



Ackerman, M., Walker, J. G., Vickerman, P. T., & Akiyama, M. (Accepted/In press). Mitigation Through On-Site Testing & Education Among Formerly Incarcerated Individuals Against Covid-19 – The MOSAIC Study: Design and Rationale. *Contemporary Clinical Trials*.

Peer reviewed version

[Link to publication record in Explore Bristol Research](#)
PDF-document

University of Bristol - Explore Bristol Research

General rights

This document is made available in accordance with publisher policies. Please cite only the published version using the reference above. Full terms of use are available:
<http://www.bristol.ac.uk/red/research-policy/pure/user-guides/ebr-terms/>

Mitigation Through On-Site Testing & Education Among Formerly Incarcerated Individuals
Against Covid-19 – The MOSAIC Study: Design and Rationale

Maxwell Ackerman^a
Connor S. Holmes^a
Jordy Rojas Antigua^a
Lindsey R. Riback^a
Chenshu Zhang^a
Josephine G. Walker^b
Peter Vickerman^b
Ann Travers^c
Micaela Linder^c
Ronald Day^c
Aaron D. Fox^a
Chinazo O. Cunningham^a
Matthew J. Akiyama^a

- a. Albert Einstein College of Medicine, Montefiore Medical Center,
1300 Morris Park Ave
Bronx, NY 10467
- b. Bristol Medical School, Population Health Sciences, University of Bristol,
Queens Road
Bristol, BS8 1QU, UK
- c. The Fortune Society,
2976 Northern Blvd,
Long Island City, NY 11101

Corresponding author:

Matthew Akiyama, MD, MS
Albert Einstein College of Medicine
Department of General Internal Medicine
3300 Kossuth Ave
Bronx, NY 10467
Phone: 718-920-7175
Email: makiyama@montefiore.org

Abstract: 250 words
Main text: 3999 words
Tables: 2
References: 75

Background: Many of the largest COVID-19 outbreaks in the United States have occurred at carceral facilities. Criminal legal system (CLS)-involved individuals typically face structural barriers accessing medical care post-release. Improving COVID-19 testing and education for CLS-involved individuals could improve health outcomes for this vulnerable population and the communities to which they return. Community-based organizations (CBO) and community health workers (CHWs) fill care gaps by connecting CLS-involved individuals with essential re-entry services. The MOSAIC study will: 1) test an onsite CHW-led SARS-CoV-2 testing and education intervention in a reentry CBO and 2) model the cost-effectiveness of this intervention compared to standard care.

Methods: We will recruit 250 CLS-involved individuals who have left incarceration in the prior 90 days. Participants will be randomized to receive onsite Point-of-Care testing and education (O-PoC) or Standard of Care (SoC). Over one year, participants will complete quarterly questionnaires and biweekly short surveys through a mobile application, and be tested for SARS-CoV-2 quarterly, either at the CBO (O-PoC) or an offsite community testing site (SoC). O-PoC will also receive COVID-19 mitigation counseling and education from the CHW. Our primary outcome is the proportion of SARS-CoV-2 tests performed with results received by participants. Secondary outcomes include adherence to mitigation behaviors and cost-effectiveness of the intervention.

Discussion: The MOSAIC study will offer insight into cost effective strategies for SARS-CoV-2 testing and education for CLS-involved individuals. The study will also contribute to the growing literature on CHW's role in health education, supportive counseling, and building trust between patients and healthcare organizations.

Keywords: SARS-CoV-2; criminal legal system (CLS)-involved individual; community health workers (CHWs); mitigation

1. Background

United States (U.S.) prisons and jails play an important role in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission,^{1,2} accounting for many of largest single-site U.S. outbreaks.^{3,4} Because 95% of criminal legal system (CLS)-involved individuals return to their communities,⁵ and CLS-involved individuals face high rates of homelessness with many living in other congregate settings post-incarceration, elevated SARS-CoV-2 risk while incarcerated, coupled with the likelihood of living in congregate settings after incarceration,^{6,7} create high risk conditions for SARS-CoV-2 transmission.

SARS-CoV-2 screening procedures have varied among carceral institutions,⁸ and typically during the early stages of the pandemic, testing was inconsistent within and across facilities.^{9,10} Moreover, greater than 50% of individuals have asymptomatic infections in carceral settings.^{11,12} National recommendations include symptom-based and asymptomatic testing in carceral facilities. This includes those who are incarcerated and have exposures in order to ensure early identification of infections (e.g. testing at intake and prior to transfer to another facility);¹³ however, there are no recommendations regarding testing CLS-involved individuals in the transition to the community, a process that may be rushed without adequate discharge planning, particularly during pandemic peaks.¹⁴

Addressing asymptomatic infections, which increase broader SARS-CoV-2 transmission risk,¹⁵⁻¹⁷ requires effective prevention and mitigation strategies, such as routine testing, masking, social distancing, and vaccination. Knowing whether one is a SARS-CoV-2 carrier could enhance CLS-involved individuals' ability to prevent transmission. Additionally, mitigation strategies require adherence to be effective.^{18,19} Uptake of these strategies among CLS-involved individuals

may be limited due to medical mistrust,^{10,20-22} poor access to personal protective equipment and vaccines,^{8,22} limited access to testing and testing fatigue,¹⁰ and inability to socially distance due to living in congregate settings,^{8,20} among many others. Given the potential for community viral transmission, research is needed into tailored prevention and mitigation strategies.

