CONFIDENT: A randomized trial to increase COVID-19 vaccine confidence in long-term care workers

Study Protocol

Principal Investigators: Glyn Elwyn and Marie-Anne Durand

Clinical trial registration number: NCT05168800

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Notes: Some sections of this protocol document replicate or are similar to the published study protocol - Stevens G, Johnson LC, Saunders CH, et al. The CONFIDENT study protocol: a randomized controlled trial comparing two methods to increase long-term care worker confidence in the COVID-19 vaccines. *BMC Public Health*. 2023;23(1):384. Available at: https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-023-15266-x

Additionally, this protocol document does not explicitly indicate all protocol changes made throughout the study. For the list of protocol changes please see the published study results manuscript, which will be attached to the study record at https://clinicaltrials.gov/study/NCT05168800, when it is available.

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List of Abbreviations

CBPR	Community Based Participatory Research
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus Disease 2019
IHI	Institute for Healthcare Improvement
LTCW	Long-Term Care Worker
NAHCA	National Association of Health Care Assistants
PI	Principal Investigator
VCI	Vaccine Confidence Index

General Information

This document provides details regarding the setup, conduct, and analysis of the Patient Centered Outcomes Research Institute (PCORI) funded study, “CONFIDENT: A randomized trial to increase COVID-19 vaccine confidence in long-term care workers.”

Key Study Personnel Approval

The contact Principal Investigator (PI) (G Elwyn) and the dual PI (M-A Durand) have discussed and approved this protocol. The investigators agree to perform the investigations and to abide by this protocol except where significant departures from it are mutually agreed upon between PIs, relevant Institutional Review Board, and PCORI in writing.

1 Protocol Summary

1.1 Lay Summary

Public health professionals think that COVID-19 vaccination is the most promising solution to the COVID-19 pandemic. Vaccination can only be successful if a large number of people get vaccinated. Some people are not sure about the COVID-19 vaccines. Some have used the term 'vaccine hesitancy' to describe this uncertainty. People are hesitant to get vaccinated for many reasons. Some people worry that scientists developed the COVID-19 vaccines too quickly. Other people worry there are not many research studies on the safety of the COVID-19 vaccine. Information on the internet is often of poor quality, or misleading. There are also some people that are actively spreading misinformation about the vaccine. As a result, many have false beliefs and mistrust about the COVID-19 vaccines. Some groups in the U.S. have higher rates of vaccine hesitancy. This includes a group of healthcare professionals who work in places like nursing homes, usually called long-term care workers (LTCWs). Many LTCWs do not want or plan to get vaccinated.

LTCWs are an important group to target because they serve a high-risk, elderly population. They have a higher risk of passing the virus on to others. LTCWs are among the lowest paid workers in the US. They come from diverse communities, including those that have experienced high rates of infection, illness and death from COVID-19. There are policy mandates that were developed in 2021 requiring LTCWs to get vaccinated, which may increase vaccine rates. The mandates may also cause some LTCWs to leave their jobs or be unhappy if they did not want the vaccine. It is therefore important to increase LTCWs confidence in the COVID-19 vaccines for their own protection and wellbeing. It is not clear how best to do this. In this trial, we will study LTCWs from nursing home and residential care settings, who are typically certified nurse assistants and residential care assistants.

We plan to compare two promising methods to increase confidence in COVID-19 vaccines. One method is a live webinar, which is a meeting that happens online using a video-conference platform. In this meeting, we will ask LTCWs to look at information about the COVID-19 vaccine, talk about concerns, and ask questions that they may have. The webinar will be led by another LTCW. Questions will be answered by a medical doctor who has experience addressing LTCW concerns about the COVID-19 vaccine. The other method is a website that will contain posts derived from social media platforms, such as Facebook, YouTube, Instagram, and Tik Tok. The posts will be short video messages and other content about the COVID-19 vaccines. Posts will be about common questions and concerns about the COVID-19 vaccines. The posts will come from people who are popular on social media and will include content from other LTCWs. LTCWs in our study will look at and reply to the posts using likes and comments.

We will invite adult LTCWs to participate in the study who have concerns about the COVID-19 vaccines or who have not received a booster vaccine. We will not include people who are pregnant or breastfeeding. We will advertise the study to LTCWs using email lists, social media, and professional networks that include LTCWs.

We will compare the live webinar and social media website methods to other information that people would usually get about the COVID-19 vaccines. We will place people in one of these three groups (the live webinar group, the social media website group, or the usual information group) based on chance. We will compare peoples' level of confidence in the vaccine across these groups. To better understand how the social media website and live webinars might influence people, we will also measure how informed people feel about the vaccines, what they believe about the vaccines, and their trust in information about the vaccines given by different people and groups. We will collect this information using online surveys. We will give the first survey to participants when they join the study. Then, we will invite them to join the live webinar, use the social media website, or access the usual information website (CDC website). Lastly, they will get three more surveys, 3 weeks, 3 months and 6 months after joining the study.

This study will tell us how to help people become more confident in COVID-19 vaccines. This may be especially helpful for people who rely on information that is out of date or wrong.

1.2 Scientific Abstract

Background and Significance: Vaccination programs have the potential to reduce the incidence of COVID-19 as well as serious illness and mortality associated with the COVID-19 pandemic. However, success depends on widespread vaccine confidence and uptake. The speed of vaccine development and limited research data on both efficacy and adverse effects have caused concerns. Misinformation and disinformation have eroded confidence in the vaccine, causing hesitancy and reduced uptake.

Long term care workers (LTCWs) report substantial vaccine hesitancy. Unvaccinated LTCWs pose a risk of transmission to vulnerable long-term care residents. Further, over 50% of LTCWs are from minority and socioeconomically disadvantaged groups, and may be more vulnerable to severe disease if they become infected. While vaccine mandates have recently been announced for workers in long-term care facilities, mandates also have the potential consequence of job losses, workplace shortages, and reduced LTCW wellbeing. It is therefore important to increase LTCWs' confidence in the COVID-19 vaccines. In this trial we will recruit LTCWs in nursing and residential care settings.

Objectives: Working with our stakeholders, we chose the following research questions:

1. What is the comparative impact of two interventions designed to increase COVID-19 vaccine confidence (primary outcome) and influence secondary outcomes, compared to enhanced usual practice in LTCWs?
2. What is the most effective intervention to increase COVID-19 vaccine confidence among different subgroups of LTCWs, including those who experience different levels of health disparities?
3. What are the delivery characteristics, contexts, and processes needed to sustain and scale up the implementation of interventions designed to increase COVID-19 vaccine confidence among LTCWs?

Design & Population: We will conduct a three-arm online randomized controlled trial, with randomization at the LTCW level. We will use an effectiveness-implementation hybrid design (type 2), guided by relevant domains of the Consolidated Framework for Implementation Research (CFIR).

We will partner with the National Association of Health Care Assistants (NAHCA) to recruit 1800 LTCWs. Eligible LTCWs will self-identify as: 1) being at least 18 years old, 2) living in the United States, 3) having worked in a long-term care setting in the past two years, 4) able to verify their LTCW status, 5) not currently be pregnant or breastfeeding, and 6) able to read, write, and understand English, and 7) being at least somewhat worried about the COVID-19 vaccines and/or not having received any COVID-19 booster vaccine. Contingent on study results, in the sustainability phase (see Figure 3), we will open the materials to other LTCWs.

Interventions: We selected two interactive interventions with our stakeholder partners, based on provisional evidence of their effectiveness and Peretti-Watel's vaccine hesitancy framework. Interventions will be co-designed and adapted with LTCWs and the Institute for Healthcare Improvement (IHI) co-investigators. We will include an enhanced usual practice arm.

Arm 1: Dialogue-Based Webinars
Six hundred LTCWs will attend virtual dialogue-based webinars in groups of 20. An existing COVID-19 conversation aid (English version) will be available to all participants. Each webinar will be co-facilitated by a LTCW and physician expert, and assisted by a communication expert.

Arm 2: Social Media Website
Six hundred LTCWs will be invited to visit a curated COVID-19 social media website, co-designed with LTCWs and NAHCA. The site will be interactive, dynamic, and have multi-component content derived from LTCW-nominated platforms, e.g., Facebook, YouTube, etc. It will address frequent concerns and topics that are deemed relevant by LTCWs.

Arm 3: Enhanced Usual Practice
Six hundred LTCWs will be directed to visit the COVID-19 vaccine information on the CDC website.

Outcomes: Our primary outcome is COVID-19 vaccine confidence as assessed by the Vaccine Confidence Index, which measures confidence in vaccine safety, efficacy, and importance. Our secondary outcomes include COVID-19 vaccine uptake (any dose, initial series completion, booster completion), an adapted Net Promoter Score (likelihood of recommending COVID-19 vaccination and booster vaccination), initial vaccine, booster, and future vaccine intent, feeling informed about the COVID-19 vaccines, identification of COVID-19 vaccine information and misinformation, and trust in COVID-19 vaccine information provided by different people and organizations. Exploratory outcomes will include identifying external factors that may contribute to vaccine decisions and contextual factors experienced before and during the study period that relate to COVID-19. We will also collect demographic information in the baseline survey,

including age, race, ethnicity, gender, zip code, duration of experience in long-term care, educational attainment, health literacy, COVID-19 vaccine status, perceived influence of others, and religiosity. Our primary, secondary, and exploratory outcomes will be collected by online surveys at baseline (T0), 3 weeks post baseline (T1), 3 months post baseline (T2), and 6 months post baseline (T3).

2 Research Team

We have established an international team that combines scientific expertise in communication in health care, dialogue-based interventions, and a track record in the areas of long-term care facilitation and vaccine confidence and hesitancy.

2.1 Principal Investigators

Glyn Elwyn, MB BCh, MSc, PhD, FRCGP

Marie-Anne Durand, MSc, MPhil, PhD, CPsychol

2.2 Research Team Members

Lisa Johnson, MBA (Project Director)

Gabrielle Stevens, PhD (Trial Manager)

Jacqueline Pogue, MPH (Project Manager)

Catherine Saunders, PhD, MPH (Jr. Project Manager)

Renata W. Yen, PhD, MPH (Data Manager)

Peter N. Schmidt, PhD (Study Statistician)

Rachael Thomeer (Research Coordinator)

Ailyn Sierpe, MSc (Research Coordinator)

Danielle Schubbe, PhD, BS (Research Coordinator)

Rachel C. Forcino, PhD, MSc (Postdoctoral Fellow)

Jaclyn Engel (Research Assistant)

Christopher Jacobs (Project Coordinator)

Eugene C. Nelson, DSc, MPH (Advisor)

Alistair James O'Malley, PhD (Advisor)

Ruth Little, EdD, MPH (Subcontract PI) East Carolina University

Alice Bonner, PhD (Subcontract PI) Institute for Healthcare Improvement

Don Goldmann, MD, Institute for Healthcare Improvement

Jennifer Lenoci-Edwards, RN, MPH, CPPS, Institute for Healthcare Improvement

Lori Porter (Subcontract PI) National Association of Health Care Assistants

Matthew Cantrell, BS, National Association of Health Care Assistants

Lisa Houck, National Association of Health Care Assistants

2.3 Consultants

Heidi Larson, PhD, London School of Hygiene & Tropical Medicine

Emilie Karafillakis, MSc, London School of Hygiene & Tropical Medicine

Professor Ève Dubé, PhD, Institut National de Santé Publique du Québec

Physician Facilitators: We have engaged four physicians who will serve as facilitators of the dialogue-based webinars to be delivered to participants in the webinar intervention arm: **Timothy Holahan**, DO, CMD, University of Rochester Medical Center; **Swati Gaur**, MD, Northeast Georgia Health Care; **Christopher Herman**, MD, affiliated with Atrium Wake Forest Baptist Hospital; and **Chetan Amin**, DO, Piedmont Family Medicine in Salisbury, NC.

2.4 Stakeholder Advisory Group

We have assembled a Stakeholder Advisory Group (SAG) who will offer their guidance and will review key study documents and examine effectiveness and implementation progress over the course of the study. The SAG includes **Terry Fulmer** (John A. Hartford Foundation), **Ted Goins** (Lutheran Services Carolinas), **Lynn Hood** (Principle LTC), **Nancy Koha** (Principle LTC), **Karen Ernst** (Voices for Vaccines), **Branden Fillbrook** (Core LTCW participant representative and trained peer), **Celeste Wooten** (Core LTCW participant representative and trained peer), **Rowena Sheppard** (Core LTCW participant representative and trained peer), **Lupita Rodriguez** (Core LTCW participant representative). Additionally, we have five additional LTCW participant representatives to the SAG: **Feng Chen**, **Jon Edwards**, **Tammy McIlnay**, **Katie Page**, and **Mary White**.

