"Motivate Vaccinate Activate" *An effectiveness-implementation trial to assess the impact of a multi-component community-based intervention to increase RSV vaccine uptake among Latino older adults*

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Abstract

Title	**"Motivate Vaccinate Activate"** An effectiveness-implementation trial to assess the impact of a multi-component community-based intervention to increase Respiratory Syncytial Virus (RSV) vaccine uptake among Latino older adults
Study Description	Through a community-based participatory research approach this study will focus on increasing RSV vaccine uptake among Latinos. In two trials we will determine the effectiveness of community health worker counseling and text-message interventions to (1) increase RSV vaccine uptake among older adults (Motivate trial) and (2) activate adults to discuss RSV vaccination with older adults in their social and family networks (Activate trial), while also gaining insights into the facilitators and barriers of these approaches.
Study Intervention	Text message nudges (arm 1) vs. community health worker counseling & text message nudge (arm 2)
Study Population	(1) Motivate Trial: Latino adults ≥50 years who are eligible for RSV vaccination (2) Activate Trial: Latino adults ages 18-49 years
Primary Objective	To assess the effectiveness of the 'Motivate, Vaccinate, Activate' strategy, which includes Community Health Worker (CHW) counseling and text-message nudges to *a.)* Increase RSV vaccine uptake among Latino older adults *(Motivate trial)* and b.) To activate Latino adults to recommend RSV vaccination to older adults in their social networks *(Activate trial).*
Secondary Objectives	To characterize implementation outcomes of the 'Motivate, Vaccinate, Activate' strategy, with implementation outcomes defined with the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework.
Recruitment Methods	Community-based recruitment in San Francisco, California.

Sample Size	*Developmental Aim, Phase 1:* *RSV Vaccine hesitancy survey: 200 adults ≥18 years and older* *Community Advisory Group: 35 adults ≥18 years* *Motivate Trial: 400 adults, ≥50 years* *Activate Trial: 350 adults, 18-49 years*
Duration of Study Participation	*Community Advisory Group (6 months)* *Motivate Trial (90 days)* *Activate Trial (90 days)*
Unique Aspects of this Study	This study will address key knowledge gaps surrounding multi-level and community-based interventions to improve vaccine uptake among Latinos and other racial and ethnic minorities in the United States: (1) comparative effectiveness of high vs. low-intensity CHW-led interventions, (2) implementation and impact of text-message from trusted community-based organizations (CBO), as opposed to health systems,(3) effectiveness of cross-generational social network strategies, ie. empowering grandchildren to discuss vaccination with grandparents,(4) barriers and facilitators to adapting interventions that were effective in a pandemic to a non-pandemic setting, where urgency and resources are lower.

List of Abbreviations

ADAPT-ITT	Assessment, Decision, Adaption, Production, Topical Experts, Integration, Training, Testing Framework
ACIP	Advisory Council on Immunization Practices
AE	adverse event
ATT	average treatment effect on the treated
BeSD	Behavioral and Social Determinants of Vaccination Framework
CAIR	California Immunization Registry
CDC	Center for Disease Control
CHW	Community Health Worker
CRF	case report form
DSMC	Data and Safety Monitoring Committee
DSMP	Data and Safety Monitoring Plan
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICF	informed consent form
ICH	International Conference on Harmonization
IDI	In Depth Interviews
IRB	Institutional Review Board
ITT	intention to treat
LTF	Latino Task Force
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance Framework
RSV	Respiratory Syncytial Virus
TMLE	Targeted Maximum Likelihood Estimation

Table of Contents

1.2. Table of Contents

Table of Contents

1. Introduction

1.1. Background on RSV Vaccine and Disparities in Vaccine Uptake

The new and effective Respiratory Syncytial Virus (RSV) vaccines have the potential to reduce the large burden of RSV disease in older adults—which causes an estimated 12,700 deaths,160,000 hospitalizations, 1.4 million outpatient visits per year.[1,2] Yet, their full public health impact will not be realized if we allow the racial and ethnic disparities in RSV vaccine uptake to mirror those observed in other respiratory virus-vaccines, from COVID-19 to influenza.[3–5] Nationally representative data[6] already demonstrate disparities in RSV vaccine confidence by race/ethnicity and income. Among older adults, Latinos have lower RSV vaccine confidence compared to non-Latino White people. The time is now to proactively generate the rigorous data needed to inform efficient and equitable interventions to increase uptake of this new vaccine.

Respiratory Syncytial Virus (RSV) causes a substantial burden of hospitalizations and deaths among older adults, with a disease burden similar to influenza.[1,2,7–10] RSV is a seasonal respiratory virus that can cause severe lower respiratory tract infections and pneumonia in young children and older adults, especially those with other co-morbid health conditions. Morbidity due to RSV is high, it causes an estimated 12,700 deaths, 159,000 hospitalizations, 119,000 emergency room visits and over 1.4 million outpatient visits per year among older adults living in the US.[2,11] A cohort study in older adults highlights the high incidence of RSV, with 5.5% in the cohort infected annually, nearly twice that of the flu.[2] The burden of RSV goes beyond hospitalization; older adults who are infected with RSV are more likely to have role limitation and decreased social functioning.[8,10] RSV disproportionately affects racial and ethnic minorities, hospitalizations due to RSV were 7.8 per 100,000, compared to 4.4 per 100,000 among non-Latino white individuals.[1] These disparities by race/ethnicity are seen broadly among acute respiratory viral infections in older adults.[7,12–14] We now have a new preventive tool to decrease this large burden of disease. The new RSV vaccines, approved in 2023, are highly effective (89%[15] and 83%[16] effective against symptomatic infection) and can have a large public health impact on morbidity and mortality in older adults. *However, timely evidenced-based data is needed to guide interventions for an equitable RSV vaccine uptake.*

In 2025 the Centers for Disease Control (CDC) and the Advisory Committee on Immunization Practices (ACIP) updated their recommendations and all adults 50 years older are eligible for one dose of the RSV vaccine. They also uniformly recommend one RSV vaccination for (1) adults 75 years and older and (2) adults 50-74 years old who have an increased risk of severe RSV disease. Persons who are considered at increased risk for RSV are those with: cardiovascular disease (e.g hypertension, coronary artery disease), lung disease (e.g COPD, asthma), advanced chronic kidney disease, diabetes, liver disorders, neurologic or neuromuscular conditions, hematologic disorders, moderate or severe immune compromise, frailty, people who reside in nursing homes, people with chronic medical conditions or risk factors that a healthcare provider determines might increase risk of severe disease due to respiratory infections.

Vaccine hesitancy is a major threat to the equitable uptake of the new Respiratory Syncytial Virus (RSV) vaccines. Since the introduction of the new RSV vaccine for older adults in 2023, uptake has been low, and significant disparities have already emerged.

According the CDC, as of May 2024, only 24% of adults over the age of 60 have received the vaccine, with uptake differing by race-ethnicity (14.5% among non-Latino, 20.7% Black, 26.5% non-Latino White), insurance status (7.7% uninsured vs. 25% insured) status, and income level (15.5% for people below the national poverty level vs. 27.9% for those above the national poverty level).[17] Multi-level, community-based interventions are needed to address the three components of RSV vaccine hesitancy: *confidence* in the safety and efficacy of the vaccine, *complacency* towards vaccine uptake, confidence in the safety and efficacy of this new vaccine, and *convenience* in accessing the vaccine.[18]

1.2. Background on Community-Based Interventions with texting and community health workers to Increase Vaccine uptake

Latino older adults, especially immigrants, experience unique barriers and facilitators to vaccine uptake and tailored strategies are needed. Studies specific to vaccine hesitancy in older adults highlight the importance of knowledge about vaccine eligibility, access, vaccine safety, and health beliefs about susceptibility of infection.[19,20] While these barriers by are shared across different race-ethnicity, Latino older adults face additional barriers, including lack of language concordant vaccine information, experiences of racial discrimination,[21–23] mistrust of government and health institutions—often rooted in systemic racism and hostility to immigrants,[24–26] and health-care access related barriers (e.g transport, insurance). Facilitators include trust in community-based organizations and health care providers for vaccine information, low-barrier language concordant vaccine sites, and familial and social influences.[24,26,27]

The COVID-19 vaccine roll-out triggered a renaissance of community-based approaches to increase vaccine uptake among Latinos and other historically marginalized communities. COVID-19 vaccination strategies that move vaccination outside of brick-and mortar health care institutions to trusted community spaces, in-partnership with the impacted community, have been successful at reducing racial/ethnic disparities.[24,28] Successful examples include vaccine promotion by community health workers and vaccination at trusted community sites (e.g., barber shops, churches, and health fairs) coupled with culturally concordant messaging about vaccine eligibility, safety, and efficacy.[24,28,29] This success is due to multi-level interventions that address both access and trust-related barriers. *While much has been learned about improving vaccine uptake during the COVID-19 pandemic, new data is needed to guide efficient and equitable adaptations of vaccinations in the post-pandemic era, where urgency for vaccination and resources for community-based organizations is decreasing.*

Our Unidos en Salud multi-component 'Motivate, Vaccinate, Activate' model is feasible and effective, and we have the opportunity to adapt it to RSV vaccination. The Unidos en Salud Collaboration,[30] a community-academic partnership between UCSF and the San Francisco Latino Task Force (Figure 1), co-designed and evaluated this strategy.[31] It includes three components: (1) Motivate: community mobilization and demand generation by CHWs, (2)Vaccinate: a low barrier vaccine site centrally located in the Latino cultural hub of San Francisco, staffed by trusted, welcoming, Spanish-speaking CHWs that does not ask for ID or insurance, (3)Activate: CHWs encouraged clients to reach out to members of their social networks who have not been vaccinated. We evaluated the implementation of this multi-component intervention among 11,098 individuals accessing our vaccine site and we found that

the intervention was effective, feasible, and reached our priority population of low-income Latino immigrants.[31] Among Latino clients, 76% had an annual household income of less than $50,000, 60% were first-generation immigrants, and 47% did not have access to primary health care services. Effectiveness measures focused on behavioral change: **58% of clients of clients stated that they were able to get vaccinated more quickly due to the vaccine site, 90% said they were more likely to recommend vaccination to their family members and friends, and 83% reported recommending the vaccine to 1 or more people in their network.** The model was highly acceptable and feasible, and participants attributed trust and convenience as the top reasons *Established community-academic partnerships, such as Unidos en Salud, can efficiently adapt strategies to promote COVID-19 vaccine uptake to RSV, while centering the priority community.*

