HHS Public Access

Author manuscript

J Adolesc Health. Author manuscript; available in PMC 2017 July 01.

Published in final edited form as:

J Adolesc Health. 2016 July ; 59(1): 44–49. doi:10.1016/j.jadohealth.2016.03.020.

Ethical considerations in recruiting online and implementing a text messaging-based HIV prevention program with gay, bisexual, and queer adolescent males

Michele L. Ybarra, MPH, PhD[a,*], **Tonya L. Prescott, BA**[a], **Gregory L. Phillips II, MS, PhD**[b], **Jeffrey T. Parsons, PhD**[c], **Sheana S. Bull, PhD**[d], and **Brian Mustanski, PhD**[b]

[a]Center for Innovative Public Health Research, San Clemente, CA

[b]IMPACT Program, Northwestern University, Feinberg School of Medicine, Chicago, IL

[c]Center for HIV/AIDS Educational Studies and Training, Hunter College and the Graduate Center of the City University of New York, NYC, NY

[d]Department of Health and Behavioral Sciences, Colorado School of Public Health, University of Colorado at Denver, Denver, CO

Abstract

Purpose—There is a dearth of HIV prevention/healthy sexuality programs developed for adolescent gay and bisexual males (AGBM) as young as 14 years old, in part because of the myriad ethical concerns. To address this gap, we present our ethics-related experiences implementing Guy2Guy, a text messaging-based HIV prevention/healthy sexuality program, in a randomized controlled trial of 302 14- to 18-year-old sexual minority males.

Methods—Potential risks and efforts to reduce these risks are discussed within the framework of the Belmont Report: Respect for persons, beneficence (e.g., risks and benefits), and justice (e.g., fair distribution of benefits and burdens),

Results—To ensure Respect for Persons, online enrollment was coupled with telephone assent, which included assessing decisional capacity to assent. Beneficence was promoted by obtaining a waiver of parental permission and using a self-safety assessment to help youth evaluate their risk in taking part. Justice was supported through efforts to develop and test the program among those who would be most likely to use it if it were publicly available (e.g., youth who own a cell phone and are enrolled in an unlimited text messaging plan), along with the use of recruitment targets to ensure a racially, ethnically, and regionally diverse sample.

[*]Corresponding author: 555 N. El Camino Real #A347, San Clemente, CA 92672; (877)302-6858 x. 801; Michele@InnovativePublicHealth.com.

Conflicts of interest: The authors do not have any conflicts of interest to declare.

Conclusions—It is possible to safely implement a sensitive and HIV prevention/healthy sexuality program with sexual minority youth as young as 14 years old when a rigorous ethical protocol is in place.

Keywords

LGB; MSM; RCT; HIV prevention; gay; bisexual; queer; ethics; LGBT

Introduction

Technology is infused in youths' everyday lives [1], leading researchers to integrate technology into their work [2–5]. This presents unique ethical challenges, particularly in terms of equity (e.g., the "digital divide"), privacy and confidentiality (e.g., ensuring privacy in participants' study interactions), and ensuring truly informed assent [6]. Because youth are a group deemed by the Belmont Report to face diminished autonomy [7], attention to these issues is crucial.

Ethical issues also arise when conducting research with sexual minority youth. Their inclusion in sexual health research is critical given disparate HIV prevalence and incidence rates among sexual minority male teens [8, 9]. Indeed, AGBM have the highest incidence rate of HIV among all people at risk for HIV [8]. At the same time, because of stigma and discrimination, sexual minority youth may be harmed if research protocols create situations where they must disclose their sexual identity to their parents to gain permission to participate in research [10–16]. Potential harm also exists if youths' identities as participants in a study for sexual minority youth became public [11].

This study builds upon the growing literature examining ethical issues of youth-inclusive research by presenting ethics-related lessons learned in the implementation of Guy2Guy, a text messaging-based HIV prevention/healthy sexuality program for adolescent gay, bisexual, and/or queer males (AGBM). To our knowledge, this is the only HIV prevention/healthy sexuality program developed for AGBM as young as 14 years of age and is among the first comprehensive HIV prevention programs delivered via text messaging. As such, lessons learned can inform future efforts using text messaging to deliver sensitive topics to youth, as well as for HIV prevention research including sexual minority adolescents.

