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Evaluating the Role of Family Context within a Randomized Adolescent HIV-Risk Prevention Trial

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Abstract

Project STYLE is a multi-site 3-arm RCT comparing family-based, adolescent-only, and general health promotion interventions with 721 adolescents in mental health treatment. This study reports 12-month outcomes for family context and sexual risk behaviors, and explores the role of baseline family context in modifying treatment response. Using the full sample, there were sustained benefits for parent-reported sexual communication ($d=.28$), and adolescent-reported parental monitoring ($d=.24$), with minimal differences in risk behaviors. Latent profile analysis identified four family context classes: *struggling* ($n=177$), *authoritative* ($n=183$), *authoritarian* ($n=175$), and *permissive* ($n=181$). The *authoritarian* and *permissive* classes were also distinguished by disagreement between parent and adolescent report of family context. Classes differed in terms of baseline mental health burden and baseline sexual risk behavior. Classes showed different patterns of treatment effects, with the *struggling* class showing consistent benefit for both family context and sexual risk. In contrast, the *authoritarian* class showed a mixed response for family context and increased sexual risk.

Keywords

Adolescents; sexual risk; family context; mental health; treatment modifiers

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Informed consent: Informed consent was obtained from all parents/caregivers and assent was obtained from all participants under the age of 18.

INTRODUCTION

Adolescents with mental health symptoms engage in sexual risk behaviors at higher rates than their peers (1,2), placing them at elevated risk for acquiring HIV, other sexually transmitted illnesses, or having an unintended pregnancy. Family context is one of a number of factors associated with increased risk in this population (3–5). In particular, parent-adolescent sexual communication, parental monitoring and supervision skills, and family affective engagement have been found to be important dynamics that influence sexual-risk behaviors (6–8). For the purposes of this manuscript, family context is used to describe a constellation of family factors including parent-adolescent communication, parenting practices, and family environment (e.g., support, cohesion, organization).

Strengthening Today's Youth Life Experiences (Project STYLE) is a family-based sexual-risk prevention intervention developed to address some of the vulnerabilities in family context that lead to sexual risk behaviors among youth with mental health concerns (9). The 3-month outcomes from a large 3-arm random controlled trial ($n=721$) of the intervention indicated benefits for sexual communication and parental monitoring for the family condition, with fewer condomless sex acts in the active prevention conditions compared to a time and attention matched control condition (rate ratio=.49; 95% CI = .28-.86) (10). This manuscript reports 12-month follow-up data from Project STYLE, along with an exploratory subgroup analysis of how baseline family context influenced treatment response.

Reduction in sexual risk may depend on initial family context. Families with clear challenges in the targeted family processes are more likely to benefit from intervention than those who are functioning according to current recommendations (e.g., engaged, supportive, authoritative parenting style) (11). Alternatively, struggling families may present with entrenched challenges beyond the reach of time-limited interventions, resulting in little therapeutic change. For families who are functioning similar to recommendations, asking them to modify processes that are currently suppressing their children's sexual risk may result in a modified family system that is less effective in suppressing risk. For example, strong parental rules have been linked with lower sexual risk behavior for families with lower social-economic standing (12), if those rules are weakened as parents move from a more authoritarian to authoritative parenting style, the result could be increased sexual risk.

Identifying which family contexts facilitate or impede the impact of family-based interventions facilitates tailoring interventions to meet the needs of vulnerable populations, informs clinical decision making, and suggests next steps for research. Tailoring interventions to the needs of a target population has been an oft stated but underutilized strategy (13). There is little data about how subgroups respond to intervention programs, which has prevented tailoring (14). The methodological challenges to providing reliable information about subgroup response have been well documented, and primarily focus on inadequate power to test interactions coupled with the risk of identifying spurious findings that accompany exploratory post-hoc analyses (15,16). One strategy to minimize this risk and, thus, increase the utility of subgroup analyses is to clearly identify analyses as exploratory, present effect-size and confidence intervals, and use cautious interpretation (16).

In the current study, we evaluated the 12-month outcomes from Project STYLE, a large clinical trial of a brief family-based sexual-risk prevention intervention among adolescents in mental health care to date, and used latent profile analyses to classify families based on baseline patterns of general communication, sexual communication, parental permissiveness, parental monitoring, and family environment to examine the influence of family context on treatment outcomes. We expected to find that the family-based versus comparison (adolescent-only and health promotion) conditions would show higher functioning on measures of family context and lower sexual risk behavior at 12 months post-intervention. Previous research on classifying family context has found have found two general dimensions—family structure (e.g., cohesion and organization) and emotional closeness (e.g., warmth, affective support) (17,18). Most subgroup classifications have found a “high functioning” class that is positive in both structure and closeness, and a “struggling” class that is low on both dimensions. There is less agreement across studies in defining classes that fall between these two extremes (17). Consistent with this literature, we expected to find a higher functioning class as well as a struggling class, with an indeterminate number of additional classes. Recognizing the exploratory nature of these group classification and the subgroup analysis, and given the anticipated limitations of statistical power, we present and interpret patterns of results from the subgroup analyses based on effect sizes (19).

