

Evidence of Efficacy of the My Personal Health Guide Mobile Phone Application on Antiretroviral Therapy Adherence: Results at 1-month of a Randomized Controlled Trial Among Young African American Men who have Sex with Men Living with HIV

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Evidence of Efficacy of the My Personal Health Guide Mobile Phone Application on Antiretroviral Therapy Adherence: Results at 1-month of a Randomized Controlled Trial Among Young African American Men who have Sex with Men Living with HIV

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Abstract

Background: Young African American men who have sex with men (AAMSM) experience disproportionately high HIV incidence and are less likely to achieve viral suppression compared to White MSM, an outcome that relies on antiretroviral therapy (ART) adherence. We created My Personal Health Guide, a talking relational agent-based mobile health (mHealth) app to improve ART adherence among young AAMSM.

Objective: The objective was to determine the efficacy of My Personal Health Guide on improving ART adherence among young AAMSM living with HIV.

Methods: We implemented a randomized controlled trial (RCT) among young (18-34 years) AAMSM with non-optimal ART adherence throughout the United States. Participants were randomized in a 1:1 ratio using permuted blocks of 8 to the intervention, My Personal Health Guide, or attention control arm. ART adherence was assessed with Wilson's 3-item self-reported adherence measurement and dichotomized at >80%. Logistic regression models using backward selection were employed to evaluate the efficacy of My Personal Health Guide on >80% ART adherence at 1-month follow-up.

Results: The sample for analysis of My Personal Health Guide app efficacy was 131 (76 intervention: 55 control). The odds of being >80% adherent to ART at 1-month follow-up was 3.97 times greater (95% CI: 1.26, 12.55) among participants randomized to the My Personal Health Guide app compared to the controls, after adjusting for ART adherence at baseline, treatment adherence self-efficacy, and ever being incarcerated.

Conclusions: Participants randomized to receive My Personal Health Guide reported nearly four times greater odds of being >80% adherent to ART compared to the attention control group at 1-month follow-up. To our knowledge, this is the first RCT demonstrating improved medication adherence using a relational agent-based behavioral intervention. These findings provide evidence of short-term efficacy of My Personal Health Guide to improve ART adherence among young AAMSM. Clinical Trial: ClinicalTrials.gov ID NCT04217174

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Original Manuscript

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Background

Young African American men who have sex with men (AAMSM) experience disproportionately high HIV incidence and are less likely to achieve viral suppression compared to White MSM, an outcome that relies on antiretroviral therapy (ART) adherence. We created My Personal Health Guide, a talking relational agent-based mobile health (mHealth) app to improve ART adherence among young AAMSM.

Objective

The objective was to determine the efficacy of My Personal Health Guide on improving ART adherence among young AAMSM living with HIV.

Methods

We implemented a randomized controlled trial (RCT) among young (18-34 years) AAMSM with non-optimal ART adherence throughout the United States. Participants were randomized in a 1:1 ratio using permuted blocks of 8 to the intervention, My Personal Health Guide, or attention control arm. ART adherence was assessed with Wilson's 3-item self-reported adherence measurement and dichotomized at $\geq 80\%$. Logistic regression models using backward selection were employed to evaluate the efficacy of My Personal Health Guide on $\geq 80\%$ ART adherence at 1-month follow-up.

Results

The sample for analysis of My Personal Health Guide app efficacy was 131 (76 intervention: 55 control). The odds of being $\geq 80\%$ adherent to ART at 1-month follow-up was 3.97 times greater (95% CI: 1.26, 12.55) among participants randomized to the My Personal Health Guide app compared to the controls, after adjusting for ART adherence at baseline, treatment adherence self-efficacy, and ever being incarcerated.

Conclusions

Participants randomized to receive My Personal Health Guide reported nearly four times greater odds of being $\geq 80\%$ adherent to ART compared to the attention control group at 1-month follow-up. To our knowledge, this is the first RCT demonstrating improved medication adherence using a relational agent-based behavioral intervention. These findings provide evidence of short-term efficacy of My Personal Health Guide to improve ART adherence among young AAMSM.

Trial Registration

ClinicalTrials.gov ID NCT04217174

Word count: 300/450

Background

African American men who have sex with men (AAMSM) have disproportionate HIV infection rates, retention in care,¹ mortality, and rates of viral nonsuppression,²⁻⁸ an outcome that relies on antiretroviral therapy (ART) adherence. Additionally, health literacy is a factor associated with ART adherence⁹ that is lower among African American people than White people.¹⁰ Therefore, interventions that bolster health literacy might improve healthy HIV-related behaviors like ART adherence, potentially resulting in personal and public health benefits.

