Increasing COVID-19 testing and vaccination among Spanish speakers in the USA: protocol for the development and evaluation of the Nuestra Comunidad Saludable intervention using a group-randomised trial design

Scott D Rhodes, Amanda E Tanner, Lilli Mann-Jackson, Jorge Alonzo, Mark A Hall, Alain G Bertoni, Thomas P McCoy, Sandy K Aguilar-Palma, Manuel Garcia, Daniela Miranda, Mari Jo Turner

ABSTRACT

Introduction Our community-based participatory research partnership aims to expand understanding of the social, ethical and behavioural implications of COVID-19 testing and vaccination to inform the development of an integrated intervention that harnesses community-based peer navigation and mHealth strategies to improve COVID-19 testing and vaccination; test the intervention; and develop and disseminate practice, research and policy recommendations to further increase COVID-19 testing and vaccination among Spanish-speaking Latine communities in the USA.

Methods and analysis We will conduct 50 individual in-depth interviews with health providers, who have conducted COVID-19 testing and/or vaccination activities within Spanish-speaking communities, and with representatives from Latinx-serving community-based organisations. We will also conduct six focus groups with 8–12 Spanish-speaking Latinx community member participants each for a total number of about 60 focus group participants. Next, we will develop the Nuestra Comunidad Saludable intervention based on findings from interviews and focus groups and use a longitudinal group-randomised trial design with two arms (intervention and delayed intervention) to evaluate the impact of the intervention. We will recruit, enrol and collect baseline data from 20 community-based peer navigators (Navegantes) and their social network members (n=8 unique social network members per Navegante). Navegantes (coupled with their social networks) will be randomised to intervention or delayed intervention groups (10 Navegantes and 80 social network members per group).

Ethics and dissemination Ethical approval for data collection was granted by the Wake Forest University School of Medicine Institutional Review Board. Following the description of study procedures, we will obtain consent from all study participants. Study findings will be disseminated through an empowerment theory-based community forum, peer-reviewed publications and presentations at scientific meetings, and reports and briefs for lay, community and practitioner audiences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Spanish-speaking Latines, who encounter multilevel barriers to COVID-19 testing and vaccination in the USA, are the focus population.

⇒ A well-established community-based participatory research partnership that has been exploring multilevel factors influencing health and developing and testing interventions designed to promote health equity among Spanish-speaking Latine communities for two decades is conducting this study.

⇒ Informed by the evidence-based weCare intervention, the Nuestra Comunidad Saludable intervention integrates the complementary strengths of peer navigation and mHealth to increase COVID-19 testing and vaccination; the underlying evidence for these strategies is emerging, and they have not been applied in combination within general Spanish-speaking Latine communities.

⇒ This study uses a novel empowerment theory-based community forum that brings together community members, partners, researchers and other constituencies to review study findings and prioritise next steps for research and practice.

⇒ The study sample size will not permit meaningful comparisons by population subgroups such as country of origin, immigration status, sexual orientation or gender identity.

BACKGROUND AND RATIONALE

Latine (a gender-neutral term similar to ‘Latinx’) is increasingly used within Latine lesbian, gay, bisexual, transgender and queer communities in the USA. Latine persons comprise 18.5% of the...
US population, and as of October 2022 comprised 25% of US COVID-19 cases. Latine persons are two times more likely to contract COVID-19 than their non-Latine White counterparts, 2.8 times more likely to die from COVID-19. These disparities are even more pronounced among Spanish-speaking Latine persons in the USA. Ongoing testing and vaccination are critical to effective control of the pandemic; however, complex issues contribute to low rates of COVID-19 testing and vaccination within Spanish-speaking Latine communities. Latine persons may lack access to culturally congruent information about COVID-19 testing and vaccination, including eligibility and ways to access these services; and assume that they must pay for testing or vaccination. They may believe they are not at risk for COVID-19, worry about missing work due to a positive test result or vaccine side effects and/or be concerned with the long-term health implications of testing and vaccination. Challenges to testing and vaccination also include institutional and structural barriers (eg, discrimination, limited transportation, conflicts between job and testing and vaccination programme scheduling and fear of engaging with government systems, including public health). These barriers to COVID-19 testing and vaccination are greater among those who do not speak English, are immigrants, are undocumented and/or live in mixed-immigration status households. A profound need remains to better understand and intervene on the factors that challenge and facilitate COVID-19 testing and vaccination interventions within these communities.

