Protocol Title:	Influencing Factors of COVID 19 Testing: Embedded Study 2022
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Population:	1280 individuals, Male, Female, 18+, general population sample drawn from the community through door-to-door outreach in Northeast Texas, Harris County and South Texas. We refer to this study as the embedded study, because it is embedded within a larger community-level intervention described below. A second piece of the study includes generating a snowball sample of a subset of questions for a social network study. We expect another 2560 people to respond to the social network survey over two layers of snowball sample recruitment.
Number of Sites:	Three sites: Houston, Lower Rio Grande Valley, Tyler, UT Houston is lead site of multi-site study
Study Duration:	Study will run from March 2023 - August 2023
Subject Duration:	Study participants will be enrolled, complete a baseline survey and participate in a brief educational intervention (for those in the intervention condition). They will be followed up by phone two months later. Study participants will also serve as seeds for the snowball sample. Participants enrolled through the snowball sample (alters) will complete a baseline survey only.

General Information

RADx-UP is an ongoing research study funded by the National Institutes of Health to address COVID-19 testing disparities in vulnerable populations. The goal of RADx-UP is to reduce the burden of disease in vulnerable populations known to be at increased risk of severe COVID-19 infection (e.g., those with

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medical comorbidities, homeless, racial/ethnic minorities, who live in rural communities). The focus of the main RADx-UP study is to examine COVID-19 testing to reduce infection transmission and prevalence. There are three sites (Houston, East Texas, and South Texas). The main study questions are being answered (approved under another IRB protocol) in a Randomized Control Trial (RCT) where priority block groups are randomized to one of three conditions: 1) Multi-Level Intervention (MLI) group; 2) Community JITAI + MLI group; 3) Control group. The outcomes of this study are measured at the population level and no individual data are gathered.

The proposed embedded study will build off this main trial with some adjustments to the design because of expanded research priorities to include factors influencing antigen testing. The intervention priority census block groups (PBGs) that received either form of intervention in the main trial will be combined into one pool of intervention PBGs for the embedded study. The control PBGs from the main trial will remain the pool of control PBGs for the embedded study. A sample of intervention PBGs will be randomly selected from across the three study regions and assigned to one of two intervention study arms. A sample of the control PBGs will be randomly selected from across the three study regions and assigned to the control condition. We will recruit and enroll individuals from the selected PBGs across the three arms using systematic sampling with a random start.

Background Information

Vulnerable populations in the U.S. experience significant COVID-19 disparities[1-4] and individuals with medical comorbidities have suffered disproportionately. Additionally, Hispanics are 1.5x more likely to be infected, 2.3x more likely to be hospitalized, and 1.8x more likely to die from COVID-19 compared to White, Non-Hispanics. Blacks are 2.4x more likely to be hospitalized, and 1.7x more likely to die.[5] The embedded study builds on our RADx-UP Phase I and Phase II work reaching these populations in three racially diverse regions: Houston/Harris County, South Texas, and Northeast Texas, leveraging the partnerships and resources of the Center for Clinical and Translational Science (CCTS) to increase SARS-CoV-2 testing, vaccination, and mitigation behaviors to reduce COVID-19 among underserved populations in Texas. The pandemic landscape and people's experiences with testing, infection, and vaccination have changed dramatically over the past two years. Vaccines have become available, testing access in local communities has waxed and waned, and attitudes toward COVID-19 severity and susceptibility have changed.[6]

Antigen self-testing kits are more available at this stage in the pandemic, but among vulnerable populations, use is still low[7] and instructions for antigen testing are not typically designed for low health literacy populations. Navigating the shifting testing-decision landscape is confusing to the public (test availability for free versus charged or requiring insurance; testing and vaccination locations change; PCR versus antigen testing; home tests versus clinically delivered; symptom-based testing, exposure-driven testing, serial testing, resources to trust or not trust, etc.). Studies are needed to explore access and use of antigen tests including serial testing among vulnerable populations and studies are needed to examine if low health literacy designed interventions improve COVID-19 testing decisions and completion behaviors.

The proposed embedded study will focus on understanding factors associated with *rapid* SARS CoV-2 testing, specifically.

Study Partners

This proposal leverages long-standing community partnerships and resources building specifically on the CCTS community engagement component and other community and organizational partnerships developed through several programs and projects across the three Texas regions. These Community

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Stakeholder Advisory Groups in each region ensure that bidirectional communication about COVID-19 and the study activities are responsive to community input and deemed culturally appropriate and impactful. Our partnerships, including those with local health departments and hospital systems, have enabled data sharing and analysis of surveillance data. New organizations, such as the UTHealth Institute for Implementation Science and Texas Epidemic Public Health Institute (TEPHI) will provide additional resources to enhance the proposed study.

