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Development and Evaluation of a Web-based Assent for Adolescents Considering an HIV Vaccine Trial

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Abstract

HIV vaccine trials with minors will likely require parental permission and informed assent from adolescents. For this to be a valid process, the information needs to be presented in a manner that promotes adolescent comprehension. Previous studies suggest that adolescent comprehension of assent is often insufficient. We developed an interactive web-based assent that included interspersed quiz questions for a hypothetical HIV vaccine trial. Efficacy of the web-based assent was compared to a standard paper assent with and without interspersed questions. One hundred twenty teen participants, ages 15-17 years, from 5 community organizations were randomized to self-administered web-based assent (n=60) or investigator-administered paper assent with (n=29) or without (n=31) interspersed quiz questions. After reviewing the assent, participants completed a 27 item comprehension test. Comprehension scores were compared between groups. The mean number of correctly answered questions were 21.2 for the full paper group and 21.1 for the web-based group ($t_{(118)}$=-0.08, p=0.94). Scores were 20.2 for the paper without interspersed questions sub-group and 22.1 for the paper with interspersed questions sub-group ($t_{(58)}$=1.96, p=0.055). Participants in the web-based group performed as well on the comprehension test as those in the paper group, and those in the paper with questions sub-group performed better than those in the

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paper without questions sub-group, suggesting that interspersed quiz questions may improve understanding of a traditional paper assent. The minimal investigator time and standardized administration of the web-based assent as well as ability to tailor the assent discussion to topics identified by incorrect comprehension test responses are advantages worthy of further investigation.

Keywords

Informed consent; clinical trials; children; HIV infection; AIDS; Research ethics; informed consent; adolescence; computer-assisted instruction

Introduction

Efforts to develop an effective Human Immunodeficiency Virus (HIV) vaccine remain a high priority in the battle to control the HIV epidemic. Once a candidate vaccine is shown to be safe and effective in adults, trials in adolescents are likely to commence. In future trials involving adolescents, those who have reached the age of majority will provide informed consent as adults. However, younger adolescents will be asked to provide informed assent; additionally, parents of minors will be asked to provide parental permission. It is possible that individual IRBs may grant investigators a waiver for the requirement of parental permission for minor adolescent participation in HIV vaccine trials, but given that such a trial would carry more than minimal risk, this cannot be assumed.

The appropriate form and content of assent for adolescent research participants is not well specified. Unlike informed consent, federal regulations do not specify any required elements for informed assent (Nelson R & Amdur RJ, 2007). However, developmental psychologists have noted that as a child moves through adolescence, s/he develops an ability to understand increasingly complex and abstract concepts. Research has generally shown that by age 14 or 15 years, most adolescents are able to function as well as adult research participants in most circumstances (C.E. Lewis, M.A. Lewis, & Ifekwunigue, 1978; Petersen & Leffert, 1995, Susman, Dorn, & Fletcher, 1992; Weithorn & Campbell, 1982). We believe that the cognitive maturity of 15 to 17 year olds is sufficient to provide assent that contains all information elements of informed consent. Furthermore, older adolescents should be provided with enough information about a trial so that they can understand and appreciate the risks and benefits of participation and make a well-reasoned and well informed decision about whether or not to participate. To be a valid process, information needs to be presented in a manner that promotes adolescent comprehension.

The best way to approach informed assent for adolescent HIV vaccine research is unclear since a large proportion of adult research participants do not understand the information presented during the informed consent process (Flory J & Emanuel E, 2004; Siminoff, 2003). Issues of concern include low health literacy, not understanding the chance nature of treatment assignments in a placebo controlled trial (Howard & DeMets, 1981), and therapeutic misconception in which the research participant “fails to grasp the distinction between the imperatives of clinical trials and of ordinary treatment, and inaccurately attributes therapeutic intent to research procedures” (Appelbaum, Roth, & Lidz, 1982;

Appelbaum, Roth, Lidz, Benson, & Winslade, 1987; Joffe, Cook, Cleary, Clark, & Weeks, 2001; Lidz CW & Appelbaum PS, 2002). Simon et al have described a related concept that is more relevant to a vaccine trial, preventive misconception, “the overestimate in probability or level of personal protection that is afforded by being enrolled in a trial of a preventive intervention” (Hosek SG & Zimet GD, 2012; Ott et al., 2013; Simon AE, Wu AW, Lavori PW, & Sugarman J, 2007).

