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Framing a consent form to improve consent understanding and determine how this affects willingness to participate in HIV cure research: An experimental survey study

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Abstract

HIV cure research carries serious risks and negligible benefits. We investigated how participants understand these risks and what influences their willingness to participate. Through internet-based and in-person convenience sampling, 86 HIV+ participants completed an experimental survey. Participants were randomized to read a standard consent form describing a hypothetical HIV cure study or one adapted using Fuzzy Trace Theory - a decision-making model to facilitate complex information processing. We measured consent understanding and cognitive (e.g., safe/harmful) and affective (e.g., concerning, satisfying) evaluations of HIV cure research. Participants who read the adapted consent form had improved consent understanding, but only positive affective evaluations were associated with a willingness to participate. Consent processes can use decision-making theories to facilitate comprehension of study information.

Keywords

HIV cure research; informed consent; fuzzy-trace theory; recruitment; HIV continuum

Introduction

The race is on for discovering a cure for HIV (Deeks et al., 2016). By the end of 2019, there were over 100 active HIV cure studies worldwide (Jeffreys, 2020). HIV cure research is a

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priority for the National Institutes of Health (NIH), with private foundations and private industries in the U.S. investing over $100 million dollars per year in this research [UCSF, 2017; Gilead, 2017; National Institutes of Health, 2016). But despite the enthusiasm for HIV cure research, there are outstanding ethical questions, such as reasons why otherwise healthy people living with HIV (PLWH) decide to participate in these high-risk studies, and if the decision to participate is related to the way consent procedures inform their estimation of risks (Bromwich & Millum, 2017).

HIV cure research is in the early investigational phases and carries wide-ranging risks, offering negligible medical benefits to participants, and no immediate possibility of a cure (Eyal, 2017; Hare, 2017). HIV cure studies encompass a range of experimental interventions and use a particularly innovative study method called analytical treatment interruptions (ATIs) (Dubé et al., 2018a; Julg et al., 2019). ATIs require PLWH with suppressed viral load to temporarily pause their HIV medications to evaluate the impact of an experimental intervention on immune control of HIV (Dubé et al., 2017b). Participants consenting to ATI studies explicitly take on risks associated with becoming *unsuppressed* for a period of time. These risks may include a diminished response to a future curative intervention or their HIV medication(s) once resumed, consequences of inflammation, and the possibility of transmitting HIV to sexual partners, which is impossible if they remain virally suppressed by not participating in the study (Garner et al., 2017). In fact, there have been two cases of HIV transmission from participants to their sex partners while participating in an HIV cure study with an ATI (Liliévre & Hocqueloux, 2019; Ugarte et al., 2020).

The debate around ATIs has led to a preponderance of willingness-to-participate studies to identify reasons for and against participation in HIV cure research (Dubé et al., 2017a; Fiorento et al., 2019; Fridman et al., 2020; Kratka et al., 2019). It is difficult to investigate why PLWH are willing to participate since most active HIV cure studies typically involve very small sample sizes, are time-consuming and intensive (Dubé, 2019a). In a typical willingness-to-participate study, a single-group of PLWH are surveyed for motivators and deterrents to participate in a future or hypothetical HIV cure study. Commonly cited motivators include HIV altruism, history of HIV activism, financial compensation, and increased clinical monitoring (Dubé et al., 2017a; Fiorento et al., 2019; Fridman et al., 2020; Kratka et al., 2019). One outstanding question is how PLWH determine their willingness to participate given the obvious imbalance of risk/benefit ratio, which most notably includes a risk of HIV transmission to sex partners during ATIs – a commonly cited deterrent to participation (Dubé et al., 2018a; Kratka et al., 2019).

Given the potential severity of risks associated with HIV cure studies, the consent form becomes a critical source of information for ensuring that prospective participants comprehend the full scope of study procedures, risks to themselves and their partners, and lack of direct benefit. Informing the development of adequate consent procedures goes beyond the benefits of making consent forms more readable – a necessary but insufficient benchmark. Rather, it is important to understand how the consent information is processed and applied to the participation decision. A promising theoretical framework for examining these questions is the Fuzzy Trace Theory (FTT), a decision-making model drawn from cognitive science (Reyna, 2004; Reyna & Brainerd, 1991).