Objectives

The primary objectives of the embedded study are to:

1) Determine the effectiveness of community level intervention using door to door recruitment and education in increasing COVID-19 testing.
2) Compare the effectiveness of the CHW- Facilitated Self-Sampling Intervention (FSSI) vs. CHW Testing Navigation Intervention (TNI).
3) Describe the relation between social networks' testing decision-making and behaviors.

Study Design:

RADx-UP Phases I & II. (The parent studies) We are completing a three-arm group-randomized trial to assess the impact of multi-level interventions influencing motivation and access to testing: Arm 1) Just-In-Time Adaptive Intervention (JITAI) where we meet regularly with community partners and exchange community-specific information about COVID-19 (testing, infection rates, etc.). Arm 2) Standard Multilevel Intervention (MLI) that reaches individuals and activates organizations to provide COVID 19 testing and information. Arm 3) Standard care control. We randomized 120 PBGs identified as communities with high levels of disparities across our three geographic regions to each condition using a covariate adaptive Randomization (Minimization) Schedule.[8-10]

Embedded study Random Selection of PBGs: For the proposed embedded study, we will combine the two intervention arms into one MC-JITAI Intervention pool of 80 PBGS (shown in the figure below) and from there randomly select 32 PBGs to one of two intervention arms. The individuals who live in these respective PBGs will be systematically sampled using a random start procedure to recruit and enroll individuals to participate in the study. From the pool of 40 control PBGs, we will enroll individuals from 32 randomly selected PBGs. We will also systematically sample using a random start procedure to recruit and enroll individuals for the embedded study from the control arm.

From the MC-JITAI arm randomly assigned 32 PBGs, 16 PBGs will be assigned to Facilitated Self-Sampling Intervention (FSSI) and 16 PBGs to Testing Navigation Intervention (TNI). The PBGs will be selected from Harris/South Texas/NE Texas region in the rate of 2:1:1, that is, 16 PBGs of MC-JITAI arm in Harris, 8 in South Texas and 8 in NE Texas. Among the 32 PBGs in the control arm, all will remain in the control group. The allocation between the three regions will also be at the 2:1:1 rate.

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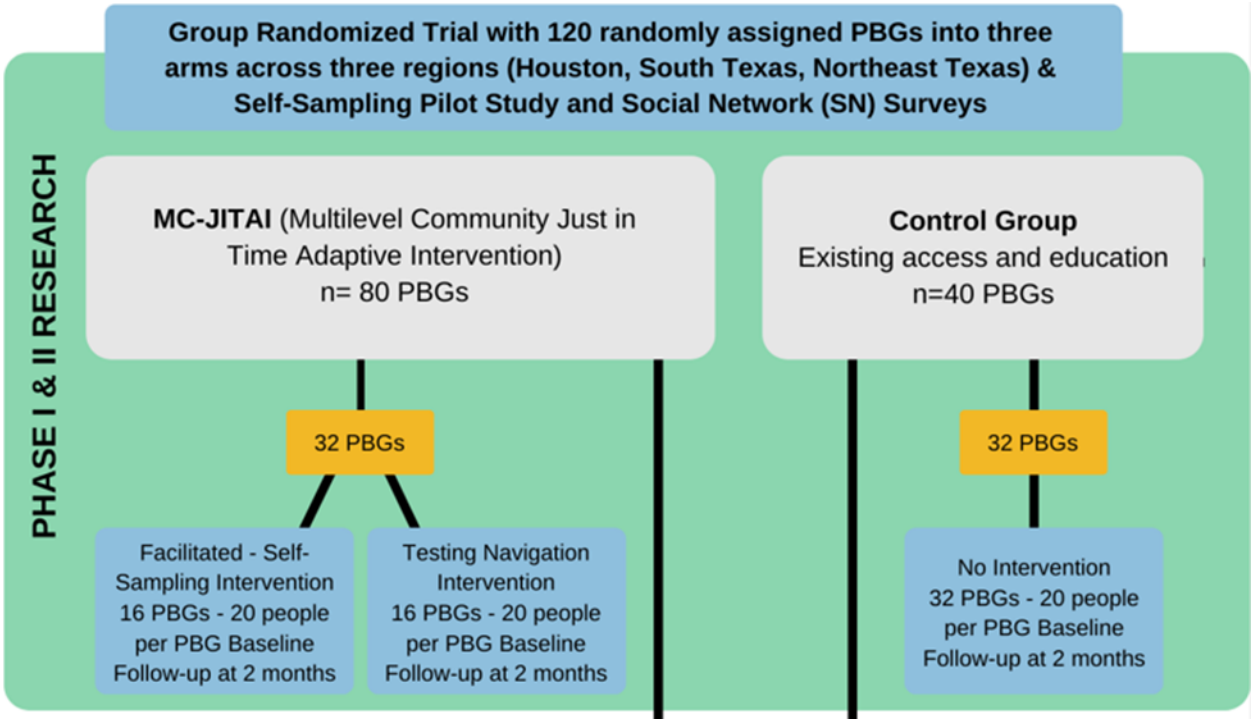

Random Selection of individuals within the PBGs:

Participants who live in a PBG randomized to one study arm will be invited to participate in the trial for that arm. Participants who live in a PBG randomized to the other study arm will be invited to participate in the trial for that arm. Participants who live in a control PBG will be invited to participate in the pre and posttest survey only. In each of the selected PBGs, 20 individual persons will be systematically sampled with a random start as described below under sample selection.

