with state lockdown/restrictions and school closures, until schools reopened in October 2020.

1.3 Study sample

The primary study sample is adolescent girls (AG) aged 10-14 years and enrolled in grades 4-8 in the current school year. We estimated a total sample size of 540 girls (270 per arm) to detect a difference of 0.5 food groups in the mean dietary diversity score. Along with each AG, we included her parent/ primary caregiver (N=540), given that parents and caregivers are usually responsible for purchasing and preparing foods for young adolescent girls.

Additionally, we interviewed school principals (1 per school), main science teacher (1 per school), and HEWs (1 per health post nearest to school). School checklists (1 per school) were conducted to assess any changes in school infrastructure and facilities, materials and supplies, operations, and staffing.

Table 1. Sample sizes

		Baseline 2019		Endline 2021	
Survey respondent type		**Intervention**	**Control**	**Intervention**	**Control**
Household survey:					
1	Adolescent girl	81	81	270	270
2	Parent/caregiver of adolescent girl	81	81	270	270
School principal/teacher survey or checklist:					
3	Principal (1 per school)	27	27	27	27
4	Science teacher (1 per school)	27	27	27	27
5	School checklist	27	27	27	27
Health worker survey:					
6	HEW (1 per school)	27	27	27	27
	Total:	**270**	**270**	**648**	**648**

II. Outcome Measures and Indicators

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

2.1 Research question 1 (impact on diets of adolescent girls)

For impact estimates, outcome measures related to adolescent diet will be used from the AG dataset only.

Table 2. Outcome measures for RQ1

Outcome	Indicator	Data source
Dietary diversity, consumption of unhealthy foods, and meal frequency	*Primary outcome*: - Dietary diversity score (# of food groups, out of 10 groups) *Secondary outcomes:* - % AG consumed unhealthy foods in past 24h (i.e., sweet foods and sweets, fried and salty foods, and sugar-sweetened beverages) - Mean meal frequency score (# meals or snacks, out of 6 times)	AG survey

2.2 Research question 2 (coverage and utilization)

For results on coverage and utilization of interventions, outcome measures will be used from the AG and Parent survey data. In the context of the overall evaluation, outcomes under this research question are considered as secondary outcomes.

Table 3. Outcome measures for RQ2

Outcome	Indicator	Data source
CORE INTERVENTIONS:		
Classroom lessons	- % AG heard about nutrition in classroom in past 3 months - % messages heard	AG survey
Flag events/assemblies	- % AG heard nutrition message during flag ceremony/assembly in past 3 months - % messages heard	AG survey
Student peer mentoring	- % AG attended girls' club meeting on nutrition - % messages discussed - % AG attended mentorship meetings on nutrition - % messages discussed	AG survey
Parent-Teacher meetings	- % Parents attend parents' meeting on nutrition - % messages discussed	Parent survey
OTHER INTERVENTIONS:		
BMI measurement and counseling	- % AG received BMI measurement in past 3 months - % AG received BMI/nutrition counseling in past 3 months	AG survey
HEW home visits and contacts	- % AG talked about nutrition with HEW in past 3 months - % messages heard - % AG talked about nutrition with community worker/WDA in past 3 months - % messages heard	AG survey, Parent survey
Community gatherings	- % AG heard about nutrition in the community - % source, messages heard - % Parents heard about nutrition in the community - % source, messages heard	AG survey, Parent survey

2.3 Research question 3 (factors related to school, health, and home environment)

For assessing factors related to delivery of interventions, measures will be used from the school checklist and Principal and Teacher survey datasets. For additional behavioral determinants related to adolescent girls' diets, measures will be used from the AG and Parent survey datasets. In the context of the overall evaluation, outcomes under this RQ3 also count as secondary outcomes.

Table 4. Outcome measures for RQ3

Outcome	Indicator	Data source
Service provider capacity-building and service provision:		
School supplies and materials and operations	- % schools with drinking water - % schools with nutrition education materials - % schools with clubs/mentorship programs - % schools provide meal/foods - % schools with break time for snack/lunch	School checklist
Training and supervision	- % P/T received training on adolescent nutrition - % P/T received supervision on adolescent nutrition - % HEW received training on adolescent nutrition - % HEW received supervision on adolescent nutrition	Principle/teacher survey, HEW survey
Principal/teacher and HEW knowledge and attitudes	- % P/T perceived adolescent nutrition as a problem - P/T adolescent nutrition knowledge score - % HEW perceived adolescent nutrition as a problem - HEW adolescent nutrition knowledge score	Principle/teacher survey, HEW survey
Delivery of interventions	- % P/T conducted parents' meeting on nutrition - % messages discussed - % P/T provided nutrition message during flag ceremony/assembly - % message provided - % P/T discussed nutrition during classroom lesson - % message provided - % P/T participated in girls' club/mentoring on nutrition - % message discussed - % P/T measured AG's BMI - % P/T provided BMI/nutrition counseling - % HEW provided adolescent nutrition counseling at HP - % HEW measured BMI of AG, provided counseling - % HEW conducted home visit and provided adolescent nutrition message - % HEW visited school to advise about adolescent nutrition - % HEW discussed adolescent nutrition at community gathering	Principle/teacher survey, HEW survey
Behavioral determinants of AG and parents:		
School attendance and participation	- % AGs missed school in past week, this year - # of days missed school in past week, this year (reason) - % AGs arrived late/leave early in past week, this year - # of days arrived late/leave early in past week, this year (reason) - % AG perceived school performance - poor/average/good - % AG intention for more schooling – up to grade 12 or higher	AG survey

