AIDS and Behavior (2019) 23:3064–3077
https://doi.org/10.1007/s10461-019-02426-7

ORIGINAL PAPER

Acceptability and Preliminary Efficacy of an Online HIV Prevention Intervention for Single Young Men Who Have Sex with Men Seeking Partners Online: The myDEx Project

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Published online: 14 February 2019

Abstract
Prevention of new cases of HIV among young gay, bisexual and other men who have sex with men (YGBMSM; ages 18–24) remains a priority. We developed and pilot tested an online intervention (myDEx) using a pilot randomized trial design with 180 online-recruited single YGBMSM who reported recent unprotected anal intercourse, self-reporting as HIV negative or status-unaware, and who met sexual partners through online dating applications. myDEx participants reported higher overall satisfaction (d = 0.46) and willingness to recommend the intervention to friends (d = 0.48) than controls. myDEx participants were less likely to report foregoing condoms to achieve an emotional connection with a partner (d = 0.43), and more likely to report greater emotional regulation during their partner-seeking behaviors (d = 0.44). myDEx participants reported fewer partners with whom they had condomless receptive anal sex (d = 0.48). Our pilot results demonstrate the potential of the myDEx intervention, suggesting that a larger efficacy trial may be warranted in the future.

Keywords mHealth · Decisional balance · Limerence · LGBT · Sexual behavior

Resumen
La prevención de nuevos casos de VIH entre jóvenes gays, bisexuales y otros hombres que tienen sexo con hombres (YGBMSM; edades 18-24) sigue siendo una prioridad. Desarrollamos una intervención en línea (myDEx) y utilizamos un estudio piloto en un diseño aleatorio controlado con una muestra de 180 YGBMSM. Los participantes, reclutados en línea, fueron elegibles si tuvieron relaciones sexuales anales sin protección, informaron ser VIH negativo o serodesconocido, y buscaron parejas sexuales a través de aplicaciones sociales. En contraste con el grupo control, los participantes de myDEx informaron mayor satisfacción (d = .46) y disposición a recomendar la intervención a sus amigos (d = .48). Los participantes de myDEx disminuyeron la propensidad a evitar el uso de condones para lograr una conexión emocional con un compañero (d = .43), y una mejora en la regulación emocional durante la búsqueda de parejas (d = .44). Los participantes de myDEx redujeron el número de parejas con las que tuvieron relaciones sexuales anales receptivas sin condón (d = .48). Nuestros resultados piloto demuestran el potencial de la intervención myDEx y justifican un estudio de eficacia en el futuro.

Introduction

More than 70% of all new HIV infections in the United States occur as a result of transmission through sexual contact among men who have sex with men (MSM). In 2015, young gay, bisexual, and other men who have sex with men (YGBMSM) accounted for 81% of new infections among people ages 13 to 24, and 27% of all new infections among men who have sex with men (MSM) [1]. These disparities are accentuated by race/ethnicity, with YGBMSM who identify as Latino and/or Black carrying a disproportionate

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burden of new infections compared to non-Hispanic White counterparts. In light of YGBMSM's disproportionate vulnerability to HIV infection [2], there has been a call for innovative HIV prevention interventions that decrease sexual risk-taking (e.g., engaging in condomless anal intercourse in the absence of pre-exposure prophylaxis (PrEP) use; CAI) and promote HIV prevention behaviors (e.g., regular HIV testing, PrEP use, HIV stigma reduction) among YGBMSM.

Online-delivered HIV prevention interventions present a number of advantages, including opportunities to tailor content specific to each user's HIV risk behaviors and context, to present material through different modes and interactive features, to access content from any location convenient to a participant, and to standardize it's delivery in order to achieve higher intervention fidelity [3, 4]. Increasingly, YGBMSM report their desire to access comprehensive sex education through the Internet, given their increased use of social media in day-to-day interactions and the ease of accessing information through tablets, laptops, and smartphones [5–9]. Accessing information online may also offer sex education opportunities unavailable within their social milieu, including formal instruction regarding the importance of routine HIV testing [10–13], how to negotiate condom use with partners [5, 14], or how to solicit PrEP [15–18]. YGBMSM may also use online sites to build social support to reduce alienation and help overcome feelings of internalized homonegativity [8, 11, 19], particularly if YGBMSM do not readily receive social support from family and peers regarding their same-sex attractions and behaviors [20–22].

Collocating online interventions are also important because YGBMSM often rely on internet-based methods (e.g., websites, apps) to meet sexual partners and refine their sexual and romantic interests [9, 23, 24]. Increasingly, researchers have acknowledged that YGBMSM may have difficulties enacting safer sex strategies if they report different types of sexual relationships (e.g., dating, hook ups, friends with benefits). For example, Bauermeister [25] found that single YGBMSM categorized their recent sexual partners into different typologies (e.g., friend with benefits, hook ups, or romantic interest), with YGBMSM who reported multiple partner types being more likely to report a greater number of instances of condomless, receptive anal sex. Similarly, Janulis and colleagues [26] found that partner typologies (e.g., casual, serious, older partner met online) moderated the relationship between condomless anal sex and drug use in a cohort of YGBMSM in Chicago. In a qualitative study exploring how YGBMSM classify partners met online, however, Sullivan and colleagues [27] found that YGBMSM partner classifications shifted, sometimes unexpectedly (e.g., a date turning into a hook up and vice versa), with YGBMSM describing some partners as possessing hybridized elements of multiple partner types. Taken together, these findings highlight the need to acknowledge differential risks ascribed to different partner types, yet also address the cognitive and affective factors shared between partner typologies in the design and implementation of innovative HIV prevention programs [28, 29].

Effective HIV prevention interventions often rely on behavior change theories (e.g., Social Cognitive Theory; Theory of Planned Behavior; Information-Motivation-Behavior Model) to address the role of cognitive factors in sexual risk-taking behaviors [3]. Cognitive factors, such as condom decisional balance (defined as the overall motivation to use condoms after considering motivations for not using condoms) and safer sex self-efficacy with partners, are supported in the behavioral literature as predisposing the likelihood of engaging in sexual risk behaviors [24, 30–32]. However, these theories have come under scrutiny in recent years, as their focus on cognition may underplay how affective motivations impact decision-making and behavior change [33]. For example, YGBMSM may be more likely to take sexual risks with partners if they believe that foregoing condoms will build intimacy or express trust [34–39]. Given these findings, cognitive-affective dual-process models have been proposed as an alternative to traditional behavior change theories in order to highlight the importance of both affective motivations and rational decision-making [33]. Within these dual process models, both cognitive and affective aspects of sexual risk-taking motivation occur in conjunction with each other to affect sexual risk-taking behaviors among YGBMSM.

