



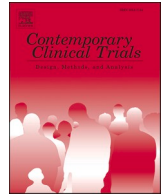
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A pragmatic randomized trial of home-based testing for COVID-19 in rural Native American and Latino communities: Protocol for the “Protecting our Communities” study

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ABSTRACT

Background: Home-based testing for COVID-19 has potential to reduce existing health care disparities among underserved populations in the United States. However, implementation of home-based tests in these communities may face significant barriers. This study evaluates the acceptability, feasibility, and success of home-based testing and the potential added benefit of active support from trusted community health workers for Native Americans and Hispanic/Latino adults living in rural Montana and Washington states.

Methods/design: The academic-community research team designed the trial to be responsive to community needs for understanding barriers and supports to home-based COVID-19 testing. The “Protecting Our Community” study is a two-arm pragmatic randomized controlled trial in which a total of 400 participants are randomized to active or passive arms. Participants of both study arms receive a commercially available home collection COVID-19 test kit, which is completed by mailing a self-collected nasal swab to a central laboratory. The primary study outcome is return of the kit to the central lab within 14 days. The cultural, social, behavioral, and economic barriers to home-based COVID-19 testing are also assessed by qualitative research methods. A survey and semi-structured interviews are conducted after the trial to evaluate perceptions and experience of home-based testing.

Discussion: Implementing home-based testing in underserved populations, including among Native American and Hispanic/Latino communities, may require additional support to be successful. The Protecting Our Community trial examines the effect of trusted community health workers on use of home-based testing, which may be adaptable for community-driven models of home-based testing in other underserved populations.

Abbreviations: CDC, Centers for Disease Control and Prevention; CHW, Community health worker; COVID-19, Coronavirus disease 2019; EUA, Emergency Use Authorization; Fred Hutch, Fred Hutchinson Cancer Research Center; IRB, Institutional review board; MSU, Montana State University; NIH, National Institutes of Health; NA, Native American; RCT, Randomized controlled trial; RADx-UP, Rapid Acceleration of Diagnostics-Underserved Populations; SKC, Salish Kootenai College; SARS-CoV-2, Severe acute respiratory syndrome coronavirus 2; UW, University of Washington; FDA, U.S Food and Drug Association.

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1. Introduction

The coronavirus disease 2019 (COVID-19), caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), became the third-leading cause of mortality in the United States during 2020 [1,2]. The severity of SARS-CoV-2 infections and deaths related to COVID-19 are disproportionate among certain ethnic and racial minority groups as well as rural populations [3]. Native American (NA) and Hispanic/Latino individuals have a 2.8-times higher rates of SARS-CoV-2 infection vs. Whites [4,5]. Additionally, NAs and Hispanics/Latinos have been hospitalized for COVID-19 at 5.3 and 4.6 times the rate of Whites, respectively [4,5]. Between March and October 2020, NAs in Montana represented 6.7% of the total population, yet accounted for 15% of all COVID-19 cases in the state [6–9]. In Washington state, Hispanics account for 13% of the population, but represented 29% of all COVID-19 cases [10,11]. There is an urgent need to enhance health equity among ethnic and racial minority populations through tailored education and diagnostic testing solutions to reduce risk of COVID-19 spread.

Among underserved populations in the US, high rates of chronic disease, such as diabetes, cardiovascular disease, and cancer [12–16] as well as other socio-economic determinants of health (i.e., education, employment, income, housing, language, social and physical environments) contribute to poor health outcomes [3–5,8]. Communities with existing disparities in health care access [17–21] and insurance [22], have seen these disparities become further exacerbated by the COVID-19 pandemic [13,14,23]. In addition, minority populations are disproportionately represented among essential workers who ensure the continuity of critical societal functions during the COVID-19 pandemic, including agriculture, and are inherently at higher risk of exposure due to the nature of their work [3].

The U.S. Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) to many COVID-19 tests for self-sampling and home-based testing [24]. While home-based testing has considerable potential, there are limited data on factors impacting uptake, implementation, utility, acceptability, and follow-up in underserved communities. For rural NA and Hispanic populations, there are additional issues such as mistrust, lack of health care providers, geographic distance between clinics or testing sites and crowded multigenerational living conditions.

