

Protocol

Tough Talks COVID-19 Digital Health Intervention for Vaccine Hesitancy Among Black Young Adults: Protocol for a Hybrid Type 1 Effectiveness Implementation Randomized Controlled Trial

Henna Budhwani^{1*}, MPH, PhD; Allysha C Maragh-Bass², PhD; Elizabeth E Tolley², PhD; Maria Leonora G Comello³, PhD; Marie C D Stoner⁴, PhD; Margo Adams Larsen⁵, PhD; Donald Brambilla⁴, PhD; Kathryn E Muessig⁶, PhD; Audrey Pettifor⁷, PhD; Christyenne L Bond¹, MPH; Christina Toval⁷, MPH; Lisa B Hightow-Weidman^{6*}, MPH, MD

¹Intervention Research and Implementation Science Lab, College of Nursing, Florida State University, Tallahassee, FL, United States

²Behavioral, Epidemiological, Clinical Sciences Division, FHI360, Durham, NC, United States

³Hussman School of Journalism and Media, University of North Carolina at Chapel Hill, Chapel Hill, NC, United States

⁴RTI International, Research Triangle Park, NC, United States

⁵Virtually Better, Inc, Decatur, GA, United States

⁶Institute on Digital Health and Innovation, College of Nursing, Florida State University, Tallahassee, FL, United States

⁷Gillings School of Global Public Health, University of North Carolina at Chapel Hill, North Carolina, NC, United States

*these authors contributed equally

Corresponding Author:

Henna Budhwani, MPH, PhD

Intervention Research and Implementation Science Lab

College of Nursing

Florida State University

98 Varsity Way

Tallahassee, FL, 32306

United States

Phone: 1 8506443296

Email: hbudhwani@fsu.edu

Abstract

Background: Interventions for increasing the uptake of COVID-19 vaccination among Black young adults are central to ending the pandemic. Black young adults experience harms from structural forces, such as racism and stigma, that reduce receptivity to traditional public health messaging due to skepticism and distrust. As such, Black young adults continue to represent a priority population on which to focus efforts for promoting COVID-19 vaccine uptake.

Objective: In aims 1 and 2, the Tough Talks digital health intervention for HIV disclosure will be adapted to address COVID-19 vaccine hesitancy and tailored to the experiences of Black young adults in the southern United States (Tough Talks for COVID-19). In aim 3, the newly adapted Tough Talks for COVID-19 digital health intervention will be tested across the following three southern states: Alabama, Georgia, and North Carolina.

Methods: Our innovative digital health intervention study will include qualitative and quantitative assessments. A unique combination of methodological techniques, including web-based surveys, choose-your-own-adventures, digital storytelling, user acceptability testing, and community-based participatory approaches, will culminate in a 2-arm hybrid type 1 effectiveness implementation randomized controlled trial, wherein participants will be randomized to the Tough Talks for COVID-19 intervention arm or a standard-of-care control condition (N=360). Logistic regression will be used to determine the effect of the treatment arm on the probability of vaccination uptake (primary COVID-19 vaccine series or recommended boosters). Concurrently, the inner and outer contexts of implementation will be ascertained and catalogued to inform future scale-up. Florida State University's institutional review board approved the study (STUDY00003617).

Results: Our study was funded at the end of April 2021. Aim 1 data collection concluded in early 2022. The entire study is expected to conclude in January 2025.

Conclusions: If effective, our digital health intervention will be poised for broad, rapid dissemination to reduce COVID-19 mortality among unvaccinated Black young adults in the southern United States. Our findings will have the potential to inform

efforts that seek to address medical mistrust through participatory approaches. The lessons learned from the conduct of our study could be instrumental in improving health care engagement among Black young adults for several critical areas that disproportionately harm this community, such as tobacco control and diabetes prevention.

Trial Registration: ClinicalTrials.gov NCT05490329; <https://clinicaltrials.gov/ct2/show/NCT05490329>

International Registered Report Identifier (IRRID): DERR1-10.2196/41240

(*JMIR Res Protoc* 2023;12:e41240) doi: [10.2196/41240](https://doi.org/10.2196/41240)

KEYWORDS

COVID-19; COVID; vaccine hesitancy framework; African American; young adults; implementation science; digital health; mHealth; behavioral intervention; vaccination; intervention; mortality; USA

Introduction

Background

Interventions for increasing the uptake of COVID-19 vaccination among young adults are central to ending the pandemic [1]. Given their high rate of asymptomatic infection [2], young adults represent a priority population on which to focus efforts for promoting COVID-19 vaccine uptake [1]. The acceptance of COVID-19 vaccination is lower among African American or Black (henceforth referred to as *Black*) young adults aged 18 to 29 years. In 2020, a population-based study indicated that only 42% of Black Americans reported being likely to accept vaccination against COVID-19, whereas 63% of White and Hispanic or Latinx adults were likely to accept COVID-19 vaccination [3]. In a nationally representative survey on the same topic, lower vaccine acceptance was associated with younger age [4]. Although the vaccination gap between the Black and White adult populations has narrowed, the disparity between Black and White young adults aged 18 to 29 years persists, with Black young adults being at about a 14% disadvantage when compared to their White peers [5]. COVID-19 has exacerbated the disparities experienced by Black young adults, particularly those residing in the southern United States, where health care access continues to be a barrier, and the vaccination gap between White and Black southern US adults is about 7.2% [5,6]. From May to August 2020, Black individuals accounted for 18.7% of COVID-19 deaths despite making up just 12.5% of the US population [7]. Stigma, discrimination, and distress are highest among those with intersectional identities (eg, Black, young, rural, etc) [8], reinforcing health inequities [9,10]. Recent studies found that respondents who reported experiences of racial discrimination had increased odds of higher vaccine hesitancy when compared to those who did not report such experiences and that vaccine hesitancy was intertwined with institutional distrust [11,12].

Over the past year, there have been notable changes in the epidemiology, public health recommendations, and pandemic-related mitigation strategies surrounding COVID-19. The rates of COVID-19 vaccination are currently at 61.8% in Alabama, 64.3% in Georgia, and 82.2% in North Carolina, and these rates continue to be lower among Black populations in these southern states [13]; yet, only 34.1%, 34.9%, and 25.1% of Alabama, Georgia, and North Carolina residents, respectively, have accepted a booster. Those who remain unvaccinated may be highly resistant toward accepting vaccination or overwhelmingly apathetic due to the numerous, fast-paced

changes in COVID-19 knowledge and messaging that occurred during the course of the past year.

Digital health interventions (DHIs) can reach young adults regardless of geographic location and stigmatizing experiences with health care institutions [14]. DHIs can enable young adults to make informed decisions about their health, using a familiar modality that young adults value and trust. DHIs are well suited for young adults, given the ubiquity of technology use. A recent report found that 96% of 18- to 29-year-old adults in the United States owned a smartphone [15]. As such, smartphones are suitable for delivering content that is tailored to each user's unique needs. Further, DHIs have been shown to increase knowledge, self-efficacy, and motivation for change while also ameliorating distrust, fear, and stigma across a variety of health conditions [16-21]. Young adults already rely on digital technologies to build their social networks, receive social support, and obtain health information [18,22,23]. Access to credible web-based resources is critical, given that the majority of young adults access COVID-19 information from web-based news and social media sites [24].

