Ethical Considerations in Recruiting Online and Implementing a Text Messaging–Based HIV Prevention Program With Gay, Bisexual, and Queer Adolescent Males

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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.

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.

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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, adolescent gay and bisexual males (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 on 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 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 and 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 [17]. Based on 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) [18,19]. Content also covered healthy and unhealthy relationships, coming out to parents and friends, and peer victimization. Participants were sent an average of eight messages daily for about 7.5 weeks.

The study was reviewed and approved by the Chesapeake Institutional Review Board and the Northwestern University Institutional Review Board. 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 [17]. First, focus groups were conducted to understand how youth make sexual decisions and to obtain feedback about study components (e.g., the Text Buddy concept, which has been used in previous text messaging programs [20,21]). Next, content advisory teams reviewed messages for salience. A β 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 United States (Table 1). Eligibility criteria included being aged between 14 and 18 years; 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 6 months, and have used text messaging in the past 6 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 gift cards as incentives: $15 to complete the intervention-end survey and $20 to complete the 3-month post-intervention end survey (with an additional $10 to those who completed the survey within 48 hours of receiving the survey invitation). The gift cards were e-mailed 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]: (1) respect for persons (i.e., respect for people’s autonomy and voluntariness and the need for added protections for people with reduced autonomy); (2) beneficence (i.e., “do not harm and maximize possible benefits and minimize possible harms”); and (3) justice (e.g., communities should not be excluded from the benefits of research) [7,23,24]. Alongside potential risks, we highlight how the protocol was designed to reduce these risks, similar to the structure presented in the article by Bull et al. [25].

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 Web site that described the RCT and included an online screener form. If responses to the screener determined ineligibility, candidates received an e-mail to the Centers for Disease Control and Prevention Web site 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 [10,26–28]: (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 consent/assent form if needed.

All youth passed the capacity to assent. Nonetheless, six youth declined participation: One discussed the study with his girlfriend and decided that participation was not in his best interest. Two declined participation at the self-safety assessment, described in the following sections. 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
The descriptions of Belmont Report components and the potential ethical issues were based on those presented in the National Institutes of Health online human subjects research course [22].

AGBM = adolescent gay and bisexual males; IRB = institutional review board; YMSM = young men who have sex with men.

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]. [Detailed assistance in applying for waivers of parental permission can be found elsewhere [11].] Even with the waiver, three candidates informed research staff that they had discussed the study with their parents before 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 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 [29]. The assessment had two components: (1) a Safety Appraisal (e.g., potential consequences if someone saw messages about sensitive topics on the participant’s phone) and (2) a Privacy Assessment (e.g., who has access to the participant’s

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**Table 1**

<table>
<thead>
<tr>
<th>Belmont Report components</th>
<th>Potential ethical issue</th>
<th>How Guy2Guy addressed them</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respect for Persons</td>
<td>Obtaining informed assent with an online recruitment protocol</td>
<td>Enrollment occurred over the phone so that research staff could gauge whether the participant understood the assent. 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.</td>
</tr>
<tr>
<td></td>
<td>Obtaining informed assent from a group with diminished autonomy (i.e., children)</td>
<td></td>
</tr>
<tr>
<td>Benefits</td>
<td>Requiring parental permission can potentially harm sexual minority youth, due to discrimination and stigma</td>
<td>We requested and were granted a waiver of parental permission by both IRBs involved in the study.</td>
</tr>
<tr>
<td></td>
<td>If youths’ phones are lost or intercepted, the text messages on the phone could result in a loss of confidentiality of their sexual identity</td>
<td>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).</td>
</tr>
<tr>
<td>Justice</td>
<td>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</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>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</td>
<td>We used Facebook, the most popular social network among adolescents, to increase the likelihood of reaching a wide pool of AGBM.</td>
</tr>
<tr>
<td></td>
<td>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</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Ensuring a racially diverse sample, particularly the inclusion of Black and African-American males given the epidemiology of HIV in the United States</td>
<td>The enrollment algorithm also set targets based upon race and ethnicity.</td>
</tr>
<tr>
<td></td>
<td>The need to include youth aged under 16 years, which has been the youngest age group included in YMSM intervention studies to date</td>
<td>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.</td>
</tr>
</tbody>
</table>

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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 tracking 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 previously, 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 perceiving 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 although both were comfortable with enrolling in the program, one of these participants refused study incentives because he was concerned his parents did not have access to his phone. Two youth chose to enroll despite perceiving 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 although 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 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 that 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, suggest that the guide was useful in helping young people consider the potential safety implications of their involvement in the program.

**Text Buddy implementation.** Based on previous research [20,21], the Text Buddy component paired intervention participants together to discuss what they were learning in the program. We posited that Text Buddies could provide an important source of social support for participants 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 [30]. 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 2 hours between 8 A.M. and 11 P.M. 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. Most 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 20s). 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, 1 in 10 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...
or 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%); non-Hispanic black (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 on 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-year-old, living in a rural area) was full. To reach our recruitment goals, Facebook advertisements 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 [32–36]. Thus, HIV prevention programs that target only those who are having sex or only those who are having risky sex are not addressing the epidemiologic 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 years of age 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.