3 Introduction

3.1 Background and Rationale

3.1.1 Background

The COVID-19 pandemic has been affecting hundreds of millions of people worldwide for nearly two years. Despite the emergence of new variants, vaccination programs continue to show the most promise at mitigating the severity of illness and mortality caused by the virus[1]. However, vaccination success depends on widespread uptake. Because of increased virulence in the most recent wave and some loss of protection as the virus mutates, coverage rates need to exceed 90%[2] to minimize the risk of outbreaks of current SARS-CoV-2 variants.

The unprecedented speed at which new vaccines were developed and the use of the mRNA technology have raised public concerns about safety[3]. While hesitancy about vaccines existed before this pandemic, such concerns have been accentuated by the lack of prior data about COVID-19 vaccines and limited follow-up data[4]. Additionally, political and ideological allegiances have reinforced certain objections and resistance to vaccination[5]. Given that the internet has become a prominent source of information for many people, it has also been difficult to limit the rapid spread of misinformation or disinformation while promoting evidence-based information[6]. Misinformation about the virus and the COVID-19 vaccine are a major threat to confidence in the importance, safety, and effectiveness of vaccines, which reinforce mistrust, and lead to vaccine hesitancy[7–11].

Some subgroups of the US population, including long-term care workers (LTCWs), have higher rates of COVID-19 vaccine hesitancy[5]. LTCWs include people who work in long-term care facilities or home-based care, and include roles such as certified nurse assistants, residential care assistants and non-clinical support. Although long-term care facilities have been epicenters of COVID-19 outbreaks, warranting widespread vaccination, there is reported low vaccination coverage among LTCWs[12,13]. LTCWs usually serve those most vulnerable to serious complications of COVID-19[14]. LTCWs are also likely to be more vulnerable to complications of COVID-19 themselves. More than 50% of LTCWs are from minority and socioeconomically disadvantaged groups, often working multiple jobs[15,16]. Given the vulnerability of the populations they serve, the possibility of transmission in their local communities, and their own increased risk of COVID-19 morbidity/mortality, it is important to increase COVID-19 uptake among LTCWs. In August 2021, the US Federal Government announced its intent to impose a mandate that LTCWs be vaccinated in order to be eligible to work. This mandate has now been expanded to include employees in all health facilities that receive federal funding. The Centers for Medicare and Medicaid (CMS), working with the Centers for Disease Control and Prevention

(CDC), will be responsible for imposing the broad mandate and planned to release an interim rule in October 2021.

While vaccine mandates have clear, positive implications for reducing COVID-19 spread and disease severity, other potential consequences should not be overlooked. At the forefront are job losses and workforce shortages if workers do not adhere to mandates, and reduced workplace trust and increased vaccine hesitancy[17]. The likely legal challenges and conflict created between management and employees may also have a damaging impact on relationships at work and the wellbeing of long-term care workers. These consequences highlight the importance of efforts to increase confidence in the COVID-19 vaccines, so decisions to vaccinate are made willingly. Increasing vaccine confidence will also help alleviate the concerns of those already vaccinated, but still hesitant to follow future vaccination recommendations.

Evidence for vaccine confidence in LTCWs is limited; a cross-sectional study in Italy of LTCWs found vaccine confidence correlated with influenza vaccine uptake[18]. In a global survey, confidence in the importance of vaccines had the strongest association with vaccine uptake compared to other factors[11]. For people who have been partially or fully vaccinated, increasing confidence in the importance of the vaccine will also be vital for future uptake, adherence to vaccination protocols, and the acceptance of scheduled boosters.

3.1.2 Rationale

The best strategy for increasing COVID-19 vaccine confidence among LTCWs remains unclear. As demonstrated by multiple reviews (and an overview of existing reviews)[19–21], addressing vaccine hesitancy is a complex task, and there is no strong evidence supporting any one single intervention. Nevertheless, there is some emerging evidence that identifies the features of the interventions that are most likely to be effective. For example, Jarrett et al. suggest that multi-component, dialogue-based interventions targeting specific unvaccinated and vaccine-hesitant populations were most effective[22]. Other evidence indicates that social media interventions can improve attitudes towards vaccines and increase uptake[23–25]. Lastly, shared decision-making (SDM) interventions that involve patients and healthcare providers sharing information and making vaccine decisions collaboratively have also been shown to improve vaccine uptake[26,27]. Thus, in this study, we will co-develop and test two scalable, multi-component interventions targeted at LTCWs – one dialogue-based that explicitly incorporates SDM principles and a conversation aid, and the other social media-based – to improve COVID-19 vaccine confidence and other outcomes in the US LTCW population.

This study will focus on three research questions that address compelling clinical and implementation questions raised by the COVID-19 vaccines:

1. What is the comparative impact of two interventions designed to increase COVID-19 vaccine confidence (primary outcome) and influence secondary outcomes, compared to enhanced usual practice in LTCWs?
2. What is the most effective intervention to increase COVID-19 vaccine confidence among different subgroups of LTCWs, including those who experience different levels of health disparities?
3. What are the delivery characteristics, contexts, and processes needed to sustain and scale up the implementation of interventions designed to increase COVID-19 vaccine confidence among LTCWs?

3.2 Aims and Objectives

Specific Aim 1: To compare the impact of two interventions delivered online: 1) a dialogue-based webinar using the existing COVID-19 Option Grid conversation aid and, 2) an interactive, dynamic, and multi-component social media website, compared to enhanced usual practice (link to Centers for Disease Control (CDC) vaccine website), on COVID-19 vaccine confidence (primary outcome), and other secondary outcomes among LTCWs (see Figure 1).

Hypothesis 1: Each intervention will be superior to enhanced usual practice at increasing vaccine confidence.

Hypothesis 2: The dialogue-based webinar intervention will be superior to the social media arm at increasing vaccine confidence.

We predict superiority of the dialogue-based webinar intervention based on stronger evidence that exists for dialogue-based approaches and SDM for improving vaccine hesitancy and/or uptake, as compared to social media approaches. While our social media website intervention includes elements of dialogue, this component is more explicit in the webinar intervention (see 'Interventions and control').

Specific Aim 2: To determine if LTCWs' characteristics and other factors mediate and moderate the interventions' impact on vaccine confidence and other secondary outcomes (See Figure 1).

Hypothesis 1: Increased perceptions of feeling informed about the vaccines, identification of vaccine information and misinformation, and trust in vaccine information provided by different sources will explain (mediate) the relationship between the interventions and vaccine confidence, as well as other secondary outcomes.

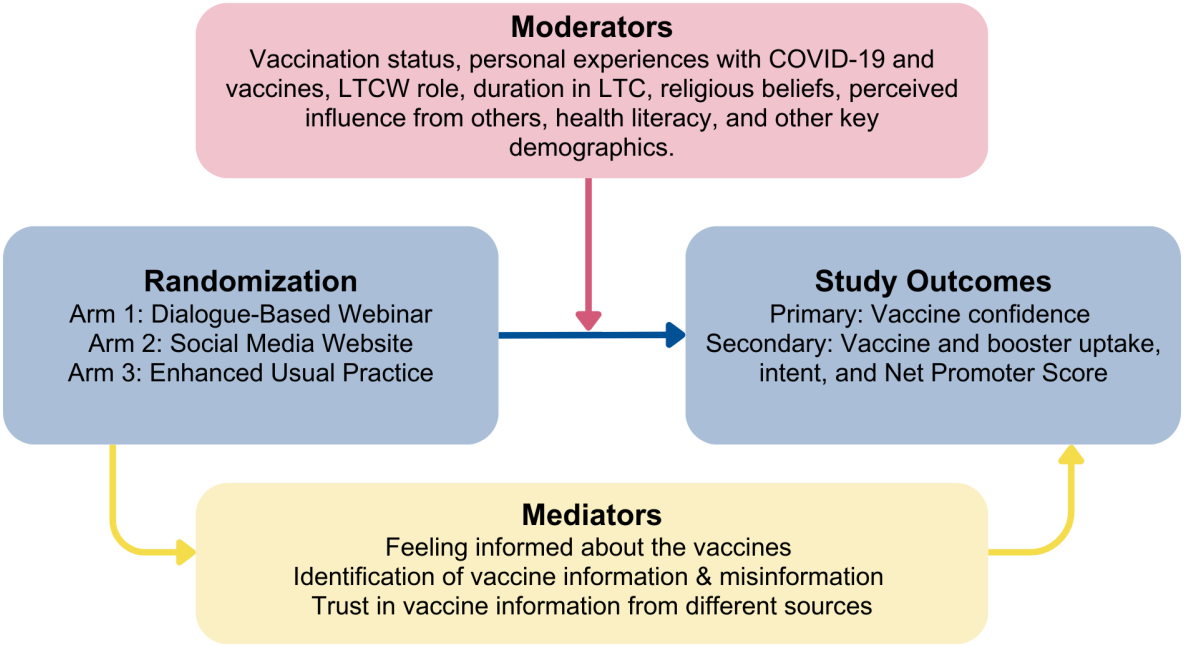
Exploratory: We will conduct exploratory heterogeneity of treatment effects (HTE) analyses to identify whether certain participant characteristics and beliefs moderate the relationship between the interventions and vaccine confidence, as well as other secondary outcomes.

Variables to be explored will include, but are not limited to, vaccination status, religious beliefs, perceived influence of others, age, race, ethnicity and personal experiences with COVID-19.

***Specific Aim 3*:** To explore the implementation characteristics, contexts, and processes needed to sustain and scale up the use of interventions designed to increase vaccine confidence among LTCWs.

Hypothesis 1: Co-developing and adapting the implementation strategy and outcomes with LTCWs and other stakeholders will facilitate implementation.

Figure 1. Study outcomes, mediators, and moderators



4 Methods

4.1 Design

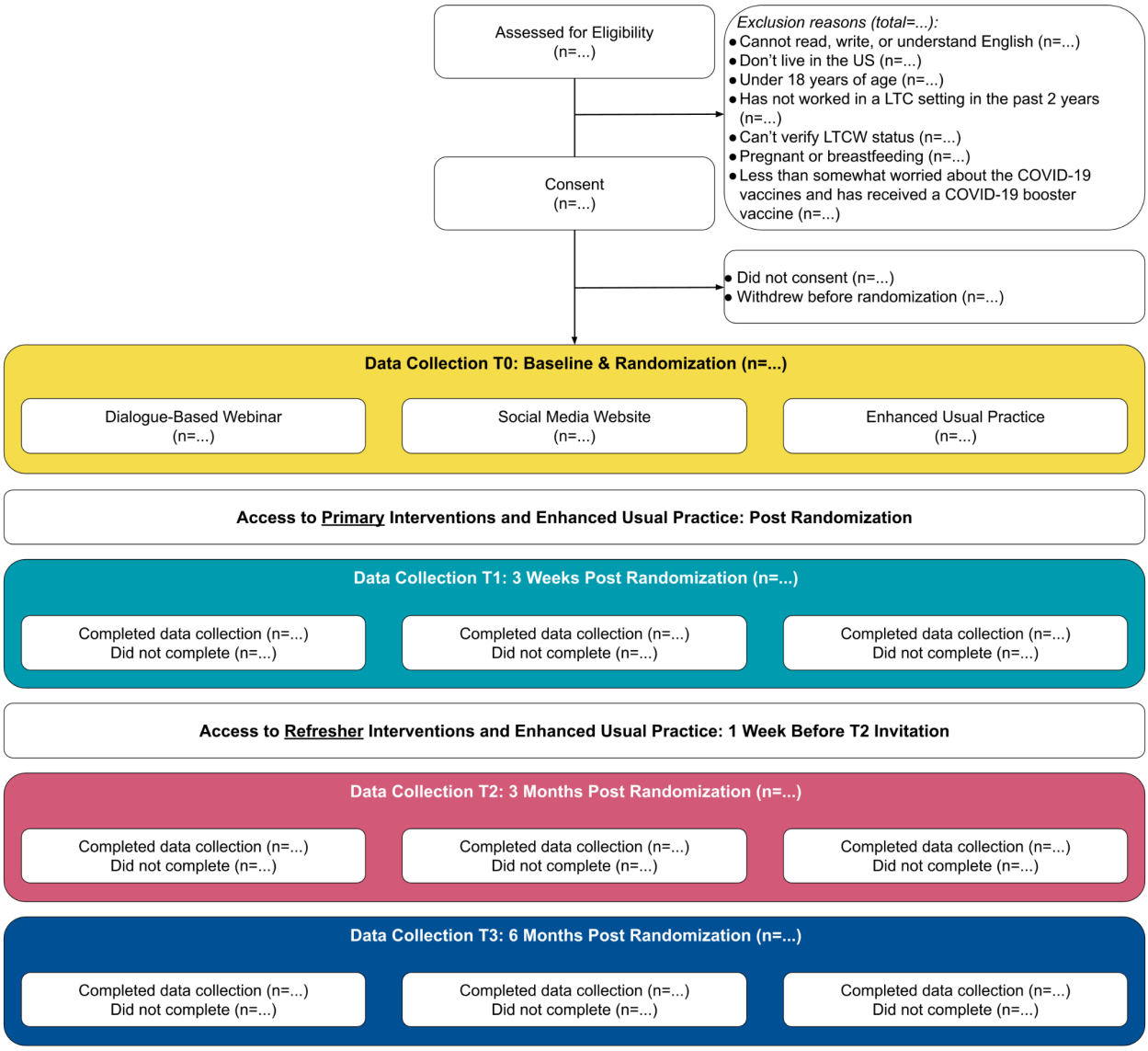
4.1.1 Design Overview

We will conduct an online randomized controlled parallel group trial with a hybrid-effectiveness implementation design type 2[28]. This design includes evaluating effectiveness in the randomized trial alongside an exploration of implementation (tasks 1-5 of implementation mapping)[29]. Contingent on the trial results, implementation will then be evaluated in a sustainability phase after randomized trial assessments are completed. If trial results do not support immediate implementation, we will focus our efforts on further engaging key stakeholders to identify possible adaptations and recommendations for future implementation. We will draw on elements of Community Based Participatory Research (CBPR), and co-design and co-manage this study with LTCWs, the National Association of Health Care Assistant (NAHCA), and the Institute for Healthcare Improvement (IHI).