Study Population:

Across the study arms, we will recruit up to 1280 individuals as primary enrolled individuals in the embedded study. Another part of the study will include generating a snowball sample for a social network analysis study who will complete a survey. The snowball sample will involve our primary enrolled participants identifying alters to generate additional individuals who are asked to complete a tailored survey (detailed below). We expect the snowball sample to include up to another 2560 people.

Inclusion/exclusion criteria. In this embedded study, the inclusion criteria for the primary enrolled individuals includes being aged 18 years or older. The exclusion criteria will include: (1) having been diagnosed with COVID-19 in the past 30 days based on a positive test (antigen or PCR) or a clinical diagnosis, (2) having tested for COVID 19 with PCR or antigen test within the past 30 days. The inclusion criteria for the social network survey of alters will only require that participants are 18 years or older.

Selection of the study population. Three large regions of Texas: 1) Houston/Harris County; 2) Cameron County in South Texas; and 3) seven counties including the city of Tyler in Northeast, Texas. The

communities prioritized in this proposal include populations with medical comorbidities, and underserved Hispanics and African Americans in three racially diverse regions: South Texas, Houston/Harris County and Northeast Texas. All regions are experiencing crisis-level surges in COVID-19 cases and fatalities.

Primary and Secondary Outcome Measures:
The pre-post surveys will assess the following behavioral measures:

1. Primary Testing Outcome: COVID 19 testing (antigen or PCR).
2. Secondary Testing Outcome: appropriate use of antigen test defined as when a test should have been taken per CDC guidelines (symptoms, known exposure); - Measures address when and why home test administered; proper use could be assessed (of the test)
3. Secondary Outcomes: Mitigation measures if a positive test is obtained including: mask wearing, isolating, and notifying close contacts.
4. Secondary Outcome: Sharing antigen tests with close contacts who need to test
5. Social Network Outcomes: COVID-19 testing behavior, COVID-19 vaccination status
6. Social Network Secondary Outcome: PBG residents' egocentric networks influence on testing and vaccination attitudes and behaviors
7. Social Network Secondary Outcome: Social capital within social networks to influence COVID-19 testing, vaccination, and mitigation behavior

Embedded Study Survey: Project personnel will use the survey platform NetCollect survey software to collect the embedded study survey responses from the participants who consent. The survey instrumentation is designed to capture all relevant demographic characteristics, personal history regarding COVID-19 infection (self, others), testing and vaccination behavior, psychosocial determinants for testing and vaccination behavior, and a network analysis survey battery. This survey is composed of all RADx Common Data Elements (CDEs) required by our funder, survey measures taken or adapted from extant COVID-19 health promotion research for the RADx Phase I 2-1-1 survey, and from published empirical social network research to capture respondents' social networks, their community engagements, and the degree of social capital nested therein. An additional survey question will ask about the organizations from which they've sought and received services and care, which will permit us to connect Phase II data to organizational network data collected for Phase I to illuminate the existence of resources which serve as nested capital which may be accessible to extended social networks.

Summary of Embedded Study Survey Constructs

Measures / Constructs	Questions	Citation/Tool
Testing behavior	Testing for COVID 19, ever tested, last 30 days, positivity, access to testing	Funder required items, Novel items
COVID-19 history	COVID 19 sickness, hospitalization (self or others)	Funder required items, Novel items
Intention to test	Likelihood of testing (ever, 30 days), intention to test as needed	Funder required items, Novel items
Self-efficacy to test	Certainty of ability to be tested given situational contexts	Adapted self-efficacy measures following Maibach (1995)[11]

Pandemic safety behaviors	Wearing masks in private settings, wearing masks in public settings, washing/sanitizing hands, intentional social distancing (Never, some of the time, very often, all of the time)	Adapted for CEAL Program from Center for Economic and Social Research Understanding America Study Coronavirus Tracking Survey . https://www.phenxtoolkit.org/covid19/source
Vaccination	Vaccine uptake, type, doses	Funder required items
Trusted Sources of Information	Sources of information (doctor, media, health department, etc)	Funder required items
Barriers to testing	The costs of the COVID 19 test would prevent you from getting your vaccine? Transportation to the testing site would prevent you from getting your vaccine?	Novel items
COVID-19 Perceived Susceptibility/Severity	How concerned are you about contracting COVID 19? How likely is it that you will get COVID 19?	Savoia E. et al, 2021[12]
Egocentric Social Network and Network-based Social Capital	Name generator questions (communication, support), strength of tie, types of support, organizational support	Hao, F., Shao, W., & Huang, W. (2021)[13] Optimise Study (Dr. Peng Wang) Elgar et al., 2011[14]; Elgar et al., 2021[15]; Trent et al., 2021[16]

