Creating Opportunities through Mentoring, Parental involvement and Safe Spaces (COMPASS) Ethiopia, a Cluster-Randomized Control Trial

Statistical Analysis Plan

Gary Yu, DrPH

Study Statistician

Aim of the study
To investigate the efficacy of a life skills and safe spaces intervention to reduce refugee adolescent girls' exposure to violence.

End points
Primary outcome measure
       Sexual violence, last 12 months- composite of:
              Unwanted sexual violence, last 12 months
              Coerced sex, last 12 months
              Forced sex, last 12 months

Secondary outcome measures
a) Unwanted sexual violence, last 12 months
b) Coerced sex, last 12 months
c) Forced sex, last 12 months
d) Physical violence, last 12 months
e) Emotional violence, last 12months
f) Transactional sex, last 12 months
g) Early marriage
h) Safe at home
i) Safe at school
j) Safe at friend's house
k) Safe at neighbor's house
l) Safe place to spend time with other girls
m) Aspiration years of schooling
n) Aspirational age of marriage
o) Aspirational age of first child
p) Attitude toward working outside home after marriage
q) Have friends
r) Have trusted non-family female adult in life

Study Design

This study used a two group wait-list cluster-randomized control trial. It enrolled 919 Sudanese and South Sudanese girls aged 13 to 19 years who spoke one of four dialects and were registered to participate in the COMPASS program. Participant enrollment took place in July 2015 in three refugee camps in Ethiopia. After participants were enrolled, baseline data were collected; endline data were collected approximately 12 months later. Study procedures were approved by the Institutional Review Board of the Columbia University Medical Center (Protocol #AAAP6855), the Administration for Refugee and Returnee Affairs in Ethiopia, and the IRC's internal review board (Protocol # WPE 1.00.003).

This study was registered at ClinicalTrials.gov with identifier NCT02384642.

Sample Size Calculation
The target sample size was originally calculated assuming 20 girls in each cluster; however, program realities in the field led to fewer girls being assigned to each group and thus necessitated a recalculation of our sample size. We assumed 30% prevalence of sexual violence among the population at baseline, and that this prevalence was likely to remain constant among the control group. To calculate the target

sample size, we assumed statistical power of 80% and a two-sided alpha of 0.05 to detect a 35% reduction in the incidence of past-year sexual violence in the intervention arm compared with the waitlist arm. We estimated that each cluster would comprise approximately 15 girls. We assumed an intraclass correlation coefficient (ICC) of 0.06 to account for clustering. We could not find a previous study that measured sexual violence among female adolescents in a sub-Saharan African site. However, a study that assessed intimate partner violence perpetrated against females ages 15-49 years across multiple sites, including Ethiopia, reported all ICCs were less than 0.06.[30] We required 62 clusters, 31 groups in each treatment arm. We expected a 10% loss to follow-up, necessitating a final sample size of at least 896 girls.

Statistical Analyses
12-month follow-up data were collected after completion of the intervention. Outcomes were analyzed using the intention-to-treat principle.

Participant characteristics
Aim: We can understand participant characteristics by analyzing each factor for each treatment group.

Expression:
    Categorical data: Number of participants and percentage.
    Continuous data: Mean, SD, median, interquartile range, maximum, and minimum

Factors:
Categorical data:
    Language
    Camp
    Parents living in home
    Live with an intimate partner
    Sexual violence, last 12 months
            Unwanted sexual violence, last 12 months
            Coerced sex, last 12 months
            Forced sex, last 12 months
    Physical violence, last 12 months
    Emotional violence, last 12months
    Transactional sex, last 12 months
    Early marriage
    Safe at home
    Safe at school
    Safe at friend's house
    Safe at neighbor's house
    Safe place to spend time with other girls
    Aspirational age of marriage
    Aspirational age of first child
    Attitude toward working outside home after marriage
    Have friends
    Have trusted non-family female adult in life

Continuous data:
    Age

Years of schooling
Aspiration years of schooling

The main statistical analysis for efficacy
The intervention's effects on binary primary and secondary outcomes at endline were assessed through mixed effects logistic regressions with random intercepts to account for clustering; the intervention's effect on a secondary continuous outcome was assessed using a linear mixed model. After estimating the first-order effect of the intervention on these outcomes, models were adjusted for baseline age, previous engagement in a romantic relationship, and presence of mother, father, or both parents in the home.

Additionally, we ran sensitivity analyses on an imputed dataset. We used multiple imputation in Stata to generate five sets of imputations for all missing outcomes.

Comparison between groups of sexual violence in the last 12 months
> **Measure:** Any form of sexual violence in the last 12 months
> **Aim:** Comparison of the adjusted odds ratios of the event between groups
> **Test:** z-test
> **Significance:** Two-sided p values of less than 0.05 were considered statistically significant.
> **Confidence Interval:** 95% confidence interval
> **Expression:** Odds ratio for two treatment groups
>
> Using mixed effects logistic regression models, unadjusted and adjusted odds rations were assessed. Participants missing values for any variables included in the model were excluded from that particular analysis.