An important contribution to our understanding of assent content for adolescent HIV research participants comes from the Adolescent Medicine Trials Network for HIV/AIDS Interventions (Murphy DA et al., 2007). An HIV vaccine trial information pamphlet was simplified by reducing reading level from 8th to 5th grade, reorganizing the form to improve flow, removing redundant information, and adding illustrations. (Murphy DA et al., 2007). Adolescents randomized to the simplified assent form scored significantly better on a post-presentation comprehension quiz than those randomized to the standard form (Murphy DA et al., 2007).

Few studies have evaluated the use of multimedia in the assent process. One study demonstrated significant improvement in understanding with use of a multi-media assent process to explain non-invasive radiology procedures to 11 to 14 year olds and parents (O'Lonergan TA & Forster-Harwood JE, 2011). However, in contrast to an HIV vaccine trial, the information presented was very brief, straightforward, and presented no more than minimal risk (O'Lonergan TA & Forster-Harwood JE, 2011).

Computers have been used in educational settings for more than three decades. A review of 35 research reports found that computer assisted instruction (CAI) supplemented by traditional teacher directed instruction resulted in superior student achievement as compared to traditional instruction alone and led to more positive student attitudes and increased motivation to learn (Cotton, 1991). CAI was found to be especially effective with lower achieving and economically disadvantaged students (Cotton, 1991). More recently, web-based approaches have successfully been used to assist adolescents who have chronic disease with preparation for transition to adult care, adolescents who have ADHD with acquisition of content knowledge, and a range of adolescents with education on adolescent health (Borzekowski, McCarthy, & Rosenfeld, 2012; Fabio & Antonietti, 2012; Huang, et al., 2014). Twenty first century adolescents are digital natives, having grown up with the internet, and prefer working online to on paper. The Pew Internet & American Life Project found that 93% of 12 to 17 year olds and 89% of 18 to 24 year olds use the Internet (Pew Internet & American Life Project 2009).

We hypothesized that a web-based assent would appeal to adolescents and result in increased motivation, improved retention, and better comprehension. To test this hypothesis, we compared a web-based assent to a previously developed paper assent.

Intervention Development

Web-Based Assent

Development of the web-based assent was informed by several phases of formative work. We conducted eight focus groups to learn what adolescents would want to know before participating in research and what research concepts are most challenging to understand. Findings have been described previously (Blake DR, Lemay CA, Kearney MH, & Mazor KM, 2011).

Fourteen cognitive interviews were conducted with adolescents as they read through the simplified assent form developed by Murphy et al (Murphy DA et al., 2007). This process identified information that continued to be difficult for teens to comprehend. Using findings from the focus groups and cognitive interviews, three topic areas were identified for video animation: 1) What is a vaccine and how does it work? 2) What is a placebo? and 3) The HIV test vaccine: will it work?

The content of Murphy's previously simplified assent(Murphy DA et al., 2007) was converted into a web-based program. An introduction was added, priming participants to consider the 8 elements of informed consent as they pertained to the hypothetical study. Content was split into smaller segments to conform to adolescent expectations for font size and ‘white space’ of a presentation viewed on a computer screen. Font type (comic sans) and background and font color (white lettering on black background) were chosen after consultation with youth. Color was used liberally to emphasize points. Clip art was included to help illustrate concepts and to increase visual appeal. Words identified as difficult to understand during cognitive interviews were underlined to denote hypertext; the definition popped up on the screen when a participant rolled the mouse over the word. All content was narrated to assist those with low literacy.

Fourteen multiple choice questions were developed to assess understanding of each element of informed consent. Questions were interspersed throughout the web-based assent, and participants were periodically required to answer a question before proceeding to the next section. The program provided feedback on whether the selected response was correct and why incorrect responses were wrong.