YGBMSM's affective motivators can be health promotive or risk enhancing. For example, researchers have noted that YGBMSM's affective motivations can be health promotive if the behaviors are developmentally consistent with the exploration of relationships (e.g., romantic ideation; i.e., "an individual's ability to conceptualize thoughts and feelings about pursuing romantic relationships"). Conversely, affective motivations may be risk enhancing when they are dysregulated during partner-seeking behaviors (e.g., limerence, or "overzealous ideation," characterized by jealousy, dependence, and intrusive thoughts about a partner). In several studies with YGBMSM, researchers have found support for the premise that both ideation and limerence are associated with sexual risk-taking behaviors. For example, Bauermeister and colleagues [40] found that romantic ideation was associated with less condomless anal intercourse occasions among YGBMSM, whereas limerence was associated with greater occasions of condomless sex. In a recent study extending this work, Goldenberg and colleagues [41] found that YGBMSM's sexual risk-taking behavior was directly associated with cognitive motivators (e.g., decisional balance to forego condoms; limited safer sex self-efficacy), whereas affective motivations (e.g., limerence) were indirectly associated with greater sexual risk behavior through

hindering YGBMSM's self-efficacy to negotiate condoms. Taken together, these findings underscore the need to consider both affective and cognitive motivations in future HIV prevention interventions aimed at decreasing YGBMSM's HIV risk-taking behaviors.

Consistent with the dual processing cognitive-emotional decision-making framework [33], we designed an online intervention (myDEx, short for 'My Desires & Expectations') for single YGBMSM presumed to be HIV-negative and who engage in unprotected (i.e., condomless) anal intercourse (UAI) with sexual partners met online. In this manuscript, we report the acceptability, usability, and preliminary efficacy of the myDEx intervention. To examine preliminary efficacy, we measured occurrence of three HIV prevention behaviors (e.g., reduction in number of risky sexual partnerships; increases in HIV testing behavior; and PrEP uptake), as well as proposed mechanisms of change (e.g., knowledge, safer-sex self-efficacy, decisional balance to forego condoms) associated with HIV risk.

Methods

Intervention Development Study Procedures

We used design-thinking principles during the intervention development process. To ensure adequate problem definition, product ideation, and prototyping, the study team convened a paid youth advisory board (YAB). YAB members worked 10–15 h per week alongside the study team and the intervention developers. YAB members were YGBMSM between the ages of 18 and 24 and diverse across race and/or ethnicity, educational attainment, socioeconomic status, faith, and urban/rural residential background. The YAB provided input into the proposed intervention design and content, including how to deliver the content in a way that promoted active learning and youth-friendly engagement, and co-facilitated trainings for the developers to learn about same-sex attractions and dating behaviors and popular MSM-specific apps used for dating and hooking up. We optimized the intervention's development process by adopting an agile methodology as a problem-solving framework during design and prototyping. As components of each intervention session were developed, for example, the YAB and research team collaboratively brainstormed what content and activities could be included in each session. Ideas were then discussed, mocked up with the study team, and annotated for the developers to consider as they designed the wireframes. Iterative feedback on different aspects of the intervention (e.g., navigation, content, activities) was collated and reconciled on a weekly basis until a final version of each intervention component was settled on.

Intervention Description

Intervention Arm

Consistent with the dual processing cognitive-emotional decision-making framework [33], the intervention (myDEx) was divided into six sessions, addressing distinct cognitive and affective content areas. Within each session, intervention content was organized into three levels: a core message, an in-depth discussion of topics linked to the core message, and an interactive activity linked to the information presented.

Session 1 ("Sexuality & Relationships") served as an introduction and focused on the importance of feeling comfortable talking about sexuality, desires within relationships, and health. Session content acknowledged and normalized YGBMSM's affective motivations and foreshadowed where participants could learn more about different topics of interest within the remaining 5 sessions of the intervention. Participants were required to complete the first session before they were able to access the remaining 5 sessions and interactive features (see Fig. 1).

Session 2 ("Desires & Behaviors") discussed different relationship types (e.g., romantic relationships, friends with benefits, hookups) and sexual decision-making. Session content highlighted the importance of knowing what kind of relationship one desires, in both the short-term and long-term, and the role of sex in exploring these relationships with different types of partners. Session 3 ("What Makes Good Sex") provided a comprehensive sex education review focused on same-sex behaviors, including the importance of sex positivity, varying sexual practices, and sexual consent. Session 4 ("Sexual Well-being") reinforced how to reduce HIV and STI risks when engaging in anal sex, including clarification on what lubricants and condoms are best suited for anal intercourse, facts about HIV and STI transmission, and the importance of status disclosure prior to sex. Session 5 ("Getting The Sex You Want") presented strategies to improve sexual communication with partners before, during, and after sex. For example, the session detailed how to discuss HIV testing history and status awareness with prospective partners online, how to ensure physical safety when meeting a new partner, and the value of discussing condoms and PrEP with partners. Session 6 ("Your Body, Your Health") summarizes key messages from prior modules and offer nearby HIV/STI testing resources and PrEP locations.

Within each session, participants had access to brief activities and videos designed to build their HIV risk reduction skills and promote self-reflection about YGBMSM's sexual health and partner-seeking behaviors. Interactive activities included role-play scenarios regarding condom use negotiation; a diary ("the Man Tap"; see Fig. 2) to log their dating experiences throughout the