Relational agents are computerized images that a person may react to as if they are in a relationship. A relational agent can be designed to promote healthy behavioral change. We developed My Personal Health Guide, an innovative theory-driven relational agent-based app with improvement of ART adherence as one of its objectives.¹¹ During iterative app development focus groups with young AAMSM living with HIV, participants reported universal acceptability for the African American realistic avatar we developed that spoke about, taught, explained, and encouraged behavior to promote healthy HIV-related outcomes.¹¹ Responding to meeting their adherence-related needs and interests, the app includes clear and simple language, an audiovisual format, and gamification. A pilot study performed in Chicago provided evidence that My Personal Health Guide has the potential to improve adherence.¹²

Here, we present preliminary short-term follow up results from a randomized controlled trial (RCT) of My Personal Health Guide that demonstrate evidence of improvement of ART adherence among young AAMSM living with HIV. We hypothesized that those randomized to the My Personal Health Guide app would have greater ART adherence compared to controls at 1-month follow-up post-randomization. Evidence of short-term improvement in ART adherence provides scientific rationale for further research of this realistic avatar and relational agent approach as an adherence intervention and informs efforts to refine the approach to produce longer term effects.

Methods

Intervention

My Personal Health Guide features a realistic talking avatar with supportive functions that were designed to inform users of HIV-related health information, encourage participants to take their medication, and facilitate adherence-related behavioral skills with reminders and push notifications to take medication and promotion of using weekly pill boxes. It also includes recordings of peers and healthcare providers offering personal and motivational messages. The app provides a private space, in one's own mobile phone, for hearing and seeing information relevant to healthy living with HIV. Users may replay information which can be especially helpful to people who are uncomfortable asking questions of their healthcare provider including asking for repeating what was said or explaining more simply.

Design, recruitment, eligibility, and enrollment

This RCT (Clinicaltrials.gov identifier NCT04217174) was performed among young AAMSM living with HIV. Participants were recruited throughout the United States between February 2020 and September 2023, predominantly through social media (e.g., the dating app Jack'd and Facebook advertisement) and also by word of mouth, provider referral, and fliers in healthcare settings of the three enrollment sites: University of Illinois at Chicago, Emory University, and University of Mississippi Medical Center. Those who were eligible identified as male sex assigned at birth, current male gender, African American or Black, 18-34 years old, had at least one male sexual partner in their lifetime, English speaking, owned a smartphone, were initiating or prescribed oral ART, and had history of non-optimal ART adherence defined as having a detectable viral load within

the past four weeks, self-reported non-optimal ART adherence within the past 30 days, or were referred by a provider for adherence concerns. Those who were on injectable ART, participating in another HIV treatment study, or did not have a stable mailing address at the time of enrollment were ineligible for participation.

Data collection and randomization

Figure 1 summarizes participant interactions with the study through the first month of follow-up. A structured, interviewer-administered baseline questionnaire included collection of demographics, baseline knowledge of HIV (items taught in the app), self-reported adherence, incarceration history, housing stability, substance use history, self-efficacy (HIV-ASES),¹³ literacy (adapted REALM-SF),¹⁴ perceived social support (MSPSS),¹⁵ and depression symptomatology (PHQ-9).¹⁶ One month after the baseline interview, participants were scheduled for the app orientation and download that included explaining how to download, setting up a password, briefly pointing out features, and encouraging app use. Additionally, a check-in call was made monthly during 6 months of follow-up that asked troubleshooting questions about the app and collected self-reported ART adherence. Participants received compensation of \$40 for the baseline interview, \$75 for an appointment to download the app, and \$10 for responding to each monthly check-in call. Permuted randomization in blocks of 8 was utilized to allocate research participants in a 1:1 ratio to the intervention or control arm. Participants randomized to the intervention arm received the My Personal Health Guide app and those randomized to the attention control arm received a Food Safety app, which featured an avatar and functions related to food and nutrition, narrated illustrated stories about food safety, an educational game about sugar content in food, and information promoting oral health.

Outcome measurement

ART adherence was assessed with Wilson's 3-item self-reported adherence measurement.¹⁷ These three questions include: 1) "In the last 30 days, on how many days did you miss at least one dose of any of your HIV medication?" (with a response range from 0-30 days); 2) "In the last 30 days, how often did you take your HIV medication in the way you were supposed to?" (with response options including Never, Rarely, Sometimes, Usually, Almost Always, Always); 3) "In the last 30 days, how good a job did you do at taking your HIV medications in the way you were supposed to?" (with response options including Very Poor, Poor, Fair, Good, Very Good, Excellent). Answers were averaged together and converted to a percentage score on a 100-point scale. Consistent with other studies,^{18, 19} 80% was defined as the cut-point for non-optimal ART adherence. HIV viral load was the intended primary outcome for this research. However, the trial was disturbed by the COVID-19 pandemic and significant difficulty occurred collecting viral load from this population. Therefore, self-reported ART adherence was utilized.