Study Procedures

Sample Selection via Systematic Sampling with Random Start

Study personnel will approach each PBG randomized to the study by mapping all streets in the selected PBG using Google maps. On each PBG map they will create four quadrants and a center point of the PBG. The quadrants will be numbered 1 - 4, and a random number generator will be used to select the order in which quadrants will be attempted for enrollments. Using this as a guide, study personnel (CHWs) will begin at the center point and walk the premapped streets moving outward and through the quadrants. Every 4th house will be approached for study participation. If there is no answer or if the residents do not wish to participate in the study, the 5th house will be approached, and again if no enrollment then the 3rd house. After these three houses are approached, the CHW will move forward to the next trio of 8, 9, 7 and so on recruiting participants until a total number of 20 participants are recruited. We expect that the 20 participants could come from any or all of the 4 quadrants. The CHWs will work in teams. One member of the team will work one side of the street and the other will work the other side of the street, both following the same sampling protocol. There may be occasions when it is appropriate that both team members work the same side of the street approaching the same houses

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together. Each attempt, successful or unsuccessful, will be recorded on a tracking sheet with items such as date and time attempted, address, identifying characteristics of households approached, whether individuals fit the inclusion and exclusion study criteria, whether individuals consented to the study, reason for refusal or no answer, whether the survey was completed, whether Wi-Fi was available, dosing of the intervention components and barriers to visit completion.

Consent

CHWs will approach each house identified using the sample selection procedure described above with scripted information describing the research study, eligibility criteria, the embedded study survey, the intervention (except control PBG), and the incentive for participating. If the resident is interested, the individual's eligibility of individuals in the household will be determined using a brief screening based on inclusion criteria described above. Participation will be limited to one person per household. If more than one individual in the home is interested and is eligible to participate, the person with the nearest birth date to the date of enrollment will be enrolled. Upon confirming eligibility and which household member will be enrolled, CHW will review the informed consent form (Attachment 1) on paper copy or electronically and acquire the individual's signature confirming consent. The individual will receive a paper copy of the consent or receive it electronically for their records.

Recruitment

The participant's consent will be documented in NetCollect survey software that was developed by SNA Toolbox Pty Ltd with a field for the participants' finger-point signature and the date that informed consent was confirmed. Once the participant's consent is confirmed, study personnel will administer the baseline embedded study survey. The baseline survey includes part A which is completed at the actual time of enrollment. There is also a part B of the survey which will be sent to the participant electronically so that they can complete those items at their convenience. The study staff will record the responses to part A of the survey for the participants into the NetCollect platform on a The University of Texas Health Science Center at Houston (UTHealth) secured device. If the participant was recruited from a PBG assigned to the control condition, study personnel will give the participant their incentive (reloadable gift card) and collect a signature on the incentive receipt form after the embedded study survey part A is complete. If the participant was recruited from a PBG assigned to either the FSSI or TNI intervention arms, study personnel will proceed to deliver the intervention after part A of the survey is complete. If the participant does not have time to complete the intervention and baseline survey part A at the initial home visit, study personnel will make an appointment to either return within 7 days or offer to complete the survey option virtually but deliver the intervention in person. The entire visit (introduction, screening, survey and intervention) may take up to 1.5 hours.

Upon completion of the baseline survey part A and intervention, the participant will receive the first incentive card valued at $50. Study personnel will also make an appointment for the 2-month follow-up post survey to be conducted by phone, and obtain contact information to follow up throughout the 2-month period and send a reminder of the 2-month follow/up appointment. Study personnel will count out 8 weeks from the initial home visit and will schedule the post-survey appointment within a range of +/- 14 days from that date. The week and day prior to the post-survey appointment, study personnel will send reminders. The phone-based post-survey will take up to 30 minutes, and the participant will be issued a

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second incentive card valued at $35 for their participation in the post survey, which will be mailed or emailed to the participant by study personnel if the follow-up was done via phone. If participant prefers, the follow-up appointment can be completed in person instead of over the phone and the incentive will be given in person as well.

Social Network Survey of Alters Data Collection

The embedded study participants will serve as "seeds" for a snowball sample recruitment approach. These embedded study "seed" participants, as part of the baseline survey part A will nominate alters who are in the "seed" respondents' social networks to complete a survey. Specifically, the network analysis survey battery completed by embedded study participants will describe the social ties among friends, family, and co-workers, composing communication networks through which individuals may access COVID-19-related services and support. The individuals comprising the alters / seeds' social networks (i.e, network members) are then contacted to complete a survey (1st snowball layer). Survey respondents comprising the 1st snowball layer will in turn nominate persons in their own social network who are then contacted to complete only Part A of the survey (2nd snowball layer). Individuals in each additional layer of the snowball sample will be contacted using the NetCollect survey software, which automatically forwards the survey through email and text-messages soliciting participation (Attachment 2) and providing a consent (Attachment 3). We will attempt to contact the participant twice via email and/or SMS before project staff attempts to call the participant to complete the survey over the phone. If twice the participant does not respond to complete the survey or to confirm that they will complete the survey on their own, the participant will be regarded as "lost to follow-up". Note that each household is a single node in the network, and while each seed can nominate and provide contact information for any individual in any number of households, they are limited to nominating one person per household. The participants of the social network survey of alters will receive an electronic gift card as an incentive valued at $25.

