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Evaluation of an Intervention among Adolescents to Reduce Preventive Misconception in HIV Vaccine Clinical Trials

Michelle Lally, MD,MSc[1], **Richard Goldsworthy, PhD**[2], **Moussa Sarr, MD**[3], **Jessica Kahn, MD, MPH**[4], **Larry Brown, MD**[5], **Ligia Peralta, MD**[6], **Greg Zimet, PhD**[7], and **Adolescent Medicine Trials Network for HIV/AIDS Interventions**

[1] Alpert Medical School of Brown University and the Lifespan Hospital System, Providence, RI

[2]Academic Edge, Bloomington, IN

[3]Westat, Rockville, MD

[4]University of Cincinnati College of Medicine and Cincinnati Children's Hospital, Cincinnati, OH

[5] Alpert Medical School of Brown University and the Lifespan Hospital System, Providence, RI

[6]University of Maryland School of Medicine, Baltimore, MD

[7]Indiana University School of Medicine, Indianapolis, IN

Abstract

Purpose—Placebo and randomization are important concepts that must be understood before youth can safely participate in HIV vaccine studies or other biomedical trials for HIV prevention. These concepts are central to the phenomenon of preventive misconception which may be associated with an increase in risk behavior among study participants related to mistaken beliefs. Persuasive messaging, traditionally used in the field of marketing, could enhance educational efforts associated with randomized clinical trials.

Methods—Two educational brochures were designed to increase knowledge about HIV vaccine clinical trials via 1 and 2-sided persuasive messaging. Through the Adolescent Medicine Trials Network, 120 youth were enrolled, administered a mock HIV vaccine trial consent, and then randomized to receive either no supplemental information or one of the two brochures.

Address correspondence to: Michelle Lally, MD, MSc, The Miriam Hospital, 164 Summit Avenue, Providence, RI 02906. Phone: 401-793-4710, mlally@lifespan.org.

Potential Conflicts of Interest Dr. Lally is a recipient of funding from Merck for ongoing trials of HPV vaccines. Dr. Zimet is a past recipient of grants from Merck related to HPV vaccination and an unrestricted program development grant from GlaxoSmithKline related to cervical cancer prevention.

Implications and Contribution
It is critical that participants in HIV vaccine trials understand the concepts of placebo and randomization. Mistaken beliefs could be associated with an increase in risk behavior. Through the Adolescent Trials Network (ATN), we have designed, tested, and demonstrated the effectiveness of using a simple brochure to help explain these concepts.

Results—The 2-sided brochure group in which common clinical trial misconceptions were acknowledgedand then refuted had significantly higher scores on knowledge of randomization and interpretation of side effects than the consent-only control group, and willingness to participate in an HIV vaccine trial was not decreased with the use of this brochure.

Conclusion—Two sided persuasive messaging improves understanding of the concepts of randomization and placebo among youth who would consider participating in an HIV vaccine trial. Further evaluation of this approach should be considered for at-risk youth participating in an actual trial of a biomedical intervention for HIV prevention.

Keywords

adolescent clinical trials; HIV vaccine trials; preventive misconception; adolescents; HIV

Background and Introduction

Given that a large proportion of HIV infections globally occur among young persons aged 15-24,[1] youth will be a target population for an approved HIV vaccine or other biomedical prevention modality. Therefore, once a candidate biomedical prevention approach, including HIV vaccination, demonstrates promising results in phase 3 trials among adults, adolescents will need to be enrolled in clinical trials in order to obtain an indication for adolescent administration. Protection of adolescents enrolled in clinical trials is particularly important given their developing cognitive and emotional capacities.[2-4] Thus, appropriate provisions must be made to ensure that youth will not only understand what is involved with participation in an HIV vaccine trial, but also be adequately protected from risks that may be associated with trial participation.[5;6]

One specific issue repeatedly raised in discussions around adolescent participation in HIV vaccine trials is behavioral disinhibition, or the concern that adolescents who participate will practice riskier sexual behaviors.[2] This concern is based on Risk Compensation Theory, which suggests that persons have an inherent set-point that determines their willingness to take risks.[7;8] According to this theory, any modification in the environment that reduces the external probability of risk will lead an individual to increase their risk-related behaviors (i.e., disinhibit), thereby neutralizing the benefits of risk-reduction strategies.

