

Evaluation of Early Adolescent Skills for Emotions (EASE) in Ethiopia: A Cluster Randomized Trial of a Youth Mental Health Intervention

Pre-Analysis Plan

July 2026

Abstract

This study evaluates the impact of the World Health Organization's Early Adolescent Skills for Emotions (EASE) intervention among 10-15-year-old adolescents in poverty contexts in Ethiopia. The intervention is implemented within Compassion International's child development program with treatment randomized at the site level. Twenty-five adolescents at each of the 70 sites have been identified by program staff as having the target selection criteria of heightened internalizing challenges resulting in a total of 1750 study participants. Half of the sites will be randomly assigned to receive the EASE intervention, and the other half will serve as control sites. As a result, approximately 875 adolescents will participate in the EASE intervention during the study period.

The study includes two waves of data collection: baseline, prior to EASE implementation, and endline, approximately two months after the intervention. Data will be collected through enumerated surveys with each youth participant. The primary outcome is psychological distress. Secondary outcomes include emotion regulation, such as acceptance of emotional responses, ability to engage in goal-directed behavior, access to emotion regulation strategies, and emotional clarity.

1 Introduction

This document provides the analysis plan for the Evaluation of Early Adolescent Skills for Emotions (EASE) in Ethiopia: A Cluster Randomized Trial of a Youth Mental Health Intervention. The following details outline the main analysis approaches the study intends to follow in order to answer key research questions on the impact of the EASE intervention on youth enrolled in the Compassion International child development program in Ethiopia. Because this is the first time Compassion is implementing such an intervention, it is possible that the following plan may be modified based on how implementation of the intervention progresses. At the time of writing, research sites and youth have been selected, sites have been randomly assigned to treatment or control groups, participants have been recruited, and data collection is underway. The descriptions below reflect this timeline.

1.1 The EASE Intervention

Early Adolescent Skills for Emotions (EASE) is an intervention published by the World Health Organization (WHO) and United Nations Children's Fund (UNICEF) that aims to help 10–15-year-old youth who are affected by internalizing problems and live in communities that are exposed to adversity. Specifically, the intervention seeks to decrease psychological distress of participating youth. The intervention is comprised of ten 90-minute sessions. Seven sessions are delivered to the adolescents in small groups of no more than 12 participants, and three sessions are delivered to the caregivers of the adolescents. The curriculum for the sessions includes topics such as the following for youth: 1) understanding their feelings, 2) calming their body, 3) changing their actions, and 4) managing their problems. The curriculum includes the following topics for caregivers: 1) active listening skills, 2) identifying feelings (theirs and their child's), 3) quality time and giving praise, and 4) self-care strategies.

EASE uses a train-the-trainer model that provides direct instruction and coaching for adults called ‘Helpers’ who implement the intervention sessions with adolescent and caregiver participants. Helpers are trained over the course of several days prior to intervention implementation and receive ongoing support during implementation. The EASE intervention is designed to be delivered by Helpers who are not required to have formal training in mental health. In this study, the intervention will be delivered in the context of Compassion International's child development program and will include youth who are already registered in Compassion's programming. Helpers will be recruited from Compassion program staff and volunteers who are based in the communities where the Compassion program is running.

For implementation of the intervention, each Compassion site in the treatment group will run two classes of approximately 12 participants each, for a total of about 25 participants at each site receiving the intervention. The authors of the intervention encourage cultural and contextual adaptations of EASE to ensure the intervention is relevant and acceptable for participants. The intervention will undergo adaptation in partnership with the Compassion International Ethiopia National Office staff team who will work to identify specific areas in which the intervention materials may benefit from adaptation for the Compassion Ethiopia context. As recommended by the WHO, adaptations will be limited to adjustments in delivery while ensuring that the content (i.e., EASE skills) remain the same. For example, implementation sites will be required to complete all ten sessions for each class cohort, but sites will be able to choose how they schedule the classes with the only requirement that all sessions be completed in the 10-week intervention window. The intervention will be implemented in the same spaces used by the Compassion program, so participants will be familiar with the location and facilities. Attendance of youth and their caregivers will be tracked to identify attrition and the level of exposure to the intervention.

1.2 Research Questions

The research questions that the study aims to answer are outlined below.

Primary research question:

Does participation in the EASE intervention significantly contribute to decreased psychological distress for 10–15-year-olds registered in the Compassion Ethiopia program?