Considering these factors, we developed this protocol to adapt a previously developed DHI in the domain of HIV status disclosure (Tough Talks) to a COVID-19 vaccine decision-making context (Tough Talks for COVID-19 [TT-C]) [25]. The TT-C intervention aims to enable Black young adults in the southern United States to make informed, autonomous decisions about COVID-19 vaccine receipt via nonstigmatizing and tailored messaging. Through engaging activities and narrative communication, TT-C will address the structural contexts (eg, issues of confidence, distrust in medicine, and stigma), misinformation (eg, vaccination knowledge), environmental barriers (eg, access to care and health insurance), and potential consequences (eg, outcomes related to accepting or refusing vaccination) [26] related to vaccine decisions. Using community-based participatory research (CBPR) methods to cocreate TT-C with Black young adults will promote personal agency, bolster resilience in the face of the pandemic, strengthen intervention quality, and increase intervention relevance and engagement [27-29].

The CBPR Approach

CBPR is a collaborative approach to science that involves authentic partnerships between researchers and the community being supported [30]. The goals of CBPR are to collaboratively create solutions, such as an intervention (as is the case in our study), that are meaningful and helpful to the community and

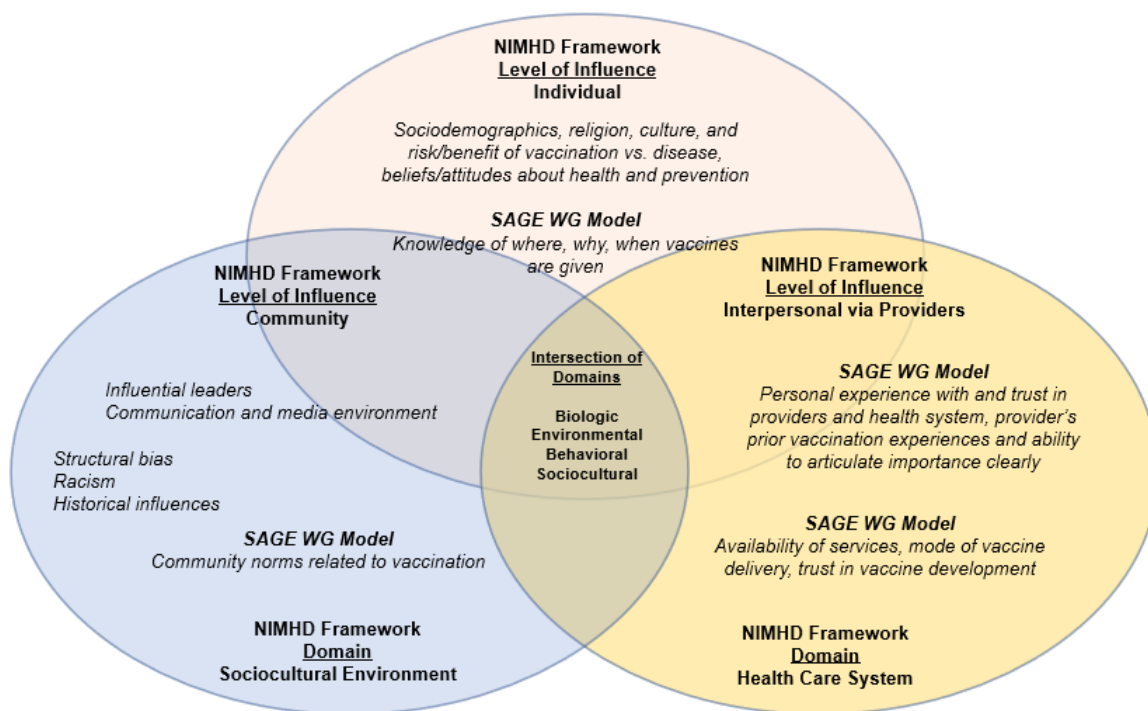
to partner with the community to address potential concerns or barriers. CBPR acknowledges that the community has expertise and that active participation and community feedback are essential to project success [30,31]. Considering the persistent mistreatment of Black communities within health care institutions that has resulted in skepticism and distrust toward new health interventions and research studies, the study team felt that it was imperative to adopt CBPR within the TT-C DHI research project.

Framework

Vaccine hesitancy is influenced by factors at the individual, community, provider, health care system, and societal levels [32]. As espoused by the World Health Organization Strategic Advisory Group of Experts, individual and social group influences, contextual influences, and vaccine-specific issues

must be identified and targeted through multicomponent and tailored interventions to increase vaccine uptake within key populations [33]. We will therefore utilize the National Institutes of Health/National Institute of Minority Health Disparities research framework to assess multilevel factors at the individual (knowledge, attitudes, and normative beliefs), interpersonal (peer and family influences), institutional (provider communication and health care system), and structural levels (stigma and discrimination) that influence COVID-19 vaccine hesitancy and refusal. We have created a model (informed by the Strategic Advisory Group of Experts Working Group; Figure 1) that depicts the determinants that are relevant to understanding and addressing vaccine hesitancy among Black young adults [34]. This model will be used to guide the development of our intervention.

Figure 1. Vaccine hesitancy model for US-based minoritized populations. The model is informed by the NIMHD research framework and the World Health Organization Strategic Advisory Group of Experts. NIMHD: National Institute of Minority Health Disparities. SAGE WG: Strategic Advisory Group of Experts Working Group.



Objectives

Our protocol includes 3 objectives (ie, specific aims). For aim 1, we conducted multimethod formative research to elicit the behavioral, cognitive, and environmental determinants influencing COVID-19 vaccine hesitancy among Black young adults. For aim 2, in collaboration with expert advisors, community partners, and Black young adult end users, we will leverage the ADAPT-ITT (assessment, decision, administration, production, topical experts, integration, training, and testing) framework [35] to develop and refine TT-C. For aim 3, we will conduct a hybrid type 1 effectiveness implementation randomized controlled trial (RCT) with 360 Black young adults from Alabama, Georgia, and North Carolina to assess the effectiveness of TT-C in increasing COVID-19 vaccine uptake while concurrently evaluating the implementation contexts that affect intervention delivery.

Timeline

Ours is a 4-year (48-month) study, and regulatory activities will be conducted between months 1 and 6 of the study. The development team will work to adapt the Tough Talks platform to create TT-C during months 6 to 18, which will include the internal testing of the platform’s features and usability (aims 1 and 2). Following feedback from the full investigative team, our expert advisors, the community, and youth advisory members, the intervention will be tested for feasibility and acceptability with youth through a technical pilot during months 18 to 24 (aim 2). We plan to launch the RCT by month 24, which will conclude at month 48 (ie, at the end of 4 years; aim 3).