Community-based organizations (CBOs) provide critical services to people coming home from carceral settings. Nearly 400 CBOs in the U.S. provide services such as employment training, housing assistance, and linkage to medical care or other social services.²³ Some CBOs have provided SARS-CoV-2 testing²⁴ and vaccine education,²⁵ suggesting these sites could provide both testing and education more broadly to improve mitigation of COVID-19 and other infectious diseases among CLS-involved individuals. Because CLS-involved individuals underutilize conventional healthcare services due to factors like medical mistrust and competing priorities (e.g., homelessness), interventions are needed to bring SARS-CoV-2 testing directly to them.²⁶⁻³⁰ Similar to point-of-care (PoC) HIV and hepatitis C (HCV) testing, SARS-CoV-2 PoC testing at CBOs among CLS-involved individuals could increase uptake and may be cost-effective.^{31,32}

Community health workers (CHWs) with lived experience of incarceration could also enhance COVID-19 prevention and mitigation by providing culturally sensitive care. CHWs are trained in health education and health system navigation and share important characteristics with the community that they serve.³³ Preliminary evidence suggests CHWs can be cost-effective in delivering community-oriented care.³⁴ For CLS-involved individuals, CHWs circumvent barriers, such as medical mistrust, discrimination, and stigma,^{35,36} to build trust, provide support and health education, and link CLS-involved individuals to healthcare services after incarceration.³⁷⁻³⁹ Under an onsite PoC testing strategy in CBOs, CHWs providing testing and education may be more cost-effective than standard healthcare services. CHW-led interventions that promote positive COVID-

19 health outcomes among vulnerable populations have been understudied,⁴⁰⁻⁴⁴ particularly among CLS-involved individuals.^{34,44-46}

The MOSAIC study will examine an onsite PoC SARS-CoV-2 testing strategy where a trained CHW will provide testing and education at a carceral-focused CBO. We hypothesize that our tailored intervention will improve testing uptake, receipt of test results, adherence to mitigation behaviors, and will be cost-effective in terms of cost per quality adjusted life year (QALY) in comparison to referral for offsite asymptomatic testing. In this paper, we describe the study's rationale, methods, planned analyses, and limitations.

2. Methods

2.1. Study design.

This randomized controlled trial will test an onsite point-of-care testing and education intervention (O-PoC) in comparison to Standard of Care (SoC), which is referral to an offsite community testing location. We will randomize 250 CLS-involved individuals 1:1 to O-PoC or SoC and follow participants over 12 months. Participants will complete quarterly questionnaires and biweekly short surveys through a mobile application, and we will collect medical record data to assess study outcomes. This trial is registered with clinical trials.gov (NCT04878328) and was approved by Albert Einstein College of Medicine's IRB.

2.2. Conceptual framework

We seek to understand CLS-involved individuals' acceptance of SARS-CoV-2 testing and adherence to mitigation behaviors. Social Cognitive Theory (SCT) informed our intervention by highlighting key determinants that affect health behaviors.⁴⁷ With knowledge as a precondition, *perceived self-efficacy* is central to SCT, meaning that one must believe that they can exercise control over their health habits.⁵³ Change occurs when one: 1) recognizes the *expected outcomes* (harms or benefits) that may result from their behaviors, 2) overcomes logistical *barriers and facilitators*, and 3) sets *goals*, with a strategy to achieve them. SCT also posits that learning occurs in a social context with a dynamic and reciprocal interaction of the person, environment, and behavior. SCT's emphasis on social influence, and external and internal social reinforcement, supports a CHW-led intervention that will occur at a carceral-focused CBO. The O-PoC intervention will address participants': 1) COVID-19-related *knowledge*, 2) *barriers to and facilitators* of SARS-CoV-2 testing and adherence to mitigation measures, 3) *expected outcomes* from SARS-CoV-2 testing and mitigation measures, and 4) *goals* for SARS-CoV-2 testing and mitigation measure adherence.

2.3. Setting

The trial will be conducted in partnership with The Fortune Society (Fortune), a New York City (NYC) CBO that serves individuals returning from jail or prison with the mission of supporting successful reentry.⁴⁸ The NYC jail system is the second largest in the U.S. with 16,179 admissions in 2021.⁴⁹ New York State prisons admitted 31,262 individuals in 2021.⁵⁰ Fortune serves roughly 10,000 CLS-involved individuals per year.

2.4. Participants

We will recruit adult CBO clients who have returned home from jail or prison within the last 90 days. Participants must be fluent in English or Spanish and plan to reside within NYC for the duration of the study. Full participant inclusion and exclusion criteria are listed in Table 1.

2.5. Recruitment, screening, and enrollment

There will be three main recruitment sources: 1) our CBO-based project coordinator will provide active referrals to a research assistant (RA) 2) CBO caseworkers will inform potential participants about the study; and 3) Passive recruitment will occur by posting study flyers at CBO locations.

The RA will screen interested clients over the phone or in-person and will determine release dates by using the NYC Inmate Lookup,⁵¹ New York State Incarcerated Lookup,⁵² and the Federal Inmates by Name databases.⁵³ Once determined to be eligible, the RA will schedule an in-person enrollment visit to conduct the informed consent procedures.