For behavioral disinhibition to be attributed to participation in a preventive clinical trial, the phenomenon of preventive misconception must be present.[2] Preventive misconception is the tendency of participants in preventative clinical trials to make two cognitive errors: 1) to overestimate the probability that they have been assigned to the experimental versus the control condition; and 2) to assume that an unproven experimental intervention is effective at preventing infection.[2;9] If trial participants practice riskier sexual behaviors because they believe they are receiving a protective vaccine, trial participation could be harmful. Although most studies have not found increased risk behavior in the context of HIV vaccine clinical trials,[10;11] the desire for, and expectation of, protection has been identified as a motivation for vaccine trial participation,[12;13] suggesting that every effort should be made to minimize preventive misconception. It is standard to monitor for any increased risk behavior

in an HIV vaccine trial. Still, ensuring protection is particularly important for adolescents, as they are a vulnerable subject population.

Prospective research trial participants may not fully understand the information they receive during the informed consent process. To date, efforts to better inform clinical trial participants have largely focused on modification of consent forms, but several difficulties have been encountered.[14] Any HIV vaccine trial will almost certainly involve multiple research sites, each with its own requirements for construction of a consent form. Furthermore, by necessity, such consent forms typically include legalistic and medical language that may be difficult to simplify. To circumvent these issues, we focused on development and assessment of *supplemental* material that specifically addresses the issue of preventive misconception for use with adolescents.

The primary objective of this study was to evaluate supplemental educational brochures designed to increase knowledge about HIV vaccine clinical trials via persuasive messaging, with a particular focus on topics central to preventive misconception. Persuasive communication theory suggests that, when seeking to persuade or inform, one can employ either a 1-sided or a 2-sided message.[14;15] In the context of the present study, the goal of which was to inform rather than persuade, a 1-sided message involved a straight forward presentation of pertinent facts associated with participation in a clinical trial (e.g., “You will have an equal chance of getting the vaccine or the placebo”). In contrast, a 2-sided message presents common misconceptions, but then refutes them with factual information (e.g., “Some people think they have a better than equal chance of being in the vaccine group. This is not true. You will have an equal chance of getting the vaccine or the placebo”). Two-sided messages are hypothesized to be more effective at adequately conveying complex information.[15;16]

A secondary objective of this study was to investigate the extent to which numeracy, health literacy, and impulsive decision-making were associated with knowledge about specific aspects of an HIV vaccine clinical trial, such as randomization, interpretation of side effects, and recognition that the vaccine is experimental.

We hypothesized that a 2-sided brochure would result in greater knowledge about HIV vaccine clinical trials than a 1-sided brochure or consent-only conditions and that there would be no difference across the three groups with respect to willingness-to-participate in a clinical trial. We also hypothesized that poorer numeracy, poorer health literacy, and higher impulsive decision-making would be associated with lower knowledge about HIV vaccine clinical trials.

METHODS

Brochure Development

Prototype brochures were created by Drs. Zimet and Lally in conjunction with Dr. Richard Goldsworthy of The Academic Edge, Inc., a company with expertise in development of health education materials. The brochures delivered 1- or 2-sided messages around the topic areas of randomization and unknown efficacy of a candidate HIV vaccine. The brochures

were revised based on feedback by adolescent members of Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) community advisory boards about appearance and content. The brochure with 1-sided messages gave accurate information about vaccine trial randomization, interpretation of common side effects, and unproven efficacy of vaccine. The brochure with 2-sided messages acknowledged some beliefs that are at odds with the information content and presented counter-arguments (See Figure 1 for images of the brochures showing the messages).

