Bass, 2021

Bibliographic Reference	Bass, Michael; Gerend, Mary A.; Madkins, Krystal; Crosby, Shariell; Korpak, Aaron K.; Phillips, Gregory L.; Mustanski, Brian; Houlberg, Magda; Evaluation of a Text Messaging-Based Human Papillomavirus Vaccination Intervention for Young Sexual Minority Men: Results from a Pilot Randomized Controlled Trial; Annals of behavioral medicine : a publication of the Society of Behavioral Medicine; 2021; vol. 55 (no. 4); 321-332

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Clinical Trial Registration NCT02994108.
Study start date	Jan-2018
Study end date	Sep-2018
Aim	To test the acceptability, feasibility and preliminary efficacy of a text messaging-based HPV vaccination intervention for young sexual minority men.
Country/geographical location	Chicago, USA
Setting	Participants were recruited online and the intervention was delivered via text messaging
Inclusion criteria	- 18–25 years old - assigned male sex at birth and have a male gender identity - self-identify as gay, bisexual, or queer, be physically attracted to men, or ever have had sex with a man - able to read and understand English - live in the Chicago area and plan to live there for the next 9 months - exclusive owner of a cell phone - have used text messaging for at least 6 months

	- plan to have the same phone number for the next 9 months - have an unlimited text messaging plan - have not received any HPV vaccine doses
Exclusion criteria	None reported
Method of randomisation	1:1 allocation ratio but specific randomisation method not reported
Method of allocation concealment	Not reported
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	- A power analysis was conducted to estimate the required sample size based on two-sided α = .05, 20% attrition, and the hypothesis that 18%–21% of intervention arm versus 6%–8% of control arm participants would receive their first dose of HPV vaccine. The analysis indicated >80% power to detect hypothesized effects by enrolling 230 participants per arm. - Descriptive statistics were calculated for sample characteristics among participants in the intervention and control conditions. To assess whether randomisation was successful, t-tests and chi-square analyses were used to compare participants across conditions. - Intervention efficacy, as indicated by the receipt of ≥1 dose of HPV vaccine, was assessed with logistic regression for all participants who were randomised and did not withdraw from the study. - Analyses were conducted using SPSS (version 26; IBM Corp., Armonk, NY).
Attrition	1359 potential participants were screened for eligibility; 175 people were eligible (primary reasons for ineligibility included having already received 1 or more doses of HPV vaccination, being outside of the age range, or not living in the Chicago area). N = 150 were randomised to intervention (n=74) or control (n=76) groups. Trial retention was high and did not vary by condition at both the 3 week follow up (intervention = 93% 67/72; control = 96% 73/76) or the 9 month follow up (intervention = 88% 63/72; control = 91% 69/76).
Study limitations	- Null effects may have reflected the lack of statistical power as the study sample size was relatively small. - A relatively low number of participants completed the three-dose series during the relatively short follow-up period. Although the recommended dosing schedule specifies the receipt of three doses over a 6 month period, research indicates that a significant

	percentage of patients take longer to complete the series. Thus, because the series takes time to complete, the current study design did not allow for a sufficient evaluation of series completion - HPV vaccination was self-reported and it was not possible to verify all reported doses in the immunisation registry, although previous research suggests a relatively high accuracy of self-reported HPV vaccination among young adults. - Only one HIV-positive participant enrolled in the trial; thus, the extent to which the current findings generalise to HIV positive sexual minority men is unknown. - Participant recruitment was limited to the Chicago area so the sample may not be representative of young sexual minority men across the USA

Study arms

Intervention (N = 72)
Txt2protect: a text-messaging based HPV vaccination intervention based on the IMB model

Control (N = 76)
Attention control text messages

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 72)	Control (N = 76)
Age Mean (SD)	22.78 (2.03)	23.06 (2.39)
Sexual orientation		
Gay	n = 53 ; % = 74	n = 57 ; % = 75