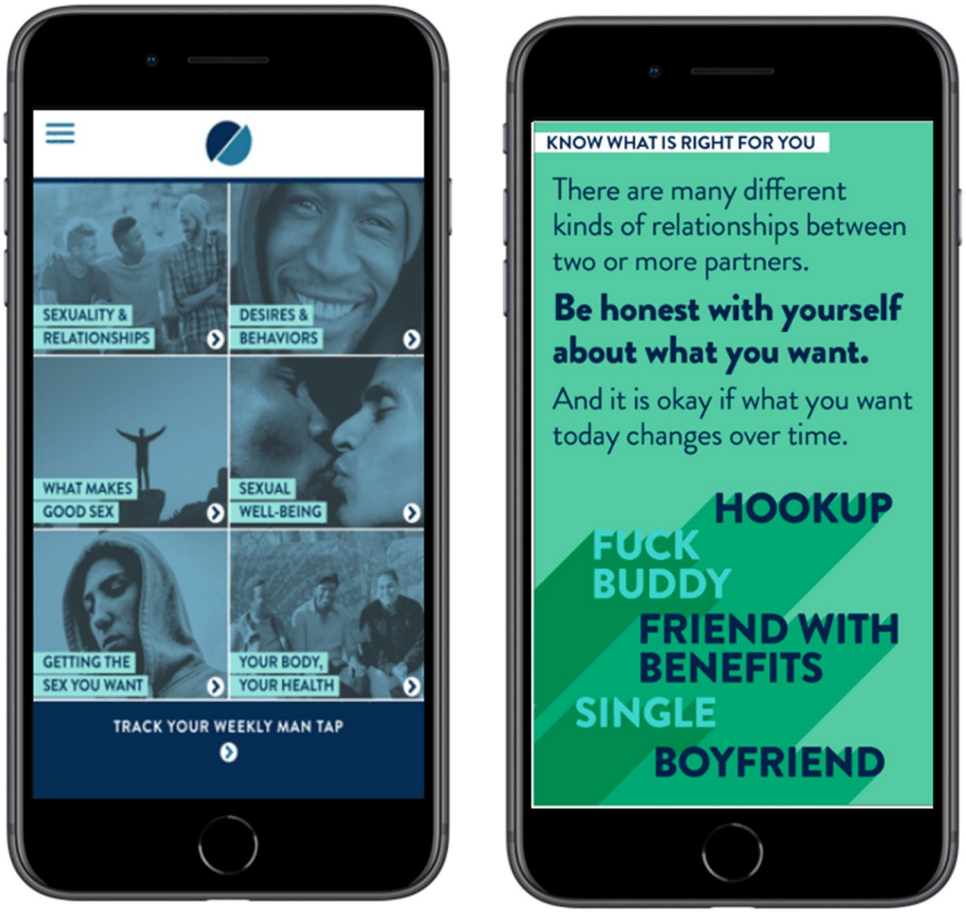

Fig. 1 Home screen for the myDEx intervention sessions and example of designed content

study; quizzes regarding their partner-seeking behaviors; and opportunities for participants to develop safer sex negotiation strategies with partners met online.

Attention-Control Condition

Our attention-control condition was an information-only site. Content mirrored the CDC's HIV Risk Reduction Tool [42], with content divided into 6-sessions to match myDEx's design (see Fig. 3). This mirroring allowed us to avoid confounding due to content (i.e., comparing myDEx to a non-HIV "health promotion" intervention) and ensured that all YGBMSM received *some* HIV prevention content given their high vulnerability to HIV. We acknowledge that having an HIV-specific attention-control condition might hinder the specificity of detection for some intervention effects during analysis; however, the primary goal for this pilot trial was to test the intervention's acceptability and preliminary efficacy in order to estimate critical parameters that may be required for adequate power estimation in a subsequent large-scale RCT trial.

Eligibility and Screener

Participants were recruited from across the U.S. via online advertisements placed on prevalent social (e.g., *Facebook*) and sexual (e.g., *Scruff, Grindr*) networking sites. Recruitment advertisements described the study and provided a link to a page containing basic study information, including a short description of study activities. To be eligible, participants had to: (1) be assigned male sex at birth and currently identify as male, (2) be between the ages of 18 and 24 (inclusive), (3) self-report as single, (4) self-report as HIV-negative or HIV-unknown, (5) speak and read English, (5) report using online dating apps, and (6) report at least one instance of unprotected anal intercourse (UAI) with a male partner met online in the prior 6 months.

We enrolled and randomized 180 YGBMSM into the trial (see trial protocol [43] for additional details). Participants' mean age was 21.67 (SD = 1.81). Most participants identified as White (67.2%), followed by Multiracial (16.1%), Black (10.0%), Asian (5.6%), Middle Eastern (0.6%), and Native American (0.6%). Thirty percent of our sample self-identified as Hispanic/Latino. The sample's highest level of educational attainment was diverse: 2.8% had some high

Fig. 2 Example of interactive activity ("ManTap") to track sexual partners in prior week

school education, 10.6% had a high school diploma or GED equivalent, 7.8% had a technical or associate degree, 40.0% reported some college education, 29.4% had graduated college, and 9.5% reported attending graduate school. The majority of participants self-identified as gay (88.3%), followed by bisexual (7.8%), and queer (3.9%).

Procedures

Individuals who expressed an interest in participation completed a short eligibility screener. Eligible participants completed a consent form, followed by an online 30-min baseline questionnaire. Individuals who did not meet eligibility criteria or who did not consent were thanked for their time and routed out of the study website. The research and ethics presented in this study were reviewed and approved by our Institutional Review Board, and registered on ClinicalTrials.gov (NCT02842060).

After completing the baseline survey, individuals were randomized to either the intervention arm (myDEx) or the attention-control arm using a stratified 2:1 block randomization design. Block randomization was stratified by racial/ethnic minority status, with equal allocation in each group, to reflect the HIV disparities encumbered by YGBMSM. Treatment assignments were generated using a pseudo-random-number generator with permutated blocks to ensure balance across participants' assigned condition. Participants had access to the intervention or control arm for the 90 days of follow-up.

Participants completed follow-up assessments at 30, 60, and 90 days post-randomization. Participants received $30 for completing baseline, $15 for completing the 30-day survey, $20 for the 60-day survey, and $25 for the ninety-day survey. We back loaded the incentives to encourage completion of all three data collection points and reduce participant attrition over time. The follow-up assessments maintained high retention rates, with 91.1% of all participants completing at least one follow-up assessment. Response rates per assessment were as follows: 79.4% (143/180) for the 30-day follow-up, 83.3% (150/180) for the 60-day follow-up, and 81.7% for the 90-day follow-up (147/180). Retention rates did not vary by treatment arm.

During data review, we found that 25 control participants were exposed to the intervention arm content due to a programming error. Given this cross-arm contamination, we excluded these cases from future trial analyses between arms. Comparing the 25 excluded cases to the rest of the sample, we observed no sociodemographic differences between the revised control arm and intervention arm across age ($t_{(153)} = -0.80$; $p = 0.43$), racial/ethnic minority status ($\chi^2_{(df = 1, N = 155)} = 0.10$; $p = 0.75$), educational attainment ($t_{(153)} = -1.24$; $p = 0.22$), or sexual orientation ($\chi^2_{(df = 2, N = 155)} = 3.23$; $p = 0.20$). Thus, we concluded that the excluded cases did not affect our randomization.