The secondary statistical analysis for efficacy

Unwanted sexual touching
> **Measure:** Experiencing unwanted sexual touching in last 12 months
> **Aim:** Comparison of the adjusted odds ratios of the event between groups
> **Test:** z-test
> **Significance:** Two-sided p values of less than 0.05 were considered statistically significant.
> **Confidence Interval:** 95% confidence intervals
> **Expression:** Odds ratio for two treatment groups and for three protocol adherence groups

Coerced sex
> **Measure:** Coerced sex in the last 12 months
> **Aim:** Comparison of the adjusted odds ratios of the event between groups
> **Test:** z-test
> **Significance:** Two-sided p values of less than 0.05 were considered statistically significant.
> **Confidence Interval:** 95% confidence intervals
> **Expression:** Odds ratio for two treatment groups and for three protocol adherence groups

Forced sex
> **Measure:** Being forced to have sex in the last 12 months
> **Aim:** Comparison of the adjusted odds ratios of the event between groups
> **Test:** z-test

Significance: Two-sided p values of less than 0.05 were considered statistically significant.
Confidence Interval: 95% confidence intervals
Expression: Odds ratio for two treatment groups and for three protocol adherence groups

Physical violence
Measure: Physical violence in the last 12 months
Aim: Comparison of the adjusted odds ratios of the event between groups
Test: z-test
Significance: Two-sided p values of less than 0.05 were considered statistically significant.
Confidence Interval: 95% confidence intervals
Expression: Odds ratio for two treatment groups

Emotional violence
Measure: Emotional violence in the last 12 months
Aim: Comparison of the adjusted odds ratios of the event between groups
Test: z-test
Significance: Two-sided p values of less than 0.05 were considered statistically significant.
Confidence Interval: 95% confidence interval
Expression: Odds ratio for two treatment groups

Transactional sex
Measure: Transactional sex in the last 12 months
Aim: Comparison of the adjusted odds ratios of the event between groups
Test: z-test
Significance: Two-sided p values of less than 0.05 were considered statistically significant.
Confidence Interval: 95% confidence interval
Expression: Odds ratio for two treatment groups

Early marriage
Measure: Entering into early marriage in the last 12 months
Aim: Comparison of the adjusted odds ratios of the event between groups
Test: z-test
Significance: Two-sided p values of less than 0.05 were considered statistically significant.
Confidence Interval: 95% confidence interval
Expression: Odds ratio for two treatment groups

Safe at home
Measure: Feel safe at home
Aim: Comparison of the Beta coefficients for the event between groups
Test: t-test
Significance: Two-sided p values of less than 0.05 were considered statistically significant.
Confidence Interval: 95% confidence interval
Expression: Beta coefficients for two treatment groups

Safe at school
Measure: Feel safe at school
Aim: Comparison of the Beta coefficients for the event between groups
Test: t-test

Significance: Two-sided p values of less than 0.05 were considered statistically significant.
Confidence Interval: 95% confidence interval
Expression: Beta coefficients for two treatment groups

Safe at friend's house
    Measure: Feel safe at friend's house
    Aim: Comparison of the Beta coefficients for the event between groups
    Test: t-test
    Significance: Two-sided p values of less than 0.05 were considered statistically significant.
    Confidence Interval: 95% confidence interval
    Expression: Beta coefficients for two treatment groups

Safe at neighbor's house
    Measure: Feel safe at neighbor's home
    Aim: Comparison of the Beta coefficients for the event between groups
    Test: t-test
    Significance: Two-sided p values of less than 0.05 were considered statistically significant.
    Confidence Interval: 95% confidence interval
    Expression: Beta coefficients for two treatment groups

Safe place with other girls
    Measure: Have a safe place to spend time with other girls
    Aim: Comparison of the Beta coefficients for the event between groups
    Test: t-test
    Significance: Two-sided p values of less than 0.05 were considered statistically significant.
    Confidence Interval: 95% confidence interval
    Expression: Beta coefficients for two treatment groups

Schooling aspirations
    Measure: Highest grade a participant believes should be completed
    Aim: Comparison of the Beta coefficients for the event between groups
    Test: t-test
    Significance: Two-sided p values of less than 0.05 were considered statistically significant.
    Confidence Interval: 95% confidence interval
    Expression: Beta coefficients for two treatment groups

Aspirational age of marriage
    Measure: Aspire to enter marriage at 18 years or older
    Aim: Comparison of the adjusted odds ratios of the event between groups
    Test: z-test
    Significance: Two-sided p values of less than 0.05 were considered statistically significant.
    Confidence Interval: 95% confidence interval
    Expression: Odds ratio for two treatment groups

Aspirational age of first child
    Measure: Aspire to have first child at 18 years or older
    Aim: Comparison of the adjusted odds ratios of the event between groups
    Test: z-test

Significance: Two-sided p values of less than 0.05 were considered statistically significant.
Confidence Interval: 95% confidence interval
Expression: Odds ratio for two treatment groups

Working outside home after marriage
    Measure: Believe working outside home after marriage is acceptable
    Aim: Comparison of the adjusted odds ratios of the event between groups
    Test: z-test
    Significance: Two-sided p values of less than 0.05 were considered statistically significant.
    Confidence Interval: 95% confidence interval
    Expression: Odds ratio for two treatment groups

Have friends
    Measure: Have friends of a similar age outside the family
    Aim: Comparison of the adjusted odds ratios of the event between groups
    Test: z-test
    Significance: Two-sided p values of less than 0.05 were considered statistically significant.
    Confidence Interval: 95% confidence interval
    Expression: Odds ratio for two treatment groups

Trusted non-family female adult
    Measure: Have a trusted non-family female adult
    Aim: Comparison of the adjusted odds ratios of the event between groups
    Test: z-test
    Significance: Two-sided p values of less than 0.05 were considered statistically significant.
    Confidence Interval: 95% confidence interval
    Expression: Odds ratio for two treatment groups

Sensitivity Analyses
    All of the above analyses were implemented on imputed data to ensure results were robust when accounting for missing data. A multiple imputation approach was utilized. Specifically, a set of five imputations was generated in Stata with 'mi impute', after which the average values represented a close estimate of a full dataset.

Exploratory Analyses
    No exploratory analyses were conducted.