Project Materials

Intervention Arms:

Facilitated Self-sampling Intervention (FSSI): CHWs will consent and enroll participants to the FSSI from the randomized PBGs. FSSI will consist of Community Health Worker (CHW) delivered education intervention about COVID-19 testing at a home visit utilizing a brief motivational interviewing approach enhanced with preparedness communication messaging. In addition, the participant will receive a batch of 6 rapid antigen tests that can be shared with people in the household or other close contacts if needed. The CHWs will provide low-literacy instructions for administering the tests, including video and may include print. The CHWs will also provide guidance if they tested positive (e.g. quarantine, notify contacts, wearing a mask). The CHWs will also be available by phone to the participants for any follow-up questions. CHW will follow up via text, email and/or phone with the participants during the two months post-intervention. In addition to the intervention, the participants will be asked to complete the pre and post test surveys. Post surveys will be administered online, over the phone, or in person two months after the initial intervention.

Testing Navigation Intervention (TNI): CHWs will consent and enroll participants to the TNI from the randomized PBGs. The TNI will consist of CHW-led intervention at a home visit utilizing a brief motivational interviewing approach enhanced with preparedness communication messaging. They will provide low health literacy materials about how and when to conduct a COVID 19 test (including antigen and PCR) using a photonovela story and resource flier that provide navigation to nearby PCR testing

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sites, and locations to purchase antigen tests. In addition to the intervention, the participants will be asked to complete the pre and post-test surveys. Post surveys will be administered over the phone, or in person two months after the initial intervention.

Control Arm:

Control PBGs: Participants in the control arm will receive an initial visit in person that includes consent and enrollment and will receive one follow-up visit by phone. The in-person visit will include an explanation of the study, consenting procedures and survey administration part A, with an electronic link to part B. Rather than an intervention, the participants will be reminded that the CDC website provides information on COVID 19 testing. The visit may last up to 30 minutes. The follow-up visit will be by phone and will consist of survey questions (administered by study personnel by phone). IRB approved study incentives will be provided for the in-person visit and the follow up phone visit. The information provided in response to the surveys will be electronically captured on a UTHealth secured device by the staff member at the door using the survey platform NetCollect.

Ethics

Participants will be approached at their home for enrollment. The trained community health workers will explain the study generally and ask if the participant would like to hear more about the study. If so, the community health worker will review the consent document and answer any questions. The participant will decide whether or not to participate and sign the documents indicating consent. A copy of the consent will be provided to the participant. The consent forms will be stored separately from the data to protect the privacy of the subjects. A unique identifier will be created to link the baseline and follow-up surveys.

The protocol for this study will also be reviewed by UTHealth - Tyler as several investigators are from this institution and one of the three study sites is in the East Texas / Tyler region.

Data Management and Security

NetCollect

NetCollect is a survey platform with an architecture capable of housing social network datasets, and is designed to facilitate snowball sample enrollment, data collection, and follow-up. Community health workers and project staff will use the survey application NetCollect survey software while in the field to track recruitment for the embedded study and to collect survey responses from enrolled participants. The decision to use NetCollect reflects the need for a survey platform suited to administer social network survey instruments, which is capable of housing social network datasets, and which is designed to facilitate snowball sample enrollment, data collection, and follow-up.

NetCollect is a web-based application developed by SNA Toolbox Pty Ltd for building and managing online surveys designed for collecting social network datasets and other data. (https://collect.optimisecovid.com.au/login) The platform consists of two virtual machines deployed on two servers. A front-end user interface (VM1) is deployed on a web server which is connected to a back-end data server (VM2) to assure data security and database integrity. Both VM run Oracle, a Linux distribution. For this project, both the front-end and back-end servers will be hosted on two servers

deployed by the Information Technology (IT) department at UTHealth, housed on-site at UTHealth's facilities in Houston. Both the front-end server and the back-end server will be protected behind a firewall maintained by UTHealth IT, and data will be backed up once every two days. As the data collected using NetCollect is hosted within UTHealth's own servers, no project data ever needs to be transmitted at any time between institutions or organizations.