Participants and Procedures

To evaluate the brochures, one hundred and twenty youth were enrolled from four ATN sites in the United States, located in New Orleans, New York City, Baltimore, and San Francisco. Study randomization was stratified by age (under 18 vs. 18 or older) and gender; enrollment was offered to 16-19 year old women and men who were sexually active with men, and who indicated that they would be willing to consider participating in an actual HIV vaccine trial.

Institutional review board approval and waivers of parental informed consent were granted at each of the four sites. Waivers of parental consent were used in this study as participation included only minimal risk. All subjects provided written informed consent. The sequence of study events is shown in Figure 2. After adolescents consented to study participation they completed an Interviewer Administered Questionnaire (IAQ Part 1). After completion of IAQ Part 1, participants were administered a mock HIV vaccine trial consent form. This consent form was based on a standard HIV Vaccine Trial Consent template provided to us by the HIV Vaccine Trials Network (HVTN). Participants were then randomized into one of three conditions: 1) No supplemental information control group; 2) Supplemental information with 1-sided messages; or 3) Supplemental information with 2-sided messages. Randomization was done at each site and within each age/gender stratum using a randomized block method with fixed block size $k = 3$. Participants completed IAQ Part 2 after reading through the consent and brochure (if applicable to their assigned group) with the research assistant. The research assistant was able to answer and clarify any questions or concerns the participant might have had while reading through the consent and brochure. A subset of adolescents (n=33) were recruited after IAQ Part 2 to participate in qualitative debriefing interviews. The findings from these interviews are beyond the scope of this paper and are reported elsewhere.[17]

Measures

IAQ Part 1 was used to obtain demographic and risk behavior information as well as assess the predictors of interest, subjective numeracy, impulsive decision making, and health literacy. The Subjective Numeracy Scale is a brief, validated measure of numeracy.[18] It consists of eight items addressing self-assessed mathematical ability and preference for display of numeric information. The Impulsive Decision-Making Scale includes 12 questions that have been validated as a brief assessment of impulsivity.[19] Health Literacy was assessed with the Rapid Estimate of Adult Literacy in Medicine-Short Form (REALM-SF), a validated 7-item measure.[20]

IAQ Part 2 was composed of the outcome measures: knowledge about HIV vaccine trials and willingness to participate in an HIV vaccine trial. With respect to knowledge, two items measured understanding of randomization (e.g., "... whether I would be in the vaccine group or the placebo group, it would be like the flip of a coin"). Two items measured interpretation of side-effects (e.g., "If... my arm felt sore from the shots that would tell me that I got the vaccine, not the placebo"). Two items measured unproven efficacy of the experimental vaccine (e.g., "If I took part in an HIV vaccine study and got the vaccine, that would mean that I would be protected from HIV infection"). Knowledge about topic areas covered by the vaccine trial consent, but not covered by the brochures was assessed with four items (e.g., "If I took part in an HIV vaccine study, I could leave the study at any time I wanted to"). Respondents were asked to respond to all knowledge items using a 5-point Likert-type response scale ranging from "Strongly Disagree" to "Strongly Agree". Scales for each knowledge area (i.e., randomization, interpretation of side-effects, unproven efficacy, and non-brochure topics) were created by calculating the mean value across the items.

Willingness-to-participate (WTP) was evaluated with three items, each of which began with the question stem, "If offered the chance, how likely would you be to participate in a clinical trial for a preventive HIV vaccine that required 3 shots over a 6 month period...?". Respondents were asked to respond to these three items using a 5-point Likert-type scale ranging from "Definitely Not Participate" to "Definitely Participate". A WTP Scale was created by calculating the mean value across the three items. The internal reliability for the scale was very good (Cronbach's coefficient alpha = .8).