Secondary research questions:

1. Does participation in the EASE intervention improve youths' emotion regulation skills among 10–15-year-olds registered in the Compassion Ethiopia program?
2. What relationship exists between adolescents' pre-intervention internalizing and externalizing problems and post-intervention outcome differences?
3. Are there differential effects of the intervention depending on baseline mental health status of participating youth?
4. Compared to their knowledge, skills, and attitudes related to adolescent mental health prior to EASE training, do EASE helpers' knowledge, skills, and attitudes after EASE training demonstrate readiness to facilitate the intervention?
5. To what extent do adolescents achieve greater outcome improvements when their EASE helpers demonstrate greater readiness to facilitate the intervention?

2 Trial Details

2.1 Sample

2.1.1 Compassion sites

Research sites were selected from all Compassion Ethiopia program sites based on either internal Compassion data that indicated the presence of adolescent mental health needs in the respective site's program population or the site's previous mental health intervention experience indicating need and interest for the intervention. To be selected, sites also needed at least 30 10–15-year-old participants registered in the standard Compassion program and at least three staff members or volunteers who were willing to implement the intervention. Additionally, a minimum level of security was required to ensure accessibility to the program and to mobilize participants and enumerators for data collection. 73 Compassion sites met these criteria, and from this group, three of the most dissimilar sites based on location type, size, and age of Compassion program were selected to serve as waitlist sites. The remaining 70 sites were enrolled in the study.

2.1.2 Youth

Within each site, 30 eligible youth were selected by Compassion site staff for participation using the following criteria:

- 1) The youth is between 10–15-years-old during EASE implementation;
- 2) The youth would benefit from the intervention (they have mild internalizing problems or challenges managing emotions but their internalizing problems are not severe);

- 3) The youth does not have externalizing problems;
- 4) The youth does not have a history of serious mental health issues (such as suicidal ideation, substance abuse, severe mental disorders, or severe depression);
- 5) The youth would likely be willing and available to attend the adolescent EASE sessions;
- 6) The youth has a caregiver who is willing and available to attend the caregiver EASE sessions. Caregivers are defined as adults (over the age of 18) who live with the participant and who assumes responsibility for the daily needs and well-being of the youth. It was requested that the adolescent's primary caregiver (the caregiver they spend the most time with) participate in the EASE sessions if possible.

Twenty-five youth at each site were selected for recruitment to the study using the SDQ teacher observation tool (see section 2.2.1 below), and the remaining five youth will serve as replacements if any of the initial 25 decline or are unable to participate. Replacements were only able to be made prior to baseline data collection. Compassion staff at each site conducted the recruitment process which included providing an informed consent form to caregivers and an assent form to youth.

2.2 Assignment to Treatment

This study is a cluster randomized controlled trial (cRCT) design with Compassion program sites serving as clusters. The selected 70 Compassion sites have been randomly assigned in a 50/50 split via a computer program to either the treatment condition in which the EASE intervention will be implemented in addition to the standard Compassion Child Development Program or the control condition which will only implement the standard Compassion Child Development program¹. Random assignment was conducted using the `randtreat` command in Stata (version 12) and a random number seed. The random assignment of Compassion sites was also blocked by the site's previous implementation of youth mental health interventions. Block 1 sites had no previous experience with youth mental health interventions, and Block 2 had implemented such interventions previously and consequently had received some training on mental health. With the blocked randomization using `randtreat`, misfits were allocated globally to ensure 35 treatment and 35 control sites in the final assignment groups. Assignments were then checked for covariate balance to confirm randomization was done correctly (see section 3.2 below). A summary of cluster assignment is given in Table 1 below.

¹ At the time of writing, the Compassion sites have been selected, random assignment has been conducted, youth have been selected and recruited, and data collection is underway.

Table 1. Sample size by treatment group block

	Treatment		Control		Total	
	<i>Clusters</i>	<i>Youth</i>	<i>Clusters</i>	<i>Youth</i>	<i>Clusters</i>	<i>Youth</i>
Block 1	25	625	24	600	49	1225
Block 2	10	250	11	275	21	525
Total	35	875	35	875	70	1,750

Youth were selected at each Compassion site prior to receiving the random assignment to avoid increasing bias in youth selection. Training was also provided to Compassion site staff to implement the selection criteria and ensure selection processes are as similar as possible across sites.