Statistical analysis

The primary statistical goal for this analysis was to determine the efficacy of the My Personal Health Guide app on ART adherence at 1-month follow-up. Participant demographic and study characteristics are presented as means and standard deviations (SD) for continuous variables and as absolute numbers (N) and proportions (%) for categorical variables stratified by randomization arm. The success of randomization was assessed using t-tests for continuous baseline characteristics, or Chi-squared tests (χ^2) for categorical characteristics. Baseline characteristics between individuals that completed both the baseline meeting and 1-month follow-up versus those who had missing data at 1-month follow-up were compared to ensure comparability between the samples. Bivariate comparisons were made between participant characteristics and ART adherence at baseline ($\geq 80\%$ vs $< 80\%$) utilizing Chi-squared (χ^2) tests for categorical data, Cochran-Armitage tests for ordinal data, and independent t-tests for continuous data. Logistic regression models with backward model

selection method were employed to evaluate the effect of the My Personal Health Guide app, adjusted for significant factors that were associated with ART adherence at Month 1. Baseline adherence was adjusted for a priori. The baseline characteristics that were considered in the logistic regression models included age, ethnicity, remote participation, residence, education, employment status, sexual orientation, currently in a committed relationship, health literacy (REALM-SF), HIV treatment adherence self-efficacy (HIV-ASES), depression symptomatology (PHQ-9), perceived social support (MSPSS), ever incarcerated, housing insecurity, and substance use seriousness (serious includes cocaine, methamphetamines, crack, heroin, opiates; less serious includes alcohol, marijuana, ecstasy, speedballs, GHB; none includes no use of substances or alcohol) at baseline. Adjusted model results are presented as odds ratios (OR) and 95% confidence intervals (CI).

Role of the funding source

The National Institute of Mental Health had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The authors were not precluded from accessing data in the study, and they accept responsibility to submit for publication.

Results

Sample characteristics

We attempted to contact the 911 men that met preliminary eligibility criteria, responded to recruitment methods, and provided contact information. Among those, 471 were either not responsive or not interested in the study, 44 were enrolled in another HIV treatment study, and 5 did not have a stable mailing address in order to receive study materials. Five participants were erroneously enrolled in the study due to either being unable to verify having a current HIV prescription (n=3) or having been previously enrolled in the study (n=2). A total of 386 men were consented. Among these, the baseline questionnaire was completed by 315 (81.6%), and 253 (65.5%) had the study apps installed on their mobile phone one month later (Figure 1) including 124 (49.0%) randomized to My Personal Health Guide and 129 (51.0%) randomized to the Food Safety attention control app. After one month, 93 participants did not respond to contact attempts to complete the Month 1 check-in call and were excluded from the current analysis. The remaining 160 participants completed the first check-in phone call and of those, 131 had complete self-reported adherence data at Month 1 (My Personal Health Guide: 76; Control: 55).