Natural helping through community-based peer navigation is potentially effective in addressing health issues in underserved communities and has potential to increase COVID-19 testing and vaccination within Latine communities. Community-based peer navigation harnesses relationships and social networks to help individuals engage with prevention or care services. Community-based peer navigators have advantages over other strategies because they can reach those who are considered ‘hard-to-reach’ by traditional service providers with targeted, tailored and personalised messaging and support. As trusted community members, peer navigators can be the first people turned to for assistance. Effective peer navigators are part of the networks in which they work, in terms of self-identity, socioeconomic status and lived experience; understand community needs and strengths and what is meaningful to members and communities; communicate in the language of network members; and incorporate culture to promote positive behaviours. In addition, community-based peer navigation strategies can be sustainable, as peer navigators often continue their work after a study or intervention implementation, and related funding ends. mHealth, a portmanteau of ‘mobile health’, describes medical and public health practice supported by mobile devices, such as smartphones and tablets. mHealth can be a powerful tool to reach Spanish-speaking Latines.

Spanish-speaking Latines have high rates of social media use, including WhatsApp, Facebook, Instagram and texting, for acquiring health information, and this use extends to COVID-related information. These rates are related to increased proliferation of mobile devices, including among Spanish-speaking Latine persons. Social media platforms can be powerful health promotion tools because they are widely available, inexpensive and instantaneous; thus, they can be effective at promoting behaviour change.

Because the health-related views of Latine persons are strongly influenced by trusted social network members and because Spanish-speaking Latines tend to be active users of social media, combining peer navigation with mHealth holds particular promise for increasing COVID-19 testing and vaccination within Spanish-speaking Latine communities. Moreover, studies suggest that Latine persons report substantial willingness to be tested and vaccinated. For example, in a national survey, eagerness to receive vaccination was more pronounced for Spanish-speaking Latine persons than English-speaking Latine persons (27% vs 11%), but Spanish-speaking Latines reported greater information gaps and uncertainty about where to seek vaccination. Thus, focused support that addresses barriers and builds on facilitators could be highly effective.

Objectives
The objectives of this community-based participatory research (CBPR) study are to expand understanding of the social, ethical and behavioural implications (SEBI) of COVID-19 testing and vaccination to inform the development of an integrated intervention that harnesses community-based peer navigation and mHealth strategies to improve COVID-19 testing and vaccination; test the intervention using a group-randomised trial design; and develop and disseminate practice, research and policy priorities and recommendations to further increase COVID-19 testing and vaccination among Spanish-speaking Latine communities in the USA.

METHODS
Ethics statement
The Institutional Review Board (IRB) at the Wake Forest University School of Medicine (WFUSM) is the IRB of record for all participating institutions (University of North Carolina Greensboro and Hispanic League). The WFUSM IRB has reviewed and approved all procedures outlined in this protocol. The study is registered with ClinicalTrials.gov (NCT05302908).

Data monitoring
The study team has guidance from a Data Safety and Monitoring Board (DSMB) composed of five members who are external to WFUSM, the University of North Carolina at Greensboro and the Hispanic League. Members include Latine community representatives.
(n=2), and representatives (n=2) from public health departments and a federally qualified health centre. The fifth DSMB member is a self-identifying Latine and a recognised prevention and care researcher focusing on Latinx communities, CBPR and social justice.

Study context and setting
This study is part of the Rapid Acceleration of Diagnostics Under served Populations (RADx-UP) initiative of the National Institutes of Health (NIH). The goals of RADx-UP are to understand and address COVID-19-related morbidity and mortality disparities for populations that are disproportionately affected by the pandemic (https://www.nih.gov/research-training/medical-research-initiatives/radx/radx-programs#radx-up).

This study is being implemented state-wide in North Carolina, USA. North Carolina has more than 1 million Latine persons, many of whom are Spanish speakers, and the COVID-19 experiences of the Latine population in North Carolina reflect experiences nationally, supporting study generalisability. In North Carolina, the rate of COVID-19 infections is higher within the Latine community, and fewer Latine persons have been vaccinated, compared with other racial/ethnic groups.

