Introduction

Human papillomavirus (HPV) infections have the potential to cause multiple types of cancer (e.g., anal, oropharyngeal, and penile cancer) and genital warts among men. Gay, bisexual, and other men who have sex with men (GBMSM) experience a high burden of HPV infection and HPV-related disease. Around 60% of GBMSM in the United States (US) who are human immunodeficiency virus (HIV)-negative have a current genital HPV infection, and genital infection is even more common among those who are HIV-positive. In comparison, about 45% of all men in the US have a current genital HPV infection. Research suggests that similar disparities exist among GBMSM for anal HPV infection and the incidence of anal cancer. Although anal cancer is relatively uncommon in the US (about 1–2 cases per 100,000 person-years), a recent meta-analysis estimated the incidence of anal cancer to be about 20 cases per 100,000 person-years among HIV-negative GBMSM and about 85 cases per 100,000 person-years among HIV-positive GBMSM.

HPV vaccination can help address these disparities among GBMSM. The US Food and Drug Administration has approved HPV vaccine to prevent multiple HPV-related diseases, including anal cancer, oropharyngeal cancer, and genital warts among males. The Advisory Committee on Immunization Practices (ACIP) currently recommends routine HPV vaccination for male and female adolescents ages 11–12, with vaccination also recommended for all persons through age 26 who are not already adequately vaccinated. Recommendations state that adults ages 27–45 can engage in shared decision-making with their healthcare providers about HPV vaccination. The recommended HPV vaccine series consists of two doses if the series is started before a person turns age 15 and three doses if the series is started after age 15.

Many young gay, bisexual, and other men who have sex with men (YGBMSM) in the US who are in the recommended age range for routine HPV vaccination remain unvaccinated. Indeed, a systematic review found that only about 40% of YGBMSM in the US have initiated the HPV vaccine series. We therefore developed and pilot tested Outsmart HPV, a web-based HPV vaccination intervention for YGBMSM. Results of the pilot test were promising and suggested that the intervention may improve outcomes related to HPV vaccination.
We were, however, limited in our ability to draw firm conclusions about the intervention's effects due to the modest sample size of the pilot test.

To address this limitation, we conducted a large randomized controlled trial of Outsmart HPV. The current article reports how the intervention affected cognitive outcomes (i.e., knowledge, attitudes, and beliefs) related to HPV and HPV vaccine. Several cognitive outcomes have been identified as key correlates of HPV vaccine acceptability, uptake, and hesitancy among various populations, including GBMSM. However, research has shown that cognitive outcomes are often suboptimal among GBMSM (e.g., having low knowledge about HPV and HPV vaccine, low perceived vulnerability to HPV-related disease). Few HPV vaccination interventions have been developed for GBMSM in the US, and our findings will provide valuable data on how Outsmart HPV impacts cognitive antecedents to HPV vaccination. This information will be valuable in guiding future vaccination efforts to help reduce existing HPV-related disparities among GBMSM.

Materials and methods

Participants

The methods for this randomized controlled trial have been described in detail elsewhere and briefly here. We recruited a convenience sample of GBMSM in the US by advertising through multiple avenues, including social media sites (e.g., Facebook, Instagram, Grindr), existing research panels, and university-based health centers and organizations. Potential participants were linked to a mobile-friendly project website and asked to complete an online eligibility screener. Potential participants were eligible if they: (a) were cisgender male; (b) were 18–25 years of age; (c) either self-identified as gay, bisexual, or queer; reported ever having oral or anal sex with a male; or reported being sexually attracted to males; (d) lived in the US; (e) had not received any doses of HPV vaccine; and (f) did not participate in the pilot test of Outsmart HPV. All potential participants meeting these eligibility criteria were then asked to provide informed consent and create a project account.

Following consent and account creation, participants completed a pretest survey online and were then immediately randomized using a 1:1:1 allocation scheme to receive either: (a) Outsmart HPV content that included monthly unidirectional vaccination reminders (Out-U group); (b) Outsmart HPV content that included monthly interactive vaccination reminders (Out-I group); or (c) standard information about HPV vaccine (control group). Participants in all study groups next viewed content on the project website about HPV vaccine (either Outsmart HPV content or standard information, as described in detail below) and then completed a posttest survey online.

