Optimization of a New Adaptive Intervention to Increase COVID-19 Testing
NCT04757298
Study Protocol
12/20/2020

NJCRI NORTH JERSEY COMMUNITY RESEARCH INITIATIVE

IRB Study Application Form

REVIEW CATEGORY:

☒ **Expedited Review**
☐ **Full Board Review**.

1. **PROJECT REVIEW**

   ☒ New project: **Optimization of a new adaptive intervention to increase COVID-19 testing among people at high risk in an urban community**
   ☐ Resubmission project:
   ☐ Date of most recent previous review:

2. **DATA COLLECTION DATES** 01/04/2021 - 05/12/2022

3. **INVESTIGATOR(S) (**copy and paste additional investigator names as needed**)**:

Investigator Name: Ellen Benoit, PhD
Department: Research, NJCRI
Address: 393 Central Ave., Newark, NJ 07103
Phone: 973-483-3444 x 281
Email: e.benoit@njcri.org

Investigator Name: Liliane C. Windsor, PhD
Department: School of Social Work, University of Illinois at Urbana-Champaign
Address: 1010 W. Nevada St., Urbana, IL 61801
Phone: 217-300-1782
Email: lwindsor@illinois.edu

4. **PROJECT TITLE/DESCRIPTION AND RECRUITMENT:**

Title: Optimization of a new adaptive intervention to increase COVID-19 testing among people at high risk in an urban community

Little is known about the acceptability of COVID-19 testing in low-income and racial/ethnic minority neighborhoods, where residents experience increased barriers to prevention and treatment (e.g., unstable housing, higher risk jobs). In this study, community members and researchers will work together as partners with a community-based organization to test an intervention to increase COVID-19 testing and adherence to science-based COVID-19 treatment and prevention recommendations. We will adapt two cost-effective, evidence-based, and culturally appropriate interventions that have been successfully used to engage people in HIV testing and treatment. Navigation services (NS) increase HIV testing and adherence to treatment while addressing structural barriers that deter treatment engagement in high-risk communities. Brief counseling

increases HIV treatment engagement. The study will assess the impact of these interventions on COVID-19 testing rates and on adherence to science-based guidelines to prevention and treatment. The study will also produce in-depth qualitative data identifying ways to overcome barriers for those who do not accept testing or adhere to NJ COVID-19 recommendations.

This study is funded by the National Institutes of Health (NIH) as a supplement to our parent study optimizing *Community Wise*, an intervention to reduce substance use among formerly incarcerated men (R01 MD010629-01). The *Community Wise* optimization study is being conducted as community based participatory research (CBPR) with the Newark Community Collaborative Board (NCCB), a group of 20 community members, service providers, and researchers. NJCRI and the NCCB are the study's community partners, connected through the Principal Investigators. Dr. Windsor is founder and chair of the NCCB; Dr. Benoit is employed by NJCRI and is an original NCCB member. For this study, the NCCB will continue to use CBPR to optimize an adaptive intervention that will take people through the COVID-19 continuum of prevention, care and treatment, starting with outreach, followed by testing, prevention intervention for those testing negative, and recommendation to quarantine, treatment, and/or referral to community based services and/or contact tracing for those testing positive.

We will recruit an intent-to-treat sample of 670 adults and estimate 15% attrition for a final sample of 582. Participants in this clinical trial will be recruited through a combination of strategies. Fliers will be posted throughout Essex County in public spaces, restaurants, and health care clinics, and community based organizations. People who call the study will be encourage to disseminate the study to their friends and family. The NCCB will reach out to their contacts and networks.

5. **PARTICIPANTS** (approximate number and all applicable categories):
Number of participants proposed: 670

☒ Female
☒ Male
☐ Children (17 or younger)
☐ Prisoners
☐ Pregnant women
☐ Inmates or prisoners
☐ Cognitive impaired persons
☐ Non-English speaking persons

6. **COST AND PAYMENTS: (Will there be incentives for this project?)**

Participants will receive $30 for completing the baseline interview and $40 for completing each of two follow-up interviews. A randomly selected sample of 35 participants who do not complete testing will receive $50 for completing an in-depth, qualitative interview. Thus, an eligible participant could receive up to $160 for completing all data collection activities.

7. **ATTACHMENTS**: All relevant project materials and documents, including

☒ Surveys, questionnaires, interview instruments
☒ Informed Consent and Assent (if applicable) forms
☐ Letters of approval on letterhead from cooperating agencies, schools, boards of education, etc.
☐ Debriefing statement or explanation sheet if applicable
☒ Participant recruitment materials (e.g., fliers, advertisements)
☐ Other:

8. **CONFIDENTIALITY OF DATA**: how data will be stored and collected

Data will be generated and collected through interpersonal computer assisted interviews, computer assisted self-interviews, group session audio recordings, in-depth qualitative interviews and SARS antigen tests for COVID-19. Each participant will complete an initial telephone screening, a computer-assisted baseline and two follow-up interviews (2 weeks and 5 weeks post

baseline) and at least one COVID test. The electronic files generated through data collection and the test results will be identified by code numbers only and kept in password-protected and HIPAA-compliant devices and cloud storage, separate from identifying information and available only to project staff. This helps to ensure that no identifying information will be disclosed in the unlikely event that computerized data are stolen or otherwise seen by unauthorized persons. All identifying electronic data will be destroyed immediately after data collection is completed. Signed consent forms and audio recordings will be kept for 3 years after study completion. De-identified electronic data will be kept indefinitely. Study participants may ask at any time to have recordings of their interview destroyed by calling/e-mailing one of the Principal Investigators at the numbers provided in the informed consent forms.