Intervention description

Guy2Guy is a text messaging-based HIV prevention and healthy sexuality program tailored to address unique concerns and considerations facing AGBM [20]. Based upon the Information-Motivation-Behavior model of HIV preventive behavior, content areas included: HIV information (e.g., what it is and how to prevent it), motivation (e.g., reasons why AGBM may choose to use condoms), and behavioral skills (e.g., how to put on a condom correctly) [21, 22]. Content also covered healthy and unhealthy relationships, coming out to parents and friends, and peer victimization. Participants were sent an average of 8 messages daily for about 7.5 weeks.

The study was reviewed and approved by the Chesapeake Institutional Review Board (IRB) and the Northwestern University IRB. A Certificate of Confidentiality was obtained from the National Institutes of Health. Youth provided informed assent (for those under 18 years old) or consent (for 18-year-olds).

The protocol and intervention components were tested for acceptability and feasibility using an iterative formative approach [20]. First, focus groups were conducted to understand how youth make sexual decisions and obtain feedback about study components (e.g., the Text Buddy concept, which has been used in previous text messaging programs [23, 24]). Next, content advisory teams reviewed messages for salience. A beta test was then implemented to test the randomized controlled trial (RCT) protocol and technology, followed by an RCT to pilot test the intervention against an attention-matched control group.

We discuss here our experiences implementing the finalized protocol in the RCT. Participants were recruited from all four regions of the U.S. (Table 1). Eligibility criteria included: being between 14 and 18 years old; male sex at birth and male gender identity; gay, bisexual, and/or queer sexual identity; and being English literate. Because Guy2Guy was a text messaging-based intervention, participants were required to: be exclusive owners of a cell phone, be enrolled in an unlimited text messaging plan, intend to keep the same phone number for the next six months, and have used text messaging in the past six months. Exclusion criteria included: knowing another person enrolled in the program and participating in another study development activity. Participants received up to $45 in Amazon.com incentives: $15 to complete the intervention-end survey and $20 (with an additional $10 to those who completed the survey within 48 hours of receiving the survey invitation) to complete the 3-month post intervention-end survey. The gift cards were emailed to participants.

Ethical Considerations

To guide the discussion, ethical considerations will be discussed within the context of the three key ethical components of the Belmont Report [7]: (a) respect for persons (i.e., respect people's autonomy and voluntariness and the need for added protections for people with reduced autonomy); (b) beneficence (i.e., "do not harm and maximize possible benefits and minimize possible harms"); and (c) justice (e.g., communities should not be excluded from the benefits of research) [7, 17, 18]. Alongside potential risks, we highlight how the protocol was designed to reduce these risks, similar to the structure presented in Bull et al.'s paper [19]

All study materials described herein are available online: http://innovativepublichealth.org/projects/guy-to-guy.

Respect for Persons

Obtaining informed assent with an online protocol—We chose to enroll youth via telephone to facilitate discussion of assent between potential participants and research staff. Youth were primarily recruited through Facebook advertisements containing links to the project website that described the RCT and included an online screener form. If responses to

the screener determined ineligibility, candidates received an email to the Centers for Disease Control and Prevention website about sexual minority health (http://www.cdc.gov/lgbthealth/). Candidates who appeared eligible or potentially eligible were sent a text by study staff to schedule an enrollment telephone call. Candidates who declined to speak on the phone were not eligible to participate in the study. Research staff spoke with 342 youth, of whom 328 individuals were eligible and were read the consent/assent form.

Obtaining informed assent from a group with diminished autonomy (i.e., children)—We followed procedures described by Mustanski [11]. Specifically, decisional capacity was demonstrated by the correct and clear response to four questions [10, 25–27]: (1) Name things you will be expected to do during the study; (2) Explain what you would do if you no longer wished to participate in the study; (3) Explain what you would do if you feel uncomfortable answering one of the questions; and (4) What are the possible risks for participating in the study? Youth were allowed to ask research staff to reread the assent/consent form if needed.

All youth passed the capacity to assent. Nonetheless, six youth declined participation: One discussed the study with his boyfriend and decided that participation was not in his best interest. Two declined participation at the self-safety assessment, described below. Two others did not have sufficient time, and the sixth decided he was not interested. That some youth actively chose not to participate during the assent process suggested the protocol to recruit online and assent over the telephone allowed for informed participation and agency to refuse participation.