Characteristic	Intervention (N = 72)	Control (N = 76)
Bisexual	n = 17 ; % = 24	n = 15 ; % = 20
Other (e.g. queer, pansexual)	n = 2 ; % = 3	n = 4 ; % = 5
Race / Ethnicity		
American Indian	n = 1	n = 1 ; % = 1
Asian	n = 4 ; % = 6	n = 7 ; % = 9
Black or African American	n = 13 ; % = 18	n = 18 ; % = 24
White	n = 42 ; % = 58	n = 38 ; % = 50
Multiracial	n = 3 ; % = 4	n = 5 ; % = 7
Unknown	n = 9 ; % = 13	n = 7 ; % = 9
Education		
Some high school / high school degree / GED	n = 23 ; % = 32	n = 19 ; % = 26
Some college or trade school certificate	n = 27 ; % = 37	n = 29 ; % = 39
College degree	n = 15 ; % = 21	n = 16 ; % = 21
Some graduate school / graduate degree	n = 7 ; % = 10	n = 11 ; % = 15
Latino		
Yes	n = 27 ; % = 38	n = 20 ; % = 26

Characteristic	Intervention (N = 72)	Control (N = 76)
No	n = 45 ; % = 62	n = 56 ; % = 74
Health insurance		
None	n = 11 ; % = 16	n = 10
Parents' insurance	n = 27 ; % = 38	n = 35 ; % = 47
Personal insurance	n = 33	n = 30 ; % = 40

Outcomes

Study timepoints

- 9 month

HPV vaccine uptake

Outcome	Intervention, 9 month, N = 72	Control, 9 month, N = 76
HPV vaccine initiation No of events	n = 14 ; % = 19.4	n = 5 ; % = 6.6
HPV vaccine completion No of events	n = 2 ; % = 2.8	n = 1 ; % = 1.3

HPV vaccine initiation - Polarity - Higher values are better
HPV vaccine completion - Polarity - Higher values are better

Study details

Rationale/theory/Goal	Current estimates indicate that although the HPV vaccine is specifically recommended for all MSM up to age 26, less than 40% have received one or more doses of the HPV vaccine. These low uptake rates coupled with the high disease burden of HPV-related disease point to the critical need for effective interventions to increase HPV vaccination uptake among young sexual minority men. Research demonstrating the keen interest of young MSM in the use of mobile technology for facilitating sexual health suggests mHealth interventions may be a particularly effective strategy for engaging young sexual minority populations in preventive health behaviour (p. 321-322).
Procedures used	- Participants were recruited via advertisements on social media sites (e.g. Facebook, Instagram and Twitter), online dating apps for MSM, and a local participant registry for sexual minority individuals interested in research. - Eligible participants received a text message with link to online consent form and baseline survey. - All participants received daily text messages for the first 3 weeks of the study (phase 1) then received monthly text messages for the remaining 8 months of the trial (phase 2) - In phase 1, participants received 10-12 messages per day, grouped into batches of 3-4 messages sent at 10am, 2pm and 6pm. In phase 2, participants received 5-8 messages on a given day once per month. - Participants completed follow-up surveys at 3 weeks and 9 months (p. 323)
Other details	Participants could earn up to $75 in gift cards for completing surveys (p. 323).

Study arms

Intervention (N = 72): Txt2protect: a text-messaging based HPV vaccination intervention based on the IMB model

Brief name	Txt2protect (p. 322)
Rationale/theory/Goal	The Information, Motivation, Behavioural Skills (IMB) model was used to guide intervention development, alongside extensive formative research with the target population and input from young sexual minority men on message content and delivery (p. 323)
Materials used	Text message software and a supporting website tailored to condition (p. 323)