METHODS

Participants

Project STYLE (10) was an 11-hour family-based intervention based on the Social-Personal Framework (4) and specifically created to address the needs of youth with mental health problems with the hope of decreasing long-term sexual risk outcomes. Participants included 721 youth (ages 13 to 18) and their caregivers recruited from inpatient and outpatient mental health settings between 2003 and 2008 (9) (see Figure 1 for CONSORT). STYLE was powered at .90 to detect 5% increase in condom use with 600 participants completing the 12 month assessment. The study was conducted at three sites: Rhode Island Hospital (Providence, RI), Emory University (Atlanta, GA), and the University of Illinois at Chicago (Chicago, IL). Participants were eligible if they had been in mental health treatment within the past year, were living with a primary caregiver for the past three months, and both parent and teen spoke English. Participants were excluded if they self-reported HIV infection, pregnancy, a known history of sexual aggression, or had a mental disability that would preclude their participation in a group. Only one caregiver from each family, selected by the family, participated in the study. Informed consent and assent were obtained from all individual participants included in the study. All procedures were in accordance with the ethical standards of the institutional and/or national research committees at each site and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Participants were randomized into one of three interventions: (1) a family-based HIV-prevention program (FAM), (2) an adolescent-only HIV prevention program with an evidence base (AO) (20), or (3) a general health promotion (HP) condition. Interventions were delivered during an 8 hour workshop to groups of 4–8 individuals/dyads and reinforced

during a 1 hour individual booster session at two weeks and a 2 hour group booster session 3 months following the workshop. The FAM condition focused on parental monitoring and supervision skills, and parent – adolescent communication. In addition, all HIV relevant material found in the AO condition was included. The AO condition focused on sexual decision making, refusal of sex, abstinence, and condom use. The HP condition targeted exercise, nutrition, sleep, smoking, and information about HIV. All conditions used similar didactic approaches including games, multimedia presentations, and discussion. The AO and FAM condition also employed skill demonstration, practice, and role-plays. Finally, the FAM condition included peer-feedback on parent-adolescent monitoring discussions, as well as facilitator feedback on dyadic sexual values discussions. Interventions were delivered by trained facilitators (one master's or doctoral-level clinician and one research assistant per group). Because the Family condition was the only condition to target family context, the FAM condition was compared to the combined AO+HP conditions throughout this manuscript.

Data Collection

Assessments were independently completed by parents and adolescents using an audio computer assisted structured interview (ACASI). Analyses reported in this manuscript use the baseline data (prior to randomization), and data collected at the 3-, 6-, and 12-month assessments.

Psychiatric Measures.—Computerized Diagnostic Interview Schedule for Children (21) is a structured computer-assisted diagnostic interview that generates the full range of DSM IV diagnoses. The following disorders were assessed: major depressive disorder, generalized anxiety disorder, posttraumatic stress disorder, mania, hypomania, oppositional defiant disorder, conduct disorder, and attention-deficit hyperactivity disorder. Disorders were counted if either parent or adolescent reported threshold or sub-threshold levels for the disorder. Spearman's correlation was used to assess agreement between parent and adolescent reports of disorders. Parent and adolescent agreement ranged from .17 to .22 for internalizing disorders, .21 to .22 for externalizing disorders, and was .11 and .12 for mania and hypomania, respectively. Eighty-four percent of adolescents met screening criteria for at least one mental disorder by either their own or their parent's report, and 69% met criteria for more than one disorder. Participants met criteria for the following: oppositional defiant disorder (ODD; 64%), attention-deficit hyperactivity disorder (ADHD; 55%), conduct disorder (CD; 41%), generalized anxiety disorder (GAD; 32%), major depressive disorder (MDD; 30%), mania (24%), hypomania (22%), and posttraumatic stress disorder (PTSD; 18%). Participants were subdivided into one of five categories to help address comorbidities, help simplify the diagnostic presentation, and highlight symptoms of mania, which have been linked to increased sexual risk behavior (22). The categories are as follow: 1) None: did not meet criterion on any diagnosis, 2) Internalizing: exceeded criterion for at least one internalizing disorder (i.e., MDD, GAD, PTSD), 3) Externalizing: exceeded criterion for at least one externalizing disorder (i.e., ODD, CD, ADHD), 4) Mixed: exceeded criterion for at least one internalizing and one externalizing disorder 5) Manic: exceeded criterion for mania or hypomania, regardless of other comorbidities.

Columbia Impairment Scale (CIS) (23) was used to assess adolescent functional impairment. The CIS is a 13-item scale that assesses interpersonal relations, broad psychopathological domains, functioning in job or school work, and use of leisure time. Individual items are measured on a 0 to 5 scale then summed to create a total score, with higher scores suggesting higher impairment (range 0–52). The scale was administered to both parents (range of across assessments = .85 to .89) and adolescents (.81 to .87). Parent-adolescent agreement on the measure, assessed using intraclass correlation coefficients (ICCs), ranged from .26 to .36.

Measures of Risk Behavior (Risk Outcomes).—Adolescents completed the Adolescent Risk Behavior Assessment (ARBA), a computer-assisted structured interview designed specifically for use with adolescents to assess their self-reported sexual and drug behaviors associated with HIV infection (24). The ARBA assesses sexual behavior during the past 90 days by asking questions for each sexual partner including type of sexual behavior (i.e., anal, vaginal) and condom use during each sexual event in the past 90 days. These questions were used to define any condomless sex and having multiple partners during the 90 day recall. Participants are also asked about low frequency, but high-risk events, including having sex while under the influence of drugs or alcohol, having sex while their partner was under the influence, and having sex with someone they met that day. These high-risk behaviors were aggregated to form a composite with ‘0’ indicating ‘no engagement’ in these behaviors and ‘1’ indicating ‘engagement’ in one or more of the behaviors. Finally, we formed a composite of sexual risk behavior (i.e., condomless sex, multiple partners, high-risk behaviors) with ‘0’ indicating no engagement in any of the risk behaviors and ‘1’ indicating engagement of one or more of the behaviors. All measures of sexual risk were aggregated across the 3-, 6-, and 12-month assessments.