Penetration tests for the NetCollect platform has been conducted by SNA Toolbox and the Swinburne Cybersecurity Laboratory to ensure the security of the data stored in NetCollect's back-end database, the software application employs various methods to protect against malicious users who may attempt to identify and exploit any security vulnerabilities in the system. Such methods will be described here in technical detail. In NetCollect, all incoming data gets intentionally filtered, sanitized, and escaped. This includes all data submitted in an HTTP Post request and all query string data found in every URL while accessing NetCollect, among other modes through which user-defined data gets submitted in the application. Server environment variables that are vulnerable to forgery by users are also checked and sanitized. All user-submitted data is properly filtered for any possibly harmful mark-up tags (e.g. <script>) and is then escaped before ever being displayed on a web page within the application. SQL queries sent to the database server from NetCollect are all properly escaped before being sent. User-defined data used within SQL queries also have their data type checked to prevent any mismatching of data types (e.g. making sure a number is really a number). These processes of sanitization, filtering, data type checking, and escaping all help to protect against methods of attack, such as Cross-Site Scripting (XSS) and SQL Injection. To specifically protect against Cross-Site Request Forgery (CSRF), which is another method of attack, NetCollect utilizes a "nonce" (a secret, user-specific token) on every web form used in the application. The nonce is generated anew on each web page as the user navigates within NetCollect during a session.

SNA Toolbox Pty Ltd will handle application deployment on UTHealth servers via SecureLink, managed by the UTHealth Information Technology department. Anytime SNA Toolbox remotely accesses UTHealth servers through Securelink for application and database maintenance, users accessing the servers through SecureLink, the research coordinator managing the survey platform receives an email documenting the remote users' activities.

Data Collection

The front-end web app will be accessible to external users on the UTHealth School of Public Health web domain at https://NetCollect.sph.uth.edu. Project staff will be provided login credentials specific to their role. For instance, the research coordinator for the survey will have full administrative control over the local application and datasets stored in the back-end server, including the ability to create new projects, modify project components, adjust the survey programming, and export survey results in various formats at any time. "Lead" users will be able to initiate surveys, open and close surveys for editing, and send reminders to participants automatically via phone or email. "Leads" will also be able to track the progress of other projects, staff during "Interviewers" will be able to navigate the application to administer surveys, and to track recruitment following the procedures described above.

The project coordinator responsible for NetCollect will perform quality assurance and quality control checks on the database collected on a weekly basis to identify inconsistent data points, missing data, and incomplete data collection.

Two forms will be prepared for each region. One form will be to administer and collect the embedded study survey among enrolled participants (Attachment 4), and will be initiated by project staff in-person upon enrollment. While the embedded study survey will be initiated in-person, the participant will also be emailed or texted a link to their unique survey form, and may be completed on their own. The second survey will be the embedded study snowball survey of alters, which will be administered to individuals recruited through the snowball sample, sent to them through text or email. (Attachment 5) We will also use NetCollect to administer follow-up surveys two months after the participant completed their first survey, which will be done during a phone call or in person with a staff member who records the responses. After multiple attempts to complete the survey via phone or in person, we will reach out to the study participant with a secondary option to complete the follow-up survey via email or text message.

All surveys initiated in NetCollect will have a unique survey identifier for the individual participant and the region where the survey is taking place and will be automatically anonymized. Embedded study survey responses will also be iterated with proper data points identifying the census block group where the participant was recruited.

All recruitment data and survey data collected for the embedded study will be recorded and maintained within NetCollect. In addition, because of funder requirements, all survey data, except the social network survey data, will be uploaded to a database in the Research Electronic Data Capture (REDCap) at UTHealth. REDCap is developed by experts at Vanderbilt University with partial funding from NIH. This free data capture system is fully compliant with the regulatory requirement by FDA.[17,18] This dataset will include the funder required RADx Common Data Elements (CDEs) and additional measures assessing the primary outcomes of testing behaviors and their psychosocial and socioeconomic determinants. Additional quality assurance and quality control procedures will be completed on the CDEs per funder requirements and then uploaded on a regular schedule to the RADx-UP Coordination and Data Collection Center (CDCC). The data will then be shared with the Duke Clinical Research Institute ("DCRI") in North Carolina. Duke was chosen by the NIH to hold the data from all RADx-UP studies. Duke will keep these non-identifiable data in a secure database for COVID-19 research at the NIH.

We are handling the data management and monitoring according to Good Clinical Practice Guidelines. This will ensure we meet the ethical and scientific quality standard for conducting trials (GCP) guidelines.[19-21] The principles of GCP help to ensure the quality and consistency of trial/study operations and data and may result in increased costs.[21]

Data Monitoring and Data Management Quality of a clinical trial study ultimately is dependent on the integrity of the data collected during the study. Well-organized and reliable data are critical to the success of a study. Data management procedures are performed to maintain data integrity and to ensure the data generated during the study will arrive at the same conclusions and interpretations equivalent to those derived from clean data. This process includes; 1) Data Monitoring, 2) Data Cleaning, and 3) Quality Control checks to ensure that the error rate is acceptable.