Beneficence

Risks and benefits—We requested, and both IRBs granted, a waiver of parental permission because requiring parental permission could increase risk to participants who may be victimized as a result of disclosing their sexual minority status [11]. [For those wanting detailed assistance in applying for waivers of parental permission, please refer to Mustanski [11].] Even with the waiver, three candidates informed research staff that they had discussed the study with their parents prior to deciding whether to provide assent. Two of these candidates assented to participate. The third did not, as he and his parents did not feel he was at risk for HIV. In another incident, as a candidate was deciding whether or not to participate, his mother found the electronic assent form and called a staff member to express her concern about her son enrolling in a study without her knowledge. The staff member provided her with contact information for one of the principal investigators and the description of the study on ClinicalTrials.gov. We did not hear from her further and do not know whether her son ultimately enrolled in the study because we lacked information to determine whose mother had called. An additional candidate declined to participate because he thought joining the study without parental permission was “sketchy.”

Of the 302 enrolled youth, research staff learned of two instances when a child’s participation in the RCT was disclosed to his parents. One participant reported that his parent confiscated his phone upon learning about his participation, and he was forced to withdraw. Another participant’s parent contacted their cell phone carrier to block the

Guy2Guy program phone number from sending messages to their child during the fifth week of program messages. Although this participant did not receive the entire program, he nonetheless completed the follow-up surveys. If other incidents of parents discovering their child's participation occurred, they did not come to the attention of research staff.

Privacy and Confidentiality—As part of the assent/consent process, research staff led youth through a self-safety assessment created for this project (available online). The assessment had two components: (a) a Safety Appraisal (e.g., potential consequences if someone saw messages about sensitive topics on the participant's phone); and (b) a Privacy Assessment (e.g., who has access to the participant's phone; how to restrict access by enabling a password; how to delete cookies in an Internet browser after completing online surveys; how to determine if a text message tracker application is installed on the participant's phone).

"How-to" guides were written for youth who were concerned for their safety but felt it could be managed if they were given tools to increase security on their phone (e.g., how to create a password, how to disable pop-up previews of incoming text messages). If participants expressed doubt, research staff would respond:

> Based upon what we're talking about here, it seems like taking part in Guy2Guy right now might not be a safe decision for you. We can talk you through how to make your cell phone more private by putting a password on it. Even then, though, someone might demand the password from you. I'm concerned about your safety. What do you think?

If candidates felt their participation could potentially place them in an unsafe situation, they were thanked for their interest in the study and deemed ineligible. The candidate always made the final decision about participating. As noted above, two individuals declined to participate during the self-safety assessment: One candidate was not out to his parents and worried how they would react if they saw program messages on his phone; the other was concerned about how his boyfriend would react if he saw messages about sex on his phone. Two youth chose to enroll despite perceived risks and used their initials instead of full names to increase their privacy. Two additional individuals were unsure of how their parents would react, and while both were comfortable with enrolling in the program, one of these participants refused study incentives because he was concerned his parents would question the source of the income. Three youth mentioned that the consequences of their parents seeing the messages would be getting grounded, having their phone possibly confiscated, or being in an uncomfortable situation. All three were confident their parents did not have access to their phone, however, and therefore passed the self-safety assessment. These discussions with youth and their subsequent decisions, prompted by the self-safety assessment, suggests that the guide was useful in helping young people consider the potential safety implications of their involvement in the program.

Text Buddy Implementation—Based upon previous research [23, 24], the Text Buddy component paired intervention participants together to discuss what they were learning in the program. We posited the Text Buddies could provide an important source of social support for each other and allow them to practice study skills together. We were also

cognizant of potential risks that could arise, including: bullying, participants meeting to have sex, the encouragement of illegal behavior (e.g., substance use), and the self-disclosure of unhealthy romantic relationships (particularly those that would fit the definition of statutory rape and potentially place the research team in a position of mandated reporting), or disclosure of significant psychological distress.

Given potential risks, a multipronged safety approach was developed: Once randomized to the intervention group, participants received a text message that linked to a Text Buddy Code of Conduct [28]. The Code of Conduct explained how to use the feature and specified acceptable behavior between Buddies (e.g., being supportive and kind), unacceptable behavior (e.g., saying mean or nasty things; sending unwanted messages), and prohibited behavior (e.g., exchanging any type of contact information). Consequences of Code of Conduct infractions were also described. Participants were required to accept the Code before being assigned a Text Buddy; those who did not agree were not paired. Moreover, Buddies were purposefully paired by sexual experience (i.e., someone who had not had sex was paired with another person who had not had sex), time zone (so that they were sending messages no more than one hour apart from each other), and distance (at least 500 miles apart, when possible, to discourage meeting each other in person).