Procedures used	- Intervention text messages followed the IMB model format; each week of phase 1 reflected a different IMB model component. - Week 1 messages covered information (e.g. information about the HPV vaccination, safety, efficacy and dosing; how and where to get first dose) - Week 2 messages covered motivation (e.g. overcoming perceived barriers such as HPV misinformation; norms for HPV vaccination; reasons other young MSM decided to get vaccinated) - Week 3 messages covered behavioural skills (e.g. vaccine cost and health insurance, list of clinics offering vaccination, search tool for local pharmacies, action plan for getting vaccinated) - Messages in phase 2 reinforced phase 1 content and encouraged continued program engagement - Intervention messages focused primarily on HPV-based content, but did also address other sexual health practices such as condom use, PrEP, and HIV testing - Text messages were supported with a website tailored to condition and included essential information about HPV and contact information for local clinics providing HPV vaccine (p. 323)
Intensity/duration of the intervention	During phase 1 (first 3 weeks), participants were sent 10-12 messages per day, grouped into 3 batches (3-4 messages, delivered at ~10am, 2pm and 6pm). During phase 2 (remaining 8 months), participants received between 5 and 8 messages on a given day, once per month (p. 322-323)
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Intervention exposure was assessed as number of texts read during phase 1: 1 = *almost none* to 6 = *all of them* (p. 323)

Actual treatment fidelity	Mean intervention exposure scores indicated that most participants had read 'almost all of the messages' (p. 327).

Control (N = 76): Attention control text messages

Materials used	Text message software and a supporting website tailored to condition (p. 323)
Procedures used	- Control participants received attention matched text messages addressing a variety of sexual health practices while providing only basic information on HPV vaccination. - In week 1, control participants received information about HIV/STI facts, prevalence, symptoms, transmission and treatments - In week 2, text messages contained information about prevention and testing, including condom use, PrEP, and STI and HIV testing - In week 3, text messages contained information about healthy relationships, communication, and meeting each others health, emotional and sexual needs (p. 323)
Intensity/duration of the intervention	During phase 1 (first 3 weeks), participants were sent 10-12 messages per day, grouped into 3 batches (3-4 messages, delivered at ~10am, 2pm and 6pm). During phase 2 (remaining 8 months), participants received between 5 and 8 messages on a given day, once per month (p. 322-323)
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported for control group
Actual treatment fidelity	Not reported for control group

Risk of Bias

Domain 1: Bias arising from the randomisation process

Risk of bias judgement for the randomisation process

Some concerns:

No information on allocation concealment but no baseline differences between groups

Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Risk of bias for deviations from the intended interventions (effect of assignment to intervention)

Low:

Participants were blinded and received automated text messages so deviations from intended intervention unlikely

Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)

Risk of bias judgement for deviations from the intended interventions (effect of adhering to intervention)

Low

Participants reported reading 'almost all of the messages' they received (although this was a self-reported outcome)

Domain 3. Bias due to missing outcome data

Risk-of-bias judgement for missing outcome data

Low:

Trial retention was high and did not vary by condition

Domain 4. Bias in measurement of the outcome

Risk-of-bias judgement for measurement of the outcome

Low:

Outcome assessment the same across groups and where possible, self-reported vaccine uptake was verified with clinic data

Domain 5. Bias in selection of the reported result

Risk-of-bias judgement for selection of the reported result

Low:

Analyses completed in line with those outlined in trial registry analysis plan

Overall bias

Risk of bias judgement

Some concerns: No information on allocation concealment

Reiter, 2018

Bibliographic Reference	Reiter, Paul L; Katz, Mira L; Bauermeister, Jose A; Shoben, Abigail B; Paskett, Electra D; McRee, Annie-Laurie; Increasing Human Papillomavirus Vaccination Among Young Gay and Bisexual Men: A Randomized Pilot Trial of the Outsmart HPV Intervention.; LGBT health; 2018; vol. 5 (no. 5); 325-329

