STUDY PROTOCOL

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1. Abbreviations & Definitions of Terms

Abbreviations used in this proposal	
ACASI	Audio Computer-Assisted Self- Interview format
BE	Behavioral economics
BL	Baseline (interview)
BLH	Black or Latino/Hispanic
CAB	Community Advisory Board
CAPI	Computer-Assisted Personal Interview format
CDC	Centers for Disease Control and Prevention
CDCC	Coordination and Data Collection Center
CDE	Common Data Elements (required by RADx-UP)
CFIR	Consolidated Framework for Implementation Research
DTA	Data transfer agreement
FEW	Frontline essential workers
FU	Follow-up (interview)
IWG	Intervention working group

MI	Motivational interviewing
MOST	Multiphase optimization strategy
NMIC	Northern Manhattan Improvement Corporation
NYC	New York City
NYU	New York University
PDI	Peer-driven intervention
RADx-UP	Rapid Acceleration of Diagnostics-Underserved Populations
RCT	Randomized controlled trial
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
TMQQ	Test messages, quiz questions
TTI	Theory of triadic influence

2. Abstract

Background. The proposed study responds to RFA-OD-21-008 which calls for community-engaged interventions to support COVID-19 testing in underserved and vulnerable populations. Among those at highest risk for exposure to COVID-19 is the large population of frontline essential workers (FEW) in lower status occupations (e.g., retail, in-home health care), among whom Black and Latino/Hispanic (BLH) persons are over-represented. The CDC recommends testing for all those experiencing symptoms of COVID-19. For those not vaccinated, testing is recommended after exposure to individuals with a COVID-19 diagnosis, and regular COVID-19 screening testing is recommended even when asymptomatic for those with frequent close contact with others in indoor settings such as FEW. However, BLH-FEW experience serious impediments to COVID-19 testing at individual/attitudinal- (e.g., lack of knowledge of guidelines, distrust), social- (e.g., social norms), and structural-levels of influence (e.g., poor access to testing). Indeed, testing rates are lower among BLH than White populations and only 25-50% of BLH-FEW are currently vaccinated.

Methods. The proposed community-engaged study is led by a collaborative team at New York University and the Northern Manhattan Improvement Corporation (NMIC). Its main goal is to optimize a behavioral intervention to boost COVID-19 testing rates for BLH-FEW. Consistent with RFA-OD-21-008, the proposed study uses the multiphase optimization strategy (MOST) framework to test four candidate intervention components grounded in our past research. The candidate components are informed by critical race theory and guided by the theory of triadic influence, are brief or do not require substantial staff time, and will be tested in a highly efficient factorial experimental design. They are A) motivational interview counseling, B) a text message component grounded in behavioral economics, C) peer education, and D) access to testing (via navigation to a test appointment vs. a self-test kit). All participants receive the standard of care, namely, health education on COVID-19 testing, and referrals.

Aims. The specific aims of the study are to: identify which of four candidate components contribute meaningfully to improvement in the primary outcome, **COVID-19 testing with documentary evidence**; the most effective combination of components will comprise the “optimized” intervention (Aim 1), identify mediators (e.g., distrust, access) and moderators (e.g., sociodemographic characteristics) of the effects of each component (Aim 2), and use a mixed-methods approach to explore relationships among barriers to, facilitators of, and uptake of COVID-19 testing and COVID-19 vaccination (Aim 3).

Sample size and population. Participants will be *N*=448 BLH-FEW who have not been tested for COVID-19 in the past six months and who are not vaccinated for COVID-19, randomly assigned to an intervention condition, and assessed at 6- and 12-weeks post-baseline; *N*=50 participants will engage in qualitative in-depth interviews. We will also uncover, describe, and plan for implementation issues so the optimized intervention can be rapidly scaled up by NMIC and other community-based organizations.

Phases. The study is comprised of three phases: Refinement (5 mos.), Implementation & Evaluation (15 mos.), and Final (4 mos.).

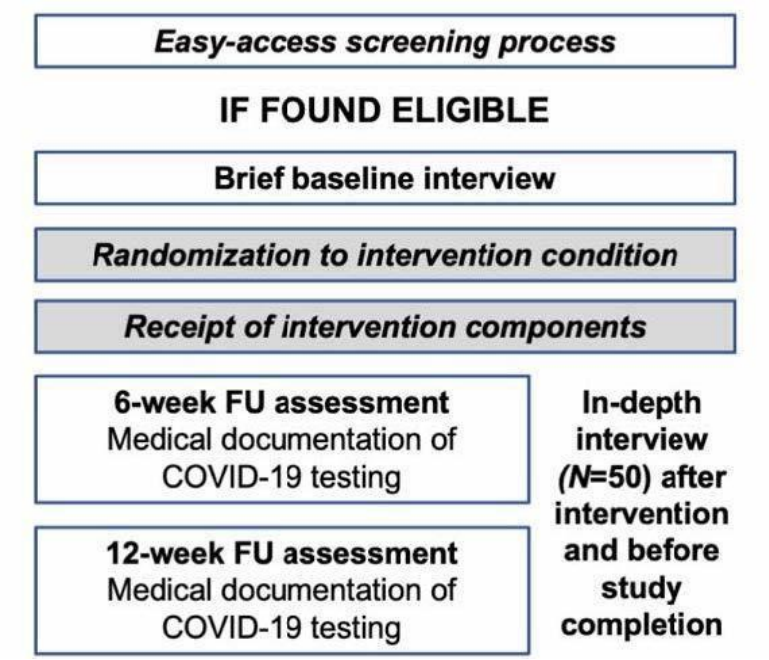
COVID-19 testing: This study does not conduct testing but provides a randomly subset of participants with a rapid antigen self-test kit for COVID-19 as part of Component D: navigation. We will provide test kits that the U.S. Food and Drug Administration (FDA) has granted emergency use authorization (EUA), the ACON Biotech Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing). We will refer to this as the "Flowflex test."

3. Schedule of Study Procedures

Table 2. Study schedule

Weeks	Activity
0	Screen for eligibility
0	Brief baseline interview
0	Randomization to an intervention condition
1	Receipt of intervention components
6	First follow-up assessment
12	Second follow-up assessment
12	In-depth interview

Study Diagram/study sequence



4. Background Information and Rationale

4.1. Introduction

Racial/ethnic disparities in COVID-19 incidence, morbidity, and mortality rates have been marked since the earliest days of the pandemic in the U.S.[8]. Estimated death rates from COVID-19 for Black populations are 178/100k and 154/100k for Latino/Hispanic populations, compared to 124/100k among White populations and 95/100k among Asian populations[27], attributed to structural racism and social determinants of health inequities[28-30]. Testing for COVID-19 is an essential component of the national strategy to control COVID-19, including for those who have delayed or declined vaccination[1]. Yet, rates of testing have dropped dramatically, which will hamper efforts to control COVID-19 spread[31].

The proposed two-year study responds to RFA-OD-21-008 which calls for community-engaged interventions to support COVID-19 testing in underserved and vulnerable populations. From the earliest days of the pandemic, social inequities between groups of workers, along with disparities in COVID-19 incidence rates, have been striking[32]. We focus on a subpopulation of the more than 30 million workers in the U.S. who are placed at very high risk for exposure to COVID-19 because they must physically report to their jobs and cannot work at home, called frontline essential workers (FEW)[33,34]. Although there is no single definition of FEW, the Department of Homeland Security and the American Community Survey provide guidance on the occupational categories most likely to be FEW[3]. Among those at highest risk for exposure to COVID-19 but with the fewest protections is the large population of FEW in lower status occupations such as food preparation and serving, retail and sales, building and grounds cleaning and maintenance, personal care and service, and home health care[3-6]. Moreover, among FEW in these occupations, Black and Latino/Hispanic (BLH) persons are substantially over-represented, and the majority of these BLH-FEW reside or work in geographical areas with high rates of socioeconomic disadvantage[4-8]. Although precise data on testing by occupation are limited, rates among

BLH populations are typically lower than among White populations[9,10]. Further, only an estimated 25-50% of BLH-FEW are currently vaccinated[10,11]. The proposed study, therefore, focuses on BLH-FEW in these lower status occupations.

The Centers for Disease Control and Prevention (CDC) recommend viral testing for SARS-CoV-2, the virus that causes COVID-19 (antigen and/or nucleic acid amplification [NAATs] tests), in the following circumstances. For those who show symptoms of COVID-19 (e.g., fever, chills, cough, shortness of breath, fatigue, muscle aches, headache, and loss of taste or smell), immediate diagnostic testing is recommended, along with a period of isolation, whether the individual is fully vaccinated or not[12]. Testing is recommended in additional circumstances for those not vaccinated. Diagnostic testing and re-testing are recommended after exposure to someone with a confirmed or suspected case of COVID-19[12] and those diagnosed should remain in isolation until they meet local criteria for discontinuing isolation[12]. Further**, testing asymptomatic persons without recent known or suspected exposure to COVID-19, but who are at risk for exposure, is critical for early identification, isolation, and disease prevention[12]**. Indeed, persons with asymptomatic or presymptomatic infection are frequent contributors to community SARS-CoV-2 transmission. Among those groups the CDC recommends prioritizing for this screening testing include racial and ethnic minority groups and other populations disproportionately affected by COVID-19 and workers in high-density worksites or worksites with large numbers of close contacts to co-workers or customers (e.g., restaurant workers, grocery store workers) [12]. The proposed study, therefore, adheres to CDC guidance on priority populations, scenarios for **SARS-CoV-2 testing and mitigation strategies, and also aligns with local guidelines.**

RFA-OD-21-008 calls for community-engaged research. The proposed study is led by a collaborative team at New York University (NYU) and the Northern Manhattan Improvement Corporation (NMIC). NYU is a large research university. NMIC is a large and well-established community-based organization founded in 1979 that serves the diverse needs of BLH in vulnerable and under-served communities. The proposed study builds on NMIC's experience with BLH-FEW, deep understanding of barriers to COVID-19 testing among BLH-FEW, and expertise in implementing health promotion interventions in community settings. The research team at NYU is highly experienced designing and testing culturally salient behavioral interventions with BLH populations that address barriers similar to those that impede COVID-19 testing[35-37].

4.1.1. Factors that promote or impede COVID-19 testing

The study is informed by critical race theory in that we "center" the experiences of BLH-FEW, focus on racism and discrimination (not just race/ethnicity) and contextual barriers, attend to counter-narratives, and highlight strengths and resilience[22]. An emerging literature identifies barriers to COVID-19 testing for BLH-FEW populations that operate simultaneously at multiple levels of influence[38], similar to other racial/ethnic health disparities[30]. The proposed study, therefore, is guided by the theory of triadic influence (TTI), a social-cognitive theory that articulates how individual, social, and structural levels of influence promote or impede health behavior[23]. These multi-level influences are shaped by the larger culture, primary among them structural racism, discrimination, and past and present maltreatment of BLH populations by institutions and systems[39]. Individual/attitudinal-level barriers to COVID-19 testing include **insufficient knowledge** about testing guidelines, and **health beliefs and emotions** such as low perceived risk for and low perceived severity of COVID (leading to COVID-19 being experienced as a distant threat), fear of consequences of a positive test (unemployment, eviction, deportation), distrust of institutional sources of information, and counter-narratives/conspiracy theories about COVID-19 and testing[13-17]. Further, there is growing interest in how **cognitive biases and heuristics** impede **behavioral intentions** to carry out a health behavior such as COVID-19 testing[18]. Indeed, individuals typically show evidence of biases in judgment and reliance on heuristic ''shortcuts'' for health decisions,[40,41] such as

present-bias (the tendency to meet current desires or needs at the price of future beneficial outcomes) and information salience (acting on the information that first comes to mind rather than on all the relevant information available)[42-44]. At the social level of influence, **social norms** impede regular COVID-19 testing (e.g., norms that support delaying or declining COVID-19 testing)[13,19]. At the same time, **altruism and a sense of collective responsibility** can be harnessed to support testing and tap into community resilience[13,19]. Structural-level barriers are systemic issues that impact one's ability to access a needed service[45-47]. Structural barriers impede **access** to testing. These include insufficient local testing sites, language barriers, and lack of paid sick leave[20,21].

4.2. The multi-phase optimization strategy (MOST)

RFA-OD-21-008 highlights the need for rigorous research designs including the multiphase optimization strategy (MOST)[48]. The proposed study leverages the MOST framework to advance interventions for the challenge of insufficient COVID-19 testing uptake among BLH-FEW. The objective of MOST is to improve and strategically balance intervention effectiveness, affordability, scalability, and efficiency ("EASE") using a three phase-model (preparation, optimization, and evaluation), and designs such as factorial experiments. The preparation phase entails identifying promising candidate intervention components and developing a conceptual model, and the optimization phase comprises the systematic testing of the candidate intervention components, the most promising of which, based on pre-specified criteria (called the "optimization objective"), can then be combined into a multi-component intervention[48]. This optimized intervention can then be tested in an RCT (i.e., the evaluation phase). MOST is economical because multiple intervention components can be tested simultaneously. By testing effects of *individual components* and their interactions, the MOST framework can determine which components contribute to effectiveness, how the presence of one component affects the performance of another, and which components can be eliminated to avoid including lengthy and costly components with little benefit.

4.3. The optimization objective

In MOST, the optimization objective is the criteria used to guide the decision making to create the new optimized intervention from the separate candidate components. The proposed study's **optimization objective** is to create an efficient multi-component intervention from the candidate components with no inactive, poorly performing, or counter-productive elements. For example, depending on findings, the optimized intervention may be comprised of 1 or 2 of the most effective components and a core session (the standard of care). This new efficient multi-component intervention can then be rapidly implemented at NMIC and other community-based organizations for maximum public health benefit, and tested in future research. We have completed the preparation phase for the proposed study, as we describe in the next section. The proposed study seeks to carry out the optimization phase; namely, an efficient factorial experiment to test four candidate intervention components and from the most effective of these, optimize a multicomponent intervention. To date, NIH has funded more than 100 studies using the MOST framework and our research team is highly experienced with MOST[37,49].