Text messages sent between Buddies were routed through the study server to protect participant confidentiality and allow research staff to monitor conversations and prevent the sharing of contact information. The software program flagged Text Buddy messages for words that indicated unhealthy or aggressive behaviors, attempts to share personally identifiable information (e.g., social networking handle), or attempts to meet in person. These words were queued for moderation by the research team before being delivered to the Buddy. At the beginning of the RCT implementation, we discovered how rapidly conversation topics could evolve and, in response, developed a protocol to monitor Text Buddy messages at least once every two hours between 8 AM–11 PM Eastern Standard Time each day that participants were active in the study.

All intervention group participants agreed to adhere to the Text Buddy Code of Conduct, except one participant who had issues with phone compatibility and never accessed the Code of Conduct. Nonetheless, nearly one-third (30%, $n = 23$) of Text Buddy pairs received at least one warning for an infraction of the Code, with three pairs being warned three times. In all cases, research staff reached out to the participant to reiterate the components of the Code of Conduct. The majority of infractions (29 pairs, six of whose infractions were not initially identified and therefore did not receive warnings) were of Buddies trying to exchange contact information. Twelve of these pairs were successful in circumventing the safeguards to share contact information. Eight Text Buddy pair conversations contained one-sided or reciprocated flirting, and three made references to meeting in person. All Buddy pairs who mentioned meeting each other lived approximately 1,000 miles apart or more, decreasing the feasibility of an in-person interaction. Other infractions included four Text Buddy pairs who attempted to exchange photographs, which were not sent as our service did not support picture text messages; and one participant who shared his mailing address so that his Buddy could send him a book. One participant told his Buddy that he was having sex with an adult

(someone in his twenties). This participant was 18 years of age, and so mandated reporting was not applicable.

Notably, positive and health-promoting messages were more common than unhealthy ones. For example, more than one-half (54%) of the pairs discussed intervention content, 27% shared their experiences coming out, and 8% discussed obtaining and using condoms. However, one in ten pairs (9%) talked about using alcohol and/or drugs, and one Buddy in each of three different pairs (4%) disclosed self-injury behaviors. Only one of these latter cases was current and necessitated assessment by a clinical psychologist. One of the participants whose Buddy mentioned self-injury requested a new Buddy.

Justice

To ensure fair distribution of benefits and burdens, steps were taken to help avoid enrolling AGBM who were easily recruited or financially motivated: Neither the recruitment advertisements nor the online recruitment screener mentioned the incentives to avoid enticement to fill out multiple screeners / enroll multiple times, or to lie about one's personal characteristics to be eligible for the program. Moreover, eligibility criteria were not clearly stated on the online screener, making it difficult for someone to guess the correct answers.

Equity—Certainly, when implementing a text messaging-based intervention relying on online recruitment methods, the digital divide must be considered. Data suggest it is diminishing: Among the 71% of teens who are on Facebook in the United States, youth of White, non-Hispanic (71%); Black-non-Hispanic (75%); and Hispanic (70%) race/ethnicity are equally likely to have a Facebook profile [1]. Among teens who own a cell phone, youth from lower income households (82%; <$30,000 annual income) are about as equally likely as youth from higher income households (93%; >$75,000 annual income) to use text messaging [1]. Thus, by using the most commonly used social networking site to recruit and the most common form of communication used by young people, we ensured equity in the recruitment and enrollment process.

As noted, among all people at risk for HIV, AGBM have the highest HIV incidence rate [8]. Because Guy2Guy was specifically developed for AGBM, advancements made in HIV prevention research should be provided to those who can benefit most from them. Moreover, the research involved persons from groups who are likely to benefit from subsequent applications of the research by mirroring those who would opt-in if the intervention were publicly available (i.e., those who owned their own cell phone and enrolled in an unlimited text messaging plan). We believe this is noteworthy, as some research protocols provide cell phones to participants or require them to undergo intensive training to use the technology. However, sustainability of these types of actions in the "real world" may be limited.

