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Adolescent and Parent Willingness to Participate in Microbicide Safety Studies

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Abstract

Study Objective—To understand adolescents' and parents' willingness to participate (WTP) in a hypothetical Phase I prevention study of sexually transmitted infections, discordance within adolescent-parent dyads, and expectations of each other during decision-making.

Design—Adolescent-parent dyads were recruited to participate in a longitudinal study about research participation attitudes.

Participants—Adolescents (14–17 years old) and their parents (n=301 dyads) participated.

Interventions—None

Main outcome measures—Individual interviews at baseline assessed WTP on a six-level Likert scale. WTP was dichotomized (willing/unwilling) to assess discordance.

Results—WTP was reported by 60% of adolescents and 52% of parents. In bivariate analyses, older adolescent age, sexual experience and less involvement of parents in research processes were associated with higher level of WTP for adolescents; only sexual experience remained in the multivariable analysis. For parents, older adolescent age, perceived adolescent sexual experience,

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and conversations about sexual health were significant; only conversations remained. Dyadic discordance (44%) was more likely in dyads where the parent reported previous research experience, and less likely when parents reported higher family expressiveness. Adolescents (83%) and parents (88%) thought that the other would have similar views, influence their decision (adolescents 66%, parents 75%), and listen (adolescents 90%, parents 96%). There were no relationships between these perceptions and discordance.

Conclusions—Inclusion of adolescents in Phase 1 clinical trials is necessary to ensure that new methods are safe, effective and acceptable for them. Given that these trials currently require parental consent, strategies that manage adolescent-parent discordance and support adolescent independence and parental guidance are critically needed.

Keywords

adolescent research participation; topical microbicides

Introduction

One of the three ethical principles of the Belmont Report is justice, which requires that there is “fairness in distribution” between the risk or burden of the disease and participation in research.[1] Given the limited success in reducing the epidemic of sexually transmitted infections (STIs) among sexually experienced adolescents,[2] they should be given the opportunity to participate in clinical trials that are developing new biomedical options for prevention.[3] In addition, there are biological and psychological characteristics of younger adolescents that would indicate it may be reasonable to assume that prevention methods or products deemed safe and effective in adults will not necessarily be safe and effective for adolescents.[4, 5] However, in order to conduct these trials in adolescents, adolescents must be willing to participate in them. Although there are efforts to allow adolescents to consent without parental permission in certain situations, at the current time, parental permission is the norm because adolescents are considered a “vulnerable population” within the federal regulations.[6] Thus, it is also critical to understand parent’s willingness to let their adolescent participate. In those cases, the adolescent and parent must agree on whether or not to participate. Research has examined adolescent-parent discordance in clinical trials for asthma treatment.[7, 8] However, the reasons underlying the discordance may be different for sensitive topics such as sexual health. Discordance may also differ in the case of prevention trials in healthy individuals since their motivation to participate differs from those participants who experience a particular disease such as asthma.[9] Discordance between adolescents and parents presents the possibility that adolescents could be coerced to participate by their parents or to be unable to participate because the parent withholds permission. Understanding adolescent’s and parent’s expectations of how each would respond to the other in terms of collaborating on the decision may be useful in understanding the risk of coercion.

Thus, we sought:

a. To evaluate the relationship between both adolescents’ and parents’ willingness to participate (WTP) in a hypothetical phase 1 clinical trial and the following

factors: demographics and sexual history, perceptions of parental involvement in research, previous experience with research, parent-adolescent report of relationship and sexual health conversations, and family characteristics.

b. To describe WTP discordance within adolescent-parent dyads, and the relationship of the variables described above on WTP discordance.

c. To describe adolescents' and parents' expectations of each other during a decision-making process, and its' relationship to WTP discordance.

Materials and Methods

Participants were recruited from adolescent medicine clinics of two large medical centers in New York City and through snowball sampling to participate in a longitudinal study on "*how teenagers and their parents feel about being in research studies, in particular studies that help teens protect their reproductive health*". As part of this study, the adolescents and parents were presented a hypothetical clinical trial examining the safety of a topical microbicide for sexually transmitted infections/human immunodeficiency virus (STI/HIV) prevention in adolescents. Adolescents were 14–17 years of age and participated with a parent. All participants spoke either English or Spanish. Institutional Review Boards (IRBs) of Columbia University Medical Center and Weill Cornell Medical College approved the study, and all participants provided written informed consent/assent. The data presented in this manuscript are from simultaneous individual interviews of adolescents and parents conducted at the baseline study visit.

