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Objective: To examine acceptability and feasibility of a Transtheoretical Model (TTM)-based computer-tailored intervention for increasing HPV vaccination in college-aged women.

Participants: 243 women ages 18-26 were recruited between February and May of 2011.

Methods: Participants completed the intervention and a 14-item evaluation of intervention content and delivery.

Results: Most participants had heard of HPV (91%), but the majority (57%) of participants were in Precontemplation for getting vaccinated. Eighty nine percent of participants rated the CTI positively across all acceptability items, and 91% endorsed intention to get vaccinated after intervention. While average ratings in each demographic subgroup were positive, Hispanic women and participants in more advanced Stages of Change rated the program more favorably than non-Hispanic and earlier stage participants. Additionally, HPV Knowledge was higher among White/Non-Hispanic participants.

Conclusions: Initial acceptability and feasibility data for this intervention is promising. Its computer-based, individually-tailored format is state of the art and ideal for inexpensive dissemination.

Keywords: human papillomavirus, Transtheoretical Model, population-based intervention, online intervention, Stage of Change

Word Count: 150 (limit is 150)

Human papillomavirus (HPV) is the most prevalent sexually transmitted infection in the United States.^{1,2} Research suggests that 80% of sexually active women are exposed to HPV at some point in their lives.³ While most HPV infections do not lead to health problems, infection with HPV is associated with 70- 90% of cases of cervical cancer, 90% of cases of genital warts, and is associated with other a variety of other anogenital and oropharyngeal cancers as well.⁴⁻⁷ In June 2006, the Food and Drug Administration (FDA) approved GARDISIL®, a quadrivalent vaccine protective against those strains of HPV most likely to produce cervical cancer and genital warts. In October 2009, the FDA approved Cervarix®, a bivalent vaccine protective against those strains of HPV most likely to produce cervical cancer. Both vaccines require three injections over the course of six months. Despite strong efficacy and minimal evidence of side effects, uptake of HPV vaccination remains low.⁸

The rate of HPV infection is particularly high among college-aged women. A study conducted by Dunne et al.¹ indicated that women ages 20-24 had the highest prevalence of HPV infection relative to other age groups. A longitudinal study that followed a cohort of female college students over three years reported that 60% of the sample contracted an HPV infection during the course of the study.⁹ Winer et al.¹⁰ evaluated the twelve-month incidence of HPV infection in college students after first sexual contact and reported a 37.2% infection rate.

Despite high infection rates, young adult women are unlikely to initiate HPV vaccination. Research has found vaccination rates among college-aged women are between 10% and 44%.^{8,11-13} In addition, research indicates that women over age eighteen are four times less likely to have received the HPV vaccination.¹³ This data suggests that college-aged women are at a high risk for contracting HPV, but many are not initiating vaccination on their own.

Despite the need for increased vaccination among women in the 18-26 year-old age range, intervention efforts have focused on early adolescent girls or their parents. This trend may be driven by the Center for Disease Control's recommendation that women be vaccinated in their early teenage years, prior to first sexual intercourse.¹⁴ While early vaccination is preferable, women who are not vaccinated during adolescence or pre-adolescence are still in need of "catch-up" vaccination; therefore, interventions targeting this older group are needed. Furthermore, several characteristics make women over 18 a promising target for intervention. First, with entry into legal adulthood, turning 18 represents a transition of responsibility for medical decisions and a second chance to vaccinate women. Additionally, benefits may seem more relevant to this age group given recent independence, onset of sexual activity, and high risk for contracting HPV.