Patient and public involvement
Throughout this study, we will continue to use CBPR. CBPR is a critical approach to increase health equity and reduce disparities among underserved populations. Blending the lived experiences of members of the public; the expertise of service providers, clinicians and public health practitioners; and sound science can ensure the feasibility and acceptability of research studies; develop deeper and more informed understandings of health and related phenomena; and yield interventions that are more relevant, more culturally congruent and more likely to be effective and sustained, if warranted. The partners conducting this study have worked together for nearly 20 years and represent lay community members, health departments, free clinics, universities, two regional health systems and community organisations. We have engaged in intensive decision-making about all aspects of this study, including the qualitative methods (ie, in-depth interviews and focus groups), the intervention strategies (ie, peer navigation and mHealth), evaluation methods (ie, the longitudinal group-randomised trial design) and priority-setting and dissemination plans (ie, empowerment theory-based community forum).

Overall study design
We will collect qualitative data to expand our understanding of SEBI of COVID-19 testing and vaccination to inform the Nuestra Comunidad Saludable intervention; develop and test the intervention (designed to increase COVID-19 testing and vaccination uptake) using a longitudinal group-randomised trial design; and develop and disseminate practice, research and policy priorities and recommendations to further increase COVID-19 testing and vaccination among Spanish-speaking Latine communities in the USA.

Explore the SEBI of COVID-19 testing and vaccination within Spanish-speaking Latinx communities
We will collect, analyse and interpret exploratory ‘deep’ qualitative data to expand our understanding of the SEBI of COVID-19 testing and vaccination within Spanish-speaking Latinx communities. We will conduct 50 individual in-depth interviews with two categories of participants: (1) health providers (including administrators, clinicians, community health workers and safety-net clinic staff), who have planned, managed or conducted COVID-19 testing or vaccination activities for Spanish-speaking communities; and (2) representatives from Latine-serving community-based organisations. While we cannot predict saturation a priori, our previous research suggests that 50 interviews will provide us sufficient range and scope of perspectives across interview groups, and we have the flexibility to expand the number of interviews and/or focus groups if warranted. We expect to interview more providers (about 70%) than representatives from Latine-serving community-based organisations (about 30%) because of the fewer number of Latine-serving community-based organisations overall.

We will also conduct six focus groups with 8–12 Spanish-speaking Latine community member participants each for a total number of about 60 focus group participants. We chose the size of focus groups based on standard focus group guidelines; focus groups that are larger than 12 become difficult to manage, and it is difficult to hear from each participant. We will screen focus group participants to ensure we obtain representation by gender, age, documentation status, county of origin and those with and without experiences of COVID-19 testing and vaccination.

A low-literacy assessment will collect demographic data from each interview and focus group participant. Interview and focus group guides will be developed iteratively with a project-specific steering committee through ongoing literature review; brainstorming of domains and constructs; and drafting, review and revision of potential questions. Our conceptual framework (figure 1) will guide interview and focus group guide development. Because this phase is exploratory and designed to be inductive, the framework is subject to revision. Interview and focus group guides will adhere to best practices (eg, creating non-leading/open-ended questions, ordering from general to specific, maintaining neutral tone and depersonalising behaviours by ‘third-person-ing’ questions) to elicit knowledge, descriptions of experiences, opinions and values. The outcome of this phase will be an increased understanding of the SEBI of COVID-19 testing and vaccination among Spanish-speaking Latinx communities.
Develop and test Nuestra Comunidad Saludable

Our process is designed to expedite the direct translation of exploratory findings into intervention. Rapid application of findings is a hallmark of CBPR47 48 59 and a priority of our partnership. Working together, we will develop the Nuestra Comunidad Saludable intervention, integrating our previous successes with peer navigation and mHealth social media strategies17 22 35 60 61 with our exploratory findings and those of other relevant COVID-19 studies; the theoretical underpinnings; and anticipated outcomes of Nuestra Comunidad Saludable. We will develop the intervention, including the peer navigator (Navegante (Navigator)) training, to build Navegante capacity to increase COVID-19 testing and vaccination within their social networks through their roles as health advisors, opinion leaders and community advocates.62

Our bilingual weCare intervention20 35 63 64 serves as the foundation for the Nuestra Comunidad Saludable intervention. weCare is based on the social cognitive and empowerment theories and social support18 65 66 and harnesses peer navigation and mHealth. The goal of Nuestra Comunidad Saludable (ie, to increase testing and vaccination among persons disproportionately impacted by COVID-19) aligns with the goal of weCare (ie, to increase HIV care engagement and improve health outcomes among members of communities disproportionately impacted by HIV). The Nuestra Comunidad Saludable Navegantes will use natural helping and mHealth strategies to address the SEBI associated with COVID-19 testing and vaccination, providing culturally congruent information and referrals, demystifying the process of testing and vaccination by reframing negative and bolstering positive norms and expectations, sharing announcements and reminders about testing and vaccination programmes, troubleshooting barriers, supporting communication with providers and staff offering testing and vaccination services, supporting additional prevention behaviours and providing feedback to testing and vaccination sites about providing culturally congruent services to Spanish-speaking Latine clients.