This article presents the study protocol for the “Protecting Our Community” randomized controlled trial (RCT) as an example of creating culturally-responsive place-based solutions through community engagement to reduce the risk of COVID-19 spread and enhance health equity among vulnerable minority populations. The trial is part of a consortium of 70+ organizations funded via the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics-Underserved Populations (RADx-UP) Initiative, to improve testing in underserved populations [25,26]. The overall goal of the “Protecting Our Community” study is to create culturally-grounded, community-centric models to increase COVID-19 home-based testing in NA and Latino communities nationally. Our primary objective is to test the effects of active (via proactive education and outreach from trusted community health workers (CHWs)) vs. passive (via participant referral to diagnostic company materials and contacts) support on the completion rates of home-based COVID-19 self-testing in a pragmatic randomized trial.

2. Methods

2.1. Community engagement in trial design, implementation and analysis

Per community-based participatory research principles, we worked with our community partners in designing the clinical trial [27]. Researchers from Montana State University (CAIRHE/MSU), University of Washington (UW), Fred Hutchinson Cancer Research Center (Fred Hutch), and Salish Kootenai College (SKC) have long-term relationships

and existing research collaborations on the Flathead Reservation and in the Yakima Community. Preliminary work done at the onset of the pandemic indicated a connection between the two communities with migrant workers moving back and forth throughout the growing season as well as concerns of both communities regarding the need for culturally responsive and place-based COVID-19 education and testing strategies.

For the RADx-UP program, we formed a larger collaboration between MSU, UW and Fred Hutch researchers and their community partners in Yakima and the Flathead Reservation. Fig. 1 provides an overview of the organizational structure of the research team and community partners, and community advisory boards (CAB). In addition, community investigators from each CAB will participate in weekly research team meetings.

The CABs will provide input on the communities’ COVID-19 testing challenges, including the need for culturally responsive COVID-19 education and testing support, stigma associated with urgent care testing, limited access to mailing services for timely sample return and lack of available testing sites. Community investigators will work with the research team to develop a COVID-19 home-based testing trial with active and passive arms that variably account for these challenges and will be reviewed and approved by both CABs. All participant-facing materials are co-developed with community investigators and will be reviewed by the CABs.

Concurrently with the clinical trial, we will conduct key informant interviews and focus groups. The 30 semi-structured key informant interviews (15 at each site) will be with clinic and public health officials, tribal council and community advisory board members, local incident commanders, and other community leaders (e.g., elders) to understand multilevel barriers (e.g., populations, institutions, community, patients) and opportunities for COVID-19 home-based testing. Focus groups (up to 10 community members per focus group, including up to 3 migrant and farm workers per group, 3 focus groups/community) will explore knowledge of COVID-19, transmission, severity, prevention, and beliefs about COVID-19 testing and vaccines. Results from the qualitative study will be used to give a more complete picture of each community’s supports and barriers to COVID-19 testing and provide contextual information necessary to ensure accurate and comprehensive analysis of clinical trial data.

2.2. Study settings

The “Protecting Our Community” study involves two community sites with large NA and Latino populations that were selected due to ongoing partnerships with the study team in addition to their demographics and vulnerabilities. The Flathead Reservation in northwestern Montana is home to the Bitterroot Salish, Pend d’Oreille, and Kootenai Tribes, and spans over 1.3 million acres [28]. The Reservation’s population of approximately 26,900 people, includes roughly 7900 (27%) people who identify as Native American [29]. The majority of the Flathead Reservation is in Lake County which has moderate to high level of vulnerability based on Centers for Disease Control and Prevention’s (CDC) Social Vulnerability Index that assesses the potential negative effects on communities caused by external stresses on human health [30]. The Yakima Community is in the Lower Yakima Valley of eastern Washington State, where much of the state’s Hispanic population is concentrated. The Lower Yakima Valley includes many small agricultural communities, and many Hispanics work in the agricultural industry. Yakima County, in southcentral Washington State, has a population of approximately 250,000, 50% of whom are of Hispanic or Latino origin [31]. The county has a high level of vulnerability based on CDC’s Social Vulnerability Index [30]. Much of the Hispanic population in the agricultural sector in Yakima served as essential workers during the pandemic. In addition, many migrant farm workers travel between the two sites throughout the growing season, creating a conduit for potential seeding of COVID-19 infections.

