Title: Evaluating a Community-Led COVID-19 Testing Intervention to Address Mistrust

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Background

The U.S. COVID-19 pandemic response has in some ways been an unprecedented success; for example, leading a world-wide charge to quickly develop several safe and effective COVID-19 vaccines. However, the public health impact of the response has been limited in a fundamentally important way—many people strongly mistrust it. In low-income housing settings this mistrust intersects with anxiety about perceived consequences exacerbated by socioeconomic vulnerability. For example, participants in our ongoing research report that a major barrier to COVID-19 testing is the expectation that a positive result will be used against them. In this environment, where housing authorities are perceived to have too much power and to be highly antagonistic, residents are primarily concerned about the consequences of a positive result with respect to employment (e.g., “Are they going to tell my employer?) and housing (e.g., “Are they going to make me quarantine away from the rest of my family?”). Participants do not seem to think that COVID-19 testing is very useful. This has likely contributed to a lack of appreciation for how proactive COVID-19 testing might be used as part of a multi-pronged strategy to mitigate the impact of COVID-19 moving forward. And while residents have indicated that they might be more amenable to in-home testing due to increased privacy, feedback suggests that lack of comfort self-administering rapid tests is another significant barrier.

Our Housing Collaborative Community Advisory Board (HC CAB) partners report that our relationship(s) with them helped overcome mistrust common in their communities. They described the nature of our interactions—which included weekly virtual meetings where we discussed current events, both related to and seemingly unrelated COVID and/or healthcare—led us to be viewed as trustworthy. A central question in discussions on this topic was how to replicate this process of trust-building. This study is an attempt to standardize a process of relationship and trust building to be used as core components of a COVID-19 testing intervention which could be exported and reproduced in other settings.

The Present Study

In an effort to reproduce the trust built with our community partners and the indirect effect that trust seems to have had on beliefs regarding healthcare recommendations, the present

study aims to implement a community-led intervention with our partner HC CAB members, with the goal of increasing trust related to COVID-19 testing. The primary aims of this study are to:

1. Implement and evaluate a preliminary Peer Mentor COVID-19 testing intervention.
2. Receive feedback from participants and Peer Mentors to identify how the intervention could be adapted.

The grant funding mechanism that supports the current project also requires the collection of common data elements (CDE) as part of our ongoing research partnership with Duke Clinical Research Institute (RADX-Up). Please see section *Sharing of Data with Duke Clinical Research Institute* for details.

The Peer Mentor model idea stemmed from our partnership with the HC CAB. The Peer Mentor model entails Peer Mentors (described fully in the Methods section) meeting weekly for 12 weeks with their respective Peer Mentees. During these sessions, Peer Mentors and Peer Mentees will discuss current events, COVID-19 related health topics, and others, with topics being standardized across the Peer Mentors. The Peer Mentor meetings will be conducted via zoom, with research team members present at every meeting. Participants who volunteer to partake in the study will be randomly assigned to either the Peer Mentor Intervention (n=32) in which they will be assigned their Peer Mentor and meet weekly for 12 weeks, or they will be assigned to the Control Group (n=32), in which they will not have weekly meetings with a Peer Mentor. All participants will complete baseline, 3-month, and 6-month questionnaires assessing psychosocial constructs related to COVID-19 testing, vaccination, trust in the government and science, experience with discrimination, and response efficacy (see Appendix A-W for a full list of questionnaires). Each participant will also be asked to take at-home COVID-19 tests at the 3-month and 6-month time period. Comfort and trust related to administering the test will also be assessed. At the end of the study, all Peer Mentors and participants in the intervention group will be asked to provide feedback during one of two feedback sessions focused on how to improve the intervention. The current study is unique in that we are attempting to standardize a trust building relationship with community members to improve responsiveness and acceptance of healthcare recommendations and guidelines.