A total of 1,227 participants were randomized from October 2019 through June 2021 (Out-U group: n = 407; Out-I group: n = 408; control group: n = 412), with study activities paused from March–August 2020 due to the coronavirus disease 2019 (COVID-19) pandemic. Retention for the posttest survey was 90%. Participants received a $40 gift card for completing both the pretest and posttest survey. The Institutional Review Board at The Ohio State University approved this study.

Study materials

Intervention content. The Out-U and Out-I groups received the same population-targeted, individually-tailored Outsmart HPV content online. Outsmart HPV was developed using a framework that included aspects of the Protection Motivation Theory, Information-Motivation-Behavioral Skills Model, and the Minority Stress Model. The online content was presented in four sequential sections that contained infographics, other visual formats, and testimonials:

1. “Learn About HPV” provided population-targeted information about HPV prevalence, transmission, and HPV-related disease among GBMSM. Participants were asked to identify what they thought was the most important thing they learned about HPV.

2. “Learn About the Vaccine” provided information about HPV vaccine, including recommendations, dosing schedule, effectiveness, and safety. It included population-targeted information for GBMSM (e.g., vaccine acceptability among GBMSM, and participants also identified their motivations for wanting to get vaccinated.

3. “Get Answers” used a question-and-answer format to address common barriers and concerns about HPV vaccination among GBMSM. The project website used information from the pretest survey to individually-tailor this content (e.g., barriers and concerns indicated on the pretest survey were at the top of this section).

4. “Get Vaccinated” provided content about vaccination logistics, including resources for accessing HPV vaccine, information about vaccine cost and health insurance, and strategies for talking with a healthcare provider about getting vaccinated. Participants also identified potential questions they have for a healthcare provider. Participants were then prompted to create an individually-tailored “Action Plan” that included a goal date for getting their first dose, schedule for subsequent doses, and next steps for getting vaccinated. Participants could print or save a version of their “Action Plan” after completing the posttest survey.

The Out-U and Out-I groups both also received monthly vaccination reminders that addressed constructs from our theoretical framework and provided a cue to action. The first reminder was sent about a month after participants joined the study and continued on a monthly basis until study participation ended about nine months later. However, the two groups differed in the type of monthly reminders they received. The reminders sent to the Out-U group were text messages sent via an automated process and were unidirectional, meaning that participants did not have the option to respond. Unidirectional reminders contained only text and provided information about HPV and HPV vaccine.

Conversely, the reminders sent to the Out-I group were interactive, providing participants with the option to respond...
and/or ask questions to obtain additional tailored information and resources. Interactive reminders were text messages sent via an automated process, with additional communications sent manually by study team members if needed. Similar to the unidirectional reminders, the text of the interactive reminders provided information about HPV and HPV vaccine. Some interactive reminders also contained a meme or brief animation in Graphics Interchange Format (GIF).

Control content. Participants in the control group received standard information about HPV vaccine. This information was patterned heavily after the Vaccine Information Statement (VIS) for HPV vaccine that was created by the Centers for Disease Control and Prevention.\textsuperscript{39} We opted to use this content for the control group because healthcare providers are required to give a copy of the VIS to patients before vaccination and because the VIS provides information about HPV vaccine that is publicly available.

Measures

Cognitive outcomes. Using items drawn from existing measures and our past work,\textsuperscript{12,21,22,34,35} we assessed cognitive outcomes that represented constructs from the theoretical framework of Outsmart HPV. Pretest and posttest surveys included identical items for these outcomes. We assessed knowledge about HPV and HPV vaccine with 7 items that had response options of “yes,” “no,” and “I don’t know.” We coded responses to each item as “correct” or “incorrect.” We examined several attitudes and beliefs with Likert-type items that were coded so that higher values indicate greater levels of a given construct. Attitudes and beliefs about HPV infection and HPV-related disease included perceived vulnerability to HPV-related disease (3 items, $\alpha = 0.87$, possible range = 1–4); perceived severity of HPV-related disease (3 items, $\alpha = 0.82$, possible range = 1–4); worry about getting HPV-related disease (3 items, $\alpha = 0.83$, possible range = 1–4); perceived relative risk of an anal cancer among men who have sex with men (MSM) relative to other men (1 item, possible range = 1–5); and stigma associated with HPV infection (3 items, $\alpha = 0.81$, possible range = 1–5).