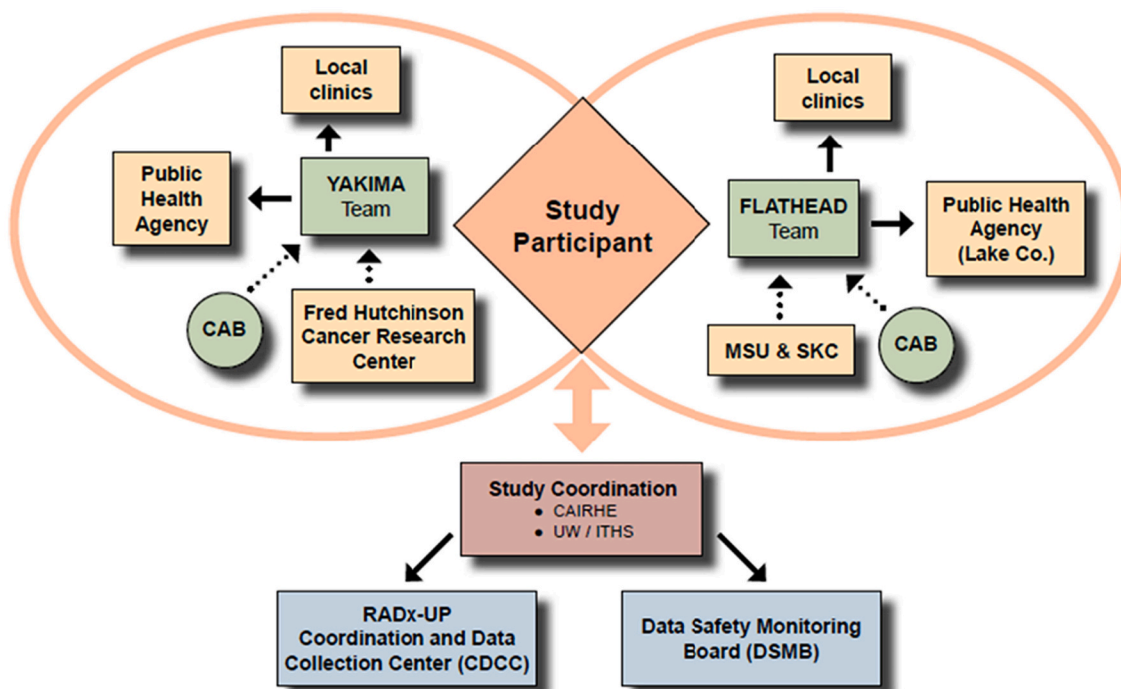


Fig. 1. Organizational structure of the Protecting Our Community study.

2.3. Trial design

The “Protecting Our Community” study is a two-arm pragmatic RCT comparing the effect of active versus passive delivery of home tests for COVID-19 among NA and Latino adults on rates of test completion. Randomization of 400 participants occurs in a 1:1 ratio by site and one of three age categories (18–25, 26–59, and 60+ years) to an active (intervention) arm or passive arm to test the hypothesis that a greater number of home samples will be returned to the testing lab within 14 days of randomization when test kit registration and completion is facilitated by CHWs versus with no study staff support. Fig. 2 illustrates the study design.

For the clinical trial, we will seek to enroll 200 adults in each of the two communities. Recruitment will be conducted through local community coordinators and CHWs using various recruitment strategies, including radio advertisements, word of mouth, community flyers and social media postings [32,33].

The standard registration process for the selected commercial home-based test requires internet access and digital literacy, which may not be feasible for many participants in our communities. Specifically, users must access an online portal to create an account, answer questions related to current symptoms of COVID-19, register or activate their home collection kit and monitor an email address to retrieve their test results via a secure online portal, developed for English speakers. Our community partners report many community members have limited and/or unreliable access to internet and internet enabled technology, therefore we hypothesized that additional support measures will be needed for successful, long-term implementation of a home-based testing program for COVID-19. CHW workers will provide support in either Spanish or English, as determined by a participant’s preferred language.