There is a need for empirically-validated, theoretically-driven behavior change interventions to increase HPV vaccination among young adult women. There is a sizable body of research on the correlates of HPV vaccination uptake,¹⁵⁻²⁰ but few studies of interventions implemented at the individual or family level.²¹ Interventions that have been reported have most often involved evaluating the effect of different versions of print materials on either acceptance of the vaccine or on intentions to receive the vaccine

oneself or to vaccinate one's daughter.²²⁻²⁶ While these interventions suggest that education and message framing may increase acceptability and intentions to vaccinate, there is a need for dynamic interventions that are **individually tailored on psychosocial and behavioral constructs that produce behavior change. Building and evaluating such an intervention is an important next step in enhancing compliance with vaccination recommendations and reducing the health toll of HPV.**

The Transtheoretical Model of Behavior Change

The Transtheoretical Model of behavior change (TTM)²⁷ offers a promising basis for designing effective interventions for increasing uptake of HPV vaccinations. The TTM is an integrative model of intentional behavior change. This model accounts for individuals' readiness to change a behavior and posits that progress toward change is driven by a set of change-producing variables. Computerized interventions tailored to individuals' readiness to change have been used to successfully modify a wide range of health risk behaviors in clinical and population-based samples, including diet, exercise, depression management, and adherence to lipid medications.²⁸⁻³¹

The central organizing variable of the TTM, Stage of Change, is a measure of readiness to modify a given behavior. The TTM posits that successful change requires moving through five ordinal stages of change. These stages are, Precontemplation (not yet intending to make a change), Contemplation (intending to change in the foreseeable future), Preparation (taking steps to prepare for change), Action (successful change of the target behavior) and Maintenance (continuous engagement in a new behavior for at least six months).²⁷

HPV vaccination is different from many other behaviors with regard to Stage of Change because once action is taken (i.e., the vaccination series is complete) maintenance is brought under biological control. Therefore, the Action and Maintenance stages were combined for this behavior.³² Similar adaptations of the TTM staging structure have been used for other behaviors where the impossibility of relapse makes Maintenance less meaningful (e.g., organ donation).³³

The TTM includes several additional core constructs: Decisional Balance, Self-Efficacy, and Processes of Change. Decisional balance represents the relative weight of Pros (advantages of change) to Cons (disadvantages of change).³⁴ Research suggests that in the earlier stages of change, the Cons of making a behavior change are more salient than the Pros. As individuals progress in their readiness to change, a shift in the importance of Pros versus Cons occurs such that the Decisional Balance scale is tipped in favor of the Pros. Meta-analysis suggests that the timing of this crossover reliably occurs between the Contemplation and Preparation Stages of Change.^{35,36} Another core change-producing construct in the TTM is Self-Efficacy or confidence in one's ability to successfully change a target behavior across a range of tempting situations.³⁷ Investigations of Self-Efficacy suggest that scores are consistently higher in later Stages of Change.³⁸ Finally, the TTM identifies ten Processes of Change that are a set of overt and covert behaviors that research suggests are important in achieving and maintaining change. The processes are divided into five experiential processes, which are cognitive, affective and evaluative in nature and tend to be more important in the earlier Stages of Change. The five behavioral processes, which are more action-oriented, tend to be more

important in the later stages of change.^{27,39} Definitions of these ten processes are provided in Table 1.

Goals of the Current Study

The goal of this study was to test the acceptability and feasibility of an online TTM-tailored intervention designed to increase HPV vaccination initiation and completion among college-aged women. The current research addresses two important gaps in the literature on HPV vaccination. First, it targets low rates of vaccination uptake for an at-risk population, college-aged women. Second, it moves beyond educational interventions by incorporating important cognitive, affective, evaluative and behavior change strategies. Empirically-supported, population-based interventions applied to college-aged women could have a large public health effect.

METHODS

Sample

Participants were recruited between February and May of 2011. Recruitment occurred in two phases and data was aggregated for analyses. During both phases, only college-aged women (i.e., 18 to 26 years old) who had not received the full, three-shot vaccination series were eligible. All human subjects procedures were approved by the university's institutional review board.

In the first phase, female college students (n=78) were recruited from a variety of undergraduate psychology courses and given research credit for their participation. The opportunity to participate was made via an automatic e-mail via an online course portal. Research credit was awarded to individuals who completed the intervention.

In the second phase, additional female, college-aged participants (n=165) were recruited by a survey sampling company called Survey Sampling International (SSI).