Measures of Family Context.—Adolescents were asked to report on the parent participating in the study for all measures of family context except those asking about the family environment in general (i.e., the Family Relationship Scale).

Sexual Communication was assessed using the Parent-Adolescent Sexual Communication Scale (PASC) (25), with six items rated on a 7-point scale from “not true for me” to “very true for me”. Both adolescents (range of across assessments = .81 to .86) and parents ($\alpha = .58$ to .64) completed the measure, with parent-adolescent agreement ranging from ICC=.15 to .19.

Parental Monitoring & Permissiveness was assessed using the Parenting Style Questionnaire (PSQ) (26). The adolescent version of the PSQ is comprised of eight items and assesses both degree of parental monitoring ($\alpha = .69$ to .84) and permissiveness ($\alpha = .75$ to .80). The parent version consists of ten items that address monitoring only. Consistent with previous publications using the STYLE cohort, the item stating, “How difficult is it for you to know where your teen is and what she is doing, now that she is getting older?” was dropped due to poor reliability. The nine-item parent report showed internal consistencies ranging from .73 to .78 across assessments, with parent-adolescent agreement ranging from ICC = .02 to .03.

Parent-Adolescent General Communication was assessed using the Parent-Adolescent General Communication Scale (PAGCS) (27). Subscales include Open Family Communication (positive communication) and Problems in Family Communication (negative communication). Parents (positive: $\alpha = .81$ to $.84$; negative: $\alpha = .68$ to $.77$) and adolescents (positive: $\alpha = .92$ to $.94$; negative: $\alpha = .78$ to $.80$) complete separate versions with agreement of ICC=.23 to .28 for positive and .08 to .12 for negative.

Family Relationship Scale (FRS) was used to assess dimensions of family environment (28). The scale has been used by previous studies to help classify family environment (29,30). Subscales include: Support (parent: $\alpha = .70$ to $.74$; adolescent: $\alpha = .81$ to $.84$; ICC = .05 to .18), Communication (parent: $\alpha = .60$ to $.78$; adolescent: $\alpha = .63$ to $.72$; ICC = .09 to .15), Organization (parent: $\alpha = .62$ to $.67$; adolescent: $\alpha = .65$ to $.75$; ICC = .04 to .11), and Cohesion (parent: $\alpha = .79$ to $.84$; adolescent: $\alpha = .86$ to $.91$; ICC= .11 to .16). Consistent with previous studies that use the FRS, we averaged the parent and adolescent report for each subscale (31).

Analytic Approach.

Average Treatment Effects.—Treatment effects between the FAM and AO+HP conditions were evaluated for family context outcomes at 3-months and 12-months and for the cumulative sexual risk outcomes across 12 months. Univariate analyses were run for each outcome. Effect sizes for family context outcomes were calculated as standardized difference scores using baseline standard deviation pooled across treatment conditions. All sexual risk variables were binary and were fit with a logit link function with effect sizes being calculated as adjusted risk differences.

Classify Family Context.—Latent class modeling was used to identify subgroups of participants (i.e., classes) who reported similar profiles on baseline measures of family context. Baseline measures used for the analysis are listed in Figure 1 and included parent and adolescent reports as well as the combined parent/adolescent report for the FRS. Models were estimated using maximum likelihood with robust standard errors. Within-class correlations were allowed for subscales of the same measure. Class enumeration proceeded by fitting models with incrementing number of classes from 1 to 10. Models were compared using negative log likelihood, Consistent Akaike's Information Criteria (CAIC), Bayesian Information Criteria (BIC), Approximate Weight of Evidence Criterion (AWE), and Vuong-Lo-Mendel-Rubin likelihood ratio test (VLMR-LRT). The potential utility of the model was evaluated based on the size of the smallest class and the differentiation among classes assessed using relative entropy (32). Visual inspection of profile plots (Figure 1) was used to label classes.

Validity of Classification.—Construct validity of the classification was evaluated by examining baseline characteristics. It was expected that adolescents with less family structure (e.g., higher parental permissiveness, less structured family environment) would show higher rates of sexual risk behavior and that those that were low on both structure and emotional closeness (i.e., the “struggling” class identified in previous studies) would report

more mental health issues than the other classes. For these descriptive analyses class membership was assigned using the highest posterior probability of group membership.

Conditional Average Treatment Effects by Class.—In order to evaluate how family context effects treatment response, Mplus 7.3 was used to fit a manual 3-step latent class analysis where the uncertainty in defining latent classes was included in the modeling of treatment effects within each class (33). For all models, differences in treatment effect among classes (moderation) were tested using the Wald test.

Imbalance in Baseline Characteristics.—Because family context was not considered during study randomization, propensity score methods were used to balance baseline characteristics between the FAM and AO+HP conditions within each family context class. Specifically, we used boosted regression trees optimized to generate inverse probability of treatment weights that minimize the maximum non-parametric effect size (i.e., Kolmogorov-Smirnov test) of differences between treatment conditions across all baseline characteristics (34). Weights were stabilized and trimmed. Stabilized weights have been shown to improve performance in smaller samples (35). These weights were used in all models of treatment effects by class. A separate model was fit for each outcome and all models used a robust maximum likelihood estimator.