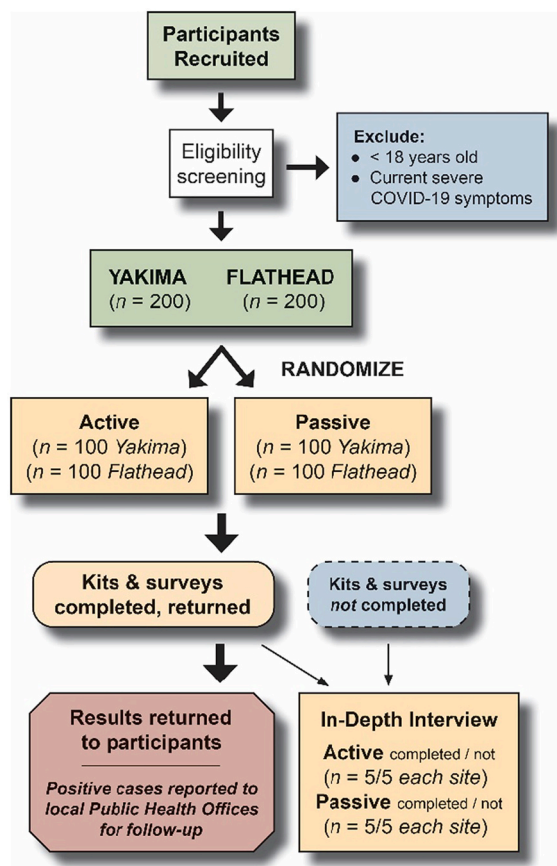


Fig. 2. Study design overview.

2.4. Eligibility criteria

Study participants must meet the following eligibility criteria: 1) being an NA (or a close non-Native family member) living on the Flathead Reservation in Montana or Latino living in the Yakima Valley

region of Washington, 2) aged 18 or older, 3) speak English or Spanish, 4) are willing to complete study pre-test questionnaire and post-test surveys, 5) have access to or willingness to create an email account. Participants will not be eligible if they or another member of the same household (individuals who live under the same roof or share same housing unit) had previously participated in any activities related to the study, such as community advisory board meetings, focus group discussions, key informant interviews, or were enrolled in the clinical trial.

All inclusion and exclusion criteria are assessed by self-report only and study staff will not attempt to verify accuracy. Pregnant women will be eligible to participate in this study, and participants previously diagnosed with COVID-19 or receiving COVID-19 vaccinations will also be eligible. Recruitment will focus on individuals who are not currently diagnosed with COVID-19, experiencing severe symptoms which may indicate COVID-19, and not hospitalized for COVID-19. Volunteers whose symptoms resolve or become mild in nature can rescreen and potentially enroll in the clinical trial later.

2.5. Informed consent and patient details

Informed consent forms, study protocol and all patient-facing materials (e.g., recruiting and supplementary testing kit materials, interview guides) will be developed in collaboration with community-based investigators and community advisory boards in Yakima and on the Flathead Reservation to ensure culturally appropriate content and graphics. The study will attain approval by the institutional review boards (IRB) at SKC and MSU, and the Confederated Salish-Kootenai Tribal Council, and the UW and Fred Hutch agree to rely on the MSU IRB under the terms of the single IRB (SMART IRB) agreement. The study will obtain a pre-screening waiver, allowing for the assessment of eligibility prior to obtaining informed consent. Once deemed eligible, informed consent will be obtained for all study participants prior to conduct of any study procedures. Documentation of written informed consent for all participants from the Flathead Reservation will be obtained as required by the SKC IRB. Waiver of written informed consent will be obtained from the MSU IRB for participants at the Yakima site. Affirming consent, both written and verbal, will be documented in REDCap, the study electronic data capture system [34] and all participants will be provided a copy of the consent form.

Table 1
Timing of study assessments and activities.

Study Assessment / Activity	Timing					Day 0–14	After test results are released on vendor secure portal	Day 1–21
	Prior to informed Consent	After Eligibility is Confirmed	After informed consent	After Demo. Quest. (Part 1)	After Randomization			
Screening	X							
Informed Consent		X						
Demographic Questionnaire (Part 1)			X					
Randomization				X				
Kit Assignment & Scheduled Kit Delivery					X			
Demographic Questionnaire (Part 2)						X		
Everlywell Kit Assignment and Test results						X		
Result Receipt Confirmation Call							X	
Post-Testing Feedback Survey (\$35 incentive)								X
In-Depth Phone Interview (\$25 incentive)								X

2.6. Data collection

Data collection will begin after confirming eligibility and obtaining informed consent by the research staff (in English or Spanish). Study assessments and activities, and timing are shown in Table 1. Part 1 of the demographic questionnaire will be used to collect information including participant's name, contact information, preferred language, COVID-19 diagnosis status, COVID-19 vaccination status, and information needed for stratified randomization to study arms. The research coordinators will also obtain a phone number, address, and other relevant contact information to support retention of each participant. The information will be recorded and entered into REDCap.