4.1.2 Randomized Controlled Trial (Aims 1 and 2)

The randomized controlled trial will have three arms, with randomization at the individual person level. Arm 1 is a dialogue-based webinar intervention. Arm 2 is a social media website intervention. Arm 3 is enhanced usual practice. Intervention and comparator arms are described in detail in section 4.4. We will use online and in-person recruitment strategies to enroll 1,800 LTCWs to the trial. Trial data will be obtained primarily via four self-reported participant surveys, delivered to each participant over a period of approximately six months (Figure 2). We will also collect online activity data in each intervention arm. In the trial set-up period, an additional online survey will be administered to a sample of ~500 people from the general population who are demographically representative of LTCWs, to test novel trial screening questions (e.g., COVID-19 vaccine concerns) and adapted outcome measures (e.g., vaccine confidence), and help refine the content of the interventions.

Figure 2. CONSORT Study Flow Diagram



4.1.3 Intervention and Implementation Mapping (Aim 3)

We are undertaking a process called "intervention and implementation mapping," which is a co-design and co-development approach to intervention design and implementation strategy[29]. In Aim 3, we hypothesized that this co-development and co-learning approach would facilitate implementation of the interventions in both the trial phase and the sustainability phase. Aim 3 will primarily involve interviews with key stakeholders, including LTCWs and others identified as current or future adopters, implementers, and maintainers of the study interventions.

Aim 3 and the associated intervention and implementation mapping processes are integrated in every stage of the broader study, including the trial setup and intervention development phase (1), trial phase (2), and sustainability phase (3) (see section 6). Aim 3 interviews will be conducted by research team members at IHI and the Center for Program Design and Evaluation (CPDE) at Dartmouth College.

Much of our intervention and implementation mapping activities will occur during the preparatory stages of the study. Guided by Fernandez's implementation mapping approach[29], we have developed a set of tasks and criteria to operationalize implementation mapping for our study. The steps are detailed in Table 1.

4.1.4 Process Evaluation

We will conduct a process evaluation as part of Aim 3[30]. Using data from Aim 3 interviews, trial participant surveys, online activity data, webinar recordings, and online observation (during and after webinars; over the course of the social media website) from team members, trained LTCW peers and expert facilitators, we will measure, analyze, and report the fidelity of delivering each intervention, the dose of intervention delivered, participants' views toward the interventions, and the achieved versus intended reach. The process evaluation will be primarily conducted by the CPDE at Dartmouth College, in order to retain more independence compared to the team responsible for the outcome evaluation (Aims 1 and 2).

For each arm, we will use a maximum variation sampling approach[31], to include data extremes for analysis (with maximum diversity), through the selection of key diversity dimensions (generic and specific to each arm). For the webinar arm, we will first record all webinars and select up to 12 webinars for process evaluation analysis, by using a range of extremes.[32] To select the webinars for analysis, key diversity dimensions may include: number of attendees, number of messages posted in the webinar chat, timing of the webinar in the context of the overall duration of recruitment (e.g., start of recruitment, two months into recruitment, six months into recruitment), duration of the webinar, proportion of male/female attendees, perceived richness of the verbal exchanges (rated at the end of each webinar by the facilitating team), presence of conflicts/heated discussions, and number of people dropping off before the end of the webinar. For each of the 12 selected webinars, we will measure, analyze, and report the fidelity of delivering each intervention, the dose of intervention delivered, and reach (proportion of eligible participants who attend the webinars). We will also conduct a thematic analysis of the chat posts and of the transcribed discussions.

We will use the same approach for the social media platform. We will analyze up to 12 independent weeks of social media platform content, by selecting a range of extremes. To select the days of social media platform content, key diversity dimensions may include: specific timepoints across the study recruitment continuum (e.g., start of recruitment, two

months into recruitment, six months into recruitment), number of visits per day, number of messages posted, number of likes, etc. For each of the 12 weeks of selected content, we will measure, analyze, and report the fidelity of delivering each intervention, the dose of intervention delivered, and reach. We will also examine how the media platform was used based on website activity data[33]. The activity data will include user ID, time stamps, and page URL of each action completed on the social media platform: reading a page, posting a comment, liking a comment, etc. We will measure the mean total time spent on the social media website, the mean number of pages accessed, identify the most frequently visited pages, the most frequently liked pages or sections, etc.

Table 1. Summary of intervention and implementation mapping activities

Step	When	Activity	Objectives	Participants	Methods
Task 1. Conduct an intervention and implementation needs assessment					
Step 1	Study set-up	Adopter, Implementer, Maintainer[29] brainstorm	Determine who will participate in the implementation consultations	Study team, including those at collaborating organizations	Group meetings and consultations (convenience sampling)
Step 2	Study set-up	Intervention consultations *1st round*	Assist in the development of the two study interventions. Includes asking about their own information needs, views and experiences with COVID-19/vaccines, and providing feedback on proposed intervention content and functionalities, among other things.	Long-term care workers (LTCWs) on our Stakeholder Advisory Group (SAG)	Interviews (one-on-one, video-based) (convenience sampling)
				Adults from the general public (demographically representative of LTCWs) recruited by Qualtrics Panel Services	Online survey (purposive sampling)
Task 2A. Finalize intervention content and delivery using co-design/user-centered design principles					
Step 3	Study set-up	Intervention consultations *2nd round (as needed)*	Continuation of Step 2, to further refine and finalize the interventions. Informal feedback on intervention design and user-testing of interventions in iterative cycles.	LTCWs on our SAG, other LTCWs not associated with the study, and study team members/collaborators	Emails, study meetings, polls, user-testing sessions (convenience sampling)
Task 2B. Identify adoption and implementation outcomes, performance objectives, determinants, and change objectives					
Step 4	Study set-up	Implementation consultations *1st round*	Determine what is required to effectively implement the two interventions during the trial, and how implementation success should be measured. Also explore how we might sustain the interventions once the trial is completed.	Study team, including those at collaborating organizations, consultants, and SAG members	Interviews (likely multiple rounds, one-on-one, video-based or telephone) (convenience sampling)

Task 3. Select theoretical methods and design implementation strategies					
Step 5	Study set-up	Implementation collaboration	Identify necessary actions to facilitate implementation and sustainability using the Consolidated Framework for Implementation Research (CFIR)[34,35].	Study team, including those at collaborating organizations, consultants, and SAG members	Group meetings and consultations (convenience sampling)
Task 4. Produce implementation protocols and materials					
Step 6	Study set-up	Implementation collaboration	Using the information gleaned from Tasks 1-3, develop implementation protocols and materials.	Study team, including those at collaborating organizations, consultants, and SAG members	Group meetings and consultations (convenience sampling)
Task 5. Select assessment metrics					
Step 7	Study set-up and trial phase	Implementation collaboration	Collaboratively generate process evaluation questions and design evaluation assessment processes for Aim 3 interviews during and post trial.	Study team, including those at collaborating organizations, consultants, and SAG members	Group meetings and consultations (convenience sampling)
Step 8	Trial phase	Implementation consultations *2nd round*	Determine views on the interventions, involvement in co-designing the implementation process (if relevant), and views on adaptations and the future sustainability of the interventions, as well as other potential ideas or approaches for improving COVID-19 vaccine confidence and uptake.	Trial participants, study team members, and other key stakeholders identified in Step 1	Interviews (convenience and purposive sampling)
Step 9	Trial and sustainability phases	Implementation assessment	Determine the success of the intervention implementation.	May include study team members, trial participants, and others TBD	Interviews, surveys (convenience and purposive sampling), online activity data, field notes

4.1.5 Controlling for Contamination

Access to interventions will be restricted to those assigned to each intervention arm, via the provision of unique access links (Arm 1: Dialogue-Based Webinar) and unique user logins (Arm 2: Social Media Website). To audit for inadvertent contamination across arms, we will monitor who registers for and accesses each intervention on a weekly basis, removing those without legitimate access. During data cleaning we will review participants who may have been exposed to content from more than one trial arm, and make decisions about the removal of these data to control for the influence of contamination.

4.2 Setting

The randomized trial will be conducted entirely online, and will be open to LTCWs residing anywhere in the United States. We will use a combination of online and in-person recruitment strategies. In-person recruitment will occur at a convenience sample of LTC settings in North Carolina, identified by our collaborator (NRL), who has extensive professional LTC experience and trusted relationships with LTC leaders in the North Carolina area. Settings will include large and smaller size for-profit and not-for-profit nursing homes and continuing care retirement communities in both rural and urban locations. Additional settings will include the New England region.

4.3 Participants

4.3.1 Randomized Controlled Trial (Aims 1 and 2)

Eligible participants will include vaccinated and unvaccinated LTCWs who self-identify as: 1) being 18 years and older, 2) living in the United States, 3) having worked in a long-term care setting in the past two years, 4) able to verify their LTCW status, 5) not currently pregnant or breastfeeding, and 6) able to read, write, and understand English, and 7) being at least somewhat worried about the COVID-19 vaccines and/or not having received any COVID-19 booster vaccine (see Table 2).

Eligible LTC settings will include nursing homes, skilled nursing facilities, assisted living facilities, home health care, hospice care, and retirement communities. The two-year timeframe will avoid excluding those who are currently unemployed, and will approximately cover the duration of time since the COVID-19 pandemic began. To ensure a high proportion of study participants represent our low confidence target group, we will use two criteria – worry about the vaccines and booster uptake – to screen participants for eligibility. These criteria are based on a preliminary analysis of panel survey data, which found associations between booster intent, worry about the vaccines, and vaccine confidence.

Table 2. Screening questions and eligibility criteria

Question	Eligible Response(s)	Ineligible Response(s)
Can you read, write, and understand English? (adapted from[36])	Yes	No
How old are you?	18-19 years; 20-24 years; 25-29 years; 30-34 years; 35-39 years; 40-44 years; 45-49 years; 50-54 years; 55-59 years; 60-64 years; 65 years or older	Less than 18
Do you live in the United States?	Yes	No
This study is for long-term care workers. We must be sure that everyone who joins is giving us the correct information about who they are. We also need to be sure that everyone has worked in a long-term care setting. It is important to our study results. The information that you provide in this survey will help us confirm your identity and that you are a long-term care worker. We will never contact your employer about your participation in the study.	N/A	N/A
Have you worked in a long-term care setting in the past 2 years? This includes nursing homes, skilled nursing facilities, assisted living facilities, home health care, hospice care, and retirement communities.	Yes	No
Below is a list of ways we can confirm you have worked in a long-term care setting in the past 2 years. Which of these can you do? Select all that apply. We will ask you to complete one of these options later in the survey.	Provide information from your workplace ID badge; Provide your Certification or Professional License Number; Email us from your work email account; Provide information from a recent pay stub (within the last 2 years);	None of the above
Are you pregnant or breastfeeding	No	Yes
Are you worried about the COVID-19 vaccines? If you have completed your initial COVID-19 vaccine series (1 Johnson & Johnson shot or 2 Pfizer/Moderna shots), have you had at least one booster shot since then?	Somewhat; Very OR No, I have not had any booster shots; I have not completed my initial series	Not at all; A little; AND Yes, I have had at least one booster shot; Not sure

4.3.2 Aim 3

Eligible participants for Intervention Consultations (as described in Table 1) will include LTCWs, including those who are members of our Stakeholder Advisory Group. We anticipate interviewing 10-12 participants for each round of consultations, until we reach thematic saturation.[32]

For Implementation Consultations (as described in Table 1), our participants will be trial participants, study team members, and other key stakeholders identified through the "Adopters Implementers and Maintainers" brainstorm who may play roles in facilitating implementation in both the trial and sustainability phases. Reporting of Aim 3 activities will adhere to the Consolidate Criteria for Reporting Qualitative Research (COREQ) checklist[37].