Community Health Workers (CHWs) played a crucial role in increasing COVID-19 vaccination. Shared language and life experiences allow CHWs to quickly establish trust. To our knowledge, there are no randomized studies on the direct impact of CHWs alone on vaccine uptake in the United States, though cross-sectional implementation-focused studies identity the importance of CHWs as part of multi-component vaccination strategies.[31,32] To our knowledge there is only one randomized study on a counseling intervention by peer vaccine ambassadors. This study included a large Latino population who inject drugs and found that a peer education and navigation intervention, designed to address both hesitancy and access related barriers, increased COVID-19 vaccine uptake by 35%[33].Outside of vaccinations, there is a large body of literature to support the importance of CHW education to increase uptake of preventative health services, especially with of cancer screening.[16,34,35] *Despite the large body of knowledge about CHWs, key scientific knowledge gaps remain about the relative effectiveness high-intensity CHW counseling sessions vs. lower-intensity 'outreach', and few studies assess the impact of CHWs on activating vaccine uptake in social networks.*

Behavioral nudges with text messages can increase vaccine uptake. In behavioral economics, nudges are small interventions or alterations in the environment that make it more likely that an individual will make a particular (preferred) choice. A text message nudge can address two barriers. First, it serves as a prompt to make the recipient aware a vaccination is due and to follow through on vaccination intentions. Second, it can provide information about how and where to schedule appointments. Text messages interventions from large health systems have demonstrated success for flu vaccination[36], childhood vaccines[37] and COVID-19[37,38], with a boost in vaccination by 4%-8%. Latinos, especially those who are uninsured, are largely left out of these studies, for example, in a large text-message study in a health system in Los Angeles, Latinos comprised only 10% of the study population despite being 48.6% of the population. While text messaging reminders are a promising intervention, we need to improve the reach of this tool to patients who are uninsured or not on digital health system portals. To date, aside from our preliminary data, *there are no studies focusing on text messaging interventions with texts originating from community-based organizations.*

Social networks can exert positive influences on vaccine uptake. Social contagion theory describes the process whereby a person adopts the health behaviors or attitudes of their social network[39] A scoping review on social networks and vaccination highlight three main areas of influence that motivate our proposed work[40]: (1) Individuals were more likely to have a positive attitude to vaccination and higher uptake if their friends or family held positive beliefs about vaccination (2) Individuals were more likely to get vaccinated or perceive a vaccine as effective

if they heard about or discussed vaccinations with peers. For example, Latina women were 4.7 x higher odds of perceiving the HPV vaccine as effective if they heard about the vaccine from friends[41]. (3) Shared race/ethnicity was high in social networks and racial/ethnic concordance. Data from our 'Motivate, Vaccinate, Activate' intervention showed a positive impact of a CHW intervention on recommending COVID-19 vaccination to family or friends. *Given the large amount of cross-sectional formative data on the influence of social networks on vaccine uptake, now is the time for randomized trials on the impact of community-based interventions to increase vaccine uptake across social networks, including cross-generational networks.*

A growing body of evidence suggests younger people can influence the health behaviors of older family members. In a vaccine uptake study from the United Kindom,[42] 35% of older people said that younger relatives pass on health messages to the, and this proportion was higher (55%) among racial and ethnic minorities compared to White people. Among older adults, at least 22% overall, compared to 44% of Black participants, said that recommendations from younger people influenced their health behaviors. Younger people report that knowledge gaps about vaccine safety and eligibility were the main barriers to recommending vaccination to older family members. *The proposed study will measure the effectiveness of a CHW and text-message intervention to enable people to discuss RSV vaccines to older persons in their social network.*

1.3. Study Rationale

Respiratory Syncytial Virus (RSV) causes a substantial burden of hospitalizations and deaths among older adults, comparable to that of influenza. The new and effective RSV vaccines have the potential to dramatically reduce RSV morbidity and mortality, yet their full public health impact will not be realized if the racial and ethnic disparities in RSV vaccine uptake mirror those observed in other respiratory virus-vaccines, from COVID-19 to influenza. We have the opportunity to adapt community-based interventions from the COVID-19 pandemic to proactively address disparities in RSV vaccine uptake. However, evidence-based data, conducted in partnership with impacted communities, are essential.

This project focuses on increasing RSV vaccine uptake among Latinos, a community disproportionately affected by respiratory vaccines and RSV. We will leverage our well-established community-academic partnership, Unidos en Salud, to adapt two components of our 'Motivate, Vaccinate, Activate' intervention—CHW counseling and text message nudges. This multi-component intervention was originally designed to increase COVID-19 vaccine uptake among Latinos and to activate people to recommend vaccination to people in one's social network. Our overall study objective is to adapt this intervention to inform effective and customizable community-based strategies to increase RSV vaccine uptake. In addition to a rigorous randomized trial design, we will collect detailed implementation outcomes to aide in generalizability and adaption to other vaccines and settings.

This study will provide timely, rigorous, and adaptable data to directly inform community-based approaches to increase RSV vaccination. In addition to providing timely data to reduce RSV vaccine disparities, these data will address key knowledge gaps surrounding multi-level interventions to improve vaccine uptake: (1) comparative effectiveness of high vs. low-intensity CHW-led interventions, (2) implementation and impact of text-message from trusted community-based organizations (CBO), as opposed to health systems, (3) effectiveness of cross-generational social network strategies, ie. empowering grandchildren to discuss vaccination with

grandparents, (4) barriers and facilitators to adapting interventions that were effective in a pandemic to a non-pandemic setting, where urgency and resources are lower. Our overall objective is to inform effective and customizable community-based strategies to increase RSV vaccine uptake among Latino older adults, with generalizability to other settings.

2. Risk/Benefit Assessment

2.1. Research Procedures Involving Study Subjects

Recruitment: Latino Task Force/Unidos en Salud Community Health Workers (CHWs) in partnership with bilingual bicultural UCSF study staff will recruit eligible participants among people who are receiving services or attending community cultural or health fairs at Latino Task Force (LTF) sites or CBOs affiliated with the Latino Task Force.

CHW Counseling: Participants in Aim 2 and Aim 3 will have a 20-minute counseling session with a community health worker. The content of the session will consist of the 5A's technique and will be informed by adaptations made in Aim 1.

Text-message nudge: Participants will receive a text message about RSV vaccination with a scheduling and informational link. The text-message will be sent on behalf of the Latino Task Force.

Questionnaires: At baseline and endline participants will complete a survey on demographics, vaccine confidence, hesitancy, and social networks. Names will not be collected in the social-network survey.

2.2. Potential Risks to Human Subjects

There are relatively few risks to study participants of study participation and include: i) inadvertent disclosure of health information, including past medical history; and ii) psychological stress during interview procedures.

2.3. Adequacy of Protection Against Risks and Informed Consent

2.3.1. Informed Consent

Consenting will be performed in the native or requested language of the participant, Spanish or English. We will seek informed consent either in person or through remote consent with DocuSign from all participants. After the participant has read the consent form, prior to seeking a signature, study staff will ask participants to summarize the study and explain the reasons why they want to participate. Any misunderstandings regarding procedures, risks, or benefits will be clarified. Individuals will be provided with information on how to contact the study staff to report adverse events. Study staff will be trained in the need to ensure that individuals provide voluntary informed consent. For adults who are illiterate, witnesses independent from the study will be required to be present for the consent discussion and to co-sign consent forms upon confirming that the participant's consent is given voluntarily and freely. Illiterate participants may mark an X on the signature line if they cannot sign themselves and the witness will provide the date next to the participant's signature line.

Study staff will document informed consent for each participant. Participants may withdraw consent at any time.

2.3.2. Protections Against Risk

Privacy: Surveys will be conducted either by staff administering them in a private location at LTF- affiliated CBOs or if preferred over the phone. In-depth interviews will occur at Mission Language Vocational School, UCSF or remotely via the online meeting platform Zoom or phone (if preferred). Community Advisory Groups will occur at Mission Language Vocational School in a private room or over Zoom.

Data Security: Study staff will collect all field electronic data on password encrypted devices. Any paper data collection forms, if necessary, will be data entered into a digital form, with paper forms stored in secure, locked offices at UCSF. Data will be stored in a secure cloud or on encrypted computers. For data collected as part of the study, participants will be assigned a unique identification number, and paper or electronic documentation that includes identifiers will be minimized. All study staff will be trained on procedures for maintaining confidentiality and undergo human subjects protection training.

2.3.3. Populations that are vulnerable to coercion or undue influence and pregnant women and neonates

Reimbursements for participation are calibrated to avoid undue coercion for participation, and most participants are unlikely to experience a significant economic gain as a result of participation. A publication by a research group (the Ethics Working Group of the HIV Prevention Trials Network) has also made the case that the use of incentives for health promotion does not necessarily undermine individual autonomy Instead, the incentives can help overcome economic obstacles or motivational deficiencies; they can promote engagement in health-related behaviors that participants regard as beneficial or worthwhile, but do not undertake due to behavioral biases such as present-biased preferences.

To minimize the likelihood of persons feeling pressured to participate in research we will emphasize the concepts of individual voluntary choice to participate in research and the need for study staff to respect the voluntary choice of others during the process of obtaining informed consent from adults and their children. Study participants will also be informed that participation can be stopped at any point during the study at their request.

2.3.4. Potential Benefits

Study participants may benefit by learning about RSV vaccination, eligibility, and navigation to vaccination. The benefits for the community may include adapted strategies to increase vaccine uptake in a community disproportionately impacted by respiratory viruses and with historically lower rates of vaccine uptake compared to non-Latino White populations.

The minimal risks to subjects are reasonable in comparison to the potential benefits to themselves and their community by improving RSV vaccine uptake. The RSV vaccine is FDA-approved and we will only enroll participants who are eligible for RSV vaccination per the CDC and ACIP.

2.3.5. Importance of the Knowledge to be Gained

The minimal risk in this study is far outweighed by the importance of the knowledge to be gained. The overall objective of the study is to inform effective, actionable, and customizable community-based strategies to increase RSV vaccine uptake among Latino older adults, with generalizability to other vaccines and settings. Findings from this study will fill key knowledge gaps about vaccine promotion in communities that experience health disparities: (1) effectiveness of high vs. low-intensity CHW counseling interventions, (2) implementation and impact of text-message from trusted community-based organizations, as opposed to health systems, (3) effectiveness of cross-generational social network strategies, ie. empowering grandchildren to discuss vaccines with grandparents, (5) facilitators and barriers to adapting interventions that were effective in a pandemic to the non-pandemic setting, where urgency and resources are lower.

