

Multi-level Intervention to Reduce Pregnancy Risk Among Adolescents: A Feasibility Trial in the Emergency Department

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Statistical analysis plan

We used R software (R Foundation for Statistical Computing) for analyses. In keeping with guidance discouraging the use of “statistical significance” and binary hypothesis testing based on arbitrary cutoffs (e.g., $P < .05$), we examined effect sizes along with P values and include P values without describing them as “significant” or “not significant.” Consistent with this approach, we did not attempt to control the familywise error rate (probability of at least one type I error across the study), which is not defined outside of binary hypothesis testing. We summarized closed-ended feasibility outcomes using descriptive statistics. We used an intention-to-treat analysis to assess preliminary efficacy and Fisher exact tests to compare arms on the percent of participants using contraception at 30 days. Dropouts during the index visit were treated as having no subsequent contraceptive use. Differences in average change score (e.g., attitudes) between arms were tested using nonparametric permutation tests.

Primary Outcome: We hypothesized the intervention would be deemed feasible by stakeholders. Drawing on similar examples in the literature, we determined a priori that the intervention would be feasible if the mean score across five Likert-scale survey items was ≥ 4 (range 1-5).