STUDY PROTOCOL

Title:	Community-based behavioral intervention to increase COVID-19 and influenza vaccination for African American/Black and Latino persons: An optimization randomized controlled trial
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SPECIFIC AIMS

Aim 1. Identify which of four candidate intervention components contribute meaningfully to improvement in the primary outcome, the receipt of the available COVID vaccine at the 6-month FU, with documentary evidence. Receipt of influenza vaccination is a secondary outcome.

Aim 2. Identify mediators (e.g., perceived risk, altruism) and moderators (e.g., sociodemographic characteristics, medical distrust) of the effects of each component to better understand the components' mechanisms of action and conditions under which they are most effective, to inform dissemination and future research and intervention programs. We will also explore perspectives in qualitative research (*N*=45).

Aim 3: Build the most cost-effective intervention package(s) from the components found to be efficacious in Aim 1.

CANDIDATE INTERVENTION COMPONENTS (SUMMARY)

Core intervention: Health education session (30 minutes)

Component A. Nurse-led shared decision-making (1 session, <60 min.).

Component B. Health & wellness interactive text message (TM) intervention (2 texts/week for 12 weeks, 1 text/week for 8 weeks, 20 weeks total, 32 texts total)

Component C: Prize at 6-month FU if vaccinated for COVID-19 with documentary evidence (gift bag with $25 gift card and low-cost items costing no more than $25), 3 reminder messages during intervention period

Component D. Peer navigation (5 months duration, introductory meeting, bi-weekly personal phone calls, texts, or emails)

AABL	African American/Black or Latino
BE	Behavioral economics
BL	Baseline (interview)
CAB	Community Advisory Board
CAPI	Computer-Assisted Personal Interview format
CDC	Centers for Disease Control and Prevention
CFIR	Consolidated Framework for Implementation Research
ERCT	Evaluation randomized controlled trial (a standard RCT)
FU	Follow-up (interview)
IIT-ICM	Intervention Innovations Team integrated conceptual model
MI	Motivational interviewing
MOST	Multiphase optimization strategy
NMIC	Northern Manhattan Improvement Corporation
NYU	New York University
ORTC	Optimization randomized controlled trial
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
TM	Text messages

SIGNIFICANCE

The proposed four-year study responds to NOT-MD-23-008: *Research to Address Vaccine Uptake and Implementation among Populations Experiencing Health Disparities.* The multiphase optimization strategy (MOST) framework will be used to test a set of candidate intervention components. Then we will optimize a brief, efficient, and cost-effective behavioral intervention to increase COVID-19 and influenza vaccination for populations with high levels of vaccine hesitancy, namely, African American/Black and Latino (AABL) persons who are not up-to-date on vaccination. The new intervention developed in the study can be scaled up in community and outpatient health settings annually. While vaccine hesitancy is not new, COVID-19 is a novel and devastating disease and new solutions are needed. There is a scientific consensus that SARS-CoV-2 (the virus that causes COVID-19) will continuously circulate in the human population, and new variants will evolve and spread, similar to influenza[44,45]. But, unlike influenza[19], which has a seasonal predominance and is unlikely to be contracted repeatedly in a year, COVID-19 can be contracted several times each year, with potentially serious consequences[46]. Because SARS-CoV-2 mutates continuously and immunity from vaccination and infection diminishes over time[47-49], the FDA and CDC have signaled that updated COVID-19 vaccinations will be needed annually[13-15,47-49]. Further, annual influenza vaccination is more important than ever to reduce the impact of respiratory illnesses in the population and resulting burdens on the healthcare system[18,50,51]. But, COVID-19 and influenza vaccination rates are insufficient among AABL persons. This section focuses first on COVID-19, then influenza.

COVID-19 case rates have varied and are currently climbing. The COVID-19 pandemic has shown a variable course. As of the summer of 2023, although surveillance is no longer comprehensive, numerous indicators show a marked rise in COVID-19 cases[52], including the National Wastewater Surveillance System[7,53]. Rates of hospitalization and death from COVID-19 are also rising[52,54.]

The effects of COVID-19 have been devastating. Over 6 million persons in the U.S. have been hospitalized, and more 1 million have died from COVID-19.[52] The acute effects of COVID-19 include fatigue, shortness of breath, chest pain, abnormal heart rhythm, parosmia, and joint pain[55]. As many as 1 in 5 persons with COVID-19 will develop Long COVID (signs, symptoms, and conditions that continue/develop after the initial COVID-19 infection).[56,57,58]. COVID-19 can lead to other serious adverse effects such as heart problems, blood clots, impaired fertility, and depression[59]. The risk of adverse effects of COVID-19, including serious illness, hospitalization, and death, increases with subsequent infections, particularly for those with co-morbidities[60-62].

Racial/ethnic disparities in COVID-19. There is a consensus that the COVID-19 pandemic exposed and intensified deep-rooted racial and economic inequities in health and health care[63]. Indeed, racial/ethnic inequities in COVID-19 incidence, morbidity, and mortality are marked[64-66]. For example, the NIH RECOVER study found racial/ethnic disparities in some symptoms of Long COVID and diabetes[67]. Importantly, although disparities have narrowed somewhat over the course of the pandemic, AABL persons are significantly more likely to be hospitalized with and to die from COVID-19 compared to White persons[3,65,68].

Mitigating the impact of COVID-19 illness. Staying up-to-date on COVID-19 vaccination is primary among the CDC's recommendations for mitigating risk, along with testing and treatment, face coverings, and indoor air filtration[69]. Vaccination for COVID-19 is highly effective in reducing the incidence of illness, severe illness, hospitalization, disability, and death[70,71]. Vaccination partially mitigates the risk for Long COVID[72,73]. Equitable vaccine uptake is essential to reduce COVID-19-related disparities in morbidity and mortality[69]. As of February 2023, 90% of adult Americans (and >80% of the AABL population) have received at least one COVID-19 vaccination dose and ~80% completed the primary series[54,74]. Yet, rates of those up-to-date on COVID-19 vaccination are unacceptably low. An updated COVID vaccine was approved in September, 2023[16,17] and data on uptake of the previous recommended vaccine (the bivalent booster) can be used to estimate the proportion that will receive this updated vaccine. Nationally only <30% received the bivalent booster, and disparities were notable: only 20% of Latino, 28% of African American/Black, and 31% of White persons who received the primary series also received the bivalent booster[74,75]. Thus, as of September 2023 only a small proportion of AABL persons were up-to-date on COVID-19 vaccination, and at the same time they continue to experience disproportional adverse health effects from COVID-19. Without intervention, insufficient uptake of COVID-19 vaccines will prolong the social and economic repercussions of the pandemic on AABL communities[76]. As COVID-19 transitions to an ongoing health challenge, strategies to tackle its long-term threats are needed[76].

Current operational definition of being up-to-date on vaccines. As of 9/2023 updated COVID-19 vaccines for 2023-24 has been approved, a monovalent COVID-19 vaccine with an XBB-lineage of the Omicron variant (**Pfizer-BioNTech and Moderna vaccine for the XXB.1.5 variant)**[16,54]. This updated vaccine is recommended regardless of whether the primary vaccine series or bivalent booster was received.[69,75] Novavax is under review at the FDA[77]. CDC tracking on variants highlights the XXB.1.5 variant is currently waning in the US, and the EG.5 variant is driving an uptick in COVID-19[78]. Because EG.5 is a subvariant or sub-strain of Omicron, the updated vaccine will provide protection against EG.5 and similar Omicron sub-strains[54].

