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Full Length Article

The COVID-19 Self-Testing through Rapid Network Distribution (C-STRAND) trial: A randomized controlled trial to increase COVID-19 testing in underserved populations

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ABSTRACT

Background

Widely available population testing is critical to public health efforts to control the ongoing COVID-19 pandemic. However, COVID-19 testing has been low in underserved communities disproportionately affected by COVID-19. One approach to increase testing rates is through the secondary distribution of self-collection kits, where an individual distributes test kits to contacts in their social network and encourages them to self-collect test specimens. We outline a randomized clinical trial, COVID-19 Self-testing Through Rapid Network Distribution (C-STRAND), and a cohort study of individuals with COVID-19, to determine the impact of a secondary distribution strategy on COVID-19 testing among medically underserved populations.

The clinical trial will seek to enroll 1048 adult index participants from federally health qualified centers in Philadelphia, PA seeking COVID-19 testing. Eligible participants will be randomized 1:1 to receive multiple selfcollection test kits or multiple referrals for standard clinic-based tests to distribute to contacts within their social network. The primary outcome will be testing among at least two network contacts at 8 weeks. Index participants and network contacts who test positive for COVID-19 from C-STRAND will be eligible to join the COVID-19 Close Contact Self-testing Study (CloseST), assessing the secondary distribution of self-collection test kits among individuals with COVID-19. The primary outcome of this cohort will be the number of close contacts who test

positive at 8 weeks. Conclusion

Novel strategies to promote COVID-19 testing are necessary, particularly among underserved populations most affected by COVID-19. We will determine the efficacy of a self-testing secondary distribution strategy. The results may inform efforts to increase testing rates during the current pandemic.

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1. Introduction

1.1. Background

Widespread testing remains a critical tool to controlling and monitoring the COVID-19 epidemic. Since the beginning of the epidemic in early 2020, COVID-19 has disproportionately affected marginalized and medically underserved communities globally [1,2]. Significantly higher rates of infection and rates among Black and Latinx populations compared with White populations have laid bare existing racial health inequities in the United States [3–5]. In addition, social determinants such as community poverty and disability levels have been found to be associated with higher rates of COVID-19 mortality [6]. At the same time, in many parts of the United States, underserved communities of color have also had lower rates of testing and higher rates of test positivity [7,8]. Given the significant disparities in the impact of COVID-19, there is an urgent need to increase the reach of COVID-19 testing among underserved populations.

One promising approach to increase testing rates is the secondary distribution of self-collection test kits, where an individual distributes multiple test kits to contacts in their social network and encourages them to test. Self-collection test kits for SARS-CoV-2, the causative virus of COVID-19, offer an opportunity to expand the reach of testing efforts. Preliminary data show that specimen self-collection and handling is feasible and has excellent sensitivity and specificity [9]. A significant advantage of self-collection test kits is that it reduces the logistical burden and for some, increased privacy and reduced stigma associated with venue-based testing [10,11]. A secondary distribution strategy is grounded in social network principles, which hold that people within the same social network are likely to share similar risk profiles, and be more likely to trust and exert influence on each other [12,13]. This approach has been effectively leveraged to increase HIV testing to reach underserved populations who previously had limited prior testing [14-16]. By decentralizing testing, this approach does not require individuals to have contact with medical systems, and can lower potential barriers to obtaining testing. An additional benefit of secondary distribution is that it can enhance public health contact tracing efforts [17], as individuals with COVID-19 can distribute tests to close contacts. This approach can increase case detection by facilitating testing among exposed individuals, and potentially ameliorate stigma, fear, and medical mistrust associated with COVID-19 among vulnerable populations because the testing process is decentralized [18-20].

In this randomized controlled trial, we will examine the impact of the secondary distribution of self-collection test kits on COVID-19 testing among underserved populations. This trial is entitled COVID-19 Self-testing Through Rapid Network Distribution (C-STRAND, Clinicaltrials. gov Identifier NCT: 04797858). In addition, we will seek to enroll individuals who test positive in the C-STRAND trial into a cohort study to examine if a secondary distribution strategy can increase case identification among close contacts of infected individuals. This study is entitled the COVID-19 Close Contact Self-testing Study (CloseST, Clinicalt rials.gov Identifier: NCT 04847479).

1.2. Objectives

Our primary aim of this trial to determine if the secondary distribution of SARS-CoV-2 self-collection tests can increase test rates compared with a clinic-based test referral strategy. We hypothesize that the secondary distribution of self-testing kits will increase testing compared with a test referral strategy among social networks of underserved populations.