The final, aggregate sample consisted of 243 college-aged women (age range 18-26, M=21.71, SD=2.57). Most of the sample was White (n=189, 77.8%), 11.5% were Black (n=28), 3.7% were Asian (n=9), and 7% fit into other racial categories (n=17). Eighty-four percent (n=203) of the sample identified as non-Hispanic. The sample included 21.8% freshmen (n=53), 17.3% sophomores (n=42), 19.8% juniors (n=48), 9.1% seniors (n=22), 4.5% fifth-year undergraduates (n=11), and 27.6% non-students (n=67). The Stage of Change distribution was 56.8% (n=138) Precontemplation, 23.5% (n=57) Contemplation, and 19.8% (n=48) Preparation.

Measures

Acceptability Questionnaire

A 14-item questionnaire was used to determine acceptability of the program. This questionnaire was based on the National Cancer Institute's Educational Materials Review Form⁴⁰ and the evaluation scale used by Rimer et al.⁴¹ Items were rated on a 4-point scale, ranging from 1 = "Strongly Disagree" to 4 = "Strongly Agree." The scale demonstrated excellent internal consistency ($\alpha=.95$).

Knowledge Questionnaire

A 13-item, questionnaire was used to determine participants' knowledge about HPV and HPV vaccination. Participants were presented with a statement (e.g., '*Condoms fully prevent against HPV transmission*'). Response options were 'true,' 'false,' or 'don't know.' Items for this scale were generated by authors based on both a literature review and discussions with two outside experts in the field of sexually transmitted infections.

These items were then refined and extended using 11 focus groups and 4 cognitive interviews with college-aged women.

Intervention

Intervention Development

Prior to intervention development, valid and reliable measures of key TTM constructs—Decisional Balance, Self-Efficacy, and Processes of Change—were developed using a sequential process (see Table 1 for definitions of these constructs and sample items). Items were developed and reviewed by experts in sexually transmitted diseases, infectious diseases, and the TTM. Exploratory and confirmatory analyses were conducted to test the measurement structures. Finally, external validity was evaluated by looking at the hypothesized relationships of key TTM constructs with Stage of Change (see Redding et al.³² for more description of measurement development).

Data collected from the measurement development sample was used as the normative sample, and therefore, provided a basis for tailoring intervention algorithms used in the computer-tailored intervention (CTI). CTIs involve alternating assessment and normative feedback on cognitive, affective, and behavioral processes to help the individual progress to the next Stage of Change. The intervention feedback is based on an individual's responses to each assessment. The goal is to boost the level of each stage-relevant construct (e.g., Pros, Self-Efficacy, Dramatic Relief, etc.) to levels commensurate with individuals in the next stage. Data from the measurement sample provided the reference for the normative use of each construct by stage. Cutoff scores were based on findings from this sample and determined whether the participant in the current intervention trial received feedback either encouraging more attention to a

particular construct or providing positive reinforcement for the participant's current level of effort.

Once measurement development was completed and decision rules were determined, intervention design began. This process involved acquiring and designing visual content (i.e., intervention screen templates and pictures) and writing feedback. The aim was for content to be appropriate for college-aged women with a high school education, of all racial, ethnic, and religious backgrounds and at varying degrees of readiness to get the HPV vaccination. Finally, the intervention was reviewed by experts in TTM as well as several women aged 18-26 (n = 5) for constructive feedback prior to testing.

Description of Intervention

Participants received alternating assessments and individualized feedback in five areas. First, participants were provided with information on their Stage of Change with regard to HPV vaccination. For example, a participant in Contemplation who had not started the vaccine series would receive the following feedback message: *“Thinking about protecting yourself from HPV by getting the vaccine is a great first step. This program will provide new information that can help you with your decision.”* Second, participants were asked a series of True/False “knowledge” questions about HPV and the HPV vaccine and received feedback regarding the accuracy of their responses. This was accompanied by informative text related to each question.