4.3.1. The preparation phase

The overall goal of the preparation phase in MOST is to create a conceptual model and identify and refine promising candidate components to address theoretical mediators in the model (that is, candidate components that show acceptability, feasibility, and evidence of effectiveness). Over the past year, in collaboration with a CAB comprised of BLH individuals, including BLH-FEW, we explored the utility of the MOST framework for the problem of insufficient COVID-19 testing among BLH-FEW. We

used the ADAPT-ITT model[50], a well-established framework for adapting evidence-based interventions to new populations, to guide the process of developing the conceptual model and identifying candidate intervention components for this problem. First, we assessed risk in the new population from the perspectives of CAB members and reviewed the literature on barriers to COVID-19 testing and potential solutions. We created a comprehensive conceptual model grounded in the TTI and informed by critical race theory that described multi-level barriers to COVID-19 testing (Fig. 1). We focused on important but modifiable barriers to COVID-19 testing. We grouped individual/attitudinal-level barriers into health beliefs and emotions (e.g., low perceived risk, distrust, fear) and cognitive biases and behavioral intentions. Insufficient knowledge was another important individual-level barrier. Social-level barriers focused on social norms that impede testing and factors that facilitate COVID-19 testing (altruism and collective responsibility), and structural-level barriers are those that impede access to testing. Next, we focused on how best to address these barriers, selecting clinical approaches and modalities of behavior change that align with TTI. With the CAB, we reviewed promising intervention approaches for each type of barrier, focusing mainly on our own past effective interventions with BLH populations. We prioritized candidate components that were brief or that would require only minimal staff time, to support future scale-up of the optimized intervention. All components are culturally salient in that they reflect the specific barriers to COVID-19 testing experienced by BLH-FEW. In an iterative process, we selected the following candidate components: A) motivational interview (MI) counseling, B) a text message (TM) intervention grounded in behavioral economics (BE), C) peer education, and D) access to testing (level 1: navigation to testing appointments vs. level 2: provision of a self-test kit; we explain why Component D contrasts alternative strategies in Approach). Further, we determined all participants would receive a core intervention comprised of the standard of care; namely, health education on COVID-19 testing and referrals to testing sites that provide FDA-authorized or approved COVID-19 testing, in compliance with CDC and local guidelines[12]. Third, we worked with the CAB to create the content for components (e.g., core messages for peer education in Component C, TMs), refined in an iterative fashion. In step 4 of the ADAPT-ITT process, we developed manuals for a core intervention session and the four candidate components while maintaining fidelity to the core elements, behavioral theory, and internal logic of the original evidence-based interventions. In step 5, the CAB reviewed the first drafts of candidate components, and feedback was incorporated (step 6). In a final step, we used qualitative cognitive interviewing[51] with CAB members to "walk through" candidate components; then the feedback was incorporated. The study's primary outcome is COVID-19 testing and secondary outcomes were identified (Fig. 1), including COVID-19 vaccination. Refinement of components will continue in the proposed study. Next, we briefly describe the evidence base for candidate components, which are described in the Approach.

4.3.2. Addressing health beliefs using the MI counseling approach

MI is an evidence-based directive and collaborative approach for behavior change that elicits participants' values, perspectives, and questions, identifies ambivalence and discrepancies, and corrects misinformation with permission, to thereby foster durable intrinsic motivation and readiness for change[52]. In reviews and metanalyses, MI interventions, including single-session MI interventions[56], have been found effective at clinically significant levels for a range of health behaviors[53-55]. MI has been found to be particularly effective with BLH populations compared to White populations[58,59]. As a non-coercive, strengths-based, and autonomy-supportive approach, it may have utility in particular when health beliefs and emotions such as distrust/fear impede behavior change[60-63]. Because MI does not rely on persuasion and is non-didactic, it has been recommended by the CDC for the problem of COVID-19 testing and contact tracing[57]. We have used MI in numerous studies[35,37,61,62], including an RCT for BLH

persons living with HIV who had delayed or declined HIV medication. Indeed, many barriers to HIV medication are similar to those that impede COVID-19 access (e.g., distrust, fear)[64,65]. The HIV intervention was feasible and acceptable and the odds of undetectable HIV viral load (the primary outcome) were more than five times greater in the intervention condition (OR=5.20)[61]. Component A will be comprised of a single counseling session using evidence-based MI techniques.

4.3.3. Circumventing cognitive biases/changing behavioral intentions with behavioral economics

Behavioral economics (BE) is a systematic framework to investigate human actions[66]. BE is grounded in traditional economics in that both perspectives accept the premise that people make decisions based on costs and benefits[42,67]. BE enriches traditional economics with insights from psychology[42,66,67]. BE recognizes that people have limited cognitive capacity and may feel overwhelmed when carrying out a complex task[42,66,67]. Recent work grounded in BE uses incentive-based strategies, including lottery-type prizes, to motivate health behavior, while considering types of biases that impede such behavior (e.g., present bias)[68]. One major advantage to BE interventions is that they can address biases and improve behavior with minimal cognitive effort[69]. Further, BE interventions typically require less staff time than traditional counseling interventions[70]. Grounded in work by Linnemayr[42], we have a program of research that uses BE approaches to overcome cognitive biases and change behavioral intentions through weekly text messages (TMs), quiz questions (QQs), and incentives and prizes to "nudge" participants toward the health behavior, HIV medication adherence[71]. Component B adapts this BE approach for the proposed study.

4.3.4. Changing social norms

The study seeks to change social norms that impede testing and harness altruism and collective responsibility using peer education. Peer-based interventions have demonstrated high rates of acceptability and effectiveness across a range of health outcomes[72-74]. Our own research uses the peer-driven intervention (PDI) model created by Broadhead and Heckathorn[75,76]. In PDI, participants educate peers in their social networks on concise culturally specific core messages in support of a specific health behavior change. PDI is effective because messages delivered by peers typically have more credibility than from professionals[76]. Further, when individuals educate the peers in their network about the benefits of a certain health behavior, their *own* commitment to the desired behavior is strengthened in large part because the act of educating or urging peers is a public affirmation of the desired behavior. Through peer education, social norms in a network may be altered[77]. Moreover, providing participants the opportunity to deliver education to peers increases individuals' self-efficacy and mastery of intervention content[76]. We used the PDI approach in a study addressing low rates of enrollment of BLH persons living with HIV in AIDS clinical trials. Barriers to AIDS clinical trials include those that impede COVID-19 access (e.g., social norms)[78]. PDI condition participants were 30 times more likely to be screened for trials than controls (49.3% vs. 3.7%; $p<.001$)[62]. In addition to the effects of the PDI as a whole, the experience of educating peers also increased odds screening for trials (AOR=1.4; $p<.05$)[62]. Component C adapts this approach and is comprised of training study participants to educate three peers who are in their social networks and, if possible, also BLH-FEW on core messages.

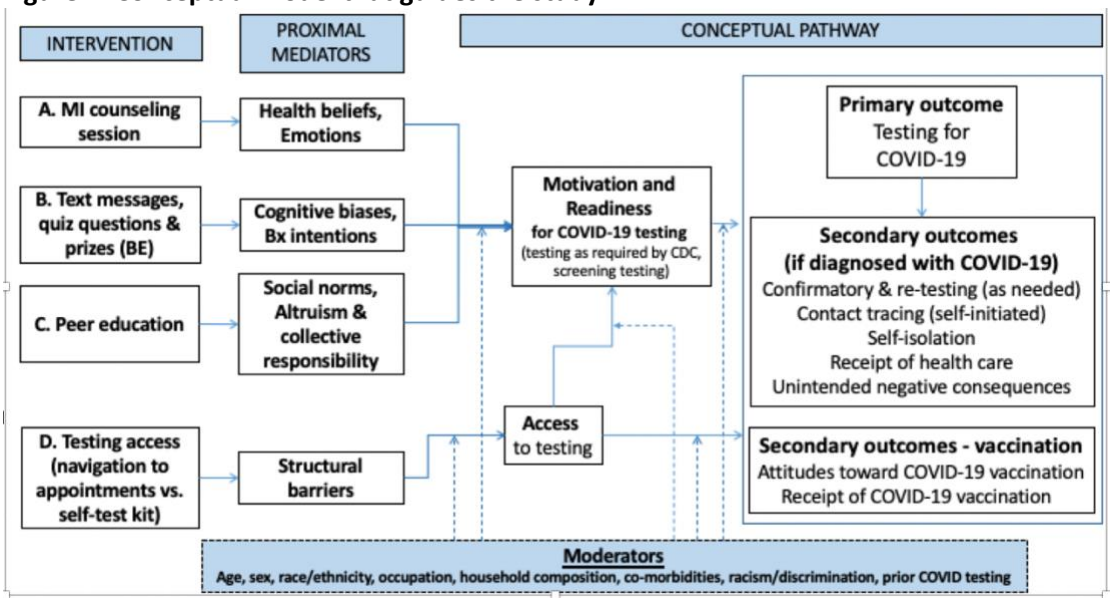
4.3.5. Circumventing structural barriers

Navigation is an individualized efficacious intervention approach first designed to reduce disparities in cancer care for low-income women of color[79-81]. Navigators help identify and resolve barriers that individuals encounter to accessing a needed health service such as COVID-19 testing[82]. We have found the navigation approach to have utility in past studies, including because it is flexible and needs-based. Component D will address access barriers and have two "levels:" navigation vs. receipt of COVID-19 self-test kits (Flowflex). We are experienced with biomedical testing components[35,83].

4.3.6. Significance and conceptual model

The proposed study fills a need for interventions to encourage COVID-19 testing for BLH-FEW. **1. Clinical practice**. The optimized intervention has the potential to provide efficient ways of increasing COVID-19 testing in BLH populations. The study methods and optimized intervention are designed to be reproducible; that is, this method should yield comparable results in a range of locations and settings, and sustainable; that is, widely accepted in community-based organizations that serve BLH-FEW and other BLH populations. The optimized intervention will complement local and national efforts to increase COVID-19 testing. **2) Research.** MOST has not yet been applied to the problem of insufficient COVID-19 testing. The proposed study has potential to increase the uptake of MOST for research on COVID-19 and similar disparities, in order to produce more effective, affordable, scalable, and efficient behavioral interventions. **3) Public Health.** Public health will potentially be improved by providing tools that can increase rates of COVID-19 testing in BLH populations, for the current COVID-19 pandemic, similar or related disparities, and to better prepare for future pandemics.

Figure 1. Conceptual model that guides the study



5. Description of the intervention components

General description of candidate components. Each component is guided by a manual in English and Spanish that includes handouts. Manuals will be comprised of a series of exercises and will be

constructed to be interactive and engaging. All candidate components are culturally salient and take a strengths-based and autonomy-supportive approach. Health information will be drawn from the CDC and will be reviewed for medical accuracy by a medical expert (Dr. Parameswaran, a study Co-I). Components address different theoretical mediators and are designed to be distinct from each other. For example, the TMs are informational health messages while the core messages for Component C are designed to tap into norms, altruism, and collective responsibility. The behavior change process for each component (e.g., MI, BE, peer education, or access) is compatible with the TTI. Each component has two levels: assigned/on vs. not assigned/off (Components A-C), or navigation vs. self-test kit (Component D). Core session: Standard of care (health education on COVID-19 testing). All participants receive a health education session (20-40 minutes) which comprises the standard of care. The goal is to increase knowledge regarding COVID-19 testing guidelines, types of tests, prevention and mitigation recommendations, and provide referrals to sites that provide FDA-authorized or approved COVID-19 testing, and (optional), referral to no-cost COVID-19 vaccination site in addition to testing sites [99]. Because all participants receive the core session, its effects on the primary outcome are not assessed. It will be included in the optimized intervention.

Component A. MI counseling. Those assigned to receive Component A will engage in a MI single session lasting approximately 30-45 minutes. The overall goal of the session is to increase participants' motivation and readiness to test for COVID-19 in various circumstances. The session uses the Engage, Focus, Evoke, and Plan framework and draws on evidence-based MI techniques such as highlighting change talk and identifying discrepancy52 and supporting participant autonomy and personal decisions about COVID-19 testing. Uncovering and discussing the structural causes of health disparities such as structural racism and freely discussing fears and counter-narratives helps build motivation and readiness. The primary core elements of this component include evoking views on COVID-19 and testing (including its severity, skepticism, counter-narratives, distrust, fears) and why we have medical and institutional distrust and counter-narratives (historical factors and structural racism); with permission and using the Elicit-Provide-Elicit method, addressing perceived COVID-19 severity and the importance of testing by providing information and data on BLH-FEW using graphics and maps; rating readiness for COVID-19 testing in various scenarios (when symptomatic, when exposed, serial screening testing) on a 1-10 scale and discuss; highlighting ambivalence and/or identify discrepancy between values and behavior to build motivation (as appropriate); and planning for testing. Theoretical targets: Health beliefs (perceived risk and severity, distrust of institutions, counter-narratives), emotions (fear of consequences if diagnosed including related to immigration status).

Component A sessions will be audio-recorded for supervision purposes.

VARIABLE: RECEIVED SESSION (YES/NO)

Component B. Text messages (TMs) and quiz questions (QQs; 6 weeks). This component is grounded in principles of BE. Its main goal is to add interest and excitement to the goal of COVID-19 testing, serve as a reminder that COVID-19 testing is recommended in a number of scenarios, and "nudge" participants toward testing and creating a habit of serial COVID-19 screening and other forms of COVID-19 testing as needed. Participants first receive a brief orientation to the component (15 min.), and the participant will put the study phone number into his/her phone and a test TM and QQ will be sent. TMs and QQs are programmed into the Telerivet program and sent automatically. Twice a week participants will receive a TM with information about COVID and COVID-19 testing followed by a true/false question about that TM two days later, for which they earn 10 points for a correct answer, and 5 points for an incorrect answer. Those who provide the correct answer receive a message of congratulations and those who

answer incorrectly receive a TM with the correct answer. Participants earn modest compensation based on their points. Participants receive feedback by TM on the number of points received to date and reminders that they have the chance to earn compensation.