Measures

Acceptability Outcomes

Intervention Acceptability, Usability and Utility

Participants rated their acceptability of the both conditions at the 30-day follow-up assessment. Across both conditions,

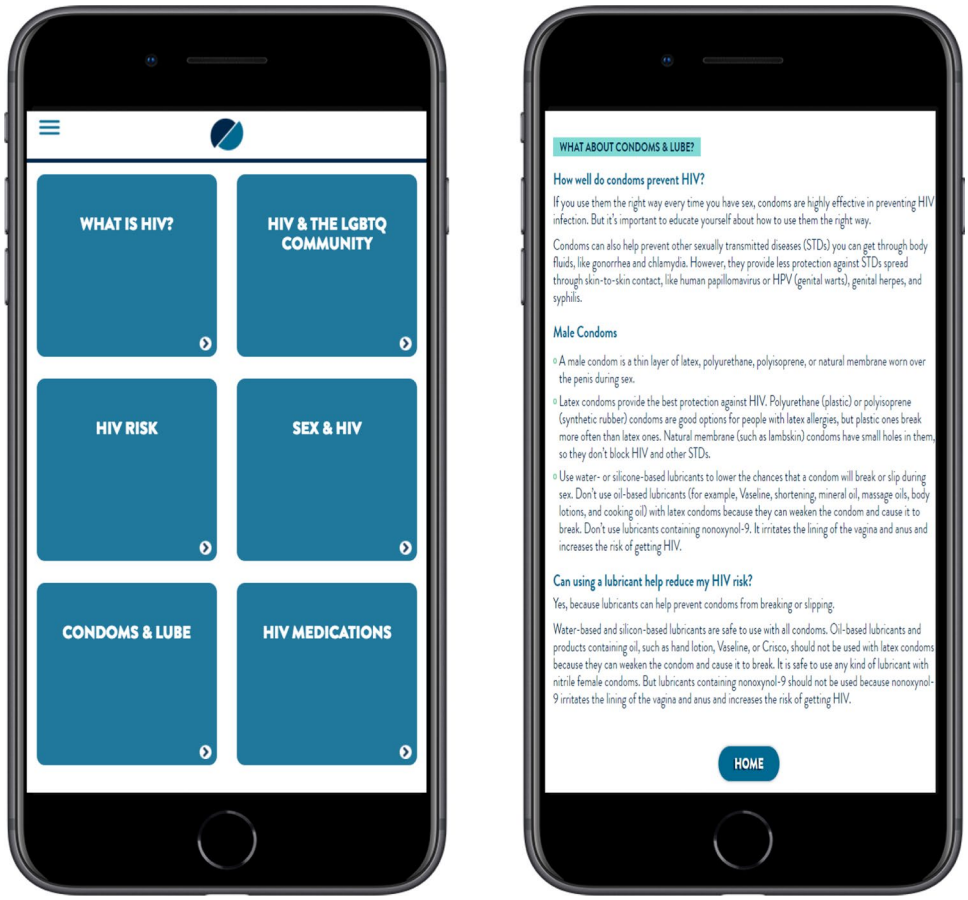

Fig. 3 Home screen and example of content for the Control condition

we ascertained YGBMSM's overall satisfaction and their willingness to recommend the intervention to friends. These items were answered using a 4-point scale (1 = Strongly Disagree; 4 = Strongly Agree). We also measured YGBMSM's likelihood to continue using the intervention if it were available in the future (1 = Very Unlikely; 5 = Very Likely).

Participants rated the intervention's usability at the 30-day follow-up assessment using 6-items from the System Quality subscale of the Information Systems Success Model (ISSM) proposed by DeLone & McLean [44, 45]. System quality refers to users' perceptions of how easy the intervention was to navigate and to be technically responsive (e.g., graphics and text load quickly; easy to use; frustrating to use [reverse coded]; easy to navigate; responds quickly when a button or link is clicked; and, user friendly). Each item was answered using a 4-point scale (1 = Strongly Disagree; 4 = Strongly Agree).

Participants rated the intervention's utility at the 30-day follow-up assessment using 7-items adapted from the Perceived Usefulness subscale of the Information Systems Success Model (ISSM) proposed by DeLone & McLean [44, 45]. Intervention utility reflects how the intervention was perceived by participants to impact their health behaviors (e.g., "the intervention makes it easier to live a healthier life," "it is useful in my life," "it improves my ability to make healthier choices about my relationships"). Each item was answered using a 4-point scale (1 = Strongly Disagree; 4 = Strongly Agree).

Primary Outcomes

Sexual Risk Behavior

At each study assessment, participants completed an adapted version of the Sexual Practices Assessment Schedule [46] to quantify the number of male partners in the prior 30 days. After participants indicated their total number of male sexual partners with whom they had sex (oral or anal), they were asked to report with how many of those men they had receptive and insertive anal sex, respectively. Based on the number reported for each sexual role, participants were then asked to indicate the number of partners with whom they did not use a condom. From their answers across the follow-up periods, we created a dichotomous variable to ascertain whether participants had engaged in condomless anal sex, either receptive and/or insertive, during the follow-up period (0 = No condomless sex; 1 = At least one condomless sex event).

Furthermore, to estimate the potential of HIV acquisition within these condomless sexual acts, participants were asked to indicate whether they knew without any doubt that their sexual partners were on PrEP (if negative) and/or virally-suppressed (if positive). From their answers, we created a dichotomous variable to indicate whether YGBMSM had engaged in condomless anal intercourse with a serodiscordant or serounknown partner where HIV transmission could be plausible (0 = No risky sexual event; 1 = At least one risky sexual event).

HIV Testing Behavior

Participants were asked if they had ever tested for HIV. Among those who reported a prior HIV, we asked YGBMSM to indicate the date (month and year) of their most recent HIV test. Using the recommended CDC guidelines encouraging high-risk YGBMSM to test every 3 months [47], we created a dichotomous variable to ascertain whether YGBMSM had tested within the prior 3 months or not (0 = Not in compliance with CDC testing guideline; 1 = In compliance with CDC testing guideline).