Attitudes and beliefs about HPV vaccination included response efficacy (i.e., perceived effectiveness) of HPV vaccine (2 items, $\alpha = 0.69$, possible range = 1–5); self-efficacy for the HPV vaccination process (2 items, $\alpha = 0.62$, possible range = 1–5); and intention to get HPV vaccine (1 item, possible range = 1–5). We examined three separate indicators of response costs (i.e., perceived barriers) of getting HPV vaccine that included if participants thought that: HPV vaccine might cause lasting health problems (1 item, possible range = 1–5); they do not have enough information to decide whether to get vaccinated (1 item, possible range = 1–5); and it would be difficult to find a healthcare provider where HPV vaccine is available (1 item, possible range = 1–5). Items regarding social norms examined if participants believed that most people who are important to them would support them getting HPV vaccine (1 item, possible range = 1–5) and if they believed that many YGBMSM are getting HPV vaccine (1 item, possible range = 1–5).

Demographics and health-related characteristics. The pretest survey assessed several demographic and health-related characteristics (Table 1). We examined participants’ disclosure of their sexual orientation to their healthcare provider, as well as concealment of their sexual orientation (3 items, $\alpha = 0.75$, possible range = 1–5).\textsuperscript{36} We also examined perceived discrimination in healthcare by asking participants about their perceived experience of receiving poor quality healthcare due to their sexual orientation (1 item, possible range = 1–5).\textsuperscript{37} Lastly, we assessed participants’ electronic health (e-health) literacy (4 items, $\alpha = 0.83$, possible range = 1–5).\textsuperscript{38}

Data analysis

We compared two analytic groups in analyses: (a) the intervention group (which combined the Out-U and Out-I groups); and (b) the control group. We combined the Out-U and Out-I groups into a single analytic group because participants in these groups received identical Outsmart HPV content between the pretest and posttest surveys, and both surveys occurred prior to any monthly vaccination reminders being sent. We first used descriptive statistics to examine participants’ demographic and health-related characteristics but, as suggested for randomized controlled trials,\textsuperscript{39} did not use statistical tests to compare analytic groups on these baseline characteristics.

We used mixed effects models applied to all-available data\textsuperscript{40} to determine if pre-post changes in cognitive outcomes differed between the intervention and control groups. These models adhere to the intent-to-treat principle when examining pre-post changes and have more statistical power and robustness than approaches that include only those participants with complete data.\textsuperscript{40} We examined each knowledge item, attitude, and belief as a separate dependent variable. Each model included an indicator of survey timepoint (pretest vs. posttest), study group (intervention vs. control), and an interaction term between these two variables. A statistically significant interaction term at $p = .05$ after Holm’s correction for multiple comparisons (as described below) indicated that pre-post changes for that dependent variable differed between the study groups. All models included an individual-level random effect to control for the correlation of outcomes from the same participant. Statistical tests were two-tailed, with Holm’s method\textsuperscript{41} used to control the overall type I error rate for multiple comparisons (7 comparisons total for knowledge items and 13 comparisons total for attitudes and beliefs). Analyses were performed with Stata version 15.0 (StataCorp, College Station, TX).

Results

Participant characteristics

Most participants self-identified as gay (66.4%), reported a history of oral or anal sex with a male (93.1%), and reported being sexually attracted to males (96.9%) (Table 1). A majority of participants were ages 22–25 (64.4%), identified as a racial/ethnic minority (52.8%), and had at least some college education (69.0%). Few participants indicated that they were HIV-positive (5.2%) or a history of genital warts (3.5%). Baseline characteristics were highly similar between the intervention and control groups.
Table 1. Participant characteristics by study group (n = 1,227).