However, differences in how sites implemented the selection may have occurred. Additionally, while youth selection happened prior to random assignment, youth recruitment must occur after random assignment due to study constraints. Consequently, individual-level baseline differences between Compassion sites and possibly between treatment and control groups could result. To identify possible differences in recruitment, replacement rates between treatment and control sites will be monitored for differences and replaced/replacement youth demographics will be reviewed as well. The potential for differences between groups is also addressed further below.

2.3 Statistical Power

The sample size of 70 sites and 25 youth per site was the maximum feasible sample size of the study as determined by implementation constraints. At 80% power and accounting for an intraclass correlation coefficient (ICC) of 0.128 between sites as calculated from similar internal Compassion data, the above sample size provides a minimum detectable effect size of 0.25 at an alpha of 0.1.

2.4 Attrition from the Sample

We do anticipate that some attrition from the sample will occur. However, because this intervention and study design is new for Compassion sites and participants, we are not certain the degree of attrition that could result. Attrition from past Compassion studies has been quite low with average response rates of 90% or more. This has been achievable due to the long-term relationships built between Compassion staff, participants, and families. Similarly, staff at the sites will be in close communication with the participants in this study to encourage high levels of participation throughout. To address the potential for higher levels of attrition, a 25% buffer was added to the sample size calculations to maintain power even in the presence of attrition.

To identify the potential for differential attrition, attrition rates will be reviewed for the entire sample, between treatment and control groups, and within subgroups of treatment and control to determine if missing data is related to treatment assignment or other attributes. Additionally, if

attrition exceeds five percent in either the treatment or control group, balance on demographics and baseline variables among treatment and control for both attriters and non-attriters will be reviewed to determine if attriters differ in any way from non-attriters across groups. Specifically, a binary missing flag will be regressed on covariates by treatment group to determine if attrition is predicted by demographic or baseline variables differently across groups. A joint test of significance will also be conducted on the interactions between treatment and each of the covariates to determine if variation in coefficients across treatment groups is larger than what would be expected due to sampling variability. Also, intervention attendance rates and attrition will be reviewed within the treatment group to identify whether adherence possibly influenced attrition as well. Finally, cluster size will also be assessed to determine if attrition has resulted in large changes.

If attrition is found to be an issue, either by being not random or not random conditional on covariates, bounds around the treatment effect will be constructed to identify the largest and smallest estimates that could be obtained.

2.5 Instruments and Data Collection

To answer the research questions, three types of quantitative data collection will be conducted. Prior to randomization, Compassion staff and volunteers at each of the sites completed the SDQ teacher observation survey for each child that was selected for study recruitment. This tool provides measures of internalization, externalization, and prosocial behaviors that were used to rank the selected youth in order of need to ensure those with the greatest need are prioritized during recruitment and to triangulate the self-reported data collected from the youth in descriptive analyses. This survey was sent via a link for the staff to complete and all surveys were submitted before random assignment was communicated to sites.

A baseline and endline survey will be enumerated with the recruited youth via a 1:1 interview with a trained data collector who is blind to site treatment condition. Data collectors will be independent from Compassion International and will not have any connection to the implementation of the intervention. The baseline survey will occur approximately 1-2 weeks before the start of the intervention, and the endline survey will occur approximately 10-11 weeks after the intervention is completed. Both instruments will include similar items such as questions on primary caregiver relationship and emotional wellness. The baseline survey also includes measures of family structure, Compassion participation, education, religiosity, social support, discipline, and socioeconomic status. The endline survey includes questions regarding intervention satisfaction for treatment youth.

Additionally, a pre- and post-training survey will be conducted with the Helpers selected at the treatment sites to capture their knowledge, skills, and confidence around intervention implementation. This survey will be sent to the Helpers via a link through which they will take

and submit the surveys. Data from this survey will be included in additional descriptive analyses to address secondary research questions four and five.

Finally, attendance data will be collected from each of the treatment sites during intervention implementation using paper tracking sheets. This data will include the youth who attended each session, youth session dates, the classes in which youth attended the sessions, the caregivers who attended each session, caregiver session dates, and the classes in which caregivers attended the sessions. To submit the attendance data, treatment sites will input the attendance data from the paper tracking sheets into a survey form at the end of the intervention.

2.6 Data Processing

For all data collected, data processing will include sample cleaning and anonymization. Participants who did not consent to participate at the beginning of the survey will be removed, duplicated records will be reconciled, demographic information will be cleaned, and all personally identifying information will be removed and observations anonymized. The identified data will be stored securely and separately from the anonymized data set. The anonymized data will then be cleaned and formatted.