At each follow-up assessment, we asked participants whether they had tested for HIV in the prior 30 days. From their answers across the follow-up periods, we created a dichotomous variable to ascertain whether participants had tested for HIV during the follow-up period (0 = No; 1 = Yes). If tested, participants were asked to indicate whether their test was reactive. Participants who did not test for HIV during the study were asked to indicate their intention to test for HIV in the next 30 days (1 = Very Unlikely; 4 = Very Likely) as part of their 90-day survey.

PrEP Uptake

At baseline, participants were asked to indicate whether they had ever heard about PrEP, whether they had ever used PrEP, and whether they were currently on PrEP. At each follow-up period, we asked whether they were currently on PrEP (0 = No; 1 = Yes). From their answers across follow-up periods, we created a dichotomous variable to assess whether participants had begun PrEP use during the trial (0 = No; 1 = Yes).

Key Mechanisms of Change

Knowledge to Perform Behavior

At the 90-day follow-up, we asked participants to report the extent to which they had used the information learned through the intervention during their sexual decision-making (1 = Never, 2 = Rarely; 3 = Occasionally; 4 = Most of the time). We offered participants six scenarios: (1) "Evaluate my personal risk for HIV/STIs"; (2) "Feel more confident in my ability to protect myself from HIV/STIs"; (3)"Reduce my anxiety about getting HIV/STIs"; (4) "Educate others about HIV/STIs"; (5) "Decide whether to ask a romantic sexual partner to get tested for HIV/STIs"; and (6) "Decide whether to ask a casual sexual partner to get tested for HIV/STIs". We created a mean score from these items ($\alpha = 0.93$), where higher scores indicated greater use of the knowledge gained through the intervention during their sexual decision-making in the prior 30 days.

Perceived Efficacy to Engage in Preventive Behaviors

We used items adapted from Fisher and colleagues' Perceived Effectiveness at AIDS Preventive Behavior scale [48] to examine YGBMSM's self-efficacy to negotiate safer sex. This set of questions was asked of participants to describe both hookup partners and partners that might be romantic interests. For each type of partner, we included 8 items focused on consistent condom use (e.g., discuss having safer sex with a [hookup partner/date] face to face; consistently use condoms with a [hookup partner/date] every time you had anal sex). Participants selected how confident they were in engaging in each preventive behavior on a 4-point scale (1 = Very Hard To Do; 4 = Very Easy To Do). We computed a mean score from these items for each partner type. The scale had a high reliability for both hookup ($\alpha = 0.79$ at baseline; $\alpha = 0.83$ at 90-day follow-up) and romantic ($\alpha = 0.82$ at baseline; $\alpha = 0.87$ at 90-day follow-up) partners. Given high self-efficacy scores at baseline, we computed a net change score by subtracting participants' mean self-efficacy score at the 90-day follow-up from their baseline mean score.

Decisional Balance to Forego Condoms

We used the Decisional Balance to Use Condoms Scale [49] to examine how YGBMSM value sex with condoms relative to sex without condoms. Participants were asked to answer 7 statements. Each statement referred first to "sex with condoms" (e.g., "Sex with condoms makes me feel very connected with my partner"), followed by an identical statement referring to, "sex without condoms" (e.g., "Sex without condoms makes me feel very connected with my partner"). Participants rated each statement using a 4-point scale (1 = Strongly Disagree; 4 = Strongly Agree).

To create a net difference score for decisional balance items, statements noting participants' preference for sex without condoms were subtracted from the counterpart statements that indicated a preference for sex with condoms. This resulted in seven scores (one for each Decisional Balance item pair) ranging from −3 to 3. Participants' total decisional balance to use condoms was computed by creating a mean score of these items. Greater positive scores reflect

greater benefits/gains associated with sex without condoms. Negative scores reflect greater benefits/gains associated with condom use. Scores hovering close to zero indicate neutrality in the costs and gains associated with sex with or without condoms. The Cronbach's alpha for the decisional balance scale was 0.89 at baseline and 0.88 at the 90-day follow-up.

Limerence

Limerence was measured in order to understand YGBMSM's experiences with intrusive and intense thoughts about their partners and the intense feelings of dependence, insecurity, and doubt that may emerge when thinking about their relationships [50, 51]. Respondents answered 8 items (e.g., "I pursue partners even though they have told me that they are not interested"; "I confuse sex with love"). Each item was measured on a 5-point scale (1 = strongly disagree; 3 = Neither agree or disagree; 5 = strongly agree). The Cronbach's alpha for the limerence scale was .83 at baseline and 0.88 at the 90-day follow-up.

Data Analytic Strategy

We first conducted descriptive analyses on demographic variables in order to characterize our sample. Consistent with the pilot nature of our RCT, the primary goal of our study was to estimate the critical parameters required to note whether one or both of the intervention conditions had sufficient acceptability and preliminary efficacy in preparation for a larger efficacy trial [52]. As a result, we were not powered to estimate small effect sizes or carry out sophisticated statistical analyses (i.e. mediation); rather, we sought to estimate key study parameters with sample means and proportions together with 2-sided 95% CIs, and test the primary null hypotheses at the traditional 2-sided level alpha of 0.05.

To test the intervention's acceptability, we compared participants' acceptability scores between the two study arms. Next, we examined our primary outcomes (i.e., sexual risk behavior, HIV testing, PrEP use) across conditions using logistic regression for binary outcomes and t-tests for continuous outcomes. We also examined whether the intervention affected key theoretical constructs (e.g., knowledge, self-efficacy, decisional balance, limerence), as informed by the cognitive-affective dual process framework. In these analyses, we first examined the mean changes from baseline to follow-up for the entire sample using paired t-tests, and then estimated whether there were differences in net gains between the two treatment arms. Given the exploratory nature of our study, we present the observed effect sizes for continuous variables (i.e., Cohen's d), where meaningful effect sizes were estimated as small ($d < 0.20$), moderate ($0.20 \geq d \leq 0.45$), and large ($d > 0.45$). For categorical variables, we present the observed effect sizes as Odds Ratios with their 95% confidence intervals, where meaningful effect sizes were estimated as small ($OR < 1.5$), moderate ($1.5 \geq OR \leq 5$), and large ($d > 5$). These critical parameters may inform the potential of our intervention in a larger trial, as large sample sizes are not required to locate these parameters adequately when planning for a subsequent trial.

