

Improving the Reproductive Health of Families
NCT03858803
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Study Protocol

We conducted a 3-arm randomized controlled trial (RCT) of the interventions we adapted in the earlier R34 assessing their effectiveness and the optimal delivery format. In Arm 1, parents and adolescents completed a baseline assessment, after which parents participated in Families Matter 2 (FM2). Both parents and adolescents completed a second assessment after which the adolescents received Living as a Safer Teen (LAST) and then were followed for six months. In Arm 2, after the baseline assessment, adolescents participated in LAST and parents in FM2, after which both parents and adolescents completed post assessment and 6 months later a third assessment. Families in Arm 3 did not receive any intervention; however, after the third assessment, families in Arm 3 were offered the interventions as an ethically justified service.

We systematically sampled from each designated residential district by approaching every third dwelling and determining whether the household contains an adolescent. If there was an adolescent in the home, we explained the programs to the parents and to the adolescent, securing informed consent and assent respectively for participation before administering the baseline surveys on ACASI notebook computers.

Statistical Analysis Plan

A 3x3 multivariate analysis of variance (MANOVA) was used to compare the three arms on the cognitive and behavioral measures. The outcome measures were previously pilot tested for psychometric adequacy. All analyses were conducted with SPSS. The 1x3 MANOVA compared parents and adolescents on their baseline equivalence and was nonsignificant, indicating that randomization by cohort had resulted in equivalent groups at baseline (for parents, $F(12, 918) = 1.09, p > .05$; for adolescents, $F(24, 886) = 1.44, p > .05$). A 3x3 (main effects for arm and main effects for time) MANOVA was significant ($F(24, 4798.01) = 1.77, p < .01$ for parents; $F(48, 4994.366) = 1.72, p < .01$ for adolescents). Significant multivariate effects were followed by univariate ANOVA. Significant main or interaction effects on the ANOVAs were then subjected to posthoc Tukey tests to clarify where there were significant differences by group, time, or interaction.