Interview Content and Measures

Willingness to Participate (WTP)—The adolescents were read the description of a typical phase I clinical trial of a microbicide and asked: "*If this study were happening today, please rate (on a 6 point Likert scale) your agreement with the statement – I would agree to be in the study*". The parents were asked to respond to the statement "*I would agree for my son/daughter to be in the study*" using the same rating scale. For both adolescents and parents, a score of 1–3 reflected disagreement with the statement (strongly, moderately and mildly) and a score of 4–6 reflected agreement with the statement (mildly, moderately and strongly). Following their answer, the adolescents and parents also were asked to rate using the same 6 level scale, their agreement that the other "*would have similar thoughts to me about my being in the study*"; the other's "*opinion would influence my decision*"; and the other "*would listen to what I wanted to do about being in the study*".

Sexual History—The interview obtained information about adolescent's sexual histories and parent's perceptions of their adolescent's sexual experience. Adolescent level of sexual activity was categorized as those who reported no sexual contact beyond kissing and those who reported contact beyond kissing. Parents could answer "*I don't know*" to questions about their adolescent's sexual activity. Thus, the parent's responses were coded either as reporting their adolescent had not engaged in any sexual activity beyond kissing, reporting that the adolescent had, or reporting that they did not know if their adolescent had engaged in sexual activity beyond kissing.

Perceptions of Parental Involvement in Research—A scale assessing opinions about parental involvement in research was developed in which adolescent and parent participants were asked to respond yes/no to statements about parental involvement in the research process for a teenager the age of the adolescent participant. Based on principal component analysis, the items formed two sub-scales.[10] The first was LEARN (parent learning test results or behaviors) and the second was PROCEDURE (parents involved in the procedures of the study).

Parent-Adolescent Report of Relationship and Sexual Health Conversations—Adolescents and parents responded yes/no to whether they had ever discussed four relationship topics (i.e., making decisions about having sex; dating and romantic relationships; sexual pressure; friends' sexual behaviors) and four sexual health topics (i.e. condoms; birth control; sexual pressure; protecting against STIs/HIV). For conversations about relationships and conversations about sexual health, the sum of each of the four items for the scale was used for purposes of analysis.

Family Environment—Six subscales (cohesion, control, organization, conflict, moral-religious emphasis, expressiveness) of the Family Environment Scale (FES)[11] were used.

Statistical Analyses

All statistical analyses were conducted using SAS 9.4. With regards to demographics, age of the adolescent was dichotomized into 14–15 years of age and 16–17 years of age. Ethnicity was dichotomized into Hispanic versus non-Hispanic.

Ordered logistic regression analyses were used to evaluate the relationship of predictors to the level of WTP for adolescents and parents. For these regression analyses, adolescent reports were used in adolescent models, and parent reports were used in parent models. Significant variables (at $p < 0.05$) in bivariate analyses were placed into a multivariable model.

To describe WTP discordance within adolescent-parent dyads and investigate the relationship between parent and adolescent predictors and WTP discordance, WTP was dichotomized as willing/unwilling to participate and then adolescent-parent dyads were characterized as concordant or discordant. With regards to concordance, the adolescent-parent dyads could both agree with being likely to participate or both disagree with being likely to participate. With regards to discordance, the parent could agree with being likely to have the adolescent participate when their adolescent disagreed, or the adolescent could agree with being likely to participate when their parent disagreed. For further understanding of discordance, significant variables in bivariate analyses were placed into a multivariable logistic model of predicting discordance. Parent report was used for Hispanic ethnicity, reports of family climate (FES), conversations and research participation; adolescent report was used for sexual history; and both adolescent and parent reports were used for attitudes about parental involvement in research. The association between expectations of adolescents and parents of "the other" in terms of decision-making regarding research participation and WTP discordance was also evaluated using logistic regression. Adjusted odds ratios (AOR)

and 95% confidence intervals (CI) are reported; for all analyses, significance was set at $p < 0.05$.