Paper Assents

We made minor modifications to Murphy's simplified paper assent (Murphy DA et al., 2007) including the addition of an introduction page, which mirrored the introduction described above for the web-based program. Some pages were reformatted to keep linked sections together in a three page spread for ease of reading. Two versions of the paper assent were created: one included the 14 interspersed quiz questions with an answer key to mimic the web-based assent, and the other did not.

Methods

Participants

A sample size of 60 subjects per group (web-based and paper) was chosen to provide 80% power to detect a predicted effect size of 0.30 between the proportion of participants answering at least 80% questions correctly in the web-based group versus the paper group. As procedures were refined, the decision was made to subdivide the initial paper group sample of 60 into paper assent with interspersed questions and paper assent without interspersed questions to isolate the effect of the interspersed questions on comprehension.

One hundred twenty adolescents were recruited from five youth-serving agencies. Eligibility criteria were age 15 to 17 years and ability to read and understand English.

Written informed assent was obtained from participants, and a waiver of the parental permission requirement was granted. Research procedures were approved by our Medical School's Committee for the Protection of Human Subjects in Research.

Measures

Participant race, ethnicity, gender, age, health insurance status, first language spoken, and HIV testing history were collected. A multiple choice question evaluated participant willingness to join the HIV vaccine trial if it were offered that day.

A comprehension test consisting of 27 questions was developed to measure participant understanding of assent content. Response options were true, false, and unsure. The unsure option was included to discourage guessing, and was scored as incorrect.

Procedures

A random number table was used to generate intervention assignments to one of three groups: 1) Web-based assent (n = 60), 2) Paper assent with interspersed quiz questions (n = 29), or 3) Paper assent without interspersed questions (n = 31). Assignments were placed in sealed envelopes by the principal investigator and opened sequentially by a co-investigator as participants were recruited.

All participants completed assessment measures on a computer regardless of assigned group. After completing the assessment, participants were administered the Sentence Comprehension subtest of the Wide Range Achievement Test: Fourth Edition (WRAT-4) to assess literacy. The WRAT-4 is a “norm-referenced test that measures basic academic skills” (PAR, Inc., Lutz, FL). The Sentence Comprehension grade equivalent score was computed for each participant. One investigator (CAL) administered the assent and assessment procedures to all participants.

Administration of Web-based Assent—The investigator answered questions, but participants navigated the program independently. Use of headphones to listen to narration was optional. Once the participant completed the web-based assent, the investigator answered questions about the hypothetical study and participants completed the web-based assessment and the WRAT-4.

Administration of Paper Assent without Questions—The investigator read the assent to the participant, pausing at the end of each page for questions. After reviewing the entire assent, participants completed the web-based assessment and the WRAT-4.

Administration of Paper Assent with Questions—This process was identical to the Paper assent without Questions except that questions were interspersed throughout the assent to check understanding. After each question was answered, participants were provided with an answer key. Incorrect answers were discussed, the correct answer provided and if needed, information previously viewed from the paper assent was reread.

Analyses

Statistical analyses were conducted with IBM SPSS (Statistical Package for the Social Sciences) Statistics Version 20.0 (Chicago, IL). Our primary outcome, comprehension of the assent, was measured in two distinct ways: 1) mean number of correctly answered true/false comprehension test questions and 2) proportion of participants who answered at least 80% of the true/false comprehension test questions correctly. We chose a threshold of 80% to be consistent with other investigators who have used 80% as a minimum standard for adequate comprehension of HIV vaccine information (Koblin BA, 1998; Murphy DA et al., 2007).

The primary outcome was first tested for all paper (n=60) versus computer (n=60) and then tested for paper with interspersed questions (n=29) versus paper without interspersed questions (n=31). Each of these outcomes was tested separately using t tests for independent continuous outcomes and Chi-square tests for proportions. The relationship between literacy and comprehension scores, for each type of assent, was measured using linear regression, and a generalized linear model was used to quantify possible differences between the sizes of these relationships.

Results

Baseline evaluation of participant characteristics is summarized in Table 1. Amongst the full sample, the average comprehension score was 21.1 out of a possible 27 (78.1%). Table 2 provides results of the comprehension test for each assignment group.