Compensation: At the 6th week (e.g., at the 6-week follow-up assessment), those with high points (60-120) receive $25 and the remainder receive $15.

Participants also have a chance to spin a prize wheel win a **lottery prize** if tested for COVID-19 and documentary evidence is provided at the 6-week FU assessment (if tested, 3/10 chance of winning $50 and 7/10 chance of $25, if not tested or no evidence provided, $15 participation bonus is provided). If participants wish to delay spinning the prize wheel until the second survey period, they may do that.

The maximum compensation participants can receive for this component is $75.

As a reminder, this compensation structure described above, with lottery prizes, is for the optimization trial phase only, not the refinement phase. In the refinement phase, participants will receive 3 weeks of TMQQs and do not have a chance to win a lottery-style prize.

TMs are comprised of information about COVID-19 and testing from the CDC website. Examples of TMs include: regular testing for COVID-19 is still an important part of controlling the COVID epidemic; people who show signs or symptoms of COVID-19 such as fever, cough, and chills should get tested right away even if they have had COVID in the past or have been vaccinated; and people can get COVID-19 testing for free. Theoretical targets: cognitive biases, behavioral intentions

VARIABLES:

1) Any participation – at least 1 point
2) "Dose" – number of points received
3) Prize has an effect (they know they are getting a prize)

Points are in REDCap

Component C. Peer education. This component has two aspects: Participants are trained to educate their peers on core messages about the importance of COVID-19 testing that address social norms about COVID-19 testing and highlight COVID-19 testing as an altruistic act (15-20 min. training). Then, participants are given the opportunity to educate three peers who are, ideally, BLH-FEW on the core messages. These peers contact the study directly and receive a brief assessment and referrals to testing, but are not enrolled in the study. The core messages (Table 3) were developed with our CAB and the peer education procedures have been tested in numerous studies[62,75,76].

The component manual includes the following activities: a) Participants receive an overview of the component and a review and discussion of the core messages. b) Then, we review when and how to educate peers; namely: whom to approach (Persons who they know by name or face and have seen in the past 30 days who are aged 18 and older, who can conduct activities in English or Spanish, and who are not already enrolled in the study, ideally other BLH-FEW), when to approach (at a time that mutually convenient and that does not disrupt work), where peer education should take place (in a confidential and private location), how to avoid COVID-19 risk during peer education (adhere to public health prevention guidelines such as masking and social distancing or conduct peer education virtually), and

how to conduct the education (introduce the core messages using an IRB-approved script, discuss but do not coerce testing). c) Participants will receive materials such as the script, a wallet card with the core messages (to guide peer education), and three coded coupons that the peer can use to contact the study directly to complete the brief interview. d) Participants will be provided with referrals to COVID-19 testing sites and COVID-19 vaccination in the event peers wish to discuss testing/vaccination. e) Participants are encouraged to conduct the peer education in the next 3 weeks; coupon numbers expire after that period of time.

Peers contact the study directly, receive a brief assessment including age, race/ethnicity, sex, occupation, and true/false questions on the core messages, and are offered referrals to COVID-19 testing and vaccination. These procedures are intended to motivate a thorough peer education experience by the peer and document peer education. Participants receive compensation (maximum $25) when the peer contacts the study. The peer also receives compensation for the brief interview ($25). Peers are not eligible for enrollment into the factorial experiment. Participants can (and should) educate peers even if they have not been tested for COVID-19 or made their final decisions about testing. Theoretical targets: social norms, altruism & collective responsibility. More details on practical and ethical considerations for this component are found below.

Table 3 provides the core messages, the true-false question associated with that message, the answer to the true-false statement, and a citation for the statement.

CORE MESSAGE edited June 16, 2022	**T/F statement for peer**	**Answer**	**Citation**
1. Regular COVID testing is still an important part of fighting the COVID-19 epidemic in our community.	COVID testing is no longer needed to fight the COVID epidemic.	False	https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html https://www1.nyc.gov/site/doh/covid/covid-19-testing.page
2. Weekly COVID testing is recommended for people who are not fully vaccinated yet.	The only time I need to get testing for COVID is when I'm exhibiting serious health symptoms.	False	https://www1.nyc.gov/site/doh/covid/covid-19-testing.page
3. COVID testing is quick, easy, and available for free at hundreds of locations without an appointment.	COVID testing is quick, easy, and available for free at hundreds of locations without an appointment.	True	https://www1.nyc.gov/site/doh/covid/covid-19-testing.page
4. Many people don't know they have COVID-19. Getting tested regularly is one important tool to protect yourself and your community.	Getting tested for COVID regularly is an important tool to protect yourself and your community.	True	https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html
5. Regular testing matters more for groups affected the most by COVID-19, such as frontline and essential workers.	Regular COVID testing is especially important for people at highest risk for exposure to COVID	True	https://www1.nyc.gov/site/doh/covid/covid-19-prevention-and-care.page

	such as frontline and essential workers.		
6. Many New Yorkers aren't fully vaccinated for COVID yet, so getting tested regularly for COVID is critical for stopping the spread of COVID in our city.	Experts recommend people who are not fully vaccinated for COVID get tested regularly to help stop the spread.	True	https://www1.nyc.gov/site/doh/covid/covid-19-testing.page
7. There are different ways to get tested for COVID, including self-tests that can be used at home, and testing at a health care facility.	There is only one way to get tested for COVID and that is by going to a hospital.	False	https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html
8. Millions of Black and Latino essential and frontline workers are doing their part and getting tested for COVID-19.	Millions of African American and Black and Latino essential and frontline workers have been tested for COVID.	True	https://www1.nyc.gov/site/doh/covid/covid-19-data.page
9. If you think you've been exposed to the COVID virus, you can do your part by getting a COVID test as soon as you can.	I DO NOT need to be tested for COVID if I think I have come into contact with someone who has COVID.	False	https://www1.nyc.gov/site/doh/covid/covid-19-prevention-and-care.page
10. If you test positive for COVID, inform your health care provider or call 311 to find out what to do to keep yourself and your community safe.	If I test positive for COVID, I should NOT tell my health care provider.	False	https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/index.html https://tinyurl.com/3fsbmzt6

VARIABLES

1) educated at least 1 peer (range 0-3 peers)
2) number of peers educated

DATA ISSUES: Please note there are duplicate records for some peers (the same coupon number shows up more than once), and sometimes two different people use the same coupon number. FERNANDA will clean that up.

1. remove duplicates (if it is the same peer)
2. if they educated 3 or fewer and used the same coupon number more than once (and it's two different people) – keep the records – change the second ID number
3. delete records if more than 3 (3 is the mx)

WE CAN DESCRIBE: peers, who they are, % of T/F correct

Component D. Access (Level 1: Navigation to FDA-authorized or approved COVID testing, Level 2: Flowflex test kits). Level 1 (navigation meeting): In as single meeting (approximately 20 minutes), navigation includes guidance to assist participants in accessing, and completing COVID-19 testing in a timely fashion and resolving barriers such as transportation or the possible need to take off work if diagnosed with COVID-19. We will make an appointment for participants if they do desire. We will provide written resources for accessing COVID-19 testing a low cost or no cost

Level 2 (self-test kits): We will provide them with Flowflex test kits (2 kits per participant) which can be given to them, picked up later, or mailed to them. We will review how to conduct the test, interpret results, its limitations, and the need to continue prevention guidelines where possible, and provide patient fact sheets as part of the test's emergency use authorization, in accordance with CDC guidelines[100].

Component D contrasts alternative strategies for addressing structural barriers to testing, since these strategies would be likely to have an antagonistic interaction (each less effective when the other is present) if they were delivered as separate on/off components. Also, we believe some form of enhanced access needs to be part of any multicomponent intervention.

VARIABLES

TWO LEVELS: NAV vs. KITS

1) attended NAV or KIT meeting (YES/NO)

6. Eligibility criteria for peers as part of Component C (optimization trial)

- Has a coded coupon
- Age 18 years and older
- Can carry out activities in English or Spanish
- Resides in NYC
- Not already enrolled in the NCAP study as a peer or participant

We will assess whether peers are African American/Black or Latino/Hispanic race/ethnicity and FEW but these are not eligibility criteria.

7. Practical and ethical considerations for Component C: Peer education

It is essential that participants conducting peer education with their peers provide accurate and up-to-date information, are not coercive, and that peers understand the nature of the interaction and what is expected of them. We are highly experienced in interventions that entail peer-to-peer education. Peer education will be carried out by participants using a set of core messages. Participants will be trained by research study staff on when, where, and how to educate peers. Participants will be provided with a handout that guide the interaction with peers.

Participants will be walked through a discussion of how to carry out peer education in a way that minimizes risk of exposure to COVID including conducting education virtually, outdoors, and the use of safety precautions such as masks.

Participants will be trained to understand that peers should not be pressured or coerced into receiving peer education or contacting the research study. In the training, participants will be instructed on:

1. WHO to approach: Persons who you know by name or face and have seen in the past 30 days. These peers should be aged 18 and older, and should not already be enrolled in the NCAP study. To maximize the benefits of this study, we recommend you educate frontline essential workers from African American or Black or Latino racial/ethnic backgrounds.

2. WHEN to approach: at a time that mutually convenient and that does not disrupt work or other activities

3. Where peer education should take place: in a confidential and private location

4**. How to avoid COVID-19 risk during peer education**: adhere to public health prevention guidelines such as masking and social distancing or conduct peer education virtually

5. What the participant should do, step-by-step:

- **Ask**- Ask for some time with the peer.

- **Find** – Find a private location (or carry out the encounter virtually)

- **Explain** – Explain the main parts of what you want to say:
    - I am part of a research project called the NCAP Project
    - The goal of the NCAP Project is to bring information about COVID-19 testing to the community.
    - Today I will share some information I have been learning about COVID testing and treatment and ask you if you are willing to contact the NCAP study to do a brief interview.
    - You can tell me if you do not wish to have a discussion today and you can decline to call the NCAP study to do the interview.

- **Educate –** Educate Peer On the Core Messages (found in Table 3 and on the handout)

- **Give –** Give peer the Core Messages wallet card. (This card will have the core messages and the study phone number)

- **GIVE –** referrals to COVID-19 testing sites if needed (handout)

- **Explain next steps** – Explain the following:

- NCAP is a research project to learn more about what people think about COVID-19 testing and the best ways to support COVID-19 testing in the community
- If you call NCAP, you would do a short interview on the phone or in-person. The interview includes some true/false questions on these Core Messages.
- Peers would get $25 for the interview.
- OPTIONAL – I will also get some compensation if you do the interview.
- Provide peer with the coupon.

Participants will be trained in talking tips:

- **Pick a good time.** Make sure the person is not busy. Ask if you could take up 5-10 minutes of their time to discuss something.
- **Pick a good place.** A place that is confidential and comfortable.
- **Stay neutral.** Keep your voice calm and pleasant. Remember, that you are only offering to provide them with information. They have a right to not be interested or not want to listen.
- **Watch your body language.** The messages you send with your body are as important as what you are saying to them. This is especially true if the peer you are educating is not very receptive.
- **Reflect and validate what they say…even if you disagree.** Validating their opinions and what they say even if you disagree with them helps to diffuse any tension. Using words such as "I hear you" or "I think I understand what you are saying (e.g., that you don't believe that COVID-19 testing is right for you, etc.).

8. The importance of medical accuracy of materials

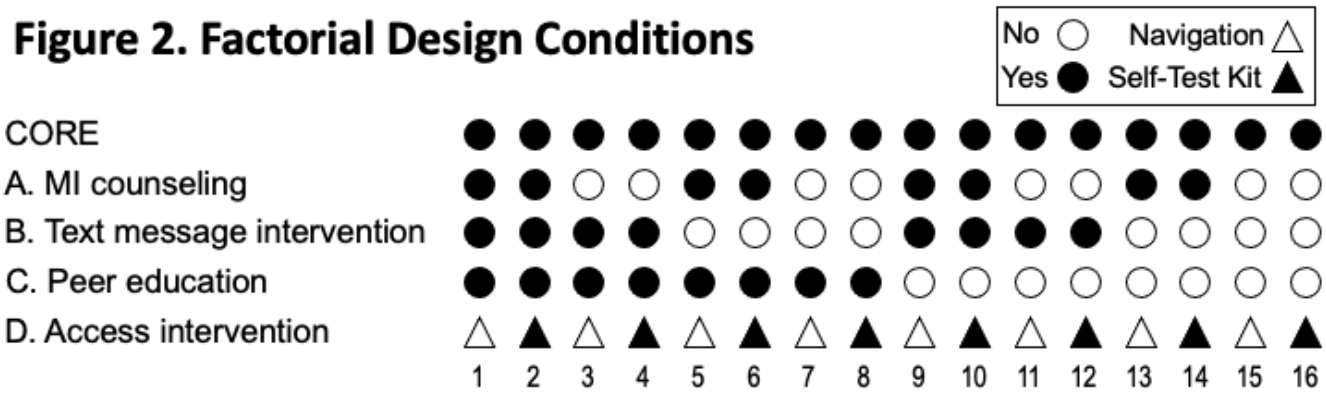
All materials and all information provided to the participants on COVID-19, COVID-19 testing, and vaccination will be reviewed regularly by our team medical expert to ensure that they are accurate and up-to-date (e.g., reviewing CDC and NYC Health information regularly and updating the information as needed). This includes the core messages for Component C (peer education).