Results

Study recruitment and enrollment have been presented previously[12, 13] but briefly, 343 participants were initially enrolled; however, one family withdrew from the study and their data were excluded from analysis; two adolescent-parent dyads were enrolled twice and only their data from their first visit is included. Of the 340 adolescent-parent dyads, there were 31 parents with two adolescent siblings and four parents with three adolescent siblings. Given the use of family-level predictors (i.e., FES) which would be assumed to be similar across sibling and parent reports, only the first sibling participant from each family was selected for analysis. The demographic characteristics of the remaining sample of 301 dyads did not differ significantly from the 340 dyads. One parent did not respond to the WTP question; therefore, the parent and dyad analyses are based on a sample size of 300. The demographics of the sample are presented in Table 1. With regard to race and ethnicity the adolescent and parent data was similar. The majority of the sample report Hispanic ethnicity and participants were from several countries (the Dominican Republic—most commonly reported, Mexico, Puerto Rico, Cuba). Race of participants included 10% Caucasian, and 31% African-American with 47% identifying their race as Hispanic.

Overall, 60% of the adolescents agreed to participate (including mildly, moderately, or strongly agree) in the hypothetical trial; 52% of parents agreed for their adolescent to participate (see Table 2). The results of the bivariate and multivariable logistic regressions with the level of WTP as the outcome variable are presented for adolescents and for parents. For adolescents (see Table 3), those who were older, reported that they had sexual experience beyond kissing, and believed that parents should be less involved in research procedures were more likely to report a higher level of WTP. In the multivariable model, only the adolescent's report of their level of sexual experience (AOR 1.75; 95% CI: 1.09 – 2.82) remained significant; adolescents who were more sexually experienced were more likely to have a higher level of WTP. For parents (see Table 4), older adolescents, parent report of the adolescent having sexual experience beyond kissing, and parent report of having more conversations about sexual health topics were associated with WTP in bivariate models. In the multivariable model, only the parent report of having conversations about sexual health topics (AOR 1.23; 95% CI: 1.02 – 1.49) was more likely to have a higher level of WTP.

Fifty-six percent of dyads were concordant and 44% of dyads were discordant regarding being willing or unwilling to agree to participate in the hypothetical trial. When dividing this into the four potential types of concordance/discordance, 22% were concordant in being unlikely to participate; 34% were concordant in being likely to participate; 26% were discordant with the adolescent being likely to agree to participate, and 18% were discordant with the parent being likely to agree to their adolescent participating. When evaluating the associations with being in a discordant dyad, only parent's report of previous research participation and report of expressiveness on the FES scale were related in bivariate models (see Table 5). Parents who reported that they or their adolescent had previous research

experience were more likely to be in discordant dyads. Parents who reported higher scores on the expressiveness scale were less likely to be in discordant dyads. In the final multivariable model, parent report of previous research experience (AOR 1.70; 95% CI: 1.01 – 2.87) and the expressiveness score of the FES scale (AOR 0.97; 95% CI: 0.95 – 0.99) remained significant.

With regards to the perception of the other member of the dyad, 83% of adolescents and 88% of parents thought that the other would have similar views regarding study participation (including mildly, moderately, or strongly agree); 66% of adolescents and 75% of parents thought that the other would influence their decision; and 90% of adolescents and 96% of parents thought that the other would listen. In logistic regression analyses, there were no relationships between any of these perceptions of the other member of the dyad and whether the dyad was discordant. As an example, the adolescents were similar with regards to their expectation that parents would share their views, i.e., 86% of adolescents in concordant dyads versus 80% in discordant dyads agreed either mildly, moderately, or strongly. For parents, it was 89% of parents in concordant dyads versus 87% of the parents in discordant dyads.