Results

Sample Characteristics

Participants included in this analysis (N = 155) had a mean age of 21.50 (SD = 1.82). Participants identified as White (N = 104, 67.1%), followed by Multiracial (N = 25, 16.1%), Black (N = 16, 10.0%), Asian (N = 8, 5.2%), Middle Eastern (N = 1, 0.6%), or Native American (N = 1, 0.6%). Thirty percent of the sample (N = 46) self-identified as Hispanic/Latino. The majority of participants self-identified as gay (N = 138, 89.0%) followed by bisexual (N = 11, 7.1%) and queer (N = 6, 3.9%).

The majority of the sample (N = 134, 86.5%) reported having ever tested for HIV. Only 45.8% (N = 71) had tested in the prior 3 months, as recommended by the CDC guidelines. Nearly twenty-percent (N = 27, 17.4%) of the sample reported being medically diagnosed with a STI in the past. The majority of the sample had heard about PrEP in the past (N = 147, 94.8%). Twenty-seven participants (17.4%) reported ever taking PrEP, with most of these PrEP-using participants (N = 21; 77.8%) self-reporting that they were on PrEP at baseline.

Participants reported having approximately three male partners in the 30 days prior to completing the baseline survey (M = 2.72, SD = 4.09). 61.9% of the sample (N = 96) reported engaging in receptive anal sex (mean number of insertive partners = 1.25, SD = 2.49) during the 30 days prior to completing the baseline survey, with over two-thirds of those engaging in receptive anal sex noting that they had engaged in condomless receptive sex (N = 67, 69.7%). Over a third of these participants (N = 25, 37.3%) engaged in condomless receptive sex with serodiscordant or serounknown partners not known to be on PrEP or virally suppressed. Forty-nine percent (N = 79) reported engaging in insertive anal sex (mean number of receptive partners = 1.08, SD = 3.09) in the 30 days prior to completing baseline, with nearly three-quarters noting that they had engaged in condomless sex (N = 57, 72.2%). Over a third of these participants (N = 21, 36.8%) engaged in condomless insertive sex with serodiscordant or serounknown partners not known to be on PrEP or virally suppressed.

Intervention Acceptability, Usability and Utility

Participants perceived both intervention arms as acceptable. Participants in the myDEx intervention arm reported greater overall satisfaction with the intervention and more willingness to recommend the intervention to their friends than those in the control arm (see Table 1). We observed a trend suggesting that myDEx participants would be more likely to continue using the intervention if it were available than those in the control arm. We found no differences between the two arms in participants' ratings of the system quality components of the site.

Overall, participants in the myDEx arm perceived greater intervention utility than those in the control arm. For example, YMSM in the myDEx arm were more likely to report that the intervention made it easier to live a healthier life than those in the control arm (see Table 1). We also observed trends suggesting that myDEx participants found the intervention to provide useful HIV prevention information, to help them make better choices about their relationships, to improve their communication skills, to understand themselves better, to make healthier choices, and to improve their ability to meet the type of partner they are looking for (see Table 1).

Preliminary Efficacy: Primary Outcomes

Sexual Behavior

We found no differences by arm in the mean total number of sexual partners reported by YGBMSM at the 90-day follow-up (myDEx (N = 95; M = 1.15(SD = 1.14) versus Control (N = 28; M = 1.50(SD = 2.05); $t_{(153)} = -0.75$, $p = 0.45$; Cohen's d = 0.16). YGBMSM assigned to the myDEx arm were less likely to have engaged in condomless receptive anal sex during the 3-month trial period than those assigned to the control arm (26.7% vs. 45.7%, $X^2_{(1)} = 4.40$, p = 0.04; Odds Ratio 0.43; 95% CI (0.20, 0.94)). We found a trend suggesting that YGBMSM in the myDEx condition were also less likely to engage in condomless receptive sex with serodiscordant or serounknown partners not known to be on PrEP or virally suppressed (8.3% vs. 17.1%, $X^2_{(1)} = 2.18$, p = 0.14; Odds Ratio 0 .44; 95% CI (0.15, 1.31)).

We found a non-significant trend suggesting that the myDEx arm was less likely to engage in insertive CAI than those in the control arm (33.3% vs. 42.9%, $X^2_{(1)} = 1.19$, p = 0.27; Odds Ratio 0.64; 95% CI (0.28, 1.44)). They were also less likely to report insertive CAI with serodiscordant or serounknown partners not known to be on PrEP or virally suppressed (10.8% vs. 20.0%, $X^2_{(1)} = 1.86$, p = 0.16; Odds Ratio 0.49; 95% CI (0.17, 1.33)).

Table 1 Intervention acceptability, usability and utility scores for YGBMSM in the myDEx intervention study at the 30-day follow-up (N = 115)

	Control (N = 27)	myDEx (N = 88)	t	p	Cohen's d
Acceptability					
Overall, I am satisfied with myDEx	2.96 (0.71)	3.33 (0.69)	2.42	0.02	0.53
I would recommend myDEx to my friends	3.04 (0.65)	3.39 (0.61)	2.55	0.01	0.56
I would continue using myDEx if it were available	3.44 (1.25)	3.79 (0.97)	1.52	0.13	0.33
System quality					
Using myDEx is very frustrating (reverse-coded)	2.96 (0.71)	3.11 (0.73)	0.94	0.35	0.21
myDEx loads all the text and graphics quickly	3.22 (0.64)	3.26 (0.72)	0.25	0.80	0.05
myDEx is easy to use	3.41 (0.50)	3.35 (0.61)	−0.43	0.67	−0.09
It is easy to go back and forth between pages on myDEx	3.19 (0.74)	3.22 (0.75)	0.19	0.85	0.04
myDEx responds quickly when I click on a link of a button	3.31 (0.68)	3.23 (0.68)	−0.51	0.61	−0.11
myDEx is user friendly	3.30 (0.47)	3.34 (0.60)	0.35	0.73	0.08
Intervention utility					
Using myDEx taught me useful information about HIV prevention and care	3.19 (0.48)	3.33 (0.60)	1.28	0.20	0.24
Using myDEx has helped me make better choices regarding who I meet online	2.89 (0.70)	3.11 (0.63)	1.58	0.12	0.35
myDEx provided me skills to communicate better with my partners	2.89 (0.64)	3.13 (0.69)	1.58	0.12	0.35
I feel like I understand myself better since I started using myDEx	2.85 (0.60)	3.07 (0.72)	1.43	0.15	0.31
Using myDEx improves my ability to make healthier choices about my relationships	3.04 (0.76)	3.23 (0.64)	1.31	0.19	0.29
Using myDEx increases my ability to meet the type of partner that I'm looking for	2.52 (0.64)	2.77 (0.72)	1.64	0.10	0.36
Using myDEx makes it easier to live a healthier life	2.93 (0.62)	3.22 (0.69)	2.08	0.04	0.46

HIV Testing Behavior

Forty-five percent of the sample (N = 70) reported testing for HIV during the 3-month follow-up time period, with no differences observed between the arms (46.7% vs. 40.0%; $X^2_{(1)} = 0.49$, p = 0.49). There were no HIV-positive diagnoses among those tested for HIV. At the 90-day follow-up, participants who did not get an HIV test during the trial (N = 56) did not differ in their intentions to get an HIV test in the following 30 days (myDEx: N = 41; M = 2.59 (SD = 0.97) versus control: N = 15; M = 2.47(SD = 1.06); $t_{(54)} = 0.60$; $p = 0.70$; Cohen's d = 0.18).