Because this is the first time Compassion has implemented this youth survey instrument and the questions included may be sensitive or challenging for the 10–15-year-old target age group, it is unknown whether there may be high numbers of ‘I don’t know’ or ‘Refused to answer’ responses, resulting in missing data. All questions will be tested in a 2-day pilot with the target age group. However, if missing data persists during data collection due to item non-response, it will not be imputed. Rather, items will be reviewed for non-response rates and those with less than 85% will be reviewed for correlation with treatment status utilizing the same procedures used for survey attrition. If a relationship is found, bounds will be constructed for the treatment estimates that are robust to this issue. Outcomes with an item non-response rate less than 80% will be omitted. Outcome scales created by averaging constituent variables will be calculated if missing variables are less than half of the total number of variables included in the scale.

It is also unknown whether any outcomes will have issues with limited variation. For outcomes wherein 95% of the observations have the same value, those outcomes will be removed from the analysis.

3 Empirical Analysis

3.1 Variables

3.1.1 Outcomes

The primary outcome of the study is psychological distress. We hypothesize that participation in the EASE intervention will decrease psychological distress as described by the WHO intervention guidance. To test this hypothesis, psychological distress will be measured at both

baseline and endline using the Child and Adolescent Psychological Distress Scale. The outcome will be calculated by taking the mean of the ten items, which focus on the dimensions of depression, anxiety, aggressive behavior, and somatic pain or complaints. The mean will be calculated if at least 50% of the variables in the scale are non-missing values. Per-item results will also be explored.

Additional outcomes will be used to measure individual-level differences in youths' emotion regulation skills that are attributable to the intervention. We hypothesize that participation in the intervention will increase youths' ability to regulate emotions, refocus on planning, and increase their likelihood of having adult support two months after the intervention. We also hypothesize that participation will decrease the youths' difficulties in regulating emotions. The outcomes that will be used to test these hypotheses include the following:

1. Ability to refocus on planning: The youth's capacity to think about how they can respond positively despite an upsetting situation, measured by a 4-item questionnaire with 5-point Likert response options
2. Has an adult to turn to for support: The youth's report of having an adult in their life who will help them when they need it, measured with "no", "sometimes", and "yes" response options
3. Increased use of slow breathing to regulate emotions: The youth's frequency of using breathing exercises to manage difficult or overwhelming emotions, measured with 5-point Likert response options
4. Difficulties in Emotion Regulation Scale (DERS-18) sub-scales including:
 - a. Nonacceptance of emotional responses: The youth's report of feeling guilt, shame, or embarrassment in response to emotions, measured by a 3-item sub-scale with 5-point Likert response options
 - b. Difficulty engaging in goal-directed behavior: The youth's inability to focus on tasks due to emotions, measured by a 3-item sub-scale with 5-point Likert response options
 - c. Limited access to emotion regulation strategies: The youth's inability to manage emotions in a healthy, productive way, measured by a 3-item sub-scale with 5-point Likert response options
 - d. Lack of emotional clarity: The youth's inability to understand their emotions, measured by a 3-item sub-scale with 5-point Likert response options
 - e. Lack of emotional awareness: The youth's inability to notice their emotions, measured by a 3-item sub-scale with 5-point Likert response options
 - f. Impulse control difficulties: The youth's inability to control their behaviors when upset, measured by a 3-item sub-scale with 5-point Likert response options

3.1.2 Moderators and covariates

To address secondary research question two, moderator variables will be collected and calculated to measure each youth's internalization and externalization at baseline. We hypothesize that intervention impacts on youths' emotional distress will be larger for those with greater internalizing challenges and smaller for those with greater externalizing challenges as described in the WHO guidance. These variables will be calculated in the following way:

1. Internalizing score: Sum of the emotional and peer problems scales in the Strengths and Difficulties Questionnaire ranging from 0-20.
2. Externalizing score: Sum of the conduct and hyperactivity scales in the Strengths & Difficulties Questionnaire ranging from 0-20.