Discussion

Among a sample of adolescents that included those who were sexually experienced and those who were inexperienced, over 50% of adolescents and parents of adolescents indicated willingness for the adolescent to participate in a microbicide safety study. For the adolescents, the only predictor that remained in the multivariable analyses was adolescent report of sexual experience, and sexual experience would likely be an inclusion criterion in the type of study that was presented to them. In the bivariate analyses, younger adolescents were less likely to be willing to participate, and they were also more likely to be sexually inexperienced. In addition, adolescents' desire for less parental involvement in the procedures of studies was related to increased likelihood of WTP, although their attitude about parents learning about their study test results was not. The lack of association between attitudes about parents learning about test results and WTP is likely because the informed consent for the hypothetical trial stated "*We will not give the results to your parent or guardian unless you ask us to*." Thus, adolescents' general attitudes may not have influenced their specific attitudes for this hypothetical study since they knew what to expect (no test results would be shared). This is in contrast to the fact that the informed consent for the hypothetical study remained silent on parental involvement in the process (knowing before the adolescent is asked to be in a study, attending a first study appointment, giving permission for questionnaire studies or studies on healthy decision-making). The relationship found in the bivariate analyses may reflect that the adolescents may have concerns that parents would have greater involvement than might have occured since these are study processes for which investigators and IRBs often allow for adolescent autonomy. For example, adolescents can be approached to be in studies before parents know (as was done sometimes in the current study); some studies have allowed adolescents to attend study appointments on their own[14] and studies involving no greater than minimal risk have been permitted to have a waiver of parental consent.[15] Investigators may be able to enhance

willingness to participate by explicitly addressing adolescents' expectations and desires regarding actual parental involvement.

For the parents, the report of conversations about sexual health topics with their adolescent was positively related to WTP, which may be an extension of research indicating that adolescent-parent communication about sexual health is associated with less sexual risk behaviors.[16, 17] Our findings may suggest that comfort or familiarity with discussing sexual topics is important for WTP in reproductive health studies, or reflect the parents' belief that research participation will serve as an opportunity for their adolescents to learn about sexual health. One longitudinal cohort study of adolescent women and STI risk found that parental permission for adolescent participation was related to parental perception that the adolescent would gain information or education from research participation.[18] Similarly, some of the parents in this study described study participation as an opportunity for sexual health education for their adolescent.[13]

The percentage of concordance (56%) regarding WTP in either direction in this study was slightly less than seen in studies of asthma trial decision-making (62% for minimal risk; 58% for above minimal risk). It seems reasonable to expect greater initial discordance in prevention trials as compared to treatment studies since one would anticipate that adolescents and their parents would have had conversations about chronic illness management. Further, unlike participation in prevention trials, participation in treatment trials may include the prospect of direct benefit to the adolescent.[9] Finally, the context of our hypothetical trial was STI/HIV prevention; it is possible that adolescents and parents may generally be more discordant about sexual health topics.

In this study, parents who reported previous research participation for either their adolescent or themselves were more likely to be in a discordant dyad. Given that the adolescent report of research participation was not related to discordance, this finding may reflect experiences the parents have had personally (either positive or negative) with research participation, which they have not shared with their adolescent. Families described by parents as being more expressive were less likely to be discordant (although the mean T-scores for both groups were within the normal range), perhaps suggesting that these families have a much better understanding of the each other's perspectives.

The results suggest that a high percentage (44%) of parents and adolescents were in discordant dyads, which theoretically presents an opportunity for parental coercion and/or undue influence. However, these adolescents and parents reported expecting the other member of the dyad to share similar views and almost all believed the other would listen to their opinion. Slightly over half of the adolescents and three-quarters of the parents expected to be "influenced" by the other's opinion; however, influence is not always "undue" and given that they also expected to be listened to by the other individual, these findings do not seem to indicate a high risk for "undue" influence.

There is need for further research to address how discordance and its' resolution is actually managed in adolescent-parent dyads and to understand an appropriate role for the investigator. Ideally, the adolescent would be able to assert his/her emerging autonomy with

guidance from the parent. It is also important to recognize that discordance is not necessarily negative, which is exactly the argument for requiring parental permission and adolescent assent. Parents and adolescents may weigh features of studies differently,[12, 13, 19, 20] and conversations between adolescents and parents can be used to foster developmental growth for the adolescent.[12] Particularly for studies involving sensitive topics or those studies focused on behaviors that the parents may be unaware of (such as sexual activity or substance use), it is critical to address the appropriate role of parents. A limitation to the current study is that the participants (both adolescents and parents) in this study were willing to participate in an interview study regarding sexual health, perhaps suggesting at least some degree of harmony in their relationship and a comfort with discussing sexual and reproductive health. Thus, the findings may not extend to those adolescents and parents who have relationships fraught with conflict. The results also are limited by the hypothetical nature of the trial and consequently, it is unknown whether the adolescents and parents would have in the end agreed to participate if actual enrollment was offered.