FTT posits that presenting specific information, such as the required risk information in consent forms for cure research, does not itself directly influence a person's reasoning. Rather, supplemental information is needed to link information surrounding potential risk to decision-making behavior (Reyna, 2008). FTT states that when presented with a stimulus (i.e., risk information), a person forms two representations of that information into their working/short-term memory (Reyna, 2008). One representation is called *verbatim*, which are the exact words, numbers, or graphs of information that is transferred to working memory (e.g., a person recalls that the consent form stated "you have a 20% chance of experiencing a side effect"). Recall of verbatim information is easily diminished if not transferred to long-term memory, and thus, may have a limited impact on decision-making (Reyna, 2008). The second representation is called *gist*, which are the qualitative, essential, and bottom-line meanings that a person derives from the stimulus. For example, the statement "you have a 20% chance of experiencing a side effect" may be interpreted as "I'm *probably* going to experience side effects." In a review of several studies of FTT and health-related outcomes, gist information – bottom-line meaning – was more strongly associated with healthier decision making, rather than verbatim information alone (Blalock & Reyna, 2016). If FTT can promote processing of the bottom-line meaning of consent form information, rather than simple recall of the details verbatim, researchers may feel more confident that individuals are making informed choices about high-risk study participation.

Objectives

Currently, PLWH can take one pill a day to achieve viral suppression, which leads to a near-normal life span and no forward transmission to sex partners. In HIV cure studies involving ATIs, PLWH stop their HIV medication(s) and take on all the aforementioned risks. Thus, a gap in scientific knowledge exists regarding whether HIV cure study information is being fully processed when stating a willingness to participate in research given that the personal risks outweigh the lack of direct benefits (Dubé et al., 2018b).

The objectives of the study were (1) to test if including gist statements (or not) increased understanding of an HIV cure research consent form, and (2) to examine how consent understanding and cognitive and affective evaluations of HIV cure research associated with a decision to agree or refrain from participation - willingness to participate. For the first objective, we adapted a standard HIV cure study consent form using FTT. One group of participants read this consent form (experimental condition), while a second group (control group) read the standard consent form.

For the second objective, we evaluated the willingness to participate in an HIV cure study between the two groups through the construct of *informed choice* (Marteau, Dormandy, & Michie, 2001). An informed choice requires both relevant knowledge and positive evaluations of the decision being weighed. We measured consent understanding as knowledge and affective evaluations (e.g., excitement or stress about participating), and valenced cognitive evaluations (e.g., judging participation as a safe or unsafe choice) of HIV cure research (Crites, Fabrigar, & Petty, 1994). Consent understanding and evaluations were applied to better understand a willingness to participate.

Methods

Recruitment and Participants

We collected all data through an online survey from June 2018 through March 2019 programmed through the Qualtrics software (Qualtrics, 2005). Participants were recruited online and in person at a local research center. Online recruitment was implemented by disseminating an advertisement that included a brief description of the study and a one-time link. The advertisements were sent to HIV/AIDS-service organizations, community-based organizations, community advisory boards, professional e-mail listservs, public health departments, and social service programs. Organizations were instructed to share the link with PLWH with whom they worked or provided services. No inclusion and exclusion criteria were stated in the descriptions as to not favor specific responses to screening questions.

Once a study link was opened, individuals were directed to an electronic consent form and screening questions. To be eligible, individuals had to electronically consent; click a reCAPTCHA security measure to confirm they were not a robot; report an HIV-positive status, an undetectable viral load, no illicit drug use or hazardous alcohol use, and less than mild depression severity ratings. They also had to answer additional security questions, provide the state they lived in (to confirm with the IP address), and lastly, submit their e-mail address. If eligible, participants were notified that our study team would send to their email address a personalized link to the full survey. This approach was to enhance security and data quality. Participants were excluded if their survey could not be verified by any of the aforementioned inclusion criteria. The strict inclusion criteria were based on standard practice that current HIV cure protocols require generally healthy PLWH.

In this study, our system did detect “ballot stuffing,” where multiple incomplete screening responses were submitted nearly simultaneously. In order to avoid fraudulent responses, we transitioned to verbal phone calls to confirm the eligibility of study participants. After completing the online screening questions above, eligible participants were instructed to leave a voicemail on our study phone stating their name, their e-mail address, and state they resided in, which we validated against their screening responses. Once validated, we sent a personalized link to the full survey. All participants were paid a $25 Amazon e-gift card.