Navegantes will conduct in-person and virtual (through FaceTime or Zoom) individual and group activities and leverage mHealth (using WhatsApp, Facebook messenger, Instagram direct messaging and text messaging) to communicate and provide social support within their social networks during the 6-month intervention. The Navegantes’ approach is personalised to each social network member’s needs and priorities. Table 1 provides an abbreviated summary of sample Navegante activities and examples of activities operationalised.

After development of the intervention is complete, we will use a longitudinal group-randomised trial design with two arms (intervention and delayed intervention) to evaluate the impact of the intervention. We will recruit, enrol and collect baseline data from 20 Navegantes and their social network members (n=8 unique social network members per Navegante). Navegantes (coupled with their social networks) will be randomly assigned to intervention or delayed intervention groups (10 Navegantes; 80 social network members per group).
Table 1  Sample activities of Navegantes in the Nuestra Comunidad Saludable intervention

<table>
<thead>
<tr>
<th>Activities</th>
<th>Examples</th>
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<tr>
<td>Raise awareness of the ongoing need for COVID-19 testing and vaccination.</td>
<td>Navegantes increase consciousness among their social networks about the need for testing and vaccination to slow the spread of COVID-19, state and local rates of testing and vaccination among Latinx populations, and the importance of taking action.</td>
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<td>Provide information and referrals.</td>
<td>Navegantes increase knowledge and provide information about COVID-19, testing and vaccination local providers of testing and vaccination services (eg, sites near a social network member’s home or workplace, days and hours of operation and whether an appointment is needed and how to make one).</td>
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<td>Demystify the process of seeking COVID-19 testing and vaccination.</td>
<td>Navegantes explain what to expect when accessing COVID-19 testing and vaccination, including where to go, how to get there by public transportation (or where to park if in a car), the presence of security, sign-in processes, what information will be requested (eg, if staff will ask for identification or insurance information), availability of interpreters or Spanish–speaking staff, what steps are involved in the testing or vaccination process and how long the process will take (eg, turnaround time for receiving test results and required observation period after receiving the vaccine).</td>
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<td>Reframe and bolster norms and expectations.</td>
<td>Navegantes increase trust in the test and vaccine (as some may not believe that they will get the real vaccine as has happened in Latin America), address other concerns and highlight how the benefits of COVID-19 testing and vaccination are linked to social network members’ priorities (eg, protecting the health of their families and communities and facilitating the ability to gather with others safely).</td>
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<tr>
<td>Share announcements and reminders.</td>
<td>Navegantes share announcements with social network members about upcoming testing and vaccination events.</td>
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<tr>
<td>Troubleshoot and problems solve SEBI of COVID-19 testing and vaccination.</td>
<td>Navegantes help overcome stigma related to COVID-19 and build trust around testing and vaccination (eg, addressing concerns about immigration status and confidentiality). Navegantes brainstorm options for overcoming barriers related to transportation (eg, if a testing or vaccination site is not on a bus line and a social network member does not have a car or a driver’s licence), schedules (eg, conflicts between work schedules and testing or vaccination site hours) and other challenges (eg, concerns about the potential impact of a positive COVID-19 test result or vaccine side effects on the ability to work).</td>
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<tr>
<td>Support communication with providers and staff.</td>
<td>Navegantes talk through ways to effectively communicate and share concerns with providers and staff at testing and vaccination sites. Navegantes may remind social network members to bring a list of questions, symptoms or information about potential COVID-19 exposures when going to get tested or vaccinated.</td>
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<tr>
<td>Support other prevention behaviours.</td>
<td>Navegantes provide guidance on recommendations for other prevention behaviours (aligning with current CDC guidelines), including mask use, social distancing and need for booster vaccination.</td>
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<tr>
<td>Provide feedback to providers and staff.</td>
<td>Navegantes meet with providers and staff at COVID-19 testing and vaccination sites to provide feedback for multilevel changes to improve accessibility for Spanish-speaking Latinx communities.</td>
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Quantitative outcome data will be collected from each Navegante and their eight enrolled social network members at two time points: (1) baseline (prior to randomisation and Navegante training) and (2) immediate postintervention (6 months after the Navegantes in the intervention group are trained). See table 2 for an overview of the measures. These data will be collected via an interviewer-administered assessment, and data will be entered using Research Electronic Data Capture.