Our second aim is to determine, if among individuals with COVID-19 infection, secondary distribution of self-collection test kits increases case detection compared with a clinic-based test referral strategy. We hypothesize that secondary distribution of SARS-CoV-2 self-tests will identify more individuals with COVID-19 compared with standard test

referrals.

1.3. Trial design

The C-STRAND study is a 1:1 randomized control trial randomizing participants to receive either multiple self-collection test kits or multiple referrals for clinic-based tests to distribute within their social networks (Fig. 1). These individuals, called *Index Participants*, will be encouraged to distribute self-collection test kits or test referral cards to others in their social networks, called *Network Contacts*. Network Contacts can include household members, friends, family, colleagues, or others in Index Participants' social networks. We will evaluate COVID-19 test uptake among Network Contacts.

To achieve our second aim, the CloseST study is a cohort study of both index participants and network contacts diagnosed with COVID-19 from the C-STRAND trial (Fig. 2). Participants will then receive additional self-collection test kits or referrals for clinic-based tests to distribute to close contacts, based on their treatment assignment group from the C-STRAND trial. We will compare test uptake among close contacts of individuals with COVID-19.

2. Methods

2.1. Study setting

The trial will be conducted in Philadelphia in a collaboration between the University of Pennsylvania and Public Health Management Corporation (PHMC), a community organization that provides comprehensive services to underserved populations in Philadelphia. Participants will be recruited from Federally Qualified Health Center (FQHC) sites that serve underserved populations in Philadelphia, including individuals across the housing spectrum, individuals with HIV, viral hepatitis, and substance use disorders, Spanish-speaking immigrant populations, and other low-income communities. Together, the population mix is approximately 47% Black, 35% Latinx, 17% White, and 1% Asian.



Fig. 1. C-STRAND study flow and timeline.



Fig. 2. CloseST study flow and timeline.

2.2. Recruitment and eligibility criteria

Participants seeking COVID-19 testing will be recruited as Index Participants with the following inclusion criteria: at least 18 years of age, have a working telephone number, obtaining COVID-19 testing, and be willing and able to provide informed consent. Exclusion criteria will be self-reported prior COVID-19 infection. Individuals who are evaluated as having a medical emergency will be referred to emergency health services and will not be eligible to enroll. Network contacts must be at least 18 years of age, have a working telephone number, and be willing and able to provide informed consent. Index Participants and Network Contacts who test positive for COVID-19 during the trial will be eligible for enrollment in the follow-up cohort study.

2.3. Ethical approval and informed consent considerations

In order to minimize in-person interactions related to the study that may increase exposure to COVID-19, we will obtain informed consent through a two-stage process. If individuals call the clinic to schedule COVID-19 testing, study staff will obtain verbal consent over the phone to participate in the study prior to formal study enrollment, and complete the baseline survey at that time. Study staff will aim to collect most survey data over the phone prior to signed informed consent. At the time of COVID-19 testing at study sites, study staff will obtain signed informed consent from participants. Among study participants who obtain COVID-19 self-test kits, each test kit will include an online link to register the test kit and complete an online e-consent form. A hotline staffed by study staff will be available if individuals have questions or are unable to consent online. Study staff can then consent individuals using self-test kits and complete registration over the phone. This clinical trial was approved by the Public Health Management Corporation Institutional Review Board and the University of Pennsylvania Institutional Review Board.

2.4. Allocation

In the C-STRAND trial, we will use permuted block randomization with varying block sizes stratified by study site to assign Index Participants to receive multiple self-collection test kits or multiple referral cards for standard clinic-based tests. Investigators will have access to arm assignment on a need-to-know basis only, but participants and research assistants will not be masked with respect to study arm.

For the CloseST study, Index Participants and Network Contacts who test positive will be assigned to the intervention arm (receiving multiple self-collection test kits) or control arm (test referrals) according to their original assigned arm in the C-STRAND trial.

2.5. Intervention

2.5.1. Secondary distribution of COVID-19 self-collection test kits

Index Participants will receive five COVID-19 self-collection test kits at study enrollment to distribute to Network Contacts. Participants will be encouraged to distribute the test kits to individuals in their social network who are symptomatic, have a known exposure to COVID-19, or are otherwise perceived to be at high risk for COVID-19 due to potential exposures. Test kits will have a link to a study website which will guide test-takers through an online informed consent page and then onto a questionnaire. The participant will be provided a tutorial, list of drop-off sites and phone number to provide further assistance. Each individual will be offered follow-up care and counseling. Index participants will be asked to complete an online follow-up survey after 8 weeks.