Locally, we also collected online survey data by directly recruiting PLWH from an observational prospective study - Zuckerberg San Francisco General Hospital (ZSFGH). The same inclusion/exclusion criteria applied. The only difference was that participants were given a computer tablet onsite to complete the full survey by themselves, and the $25 compensation was provided in cash.

To reduce the influence of attentional factors on consent understanding and to increase participant motivation, we used the pseudo bogus pipeline technique (Festinger, Marlowe, Croft, Dugosh, Arabia, & Benasutti, 2009). Prior to starting the survey, participants read a statement about how payment was based on their performance on the measure of consent understanding (but all received the same amount). No personal or identifying information

was collected and the research was approved by the University of California, San Francisco (UCSF) Institutional Review Board.

A total of 117 people completed the screener questions, 20 of whom did not meet inclusion criteria (8 reported illicit drug use, 6 screened positive for depression, 2 reported hazardous drinking, 2 reported a detectable viral load, 1 reported illicit drug use and screened positive for depression, and 1 screened positive for depression and reported a detectable viral load). Ninety-seven participants completed the full survey, but 7 surveys could not be verified and 4 participants did not report on the outcome. A total of 86 surveys were available for analysis (24 from in-person recruitment).

Survey Format and Experimental Design for Gist Statements within the Consent Form

We created one 5-page consent form describing a hypothetical HIV cure study using a possible experimental intervention and an ATI. The consent form was based off of a review paper of 13 HIV cure study consent forms (Henderson, 2014) and an internal review of additional HIV cure study consent forms we obtained. Our consent form had five unique sections: 1) purpose of the study, 2) study procedures, 3) study risks, 4) study benefits, and 5) the process for dealing with study-related injuries. All proprietary information (e.g., drug names, sponsors) were fictional, and, prior to launching, the acceptability of the study was informally reviewed by the UCSF Division of Prevention Science Community Advisory Board.

The consent form language reflected the information currently contained in HIV cure research consent forms (Henderson, 2014). The *control group* and the *experimental group* received the same consent information in the same order of presentation, with the following difference. For the experimental group, each unique consent section was followed by "gist" statements developed by following guidelines set by Blalock and Reyna (2016). First, we sent the consent form to five researchers involved in HIV cure research and asked them to write statements reflecting the "gist" of each section (i.e., write the bottom-line meaning of each section). Next, we aggregated all statements into one set of statements that were presented only to the experimental group (Blalock & Reyna, 2016).

The consent form was presented after participants were e-consented. The first half of the consent form was presented and locked so participants could not proceed until after three minutes. Then, they were presented with the first set of test questions, followed by corrective feedback to increase motivation (i.e., current score and payment reminder) (Festinger et al., 2009). They then continued to the second half of the consent form and test questions.

Measures.

Demographic Variables and Covariates.—A brief optional demographic questionnaire was used to collect information on age, date of HIV diagnosis, sexual orientation, and race/ethnicity. For a covariate, given the strength of relationship of altruism with research participation, we administered the Altruism subscale from the HIV Vaccine Attitude Measure (Lee, Newman, Duan, & Cunningham, 2014). The subscale included four items that capture a person's motivation to participate in an HIV vaccine study, which were

adapted for the HIV cure research context. For example, participants responded from 1 (*strongly disagree*) to 5 (*strongly* agree) to the questions "I would participate in an *HIV cure experiment* even if I thought I would not be cured" and "I would be one of the first people to enroll in a *HIV cure experiment*." Items were summed up to create a total score.

The UCSD Brief Assessment of Capacity to Consent – Consent Understanding

Consent understanding was measured by using a customizable 10-item measure that assesses a person's decisional capacity to participate in research (Jeste et al., 2007). Participants responded to questions regarding the hypothetical study's purpose, procedures, risks and benefits, etc. Answers to each question were scored from 0 (*incorrect response*) to 2 (*full and accurate response)* per instructions, but we treated any partial credit responses (scores of 1) as incorrect given the stakes of actual HIV cure research studies. Correct answers were explicitly stated in the hypothetical consent form. For example, participants were asked "Do you believe this [hypothetical study] is primarily research or primarily treatment" and provided full credit for the correct response: "This is research – My HIV treatment is not the focus of the study" and zero credit for either "This is treatment…" or "This is a mix of research and treatment." Scores ranged from 0 to 20 and were analyzed continuously.