| Demographic Characteristics | Intervention (n = 815) | Control (n = 412) |
|-----------------------------|------------------------|-------------------|
| Age (years)                 |                        |                   |
| 18–21                       | 295 (36.2)             | 142 (34.5)        |
| 22–25                       | 520 (63.8)             | 270 (65.5)        |
| Race / ethnicity            |                        |                   |
| Non-Hispanic white          | 391 (48.0)             | 188 (45.6)        |
| Non-Hispanic black          | 92 (11.3)              | 37 (9.0)          |
| Hispanic                    | 222 (27.2)             | 130 (31.6)        |
| Non-Hispanic other          | 110 (13.5)             | 57 (13.8)         |
| Relationship status         |                        |                   |
| Single and not having sex   | 105 (12.9)             | 65 (15.8)         |
| Single and having sex casually dating | 523 (64.2) | 270 (65.5) |
| In a relationship           | 187 (22.9)             | 77 (18.7)         |
| Education level             |                        |                   |
| High school or less         | 259 (31.8)             | 121 (29.4)        |
| Some college or more        | 556 (68.2)             | 291 (70.6)        |
| Employment status           |                        |                   |
| Employed full time or part time | 228 (28.0) | 121 (29.4) |
| Other                       | 587 (72.0)             | 291 (70.6)        |
| Sexual identity             |                        |                   |
| Gay                         | 540 (66.3)             | 275 (66.8)        |
| Bisexual                    | 212 (26.0)             | 105 (25.5)        |
| Something else              | 63 (7.7)               | 32 (7.8)          |
| Ever had sex with a man     |                        |                   |
| No                          | 48 (5.9)               | 37 (9.0)          |
| Yes                         | 767 (94.1)             | 375 (91.0)        |
| Sexually attracted to males |                        |                   |
| No                          | 27 (3.3)               | 11 (2.7)          |
| Yes                         | 788 (96.7)             | 401 (97.3)        |
| Region of residence         |                        |                   |
| Northeast                   | 151 (18.5)             | 77 (18.7)         |
| Midwest                     | 153 (18.8)             | 71 (17.2)         |
| South                       | 282 (34.7)             | 146 (35.4)        |
| West                        | 228 (28.0)             | 118 (28.6)        |
| Health-Related Characteristics|                       |                   |
| Health insurance            |                        |                   |
| Private insurance           | 509 (62.5)             | 259 (62.9)        |
| Public insurance            | 135 (16.6)             | 71 (17.2)         |
| None/don’t know             | 171 (21.0)             | 82 (19.9)         |
| Last preventive healthcare visit | 366 (44.9)   | 195 (47.3) |
| Within last year            |                         | 449 (55.1)        |
| More than a year ago        |                         | 217 (52.7)        |
| Ever talked with a healthcare provider about HPV vaccine | 698 (85.6) | 351 (85.2) |
| No                          |                         | 61 (14.8)         |
| Yes                         |                         |                   |
| Disclosure of sexual orientation to healthcare provider | 117 (14.4) | 391 (94.9) |
| Provider definitely knows   | 276 (33.9)             | 153 (32.8)        |
| Provider probably knows, might know, or definitely does not know | 539 (66.1)| 277 (67.2) |
| Concealment of sexual orientation, mean (SD)b | 2.63 (1.21) | 2.67 (1.20) |
| Perceived discrimination in healthcare, mean (SD)b | 2.38 (1.16) | 2.39 (1.21) |
| HIV status                  |                         |                   |
| Negative                    | 772 (94.7)             | 391 (94.9)        |
| Positive                    | 43 (5.3)               | 21 (5.1)          |
| Ever had genital warts      |                         |                   |
| No                          | 786 (96.4)             | 398 (96.6)        |
| Yes                         | 29 (3.6)               | 14 (3.4)          |
| Electronic health literacy, mean (SD)c | 3.95 (0.78) | 3.90 (0.75) |

Percentages may not total 100% due to rounding. HPV=human papillomavirus; SD=standard deviation; HIV=human immunodeficiency virus.

a 5-item scale; items had a 5-point response scale ranging from “never” to “always” (coded 1–5)
b 5-item with a 5-point response scale ranging from “strongly disagree” to “strongly agree” (coded 1–5)
c 4-item scale; items had a 5-point response scale ranging from “strongly disagree” to “strongly agree” (coded 1–5)