The mean scores were similar in the computer group and the paper group. The mean score was highest in the paper with interspersed questions group and lowest for the paper without questions group. Although the difference between the two groups in the latter comparison was not statistically significant, the 95% confidence intervals overlapped by an increment of less than one question.

There was a positive relationship between comprehension score and literacy level for the full sample (adjusted $R^2 = 0.36$; Beta=0.60, $p<0.001$). This relationship varied between assent assignment groups (Figure), but the differences were not statistically significant ($p = 0.93$).

If enrollment in the hypothetical HIV vaccine study were offered on the day that participants reviewed the assent, those in the two paper assent groups were more likely to say that they were willing (definitely or probably) to join the study than those in the web-based group

($X^2_{(1)}$ =4.04, p=0.04), and although not statistically significant a larger proportion in the paper without questions group (0.65) were willing than in the paper with questions group (0.48).

Results for each of the individual true/false comprehension questions are found in Table 3. There is substantial variability in the proportion answering individual items correctly within assignment groups and between groups.

Headphones were used by 72% (43 of 60) of the participants randomized to the web-based program. Those who did not use headphones answered an average of one more question correctly than those who did use headphones (21.8 versus 20.8). Furthermore, the average literacy grade equivalent of those who did not use headphones was 8.0 (95% CI [6.7, 9.2]) versus 6.8 (95% CI [6.1, 7.5]) in the group who did use headphones, but the difference in this small sample was not statistically significant (p = 0.1).

Discussion

We evaluated a web-based assent for 15 to 17 year old adolescents who were asked to consider participation in a hypothetical HIV vaccine trial. We chose this age range because this group is likely to be cognitively mature enough to provide informed assent equivalent to the consent provided by their slightly older peers who have reached the age of majority. Our web-based assent included many features intended to appeal to youth including, liberal use of color, interesting font, clip art, hypertext, video animations, and optional audio. We used a variation on the ‘testing with feedback’ method, an approach that resulted in improved comprehension in a previous study on consent for an HIV vaccine trial (Coletti et al., 2003). Our participants answered questions about information presented in each section and received feedback on incorrectly answered questions before progressing to the next section.

We hypothesized that asking questions after each section would improve adolescent understanding by reinforcing information presented. Although no clear relationship emerged to suggest that interspersed questions led to answering more comprehension questions correctly, the correct response rate was higher than 80% for more comprehension questions in the web-based and paper with questions groups than in the paper without questions group.

We hypothesized that our intervention would be more successful than previous computer interventions with adults because today's adolescents are digital natives who often prefer web-based technologies (DeBell & Chapman, 2003). Furthermore, we implemented a text-to-speech feature into the web-based application, thus diminishing the level of reading ability required. In fact, the average literacy grade equivalent among those choosing to wear headphones was 1.2 grades lower than those choosing not to wear headphones, suggesting that participants with lower literacy may have found the audio feature to be helpful.

Simulation trials are often criticized for possible bias toward the experimental condition because these designs usually evaluate only information obtained from the consent form and do not consider the entire consent process, which typically includes a discussion about the information in the consent form (Flory J & Emanuel E, 2004). However, our design may actually have biased results against the experimental condition because participants

randomized to the web-based assent were not asked if they had questions until they completed the web-based program. In contrast, participants assigned to a paper assent were asked if they had questions after completing each page of the assent.

We can only speculate about the comparability of assent administered by our study investigator versus that of typical study staff because we did not compare our investigator's technique to that of other personnel recruiting participants for a real clinical trial. However, in our study the paper assents across both conditions were administered by a highly trained researcher with a background in nursing, whose only task was to explain this hypothetical study to participants and answer their questions. In contrast to a typical clinical trial, our investigator was not involved in other aspects of a clinical practice and had no other responsibilities or demands on her time. In this way, the rigorous assent procedures used here represented an ideal condition. It stands to reason that variability will exist in the quality of the assent process depending on who is conducting it, a topic worthy of additional research as well as rationale for developing methods to standardize the process.