Missing data.—Depending on the measure, missing data ranged from 1% to 6% at baseline, and from 11% to 23% across the 3-, 6-, and 12-month follow-up assessments. These numbers reflect all sources of missing data (e.g., loss to follow-up, missing assessment, refused to answer). Missing data were addressed with multiple imputations, with the imputations being generated using chained equations (36). The imputation included all outcomes along with the inverse probability weights, class membership, and individuals' probability of assignment to each class. Analyses were run using Mplus 7.3 and the following R packages: *mice* v2.25, *twang* 1.4–9.5.

RESULTS

Average Treatment Effects at 12-Months

Unadjusted descriptive statistics for each arm along with effect-sizes are presented in Tables I & II. At three months post-intervention, adolescents in the FAM vs. AO+HP condition reported higher parental monitoring, higher positive communication, and higher sexual communication. There were minimal differences in parent reports between conditions. The combined parent-adolescent report of family environment showed an increase in family cohesion. At 12 months adolescents in the FAM vs. AO+HP condition continued to report higher parental monitoring, parents reported higher sexual communication, and family environment was similar across conditions. Adolescents in the FAM vs. AO+HP conditions reported similar amounts of sexual-risk behavior across the 12-month follow-up.

Classify Family Context

A four-class solution was determined by considering multiple indicators of model fit, the potential utility of the model, and class differentiation (Appendix A). While the BIC and

CAIC indices suggested a six- and five-class solution, respectively, the minimum class-sizes for these solutions were too small to be informative. The AWE and VLMR-LRT p -value suggested a four-class solution, where the minimum class size was more reasonable ($n = 170$). The four-class solution showed distinct and interpretable classes (Figure 2). Class characteristics based on baseline measures of parenting, parent-adolescent communication, and family functioning are described below.

Agreement: “Struggling” ($n = 177, 25\%$): Adolescent and parent agree and generally report lower functioning on all baseline measures. This pattern is consistent with the “Struggling” class identified by previous literature (11). Of note are the low levels of adolescent reported positive communication with their parents.

Agreement: “Authoritative” ($n = 183, 26\%$): Adolescent and parent agree and report relatively high functioning on all baseline measures of family context. This class is similar to the “high functioning” class identified in previous literature that is high on both structure and closeness/warmth and is consistent with an authoritative style of parenting (18,37). Importantly, this classification is relative to the other classes in this indicated sample and families in the *authoritative* class may or may not be classified as authoritative when compared to community samples.

Disagreement: “Authoritarian” ($n = 175, 24\%$): This class shares similarities with an authoritarian style of parenting (18,37), in that they report relatively high amounts of family structure with adolescents perceiving little emotional closeness. Specifically, adolescents’ reports of low levels of parental permissiveness, parents’ reports of high monitoring, and combined adolescent and parent reports of relatively high levels of family organization suggest higher structure; whereas, the reported low levels of cohesion, family communication, support, and adolescent report of low positive communication suggest, lower levels of closeness. There are some important differences between this class and an authoritarian parenting style, most notably, the low levels of adolescent reported parental monitoring, which is indistinguishable from the *struggling* class.

Disagreement: “Permissive” ($n = 181, 25\%$): This class shares similarities with a permissive style of parenting (18,37). Adolescents in this class reported relatively high communication and parental monitoring, along with the highest amount of parental permissiveness of any class. Parents reported low levels of monitoring and generally poor communication. Families in this class also reported levels of family organization that were similar to the *struggling* class. One difference with the permissive style found in the prior research is the direction of parent adolescent disagreement. Previous literature suggests that parents tend to report a more positive view of family functioning than adolescents (38), our sample showed the reverse. It is not clear what is behind this discrepancy; it may be that parents in this class have low levels of parenting self-efficacy (39), have a high mental-health burden, are conflict avoidant, or the adolescent is comfortable with the relatively low level of parental involvement.

Class Validation

Demographics and baseline characteristics by class are presented in Tables III and IV. There were minimal to no differences between classes for age, gender, race, ethnicity, or whether the adolescent lived in a single parent household. There were small to moderate differences for parental education and household income with the *authoritative* and *authoritarian* classes reporting higher parental education and the *authoritarian* class reporting higher family income, with the *permissive* class reporting the lowest family income.

As expected, there were small to medium differences among classes for mental health diagnosis, number of days hospitalized, and both parent and adolescent report on the CIS. Specifically, the *struggling* class showed higher rates of mania, more days hospitalized, and higher impairment on the adolescent report of the CIS than the other classes; the *struggling* and *permissive* classes showed higher functional impairment on the parent report of the CIS; and the *authoritative* class showed fewer diagnoses, fewer days in the hospital, and lower impairment on both parent and adolescent report of the CIS.

There were also differences among classes for baseline sexual behaviors (ever engaged in vaginal/anal sex) and sexual risk behaviors (high-risk behaviors, two or more partners, and sexual risk composite). As expected, fewer adolescents in classes with more structure (*authoritative*, *authoritarian*), reported ever having sex (50% and 43%), and less risk behavior (any risk during previous 90 days 20% and 22%) than those in classes with lower structure (*struggling* & *permissive*; ever having sex: 62% and 61%; any risk behavior 32% and 28%). Importantly, sexual risk behaviors in all classes were higher than would be expected from community samples (40).

Conditional Average Treatment Effects by Class.

Wald tests of treatment effects differing among class were not statistically significant for measures of family context (range of p -values = .18 to .94) or for measures of sexual-risk behaviors (p -values=.31 to .64). Because the Wald tests were under powered, the patterns of effect sizes and confidence intervals were interpreted by class. Small to medium effect sizes for each class are presented for measures of family context in Figure 3, and for sexual-risk behaviors in Figure 4. See Appendix B for full listing of results.