2.6. Intervention

We will train one CHW with lived experience of incarceration to provide SARS-CoV-2 testing, education, and navigation services. The CHW will deliver the following services: 1) COVID-19 education; 2) Onsite SARS-CoV-2 testing with Cepheid Xpert Xpress PCR test⁵⁴ at

CBO facilities; 3) Needs assessments for unmet social needs and facilitated access to masks and hygiene supplies; 4) Navigation to vaccination sites; and 5) General psychosocial support. If participants test PCR positive, the CHW will also provide guidance on maximizing social distancing capabilities. GeneXpert results are available in approximately 30 minutes. While awaiting results, the CHW will provide COVID-19 education, needs assessments, and supportive counseling. Follow-up testing visits will be scheduled every 3 months for one year and will follow the same format. Either the CBO-based project coordinator or the CHW will attempt to contact clients a total of 3 times if testing and education visits are missed. If no contact is established, they will attempt outreach two weeks later for another 3 times. After this, the visit will be considered as a missed visit.

The CHW will be recruited by the CBO, and training will be provided by CBO staff as per their standard procedures. They will also receive training on HIPAA confidentiality, use of GeneXpert and updated information on COVID-19 prevention, testing and vaccination sites in NYC. COVID-19-related training will be provided through Fortune's partnership with the NYC Test and Trace Corps.

The comparison arm is Standard-of-Care (SoC). Participants in both groups will receive education about the role of asymptomatic testing and be advised to test every 3 months. However, the SoC arm will be referred for testing at an offsite testing location using the NYC COVID-19 Test Site Finder.⁵⁵ This can include community health sites, hospitals, urgent care centers and street vendors. The CBO project coordinator will help participants in the SoC arm to find a convenient offsite location, and will also collect and record the results from offsite testing.

Similar to the O-PoC arm, the CBO project coordinator will attempt outreach 3 times to remind participants to get tested at the community testing site. If no contact is established, they will attempt outreach two weeks later for another 3 times, and the test will be considered as missed if contact is not established.

2.7. Data Collection

2.7.1 Data Sources

Data sources will include quarterly questionnaires, biweekly short surveys, CBO program logs, and healthcare records.

Questionnaires: At quarterly research visits, RAs will administer questionnaires using REDCap (Nashville, Tennessee), a web-based data platform.⁵⁶ Questionnaires will include key demographic, socioeconomic, comorbidity, COVID-19-related knowledge variables, and mitigation behaviors (e.g., masking, ability to socially distance, and other protective measures) (see Table 2). We will also assess health status using the SF-36,⁵⁷ and ascertain barriers to testing, including attitudes toward COVID-19, mistrust of the healthcare system, and perceptions of risk.

Brief surveys: Participants will also complete web-based surveys using a mobile application (Ethica, Toronto, Canada) on study smartphones every 2 weeks for 12-months (26 total surveys). These surveys will take five to ten minutes to complete and include questions about participants'

housing, COVID-19-related risk, and mitigation behaviors. Collecting these data between quarterly research visits will enhance precision regarding adherence to mitigation behaviors.

CBO program logs: Uptake for individuals in the SoC will be recorded by the CBO project coordinator through program logs. Copies of test results will be collected from participants getting tested at community testing sites.

Healthcare records: Medical record data will be extracted from medical facilities that participants visited 30 days prior to enrollment through the end of their time in the study including COVID-19 test results and date of test. Study participants are instructed to share a copy of their test results with the research team. Trained research staff will obtain and extract medical record data for individuals who are unable to share their test results with the research team directly.

2.8. Outcomes measures

2.8.1. Primary outcome

The primary outcome will be a dichotomous outcome of having at least one *complete SARS-CoV-2 test*, meaning having a test performed with results received by participants. To measure this, we will use program logs and healthcare record extraction. We will also ask participants to self-report whether they received the test results. The composite measure of tests performed, and results received by participants will be most clinically relevant because receiving test results will

aid participants in adjusting mitigation behaviors. We will also report the total number of complete SARS-CoV-2 tests with up to 5 tests being possible (at times 0, 3, 6, 9, and 12 months).

2.8.2. Secondary outcomes

2.8.2.1. Adherence to mitigation measures

We will measure adherence to mitigation measures in two parts – quarterly research visits and biweekly Ethica surveys.

Participants will be asked at their quarterly research visits: Which of the following have you done in the last two weeks to keep yourself safe from coronavirus? Worn a mask or other face covering; Washed your hands with soap or used hand sanitizer several times per day; Avoided contact with people who could be high-risk; Avoided public spaces, gatherings, or crowds.

For the biweekly Ethica surveys, participants will also report their social distancing efforts by estimating how frequently they went to places where they could encounter in the past two weeks. Participants will be given a list of places (bars, stores, pharmacies, public transportation, religious services, offices or other workplaces, etc.) and response items for frequency will be: once, a few times, or daily. Participants will also select how often they have worn a mask or face covering during these activities in the last two weeks: Always, Most of the time, Sometimes, Rarely and Never.

For each data source, quarterly and biweekly, we will measure adherence to each mitigation measure as a composite score in which we will calculate the mean followed by the sum score to account for missing items. Composite scores will then be calculated for combined adherence measures. To do this, we will assign a score with higher adherence to mitigation measures as higher scores (from 1 to 14) and create a composite score averaging 2-week questionnaires conducted over the course of the last 3 months.

2.8.3. Assessment of intervention fidelity

CBO project coordinator logs will determine testing uptake and the proportion of tests performed. The CBO project coordinator will document: 1) all outreach calls made to clients to provide education about the importance of asymptomatic testing, 2) appointments scheduled for O-PoC, 3) referrals to SoC offsite testing, 4) tests performed, test results, and whether or not they were received by the client. Fidelity visits will be conducted by study staff via a uniform checklist to ensure protocol is followed and information given to participants is accurate.