Racial/ethnic disparities in influenza and influenza vaccination. There are serious racial/ethnic disparities in influenza-associated hospitalization rates; they are highest in AABL populations compared to White populations, with AABL hospitalization rates ranging from 1.5 to 2.4 times the rates for White adults[6,79]. AABL people are also more likely to die from influenza than White people[6]. As noted above, annual vaccination for influenza is vital[18]. But, racial/ethnic disparities in influenza

vaccination rates are serious and persistent: Only 30-40% of adult AABL persons receive the influenza vaccine annually compared to >55% among White persons[6,47]. Thus, COVID-19 and influenza share important similarities, including the need for annual updated vaccinations, persistent racial/ethnic disparities in vaccine uptake, and resultant greater morbidity and mortality among AABL populations compared to White populations.

MOST is an engineering-inspired framework for intervention development[35]. MOST allows for the testing the effects of individual intervention components in a fully powered experiment called an optimization randomized controlled trial (ORCT). Then, using findings from the ORCT, pre-specified criteria are applied to develop a multi-component intervention. These pre-specified criteria are called the optimization objective. For the proposed study, the optimization objective is to identify the most cost-effective combination(s) of components. The NIH has funded >250 ORCTs to date. We are highly experienced with the MOST framework, developing intervention components to reduce racial/ethnic disparities, and ORCTs[36-38]. MOST is described in detail below.

Addressing racial/ethnic disparities. For over two decades, our research group, the Intervention Innovations Team (IIT), has studied the structural, social, cultural, and individual-level factors that impede health among AABL populations and created effective interventions to improve health outcomes[36,81-85]. Our studies are informed by a model we developed and have applied in numerous efforts called the IIT integrated conceptual model (IIT-ICM)[85,86]. The IIT-ICM combines critical race theory, harm reduction, and self-determination theory. As such, it centers the perspectives of AABL communities and *addresses the role of systemic and structural factors, history, and culture in creating and shaping impediments to health behavior, supports any positive change, and guides toward health behavior without pressure or judgment, thereby supporting participants' autonomy. The IIT-ICM taps into the importance of* structural salience (health disparities have structural roots)[126] and cultural salience (culture informs health decisions)[127] in intervention content. The IIT-ICM has shown high acceptability and has contributed to intervention engagement and improved health outcomes in past studies with AABL populations[*36-38, 81-85,86*]. The IIT-ICM informs the intervention components to be tested in the proposed study, and the study is guided by a conceptual model that aligns with the IIT-ICM (Fig. 1).

Expertise in COVID-19 vaccination hesitancy. We are currently carrying out a study on COVID-19 *testing* (U01MD017418) as part of the RadX-UP initiative, in collaboration with our community partner, the Northern Manhattan Improvement Corporation (NMIC). That study is a community-based ORCT to test intervention components and then optimize an intervention to increase COVID-19 *testing* for AABL frontline essential workers who are not up-to-date on COVID-19 vaccinations (U01MD017418). That study does not intervene to improve COVID vaccination rates, but we use quantitative and qualitative methods to study vaccination knowledge, attitudes, intentions, and uptake, and these data inform the present study, along with the larger empirical literature and a pilot study we carried out. In the COVID testing study (N=400/448 enrolled to date), half have at least one COVID vaccine dose but vaccine hesitancy is high. Concern about COVID-19 is low (63% not at all worried). Trust in COVID-19 vaccine safety is low (22%), and only 13% intend to get recommended booster shots. Impediments to COVID-19 vaccination include cost (67%), lack of convenience (65%), safety concerns (59%), and questions about vaccine efficacy (55%). The main reason in favor of vaccination for COVID-19 would be to keep family safe (43%). Only 9% received an influenza vaccine in the past year. During the follow-up period, vaccination rates are persistently low (~2%), consistent with our focus on COVID *testing* in the study. We incorporate these findings into the description of vaccine barriers below.

There is a growing literature on interventions to increase COVID-19 vaccine uptake, and gaps that remain. Andreas et al.[87] conducted a scoping review on COVID-19 vaccination research. They characterized promising interventions as focused on communication, education, multi-dimensions, and using incentives. A smaller number of studies focused on increased access. The studies' outcome was generally attitudes (willingness to be vaccinated). Few studies examined COVID-19 vaccine uptake[87], focused exclusively on AABL populations, and almost none were carried out in Spanish[87]. Another review also found that behavioral outcomes are rarely used in COVID vaccine studies to date[88]. The

proposed study addresses these gaps, along with using the MOST framework. Interventions to increase influenza vaccination have been similar in scope and focus and included those based on communications research (improving knowledge, changing attitudes)[89,90]. The proposed study incorporates and extends the existing literature, as we describe throughout this proposal.

Barriers to vaccination are *largely comparable* in AABL populations. AABL populations are among those with the lowest rates of COVID-19 and influenza vaccination but the highest rates of adverse consequences from COVID-19 and influenza. Past research has found that the major barriers to vaccination, described below, operate *comparably* for the two racial/ethnic groups[28,31,32,91,92]. It would be possible for the proposed study to focus on either African American/Black or Latino populations. But, for maximum reach and impact, the proposed study focuses on AABL populations together, as we and others have shown to be feasible and effective in past research[37,81,85,93,94]. To do so, the intervention components to be tested focus on the primary barriers that AABL populations experience to vaccination, and any staff-delivered components are flexible and individually tailored to respond to individual and cultural concerns.

Factors that drive multi-level vaccine hesitancy in AABL populations. To be acceptable and effective, behavioral interventions must address the specific barriers to health behavior experienced by the population under study. This section describes the primary barriers that AABL populations experience to COVID-19 and influenza vaccination. Barriers to COVID-19 and influenza vaccination are *similar* for AABL[33,34]. But, in part because COVID-19 is new, AABL have greater barriers to COVID-19 vaccination than to influenza[33,34]. Thus, we focus mainly on COVID-19 in this section. There is a consensus that vaccine hesitancy is driven by complex barriers and impediments[20] and must be considered in its systemic/structural and cultural contexts. We organize the impediments to vaccination for COVID-19 and influenza using the theory of triadic influence [21]. This is a social-cognitive theory, which aligns with the IIT-ICM, highlighting three streams of influence on health behavior: the individual, social, and structural. At the individual level, barriers include **lack of knowledge of COVID**, the belief that COVID-19 is **not a risk/not severe and vaccination is not necessary**, along with **medical and institutional distrust** and counter-narratives about COVID-19 (sometimes called conspiracy theories)[22,26-28,95-97]. The lack of information regarding and level of distrust of the COVID-19 vaccination cannot be overstated, even among those who have received a dose of the vaccine[98,99]. Together, these attitudes and beliefs reduce **behavioral intentions** to be vaccinated for COVID-19[100]. Further, **cognitive biases** impede health behavior such as COVID-19 vaccination[101]. Cognitive biases are systematic thought processes resulting from the human mind's tendency to simplify information processing through a filter of personal experience and preferences[102]. Individuals typically show evidence of biases in judgment and reliance on heuristic ‘‘shortcuts’’ for health decisions.[103,104] Relevant to vaccination are biases such as information salience (acting on the information that first comes to mind rather than on all the relevant information available)[105-107], and present bias (the tendency to meet current desires or needs at the price of future beneficial outcomes). Interventions grounded in behavioral economics (BE) can circumvent cognitive biases to support health behavior[108,109].