1) **Data Monitoring:** We will regularly conduct data monitoring to identify potential discrepancies in the data and communicate with staff to resolve the discrepancies. The primary focus for data monitoring is critical to protect human subjects, maintaining the integrity of study data, and compliance with applicable regulations. We will be devoted to assessing the critical study data and processes and evaluating significant risk and potential site non-compliance. We will identify data entry errors and missing data. A data monitoring report will be sent to the research

coordinator and the PI. The monitor should follow-up with the site staff to ensure that the issues raised by the monitor are addressed in a satisfactory manner. The recommendations provided by the monitor are meant to ensure compliance and data quality and improve site practices that could result in inadequate human subject protection and/or poor data quality.

2) **Data Cleaning:** Data cleaning activities will include; a) developing and running various rules to identify potential anomalies in the data submitted by the sites, b) creating an Edit Check Program (ECP) is created in SAS that check for missing data, implausible data (that which complies with the codebook but is not in the range/suspect), improbable data (potential outliers' lab values (Mean±5SD)), or for other measurements with normal distributions (Mean ±3SD). For skewed distributions this could vary between 4 SDs and 5 SDs, impossible data (does not comply with the codebook /incorrect), and c) protocol deviations. The ECP will also look for missing and discrepant data. The list of missing and discrepant data will be communicated to the research coordinator and the PI and sent for further checking/correction; any corrected data will again be entered into the database. Data cleaning will be done periodically (biweekly/monthly) until the errors are amended as an iterative process.
3) **Missing data**: Every effort will be made to keep all participants in the study and to obtain required data at each scheduled time point. All information for patients who dropped out from the study will be recorded and stored in the database. Traditional regression techniques usually assume that all data are complete and will produce unbiased estimates and valid inferences under missing completely at random (MCAR) assumption. We will examine drop-outs, missing data and measurement errors which are common problems with longitudinal data structure to be able to identify accurate missing data mechanisms and patterns so that we can select the best statistical approach among those formal missing data methods such as joint modeling, inverse probability weighting equation method, multiple imputation, and semiparametric models. If the missing data are non-ignorable/informative in the sense that missingness may depend on the missing observations, modeling of the informative missing data or dropout processes will be required. An attempt will be made to incorporate the missing values mechanism into the model as discussed in Little and Rubin.[22] Sensitivity analyses under various missing data mechanisms will be also conducted to verify if the underlying assumptions are met. All Analyses will be performed primarily using widely available tools in SAS® version 9.4 (SAS Institute, Cary, NC)[23] or R[24], at a significance level of 0.05.
4) **Quality Assurance (QA) & Quality Control (QC) Procedure** Upon completion of resolving discrepancies in data entry, data cleaning, the data quality control process will be initiated. In the QC process, we will select critical variables that determine safety/effectiveness that will be used in statistical analysis. The resulting discrepancies will be adjudicated in the presence of the clinical team and RDCC.

Data Safety and Monitoring Board (DSMB) If needed, a Data Safety and Monitoring Board will be established to oversee the conduct of this study to ensure participant safety and quality of the data. The DSMB would be convened to monitor activities conducted at all intervention and control sites, and to oversee data collection and implementation at all community and clinic organizations. The functions of the DSMB could include the following: 1) To review and approve a plan for data quality assurance and safety monitoring for this trial, 2) To review data on a timely basis, to ensure proper conduct and progress of the study, 3) To review credentials of all project staff and consultants with relation to data quality and safety, 4) To make recommendations to project investigators and staff regarding issues of concern, 5) To review and address any adverse events, 6) To review and address any potential ethical issues, 7) To

approve any changes made in response to recommendations made by the DSMB, and 8) To alert NIH to any concerns that are not properly addressed by the study investigators.

Statistics

Statistical Analysis - Embedded Study Primary Outcomes. The primary outcomes of the embedded study will be examined with the following analysis plan. We will conduct intention-to-treat (ITT) and according to protocol (ATP) analyses for all testing outcomes. We will use Fisher's Exact Test to assess statistical differences in participation between arms on testing completion (primary outcome). We will use Generalized Linear Mixed Modeling (GLMM) with participant-level data to evaluate differences in effectiveness between arms, and conduct a modified ITT analysis of the effectiveness of FSSI and TNI that considers all eligible participants as the denominator. Secondary analyses will examine the relation between knowledge, attitudes, and intentions on testing decisions and we will use GLMM to evaluate the effect of these predictors.

To examine the reach and effectiveness of the conditions we will examine how many participants enroll vs invited, accept the testing batch, complete the intervention sessions, use tests from the batch (#), are navigated to federal tests, complete PCR or antigen tests from any source during the 2 months post intervention, share tests with close contacts during the 2 months post intervention. The primary research question compares testing outcomes by FSSI and TNI conditions to control arm.