2.9. Statistical Analysis

For our primary outcome, we hypothesize that O-PoC (vs. SoC) will result in a greater proportion of tests performed and results received. For our secondary outcome, we hypothesize that: O-PoC (vs. SoC) will report a greater proportion of mitigation behaviors (described in section 2.7.2.1); higher O-PoC intervention dose (i.e., attending more testing visits with the

CHW) will be associated with better adherence to mitigation behaviors; and O-PoC (vs. SoC) will be cost-effective in terms of cost per COVID-19 case identified and averted.

All primary analyses will be intention to treat, including participants lost to follow-up. We will also conduct per-protocol analyses to focus on outcomes among participants who received at least one SARS-CoV-2 PCR test at the CBO or an offsite community testing site. We will conduct additional exploratory analyses on a per-protocol basis to assess other outcomes (e.g., mitigation measures).

Our primary analysis will determine the effect of the O-PoC intervention on SARS-CoV-2 tests performed and test results received. We will conduct logistic regression with study arm as the main independent variable and having at least one *complete SARS-CoV-2 test* during the 12-month study period as the dependent variable, which will give the odds of having a test done and receiving the results when the O-PoC arm is compared with referral offsite. We will also conduct separate bivariate and multivariate Poisson regression models to compare between study arms the total number of SARS-CoV-2 tests performed and the number of SARS-CoV-2 test results received during the 12-month study period.

Secondary analyses will be conducted using mixed effect linear regression models (SAS Proc Mixed). These analyses will be used to determine the association between: (1) O-PoC testing (vs. SoC) and mitigation measures; and (2) O-PoC intervention dose and subsequent adherence to mitigation measures (O-PoC arm only). Participants' 26 brief surveys assessing mitigation measures over 2-week intervals will be the unit of analysis, however given that there are two

sources of data collection reporting on the same time-points we will conduct sensitivity analyses using the quarterly data and compare the results. In the first model, the primary dependent variable will be the composite score reflecting adherence to mitigation measures. The main independent variable will be randomization arm (O-PoC or SoC). We will include key baseline variables (e.g., sex, race/ethnicity, history of SARS-CoV-2 testing and infections) that are unbalanced in the two groups in the multivariate analyses. In the second model, the independent variables will be attendance statuses O-PoC visits (0, 3, 6, 9 months), which will be a time varying dichotomous variable. The dependent variable will be the corresponding quarterly or biweekly summary scores (mean or proportion) of adherences to mitigation measures between visits both individually and as a composite score. In addition, we will also conduct linear regression analyses to examine the association between the proportion of O-PoC attendance and overall mitigation measures over 12 months.

2.10. Cost effectiveness analysis

We will evaluate the cost-effectiveness of O-PoC (vs. SoC) in terms of cost per case identified, cost per direct transmission event averted, and cost per quality adjusted life year (QALY) gained. Costs will be collected from the perspective of the healthcare sector. We will assume an intervention time horizon of one year, and account for cases averted within that year, but project the long-term impact in terms of QALYs gained per infection averted in the intervention year over the lifetime of the cohort.

We will evaluate costs using an ingredients-based costing, identifying unit costs for each resource used by study participants. O-PoC testing involves set-up costs and intervention delivery costs, including materials, consumables, and staff and CHW time for onsite testing, education, counseling, and patient navigation. SoC involves the cost of referral offsite and implementation of offsite tests. As well as costs of testing, we will account for ED visits, hospitalization costs, and other healthcare required for COVID-19 cases.

Resource use per individual will be recorded in study data (such as visits attended, supplies distributed, etc.), and through time and motion studies. Unit costs of consumables per activity or per month will be gathered from study and CBO expenditure records. The cost and resource use of COVID-19 treatment/hospitalization will be gathered from medical records and through reimbursement records.

The total and per study participant difference in cost between the O-PoC intervention and offsite testing will be compared to the difference between cases identified in the two arms to calculate the incremental cost per case identified of O-PoC intervention vs. SoC. *Health status* will be evaluated using the SF-36 questionnaires⁵⁷ conducted at research visits, and converted into QALY weights.⁵⁸ Regression analysis will be used to evaluate associations between QALY weight, COVID and other health status (including vaccination status), study arm, and participant demographics. *Incremental cost effectiveness ratios (ICERs)* will be used to compare cost per QALY gained for the O-PoC program compared to SoC. This will account directly for any improvement in quality of life achieved through engagement with healthcare, knowledge of COVID-19 status, and counselling received. The intervention will be considered cost-effective if

the cost per QALY is less than the willingness to pay threshold of \$104,000 per QALY (in 2019 USD).⁵⁹

We will use a mathematical simulation model (Markov model) to estimate the cost per QALY gained and cost per direct transmission event averted between the O-PoC and SoC model. The model will assume a potential for transmission of COVID-19 from infected cases to close contacts (secondary attack rate) as reported in the literature through contact tracing and observational studies.^{60,61} We use a short time horizon of one year for the intervention, and do not account for the dynamics of further onward transmission due to uncertainty the severity and frequency of seasonal outbreaks going forward. For a lifetime horizon impact of QALYs gained per infection averted, we will also incorporate projections of QALYs gained per infection averted, based on life table methods, adjusted for the age of the population and comorbidities.⁶² We will explore the impact of vaccination reducing transmission risk and disease severity in sensitivity analysis.