Cluster-level variables used to review balance after randomization and for possible inclusion as a covariates in the outcome model include the following:

- Region
- Urbanicity
- Length of Compassion partnership
- Percent female
- Size of Compassion program
- Size of 10–15-year-old cohort
- Number of conflict events reported within 5 miles of the site between November 2020 and January 2026
- Other mental health interventions being implemented

Individual-level baseline variables used to review balance and for possible inclusion as a covariate include the following:

- Age
- Gender
- Education level at baseline (grade level)
- Number of children in the family
- Birth order
- Family social support
- Exposure to violent discipline
- Caregiver relationship including
 - Number of caregivers
 - Frequency of communication with primary caregiver
 - Number of hours per week spent with primary caregiver
 - Primary caregiver relational resilience score
- Number of years registered in the Compassion program

- Frequency of attendance to the Compassion program
- Number of hours per week spent at the Compassion program
- Previous participation in similar intervention in Compassion or elsewhere
- Peer social support score: Mean of the Multidimensional Scale of Perceived Social Support friends sub-scale
- Religiosity score: Mean of the Measurement of Diverse Adolescent Spirituality scale
- Neuroticism score: Mean of the NEO Five-Factor Inventory neuroticism sub-scale
- Poverty level indicators:
 - Characteristics and items in the youth's home including
 - Electricity
 - Radio
 - Television
 - Refrigerator
 - Electric mitad
 - Table
 - Chair
 - Bed with cotton, sponge, or spring mattress
 - Piped water source
 - Family's consumption of food in the last week:
 - Potatoes
 - Tomatoes
 - Tea

Select individual-level variables will also be aggregated to the cluster level for balance review and possible inclusion as covariates.

3.2 Balancing Checks

Balance of cluster-level covariates were reviewed after random assignment to ensure randomization was conducted correctly and to identify any imbalanced covariates that may be included in the final regressions to improve precision. Balance was assessed by regressing treatment assignment on cluster-level covariates, including the blocking variable used to randomly assign clusters. An omnibus F-test and a randomization inference test was also conducted with covariates that are believed to be highly correlated with the outcomes of interest or that are important to the study context.

After baseline data collection, cluster-level balance will be reviewed again using the same process outlined above with aggregated individual-level baseline variables. These variables will include demographics and mean baseline scores of outcome variables. Any imbalanced variables will be considered for inclusion as a covariate in the final model.

As noted above, because Compassion sites have selected youth for participation using defined criteria rather than through random sampling and because recruitment occurred after sites received their assignment to treatment or control, there may be differences at the individual level between treatment and control groups, resulting in possible selection bias. To check for any confounding, prior to outcome analysis the data will be reviewed for any relationships between the baseline variables and the treatment and outcome variables. Imbalance will also be assessed between groups using Cohen's D and Kramer's V with thresholds of 0.1 and 0.05 respectively. If evidence of potential confounding is surfaced, propensity score methods such as matching or weighting will be considered to address selection bias between the groups.

3.3 Treatment Effects

The study's central hypotheses are that participation in the intervention will decrease emotional distress of participants, increase their ability to regulate emotions and refocus on planning, increase their likelihood of having adult support, and decrease their difficulties in emotion regulation two months after the intervention.

The main estimand of the study will be intention-to-treat (ITT), or the average treatment effect of the intervention based on youths' assignment to the intervention. This analysis will compare the outcomes for youth who were selected at sites that were randomized to implement the intervention compared to those who were selected at sites that were randomized to not implement the intervention.

To conduct this analysis, a three-level random intercept model will be used with a time-period flag (baseline/endline) at level one nested within individual at level two nested within Compassion site at level three. An interaction between treatment and time-period flag will be used to identify the estimated effect of the intervention. Dummy variables indicating the Compassion site blocking groups will be included in the model in addition to imbalanced site-level variables that are found to be prognostic through the exploratory data analysis process discussed above. Additionally, the respective baseline outcome mean aggregated to the site level will also be included as a control. Individual-level baseline variables will also be included as controls to address any differences occurring through participant selection or recruitment. Individual-level demographic variables such as gender and age will also be included. Propensity score weights may also be used depending on whether such adjustment is needed as determined by the exploratory data analysis described above.

Additional analyses will also be conducted per protocol using the average treatment effect on the treated (ATT) estimand, or the average treatment effect of the intervention for youth who actually did participate in the intervention. Because the intervention includes seven youth sessions and three caregiver sessions, attendance data will be reviewed prior to analysis to identify dosage groups that are most informative such as youth who attended all of the sessions or at least four of the sessions. Similarly, caregiver attendance will also be reviewed and combined with youth

dosage data to create informative categories such as youth who attended all sessions and whose caregiver attended all sessions. Because the EASE intervention is new to Compassion, it is uncertain at this time how frequently youth and their caregivers will attend intervention sessions and thus how to define dosage categories.