Method

Participants and Recruitment

1. **HC CAB Members as Peer Mentors.** The 18-person HC CAB will make up the potential pool of Peer Mentors. We will recruit 8 Peer Mentor participants by announcing the study during one of the HC CAB weekly meetings. We will review the requirements and expectations of the study, training that Peer Mentors will receive, and compensation. HC CAB members interested in being Peer Mentors will contact the research team. Research team members will describe the informed consent information, the required planning and Peer Mentor virtual meetings, and send the informed consent to be signed. The informed consent process will be completed virtually through REDCap. Following the completion of the informed consent, the study team will schedule the Peer Mentor facilitator training via zoom. Facilitator training is expected to take 2 hours and will cover key tenants of respect for persons and ideas, nonjudgmental listening, understanding of participants' rights, practice leading brief discussions, and confidentiality.
    a. **Peer Mentor** inclusion criteria are:
        i. Being a current member of the HC CAB.

ii. Can commit to a facilitator training session, and a one-hour planning meeting and one-hour Peer Mentor meeting each week for 12 weeks.

2. **Intervention (Peer Mentee) & Control Participants:** A total of 64 participants (32 per group) are needed for the intervention and control groups. In order to plan for attrition, incorrect contact information/lost to follow-up, and attention check failures, we are requesting approval to recruit up to 120 participants so that we will have approximately 64 participants (32 participants per group) for study completion. Half of the participants will be randomly assigned to be in the Peer Mentee intervention and half of the participants will be randomly assigned to the control group. We will only recruit adults who live in a low-income housing community managed by one of the following housing agencies: (1) Chesapeake Redevelopment and Housing Authority (CRHA), (2) Hampton Redevelopment and Housing Authority (HRHA), (3) Newport News Redevelopment and Housing Authority (NNRHA), (4) Norfolk Redevelopment and Housing Authority (NRHA), (5) Portsmouth Redevelopment and Housing Authority (PRHA), (6) Richmond Redevelopment and Housing Authority (RiRHA), (7), Roanoke Redevelopment and Housing Authority (RoRHA), (8) Suffolk Redevelopment and Housing Authority (SRHA), and (9) Virginia Beach Department of Housing and Neighborhood Preservation (VBDHNP). Recruitment will include contacting participants from previous studies who indicated an interest in future studies, posting study announcement flyers in HC authorities, and through word-of-mouth invitations. The research team will also inform each housing community's tenant advisory board members of the study (contact information will be provided by each housing agency). In the event that we need to perform targeted recruitment (e.g., to recruit additional men), we will ask housing agency staff for suggestions. Housing authority staff will have no other involvement with participants.

   Study participants will contact the research team to obtain information about the study and confirm eligibility. After confirming that the participant meets inclusion criteria, the participant will be added to the list of participants. Once all participants have been recruited, stratified randomization will be done to randomize participants by building into their respective intervention or control group. Once randomized, participants will be emailed their respective informed consent to electronically sign. The informed consent process will be completed virtually through REDCap. If the participant has any questions while completing the consent form, an investigator or authorized staff can be reached by phone to ensure the participant understands the risks and benefits of participating in the study.

   a. **Intervention/control group** participant inclusion criteria are:
      i. Being 18 years or older.
      ii. Being a resident of one of the 9 housing authority agencies.
      iii. Being willing to participate in Zoom meetings and complete online assessments as baseline, 3-month, and 6-month timepoints.
      iv. Ability to read, speak, and understand English.

Randomization

To protect internal validity and eliminate contamination of study groups, we will randomize participants into intervention or control group based on building. There is a real probability that otherwise, participants (residents) in intervention/control groups will discuss the project with others who reside in the same building. Thus, we will utilize stratified randomization by building

– e.g., if a city's Housing Authority has two buildings with active participants; one building will be randomly assigned as control and the other building will be randomly assigned as intervention.

Peer Mentor Groups
Each Peer Mentor (n=8) will be assigned 4 Peer Mentees who they will lead through weekly virtual discussions. The virtual meetings will be conducted in pairs such that 2 Peer Mentors will meet with 8 Peer Mentees during the weekly meeting. This dual-Peer Mentor meeting is planned in the event that one Peer Mentor needs to cancel, the meeting can still be held that week. A research team member will be present at every Peer Mentor meeting to observe and be available should the Peer Mentors or Peer Mentee participants have any questions.

Planning Meetings
Virtual planning meetings will be held each week with the research team and the Peer Mentors in order to outline the discussion planned for that week. Peer Mentors will be given the opportunity to ask questions and ensure they feel comfortable discussing the topic. Planning meetings are expected to take 60 minutes.