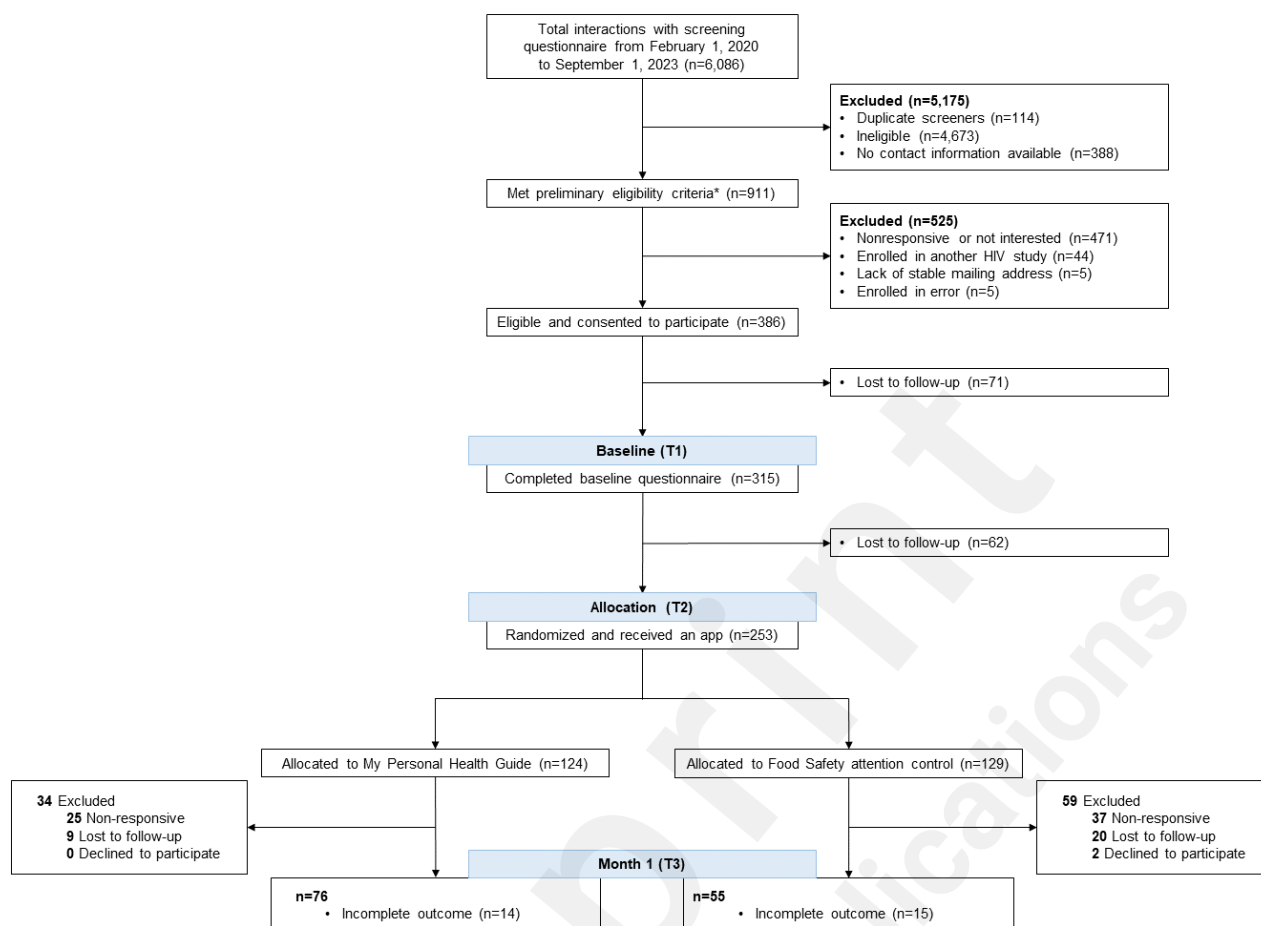


Figure 1. CONSORT diagram.

* Preliminary eligibility did not include verifying age and active HIV prescription.

The mean age of the 253 participants at baseline was 29.4 ± 3.7 years (Range:18, 35); most (87.4%) were 25-34 years old. Few (7.1%) identified as Hispanic. Most participated remotely (79.8%). Most participants were enrolled by the University of Illinois at Chicago (51.8%) and Emory University (41.9%), and 6.3% were enrolled by the University of Mississippi Medical Center. Over half (57.3%) of participants resided in the Southern United States but all U.S. regions were represented in the sample. Nearly half (42.3%) had some college education and over half (57.7%) reported being employed. Three-quarters (71.1%) identified as homosexual or gay and were not currently in a committed relationship with a male partner (78.3%). Over one-third (37.9%) had less than optimal literacy (adapted REALM-SF). Over half reported mild-severe depressive symptomatology, with 25.7% reporting mild (PHQ-9 5.0-9.9), 13.8% reporting moderate (PHQ-9 10.0-14.9), 9.1% reporting moderately severe (PHQ-9 15.0-19.9), and 4.3% reporting severe (PHQ-9 >20.0) depressive symptomatology. The median HIV treatment adherence self-efficacy (HIV-ASES) was 104 [IQR: 89, 114]. Although most (59.3%) reported high perceived social support (MSPSS >5.0), 9.1% had low (MSPSS <3.0) perceived social support and 31.6% had moderate (MSPSS 3.0-5.0) perceived social support. Approximately one-quarter experienced housing insecurity in the past 6 months (24.1%) and nearly one-third were ever incarcerated (30.4%). Fifteen-percent (15.4%) reported serious substance use in the past two weeks. Nearly three quarters (70.4%) reported less serious substance use, including alcohol, marijuana, ecstasy, speedballs, or GHB. Most (71.1%) self-reported being $\geq 80\%$ adherent to ART at baseline. Group comparisons for all baseline characteristics and ART adherence at baseline (Table 1) revealed that randomizations were successful.

Primary outcome

Among the 253 participants who were randomized and downloaded an app, 131 (51.8%) completed the 1-month follow-up for ART adherence and 122 (48.2%) did not. A significantly greater proportion of those randomized to the Food Safety app were missing 1-month follow-up data compared to the My Personal Health Guide app (57.4% vs. 38.7%; p -value=0.0045). Bivariate analysis (Table 2) revealed the mean HIV treatment adherence self-efficacy (HIV-ASES) (103 ± 15.8 vs. 86.4 ± 28.5 ; p -value=0.021) was significantly higher in those who had $\geq 80\%$ adherence to ART at 1-month as compared to those who had $< 80\%$ adherence at 1-month. The mean depression symptomatology scale (PHQ-9) was moderately significantly lower among those who were $> 80\%$ adherent to ART at 1-month as compared to those who were $< 80\%$ adherent to ART at 1-month (5.70 ± 4.96 vs. 9.00 ± 7.43 ; p -value=0.069). There was also a significantly higher prevalence of being in a committed relationship with a male partner among those who had $\geq 80\%$ adherence to ART at 1-month as compared to those who had $< 80\%$ adherence at 1-month (22.5% vs. 0.0%; p -value=0.013).