4.3.3 Feasibility of Recruitment

We will utilize a diverse range of recruitment methods, both online and in-person. First, we plan to recruit and engage LTCWs using methods that have been previously effective for our partners at NACHA. We will therefore use NAHCA's communication channels and their networks, consisting of social media followers and contacts with NAHCA registered employers. NAHCA membership is characterized by care workers who place value on professional development, however this does not apply to NAHCA non-members who are NAHCA followers on Facebook and YouTube. NAHCA has the capability to reach care workers in all 50 US states, and has members in all states, except Alaska. NAHCA has 24,500 members, with 22,685 subscribing to their list-serv, 2,150 YouTube subscribers, and 18,263 Facebook followers. Response rates to emails via their list-serv average a 33% open rate and a 12% click rate. Typical engagement on their Facebook posts ranges from 5% to 15%; and their YouTube videos reach 3,500 views on average. Using these estimates and given the survey-response incentives ($30 per time-point), we anticipate interest from at least 2,722 LTCWs via the list-serv and 900 LTCWs via Facebook using a conservative 5% engagement level (3,622 in total). These numbers combined exceed the 1,800 LTCWs that we need to power the trial.

Our collaborator, Dr. Tim Holahan, Clinical Director of the American Medical Director Association, has confirmed excellent collaborative arrangements with NAHCA to support recruitment. Both Lori Porter (NAHCA CEO) and Matthew Cantrell (NAHCA COO) confirm that LTCWs can be effectively engaged using their membership list outreach methods and social media.

To further enhance diversity and reach, we will also utilize paid social media and online advertisements for study recruitment. Lastly, in-person recruitment strategies will include sharing recruitment materials via visits to LTC settings, conferences, and other events, and outreach to LTC settings with requests to display study recruitment materials.

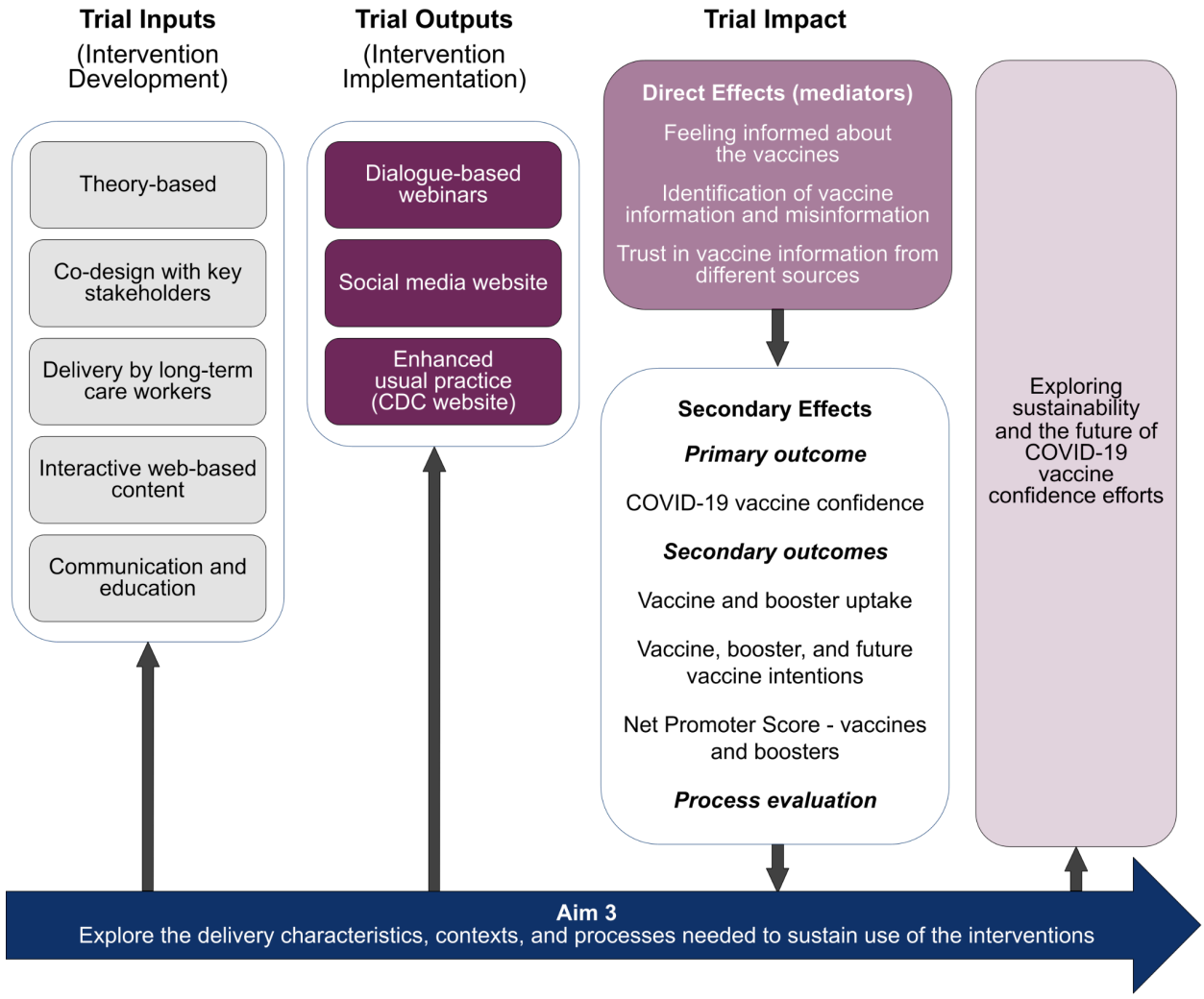
We also intend to make all recruitment and other study materials available via mobile technology so that participants can easily access them on a telephone or tablet if they do not have reliable access to desktop computing.

4.4 Interventions and Comparator

4.4.1 Theory and Content Foundations

We designed two multi-component, interactive, online interventions (arms 1 and 2), informed by theoretical and practical information from the vaccine confidence and hesitancy literature. Notably, our intervention development and hypothesized mediators (see Figure 3) were initially informed by Peretti-Watel's vaccine hesitancy framework, which conceptualizes vaccine decision-making as a process. The framework also distinguishes between two types of vaccine hesitant people: 1) those with poor knowledge of and/or indifference to vaccination issues, and 2) those who are interested in vaccination issues and seek more information, yet are hesitant[38]. We were also informed by the Report of the SAGE Working Group on Vaccine Hesitancy and its conceptualization of the "three Cs" of vaccine hesitancy: Confidence, Complacency and Convenience; and, we considered all three Cs[39]. Additionally, our interventions were informed by the literature on reducing vaccine hesitancy, which suggests multi-component, dialogue-based interventions (such as conversation-based and social media interventions) are most effective, as well as those tailored for specific populations[22]. The interventions were co-designed, co-adapted, and pre-tested with LTCWs as well as NAHCA, IHI, and other co-investigators. The control arm (enhanced usual practice) is online COVID-19 vaccine information provided by the CDC.

Figure 3. Randomized controlled trial logic model



4.4.2 Development

The overall designs of the dialogue-based webinar and social media website interventions were informed by prior studies[22,23,26] and developed using participatory research approaches[40,41]. In developing content for each intervention, our goal was to maximize consistency of major topics across interventions, in order to isolate effects of each intervention delivery method.

To inform the intervention content, we initially derived topics from several sources, including social media monitoring, news surveillance, online public opinion polls[42,43], and peer-reviewed literature[39]. The major topics for inclusion in both interventions were then refined via interviews with our LTCW partners as part of Aim 3. Additional information was gathered to inform the development of the social media website intervention, the details of which are published

elsewhere[44]. The final list of major topics includes COVID-19 in general, vaccine benefits, vaccine risks, and vaccine development[44].

We also developed community standards to ensure all participants felt welcome and comfortable when engaging with the interventions. These standards, which are similar across both interventions, were based on the rules of existing vaccine discussion forums and were co-created with our LTCW partners[44]. Also included in both interventions is a video that we developed featuring LTC residents voicing their views on why it is important for LTCWs to be vaccinated.

In response to low intervention exposure in one trial arm (webinar attendance) experienced in the first several weeks of data collection, we developed intervention 'refreshers' for each trial arm. The refreshers for trial arms 1 and 2 are briefer, modified versions of each primary intervention. They include content on new and emerging COVID-19 and vaccine-related topics, as well as popular questions trial participants have voiced through their primary intervention engagement. New and emerging topics were derived from several sources, including social media monitoring, news surveillance, online public opinion polls[45], and consultation with our LTCW partners and other stakeholders. Topics for inclusion were refined primarily via a poll to identify stakeholders' information needs (process adapted from[46]). Refreshers for trial arms 1 and 2 will be updated as required when there is sufficient new and emerging COVID-19 related public discourse.

4.4.3 Intervention 1: Dialogue-Based Webinar

LTCWs will attend one-time virtual webinars in groups of no more than 20, scheduled at different times, and different days (including weekends). Each webinar will be led by a LTCW peer trained in SDM principles. It will also be co-facilitated by a physician with expertise in COVID-19 vaccination, and a communication expert with experience in SDM.

The webinar intervention agenda is as follows: i) the LTCW facilitator will introduce the session and go over important instructions, including the set of community standards, ii) the physician facilitator will review the COVID-19 vaccine Option Grid™ conversation aid (see Appendix A) and other related topics of interest using the principles of the SDM three-talk model[47]. A link to the online Option Grid™ will also be sent to participants prior to their webinar commencing iii) participants will then be presented with the four major content topics pertaining to COVID-19 and the vaccines (consistent with those listed above in section 4.4.2) and will vote (via a poll) on the two content topics that matter most to them. The physician facilitator will then start by answering questions from participants related to the top voted content areas, and then open questioning up to all topics until there are no remaining queries. The webinars will end with the LTC resident video described earlier.

Throughout the webinars, the communication expert will assist with any related discussions where needed and respond to study-related questions/issues or technical troubleshooting. Webinar durations will vary, running up to 1 hour, or less if there are no remaining questions. Participants will also be invited to join a facilitated online discussion in the webinar chat and their engagement will be monitored (e.g., number of chat messages posted during each webinar and webinar content).

A dialogue-based webinar refresher will also be delivered to all participants in this arm one week prior to their T2 survey invitation (see Figure 2). The refresher will be a pre-recorded webinar (video and audio-only versions) lasting ~20 minutes, sent to participants via email. The structure of the recorded webinar will closely resemble that of the primary intervention, and will include a review of the COVID-19 Option Grid™, question and answer discussion, and LTC resident video. It will be available to participants as a video and an audio-only recording.

4.4.4 Intervention 2: Social Media Website

LTCWs will be invited to visit a social media website. The website is curated with popular and topical posts from social media platforms such as Facebook, TikTok, and YouTube that are made by medical experts, LTCWs, and other creators. The content and topics addressed on the website are dynamic in nature, with two new posts added daily.

The top of the website homepage features the four major content topics pertaining to COVID-19 and the vaccines (consistent with those listed above in section 4.4.2). Participants can navigate the website by selecting from these major topics, selecting subtopics listed in the sidebar menu or as hashtags assigned to each post, or by scrolling the remainder of the homepage (organized as an infinite scroll of all posts, sorted by most recently uploaded). The website supports participant interaction with features such as reactions and comments. Participants also receive email notifications when other users react or reply to comments they have made.

Three special website users affiliated with the study team who have worked as CNAs in LTC settings contribute to the website as ‘Community Ambassadors’. Their role is to promote user engagement by reacting and replying to posts and participants’ comments based on their own experiences as CNAs. Ambassadors also provide factual information on COVID-19, the vaccines, and boosters should participants ask any direct questions.

A social media website refresher will also be delivered to all participants assigned to this arm one week prior to their T2 survey invitation (see Figure 2). The refresher will be an email with previews and links (back to the full post on the social site) to a selection of featured website content.

4.4.5 Comparator

LTCWs will be directed to COVID-19 vaccine information on the CDC website (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html). The CDC website addresses common questions about the COVID-19 vaccines and provides information on related topics, such as specifics about getting vaccinated and staying up to date on the vaccines and boosters. To address concerns of intervention inferiority, LTCWs will be given access to active trial arms shown to have impact, after their 6 month follow-up.

An enhanced usual practice refresher will also be delivered to all participants assigned to this arm one week prior to their T2 survey invitation (see Figure 2). The refresher will be an email with a link to COVID-19 vaccine information on the CDC website.