9. Description of the factorial design and figure

A factorial experiment testing four intervention components, each with two levels, is comprised of 16 conditions (2^4, see Fig. 2). Importantly, the design is not a 16-arm RCT. Factorial experiments separate component effects, enabling estimation of the main effect contribution of each component. Factorial experiments can be economical compared to alternative designs, because they require substantially fewer participants to achieve the same goals[48]. For example, conducting four individual experiments using the RCT design, one for each component, would require *N*=1792 (448 participants per trial). Thus, the purpose and logical underpinnings of the factorial experiment are different from those of an RCT. The purpose of an RCT is a direct comparison of the efficacy of two or more versions of an intervention. By contrast, a factorial design never calls for a direct comparison of experimental conditions to see which one is best. Instead, the purpose is to identify which components show effectiveness. Efficiency comes from basing all estimated main effects on all 16 conditions in the factorial experiment. For example, the main effect of Component C will be estimated by comparing the mean outcome across Conditions 1-8 vs. across Conditions 9-16. All participants are included in the estimate of each main effect. Factorial experiments can have a small per-condition *N* (*N*=28) and still achieve study aims if the total *N* (*N*=448) is sufficient. All participants receive the core intervention, two conditions (15 & 16)

receive 1 component (access, either navigation or a self-test kit), 2 conditions (1 & 2) receive all components, and the remaining 12 conditions receive 2-3 components (Fig. 2).

Figure 2. Factorial Design Conditions



10. Compliance Statement

This study will be conducted in full accordance all applicable Policies and Procedures of the UCAIHS at NYU and all applicable Federal and state laws and regulations including 45 CFR 46. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in accordance with UCAIHS and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

11. Study Objectives

11.1. Primary aims

11.1.1. Aim 1

Aim 1. Identify which of four components contribute meaningfully to improvement in the primary outcome, COVID-19 testing with documentary evidence, and from these results, optimize an efficient multicomponent intervention. Participants will be English and Spanish-speaking BLH-FEW (ages 18-70 years; *N*=448) in New York City who have not been tested for COVID-19 in the past six months and who are not vaccinated for COVID-19. Participants will be randomly assigned to an intervention condition, engage in the assigned components, and assessed at 6- and 12-weeks post-baseline.

11.1.2. Aim 2

Aim 2. Identify mediators (e.g., distrust, altruism, access) and moderators (e.g., sociodemographic characteristics) of the effects of each component to better understand the intervention components' mechanisms of action and conditions under which they are most effective to advance future research and inform implementation of the optimized intervention.

11.1.3. Aim 3

Aim 3. Explore the relationships among barriers to, facilitators of, and uptake of COVID-19 testing and COVID-19 vaccination. In qualitative research we will explore participants' experiences with and perspectives on the intervention components and on COVID-19 testing and vaccination (*N*=50) and integrate qualitative and quantitative results using the joint display method to inform intervention implementation and future research.

12. Investigational Plan

12.1. General schema of study design

The study design is presented in Figure 1 above.

12.2. Refinement phase/pilot study

We will carry out additional refinements of the components in this first phase of the study. We anticipate these to be minor (e.g., wording and length of exercises). To do so, we will form an intervention working group (IWG) led by Dr. Gwadz and comprised of the project coordinator at NMIC, the CAB, and Drs. Cleland, Hawkins, Parameswaran and senior project staff members. We will also form a community advisory board. We will carry out an initial review of materials and then carry out a pilot study with members of the target population. Participants will engage in the pilot test virtually or in-person. Participants may engage in more than one 2.5 hour meeting depending on their interest and availability.

Procedures for the pilot study in the refinement phase are as follows:

- Potential participants will be recruited using the hybrid method described in this protocol (see below)
- Verbal consent will be obtained for screening
- They will be screened for eligibility using a structured instrument
- Consent will be obtained for enrollment in the pilot study (signed consent if in-person or verbally if virtual contact)
- Locator form completed
- Intervention session comprised of a subset of intervention components and a cognitive interview lasting approximately 2.5 hours in-person, over Zoom, or in the phone
    - All participants will receive the core session
    - Participants will be asked to engage in two of the following: 1) one **counseling session** (lasting about 30-45 minutes) with a study counselor to discuss your health decisions, and discuss what you think about COVID testing; 2) **receiving text messages** over 3 weeks (2 messages a week) with information about COVID and COVID-19 testing, along with quiz questions for which you earn 10 points for a correct answer and 5 points for an incorrect answer and compensation based on total points (max. points is 60); 3) training on **peer education** (15-20 minutes), where you will be trained to educate peers on core messages about the importance of COVID-19 testing, and you will be given the opportunity to educate three Black and Latino/Hispanic peers on these core messages, and

    - Also, participants will be randomly assigned (by a coin flip) to receive **navigation** guidance to assist them in accessing COVID-19 testing OR **FlowFlex rapid COVID test kits,** along with instructions on conducting the test and interpreting results.
- Some participants will have the opportunity to educate up to 3 peers. Peers will contact the study directly and receive a brief assessment.
- Some participants will receive the TMQQs for 3 weeks after the initial meeting
- A subset will receive an open-ended follow-up interview lasting < 60 minutes to review experiences with components and solicit perspectives on improving components. This will not be audio-recorded but notes will be taken.

Sample size for refinement phase/pilot study: We will test the components with approximately *N*=30 participants (6 participants for each component and the core session minimum) and up to 50 participants as needed, since some components may need more pilot testing and refinement than others.

Structure of the pilot study: The pilot study will be structured as a single meeting with participants lasting approximately 2.5 hours. In this meeting, participants will receive the core session, 2 components from among Components A, B, and C, and Component D (with level of component D decided by a coin toss) . Participants will receive the component and be asked to reflect on the clarity, acceptability, and utility of each major section of the component (the cognitive interview).

Eligibility for the refinement phase: Eligibility criteria will be similar to the larger trial.

1. age 18-70 years
2. can engage in study activities in English
3. Black or African American (including Caribbean, African, or multi-ethnic Black) and/or Latino or Hispanic race/ethnicity
4. resides in NYC
5. in the past month, was employed as a frontline worker in the occupations listed in this protocol
6. has a phone that can be used for study participation and can receive text messages
7. is not "fully vaccinated" for COVID-19
8. has not been tested for COVID-19 in the past six months
9. if previously diagnosed with COVID-19, has not been symptomatic in the past two weeks or 90 days has passed since treatment with monoclonal antibodies or convalescent plasma[98]
10. willing to be assigned to one or more intervention components

Recruitment procedures for the refinement phase: These will be the same as recruitment procedures described for the larger trial.

Each pilot test session includes an in-depth qualitative cognitive interview[51] and an assessment of acceptability. Cognitive interviewing is a psychologically oriented method for empirically studying the ways in which individuals process and respond to survey questionnaires and intervention content[51] (e.g., critique of each core message or TMQQ). The feedback and acceptability ratings, along with feasibility ratings, will be brought to the IWG for discussion and recommendations for refinement. If the intervention is not adequately refined at this point it will undergo another round of pilot testing.

Peers in Component C: In addition, as part of Component C, 18 peers will be educated by study participants, will contact the study themselves, and will be assessed to evaluate Component C. This assessment will include brief semi-structured questions to explore the peer education process.

Follow-up interview: In some cases, participants will be contacted for an unstructured, qualitative follow-up interview, including dates and types of COVID-19 testing and/or vaccination (showing test results or certificates where appropriate). The interview will take place within one month of the first

component test meeting. They will be asked to reflect back on the component and ways it was helpful and ways it could be improved.

Goals of the refinement phase: At the conclusion of this phase, the intervention component protocols and study procedures will be complete, and assessments will be programmed in REDCap. Materials will be translated into Spanish. The activities in this phase are feasible: We will modify an existing REDCap database for a MOST study, and have already drafted and tested intervention component manuals.

12.3. Study duration, enrollment and number of sites

This is a 2-year study. There is one performance site (NYU). Study activities will be carried out by NYU study staff.

12.3.1. Study location

The study will be located in NYC.

12.4. Total number of study sites/total number of subjects projected

There is one study performance site (NYU). NYU manages field site spaces. The address of the NYU field site is NYU, 285 Mercer, 3rd floor, New York, NY 10003.

A total of 48 participants (estimated minimum) will be enrolled in the refinement phase.

A total of 448 participants will be enrolled in the optimization trial.

Peers will be assessed as part of Component C (*N*=672) in the optimization trial.

12.4.1. Duration of study participation

Participants will be enrolled in the study for 12 weeks.

12.5. Study population

Adult Black and Latino/Hispanic frontline essential workers (FEW) in lower status occupations

The occupations of interest are:

- food preparation and serving (e.g., deli, bodega, restaurants, fast food)
- retail and sales (e.g., grocery, drug, and convenience stores and other kinds of stores)
- building and grounds cleaning and maintenance (e.g., janitorial services, security, reception, landscaping)
- building and home construction (including carpentry)
- personal care and service (e.g., in-home childcare workers, barbers, nail technicians, cosmetologists)
- in-home health care services (e.g., home health aides)

Retail work is any type of employment that involves customer interaction and sales. Includes:

- Sales associates are responsible for assisting customers as they look for products, keeping the store clean, ensuring the shelves are well-stocked and occasionally helping customers check out.

- Cashiers are responsible for checking customers out at the point of sale, helping customers return or exchange items and answering telephone calls at the sales desk area.
- Inventory associates are responsible for managing inventory, recording the details of shipments and sales and stocking particular items in the warehouse or front of the house.
- Customer service representatives manage online or phone-based customer comments, questions and concerns, resolve issues with customers and document customer interactions.
- Warehouse clerks receive and manage goods and products, package and send orders to customers, maintain stock organization and track all products in the warehouse.
- Assistant store managers maintain the employee work schedule, handle day-to-day store oversight, manage customer concerns and assist the store manager as needed.
- And other job titles

12.5.1. Eligibility criteria for the optimization trial and definitions where needed (REVISED MAY 2, 2023)

1) age 18-70 years

2) can engage in study activities in English or Spanish

3) Black or African American (including Caribbean, African, or multi-ethnic Black) and/or Latino or Hispanic race/ethnicity

4) resides in NYC

5) in the past month, was employed as a frontline worker in a frontline essential occupation in one or more of the domains listed above

6) has a phone that can be used for study participation and can receive text messages

7) has not received any dose of a vaccine for COVID-19 (including booster doses) in the past 12 months (FORMERLY: is not "fully vaccinated" for COVID-19; see below for definition)

8) has not been tested for COVID-19 in the past three months (FORMELRY: has not been tested for COVID-19 in the past six months)

9) if previously diagnosed with COVID-19, has not been symptomatic in the past two weeks or 90 days has passed since treatment with monoclonal antibodies or convalescent plasma[98]

10) has not been educated/interviewed as a peer for Component C

11) willing to engage in a core session and be randomly assigned to receive 1-4 components

12) not a member of the study's Community Advisory Board

13) was not enrolled in the study's refinement phase (the pilot study)

Activities will be carried out in English and Spanish.

Consistent with the NYC DOHMH, we define "fully vaccinated" as: People who have received either both doses of the Pfizer or Moderna primary vaccine series or the one dose of the Johnson & Johnson/Janssen primary vaccine series (https://www1.nyc.gov/site/doh/covid/covid-19-data-glossary.page).

Participants who do not meet all of the eligibility criteria will not be enrolled. Any violations of these criteria will be reported in accordance with UCAIHS Policies and Procedures.

13. Study Procedures for the optimization trial

13.1. Participant identification number

The participant identification number used on all forms will be comprised of

- First two letters of first name
- First two letters of last name
- Birth date (MM/DD/YY)

13.2. First screening interview (a three-step process carried out in a single interview)

- Participants contact the study themselves by phone (text, phone, or email contact) or are approached by an NYU study staff member in an indoor or outdoor venue. Participants may contact the study themselves using an online contact form linked to a QR code in ads and flyers.

- **Consent**: Potential participants will provide verbal informed consent for the screening interview following an IRB-approved script

- **Screening interview:** After consent is obtained, they will participate in a brief (< 15 minute) structured screening interview using the Computer-Assisted Personal Interview (CAPI) format in REDCap to determine eligibility.

- **Part 1** will comprise basic demographic information including whether the participant resides in New York City. If participants meet the eligibility criteria in Part 1, they will continue to Part 2.

- Part 1 will ask:
    - how participant heard about the study
    - how interview will be conducted (virtually or in person)
    - date of birth
    - age
    - can engage in study activities in English or Spanish
    - resides in NYC (by self-report and confirmed by eliciting a New York City mailing address.)

- Part 2 will ask the remaining eligibility criteria, except for vaccination.

- Part 3 will ask about vaccination and check documentary evidence of vaccination.

- **Part 3 includes eliciting documentary evidence of vaccination**: There are three ways to document COVID vaccination status: 1) by accessing or allowing us to access the "My Vaccine Record" through NYC Health (as described in more detail below), 2) the participants may provide documentary evidence of COVID-19 vaccination such as the CDC vaccine card or MyChart record. They can provide a photograph of their vaccine card to the study; or 3) self-report. This information will be entered into REDCap (dates and type of vaccine for each dose of vaccine).

- Those who do not meet all eligibility criteria in Parts 1 and 2 will not be asked to complete My Vaccine Record, since that is time consuming. But, they will be asked to provide their vaccination card or vaccination information by self-report.

- **Locator:** Those found eligible and who did not complete the contact form will provide some locator information, to facilitate future contact and scheduling. Those who completed the contact form may not need to provide additional locator information at this stage.

- Screening can take place in recruitment venues, the NYU study field site, or virtually.

- During the informed consent process (for screening and enrollment), participants will be informed that their participation is voluntary and that their declining to enroll in the study will not affect any services or resources they might otherwise receive. They will be given opportunities to ask questions about the study. They can delay providing informed consent until another time and date.

- Note that we will not compensate participants for screening.

- Regarding COVID-19 precautions, NYU staff and other investigators and participants will follow NYU guidelines including completing the daily screener app, wearing face coverings, and social distancing, as appropriate. NYU staff and other investigators will be vaccinated for COVID-19 and their COVID-19 vaccination card will be uploaded to the NYU health portal and approved.