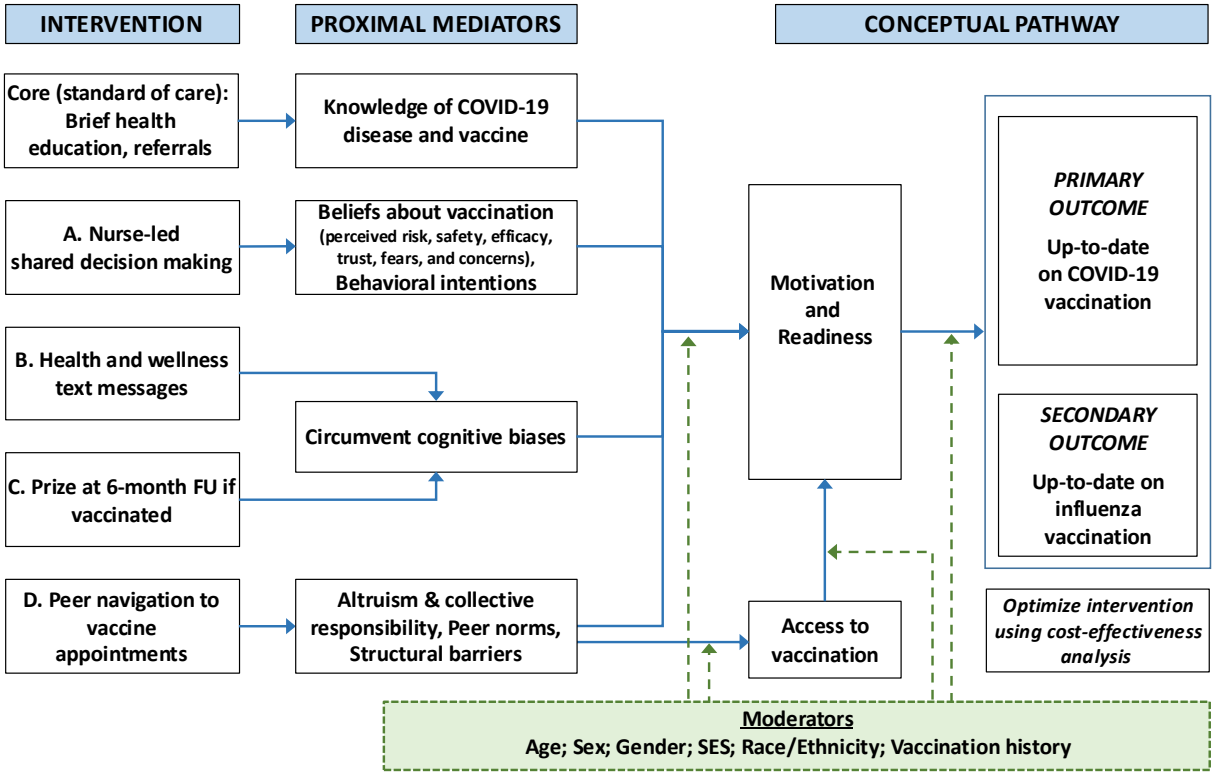
At the social level of influence, **peer norms** discourage COVID-19 vaccination[110-112]. Peer norms are the perceived informal rules that define acceptable and appropriate actions within a social group or community and that guide human behavior[110]. **Altruism and a sense of collective responsibility** are powerful social forces that can be harnessed to support vaccination[113,114]. At the structural level, access to COVID-19 vaccination can be challenging due to poor access to primary care, perceived discrimination, perceived cost, work schedules, and geographical inaccessibility (lack of transportation, inconvenient hours, lack of local vaccination sites)[20]. These are **structural barriers**. Barriers at these three levels of influence combine to reduce motivation and readiness to vaccinate for COVID-19 and influenza and thereby reduce vaccination rates in AABL populations (as noted above, barriers operate similarly for COVID-19 and influenza but barriers are more numerous and potent for COVID-19 than influenza[33,34]). Taken together, these barriers comprise multi-level vaccine hesitancy.

The MOST framework has three phases: Preparation (developing promising components and a conceptual model), optimization (testing components, optimizing the intervention), and evaluation (if

appropriate, testing the new optimized intervention in a standard RCT, referred to here as an evaluation RCT [ERCT]). In collaboration with our community partner, NMIC, we have completed the proposed study's preparation phase (developed components and a conceptual model) and the proposed study comprises an optimization phase. We propose to test four promising structurally and culturally salient candidate intervention components grounded in the literature, a pilot study we carried out in 2023, and our past research. Each component addresses a critical theoretical barrier or set of barriers to COVID-19 and influenza vaccination, and, to promote future scalability, some components are either brief or require only minimal staff time to implement. The primary outcome of the trial is being up-to-date on COVID-19 vaccination at the 6-month FU, that is, receiving the available vaccine dose. Influenza vaccine receipt is the secondary outcome. The candidate intervention components to be tested in the proposed study address barriers at the three levels of influence (Fig. 1). The components are: A) nurse-led shared decision-making, B) a text message intervention, C) prize for vaccination, and D) peer navigation to vaccination appointments. All participants will also receive the standard of care (health education, referrals). Components are described in the Approach.

The main product from the proposed study will be an efficient and cost-effective optimized behavioral intervention or interventions **to actively reach out to AABL communities annually** and increase COVID-19 and influenza vaccination rates. The components are constructed as having key elements and core characteristics (that cannot be changed), and modules that can be updated as COVID-19 and influenza recommendations change, as we note in Approach. The study focuses on the large population of AABL persons who are not up-to-date on COVID-19 and influenza vaccinations but who have received at least one dose of the COVID-19 vaccination[42,43]. The majority of AABL persons in the U.S. (>80%) have at least one COVID-19 vaccine dose[8]. The modest population of AABL persons who have never been vaccinated for COVID-19 require different interventions than those not up-to-date but who have received at least one dose[115]. COVID-19 and influenza vaccine hesitancy are serious concerns among AABL populations[42,43], and active outreach/community-based intervention approaches are urgently needed, as we propose here.

Fig. 1: Conceptual Model guiding the proposed study (rev)



B. INNOVATION. NIH has called for research that "seek(s) to shift current research…paradigms or methodologies"[116]. 1) The MOST framework is a paradigm shift in intervention development methods. This project will be one of the first applications of the MOST framework to COVID-19 and influenza vaccine hesitancy research. 2) A second innovation entails the underlying approach taken in intervention components, which are both structurally and culturally tailored to the barriers that AABL persons experience to vaccination. E.g., The understandable causes of vaccine hesitancy are validated, and fear, distrust, and counter-narratives about COVID-19 and influenza vaccination are elicited/discussed, which foster project trustworthiness and participant engagement. Also, barriers to COVID-19 and influenza vaccination are addressed in new ways (e.g., informed by BE, peer navigation). 3) We will optimize the intervention for cost-effectiveness. This is innovative. 4) As described in the Approach, we will develop an implementation strategy manual to facilitate rapid scale-up of the new optimized intervention in community-based and outpatient health care settings.

C. APPROACH

Overview. This is a four-year community-engaged study to be carried out by a collaborative research team at NMIC and NYU. For maximum scientific and real-world impact, it has both pragmatic (flexibility, closeness to real-world settings, real-world outcomes) and explanatory (e.g., examination of mediators) aspects. Study activities will take place in English and Spanish. The candidate intervention components will be tested in an efficient factorial experiment. Participants (*N*=560) are randomly assigned to an experimental condition. Follow-up (FU) assessments will be carried out at 3- and 6-months post-baseline (BL), and a brief check of vaccination status will take place at 12-months post-BL. The optimization objective is to create the most efficient combination(s) of components. A subset of participants will engage in qualitative research, and qualitative and quantitative results will be integrated, consistent with a concurrent parallel mixed methods design[117]. We will create an implementation manual to support uptake of the new optimized multi-component intervention(s) by community-based and outpatient health care settings. The proposed study has three phases: 1) Set-up and Refinement (6 mos.), 2) Implementation and Evaluation (34 mos.), and 3) Analysis, Decision-making, and Dissemination (8 mos.). Study activities can take place in person or virtually (over Zoom).