In multivariable analysis, the odds of being $\geq 80\%$ adherent to ART at 1-month follow-up was almost 4 times greater (OR: 3.97; 95% CI: 1.26, 12.55) among participants randomized to the My Personal Health Guide app as compared to the Food Safety app after adjusting for other characteristics that were also associated with ART adherence at 1-month, including HIV treatment adherence self-efficacy and having history of ever being incarcerated. Every one-point increase in the HIV-ASES increased the odds of $\geq 80\%$ ART adherence by 3% (OR: 1.03; 95% CI: 1.00, 1.06). A history of ever being incarcerated reduced the odds of $\geq 80\%$ ART adherence (OR: 0.31; 95% CI: 0.09, 1.06). ART adherence at baseline was marginally associated with $\geq 80\%$ ART at 1-month follow-up (OR: 2.97; 95% CI: 0.88, 9.99).

Discussion

Participants randomized to receive My Personal Health Guide demonstrated nearly four times greater odds of being $\geq 80\%$ adherent to ART compared to participants who received the Food Safety control app at 1-month follow-up. This is a substantial magnitude and, although these are short-term follow-up results, these data provide strong evidence that a relational agent approach to improving medication adherence is promising.

Our study is the first of its kind in the field of HIV medication adherence. We are aware of only two other published RCTs of a relational agent for behavior change. Rubin et al. performed an RCT of a relational agent to deliver a brief alcohol intervention and referral to treatment to veterans within VA primary care clinics.²⁰ Their approach involved two meetings with the relational agent who requested a commitment to change. They reported that their relational agent elicited concern about the consequences of drinking and bolstered motivation to change. Although they did not observe accelerated decline in drinking during 3 months with their intervention compared to their control group, they noted that their intervention group was more likely to receive referrals for follow-up and that this approach allowed for more screening and brief intervention without increasing the burden on clinic staff. Another study by Prochaska et al. studied a smartphone intervention called Woebot for Substance Use Disorders that employed a therapeutic relational agent delivering cognitive behavioral therapy.²¹ At 8 weeks, they reported reduced substance use occasions compared to a waitlist group. Given that these studies and ours are RCTs, they provide strong scientific rationale for consideration of relational agents in the design of behavioral interventions, especially involving conditions where stigma about diagnosis or treatment could create hesitancy with face-to-face healthcare provider education or counseling.

In addition to our study demonstrating a large magnitude efficacy, there are several other strengths and considerations. First, our study began shortly before the COVID pandemic spread throughout the U.S., disrupting in-person research with lockdowns and other restrictions. This led to a nearly entirely remote rather than facility-based administration and may have made the meeting with research staff for orientation to the app less interactive than it might have been otherwise. The

remote approach could have diminished the participant's feeling of accountability to the study or facilitated participation by reducing the barrier of travel to a study activity. Second, unlike medication or immunization, our app intervention involves a passive approach. In other words, patients are encouraged to use it but it is their choice how much of the app they experience and how often they open it. The app was designed to have new functions and experiences occur with repeated use to encourage return to the app. However, we have no control to ensure regular app exposure. Despite these issues, we observed a significant effect in achieving the adherence goal. This suggests that the effect might increase further and benefit more patients with additional app refinement and involvement of healthcare providers or case managers in implementation who could refer the app to their patients and check in with them at future appointments. Third, our study sample was diverse, including a large proportion who experienced housing insecurity, screened for moderate or severe depression, and reported a history of incarceration. Additionally, our sample included an overrepresentation of men living in the Southern United States, a high HIV incidence region where many experience structural barriers to HIV care²² and where a low cost, scalable intervention like ours could contribute to achieving higher prevalence of viral suppression and help end the HIV epidemic. Finally, our study also demonstrated an independent effect of self-efficacy on being ≥ 80 adherent. This finding is consistent with other studies such as by Dworkin et al., Barclay et al., and Waldrop-Valverde et al.²³⁻²⁵ However, this is the first study to report this specifically in a population of young AAMSM living with HIV.

Limitations

Limitations of this study include that many subjects were recruited using a social media dating app which may limit generalizability. Additionally, generalization to all young AAMSM living with HIV is limited because we were unsuccessful in contacting approximately 48% of those who were randomized.

Study procedures were disrupted by the COVID-19 pandemic, necessitating the change from a facility-based trial to online. While this pivot allowed for further recruitment and retention, it compromised the collection of viral load data from participants' clinics, which was initially an outcome of interest. This change also impacted the collection of dried blood spots at the 6-month follow-up, which was initially intended to be conducted on-site and changed to be self-administered in the participant's home to accommodate COVID-19 stay-at-home orders. This resulted in a high proportion of missingness. Additionally, the laboratory methodology for threshold of detection changed during the study period and utilized a higher threshold (<839 copies/mL) than the clinical definition of undetectable viral load (<200 copies/mL). Similarly, the usage of Wisepill devices to monitor ART adherence was low, so self-report was utilized as the primary outcome of interest. Utilizing self-reported ART adherence also had limitations. Self-report can overestimate individual medication taking behavior and therefore may introduce recall and social desirability bias. However, self-reported adherence is often used to assess ART adherence in both routine care and research settings and has been correlated with viral load and other objective markers of adherence.²⁶ Lastly, these findings are limited to the first month of observation. Additional follow-up analysis from this trial is planned to determine evidence of longer term effect.