Navegantes will complete and submit monthly Activity Logs. Activity Logs aid in our process evaluation and serve as triggers for Navegantes to initiate activities. They document whom the Navegante worked with during each activity (eg, codes for those within and outside of their eight enrolled social network members); the type of helping activity; whether it was an individual or group activity (and the number of people involved); and whether, which and how mHealth social media platforms were used. Importantly, the Activity Log will allow us to assess the Navegantes’ work beyond their enrolled social network members to better assess the diffusion of intervention effects and possible contamination.

Develop and disseminate priorities and recommendations to increase COVID-19 testing and vaccination among Spanish-speaking Latinx communities

We will organise and conduct a bilingual empowerment theory-based community forum to translate findings into practice, research, intervention and policy priorities and recommendations. We will invite CBPR partnership members, organisation representatives (eg, providers and clinic and community organisation staff), community members and academic researchers to review and discuss study findings, including results from the

Nuestra Comunidad Saludable trial. As a group, they will respond to four empowerment theory-based trigger questions that move from concrete (‘What do you see in these findings?’ and ‘In what ways do these findings make/not make sense to you?’) to action (‘What can be done?’ and ‘What can we do?’; figure 2).

Next, using a nominal group process, attendees will evaluate the list of priorities that were generated during the discussion based on two criteria (importance and feasibility) to ensure priorities have potential to decrease COVID-19 disparities within Spanish-speaking communities. Attendees will then divide into small groups based on the identified priorities, develop recommendations and next steps for carrying out those priorities and then reconvene to present plans to the larger group of attendees. Recommendations may include a timeline for next steps or a list of other individuals and organisations to engage. The forum also may identify priorities for subsequent research and intervention development. We will develop a final report of findings and practice, research, intervention and policy priorities and recommendations to distribute to attendees and others for whom the findings will be relevant (eg, local and state-level health department leaders).

### Participants

To participate in the in-depth interviews as a health provider, a participant must (a) be employed at a clinic, health centre or other organisation that has planned, managed or conducted COVID-19 testing or vaccination activities for Spanish-speaking communities, (b) be ≥18 years old and (c) provide informed consent. To be eligible to participate in the interviews as a Latine-serving community-based organisation representative, a participant must (a) be affiliated with a Latine-serving community-based organisation, (b) be ≥18 years old and (c) provide informed consent. To be eligible to participate in the focus groups, a participant must (a) self-identify as Hispanic/Latine, (b) be Spanish speaking, (c) be ≥18 years old and (d) provide informed consent. Potentially eligible participants will be identified through our community and clinical partners. Those who express interest will be screened to determine eligibility. Each participant who completes the interview or focus group will receive $50 compensation.

Because each Navegante must be a leader within existing social networks, we will recruit Navegantes primarily through our partnership’s extensive community networks.

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**Table 2** Measures for baseline and follow-up data collection to test the Nuestra Comunidad Saludable intervention