Although we found no statistically significant difference in comprehension between the web-based assent and the two versions of the paper assent, several important lessons were learned. First, it is noteworthy that in this sample the web-based assent performed as well as the traditional paper method. This finding might lead investigators to develop a menu of options to offer trial participants. If recruiting a large sample, developing a web-based assent to introduce the study will standardize the process and potentially save investigator time. Participants can self-select whether to use audio and can move at their own pace. Comprehension test results could be used to determine which concepts a participant misunderstood. Study personnel time could then be used more effectively to tailor the assent discussion to clear up confusion and answer participant questions. If engaging in a smaller study with a smaller budget, developing a web-based assent may not be feasible, but incorporating interspersed questions within a paper assent may improve participant comprehension and understanding of the study.

If this approach were adopted, some concepts will likely require more attention than others. Our findings raise concern about several misunderstandings. Specifically, more than one quarter of participants in all three assignment groups appeared not to understand that a study vaccine could harm a participant (Question 3), that needing special HIV tests could cause personal problems (Question 15), and that the anticipated outcome of the candidate vaccine was preventive rather than curative (Question 22).

It is possible that individual IRBs will determine that older minor adolescents may provide their own consent without parental permission for participation in an HIV vaccine trial, especially if adolescents in their locations are allowed under state law to consent for vaccines for clinical care (Nelson, LL Lewis, Struble, & Wood, 2010). In fact, the Society for Adolescent Medicine (SAM), in its position paper on Guidelines for Adolescent Health Research, also recognized that adolescents at this age are generally capable of providing their own consent for research that involves no more than minimal risk (Santelli et al, 2003). However, the Guidelines recommend that for research involving greater than minimal risk investigators should make an individual assessment of each minor participant's capacity to

provide consent (Santelli et al, 2003). A consent process that improves adolescent understanding and appreciation of risks and benefits of the research would likely be a prerequisite to consideration of waiving the requirement for parental permission for an HIV vaccine trial.

Our study had limitations. First, a simulated study design was necessary because a candidate HIV vaccine that is ready for trials with adolescents does not yet exist. However, when such a vaccine is ready for testing in adolescents, institutional review boards are more likely to approve adolescent trials if an assent with demonstrated acceptable comprehension by minors is already available. Second, some of our results were limited by our sample size, which was based on a predicted effect size that was not achieved. The sample was not large enough to determine whether some of the clinically significant secondary findings were statistically significant (e.g. difference in comprehension scores and willingness to join the study between the paper with questions group versus the paper without questions group, and difference in literacy between those in the web-based group who chose to use headphones and those who chose not to). Future validation studies are needed where the process can be replicated in a real HIV vaccine trial environment and we can explore whether use of a web-based assent plus review of incorrect evaluation answers improves overall understanding by adolescents.

Conclusion

Our web-based method of assent appears to perform as well as a traditional paper assent. Use of this approach has the potential to standardize the initial assent process, saving personnel time in large clinical trials, and utilizing study personnel more effectively to review results of a comprehension test and tailor the assent discussion to the concepts that were not well understood. Participants can be given the choice to use the text-to-speech feature depending on their literacy and comfort. Alternatively, youth could be given the choice of assent information methods best suited to them. If using a traditional paper assent, the addition of interspersed questions throughout the assent may improve overall comprehension.

