Creating Opportunities through Mentoring, Parental involvement and Safe Spaces (COMPASS) Democratic Republic of Congo, a Cluster-Randomized Control Trial

Statistical Analysis Plan

Ilana Seff, MPH, DrPH (c)

Study Statistician

Aim of the study
To investigate the incremental effectiveness of adding a caregiver component to a girls' life skills and safe spaces program to reduce internally displaced adolescent girls' exposure to violence.

End points
Primary outcome measure
    Girls
    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
    Girls
    Unwanted sexual violence, last 12 months
    Coerced sex, last 12 months
    Forced sex, last 12 months (ages 13-14)
    Physical violence, last 12 months
    Emotional violence, last 12months
    Neglect, last 12 months
    Early marriage
    Transactional sex, last 12 months

    Caregivers
    Attitudes toward gender inequitable norms
    Attitudes toward physical discipline of children
    Parental behaviors and feelings toward children

Study Design

This study used a two group wait-list cluster-randomized control trial. It enrolled 869 girls and 764 caregivers who were registered to participate in the COMPASS program. Girls were aged 10 to 14 years and both girls and caregivers spoke Mashi or Swahili. Participant enrollment took place across 14 sites in South Kivu, DRC from July 2015 to October 2016. 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) and the Ministry of Gender in South Kivu, DRC.

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

Sample Size Calculation
Sample size calculations assumed 30% prevalence of sexual violence in the target population. Given that girls in both treatment arms received the COMPASS life skills component of the intervention, we expected this prevalence to decline to approximately 25% in the control groups. Calculations assumed statistical power of 80% and a two-sided alpha of 0.05 in order to detect 50% reduction in the incidence of past-year exposure to sexual violence in the intervention arm compared with the waitlist arm. We assumed cluster sizes of 23 girls and an intraclass correlation coefficient (ICC) of 0.06 to account for clustering. A study assessing experiences of intimate partner violence among females ages 15-49 years

across multiple sites, including countries in sub-Saharan Africa, reported ICCs for all study sites were less than 0.06.[43] We required at least 34 clusters, with 17 clusters in each treatment arm. With an expected loss to follow-up of 10%, we needed a minimum final sample size of 869 girls.

Statistical Analyses
12-month follow-up data were collected after completion of the intervention. Outcomes were analyzed using the intention-to-treat and per protocol principles. For girl outcomes, protocol adherence was defined as both the adolescent girl and her caregiver attending at least 75% of program sessions; for caregiver protocol adherence meant caregivers attended at least 75% of caregiver sessions. Per protocol analysis looked at differences in outcomes across the control arm, those with low treatment adherence (assigned to the treatment arm but did not adhere to protocol), and those with high treatment adherence (assigned to the treatment arm and adhered to protocol).

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

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

Factors:
Categorical data:
 <u>Girls</u>
 Language
 Attended school, last 12 months
 Worked for pay, ever
 Parents living in the 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
 Neglect, last 12 months
 Early marriage
 Transactional sex, last 12 months

 <u>Caregivers</u>
 Gender

Continuous data:
 <u>Girls</u>
 Age (years)
 Years of schooling

Caregivers
Age (years)
Attitudes toward gender inequitable norms
PARQ warmth/affection subscale
PARQ total scale
Attitudes toward physical discipline

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

Program effects were also assessed using per protocol (PP) analysis. PP analysis for girls' outcomes examined the effect of both the adolescent girl and her caregiver attending at least 75% of program sessions. PP analysis thus assesses differences in outcomes across three groups: girls in the control arm, girls in the treatment arm who attended less than 75% of program sessions, or whose caregivers attended less than 75% of program sessions (low treatment adherence), and girls in the treatment arm who, along with their caregivers, attended at least 75% of program sessions (high treatment adherence). PP analysis for caregiver outcomes assessed the effect of the caregiver attending at least 75% of program sessions.

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 and for three protocol adherence groups

  Using mixed effects logistic regression models, unadjusted and adjusted odds ratios were assessed. Participants missing values for any variables included in the model were excluded from that particular analysis.

The secondary statistical analysis for efficacy

Girls
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: Being hit or beaten 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

Emotional violence
      Measure: Being screamed at loudly or aggressively 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 and for three protocol adherence groups

Neglect
      Measure: Felt uncared for by person that is meant to provide care 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 and for three protocol adherence 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 and for three protocol adherence groups

Transactional sex
      Measure: Having sex with someone in exchange for money, food, or gifts 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 and for three protocol adherence groups

<u>Caregivers</u>
Attitudes toward gender inequitable norms
      Measure: Scale (0 to 10; higher values indicate more inequitable attitudes)
      Aim: Comparison of the beta coefficients 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 coefficient for two treatment groups and for three protocol adherence groups

      Using mixed linear regression models, beta coefficients were assessed. Participants missing values for any variables included in the model were excluded from that particular analysis.

Attitudes toward physical discipline of children
      Measure: Scale (0 to 11; higher values indicate greater acceptance of physical discipline)
      Aim: Comparison of the beta coefficients 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 coefficient for two treatment groups and for three protocol adherence groups

Parental behaviors and feelings toward their children
      Measure: Parental Acceptance-Rejection Questionnaire (PARQ) (0 and 96; higher values indicate greater rejection of children)
      Aim: Comparison of the beta coefficients 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 coefficient for two treatment groups and for three protocol adherence groups

      Measure: PARQ Warmth/affection subscale (0 to 32; higher values indicate greater lack of affection toward children)
      Aim: Comparison of the beta coefficients 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 coefficient for two treatment groups and for three protocol adherence groups

Exploratory Analyses

No exploratory analyses were conducted.