Statistical Methods

All statistical tests were performed using SAS™ 9.2 software [SAS 9.2, 2009, SAS Institute, Cary, NC]. Means and proportions were generated to describe the study population. One-way analysis of variance (ANOVA) was used to assess the association between the 3 Intervention Groups (Consent Alone, Consent and 1-Sided, Consent and 2-Sided) and study outcome variables, with Tukey post-hoc tests used to identify pairwise differences. Outcome variables included knowledge scales and the WTP scale. Finally, Pearson product-moment correlation coefficients were used to measure the association of health literacy, subjective numeracy, and impulsive decision-making with the outcome variables.

RESULTS

Study Subject Characteristics

Table 1 presents the characteristics of the study population. The mean age of participants was 17.7 (SD = 1.1) and 50% were male. With respect to race/ethnicity, 64% identified as non-Hispanic Black/African-American, 14% as non-Hispanic White, and 21% as Hispanic. Study participants in the three experimental groups did not differ significantly by any of the demographic characteristics or by the key predictors, subjective numeracy, impulsive decision-making, and health literacy, indicating that randomization was successful.

Effect of Brochures on Knowledge Outcomes

For the knowledge outcomes (see Table 2), ANOVA tests revealed significant intervention effects on randomization (overall $p < .01$) and interpretation of side effects (overall $p < .01$). Pair-wise comparisons based on Tukey post-hoc tests indicated that the 2-sided brochure group had significantly higher scores on knowledge of randomization and interpretation of side effects than the consent-only control group. The 1-sided brochure group did not differ on any knowledge measure from either the consent-only or the 2-sided brochure group. Although neither brochure group had significantly higher knowledge related to unproven efficacy, the non-significant trend was in the same direction as the other brochure-related knowledge scales ($p < .12$). Non-brochure knowledge did not differ across intervention groups.

With respect to willingness-to-participate, the overall ANOVA was significant ($p < .01$), with post-hoc tests indicating that the 1-sided brochure group had significantly lower scores on this scale compared to either the consent-only or the 2-sided brochure group, which, in turn, did not differ from each other (see Table 2).

Factors Associated with Knowledge

Table 3 shows that health literacy and subjective numeracy were significantly correlated with most of the knowledge variables. Health literacy showed significantly positive correlations with randomization ($r = 0.26$, $p < .01$), unproven efficacy($r = 0.35$, $p < 0.01$) and non-brochure topics ($r = 0.35$, $p < 0.01$). Subjective numeracy had only a borderline significant correlation with unproven efficacy ($r = 0.17$, $p < 0.06$), but showed significantly positive correlations with randomization ($r = 0.28$, $p < 0.01$) and non-brochure topics ($r = 0.26$, $p < 0.01$) in addition to interpretation of side effects ($r = 0.23$, $p < 0.01$).

DISCUSSION

This study demonstrates that use of a supplemental brochure that delivers 2-sided messaging among youth considering participation in an HIV vaccine trial improves targeted knowledge around the concepts related to preventive misconception as compared to the use of an informed consent document alone, and does not compromise willingness to participate. In partial confirmation of our hypothesis, the 2-sided brochure resulted in higher knowledge scores for placebo and randomization than the consent-only control group. Understanding these concepts is critical in order to guard against the phenomenon of preventive misconception. Among youth, willingness-to-participate in an HIV vaccine trial was not compromised with the use of this 2-sided brochure. In contrast, the 1-sided brochure decreased willingness to participate in an HIV vaccine clinical trial, a result that we did not find for the 2-sided brochure.