Mediator – Informed Choice

Following the work of Marteau et al. (2001), to ensure that the outcome of willingness to participate in an HIV cure study is valid, we conceptually defined informed choice as participants having adequate consent understanding of the hypothetical study and a positive/negative evaluations of HIV cure research (i.e., attitudes). The rationale for applying informed choice criteria is that having adequate knowledge (scores on a measure of consent understanding) would not favor a willingness to participate if it were reinforced by a negative evaluation of HIV cure research, but would be favored if counteracted by a positive evaluation.

For measuring evaluations, which psychological science defines as attitudes towards objects/decisions, we used semantic differential items (Crites et al., 1994). Each item measured affectively-driven and cognitively driven-evaluations of HIV cure research. Six items measured evaluation of participation in general, six items measured evaluations of risks described in the consent form, and six items measured evaluations of ATIs that requires participants pausing their treatment. Half of the items measured affectively-driven evaluations (e.g. stressful, concerning vs. satisfying), while the other half measured cognitively-driven evaluations (e.g. foolish vs. safe, wise). Participants marked the position that described their evaluation (Crites et al., 1994). For example, participants read "Participating in an HIV cure experiment that requires you to stop taking your HIV medications for a period of time would be" and asked to rate their evaluation using two semantic anchors from 1 to 7 (*Foolish* _ _ _ _ _ _ _ *Wise) and (Stressful* _ _ _ _ _ _ _ *Satisfying*). Item scores were added up and divided by the number of questions (1 to 7) with higher scores indicating more positive evaluations.

Outcome Measure

Participants' willingness to participate in a hypothetical HIV cure study was coded as a binary outcome. Prior research on willingness to participate in HIV cure studies has used a similar approach to measure how important each type of procedure (blood draw, latency-reversing agent, vaccine) would motivate or deter a person from participating (Dubé et al., 2017a). Participants were directly asked "*If you were asked to be in a study exactly like the hypothetical HIV cure experiment you just read about, would you be willing to participate?"* Responses were coded as 1 (*Yes*) and 0 (*no or undecided*).

Statistical Analysis

Brief basic demographic information on variables measured are presented for descriptive purposes only. For our objectives, we used the M*plus* statistical software for a multiple mediator analysis using maximum likelihood estimation (Hayes, 2009). We tested whether the experimental group (1) versus control group (0) had lower odds for reporting a willingness to participate (0 or 1), and whether this relationship was mediated through consent understanding (M1), cognitive evaluations (M2) and affective evaluations (M3), which make up the dimensions of informed choice. A bootstrapping approach generated regression coefficients/effect size for the relationship of X on Y through $M_{1\text{-}3}$, and each path (X on $M_{1\text{-}3}$, $M_{1\text{-}3}$ on Y). Repeated samples yielding 100 randomly generated estimates of mediated effects approximated the empirically-derived sampling distribution (Hayes, 2009). Because responses on demographic questions were not required, missing data could not be judged as meeting eligibility to be imputed, which precluded us from incorporating them as covariates. We did control for level of HIV cure research altruism (Lee et al., 2014)

Results

Demographics

Eighty-six surveys were analyzed (62 were completed online and 24 were completed in person). The majority of participants identified as cisgender male, exclusively gay/lesbian, non-Latinx White and had completed some college. Demographics can be found in Table 1.

Descriptive Statistics and Bivariate Associations for the Total Sample

Table 1 provides the frequency and percentage of responses for participants in the gist and standard consent condition. For the total sample, 59% of participants reported that they would not, or were undecided about, participating in the study they read about. The remaining 41% participants stated they would participate. For affective evaluations, the total sample averaged a score of 3.8 ($SD = 1.05$) on a scale from 1 to 7, indicating slightly positive feelings about participating in HIV cure research. Cognitive evaluations – anticipated positive or negative consequences of participation – were similarly positive with a mean score of 4.3 ($SD = .91$).

Cognitive and affective evaluations were also positively correlated with each other ($r = .56$, $p < .001$). Regarding consent understanding, participants in the gist group scored 13.3 points (SD = 1.9) as compared to the standard consent group, who scored an average of 9.8 points (SD = 1.8). Both were less than optimal as a perfect score was 20.