2.11. Power analysis

Recruiting and enrolling 250 participants (125 per arm, assuming a 1:1 ratio) will provide sufficient power to detect significant differences in testing uptake and receipt (primary outcome) and mitigation measures (secondary outcome). Conservatively, accounting for a 15% attrition, we will have a sample size of 212 (106 per arm). For our primary outcome, this will allow us to detect a 19% difference (70% vs. 51%) between arms in percentage of participants with at least one test performed and results received with at least 80% of power at a significant level of 5%

(two-sided test). With our first secondary outcome, the sample size can detect a moderate difference of 0.3 (Cohen's d) in mitigation measures 80% of the time with a more stringent condition (i.e., personal level intra class correlation (ICC)=0.6). Additionally, with our second secondary outcome hypothesis (O-PoC will improve adherence to mitigation measures), we will have 90% power to detect a moderate difference of 0.3 (Cohen's d) in mitigation measures between participants attending one or more O-PoC visits vs. those who do not when ICC=0.4 and two-tailed alpha=0.05. Since O-PoC attendance is a time-varying variable, the power will be greater when ICC is greater.

2.12. Missing data.

We will conduct multiple imputations using Markov Chain Monte Carlo imputation methods for missing continuous data. To satisfy the missing at random assumption required for this method, the imputation models will include interventions and baseline demographic variables. Based on the method proposed by Rubin,⁶³ we will pool analytic results from the multiple imputed data sets into a single result. Alternatively, we will apply full information maximum likelihood approach to treat missing data.

2.13. Data safety and monitoring plan

A Data and Safety Monitoring Committee (DSMC) will comprise clinicians and researchers from Albert Einstein College of Medicine unaffiliated with the research study. The DSMC will meet prior to enrollment and vote on approval of the protocol prior to initiation. All adverse events and protocol deviations will be recorded consistent with institutional and federal guidelines and will be discussed at DSMC committee meetings. The investigative team and the DSMC will meet every 6 months until the end of study to review of data and findings.

3. Discussion

In this study, we seek to reduce COVID-19 spread among recently incarcerated individuals by offering routine CHW-led SARS-CoV-2 testing and education at a carceral-focused CBO. This trial draws on past studies that increased HIV testing uptake by offering testing services onsite at community-based programs,^{64,65} and increased HCV testing through peer-delivered counseling and education.⁶⁶⁻⁶⁸ If successful, this intervention could provide a strategy to improve COVID-19 mitigation among CLS-involved individuals and deepen understanding of CBOs and CHWs' potential roles in improving public health interventions for hard-to-reach populations.

We chose to incorporate CHWs into our intervention to address barriers, such as medical mistrust, discrimination, and stigma, which CLS-involved individuals face in accessing healthcare services.³⁵ CHW interventions are well studied in HIV care,⁶⁹⁻⁷¹ and post-incarceration models in which trained CHWs build trust and provide support to improve engagement in healthcare.³⁷⁻³⁹ For this intervention, we are training the CHWs to use PCR machines for SARS-CoV-2 tests, and this approach could have broader salience for HIV, HCV,

or STI testing in settings servicing persons at risk that cannot afford to hire medical providers. Rigorous data collected on communications between the CHW and participants will contribute to the literature on the expanding role for CHWs in the U.S.

To inform the potential to scale this intervention, we will also determine its cost-effectiveness in preventing excess COVID-19 cases. Past studies have demonstrated that referral for offsite HIV and HCV testing is less efficient and less cost-effective than strategies employing onsite O-PoC testing.^{31,72} Previous studies examining the cost-effectiveness of COVID-19 testing strategies have modeled levels of testing under different transmission scenarios in a hypothetical general population.^{73,74} Here, we examine a real-life intervention and consider the benefits of ongoing screening for COVID-19 for an at-risk population.

The study may have limitations. First, lack of blinding could introduce bias; however, we will follow a set protocol for participant outreach and conduct fidelity visits to assess intervention performance. Second, having one CHW could diminish a personal fit between some study participants and the CHW; however, this decision was made in collaboration with the partner organization due to the candidate's prior experience with providing individualized COVID-19 education to a large number of clients and to allow for consistency in education, demeanor, and interactions across all onsite participants. Third, our participants will come from one CBO which may limit generalizability to CBOs in suburban, rural or other urban areas outside of NYC. Fourth, adherence to mitigation behaviors will be self-reported and we cannot objectively determine participants' social distancing, masking, or other mitigation behaviors. Fifth, we are not pairing serologic assessment alongside PCR testing. While this approach could add data on SARS-CoV-2 exposure and vaccine uptake in the context of changing serostatus, we decided against it because conducting blood draws could risk clients disengaging from the

nasopharyngeal testing and education offered through the study. Lastly, our intervention does not include carceral staff, such as officers, who come from and return to their communities daily.

Due to their probable role in carceral-community SARS-CoV-2 transmission, carceral officers should be considered for future interventions.⁷⁵ Despite these potential limitations, our study will expand the knowledge base on ways in which communicable diseases such as COVID-19 can be effectively mitigated among CLS-involved and other vulnerable populations.

In summary, interventions to reduce COVID-19 spread among CLS-involved individuals are needed and improving uptake of surveillance testing and mitigation measures may be one important strategy. Future studies could use this as a framework to develop other interventions to test for and educate on SARS-CoV-2 and other infectious diseases to mitigate transmission among CLS-involved individuals and other marginalized populations. This novel strategy in which CHWs will provide testing, education, and patient navigation for COVID-19, may also impact policy by providing an evidence base for a cost-effective strategy to reduce the impact of future pandemics.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have influenced work reported on in this paper.