Struggling.—Participants in the *struggling* class reported more benefits from the family-based intervention than the other classes at three months, with two exceptions. Compared to *struggling* families in the AO+HP conditions, *struggling* families assigned to the FAM intervention reported more adolescent-reported negative communication and worse parent-reported sexual communication at three months. By 12 months there were no longer differences between the FAM and AO+HP conditions for negative communication and there were small benefits in adolescent-reported sexual communication, positive communication, and monitoring; parent-reported sexual communication; and family organization. In terms of sexual risk behavior, adolescents in the *struggling* class who participated in the AO+HP conditions continued reporting high rates of risk behaviors (adjusted marginal probability for any risk behavior was .56 [.46;.67]) but those who participated in the FAM condition reported a 14% reduction in risk relative to controls with probabilities (.43[.26;.59]) more

similar to adolescents in the *authoritative* and *authoritarian* classes than the *struggling* AO+HP or *permissive* class (Figure 3). Adolescents in the FAM vs AO+HP condition also reported fewer transitions into sexual activity, less engagement in recent sexual activity, fewer participants reporting multiple partners, and fewer reporting any high-risk behaviors.

Authoritative.—At three months post-intervention, those in the *authoritative* class who participated in the FAM vs. AO+HP conditions reported small to medium benefits for adolescent-reported monitoring, adolescent-reported parental permissiveness, parent-reported negative communication and parent-reported positive communication. At 12 months post-intervention, there were small to medium benefits for parent-reported positive communication and sexual communication, as well as a combined parent-adolescent report of general family communication. There was also evidence of lower support for those in the FAM vs. AO+HP conditions. In terms of sexual risk behaviors, the response of participants in the *authoritative* class depended on the risk behavior with those in the FAM vs AO+HP conditions reporting 6% less risk for high-risk behaviors but a 9% increase in risk for condomless sex.

Authoritarian.—At three months, adolescents in the FAM vs. AO+HP conditions reported benefits for parental monitoring, positive communication, and sexual communication. In contrast, they also reported slightly more negative communication. There were minimal differences for parent-reported outcomes. The combined adolescent-parent report of family environment showed slightly higher reports of family support. At 12 months, adolescents reported small to medium benefits for parental monitoring and negative communication. They also reported a slightly higher parental permissiveness. Parents reported a benefit for sexual communication and there were minimal differences in family environment. Regarding sexual risk behavior, members of this class assigned to AO+HP conditions showed the lowest probability of engaging in sexual risk behaviors (.35 [.26;.59]). However, those in the FAM condition reported 9% higher probability (.44[.27;.61]) than the controls. Those in the FAM vs. AO+HP conditions were also more likely to report recent sexual activity, multiple partners, condomless sex, and high-risk behaviors.

Permissive.—At 3 months adolescents in the FAM vs. AO+HP conditions reported small to medium benefits for parental monitoring, negative communication, and sexual communication. Parents reported benefits for sexual communication. There were also benefits for general family communication and family cohesion. At 12 months adolescents continued to report small to medium benefits for parental monitoring and sexual communication, while their parents continued to report benefits for sexual communication. There was also a slight benefit for general family communication at 12 months. Regarding sexual risk behavior participants in the FAM vs. AO+HP conditions were somewhat less likely to report condomless sex and somewhat more likely to report high-risk sexual behavior.

DISCUSSION

In this study, we reported the 12-month outcomes from the largest clinical trial of a brief family-based sexual-risk prevention intervention among adolescents in mental health care,

and a subgroup analysis of how family context impacted the response to the intervention. On average families benefited from the brief intervention, with some benefits lasting for up to a year (sexual communication and parental monitoring). Contrary to expectations, these benefits in family context did not translate into appreciable differences in sexual risk behavior across the 12-month follow-up.

It is not clear why the benefits in family context did not translate into lower sexual risk behavior in this study. It may be that the intervention was not powerful enough to affect change in sexual risk behaviors. There is some work suggesting that disadvantaged families may benefit more from one-on-one interventions than the group-based format used in this study (41). Moreover, families may have needed smaller doses spread over a longer period to make substantive changes to the family context (42). Another potential reason for the limited treatment effect for sexual risk is that family context is only one aspect of adolescents' social-personal framework, and vulnerabilities and/or protective factors in the other domains (e.g., peer and partner relationships, environmental conditions, personal attributes) may have outweighed positive changes in the family domain. Finally, it could be that there is variability in how caregivers and adolescents responded to the family-based intervention. There may be some families who benefited more from the intervention than others.

To explore one potential source of treatment heterogeneity, we classified families based on parent and adolescent reports of family context. Classes were separated both by levels of agreement between parent and adolescent, and along dimensions of structure and emotional closeness. As expected, and similar to previous literature, we found a relatively higher functioning class (*authoritative*) and a struggling (*struggling*) class (11,17). The other two classes (*authoritarian* and *permissive*) highlighted disagreement between parents and adolescents and an imbalance between structure and closeness. As expected, the classes differed in terms of baseline sexual risk and mental-health burden with the less structured family environments (*struggling*, *permissive*) reporting higher sexual risk behavior, the *struggling* class reporting the highest mental health burden, and the *authoritative* class reporting the lowest burden.

Looking at the size of treatment effects among family context classes, it appears that each class generally responded positively to the intervention, with each showing benefits relative to control conditions in one or more domains of family context. Effect-sizes were comparable to those of other family-based interventions targeting adolescent sexual-risk behavior (43). The pattern of response, however, differed among classes as did the pattern of sexual risk behavior across the 12-month follow-up. Although power to ascertain differences among classes is limited, there are a few interesting patterns that merit additional study.