2.7. Randomization: sequence generation, allocation concealment, implementation

Eligible participants will be randomized by site location and age (18–25, 26–59, and 60+ years) into either the active or passive arm, using block sizes of four, via REDCap. Following randomization, part 2 of the demographic questionnaire will be administered, collecting information related to employment, education, income, household size, health status, and experiences related to the COVID-19 pandemic. Most part 2 questionnaires will be completed prior to the participant receiving their home testing kit. If these demographic questions are not collected within 14 days of randomization, this portion of the assessment will be considered incomplete. However, the participant will not be considered lost to follow-up and future study assessments may continue.

2.8. Active vs. passive arms of intervention

To control for known barriers to home testing in this population, unrelated to the intervention, such as English language proficiency, and access to mail delivery services (UPS, FedEx, etc.), participants in both study arms will be provided kit delivery and sample return support coordinated by study staff. Home testing kits will also be augmented with graphically enhanced, culturally appropriate materials in English and Spanish, as described below. Coordination support options include (1) pick up / drop off at the research site, (2) shipping the home testing kit to the participant's mailing address by USPS or (3) home delivery/pick up to accommodate those with mobility concerns.

Participants randomized to the passive arm will receive a home test

kit with instructions on how to self-register their kit online and will be directed to the test manufacturer for assistance, if needed. Preliminary reports from study staff indicate many participants randomized to the passive are experiencing difficulty (e.g., understanding kit instructions, kit registration). To be responsive to the communities' needs and ensure participants can complete tests and obtain results, CHWs will be providing and documenting additional support as requested. Subsequent analysis will incorporate additional support provided.

Participants randomized to the active arm will have their home collection kit registered on their behalf by CHWs at enrollment. Participants will receive their test kit with a supplemental card, which provides the account login information to obtain their test results and instructions to contact the CHWs for assistance instead of Everlywell customer service (see below) for any additional testing and results support needed.

2.9. COVID-19 test home collection kit

We will use an FDA EUA-approved COVID-19 PCR (polymerase chain reaction) Home Collection Kit (Everlywell Inc., Austin, TX, USA), which is the best home test option available at the onset of the RCT in 2020. The Everlywell COVID-19 Test Home Collection Kit DTC (direct-to-consumer) is composed of sample registration instructions, sample collection instructions, an information sheet, sample preparation and shipping instructions, anterior nasal swab, saline in a tube, shipping materials, and return labels [35,36]. In addition to the materials provided in the Everlywell Kits, the study team will augment the kits with supplemental materials created by the study team to clarify the additional actions participants will need to do as part of the research study. Written supplemental materials will include: (1) "Study Welcome" card, (2) self-swab instructions (with culturally appropriate graphics), (3) site-specific shipping instructions and directions to local courier collection locations, (4) information about how participants will receive their test results (specifying when the Everlywell clinicians and CHW will be contacting participants), and (5) an infographic on how to interpret COVID-19 test results.

Test kits will be mailed in bulk to each community for local distribution to participants via mail delivery or participant pickup at designated sites. Each kit includes a unique identification code and a pre-paid mailing envelope and packaging materials to mail the completed sample back to the Everlywell laboratory for testing. Laboratory testing utilizes Clinical Laboratory Improvement Amendments-certified rRT-PCR (real-time reverse transcription polymerase chain reaction) tests and reports results to participants within 24 to 48 h of receipt. All participants will receive test results from an online portal and receive result notifications via email and text, as well as follow up by the CHW to ensure results are obtained by the participant.

2.10. Reporting of test results

Participants testing positive for COVID-19 will receive a phone call from an Everlywell-contracted clinician [35]. The clinicians will make three attempts to notify participants by phone (1 call per day) and mail a letter to the individual if they are unable to speak with them. The letter will not contain test results but will act as a final attempt to remind participants to view their results online as soon as possible. The Everlywell laboratory and the Everlywell-contracted clinician will report positive test results to appropriate public health authorities for disease tracking and prevalence, as required by the U.S. Department of Health and Human Services.

In the event participants are unable to retrieve their test results from the online portal or have questions, the local CHWs have access to the results portal and are trained to disclose the participant's test results. Participants testing negative are encouraged to maintain their usual local public health protocols. Participants testing positive are counseled on quarantine protocols, given information about self-isolation (e.g.,

isolation when living in a multigenerational home) and local testing sites, and encouraged to engage with local health care providers.