Inclusion of women, minorities, and children in research—To ensure a diverse sample, recruitment targets were identified based upon sexual experience, race, ethnicity, age, and urbanicity (Table 2). Youth who appeared eligible were contacted sequentially until their particular recruitment "bin" (e.g., sexually experienced, non-Hispanic Black, 14 to 15 years old, living in a rural area) was full. To reach our recruitment goals, Facebook ads were targeted based on location (i.e., United States), sex (i.e., male), age (i.e., between 14–18

years old), and attraction as indicated in their profile (i.e., “interested in men”; “interested in men and women”). Advertising targets were modified based on recruitment goal needs (e.g., to reach more 14-year-olds).

In addition to ensuring a racially diverse sample, we believe it is ethically imperative to include an age-diverse sample, particularly for HIV-related research for AGBM populations. Several studies have shown that one of the strongest predictors of current condom use is whether a condom was used at first sex [29–33]. Thus, HIV prevention programs that target only those who are having sex or only those who are having risky sex are not addressing the epidemiological imperative of giving youth who have not yet had sex the skills and motivation they need to never start risky behaviors (i.e., to only have healthy sex). Guy2Guy included youth as young as 14 and purposefully balanced half the sample to include participants who had never had anal or vaginal sex. Although this diminished our power to detect significant differences in condom use over time, we believed the potential public health impact was of greater importance.

Discussion

Similar to previous research [19], our findings highlight the importance of paying special attention to potential risks posed by the integration of technology into research, especially in terms of obtaining truly informed assent/consent, protecting confidentiality, and promoting security. Lessons learned in implementing Guy2Guy provide further empirical evidence that HIV prevention/healthy sexuality programs can be safely implemented with sexual minority youth. For the first time, this is demonstrated with youth as young as 14 years of age. We second Mustanski’s call for IRBs to rely on evidence-based processes rather than subjective criteria when evaluating protocols involving children [11].

We also want to emphasize the benefits of empowering youth to determine for themselves their own safety in participating. Given that sexual minority youth appraise their safety on a daily basis (e.g., in school hallways), this protocol simply acknowledges their reality and helps youth expand their appraisal skills to research participation.

The ethical importance of waivers of parental permission in studies like this cannot be understated. It is notable that even with this waiver, some youth chose to tell their parents about the study. A very small number of problems resulted, including those resulting from parental intervention. Some AGBM may underestimate parental concerns regarding participation in interventions focused on sexual behavior, and continued efforts to obtain such waivers in future trials is warranted.

Limitations

Recommendations that emerged from this work with AGBM may not generalize to other populations. For example, youth who have indicated in their profile that they are interested in men and respond to online recruitment approaches targeted to youth are unlikely to be representative of the larger AGBM population. Moreover, it is possible that concerning incidents occurred that did not come to the attention of research staff. Our high follow-up

rates (92% completed the 3-month follow-up assessment) provide reason for optimism that this was uncommon.

Conclusion

Youth-inclusive research is less common than adult research due to issues related to obtaining parental permission and ensuring youths' safety. Our experiences in the Guy2Guy RCT demonstrate that it is possible to safely implement a sensitive and sexual identity-explicit intervention with people as young as 14 years of age if a rigorous ethical protocol is in place.

Acknowledgments

The project described is supported by Award Number R01 MH096660 from the National Institute of Mental Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Mental Health. We would like to thank the entire study team at the Center for Innovative Public Health Research and the IMPACT Program at Northwestern University for their contributions to the research and the participants for their time in the study.

Abbreviations

AGBM	adolescent gay, bisexual, and queer males
HIV	human immunodeficiency virus
IRB	institutional review board
RCT	randomized controlled trial

