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Study Protocol

Title of the study:

A Risky Sex Prevention Intervention for Middle School Age Minority Girls

NCT number:

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The study objectives were to address the following research questions (RQs):

RQ1. What is the efficacy of the intervention in delaying initiation of sex or reducing risky sex behaviors by young Black girls?

RQ2. Does the intervention produce changes in black middle school girls' knowledge of HIV, communication with mothers (including bonding and monitoring), self-esteem, racial pride, empowerment and sexual assertiveness?

RQ3. Does the intervention produce changes in mothers' mother-daughter communication, bonding, and maternal monitoring?

Study design

A quasi-experimental, longitudinal design was used to test the efficacy of a family-level HIV preventive intervention for young Black girls relative to girls in a comparison group to assess HIV knowledge, communication and bonds with their mothers, racial/ethnic pride, self-esteem, and assertiveness and to empower girls. Data were collected for all participants at baseline (prior to the intervention), immediately post-intervention (three months post-baseline), and at three- and nine-month follow-up.

The study statistical analysis plan is uploaded as a separate document to clinicaltrials.gov.