Acknowledgements

This study is supported by NIH R01MD016744 (PI: Akiyama). This source had no further role in study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the report for publication. We would like to thank Fortune Society

including our project coordinator Kadiata Kaba, community health worker Jamile Torres, and Evaluation and Quality Improvement program manager Michael Harris for their support and our participants for their valuable time.

Author contributions

Maxwell Ackerman – writing – original draft, review and edits, software, investigation; Connor S. Holmes – investigation; Jordy Rojas Antigua – investigation; Lindsey R. Riback – project administration, software, data curation, review and edit, investigation; Chenshu Zhang – methodology, formal analysis; Josephine G. Walker – methodology, formal analysis, review and edit; Peter Vickerman – methodology, formal analysis; Ann Travers – conceptualization, funding acquisition; Micaela Linder – conceptualization, supervision, writing – review & edit; Ronald Day – conceptualization, supervision; Aaron D. Fox – conceptualization, supervision, writing – review & edit; Chinazo O. Cunningham – conceptualization, supervision, funding acquisition, writing – review & edit; Matthew J. Akiyama – conceptualization, methodology, investigation, writing – original draft, review & edit, supervision, funding acquisition.

References

1. Akiyama MJ, Spaulding AC, Rich JD. Flattening the Curve for Incarcerated Populations - Covid-19 in Jails and Prisons. *N Engl J Med*. 2020;382(22):2075-2077.
2. Kinner SA, Young JT, Snow K, et al. Prisons and custodial settings are part of a comprehensive response to COVID-19. *Lancet Public Health*. 2020;5(4):e188-e189.
3. Lemasters K, McCauley E, Nowotny K, Brinkley-Rubinstein L. COVID-19 cases and testing in 53 prison systems. *Health Justice*. 2020;8(1):24.
4. Project TCP. The COVID Prison Project tracks data and policy across the country to monitor COVID-19 in prisons. <https://covidprisonproject.com/>. Published 2022. Accessed 28 October, 2022.
5. Confronting Confinement. Vera Institute. <https://www.vera.org/publications/confronting-confinement>. Published 2006. Accessed.
6. Levanon Seligson A, Parvez FM, Lim S, et al. Public Health and Vulnerable Populations: Morbidity and Mortality Among People Ever Incarcerated in New York City Jails, 2001 to 2005. *J Correct Health Care*. 2017;23(4):421-436.
7. Lim S, Seligson AL, Parvez FM, et al. Risks of drug-related death, suicide, and homicide during the immediate post-release period among people released from New York City jails, 2001-2005. *Am J Epidemiol*. 2012;175(6):519-526.
8. Riback LR, Dickson P, Ralph K, et al. Coping with COVID in corrections: a qualitative study among the recently incarcerated on infection control and the acceptability of wastewater-based surveillance. *Health Justice*. 2023;11(1):5.
9. The Marshall Project. A State-by-State Look at Coronavirus in Prisons. <https://www.themarshallproject.org/2020/05/01/a-state-by-state-look-at-coronavirus-in-prisons>. Accessed August 1, 2020.
10. Gonzalez-Montalvo MDM, Dickson PF, Saber LB, et al. Opinions of former jail residents about self-collection of SARS-CoV-2 specimens, paired with wastewater surveillance: A qualitative study rapidly examining acceptability of COVID-19 mitigation measures. *PLoS One*. 2023;18(5):e0285364.
11. So LS, G. In four U.S. state prisons, nearly 3,300 inmates test positive for coronavirus -- 96% without symptoms. *Reuters*2020.
12. Johnson K. Mass virus testing in state prisons reveals hidden asymptomatic infections; feds join effort. *USA Today*2020.
13. Centers for Disease Control. Interim Considerations for SARS-CoV-2 Testing in Correctional and Detention Facilities. <https://www.cdc.gov/coronavirus/2019-ncov/community/correction-detention/testing.html>. Accessed November 10, 2020.
14. Servick K. Pandemic inspires new push to shrink jails and prisons. <https://www.sciencemag.org/news/2020/09/pandemic-inspires-new-push-shrink-jails-and-prisons>. Accessed October 30, 2020.
15. Franco-Paredes C, Jankousky K, Schultz J, et al. COVID-19 in jails and prisons: A neglected infection in a marginalized population. *PLoS Negl Trop Dis*. 2020;14(6):e0008409.
16. Saloner B, Parish K, Ward JA, DiLaura G, Dolovich S. COVID-19 Cases and Deaths in Federal and State Prisons. *JAMA*. 2020;324(6):602-603.
17. Mizumoto K, Kagaya K, Zarebski A, Chowell G. Estimating the asymptomatic proportion of coronavirus disease 2019 (COVID-19) cases on board the Diamond Princess cruise ship, Yokohama, Japan, 2020. *Euro Surveill*. 2020;25(10).