<table>
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<tr>
<th>Outcome variables</th>
<th>COVID-19 testing and vaccination (measured through self-report and photos of test results and vaccination card), including vaccine and booster type (eg, Pfizer, Moderna and Johnson &amp; Johnson) and number of doses received (inclusive of boosters)</th>
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<tbody>
<tr>
<td>Demographic variables</td>
<td>Age and date of birth; birthplace; ethnicity/race; language use; current living situation; zip code; marital/partner status; family structure (eg, children); educational attainment; current employment; financial status; immigration status; pregnancy status; insurance status</td>
</tr>
<tr>
<td>Symptoms</td>
<td>COVID-19 symptoms and exposure to assess need for testing</td>
</tr>
<tr>
<td>Potentially mediating variables</td>
<td>Awareness and knowledge about risk, testing and prevention of COVID-19; intentions and readiness for COVID-19 testing and vaccination; perceived COVID-19 testing and vaccine access; knowledge of how to access testing and vaccination services; service use self-efficacy; perceived barriers to services; usual source of care; skills and self-efficacy to communicate effectively with providers; provider trust; history seeking and using prevention and care services; self-efficacy to overcome barriers; perceived provider discrimination; stigma related to COVID-19; social support; community attachment; perceived impact of positive test on job security; access to transportation; previous experiences with testing and vaccination</td>
</tr>
<tr>
<td>Other variables</td>
<td>Intervention acceptability; satisfaction with participation in intervention; interactions with Navegante and enrolled and unenrolled social network members regarding COVID-19 testing and vaccination (to assess contamination)</td>
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**Figure 2** Triggers used in the empowerment theory-based community forum.
across North Carolina and through word of mouth. We have had much success with both of these strategies.\textsuperscript{73} To be eligible to participate as a \textit{Navegante}, a participant must (a) self-identify as Hispanic/Latine, (b) be Spanish speaking, (c) be \(\geq 18\) years of age, (d) provide informed consent and (e) report having been vaccinated against COVID-19. Our partnership chose the vaccination requirement because \textit{Navegantes} serve as role models within the community. Access to a smartphone will not be an inclusion criterion. We have some flexibility to provide smartphones and data plans for \textit{Navegantes} without them, though given smartphone proliferation and our past research experiences, this will likely be unnecessary.

To be eligible to participate as a social network member, a participant must (a) self-identify as Hispanic/Latine, (b) be Spanish speaking, (c) be \(\geq 18\) years of age and (d) provide informed consent. We will screen and enrol eight unique members of each \textit{Navegante}'s social network. If a \textit{Navegante} cannot recruit eight unique social network members, we will recruit, interview and select other \textit{Navegantes} until we have 20 \textit{Navegantes} each with eight unique social network members. After 20 \textit{Navegantes} and 160 unique members of their social networks enrol and complete the baseline assessment, group-level randomisation will be done using nQuery software to generate random numbers. Consent will be obtained by trained and experienced bilingual study staff.

This project is designed to understand and meet the unique needs and priorities of Spanish speakers. Focus group participants, \textit{Navegantes} and social network members who speak other languages (eg, English and indigenous languages such as Mayan languages) in addition to Spanish are eligible to participate.

\textbf{Sample size and power}

Sample size calculations are based on a follow-up baseline-adjusted (analysis of covariance, ANCOVA) model. We estimated the sample size needed (20 \textit{Navegantes} and 160 social network members) by performing calculations in \textit{nQuery} V8.7. We assume a within-social network correlation coefficient (intraclass correlation coefficient (ICC)) of 0.01 (although the observed ICC in previous studies of Latine persons was lower (ie, ICC=0.005))\textsuperscript{74}, type I error rate of 0.05 and a repeated measures correlation of 0.40. A typical assumption in sample size calculations for longitudinal modelling is that adjacent time points are moderately correlated at 0.50, although they typically decrease with increasing time separation.\textsuperscript{75} Our previous studies with Latine populations have demonstrated smaller repeated measures correlations, especially among categorical outcomes\textsuperscript{26,76}; we therefore attenuated the assumed correlation to 0.40 as a compromise. We also assume a 10% dropout rate at follow-up, given our previous studies have had very high retention rates within Latine communities due to our CBPR approach.\textsuperscript{73} We will be able to detect a range of improvements from 13% (from 5% to 18%) to 20% (from 50% to 70%) in past 6-month COVID-19 testing with at least 80% power under the above assumptions. These estimates are conservative if ICCs are lower or dropout is less. Our intervention also seeks to increase COVID-19 vaccination. Based on current data, it is estimated that 32% of Latine persons nationally (and 31% in North Carolina) have had at least one dose of a COVID-19 vaccine.\textsuperscript{46} For our calculations, we have raised this baseline percentage to 40% given ongoing US vaccination efforts. Under the same ICC, repeated measures correlation and missing data assumptions as for COVID-19 testing, we will be able to detect an increase in COVID-19 vaccination from 40% to 60.5% (a 20.5% improvement) with at least 80% power. Testing data within Latine communities is much less precise; thus, we assumed baseline testing rates of 5%–50%, maximising the sample size required to detect differences in testing over the 6 months.