2.5.2. Self-collection test kits

The intervention will use COVID-19 self- collection PCR test kits that have been authorized under FDA Emergency Use Authorization. Test kits use a mid-nasal swab that is sent to a central lab, with results returning in 24 to 48 h. Each kit includes a test swab, test tube, a prepaid return shipping envelope, and instruction sheet in English and Spanish.

2.5.3. Registration of test kits

Test kits must be registered online on the study website, and participants must consent to participate in the study to activate the test kits. Participants must provide a name, date of birth, and phone number to register test kits. If participants do not have access to the Internet, they may call study hotline and study personnel will obtain informed consent and register the individual online.

2.6. Control

2.6.1. Secondary distribution of COVID-19 test referrals

After confirming eligibility and completing informed consent, individuals in the control arm will complete a baseline survey. Thereafter, they will receive five test referral cards at study enrollment to offer free, facility-based COVID-19 testing at clinic sites for their network contacts. Participants will be encouraged to distribute referrals to individuals in their social network who are symptomatic, have a known exposure to COVID-19, or are otherwise at high risk for COVID-19 due to potential exposures. Each referral card will be assigned a unique referral number associated with the index participant. The index participant will be provided a text message with instructions that can be disseminated to his social network along with the referral cards. Test results will be released via phone call by study staff, and a paper or electronic copy of test results will be available upon request. Consistent with public health authority guidelines, multiple efforts will be made to contact participants with positive results. Each individual will be offered follow-up care and counseling. Index participants will be asked to complete an online follow-up survey after 8 weeks.

2.7. Follow-up

Index participants and network contacts who test positive for SARS-CoV-2 and provide verbal informed consent for the cohort study will have baseline surveys completed online or through phone. Index participants and network contacts from the treatment arm (exposed group) will be offered 3 additional self-collection test kits to distribute to close contacts. Index participants and network contacts from the control arm (unexposed group) will be offered 3 additional test referral cards to be distributed to close contacts. Test results will be released via phone call by PHMC staff. Each individual will be offered follow-up care and counseling by clinical providers of PHMC.

2.7.1. Measuring COVID-19 test uptake

In order to link Network Contacts who obtain COVID-19 tests to Index Participants, each Index Participant will be assigned a Referral Identification (ID) number. This number will appear on all test referral cards and text messages in the control group, and on test kits in the intervention group. When network contacts request testing, they will be asked to provide the Referral ID number linking them to the Index Participant. We will measure test uptake among self-testers through testing completed at the partner self-testing lab. Among facility-based testers, test uptake will be measured through testing at one of the clinic sites. Study personnel will communicate all test results back to study participants via telephone, with an electronic copy of test results available upon request.

2.8. Outcomes

The primary outcome in the C-STRAND trial is the proportion of Index study participants linked to at least two Network Contacts who completed testing. Secondary outcomes at the end of the follow-up (week 8) and end of the study by each arm include: number of contacts tested, number of network contacts who test positive, test positivity rate and proportion of first-time test takers. All of these outcomes will be assessed with collected testing results and not rely on self-reported measures. Baseline and follow-up surveys will provide self-reported outcomes related to socio-demographic characteristics as well as COVID-19 exposure, symptoms, testing, and vaccine acceptance.

For the CloseST study, the primary outcome is the number of close contacts who test positive in each group. Secondary outcomes at the end of the follow-up (week 8) by each group, include number of contacts tested and number of new cases identified. Similarly, baseline surveys of network contacts in the cohort study will provide similar self-reported outcomes as in aim 1.

2.9. Timeline

This study is estimated to last 24 months from recruitment to data analysis. We began enrolling participants in May 2021. The intervention phase will occur over 12 weeks per participant. All participants will be surveyed at baseline enrollment and follow-up at 8 weeks. Data analysis will follow completion of the intervention.

2.10. Sample size

The sample size for the C-STRAND trial was calculated based on the primary outcome of Aim 1. Power calculations were completed using STATA 15.1 (STATA Corp, College Station, TX). With an estimate that 45% in the control group achieve success, defined as at least two network contacts completing testing, we calculated a sample size of 1048 needed to detect a 10% difference (two-tailed alpha of 0.05, power of 90%). If in fact we observe a success rate as low as 25% in the control group, with a sample size of 1048, we will have 90% power to detect as small as an 8% difference (Supplemental Table S1).