4.4.6 Adaptation of Interventions

To monitor the adaptations made to the interventions over the course of the project (and primarily in the sustainability phase), we will collect data from online activity data, field-notes, and observations using FRAME (expanded Framework for Reporting Adaptations and Modifications to Evidence-based interventions)[48].

According to the FRAME, an adaptation is defined as a "process of thoughtful and deliberate alteration to the design or delivery of an intervention, with the goal of improving its fit or effectiveness in a given context"[48]. This is particularly relevant in the context of implementation and thus most applicable to the second part of this project: during the sustainability phase of the study. Understanding what, how and when adaptations are made is an essential aspect of implementation science. In this context, adaptation will primarily be made and documented during the sustainability phase (year 03 of the project).

Whereas the content of the interventions will be responsive to participant engagement, significant adaptations to format and delivery during the randomized controlled trial (years 01 and 02) will be minimal and only implemented if judged essential by the research team. These adaptations will also be documented using the FRAME guidance.

4.4.7 Criteria for discontinuing or modifying allocated interventions

Individual participants may choose to not participate in a study intervention. They can also actively withdraw from the study at any time by either opting out of both forms of contact (email and text), directly contacting the research team to request withdrawal, or they may withdraw passively by choosing to not complete study surveys. Because interventions are not administered to participants on an individual basis, it is not possible to modify allocated interventions for any one specific person.

Throughout the trial, each intervention will be monitored by trained team members to identify any breaches to community guidelines or other potential safety events. Intervention moderators will have the ability to limit participants' ability to interact within the interventions to varying degrees, in the event of disruptive or unwelcome behavior.

4.4.8 Strategies to improve adherence to intervention protocols

Adherence to intervention protocols will be monitored regularly via fidelity observation grids completed by team members involved in the delivery of each intervention. Feedback on protocol adherence or nonadherence will be shared with relevant parties involved in intervention delivery on a regular basis, via meetings.

4.4.9 Concomitant interventions permitted during the trial

We will not prevent participants from participating in other research studies or interventions related to COVID-19 or the vaccines, during the study. We will, however, assess whether participants have joined any other related research studies in each of our trial surveys.

4.5 Outcomes

We chose outcome measures with our stakeholders. These outcomes were selected to address vaccine confidence. To minimize respondents' burden, we will use validated short-form questionnaires when possible. Our primary, secondary, and other outcomes will be collected via web-based electronic surveys at baseline (T0), 3 weeks post-baseline (T1), 3 months post-baseline (T2), and 6 months post-baseline (T3) (see Table 3).

4.5.1 Primary Outcome Measure

COVID-19 vaccine confidence. We will assess participants' confidence in the COVID-19 vaccines using an adapted version of the Vaccine Confidence Index (VCI)[49] for COVID-19. The COVID-19 VCI is a 3-item measure that assesses vaccine confidence across three domains: safety, effectiveness, and importance (see Table 3). Each item is rated on a 5-point scale ranging from 1 ('Strongly disagree') to 5 ('Strongly agree'). Participants will be considered 'confident' (score of '1') if they respond 'Agree' or 'Strongly agree' on all three items and 'not confident' (score of '0') if one or more item responses is not 'Agree' or 'Strongly agree'.

4.5.2 Secondary Outcomes and Other Data

Change from baseline in COVID-19 Vaccine Confidence. Additional analysis of the VCI data will include the proportion of positive VCI responses at subsequent evaluations and the individual change in VCI between baseline and each follow-up evaluation. Subdomains of the VCI will be evaluated separately from the composite score.

Likelihood of recommending (promoting) COVID-19 vaccination. Adapted Net Promoter Score (NPS) questions[50] will assess the likelihood that participants would recommend 1) COVID-19 vaccination to others who are unvaccinated, and 2) COVID-19 booster vaccination to a coworker. Similar questions have been recommended previously[51,52]. We will adopt the traditional scoring approach that categorizes respondents as promoters, passives, or detractors.

COVID-19 vaccine uptake and intent. We will assess uptake of the COVID-19 vaccines (any dose, initial series completion, and booster completion) using four questions that we developed. For those who report not being vaccinated or boosted, intent to get a COVID-19 vaccine (initial series or booster) will be assessed using two questions broadly adapted from prior work[53]. All participants will also be asked if they would get regular vaccines in the future if they are recommended, using a single question.

Feeling informed about the COVID-19 vaccines. We will assess the degree to which participants' feel informed about the COVID-19 vaccines (have enough information and understand that information), using two self-developed questions. Our operational definition of feeling informed was influenced by the Decision Self-Efficacy Scale[54].

Identification of COVID-19 vaccine information and misinformation. We will assess participants' identification of COVID-19 vaccine-related information and misinformation, using four questions that were shown to have low rates of correct identification in the pre-launch survey data (see 4.1.2). Some questions were self-developed and some were adapted from prior work[43].

Trust in COVID-19 information from different sources. We will assess participants' trust in COVID-19 information provided by different people and organizations, using three items broadly adapted from prior work[55].

Change from baseline in secondary outcomes. Additional analysis of secondary outcomes will include their assessment at subsequent evaluations and the individual change in secondary outcomes between baseline and each follow-up evaluation.

As-treated analysis of primary and secondary outcomes. Primary and secondary outcomes will also be assessed amongst participants who were exposed to their relevant primary study intervention.

Contextual factors. We will identify contextual factors that may contribute to COVID-19 vaccine intentions and decisions, including personal COVID-19 and vaccine experiences and participation in other COVID-19 vaccine research, using a single self-developed question.

External contextual factors. Outside of the study surveys and throughout the trial, we will monitor external factors that may impact participants' views and actions towards the COVID-19 vaccines. This may include monitoring policy and mandate changes for LTCWs and changes in the nature of the pandemic, among other things.

Participant characteristics. We will assess several participant characteristics including age, gender (adapted from[56,57]), zip code, educational attainment (adapted from[58]), race and ethnicity (adapted from[58]), health insurance (adapted from[58,59]), health literacy[60,61], religiosity[62], LTCW role, duration of experience in long-term care, extent influenced by others regarding COVID-19 vaccination, and baseline vaccination status.

Intervention engagement. We will monitor the extent to which participants engage with their assigned primary and refresher intervention content. We will collect online activity data (i.e., social media website user history, webinar attendance records, email click rates) and participant self-reported engagement data via surveys. We will prioritize the use of online activity data to minimize potential measurement error[36]. However, survey questions may be used where online activity data is not available or is incomplete; for example, to determine engagement with the webinar refresher recording (adapted from[36]) and enhanced usual practice information. Data on engagement will be used to inform secondary trial analyses, as well as Aim 3.

Process evaluation. We will conduct a process evaluation as a component of Aim 3 to inform implementation and sustainability activities. Process evaluation questions will be administered in all follow-up surveys (T1-T3). Acceptability of the interventions and control arm will be determined via adapted NPS questions[50] (i.e., likelihood of recommending to a coworker). Similar approaches have previously been used for evaluating SDM interventions[36,63–65]. We will also assess how new the information was that participants were exposed to, the comprehension of and trust in the information (informed by[66]), the degree to which they felt listened to and respected by those running the interventions (informed by[67]), and reasons for not engaging with the primary or refresher interventions or control arm (adapted from[65]).

Table 3. Primary, secondary, and other outcomes

Measures **(Validated Y/N)**	**Time points for outcome assessment**			
	T0 **Baseline**	**T1** **3 week follow-up**	**T2** **3 month follow-up**	**T3** **6 month follow-up**
Participant characteristics (~12 items)	✓			

Contextual factors (1 item)	✓	✓	✓	✓
Process evaluation (including intervention exposure and acceptability) (up to 8 questions)		✓	✓	✓
Vaccine Confidence Index[49], adapted for COVID-19 (3 items) **(primary outcome measure)** (N)		✓		
Change from baseline in COVID-19 vaccine confidence (N)	✓	✓	✓	✓
Likelihood of recommending COVID-19 vaccination (others not vaccinated), adapted Net Promoter Score (NPS)[68,69] for COVID-19 vaccines (1 item) (N)		✓		
Likelihood of recommending COVID-19 booster vaccination (coworker), adapted NPS[68,69] for COVID-19 vaccines (1 items) (N)		✓		
COVID-19 vaccine uptake (any dose) (1 item) (N)		✓		
COVID-19 vaccine uptake (initial series completion) (2 items) (N)		✓		
COVID-19 vaccine uptake (booster completion) (1 item) (N)		✓		
COVID-19 vaccine intent (any dose) (1 item) (N)		✓		
COVID-19 vaccine intent (booster) (1 item) (N)		✓		
COVID-19 vaccine intent (future vaccine recommendations) (1 item) (N)	✓	✓	✓	✓
Feeling informed about COVID-19 vaccines (2 items) (N)		✓		
Identification of COVID-19 vaccine information and misinformation (4 items) (N)		✓		
Trust in COVID-19 vaccine information provided by different sources[55] (3 items) (N)		✓		
Change from baseline in secondary outcomes	✓	✓	✓	✓
As-treated analysis of primary and secondary outcomes	✓	✓	✓	✓

4.6 Sample Size and Power Calculation

Using historical Vaccine Confidence Index (VCI) data[70] and current vaccination rates[71], a VCI threshold was determined that was significantly correlated with rates of vaccination (p=0.0001). Assuming the analytic approaches outlined in sections 4.7.2 and later, the sample size of 1,800

LTCWs (600 per arm) provides 80% power to detect an 8% difference in the rate of scores above this threshold between groups with a two-sided test at type I error rate of 0.05. The sample size is sufficient to retain 80% power to detect a 10% difference (assuming outcomes are randomly distributed across retained and lost subjects) after 40% attrition.

4.7 Trial Procedure

4.7.1 Recruitment and Screening

Prospective participants will be recruited via several online channels. We will co-design engaging recruitment materials with our stakeholder partners, including brief animated videos that describe the study. We will utilize the existing networks of our partner organizations, stakeholders, and consultants, to share recruitment messaging. This will include email listservs and social media platforms (e.g., Facebook groups). We will also utilize paid, targeted social media advertising to share recruitment messaging on various platforms, including Facebook and Instagram, among other platforms. Lastly, we will utilize in-person recruitment which will include sharing recruitment materials during visits to LTC settings, conferences, and other events, and outreach to LTC settings with requests to display study recruitment materials.

Recruitment messaging (i.e., emails, social media ads, posters, table tents, and business cards) will include links to: 1) a study landing page where prospective participants can learn more about the study via brief, plain-language study information in both video and written formats, and, 2) a Qualtrics survey where they can proceed straight to eligibility screening. Screening will involve prospective participants answering a series of questions to self-assess their eligibility (see Table 2). The study landing page will also include a link to the Qualtrics survey.

4.7.2 Consent, Identity Verification, and Baseline Assessment

Those who meet the eligibility criteria will proceed to a study Information Sheet that will provide information about the study objectives, processes, risk, benefits, and data protection and sharing. To improve accessibility and facilitate the uptake of study information, we are also developing an animated video version of the Information Sheet that will contain the same information as the text version. Participants will be able to choose if they want to watch the video or read the text version of the Information Sheet in the online Qualtrics survey platform (or see both). At the end of the Information Sheet, prospective participants will be asked if they have read/watched and understood the information and if they agree to take part in the study. Those who respond '*Yes*' to both questions will be considered to have consented to the study and will proceed to the T0 Survey.

Because of the online nature of the trial, incentives provided, and early instances of fraudulent activity[72], we will implement several strategies to prevent, detect, and respond to fraudulent study enrollment. The strategies we will adopt were informed by a prior review of methods[73]

and recommendations[74,75] on this topic. We also engaged our stakeholders in this development process to ensure a range of strategies feasible and acceptable to LTCWs.

First, in the baseline survey, we will add a reCAPTCHA bot detection filter[73,74,76], cookie-based settings that prevent multiple submissions from the same web browser[73,74,77], and a message discouraging duplicate survey completion[73,74]. After consent, participants will be asked to provide the name of their current or former workplace and the type of long-term care setting it is. Additionally, in order for us to verify that they have worked in a long-term care setting within the last 2 years, they will be required to choose one of four different verification options:

1) Work ID badge. Participants will be able to directly upload a photo of their work ID badge, or, arrange a time to speak with us to show their badge over a brief Zoom video call. We will review badge images uploaded/shown to ensure the participant's name, place of work, and LTCW role (if listed) matches the information they have provided in the T0 (baseline) Survey. We will also conduct an online search (using Google Chrome Incognito mode) of workplace names to confirm they are a long-term care setting. Participants' zip codes may also be used to aid in this search, if required.