Objective 1 - Testing including gist statements (or not) increased consent understanding for a cure research consent form.

In the multiple mediator analysis (see Figure 1) with HIV cure research altruism as a covariate, participants in the experimental group, compared to the control group, scored over 3 points higher on the consent understanding measure ($M_1 b = 3.62$, $SE = .48$, $p < .001$). These participants also reported more positive cognitive evaluations – perceived the study as safer or less harmful) – ($M_3 b = 4.53$, $SE = 1.34$, $p < .002$) and affective evaluations – felt better or less concerned about the study – ($M_2 b = 3.60$, $SE = 1.82$, $p < .05$), compared to the control group.

For the covariate, greater HIV cure research altruism was positively associated with cognitive ($b = 1.27$, $SE = .25$, $p < .002$) and affective evaluations of HIV cure research ($b = 1.25$, $SE = .32$, $p < .001$), but was not associated with consent understanding ($b = -.13$, $p = .12$).

Objective 2 - How consent understanding and cognitive and affective evaluations of HIV cure research participation associated with a decision to agree or refrain from participation - willingness to participate.

The experimental group and control groups showed no difference in the odds of reporting a willingness to participate (direct effect of X on Y) ($OR = .86$, $p = .86$). Of the three mediators, only affective evaluations were directly associated with a greater willingness to participate (direct effect of M3 on Y) ($b = .11$, $SE = .05$, $p < .05$). This coefficient converts to an odds ratio of 1.11, which is interpreted as each 1-unit increase on the affective evaluations measure is associated with 1.11 times the odds of a stating a willingness to participate in the hypothetical HIV cure study. No evidence emerged for full mediation, and HIV cure-related altruism was not directly associated with the willingness outcome.

Discussion

Using Fuzzy-Trace Theory, a judgement and decision-making approach, we modified a consent form to describe the essential and bottom-line meaning of complex HIV cure information. This modification is not the same as making consent forms easier to read, but rather, making complex information easier to cognitively process. The first major finding was that the experimental group – participants who read the modified consent form – performed better than the control group on the test of consent understanding. Unexpectedly, the experimental group also reported more positive cognitive and affective evaluations of HIV cure research. This was unexpected because evaluations as attitudes towards a topic, like HIV cure research, are considered stable and less susceptible to shifts when encountering new information (Glasman & Albarracin, 2006).

The second major finding was that only affective evaluations towards HIV cure research predicted the primary outcome – a willingness to participate in the hypothetical HIV cure study. For one, participation in high-risk research may be partly driven by optimism or how people feel about HIV cure, especially given its momentum, rather than, perhaps, a logical appraisal of the risks or comprehension of study procedures (Gilbertson et al., 2019; Herling

de Oliveira, Nickenig Vissoci, de Lara Machado, Rodrigues, & Limkakeng, 2017; Horng & Grady, 2003). And given the inherent altruistic nature of people who participate in high-risk studies, our data did show that affective evaluations were also associated with HIV cure altruism. In summary, FTT provided an approach to enhance the processing of consent form information, but this did not lead to more or less willingness to participate in a hypothetical HIV cure study. Only affective evaluations – emotional attitudes towards HIV cure research – were associated with a willingness to participate. However, other data from novel HIV trials has shown that hypothetical willingness responses do not always match actual enrollment numbers (Buchbinder et al., 2004); thus, our estimates of willingness are likely overestimated.

This study focused on consent forms to relay study information. While the limitations of consent forms are well documented (Bromwich & Millum, 2016; Kass, Chaisson, Taylor, & Lohse, 2011) and are only one part of a comprehensive informed consent process, they are important in HIV cure research as they must fully describe the research risks and little-to-no direct benefits. In a published review of 13 HIV cure study consent forms, there was no overstating of a potential direct benefit, but all included likelihood statements of potential societal benefits and unique scientific knowledge to be gained (Henderson, 2015). Regarding risks, some were written as being “unknown” or “theoretical,” whereas others were described numerically (e.g., “>50%”), in short phrases (“rare, but serious…may occur”), or in a general prose (e.g., “[If treatment is stopped] the level of HIV in your body may increase”) (Henderson, 2015). The variability of how consent forms are written may not only lead to misunderstandings, but a conflation of direct benefits with a potential societal or scientific benefits. Thus, this may exacerbate any level of therapeutic misconception or misunderstandings that challenge the validity of obtained consent (Horng & Grady, 2003).