For the CloseST study, we will aim to recruit up 210 study participants in the C-STRAND trial diagnosed with COVID-19. Data from the Philadelphia Department of Public Health shows that the median number of close contacts provided per individual with COVID-19 is approximately three [21]. Assuming the mean number of close contacts *infected* with COVID-19 is approximately one, and 50% obtain testing, we can expect the mean number of positive tests per index COVID-19 positive index participant to therefore be approximately 0.5. We assumed a conservative allocation ratio of 2:1 and estimated the standard deviation of the number of positive tests in the network of COVID- 19 positive index participants to be between 0.6 and 0.8. We considered a doubling from 0.5 to 1.0 new cases identified per positive index to be clinically significant. At the low end of the standard deviation range, we would need a total N = 54 for 80% power with a p = 0.05 (Supplemental Table S2). With a standard deviation as high as 1.0, we would need a total N = 192 to have 90% power to detect a difference between groups. A total of 210 individuals (representing a 20% positivity rate among Index Participants), even with a standard deviation of 1.0, would give us 93% power to detect a doubling of positive cases identified.

2.11. Data analysis

All analyses will be performed based on intention-to-treat. In the C-STRAND trial, the primary analysis will use the Cochran-Mantel-Haenszel test, adjusting for study site, to compare the proportion of individuals in each arm who succeeded in getting two contacts tested. Sex will be included with an interaction term in multivariable models using logistic regression. In secondary analyses, Wilcoxon Rank-sum tests and linear regression or negative binomial regression will be used to compare each of the count and continuous outcomes (e.g., total number of contacts tested).

In the CloseST study, we will use Poisson regression to compare the number of contacts who test positive at week 8 among contacts of SARS-COV-2 positive individuals who received the intervention or the control. Additional comparisons will follow the same approach for the secondary outcomes. Standardized mean differences (SMDs) > 0.1 will be used to determine balance between arms and identify potential confounders between participants in either study arm. If there is imbalance in the characteristics between the arms, additional analyses will consider potential confounders, including age, race/ethnicity, education, employment status, socioeconomic status, housing status, household size, relationship status, risk of COVID-19 exposure, and site of recruitment.

3. Discussion

Effective strategies are needed to increase testing among individuals at risk of COVID-19. This study will compare two strategies, distribution of self-collection test kits versus distribution of clinic referrals, to increase COVID-19 testing among underserved populations. We hypothesize that distribution of self-collection test kits will result in higher test uptake compared with a clinic referral strategy.

Although data on COVID-19 self-testing and self-collection of testing is limited, prior research on self-testing or self-collection for HIV and STI have demonstrated that these strategies are feasible and can increase testing [22–24], and may be applicable to expanding COVID-19 testing. In addition, a secondary distribution testing strategy grounded in social network principles has been shown to increase testing, particularly in marginalized populations such as sex workers and men who have sex with men [14-16]. Nonetheless, there are some key differences between COVID-19 testing and HIV/STI testing. One, indications for COVID-19 testing may be more dynamic in communities with high disease burden, and an individual may need frequent testing depending on their exposures. Second, because COVID-19 can be transmitted through respiratory and airborne contact, the number of potential contact exposures may be much greater among individuals with COVID-19 compared with HIV infection. Finally, with the development of safe, efficacious COVID-19 vaccinations, demand for testing may wane over time.

This complex study design was necessary to mitigate risks associated with COVID-19. Specimen self-collection offers one potential strategy to minimize infectious exposures to COVID-19 associated with facilitybased testing. Among individuals obtaining facility-based testing, we will attempt to minimize face-to-face interactions and obtain survey data over the phone. Finally, we will attempt to measure COVID-19 testing through tracking self-collection test kit use and clinic-based testing. Our strategy of tracking the relationship between the Index Participant and Network Contacts will allow us to directly measure testing among Network Contacts, rather than relying on self-report.

There are several limitations to consider in this trial. First, the study will not be able to track or incorporate test data from individuals who choose to get tested outside of the study. However, by measuring actual testing among network contacts through test registrations, we will be able to assess the comparative efficacy of the interventions at lowering barriers to access, and will not be affected by the limitations of a selfreported outcome. Second, individuals in the control arm using test referrals will be able to refer more people than individuals in the intervention arm who will only be given five home test kits. However, if this is the case, results will be biased towards the null hypothesis, so an observed difference would further support the intervention being truly effective. Finally, our study is focused on underserved populations within a single city, and findings may not be generalizable to other populations. However, the overarching goal of this study is to identify strategies to reduce health inequities with a focus on underserved populations.

In summary, this study aims to evaluate the secondary distribution of self-testing kits as a strategy to increase testing among underserved populations. If found to be efficacious, this intervention may be implemented in other regions where increased COVID-19 testing is needed for the current pandemic and may be applicable to future scenarios.

Declaration of Competing Interest

No competing interests declared.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cct.2021.106585.

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