\textbf{Analyses}

\textbf{Exploratory phase}

We will analyse the qualitative data from the in-depth interviews and focus groups using constant comparison, a systematic approach to developing grounded theory that is well suited to uncovering participants’ meanings and experiences. It combines inductive coding with simultaneous comparison; initial observations are continually refined throughout data collection and analysis.\textsuperscript{77} The goal is to identify themes, not to quantify participant experiences. Analytical steps include interviewers documenting postinterview and focus group impressions (eg, content, process and themes); professionally transcribing and translating (if needed) interviews and focus groups; and verifying transcripts by reviewing and correcting discrepancies while listening to the recording. Transcripts will be managed using NVivo software (Chicago, Illinois) and examined to identify and code domains for theme development. This will begin with the analysts developing and refining an analytical coding scheme system and data dictionary. For data triangulation, analysts will develop, compare, then revise matrices that identify similarities and differences and explore emic and etic perspectives within and across participant categories (eg, health providers vs Latine-serving community-based organisation representatives; and health provider/organisation representative interview vs Spanish-speaking Latine community member focus group). Finally, members of our CBPR partnership will review themes for validity (eg, rigour, credibility and trustworthiness).\textsuperscript{74}

\textbf{Evaluation of the Nuestra Comunidad Saludable intervention}

Data analysis will include study group description and intervention impact evaluation. The study group description will include frequencies and percentages for categorical variables, and means, medians, SDs and ranges for continuous variables will be tabulated to describe the sample. Reliability for measures will be estimated via internal consistency using coefficients alpha and omega.\textsuperscript{78} Baseline intervention and delayed intervention group comparisons will be performed. Correlation analyses...
will evaluate the associations between pairs of variables. Non-parametric statistics will be used when appropriate to evaluate significance of associations. To evaluate the intervention impact, data will be analysed with an intention-to-treat approach. Randomisation at the social network level will likely balance cluster-level baseline characteristics; however, as randomisation may not precisely balance these, and there may be differences in social network member characteristics after network randomisation, inverse probability weighting using propensity scores will be explored to balance baseline characteristics (both network and individual) between arms using best practices. Balance on propensity scores between intervention groups will be assessed using standardised differences. Propensity scores have been used in cluster randomised controlled trials.

To test our hypothesis that participants in the intervention group, relative to their counterparts in the delayed intervention group, will demonstrate increased past 6-month COVID-19 testing and vaccination, we will compare rates of past 6-month COVID-19 testing (defined as at least one test) and vaccination completion (defined as complete dosage of approved vaccination (eg, two Pfizer or Moderna doses or one Johnson & Johnson dose, plus boosters as recommended and eligible)) between intervention and delayed intervention group social network members at immediate post-intervention (6 months after the intervention group Navegantes are trained), adjusting for baseline rates. This ANCOVA approach has the advantage of being unaffected by baseline differences; if baseline rates, by chance, were different, the intervention effect would be overestimated by looking at change scores and underestimated by a follow-up score analysis. The ANCOVA approach is robust even with baseline imbalance, and generally has greater statistical power to detect an intervention effect than the other methods. Statistical analysis will be performed using generalised linear mixed modelling for binary outcomes (random-effects logistic regression). These models can assume a logit link for binary data (ie, tested or vaccinated in the past 6 months: yes/no) and can account for the within-Navegante association of outcomes with random effects. If participants have repeated COVID-19 testing performed then an additional random effect for multiple testing will be considered, where appropriate.

Data sharing
Data and measures from this study will be readily available through coordination with the RADx-UP Coordinating and Data Collection Center and the NIH RADx Data Hub. All efforts will be made to rapidly release data through the publication of results as quickly as it is possible, and all publications will indicate in the author note how investigators can obtain access to data from this project. As needed, data and associated documentation (including codebooks) will be available from the principal investigator under a data sharing agreement with users that provides for a commitment to: using the data for research purposes; securing the data using appropriate computer technology; destroying or returning the data after analyses are completed; not making unauthorised copies of the data sets; and proper acknowledgement of the data resource.

Timeline
This study was funded on 1 January 2022. Qualitative research activities to explore the SEBI of COVID-19 testing and vaccination within Spanish-speaking Latine communities began in April 2022, and the refinement of the Nuestra Comunidad Saludable intervention is ongoing. Baseline data collection to evaluate the intervention is expected to begin in September 2022, and intervention implementation should begin in December 2022. Follow-up data collection to evaluate the intervention is expected to be completed in July 2023, at which point the delayed intervention group Navegantes will be trained. Final evaluation results are anticipated for Fall 2023. The empowerment theory-based community forum will be conducted in Fall 2023.