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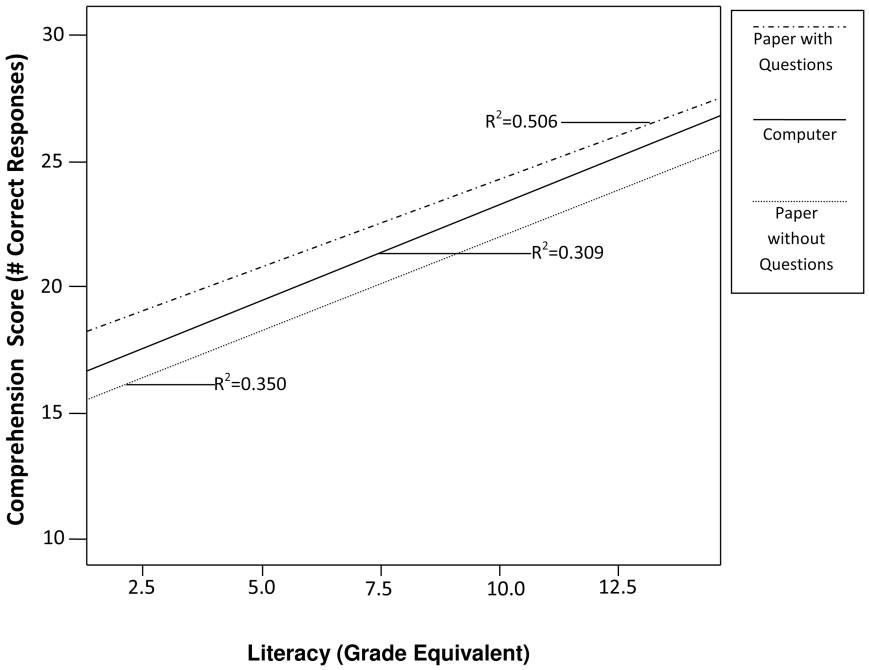

Figure.

Relationship of assent comprehension score and literacy grade equivalent measured by linear regression (adjusted R2) for each assignment group.

Table 1

Participant Characteristics

Participant Characteristic	Computer N=60	Paper with Interspersed Questions N=29	Paper without Interspersed Questions N=31	Statistical Test
Age mean yrs [95% CI]	16.0 [15.7, 16.2]	16.3 [16.0, 16.6]	15.9 [15.6, 16.2]	$F_{(2,117)}$=1.94, p=0.15
Female	47%	52%	45%	$X^2_{(2)}$=0.29, p=0.86
Hispanic	43%	45%	55%	$X^2_{(2)}$=1.14, p=0.57
RACE				$X^2_{(8)}$=7.63, p=0.47
Asian	12%	24%	16%	
Black	28%	28%	23%	
White	17%	7%	6%	
Multiracial	18%	10%	29%	
Other[1]	25%	31%	26%	
FIRST LANGUAGE				$X^2_{(6)}$=4.23, p=0.65
English	73%	65%	77%	
Spanish	20%	21%	16%	
Vietnamese	2%	7%	7%	
Other	5%	7%	0	
INSURANCE				$X^2_{(6)}$=3.97, p=0.68
Private	12%	17%	23%	
Public	70%	59%	55%	
None	2%	0	3%	
Unsure	17%	24%	19%	
Previous HIV test	28%	34%	23%	$X^2_{(2)}$=1.04, p=0.59
LITERACY				
Mean grade equivalent[2] [95% CI]	7.1 [6.5, 7.8]	7.4 [6.2, 8.6]	7.7 [6.5, 8.8]	$F_{(2,117)}$=0.38, p=0.69

[1] Most who chose Other, wrote in some subcategory of Hispanic (e.g. Puerto Rican, Dominican)

[2] Sentence comprehension

Table 2

Evaluation Results

Measures Variable	Computer N=60	All Paper N=60	Statistical Test	Paper with questions N=29	Paper w/out questions N=31	Statistical Test
True/False Questions						
Mean number questions correct of possible 27 [95% CI]	21.1 [20.2 to 22.0]	21.2 [20.2 to 22.2]	$t_{(118)}$=- 0.08 p=0.94	22.1 [20.8 to 23.4]	20.2 [18.8 to 21.6]	$t_{(58)}$=1.96, p=0.055
Proportion with >80% items correct [95% CI]	53% [40% to 66%]	57% [44% to 70%]	$X^2_{(1)}$=0.14, p=0.71	69% [52% to 86%]	45% [27% to 63%]	$X^2_{(1)}$=3.46, p=0.06
Willingness to join study if offered today						
Proportion definitely or probably willing [95% CI]	38% [26% to 50%]	57% [44% to 70%]	$X^2_{(1)}$=4.04, p=0.04	48% [30% to 66%]	65% [48% to 82%]	$X^2_{(1)}$=1.61, p=0.30