There remains much discussion of the role of parents in consenting for adolescents to participate in studies of reproductive health,[21, 22] and there are studies that support that adolescents can make meaningful decisions about clinical trial participation on their own.[23] This study was not designed to address this issue, and phase I clinical trials have typically required parental consent. So given the continued high rate of STIs in adolescents and the need for novel bio-medical options, it is crucial to promote adolescent inclusion in clinical trials now.[24] Studies such as the hypothetical phase I study presented to these participants often have a small number of subjects; our study supports there should be a sufficient number of adolescents able to participate even if parental consent is required. Other research has supported that adolescents and parents can be satisfied with a consent process that supports adolescent involvement and parental permission.[20] Thus, we must simultaneously advocate for adolescent participation and look for new models for parental involvement and consent.

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Table 1

Sample Characteristics of 301 Adolescents and 300 Parents Representing Unique Dyads

Adolescent Demographics and Covariates	**% or Mean (SD)**
Age (14–15y)	47
Gender (female)	62
Ethnicity (Hispanic)	72
Lack of Sexual Experience (no experience beyond kissing)	65
Previous Research Participation for adolescent (had experience)	13
Parental Conversations (scale 1–4; higher score indicating more conversations)	
Relationships (talks with parent about dating, sexual pressure, etc.)	2.72 (1.27)
Sexual Health (talks with parent about condoms, birth control, etc.)	3.09 (1.27)
Parental Involvement (PI) (scale 1–4; higher score indicating more PI)	
LEARN (parent learning about test results)	2.95 (1.33)
PROCEDURE (parent involved in the procedures of the study)	3.07 (1.11)
Parent Demographics and Covariates	
Gender (female)	91
Ethnicity (Hispanic)	71
Perceived Level of Adolescent Sexual Experience	
No experience beyond kissing	46
Sexual contact beyond kissing	25
Don’t know	29
Previous Research Experience for either parent or adolescent (had experience)	27
Adolescent Conversations (scale 1–4; higher score indicating more conversations)	
Relationships (talks with adolescent about dating, sexual pressure, etc.)	2.85 (1.25)
Sexual Health (talks with adolescent about condoms, birth control, etc.)	3.16 (1.15)
Parental Involvement (PI) (scale 1–4; higher score indicating more PI)	
LEARN (parent learning about test results)	3.73 (0.75)
PROCEDURE (parent involved in the procedures of the study)	3.74 (0.69)
Family Environment Scale (t-scores: Mean=50, SD=10)	
Cohesion	52.0 (12.1)
Control	58.0 (8.2)
Organization	54.6 (11.4)
Conflict	49.7 (11.2)
Moral-religious emphasis	57.2 (8.3)
Expression	50.4 (9.4)

Table 2

Frequency Distribution of Adolescent (n=301) and Parent (n=300) Report of Willingness to Participate (WTP)

	Adolescent n (%)	Parent n (%)
Strongly Disagree	33 (11)	106 (35)
Moderately Disagree	39 (13)	17 (6)
Mildly Disagree	46 (15)	21 (7)
Mildly Agree	88 (29)	42 (14)
Moderately Agree	64 (21)	49 (16)
Strongly Agree	31 (10)	65 (22)

Table 3

Bivariate and Multivariable Analysis of the Association between Adolescent Demographic, Family Characteristics and WTP

	Bivariate		Multivariable	
Predictors of WTP	**OR (95% CI)**	***P***	**AOR (95%CI)**	***P***
Age (16–17 vs. 14–15)	**1.50 (1.00 – 2.24)**	**0.0490**	1.10 (0.70–1.73)	0.6682
Female gender	1.30 (0.86 – 1.96)	0.2161		
Hispanic Ethnicity	1.15 (0.73 – 1.79)	0.5526		
Sexual Experience	**1.97 (1.29 – 3.02)**	**0.0018**	**1.75 (1.09–2.82)**	**0.0201**
Previous (adolescent) research participation	1.02 (0.56 – 1.87)	0.9398		
Parental Conversations				
Relationships	1.13 (0.96 – 1.32)	0.1372		
Sexual Health	1.17 (0.99 – 1.37)	0.0550		
Parental Involvement				
LEARN	0.89 (0.76 – 1.03)	0.1149		
PROCEDURE	**0.83 (0.70 – 1.00)**	**0.0498**	0.89 (0.74–1.07)	0.2169
Family Environment Subscales (FES)				
Cohesion	0.99 (0.98 – 1.01)	0.4597		
Expression	1.00 (0.98 – 1.02)	0.9663		
Conflict	1.01 (0.99 – 1.03)	0.3912		
Moral-religious emphasis	0.99 (0.97 – 1.01)	0.4538		
Organization	1.00 (0.98 – 1.02)	0.9799		
Control	0.99 (0.98 – 1.02)	0.8084		