Limitations

Our findings must be interpreted in light of several limitations. First, we collected no personal or identifiable information from participants and reporting of key demographic information was optional. This limited our ability to fully characterize our sample. However, given the specific recruitment strategy (e.g., HIV service organizations and HIV-specific networks) and robust security measures, the online data we did collect was high quality. Second, while we focus on consent forms, we recognize that complex and high-risks studies are likely to involve several in-depth conversations between participants and study staff. Thirdly, there is a potential bias in having researchers create the gist statements, and these statements are only useful if they can be accurately recalled. Lastly, given the limited availability of covariates, we could not fully adjust our analysis to help interpret our findings.

Best Practices

We offer two key recommendations from our approach and data. Given the need to complete what are often intense HIV cure study protocols, most active participants are required to be in good health. Because of this requirement, we had to employ a rigorous screening method to ensure our sample led to findings that could be generalizable to the population of PLWH

most likely to participate in HIV cure research. With this in mind, our first recommendation is that consent form templates could incorporate strategies to facilitate the comprehension of study information. For example, in studies with an ATI, researchers should go beyond stating the risk that a participant "may become viremic," which means the virus is no longer suppressed (Julg et al., 2019). While useful, ultimately, an important meaning of this risk is that a person will be infectious again and has the possibility to transmit the virus to sex partners. For research in the early investigational stages, risks that are "unknown" and benefits that are "societal" should be better defined to get at the bottom-line meaning of what is most important. FTT may improve the study of informed consent processes as it is the application of the cognitive sciences (e.g., studies of decision-making, information processing, etc.) to human ethics research.

Our findings show that attitudes towards specific research topics play a role in whether a person chooses to participate in that research. Therefore, in addition to capturing the level of consent understanding as part of a comprehensive informed consent process, we suggest that administering even brief measures of attitudes may yield useful information about participation decisions. While participation decisions are often thought of as being driven by logic and reasoning regarding risks/benefits and study procedures, they are likely also influenced by a combination of emotions as well, which are a less commonly explored area of research.

Research Agenda

The use of FTT for adapting consent forms to enhance information processing warrants further research. First, there is the question of *who gets to create the gist*? Our gist statements were an aggregated summary of what researchers felt were the essential and bottom-line meaning of specific HIV cure study information, and may not reflect what PLWH who are in positions to participate and to contribute to science perceive. Given this new application of FTT to HIV cure research, a more robust method for creating gist statements is warranted. Second, using gist information when making decisions requires that it be accurately recalled from memory. For example, a participant may understand what a particular risk is, but recalls the probability of it occurring as low, when in reality it is high. For gist to promote better decision making, all information must be recalled accurately. Next steps would include research to not only promote gist information, but promote the accurate recall of it. Because researchers often rely on comprehension test when conducting the informed consent process, researching whether a brief test of recall of gist information could be useful.

Further, we recommend conducting a similar experimental study as part of active HIV cure studies utilizing ATIs. Participants could be similarly randomized to a gist (experimental) versus control group to ascertain retention of study information, cognitive and affective evaluations of the proposed research, and willingness to participate in the actual study. Implementing evidence-based gist practices as part of the informed consent process could improve decision satisfaction. Emerging socio-behavioral sciences data have revealed that HIV cure research participants oftentimes carry minor understandings about a study and

over-estimate the likelihood of personal benefits (Dubé, Barr, Palm, Brown, & Tayor, 2019b; Power et al., 2020).

Educational Implications

While the application of FTT to research on the consenting process is limited [59, 60], we believe the basic tenets of FTT can be easily learned and applied. Given that researchers, key stakeholders, and ethics review committees must ensure that complex study information be presented as easily digestible information, we fully support the continued use of surface level strategies, such as aiming for a specific reading level, avoid using jargon, using bullet points, among others. However, FTT may be an additional tool to support deeper processing. The basic idea with FTT is that by knowing how complex information is processed by the human brain (i.e., two representations – gist and verbatim – are formed from one stimulus), we can promote the understanding of qualitative and bottom-line meaning of the critical parts of the study.