Sample Size for Embedded Study. We have powered the panel study to detect a difference of cohen's size as small as 0.2, with statistical power of 95% with Type-I error of 0.0.5. With a conservative estimate of lost to follow-up rate of 15%, we will have 90% power to detect a cohen's effect of 0.2. The estimated power will reduce to 85% if the lost to follow-up increase to 30%, but remain sufficient for this study.

Statistical Analysis - Social Network Study.

Network analyses will be centered on individual respondents living in PBGs assigned to either the control or MC-JITAI intervention conditions in order to explore the reach of intervention effects disseminated through multilevel COVID-19 communication networks. The effect of social networks on COVID-19 preventive behaviors will be used to compute intervention performance indices, modeling outcomes using traditional regression-based models and statistical models for snowball sampled networks, namely exponential random graph models (ERGM) and auto-logistic actor attribute models (ALAAM)[25,26] that are capable of modeling both intervention outcomes and multilevel network structures simultaneously. Comparing ALAAMs between the control and intervention group will reveal the impact on how outcomes and attitudes/intentions are defused at the community level and provide a detailed assessment of how the intervention affected egos, immediate networked neighbors (i.e. alters), and alters' alters who may be exposed to the intervention indirectly. This provides assessments on the "reach" (or the depths) of the intervention impact.

For snowball sampled network data in all regions, MC-NET-JITAI participants' network structural characteristics will be used to model the impact of social networks on intervention outcomes. The snowball sampling approach will collect data towards local social structures and enable computation of social influence models, or auto logistic actor attribute models (ALAAM), which can apprehend the reach of intervention outcomes that may spread through networks of social ties. Our use of ALAAMs will combine inter-organizational network data collected in Phase I of the main study and interpersonal

network data collected in Phase II as part of the embedded study to derive networks of their mutual affiliations for multilevel network models capable of assessing the diffusion of intervention outcomes through multi-level networks. Analytical results for each region are largely made by comparing MC-JITAI only data versus MC-NET-JITAI data, each of which is compared with the control data (i.e., participants are randomly recruited).

Resource Sharing. All unique research resources developed as part of the proposed collaboration between the UTHealth, the University of Texas Health Science Center at Tyler (UTHSC-T), and other project partners will be made available to the public upon request at the end of the grant period. Examples include models for dissemination, recruitment and data collection protocols, and study instruments. All requests for research resources should be sent electronically to the primary PI.

Data Sharing. We recognize that the funder requires the RADx-UP testing intervention projects to use rapid scale-up of rigorous research strategies and integrate data collected across the sites to maximize improvements in public health control of the pandemic. Thus, to the extent possible, data acquisition, collection, and curation strategies will be coordinated with the CDCC guidance for annotation and benchmarking of data, including obtaining appropriate consent for data sharing. A data-sharing plan will apply to qualitative, quantitative, and process data collected during the research studies. Project study staff will make RADx-UP intervention data available after the primary findings manuscript is accepted for publication or 18 months after Phase II study completion, whichever occurs first. The guidelines for data sharing and use of multisite data in our region will be used for sharing data by the participating site in our proposal. The complete study data files, with sufficient data documentation for proper analysis, will be made available to the public on a secure website requiring password identification for access. The final datasets will be stripped of all personal identifiers prior to release for sharing, but to ensure confidentiality of all participants, and that the data are used only for research, we will also require a data sharing agreement that provides for: (1) a commitment to using the data only for research purposes and not to identify any individual participant; (2) a commitment to using best statistical and ethical practices in analyzing and reporting finding; (3) a commitment to securing the data using appropriate information technology; (4) a commitment to crediting the source and the funding agencies of the original project in all publications and presentations; and (5) a commitment to destroying or returning the data after analyses are completed.

Publication Plan: The following guidelines have been established by our project, through a publication committee, for requesting data and for the utilization of data.

General Guidelines:

1) Data requested must be for the purpose of performing research and publishing the results. Any extrinsic use of this multisite data must be approved by our publication committee, including abstracts, manuscripts, public presentations, and preliminary data in grant applications.

2) The Publication Committee will review all proposals to ensure absence of conflict with previously approved proposals, determine merit, and record the date and the approval of proposals. Members of the publication committee will also have the opportunity to voluntarily assist with the proposed research and form a writing group.

3) The electronic dataset files will be stored in a confidential manner on a password-protected computer in a locked office or in a locked file cabinet in a locked office so as to protect the confidentiality of subject information, if applicable. Multisite data will not be released to individual PIs without written consent of all other site PIs who contributed data to the multisite data.

4) Errors and uncertainty are inherent in all data and any errors may affect the final results and research findings. For this reason, any data discrepancies or anomalies identified during data management and analysis can address these issues, maintain the quality of all data.

ATTACHMENTS

1. Consent document for embedded study
2. Email and SMS Invitation to Complete UTHealth Survey for Alters
3. Consent Document for the Snowball Survey of Alters
4. Survey of Primary enrolled participants in the Embedded Study
5. Survey of Alters forming snowball sample

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