It is interesting to note that the utilization of 2-sided messaging has a potential benefit of providing prospective protection against subsequent attitude slippage (i.e., changing attitudes in the face of introduction of new information).[21] This effect may be particularly important in HIV vaccine clinical trials, when participants may sometimes incorrectly interpret side-effects (e.g., local tenderness, mild fever) as an indication of assignment to the

experimental vaccine group.[22] The finding that the 2-sided messages, in contrast to the 1-sided messages, did not compromise willingness-to-participate also was an encouraging result, which may be explained by Attribution Theory.[23] This theory would predict that the acknowledgement of contrary beliefs inherent in 2-sided messages would increase the perceived trustworthiness and credibility of the message source, an effect that would not be expected with 1-sided messages.[15;24;25]

Persuasive communication techniques have been evaluated and used for years in marketing research, with a primary focus on consumer decision-making and purchasing behaviors. More recently, researchers have applied some of these marketing approaches to health behavior and health decision-making.[26-29] To our knowledge, these kinds of techniques have not previously been applied to efforts to maximize potential clinical trial participants' understanding of research and to minimize the occurrence of preventive misconception. However, as indicated by our results, persuasive message communication may be well-suited for the task of educating individuals recruited to participate in HIV prevention clinical trials.

This study also demonstrates that youth participants with higher baseline scores on health literacy and subjective numeracy scales demonstrated superior knowledge of important study characteristics regardless of the intervention group to which they were assigned. Although this finding is not surprising, to our knowledge the importance of health literacy and numeracy have not previously been demonstrated among adolescents. Some work does support the importance of both health literacy and numeracy for clinical trial participation among adults.[30,31] This set of results suggests that screening for health literacy and numeracy among potential trial participants could be important. Individuals identified as low in either of these domains may require additional time with study staff to allow for additional education around key elements of clinical trials. We did not find that impulsive decision-making was associated with knowledge about clinical trials. However, impulsivity may still be a factor in terms of behavioral disinhibition in the context of clinical trial participation and deserves further study.

This study has several limitations. First, this was not an actual HIV vaccine clinical trial. Youth who actually participate in a trial may be different from those willing to enroll in a study that essentially assesses understanding of trial concepts. However, a key aim of the ATN is to provide a research infrastructure and access to high risk HIV infected and uninfected youth for biomedical HIV treatment and prevention trials. Participants were specifically recruited through ATN sites so that results would be applicable to the adolescents most likely to be enrolled in future biomedical prevention trials. Next, the youth under age 18 were able to enroll in this study without parental consent. As an actual HIV vaccine trial would pose greater than minimal risk to participants, those under 18 years of age would require parental involvement in the consenting process. Finally, although this study assessed understanding of trial concepts related to prevention misconception, true efficacy of the supplemental brochures will need to be assessed in an actual HIV vaccine study, with behavioral as well as knowledge outcomes. Adolescents at risk for HIV infection, who would qualify as candidates for a biomedical prevention trial, represent a vulnerable group. Ethical implementation of this kind of research must include assurances

that risk of harm will be minimized, including risks related to preventive misconception and behavioral disinhibition.[17] It is essential that effective behavioral sexual risk-reduction interventions are provided for all adolescent participants in biomedical HIV prevention clinical trials research.[2]

This study demonstrates that youth, even those as young as 16, can understand key concepts required for participation in an HIV vaccine trial. The use of a supplemental brochure that employs 2-sided messaging can help to convey the concepts of randomization and placebo that are critical to protect against harms that might be associated with trial participation. Youth will need to participate in trials that investigate the effectiveness of biomedical approaches to HIV prevention, and future research should investigate the use of a supplemental 2-sided brochure in actual pre-exposure prophylaxis (PrEP), microbicide, and/or HIV vaccine trials in order to determine the feasibility and utility of such a tool.[32]

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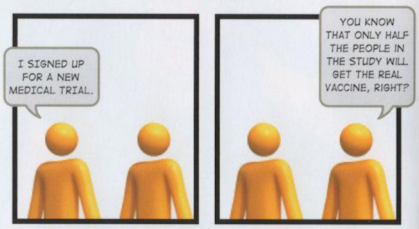
Three Important Facts about HIV Vaccine Trials

You have a 50/50 chance of being in the "real" group.