Conclusion

We demonstrated that it may be possible to produce empirically-derived recommendations for the framing of risks and benefits for participation in HIV cure research in consent forms. These considerations may be applied to discussions as part of the overall informed-consent process – particularly for early-phase trials involving high-risks and minimal prospects of direct benefits. Rather than focusing exclusively on reading level, word counts, or language, we shift the focus to understanding how people process information and using that process to guide the writing of consent forms. Ultimately, we have early evidence that the communication of HIV cure research risks can be adapted to maximize patient autonomy and facilitate more informed decision-making.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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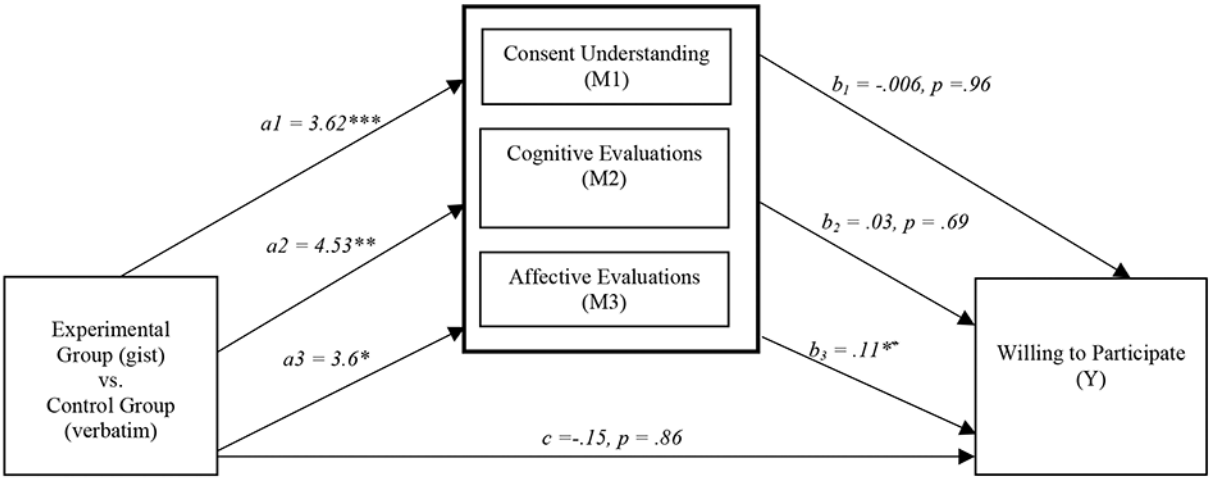

Figure 1.

Multiple Mediator Model: Comparing control group versus experimental condition group on measures of consent understanding and evaluations of HIV cure-related research, and their association with a willingness to participate in a hypothetical HIV cure-related study

Note. ***$p < .001$, **$p < .01$ *$p < .05$. The odds ratio for the b_3 regression coefficient is 1.11. See Results section for associations of HIV cure-related altruism with mediators and outcome.

Table 1

Means, standard deviations and percentages for demographic data, capacity willingness to participate

	Control Group N = 41 M (*SD*) / %	Experimental Group N = 45 M (*SD*) / %
Age	49.7 (*17.1*)	46.7 (*17.2*)
Greater than high school education	86%	84.4%
Employment Status	46.3%	54.5%
Working full-time	24.4%	27.3%
Receiving disability		
Sexual Orientation		
Gay/Lesbian exclusively	65.1%	64.5%
Bisexual	18.6%	15.6%
Heterosexual exclusively	16.3%	15.6%
Other	0%	4.4%
Gender Identity		
Male	74.4%	86.7%
Female	23.3%	13.5%
Transgender Male	0%	0%
Transgender Female	2.3%	0%
Race		
Non-Latino White	64%	61.4%
African American	23.1%	29.5%
Asian/Pacific Islander	10.3%	2.3%
Native American	0%	2.3%
Mixed Race	2.6%	4.5
Ethnicity Latinx	8.9%	2.1%
Cognitive Evaluations of HIV Cure Research	4.00 (*.97*)	4.63 (*.76*)
Affective Evaluations of HIV Cure Research	3.5 (*1.13*)	4.0 (*.92*)
Mean Capacity to Consent Score	9.8 (SD = 1.8)	13.3 (SD = 1.9)
Willing to Participate		
Yes	36.6%	47.7%
No or Undecided	63.4%	52.3%