The proposed study has a strong scientific premise, rigor, and reproducibility. The proposed study is grounded in past research, strengthening its scientific premise. The study has rigor: we will use a factorial design, follow a detailed protocol (which will be published), randomly assign to an experimental condition, use fidelity and quality assurance checks, use PhenX Toolkit and NIH Public Health Emergency and Disaster Research Response (DR2) measures for assessment (as NOT-MD-23-008 recommends)[118,119], and empirically validate study endpoints. The study methods and 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.

The Investigative Team. The study will be carried out by a multi-disciplinary team (psychology, medicine [infectious diseases], nursing, health services research/policy, social work, quantitative psychology, biostatistics, anthropology), diverse with respect to sex, gender, age, sexual orientation, language, race/ethnicity, and work setting. The team members have worked together on past projects. **Dr. Gwadz** (Principal Investigator) has led research to address racial/ethnic disparities in health for over two decades. **Lalitha Parameswaran, MD, MPH** (Co-Investigator) is a Clinical Assistant Professor at the NYU Grossman School of Medicine, a co-leader of the NYU Vaccine Treatment Evaluation Unit, and Co-I on Dr. Gwadz's COVID testing study. She will review all materials for medical accuracy and provide guidance on medical aspects of vaccination and the health care system. **Dr. Charles Cleland** (Co-Investigator) will serve as the senior biostatistician. Dr. Cleland is experienced with designing and analyzing data from studies using MOST including factorial designs. **Dr. Siyu Heng** (Co-Investigator) is an Assistant Professor and statistician experienced with MOST and will carry out the primary analyses, with Dr. Cleland. **Dr. Heather Gold** (Co-Investigator) is an expert on cost-effectiveness research, and will advise on the collection of cost data and cost-effectiveness analyses. **Rauly Chero, LMHC** (Co-Investigator) is the coordinator of wellness services at NMIC, a member of our COVID testing team, and an expert on COVID vaccination in the community context.

Consultants and Community Advisory Board (CAB). **Angela Banfield, RN** is a registered nurse, a **COVID-19 Vaccine RN,** a member of our COVID testing team, and expert in health education and interventions for AABL populations. She will advise on the nurse-led study component and study implementation generally. **Dr. Robert Hawkins**, a consultant to the proposed study, is an expert on the role of racism in health outcomes among AABL populations (including COVID-19). He will provide guidance on refining the intervention content and messaging, and the interpretation and integration of findings. **Mx. Robin Freeman** is an anthropologist with expertise in qualitative methods, COVID-19, and AABL populations. They will carry out the qualitative study component. A CAB will be active in all phases. **CAB members** are AABL persons and diverse with respect to age, sex, occupation, and vaccination experiences. They are highly knowledgeable about barriers to COVID-19/influenza vaccination in their communities, and potential solutions. The study is community-engaged in a number of respects (consistent with NOT-MD-23-008): It is co-led by Ms. Chero, a leader at our community partner, NMIC; a CAB is engaged in all phases; and participants will be recruited in their communities.

The study's primary outcome is receipt of the available COVID-19 vaccine, confirmed with documentary evidence (e.g., CDC COVID-19 Vaccination Record Card, MYVAXRECORDS, a doctor's note or patient portal electronic health record note [e.g., from MyChart]). The available COVID-19 vaccine will change during the study. CDC Advisory Committee on Immunization Practices guidelines will be followed. The secondary outcome is receipt of the available influenza vaccination[50,120], confirmed with documentary evidence.

The study eligibility criteria are:

1. age 18-64 years
    a. Note: Those ages 65 and older have a different COVID-19 vaccination schedule than those ages 64 years and younger

2. can engage in study activities in English or Spanish

3. Black or African American or Latino/Hispanic race/ethnicity

4. resides in New York City

5. has received at least one dose of a COVID-19 vaccination in their lifetime, confirmed with documentary evidence (CDC vaccine card, My Vaccine Record, MyChart)

6. not up-to-date on COVID-19 vaccination, defined as has not received the most recently available vaccine, confirmed with documentary evidence.
    a. As of October 3, 2024 the most recent vaccine is the "updated 2024-2025 COVID-19 vaccine." Documentary evidence includes:

        i. MY VACCINE RECORD (the preferred method)
        ii. MyChart record
        iii. Other electronic health record
        iv. Doctor's note

7. eligible to receive the COVID-19 vaccine (has not had anaphylaxis, myocarditis, pericarditis, or thrombosis with thrombocytopenia syndrome or other adverse effects deemed by a physician to be related to the COVID-19 vaccine[121] by self-report

8. if previously diagnosed with COVID-19, a minimum of 10 days has elapsed since last test positivity[122,123] by self-report

9. is not up-to-date on influenza vaccination defined as not yet receiving the most recently available influenza vaccine. This will be documented where possible, but self-report is acceptable since not all influenza vaccines are reported to MY VACCINE RECORD.
    a. As of October 3, 2024 the most recent vaccine is the "updated 2024-2025 influenza vaccine."

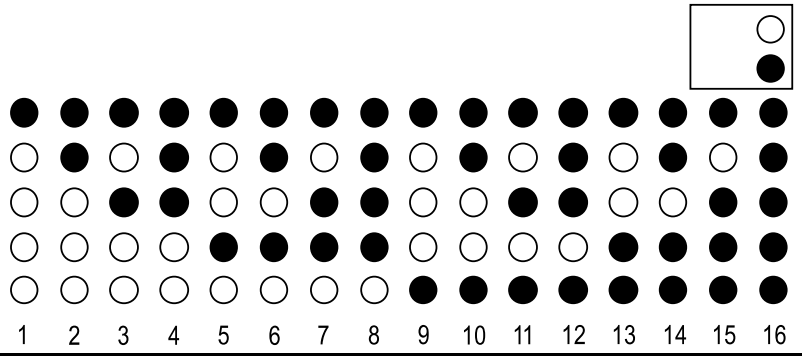
10. has a phone that can be used for study participation and can receive text messages

11. willing to follow NYU's COVID protocols, if any are in place at that time (e.g., face coverings, not presenting to NYU when symptomatic with or testing positive for COVID)

Those not found eligible will be told it is critical to discuss vaccination with their health care provider and given referrals.

Seasonality. COVID-19 incidence waxes and wanes but it is not a seasonal disease[124]. In temperate climates such as the US, seasonal influenza epidemics occur mainly during winter. Updated vaccinations for influenza are available each fall, and there is less utility to receiving it after influenza season has ended. The proposed research study will take place year-round, and will address seasonality in influenza vaccine by taking into consideration that this vaccine may not be available or recommended for part of the year.

Study design. We will carry out a factorial experiment to test four candidate intervention components. Each component has two levels: "off" (the component is not received) or "on" (the component is received). The design is comprised of 16 experimental conditions (2^4, Fig. 2), where each condition comprises a unique combination of intervention components. We wish to point out 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[35]. For example, conducting four individual experiments using the RCT design, one for each component, would require *N*=2240 (560 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 D 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* and still achieve study aims if the total *N* is sufficient. All participants receive the core intervention. Condition 1 receives no other component. Conditions 2, 3, 5, and 9 receive one candidate component, Conditions 4, 6, 7, 10, 11, and 13 receive two candidate components, Conditions 8, 12, 14, and 15 receive three components, and Condition 16 receives all components.