2) Recent pay stub from the past 2 years. Participants will be able to directly upload a photo of a prior pay stub from within the past 2 years, or arrange a time to speak with us to show their pay stub over a brief Zoom video call. We will review pay stub images uploaded/shown to ensure the participant's name and place of work matches the information they have provided in the T0 (baseline) Survey. We will also conduct an online search (using Google Chrome Incognito mode) of workplace names to confirm they are a long-term care setting. Participants' zip codes may also be used to aid in this search, if required.

3) Certification or professional license number. Participants with certain roles (e.g., certified nursing assistants in most states, health care providers) will be able to provide their Certification Number or Professional License Number, alongside the state they are registered in and their associated professional role. We will verify Certification/License Numbers by searching state online registries (e.g., https://forms.nh.gov/licenseverificationtest/). Participants' names may also be used to aid in this search, if required. We will also conduct an online search (using Google Chrome Incognito mode) of workplace names reported in the T0 (baseline) Survey to confirm they are a long-term care setting. Participants' zip codes may also be used to aid in this search, if required.

4) Work email account. Participants who have workplace email accounts will be able to email us directly from their account with their first and last name, the name of their workplace, and the name of the study. We will conduct an online search (using Google Chrome Incognito mode) of workplace names and associated email domains to confirm they match, and that this

place of work matches the information they have provided in the T0 (baseline) Survey and is a long-term care setting. Participants' zip codes may also be used to aid in this search, if required.

We will also employ TransUnion's TLOxp verification service (www.tlo.com), to confirm the identity of participants recruited online[75]. TLOxp aggregates publicly available databases and records to authenticate and verify identity information. We will develop a standardized process for identity verification using participant name, zip code, age range, cell phone number, and email address.

We will inform those who select the option to upload an image of their badge or recent pay stub that we only need to see their name, workplace, and LTCW role (if listed). They will be instructed to cover up any other sensitive information or information they do not wish to share.

Reminder messages (text and email) and phone calls[73,74] will be utilized to gather further information from participants who fail to provide the requested information in the time frame specified. Participants recruited in person will be presented with the same verification survey questions as other participants, however, the need for follow-up contact to confirm their LTCW status in some situations will be relaxed due to verification not being necessary for this sub-population.

Participants who do not pass a verification check (including those who fail to provide the requested information in the time frame specified) will be sent a message stating that they can no longer remain in the study and will be unenrolled[74].

Once participants have provided verification information or selected a verification option that requires completion later (e.g., scheduling a video call with a member of the research team), they will proceed to the remainder of the T0 Survey. The T0 Survey will include capturing participant contact information and an assessment of outcomes indicated in Table 3 and participant characteristics.

4.7.3 Allocation of Interventions

We will use the randomizer function built into the online Qualtrics survey platform to allocate participants to a trial arm and associated intervention. At the very end of the T0 Survey, the Qualtrics survey platform will automatically generate participants' trial arm and they will be presented with basic information pertaining to their assigned intervention at that time. A 1:1:1 allocation ratio will be used. After submitting their survey, those randomized to Arm 1 (Dialogue-Based Webinar) will be automatically redirected to a separate Qualtrics survey where they can sign up for one of several pre-scheduled webinar sessions. Those randomized to Arm 2 (Social Media Website) will be automatically redirected to the Social Media Website. In order

to access website content, they will first be required to create a username and password for the site. Those randomized to Arm 3 (Enhanced Usual Practice) will be automatically redirected to a specific page(s) on the CDC website (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html).

4.7.4 Blinding

Due to the nature of the interventions and intervention delivery, it is not possible to blind facilitators, research team members or participants to the allocation. Participants may be aware that they are in a control or intervention arm. The data analyst will be blinded to arm allocation where possible.

4.7.5 Follow-up Assessments

Participants will be invited to complete three follow-up surveys. For all participants, the follow-up surveys will be delivered three weeks post-baseline survey/randomization (T1), three months post-baseline survey (T2), and six months post-baseline survey (T3).

4.7.6 Monitoring Enrollment

We will monitor trial enrollment on a daily basis. Particular attention will be paid to ensuring that enrollment numbers do not exceed the capacity of scheduled Dialogue-Based Webinars. Should enrollment numbers exceed the capacity of these webinars, we will pause study enrollment across all trial arms. In this situation, prospective participants would still be screened for eligibility but instead of proceeding to consent and the T0 Survey questions, their contact information would be retained by the study team, and we would reach out to them when recruitment opens up again.

We will also pay particular attention to recruitment milestones for 25%, 50%, 75% and 100% enrollment targets. If enrollment numbers suggest we will not meet a recruitment milestone, we will employ additional recruitment efforts, such as increased advertising and outreach to additional people and organizations to utilize existing LTCW networks.

4.7.7 Tracking and Retaining Participants

Participant tracking and retention will be facilitated by several strategies.

Salesforce Customer Relationship Management (CRM). We will utilize Salesforce CRM software to manage participant recruitment and retention. Selected survey data collected in Qualtrics will be pushed into Salesforce on a real-time basis, through an automated integration. The Salesforce platform will allow us to link participant data across all four surveys in one central database, in order to reliably and efficiently track participants throughout the trial. Through Salesforce, we will also automate all survey invitations and survey and intervention reminders

(sent via email or text message), to ensure that communication is timely and consistent across all participants.

Multiple reminders in various formats. We will utilize several reminders for primary and refresher intervention/usual practice information, follow-up surveys, and to obtain information needed for participant verification For each series of reminders, we will utilize multiple forms of contact to maximize engagement, including email, text messaging, and phone calls.

In the baseline survey we will request that each participant provide us with an email address and cell phone number, and indicate their preferred method of contact (email or text). Preferred methods of contact will be used for most study messaging, and where possible telephone calls will be used for final reminders where email or text message reminders are not successful.

Compensation. Participants will be sent a $30 Amazon.com gift card after completing each study survey, to thank them for their time. Gift cards will be distributed to participants via email within a few days of completing a study survey.

4.7.8 Adherence to Protocol and Supervision

We will train all relevant study personnel in the trial procedures to maximize protocol adherence. We will also ensure that all stakeholders involved in activities where they will have direct contact with participants have received appropriate human subjects research training.

4.7.9 Reporting Plan and Study Termination

Our reporting plan will adhere to the CONSORT (Consolidated Standards of Reporting Trials) 2010 statement for reporting randomized trials[78] and the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) Statement[79], and will be sufficiently transparent and comprehensive to allow for assessment of the study's internal and external validity.

Each participant will remain in the trial for approximately 6 months after their initial T0 Survey completion, or after all of their Aim 3 interviews have been conducted (during the Sustainability Phase for Implementation Consultations). Once all participants have been sent their final T3 Survey, those originally assigned to Arm 3: Enhanced Usual Practice, will be given access to the study interventions. Separate to the trial itself, we will monitor their engagement with the interventions and administer a brief survey 3 months after initial exposure.

4.8 Statistical Analysis

4.8.1 Data Source Accuracy

Initial examination of data will include descriptive statistics and frequency distributions in order to check planned analysis assumptions, identify missing data, and check data source adequacy. This process will also inform any necessary variable re-coding prior to data analysis.

4.8.2 Analyses Corresponding to Trial Aims 1 and 2

All analyses pertaining to study Aims 1 and 2 will be conducted on an intention-to-treat (ITT) basis (i.e. the arm participants were assigned to) and as-treated basis (i.e. whether they engaged with their assigned intervention or control). A detailed data analysis methodology, including planned statistical tests, timepoints for outcome assessment, and treatment of missing data, is included in Appendix B.

For Aim 1, hypothesis 1.1, we will conduct one-tailed tests (superiority analysis) to compare the impact of each of the two intervention arms against the enhanced usual practice arm on primary and secondary outcomes. For Aim 1, hypothesis 1.2, we will conduct a two-tailed test (equivalence analysis) of primary and secondary outcomes between the two intervention arms. While we hypothesize that the dialogue-based webinar intervention (Arm 1) will be superior to the social media website intervention (Arm 2), a finding of superiority, inferiority, or no distinguishable difference will be a valuable finding.

For Aim 2, hypothesis 2.1, our mediation analyses seek to identify the relationship between the interventions, mediator variables, and primary and secondary outcomes. We are interested in whether interventions operate through the mediator rather than directly affecting the outcome. If the results for Aim 1 are non-significant, we will determine whether it is a null effect of the intervention on the mediator or a null effect of the mediator on the outcome. We will determine mediation strength and mechanism generalizability by comparing effects across subgroups.

For Aim 2, hypothesis 2.2, our exploratory moderation analyses (also referred to as heterogeneity of treatment effects (HTE) analyses) seek to understand whether certain participant characteristics and beliefs influence the relationship between the interventions and vaccine confidence, as well as other secondary outcomes. We will explore moderators including (but not limited to) vaccination status, religious beliefs, age, race, ethnicity, perceived influence of others, and personal experiences with COVID-19.

Because of the size, scope, and complexity of this study, exploratory analyses of relationships within the data will be conducted to identify factors to inform future analysis (see Additional File 4). Exploratory, hypothesis-free analyses will be performed using data clustering to analyze participants' demographic, geographic, or temporal links, which may define statistically unlikely

outcome groupings.

4.8.3 Data Linkage

All trial survey data will be linked to other study data (Salesforce, online activity data) at the participant-level, using participants' email address and/or other unique variables that are available. These data will be linked following exports from Salesforce and the respective online platforms (social media website, analytics platforms, and Zoom). During the trial, a minority of online activity data will be imported directly into Salesforce (either by automated integration of manual input) in order to facilitate participant tracking and the distribution of tailored invitation and reminder messages for participants in each intervention arm.

4.8.4 Analyses Corresponding to Aim 3

Using a framework analysis, guided by relevant domains of CFIR[34,80], we will answer the following questions: 1) How were characteristics of the interventions perceived by participants and stakeholders (CFIR i); 2) How did external contextual factors influence intervention use (CFIR ii); and, 3) What factors affected implementation (CFIR iii/CFIR iv)[35]. We will collect data from relevant stakeholders. We will also use online activity data, webinar recordings, observations, and meeting note templates from CFIR, adapted with stakeholders, as a part of our learning community[29,34,80]. We will adapt Codebook Templates, double code the interviews, and where possible integrate qualitative and quantitative data sources (e.g., interview, observational, recording, and online activity data to inform the Process Evaluation (fidelity, dose, acceptability, and reach of interventions). Where possible, these data will also be triangulated with data from Aims 1 and 2, to inform interpretations and study conclusions.

4.9 Data Management

4.9.1 Data Management Plan

Collecting data. The primary source of trial data will be collected via online surveys administered to recruited study participants. We will also use activity data from the social media website and associated analytics software (Google Analytics and Google Cloud Platform), (b) Zoom webinar content/recordings and registration and attendance data, and (c) user-entered or participant-generated data from Salesforce. Data from Aim 3 interviews will be collected via audio recordings and subsequently transcribed by a transcription company (Civicom, Inc.). Table 4 below details all platforms and organizations that will receive study data during the trial, and which data they will receive.

Table 4. Data platforms and data received

Location	Description of Data Received
Qualtrics *(Participant survey portal)*	All participant survey data (e.g., screening and consent information, contact information, participant characteristics, and primary and secondary study outcomes).
Salesforce *(Participant management; data will automatically flow in from Qualtrics and Zoom)*	Participant information flowing from Qualtrics/Zoom includes contact information, characteristics, vaccine and booster status, trial arm assignment, Zoom registration, and survey metadata (e.g., completion date, unique study ID). Data will also be generated in Salesforce by research team members' manual entry of information (e.g., call logs) or participant-generated information (i.e., response to a text message sent from within Salesforce).
Mogli/Telnyx *(Integration for Salesforce that supports text messaging)*	Participants' first name, cell phone number, and study-related messaging (includes unique links to surveys and interventions).
ActiveCampaign *(Email marketing software for sending intervention refreshers)*	Participants' first name, last name, email address, and study-related messaging.
Zoom (*Includes Panopto for Zoom video storage*)	Participants' name, email address, meeting registration, meeting attended, time joined and left meeting, chat logs, meeting recordings (audio and visual, including participant faces if they choose to show their video).
Social Media Website (*WordPress site that will be hosted on a Dartmouth College server*)	Participants' name, username and password, email address, and any other information related to their website engagement.
Google Analytics *(Analytics of WordPress site data)*	Anonymous participant website engagement information (aggregate data at user and site level) (e.g., total number of site visits, location of users, number of unique page visits per user and per page).
Google Cloud Platform	Participant website engagement information stored in Google Analytics.
Civicom	Interview and webinar audio recordings.

(Transcription company)	
Dartmouth SharePoint	Any raw and individual-level study data that needs to be shared between members of the research team (at Dartmouth and collaborating institutions) and Data and Safety Monitoring Board (DSMB) members.
TLOxp *(Identity verification service)*	Participant information entered into the online system to conduct identity verification. Information will include participant name, zip code, age range, cell phone number, and email address.