Conclusion

These findings provide evidence that My Personal Health Guide has short-term efficacy improving ART adherence among young AAMSM living with HIV and contribute to the emerging field of technology-based behavioral interventions promoting health using relational agents. We recommend further research of the inclusion of relational agents in behavioral research, especially in populations affected by stigma and non-optimal health literacy where this nonhuman supportive and educational approach may be complementary to healthcare systems.

Contributors

MD and SL contributed to the conceptualization. MD, RG, and SL contributed to the funding acquisition. MD, JJ, AJ, RG, and SL contributed to the methodology. MD, KH, SU, JJ, and PB contributed to project administration. MD, JJ, PB, RG, and SL contributed to the resources. MS, JJ, and PB contributed to the supervision. KH, SU, CL, MW, and SL contributed to the data curation. KH, SU, CL, LL, and RR contributed to the formal analysis. KH, SU, and CL contributed to the investigation. KH, SU, CL, and SL contributed to the software. MS, KH, SU, CL, JJ, LL, and RR contributed to the validation. KH, SU, and RR contributed to the visualization. MD, KH, SU, CL, LL, and RR contributed to writing the original draft. All authors reviewed and edited the final manuscript.

Declarations of Interests

The authors report no declarations of interest.

Data sharing

A de-identified data set, a data dictionary defining each field in the set, the study protocol including the statistical analysis plan, and informed consent forms will be made available upon request and with publication acceptance. Per University protocol, all sensitive and high-risk data will be transmitted via an encrypted protocol, or SFTP, to individuals outside of the University with investigator support, approval from the data safety and monitoring board, and a signed data access agreement.

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Table 1. Baseline demographic characteristics and ART adherence of young AAMSM living with HIV stratified by randomization arm (N=253), 2020-2024

	Overall (N=253)	Intervention (N=124)	Control (N=129)	p-value
Age in years, mean (SD)	29.4 (3.7)	29.6 (3.5)	29.1 (4.0)	0.46 ¹
18-24	32 (12.6%)	13 (10.5%)	19 (14.7%)	0.409 ²
25-34	221 (87.4%)	111 (89.5%)	110 (85.3%)	
Ethnicity				
Hispanic	18 (7.1%)	9 (7.3%)	9 (7.0%)	1 ²
Not Hispanic	235 (92.9%)	115 (92.7%)	120 (93.0%)	
Enrollment site				
University of Illinois at Chicago	131 (51.8%)	59 (47.6%)	72 (55.8%)	0.175 ²
Emory University	106 (41.9%)	54 (43.5%)	52 (40.3%)	
University of Mississippi Medical Center	16 (6.3%)	11 (8.9%)	5 (3.9%)	
Remote participation				
Yes	202 (79.8%)	98 (79.0%)	104 (80.6%)	0.874 ²
No	51 (20.2%)	26 (21.0%)	25 (19.4%)	
Residence				
Midwest	77 (30.4%)	34 (27.4%)	43 (33.3%)	0.424 ⁴