Study details

Trial registration number	Trial is registered at Clinical Trials.gov: identifier NCT02835755
Study start date	July and September 2016
Aim	To pilot test a web-based human papillomavirus (HPV) vaccination intervention among young gay and bisexual men (YGBM)
Country/geographical location	Ohio, USA
Setting	Digitally (online) delivered survey
Inclusion criteria	Male, be aged 18–25 years, reside in the United States, self-identify as gay or bisexual, and not have received any HPV vaccine doses. Age 25, instead of age 26 was used as the study's upper age limit so that men did not ''age out'' of the recommended HPV vaccination age range during the study
Exclusion criteria	Not reported
Method of randomisation	Participants were randomised using a 1:1 allocation ratio to receive either intervention or control group materials
Method of allocation concealment	Not reported
Unit of allocation	Individual
Unit of analysis	Individual
Statistical method(s) used to analyse the data	Descriptive statistics to examine demographic and health-related characteristics. Logistic regression models were used to compare study groups on all outcomes and produce odds ratios (ORs) and 95%confidence intervals (CIs). All analyses were intent-to-treat and used two-tailed statistical tests with a critical alpha of 0.05. Authors categorised participants who did not complete follow up surveys as 'no' for all outcomes
Attrition	26% loss to follow up after 7 months
Study limitations	Small sample size and self-reported HPV vaccination data. However, authors claim that self-reported HPV vaccination data among young adults result in only a 2% net bias compared to medical records.

	Authors did not collect data on the type of healthcare provider or clinic where participants received the HPV vaccine, or whether participants were trans people. Participants were recruited through Facebook, which could limit generalizability of results, although participants in our study were demographically similar to YGBM from other national studies.

Study arms

Outsmart HPV intervention (N = 76)

The Outsmart HPV intervention was based on the protection-motivation theory and consisted of two components: (a) population-targeted, individually tailored content about HPV and HPV vaccine; and (b) monthly HPV vaccination reminders sent via email and/or text message.

The first component (a) had 4 sequential sections:

1. ‘‘Learn about HPV’’ provided targeted information about the prevalence and transmission of HPV and HPV-related disease among gay and bisexual men
2. ‘‘Learn about the Vaccine’’ provided information about HPV vaccine recommendations for YGBM and vaccine effectiveness, as well as individually tailored testimonials that illustrated reasons why men may decide to get vaccinated.
3. ‘‘Get Answers’’ provided information to address potential barriers and concerns about HPV and HPV vaccine using a question and answer format.
4. ‘‘Get Vaccinated’’ provided resources for accessing HPV vaccine (e.g., finding a healthcare provider and potential transportation options), information about vaccine cost and health insurance, and skills-building strategies for talking with a provider about the vaccine.

Control (N = 74)

The control group received standard information about HPV and the HPV vaccine, which was modelled after the Centres for Disease Control and Prevention: Vaccine information statements (VIS) for HPV vaccine

Characteristics

Study-level characteristics

	Study (N = 150)
Gender Male	150

Arm-level characteristics

	Outsmart HPV intervention (N = 76)	Control (N = 74)
Age		
18-21 years	n = 31; % = 41	n = 31; % = 42
22-25 years	n = 45; % = 59	n = 43; % = 58
Sexual orientation		
Bisexual	n = 14; % = 18	n = 12; % = 16
Gay	n = 62; % = 82	n = 62; % = 84
Ethnicity		
White	n = 44; % = 58	n = 41; % = 55
African American	n = 8; % = 11	n = 12; % = 16
Other race	n = 5; % = 7	n = 5; % = 7
Hispanic	n = 19; % = 25	n = 16; % = 22
Education level		
Some college or less	n = 49; % = 64	n = 45; % = 61
College degree or more	n = 27; % = 36	n = 29; % = 39
History of sexually transmitted infection (STI)		
No	n = 60; % = 79	n = 59; % = 80
Yes	n = 16; % = 21	n = 15; % = 20

Outcomes

Study timepoints	7 (month)

HPV vaccination uptake

	Outsmart HPV intervention	Control
	7 (month)	**7 (month)**
	N = 76	N = 74
HPV vaccine initiation	n = 34; % = 45	n = 19; % = 26
Odds ratio	OR 2.34 (1.18 to 4.67)	
Relative risk (calculated)	RR 1.74 (1.10 to 2.76)	
HPV vaccine completion	n = 8; % = 11	n = 2; % = 3
Odds ratio	OR 4.24 (0.87 to 20.66)	
Relative risk (calculated)	RR 3.89 (0.86 to17.74)	