### Table 2
Demographics of screened and enrolled participants

<table>
<thead>
<tr>
<th>Demographic characteristic</th>
<th>Phone contact&lt;sup&gt;a&lt;/sup&gt; (n = 345)</th>
<th>Phone eligible&lt;sup&gt;b&lt;/sup&gt; (n = 329)</th>
<th>Consented/assented&lt;sup&gt;c&lt;/sup&gt; (n = 323)</th>
<th>Randomized&lt;sup&gt;d&lt;/sup&gt; (n = 302)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>42 (12.1)</td>
<td>39 (11.9)</td>
<td>39 (12.1)</td>
<td>38 (12.6)</td>
</tr>
<tr>
<td>White</td>
<td>209 (60.6)</td>
<td>204 (60.4)</td>
<td>193 (59.7)</td>
<td>181 (59.9)</td>
</tr>
<tr>
<td>Asian</td>
<td>9 (2.6)</td>
<td>9 (2.7)</td>
<td>9 (2.8)</td>
<td>9 (3.0)</td>
</tr>
<tr>
<td>Native Hawaiian</td>
<td>4 (1.2)</td>
<td>4 (1.2)</td>
<td>4 (1.2)</td>
<td>4 (1.3)</td>
</tr>
<tr>
<td>Native American/American/</td>
<td>8 (2.3)</td>
<td>7 (2.1)</td>
<td>7 (2.2)</td>
<td>6 (2.0)</td>
</tr>
<tr>
<td>Other</td>
<td>73 (21.2)</td>
<td>71 (21.6)</td>
<td>71 (22.0)</td>
<td>64 (21.2)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>82 (23.8)</td>
<td>85 (25.8)</td>
<td>83 (25.7)</td>
<td>71 (23.5)</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>274 (73.6)</td>
<td>241 (73.2)</td>
<td>240 (74.3)</td>
<td>223 (73.8)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14–15 years</td>
<td>131 (38.0)</td>
<td>129 (39.2)</td>
<td>125 (38.6)</td>
<td>114 (37.7)</td>
</tr>
<tr>
<td>16–18 years</td>
<td>214 (62.0)</td>
<td>205 (62.3)</td>
<td>198 (58.4)</td>
<td>187 (61.9)</td>
</tr>
<tr>
<td>Sexual identity&lt;sup&gt;e&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gay/lesbian</td>
<td>253 (73.3)</td>
<td>244 (74.2)</td>
<td>234 (72.4)</td>
<td>221 (73.2)</td>
</tr>
<tr>
<td>Bisexual</td>
<td>131 (38.0)</td>
<td>130 (38.5)</td>
<td>125 (38.6)</td>
<td>114 (37.7)</td>
</tr>
<tr>
<td>Queer</td>
<td>27 (7.8)</td>
<td>26 (7.9)</td>
<td>26 (8.0)</td>
<td>25 (8.3)</td>
</tr>
<tr>
<td>Heterosexual/straight</td>
<td>4 (1.2)</td>
<td>4 (1.2)</td>
<td>4 (1.2)</td>
<td>4 (1.3)</td>
</tr>
<tr>
<td>Other</td>
<td>44 (12.8)</td>
<td>52 (15.8)</td>
<td>50 (15.5)</td>
<td>41 (13.6)</td>
</tr>
<tr>
<td>Rural&lt;sup&gt;f&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>81 (23.5)</td>
<td>77 (23.4)</td>
<td>76 (23.5)</td>
<td>68 (22.5)</td>
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<tr>
<td>Urban</td>
<td>258 (74.8)</td>
<td>252 (76.6)</td>
<td>242 (74.9)</td>
<td>231 (76.5)</td>
</tr>
<tr>
<td>Region&lt;sup&gt;g&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Northeast</td>
<td>52 (15.1)</td>
<td>49 (14.9)</td>
<td>47 (14.6)</td>
<td>46 (15.2)</td>
</tr>
<tr>
<td>South</td>
<td>112 (32.5)</td>
<td>109 (33.1)</td>
<td>105 (32.5)</td>
<td>100 (33.1)</td>
</tr>
<tr>
<td>Midwest</td>
<td>87 (25.2)</td>
<td>83 (25.2)</td>
<td>82 (25.4)</td>
<td>73 (24.2)</td>
</tr>
<tr>
<td>West</td>
<td>94 (27.2)</td>
<td>93 (28.3)</td>
<td>89 (27.6)</td>
<td>83 (27.5)</td>
</tr>
<tr>
<td>Sexually experienced</td>
<td>168 (48.7)</td>
<td>157 (47.7)</td>
<td>152 (47.1)</td>
<td>139 (46.0)</td>
</tr>
<tr>
<td>No</td>
<td>177 (51.3)</td>
<td>172 (52.4)</td>
<td>171 (52.9)</td>
<td>163 (54.0)</td>
</tr>
</tbody>
</table>

All data are from online screener responses.

<sup>a</sup> Phone contact refers to those whom staff verbally spoke with on the phone.

<sup>b</sup> Multiple selections allowed.

<sup>c</sup> Rural versus urban residence was based on the participants’ Metropolitan Statistical Area [31] as determined by the ZIP code they provided at enrollment.

<sup>d</sup> Region was determined based on the participant’s self-reported ZIP code.

### Discussion

Similar to previous research [25], 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 are 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.

In conclusion, youth-inclusive research is less common than adult research because of 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.

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