Peer Mentor Meetings
Once participants are assigned to the Peer Mentor intervention group, they will be emailed the tentative session agenda with zoom links for each meeting. The research team will be available to assist with any technical difficulties and/or support. On the scheduled Peer Mentor meeting day, participants will log into the zoom meeting and meet for 1-hour with their fellow Peer Mentees, Peer Mentor, and research team member. Peer Mentors will guide the group through the discussion, with active involvement encouraged from all participants.

Figure 1. Peer Mentor Activities

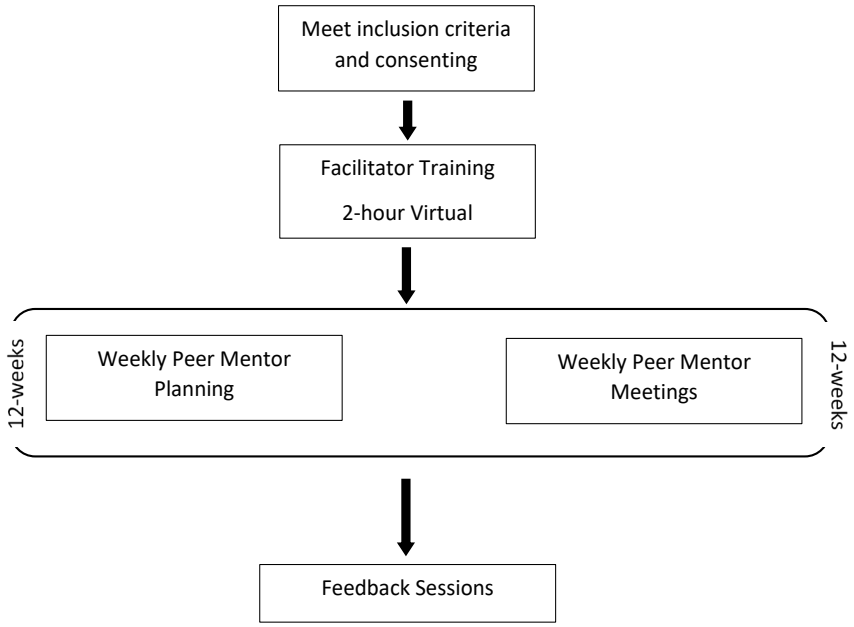
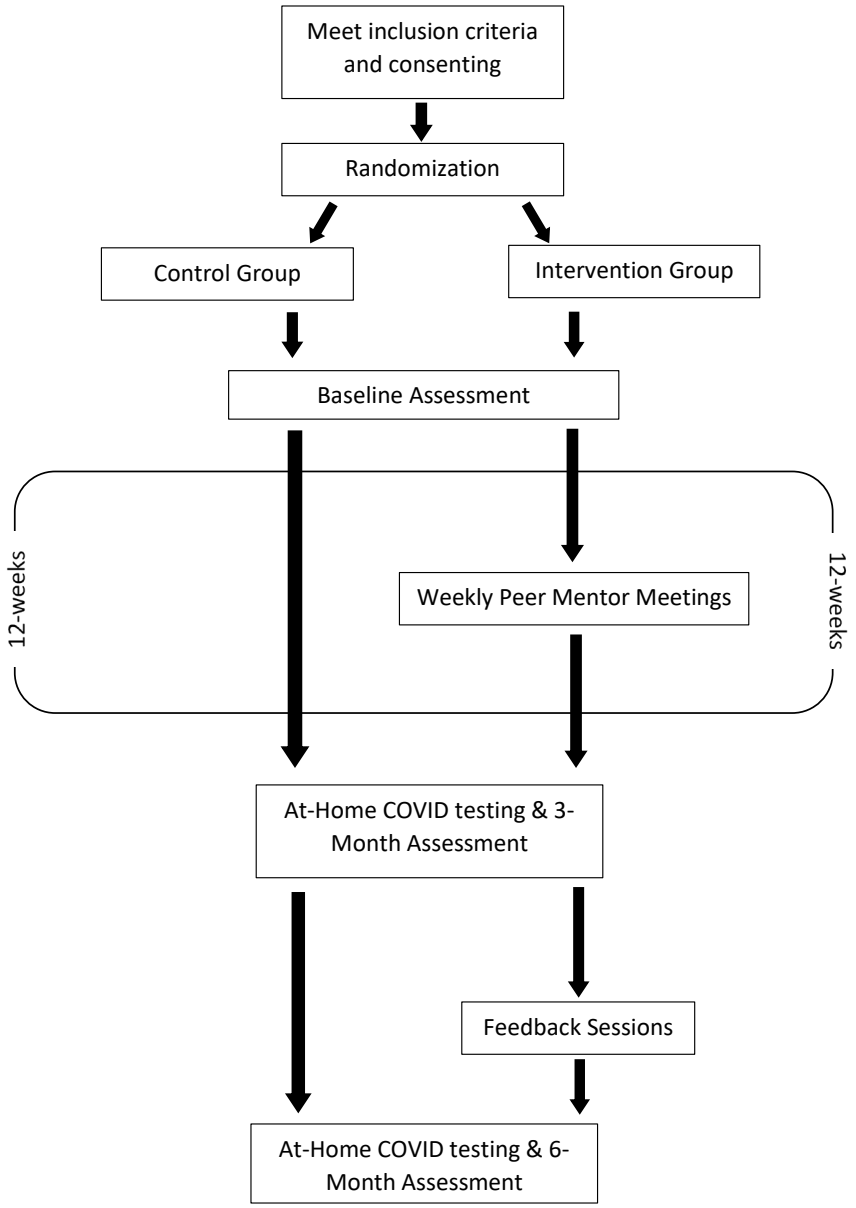