Study details

Brief name	Increasing Human Papillomavirus (HPV) vaccination among young gay and bisexual men (YGBM)
Rationale/theory/Goal	To pilot test a web-based human papillomavirus (HPV) vaccination intervention among YGBM
Materials used	Paid Facebook advertisements to recruit participants. Advert was then linked to project website. Potential participants completed an eligibility screener. Online consent forms.
Procedures used	Intervention was mobile friendly and accessible by desktop, laptop, tablet computer or smartphone. After participants gave consent, they completed a survey. Additional follow-up surveys occurred 3 and 7 months later.
Provider	Not reported
Method of delivery	Digitally (online) delivered.
Setting/location of intervention	Ohio, USA
Intensity/duration of the intervention	Not reported
Tailoring/adaptation	Intervention tailored to YGBM
Unforeseen modifications	Not applicable
Planned treatment fidelity	Not applicable

Actual treatment fidelity	Not applicable
Other details	Authors used self-reported HPV vaccination data to examine vaccination outcomes (yes or no for each): HPV vaccine initiation (receipt of one or more doses) and completion (receipt of all three doses recommended for our study's age range). McRee, Annie-Laurie, Shoben, Abigail, Bauermeister, Jose A et al. (2018) Outsmart HPV: Acceptability and short-term effects of a web-based HPV vaccination intervention for young adult gay and bisexual men. Vaccine 36(52): 8158-8164 Authors received research grants from Merck Sharp & Dohme Corp. and Cervical Cancer-Free America, through an unrestricted educational grant from GlaxoSmithKline. Grants were not used to support the research study.

Risk of Bias

Domain 1: Bias arising from the randomisation process
Risk of bias judgement for the randomisation process Some concerns: no details on randomisation and allocation concealment
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)
Risk of bias for deviations from the intended interventions (effect of assignment to intervention) Low
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)
Risk of bias judgement for deviations from the intended interventions (effect of adhering to intervention) Low
Domain 3. Bias due to missing outcome data
Risk-of-bias judgement for missing outcome data Some concerns: Though intention-to-treat analysis was conducted, a 27% loss to follow up was reported.
Domain 4. Bias in measurement of the outcome
Risk-of-bias judgement for measurement of the outcome

Low
Domain 5. Bias in selection of the reported result
Risk-of-bias judgement for selection of the reported result Low
Overall bias
Risk of bias judgement Some concerns

Vet, 2014

Bibliographic Reference	Vet, Raymond; de Wit, John B F; Das, Enny; The role of implementation intention formation in promoting hepatitis B vaccination uptake among men who have sex with men.; International journal of STD & AIDS; 2014; vol. 25 (no. 2); 122-9

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Not reported
Aim	To assess the effects of, and associations between, intention strength, implementation intention formation and completeness of implementation intentions with respect to obtaining HBV vaccination among MSM. Authors hypothesized that MSM who form implementation intentions to obtain HBV vaccination will be more likely to attain this goal than MSM who do not form an implementation intention.
Country/geographical location	The Netherlands
Setting	Not reported

Inclusion criteria	(a) being male; (b) having had sex with a man in the previous year; (c) not being infected with HBV and (d) not having been vaccinated against HBV before
Exclusion criteria	(a) women; (b) men who only had sex with women; (c) men who were previously infected with HBV; (d) and men who were vaccinated against HBV
Method of randomisation	Not reported
Method of allocation concealment	Not reported
Unit of allocation	Individual
Unit of analysis	Individual
Statistical method(s) used to analyse the data	A randomization check was undertaken by conducting a multivariate logistic regression analysis with study condition as dependent variable and age, education and ethnicity as independent variables. To test for differences in attrition according to study condition, a multivariate logistic regression analysis was performed with respondents' provision of a valid code to identify HBV vaccination uptake from the vaccination registry as a dependent variable and age, education and ethnicity as independent variables. A logistic regression analysis was performed to examine the effect of the interaction between intention strength and implementation intention formation on vaccine uptake.
Attrition	51% attrition. Analysis conducted based participants with valid data linkage code. Authors claim attrition was not significantly affected by participants' characteristics. Attrition analysis found no significant differences between participants in the experimental and control groups or between men who did and did not provide a valid code for data linkage. This indicates the participants in the conditions were similar and that attrition was not selective.
Study limitations	A potential limitation of this study is the substantial drop out that occurred at different points in the data collection process. However, randomization check and attrition analysis found no significant differences between participants in the experimental and control groups or between men who did and did not provide a valid code for data linkage.