Methods

Ethics Approval

All study materials and procedures were reviewed and approved by the University of North Carolina, Chapel Hill Institutional Review Board (approval number: 21-1746) and by the Florida State University Institutional Review Board (STUDY00003617). Informed consent will be collected digitally from all study participants prior to data collection and randomization. Study data will be deidentified and stored on a secure server. Study participants will receive an incentive of a US \$50 gift card payment for each data collection.

Young Adult Advisory Board

Young adults from 3 states will be recruited for the TT-C young adult advisory board (YAB) through our community and academic partners, and we will pay special attention to ensuring diversity in age, gender, and vaccine-related perceptions. The TT-C YAB will be formed in the first quarter of the study and will meet monthly for the entire project period. The TT-C YAB will provide guidance on (1) young adults' knowledge, beliefs, and attitudes toward COVID-19 vaccination; (2) sources of vaccine misinformation and disinformation, support, and resource needs; and (3) strategies for communicating with Black young adults to address vaccine hesitancy. The health inequities laid bare by the pandemic and the calls for social justice for racial minorities will be the center of this approach. We will ensure that TT-C YAB members are supported to share their lived experiences and advise the investigator team on addressing racism and discrimination in TT-C.

Community Advisory Group

We include respected experts in health disparities, social justice and equity, CBPR, community activism and advocacy, and stigma. Our advisory board includes scientists of color, leadership from historically Black colleges and universities, and community advocates. Members will provide guidance on all aspects of the study. The full board will meet biannually; individual board members will meet with the study team as needed to provide feedback.

Recruitment

For all aims, our recruitment strategy includes (1) free and paid advertising and posting on social media sites; (2) information distribution through national organizations working with Black young adults, including historically Black colleges and universities; and (3) information distribution through our community partners and other network collaborations. We will use methods that were successfully deployed in our prior studies to recruit participants through social media sites that are frequented by Black young adults and rely on our network of community and academic partners for additional dissemination [36,37]. The recruitment procedures may vary slightly depending on the community organization and study phase, but all recruitment materials will use consistent messaging that frames the study as a mechanism for learning more about COVID-19 vaccines.

Eligibility Criteria

The aim 1 eligibility criteria include being aged 18 to 29 years; identifying as Black; being proficient in English; having access to a personal smartphone; and being a current resident of Alabama, Georgia, or North Carolina. The aim 2 eligibility criteria include being aged 18 to 29 years; identifying as Black; being proficient in English; having access to a personal smartphone; being a current resident of Alabama, Georgia, or North Carolina; and being hesitant toward COVID-19 vaccines. The aim 3 eligibility criteria include being aged 18 to 29 years; identifying as Black; being proficient in English; having access to a personal smartphone; being a current resident of Alabama, Georgia, or North Carolina; and being out of compliance with vaccination guidelines [38]. Participants who do not comply with vaccination guidelines include both individuals who have never received a COVID-19 vaccine and those who have not received any booster.

Screening for Eligibility

All potential participants (whether recruited via the internet or in person) will complete a web-based screening survey via Qualtrics (Qualtrics International Inc) to provide consent for screening and verify all inclusion criteria. For those who met the eligibility criteria for aim 1, the screening survey directed participants to an informed consent video with accompanying text. Those who meet eligibility criteria for aims 2 and 3 will be asked to record their first name, email address, and phone number if they are interested in participating in the study. Those who are disinterested in participating can decline by exiting the website. Potential participants who do not meet the eligibility criteria will be asked if they would like to be contacted about other research studies and, if so, to provide contact information.

Aim 1

Overview

At the time of publication, data collection for aim 1 has already been completed. Aim 1 included the following two distinct phases: a web-based survey and digital storytelling workshops. A total of 150 Black young adults were recruited from Alabama, Georgia, and North Carolina to participate in a web-based survey. A subsample was invited to participate in a web-based digital storytelling workshop to produce digital stories that will become part of the TT-C intervention.

Aim 1 Survey

Participants completed a one-time web-based survey through the Qualtrics survey platform, which included both validated survey constructs and choose-your-own-adventure formats [39,40]. Within the choose-your-own-adventure portion, participants were presented with culturally and contextually realistic scenarios, and we asked them to make decisions and reflect on the outcomes of these decisions. Each story path included multiple branch points where participants made a behavioral choice. Each choice impacted the subsequent information presented and later scenario branches. Short multiple-choice questions and open-ended questions were included within each path to assess how participants made their choices and to capture their reflections on these decisions. This survey took about 30 to 45 minutes to complete. Participants

who reported high levels of vaccine confidence were invited to participate in the digital storytelling workshop.

Aim 1 Digital Storytelling Workshop

Interested and eligible survey respondents were directed to informational text that described the digital storytelling workshop and its purpose [41]. Once the participants consented, they were invited to participate in 1 of 2 web-based digital storytelling workshops; each consisted of 3 sessions. Each workshop session lasted about 3 hours, and sessions were conducted 1 week apart. Participants were informed that the goal was to develop a video that would be included in an intervention that aims to help peers learn from their COVID-19 pandemic-related lived experiences. During the workshops, participants created digital stories (1- to 3-minute videos) that included still and moving images, voice-over recordings of the participants telling their stories, and background music or text to document their experiences related to the COVID-19 pandemic and why they chose to be vaccinated. Select digital stories will be incorporated into a TT-C module entitled “Hear from you peers.” This module will be available to aim 3 participants who are randomized to the intervention condition.

Aim 2

Overview

Up to 16 young adults who have expressed COVID-19 vaccine hesitancy will participate in web-based focus groups. The focus groups will consist of 2 rounds of usability testing activities that will be conducted 1 to 2 months apart. During round 1, participants will review TT-C content, generate additional ideas, and identify assets on which to build, guided by the ADAPT-ITT framework (Table 1) [35]. Young adults will provide recommendations and context-relevant insights regarding any requested additions or changes. The study team will collectively review the recommendations and prioritize and address the actionable ideas to be presented for further feedback and testing with YAB members. Beta testing will (1) allow for a full assessment of intervention content (eg, identification of any remaining spelling, text, or graphical errors) and technical functionality, (2) ensure that the back-end collection of app analytics data is being performed appropriately, and (3) help finalize pilot test procedures. All errors and technical bugs will be addressed or optimized prior to the RCT.

Table 1. ADAPT-ITT^a model: Phases and methodology.

ADAPT-ITT phase	Aim	Study method
Assessment	1	Formative research with Black young adults via a web-based survey, digital storytelling, and focus groups
Decision	2	Adapt Tough Talks based on established feasibility, acceptability, and early effectiveness data
Administration	2	Usability testing with Black young adults in Alabama, Georgia, and North Carolina
Production	2	Produce initial intervention prototype
Topical Experts	2	Review TT-C ^b with identified scientific and community experts and young adult advisors
Integration	2	Integrate content from topical experts, young adult advisors, and Black young adult participants of the technical pilot
Training	2	Train staff on TT-C app functionality
Testing	3	Conduct hybrid type 1 effectiveness implementation randomized controlled trial

^aADAPT-ITT: assessment, decision, administration, production, topical experts, integration, training, and testing.