13.3. Procedures to access "My Vaccine Record"

1. We will ask for the participant to access their vaccine records on "My Vaccine Record" through NYC Health.

2. Send the participant the link/url to the "My Vaccine Record" website via text or email: https://myvaccinerecord.cityofnewyork.us/myrecord/

3. The participant will submit a certification statement that certifies that they are the individual to whom the vaccine record relates.

4. The following information will be needed to search for the participant's vaccine record:
   - Name
   - Date of birth
   - Sex assigned at birth
   - Mother's first name and maiden name
   - Mother's date of birth
   - Address at time of vaccination
   - Phone number at time of vaccination

5. The participant will authenticate their identity by submitting their IDNYC number or by having a code sent to their mobile phone or email. The code will be entered to access the record.

6. Participants will be asked to save and send the vaccine record to the NCAP team. They can also print the file and bring it to their in-person interview.

13.4. Enrollment, intervention, and follow-up phase

13.4.1. Visit 1 (Enrollment)

- Enrollment will take place at the NYU field site or virtually.

- Participants will provide electronic signed informed consent in REDCap for enrollment, complete a more detailed locator form to facilitate longitudinal FU, and participate in a structured BL interview programmed in REDCap.

- **Consent**: Those who participate virtually will provide verbal consent and a copy of the consent form will be mailed or emailed to them. Those who participate in-person can provide signed informed consent using the eConsent feature. A copy of the consent form will be provided to them.

- **Locator**: Then, more detailed locator information will be obtained to facilitate future contact.

- **Baseline**: They will then complete the baseline interview using CAPI and ACASI in REDCap. The baseline survey will last < 60 minutes.

- **Randomization**: They will be randomly assigned to an intervention condition using a randomization table in REDCap.

- **Core session**: Then, they have the opportunity to engage in the core session, or to schedule it for the next 1-2 weeks. Typically, the baseline and core session will be carried out on the same day.

- Compensation and funds for local round-trip transportation provided

- **A thank you card** will be sent to the participant by mail and electronically after enrollment (text will be IRB-approved)

- The project will send **birthday cards** to participants by mail and electronically (text will be IRB-approved)
- The project will send regular **holiday cards** to participants by mail and electronically (text will be IRB-approved)

13.4.2. Intervention components

- Intervention components will generally be administered after the baseline interview, and within the 1-2 weeks after enrollment. Components are brief or carried out mainly independently, thus Components A-D can be implemented in a single session.

- Intervention components can be carried out in person at the NYU field site or virtually over the phone or Voice over Internet Protocol such as Zoom.

- **During the core session, participants will be reminded to collect and retain documentary evidence of any COVID testing for the follow-up assessments.**

13.4.3. Time 2 and Time 3 assessment (6-weeks and 12-weeks post BL)

- Takes place in-person in a private office at the NYU field site or virtually

- Within 2-4 weeks prior to the assessment, the participant will be contacted and reminded to provide documentary evidence of COVID-19 testing, if any, and to attend the follow-up interview even if not tested for COVID-19. Participants can provide evidence of as many tests as they like.

- Participants will also be asked to provide documentary evidence of COVID-19 vaccination if they have it (e.g., the CDC vaccination card).

- Follow-up (FU) assessments will be carried out 6- and 12-weeks post-BL in ACASI or CAPI in the REDCap platform.

- The FU interviews will last approximately 35-45 minutes. The 6- and 12-week FUs will assess the period since the last interview.

- The locator form may be confirmed or updated at each phone or in-person contact with participants

- In-between FUs, participants may contact the study to update contact information.

13.4.4. Qualitative in-depth interview (subset of participants; *N*~50)

- Participants will be purposively sampled for the qualitative in-depth interviews for maximum variability on the following criteria: age, sex, language (English or Spanish), race/ethnicity, type of occupation, whether engaged in assigned components or not, and whether was tested for COVID-19 or not (*N*=50).

- We will explore participants' experiences with and perspectives on the intervention components (including acceptability) and on barriers to and facilitators of COVID-19 testing, as well as barriers to and facilitators of vaccination, and on the relationship between COVID-19 testing and vaccination.
- The qualitative interview will follow a semi-structured guide that has main questions linked to the conceptual model and probes. We will also attend to emergent topics.
- Interviews will be audio-recorded and transcribed.
- Qualitative and quantitative results will be integrated, as described below.
- The qualitative sample size was determined following procedures outlined by Malterud[119] called information power. Greater sample heterogeneity and a cross-case analysis strategy as we propose here call for larger samples; *N*=50 is a larger sample size.
- Takes place in-person at the field site or virtually (phone or Voice over Internet Protocol such as Zoom)
- 60-90 minutes
- Compensation and funds for local round-trip transportation provided

13.5. Acuity

We will use the Acuity program for participant scheduling. In Acuity, participants can be sent a link with available slots and can schedule an appointment. They can enter their name and contact information and Acuity will send reminder texts or emails.

The Acuity program maintains participant confidentiality. It is a password protected program (on a password protected computer) and participants see only available slots, not the names of other participants.

Participants can schedule their own visits and we can use Acuity to schedule appointments for them.

13.6. Preventing repeat enrollments

Staff members will check and flag data as possibly fraudulent (i.e., the same person[s] attempting to complete the screening interview and/or enroll in the study multiple times) using an algorithm based on a combination of geolocation data, survey data, and personal information (Ballard et al., 2019). Data that will be reviewed by staff for potential fraud include geolocation outside the study area based on IP or mailing addresses, multiple entries from the same IP or mailing address address, phone numbers that are invalid or belong to a business or organization, phone numbers that match previous entries, unusual email addresses (e.g., containing alternating letters and numbers), email address that matches previous entries, date of birth/name that match previous entries, duration of the survey was less than 5 minutes. Staff members will contact participants suspected of fraud to inform them that their entry was flagged and to request they contact staff members to verify their entry to receive compensation. Participants who cannot be verified will be determined fraudulent and not included in the final dataset.

The informed consent forms state that participants should not take the survey more than once, and if this occurs, incentives will not be received more than once.

Ballard AM, Cardwell T, Young AM. 2019. Fraud Detection Protocol for Web-Based Research Among Men Who Have Sex With Men: Development and Descriptive Evaluation. JMIR Public Health Surveillance;5(1):e12344.

13.7. Implementation manual

The COVID-19 pandemic requires a rapid public health response but the rapid scale-up of effective interventions in community settings lags substantially[116]. The proposed study will draw on implementation science principles to support timely implementation of the optimized intervention if found effective. We will develop an implementation strategy manual, detailing requirements and recommendations for implementation in NMIC and similar community-based settings. To create the manual, we will conduct CAB meetings with stakeholders at NMIC including staff and clients who are BLH-FEW. Guided by the Consolidated Framework for Implementation Research (CFIR)[117], the meetings will explore potential barriers and facilitators to implementation of the optimized intervention in community-based settings. The CFIR is one of the most widely utilized frameworks in implementation science[117]. It is a meta-theoretical framework that provides a standardized list of constructs found to be implementation determinants across five major domains[117]. We will probe for barriers and facilitators organized by CFIR domains: outer setting factors (i.e., funding, policies), inner setting (i.e., leadership, organizational readiness), the intervention (i.e., complexity), the people involved (i.e., self-efficacy) and the implementation process (i.e., planning). After each CAB meeting, we will map group suggestions onto existing implementation strategies[118]. Dr. Stanhope, a study Senior Advisor and expert on implementation science, will play a leadership role in this effort along with our partners at NMIC. Further, integrated qualitative and quantitative results from the factorial experiment will be presented to the CAB and included in the evaluation of implementation factors. Ultimately, the findings will form the basis of a manual providing tailored guidance related to the organizational context to support rapid adoption of the optimized intervention after the study is concluded.

13.8. Subject completion/withdrawal

Participants may withdraw from the study at any time without prejudice to their care. They may also be discontinued from the study at the discretion of the Investigator if they violate the study plan, due to adverse events, or to protect the subject or staff for reasons of safety or for administrative reasons.

14. Study Evaluations and Measurements

14.1. Screening assessment domains

We will assess the following by self-report:

1. Age
2. Able to conduct activities in English or Spanish
3. African American or Black and/or Latino or Hispanic race/ethnicity
4. Residence in the NYC
5. In the past month, was employed as a frontline worker in an essential occupation listed in this protocol
6. Has a phone that can be used for study participation and can receive TMs (in the event the participant is assigned to Component B)
7. Has not been fully vaccinated for COVID-19 (we will ask to see vaccine certificates if available but this is not required and those who have not received any dose of a vaccine will not have a certificate)

8. Has not been tested for COVID-19 in the past six months
9. If previously diagnosed with COVID-19, has not been symptomatic in the past two weeks or 90 days has passed since treatment with monoclonal antibodies or convalescent plasma
10. Has not been educated/interviewed as a peer for Component C
11. Willing to engage in a core session and be randomly assigned to receive 1-4 components
12. Not a Community Advisory Board member
13. Willing to follow NYU's COVID-19 guidelines (e.g., complete daily screener, facial coverings, social distancing)
14. Willing to provide locator information

14.1.1. Domains in the assessment battery (BL and FU), Table 4

We will use the Common Data Elements developed by the RADx-UP group for the majority of domains described in Table 4.

Table 4. Description of the measures in the assessment battery (RADx-UP Common Data Elements will be used)	
	Moderating influences
Screening CDE	Identity, Age, race/ethnicity, sex assigned at birth, preferred language (CDE), ZIP code of residence, essential worker (Are you considered an essential worker? An essential worker is someone who was required to go to work even when stay at home orders were in place.)
Socio-demographics, background factors	sexual orientation, gender identity, immigration status,
	racism and discrimination experiences, [103]
	Health status - CDE
	Highest level of education – CDE
	Housing Employment and Insurance - CDEs
	Effects of COVID - CDEs
	Family income – CDE
	Past COVID-19 testing - CDE
	Medical History - CDE
	Other CDEs
Alcohol and tobacco	Alcohol and tobacco
	Work PPE and Distancing
	Individual/attitudinal influences
Knowledge	8-item true-false questionnaire on aspects of COVID-19[104]
Perceived susceptibility to, severity of COVID-19	Wong perceived susceptibility to (three items), and perceived severity of COVID-19 infection (three items) scales[105]
Perceived benefits of COVID-19 testing	Guidry 4-item Perceived Benefits of COVID testing[106]; α = 0.82
Distrust and fear of COVID-19 testing	10-items assessed on a 5-point Likert-type scale drawn from existing reliable scales[106-108]
Counter-narratives (conspiracy theories)	6-items assessed on a 5-point Likert-type scale drawn from existing reliable scales (e.g., I could be a guinea pig for a test with unknown consequences). [109,110]
Cognitive biases	Measurement of BE biases[42]
Behavioral Intentions	Various testing scenarios assessed with 3 items (e.g., I intend to get a COVID-19 test regularly) on a 6-item Likert scale[106]
Motivation/readiness	Importance of COVID testing and confidence in ability to get serial screening and tested as needed on a 1-100 scale.[111]
	Social influences
Perceived social norms	Adapting Latkin we will assess social norms using four items: injunctive (e.g., My co-workers encourage me to get a COVID test); descriptive (e.g., What percent of your co-workers do you think have gotten a COVID test)[112]. α = 0.77.
Altruism & collective responsibility	Three items on testing as an altruistic act (e.g., My getting tested helps my community reduce the spread of COVID)[108]
	Structural influences
Structural barriers to COVID-19 testing	Perceived barriers including poor access related to insufficient local sites, lack of paid sick leave, lack of childcare, language barriers [113]
	PRIMARY OUTCOME
COVID-19 testing	COVID testing behavior (see protocol for definition)
	SECONDARY OUTCOMES
COVID-19 testing	Confirmatory and/or re-testing, contact tracing (by participant), self-isolation, health care, unintended consequences of testing
	Testing behavior - CDE
Vaccination	Vaccine Acceptance - CDE
	Attitudes toward COVID-19 vaccination[106-108], receipt of vaccination doses
	Intervention process domains
Intervention acceptability	Client Satisfaction Questionnaire (YCSQ) –17 items; reliable and valid measure [114]
Intervention social harms	Assessment of project-related social harms experienced in social and occupational domains.
	Feasibility/Intervention dose
Intervention dose	Number of assigned components attended, if assigned: number of peers educated, navigation contacts completed and their characteristics/content

14.1.2. Assessment of peers as part of Component C

Peers will call the study or carry out the assessment independently in REDCap. The peer coupon includes a QR code that brings peers to the peer assessment as well as the study phone number.

If the peer is interviewed by a staff member, peers will provide verbal informed consent following an IRB approved form and receive a brief interview that includes their coupon number, age, race/ethnicity, sex, occupation, relationship to the participant, true/false questions on the core messages, COVID-19 testing experiences, and COVID-19 vaccination experiences. They will be given referrals to COVID-19 testing and vaccination locations as needed.

If the peer follows the QR code, peers will read the informed consent form in REDCap and indicate their informed consent, then carry out the brief interview.

We will collect some identifying information on the peer (name, email address, mailing address) in order to compensate the peer for the interview and inform the participant educator that the peer contacted the study.

14.1.3. Qualitative interviews

Qualitative interviews will follow a semi-structured interview guide with questions and prompts focused on barriers to and facilitators of COVID-19 testing and vaccination, and regarding acceptability of the intervention components.

14.1.4. COVID-19 self-test kit (with FDA EUA)

The present study does not test participants for COVID-19 but as part of Component D: navigation, half the sample will be provided with rapid antigen self-test kits for COVID-19 that has received U.S. Food and Drug Administration (FDA) emergency use authorization (EUA) or full FDA approval.

We will provide the ACON Biotech Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing). We will refer to this as the FlowFlex test.

This test is provided in a white box. (FlowFlex tests in a dark blue box do not have FDA EUA.)

An independent evaluation conducted by the National Institutes of Health's (NIH) RADx program has indicated that the Flowflex™ COVID-19 Antigen Home Test does detect the Omicron variant in live clinical samples (https://www.aconlabs.com/flowflex-documents-new/).