Outcome	Indicator	Data source
Food environment	- % received any free food or drinks at school - # of shops/stalls selling fruits or veg on way to/from school - # of shops/stalls selling packaged snacks on way to/from school - # of shops/stalls selling fried foods on way to/from school - % food groups available at home in past 7 days - % junk foods available at home in past 7 days - % schools with canteen, types of foods - % schools with food vendors within 1-minute distance	AG survey, Parents survey, School checklist
Parent-AG interactions	- % AG interaction with parents - % AG reported parental food control - % Parents interaction with AG - % Parents reported control of AG's foods	AG survey, Parents survey
Parents' knowledge and attitudes	- Parents adolescent nutrition knowledge score	Parents survey
Parents' dietary and feeding behaviors	- Parents' dietary diversity score - % Parents consumed unhealthy foods in past 24h (i.e., sweets, fried and salty foods, and sugar-sweetened beverages) - % Parents prepared food in past week, # of days (out of 7)	Parent survey
AG's knowledge and attitudes	- AG nutrition knowledge score	AG survey
AG's other eating and snacking behaviors	- % currently fasting, # of continuous fasting days - % ate junk foods in past week, # of days (out of 7)	AG survey

III. Statistical Analysis Plan

3.1 General principles and methods

Data analyses will be performed using STATA version 17.0 (StataCorp LLC). All applicable statistical tests will be two-sided to allow potential findings of unexpected effects. Statistical significance will be presented at levels of $p<0.05$, $p<0.01$, and $p<0.001$.

A diagram presenting the flow of clusters and individuals through the trial, based on the Consolidation Standard of Reporting Trials (CONSORT) statement: extension to cluster randomized trials (1,2), is shown as follows.