Table 3
Correct Responses for True/False Evaluation Questions

True/False Evaluation Question	Overall N=120	Group 1 Computer N=60	Group 2 Paper with N=29	Group 3 Paper w/out N=31
1) All of the people who join the study will get a shot that we know will protect them from HIV.	105 (88%)	52 (87%)	27 (93%)	26 (84%)
2) If I join the study, I will be asked to give blood for tests.	109 (91%)	53 (88%)	28 (97%)	28 (90%)
3) Researchers could never test vaccines on people that might cause health problems.	50 (42%)	22 (37%)	15 (52%)	13 (42%)
4) Some of the people who join the study will get a placebo instead of the test vaccine.	108 (90%)	55 (92%)	25 (86%)	28 (90%)
5) If I join the study, I'll have to take special HIV tests instead of regular HIV tests.	94 (78%)	49 (82%)	20 (69%)	25 (81%)
6) One goal of this study is to find out whether the vaccine we are testing will protect people from catching HIV.	98 (82%)	50 (83%)	22 (76%)	26 (84%)
7) The study shots and blood tests may hurt a little and make me feel bad for a few days.	110 (92%)	53 (88%)	28 (97%)	29 (94%)
8) If I join the study, I will be asked to take research pills for 2 years.	81 (68%)	43 (72%)	17 (59%)	21 (68%)
9) The test vaccine could make it look like I have HIV even if I don't.	93 (78%)	40 (67%)	27 (93%)	26 (84%)
10) The placebo should work almost as well.	90 (75%)	48 (80%)	23 (79%)	19 (61%)
11) This study will help to find out if the test vaccine causes health problems.	84 (70%)	37 (62%)	24 (83%)	23 (74%)
12) The study staff will guarantee that no one outside of the study finds out any private information about me.	48 (40%)	30 (50%)	15 (52%)	3 (10%)
13) If I join the study, the shots I get could cause harmful side effects.	100 (83%)	55 (92%)	25 (86%)	20 (64%)
14) If I join the study, the person who gives me the shots will decide whether I get test vaccine or placebo.	96 (80%)	54 (90%)	25 (86%)	17 (55%)
15) Not being able to take regular HIV tests could cause me personal problems.	85 (71%)	42 (70%)	21 (72%)	22 (71%)
16) If I join the study, I will be asked to come to the study clinic for at least 10 visits.	68 (57%)	25 (42%)	20 (69%)	23 (74%)
17) While I am in the study, I won't be told whether my shots contain test vaccine or placebo.	102 (85%)	47 (78%)	25 (86%)	30 (97%)
18) My participation in this study could help other people.	113 (94%)	55 (92%)	27 (93%)	31 (100%)
19) If I join the study I can't drop out because I made an agreement with the researchers.	110 (92%)	54 (90%)	28 (97%)	28 (90%)
20) The study doctors and nurses will take care of all of my medical problems even if they are not caused by the study shots.	87 (73%)	50 (83%)	19 (66%)	18 (58%)
21) If the researchers find that I have HIV, they will tell the state health department.	101 (84%)	50 (83%)	27 (93%)	24 (77%)
22) The vaccine that is being tested in this study could cure an HIV infection.	74 (62%)	40 (67%)	20 (69%)	14 (45%)
23) I don't have to join this study if I don't want to.	119 (99%)	59 (98%)	29 (100%)	31 (100%)
24) If I join the study, I can count on the shots I get to protect me from catching HIV.	103 (86%)	51 (85%)	26 (90%)	26 (84%)
25) Getting shots in a research study is just as good for my health as getting shots at my doctor's office.	81 (68%)	39 (65%)	22 (76%)	20 (64%)
26) It is okay for a female to become pregnant during the study.	119 (99%)	59 (98%)	29 (100%)	31 (100%)

True/False Evaluation Question	Overall N=120	Group 1 Computer N=60	Group 2 Paper with N=29	Group 3 Paper w/out N=31
27) I will receive free health care for any medical problems that are directly related to the study.	107 (89%)	54 (90%)	28 (97%)	25 (81%)