^bTT-C: Tough Talks for COVID-19.

TT-C Intervention and Control Condition

The TT-C intervention will be finalized to be self-directed and fully asynchronous, so that there will be no need for the participants to engage with an interventionist. The initial assessments suggest that to complete all activities and review all content, the study participants will need to dedicate about 2 to 4 hours of time (spread across 1 month). Our standard-of-care control will be the provision of COVID-19 vaccine materials, which will be adapted from the Centers for Disease Control and Prevention and shared via email. Standard-of-care materials will be hosted via the internet and will be accessible to the general public. In the final phase of aim 2, the YAB and community partners will participate in an assessment of the TT-C intervention to assess intervention feasibility and acceptability and finalize RCT study procedures.

Aim 3

Overview

In aim 3, we will conduct a hybrid type 1 effectiveness implementation RCT. We will enroll 360 Black young adults from Alabama, Georgia, and North Carolina who are unvaccinated, have only received 1 dose of a 2-dose series, or have not received boosters against COVID-19 in accordance with current Centers for Disease Control and Prevention booster eligibility criteria [42]. After collecting informed consent, using block randomization by state, we will allocate 180 participants to each arm. The web-based screener will automatically randomize participants (N=360) to the control condition (n=180) or the TT-C intervention arm (n=180). Self-report data, including vaccination status, will be collected at baseline and at 1 and 3 months after baseline.

Statistical Power

Power calculations were conducted based on the assumptions that dropout would be equivalent across arms and approximately 15% of participants would be lost to follow-up; therefore, we assume that 306 participants will complete the primary end point assessment. If the rate of COVID-19 vaccination in the control arm is between 10% and 20%, we will have 80% power to detect an odds ratio of 1.92 to 3.21 when comparing vaccination uptake between arms, assuming a sample size of 306 and a 2-sided α of .05. We anticipate that the vaccination rate in the control arm will be low, given that COVID-19 vaccines have been available for some time. Therefore, we expect that a total sample size of 360 will provide sufficient

power to detect a clinically meaningful difference in vaccine uptake.

Aim 3 Effectiveness Measures and Analysis

The aim 3 primary effectiveness outcome is COVID-19 vaccine uptake, which will be defined as the receipt of any COVID-19 vaccine (primary series or boosters). The secondary effectiveness outcomes are vaccine hesitancy and confidence [43], as well as vaccine knowledge, attitudes, and beliefs [44]. We will also collect quantitative data on implementation outcomes, the social cognitive theory constructs targeted by TT-C, COVID-19-specific risks and behaviors, and pertinent constructs that have been validated in the extant literature on Black young adults (Table 2).

Table 2. Effectiveness measures.

	Baseline	Follow-up
Number and percentage of participants who receive any new vaccine during the study period (eg, participants who accept the first dose of a COVID-19 vaccine, complete the vaccine series, or receive a booster shot)		✓
Vaccine hesitancy [32], confidence [43], knowledge [45], attitudes, and beliefs [32]	✓	✓
Usability (including acceptability; ie, TT-C ^a satisfaction and completion), demand (including the number of youths screened, enrolled, and retained), and practicality (based on the TT-C intervention's cultural appropriateness and fit) [46]		✓
Physical environmental factors (access, utilization, and vaccine misinformation), social environmental factors (discrimination, as measured via the Adapted Everyday Discrimination Scale for Medical Settings [47]; stigma; social support, as measured via the MOS ^b social support survey [48]; social norms; and medical mistrust, as measured via the Group-Based Medical Mistrust Scale [49]), outcome expectations (COVID-19-specific knowledge, attitudes, and beliefs), observational learning (vaccination [eg, flu or HPV ^c] experiences of self or others), and perceived self-efficacy (vaccination barriers and facilitators)	✓	✓
Sociodemographic characteristics (age, race, ethnicity, gender identity, income, employment, and education [eg, current student])	✓	✓
Pre-existing conditions (eg, diabetes, cardiovascular conditions, etc)	✓	✓

^aTT-C: Tough Talks for COVID-19.

^bMOS: Medical Outcomes Study.

^cHPV: human papillomavirus.

We will use logistic regression to determine the effect of the treatment arm on the probability of vaccination uptake (“yes” or “no”) at month 3. We will focus on the odds ratios for comparing the probability of vaccination in the treatment group with the probability of vaccination in the control group. As an exploratory analysis, we will examine primary and secondary outcomes by enrollment vaccination status (not vaccinated vs vaccinated with 1 or 2 doses and no booster shot). The secondary outcomes—vaccine hesitancy [4]; vaccine confidence [43]; and vaccine knowledge, attitudes, and beliefs [44]—will all be assessed by using previously validated scale scores, of which each will consist of the continuous sum of responses to a series of questions with Likert scale responses. We will use linear regression models with treatment group as the exposure to determine whether continuous secondary outcomes vary among treatment groups. Lastly, we will use the causal mediation framework proposed by Valeri and Vanderweele [50] to understand the mechanisms for any intervention effects through each of our hypothesized mediators [50-53]. We will use the *g-formula* command in Stata (StataCorp LLC), which uses the mediational *g-formula*, to estimate the controlled direct effects,

natural direct effects, and natural mediated (indirect) effects [54].

In sensitivity analyses, we will also use inverse probability of treatment weights to account for missing data and potential differential retention between study arms over the study period. We will weight outcome models by using stabilized inverse probability of censoring weights that include the treatment arm as a predictor to account for differential loss to follow-up.

Aim 3 Implementation Outcomes and Analysis

We will conduct qualitative interviews with a group of purposively selected participants (we estimate 18-24 participants) to assess how the intervention was internalized and experienced. We will conduct in-depth exit interviews on a rolling basis after participants have concluded the 3-month study cycle. All interviews will be audio-recorded and transcribed verbatim. Qualitative analyses will be conducted in the NVivo (QSR International) coding program. Study participants will be asked questions on how sociocultural nonintervention contexts affected the likelihood of vaccine acceptance, vaccine series completion, and vaccine hesitancy.

Interviews will last about 1 hour. We will perform a rapid content analysis, which is routinely used in implementation science to assess and disseminate results quickly and accurately [55]. The findings will be explored as a function of participant age, sex, and state. Qualitative findings will provide direct insight into real-world implementation considerations.

Results

Our study was funded at the end of April 2021. Approval from the University of North Carolina, Chapel Hill Institutional Review Board was obtained shortly thereafter. Aim 1 data collection concluded in early 2022. The entire study is expected to be complete at the end of January 2025.

Discussion

Overview

The TT-C intervention will address COVID-19–related vaccine hesitancy among Black young adults in Alabama, Georgia, and North Carolina by including tailored content to engage Black young adults and promote agency and autonomy in decision-making related to vaccination, while also addressing the persistent effects of historic contexts and structural stigma and racism against Black populations in the United States. The TT-C DHI will address issues that not only impact COVID-19 vaccine uptake but also influence the acceptance of other

vaccines and health services, such as addressing medical distrust, highlighting the role of Black scientists in vaccine development and medicine, and providing tailored content on how to assess misinformation. The TT-C app will be developed to retain relevance as the pandemic shifts, and it can be adapted to address other conditions that disproportionately affect Black young adults.