Knowledge

A majority of participants overall correctly responded on the pretest survey that HPV causes health problems for males (63.2%); you cannot always tell if someone has HPV (78.8%); HPV vaccine cannot protect you from other sexually transmitted infections, such as HIV (59.1%); HPV vaccine is recommended for all people who are ages 18–26 (66.2%); and HPV vaccine is recommended for all gay, bisexual, and men who have sex with men who are ages 18–26 (70.3%) (Table 2). Fewer participants correctly responded on the pretest survey that HPV is the most common sexually transmitted infection in the US (36.6%) and that HPV is the main cause of genital warts and anal cancer (38.5%).
As shown in Table 2, the intervention group had significantly larger pre-post increases in the percentage of participants who provided correct responses compared to the control group for: HPV causes health problems for males (pre-post increases: 19.9% (intervention) vs. 8.7% (control)); HPV is the most common sexually transmitted infection in the United States (pre-post increases: 40.5% vs. 14.8%); HPV is the main cause of genital warts and anal cancer (pre-post increases: 41.6% vs. 19.2%); HPV vaccine is recommended for all people who are ages 18–26 (pre-post increases: 22.1% vs. 12.1%); and HPV vaccine is recommended for all gay, bisexual, and men who have sex with men who are ages 18–26 (pre-post increases: 22.9% vs. 9.9%) (all statistically significant at p = .05 after Holm’s correction for multiple comparisons).

### Attitudes and beliefs

On the pretest survey, participants reported moderate levels of perceived vulnerability to HPV-related disease (mean = 2.38, standard deviation [SD] = 0.70); response efficacy of HPV vaccine (mean = 3.52, SD = 0.70); self-efficacy for the HPV vaccination process (mean = 3.97, SD = 0.76); intention to get HPV vaccine (mean = 3.33, SD = 0.94); and believing that they do not have enough information to decide whether or not to get vaccinated (mean = 3.38, SD = 1.19) (Table 3). Participants tended to perceive that HPV-related disease would be severe (mean = 3.50, SD = 0.69).

The intervention group had larger pre-post increases than the control group in the mean levels of the following attitudes and beliefs (Table 3): perceived vulnerability to HPV-related disease (pre-post increases: 0.19 (intervention) vs. 0.06 (control)); worry about getting HPV-related disease (pre-post increases: 0.73 vs. 0.51); perceived relative risk of anal cancer among MSM relative to other men (pre-post increases: 0.52 vs. 0.20); response efficacy of HPV vaccine (pre-post increases: 0.57 vs. 0.38); self-efficacy for the HPV vaccination process (pre-post increases: 0.23 vs. 0.10); intention to get HPV vaccine (pre-post increases: 0.70 vs. 0.28); and believing that many YGBMSM are getting HPV vaccine (pre-post increases: 0.53 vs. 0.30) (all statistically significant at p = .05 after Holm’s correction for multiple comparisons). The intervention group had a larger pre-post decrease in the mean level of participants believing that they do not have enough information to decide whether to get vaccinated (pre-post decreases: −0.93 vs. −0.66) (statistically significant at p = .05 after Holm’s correction for multiple comparisons).

### Discussion

Several HPV-related disparities exist among GBMSM,1,3,5,6 yet many YGBMSM in the US remain unvaccinated against HPV.10*Outsmart HPV* is one of the first theoretically-informed HPV vaccination interventions for YGBMSM with the potential for wide dissemination given its web-based format. Building upon a promising pilot test,11,12 the current study examined the effects of Outsmart HPV on cognitive outcomes among a large national sample of YGBMSM. Results show that the intervention, in comparison to a control group, resulted in larger improvements in most of the knowledge items, attitudes, and beliefs examined. Thus, these findings begin to establish an evidence base for Outsmart HPV being efficacious at improving key outcomes related to HPV vaccination.

Increasing knowledge about HPV and HPV vaccine is important, as knowledge is a key correlate of HPV vaccine acceptability and uptake.10 The intervention group that received Outsmart HPV content had larger – in some cases much larger – increases in knowledge about several aspects of HPV (i.e., who it affects, how common it is, diseases it can cause) and HPV vaccine (i.e., who the vaccine is recommended for) compared to the control group. Notably, these larger increases occurred when being compared to a strong control group that received information about HPV vaccine that was patterned heavily after the VIS.33 The larger increases in the intervention group may be due to Outsmart HPV content providing the information in a variety of formats, including some that were likely more engaging and user-friendly for participants (infographics, testimonials, etc.). Conversely, the control group information was provided predominantly in a text-only format, similar to the VIS.33 Past research has shown that presenting information in more visual and engaging formats can be a more effective approach in communicating health information and affecting outcomes,40,43 and our findings underscore the need to move beyond providing