Rationale for the design. NOT-MD-23-008 calls for "appropriate intervention study designs." The proposed study uses a factorial design and cost-effectiveness as its optimization objective. The intervention developed in the study will have a substantial evidence base, as we describe below, will be brief and efficient, and, if cost-effective, can be disseminated at the end of the proposed study. Indeed, urgent problems such as vaccine hesitancy call for innovative and timely solutions. We will also consider the potential benefits of a future ERCT.

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[125]. We have developed REDCap databases for past MOST studies and will adapt this database architecture for the proposed study.

General description of the candidate intervention components. Candidate intervention components must show "promise" (i.e., acceptability, feasibility, and potential for effects) to be included in an ORCT[35]. In the proposed study, the core elements and key characteristics of the components are drawn from the existing literature (past effective interventions), past acceptable, feasible, and effective interventions created by our team, and a pilot study on COVID-19 and influenza vaccination we conducted. Our preliminary studies also yielded information on components or aspects of components that are challenging to implement for this public health problem or have insufficient acceptability (e.g., peer-to-peer education, frequent text messages about COVID, large financial incentives). The candidate components are designed to be as brief and efficient as possible, while still showing promise with respect to changing mediators and vaccination behavior. The candidate components are guided by manuals in English and Spanish. Manuals are comprised of a series of exercises and modules and are constructed to be interactive and engaging (core, Components A and D); Components B and C have written guidance but staff time to implement is minimal. Since recommendations for vaccination will continue to change, each component has key elements and core characteristics that cannot be modified, and modules that can be updated as COVID-19 and influenza recommendations evolve, in accordance with the CDC's Advisory Committee on Immunization Practices. The study interventionists do not make medical decisions. They serve as health educators. Medical decisions will be made by participants and their health care providers.

Underlying approach in components. The IIT-ICM (described above) underlies the intervention components, *which* are designed to be structurally and culturally salient (as defined above)[126,127]. Aspects of structural and cultural salience include validating the understandable roots of vaccine hesitancy and institutional/medical distrust in all components, primary among them structural racism and structural inequality, and supporting participants' own decisions about health behavior without pressure or judgment[85,86]. This is consistent with the motivational interviewing (MI) counseling approach[85,86]. In particular, past research has found that in the context of medical/institutional distrust, emphasizing autonomy and participants' choices (and providing and respecting their choices) fosters meaningful engagement in intervention content[85,86]. A general MI approach is woven throughout components (e.g., roll with resistance, support autonomy), and each component has its own theoretical mediator(s) and behavior change techniques (e.g., navigation, BE). The study has a "stance" that COVID-19 and influenza vaccination are beneficial for individuals and communities but participants do not need to agree with the stance to engage in the study. The concept of vaccination as helpful to individuals and communities will be integrated into all components. It will be made clear that participants' decisions about vaccination will be respected. This underlying approach and stance enhance components' acceptability, feasibility, engagement, and effects[85,86]. Health information within the components will be drawn from the CDC and local health department and will be reviewed for medical accuracy by an expert (Dr. Parameswaran, a study Co-I). Candidate components address different theoretical mediators and are designed to be methodologically and/or theoretically distinct from each other. We will elicit (Component A) and/or attend to (core, Component D) and discuss fear, distrust, and counter-narratives about COVID-19, influenza, and vaccination, which are important aspects of project trustworthiness and building trust, as well as the participant's behavior change process. In part this is because knowledge, attitudes, and emotions about COVID-19 cannot easily be

disentangled and must be addressed together[85,86]. AABL persons report there are few venues where they can discuss fears, distrust, and counter-narratives[85,86]. Although we address/validate medical and institutional distrust in components, we have not found in past research that levels of distrust change in response to interventions, even when the behavioral outcome is achieved[81,140]. Thus, we examine distrust as a moderator. The empirical evidence base for each component is provided below and draws from the existing literature, our past research, and a pilot study we conducted on COVID/influenza vaccination with AABL persons who are not up-to-date on vaccines. As noted above, because barriers to COVID-19 vaccination are greater than to influenza, components focus mainly on COVID-19 and secondarily on influenza[33,34].

Core session: Standard of care (health education, referrals, ~30 minutes). Knowledge about COVID-19 vaccination is insufficient among AABL populations, it is challenging for people to access reliable health information (particularly as COVID-19 is less in the media and public health campaigns have largely waned), and health education is needed[99,129]. This component, which all participants receive, takes a health education approach and is interactive[128]. The first aim of the session is to introduce the participant to the study, its goals, and its ethos (e.g., supports autonomy, respects personal decisions) to promote engagement and retention. The second is to provide basic information regarding current COVID-19 and influenza vaccination guidelines and written referrals to no-cost vaccination sites. Modules include: Current CDC COVID-19 and influenza recommendations, the purpose of COVID-19 and influenza vaccines at individual and population levels (e.g., prevent serious disease, hospitalization, and death), the importance of vaccination for community health, expected side effects, and written referrals to free vaccinations[130]. Because all participants receive the core session, its effects on the primary outcome are not assessed. It would be included in any optimized intervention. Theoretical target: knowledge.

Component A. Nurse-led shared decision-making (1 session, <60 min.). AABL persons want and benefit from the opportunity to discuss COVID-19/influenza vaccination with and ask questions of trusted health professionals from AABL backgrounds, such as nurses[24,31,32,131]. We selected a shared decision making (SDM) approach for this component. SDM is a well-established and acceptable model with a promising empirical evidence base, particularly for affective, cognitive, and longer-term outcomes[132,133]. SDM is an approach to assist patient decision-making, where clinicians and patients share the best available evidence and where patients are supported to consider options and achieve informed preferences. Instead of assuming that health-related decisions should be guided by scientific consensus about effectiveness, SDM proposes that informed preferences, that is, what matters to patients, should play a major role in decision-making processes[134,135]. The principles of SDM are well documented and the common elements have been summarized in the literature[136]. In brief, SDM draws on and deepens the principles of patient-centered care[134,135]. SDM represents an important shift in the roles of both patients and clinicians. SDM recognizes the need to support autonomy by respecting both individual competence and interdependence on others. At its core, SDM is a process where decisions are made in a collaborative way, where trustworthy information is provided in accessible formats about a set of options, typically in situations where the concerns, personal circumstances, and contexts of patients play a major role in decisions[134,135]. Experts have called for SDM for COVID-19 vaccination decisions[137-139]. This component uses a practical and empirically-tested SDM model developed by Elwyn and colleagues called the three-step model comprised of team talk, option talk, and decision talk to guide a process of collaboration and deliberation[134,135]. Theoretical targets: perceived risk and necessity, behavioral intentions.

Component B. Health & wellness interactive text message (TM) intervention (2 texts/week for 12 weeks, 1 text/week for 8 weeks, 20 weeks total, 32 texts total, participants will be asked to acknowledge receipt). Cognitive biases interfere with health behavior[101]. This component is grounded in BE, a field that combines insights from psychology and economics[105]. Past studies that have taken or advocated for a BE approach for COVID-19[108,141,142]. The component's main aims are to support participants staying actively engaged in the study and serve as a reminder to consider COVID-19 and influenza vaccinations. In BE terms, the TMs will "nudge" participants to stay engaged and toward

vaccination. TM interventions can be effective and cost-efficient for improving mental and physical health behavior, including related to COVID[143-145]. Our team is experienced with TM interventions grounded in BE[83,84]. Our past research indicates that when participants have ambivalent views on COVID, as expected in the proposed study, bi-weekly texts about COVID are not acceptable and can raise resistance, but a modest number of TMs on COVID are useful.