2.11. Post-testing measures

Participants returning a home collection sample to the lab for testing within 14 days of randomization are offered a phone delivered post-testing feedback survey in participants' preferred language (Spanish or English). The survey captures participants' thoughts and perceptions based on their experience using the home-based COVID-19 testing kit. Administration of the post-testing feedback survey will occur between 1 and 3 weeks after randomization. Participants who do not complete the home testing kit are asked to share why they did not complete the home testing kit and their response is recorded. Upon completion of the post-testing feedback survey, participants will receive a \$35 incentive for their participation in the clinical trial. These strategies have been successfully employed by our teams in the past [37,38].

3. Outcomes

3.1. Statistical methods

Our primary analysis will compare differences in the proportion of subjects in active and passive study arms who return collection kits within 14 days of randomization. Outcomes will be assessed overall and stratified by community. Secondary analyses will evaluate demographics differences and associated characteristics of test completers and non-completers.

Study staff have access to the Everlywell portal to check on kit return and results for each participant. A home testing kit is considered completed when participants have collected their home sample and results are available on the online portal within 14 days of randomization. If a replacement home testing kit is provided, home testing will be considered complete when results are available on the Everlywell portal within 14 days of the date the replacement kit was issued. Study staff will document when replacement kits are sent and why they are requested.

Quantitative analysis of the post-testing feedback survey will include creation of summary statistics that characterize the response to key survey items, enabling us to understand acceptability and feasibility of home testing. An important statistical consideration is non-response to survey and the potential for non-representative samples. If response rates fall below 90%, logistic regression will be used to model univariate association between post-test survey completion and the following predictors: age category, sex, and preferred language. For variables with a significant association with nonresponse, post-stratification weights will be estimated and used in analyses to correct for any potential nonresponse bias associated with measured factors [39,40].

3.2. Sample size

We assume a relative increase of 20% (absolute increase of 14%) to be a meaningful impact associated with active arm, and therefore will select a sample with adequate power to detect such a difference. With 400 total subjects (stratified by community) we will have 90% power to detect an effect size associated with a rate ratio of 1.20, or an absolute difference of 14% (70% in passive, 84% in active). We will evaluate our design for robustness to assumptions regarding the passive return rate, and we will have >80% power to detect an absolute difference of 14% (relative rate of 1.23) if the passive return rate is 60%. Passive return rate estimates are based on prior work with passive strategies, which produced return rates of approximately 80% [41,42]. We will make no correction for missing outcomes since the outcome is negative if no kit is returned. In addition, we will explore the impact of using regression adjustment (logistic regression with an identity link) to account for community stratification, and our primary analysis will maintain >80%

power for a range of passive rate differences across communities (ranging from 5% to 10%). All power calculations use the R statistical package and the PWR library and simulation methods [43].

3.3. Blinding

Study staff at both sites will be blinded to the study arm assignment, except site CHWs and appropriate clinical staff. The clinical trials manager and other staff from MSU and UW will be blinded to which arm (active or passive) individual study participants are assigned.

3.4. Qualitative sub-study

In-depth semi-structured interviews are conducted in the participants' preferred language (English or Spanish) over phone or Zoom with 40 participants (20 participants at each site) within 21 days of randomization to collect perceptions of and experience with the home testing kit, vaccinations, and other issues related to the pandemic. Participants are asked open-ended questions to understand their experience participating in the study, including what they perceived easier or challenging regarding the completion (or incompleteness) of their at-home test kit. To understand participants' experience during the pandemic, questions are included to understand participants' family experiences, impact of the pandemic on participant and family physical and emotional health, thoughts on returning to "normal life", and lessons learned on how to move forward. To facilitate collection of data at multiple timepoints in the study, interviews will be staggered. Interviews will occur roughly every two weeks over a 10-week period. We will attempt to match interviews by active and passive arm assignment, completer and non-completer status, and timepoint when participants entered the study. We will conduct a total of 40 interviews with 10 participants who complete their home testing kits and 10 who do not, among those randomized to the active arm and passive arm respectively. Participants who complete the in-depth, semi-structured phone interview will receive a \$25 incentive. Qualitative analysis of semi-structured interviews occurs as described above (Pre-Trial Qualitative Study).

3.5. Trial monitoring procedures and assessment of futility

A Data Safety Monitoring Board has been established and will meet monthly to provide an unbiased review of safety and futility measures. Tribal Council and Community Advisory Board members meet regularly (monthly during study startup and quarterly thereafter) to oversee all study activities and advise on community needs and impacts. Adverse events will be reported to the IRB of Record at MSU and the data safety monitoring board chair within 3 calendar days, and Tribal Council and community advisory board members within one week. After completing the enrollment of at least 25% of the expected cohort, if the rate of test return for either the passive or active arm is <50%, then the study may be stopped early for futility of the intervention.