Third, participants received feedback on Pros and Cons of HPV vaccination. Feedback was based on their ratings of the Pros and Cons relative to the normative sample. For example, a participant who rated the Pros of the vaccine low relative to

others in the same Stage of Change was encouraged to consider other benefits of vaccination. Common “Pros” of vaccination were provided such as “The vaccine reduces my risk of getting genital warts and cervical cancer.” Participants were also asked to indicate what their *‘biggest reason for getting the HPV vaccine’* would be. Fourth, participants in the Contemplation and Preparation Stages received tailored feedback on their Confidence that they could achieve their goal of getting the vaccine series. They were given guidance on successful ways to cope with different situational barriers. Participants in Precontemplation did not received feedback on the ‘Confidence’ construct because they were not planning to receive the HPV vaccine in the near future. Finally, all participants received tailored feedback on stage- matched Processes of Change. Decisions on which Processes of Change to provide feedback on for each stage were made based on theory and also on data from our measurement development sample indicating which Processes were most frequently used by individuals in each stage. Feedback on processes consisted of praise for those using a given Process of Change and guidance on how to engage in Processes of Change not currently being used. For example, an individual in the Precontemplation stage who reported using less Consciousness Raising than other participants might receive the following feedback, *“Information about HPV vaccination and its health benefits are everywhere. Try to notice advertisements, information online and other messages about the HPV vaccine from credible sources. Being more aware of the benefits of the HPV vaccine will help you decide what is best for you. This program will help you get the facts you need.”*

Procedure

Interested participants accessed the program via the internet. After reading the consent form, participants could choose to continue with the program (indicating consent) or exit the program. Participants who chose to continue were linked to a set of the screening questions related to sex, age, and HPV vaccination status. At this point ineligible students were screened out. Upon completion of the intervention, participants completed an acceptability questionnaire. Data collected during the intervention and program evaluation questionnaire were entered into SPSS for analyses.

RESULTS

The distributions of responses for each item in the acceptability questionnaire are displayed in Table 2. Overall, participants rated the program favorably, with an average rating of 3.27 (out of 4.0) on every item. The majority of participants either ‘strongly agreed’ or ‘agreed’ that the program was useful (91.8%), could help them be healthier (92.1%), and could help them make changes (90.9%). Most participants ‘strongly agreed’ or ‘agreed’ that the program was easy to use (95.1%), the feedback was understandable (95.9%), and the program was easy to navigate (97.9%). Aesthetics of the program were also received particularly favorably with 95.9% of the participants indicating that they liked the way the program looked. Finally, most participants endorsed the statements that the program was designed for people like them (88.9%) and they would recommend the program to others (89.3%).

Demographic differences in the sum score of ratings of the acceptability questionnaire items were evaluated. ANOVAs determined whether evaluation scores were different across racial groups, ethnic groups and Stages of Change groups. No significant differences were observed between participants who identified as White and

those who identified as part of a racial minority group, $F(1, 243)=1.02$, $p = .31$, $\eta^2=.004$. Differences were observed between Hispanic and non-Hispanic participants, $F(1, 243)=5.75$, $p = .017$, $\eta^2=.02$, with Hispanic participants rating the program significantly more favorably ($M=3.59$, $SD = 0.50$) than non-Hispanic participants ($M = 3.37$, $SD = .05$). Significant differences were also observed across Stage of Change groups, $F(2, 243)=11.14$, $p = .000$, $\eta^2=.09$. Follow-up Tukey tests indicated that scores among participants in Precontemplation were significantly lower ($M = 3.27$, $SD = 0.6$) than those of individuals in either Contemplation ($M = 3.56$, $SD = 0.4$) or Preparation ($M = 3.61$, $SD = 0.4$).

Differences between stage, racial, and ethnic groups were also evaluated in terms of response accuracy on questions evaluating participant's knowledge about HPV and the HPV vaccine. No significant knowledge differences were observed across Stage groups, $F(2, 243)=0.35$, $p = .697$, $\eta^2=.003$ or ethnicity groups (Hispanic vs. Non-Hispanic), $F(1, 243)= .48$, $p = .49$, $\eta^2=.002$. Non-white participants, however, obtained significantly lower scores on the knowledge scale ($M = 2.11$, $SD = 1.04$) than white participants ($M = 2.46$, $SD = 1.07$; $F(1, 243)=4.50$, $p = .035$, $\eta^2=.018$).