### Table 2. Knowledge about HPV and HPV vaccine by study group (n = 1,227).

|                      | Intervention | Control |
|----------------------|--------------|---------|
|                      | Pre-test    | Post-test| Pre-test | Post-test |
|                      | (n = 815)   | (n = 722)| (n = 412) | (n = 379) |
| HPV causes health problems for males | 501 (61.5) | 588 (81.4) | 274 (66.5) | 285 (75.2) |
| HPV is the most common sexually transmitted infection in the United States | 295 (36.2) | 554 (76.7) | 154 (37.4) | 198 (52.2) |
| HPV is the main cause of genital warts and anal cancer | 299 (36.7) | 565 (78.3) | 173 (42.0) | 232 (61.2) |
| You can always tell if someone has HPV* | 633 (77.7) | 620 (85.9) | 334 (81.1) | 334 (88.1) |
| HPV vaccine can protect you from other sexually transmitted infections, such as HIV* | 487 (59.8) | 432 (59.8) | 238 (57.8) | 218 (57.5) |
| HPV vaccine is recommended for all people who are ages 18-26 | 542 (66.5) | 640 (88.6) | 270 (65.5) | 294 (77.6) |
| HPV vaccine is recommended for all gay, bisexual, and men who have sex with men who are ages 18-26 | 567 (69.6) | 668 (92.5) | 295 (71.6) | 309 (81.5) |

*p-values are for an interaction term between study group and survey timeline in a mixed effects model applied to all available data. HPV= human papillomavirus; HIV=human immunodeficiency virus.

Correct response was “no” for this item.
*Statistically significant at p = .05 after Holm’s correction for multiple comparisons.
Table 3. Attitudes and beliefs about HPV and HPV vaccine by study group (n = 1,227).

| Attitude / Belief                                                                 | Intervention Pre-test (n=815) | Intervention Post-test (n=722) | Control Pre-test (n=412) | Control Post-test (n=379) | p       |
|----------------------------------------------------------------------------------|-------------------------------|-------------------------------|--------------------------|----------------------------|---------|
| Perceived vulnerability to HPV-related diseasea                                  | 2.37 (0.70)                   | 2.56 (0.78)                   | 2.41 (0.69)              | 2.47 (0.74)              | 0.003*  |
| Perceived severity of HPV-related diseaseb                                       | 3.51 (0.68)                   | 3.51 (0.67)                   | 3.47 (0.71)              | 3.51 (0.65)              | 0.660   |
| Worry about getting HPV-related diseasec                                         | 1.90 (0.85)                   | 2.63 (0.93)                   | 1.97 (0.86)              | 2.48 (0.92)              | <0.001* |
| Perceived relative risk of anal cancer among men who have sex with men relative to other mend | 3.71 (0.96)                   | 4.23 (0.84)                   | 3.78 (0.90)              | 3.98 (0.90)              | <0.001* |
| Stigma associated with HPV infectione                                           | 3.87 (0.90)                   | 3.81 (1.02)                   | 3.81 (0.91)              | 3.85 (0.99)              | 0.047   |
| Response efficacy of HPV vaccinef                                                | 3.51 (0.71)                   | 4.08 (0.72)                   | 3.55 (0.69)              | 3.93 (0.76)              | <0.001* |
| Self-efficacy for the HPV vaccination processg                                   | 3.97 (0.77)                   | 4.20 (0.72)                   | 3.97 (0.73)              | 4.07 (0.79)              | 0.004*  |
| Intention to get HPV vaccined                                                   | 3.32 (0.94)                   | 4.02 (0.87)                   | 3.36 (0.93)              | 3.64 (0.94)              | <0.001* |
| Vaccine might cause lasting health problems (response cost)f                     | 2.78 (0.95)                   | 2.64 (1.20)                   | 2.75 (0.88)              | 2.60 (1.07)              | 0.680   |
| Do not have enough information to decide whether to get vaccinated (response cost)f | 3.40 (1.20)                   | 2.47 (1.20)                   | 3.34 (1.17)              | 2.68 (1.20)              | 0.003*  |
| It would be difficult to find a healthcare provider where HPV vaccine is affordable (response cost)f | 2.95 (1.12)                   | 2.66 (1.24)                   | 3.02 (1.08)              | 2.75 (1.19)              | 0.950   |
| People who are important to participants would support them getting HPV vaccine (social norm)g | 3.89 (0.94)                   | 4.08 (0.91)                   | 3.93 (0.91)              | 3.98 (0.93)              | 0.015   |
| Many young gay, bisexual, and other men who have sex with men are getting HPV vaccine (social norm)g | 3.15 (0.82)                   | 3.68 (0.93)                   | 3.15 (0.84)              | 3.45 (0.91)              | <0.001* |

Table reports the mean and standard deviation for each attitude and belief. Reported p-values are for an interaction term between study group and survey timepoint in a mixed effects model applied to all-available data.