Limiting the sample to those who adhered to the selected dosage definition may introduce bias. To address this, once the dosage categories are defined and prior to conducting the per protocol analysis, the balance between the treatment group that adhered to the selected dosage definition and the control group will be reviewed according to the process outlined in section 3.2. Any imbalance between the groups will be identified and propensity score methods will be considered such as inverse probability weighting (IPW) to conduct the analysis.

In all analyses, the intervention's impact will be examined at alphas of 0.1 and 0.05, with both p-values < 0.1 and < 0.05 being reported.

3.4 Heterogeneous Effects

Heterogeneous treatment effects on the primary outcome of psychological distress will be explored based on three characteristics: internalizing scores, externalizing scores, and baseline emotional distress scores.

Regarding the first two characteristics, we hypothesize that those with higher baseline internalizing scores will see larger treatment effects because the intervention has been designed to help adolescents with these challenges specifically. We hypothesize that those with higher baseline externalizing scores will see smaller treatment effects because such challenges are likely to inhibit the therapeutic benefits due to a decreased ability to participate productively in the group-based sessions. The intervention guidance as created by the WHO aligns with these hypotheses and specifically identifies internalizing and externalizing problems as important screening criteria. This analysis seeks to illuminate whether implementing such a screening during participant selection would in fact lead to greater effects for participants.

To conduct this analysis, two separate models will be used, one for estimating the moderating effects of the internalization score and one for estimating the moderating effects of the externalization score. The base model for each will be the same specification as the main treatment effect model noted above but will include a treatment-moderator interaction. In these models, both measures will be analyzed using the continuous version of the moderating variable. Additionally, thresholds for each measure will be explored and possibly combined to form participant groups:

- a) High externalization and low internalization
- b) High externalization and high internalization
- c) Low externalization and low internalization
- d) Low externalization and high internalization

These groups may then be used in a single model to identify the combined moderating effect of the two measures. While the separate, continuous variable models will provide more granular insight into any moderating effects of youths' internalization and externalization, the combined group-based analysis will potentially offer a more actionable way to consider the combined effects of each that can then inform future screening processes.

For each model identified above, a random intercept-only model and a random slope model will be run and compared. Because this intervention and study are new for Compassion, it is not known whether slopes may vary by cluster site. Consequently, both versions will be run to identify whether and to what degree slopes may differ. Also, in each model the moderator variable, interaction, and all covariates will be centered.

For the third group, we are uncertain as to whether those with higher baseline emotional distress scores will experience different effects compared to those with lower scores. While the intervention is aimed at decreasing emotional distress, it is unclear whether a youth's baseline level would result in differential effects of the intervention. The WHO intervention documentation does not address this, but it is an important question for Compassion to understand in order to inform future implementation of the intervention. For this analysis, a flag will be created indicating if an observation scored above a baseline emotional distress score threshold that is either defined by literature or defined empirically such as the median. The models from the main analysis will be re-run with an interaction between treatment and the emotional distress flag. The results from this analysis will provide insight into types of youth who may be most responsive to the intervention.

For all of the analyses described above, the ITT estimand will be the primary analysis used to identify heterogeneous treatment effects. Additionally, the per protocol analyses will also be conducted as power allows to observe any potential differences in effect by group for those who participated in the intervention.

All analyses of heterogeneous treatment effects above may also require adjustments depending on whether propensity score methods are needed per the exploratory data analysis results.

3.5 Standard Error Adjustments

Clustering will be addressed in the analysis through the use of mixed effects models with time period (baseline/endline) nested within individual and individual nested within Compassion site.

The analyses above include testing multiple hypotheses as seen in Table 2 below. Currently, the analysis plan anticipates running a possible 28 total hypothesis tests. To address the potential for type I errors, Bonferroni or False Discovery Rate approaches will be used to adjust for multiple hypothesis tests when assessing the robustness of the findings.

Table 2. Number of hypothesis tests

	Primary outcome	Secondary outcomes	Internalizing moderator	Externalizing moderator	Internalizing and externalizing combined moderator	Baseline emotional distress subgroup	Total
ITT	1	7	2	2	1	1	17
ATT	1	7	2	2	1	1	17
Total	2	14	4	4	2	2	28