Figure 2. Intervention and Control Group Participant Activities



Data Collection

Questionnaires. All intervention and control group participants will be emailed a REDCap survey link to complete at baseline, 3-months, and 6-months. The survey link(s) will be re-sent up to 3 times over a 3-week period of time before the survey will be closed for completion. See the following for a full list of questionnaires. To assist in maintaining the integrity of data collected, attention check questions will be mixed throughout the surveys to identify participants who are not reading the questions carefully.

Screening Questionnaire (Appendix A) A basic questionnaire will be used to confirm study participation eligibility.

The PhenX Toolkit (Appendix B) assesses participant COVID-19 knowledge, attitudes, and avoidant behaviors. A short version of the toolkit will be included in the present study.

The Efficacy and Threat Questionnaire (Appendix C) will be used to assess participants' perceived threat and efficacy about COVID-19.

The God Locus of Health Control scale (Appendix D) is a 6-item assessment focused on participants' belief if God has control over one's health.

The Discrimination in Healthcare Scale (Appendix E) is a 7-item assessment of distrust of the healthcare system.

The Conspiracy Belief Scale (Appendix F) is an 8-item scale that will assess participants' general belief in conspiracy theories.

The Rosenberg Self-Esteem Scale (Appendix G) is a 10-item scale that will measure participants' feelings, positive and negative, about oneself.

The Self-Efficacy Scale (Appendix H) is a 10-item scale that will be used to measure participants' belief to achieves one's goals.

The Brief Self-Control Questionnaire (Appendix I) is a 13-item measure assessing participants' control over one's behavior.

The Vaccine Hesitancy Questionnaire (Appendix J). is an 18-item measure that will assess participants' attitudes and beliefs about the COVID-19 vaccine.

BRIEF Health Literacy Screening Tool (Appendix K) is a 3-item measure that will be used to assess participants' comfort in understanding medical instructions and diagnoses.

Media Trust (Appendix L) is a 9-item measure created by the research team to assess participants' trust of information from media sources relating to COVID-19.

Demographics Questionnaire (Appendix M) A basic demographic questionnaire will ask participants about their gender, age, race, city of residence, employment, and educational attainment.

The Perceived Stress Scale (Appendix N) is a 10-item scale that will assess participants' perception of stress.

The Trust Questionnaire (Appendix O) is a measure created by the research team to assess participants' trust of information provided by various institutions and individuals relating to COVID-19.

The Anti-Science Scale (Appendix P) is a measure to assess participants' beliefs and attitudes toward the validity of science.