PrEP Uptake

Nine participants reported PrEP uptake during the trial period, with a non-significant trend suggesting that YGBMSM assigned to myDEx were more likely to start PrEP than those in the control condition (8.9% vs. 3.7%; $X^2_{(1)} = 0.91$, p = 0.39; Odds Ratio 2.54; 95% CI (0.30, 21.24)).

Preliminary Efficacy: Proposed Mechanisms of Change

Knowledge to Perform Behavior

At the 90-day follow-up, YGBMSM assigned to the myDEx arm (N = 95; M = 2.61, SD = 0.91) tended to report a greater use of the sexual decision-making knowledge gained through the intervention than those in the control arm (N = 28; M = 2.27, SD = 0.88; $t_{(121)} = 1.75$, p = 0.08; Cohen's d = 0.38).

Safer-Sex Self-Efficacy

We observed improvements in safer-sex self-efficacy with hookup partners for the entire sample from baseline (M = 1.88; SD = 0.56) to the 90-day follow-up (M = 2.01; SD = .54; $t_{(122)} = 2.51$; p = 0.01). However, this net gain did not differ between the two study arms ($t_{(121)} = 0.76$; p = 0.45).

We found no changes over time for the entire sample in YGBMSM's self-efficacy to engage in safer sex behaviors with partners with whom they were romantically interested from baseline (M = 2.05; SD = 0.55) to the 90-day follow-up (M = 2.10; SD = .57; $t_{(122)} = 1.10$; p = 0.28). Net gain differences between study arms were also not found ($t_{(120)} = 0.43$; p = 0.67; Cohen's d = 0.09).

Decisional Balance to Forego Condoms

We observed improvements in decisional balance for the entire sample from baseline (M = − 0.50; SD = 0.99) to the 90-day follow-up (M = − 0.34; SD = 0.89; $t_{(122)} = -2.48$; p = 0.015). At the 90-day follow-up, YGBMSM assigned to the control condition (n = 28; M = − 0.63, SD = 0.95) were more likely than myDEx participants (N = 95; M = − 0.26, SD = 0.86) to report a willingness to forego condoms in order to make an emotional connection with a partner ($t_{(121)} = -1.98$, p = 0.05; Cohen's d = 0.43).

Limerence

We observed no changes in limerence for the entire sample from baseline (M = − 2.89; SD = 0.07) to the 90-day follow-up (M = 2.89; SD = 0.89; $t_{(122)} = -0.07$; p = 0.95). YGBMSM assigned to the control condition (N = 28; M = 3.13, SD = 0.64), however, reported greater limerence scores than those assigned to the myDEx arm (N = 95; M = 2.81, SD = 0.95; $t_{(121)} = 2.02$, p = 0.05; Cohen's d = 0.43).

Discussion

YGBMSM engaging in online partner-seeking behaviors are at risk for HIV infection, yet there are currently few mHealth HIV and STI prevention interventions that address the risks unique to these behaviors [4, 9]. Given the increased popularity of online partner-seeking applications, efforts to supplement comprehensive sex education initiatives are needed as these programs may not address the needs of YGBMSM in school-based programs, or may not cover strategies for YGBMSM to engage in risk reduction behaviors within these contexts [7]. Our study aimed to assess the acceptability and preliminary efficacy of myDEx, an online intervention focused on encouraging HIV/STI risk reduction behaviors among single, high-risk YGBMSM seeking partners online. The pilot nature of our study, which included a small sample size and short follow-up periods, precluded us from testing for efficacy. In estimating the parameters for a future efficacy trial, however, we were delighted to see that several of our behavioral outcomes and purported theoretical mediators had moderately strong effect sizes, with strong enough differences between the two study arms to achieve statistical significance.

Intervention acceptability was high across both conditions, with participants assigned to the myDEx arm more likely to report satisfaction with the intervention and to suggest the intervention to their friends. YGBMSM in the myDEx arm were also more likely to perceive the intervention's content as more useful and relevant compared to YGBMSM in the attention-control arm. The absence of

differences by arm in YGBMSM's perceived system quality suggested that the observed differences in YGBMSM's intervention acceptability and utility were not attributable to the differences in design and navigation between the study arms. Thus, consistent with Noar's meta-analysis [53, 54]—recommending the inclusion of tailored content within online behavior change interventions—we attribute the aforementioned differences to the fact that YGBMSM in the myDEx condition received developmentally-tailored content regarding partner-seeking behaviors, cognitive and affective motivations to engage in sexual risk behaviors, and opportunities to engage in risk reduction behaviors.

Preliminary efficacy data for our primary outcomes indicated support for the myDEx intervention. Although there were no differences observed from baseline to 90-day follow-up in YGBMSM's total number of sexual partners, those in the myDEx intervention were more likely than those in the control arm to report a two-fold decrease in the number of partners with whom they engaged in condomless, receptive anal intercourse during the follow-up period. We also detected trends suggesting moderate decreases among myDEx participants in unprotected sex with serodiscordant or serounknown partners and fewer number of partners with whom YGBMSM had condomless, insertive sex. Given participants' relative lower engagement in insertive sex compared to receptive sex, the moderate effect sizes observed are promising and warrant further examination in a future efficacy trial.