First, benefits were particularly strong for the *struggling* class. These benefits were present despite parent and adolescent agreement that there were significant challenges in the family, the most severe profile of mental health symptoms, and high levels of baseline sexual risk. Families appeared to overcome these obstacles and apply the content of the brief family-based intervention, which speaks both to the needs of the families and the importance of matching the intervention to those needs.

Second, it can take time for some families to implement the skills learned during the intervention. Participants in both the *struggling*, and *authoritarian* classes who were randomized to the family intervention initially reported higher negative communication relative to control conditions, as well as higher positive communication and sexual communication. Together, these findings suggest the families were attempting to implement what they had learned, but may not have mastered these communication skills by the 3-month assessment. By 12 months, negative communication was no longer higher than that in the comparison conditions and the benefits in sexual communication remained.

Third, as evidenced by previous literature (44), family structure and rules may be an important key to reducing sexual risk among adolescents with mental health concerns. Families with more structure (*authoritarian*, *authoritative*) showed lower risk behavior at baseline and the two classes (*authoritarian*, *struggling*) that showed any treatment related movement on domains assessing structure (i.e., family organization and parental permissiveness) at 12 months were also the two that showed the most treatment related movement on sexual risk behaviors. Specifically, the family versus control conditions in the *struggling* class showed slightly higher family organization and lower sexual risk, while the family versus control conditions in the *authoritarian* arm showed higher parental permissiveness and higher sexual risk. It appears that family rules and structure around sexual risk behavior is an important component of treatment, but care must be taken when intervening in families with more structure (*authoritative*, *authoritarian*), as abrupt changes to the rules and expectations around sexual behavior may result in increased risk. Importantly, adolescents in the *authoritative* and *authoritarian* classes still reported more risk behavior than their peers in community samples suggesting they are still at risk and in need of support to help reduce their risk; support that may include identifying approaches to improve monitoring and communication while also maintaining existing rules and structure. Alternatively, reducing risk for adolescents with more structured families may require interventions focused on complimentary domains of the social-personal framework such as emotional regulation.

Finally, results indicate that matching interventions to the needs of the family is beneficial. Although all classes showed some improvement relative to controls for domains of family context, the two in most need of family intervention (*struggling*, *permissive*) showed the most consistent benefits in measures of family context and in the case of the *struggling* class for sexual risk behavior, while those least in need of family intervention (*authoritarian*, *authoritative*) showed mixed results for measures of family context and sexual risk behavior.

Limitations.

Despite the interesting and potentially informative pattern of results, the exploratory nature of the subgroup analysis limits the findings. All subgroup analyses were underpowered and to balance the dual challenges of low power and risk for spurious findings, we opted to interpret effect sizes and confidence intervals. In the context of a randomized trial, subgroup analyses do not guarantee balance between treatment conditions within each subgroup. Our use of propensity score methods helps to reduce, but not eliminate potential imbalance (Appendix C). In terms of classification of family context, we tested the validity

of the classes by examining associations with markers of mental health and sexual-risk behaviors, but did not cross-validate the classification using other samples or across time and thus the classification should be viewed as exploratory and care must be taken not to reify class membership or the labels we used to describe them. Finally, the sample in this study was recruited from inpatient and outpatient mental health settings and findings may not generalize to non-clinical populations. Specifically, the family classifications may differ in a non-clinical sample with some of the families classified as *authoritative* may not be so-classified when compared to non-clinical peers. It is also possible that the constellation of factors influencing sexual risk behavior may differ between clinical and non-clinical samples. Overall, these limitations suggest results should be viewed with caution and conclusions should be tentative until they can be confirmed with replication.

CONCLUSIONS

Tailoring interventions to the needs of vulnerable populations requires identifying sub-populations who may benefit or be hindered by interventions. For family-based interventions, initial family context appears to influence how changes in family communication and parenting practices influence sexual risk. More work is needed to better understand how family processes change following intervention and how these changes influence sexual risk. It will also be important to place the work in the context of the broader social-personal framework. For example, while participants within each class shared similar family contexts, they likely differed in terms of the other domains within the social-personal framework (i.e., personal attributes, environmental conditions, peer and partner relationships) related to sexual risk. Finally, there are likely other participant characteristics outside of family context that may influence the effectiveness of the family-based intervention (e.g., gender, age, race, ethnicity, social-economic standing, psychiatric symptoms, etc.). There are exciting developments in principled approaches to examining treatment heterogeneity (45), but more work is needed to better implement these approaches to identify who best responds to interventions.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Project STYLE consort

Figure 2.

Baseline Profiles for Family Context Variables **Notes:** Mean and 95% CI from latent profile analyses. All measures were z-scored. (-) Measures were reverse scored so that higher scores are healthier.

Figure 3.

Small-to-Large Treatment Effects for Family Context **Notes:** Adjusted standardized difference score (d) for FAM vs. AO+HP within each family context class at 3-month and 12-month assessments. Thin line represents 95% CI and thick line ± 1 standard error. The x-axis values correspond to Cohen's guidelines for *small*, *medium*, *large* effect-sizes. Only findings with small or larger effect sizes are depicted in this figure. A full listing of results can be found in Appendix C. AR=Adolescent Report; PR=Parent Report.

Figure 4.