Study arms

Intervention (N = 161) Intervention group received instructions to promote the formation of implementation intentions on the uptake of hepatitis B vaccination (HBV). Instructions were: ''*You are about to make an appointment to obtain vaccination against HBV. A good intention! But often people do not act upon their good intentions. It can help*

if you record your intention now by making an agreement with yourself. Now, think about when, where and how to make an appointment for hepatitis B vaccination.''   Upon completion of the implementation intention formation, participants received information about their site of choice offering HBV vaccination.
Control (N = 455)   Participants in the control group were routed to a general information page providing contact details of Public Health Services offering HBV vaccination

Characteristics

Study-level characteristics

	Study (N = 616)
Age	Not reported
Gender	Male
Sexual orientation	Men who have sex with men
Ethnicity	Not reported
Education level	Not reported
History of sexually transmitted infection (STI)	Not reported

Outcomes

Vaccine uptake

	Intervention	**Control**
	Analysis data available for N = 99	Analysis data available for N = 201
MSM who obtained HBV vaccination by motivational information	n = 21; % = 21.2	n = 18; % = 9
Odds ratio	OR 2.74 (1.38 to 5.42)	
Relative risk (calculated)	RR 2.37 (1.32 to 4.24)	

Study details

Brief name	The role of implementation intention formation in promoting hepatitis B vaccination uptake among men who have sex with men
Rationale/theory/Goal	To assess the effects of, and associations between, intention strength, implementation intention formation and completeness of implementation intentions with respect to obtaining HBV vaccination among MSM.
Materials used	Survey asking if participants wanted to make an appointment for HBV vaccination. HBV vaccination uptake was determined from the HBV vaccination registry of the joint Public Health Services in the Netherlands
Procedures used	Participants were recruited online, via banners and other links placed on a variety of Dutch websites for MSM and routed to the newly developed website of the HBV vaccination project for MSM in the Netherlands, where they were asked to provide online informed consent. Of the men who completed this assessment, those who immediately wanted to make an appointment online were excluded from the full study and were instead directly routed to an online agenda to make an appointment for HBV vaccination to ensure that during the study period standard of care services would be provided through the website as much as possible
Provider	Not reported
Method of delivery	Online survey. Completeness of implementation intentions was rated and hepatitis B virus uptake was assessed through data linkage with the joint vaccination registry of the collaborating Public Health Services
Setting/location of intervention	The Netherlands
Intensity/duration of the intervention	Not reported
Tailoring/adaptation	Not reported
Unforeseen modifications	Not reported
Planned treatment fidelity	Not applicable
Actual treatment fidelity	Not applicable
Other details	Study was supported by a grant from the Netherlands Organization for Health Research and Development (ZonMw; grant number 23000032). Authors claim funder was not involved in the study design; the collection, analysis and interpretation of data; the writing of the report and the decision to submit this article for publication

Risk of Bias

Domain 1: Bias arising from the randomisation process

Risk of bias judgement for the randomisation process
Some concerns: no details on randomisation and allocation concealment
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)
Risk of bias for deviations from the intended interventions (effect of assignment to intervention)
Low
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)
Risk of bias judgement for deviations from the intended interventions (effect of adhering to intervention)
Low
Domain 3. Bias due to missing outcome data
Risk-of-bias judgement for missing outcome data
Low
Domain 4. Bias in measurement of the outcome
Risk-of-bias judgement for measurement of the outcome
Some concerns: outcome measurement was subjective scale. Not based on a validated measurement scale.
Domain 5. Bias in selection of the reported result
Risk-of-bias judgement for selection of the reported result
Low
Overall bias
Risk of bias judgement

Some concerns