3. Study Objectives and Endpoints

3.1. Primary Objectives

Our overall study objective is to assess the effectiveness and implementation of the Unidos en Salud (UES) 'Motivate, Vaccinate, Activate' strategy, which includes CHW counseling and text-messaging on increasing RSV vaccine uptake among older Latino adults. Our primary hypothesis is that language- and culturally-concordant CHW motivation and activation counseling sessions, coupled with text message nudges, will increase RSV vaccine confidence by addressing trust, knowledge, and access-related barriers. To achieve this objective, we will first adapt the key intervention components in Aim 1, then will determine the effectiveness of a multicomponent intervention (CHW counseling and text-message nudges) on increasing vaccine uptake in Latino older adults (Aim 2) and encouraging Latino adults (18-49 years) to discuss RSV vaccination among older adults in their family and social networks (Aim 3). The primary outcomes are summarized in Table 1.

The Study Aims are:
Aim 1: Adapt a CHW counseling and text-message intervention to increase RSV vaccine uptake and activate younger adults to discuss RSV vaccination with older adults in their social networks. In his developmental aim, we will use the ADAPT-ITT framework[43] to adapt two intervention components CHW counseling and text-messages nudges, to increase RSV vaccine uptake in Latino older adults (≥50 years)
Aim 2: Determine the effectiveness of CHW counseling and text-message nudges from a CBO on RSV vaccine uptake among Latino older adults. In a randomized two-arm trial, will compare CHW counseling *and* text message nudges vs. CHW delivered RSV vaccine flyer + text-message nudges in 400 Latino adults ≥50 years. Study interventions are adapted in Aim 1a. *Our hypothesis is text messages coupled with a community health worker counseling session will increase RSV vaccine uptake compared to texts alone.* Primary Outcome: RSV vaccine uptake at 60 days. Secondary outcomes include change in motivation to get and confidence in the RSV vaccine, implementation per the RE-AIM framework[44], with a focus on *implementation, adoption and maintenance* assessed via mixed methods.

Aim 3: Determine the effectiveness of CHW 'activation' counseling and text-message nudges from a CBO on activating adults to discuss RSV vaccination with older adults in their social network. In a parallel design to Aim 2, we will compare: CHW 'activation' counseling *and* text message nudges vs. RSV vaccine flyer at enrollment + text-message nudges in 350 Latino adults (18-49 years). Study interventions will be adapted in Aim 1b. Our

hypothesis is *text messages coupled with CHW counseling will activate participants to discuss RSV vaccination with older adults in their network, compared to text-message alone.* Our primary outcome is average proportion of older adult (≥50 years old) network contacts with whom RSV vaccination was discussed. Secondary outcomes include change in knowledge about the RSV virus and the vaccine, change in motivation to discuss the RSV vaccine with eligible family members or friends, implementation per the RE-AIM framework, with a focus on *implementation, adoption, and maintenance components* assessed via mixed methods

Table 1: Primary Objectives

Primary Objective	Endpoint(s)	Time Frame
1. Aim 1 (Developmental Aim) -Community-based survey on RSV vaccine hesitancy -Community advisory group adapts intervention components. -In depth interviews	N/A	1 year
2. Aim 2 (Motivate Trial): Determine the effectiveness of CHW counseling and text-message nudges from a CBO on RSV vaccine uptake among Latino older adults.	RSV Vaccine uptake at 60 days per California Immunization Registry (CAIR) or per medical record	60 days from time of intervention
3. Aim 3 (Activate Trial): Determine the effectiveness of CHW 'activation' counseling and text-message nudges from a CBO on activating adults to discuss RSV vaccination with older adults in their social network.	Self-reported average proportion of social network contacts ≥50 years with whom participant discussed RSV vaccination at 60 days.	60 days from time of intervention

3.2. Secondary Objective(s)

Aim 1 (Development aim).

- *Secondary:* Predictors of RSV Vaccine hesitancy, Adaptation of text-message and CHW counseling intervention with Community Advisory Board.

Aim 2:

Secondary:

- RSV Vaccine uptake at 60 days (self-report)
- RSV Vaccine uptake at 90 days per CAIR or per medical record
- RSV Vaccine uptake at 6 months per CAIR or per medical record
- Median time to vaccination (days)
- Appointment made at 60 days in clinic or a pharmacy with intent to get RSV Vaccine per self-report
- Increase in RSV Vaccine confidence (BeSD indicator) by 1 point

- Increase in motivation to get RSV Vaccine (BeSD indicator) by 1 point
- Increase in RSV vaccine knowledge by 1 point (Likert scale): Before today how much did you know about the RSV vaccine (1 = nothing, 2= a little, 3= some, 4= a lot)
- Average proportion of social network contacts ≥50 years with whom participant discussed RSV vaccination at 60 days.
- Implementation outcomes per Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) framework (Table 2)

Aim 3:

Secondary:

- Discussed RSV vaccination with ≥1 eligible family member or friend within 60 days of enrollment
- Implementation outcomes per Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) framework (Table 2)
- Increase in RSV Vaccine confidence (BeSD indicator) by 1 point
- Increase in motivation to discuss the RSV Vaccine with eligible family members or friends(BeSD indicator) by 1 point
- Increase in confidence in the RSV Vaccine (BeSD indicator) by 1 point
- Increase in RSV vaccine knowledge by 1 point (Likert scale): Before today how much did you know about the RSV vaccine (1 = nothing, 2= a little, 3= some, 4= a lot)

Table 2: RE-AIM Outcomes for Motiviate and Activate Trials

RE-AIM Domain/Outcomes
REACH Enrollment by key subgroups for reach: income, birth country, age strata. **Measurement: Screening Tool**
EFFECTIVENESS (Participant level) Primary outcome in Aim 2 and 3 Trials
ADOPTION (Provider and staff level) Thematic results on barriers and facilitators of adopting intervention in other CBO settings, other populations **Measurement: Endpoint Survey, Qualitative**
IMPLEMENTATION (Participant, CBO-level) Fidelity: -Fidelity to CHW script (content, structure) -% participants completing receiving text -% completing CHW counseling if assigned Adaptations: Type, timing and reasons to CHW counseling or recruitment Process: Time spent on interventions, number of CHW follow-ups for navigation Satisfaction with intervention components: Participant level: Median scores for domains within patient satisfaction survey; Thematic results from IDIs and barriers and facilitators of vaccination and recommending vaccine to eligible people in social networks CHWs/Stakeholders: Perceived barriers and facilitators on adapting the intervention to other vaccines or in other settings Health system barriers and facilitators of getting RSV vaccination **Measurement: CHW logs, Endpoint survey, Qualitative**
MAINTENANCE (CBO-level) Barriers and facilitators of maintaining the intervention **Measurement: Endpoint Survey, Qualitative**

4. Study Design

4.1. Characteristics

Study Overview. In this type 1 hybrid-implementation study we will leverage our well-established UES collaboration, a community-academic partnership. We will uphold community-based participatory research principles throughout the study.[45] **In Aim 1,** a developmental aim, we will use the ADAPT-ITT framework to adapt two intervention components, CHW counseling and text-messages nudges from a CBO, to increase RSV vaccine uptake in Latino older adults (≥50 years) who are eligible for RSV vaccination (Aim 1a) and to activate Latino adults (18-49 years) to discuss RSV vaccination with older adults in their family and social network (Aim 1b).

We will also conduct a community-based anonymous survey to assess knowledge and perceptions about RSV and RSV vaccine knowledge. Then, in **Aim 2 (Motivate Trial),** we will randomize 400 Latino older adults to CHW counseling *and* text message nudges vs. CHW delivered RSV vaccine information flyer at enrollment + text-message nudges, all adapted in Aim 1a. The primary outcome in Aim 2 is RSV vaccine uptake. In **Aim 3 (Activate trial),** using a parallel design we will randomize 350 Latino adults (18-49 years) to CHW 'activation' counseling to encourage them to discuss RSV vaccine with people over 50 and older in their network *and* text-message nudges vs. RSV vaccine information flyer at enrollment + text-message nudges, all adapted in Aim 1b. The primary outcome for Aim 3 is average proportion of older adults in participants' social network with whom they discussed RSV vaccination. We will incorporate implementation outcomes as secondary outcomes, which we will evaluate using the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework,[44,46] an integrated framework to improve adoption and sustainable implementation of interventions and includes an explicit focus on equity to address dynamic implementation contexts. Our overall study design is in line with a type-1 hybrid effectiveness-implementation trial,[47] which tests an intervention effectiveness as a primary aim, while gathering information on its delivery or implementation in the real-world. Table 3 provides an overview of the overall study design and primary outcomes.

Table 3: Study Overview

Aim	Study Population	Study Design and Intervention	Outcomes
1	1. Community Advisory Group: 1a. Latino adults ≥60yr 1b. Latino adults 18-50 yrs. N~35 2. Anonymous Community Vaccine Hesitancy Survey (18+ years)	1. Adaptation of intervention components using ADAPT-ITT framework. Includes in-depth interviews and formation of community advisory groups for 1a and 1b. 2. Predictors of vaccine hesitancy	Developmental Aim Products Primary: Adapted intervention components Secondary: Publication on ADAPT-IT process of adapting core-intervention components
2	400 Latino adults ≥ 50 years, who have not received the RSV vaccine	**Motivate Trial: Randomized Trial with 2 groups** 1. Flyer & text-message nudge from CBO 2. Flyer & text-message nudge from CBO AND CHW counseling	Primary: RSV vaccine uptake at 60 days per CAIR Secondary: RSV vaccine uptake at 60 days per self-report; RSV vaccine uptake at 90 days per CAIR; appointment made at 60 days in clinic or pharmacy with intent to get RSV vaccine; median time to vaccination; increase in RSV vaccine confidence; increase in motivation to get RSV vaccine; increase in RSV vaccine knowledge; average proportion of social network contacts ≥50 with whom participant discussed RSV vaccination at 60 days; implementation outcomes per the RE-AIM framework
3	350 adults, 18-50 with stratified sampling by age-group.	**Activate Trial: Randomized Trial with 2 groups** 1. Flyer & text-message nudge from CBO 2. Flyer & text-message nudge from CBO AND CHW 'activation' counseling	Primary: Average proportion of social network contacts ≥50 with whom participant discussed RSV vaccination at 60 days (referred to as 'Activation') Secondary: Implementation outcomes per RE-AIM framework; increase in RSV vaccine confidence; increase in motivation to discuss the RSV vaccine with eligible family members or friends; increase in RSV vaccine knowledge; discussed RSV vaccination with ≥1 ≥50-year-old at 60 days