SD = standard deviation; HPV = human papillomavirus.

*3-item scale; items had a 4-point response scale ranging from "no chance" to "high chance" (coded 1–4)

*3-item scale; items had a 4-point response scale ranging from "not at all" to "very" (coded 1–4)

*3-item scale; items had a 4-point response scale ranging from "not at all" to "a lot" (coded 1–4)

*1-item with a 5-point response scale ranging from "strongly disagree" to "strongly agree" (coded 1–5)

*3-item scale; items had a 5-point response scale ranging from "strongly disagree" to "strongly disagree" (coded 1–5)

*2-item scale; items had a 5-point response scale ranging from "strongly disagree" to "strongly agree" (coded 1–5)

*Statistically significant at p = .05 after Holm’s correction for multiple comparisons.
information about HPV vaccine in a text-only or text-heavy format and include more visual and engaging formats, when possible.

Outsmart HPV content also produced larger improvements in beliefs and attitudes about HPV and HPV vaccine, many of which are important determinants of HPV vaccine acceptability and uptake. The intervention’s larger effects on attitudes and beliefs may be attributed to the close alignment of content within each of the Outsmart HPV sections with our theoretical framework and its constructs. We developed Outsmart HPV content so that: (a) “Learn About HPV” and “Learn About the Vaccine” targeted perceived vulnerability, worry, perceived relative risk, social norms, response efficacy, and intention; (b) “Get Answers” targeted response efficacy, response costs, and intention; and (c) “Get Vaccinated” (including the individually-tailored “Action Plan”) targeted self-efficacy and intention. Importantly, to deliver this content, we used multifaceted strategies that can improve cognitive outcomes and health behaviors, including providing population-targeted and individually-tailored information, addressing barriers and concerns, and action planning. This helps reiterate the importance of including multiple components and strategies in interventions. Our study also provides further support for the use of theoretically-informed interventions for outcomes related to HPV vaccination. Specifically, our findings suggest the Protection Motivation Theory, which helped form the theoretical framework of our intervention, can be a useful theory in studying such outcomes among YGBMSM in the US, which aligns well with past studies examining use of this theory among other populations.

Overall, results of the current analyses concerning knowledge, attitudes, and beliefs begin to establish an evidence base on the efficacy of the Outsmart HPV intervention. Although these findings on cognitive outcomes are quite promising, it is important to continue to build the evidence base for this intervention by determining its effects on actual HPV vaccine uptake and to examine if cognitions mediate its effects on vaccine uptake. Such analyses will be conducted in the future as part of this randomized controlled trial. However, given the importance of cognitive outcomes as key antecedents to HPV vaccination, it is worthwhile and necessary to first understand the intervention’s effects on these more proximal outcomes. If the intervention is also shown to be efficacious in increasing HPV vaccine uptake in our future analyses, Outsmart HPV could then be utilized by clinical and other healthcare settings that provide services to YGBMSM. Indeed, Outsmart HPV has the potential to help optimize patient-provider interactions during clinical visits by providing population-targeted, individually-tailored content about HPV and HPV vaccine to YGBMSM and by priming them to talk with healthcare providers about vaccination. Given its web-based delivery, Outsmart HPV could be easily adapted by and disseminated across such settings.

Study strengths include a large national sample of YGBMSM, a randomized controlled trial design, and the inclusion of several cognitive outcomes. Our study also had some potential limitations. We recruited a convenience sample of participants mostly via social media and other online avenues, though about 99% of young adults in the US use the internet and over 80% use social media. With web-based research, there is a risk of fraudulent accounts, but as previously described, we used recommended strategies for minimizing this risk. Although there may be a chance for contamination in this study, we think it is unlikely since participants were from throughout the US, the project website required login, and participants received only the study materials for their randomized group. Lastly, future efforts involving Outsmart HPV should expand to also include transgender individuals.