Limitations

In assessing trial designs, we considered stepped wedge and waitlist formats. However, since our aim is to reach Black young adults who are often not engaged in care, particularly those in the southern United States, we determined that multipronged recruitment and individual-level randomization would be the best approaches. Because the landscape of COVID-19 prevention and related science are quickly changing (eg, masking, the definition of *fully vaccinated*, etc), ideally, the app should be flexible and responsive. Although the content delivered through the TT-C app is adaptable, not all components can be adjusted once they are developed.

Conclusion

If the TT-C DHI is effective in increasing COVID-19 vaccination uptake among Black young adults in the southern United States, we will be poised for rapid dissemination and broad implementation to reduce COVID-19 morbidity and mortality among unvaccinated or partially vaccinated Black young adults in the southern United States.

Acknowledgments

The research reported in this publication was supported by the National Institute of Minority Health Disparities of the National Institutes of Health under award number R01MD016834. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Data Availability

The data sets generated during aim 3 of our study will be shared in compliance with National Institutes of Health data sharing policies and will be made available from the senior author on reasonable request.

Authors' Contributions

LBHW (contact principal investigator) and HB are co–principal investigators of the study. HB is the first and lead author. LBHW is the last and senior author on this protocol manuscript. MAL is the mobile app development lead. EET, ACMB, and MLGC provided leadership on digital storytelling and community engagement. MCDS and DB are statistical and quantitative experts. KEM and AP are epidemiology and intervention scholars who are contributing their expertise to the study. CT and CLB are part of research operations. All authors contributed to the writing and editing of this protocol.

Conflicts of Interest

None declared.

References

1. Goldstein E, Lipsitch M. Temporal rise in the proportion of both younger adults and older adolescents among COVID-19 cases in Germany: evidence of lesser adherence to social distancing practices? medRxiv Preprint posted online on April 11, 2020. [FREE Full text] [doi: [10.1101/2020.04.08.20058719](https://doi.org/10.1101/2020.04.08.20058719)] [Medline: [32511603](https://pubmed.ncbi.nlm.nih.gov/32511603/)]
2. Huang L, Zhang X, Zhang X, Wei Z, Zhang L, Xu J, et al. Rapid asymptomatic transmission of COVID-19 during the incubation period demonstrating strong infectivity in a cluster of youngsters aged 16-23 years outside Wuhan and characteristics of young patients with COVID-19: A prospective contact-tracing study. J Infect 2020 Jun;80(6):e1-e13 [FREE Full text] [doi: [10.1016/j.jinf.2020.03.006](https://doi.org/10.1016/j.jinf.2020.03.006)] [Medline: [32283156](https://pubmed.ncbi.nlm.nih.gov/32283156/)]