Qualitative Studies for Aim 2 and 3: In-depth interviews from participants in each group including those who meet the primary outcome and those who do not
Focus Groups: CHWs, key stakeholders focusing on implementation outcomes

4.1.1. Study Setting

This study will take place in San Francisco at Latino Task Force (LTF)-affiliated community sites and will leverage the existing infrastructure and reach of the Unidos en Salud collaboration, a community academic partnership between the Latino Task Force and UCSF. The Latino Task

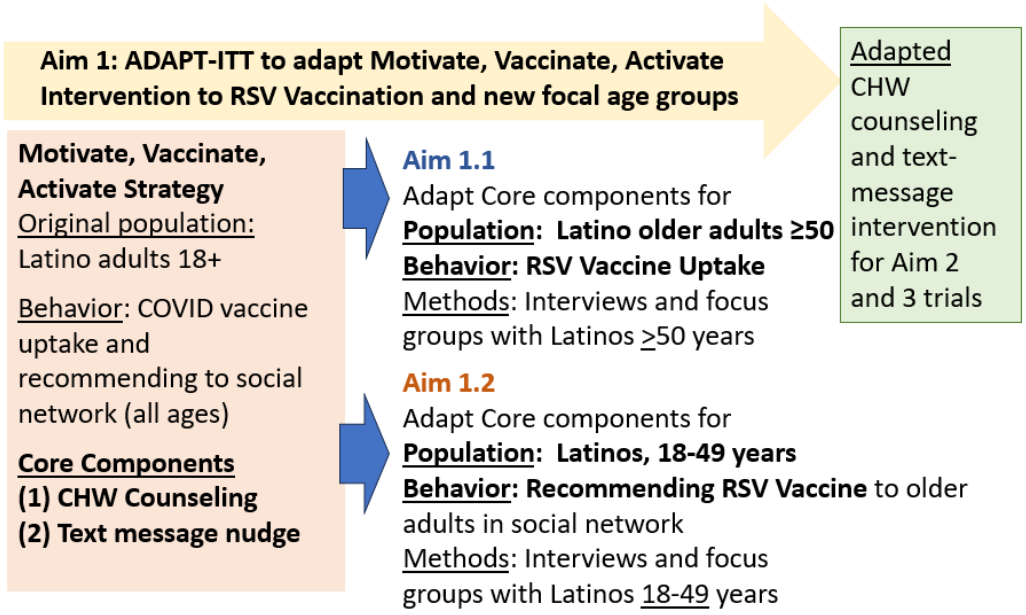
force is a coalition of over 30 Latino focused CBOs and based at the Mission Language Vocational School (MLVS), a CBO in San Francisco's Mission District.

4.2. Study Design for Developmental Aim 1

The overall objective of Aim 1 is to adapt the 'Motivate, Vaccinate, Activate' CHW counseling and text-message intervention to increase RSV vaccine uptake and to activate younger adults to discuss RSV vaccination with older adults in their social networks**.**

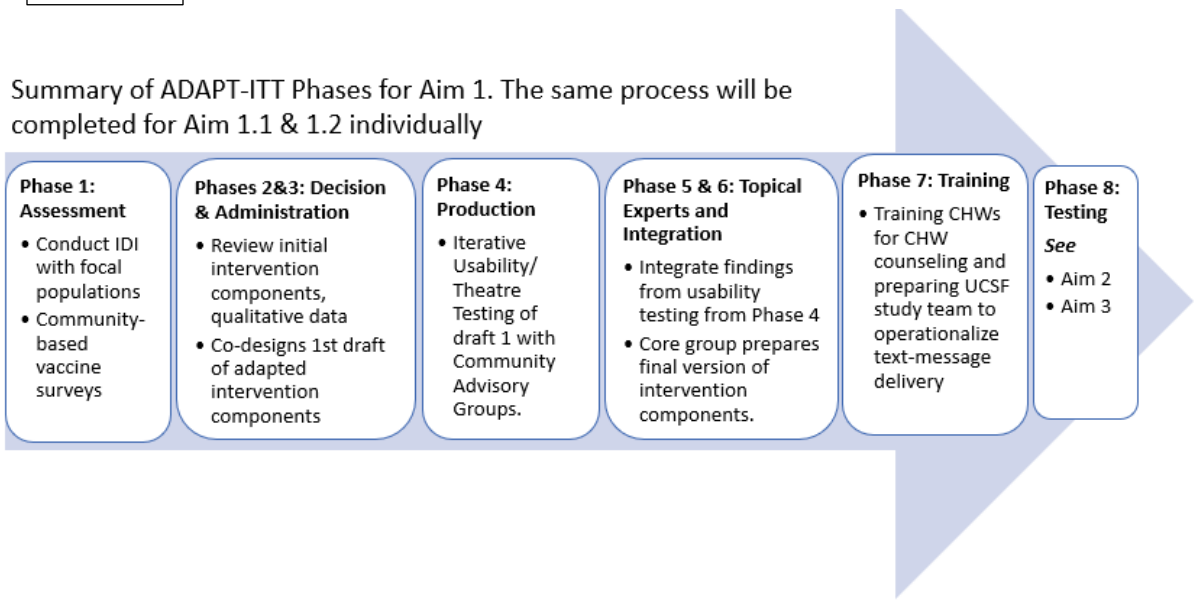
4.2.1. Overview of Aim 1 (Figure 1)

Figure 1: Overview of Aim 1



In this developmental aim, we will use the ADAPT-ITT[43] (Figure 2) implementation science framework to adapt two core intervention components from our Motivate, Vaccinate Activate Strategy (CHW vaccine counseling and text-message nudges) to promote RSV vaccine uptake among Latino older adults (≥50 years) **(Aim 1.1)** and activate adults (18-49 years old) to discuss RSV vaccination with older adults in their social and family networks **(Aim 1.2)**. In Figure 2 we outline the ADAPT-ITT process. As part of the Assessment phase of ADAPT-ITT we will (1) administer an anonymous community-based survey adults 18 years and older on knowledge and perceptions about RSV and RSV vaccination for Aim 1 and (2) Conduct In depth Interviews (3) Community advisory board meetings using the ADAPT-ITT process to assess perceptions of RSV Vaccination and preferences for intervention components and knowledge and attitudes about RSV Vaccination. The ADAPT-ITT framework was designed to assist CBOs in adapting evidence-based interventions to fit new populations.

Figure 2

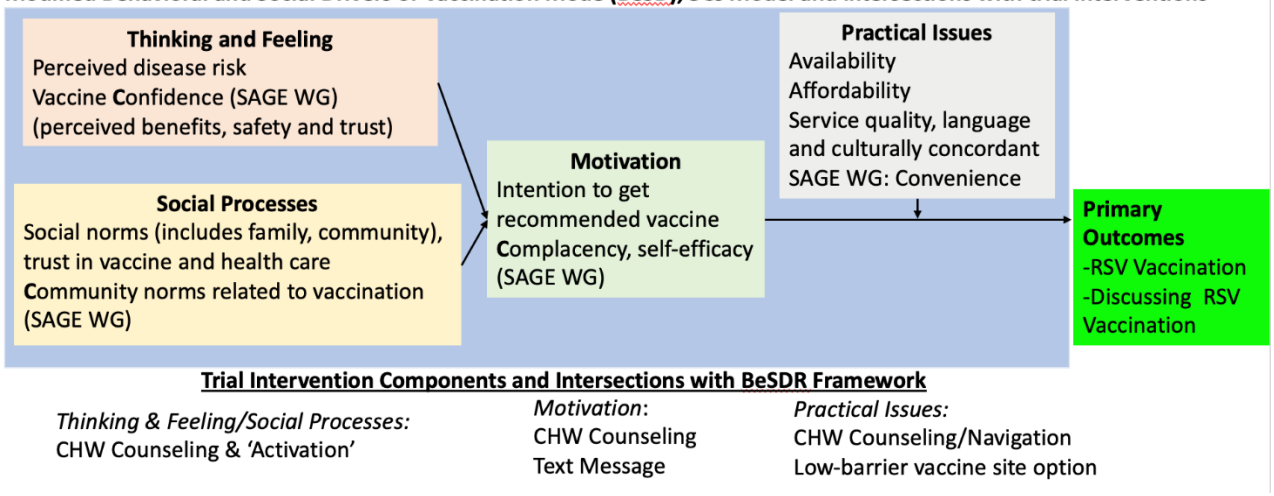


While our Unidos en Salud 'Motivate, Vaccinate, Activate' strategy is acceptable, feasible and effective for COIVD-19 vaccine uptake among Latinos, the core-components need adaptations for a different vaccine and infection (RSV), a non-pandemic setting, and different age-groups.

We will use the **Behavioral and Social Determinants (BeSD) of vaccination framework and core questions**[48,49] for developing and coding our interview guides and to examine potential mediators of the effect of our interventions. The BeSD framework is informed by multiple theoretical models: COM-B, 3C's[50], socio-ecological model, and the Increasing Vaccination Model[51] and identifies 2 domains, '*thinking and feeling' and 'social processes'* , as most associated with lack of vaccine confidence '*motivational* conflict', and a fourth domain '*practical issues'* as a domain that moderates the relationship between lack of vaccine confidence. In Figure 3 we present an adapted BeSD framework, which highlights intersections with our 'Motivate, Vaccinate, Activate intervention and highlights integration of the 3C's from the SAGE working group.[18,52].

Figure 3

Modified Behavioral and Social Drivers of Vaccination Mode (BeSD), 3Cs Model and intersections with trial interventions



4.2.2. Aim 1 Duration

a. Community-based survey on RSV Knowledge and Vaccine Confidence: Cross-sectional survey, which will last up to 25 minutes for 1 study visit.
b. Community Advisory Boards Meetings for ADAPT-ITT: Community Advisory Board members will participate in 3-5 design sessions. The anticipated duration of involvement will be 12 months.
c. In Depth Interviews: In-depth interviews on RSV vaccine confidence and preferences on text messaging and CHW counseling sessions for Aim 2 and 3. CAB members can participate in IDIs.

4.2.3. Aim 1 Sample Size

Aim 1 is a developmental Aim. Sample size is extrapolated for standard sample sizes needed for the ADAPT-ITT framework and to reach saturation for In Depth Interviews (IDIs).