14.1.5. Update to Flowflex EUA – serial testing for asymptomatic or symptomatic individuals is required

On June 21, 2022, the FDA updated the Flowflex EUA letter (https://www.fda.gov/media/152700/download) to require serial testing for asymptomatic individuals. As it is worded in the EUA, "the test is authorized for individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when **tested twice over three days with at least 24 hours (and no more than 48 hours) between tests."**

All RADx-UP projects using Flowflex must modify their testing strategy to ensure participants are informed that "testing" means they are tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

The present study adherence to FDA guidelines. Study intervention materials and assessment instruments were revised to reflect these changes.

14.2. Primary outcome

The study's primary outcome is **COVID-19 testing confirmed with documentary evidence** (e.g., a doctor's note or patient portal electronic health record note [e.g., from MyChart] that includes the type of test, date of testing, and the result, or a photograph of a self-test result).

As of March 16, 2022, the NYC Department of Health and Mental Hygiene recommends the following: "People who have frequent in-person contact with others and are not fully vaccinated should consider getting tested weekly. This is especially true for people in close contact with others who are not wearing masks indoors" (https://www1.nyc.gov/site/doh/covid/covid-19-testing.page).

This is consistent with CDC guidelines: "The CDC recommends conducting screening testing of unvaccinated, asymptomatic workers without known or suspected exposures at least weekly (https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/testing-non-healthcare-workplaces.html#anchor_1615914276994).

14.3. Primary outcome definition and evaluation

The study's primary outcome is at least one instance of diagnostic **COVID-19 testing in the past six weeks (that is, not antibody testing), confirmed with documentary evidence of the result** (e.g., a doctor's note or patient portal electronic health record note [e.g., from MyChart] that includes the type of test, date of testing, and the result, or a photograph of a self-test result or self-test results).

The present study does not test participants for COVID-19. Instead, the present study tests a number of intervention components intended to increase regular COVID-19 testing in this population. Participants can receive testing at any community site or carry out home testing.

The present study does provide half of the participants with FlowFlex test kits as part of Component D: navigation. Thus, we expect that many participants will use the FlowFlex test. (We provide two test kits in the self-test level of Component D. Starting in January of 2023, we inform participants in the self-test level of Component D that three tests are recommended in certain circumstances. We provide information on how to obtain tests.)

Many self-tests require serial testing within a proscribed window of time in certain circumstances (e.g., BinaxNOW, Nano-Check, INDICAID, InteliSwab, Flowflex), while other tests require a single test. Tests with current EUAs are listed here: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2

The number of rapid tests required for a complete test for several of the serial rapid test kits has changed during the pandemic, including the test we use in the project (Flowflex). This makes assessing rapid test completion complicated. **Thus, we will define an "instance" of COVID testing as any single time a COVID test was administered, whether a rapid, PCR, or other type of test.**

We will also assess test COMPLETION as a secondary outcome. Test completion is defined below.

Thus, we will assess "instances" of testing for COVID-19 at follow-up and for each instance will assess:

- Main reason for testing (e.g., screening testing/asymptomatic, exposure, upcoming travel, return from travel, preparing for upcoming event, work requirement, symptomatic, other) over the prior 6 weeks.
- Mechanism of test: Self-test (rapid) or self-test collection vs. facility-based testing
- Type of COVID-19 test (rapid/antigen, PCR/molecular)
- If self-test, brand name of self-test (e.g., FlowFlex, Inteliswab, BinaxNOW, etc). Participants can send a photograph of the test kit box to aid in determining which test was conducted.
- Number of self-tests required in this instance
- Number of self-tests carried out in this instance
- If serial testing was carried out, number of hours between the first and second test
- If facility-based testing was carried out, location of testing (laboratory, a standalone testing site, a doctor's office or health clinic, hospital, other)
- Dates of test(s)
- Result of test(s) – positive, negative, inconclusive, unknown

We will code these data regarding COVID testing behavior in the following manner:

- For non-serial test kits: testing was PERFORMED COMPLETELY if one self-test was completed
- For serial test kits that require two tests within a certain window of time (e.g., Flowflex until December of 2022, BinaxNOW), testing was PERFORMED COMPLETELY if two tests were carried out in compliance with the package instructions. If one test was completed, and no PCR test was completed, we will code the test as PERFORMED INCOMPLETELY
- For serial test kits that require three tests within a certain window of time (e.g., Flowflex after December of 2022), testing was PERFORMED COMPLETELY if three tests were carried out in compliance with the package instructions. If one or two tests were completed, and no PCR test was completed, we will code the test as PERFORMED INCOMPLETELY
- For serial test kits, if participants receive one self-test followed by a PCR test, testing will be coded as PERFORMED COMPLETELY
- When participants receive a PCR test, testing will be coded as PERFORMED COMPLETELY

We will request documentary evidence for the result of each test. Documentary evidence will be coded as present or absent for each test.

14.4. Secondary outcome evaluation

Secondary outcomes include:

- Result of each COVID test
- If diagnosed with or has a positive COVID test result
    - confirmatory testing, as needed (PCR testing is recommended for symptomatic negative and asymptomatic positive persons who carry out a rapid test)
    - contact tracing
    - self-isolation
    - health care receipt
    - unintended consequences

For all participants:

- attitudes toward COVID-19 vaccination
- receipt of COVID-19 vaccination (the CDC vaccination card will be shown if possible)

These primary and secondary outcomes will be examined in mixed methods and integrated analyses.

15. Statistical Considerations

15.1. Sample size, precision, and statistical power

For the primary outcome, COVID-19 testing by the final follow-up, we used PASS 2021[139] to estimate the sample size needed for individual main effects of intervention components corresponding to odds ratios of 2.0 in logistic regression, given α=.05. Assuming participants not receiving or receiving the lowest intensity of each component have a 20% chance of testing by the final follow-up, a sample size of n=352 (n=22 in each of 16 conditions) provides 80% power to detect an odds ratio of 2.0 (i.e., 20% vs. 33% tested). To account for attrition of up to 20% of enrolled participants, we propose a total sample size of 448 participants (n=28 in each of 16 conditions), ensuring complete data for at least n=22 per condition. Given the proposed sample size, when the main effect of an intervention component on a continuous measure of a secondary outcome or mediator is estimated in a linear model or independent-samples t-test, the sample size provides 80% power to detect a small standardized mean difference (*d* = .30). Moderator effects corresponding to an odds ratio of OR=1 in one subgroup and OR=4 in another can be detected with 83% power if subgroups sizes are roughly equal. To estimate the size of a mediated effect that can be detected given the proposed sample size, we use the approach described by Vittinghoff and colleagues[140] as implemented in PASS 2021. Given a substantial correlation between an intervention component and a hypothesized mediator (*r*=.50), an odds ratio of 1.50 can be detected with >80% power for the effect of a one-SD increase in a continuous mediator on the COVID-19 testing outcome, controlling for treatment assigned.

15.1.1. Missing data

Missing data in longitudinal studies are inevitable despite best efforts at retention. Several procedures based on differing assumptions about the randomness of the missing data will be implemented[157]. Missing values may be handled by full information maximum likelihood (FIML)[158,159]. Inverse probability weighting[160,161] and multiple imputation[162] will be considered as well. These approaches to handling missing data assume data are missing at random (MAR). In addition, methods for non-ignorable missing data (missing not at random; MNAR) such as Heckman's selection model[158,163] and pattern-mixture models[162,164,165] will be used. Sensitivity analyses will assess the degree to which results depend on untestable assumptions.

15.2. Primary endpoint/outcome

The primary outcome is at least one instance of COVID-19 testing in the past 6 weeks, with documentary evidence of the testing.

15.3. Secondary endpoints/outcomes

Secondary outcomes include:

- Result of each COVID test
- If diagnosed with or has a positive COVID test result
    - confirmatory and re-testing (as needed)
    - contact tracing
    - self-isolation
    - health care receipt
    - unintended consequences
- attitudes toward COVID-19 vaccination
- receipt of COVID-19 vaccination

These primary and secondary outcomes will be examined in mixed methods and integrated analyses.

15.4. Data Transfer Agreement (DTA) Security Level

As per our Notice of Award, data will be transmitted to the RADx-UP Coordination and Data Collection Center (CDCC) weekly.

Our data security level is LIMITED.

We will not provide: Names, street address (city, county, state, and zip code are allowed), Telephone / Fax numbers , email, Medical record numbers, Health plan beneficiary numbers.

This corresponds to the following Common Data Elements (CDEs): first_name, last_name, current_street, current_street2, mobile_phone, home_phone, other_phone, personal_email, other_email, mrn

All other data including the Tier 1 CDEs will be transmitted to the CDCC on the schedule determined by the CDCC (e.g., quarterly).

15.5. Statistical methods

15.5.1. Quantitative data analysis

Intent-to-treat analysis will be our primary analytic approach and exploratory analyses will examine complier average effects of intervention components[124,125]. Approaches to missing data will include full information maximum likelihood estimation[126] and multiple imputation[127]. In sensitivity analysis, missing data will be treated as failure to achieve the desired outcome. If data are missing not at random (MNAR), we will employ sensitivity analysis, using selection[128] or pattern mixture[129,130] models.

Aim 1: **Identify which of four components or interactions between components contribute meaningfully to improvement in the primary outcome, COVID-19 testing with documentary evidence, and from these results, optimize a multicomponent intervention.**

The primary outcome for Aim 1 is COVID-19 testing with documentary evidence by the final follow-up point (12-weeks post-baseline). Logistic regression will be used to estimate effects of components on the odds of COVID-19 testing. Intervention components will be effect-coded to estimate main effects, two-way, three-way, and four-way interactions of all four components (see **Equation 1**). The coefficient for an effect-coded main effect term (e.g., b_1), multiplied by two and exponentiated, will estimate the effect of the component (e.g., Component A) on the odds of testing. Similarly, the coefficient for an effect-coded interaction term, multiplied by two and exponentiated, will estimate interaction effects between or among components on the odds of testing. Similar logistic regression analyses will estimate effects of components on secondary outcomes.

Equation 1

Intervention optimization. Based on main and interactive effects estimated in Aim 1, we will use a decision-making process to select the most effective combination of component levels, eliminating ineffective or poorly performing components. The decision-making process will be led by Drs. Gwadz, Cleland, Lizardo, Bangser, and Parameswaran and using procedures outlined in Collins[48]. To identify

important component main effects, we consider both statistical significance at p <.05 as well as the probability the more effective component level multiplies the odds of testing by at least OR=1.2. This effect size threshold is based on the idea that several components with an effect as large or larger would comprise a potent multicomponent intervention. We will use a Bayesian generalized linear model with non-informative priors to calculate the probability of OR ≥ 1.2 from the posterior distribution. Component main effects that are statistically significant ($p < .05$) and have a probability > .5 of OR ≥ 1.2 will be considered important and placed into a screened-in set. Membership in the screened-in set will be reconsidered in light of any important interactions. Interactions that are statistically significant ($p < .05$) and have a probability > .5 of OR ≥ 1.2 will be considered important. For example, a component level that does not meet criteria for an important main effect could be included if it enhances the effectiveness of another component. Component levels that make up the optimized intervention are comprised of the higher levels from the screened-in set and the lower levels from the screened-out set.

Aim 2: Identify mediators and moderators of the efficacy of each intervention component. To examine potential mediating mechanisms, analysis for **Aim 2** will use the potential outcomes framework[132-134]. This framework highlights assumptions needed to identify direct and indirect effects of interest: no unmeasured cofounders of the exposure (an intervention component) and outcome (COVID-19 testing) relation; no unmeasured confounders of the mediator and outcome relation; no unmeasured confounders of the exposure and mediator relation; and no measured or unmeasured confounders of the mediator and outcome relation affected by exposure. Since intervention components are randomly assigned, the key issue for the proposed study is addressing confounding of the relation between mediators and outcomes. Mediators measured at baseline will be included as confounders of the relation between follow-up mediators and COVID-19 testing by the final follow-up. Because unmeasured confounding of relations between mediators and outcomes may remain despite attempts to measure and include known confounders in the models, sensitivity analysis will be undertaken to determine how the size of the correlation between error for the mediator model and error for the outcome model impacts inferences for direct and indirect effects. The total natural indirect effect (TNIE) and pure natural direct effect (PNDE) of each component will be estimated using the *mediation* R package[135]. The TNIE compares the outcome when subjects are exposed (e.g., receive a component), and the mediator varies as it would naturally under exposure, versus the outcome when subjects are exposed but the mediator varies as it would naturally in the absence of exposure (i.e., component not received). In other words, the difference estimated by the TNIE compares the expected outcome when the intervention has its natural impact on the mediator versus the expected outcome when the action of the mediator is blocked. The PDNE compares participants at different levels of a component (e.g., On vs. Off) when a mediator is blocked.

Potential moderator effects will be examined by adding interaction terms to the model described for **Aim 1**. We will include sociodemographics (e.g., age) and occupation as covariates and explore the interactions of these variables with intervention components. When interaction effects are detected, we will estimate the simple main effects of the intervention component across levels of the moderator variable (e.g., MI counseling effects on testing for younger vs. older participants). Identified moderators will inform future adaptive interventions[138].

15.5.2. Qualitative analyses

Aim 3. Explore the relationships among barriers to, facilitators of, and uptake of COVID-19 testing and COVID-19 vaccination. Coding and analytic methods of qualitative data from in-depth interviews will employ a directed content analysis approach[141]. Analyses will be carried out in the Dedoose platform and will begin with pre-determined codes based on the conceptual model (i.e., a "start list"), which will be expanded based on emergent findings. This start list fosters data integration across qualitative and quantitative data sets, because the same core constructs are assessed in each method. The primary

qualitative data analyst will lead the process of organizing codes into themes, in collaboration with an "interpretive community"[142] made up of research team members at NYU (including study Co-Investigators and the Senior Advisors, Drs. Hawkins and Stanhope) and NMIC. We will attend to trustworthiness and rigor in analysis using an audit trail and with member checking with the CAB and study participants. Integration of qualitative/quantitative results will use the joint display method[26]. A joint display is a state-of-the-art visual tool (i.e., a side-by-side visual presentation of results) to integrate data sources. Dr. Gwadz will lead the effort to integrate data with the interpretive community. This will be an iterative process in which each joint display table reveals insights about the merged findings that shape subsequent iterations. Thus, joint displays are both a method and a cognitive framework for data integration and facilitate the production of new inferences[26]. We are experienced with mixed methods data integration and joint display methods[36,92-93,96,143].