References

1. Lenhart, A. Teens, social media, & technology overview 2015. Available at: http://www.pewinternet.org/2015/04/09/teens-social-media-technology-2015/. [Accessed March 1, 2016]
2. Seko Y, Kidd S, Wiljer D, et al. Youth mental health interventions via mobile phones: a scoping review. Cyberpsychol Behav Soc Netw. 2014; 17:591–602. [PubMed: 25007383]
3. Sharkey S, Jones R, Smithson J, et al. Ethical practice in internet research involving vulnerable people: Lessons from a self-harm discussion forum study (SharpTalk). J Med Ethics. 2011; 37:752–758. [PubMed: 21947802]
4. Allison S, Bauermeister JA, Bull S, et al. The intersection of youth, technology, and new media with sexual health: Moving the research agenda forward. J Adolesc Health. 2012; 51:207–212. [PubMed: 22921129]
5. Muessig KE, Nekkanti M, Bauermeister J, et al. A systematic review of recent smartphone, Internet and Web 2.0 interventions to address the HIV continuum of care. Curr HIV/AIDS Rep. 2015; 12:173–190. [PubMed: 25626718]
6. Drotar D. Contemporary directions in research ethics in pediatric psychology: Introduction to the special section. J Pediatr Psychol. 2011; 36:1063–1070. [PubMed: 21933810]
7. Department of Health Education and Welfare. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research; 1979. Report No: (OS) 78–0012.
8. Centers for Disease Control and Prevention. HIV Surveillance in Adolescents and Young Adults. Available at: http://www.cdc.gov/hiv/pdf/statistics_surveillance_Adolescents.pdf. [Accessed March 1, 2016]
9. Mustanski BS, Newcomb ME, Du Bois SN, et al. HIV in young men who have sex with men: A review of epidemiology, risk and protective factors, and interventions. J Sex Res. 2011; 48:218–253. [PubMed: 21409715]

10. Mustanski B, Newcomb M, Garofalo R. Mental health of lesbian, gay, and bisexual youth: A developmental resiliency perspective. J Gay Lesbian Soc Serv. 2011; 23:204–225. [PubMed: 21731405]
11. Mustanski B. Ethical and regulatory issues with conducting sexuality research with LGBT adolescents: A call to action for a scientifically informed approach. Arch Sex Behav. 2011; 40:673–686. [PubMed: 21528402]
12. Carnelley KB, Hepper EG, Hicks C, et al. Perceived parental reactions to coming out, attachment, and romantic relationship views. Attach Hum Dev. 2011; 13:217–236. [PubMed: 21506028]
13. Rothman EF, Sullivan M, Keyes S, et al. Parents' supportive reactions to sexual orientation disclosure associated with better health: Results from a population-based survey of LGB adults in Massachusetts. J Homosex. 2012; 59:186–200. [PubMed: 22335417]
14. Ryan C, Huebner D, Diaz RM, et al. Family rejection as a predictor of negative health outcomes in white and Latino lesbian, gay, and bisexual young adults. Pediatrics. 2009; 123:346–352. [PubMed: 19117902]
15. White D, Stephenson R. Identity formation, outness, and sexual risk among gay and bisexual men. Am J Mens Health. 2014; 8:98–109. [PubMed: 23690365]
16. Fisher CB, Mustanski B. Reducing health disparities and enhancing the responsible conduct of research involving LGBT youth. Hastings Cent Rep. 2014; 44:S28–31. [PubMed: 25231783]
17. Rogers A, D'Angelo L, Futterman D. Guidelines for adolescent participation in research: Current realities and possible resolutions. IRB. 1994; 16:1–6. [PubMed: 11654135]
18. Santelli JS, Rogers AS, Rosenfeld WD, et al. Guidelines for adolescent health research. A position paper of the Society for Adolescent Medicine. J Adolesc Health. 2003; 33:396–409. [PubMed: 14596961]
19. Bull SS, Breslin LT, Wright EE, et al. Case study: An ethics case study of HIV prevention research on Facebook: the Just/Us study. J Pediatr Psychol. 2011; 36:1082–1092. [PubMed: 21292724]
20. Ybarra ML, Prescott TL, Phillips GL, et al. Iteratively developing an mHealth HIV prevention program for sexual minority adolescent men. AIDS Behav. 2015
21. Fisher, JD.; Fisher, WA. Theoretical approaches to individual-level change in HIV risk behavior. In: Peterson, JL.; DiClemente, RJ., editors. Handbook of HIV Prevention. New York, NY: Kluwer Academic/Plenum Press; 2000. p. 3-55.
22. Fisher JD, Fisher WA. Changing AIDS-risk behavior. Psychol Bull. 1992; 111:455–474. [PubMed: 1594721]
23. Rodgers A, Corbett T, Bramley D, et al. Do u smoke after txt? Results of a randomised trial of smoking cessation using mobile phone text messaging. Tob Control. 2005; 14:255–261. [PubMed: 16046689]
24. Ybarra ML, Holtrop JS, Prescott TL, et al. Pilot RCT results of Stop My Smoking USA: A text messaging-based smoking cessation program for young adults. Nicotine Tob Res. 2013; 15:1388–1399. [PubMed: 23348969]
25. Dunn LB, Jeste DV. Enhancing informed consent for research and treatment. Neuropsychopharmacology. 2001; 24:595–607. [PubMed: 11331139]
26. Moser DJ, Schultz SK, Arndt S, et al. Capacity to provide informed consent for participation in schizophrenia and HIV research. Am J Psychiatry. 2002; 159:1201–1207. [PubMed: 12091200]
27. The University of California at San Diego Task Force on Decisional Capacity. Procedures for Determination of Decisional Capacity in Persons Participating in Research Protocols. San Diego: The University of California; 2003.
28. Center for Innovative Public Health Research, IMPACT Program. Text Buddy Code of Conduct. Available at: https://innovativepublichealth.org/wp-content/uploads/2013/09/Guy2Guy-Phase-3.-Beta-test-Text-Buddy-Code-of-Conduct.pdf. [Accessed March 1, 2016]
29. Shafii T, Stovel K, Davis R, et al. Is condom use habit forming?: Condom use at sexual debut and subsequent condom use. Sex Transm Dis. 2004; 31:366–372. [PubMed: 15167648]
30. Robertson A, Levin ML. AIDS knowledge, condom attitudes, and risk-taking sexual behavior of substance-abusing juvenile offenders on probation or parole. AIDS Educ Prev. 1999; 11:450–461. [PubMed: 10555628]