Thus, TMs for the present study will provide content in four main areas:

- General information about COVID-19 and influenza
- Information about COVID-19 and influenza vaccination
- Vaccination as protection for the community as well as individuals
- General health information
- Reminder about project activities and the need to let us know if contact information changes

Messages are informative, instructional, motivational, and/or supportive. Overall, messages will take a gain (rather than loss) frame and will be clear and simple. Links for more information will be provided where possible. Messages were developed with the CAB during the study's preparation phase and informed by the health communications literature[146]. Health-related messages will be drawn from the CDC website and reviewed for medical accuracy.

Specific structure of Component B: TMs are programmed into the Twilio program and sent automatically. The component is structured as follows: Participants first receive a brief orientation to the component (5 minutes) after the core session or baseline, and will put the study phone number into his/her/their phone. Then a test TM will be sent. TMs will be sent twice a week for 12 weeks, then 1 text/week for 8 weeks (total TMs = 32). Participants will be asked to provide a numerical response to the TM to indicate that it was read and received. These responses will be used to generate points (1 point/response), and participants will receive $1 for each point (maximum $32). This modest compensation will add interest to the component. "Gamification" principles will be used where participants will be sent a message at every 10 points such as "Achievement unlocked!" This is referred to as a "badge." Theoretical targets: circumvent cognitive biases.

Component C. Prize at 6-month FU if vaccinated for COVID-19 with documentary evidence (a gift bag with $25 gift card and low-cost items costing no more than $25, 3 reminder messages sent at regular intervals during intervention period). The goal of this component is to provide the participant with a type of "deadline" for vaccination and nudge them toward vaccination. This component will be explained to participants after the core session, ideally, or baseline (<5 minutes). We will put the study phone number into his/her/their phone. Then a test text message will be sent.

Timing will be: 1 month post-BL, 3 months post-BL, and 5 months post-BL.

The three reminder messages were refined by the CAB.

The reminder messages will read as follows:

1. "PRIZE REMINDER! Just a reminder that you are eligible to receive a prize at your 6-month follow-up interview if you get vaccinated for COVID-19 before that time! Just bring some documentation of the vaccination. Let us know if you have questions at PHONE or NCAP2@nyu.edu"

2. Don't miss out! A prize is waiting for you. Just bring some documentation of the COVID vaccination. Let us know if you have questions at PHONE or NCAP2@nyu.edu

3. Win a prize! Your 6-month follow-up can come with a reward – if get your COVID vaccine before then and bring proof to your visit. If you have any questions, reach out at PHONE or NCAP2@nyu.edu

Documentation of COVID-19 vaccination can include information from the pharmacy that shows the date and type of vaccine, along with the other methods listed in this protocol.

Participants who provide documentary evidence of vaccination at the 3-month follow-up can receive the prize then.

Theoretical targets: circumvent cognitive biases.

Component D. Peer navigation (5 months duration, introductory meeting, twice-a-month personal phone calls, texts, or emails). Peer navigation is a flexible, individualized, and effective approach to guiding clients through the health care system and helping overcome barriers that prevent them from getting care[156-158]. In these models, services are provided by peers or near-peers who are from similar sociodemographic backgrounds as participants and who serve as role models. *Peer* navigation was selected as a means of tapping into the concepts of vaccination as an altruistic act, the importance of collective responsibility, and to challenge norms that AABL people do not commonly get updated COVID-19 and influenza vaccinations[113,114,159]. We are experienced with peer navigation interventions[36,37]. The component also includes strategies and supports to circumvent structural barriers around access to vaccination. It will have a different look and feel than Component B (e.g., will not provide information about COVID-19 but will focus on scheduling issues).

The navigation period (5 months) starts at baseline. The introductory session will take place as soon as possible after baseline (0-2 weeks after baseline). It can be done virtually, preferably on Zoom because we are showing slides. If the introductory session is conducted late, the navigation period will be shortened.

Weekly automated messages start **after** the introductory session.

The component is structured as follows:

- In-person session lasting < 60 min. (introductions; discussion of vaccination as a form of altruism and a contribution to the community with handouts; assessment of readiness/willingness to be vaccinated; determine if participant want an appointment at this time and make appointments or referrals to free vaccines as appropriate)

- Bi-weekly (every two weeks) personal phone calls, texts, or emails (10 contacts initiated total maximum); e.g., “Checking in. I am here if you have any questions about scheduling an appointment.”

- Automated message and in-person contact will be on alternate weeks where possible.

Theoretical targets: altruism, collective responsibility, peer norms, structural barriers.

SET UP AND REFINEMENT PHASE

The main goals of the Set-up and Refinement Phase are to program the instrument to collect cost data, screening instrument, randomization table, and assessment batteries in REDCap. Assessment batteries will be tested for clarity and length. In collaboration with the CAB and scientific advisors, we will refine recruitment plans. We will carry out refinements of the candidate intervention components. We anticipate these to be minor (e.g., wording and length of exercises). To do so, we will bring together an intervention working group led by Dr. Gwadz and comprised of team members and the CAB as well as scientific advisors.

REFINEMENT PHASE

Recruitment – refinement phase

Community Advisory Board (CAB) members will be recruited from our prior study of COVID testing interventions (NCAP) and the local community via social media and outreach. CAB members are not human subjects.

Procedures and activities

Activities can take place in-person at an NYU field site or virtually.

CAB members will engage in the core intervention and 1-2 of the components (Components A, B, or D). This will include exploration on experiences with the component and how it can be improved in the

form of an in-depth qualitative cognitive interview[161] and assessment of acceptability. Cognitive interviewing is a psychologically oriented method for empirically studying the ways in which individuals process and respond to intervention content[161] (e.g., critique of each handout, exercise, or TM). We will ask participants if we can send TMs or call them for navigation after the meeting, as part of testing the component (Component B and D). We will collect minimal locator information (email address, phone number). This meeting will last two hours or less. Participants may engage in more than one pilot study session but will not receive the core session twice.

Compensation – refinement phase

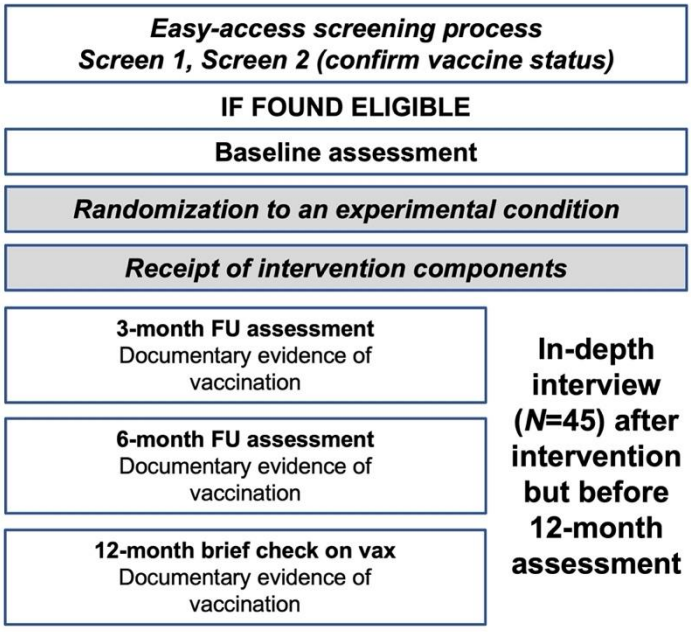
Participants will receive $75 for each CAB meeting and funds for local public transportation if the meeting takes place in person.