4.3. Study Design of Aim 2-Motivate Trial

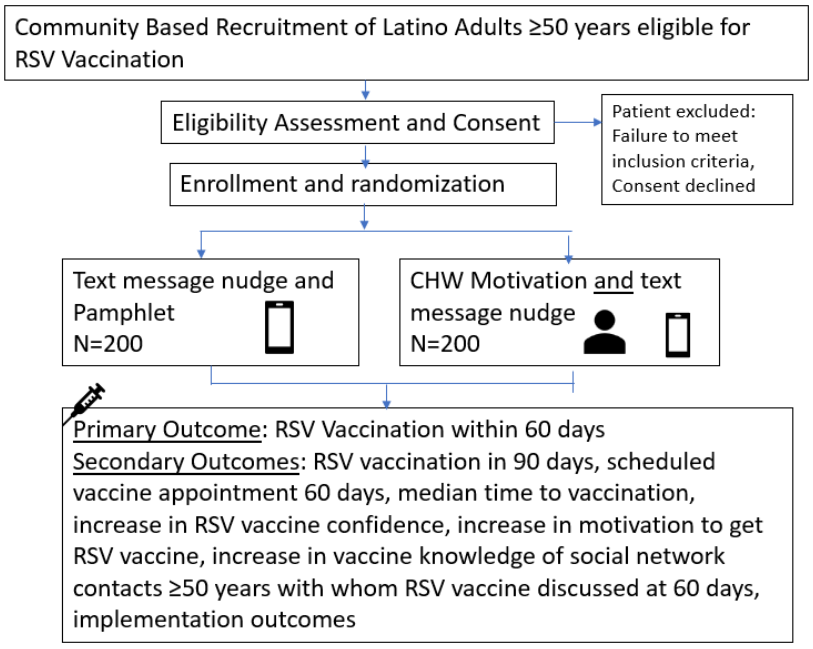
4.3.1. Introduction and Rationale to Aim 2

Drawing on our 'Motivate, Vaccinate, Activate' multi-component strategy and adaptations for RSV vaccination from Aim 1a, we will rigorously evaluate the effectiveness of a multi-component *CHW counseling session* and *CBO text-message intervention compared to text alone* (Figure 4). Our primary Hypothesis is that *text messages coupled with a community health worker counseling session will increase RSV vaccine uptake compared to text-message alone. We hypothesize that the CHW counseling session will improve trust in the vaccine ability to navigate access-related barriers, and that this intent to vaccinate is reinforced by a text-message from a trusted source.*

Understanding if there is an additional benefit to the more time-intensive CHW counseling will provide the evidence needed for CBOs and public health departments to design community-based RSV vaccination strategies for Latinos. We have chosen to not have a 'standard of care arm', but instead will compare the multi-component intervention to text-messages for three reasons: (1) Text-messaging interventions are low-cost intervention, which are effective in our

preliminary data (2) given the moderate anticipated effect size, power to detect benefit of adding text to the CHW intervention would require a sample size too large to be feasible given the intensity of the CHW intervention, and (3) we have modeled Arm 1 to mirror a 'lower intensity' CHW intervention akin to CHW outreach, with CHWs handing out an informational flyer at enrollment and receipt of a text message nudge.

Figure 4: Schema of Aim 2 'Motivate Trial'



4.3.2. Study Population

CHWs and study staff will recruit from people accessing services or community fairs at LTF-affiliated CBOs in San Francisco. Study inclusion criteria include adults 50 and over who are eligible for the RSV Vaccine; detailed inclusion criteria are outlined in section **5.1.1.**

4.3.3. Study Design and Description of Intervention Groups

This is a two-arm randomized type-1 effectiveness-implementation individually randomized trial (Figure 4), with **study groups**:

i) Arm 1- Text message nudge from CBO: Participants will receive an educational flyer from a CHW about RSV vaccination and how to schedule it. Then 4 weeks after enrollment they will receive a text-message nudge, with message content based on findings in Aim 1a. This text message will also provide a flyer with vaccine information and eligibility. A phone number to the CHW team, the LTF hotline, for help with navigation will be provided on the flyer and in the text-message.

ii) Arm 2: CHW counseling and text message nudge from a CBO: At enrollment, participants will receive an educational flyer from a CHW, as in Arm 1, and will set up a time for the CHW counseling session. They can select remote (phone or web-based platform such as Zoom) or in-person counseling within 2 weeks of enrollment, and weekend hours will be offered. CHW counseling will consist of a 20-minute semi-scripted conversation grounded in the motivational interviewing principals of Five A's[53] and adapted in Aim 1a. CHWs will assess participants beliefs and knowledge about RSV susceptibility and vaccine effectiveness, safety, and eligibility. They will advise and provide general information on vaccine eligibility and RSV susceptibility. Then, assist by assessing personal or structural barriers to vaccination and providing problem-solving techniques. Then arrange next steps: for navigation to a vaccine provider or interest in a follow-up call. CHWs will write down an action plan and give it to the participant, e.g. call clinic to make vaccine appointment in 5 days or follow-up call with CHW in 1 week. CHWs can provide general education about the vaccines: safety, eligibility, testimonials, but they will refer

individual medical questions to the participant's physician. CHWs will also provide a hotline for any questions or assistance with navigating health and vaccine linkage for participants.

4.3.4. Location of interventions and survey procedures

The CHW counseling and baseline survey will be done via phone, Zoom or in person at the Mission Language Vocational School (Latino Task Force headquarters), ZSFG Clinical Research Center or in private locations in LTF-affiliated community venues. Endpoint follow-up can be done in-person in the same locations as the baseline visit or over the phone or Zoom, with survey completion done remotely using REDCap.

4.3.5. Duration of study procedures

The duration of study procedures is 90 days, but participants can be in the study up to 24 months from enrollment if they are selected for in-depth interviews.

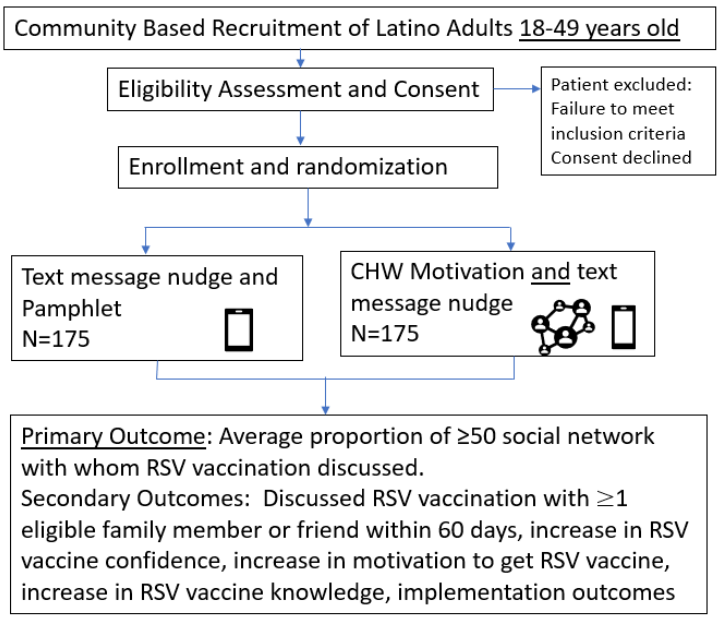
4.4. Study Design of Aim 3 – Activate Trial

4.4.1. Introduction and Rationale:

The objective of Aim 3 is to determine the effectiveness of CHW 'activation' counseling and text-message nudges from a CBO on activating adults to discuss RSV vaccination with older adults in their social network.

In a parallel structure to Aim 2 we will conduct a randomized trial (Figure 5) of the intervention components (CHW counseling and text-message from a CBO) adapted in Aim 1.2. Recommending vaccination not only requires confidence in the vaccine and knowledge about eligibility, but also capability and opportunity to initiate the conversation. We hypothesize that text messages coupled with a CHW 'activation' counseling session will increase the proportion of eligible people (≥50 years) in with whom participants discuss RSV vaccination with, compared to text alone. Hypothesized mechanisms are that CHW counseling improves trust and knowledge of RSV vaccination and susceptibility, and the text-message nudges them to act on their intention to discuss RSV vaccine with family and people in their network.

Figure 5: Schema of Aim 3 'Activate Trial'



Rationale: Interventions targeted to the social network have the potential to reach a large number of people with one contact point (i.e. the effect of CHW counseling with one person can be amplified to reach 5 of their social network contacts) and can impact social norms at the inter-personal or community level. Prior studies assessing the impact of interventions on participant's social network have been hampered by challenges documenting impact on social network contacts.

To address this we will use 'name generation techniques'[54,55] used in our prior studies to elicit the eligible contacts (adults ≥50 years) of the 18-49 year old participants.

4.4.2. Study Population

CHWs and study staff will recruit from people accessing services or community fairs at LTF-affiliated CBOs or attending cultural events in San Francisco. Study inclusion criteria include Latino adults 18-49. Detailed inclusion criteria are outlined in section **5.1.1.**

4.4.3. Study Design Aim 3 and Intervention Groups

This is a two-arm type 1 effectiveness-implementation RCT randomized at the level of the individual (Figure 5) with the following **study groups**:

Arm 1: Text message from a CBO: Participants will receive an educational flyer from a CHW about RSV vaccination and how people in their network can schedule vaccines and the 'LTF hotline' for help with navigation if needed. Then 4 weeks later receive a text-message nudge, with message content based on findings in Aim 1b. As in Aim 2, the text message will also provide a flyerwith vaccine information, eligibility, and scheduling from the LTF.

Arm 2: CHW 'activation' counseling with text-message nudge: At enrollment participants will receive the same flyer as in Group 1. Then, within 2 weeks of enrollment participants will have a 20-minute scripted conversation (in person or phone) grounded in motivational interviewing principals of Five A's. CHWs will assess participants beliefs and knowledge about RSV and vaccine effectiveness, safety, eligibility, *and* interest and barriers in recommending RSV vaccination to their friends or family. Then they will advise how to initiate conversations about RSV vaccination. CHWs will then assist, by assessing personal barriers to discussing vaccination with older adults. Then arrange next steps: CHWs will write down an action plan and give it to the participant. CHWs will also provide a hotline number for participants or their contacts to use for questions or support scheduling an appointment. Participants will receive a text-message nudge with scheduling and information 1 month after enrollment.

4.4.4. Location of CHW interventions and survey procedures

The CHW counseling and baseline survey will be done via Zoom or in person at either Mission Language Vocational School (Latino Task Force headquarters), ZSFG Clinical Research Center. Endpoint follow up can be done in-person or remotely over Zoom or the phone.

4.4.5. Duration of study intervention

The intervention will be received at baseline (CHW counseling) and the text will be received 4 weeks after follow-up. The duration of study procedures is 90 days, but participants can be in the study up to 24 months from enrollment if they are selected for in depth interviews.