31. Lawrence JS, Scott CP. Examination of the relationship between African American adolescents' condom use at sexual onset and later sexual behavior: Implications for condom distribution programs. AIDS Educ Prev. 1996; 8:258–266. [PubMed: 8806954]

32. Hendriksen ES, Pettifor A, Lee SJ, et al. Predictors of condom use among young adults in South Africa: The Reproductive Health and HIV Research Unit National Youth Survey. Am J Public Health. 2007; 97:1241–1248. [PubMed: 17538062]

33. Shafii T, Stovel K, Holmes K. Association between condom use at sexual debut and subsequent sexual trajectories: A longitudinal study using biomarkers. Am J Public Health. 2007; 97:1090–1095. [PubMed: 17463388]

34. NIH Office of Extramural Research. Protecting Human Research Participants. Available at: https://phrp.nihtraining.com/users/login.php. [Accessed March 1, 2016]

35. Hadden, L.; Zdeb, M. A well-kept SAS® secret. 31st Annual SAS® Users Groups International Conference (SUGI 31); San Francisco, CA. 2006;

Implications and Contributions

Youth-inclusive research is less common than adult research because of ethical concerns (e.g., parental permission). When a rigorous ethical protocol is in place, our experiences demonstrate that it is possible to safely implement a sensitive and sexual identity-explicit intervention with sexual minority youth as young as 14 years of age.

Table 1

Potential Ethical Issues and How Guy2Guy Addressed Them.