18. Greenhalgh T, Schmid MB, Czypionka T, Bassler D, Gruer L. Face masks for the public during the covid-19 crisis. *BMJ*. 2020;369:m1435.
19. Alsan M, Stantcheva S, Yang D, Cutler D. Disparities in Coronavirus 2019 Reported Incidence, Knowledge, and Behavior Among US Adults. *JAMA Netw Open*. 2020;3(6):e2012403.
20. Ortiz-Paredes D, Varsaneux O, Worthington J, et al. Reasons for COVID-19 vaccine refusal among people incarcerated in Canadian federal prisons. *PLoS One*. 2022;17(3):e0264145.
21. Kramer C, Song M, Sufrin CB, Eber GB, Rubenstein LS, Saloner B. COVID-19 vaccination hesitancy and uptake: Perspectives from people released from the Federal Bureau of Prisons. *Vaccine*. 2023;41(7):1408-1417.
22. Liu YE, LeBoa C, Rodriguez M, et al. COVID-19 Preventive Measures in Northern California Jails: Perceived Deficiencies, Barriers, and Unintended Harms. *Front Public Health*. 2022;10:854343.
23. Reentry Services Directory. The National Reentry Resource Center. <https://nationalreentryresourcecenter.org/reentry-services-directory/>. Accessed November 14, 2020.
24. Searcy JA, Cioffi CC, Tavalire HF, et al. Reaching Latinx Communities with Algorithmic Optimization for SARS-CoV-2 Testing Locations. *Prev Sci*. 2023:1-12.
25. Williams NJ, Gill E, Punter MA, et al. Rapid Community Engagement in Response to SARS-CoV-2 Funding Opportunities: New York City, 2020–2021. *Am J Public Health*. 2022;112(S9):S904-S908.
26. Puglisi L, Calderon JP, Wang EA. What Does Health Justice Look Like for People Returning from Incarceration? *AMA J Ethics*. 2017;19(9):903-910.
27. Wang EA, White MC, Jamison R, Goldenson J, Estes M, Tulsy JP. Discharge planning and continuity of health care: findings from the San Francisco County Jail. *Am J Public Health*. 2008;98(12):2182-2184.
28. Walsh-Felz D, Westergaard R, Waclawik G, Pandhi N. "Service with open arms": enhancing community healthcare experiences for individuals with a history of incarceration. *Health Justice*. 2019;7(1):20.
29. Valera P, Boyas JF, Bernal C, Chiongbian VB, Chang Y, Shelton RC. A Validation of the Group-Based Medical Mistrust Scale in Formerly Incarcerated Black and Latino Men. *Am J Mens Health*. 2018;12(4):844-850.
30. Kutnick AH, Leonard NR, Gwadz MV. "Like I Have No Choice": A Qualitative Exploration of HIV Diagnosis and Medical Care Experiences While Incarcerated and Their Effects. *Behav Med*. 2019;45(2):153-165.
31. Schackman BR, Leff JA, Barter DM, et al. Cost-effectiveness of rapid hepatitis C virus (HCV) testing and simultaneous rapid HCV and HIV testing in substance abuse treatment programs. *Addiction*. 2015;110(1):129-143.
32. Shrestha RK, Chavez PR, Noble M, et al. Estimating the costs and cost-effectiveness of HIV self-testing among men who have sex with men, United States. *J Int AIDS Soc*. 2020;23(1):e25445.
33. Olaniran A, Smith H, Unkels R, Bar-Zeev S, van den Broek N. Who is a community health worker? - a systematic review of definitions. *Glob Health Action*. 2017;10(1):1272223.
34. Waters R. Community Workers Lend Human Connection To COVID-19 Response. *Health Aff (Millwood)*. 2020;39(7):1112-1117.
35. Frank JW, Wang EA, Nunez-Smith M, Lee H, Comfort M. Discrimination based on criminal record and healthcare utilization among men recently released from prison: a descriptive study. *Health Justice*. 2014;2:6.
36. Howell BA, Earnshaw VA, Garcia M, Taylor A, Martin K, Fox AD. The Stigma of Criminal Legal Involvement and Health: a Conceptual Framework. *J Urban Health*. 2022;99(1):92-101.

37. Wang EA, Hong CS, Samuels L, Shavit S, Sanders R, Kushel M. Transitions clinic: creating a community-based model of health care for recently released California prisoners. *Public Health Rep.* 2010;125(2):171-177.
38. Fox AD, Anderson MR, Bartlett G, Valverde J, Starrels JL, Cunningham CO. Health outcomes and retention in care following release from prison for patients of an urban post-incarceration transitions clinic. *J Health Care Poor Underserved.* 2014;25(3):1139-1152.
39. Wang EA, Hong CS, Shavit S, Sanders R, Kessell E, Kushel MB. Engaging individuals recently released from prison into primary care: a randomized trial. *Am J Public Health.* 2012;102(9):e22-29.
40. Centers for Disease Control. <https://www.cdc.gov/coronavirus/2019-ncov/global-covid-19/home-based-care.html>. Accessed November 15, 2020.
41. Ballard M, Bancroft E, Nesbit J, et al. Prioritising the role of community health workers in the COVID-19 response. *BMJ Glob Health.* 2020;5(6).
42. Bhaumik S, Moola S, Tyagi J, Nambiar D, Kakoti M. Community health workers for pandemic response: a rapid evidence synthesis. *BMJ Glob Health.* 2020;5(6).
43. Partners in Health. <https://www.pih.org/pages/coronavirus-full-response>. Accessed November 15, 2020.
44. Peretz PJ, Islam N, Matiz LA. Community Health Workers and Covid-19 - Addressing Social Determinants of Health in Times of Crisis and Beyond. *N Engl J Med.* 2020;383(19):e108.
45. Rahman R, Ross A, Pinto R. The critical importance of community health workers as first responders to COVID-19 in USA. *Health Promot Int.* 2021;36(5):1498-1507.
46. Goldfield NI, Crittenden R, Fox D, McDonough J, Nichols L, Lee Rosenthal E. COVID-19 Crisis Creates Opportunities for Community-Centered Population Health: Community Health Workers at the Center. *J Ambul Care Manage.* 2020;43(3):184-190.
47. Bandura A. Health promotion by social cognitive means. *Health Educ Behav.* 2004;31(2):143-164.
48. Society TF. Mission. <https://fortunesociety.org/mission-statement/#:~:text=The%20Fortune%20Society's%20mission%20is,power%20of%20individuals%20to%20change>. Published 2022. Accessed 28 October, 2022.
49. Grillo L SD. *Mayor's Management Report*. New York City: Mayor's Office of Operations;2022.
50. New York's Prison Population Continues Decline, But Share of Older Adults Keeps Rising [press release]. 2022.
51. Corrections NDo. Inmate Lookup Service. <https://a073-ils-web.nyc.gov/inmatelookup/pages/home/home.jsf>. Published 2022. Accessed 28 October, 2022.
52. Corrections NYSDo. Incarcerated Lookup. <https://nysdoccslookup.doccs.ny.gov/>. Published 2022. Accessed 28 October, 2022.
53. Prisons FBo. Find an inmate. https://www.bop.gov/mobile/find_inmate/byname.jsp. Published 2022. Accessed 28 October, 2022.
54. Cepheid. Xpert® Xpress SARS-CoV-2. https://www.cepheid.com/en_US/tests/Critical-Infectious-Diseases/Xpert-Xpress-SARS-CoV-2. Published 2022. Accessed 28 October, 2022.
55. NYC.gov. COVID-19 Test Site Finder. <https://maps.nyc.gov/covid-testing/#/>. Accessed June 23, 2023.
56. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform.* 2009;42(2):377-381.
57. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care.* 1992;30(6):473-483.