4.5. Primary Completion

The expected completion of the primary outcome of Aim 2 and 3 is 4 years after the study opens to accrual.

4.6. Study Completion

The expected study completion date is 5 years after the study opens to accrual.

5. Selection and Enrollment of Participants

5.1. Eligibility Criteria

5.1.1. Inclusion Criteria and Exclusion Criteria

Inclusion and Exclusion criteria for all three aims are outlined in Table 4.

Table 4: Inclusion and Exclusion Criteria

Study	**Inclusion Criteria**	**Exclusion Criteria**
Aim 1		
RSV Vaccine Confidence Survey	(a) Adult age ≥18 years (b) Speaks Spanish or English	Not able to provide informed consent
Community Advisory Groups for Adaptation of Intervention	1. Group 1: a. age ≥60 years b. speaks Spanish or English c. self-identifies as Latino/a/e/x and/or indigenous group from Latin America d. lives or works in San Francisco County or Daly City and able to come to in-person meetings in San Francisco 2. Group 2: a. age 18-50 b. speaks Spanish or English c. Self-identifies as Latino/a/e/x and/or indigenous group from Latin America d. lives or works in San Francisco or Daly City and able to come to in-person meetings in San Francisco	Not able to provide informed consent Planning on moving out of San Francisco or Daly City area in 12 months
In Depth Interviews (Aim 1)	(a) Self-identifies as Latino/a/e/x and/or indigenous group from Latin America (b) Speaks Spanish or English (c) Age ≥18 years	Not able to provide informed consent
Aim 2 'Motivate Trial'	Inclusion Criteria: (a) Age ≥50 years (b) Self-identify as Latino/a/x and/or indigenous groups from Latin America	(a) Intent to move outside of San Francisco in the next year

	(c) Eligible for RSV vaccination per current CDC/ACIP recommendations* (c) Fluent in Spanish or English (d) Has not received the RSV vaccine (e) Has a cell phone (f) Lives or works in San Francisco or Daly City (f) Able to provide informed consent <u>* CDC/ACIP Eligibility for RSV Vaccination:</u> (1) Age 75 years and older (2) Age 50-74 and one of the following medical comorbidities: cardiovascular disease (e.g coronary artery disease), lung disease (e.g COPD, asthma), advanced chronic kidney disease, diabetes, liver disorders, neurologic or neuromuscular conditions, hematologic disorders, moderate or severe immune compromise	(b) Nursing home resident (c) Household member participating in Aim 1 or 2 (d) Unable to provide consent
Aim 3 'Activate Trial'	<u>Inclusion Criteria:</u> (a) Age 18-49 years (b) Self-identify as Latino/a/x and/or indigenous groups from Latin America (c) Fluent in English or Spanish (e) Has a cell phone (f) Has $\geq$1 family member or friend 50 years or older who they have seen or spoken to for $\geq$15 minutes in the last 6 months and who lives in the United States	<u>Exclusion Criteria:</u> (a) Household member enrolled in Aim 1 or 2 (b) Unable to provide consent

5.2. Recruitment Methods for Aims 1-3

5.2.1. Recruitment

Bilingual study staff in partnership with community health workers will recruit eligible participants among people who are receiving services or attending community cultural or health fairs at Latino Task Force (LTF) community sites, CBOs affiliated with the Latino Task Force, or other events in the community. Study team will present the study to Latino Task Force community

meetings. Staff and community health workers will distribute IRB-approved flyers about the study at community-events and answer questions about the study. While CHWs will participate in outreach, enrollment will be done by UCSF study staff. Information about the study will be shared at Latino Task Force meetings and affiliated CBOs will receive recruitment flyers, that they can also post and share with client. If a client expresses interest in the study, the study staff will follow-up with the client to discuss the study further, screen for eligibility, and set a date for the baseline visit if the individual is interested in participating.

5.2.2. Participant Incentives

Participants will receive a gift card or cash incentive as compensation for their time. The amount of the incentive is suitable to compensate for time and transport, without being coercive and the amount has been reviewed with community partners. Incentive amount will be based on time and participants can receive up to the following amounts in gift card or cash:

(1) Aim 1 vaccine confidence survey: up to $20
(2) Aim 1 Community Advisory Board Meetings up to $60 per 60-90 minute sessions

(3) Aims 1-3 90 min in-depth interviews over one study visit: up to $100

(4) Baseline and Endpoint 30-minute Questionnaires for Aim 2 and Aim 3: up to $40 at Baseline visits and up to $40 for Endpoint visits

(5) Participation in CHW Counseling Session 30 minutes: Up to $30

5.3. Inclusion of Women and Minorities

All participants in this study will self-identify as Latino and will be residents of work in San Francisco. The study is focused on Latinos, a health disparity population in the United States, because of the need to increase respiratory virus vaccine uptake in the Latino community. Latinos in the United States are disproportionately impacted by acute respiratory viral infections, and they historically have respiratory virus vaccine uptake compared to non-Latino White people. Women are expected to comprise approximately half of the participants this proposal.

5.3.1. Recruitment of Women and Minorities

To achieve representation of Latinos and women, we have partnered with the Latino Task Force and community groups that are trusted by the Latino community. in partnership with bilingual bicultural study staff, will recruit eligible participants among people who are receiving services or attending community cultural or health fairs at Latino Task Force (LTF) sites or Community Based Organizations (CBOs) affiliated with the Latino Task Force. The Latino Task Force hosts core activities at the Mission Language Vocational School.

5.4. Inclusion Across the Lifespan

This study will include adult participants aged 18-49 years old (Aim 1b & 3) and $\geq$50 years and older (Aims 1a & Aim 2). There is no upper age limit to this study. Children (age <18 years) are not included in this study as the study outcomes are not appropriate for children, as children are not eligible for RSV vaccination and not able to either discuss RSV vaccination with older adults

or not able to fully understand information being discussed during the Community Health Worker 'activation' counseling session.

5.5. Participant Registration

For Aims 2 & 3 (Activate and Motivate trials) a written, signed, informed consent form (ICF) and, for Aim 2 only, a Health Insurance Portability and Accountability Act (HIPAA) authorization must be obtained before any study-specific assessments are initiated. A copy of the signed ICF will be given to the participant. The original will be kept on file with the study records.

For Aim 1 community-based vaccination survey participants will review an informed consent information sheet prior to completing the anonymous survey.

6. Study Intervention and Randomizations

6.1. Randomization (Aim 2 & 3)

Both Aims 2 and 3 are 2 arm trials and intervention groups are described in 4.3.3 (Aim 2) and 4.4.3 (Aim 2). After enrollment participants will then be randomized to one of two study groups. Randomization will be computer generated, block randomization with random block sizes of 2, stratified by sex.

6.2. Interventionist Training, Tracking and Fidelity

To ensure fidelity of the intervention we have outlined a detailed training program and fidelity checklist. In Figure 1 we outline our training timeline. In year 1, Dr. Marquez will adapt the training content from our COVID-19 'Motivate, Vaccinate, Activate' intervention for RSV vaccination. The training materials will be reviewed by our community-academic core team and refined with CHWs during the production phase of Aim 1. In year 2, we will train CHWs to deliver the intervention and assess competency with written assessments and direct observation at the end of training. We will score competency with a fidelity checklist that includes fidelity to the intervention, accuracy of content, and participant satisfaction. Throughout the trial there will be direct observation to ensure fidelity to the CHW counseling sessions (first 5 participants and quarterly) and we will hold monthly CHW meetings to reinforce skills and address questions. This plan is guided by the NIH Behavior Change Consortium recommendations to ensure fidelity of treatment delivery[56] through standardized training, ensuring provider skill acquisition, minimizing drift (with observation and feedback), and accommodating provider differences (tailoring intervention to CHWs).

Details on measuring the fidelity counseling intervention in Aims 2 & 3. We will measure four dimensions of fidelity: (1) **adherence** (delivery as designed) through fidelity checklists—direct observation and CHW fidelity-checklists (2) **dosage** (amount of intervention delivered) time and content measured through a CHW fidelity checklist, (3) **quality**, through participant post-intervention rating and an empathy question on the fidelity checklist (4) **program differentiation**, through fidelity checklist in the intervention and control (Table 2).[57–59] The primary fidelity measure will be percent of activities completed on the fidelity checklist, measured by direct observation. In developing the fidelity checklists, we will follow the process outlined by Walton et al. 2020[59] and will assess adherence to each of the 5As. For example, for **'A**ssess', observers will choose 'Done', 'To Some Extent', 'Not Done' after observing if the CHW assessed participants' beliefs and knowledge about RSV susceptibility. Additionally, we will

assess quality of delivery using the validated empathy question from the Motivational Treatment Integrity Scale.[60]

6.3. Participant Discontinuation/Withdrawal from the Study

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may discontinue a participant from the study for the following reasons:

- Unacceptable adverse event(s)
- Significant study intervention non-compliance.
- Lost-to-follow up; unable to contact participant (see Section 6.4 - Lost to Follow-Up)
- Any event or medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant .
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

6.4. Lost to Follow-up

A participant will be considered lost to follow-up if he or she fails to return for scheduled visits and study staff are unable to contact the participant after at least 3 attempts. Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a letter to the participant's last known mailing address or local equivalent methods). These contact attempts will be documented in the participant's study file. Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

7. Study Procedures and Assessments

7.1. Informed Consent and Enrollment

Prior to consent, participants will be screened to determine eligibility in the intervention. A waiver of consent will be obtained to confirm eligibility during the screening process. Written informed consent to participate in the study will be obtained from all participants. Consent forms will be translated from the original English to Spanish. Participants who agree to take part and sign the consent form will be enrolled in the study. Participants who can neither read nor write will have an impartial witness present during the consenting process who will sign and date the consent form on a line provided for witnesses upon confirming that the participant's consent is given voluntarily and freely. Illiterate participants may mark an X on the signature line if they cannot sign themselves and the witness will provide the date next to the participant's signature line.

Aim 1: Informed Consent procedures:

- Community RSV Vaccine Confidence Survey: Informed consent information sheet.
- Community Advisory Board Meetings: Electronic or written informed consent.
- In depth interview: Electronic or written informed consent.

Study Procedures AIM 1 (Developmental Aim)

Prior to implementation of the randomized trial, we will adapt the intervention using the ADAPT-ITT process (Figure 2). Study procedures will include: a community member vaccine hesitancy survey (anonymous), observation of 3-5 community advisory groups process in adapting intervention, and qualitative interviews.