9. **RISKS AND BENEFITS**: Describe Risks and Benefits

The main potential risks of this study include inadvertent violation of confidentiality and emotional distress on the part of participants. The procedures described above are intended to prevent violations of confidentiality. It is important to be aware that the prospect of testing positive for COVID-19 may be a cause of substantial fear and anxiety among participants. We anticipate that more than half of our participants will be African American or Hispanic and may lack trust in medical science and practice as a legacy of medical mistreatment. Many participants will have lost loved ones to COVID-19 and all of them will be medically or socially vulnerable to poor outcomes if they become infected themselves. They live with disproportionate risk caused by any of several factors, including but not limited to employment as essential workers, poverty, inadequate or unstable housing and underlying medical conditions.

It is also possible that participants who decline testing and attend Critical Dialogue sessions may be disturbed by sensitive questions raised during those sessions. Questions and discussions regarding stigma, racism, discrimination and structural inequality may cause anxiety, anger, suspicion, or other emotions. While we expect our sample to be predominantly African American, there will be some White and Latino participants as well and talking about racism in the group will elicit strong emotions. Differences among group members have the potential to harm or cause discomfort for a participant or to revive psychological dynamics that could threaten to renew old conflicts. We are using a trained facilitator who is from the community and has a great deal of experiential knowledge dealing with these sensitive topics and with this marginalized population. In the unlikely event a discussion escalates to the point that it may challenge the safety of the group, there is an emergency protocol in place where trained clinical staff and security can intervene and deflect potential violence or stabilize medical emergencies.

The potential benefits to participants in this study and other members of the community are significant and may be long lasting. Significant short-term benefits include detecting and treating cases of COVID-19 and preventing further transmission of the disease. While participants are enrolled in the study, referrals to resources to address social determinants of health (e.g., housing, food insecurity) may provide immediate tangible benefits. In addition, if participants express a need for mental health assistance at any time, the project team and the NCCB are well equipped to either provide service or make appropriate referrals. After engaging in the interventions, participants may experience increased feelings of empowerment and self-esteem, both of which have been associated with improved health outcomes. If the study succeeds in reducing medical mistrust and increasing health literacy, those benefits may be long-lasting. Both the short-term and long-term potential benefits of this study justify the potential risks involved in participation.

10. **INFORMED CONSENT**: Description of consents

Eligible individuals will provide written informed consent before participating in the study. During the informed consent process, the study outreach worker or research assistant will explain the study design in detail, including its purpose, the source of funding, why individuals are invited to participate, what they will be asked to do, how long the study will last and how many people are expected to take part in the study. They will explain the processes of SARS antigen testing and

randomization, the interventions being tested, potential sources of risk and discomfort and measures designed to minimize both. They will answer all participant questions and will ask participants to describe in their own words what they expect to do in the study before obtaining signatures. Participants who do not comprehend the study description will not be enrolled. Participants who would like some time to think before deciding will be able to take informed consent material home with them for review and consideration. All participants who provide written consent will receive a copy of the consent document which, in addition to the study description outlined above, includes names and contact information (phone numbers and email) for the Principal Investigators and for the appropriate ethics officials at NJCRI.

11. **COLLABORATION: Describe any collaborations, Memorandums of Agreements or sub grantees**

The primary grantee is the University of Illinois at Urbana-Champaign (UIUC), the home institution of Principal Investigator (PI) Liliane Windsor. NJCRI, the home institution of the second PI, Ellen Benoit, is a sub grantee. Because all of the human participant research will take place at NJCRI, the IRB at UIUC has agreed to sign a deferral letter recognizing the IRB at NJCRI as the IRB of review. UIUC will submit this letter upon receipt of documentation that NJCRI's IRB has approved the study protocol.

The University of Michigan at Ann Arbor is also a sub grantee, to support the effort of Co-Investigator Rogério Pinto. The University has agreed to sign a deferral letter recognizing the IRB at NJCRI as the IRB of review and to submit the letter upon receipt of documentation that NJCRI's IRB has approved the study protocol.

NJCRI

NORTH JERSEY COMMUNITY RESEARCH INITIATIVE

Seeking Cures for Tomorrow, Providing Support for Today.

TO: Liliane Cambraia Windsor, PhD University of Illinois at Urbana- Champaign and Ellen Benoit, PhD North Jersey Community Research Initiative (NJCRI)

FROM: James Oleske, MD, MPH Chairman of the NJCRI IRB FWA# 00001870

APPROVAL DATE: December 23.2020

Re: IRB Review and Approval of the Project: **Optimization of a new adaptive intervention To increase COVID-19 testing among people at high risk in an urban community,**
Protocol #: CWCOVIDSUPP-UIUC-NJCRI 102497-18274-267805 version 1.0

The NJCRI IRB has reviewed and approved the project for Initial Submission**: Community Wise COVID Supplement: Optimization of a new adaptive intervention to increase COVID-19 testing among people at high risk in an urban community on December 23, 2020.** All documents that were approved: Informed consent, surveys/ instruments, questionnaires, interview and recruitment materials.

Please keep the IRB updated on the outcomes of this project and send all correspondence or updated study documents to the NJCRI IRB for review. Any proposed changes to the project must be submitted to the IRB as an amendment for review and approval prior to implementation.

The next continuing review and update will be on December 23, 2021. If there are any anticipated problems involving risk to subjects or others must be reported to the IRB. The IRB has reviewed and approved the consent and/or assent process, waiver and/or alteration described in this protocol as required by 45 CFR 46 and 21 CFR 50, 56, (if FDA regulated research). Only the versions of the documents included in the approved process may be used to document informed consent and/or assent of study subjects; each subject must receive a copy of the approved form(s); and a copy of each signed form must be filed in a secure place in the subject's medical/patient/research record. Please notify the IRB when the study has been completed or stopped for any reason.

James Oleske, MD, MPH Chairman of the NJCRI IRB — 12/23/2020 Date

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