Nearly half of the sample reported HIV testing during the study follow-up period, yet HIV testing behavior did not differ between study arms. It is important to note that we evaluated two competing HIV prevention interventions in our study design (e.g., myDEx vs. CDC Risk Reduction Tool). Although the inclusion of a non-HIV control group could have allowed us to discern whether myDEx promoted HIV testing rates among YGBMSM, we felt that withholding referrals to care to our population would be unethical given their vulnerability to HIV. However, our HIV testing rates are comparable to intervention effects observed in other mHealth HIV testing interventions for YGBMSM [10, 12, 55]. In addition, our estimate of recent HIV testing is higher than rates observed in surveillance studies with high-risk YGBMSM seeking partners online. For example, in a large sample of YGBMSM using Grindr to meet sexual partners, Rendina and colleagues [56] found that 29% of their sample had tested for HIV in the prior 3 months. Consequently, our preliminary data suggest that both myDEx and the CDC's Risk Reduction Tool could be efficacious, yet the true magnitude of effect will require a no-treatment control group in the future trial.

Consistent with national trends and the timing of our study (2016–2017), PrEP use and uptake among YGBMSM was relatively low in our study [18, 57]. Compared to the control arm, however, trends suggested that myDEx participants were two times more likely to begin PrEP during the study period. These moderate effect sizes suggest that the myDEx intervention might be more persuasive in promoting PrEP uptake than the attention-control condition.

Unfortunately, we were unable to examine whether myDEx could support YGBMSM across the remaining steps of the PrEP continuum, including assessing optimal adherence among PrEP users beyond self-report. Given recent findings suggesting high levels of PrEP non-adherence or PrEP discontinuation among YGBMSM over time, additional intervention strategies aimed at supporting PrEP adherence through myDEx may be warranted. Moreover, the reliable measurement of PrEP uptake and adherence (e.g., dried blood spots; urine assays) will need to be implemented and evaluated as part of a large-scale randomized trial.

We also noted improvements in secondary outcomes linked to risk reduction. Consistent with the dual process model, myDEx was designed to address affective and cognitive motivations during partner-seeking behaviors. To this end, we found that YGBMSM in the myDEx intervention reported less willingness to forego condoms as a strategy to make an emotional connection with a sexual partner and noted fewer feelings of limerence than peers assigned to the control arm at the 90-day follow-up. myDEx participants were also more likely than YGBMSM in the control arm to report having recently used the knowledge gained during the intervention during sexual decision-making. Gains in YGBMSM's self-efficacy to negotiate safer sex with hookup partners were observed in both study arms, yet no gains were observed in participants' safer sex negotiation self-efficacy with individuals deemed romantic interests. These findings would suggest that cognitive-based intervention strategies within myDEx served to change some risk correlates, but not others. These findings are promising and suggest that myDEx may curtail both cognitive and affective correlates of sexual risk taking behaviors. However, we are currently unable to examine whether changes in these secondary outcomes led to the observed changes in sexual risk behavior. Given the pilot nature of this trial, we are unable to tease out these mediation mechanisms at this time. Future research testing the efficacy of these secondary outcomes, as well as their role as key mechanisms of change within the myDEx intervention, are warranted.

Several limitations are worth noting. Across primary and secondary outcomes, we noted that intervention effects moved in favor of the myDEx intervention; however, given the pilot nature of our trial, our ability to detect these effects with statistical precision was limited by our small sample size and short follow-up period. Moreover, given the small sample size [58], we were unable to test for the mediation of our proposed mechanisms of change on our outcomes of interest or examine whether there were racial/ethnic

differences in our intervention. In future scaled-up versions of the intervention, we intend to have a larger sample size, including being able to test for mediation and moderation, in order to examine efficacy and effectiveness more precisely across a longer follow-up period. Second, our decision to use an HIV prevention attention-control arm may have made it harder to detect the myDEx intervention's true effects sizes; nevertheless, our findings suggest that myDEx is a promising intervention approach. Third, the unequal sample sizes between the attention control and intervention arm may have also limited our ability to detect accurate differences between the arms. While this is less of a concern to this pilot trial (i.e., our study did not seek to detect differences), we foresee including comparable sample sizes between the study arms of the future efficacy trial to ensure optimal comparison between the arms. Moreover, given our inability to include 25 control cases in our analyses due to cross-arm contamination, we urge scholars to continuously examine paradata files during data collection to identify any unforeseen programming errors and reduce the potential of unintentional contamination during data collection.

In the absence of a robust probability sampling frame from which to derive a representative sample of YGBMSM, we had to rely on the recruitment of a convenience sample; as such, our findings may be not be generalizable. Finally, primary and secondary outcomes relied on participants' self-report. Prior research has suggested that YGBMSM's changes in sexual behavior over time may be the result of participants' reflection on their sexual practices as they complete their sexual history assessments at each follow-up [59]; however, we found no observable evidence of this bias in our analyses. For instance, we would have expected to see changes in YGBMSM's total number of partners due to self-reflection, yet no decreases in overall number of sexual partners across the sample were found. Instead, we observed changes only on the intended sexual risk behaviors, consistent with our intervention messaging on sexual risk reduction. Nevertheless, to circumvent potential biases due to self-report (e.g. social desirability), the tracking of HIV testing and PrEP prescriptions through electronic medical records and testing of participants and their sexual partners using biomarkers to ascertain HIV/STI incidence and PrEP adherence may be warranted in a future, large-scale efficacy trial.

In conclusion, myDEx was designed to address cognitive and emotional factors that influence sexual risk-taking behaviors among YGBMSM seeking partners online. YGBMSM found the intervention to be highly acceptable and useful. Compared to the control condition, our preliminary efficacy data suggested that YGBMSM assigned to the myDEx intervention reported greater trends in sexual risk reduction, improvements in HIV prevention behaviors, and positive changes in their emotional and cognitive decision-making. This intervention provided definite gains with regard to the creation of digital environments where YGBMSM can access and practice responsive sexual health information. In addition, it is worth emphasizing the potential benefits obtained from technological mechanisms that are required to implement online interventions such as real-time HIV surveillance, refined sexual behavior profiles, and intervention optimization. These findings highlight the importance of applying a cognitive-affective dual-process model when examining sexual risk-taking behaviors among YGBMSM. Based on our findings, future research examining the efficacy of myDEx as HIV risk reduction intervention is warranted.

Acknowledgements We greatly appreciate the hard work of the study staff, and are indebted to the study participants for volunteering their time. This research was sponsored by the US National Institutes of Health (NIH), under R34 MH101997. The content is solely the responsibility of the authors and does not necessarily represent the official views of NIH.

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Compliance with Ethical Standards

Conflict of interest The authors declare that there are no conflicts of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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