Phase 1:

a. Community RSV vaccine hesitancy survey: A 25-minute survey will include demographics (age, gender, income, country of birth), BeSD core questions, prior vaccine history, self-rated health, experiences with healthcare discrimination,[21,23] social network influences about health decisions, acculturation scale.[61]

b. In-depth Interviews (IDI): 90-minute interviews will focus on (1) Drivers of RSV vaccine confidence to guide adaptation of CHW counseling (2) cultural tailoring and preferences for content of text message, CHW counseling and informational link in the text message, (3) Older adults' preferences and attitudes about how best younger people can discuss RSV vaccination with them (≥60 years) and (4) Barriers and facilitators to discussing vaccines with older adults in the IDI (18-50 years). Interviews will be conducted by bilingual and bicultural staff from UCSF, trained in qualitative methods. *Based on our prior qualitative work on intervention design we anticipate adequate thematic saturation with N~40 in total for Aim 1.1 & 1.2.*

Community Advisory Board meetings (ADAPT-ITT): Over 3-5 CAB meetings, the CAB will discuss RSV vaccine hesitancy, perceptions of intervention components (text and CHW counseling) and work with the study team to adapt the intervention components. After the first iteration of the adapted intervention component they will 'theatre test' the intervention components with th study team and provide feedback to develop the final version of the intervention components for Aims 2 and 3. *The size of community advisory groups* is based on sizes used in ADAPT-ITT interventions[43,62] and the language distribution mirrors the community that served by the LTF and UES. Groups are larger for 18–50-year-olds to incorporate the diversity of preferred languages and any differences in preferences among young adults (18-24 years) vs. adults 25-50 years.

7.2. Randomization and Interventions for Trials

7.2.1. Randomization and Interventions for 'Motivate' Trial (Aim 2)

This is a two-arm randomized type-1 effectiveness-implementation individually randomized trial. We will randomize individuals to one of the two study groups (see 8.2.2) with random block sizes of 2 and stratified by sex.

The two randomization groups are described in 4.3.3 and are:

Arm 1- Text message nudge

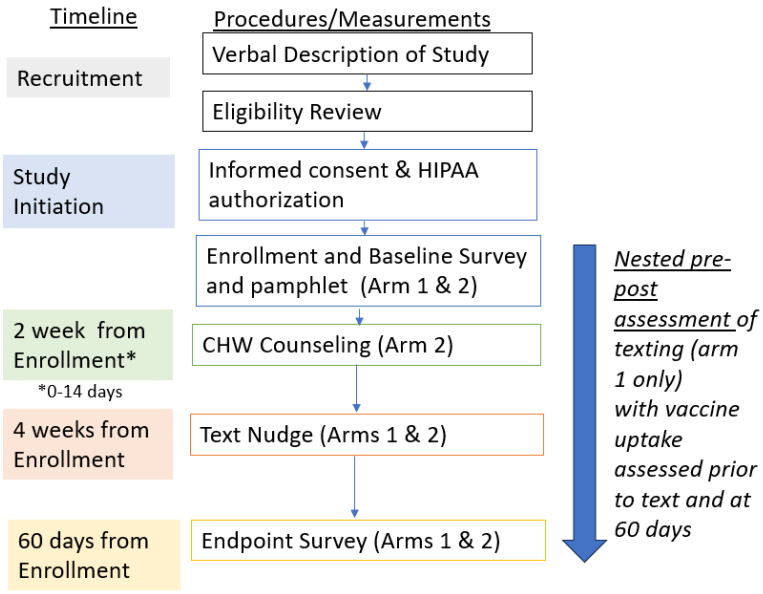
Arm 2: CHW counseling and text message nudge

7.2.1.1. Procedures Aim 2

Baseline survey: After providing informed consent, participants will complete a 30 minute baseline survey, which will include questions on demographics, knowledge of RSV and the RSV vaccine, vaccine confidence, acculturation scale. We will use the standardized vaccine hesitancy scale and BeSD vaccine hesitancy scale.

Intervention delivery: The schedule of interventions is outlined in Figure 6 and outlined in the Schedule of Activities in **Section 7.3**. With texts sent 4 weeks post-enrollment in both arms and the CHW counseling within 2 weeks of enrollment.

Figure 6: Schedule of Evaluations and Procedures



Endpoint survey: Participants will receive a 60-day endpoint survey with similar questions to those asked at baseline: vaccine confidence, BeSD framework core-questions, self-reported vaccination status and location, location of vaccination, self-reported number of discussions of RSV vaccination with people ≥50 years, proportion who received text message. We will also assess implementation-specific factors: (1) Process measures (e.g. text messages received, access-related challenges in getting vaccinated, called LTF hotline), location of vaccination, access-related barriers to vaccination (i.e. challenges making an appointment) and (2) Pathways: (a) whether the interventions elicited responses along the intended pathways, e.g. did the text message positively *reinforce* or remind people to take action on intended behavior, did CHW counseling improve trust and perceptions of RSV susceptibility and (b) assess subjective rating or satisfaction of interventions by participants with Likert-style questions.

Process Metrics/CHW log: CHW will enter the following process measures into a log that will be entered in REDcap: fidelity to counseling script, time for each motivation session, perceived client-specific barriers and facilitators, number of calls received or made for navigation and counseling.

Text message receipt confirmation: Text-messages will be sent 4 weeks post-enrollment. Successful receipt will be assessed retrospectively via Twilio and self-report of reading the text will be assessed at the time of the endpoint questionnaire.

Ascertainment of vaccination status: Vaccine status will be ascertained prior to text nudge and at 60 and 90 days through the medical record or California Immunization Registry (CAIR), the medical record, or proof of vaccination from a pharmacy.

Semi-structured IDI with participants: In accordance with principles of Grounded Theory[63], we will iteratively collect and rapidly analyze interview transcript data, continuing to select

participants within theoretically informed categories (e.g. not only categories such as study group and vaccine uptake, but levels of acculturation or baseline level of engagement with primary care). The interview guide will be designed to elicit: i) perceptions, attitudes, preferences related to the study interventions received, ii. motivations and barriers to getting RSV vaccination (per BeSD framework, Figure 3), iii. implementation outcomes: satisfaction with intervention components. Based on prior qualitative work on behavioral interventions, we anticipate adequate thematic saturation with N-10-20 in each arm.

Focus Groups with Key Stakeholders: We will conduct focus groups of CHWs and CBO leaders to assess barriers and facilitators of implementation, adoption, and maintenance of the intervention. We will conduct purposive sampling until we attain saturation of key themes, which we anticipate will be 2 focus groups of 6 *CBO* leaders within the LTF (N~12) in English and on Zoom and 2 in-person focus groups in Spanish with CHWs delivering the intervention (N~12).

7.2.2. Randomization and Interventions for 'Activate' Trial (Aim 3)

In a parallel structure to Aim 2 we will conduct a randomized trial of the intervention components (CHW counseling and text-message from a CBO) adapted from the Development phase (aim 1). This is a two-arm type 1 effectiveness-implementation RCT randomized at the level of the individual with the following study groups outlined in **section 4.4.3:**

Study Group 1: Text message nudge

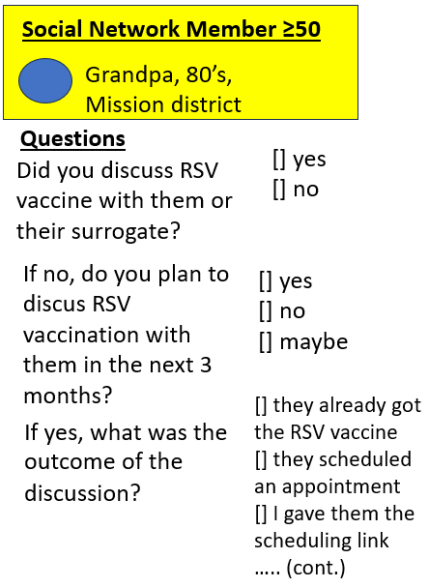
Study Group 2: CHW 'activation' counseling with text-message nudge

7.2.2.1. Study Procedures Aim 3

Enrollment and Randomization: Enrollment, randomization, and intervention delivery procedures are identical to Aim 2. We will use block randomization with block sizes of 2, with stratification by sex.

Baseline Survey: The 25-minute questionnaire will include (1) RSV vaccine hesitancy questionnaire and demographics used in Aim 1 & 2, (2) questions on capability and confidence in recommending the vaccine, (3) Ego-centric (ego=participant) 1st degree social networks of people ≥50 years (Figure 7). Using 'name generation' techniques used widely in our prior studies, participants will be asked to list the age, gender, race/ethnicity, type of relationship, residence (district, city) and perceived RSV vaccine status of family and friends age of 50 and above. This number will be used as the denominator for the primary outcome and outcomes for each social network contact named will be assessed during the endpoint survey.

Figure 7: Sample questions



Endpoint Survey: Participants will complete a 60-day follow-up survey (in person preferred, but phone possible) to assess the proportion of people in their 'named' network at baseline with whom they discussed RSV vaccination. Participants will be shown the characteristics of each person (relationship, age) 'named' in their 1st degree older adult network and they will answer whether they discussed vaccination with that person, why or why not, and

the outcome of the conversation. See Figure 7 for an example of survey questions. Implementation barriers and facilitators will be assessed as in Aim 2, with a specific focus on whether the interventions elicited responses along the intended pathways and assess subjective rating or satisfaction of interventions by participants with Likert-style questions. The endpoint survey will also include questions about vaccine confidence and specifically assess changes in trust with the BeSD core question “How much do you trust the RSV vaccine?”.

Process Metrics/CHW log: Same process measures and data collection method as described in Aim 2.

Semi-structured IDI (participants) and key stakeholders: will be assessed: We will recruit a purposive sample from each study group who completed the study procedures to understand the mechanisms by which the interventions failed or succeeded and the characteristics of who did not respond to interventions. We will use the same procedures for IDIs as discussed in Aim 2 and anticipate a sample size of N~15-25 per study group.

Focus Groups with Key stakeholders: Methods are described in Aim 2 and we will use the same focus groups with key stakeholders to assess implementation barriers for both Aims 2 and Aim 3 during the end of year 4 and quarter 1 of year 5.

7.3. Schedule of Activities (Aim 2 and 3)

Aim 2 and 3 trials have a parallel structure, but differ by study population and content of interventions. However, the schedule of assessments and procedures is the same.