CONCLUSION OF REFINEMENT PHASE

The feedback and acceptability ratings will be brought to the intervention working group for discussion and recommendations for refinement. If the intervention is not adequately refined at this point it will undergo another round of review and refinement. Materials will be professionally translated into Spanish using the back-translation method[160]. The activities are feasible: We will modify an existing REDCap MOST database, use measures from the PhenX Toolkit and NIH Public Health Emergency and Disaster Research Response (DR2) where possible (as recommended in NOT-MD-23-008)[118,119], and have already created intervention manuals.

Tracking program time and costs**.** Time and resources will be tracked following procedures developed by Dr. Gold (study Co-Investigator)[39-41]. The costs are those needed to implement the candidate intervention components. Research-related costs will not be included. We will capture the following: location costs, participant compensation, supplies, and personnel costs. The intervention components will have different durations, consist of different in-person or remote activities, and involve different personnel, categorized as either administrative staff or intervention facilitators. Administrative staff (e.g., research assistant, clinical supervisor) work on all program components. Intervention facilitators work only on the intervention, with their time estimated by tracking the number and duration of intervention sessions and contacts. We also will capture additional program time for training, supervision, and other related intervention time. For each unit of staff time, we will assign a dollar value based on the wage and fringe rate by occupation class of those who perform the activity using national average labor and fringe rates from the US Bureau of Labor Statistics[202], as outlined in US guidelines. Sensitivity analysis will be conducted using actual staff wages and fringe.

Fig. 3: Sequence of study activities



Implementation and Evaluation Phase

We will use a hybrid recruitment plan with active outreach and passive strategies to efficiently the study population. The recruitment approach includes: 1) flyers describing the study in English and Spanish that can be used to directly recruit potential participants using ethnographic street recruitment methods (e.g., recruitment in parks and on the street)[162]; 2) ads placed in the medical research section of free newspapers (e.g., *amMetro, Latino Impact*), 3) ads disseminated on social media and Craig's List, and

4) peer-to-peer recruitment (recruiters will be compensated $15 for each peer referral, maximum 10 referrals/participant). In past studies, peer-to-peer recruitment was the most efficient and productive recruitment method[38,83,163].

Contact form. Potential participants will complete an online contact form linked to a QR code in recruitment materials or they can call the study directly.

Screening for eligibility in two stages. First, verbal informed consent for screening is obtained following an IRB-approved script followed by a brief (< 15 minute) structured screening interview using the Computer-Assisted Personal Interview (CAPI) format in REDCap to determine eligibility. Those found eligible will provide locator information. In a second step, documentary evidence of vaccination will be checked and logged. Screening can take place in recruitment venues, the study field site, or virtually (Fig. 3). Those found eligible can enroll.

Table 3. Description of the measures in the assessment battery (Phenix toolkit and DR2 will be used where available)

	Moderating influences
Socio-demographics, background factors	Age, race/ethnicity, sex assigned at birth, occupation, sexual/gender minority status, immigration status, preferred language, ZIP code of residence, health status, co-morbidities, racism and discrimination experiences, past COVID-19 diagnosis, vaccination, past influenza vaccination, children in the home
Distrust of vaccination	6-items assessed on a 5-point Likert-type scale [100,166]
Counter-narratives (conspiracy theories)	6-items assessed on a 5-point Likert-type scale drawn from existing reliable scales [168,169]
	Individual/attitudinal influences
Vaccine and COVID Knowledge	10-item true-false questionnaire on aspects of vaccination, influenza, and COVID-19[170]
Perceived risk	Risk of COVID-19 and influenza, 2 items
Necessity of vaccination	Perceived necessity of vaccination for COVID-19 and influenza, 2 items
Behavioral Intentions	Vaccination scenarios assessed with 4 items
Cognitive biases	Measurement of perceived cognitive biases[105], engagement in Component B
Motivation/readiness	Importance of COVID/influenza vaccination and confidence in ability to get vaccinated on a 1-100 scale.[171]
	Social influences
Peer norms	Assess peer norms re: COVID/influenza vaccination using 6 items[172]
Altruism & collective responsibility	6 items on COVID/influenza vaccination as an altruistic act/a collective responsibility [100]
	Structural influences
Structural barriers	Perceived structural barriers: insufficient local sites, cost, perceived access
	PRIMARY OUTCOME
COVID-19 vaccination	Documentary evidence, date, name of vaccine(s), place of vaccination(s)
	SECONDARY OUTCOME
Influenza vaccination	Documentary evidence, date, name of vaccine, place of vaccination
	Intervention process domains
Acceptability	Client Satisfaction Questionnaire (YCSQ) –17 items [173]
Social harms	Assessment of possible harms experienced in social, occupational domains.
	Feasibility/Intervention dose
Intervention dose	Attended core, Component A: Component B: number of TM responses; Component C: size of prize; Component D: number of navigation contacts completed and their characteristics/content

Enrollment and study activities. Enrollment will take place at a study field site or virtually. Participants will provide electronic signed informed consent in REDCap (using the "eConsent" feature) for enrollment (or verbal consent if virtual), complete a more detailed locator form to facilitate longitudinal FU, and participate in a structured BL interview in REDCap. They will be randomly assigned to an experimental condition using REDCap. Participants have the opportunity to engage in the core session on the same day, or as soon as possible (ideally within 1-2 weeks). Then, other assigned components will be administered.

Assessment battery in REDCap (Table 3). The BL will last ~30-45 minutes. Follow-up (FU) assessments will be carried out 3- and 6-months post-BL. FU interviews last ~25-35 minutes. BL interviews will assess the lifetime and past 3-month period, and the FUs will assess the period since the last interview[118,119].

At 12-months post-baseline we will check COVID-19 and influenza vaccination status by self-report and with documentary evidence for COVID-19.

Qualitative interviews. Participants will be purposively sampled for maximum variability on the following criteria: age, sex, language (English or Spanish), race/ethnicity, and whether is up-to-date on COVID-19 and/or influenza or not (*N*=45). We will explore participants' experiences with and perspectives on the intervention components (including acceptability) and on barriers to and facilitators of 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. The qualitative sample size was determined following procedures outlined by Malterud called information power[164]. Greater sample heterogeneity as we expect here calls for larger samples; *N*=45 is a larger sample size.

Compensation is provided using the Greenphire ClinCard system, a refillable debit card designed for research study reimbursement[165]. The maximum compensation amount is $407.

Participants can receive:

- $60 for the BL
- $25 for the core session
- $25 for Component A
- Up to $32 for Component B at conclusion of component
- Prize for Component C (Gift bag with $25 and small items such as pens)
- $25 for Component D
- $50 for each FU interview and $20 for bringing documentary evidence of COVID-19 vaccination (regardless of whether vaccinated or not) or allowing us to help them access it or observe them accessing it; e.g., allowing us to help them check MY VACCINE RECORD or My Chart health records
- $25 for 12-month check of vaccination with documentary evidence
- $50 for the qualitative interview
- funds for local public transportation

Project staff will be highly trained, supervised, and diverse with respect to age, race/ethnicity, sex, sexual/gender minority status, socioeconomic status backgrounds, and language (bilingual in English and Spanish). Intervention components will be led by trained, supervised, health educators or clinicians. Component A will be led by a nurse/nursing student from an AABL background. Component D will be led by an AABL individual (peer/near-peer) with an understanding of the cultural/structural roots of vaccine hesitancy and background in health education.

Retention/tracking. We are leaders in successful retention strategies[163,174-177]. The research team has over 20 years of experience with longitudinal studies, typically with follow-up rates of 85%-95% and intervention retention of 70-98%. Successful retention is a multifaceted effort requiring simultaneous strategies at the management, staff, project, and compensation levels. We estimate a >80% retention rate.