Outsmart HPV is a web-based HPV vaccination intervention for YGBMSM that has the potential for wide dissemination. Findings from this randomized controlled trial indicate that the intervention improves key cognitive antecedents to HPV vaccination among YGBMSM, including knowledge, attitudes, and beliefs. Although it is important for future efforts to further determine the intervention’s effects on HPV vaccine uptake, the current results demonstrate the promise of Outsmart HPV as a tool that allows YGBMSM to learn about HPV vaccination and promotes vaccination.

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Trials registration
The trial is registered at ClinicalTrials.gov: NCT04032106 (available at: https://clinicaltrials.gov/ct2/show/NCT04032106).

References
1. Gillison ML, Chaturvedi AK, Lowy DR. HPV prophylactic vaccines and the potential prevention of noncervical cancers in both men and women. Cancer. 2008;113:3036–3046.
2. Lacey CJ, Lowndes CM, Shah KV. Chapter 4: burden and management of non-cancerous HPV-related conditions: HPV-6/11 disease. Vaccine. 2006;24:S3/35–41.
3. Smith S, Gilbert PA, Melendy A, Rana RK, Pimenta JM. Age-specific prevalence of human papillomavirus infection in males: a global review. J Adolesc Health. 2011;48:540–552.
4. Han JJ, Beltran TH, Song JW, Klaric J, Choi YS. Prevalence of genital human papillomavirus infection and human papillomavirus vaccination rates among US adult men: national health and nutrition examination survey (NHANES) 2013-2014. JAMA Oncol. 2017;3:810.
42. Garcia-Retamero R, Cokely ET. Communicating health risks with visual aids. Curr Dir Psychol Sci. 2013;22(5):392–399. doi:10.1177/0963721413491570.
43. Trevena LJ, Zikmund-Fisher BJ, Edwards A, Gaissmaier W, Galesic M, Han PK, King J, Lawson ML, Linder SK, Lipkus I, et al. Presenting quantitative information about decision outcomes: a risk communication primer for patient decision aid developers. BMC Med Inform Decis Mak. 2013;13(Suppl 2):S7-S7.
44. Rimer BK, Glassman B. Is there a use for tailored print communications in cancer risk communication? J Natl Cancer Inst Monogr. 1999;25:140–148.
45. Kreuter MW, Strecher VJ, Glassman B. One size does not fit all: the case for tailoring print materials. Ann Behav Med. 1999;21:276–283.
46. Timmerman GM. Addressing barriers to health promotion in underserved women. Fam Commun Health. 2007;30:34.
47. Malaguti A, Ciocanel O, Sani F, Dillon JF, Eriksen A, Power K. Effectiveness of the use of implementation intentions on reduction of substance use: a meta-analysis. Drug Alcohol Depend. 2020;214:108120.
48. Hagger MS, Luszczynska A. Implementation intention and action planning interventions in health contexts: state of the research and proposals for the way forward. Appl Psychol Health Well Being. 2014;6:1–47.
49. Smulian EA, Mitchell KR, Stokley S. Interventions to increase HPV vaccination coverage: a systematic review. Hum Vaccin Immunother. 2016;12:1566–1588.
50. Gainforth HL, Cao W, Latimer-Cheung AE. Determinants of human papillomavirus (HPV) vaccination intent among three Canadian target groups. J Cancer Educ. 2012;27:717–724.
51. Huang R, Wang Z, Yuan T, Nadarzynski T, Qian H-Z, Li P, Meng X, Wang G, Zhou Y, Luo D, et al. Using protection motivation theory to explain the intention to initiate human papillomavirus vaccination among men who have sex with men in China. Tumour Virus Res. 2021;12:200222.
52. Pew Research Center. Internet/broadband fact sheet; 2021. https://www.pewresearch.org/internet/fact-sheet/internet-broadband/.
53. Pew Research Center. Social media fact sheet; 2021. https://www.pewresearch.org/internet/fact-sheet/social-media/.
54. Teitcher JE, Bockting WO, Bauermeister JA, Hoefer CJ, Miner MH, Klitzman RL. Detecting, preventing, and responding to “fraudsters” in internet research: ethics and tradeoffs. J Law Med Ethics. 2015;43:116–133.