Northeast	27 (10.7%)	12 (9.7%)	15 (11.6%)	
South	145 (57.3%)	77 (62.1%)	68 (52.7%)	
West	4 (1.6%)	1 (0.8%)	3 (2.3%)	
Education				
College	68 (26.9%)	30 (24.2%)	38 (29.5%)	0.592 ²
Some college	107 (42.3%)	51 (41.1%)	56 (43.4%)	
High school or GED	65 (25.7%)	36 (29.0%)	29 (22.5%)	
Less than high school	13 (5.1%)	7 (5.6%)	6 (4.7%)	
Employment				
Active duty	1 (0.4%)	0 (0%)	1 (0.8%)	0.449 ²
Employed	146 (57.7%)	75 (60.5%)	71 (55.0%)	
Student	18 (7.1%)	10 (8.1%)	8 (6.2%)	
Unable to work or unemployed	83 (32.8%)	36 (29.0%)	47 (36.4%)	
Missing	5 (2.0%)	3 (2.4%)	2 (1.6%)	
Sexual orientation				
Homosexual or gay	180 (71.1%)	85 (68.5%)	95 (73.6%)	0.809 ²
Bisexual	49 (19.4%)	27 (21.8%)	22 (17.1%)	
Heterosexual or straight	4 (1.6%)	2 (1.6%)	2 (1.6%)	
Other	20 (7.9%)	10 (8.1%)	10 (7.8%)	
Currently in a committed relationship with a male partner				
Yes	55 (21.7%)	25 (20.2%)	30 (23.3%)	0.657 ²
No	198 (78.3%)	99 (79.8%)	99 (76.7%)	
Marital status				
Legally married	10 (4.0%)	4 (3.2%)	6 (4.7%)	0.689 ²
Registered domestic partnership	1 (0.4%)	1 (0.8%)	0 (0.0%)	
Widowed	1 (0.4%)	0 (0.0%)	1 (0.8%)	
Divorced	8 (3.2%)	5 (4.0%)	3 (2.3%)	
Separated	5 (2.0%)	2 (1.6%)	3 (2.3%)	
Never married	228 (90.1%)	112 (90.3%)	116 (89.9%)	
Health literacy (adapted REALM-SF)				
Non-optimal (At least one wrong)	96 (37.9%)	47 (37.9%)	49 (38.0%)	1 ²
Optimal (None wrong)	157 (62.1%)	77 (62.1%)	80 (62.0%)	
Patient Health Questionnaire for Depression (PHQ-9), mean (SD)				
None or minimal (<5.0)	117 (46.2%)	55 (44.4%)	62 (48.1%)	0.7087 ³
Mild (5.0-9.9)	65 (25.7%)	35 (28.2%)	30 (23.3%)	
Moderate (10.0-14.9)	35 (13.8%)	14 (11.3%)	21 (16.3%)	
Moderately severe (15.0-19.9)	23 (9.1%)	11 (8.9%)	12 (9.3%)	
Severe (≥20.0)	11 (4.3%)	7 (5.6%)	4 (3.1%)	
Missing	2 (0.8%)	2 (1.6%)	0 (0%)	
HIV Treatment Adherence Self-efficacy Scale (HIV-ASES), mean (SD)				
Median [Q1, Q3]	98.1 (20.2)	99.5 (18.1)	96.8 (22.0)	0.29 ¹
Missing	104 [89.0, 114]	105 [88.3, 114]	103 [89.0, 115]	
Multidimensional Scale of Perceived Social Support (MSPSS), mean (SD)				
Low (<3.0)	5.08 (1.36)	5.09 (1.45)	5.08 (1.28)	0.976 ¹
Moderate (3.0-5.0)	23 (9.1%)	13 (10.5%)	10 (7.8%)	0.681 ²
High (≥5.1)	80 (31.6%)	37 (29.8%)	43 (33.3%)	0.8117 ³
	150 (59.3%)	74 (59.7%)	76 (58.9%)	

Ever incarcerated				
Yes	77 (30.4%)	45 (36.3%)	32 (24.8%)	0.0646 ²
No	176 (69.6%)	79 (63.7%)	97 (75.2%)	
Housing insecurity in previous 6 months				
Yes	61 (24.1%)	32 (25.8%)	29 (22.5%)	0.637 ²
No	192 (75.9%)	92 (74.2%)	100 (77.5%)	
Substance use seriousness in previous 2 weeks ^a				
None	36 (14.2%)	17 (13.7%)	19 (14.7%)	0.318 ²
Less serious	178 (70.4%)	92 (74.2%)	86 (66.7%)	
Serious	39 (15.4%)	15 (12.1%)	24 (18.6%)	
Adherence to ART (baseline)				
Yes (≥80%)	180 (71.1%)	94 (75.8%)	86 (66.7%)	0.143 ²
No (<80%)	73 (28.9%)	30 (24.2%)	43 (33.3%)	
Adherence to ART (month 1)				
Yes (≥80%)	111 (43.9%)	69 (55.6%)	42 (32.6%)	0.0434 ²
No (<80%)	20 (7.9%)	7 (5.6%)	13 (10.1%)	
Missing data (month 1)				
Yes	122 (48.2%)	48 (38.7%)	74 (57.4%)	0.0045 ²
No	131 (51.8%)	76 (61.3%)	55 (42.6%)	

^aSerious includes cocaine, methamphetamines, crack, heroin, opiates; less serious includes alcohol, marijuana, ecstasy, speedballs, GHB

¹Independent samples *t*-test

²Chi-square (χ^2) test for comparison

³Cochran-Armitage test

⁴Fisher's Exact test

Table 2b. Bivariate analysis of demographic characteristics of young AAMSM living with HIV by ART adherence at 1-month (N=131), 2020-2024