58. Brazier J, Roberts J, Deverill M. The estimation of a preference-based measure of health from the SF-36. *J Health Econ.* 2002;21(2):271-292.
59. Vanness DJ, Lomas J, Ahn H. A Health Opportunity Cost Threshold for Cost-Effectiveness Analysis in the United States. *Ann Intern Med.* 2021;174(1):25-32.
60. Rosenberg ES, Dufort EM, Blog DS, et al. COVID-19 Testing, Epidemic Features, Hospital Outcomes, and Household Prevalence, New York State-March 2020. *Clin Infect Dis.* 2020;71(8):1953-1959.
61. Jing QL, Liu MJ, Zhang ZB, et al. Household secondary attack rate of COVID-19 and associated determinants in Guangzhou, China: a retrospective cohort study. *Lancet Infect Dis.* 2020;20(10):1141-1150.
62. Briggs A. Estimating QALY losses associated with deaths in hospital (COVID-19). <https://avalonecon.com/wp-content/uploads/2020/04/COVID-19-QALYs-v3.pdf>. Accessed November 30, 2020.
63. Rubin DB. Multiple Imputation after 18+ Years. *Journal of the American Statistical Association.* 1996;91:473-489.
64. Frimpong JA, D'Aunno T, Helleringer S, Metsch LR. Spillover effects of HIV testing policies: changes in HIV testing guidelines and HCV testing practices in drug treatment programs in the United States. *BMC Public Health.* 2016;16:666.
65. Kyle TL, Horigian VE, Tross S, et al. Uptake of HIV testing in substance use disorder treatment programs that offer on-site testing. *AIDS Behav.* 2015;19(3):536-542.
66. Aitken CK, Kerger M, Crofts N. Peer-delivered hepatitis C testing and counselling: a means of improving the health of injecting drug users. *Drug Alcohol Rev.* 2002;21(1):33-37.
67. Bajis S, Dore GJ, Hajarizadeh B, Cunningham EB, Maher L, Grebely J. Interventions to enhance testing, linkage to care and treatment uptake for hepatitis C virus infection among people who inject drugs: A systematic review. *Int J Drug Policy.* 2017;47:34-46.
68. Schwartz RP, Stitzer ML, Feaster DJ, et al. HIV rapid testing in drug treatment: comparison across treatment modalities. *J Subst Abuse Treat.* 2013;44(4):369-374.
69. Collica-Cox K. Female Offenders, HIV Peer Programs, and Attachment: The Importance of Prison-Based Civilian Staff in Creating Opportunities to Cultivate Prosocial Behaviors. *Int J Offender Ther Comp Criminol.* 2018;62(2):524-550.
70. Collica-Cox K. Counting down: HIV prison-based peer education programs and their connection to reduced disciplinary infractions. *Int J Offender Ther Comp Criminol.* 2014;58(8):931-952.
71. Cunningham WE, Weiss RE, Nakazono T, et al. Effectiveness of a Peer Navigation Intervention to Sustain Viral Suppression Among HIV-Positive Men and Transgender Women Released From Jail: The LINK LA Randomized Clinical Trial. *JAMA Intern Med.* 2018;178(4):542-553.
72. Schackman BR, Metsch LR, Colfax GN, et al. The cost-effectiveness of rapid HIV testing in substance abuse treatment: results of a randomized trial. *Drug Alcohol Depend.* 2013;128(1-2):90-97.
73. Du Z, Pandey A, Bai Y, et al. Comparative cost-effectiveness of SARS-CoV-2 testing strategies in the USA: a modelling study. *Lancet Public Health.* 2021;6(3):e184-e191.
74. Neilan AM, Losina E, Bangs AC, et al. Clinical Impact, Costs, and Cost-Effectiveness of Expanded SARS-CoV-2 Testing in Massachusetts. *medRxiv.* 2020.
75. Dubey P, Hoover CM, Lu P, et al. Rates of SARS-CoV-2 transmission between and into California state prisons. *medRxiv.* 2023.