15.5.3. Data integration

Integration of qualitative and quantitative results will follow procedures outlined by Fetters and colleagues (2013) and use the joint display method[182]. A joint display is a state-of-the-art visual tool (i.e., a side-by-side visual presentation of results) to integrate data sources. The process brings about new insights beyond the information gained from the separate quantitative and qualitative results. Drs. Gwadz will lead the effort to integrate data with the interpretive community (including CAB). This will be an iterative process in which each joint display table reveals insights about the merged findings that shape subsequent iterations. Thus, joint displays are both a method and a cognitive framework for data integration and facilitate the production of new inferences[182]. We are experienced with data integration and joint display methods[183-185].

All data provided to the CAB will be de-identified.

16. Safety Management & Study Administration

16.1. Data collection and management

16.1.1. REDCap

REDCap (Research Electronic Data Capture) will be used through all study phases. REDCap is a secure web-based application for building and managing online surveys and databases. Data can be entered from anywhere in the world over a secure web connection with authentication and data logging. It allows for multi-site access; that is, REDCap databases/surveys can be used by researchers from multiple sites and institutions. It includes features such as a built-in project calendar, a scheduling module, and reporting tools. REDCap can be installed in a variety of environments for compliance with such standards as HIPAA, 21 CFR Part 11, FISMA (low, moderate, high), and international standards. Only trained study staff will have access to the REDCap database. We have developed a comprehensive REDCap database for two ongoing studies and can adapt this database architecture for the proposed study. Thus private, identifiable information will be collected, but will be kept confidential.

16.1.2. Protection of confidentiality in REDCap

Participants will be identified by their Participant Identification Number in the REDCap database. A separate form linking participants' names with the Participant Identification Number will also be included in REDCap. All consent forms will be signed in REDCap (the eConsent feature) and all assessments will be conducted in REDCap. Documentary evidence of COVID tests results will also be entered into REDCap. REDCap was designed specifically to protect patient and research participant

privacy and confidentiality while assisting investigators in conducting clinical research. The REDCap database can be shared among NYU authorized staff.

We will use computer-assisted personal interviewing (CAPI) and audio computer-assisted self-interviewing (ACASI) for sensitive sections of the assessments. In ACASI the respondent listens to digitally recorded questions and response categories through headphones, and enters her/his answers by using the computer keyboard or touching the computer screen. We have used ACASI with participants in past studies and found that participants were comfortable with using computers and appreciated the privacy it afforded. At each assessment period, the participant can opt out of the entire assessment or any part of the assessment.

Audio-recordings and transcripts will be stored on NYU's cloud-based and password-protected application, NYU Box. Recordings will be professionally transcribed within six months of collection and audio-recordings will be deleted within six months of transcription. Transcriptions will not include identifying information and are labeled with the participant's identification number.

Participant safety will be monitored by query regarding adverse events at all contacts and social harms in domains such as occupation, health care, and housing will be assessed at FU assessments.

16.1.3. Locator form

We are leaders in the development of successful tracking and retention strategies. Minimal contact information will be collected during the screening process. At the time of enrollment, after providing signed informed consent, the participant will complete a detailed locator form, which is stored in the REDCap database. The project staff member will solicit the names and contact information of at least three individuals who will know how to reach the participant in the future. Participants may provide the names of case managers and other professionals, as well as personal contacts. A locator form is a crucial component of the retention strategy. We will obtain email addresses, cell phone numbers, Facebook IDs, and other social media IDs, if participants are comfortable being contacted at these virtual locations. The project will maintain an open Facebook page to facilitate communication. The locator form is updated with participants at regular intervals. Participants are instructed to get in touch with the study if contact information changes. Staff will reach out to update locator information in between follow-up periods.

16.1.4. Retention plan

We will use a detailed locator form that is updated regularly, maintain regular contact with participants, ensure adequate, prompt, fair, and timely compensation with Clincard[190] (funds are available to participants almost immediately), implement specific technical tracking strategies, and train all staff on retention strategies[191]. For the participant, contact info will include cell phone number, email address, physical address, and social media handles, as well as contact information for at least three individuals who will know how to reach the participant. Attrition is highest in the early phases of studies, and regular contact during this period fosters retention[192]. Thus, participants will be contacted within one month to update locator information. Participants will receive compensation if they contact the study to update contact information. (Compensation amounts are provided below.) We will send birthday and holiday cards to build rapport, and returned mail will help identify participants at risk of attritting. Tracking includes direct contact tracking and network-based tracking. This begins with text and social media messages, phone calls, and letters to the participant and individuals on the locator form; repeated attempts will be made as necessary. If place-based tracking methods are unsuccessful, we will initiate systems-level tracking (e.g., searching web-based directories). We will create a positive project

ethos to increase engagement (communicating respect, no judgement, confidentiality, autonomy/ choices) and tap into altruism[191]. We estimate ≥ 80% of assessments will be completed.

16.1.5. Data sources for optimization trial

- Consent forms – screening, enrollment
- Locator form
- Structured assessment batteries: screening, BL, FU
- Brief assessment of peers as part of Component C
- COVID testing form (date, location/type of test, test result, type of confirmation, etc)
- COVID vaccination form (date or dates of vaccination doses, type of vaccine)
- Intervention component manuals
- Qualitative interview guide

16.2. Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies on subject privacy. The Investigator and other site personnel will not use such data and records for any purpose other than conducting the study.

The safeguards to maintain subject confidentiality are described in the section on Data Collection and Management.

Eligible participants are told about the longitudinal component of the study as part of the enrollment informed consent procedure, and the consent form states that we will try to contact them in the future and how we will do so. We inform participants that we will not disclose anything about them as part of the tracking process other than that they are a participant in a "community health project." We will use a generic name for the study that does not disclose anything about the participant.

16.3. Data sharing with RADx-Up

The study will obtain permission from participants to collect and share de-identified data with the NIH RADx -UP Coordination and Data Collection Center (CDCC) and RADx Data Hub using specific language in the Informed Consent Forms (ICF).

16.4. Regulatory and ethical considerations - Data and safety monitoring plan (DSMP)

16.4.1. Data safeguards

The project will maintain study offices in a field site maintained by the NYU Silver School of Social Work located in lower Manhattan. Access to NYU offices is restricted to research staff. The NYU Silver field site building is secure and monitored by security staff.

The secure and password-protected REDCap database is used for study activities. Consent forms will be signed (as appropriate) and structured assessments will be conducted in REDCap. REDCap was designed specifically to protect patient and research participant privacy and confidentiality while assisting investigators in conducting clinical research. System-level and application-level security features include SSL encryption of internet traffic (e.g., https pages), hosting in a secure data center with nightly backup, fine-grained control over user privileges, detailed audit trails, record-locking, and de-identification functions for data export. Participants will be identified by their Participant Identification Number (PIN) in REDCap forms and assessments. Only research study staff have access to the REDCap database.

All computerized data that are not in REDCap (transcripts of qualitative interviews, audio-recordings) are kept on computers that are double password-protected and are only labeled with PINs. Audio files are transferred to a secure cloud-based storage system daily (NYU Box), which is also double password protected and available only to project staff. Audio-recordings are deleted within six months of their creation date.

16.4.2. Confidentiality safeguards

All participants receive a participant identification number (PIN). This number will be used for all materials, audio-recordings, transcripts, study visit notes, and assessments. No other information that would disclose the participant's identity will be found on any assessments, notes, audio files, or in the transcripts of qualitative interviews.

Study staff do not collect paper forms; all materials are located in the secure REDCap database. Participants provide signed consent electronically and the signature is recoded in REDCap. Staff receives training about confidentiality. Participants will be provided a paper copy of the consent form that includes contact information for the research team PI and the IRB as appropriate. Participants can use this contact information to report adverse events or unanticipated problems.

Names and other identifying information will be redacted from transcripts.

16.4.3. Ethics training

All research personnel will have completed Collaborative Institutional Training Initiative (CITI) training or an equivalent training before the research begins.

16.4.4. Certificate of Confidentiality

Participants will be informed that the study will obtain a Certificate of Confidentiality from the awarding institute at the NIH to support protection of their data. All data will be used strictly for research purposes.

16.5. Collection and reporting of “Reportable Events”

Several mechanisms will be put in place to monitor potentially adverse events that participants may experience while enrolled in the study, whether they are related to project participation or not. These events are classified as either Reportable, Adverse, or Not Harmful/Expectable, as described below, and will be reported to the IRB and Program Official at the study’s awarding institute (i.e., the Sponsor) accordingly, as described below.

In accordance with federal regulations governing Institutional Review Boards (45 CPR 46 and 21 CPR 50 and 56) and Guidance on Reportable Events from the Office of Human Research Protection, the Food and Drug Administration, and NYU, the IRB will review only unanticipated problems involving risks to participants or others. An unanticipated problem means that the incident, experience, or outcome is not expected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent documents; and the characteristics of the subject population being studied.

While there are many terms used by behavioral/social, clinical, and biomedical scientists to define a given type of reportable event (e.g., serious adverse event [SAE], adverse event [AE], adverse

experience, etc.), the IRB uses the following single definition for an immediate, single-incident IRB-reportable event: A Reportable Event is an unanticipated problem involving risks to participants or others ("Unanticipated Problem") and any event or information that (1) was unforeseen and (2) indicates that the research procedures caused harm to participants or others or indicates that participants or others are at increased risk of harm. (Other types of adverse events will be reported in aggregate or summary form to the IRB and Sponsor, as we describe below.)

The following definitions are used by IRB at NYU:

Unanticipated - An event is unanticipated when its specificity or severity is not consistent with, and not included in, the current investigator brochure, protocol, consent form, package insert or label; or unanticipated in its frequency, severity, or specificity.

Related - An event is related to research procedures if in the opinion of the Principal Investigator, it was more likely than not to be caused by the research procedures or if it is more likely that not that the event affects the rights and welfare of current participants.

Harmful - An event is harmful if it has caused harm to participants or others, or placed them at increased risk of harm. The harm does not have to be a direct harm to be reportable. The harm, as assessed by the Principal Investigator, may have created increased risk (e.g., losing a laptop with participant data such as an audio-recording). Additionally, the harm does not have to be harm to participants; it could involve risk to others (researchers, technicians, bystanders, the public, etc.).

Note: Non-medical events (e.g., breach of confidentiality, emotional breakdown, loss of insurance due to study participation, etc.), if unanticipated, would also be reportable to the IRB.

Thus, some examples of Reportable Events for the present study might be the following:

- Emotional breakdown requiring psychiatric intervention as a result of study participation
- Suicidal threat or behavior as a result of study participation; namely, the serious threat or attempt to inflict serious bodily harm to oneself that may result in death
- Serious violent threats or behaviors as a result of study participation including any threats, ideations or attempts to seriously injure or kill another person
- Experiences of domestic violence as a result of study participation
- Loss of employment or income as a result of study participation (participant was turned down for a new job, lost a job, or experienced other problems at work)
- Loss of education as a result of study participation (participant was turned down by an educational program, told to leave an educational program, or experienced other problems at school)
- Refused medical or dental care as a result of study participation
- Problems with health insurance as a result of study participation (participant lost health insurance, had a problem getting new health insurance, or experienced other problems related to health insurance)
- Problems with housing as a result of study participation (participant had trouble getting or keeping housing, or had other problems related to housing)
- Incarceration of an enrolled participant through the study period because the study is not approved to include prisoners. (The present study will not be approved to conduct research activities with participants while they are incarcerated, and any subjects incarcerated during the course of the study and unable to attend study visits will be withdrawn.)

- An unresolved participant complaint that indicates a potential increase or unexpected risk
- New information that presents a change to the risks or potential benefits
- A deviation or violation from the IRB approved protocol
- Unintentional direct or indirect violation of participant confidentiality by study staff.

Table 5: Summary of Events Classification and Actions Taken

Level of event	Examples	Action Taken
Reportable (unanticipated, related to study participation, harmful)	Hospitalizations at least overnight for any medical and/or psychiatric reason associated with study participation; suicidal or homicidal ideation related to study participation; incarceration of an enrolled participant through the study period; an unresolved participant complaint that indicates a potential increase in risk or unexpected risk; new information that presents a change to the risks or potential benefits; a deviation or violation from the IRB-approved protocol; unintentional direct or indirect violation of participant confidentiality by study staff.	(1) Report event to the IRB within **24 hours**, (2) Report event to Sponsor's Program Official within **24 hours**, (3) Report additional details of event and actions taken to the NYU IRB and NIH Program Official within **72 hours**, (4) Respond to requests for additional information by and/or recommendations from the IRB and NIH.
Adverse but not "Reportable" (anticipated in the consent form or unanticipated, may or may not be associated with study participation, harmful)	Hospitalizations at least overnight for any medical and/or psychiatric reason not associated with study participation; suicidal or homicidal ideation not related to study participation; drug overdose, namely, an emergency room visit and/or hospitalization due to a reaction to non-prescribed medications not associated with study participation; life threatening or disabling/incapacitating events affecting health and well-being such as serious accidents or physical attacks that result in injury not related to study participation; death not related to study participation; serious distress as a result of study procedures.	1) Document event on internal Events Log Form including whether it appears to be related to study participation, (2) Report events in aggregate or summary form to IRB annually, (3) Report events in aggregate or summary form to Program Official at NIH at the time of the Progress Report, (4) Provide clinical referral as appropriate at the time of event.
Not Harmful/Expectable (largely anticipated, not harmful)	Mild to moderate distress or anxiety as a result of study procedures	Not reported to IRB or NIH but provide clinical referral as appropriate at the time of event.