Fact 1

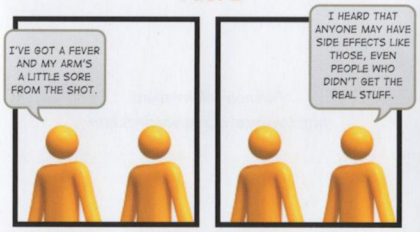


When people take part in an HIV vaccine trial, they may either receive the actual vaccine or a placebo.

You will have an equal chance of getting the vaccine or the placebo, just like the flip of a coin.

People in both groups can experience side effects.

Fact 2

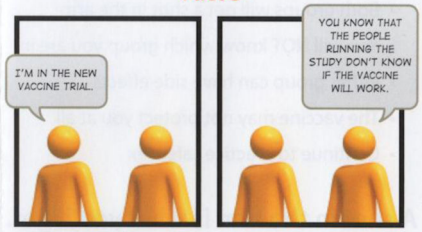


You may have side effects such as pain or soreness in your arm or a slight fever after you receive the shot.

Both the placebo and the vaccine can cause these side effects.

You may receive *no* protection from HIV.

Fact 3



The vaccine is experimental and we do not know if the vaccine will work.

The vaccine may provide *no* protection from HIV. Continue to practice safer sex.

Continue to practice safer sex.
Use a condom every time.

You should continue to protect yourself from HIV and other sexually transmitted infections by using latex condoms for all sexual activity, including anal, oral, and penile-vaginal sex.

What's a Placebo? *A placebo is a substance like salt water that does not contain the vaccine.*