3.6. Reporting and dissemination

Results of the trial will be reported according to the CONSORT 2010 statement [44]. All publications, presentations and other scholarly work resulting from this study will be vetted by the MSU/UW Coordinating Center and reviewed by the Yakima and Flathead community advisory boards prior to dissemination. Sharing of identifiable data (i.e., protected health information) is prohibited by existing data use agreements and memoranda of understanding with community partners (e.g., community advisory boards, Tribal Council). A memorandum of understanding with the Confederated Salish and Kootenai Tribes and existing partnership agreements with Latino community members prohibit the release of identifiable patient data. Patient-level de-identified data from the trial will be provided to the RADx-UP Coordination and Data Collection Center. A limited dataset will be made available on a

public repository according to guidance from the NIH RADx-UP consortium in accordance with a data transfer agreement between the RADx-UP Coordination and Data Collection Center and MSU.

4. Discussion

Significant efforts have gone into developing new tests for COVID-19; it is likely that these will continue to be needed for the foreseeable future despite vaccination efforts, given emergence of variants of the virus, and return to social activities, school, and employment. Health care disparities in access to testing for COVID-19 in rural and underserved communities could potentially be mitigated by tests that individuals can use at home. While there is robust evidence that individuals can obtain the needed samples themselves (e.g., nasal, saliva) for COVID-19 with similar accuracy to clinicians, leading to FDA EUA for several self-collected sampling test manufacturers, there are multiple other barriers to accessing, conducting, and acting on tests [24,45–47]. These are particularly prominent in communities where access to healthcare is limited by geography, healthcare disparities, and concerns about impacts of test results on livelihoods.

This study attempts to mitigate known barriers, such as English proficiency and literacy, and geography, by augmenting existing kit inserts with graphically-enhanced materials in English and Spanish and providing local mailing and delivery instructions and support. CHWs will provide technological support to all participants in the active study arm and to those randomized to the passive arm upon request to address issues related to digital literacy, as well as other testing aspects. However, access to reliable internet and computer/smart phones remain problematic and is a barrier that is beyond the scope of this study.

With the approval and authorization by the FDA of multiple COVID-19 tests, including tests that are completed entirely at home, as well as those that involve returning a sample to a central lab for testing, it is important to understand how communities who most need these tests, can best be served. In particular, it is vital to understand whether barriers in technology, language, literacy, dexterity, understanding test procedures, obtaining, and returning tests, and trust in testing procedures can be mitigated using more 'hands on' assistance, or whether this is not necessary and what consists of sufficient support. These findings may also be impactful for informing the types of studies that test manufacturers are required to complete as part of regulatory submission for the growing array of home-based testing options for COVID-19 (and potentially other point of care tests).

Strengths of our study include the generation of evidence regarding the impact of active assistance in testing, which will provide valuable information for test implementation efforts using a robust RCT design. This may be particularly important for supporting testing in non-English speaking communities, those with limited digital literacy or internet access, advanced age or health conditions impacting ability to administer the test (e.g., dexterity to self-swab, ability to see instructions), support for test pickup/drop off, and interpretation of results. Working with communities where our research team has strong relationships will also allow us to gather unique insight using our multi-methods approach. These will be used to inform national efforts at home-based testing in NA and Latino communities in the United States.

A limitation in our study design is that the Everlywell auto-generated email and text updates about availability of test results are only available in English, but the study includes Spanish-speakers. Everlywell is developing the end-to-end Spanish workflow, which may or may not be commercially implemented by the time our study ends. However, this mirrors activities of most test companies where English language is prioritized for initial implementation. A further potential limitation may be challenges with recruitment, which may be impacted by vaccination and community testing efforts underway in our research sites. We are unable to test the immediate impact of test results on actions by tested individuals, given that the sample needs to be returned to a central laboratory for analysis. Our findings therefore may not apply to

emerging tests that can be completed entirely at home.

As home-based testing technologies become more widely available for COVID-19 (and potentially other infections), understanding the types of support needed for their implementation in underserved communities will be essential to achieve their full impact. We anticipate the results of ‘Protecting our Communities’ trial will provide impact for national efforts to support COVID-19 testing.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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