3. Funk C, Tyson A. Intent to get a COVID-19 vaccine rises to 60% as confidence in research and development process increases. Pew Research Center. 2020 Dec 03. URL: <https://www.pewresearch.org/science/2020/12/03/intent-to-get-a-covid-19-vaccine-rises-to-60-as-confidence-in-research-and-development-process-increases/> [accessed 2023-01-24]
4. Mercadante AR, Law AV. Will they, or won't they? Examining patients' vaccine intention for flu and COVID-19 using the Health Belief Model. *Res Social Adm Pharm* 2021 Sep;17(9):1596-1605 [FREE Full text] [doi: [10.1016/j.sapharm.2020.12.012](https://doi.org/10.1016/j.sapharm.2020.12.012)] [Medline: [33431259](https://pubmed.ncbi.nlm.nih.gov/33431259/)]
5. Kriss JL, Hung MC, Srivastav A, Black CL, Lindley MC, Lee JT, et al. COVID-19 vaccination coverage, by race and ethnicity - National immunization survey adult COVID module, United States, December 2020-November 2021. *MMWR Morb Mortal Wkly Rep* 2022 Jun 10;71(23):757-763 [FREE Full text] [doi: [10.15585/mmwr.mm7123a2](https://doi.org/10.15585/mmwr.mm7123a2)] [Medline: [35679179](https://pubmed.ncbi.nlm.nih.gov/35679179/)]
6. Murthy BP, Sterrett N, Weller D, Zell E, Reynolds L, Toblin RL, et al. Disparities in COVID-19 vaccination coverage between urban and rural counties - United States, December 14, 2020-April 10, 2021. *MMWR Morb Mortal Wkly Rep* 2021 May 21;70(20):759-764 [FREE Full text] [doi: [10.15585/mmwr.mm7020e3](https://doi.org/10.15585/mmwr.mm7020e3)] [Medline: [34014911](https://pubmed.ncbi.nlm.nih.gov/34014911/)]
7. Gold JAW, Rossen LM, Ahmad FB, Sutton P, Li Z, Salvatore PP, et al. Race, ethnicity, and age trends in persons who died from COVID-19 - United States, May-August 2020. *MMWR Morb Mortal Wkly Rep* 2020 Oct 23;69(42):1517-1521 [FREE Full text] [doi: [10.15585/mmwr.mm6942e1](https://doi.org/10.15585/mmwr.mm6942e1)] [Medline: [33090984](https://pubmed.ncbi.nlm.nih.gov/33090984/)]
8. Devakumar D, Shannon G, Bhopal SS, Abubakar I. Racism and discrimination in COVID-19 responses. *Lancet* 2020 Apr 11;395(10231):1194 [FREE Full text] [doi: [10.1016/S0140-6736\(20\)30792-3](https://doi.org/10.1016/S0140-6736(20)30792-3)] [Medline: [32246915](https://pubmed.ncbi.nlm.nih.gov/32246915/)]
9. Millett GA, Jones AT, Benkeser D, Baral S, Mercer L, Beyrer C, et al. Assessing differential impacts of COVID-19 on black communities. *Ann Epidemiol* 2020 Jul;47:37-44 [FREE Full text] [doi: [10.1016/j.annepidem.2020.05.003](https://doi.org/10.1016/j.annepidem.2020.05.003)] [Medline: [32419766](https://pubmed.ncbi.nlm.nih.gov/32419766/)]
10. Poteat T, Millett GA, Nelson LE, Beyrer C. Understanding COVID-19 risks and vulnerabilities among black communities in America: the lethal force of syndemics. *Ann Epidemiol* 2020 Jul;47:1-3 [FREE Full text] [doi: [10.1016/j.annepidem.2020.05.004](https://doi.org/10.1016/j.annepidem.2020.05.004)] [Medline: [32419765](https://pubmed.ncbi.nlm.nih.gov/32419765/)]
11. Savoia E, Piltch-Loeb R, Goldberg B, Miller-Idriss C, Hughes B, Montrond A, et al. Predictors of COVID-19 vaccine hesitancy: Socio-demographics, co-morbidity, and past experience of racial discrimination. *Vaccines (Basel)* 2021 Jul 09;9(7):767 [FREE Full text] [doi: [10.3390/vaccines9070767](https://doi.org/10.3390/vaccines9070767)] [Medline: [34358184](https://pubmed.ncbi.nlm.nih.gov/34358184/)]
12. Budhwani H, Maycock T, Murrell W, Simpson T. COVID-19 vaccine sentiments among African American or Black adolescents in rural Alabama. *J Adolesc Health* 2021 Dec;69(6):1041-1043 [FREE Full text] [doi: [10.1016/j.jadohealth.2021.09.010](https://doi.org/10.1016/j.jadohealth.2021.09.010)] [Medline: [34666953](https://pubmed.ncbi.nlm.nih.gov/34666953/)]
13. Centers for Disease Control and Prevention. CDC COVID data tracker. Centers for Disease Control and Prevention. URL: <https://covid.cdc.gov/covid-data-tracker> [accessed 2023-01-24]
14. Budhwani H, Kiszla BM, Hightow-Weidman LB. Adapting digital health interventions for the evolving HIV landscape: examples to support prevention and treatment research. *Curr Opin HIV AIDS* 2022 Mar 01;17(2):112-118. [doi: [10.1097/COH.0000000000000721](https://doi.org/10.1097/COH.0000000000000721)] [Medline: [35225251](https://pubmed.ncbi.nlm.nih.gov/35225251/)]
15. Faverio M. Share of those 65 and older who are tech users has grown in the past decade. Pew Research Center. 2022 Jan 13. URL: <https://www.pewresearch.org/fact-tank/2022/01/13/share-of-those-65-and-older-who-are-tech-users-has-grown-in-the-past-decade/> [accessed 2023-01-24]
16. Bauermeister JA, Muessig KE, LeGrand S, Flores DD, Choi SK, Dong W, et al. HIV and sexuality stigma reduction through engagement in online forums: Results from the HealthMPowerment intervention. *AIDS Behav* 2019 Mar;23(3):742-752 [FREE Full text] [doi: [10.1007/s10461-018-2256-5](https://doi.org/10.1007/s10461-018-2256-5)] [Medline: [30121727](https://pubmed.ncbi.nlm.nih.gov/30121727/)]
17. Mulawa MI, Rosengren AL, Amico KR, Hightow-Weidman LB, Muessig KE. mHealth to reduce HIV-related stigma among youth in the United States: a scoping review. *Mhealth* 2021 Apr 20;7:35 [FREE Full text] [doi: [10.21037/mhealth-20-68](https://doi.org/10.21037/mhealth-20-68)] [Medline: [33898604](https://pubmed.ncbi.nlm.nih.gov/33898604/)]
18. Hightow-Weidman LB, Muessig KE, Bauermeister J, Zhang C, LeGrand S. Youth, technology, and HIV: Recent advances and future directions. *Curr HIV/AIDS Rep* 2015 Dec;12(4):500-515 [FREE Full text] [doi: [10.1007/s11904-015-0280-x](https://doi.org/10.1007/s11904-015-0280-x)] [Medline: [26385582](https://pubmed.ncbi.nlm.nih.gov/26385582/)]
19. Lelutiu-Weinberger C, Pachankis JE, Gamarel KE, Surace A, Golub SA, Parsons JT. Feasibility, acceptability, and preliminary efficacy of a live-chat social media intervention to reduce HIV risk among young men who have sex with men. *AIDS Behav* 2015 Jul;19(7):1214-1227 [FREE Full text] [doi: [10.1007/s10461-014-0911-z](https://doi.org/10.1007/s10461-014-0911-z)] [Medline: [25256808](https://pubmed.ncbi.nlm.nih.gov/25256808/)]
20. Rhodes SD, Hergenrather KC, Duncan J, Vissman AT, Miller C, Wilkin AM, et al. A pilot intervention utilizing Internet chat rooms to prevent HIV risk behaviors among men who have sex with men. *Public Health Rep* 2010;125 Suppl 1(Suppl 1):29-37 [FREE Full text] [doi: [10.1177/00333549101250S105](https://doi.org/10.1177/00333549101250S105)] [Medline: [20408385](https://pubmed.ncbi.nlm.nih.gov/20408385/)]
21. Muessig KE, Nekkanti M, Bauermeister J, Bull S, Hightow-Weidman LB. A systematic review of recent smartphone, internet and Web 2.0 interventions to address the HIV continuum of care. *Curr HIV/AIDS Rep* 2015 Mar;12(1):173-190 [FREE Full text] [doi: [10.1007/s11904-014-0239-3](https://doi.org/10.1007/s11904-014-0239-3)] [Medline: [25626718](https://pubmed.ncbi.nlm.nih.gov/25626718/)]