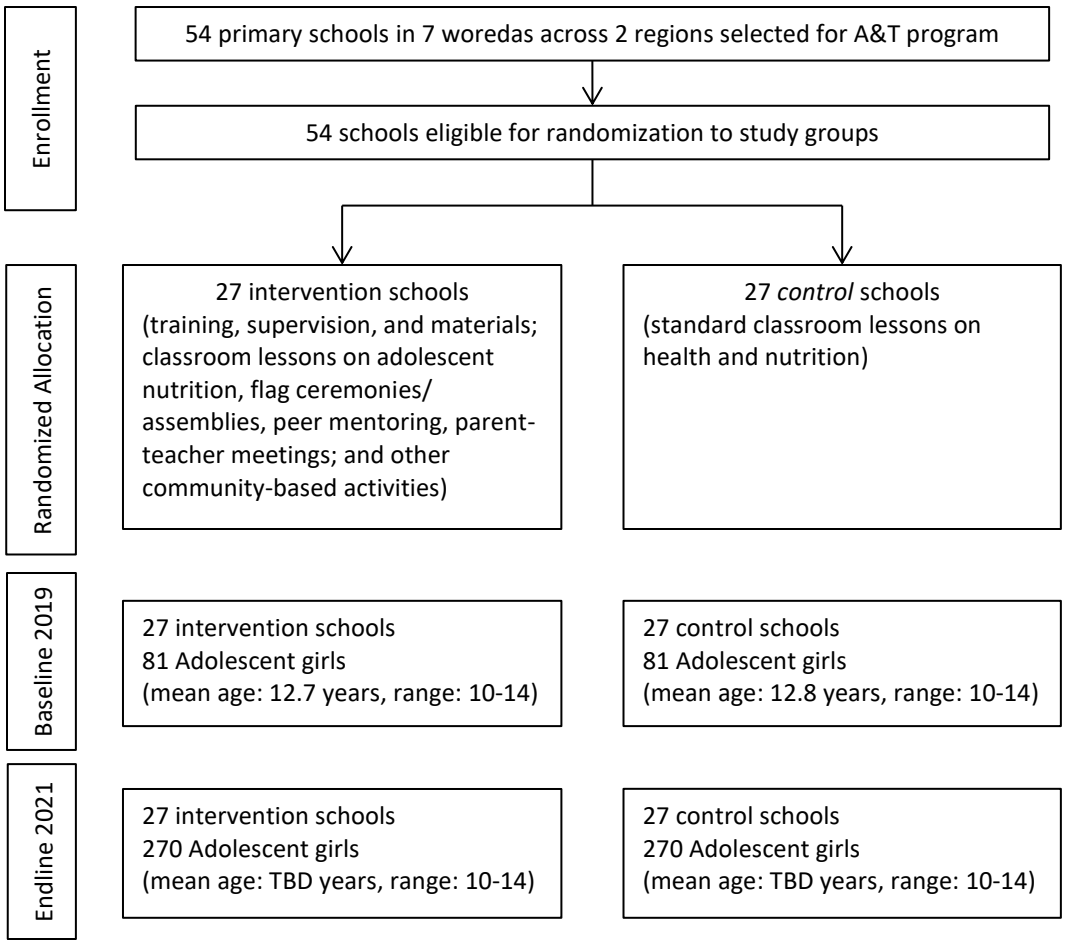

Figure 1. CONSORT flow diagram for repeated cross-sectional surveys

3.2 Sample characteristics

Baseline and endline characteristics will be reported between randomized program groups (A&T and control). For household samples, indicators of the adolescent girl characteristics (age, grade), parent's characteristics (age, marital status, education, occupation, religion), and household characteristics (member composition, food security, livelihood, and socioeconomic status). Binary variables will be summarized as proportions, and continuous variables will be summarized as mean values with standard deviations (when normally distributed) or as median with interquartile range (for non-normal distribution variables). T-test will be used to compare and infer significant difference between the program groups by survey round.

Table 5. Dummy table for sample characteristics

Indicator	**Baseline**		**Endline**	
	A&T (N=)	**Control (N=)**	**A&T (N=)**	**Control (N=)**
	Percent/Mean (SD)	**Percent/Mean (SD)**	**Percent/Mean (SD)**	**Percent/Mean (SD)**
Age of respondent (years)				
Marital status				

Education level				
Occupation				
Religion				

3.3 Impact estimates

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

The main impacts of the interventions will be estimated for: (1) dietary diversity score, (2) consumption of unhealthy foods/junk foods, and (3) meal frequency. Secondarily, impact will be estimated for exposure to the core interventions: classroom lessons about adolescent nutrition and healthy diets, flag ceremonies/assemblies to remind about key healthy eating messages, adolescent girls club/student peer mentoring on adolescent nutrition, and parent-teacher meetings to educate parents about adolescent nutrition and healthy diets. All impact indicators will be assessed among adolescent girls, except for the exposure to parent-teacher meetings which will be assessed from parents.

Given that the main impact indicators with full sample sizes were collected at endline only, linear regression models will be used to test the means of the outcome for estimates of group differences (intervention vs. control) at endline, with standard errors clustered at the school level. In the adjusted models, we will control for covariates such as adolescent girl age and other variables that differed between study arms. Robustness tests will be conducted using difference-in-differences analysis where outcome variables exist at baseline.

Table 6. Dummy table for impact estimates

Indicator	**Baseline**		**Endline**			
	A&T (N=)	**Control (N=)**	**A&T (N=)**	**Control (N=)**	**Unadjusted impact est.[1]**	**Adjusted impact est.[2]**
	Percent/Mean (SD)	**Percent/Mean (SD)**	**Percent/Mean (SD)**	**Percent/Mean (SD)**		
Dietary diversity score						
Consumption of unhealthy foods						
Meal frequency						

[1] Controlling for clusters by school only.

[2] Adjusted for AG age, household food security and wealth tertile, and clustered by school.

*** p<0.01; ** p<0.05; * p<0.1

3.3.1 Analysis of program impact pathways [RQ3]

In addition to the estimation of impacts, we will conduct plausibility analysis to provide further evidence for the likelihood or strength of our impact estimates, by examining the intermediate outcome indicators along the program impact pathways (from service delivery to exposure and behavioral

determinants) to determine whether the program resulted to the outcomes as intended by design. The program impact pathway (PIP) was developed in collaboration with the A&T program team to map out the mechanisms through which the interventions were expected to achieve impact. The purpose of the PIP analysis is to lay out the theoretical causal links between program activities, outcomes, and impacts. We will examine key indicators along the components of pathways (presented in RQ3), to interpret and support the impact evaluation results. We will compare differences between program groups for indicators along the pathway matched to the relevant outcomes, using linear regression models accounting for school clustering.

IV. References

1. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: Extension to randomised pilot and feasibility trials. BMJ. 2016;355.
2. Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: Extension to cluster randomised trials. BMJ. 2012;345(7881):1–21.