Treatment Effects for Sexual Risk Behavior **Notes:** Adjusted risk difference between FAM vs. AO+HP for each family context class. Risk behaviors were aggregated across the 3, 6, and 12 month assessments. ^aTwo or more partners within any of the 3-month recall periods across the 12-month follow-up. Thin line represents 95% CI and thick line ± 1 standard error. Adjusted marginal probabilities for the FAM and AO+HP conditions are listed to the right of the figure.

Table I.

Overall Family Context Treatment Outcome

	FAM				AO+HP				Effect Size ^a (95% CI)	
	0M	3M	12M	0M	3M	12M	3M	12M	3M	12M
Adolescent Report										
Monitoring	-0.04 (1.01)	0.10 (1.01)	0.08 (1.04)	0.02 (0.99)	-0.13 (1.14)	-0.15 (1.20)	0.26 [*] (0.07; 0.46)	0.25 [*] (0.04; 0.45)		
Permissiveness	0.04 (1.02)	0.10 (1.02)	0.43 (1.11)	-0.02 (0.99)	0.22 (1.08)	0.35 (1.10)	-0.14 (-0.32; 0.03)	0.08 (-0.11; 0.27)		
Negative Communication	0.03 (1.00)	0.03 (0.9)	-0.09 (0.98)	-0.01 (1.00)	-0.04 (1.04)	0.03 (0.97)	0.08 (-0.09; 0.25)	-0.10 (-0.28; 0.08)		
Positive Communication	0.09 (0.92)	0.17 (0.87)	0.12 (0.99)	-0.04 (1.03)	-0.08 (1.05)	0.01 (1.01)	0.35 [*] (0.11; 0.59)	0.09 (-0.18; 0.36)		
Sexual Communication	0.06 (0.98)	0.16 (0.87)	0.07 (0.92)	-0.03 (1.01)	-0.16 (0.96)	-0.11 (0.93)	0.46 [*] (0.24; 0.68)	0.21 (-0.03; 0.45)		
Parent Report										
Monitoring	0.02 (0.95)	0.08 (0.92)	0.12 (1.04)	-0.01 (1.02)	0.06 (1.03)	0.00 (1.10)	0.06 (-0.14; 0.26)	0.11 (-0.12; 0.34)		
Negative Communication	-0.01 (1.01)	-0.12 (1.00)	-0.17 (1.09)	0.00 (0.99)	-0.07 (1.03)	-0.09 (1.09)	-0.08 (-0.27; 0.1)	-0.09 (-0.31; 0.12)		
Positive Communication	-0.02 (1.00)	0.12 (0.97)	0.19 (1.05)	0.01 (1.00)	0.05 (1.03)	0.12 (1.02)	0.12 (-0.1; 0.33)	0.08 (-0.16; 0.31)		
Sexual Communication	0.08 (1.05)	0.15 (0.97)	0.35 (0.9)	-0.04 (0.97)	0.07 (0.96)	0.06 (0.96)	0.1 (-0.09; 0.28)	0.28 [*] (0.09; 0.47)		
Combined Report										
Family Organization	-0.02 (1.02)	0.03 (1.07)	0.14 (1.09)	0.01 (0.99)	0.08 (1.01)	0.02 (1.11)	-0.04 (-0.23; 0.14)	0.06 (-0.14; 0.26)		
Family Communication	-0.02 (0.98)	0.10 (0.91)	0.09 (1.03)	0.01 (1.01)	-0.02 (1.08)	0.03 (1.05)	0.15 (-0.04; 0.35)	0.07 (-0.14; 0.29)		
Family Cohesion	0.03 (0.92)	0.07 (0.94)	-0.02 (1.06)	-0.01 (1.03)	-0.12 (1.20)	-0.08 (1.18)	0.25 [*] (0.04; 0.46)	0.05 (-0.18; 0.27)		
Family Support	-0.04 (1.00)	0.17 (1.02)	0.25 (1.04)	0.02 (1.00)	0.14 (1.03)	0.25 (1.09)	0.04 (-0.14; 0.23)	-0.05 (-0.25; 0.15)		

All continuous outcomes were standardized to the baseline response with standard deviation pooled across treatment conditions.

FAM family-based HIV-prevention program, AO adolescent-only HIV prevention program, HP general health promotion condition, M month

^a Effect sizes are standardized difference scores (*d*).

^{*} Effect was significant at $p < .05$

Table II.**Overall Sexual Risk Treatment Outcome**

	FAM		AO+HP		Effect Size ^a (95% CI)
	0M	12M	0M	12M	12M
Sexual Risk					
Vaginal/Anal ever, % (n)	51% (115)	70% (157)	55% (271)	72% (354)	−0.02 (−0.10; 0.05)
Any Vaginal/Anal sex	32% (72)	50% (112)	32% (156)	53% (258)	−0.02 (−0.10; 0.07)
Any High-risk behaviors	9% (20)	24% (54)	12% (61)	25% (125)	−0.01 (−0.08; 0.06)
Any Condomless Sex	18% (40)	31% (69)	16% (78)	31% (150)	0.01 (−0.07; 0.08)
2+ Partners	12% (27)	28% (64)	14% (70)	29% (144)	0.00 (−0.08; 0.07)
Any Risk	23% (52)	41% (92)	26% (130)	44% (214)	−0.02 (−0.10; 0.06)

FAM family-based HIV-prevention program, AO adolescent-only HIV prevention program, HP general health promotion condition, M month

^aEffect sizes are risk difference scores comparing FAM vs AO+HP

* Effect was significant at $p < .05$

Table III.