16.5.1. Reporting of adverse events that are not "reportable events"

Adverse Events do not meet the criteria to be considered a Reportable Event, may be unanticipated or anticipated (that is, described in the protocol or consent form), may or may not be associated with study participation, and are harmful or potentially harmful to the health and well-being of participants and others.

Thus, events uncovered during the course of the study will be classified as Reportable, Adverse, or Not Harmful/Expectable. A description of these three types of events and the actions to be taken for each are presented in Table 5.

16.6. Assessing events

As means of assessing events, some of which may be Not Harmful/Expectable, Adverse, or Reportable, we will administer a Social Impact Form that prompts for events that could occur as a result of participation in a study. Social impact will be assessed using a structured interview at each FU assessment. This assessment will probe for social, psychological, physical, housing, and other problems that have occurred as a result of study participation.

Furthermore, participants will be reminded to report problems, whether related or potentially related to study participation or not, to study personnel between scheduled assessments. They will be instructed on how to contact study personnel should problems occur between visits. Event impact will be formally and informally monitored, formally documented, and steps will be taken to prevent future similar events from occurring.

When an event is reported, it will be documented on an internal Events Log Form. The Events Log Form will assess the details, seriousness, and outcome of the event. As noted in Table 5, events are categorized as Not Harmful/Expectable, Adverse, or Reportable. Dr. Gwadz will determine whether an event is Not Harmful/ Expectable, Adverse, or Reportable.

16.7. Reporting of reportable events to the IRB

The NYU IRB requires that researchers decide whether the event is RELATED, UNANTICIPATED AND HARMFUL before submitting a Reportable Event to the IRB.

In the event that a RELATED, UNANTICIPATED AND HARMFUL event is reported to the Principal Investigator, Dr. Gwadz will use the NYU IRB's report form to report the event to the IRB within 24 hours of learning of it.

The following events will also be treated as Reportable Events as noted in Table 5, and as required by the IRB: Incarceration over the study period of an enrolled participant when the study was not approved to include prisoners; an unresolved participant complaint that indicates a potential increase in risk or unexpected risk; new information that presents a change to the risks or potential benefits; a deviation or violation from the IRB-approved protocol.

16.8. Reporting of adverse events

Adverse events discovered during the study that are not Reportable according to the above criteria because they are not related to the research (but are harmful and unanticipated/anticipated), will be communicated to the IRB at the time of continuing review in summary or aggregate form, and to the Program Officer at NIH in aggregate/summary form in the annual Progress Report. Non-harmful/expectable events are not recorded or reported to the IRB, as noted in Table 5.

16.8.1. Reporting of reportable events to NIH

First, Dr. Gwadz will report the Reportable Event to the study's Program Official at the NIH by phone or email within 24 hours and follow-up with a written report (by fax or email) within 72 hours, detailing any additional information and whether or not the event is related to participation in the study or may affect future participation in the study.

16.8.2. Suspension of data collection, further IRB review, or modification of the protocol

If the Principal Investigator determines that there is sufficient evidence of the need to suspend data collection, further IRB review, modification of the protocol, or other changes, the Principal Investigator shall make this recommendation to the Chairperson of the IRB. The IRB will reach a determination whether to suspend data collection or to stop the study from proceeding. Resumption shall be based on the concurrence of the Principal Investigator and the Chairperson of the IRB. The Program Official at NIH will be informed of this determination and will receive a report by email within 24 hours of any such suspension and/or resumption of data collection.

16.8.3. Clinical care and referrals when adverse and reportable events are uncovered

A plan has been developed for referral to clinical care in the event that Adverse and Reportable Events occur among the research participants. Individualized referrals to medical care, case management, or counseling for treatment or support will be made for participants experiencing Adverse and Reportable Events. In rare cases, referrals may be made for Non-harmful/Expectable events. Dr. Gwadz and the Project Director will determine the nature of the event, whether a referral is warranted, and the type of referral needed. Dr. Gwadz will ask whether the individual wishes to receive services in his/her community or outside it. A referral and follow-up with the participant within 24 hours will be completed to determine whether s/he made or attended an appointment.

16.9. If no adverse or reportable events are identified

The Principal Investigator will provide an annual summary report of all Adverse and Reportable Events to the IRB as part of the annual review. She will also report all Adverse and Reportable Events to the NIH as part of the annual Progress Report. If no Adverse or Reportable Events have occurred, the report will state, "No Adverse or Reportable Events affecting human subjects have occurred during this project year."

16.10. Report of changes or amendments to the protocol

Prior to implementation of the study protocol, the protocol, informed consent forms, recruitment materials, and other requested documents will be approved by the IRB. The responsible IRB will review the protocol at least annually. The Principal Investigator will provide progress reports to the IRB at least annually and within three months of study termination or completion. These reports will include the total number of participants enrolled in the study and the number of participants who completed the study.

Substantive changes to the protocol that have the potential to affect study aims will be approved by the study's Program Official at the NIH prior to submission to the IRB for approval.

Changes to the protocol will be submitted to the IRB for approval and will not be implemented prior to approval.

The Program Official at NIH will be informed of any other (that is, any minor) changes to the study's protocol on an annual basis as one component of the Progress Report.

16.11. Risk assessment

The study is minimal risk.

16.12. Potential benefits of study participation

The proposed study has high potential significance and high innovation. Testing for COVID-19 is an essential component of the multipronged national strategy to control the COVID-19 pandemic and reduce racial/ethnic disparities in COVID-19. The proposed study responds to RFA-OD-21-008 which calls for community-engaged interventions to support COVID-19 testing in underserved and vulnerable populations. Among those at highest risk for exposure to COVID-19 is the large population of FEW in lower status occupations such as food preparation and serving, retail and sales, building and grounds cleaning and maintenance, personal care and service, and home health care. Among FEW in these occupations, Black and Latino/Hispanic (BLH) persons are substantially over-represented. Moreover, although precise data are limited, testing rates among BLH populations are lower than among White populations and only an estimated 25-50% of BLH-FEW are currently vaccinated. Yet, testing for COVID-19 is recommended in a number of scenarios for symptomatic and asymptomatic individuals in order to identify asymptomatic cases, break transmission chains, and reduce community transmission. Yet, BLH-FEW have serious multi-level barriers to COVID-19 testing. The proposed study focuses on BLH-FEW in these lower status occupations and seeks to optimize an efficient and effective behavioral intervention to increase COVID-19 testing rates for this population. Participants may find the study activities useful.

16.13. Importance of the knowledge to be gained

BLH-FEW are at high risk for exposure to COVID-19, but have serious barriers to COVID-19 testing. The proposed study fills a need for interventions to encourage COVID-19 testing for BLH-FEW. The optimized intervention has the potential to provide efficient ways of increasing COVID-19 testing in BLH populations. The study methods and intervention components, and, therefore the optimized intervention, are designed to be reproducible; that is, this method should yield comparable results in a range of locations and settings, and sustainable; that is, widely accepted in community-based organizations that serve BLH-FEW and other BLH populations. Second, MOST has not yet been applied to the problem of insufficient COVID-19 testing. The proposed study has potential to increase the uptake of MOST for research on COVID-19 and similar disparities, in order to produce more effective, affordable, scalable, and efficient behavioral interventions. Last, public health will potentially be improved by providing tools that can increase rates of COVID-19 testing in BLH populations, for the current COVID-19 pandemic, similar or related disparities, and to better prepare for future pandemics. The optimized intervention created in the proposed study will complement existing local and national efforts to increase COVID-19 testing.

16.14. Risk-benefit assessment

16.14.1. Risks: Loss of confidentiality

One risk to participants is loss of confidentiality. The research team will make every effort to protect participants' privacy and confidentiality. Nonetheless, it is possible that confidentiality may be breached as a result of participation in the study. It is also possible that negative social impact will result from such a breach. However, we are highly experienced with research with populations in from low-income backgrounds and in high-risk settings and with longitudinal tracking methods with populations at risk.

16.14.2. Risks during assessment and intervention activities

The risk of gathering information from participants in assessments and interviews and conducting intervention sessions with participants by properly trained and supervised professional staff is minimal. However, it is possible that participants may experience negative affect or distress from answering questions about COVID-19, and health in general. The project staff, including intervention facilitators, will closely monitor participants for potential distress. If assessments or interventions are unduly distressing, the participant will be debriefed and linked to mental health care or support services.

16.14.3. Risks during interviews

The risk of gathering information from participants in assessments and interviews by properly trained and supervised professional staff is minimal. However, it is possible that participants may experience negative affect or distress from answering questions about COVID-19, , and health in general. The project staff will closely monitor participants for potential distress. If assessments or intervention activities are unduly distressing, the participant will be debriefed and linked to mental health care or support services.

16.15. Level of risk

Overall, the level of risk to participants in the proposed study is low.

16.16. Recruitment strategy

We will use a hybrid recruitment plan with both active outreach and passive strategies to reach BLH-FEW efficiently.

The recruitment approach includes:

- Flyers describing the study in English and Spanish. Study staff will use these flyers to directly recruit potential participants using ethnographic street recruitment methods (e.g., recruitment in parks and on the street)[102] and in settings where BLH-FEW are located, but without disrupting work activities. These recruitment efforts will focus mainly on the ZIP codes with the lowest rates of vaccination (< 50% fully vaccinated)[97].
- Ads placed in the medical research section of free newspapers (e.g., *amMetro, Latino Impact*), and
- Ads disseminated on social media (Twitter, Snapchat, Tik Tok, Facebook), Reddit, and Craig's List.

The recruitment plan does not include peer referral methods to reduce the probability of contamination across intervention conditions.

16.16.1. Sampling for qualitative interviews

Participants will be purposively sampled for the qualitative in-depth interviews for maximum variability on the following criteria: age, sex, language (English or Spanish), race/ethnicity, type of occupation, whether engaged in assigned components or not, and whether was tested for COVID-19 or not (*N*=50).

16.17. Informed consent/assent and HIPAA authorization

NYU at Washington Square is not a HIPAA-covered entity.

Consent will be obtained by NYU research staff. Participants will give verbal or signed informed consent prior to participation in all study activities. Informed consent will be obtained from highly trained and experienced research staff members. Participants will provide signed consent to have the qualitative interviews audio-recorded. Participants may decline to have their qualitative interviews recorded and still continue with the interviews. The voluntary nature of all study activities is emphasized in the consent forms.

Consent will be obtained in a private and confidential location such as a private office. Ample time will be provided for participants to make their decision about whether to enroll. We will remind participants that their participation is voluntary to avoid coercion. Once enrolled, participants can decline to engage in any activity and remain in the study.

As part of the enrollment consent, we will review each assessment and intervention activity and the potential risks and benefits of each. We will review the compensation amounts for each activity.

We will emphasize that participation is voluntary, that participants are free to stop participation at any time and are free to refuse to answer specific questions in any assessment and can decline participation in any activity. Participants will be informed that their decision to participate or decline to enroll in the study or any aspect of the study will not affect any other services they receive elsewhere.

16.17.1. Compensation: CAB members

CAB members will be compensated $100 per meeting (~1.5 hour meeting) by Clincard, cash, or electronic gift certificate.

CAB members are not Human Subjects.

16.18. Compensation in Phase 1: Refinement phase pilot study

Compensation will be provided as follows:

- $125 for participating in the 2.5 hour meeting
- $25 for the follow-up interview
- If asked to engage in the peer education experience, $25 for each peer who contacts the study (up to 3 peers; participant receives $15 when the peer contacts the study and a $10 bonus if the peer receives a score of $\geq$50% on the true/false knowledge quiz. This is intended to motivate the participant to carry out the peer education.)
- If receives text message component, $25 if earns at least 45/60 points from responding to quiz questions over 3 weeks (2 text messages and quiz questions a week)
- Compensation for round-trip public transportation for these activities if they take place in-person.
- 18 peers interviewed will receive $25 each

16.19. Compensation to participants: Phase 2 (optimization trial)

Participants will be compensated for study activities in Phase 2 (the trial) as follows:

- $30 for baseline interview and $5 bonus if documentary evidence of vaccination was shown at screening, either the CDC card or similar record or the My Vaccine Record website (max. $35)
- $40 for each FU interview (max. $80)
- $5 for showing documentary evidence of COVID-19 vaccination at FU, either the CDC card or similar record or the My Vaccine Record website (max. $10)
- $35 for in-depth qualitative interviews
- Core session: $30
- Component A: $30
- Component B: up to $75 for Component B depending on engagement in TMQQ
- Component C: up to $75 (up to $25 per peer who contacts the study; participant receives $15 when the peer contacts the study and a $10 bonus if the peer receives a score of $\geq$50% on the true/false knowledge quiz; 5 or more questions correctly answered receives the bonus)
- Component D: $20
- Peers assessed as part of Component C (*N*=672) receive $25. (Peers will be compensated in cash or through an electronic gift card provided through the Tango platform or Amazon e-gift card)

- Funds for local round-trip public transportation for in-person encounters

16.19.1. Timing of compensation

For all activities, compensation will be provided immediately after the activity is completed or as soon as possible after the activity is completed.

16.19.2. ClinCard research participant compensation system

Compensation will be managed with Greenphire's ClinCard Program. ClinCard provides a cost-effective and HIPAA-safe payment solution utilizing anonymous, reloadable prepaid debit cards that allows organizations in the behavioral and medical sciences to streamline their payment operations and improve recruitment and retention. ClinCard is more efficient and less labor intensive than cash or check compensation systems. Participants are compensated upon completion of each visit. ClinCard payments are entered by the staff member into an online program, and funds are available on the participant's card usually within one hour. We have found the ClinCard system to be acceptable to participants in past studies, and it is used widely at NYU and other academic and research institutions.

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