Handling data. Oversight of trial data will be the responsibility of the Trial Manager and Data Manager. Prior to data collection commencing, we will work with a third party vendor, Cloud for Good, to implement our Salesforce platform. This will include setting up a secure integration with Qualtrics and Zoom, so that data being generated in these platforms will flow directly into Salesforce, in real time. The Cloud for Good team will also integrate a text messaging application (Mogli) within Salesforce, to facilitate automated text messaging to participants. All data in Salesforce will be backed up on a weekly basis, and stored on one or more password-protected and encrypted external hard drives.

Access to all software and platforms where data are being handled will be password-protected, and will only be afforded to research team members involved in data collection, management, and/or analysis and reporting. Versions of study datasets from all originating sources will be managed by a single version control document. This document will be maintained by the Data Manager and Trial Manager, and will include identified and de-identified data sets used by Dartmouth team members internally and those shared with team members at collaborating institutions.

Describing and organizing data. Prior to the analysis of trial data, a data dictionary will be developed for all survey variables. This dictionary will be used by anyone involved in data analysis and reporting. The dictionary will accompany datafiles that are subsequently shared with others outside the research team (see Sharing Data below). Data stored in Qualtrics, Salesforce, the social media website, Google Analytics/Google Cloud Platform,, and Zoom/Panopto will be exported in file formats (to be determined) that best support analysis.

Storing and preserving data. Any data exported from Qualtrics, Salesforce, the social media website, Google Analytics/Google Cloud Platform, or Zoom/Panopto, will be stored on password-protected computers or external hard drives. Data will also be stored in the Dartmouth SharePoint system, to facilitate secure file management and sharing between research team members at Dartmouth College and other collaborating institutions, as well as members of the DSMB.

De-identification, crosswalks, and data destruction. To reduce the duration that identifying information will be linked to other study data, at the completion of data collection, we will download all data that was collected and stored in cloud-based systems and set up crosswalks for each of the downloaded datasets. We will do the same for any local files used in the process of participant management, such as tracking spreadsheets. The crosswalks will utilize a unique and anonymous 'Study ID' variable and identifiable variable fields depending on the data source. We will set up a master key file that will include only Study ID and all identifiable variable fields. This key file will be used for all data crosswalks. The master key file will be stored separately to the other study data in the secure SharePoint cloud system as well as on one or more encrypted and password-protected external hard drives. Remaining deidentified datasets will include the Study ID variable, which will be the only link between them and the identifiable study data. The only exception to this de-identification and crosswalk process is the video and audio recordings of webinar intervention sessions, as these will be needed for process evaluation analyses which will continue past data collection completion.

It is not possible to create crosswalks and remove identifying information from participant data prior to data collection completion, as many of our cloud-based systems and participant management processes require the identifying information for our study to function correctly (e.g., Salesforce for participant communication; study website to manage user registrations and notifications; question responses cannot be deleted from active Qualtrics survey datasets, Zoom video/audio recordings for process evaluation). We will also need to create weekly back-ups of all data contained in Salesforce (including identifiers) to ensure we are protected in the event of any data loss.

At the completion of data collection and following the downloading of data from cloud-based systems, we will delete all participant data in cloud-based systems (excluding SharePoint) by working with Dartmouth IT and external study vendors to the best of our ability.

Once all study publications and reports are finalized, we will delete all copies of the master key file that contain participant identifying information from SharePoint and external hard drives (using secure hard drive erase procedures) and with the assistance of Dartmouth IT services. De-identified study data will be stored indefinitely.

Maintaining data. Upon completion of the project, we will prepare a full data package of all randomized controlled trial data. The full data package will be maintained for at least seven years. Information provided to prospective participants at the time of consent will include a statement that de-identified data collected as part of the study may be used for other studies and shared with researchers not part of this study team. The Principal Investigators (PIs) will be responsible for maintaining and responding to data-related inquiries.

Sharing data. Any raw, individual-level data shared between members of the study team (e.g., survey datasets, interview recordings and transcripts) or the DSMB during and after the completion of data collection will be done so via the secure Dartmouth SharePoint platform. For data security purposes, non-Dartmouth team members will be required to obtain a Dartmouth Sponsored Account in order to access the SharePoint system.

Following completion of the study, and as per PCORI's requirements, we will make the Full Data Package available to a PCORI-designated data repository, to facilitate data sharing with the broader scientific community.

4.9.2 Data and Safety Monitoring Plan

A Data and Safety Monitoring Board (DSMB) will be appointed to provide additional oversight in the trial. The attached DSMB Charter describes the DSMB's scope and procedures in detail.

To summarize, the DSMB will meet and review data annually throughout the project (data review in meetings 2 and 3 only - see Charter previously submitted to PCORI for details), with three planned meetings held in total. The DSMB will include a Chair who has no direct involvement in the trial (see DSMB Charter). The DSMB will also include the following individuals who have not had prior involvement in the trial:

1. Board member with expertise in data safety monitoring of clinical trials
2. Board member with expertise in biostatistics and clinical trials methodology
3. Executive Secretary with experience in SDM research

The DSMB will operate independently from the study sponsor and funder.

Independence is essential to ensure that the DSMB members are objective and capable of an unbiased assessment of the study's safety and efficacy of data. No members of the DSMB should have financial, proprietary, professional or other interests that may affect impartial decision making by the DSMB. The following will ensure the independence of the DSMB:

- Members of the DSMB will not participate as investigators in the study under review.
- Members of the DSMB must not have a direct interest in knowing or influencing trial outcomes or have a financial, proprietary, or intellectual interest in the outcomes of the study under review.
- DSMB members must disclose all potential new conflicts of interests (COIs).

The DSMB will review the protocol, data collected, and advise the PIs on any potential risks and risk mitigation plans. The DSMB recommendations will be discussed with the PIs as well

as the Trial Steering Group, which meets quarterly. The Trial Steering Group will consider all DSMB recommendations and revise relevant aspects of the trial accordingly. Those recommendations will also be fed back to PCORI annually as part of the progress reports. The PIs will also be responsible for sending a summary of DSMB recommendations to the Dartmouth CPHS (IRB) after each DSMB meeting. If there are adverse or unanticipated events/problems that require reporting, PCORI and the CPHS will be notified within a day of the DSMB meeting. If there are no adverse or unanticipated events/problems that require reporting, DSMB meeting minutes and recommendations will be communicated to PCORI in the interim progress report.

Trial activity will also be monitored by members of the study team on an ongoing basis, outside of annual DSMB meetings. We believe the likelihood of Serious Adverse Events (SAEs) in the trial that would require immediate reporting to be extremely low, as there are no invasive procedures related to the interventions. However, it is possible that a participant may experience psychological discomfort or distress as a result of answering certain survey questions or through engagement in either of the two study interventions. All potential adverse events or unanticipated events/problems, regardless of their severity, will be reported to the PIs. All events will be discussed by the PIs and relevant members of the study team, and a determination will be made as to whether they constitute Reportable New Information (e.g., it increases the risk to subjects; a subject experienced unexpected harm). Any event deemed to be Reportable New Information will be reported to Dartmouth CPHS (IRB) and the DSMB will convene urgently and review the event in question.

4.9.3 Auditing of Trial Conduct

This trial will have no formal auditing process, however, trial conduct will be overseen by the Dartmouth Center for the Protection of Human Subjects (CPHS) and the DSMB. Our intervention process evaluation will also be carried out by the Center for Program Design and Evaluation (CPDE).

5 Ethics, Write-up and Dissemination

5.1 Research Ethics Approval

The randomized controlled trial was initially approved by the Dartmouth CPHS on January 11th, 2022. The initial approval for Aim 3 activities was granted on September 10th, 2021.

5.2 Protocol Amendments

Throughout the course of the study, protocol modifications will be reported to the relevant parties and groups (e.g., project investigators, PCORI, Dartmouth CPHS), where required. This may include changes to trial procedures, materials, and planned analyses.

5.3 Dissemination and Implementation in Other Settings

The proposed research findings are highly relevant to public health as we seek to address vaccine confidence among LTCWs. Because the interventions are scalable, study outputs will interest a wide variety of target audiences ranging from large public health organizations like the Centers for Disease Control, IHI, and the Agency for Healthcare Research and Quality, and organizations dedicated to long-term care like NAHCA, American Medical Directors Association (AMDA), and to LTCWs. We will work with each target audience to create dissemination and implementation strategies that are tailored to their needs and interests and are understandable to them. Evidence generated from this study is also likely to be applicable and generalizable to future COVID-19 vaccines and to other vaccination programs.

5.3.1 Academic Channels

Although peer-reviewed scientific journals are not commonly accessed by LTCWs, they remain the primary source of knowledge and dissemination of research findings to influence health professionals, policy makers, and healthcare systems. Open-access journals will systematically be used to ensure that LTCWs, their employers and other non-academic stakeholders have free and easy access to our findings and are able to rapidly and successfully implement the intervention(s) and/or enhanced usual practice in long-term care facilities. We will also present the findings at up to four domestic and international scientific conferences and professional meetings.

5.3.2 Professional organizations and healthcare delivery systems

We will prioritize working with national organizations, such as NAHCA, and IHI, and utilizing their well-established dissemination channels to distribute our findings to LTCWs and other community stakeholders. Specifically, IHI has a dissemination engine, and we will collaborate with Alice Bonner from IHI in our communications, who has worked extensively with the Age Friendly initiative, which has gained substantial traction recently. We will also create newsletters

and press releases using lay language. All documents will be written in partnership with our stakeholder partners and SAG, and will be freely available on the study website.

5.3.3 Social Media and Lay Press

We will also use social media and partner with NAHCA, which consistently engages their members through social media, to disseminate key study messages. We will work with our SAG to plan an effective social media campaign using regular Twitter feeds, blogs on the study website, and planned "tweet chats". We will also reach the lay public who may not have access to social media by using newspaper editorials, lay press, and magazine print. We have successfully used this approach in PCORI-funded studies before.

5.4 Possible Barriers to Dissemination and Implementation

We understand that one of the greatest challenges to implementing results in routine settings is engagement from LTCWs and the organizations that represent them. To ensure that we have sustainable partnerships, we have reached out to recognized organization leaders in the field of public health and long-term care facilities (IHI, NAHCA). We have also collaborated with multiple stakeholder partners who will be involved in all aspects of the project, including its dissemination and implementation. We will also work with influencers on social media to try and reach a broader group. We also recognize that language may be a barrier to implementation. Not all LTCWs will feel comfortable using an intervention written and delivered in English. We will thus plan to translate the successful intervention(s) in the most commonly spoken languages for this target group.

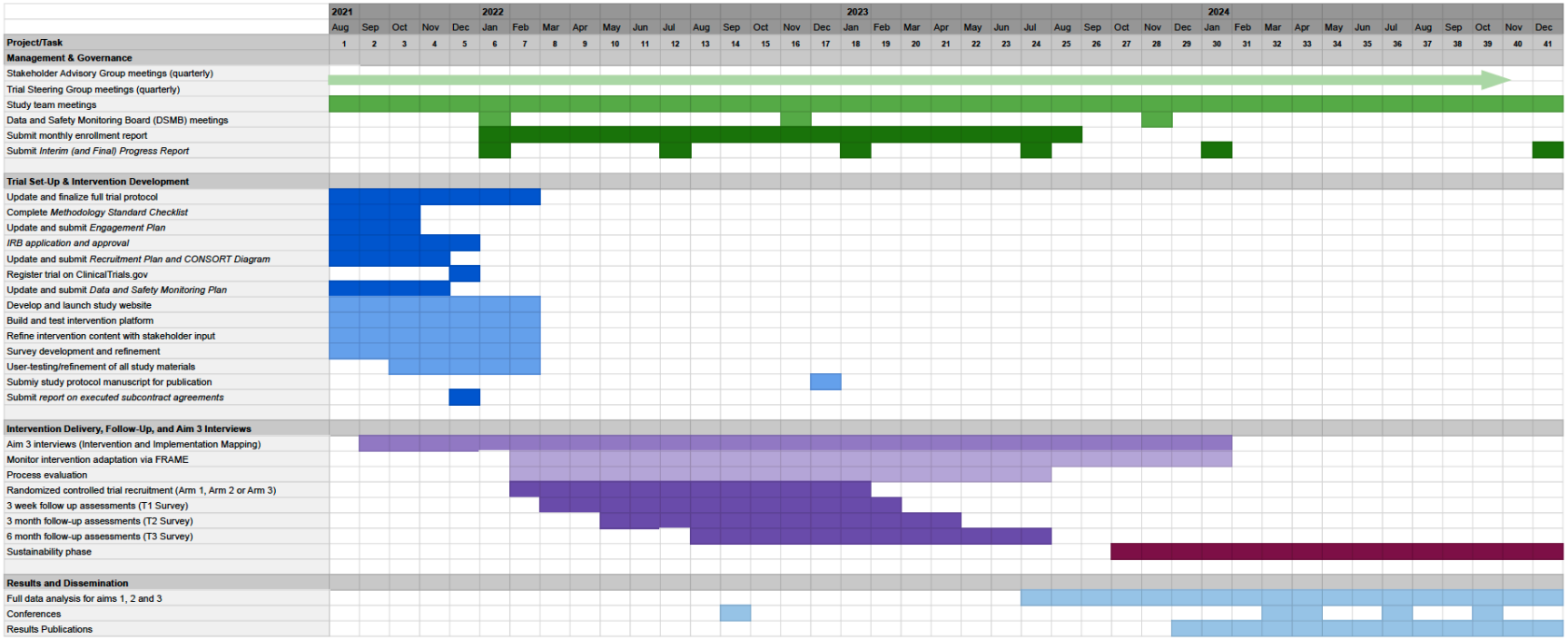
5.5 Making Results Available to Participants

In the final study survey, we will ascertain participants' preferences for receiving (via email or mail) information on the study's findings. Once all study data are collected and analyzed, we will begin developing a pictorial lay summary of the research aims, methods, and key findings.