DISCUSSION
Spanish-speaking Latine communities face a myriad of challenges related to COVID-19 testing and vaccination resulting in disparities in COVID-19-related morbidity and mortality. Innovative, culturally congruent interventions are critically needed to reduce disparities. This study will increase understanding of the SEBI of COVID-19 testing and vaccination and translate these exploratory data into a novel evidence-based intervention. Based on our partnership’s weCARE intervention that increased care engagement among persons living with HIV, the Nuestra Comunidad Saludable intervention integrates two evidence-based strategies: community-based peer navigation and mHealth. Based on natural helping, peer navigation harnesses relationships and networks to help individuals engage with prevention and/or care services; however, peer navigation remains largely untapped within this context. The intervention also leverages social media via existing platforms that Spanish-speaking Latine persons already use (eg, WhatsApp, Facebook, Instagram and texting). Thus, the behaviour change focuses on testing and vaccination behaviours, not the antecedent behaviour of downloading, learning and using a new ‘app’, which some mHealth strategies rely on for implementation. We hypothesise that participants randomised to the Nuestra Comunidad Saludable intervention, relative to their counterparts randomised to the delayed intervention, will demonstrate increased past 6-month COVID-19 testing and vaccination.

Furthermore, we also include a novel strategy to dissemination that our partnership has developed. Designed to be low burden for attendees, our theory-based community forum brings together community members, partners and other stakeholders to review study findings and develop next steps for both practice and research.
It is important to note the potential limitations of this study. This study sample size will not permit meaningful comparisons by population subgroups such as country of origin, immigration status, sexual orientation or gender identity. Second, there is potential for contamination (also known as diffusion of intervention effects) in Aim 2, although we will assess information sharing from Navigantes (directly or through social media) to delayed intervention group or with non-enrolled persons through the Activity Logs and the postintervention assessment, and these will be controlled for as covariates in sensitivity analyses if warranted. Finally, results may be generalisable to other Spanish-speaking communities; however, the healthcare systems and the provision of COVID-19 testing and vaccination in other states might be different and thus require slight revisions to the intervention. Given the strategies used in the intervention (peer navigation and mHealth) and the ability to have content that is targeted, tailored and personalised, the intervention may also be useful for other communities facing barriers to testing and vaccination, but again, tweaks to the intervention will be required.

In sum, the Nuestra Comunidad Saludable intervention may fill an important gap in supporting COVID-19 prevention efforts within a community disproportionately affected by COVID-19. Spanish-speaking Latinx persons are disproportionately affected by COVID-19 in the USA, and to date, interventions designed for this unique population are limited. There is a dearth of effective interventions to increase testing and vaccination within this population. Reducing the burden borne by Spanish-speaking Latinx communities also will benefit larger communities in general because there will be fewer infections and the virus will become weaker and not mutate as rapidly. In fact, the potential for the COVID-19 pandemic to end increases as more and more people are tested and vaccinated. Thus, it is imperative that effective strategies be identified and disseminated to promote testing and vaccination among those most impacted.

**Author affiliations**

1Department of Social Sciences and Health Policy, Wake Forest University School of Medicine, Winston-Salem, North Carolina, USA
2Department of Public Health Education, The University of North Carolina at Greensboro, Greensboro, North Carolina, USA
3Wake Forest University School of Law, Winston-Salem, North Carolina, USA
4Department of Epidemiology and Prevention, Wake Forest University School of Medicine, Winston-Salem, North Carolina, USA
5School of Nursing, The University of North Carolina at Greensboro, Greensboro, North Carolina, USA
6Hispanic League, Winston-Salem, North Carolina, USA
7Twitter Scott D Rhodes @Scott_D_Rhodes and Amanda E Tanner @ae_tanner

**Contributors**

SDR, AET, LM-J, JA, MAH, TPM, MG and MJT conceptualised this study in partnership with members of the North Carolina Community Research Partnership, a long-standing community-based research partnership based in North Carolina, USA. They drafted sections of the NIH application, reviewed and edited sections iteratively and took responsibility for its final submission. AGB edited sections of the draft application. SKAP and DM joined the team after the project was funded and have been involved in refining and initiating the project. All authors of this paper were heavily involved with its preparation, and SDR takes full responsibility for the overall content and finished work as guarantor.

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None declared.

**Patient and public involvement**

Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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Not applicable.

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**ORCID iDs**

Scott D Rhodes http://orcid.org/0000-0002-9797-8114
Amanda E Tanner http://orcid.org/0000-0003-4488-7160

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