COMMENT

This study supports the feasibility and acceptability of a computerized TTM-tailored intervention to increase HPV vaccination for college-aged women. Unvaccinated women, ages 18-26, were recruited to participate in this study. Mean ratings of 3.0 or greater on a 4-point scale with higher numbers indicating greater acceptability were set a priori as the cutoff for determining acceptability. The mean rating on questions

evaluating this program was 3.27, suggesting that this program was acceptable to participants in this study, and supporting a larger-scale evaluation of this program's effectiveness. The program was consistently rated acceptable by participants with different racial and ethnic backgrounds and in different stages of change. Results also provide qualitative support of program effectiveness insofar as over 90% of participants either 'strongly agreed' or 'agreed' that the program was useful, could help them be healthier, and could help them make changes. Analyses revealed lower scores on the acceptability items for women in the Precontemplation Stage of Change and those who identified as non-Hispanic. However, the mean scores for these groups were still high and above 3.0 (out of 4.0), indicating that even these groups had a positive opinion of the intervention overall. This is an important finding since most programs would not target these early stage groups.

The successful recruitment of participants on and off-campus as well as the low rate of partial-completion among eligible participants supports the feasibility of using a computer-tailored intervention to increase HPV vaccination in college-age women. These results suggest that such a program may be successfully implemented on college campuses as well as off campus among college-aged women who are not students. The program is population-based, and therefore, appropriate for use by all college-aged women who have not completed the three-shot HPV vaccine series. Additionally, this program's online delivery makes it easily accessible, increases consistent implementation, and reduces delivery costs.

The intervention evaluated in this study is based on theory that has been applied to and empirically-supported across a number of health risk behaviors. The TTM has

provided an effective framework for intervening on smoking, exercise, sun protection and medication adherence, to name a few.^{30, 43-45} Data on efficacy and mode of delivery of this and other TTM-based interventions suggests that these programs translate well across settings and populations. For example, bullying prevention and fruit and vegetable consumption interventions have produced strong outcomes at both the middle and high school levels.^{28, 46} TTM-based interventions have also been effectively disseminated via primary care practices and community health clinics.⁴⁷⁻⁴⁸ On college campuses, such a program may be delivered through university health care centers or as a component of freshman orientation. Off college campuses, such a program may be delivered via primary care practices or community health centers.

Limitations

This study has several limitations. First, two different sampling methodologies were used to allow for evaluation of acceptability and feasibility in young adult women who both attend college and who do not attend college. While, this sample was appropriate for this study, replication of these findings in more diverse samples, especially including males, would be important. Another study limitation was the absence of a post-intervention behavioral assessment of vaccination initiation, as well as a longer term follow-up assessments. One important next step will be to conduct a randomized controlled trial of the current intervention, with follow-ups that enable assessment of progress through the Stages of Change over time.

Conclusions

Results from this study contribute to the evidence base supporting use of computerized TTM-tailored interventions to address behavioral health issues in college-

aged samples. This finding is important because while CTIs provide both low cost and ease of dissemination, there is insufficient knowledge on their feasibility and acceptability in different populations. These findings support the acceptability and feasibility of a TTM-tailored, computerized intervention for HPV vaccine uptake for young adult women. Participants reported very positive evaluations and the majority of the sample reported that this intervention could help them make changes. Young adult women are at high risk for contracting HPV, but are often overlooked by the HPV vaccine intervention literature given the recommendations for early vaccination. The current research adds to a second wave of interventions for young adult women, which has the potential to bring the U.S. closer to full vaccine compliance. Women in the 18-26 age range have legal responsibility for healthcare decisions and are at high risk for contracting HPV. A TTM-tailored intervention provides a way to reach women at all Stages of Change, even among those who are not yet ready to get the vaccine (Precontemplation stage) to progress toward vaccination. Finally, this program was designed for low-cost implementation in a range of settings, including on college campuses, in primary care or clinic settings, requiring minimal staff time with a large potential benefit to women's health.

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