22. Allison S, Bauermeister JA, Bull S, Lightfoot M, Mustanski B, Shegog R, et al. The intersection of youth, technology, and new media with sexual health: moving the research agenda forward. *J Adolesc Health* 2012 Sep;51(3):207-212 [FREE Full text] [doi: [10.1016/j.jadohealth.2012.06.012](https://doi.org/10.1016/j.jadohealth.2012.06.012)] [Medline: [22921129](https://pubmed.ncbi.nlm.nih.gov/22921129/)]
23. Pingel ES, Thomas L, Harmell C, Bauermeister J. Creating comprehensive, youth centered, culturally appropriate sex education: What do young gay, bisexual and questioning men want? *Sex Res Social Policy* 2013 Dec 01;10(4):10.1007/s13178-013-0134-5 [FREE Full text] [doi: [10.1007/s13178-013-0134-5](https://doi.org/10.1007/s13178-013-0134-5)] [Medline: [24348222](https://pubmed.ncbi.nlm.nih.gov/24348222/)]
24. Hill PW, Diamond J, Spiegel AN, VanWormer E, Leadabrand M, McQuillan J. Accuracy of COVID-19 relevant knowledge among youth: Number of information sources matters. *PLoS One* 2022 Dec 27;17(12):e0267871 [FREE Full text] [doi: [10.1371/journal.pone.0267871](https://doi.org/10.1371/journal.pone.0267871)] [Medline: [36574374](https://pubmed.ncbi.nlm.nih.gov/36574374/)]
25. Muessig KE, Knudtson KA, Soni K, Larsen MA, Traum D, Dong W, et al. "I DIDN'T TELL YOU SOONER BECAUSE I DIDN'T KNOW HOW TO HANDLE IT MYSELF." Developing a virtual reality program to support HIV-status disclosure decisions. *Digit Cult Educ* 2018;10:22-48 [FREE Full text] [Medline: [30123342](https://pubmed.ncbi.nlm.nih.gov/30123342/)]
26. May T, Perry B. *Social Research & Reflexivity: Content, Consequences and Context*. Thousand Oaks, CA: SAGE Publications Ltd; 2011.
27. Herrick AL, Lim SH, Wei C, Smith H, Guadamuz T, Friedman MS, et al. Resilience as an untapped resource in behavioral intervention design for gay men. *AIDS Behav* 2011 Apr;15 Suppl 1:S25-S29. [doi: [10.1007/s10461-011-9895-0](https://doi.org/10.1007/s10461-011-9895-0)] [Medline: [21344306](https://pubmed.ncbi.nlm.nih.gov/21344306/)]
28. Earnshaw VA, Bogart LM, Dovidio JF, Williams DR. Stigma and racial/ethnic HIV disparities: moving toward resilience. *Am Psychol* 2013;68(4):225-236 [FREE Full text] [doi: [10.1037/a0032705](https://doi.org/10.1037/a0032705)] [Medline: [23688090](https://pubmed.ncbi.nlm.nih.gov/23688090/)]
29. Pavarini G, Lyreskog D, Manku K, Musesengwa R, Singh I. Debate: Promoting capabilities for young people's agency in the COVID-19 outbreak. *Child Adolesc Ment Health* 2020 Sep;25(3):187-188 [FREE Full text] [doi: [10.1111/camh.12409](https://doi.org/10.1111/camh.12409)] [Medline: [32791558](https://pubmed.ncbi.nlm.nih.gov/32791558/)]
30. Israel BA, Schulz AJ, Parker EA, Becker AB, Allen AJIII, Guzman JR, et al. Critical issues in developing and following CBPR principles. In: Wallerstein N, Duran B, Oetzel JG, Minkler M, editors. *Community-Based Participatory Research for Health: Advancing Social and Health Equity*, 3rd Edition. Hoboken, NJ: John Wiley & Sons; 2017:32-35.
31. Brush BL, Mentz G, Jensen M, Jacobs B, Saylor KM, Rowe Z, et al. Success in long-standing community-based participatory research (CBPR) partnerships: A scoping literature review. *Health Educ Behav* 2020 Aug;47(4):556-568 [FREE Full text] [doi: [10.1177/1090198119882989](https://doi.org/10.1177/1090198119882989)] [Medline: [31619072](https://pubmed.ncbi.nlm.nih.gov/31619072/)]
32. Shapiro GK, Tatar O, Dube E, Amsel R, Knauper B, Naz A, et al. The vaccine hesitancy scale: Psychometric properties and validation. *Vaccine* 2018 Jan 29;36(5):660-667. [doi: [10.1016/j.vaccine.2017.12.043](https://doi.org/10.1016/j.vaccine.2017.12.043)] [Medline: [29289384](https://pubmed.ncbi.nlm.nih.gov/29289384/)]
33. SAGE Working Group. Report of the SAGE Working Group on vaccine hesitancy. Action plan on Science in Society related issues in Epidemics and Total pandemics. 2014 Nov 12. URL: https://www.asset-scienceinsociety.eu/sites/default/files/sage_working_group_revised_report_vaccine_hesitancy.pdf [accessed 2023-01-24]
34. Alvidrez J, Castille D, Laude-Sharp M, Rosario A, Tabor D. The National Institute on Minority Health and Health Disparities research framework. *Am J Public Health* 2019 Jan;109(S1):S16-S20. [doi: [10.2105/AJPH.2018.304883](https://doi.org/10.2105/AJPH.2018.304883)] [Medline: [30699025](https://pubmed.ncbi.nlm.nih.gov/30699025/)]
35. Wingood GM, DiClemente RJ. The ADAPT-ITT model: a novel method of adapting evidence-based HIV interventions. *J Acquir Immune Defic Syndr* 2008 Mar 01;47 Suppl 1:S40-S46. [doi: [10.1097/QAI.0b013e3181605df1](https://doi.org/10.1097/QAI.0b013e3181605df1)] [Medline: [18301133](https://pubmed.ncbi.nlm.nih.gov/18301133/)]
36. Hightow-Weidman LB, LeGrand S, Muessig KE, Simmons RA, Soni K, Choi SK, et al. A randomized trial of an online risk reduction intervention for young Black MSM. *AIDS Behav* 2019 May;23(5):1166-1177 [FREE Full text] [doi: [10.1007/s10461-018-2289-9](https://doi.org/10.1007/s10461-018-2289-9)] [Medline: [30269231](https://pubmed.ncbi.nlm.nih.gov/30269231/)]
37. Bauermeister J, Sullivan PS, Gravens L, Wolfe J, Countryman K, Smith-Bankhead N, et al. Reducing HIV vulnerability through a multilevel life skills intervention for adolescent men (the iREACH project): Protocol for a randomized controlled trial. *JMIR Res Protoc* 2018 Jul 10;7(7):e10174 [FREE Full text] [doi: [10.2196/10174](https://doi.org/10.2196/10174)] [Medline: [29991470](https://pubmed.ncbi.nlm.nih.gov/29991470/)]
38. Centers for Disease Control and Prevention. Getting your COVID-19 vaccine. Centers for Disease Control and Prevention. URL: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect.html?s_cid=11781:vaccine%20after%20covid%20infection.sem.ga:p:RG:GM:gen:PTN:FY22 [accessed 2023-01-24]
39. Stoner MC, Browne EN, Tweedy D, Pettifor AE, Maragh-Bass AC, Toval C, et al. Exploring motivations for COVID-19 vaccination among Black young adults in 3 southern US states: Cross-sectional study. *JMIR Form Res* 2022 Sep 02;6(9):e39144 [FREE Full text] [doi: [10.2196/39144](https://doi.org/10.2196/39144)] [Medline: [35969516](https://pubmed.ncbi.nlm.nih.gov/35969516/)]
40. Stoner MCD, Tweedy D, Comello MGL, Toval C, Pettifor AE, Larsen MA, et al. Using narratives to inform the development of a digital health intervention related to COVID-19 vaccination in Black young adults in Georgia, North Carolina and Alabama. *Vaccine* 2022 Nov 15;40(48):6908-6916 [FREE Full text] [doi: [10.1016/j.vaccine.2022.10.027](https://doi.org/10.1016/j.vaccine.2022.10.027)] [Medline: [36280559](https://pubmed.ncbi.nlm.nih.gov/36280559/)]
41. Maragh-Bass A, Comello ML, Tolley EE, Stevens DJ, Wilson J, Toval C, et al. Digital storytelling methods to empower young Black adults in COVID-19 vaccination decision-making: Feasibility study and demonstration. *JMIR Form Res* 2022 Sep 26;6(9):e38070 [FREE Full text] [doi: [10.2196/38070](https://doi.org/10.2196/38070)] [Medline: [36155984](https://pubmed.ncbi.nlm.nih.gov/36155984/)]
42. Centers for Disease Control and Prevention. Stay up to date with COVID-19 vaccines including boosters. Centers for Disease Control and Prevention. URL: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html?s_cid=11737:cdc%20covid%20booster%20shot%20guidelines.sem.ga:p:RG:GM:gen:PTN:FY22 [accessed 2023-01-24]