In this study, COVID vaccination status is not protected health information (PHI) subject to HIPAA. Vaccination information can in some cases be classed as PHI and is covered by the HIPAA Rules. However, HIPAA only applies to HIPAA-covered entities – healthcare providers, health plans, and healthcare clearinghouses – and their business associates. NYU is not a HIPAA-covered entity. Nonetheless, it is not a HIPAA violation to ask for vaccination status. The participant can decide whether to provide the information to the study or not. The use of PHI involves no more than a minimal risk to the privacy of individuals in this study. See: https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html

Fidelity, process ratings, and quality assurance. After each session or contact, the interventionist will complete process ratings in REDCap to assess fidelity to exercises in manuals[178]. Sessions (Core, Component A, D) will be audio-recorded and ~10% selected at random will be reviewed for quality assurance and supervision purposes, then destroyed. The intervention facilitators will attend monthly supervision.

Implementation strategy manual. We will draw on implementation science principles to support timely implementation of the optimized intervention(s)[179]. We will develop an implementation strategy manual, detailing requirements and recommendations for implementation in community-based and outpatient health settings. We will conduct meetings with staff stakeholders at NMIC and similar organizations. Guided by the Consolidated Framework for Implementation Research (CFIR)[180], the meetings will explore potential barriers to and facilitators of implementation of the optimized intervention. The CFIR is one of the most widely utilized frameworks in implementation science[180]. It is a meta-theoretical framework that provides a standardized list of constructs found to be implementation determinants across five major domains[180]. 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 meeting, we will map group suggestions onto existing implementation strategies[181]. Results from Aims 1-3 will be integrated into the manual.

Quantitative data analysis. Intent-to-treat analysis will be our primary analytic approach and exploratory analyses will examine complier average effects of intervention components[182,183]. Approaches to missing data will include full information maximum likelihood estimation[184] and multiple imputation[185]. 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[186] or pattern mixture[187,188] models.

Aim 1: **Identify which of four candidate intervention components contribute meaningfully to improvement in the primary outcome, receipt of the available COVID vaccine, with documentary evidence at the 6-month FU**. The primary outcome for Aim 1 is receipt of the available COVID vaccine (documented) by the final follow-up. Logistic regression will estimate effects of components on the odds of receiving the available COVID vaccine. Intervention components will be effect-coded to estimate main effects and 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 vaccination. Similarly, the coefficient for an effect-coded interaction term, multiplied by two and exponentiated, will estimate interaction effects on the odds of vaccination. Similar logistic regression analyses will estimate effects on the secondary outcome.

Equation 1

$$\log\left(\frac{\pi_i}{1-\pi_i}\right) = b_0 + b_1X_A + b_2X_B + b_3X_C + b_4X_D + b_5X_{A*B} + b_6X_{A*C} + b_7X_{A*D} + b_8X_{B*C} + b_9X_{B*D} + b_{10}X_{C*D} + b_{11}X_{A*B*C} + b_{12}X_{A*B*D} + b_{13}X_{A*C*D} + b_{14}X_{B*C*D} + b_{15}X_{A*B*C*D}$$

Aim 2: Identify mediators and moderators of the efficacy of each intervention component. To examine potential mediators, analysis for **Aim 2** will use the potential outcomes framework[189-191]. This framework highlights assumptions needed to identify direct and indirect effects of interest: no unmeasured cofounders of the exposure (an intervention component) and outcome (vaccination) 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 vaccination. Sensitivity analysis will 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[192]. 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). 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 and other covariates (e.g., medical distrust) 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. Identified moderators will inform dissemination and future adaptive interventions[193].

Power Analysis. For the primary outcome, vaccination with the available COVID vaccine, we used PASS 2023[194] to estimate the sample size needed for main effects of intervention components corresponding to odds ratios of 1.9 in logistic regression, given α=.05. Assuming a 40% chance of vaccination by the final follow-up overall, a sample size of n=448 (n=28 in each of 16 conditions) provides 87% power to detect an odds ratio of 1.9. To account for attrition of up to 20%, we propose a total sample size of 560 participants (n=35 in each of 16 conditions), ensuring complete data for at least n=28 per condition. When the main effect of an intervention component on a continuous mediator is estimated in a linear model, the sample size provides 80% power to detect a small standardized mean difference (*d* = .27). 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[195] as implemented in PASS 2023. Given a substantial correlation between an intervention component and a hypothesized mediator (*r*=.50), an odds ratio of 1.40 can be detected with >80% power for the effect of a mediator on the vaccination outcome.

Qualitative data analysis and integration. Qualitive analyses will focus on experiences with the candidate intervention components, to inform intervention implementation and future research. Coding and analytic methods of qualitative data will employ a directed content analysis approach[196]. Analyses will begin with pre-determined codes based on the conceptual model (i.e., a "start list"), which will be expanded based on emergent findings. We will attend to trustworthiness and rigor. Integration of qualitative/quantitative results will use the joint display method[197]. A joint display is a state-of-the-art visual tool to integrate data sources[198-200].

Aim 3: Build the most cost-effective intervention package(s) from the components found to be efficacious in Aim 1. We will estimate the total cost of each experimental condition, rank them low to high, and remove any due to dominance (higher cost with lower effectiveness). Then, we will calculate the incremental cost-effectiveness ratio comparing each condition with the next lower cost condition, $[(cost_1 – cost_2)/(outcome_1 – outcome_2)]$, to yield for each component the *incremental cost per participant receiving vaccinatio*n and *incremental cost per percentage point change in vaccination rate* (from Aim 1); we also will explore the *incremental cost per participant*.

The decision-making process will be led by Dr. Gwadz and include the study Co-Investigators (Cleland, Parameswaran, Heng, Gold, Chero) and consultants[35]. The decisions will be reviewed with the CAB before being finalized. STEP 1: Carry out Aim 1 analyses, which detail the effectiveness of each component (% vaccinated) as well as interaction effects. This allows us to predict % vaccinated for each experimental condition, adjusting for any covariates. STEP 2: Carry out Aim 2 analyses, qualitative analyses, and the joint display to determine how components work and under what conditions, along with acceptability and feasibility. These data will be integrated into the implementation manual. STEP 3: Use cost estimates and incremental cost-effectiveness ratios from Aim 3 and rank-order experimental conditions by incremental cost-effectiveness ratio. STEP 4: Carry out same steps for influenza and consider that in decision-making. FINAL STEP: There may be several good options for improving outcomes at different levels of cost. We will create an efficient frontier for these experimental conditions using methods developed by our colleagues at NYU called decision analysis for intervention value efficiency (DAIVE), a decision-making framework for use in MOST[201]. DAIVE is a user-friendly method for evaluating interventions based on a wide variety of decision-maker preferences, including those that involve multiple outcome variables. We have used DAIVE in a past study[201]. Using data from the previous steps as inputs, DAIVE will be used to create an efficient frontier of interventions for COVID alone, influenza alone, and COVID and influenza together (where we can

weight the relative importance of COVID and influenza vaccination equally or prioritize one based on prevalence and harm at the time of our cost-effectiveness analysis). The final decisions and recommendations and the implementation manual will be disseminated widely and the PI will provide technical assistance to interested parties. Ultimately, end users in community-based and health settings can decide which intervention package is most feasible for their setting.

The future optimized intervention can adapt to changing vaccine recommendations. The candidate components include modules that can be revised as vaccines are updated and/or if CDC recommendations change. Thus, the intervention produced will keep current with the recommendations of the CDC's Advisory Committee on Immunization Practices. Dr. Gwadz's team has a website and the most up-to-date intervention manuals, guidance, and implementation manual will be located there, along with updates pushed out to users.

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