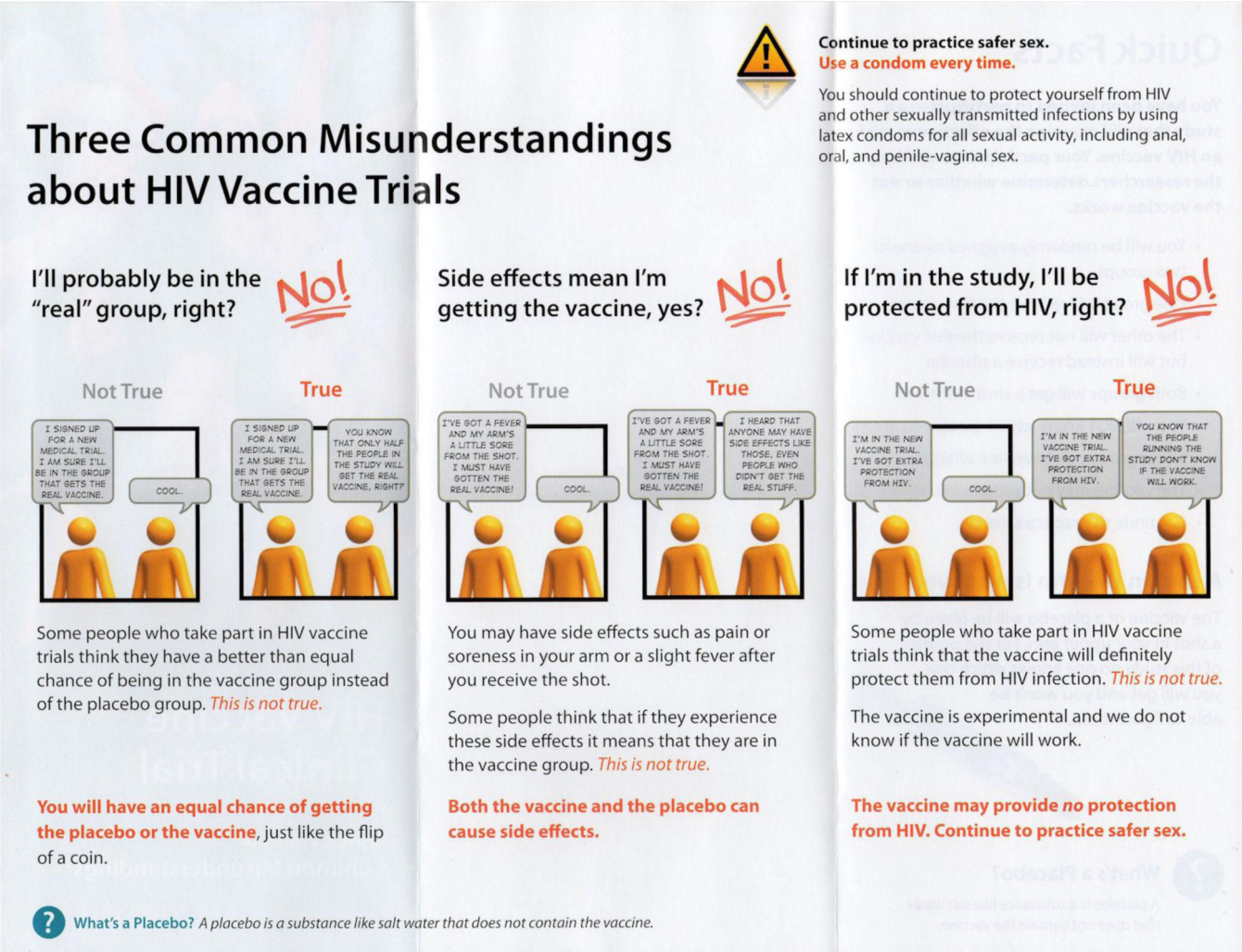


Figure 1.

Displayed are the inner contents of the brochures using 1-sided (*Three Imortant Facts*...) and 2-sided (*Three Commmon Misunderstandings*...) messages.