Table 4

Bivariate and Multivariable Analysis of the Association between Parent Demographic, Family Characteristics and WTP

	Bivariate		Multivariable	
Predictors of WTP	**OR (95% CI)**	***P***	**AOR (95%CI)**	**P**
Adolescent age	**1.85 (1.22 – 2.78)**	**0.0034**	1.47 (0.94 – 2.29)	0.0901
Adolescent female gender	0.85 (0.56 – 1.29)	0.4472		
Hispanic Ethnicity	1.50 (0.95 – 2.35)	0.0796		
Perceived Adolescent Sexual Experience				
Yes vs. no	**2.10 (1.27 – 3.49)**	**0.0012**	1.60 (0.92 – 2.76)	0.0962
Don't know vs. no	1.86 (1.15 – 3.02)	0.2777	1.78 (1.08 – 2.92)	0.7085
Previous (adolescent or parent) research participation	1.11 (0.70 – 1.75)	0.6715		
Adolescent Conversations				
Relationships	1.11 (0.95 – 1.31)	0.1961		
Sexual Health	**1.27 (1.06 – 1.53)**	**0.0093**	**1.23 (1.02 – 1.49)**	**0.0323**
Parental Involvement				
LEARN	0.80 (0.61 – 1.05)	0.1147		
PROCEDURE	0.77 (0.57 – 1.03	0.0783		
Family Environment Subscales (FES)				
Cohesion	1.00 (0.98 – 1.02)	0.9970		
Expression	1.01 (0.99 – 1.04	0.2046		
Conflict	0.99 (0.98 – 1.01)	0.6606		
Moral-religious emphasis	1.02 (0.99 – 1.04)	0.1381		
Organization	1.00 (0.98 – 1.02)	0.9506		
Control	1.01 (0.98 – 1.03)	0.5617		

Table 5

Bivariate and Multivariable Analysis of the Association of Demographic/Family Characteristics and Dyad Discordance

	Bivariate		Multivariable	
Predictors of Dyad Discordance	**OR (95% CI)**	***P***	**AOR (95%CI)**	***P***
Adolescent age	0.95 (0.60 – 1.50)	0.8230		
Adolescent female gender	1.48 (0.93 – 2.37)	0.1019		
Parent Hispanic ethnicity	0.84 (0.51 – 1.38)	0.4859		
Sexual Experience (adolescent report)	0.83 (0.51 – 1.33)	0.4354		
Previous research participation				
Parent report	**1.76 (1.05 – 2.95)**	**0.0328**	**1.70 (1.01 – 2.87)**	**0.0479**
Conversations (parent report)				
Relationships	0.95 (0.79 – 1.14)	0.5819		
Sexual Health	1.11 (0.92 – 1.32)	0.5964		
Parental Involvement				
LEARN (adolescent report)	0.95 (0.80 – 1.12)	0.5281		
LEARN (parent report)	0.83 (0.61 – 1.15)	0.2670		
PROCEDURE (adolescent report)	1.14 (0.93 – 1.40)	0.2000		
PROCEDURE (parent report)	0.77 (0.54 – 1.11)	0.1669		
Parental Family Environment Subscales (FES)				
Cohesion	0.99 (0.97 – 1.01)	0.2279		
Expression	**0.97 (0.94 – 0.99)**	**0.0113**	**0.97 (0.95 – 0.99)**	**0.0153**
Conflict	1.01 (0.99 – 1.03)	0.3415		
Moral-religious emphasis	0.99 (0.96 – 1.01)	0.3177		
Organization	0.99 (0.98 – 1.02)	0.8519		
Control	1.01 (0.98 – 1.04)	0.3888		