Table 5: Participant Schedule of Activities

Assessments/Procedures	Screening	Study Intervention Period				End of Study Intervention
Study Visit / Day (Window, # Days)	Visit 0* (-60 to 0 days to D1)	Visit 1 / D1 (+/14)	Day 14 (Up to 14§ days after D1)	Day 28	Visit 2 / D 60 (+ 14)^	
Informed Consent[1^]	X					
Inclusion/Exclusion Criteria^	X					
Randomization^		X				
Baseline Questionnaire^	X					
CHW counseling session and navigation^ (Arm 2 only)			X			
Text-message				X		
Endpoint questionnaire^					X	
Outcome Ascertainment - via medical record or California Immunization Registry						X
In-depth interviews^†						X

[1] Informed consent must be obtained prior to any study-specific procedures and may be obtained prior to the screening window.
[§]Can take place up to 60 days after D1 if needed
^Can done in-person or remotely (telephone or web-based platform such as Zoom)
*Can be combined with Visit 1
[†]For a subset of participants only

8. Reporting of Adverse Events

This study includes 2 behavioral interventions (texting and CHW counseling) as well as completing surveys. This is a minimal risk to participants. Care will be taken to protect the privacy of participants in this study. However, there is a risk that others may inadvertently see participants' research or medical information, and thus privacy may be compromised. In the unlikely event that a serious adverse event (SAE) is considered possibly, probably or definitely related to the study, or in the event of major incidents or major protocol violations, reporting to University of California-San Francisco IRB will be reported as outlined in Table 6. Suspected events will be reviewed by study investigators prior to submission to the IRB.

Table 6. Event Reporting Timeline

Institution	Type of Events	When to Report
UCSF Human Research Protections Program (HRPP)	Adverse events that UCSF PI determines are 1) serious, 2) related, and 3) unexpected or more frequent or severe than expected	• Most events: Within 5 working days of awareness • Related deaths and life-threatening *events*: Immediately
	Major protocol violations	Within 10 working days of awareness
	Major incidents	• Major incidents that are potential breaches of confidentiality: Within 48 hours • Other major incidents: Within 10 working days of awareness

9. Statistical Considerations

This study includes a developmental aim (Aim 1) to adapt interventions tested in Aim 2 and 3. Herein we present the statistical design and power for randomized trials in Aim 2 and 3.

In Aim 2, we will compare the effectiveness of two strategies— Arm 1: RSV vaccine information flyer at enrollment + text-message nudges vs. Arm 2: Community Health Worker (CHW) counseling *and* text message nudges—on RSV vaccine uptake among 400 Latino adults ≥50 years. In Aim 3, we will compare the effectiveness of two strategies: Arm 1: RSV vaccine information flyer at enrollment + text-message nudges vs. Arm 2: Community Health Worker (CHW) 'activation' counseling *and* text message nudges —on enabling participants (18-49 years old) to discuss RSV vaccination with older adults in their family and social network. We will conduct in-depth qualitative interviews with a subset of participants from Aim 2 and 3, with stratified sampling based on key outcome measures. We will also describe implementation outcomes for text-messaging and CHW counseling, using metrics that align with the RE-AIM framework.[64]

9.1. Aim 1 Statistical Considerations

Aim 1 is primarily a qualitative study and developmental aim, but it includes one quantitative survey. We will use logistic regression to assess predictors of vaccine hesitancy with the primary outcome being unlikely to get or recommend the RSV Vaccine. Primary predictors include age, sex, acculturation level, preferred language.

9.2. Aim 2 (Motivate Trial) Statistical Considerations

Study Design: Two-arm randomized type-1 effectiveness-implementation individually randomized trial.

Analysis Plan. We will compare the primary outcome of RSV vaccine uptake within 60 days between the two study arms using two broad statistical approaches: unadjusted analyses to explore average treatment effects and model adjusted estimates to reduce variance and examine effects for subpopulations. First, we will examine the intention-to-treat (ITT) effect, over all participants, for the primary outcome of vaccine uptake using the Fisher exact test. To account for participants which the CHW may not be able to reach, we will examine the average treatment effect on the treated (ATT).[65] Second, we will use targeted maximum likelihood estimation (TMLE), a pre-specified approach to data-adaptively adjust for stratified randomization factors and additional baseline predictors of the outcome in order to improve precision. RSV vaccine uptake will be ascertained through the California Immunization Registry, the medical record, or proof of vaccination from a pharmacy. Using an analogous approach, we will also compare intervention effectiveness on pre-specified secondary outcomes and within pre-specified subgroups: baseline high vaccine hesitancy, low trust of healthcare system, low acculturation (score<3.0), sex.[66–68] These will be augmented by predictor analyses to elucidate risk factors for poor vaccine uptake, overall and by arm and exploratory machine learning analysis for treatment effect heterogeneity.[69,70] Additionally, we will examine pathways of intervention action (i.e. direct and indirect effects) using formal mediation analyses, considering mediation by post-baseline trust and perceived benefits in the vaccine. Both predictor and mediation analyses will use TMLE.

Implementation Outcomes: We will calculate implementation outcomes using the RE-AIM framework for each, through quantitative and qualitative analyses.

Analysis of qualitative data: Interviews will be transcribed and analyze by the bilingual study team (Co-I, UCSF research staff, CHW) with a thematic analysis guided by initial analytic code list based on the Behavioral and Social Determinants (BeSD) of Vaccination Framework[48,71], quantitative survey results, and outcomes for the RE-AIM framework. As not all responses may not map onto BeSD determinants and other pre-determined themes, an inductive approach will also be used to generate sub-themes within the initial coding scheme. At defined stages of the analysis, codes and definitions will be refined or expanded as needed. In weekly team meetings, members will discuss coding of rich or difficult segments to achieve consensus.

9.2.1. Aim 2 Sample Size Considerations

Based on our preliminary data and a national survey, we anticipate 28% RSV vaccine uptake in our text-only arm (20% with no intervention and 8% increase with text). Assuming complete data for the primary outcome of vaccine uptake reported by CAIR, the medical record, or proof of vaccination from a pharmacy and α=0.05, our sample size of N=200 per arm will conservatively

provide a minimum detectable ITT effect size of 10%. Assuming CHWs will be able to reach 90% of participants assigned to the counseling arm, our sample will be able to provide a minimum detectable ATT of 10.9%; if participants assigned to counseling are particularly hard to reach and only 80% take part in CHW counseling, we will be able to provide a minimum detectable ATT effect 12.3%.

Statistical power for secondary outcomes will depend on participation in the 60-day follow-up survey. If 10% of participants are lost to follow-up, the minimum detectable effects increase to 10.6% for ITT, 11.5% for ATT if 90% of intervention arm participants receive counseling and 12.9% for ATT if 80% of intervention arm participants receive counseling. Under a setting of high loss to follow-up, where 20% of participants in both arms are not reached for a follow-up survey, the minimum detectable effects increase to 11% for ITT, 12.2% for ATT if 90% of intervention arm participants receive counseling and 13.7% for ATT if 80% of intervention arm participants receive counseling.

Estimated treatment effects for all outcomes will be improved with statistical modeling with TMLE.

In a nested secondary pre-post analysis we will compare the proportion of people who received the RSV vaccine prior to the text-message to 30 days after the text.

9.3. Aim 3 (Activate Trial) Analysis Plan

Aim 3 Study Design: Two-arm randomized type-1 effectiveness-implementation individually randomized trial.

Aim 3 Analysis Plan: We will take an analogous analytic approach to Aim 2 to evaluate our primary outcome, 'the average proportion of older adult contacts with whom RSV vaccination was discussed' between the two study arms' and secondary outcomes, together with pre-specified subgroup analyses (age group 18-29 vs. 30-49 years). We will also undertake additional social network analyses to assess the relationship between egocentric network characteristics and the odds of discussing RSV vaccination: network size, type of relationship (e.g grandmother vs. aunt), characteristics of the participant (e.g. lives in multigenerational household, vaccine confident, age, acculturation), by study arm and pooled across arms. Implementation Outcomes: We will use definitions outlined in Table 2 and analogous quantitative and qualitative methods outlined in Aim 2.

In a nested secondary pre-post analysis we will compare the proportion of people who discussed the RSV vaccine with eligible family or friends prior to the text-message to 30 days after the text.

9.3.1. Aim 3 Sample size considerations

As with the secondary outcomes for Aim 2, statistical power will depend of participation in the 60-day follow-up interview. Assuming 10% attrition for the 175 participants in each arm, we will be able to detect a minimum ITT effect of 11% for any binary outcomes. For our primary outcome, assuming a standard deviation (Standard Deviation) of 0.3 for the proportion of adults contacted, with 175 participants/arm we will have 80% power (using α-0.05) to detect at least a 10% absolute increase (e.g. from 30% to 40%) in the average proportion of older adult contacts with whom RSV vaccination was discussed.

9.3.2. Randomization and Blinding

Randomization for Aim 2 and 3 are referenced in section 6.1. The study statistician will be blinded to treatment arm.

9.3.3. Stratification Factors

We will also compare intervention effectiveness on pre-specified secondary outcomes and within pre-specified subgroups: baseline high vaccine hesitancy, low trust of healthcare system, low acculturation (score<3.0)[61], sex. These will be augmented by predictor analyses to elucidate risk factors for poor vaccine uptake, overall and by arm,[67,72] and exploratory machine learning analysis for treatment effect heterogeneity[69,70]. Block randomization by sex: Rationale is to facilitate even allocation of intervention for men and women.

10. Study Management

10.1. Pre-study Documentation

Before initiating this trial, the PI will have written and dated approval from the Institutional Review Board for the protocol, written informed consent form, subject recruitment materials, and any other written information to be provided to participants before any protocol related procedures are performed on any participants.

The PI must comply with GCP/ICH guidelines and all applicable regulatory requirements.

10.2. Institutional Review Board Approval

The protocol, the proposed informed consent form, and all forms of participant-facing materials related to the study (e.g., advertisements used to recruit participants) will be reviewed and approved by the IRB. The initial protocol and all protocol amendments must be approved by the IRB prior to implementation.

10.3. Changes in the Protocol

Once the protocol has been approved by the IRB, any changes to the protocol must be documented in the form of an amendment. The amendment must be signed by the PI and approved by the IRB prior to implementation.

If it becomes necessary to alter the protocol to eliminate an immediate hazard to participants, an amendment may be implemented prior to IRB approval. In this circumstance, however, the PI must then notify the IRB according to institutional requirements.

10.4. Publications

The preparation and submittal for publication of manuscripts containing the study results shall be in accordance with a process determined by mutual written agreement among the Sponsor-Investigator and collaborators.

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