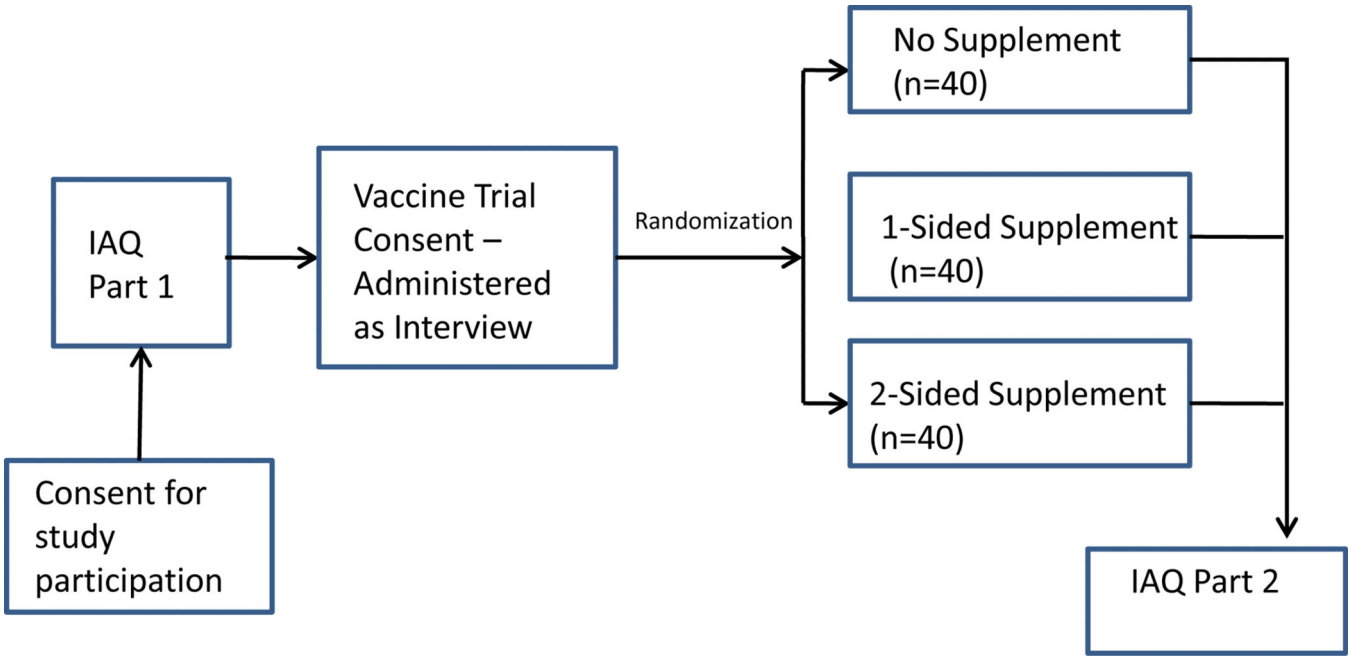


Figure 2.
Study Flow

Table 1

Characteristics of study sample

	Overall n = 120	Intervention Groups			*p*-value*
		Consent Alone n = 42	Consent 1-Sided n = 39	Consent 2-Sided n = 39	
Race, n (%)					
Black	76(64%)	25(59%)	25(64%)	26(67%)	0.55
White	17(14%)	7(17%)	7(18%)	3(8%)	
Other	26(22%)	10(24%)	6(16%)	10(26%)	
Hispanic (Spanish) or Latino origin, n (%)					
Hispanic	25(21%)	9(21%)	7(18%)	9(23%)	0.89
Non_Hispanic	95(79%)	33(79%)	32(82%)	30(77)	
Birth Gender, n (%)					
Male	60(50%)	20(48%)	20(51%)	20(51%)	0.95
Female	60(50%)	22(52%)	19(49%)	19(49%)	
Age					
Mean (SD)	17.69 (1.07)	17.67 (0.93)	17.79 (1.13)	17.62 (1.16)	0.75
Subjective Numeracy					
Mean (SD)	3.93 (0.94)	3.96 (0.99)	3.77 (0.78)	4.04 (1.01)	0.42
Impulsive Decision-Making					
Mean (SD)	2.90 (0.66)	2.99 (0.61)	2.90 (0.67)	2.82 (0.69)	0.49
Health Literacy					
Mean (SD)	5.48 (1.51)	5.40 (1.73)	5.54 (1.27)	5.51 (1.50)	0.92

**P*-value is from ANOVA for continuous variables and from Fisher's Exact test or Chi-Square statistics for categorical variables

Table 2

Effect of intervention on outcome variables

Outcome Variables	Intervention Groups		
	Consent Alone	Consent & 1-Sided	Consent & 2- Sided
	Mean (SD)	Mean (SD)	Mean (SD)
Knowledge Scales			
Randomization*	3.61 (0.48)[a]	3.88 (0.54)[a,b]	3.95 (0.56)[b]
Interpretation of Side-Effects*	3.48 (0.96)[a]	3.87 (0.77)[a,b]	4.03 (0.77)[b]
Unproven Efficacy	3.73 (0.91)	4.04 (0.75)	4.05 (0.70)
Non-Brochure Topics	4.13 (0.55)	4.13 (0.48)	4.26 (0.54)
Willingness-to-Participate*	3.50 (0.91)[a]	2.92 (0.97)[b]	3.46 (0.90)[a]

Superscripts that differ indicate significant pair-wise differences.

*$p<.01$ for overall ANOVA.

Table 3

Pearson correlation coefficients between participant characteristics and outcome measures

	Health Literacy	Subjective Numeracy	Impulsive Decision-Making
Knowledge Scales			
Randomization	.26*	.28*	−.18
Interpretation of Side Effects	.13	.23*	−.11
Unproven Efficacy	.35*	.17	−.16
Non-Brochure	.35*	.26*	−.10
Willingness-to-Participate	−.11	.16	.06

* $p<01$