The Perceived Legitimacy Scale (Appendix Q) is a 22-item scale that will measure participants' view regarding the legitimacy, or trustworthiness, in the norms of institutions, their PHA and society as a whole.

The Brief Sense of Community Scale (Appendix R) is an 8-item scale created to assess participants' feelings about the sense of community in their neighborhood.

The Testing Comfort and Confidence Questionnaire (Appendix S) is an 8-item scale created by the research team to assess participants' comfort of COVID-19 tests being conducted by different individuals and confidence in proper test-kit handling and understanding of results.

The Testing Openness Questionnaire (Appendix T) is an 8-item scale created by the research team to assess participants' openness to be tested for COVD-19.

The Vaccine Intention Questionnaire (Appendix U) is a 7-item scale that will assess the participants' intention of receiving the COVID-19 vaccine.

The RADXUP CDEs Survey (Appendix V) will be used to assess participants' understanding of pandemic experiences and health impacts of COVID. The items assess knowledge and views about social distancing, COVID-19 symptoms and treatment, COVID-19 related testing, vaccine status, COVID-19 related impact and health history.

The Attention Check Questionnaire (Appendix W) are various attention check questions that will be mixed throughout the surveys in order to identify participants who are not reading the questions carefully.

COVID-19 Tests. Participants will be mailed 2 COVID-19 tests and instructed to take the tests at the 3-month and 6-month time period prior to completing the questionnaires. Participants will be provided detailed instructions of COVID-19 protocols should they test positive or negative. See below for the current protocols per CDC guidelines.

Protocols for Participants Testing Positive for COVID-19

1. Immediate Isolation: Participants who test positive will be advised to immediately start isolation to prevent the spread of the virus, irrespective of their vaccination status or symptoms.
2. Duration of Isolation:
    - For asymptomatic cases, isolation begins from the test date (Day 0) with the following day being Day 1.
    - For symptomatic cases, Day 0 is the onset of symptoms.
3. Reassessment of Symptoms: If a participant develops symptoms within 10 days of testing, the isolation period restarts from the day symptoms appear.
4. End of Isolation: Specific criteria for ending isolation will be based on the latest CDC guidance, including the resolution of symptoms and passage of the recommended isolation period.

Protocols for Participants Testing Negative for COVID-19

1. End of Isolation: Participants who test negative and do not exhibit symptoms can end their isolation immediately; or resume normal activity.
2. Monitoring: We will continue to monitor these participants for any subsequent development of symptoms and advise retesting if necessary.

Additional Resources

- Education and Support: All Peer Mentees and Control participants will receive comprehensive information and support on how to effectively isolate, monitor symptoms, and seek medical attention if necessary.

- Updates on Guidelines: We will regularly update these protocols to reflect any changes in the CDC guidelines or public health recommendations.

Our aim is to ensure the health and safety of all participants while maintaining the integrity of our study. We believe these protocols, in alignment with CDC guidelines, provide a robust framework for managing COVID-19 risks among our study participants.

Feedback Sessions

We expect that intervention adaptation will likely be required. For example, a combination of one-on-four peer mentor support provided by community members coupled with larger group discussions with academic partners might be an ideal combination for building trust. As such, to fulfill Aim 2 of the present study, participants will be invited to participate in feedback sessions about the Peer Mentor intervention. Discussion questions will center on participant experiences in the study that would not necessarily have been captured during the quantitative assessment. Our goal will be to include all 32 Peer Mentee participants and all 8 Peer Mentors (in two separate sessions). We will ask questions related to the following prompts:

1. What have you liked the most about being in the study?
2. What have you disliked about being in the study?
3. What did you like or not like about the virtual format of the study?
4. Would in-person sessions make you feel more or less comfortable?
5. Did the tablets and technical support help make you more comfortable sharing things with us?
6. How did being in the study change how you feel about COVID-19 testing?

Compensation. All participants (peer mentors, peer mentees, and control) will be paid using reloadable prepaid cards. The reloadable cards enable repeated payments and are most efficient and economical for studies in which participants are paid repeatedly throughout the duration of a study.