Demographics by Family Context Class

	Family Context Class				Total (N = 716)	Effect Size ^a
	Struggling (n =177)	Authoritative (n =183)	Authoritarian (n =175)	Permissive (n =181)		
Treatment: FAM, % (n)	29% (51)	31% (57)	33% (57)	33% (60)	31% (225)	0.07
Female	56% (99)	63% (115)	55% (96)	54% (98)	57% (408)	0.14
Race						0.14
African American	56% (99)	56% (102)	54% (95)	64% (116)	58% (412)	
Caucasian	27% (47)	28% (51)	35% (61)	24% (43)	28% (202)	
Other	15% (26)	15% (27)	9% (15)	11% (20)	12% (88)	
Hispanic	12% (22)	12% (21)	13% (22)	7% (13)	11% (78)	0.14
Parent Education						
High School	55% (98)	39% (72)	42% (74)	54% (97)	48% (341)	0.28 *
Household Income						
< 35k	68% (120)	67% (123)	59% (104)	72% (131)	67% (478)	0.22 *
Single Parent	50% (89)	56% (102)	48% (84)	57% (103)	53% (378)	0.14
Adolescent age, mean (SD)	14.80 (1.27)	15.04 (1.30)	14.75 (1.38)	14.80 (1.28)	14.85 (1.31)	0.18

FAM family-based HIV-prevention program

^a All effect sizes were translated to the metric of Cohen's *d*. Effect size estimates were originally as follows: Cramer's V calculated for categorical variables; η^2 calculated for continuous variables

* Effect was significant at $p < .05$

Table IV.

Adolescent Baseline Mental Health Characteristics by Family Context Class

	Family Context Class					Effect Size ^a
	Struggling (n =177)	Authoritative (n =183)	Authoritarian (n =175)	Permissive (n =181)	Total (N = 716)	
Days hospitalized, mean (SD)	10.77 (15.16)	4.49 (9.33)	5.50 (10.16)	5.97 (10.05)	6.67 (11.63)	0.42 *
Hospitalized	57% (101)	32% (58)	40% (69)	44% (79)	43% 307	0.38 *
Psych meds past 3 months	58% (103)	46% (85)	52% (91)	49% (88)	51% (367)	0.18
Substance Use						
THC past 30 days	24% (42)	17% (31)	22% (38)	30% (53)	23% (164)	0.22 *
Cigarettes past 30 days	36% (63)	19% (35)	22% (38)	33% (58)	27% (194)	0.31 *
Alcohol past 30 days	26% (46)	18% (32)	19% (32)	21% (38)	21% (148)	0.16
Drug tx ever	11% (19)	7% (13)	4% (7)	10% (18)	8% (57)	0.20
Self cutting past 30 days	17% (30)	14% (26)	21% (36)	13% (23)	16% (115)	0.17
C-DISC^b						0.33 *
None	9% (15)	28% (50)	16% (27)	6% (11)	15% (103)	0.49 *
Manic	33% (58)	17% (31)	23% (39)	26% (47)	25% (175)	0.28 *
Mixed	33% (58)	21% (39)	26% (45)	33% (58)	28% (200)	0.22 *
Internal	3% (6)	7% (13)	6% (10)	3% (6)	5% (35)	0.15
External	21% (37)	27% (48)	30% (52)	32% (56)	27% (193)	0.18
# of diagnoses, mean (SD)	3.72 (2.04)	2.05 (1.92)	2.59 (1.93)	3.29 (2.02)	2.91 (2.07)	0.65 *
CIS						
Adolescent total, mean (SD)	19.88 (8.95)	12.74 (7.67)	16.65 (8.30)	16.99 (8.96)	16.50 (8.84)	0.61 *
% above the clinical-cut-off	67% (110)	37% (64)	55% (88)	55% (91)	53% (353)	0.45 *
Parent total, mean (SD)	23.37 (8.70)	13.86 (8.36)	17.02 (8.77)	22.15 (9.32)	19.07 (9.59)	0.88 *
% above the clinical-cut-off	82% (139)	42% (73)	52% (88)	76% (133)	63% (433)	0.74 *
Sexual Risk						
Vaginal/Anal ever, % (n)	62% (109)	50% (91)	43% (75)	61% (111)	54% (386)	0.32 *
Vaginal/Anal past 90 d	36% (64)	30% (54)	25% (44)	36% (65)	32% (227)	0.20
2+ Partners past 90 d	20% (35)	7% (12)	11% (20)	17% (30)	14% (97)	0.30 *
Condomless Sex past 90 d	20% (36)	13% (24)	13% (23)	19% (35)	16% (118)	0.18
High-risk behaviors	25% (45)	17% (31)	16% (28)	23% (42)	20% (146)	0.22 *
Risk past 90 d	32% (57)	20% (36)	22% (38)	28% (51)	25% (182)	0.23 *

^a All effect sizes were translated to the metric of Cohen's *d*. Effect size estimates were originally as follows: Cramer's V calculated for categorical variables; η^2 calculated for continuous and log-transformed count variables.

^b The 5 C-DISC categories were defined as follows: None: did not meet sub-threshold level on any diagnosis; Manic: exceeded sub-threshold for mania or hypomania, regardless of other comorbidities; Mixed: exceeded sub-threshold for at least one internalizing and one externalizing disorder; Internalizing: exceeded sub-threshold for at least on internalizing disorder (i.e., Major Depressive Disorder, Generalized Anxiety Disorder, Post-

Traumatic Stress Disorder); Externalizing: exceeded sub-threshold for at least one externalizing disorder (i.e., Oppositional Defiant Disorder, Conduct Disorder, Attention Deficit/Hyperactivity Disorder)

* Effect was significant at $p < .05$

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