43. Gilkey MB, Reiter PL, Magnus BE, McRee AL, Dempsey AF, Brewer NT. Validation of the Vaccination Confidence Scale: A brief measure to identify parents at risk for refusing adolescent vaccines. *Acad Pediatr* 2016;16(1):42-49 [FREE Full text] [doi: [10.1016/j.acap.2015.06.007](https://doi.org/10.1016/j.acap.2015.06.007)] [Medline: [26300368](https://pubmed.ncbi.nlm.nih.gov/26300368/)]
44. Matranga D, Lumia C, Guarneri R, Arculeo VM, Noto M, Pivetti A, et al. The vaccinaTion & Hpv Knowledge (THinK) questionnaire: a reliability and validity study on a sample of women living in Sicily (southern-Italy). *PeerJ* 2019 May 09;7:e6254 [FREE Full text] [doi: [10.7717/peerj.6254](https://doi.org/10.7717/peerj.6254)] [Medline: [31119063](https://pubmed.ncbi.nlm.nih.gov/31119063/)]
45. Zingg A, Siegrist M. Measuring people's knowledge about vaccination: developing a one-dimensional scale. *Vaccine* 2012 May 28;30(25):3771-3777. [doi: [10.1016/j.vaccine.2012.03.014](https://doi.org/10.1016/j.vaccine.2012.03.014)] [Medline: [22445808](https://pubmed.ncbi.nlm.nih.gov/22445808/)]
46. Zaharias P. Developing a usability evaluation method for e-learning applications: From functional usability to motivation to learn. *Int J Hum Comput Interact* 2003;25(1):1-12. [doi: doi.org/10.1080/10447310802546716]
47. Peek ME, Nunez-Smith M, Drum M, Lewis TT. Adapting the everyday discrimination scale to medical settings: reliability and validity testing in a sample of African American patients. *Ethn Dis* 2011;21(4):502-509 [FREE Full text] [Medline: [22428358](https://pubmed.ncbi.nlm.nih.gov/22428358/)]
48. Sherbourne CD, Stewart AL. The MOS social support survey. *Soc Sci Med* 1991;32(6):705-714. [doi: [10.1016/0277-9536\(91\)90150-b](https://doi.org/10.1016/0277-9536(91)90150-b)] [Medline: [2035047](https://pubmed.ncbi.nlm.nih.gov/2035047/)]
49. Thompson HS, Valdimarsdottir HB, Winkel G, Jandorf L, Redd W. The Group-Based Medical Mistrust Scale: psychometric properties and association with breast cancer screening. *Prev Med* 2004 Feb;38(2):209-218. [doi: [10.1016/j.ypmed.2003.09.041](https://doi.org/10.1016/j.ypmed.2003.09.041)] [Medline: [14715214](https://pubmed.ncbi.nlm.nih.gov/14715214/)]
50. Valeri L, Vanderweele TJ. Mediation analysis allowing for exposure-mediator interactions and causal interpretation: theoretical assumptions and implementation with SAS and SPSS macros. *Psychol Methods* 2013 Jun;18(2):137-150 [FREE Full text] [doi: [10.1037/a0031034](https://doi.org/10.1037/a0031034)] [Medline: [23379553](https://pubmed.ncbi.nlm.nih.gov/23379553/)]
51. Stoner MCD, Edwards JK, Miller WC, Aiello AE, Halpern CT, Julien A, et al. Does partner selection mediate the relationship between school attendance and HIV/herpes simplex virus-2 among adolescent girls and young women in South Africa: An analysis of HIV Prevention Trials Network 068 data. *J Acquir Immune Defic Syndr* 2018 Sep 01;79(1):20-27 [FREE Full text] [doi: [10.1097/QAI.0000000000001766](https://doi.org/10.1097/QAI.0000000000001766)] [Medline: [29847479](https://pubmed.ncbi.nlm.nih.gov/29847479/)]
52. VanderWeele TJ, Tchetgen EJT. Mediation analysis with time varying exposures and mediators. *J R Stat Soc Series B Stat Methodol* 2017 Jun;79(3):917-938 [FREE Full text] [doi: [10.1111/rssb.12194](https://doi.org/10.1111/rssb.12194)] [Medline: [28824285](https://pubmed.ncbi.nlm.nih.gov/28824285/)]
53. Ranganathan M, Kilburn K, Stoner MCD, Hughes JP, MacPhail C, Gomez-Olive FX, et al. The mediating role of partner selection in the association between transactional sex and HIV incidence among young women. *J Acquir Immune Defic Syndr* 2020 Feb 01;83(2):103-110 [FREE Full text] [doi: [10.1097/QAI.0000000000002225](https://doi.org/10.1097/QAI.0000000000002225)] [Medline: [31714368](https://pubmed.ncbi.nlm.nih.gov/31714368/)]
54. Daniel RM, De Stavola BL, Cousens SN. gformula: Estimating causal effects in the presence of time-varying confounding or mediation using the g-computation formula. *Stata J* 2011;11(4):479-517 [FREE Full text] [doi: [10.1177/1536867x1201100401](https://doi.org/10.1177/1536867x1201100401)]
55. Gale RC, Wu J, Erhardt T, Bounthavong M, Reardon CM, Damschroder LJ, et al. Comparison of rapid vs in-depth qualitative analytic methods from a process evaluation of academic detailing in the Veterans Health Administration. *Implement Sci* 2019 Feb 01;14(1):11 [FREE Full text] [doi: [10.1186/s13012-019-0853-y](https://doi.org/10.1186/s13012-019-0853-y)] [Medline: [30709368](https://pubmed.ncbi.nlm.nih.gov/30709368/)]

Abbreviations

ADAPT-ITT: assessment, decision, administration, production, topical experts, integration, training, and testing
CBPR: community-based participatory research
DHI: digital health intervention
RCT: randomized controlled trial
TT-C: Tough Talks for COVID-19
YAB: Young Adult Advisory Board

Edited by A Mavragani; submitted 20.07.22; peer-reviewed by C Lelutiu-Weinberger, G Sabben; comments to author 01.11.22; revised version received 28.12.22; accepted 12.01.23; published 13.02.23

Please cite as:

Budhwani H, Maragh-Bass AC, Tolley EE, Comello MLG, Stoner MCD, Adams Larsen M, Brambilla D, Muessig KE, Pettifor A, Bond CL, Toval C, Hightow-Weidman LB

Tough Talks COVID-19 Digital Health Intervention for Vaccine Hesitancy Among Black Young Adults: Protocol for a Hybrid Type I Effectiveness Implementation Randomized Controlled Trial

JMIR Res Protoc 2023;12:e41240

URL: <https://www.researchprotocols.org/2023/1/e41240>

doi: [10.2196/41240](https://doi.org/10.2196/41240)

PMID: [36689557](https://pubmed.ncbi.nlm.nih.gov/36689557/)

©Henna Budhwani, Allysha C Maragh-Bass, Elizabeth E Tolley, Maria Leonora G Comello, Marie C D Stoner, Margo Adams Larsen, Donald Brambilla, Kathryn E Muessig, Audrey Pettifor, Christyenne L Bond, Christina Toval, Lisa B Hightow-Weidman. Originally published in JMIR Research Protocols (<https://www.researchprotocols.org>), 13.02.2023. This is an open-access article distributed under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Research Protocols, is properly cited. The complete bibliographic information, a link to the original publication on <https://www.researchprotocols.org>, as well as this copyright and license information must be included.