Belmont Report components		**Potential ethical issue**	**How Guy2Guy addressed them**
Respect for Persons		Obtaining informed assent with an online recruitment protocol	Enrollment occurred over the phone so that research staff could gauge whether the participant understood the assent.
		Obtaining informed assent from a group with diminished autonomy (i.e., children)	The assent form was written in easy-to-understand language, and the capacity to consent ensured that all children who enrolled understood the risks and voluntariness.
Beneficence	Risks and benefits	Requiring parental permission can potentially harm sexual minority youth, due to discrimination and stigma	We requested and were granted a waiver of parental permission by both IRBs involved in the study.
	Privacy and confidentiality	If youths' phones are lost or intercepted, the text messages on the phone could result in a loss of confidentiality of their sexual identity	We created a self-safety assessment to help youth determine whether they could take part in the study safely. We also provided how-to instructions to help youth change the settings on their phone to increase their privacy (e.g., adding a password).
Justice	Fair distribution of benefits and burdens	The choice of participants needs to be considered carefully to ensure that groups are not selected for inclusion mainly because of easy availability, compromised position, or manipulability	Although we used Facebook as our main recruitment source, which means we attracted youth who were easily available and perhaps manipulable (e.g., they clicked on our advertisement), we developed a complex and rigorous safety protocol.
		Equity: The digital divide may mean that those who are least likely to have access to HIV prevention programming designed for AGBM are also least likely to be in the recruitment pool	We used Facebook, the most popular social network among adolescents, to increase the likelihood of reaching a wide pool of AGBM.
		When research leads to the development of new treatments, procedures, or devices, justice demands both that: • These advancements are provided to those who can benefit from them, and • The research should involve persons from groups who are likely to benefit from subsequent applications of the research	Our hypothesis is that text messaging represents an opportunity to put sexual health and HIV prevention programming in the hands of youth. As such, we thought it important to develop and test the program among those most likely to take part in a similar program in the “real world”: those who currently own their own phone, use text messaging, and are enrolled in an unlimited text messaging plan.
	Inclusion of women, minorities, and children in research	Ensuring a racially diverse sample, particularly the inclusion of Black and African American males given the epidemiology of HIV in the U.S.	The enrollment algorithm also set targets based upon race and ethnicity.
		The need to include youth under 16 years old, which has been the youngest age group included in YMSM intervention studies to date	We included participants as young as 14 years old, and our enrollment algorithm ensured that 14- to 15-year-olds represented 40% of the study sample.

The descriptions of Belmont Report components and the potential ethical issues were based upon those presented in the NIH online human subjects research course [34].

Table 2

Demographics of Screened and Enrolled Participants.

Demographic characteristics	Phone Contact[a] (*n* = 345)	Phone Eligible (*n* = 329)	Consented/ Assented (*n* = 323)	Randomized (*n* = 302)
	***n* (%)**	***n* (%)**	***n* (%)**	***n* (%)**
Race				
Black	42 (12.1)	39 (11.9)	39 (12.1)	38 (12.6)
White	209 (60.6)	204 (60.4)	193 (59.7)	181 (59.9)
Asian	9 (2.6)	9 (2.7)	9 (2.8)	9 (3.0)
Native Hawaiian	4 (1.2)	4 (1.2)	4 (1.2)	4 (1.3)
Native American/Alaska Native	8 (2.3)	7 (2.1)	7 (2.2)	6 (2.0)
Other	73 (21.2)	71 (21.6)	71 (22.0)	64 (21.2)
Ethnicity				
Hispanic	82 (23.8)	85 (25.8)	83 (25.7)	71 (23.5)
Non-Hispanic	274 (73.6)	241 (73.2)	240 (74.3)	223 (73.8)
Age				
14–15 years	131 (38.0)	129 (39.2)	125 (38.6)	115 (38.1)
16–18 years	214 (62.0)	205 (62.3)	198 (61.3)	187 (61.9)
Sexual identity[b]				
Gay/lesbian	253 (73.3)	244 (74.2)	234 (72.4)	221 (73.2)
Bisexual	131 (38.0)	130 (39.5)	125 (38.6)	114 (37.7)
Queer	27 (7.8)	26 (7.9)	26 (8.0)	25 (8.3)
Heterosexual/Straight	4 (1.2)	4 (1.2)	4 (1.2)	4 (1.3)
Other	44 (12.8)	52 (15.8)	50 (15.5)	41 (13.6)
Residence[c]				
Rural	81 (23.5)	77 (23.4)	76 (23.5)	68 (22.5)
Urban	258 (74.8)	252 (76.6)	242 (74.9)	231 (76.5)
Region[d]				
Northeast	52 (15.1)	49 (14.9)	47 (14.6)	46 (15.2)
South	112 (32.5)	109 (33.1)	105 (32.5)	100 (33.1)
Midwest	87 (25.2)	83 (25.2)	82 (25.4)	73 (24.2)
West	94 (27.2)	93 (28.3)	89 (27.6)	83 (27.5)
Sexually experienced				
Yes	168 (48.7)	157 (47.7)	152 (47.1)	139 (46.0)
No	177 (51.3)	172 (52.4)	171 (52.9)	163 (54.0)

Note. All data are from online screener responses.

[a] Phone contact refers to those whom staff verbally spoke with on the phone.

[b] Multiple selections allowed.

[c] Rural versus urban residence was based upon the participants' Metropolitan Statistical Area [35] as determined by the ZIP code they provided at enrollment

[d] Region was determined based on the participant's self-reported ZIP code.