Peer Mentors. In order to support the required weekly digital connectivity with participants, Peer Mentors will receive an Apple iPad and will also be compensated $20 for each study activity (each planning meeting, each Peer Mentor meeting, and the feedback session). As part of the HC CAB, peer mentors are already provided with internet connectivity and technical support from the research team.

Peer Mentees*.* In order to support the required weekly digital connectivity with participants assigned to the Peer Mentor intervention group, these participants will receive Samsung tablets with HD webcams, internet connectivity for the duration of the study, and basic digital literacy instruction and technical support. They will also be compensated $20 for each study activity (each Peer Mentor meeting, each data collection period, and the feedback session).

Control Group. Control group participants will be compensated $20 for each study activity (each data collection period).

Please see the table below for a breakdown of participant payment by participant type.

Payment Breakdown				
Activity	**Payment per activity**	**Peer Mentor Total**	**Participant Total**	**Control Total**
Weekly Meeting (12)	$20	$240	$240	$0
Weekly Planning Meeting (12)	$20	$240	$0	$0
Surveys (baseline, COVID-19 test and 3-month assessment, COVID-19 test and 6-month assessment)	$20	$0	$60	$60
RADX-Up Assessment	$20	$0	$20	$20
Feedback session (1)	$20	$20	$20	$0
Total compensation based on role		$500	$340	$80

Tablet Usage Agreement

Each participant in an intervention group will be asked to review and sign a Tablet Usage Agreement (See Appendix X) before they are provided with their tablet and internet service. The tablets (Samsung Galaxy Tab A or similar) will be for the participants to keep, regardless of whether they continue to participate. However, internet service (unlimited data from T-Mobile, 11GB of hotspot data per month) will only be provided for the duration of the study to active participants who do not miss more than two study activities during any 30-day period.

Risks and Benefits

Participants have the potential to benefit from their study participation by using the tablets and internet service that we will provide for non-research purposes, such as telework or for interacting with family and friends.

We anticipate that conducting the feedback sessions and the administration of survey questionnaires and other measures represent only minimal risk to participants and that the greatest potential risks to participants involve privacy and confidentiality. Raw data will contain participant identifiers. However, steps will be taken to safeguard this information. Questionnaire data will be completed and stored in REDCap.

Only the research team will have access to raw data on REDCap. Raw data will be downloaded and de-identified before analysis. Only aggregate results will be disseminated.

Videos of Peer Mentor sessions will be created using the “record” command in Zoom and will be saved on a secure EVMS server. The videos will be saved for the duration of the study and accessed only on an as needed basis.

We have also incorporated safeguards to reduce the impact of related harms if a breach of

confidentiality should occur. Most importantly, partner PHAs have agreed that study data or study involvement will not be used against participants in the event of an accidental disclosure. This includes instances when participants might disclose their involvement in the study and study information to PHA staff on their own.

Sharing of Data with Duke Clinical Research Institute (RADX-Up)

As part of our ongoing research with the Duke Clinical Research Institute (RADX-Up), and in compliance with the requirements set forth by our funding agency, we will include Common Data Elements (CDE) in our study. These CDEs include 130 items assessing demographic information, health status, and questions regarding attitudes about COVID-19 behaviors and guidance. The CDEs are intended to standardize data collection across studies, facilitating broader data analysis and comparison. This integration supports our aim to contribute to a larger dataset that enhances the value and impact of research in our field.

At the time of informed consent, participants will also be presented with a separate informed consent to complete CDEs. This will ensure that participants are fully informed about the nature of these questions and the purpose behind them. Participation in the CDE component of the study is entirely voluntary. Participants will be informed that they have the right to decline to answer these questions without any impact on their participation in the rest of the study. The CDE questions will be administered at the three-month mark of the study. These questions will be included as part of a questionnaire sent to participants through REDCap. All data collected through these questions will be handled in accordance with our existing data use and sharing agreements with RADX-Up. We are committed to maintaining the highest level of confidentiality and will ensure that all data is stored and shared in compliance with NIH and HIPAA.

The integration of CDE questions into our study is a critical component of our commitment to contributing valuable data to the wider research community. We believe that with the proper consent process and data handling protocols, we can effectively implement this aspect of the study without compromising participant privacy or data integrity.

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