	Overall (N=131)	<80% ART Adherence (N=20)	≥80 ART Adherence (N=111)	<i>p</i> -value
Randomization				
My Personal Health Guide (intervention)	76 (58.0%)	7 (35.0%)	69 (62.2%)	0.028 ²
Food Safety (control)	55 (42.0%)	13 (65.0%)	42 (37.8%)	
Age in years, mean (SD)	29.5 (3.62)	29.9 (2.60)	29.4 (3.78)	0.528 ¹
25-34 years	115 (87.8%)	20 (100.0%)	95 (85.6%)	0.129 ²
18-24 years	16 (12.2%)	0 (0.0%)	16 (14.4%)	
Ethnicity				
Hispanic	7 (5.3%)	0 (0.0%)	7 (6.3%)	0.594 ²
Not Hispanic	124 (94.7%)	20 (100.0%)	104 (93.7%)	
Remote participation				
Yes	119 (90.8%)	17 (85.0%)	102 (91.9%)	0.393 ²
No	12 (9.2%)	3 (15.0%)	9 (8.1%)	
Residence				
Midwest	33 (25.2%)	7 (35.0%)	26 (23.4%)	0.626 ²
Northeast	12 (9.2%)	2 (10.0%)	10 (9.0%)	
South	84 (64.1%)	11 (55.0%)	73 (65.8%)	
West	2 (1.5%)	0 (0.0%)	2 (1.8%)	

Education				
College	68 (26.9%)	18 (26.5%)	50 (73.5%)	0.747 ²
Some college	107 (42.3%)	30 (28.0%)	77 (72.0%)	
High school or GED	65 (25.7%)	22 (33.8%)	43 (66.2%)	
Less than high school	13 (5.1%)	3 (23.1%)	10 (76.9%)	
Employment				
Employed, student, active duty	95 (72.5%)	12 (60.0%)	83 (74.8%)	0.269 ²
Unemployed or unable to work	34 (26.0%)	7 (35.0%)	27 (24.3%)	
Missing	2 (1.5%)	1 (5.0%)	1 (0.9%)	
Sexual orientation				
Homosexual or gay	96 (73.3%)	18 (90.0%)	78 (70.3%)	0.442 ²
Bisexual	24 (18.3%)	2 (10.0%)	22 (19.9%)	
Heterosexual or straight	2 (1.5%)	0 (0.0%)	2 (1.9%)	
Other	9 (6.9%)	0 (0.0%)	9 (8.1%)	
Currently in a committed relationship with a male partner				
Yes	25 (19.1%)	0 (0.0%)	25 (22.5%)	0.013 ²
No	106 (80.9%)	20 (100.0%)	86 (77.5%)	
Health literacy (adapted REALM-SF)				
Non-optimal (At least one wrong)	46 (35.1%)	7 (35.0%)	39 (35.1%)	1 ²
Optimal (None wrong)	85 (64.9%)	13 (65.0%)	72 (64.9%)	
Patient Health Questionnaire for Depression (PHQ-9), mean (SD)	6.21 (5.51)	9.00 (7.43)	5.70 (4.96)	0.069 ¹
Missing	1 (0.8%)	0 (0%)	1 (0.9%)	
HIV Treatment Adherence Self-efficacy Scale (HIV-ASES), mean (SD)	100.0 (19.2)	86.4 (28.5)	103.0 (15.8)	0.021 ¹
Missing	3 (2.3%)	0 (0.0%)	3 (2.7%)	
Multidimensional Scale of Perceived Social Support (MSPSS), mean (SD)	5.19 (1.33)	4.81 (1.36)	5.26 (1.32)	0.182 ¹
Ever incarcerated				
Yes	34 (30.4%)	7 (35.0%)	27 (24.3%)	0.405 ²
No	97 (74.9%)	13 (65.0%)	84 (75.7%)	
Housing insecurity in previous 6 months				
Yes	34 (26.0%)	7 (35.9%)	27 (24.3%)	0.405 ²
No	97 (74.0%)	13 (65.0%)	84 (75.7%)	
Substance use seriousness in previous 2 weeks ^a				
Serious	19 (14.5%)	6 (30.0%)	13 (11.7%)	0.120 ²
Less serious	101 (77.1%)	13 (65.0%)	88 (79.3%)	
None	11 (8.4%)	1 (5.0%)	10 (9.0%)	

^aSerious includes cocaine, methamphetamines, crack, heroin, opiates; less serious includes alcohol, marijuana, ecstasy, speedballs, GHB

¹Independent samples *t*-test

²Fisher's Exact test

Table 3. Multivariable logistic regression for the association between My Personal Health Guide and $\geq 80\%$ ART adherence at 1-month follow-up among young AAMSM living with HIV (N=131), 2020-2024

	Unadjusted Odds Ratio	Adjusted Odds Ratio	95% Confidence Interval	p-value
Randomization				
My Personal Health Guide (intervention)	4.55	3.97	(1.26, 12.55)	0.019
Food Safety (control)	REF	REF	-	-
ART adherence at baseline				
$\geq 80\%$	3.05	2.97	(0.88, 9.99)	0.079
$< 80\%$	REF	REF	-	-
HIV Treatment Adherence Self-efficacy Scale (HIV-ASES)	1.04	1.03	(1.00, 1.06)	0.038
Ever incarcerated				
Yes	0.60	0.31	(0.09, 1.06)	0.061
No	REF	REF	-	-

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Supplementary Files

Figures

CONSORT Diagram.