Information on study results in the final lay summary will be emailed via the email address participants provided at the outset of the study or directly mailed to the study participants if that is their preference. The email will also contain a link to the full results publication online as well as the study website, which will contain additional information about the study and its dissemination efforts. For participants who chose to receive the summary in the mail, we will send a copy of the published manuscript to them as well.

In addition to direct communication of aggregate study results via email or mail, participants may also become aware of study results via the broader dissemination efforts described earlier, targeting community stakeholder organizations (e.g., press releases, newsletters, social media outreach).

6 Timeline


2021
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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41
Project/Task
Management & Governance
Stakeholder Advisory Group meetings (quarterly)
Trial Steering Group meetings (quarterly)
Study team meetings
Data and Safety Monitoring Board (DSMB) meetings
Submit monthly enrollment report
Submit Interim (and Final) Progress Report
Trial Set-Up & Intervention Development
Update and finalize full trial protocol
Complete Methodology Standard Checklist
Update and submit Engagement Plan
IRB application and approval
Update and submit Recruitment Plan and CONSORT Diagram
Register trial on ClinicalTrials.gov
Update and submit Data and Safety Monitoring Plan
Develop and launch study website
Build and test intervention platform
Refine intervention content with stakeholder input
Survey development and refinement
User-testing/refinement of all study materials
Submiy study protocol manuscript for publication
Submit report on executed subcontract agreements
Intervention Delivery, Follow-Up, and Aim 3 Interviews
Aim 3 interviews (Intervention and Implementation Mapping)
Monitor intervention adaptation via FRAME
Process evaluation
Randomized controlled trial recruitment (Arm 1, Arm 2 or Arm 3)
3 week follow up assessments (T1 Survey)
3 month follow-up assessments (T2 Survey)
6 month follow-up assessments (T3 Survey)
Sustainability phase
Results and Dissemination
Full data analysis for aims 1, 2 and 3
Conferences
Results Publications

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Appendix A

COVID-19 Vaccine Option Grid™

Note: This version of the Option Grid is dated May 2022 and has had multiple updates to content since this date. The current version is available at https://decisions.dynamed.com/tools/vaccine-options-for-covid-19

COVID-19 Vaccine Options

This decision aid is for people or caregivers of people 5 years or older. Only the Pfizer/BioNTech vaccine is available for people less than 18 years old. People with serious allergic reactions in the past should talk with their healthcare professional before getting the vaccine. This information is for vaccines available in the United States.

QUESTIONS	No Vaccine	Pfizer/BioNTech and Moderna Vaccines	Johnson & Johnson/Janssen Vaccine
What does the option involve?	**Continue to distance**, avoid gatherings, wear a mask, and clean your hands often.	You will get a total of **2 shots in your arm, 3 to 8 weeks apart**. Some countries use different times for the shots.	You will get **1 shot in your arm.**
What are the benefits?	You will **not have the side effects** that are common with the COVID-19 vaccine.	The vaccine helps lower your risk of getting COVID-19. You will also be **much less likely** to get **seriously ill** if you get COVID-19. **2 weeks** after the **second shot**, it is **safer to do things you did before the pandemic.** You should **still follow rules** and **guidance** about wearing a mask and distancing. People being fully vaccinated **helps keep COVID-19 under control**.	The vaccine helps lower your risk of getting COVID-19. You will also be **much less likely** to get **seriously ill** if you get COVID-19. **2 weeks** after the **shot**, it is **safer to do things you did before the pandemic.** You should **still follow rules** and **guidance** about wearing a mask and distancing. People being fully vaccinated **helps keep COVID-19 under control**.

COVID-19 Vaccine Options *(Continued)*

QUESTIONS	No Vaccine	Pfizer/BioNTech and Moderna Vaccines	Johnson & Johnson/Janssen Vaccine
What are the short-term side effects or harms?	You will be at **higher risk of getting COVID-19**. **Symptoms** of COVID-19 include: • feeling tired. • fever or chills. • body aches. • shortness of breath and cough. • problems with taste or smell. COVID-19 can also lead to **serious illness**. This can result in a **hospital stay, needing a machine to breathe**, or **death**.	**Common side effects** within the first 3 days include: • feeling tired. • fever or chills. • body aches. • headache. • soreness from the shot. These effects are **more likely with the second shot** and are normal effects the vaccine can have. They typically **go away in 1 to 2 days**. **Serious side effects or harms are rare**.	**Common side effects** within the first 3 days include: • feeling tired. • fever. • body aches. • headache. • soreness from the shot. These are the normal effects the vaccine can have and typically **go away in 1 to 2 days**. **Serious side effects or harms are rare**.
What are the long-term side effects or harms?	Sometimes short-term **symptoms from COVID-19 can last for a long time**. Some people get new symptoms that can include hair loss, trouble with focus or memory, or lung damage.	There are no long-term studies on COVID-19 vaccines. But **side effects or harms from vaccines are uncommon after 6 weeks.**	There are no long-term studies on COVID-19 vaccines. But **side effects or harms from vaccines are uncommon after 6 weeks.**

COVID-19 Vaccine Options *(Continued)*

QUESTIONS	No Vaccine	Pfizer/BioNTech and Moderna Vaccines	Johnson & Johnson/Janssen Vaccine
What else do I need to know?	If you do not want a vaccine now but change your mind later, you can get it then.	• After at least 5 months, **most** people 5 years or older **should** get a **booster shot**. **Some** people **may** get a **second booster** at least 4 months after their first. • The vaccine **cannot give you COVID-19**. • The vaccine **cannot change your DNA**. • There is **no microchip** in the vaccine. • If you have had COVID-19, the **vaccine may still lower your risk** of getting it again.	• After at least 2 months, **most** adults **should** get a **booster shot**. **Some** people **may** get a **second booster** at least 4 months after their first. • The vaccine **cannot give you COVID-19**. • The vaccine **cannot change your DNA**. • There is **no microchip** in the vaccine. • If you have had COVID-19, the **vaccine may still lower your risk** of getting it again.

Definitions:

Rare side effects or harms
These may include: Guillain Barré syndrome, blood clots with low platelets, and heart inflammation. COVID-19 can cause similar problems.

Guillain Barré syndrome
This is an inflammation of the nerves that may need hospital care. Most people get better, but full recovery can take a year or more.

Many people have seen numbers about how much vaccines can lower the risk of getting COVID-19. Sometimes, these numbers seem different between vaccines. Trying to compare these numbers is not a fair scientific comparison and could mislead. That is why this decision aid does not show these numbers.

DynaMed Decisions' Option Grid™ decision aids are reviewed on an ongoing basis and updated to reflect the latest evidence. **Last Update:** May 19, 2022

Appendix B

Data Analysis Methodology - Study Aims 1 and 2

Data collection summary

Below is a summary table of primary and secondary outcomes and other data collected (including demographic characteristics, contextual factors, and intervention engagement) and corresponding time points for analyses.

Table 1. Time points for outcome and other data assessment

Data Category	Name of Outcome / Data	Time Point / Survey			
		T0 baseline	**T1 3 weeks post-baseline**	**T2 3 months post-baseline**	**T3 6 months post-baseline**
Participant characteristics	Age, gender, zip code, race/ethnicity, education, insurance status, health literacy, religiosity, extent influenced by others, long-term care (LTC) role, duration of experience in LTC, baseline vaccination status	✓			
Contextual factors	Personal experiences related to COVID-19, COVID-19 vaccines, and other vaccines	✓	✓	✓	✓
Intervention and usual practice engagement*	Engagement with each intervention and enhanced usual practice information (including refreshers)		✓	✓	✓
Primary outcome	COVID-19 vaccine confidence		✓		
Secondary outcomes	Change from baseline in COVID-19 vaccine confidence	✓	✓	✓	✓

	COVID-19 vaccine uptake (any dose)		✓		
	COVID-19 vaccine uptake (initial series completion)		✓		
	COVID-19 vaccine uptake (booster completion)		✓		
	Likelihood of recommending (promoting) COVID-19 vaccination		✓		
	Likelihood of recommending (promoting) COVID-19 booster vaccination to coworker		✓		
	COVID-19 vaccine intent (initial series)		✓		
	COVID-19 vaccine intent (booster)		✓		
	COVID-19 vaccine intent (future vaccine recommendations)		✓		
	Feeling informed about the COVID-19 vaccines		✓		
	Identification of COVID-19 vaccine information and misinformation		✓		
	Trust in COVID-19 vaccine information from different sources		✓		
	Change from baseline in secondary outcomes	✓	✓	✓	✓
	As treated analyses of primary and secondary outcomes	✓	✓	✓	✓

*Data on intervention engagement will be collected via a combination of online activity data and participant survey questions

Statistical principles

Confidence intervals and p-values
P-values ≥0.0001 will be reported to 4 decimal places; p-values less than 0.0001 will be reported as "<0.0001". The mean, standard deviation, and any other statistics other than quantiles, will be reported to one decimal place greater than the original data. Quantiles, such as median, minimum, or maximum will use the same number of decimal places as the original data. Estimated parameters, not on the same scale as raw observations (e.g. regression coefficients) will be reported to 3 significant figures.

Adherence to interventions
Analysis of both intention-to-treat (ITT) and as-treated populations will be performed. All participants who are randomized to a trial arm will be included in the ITT analyses. Participants who adhere to major engagement criteria for their primary intervention will be included in the as-treated analyses.

Analysis methodology

Aim 1
To compare the impact of two interventions delivered online: 1) a dialogue-based webinar (webinar) using the existing COVID-19 Option Grid conversation aid and, 2) an interactive and, dynamic, and multi-component social media web application (social media website), compared to enhanced usual practice (link to Centers for Disease Control (CDC) vaccine website), on COVID-19 vaccine confidence (primary outcome), and other secondary outcomes among LTCWs. We hypothesize that each intervention will be superior to enhanced usual practice at increasing vaccine confidence (*Hypothesis 1.1*) and that the dialogue-based webinar intervention will be superior to the social media arm at increasing vaccine confidence (*Hypothesis 1.2*).

Corresponding analyses

Primary outcome
The primary outcome is the binary classifier of vaccine confidence derived from the three-item Vaccine Confidence Index (VCI), evaluated at 3 weeks post-randomization, which will be analyzed by randomization arm. The determined binary predictors of intervention outcomes will be compared using two-proportion z-tests to identify significant differences between each intervention and enhanced usual practice (Arm 1 vs Arm 3 & Arm 2 vs Arm 3 - superiority analyses) and between the intervention arms (Arm 1 vs Arm 2 - two-tailed equivalency analysis).

Secondary outcomes
- *Change from baseline in COVID-19 Vaccine Confidence.* Analysis of change from

baseline will be based on a binary classifier whether the average score increases (1) or does not increase (2) at T1, T2, and T3 versus baseline.

- *Likelihood of recommending COVID-19 vaccination (others not vaccinated).* This question will be evaluated using a Net Promoter Score (NPS) approach, adding one for each positive response, zero for neutral, and subtracting one for each negative response, then dividing by the number of non-missing responses for each trial arm. NPS values will be compared using Wald intervals [1].

- *Likelihood of recommending COVID-19 booster vaccination (coworker).* This question will be evaluated using the NPS approach, described above.

- *COVID-19 vaccine uptake (any dose).* This will be evaluated as a binary classifier compared across trial arms using two-proportion z-tests.

- *COVID-19 vaccine uptake (initial series completion).* For participants who have received any dose of a COVID-19 vaccine, this will be evaluated as a binary classifier compared across trial arms using two-proportion z-tests.

- *COVID-19 vaccine uptake (booster completion).* For participants who have completed their initial vaccine series, this will be evaluated as a three category variable (No, Not sure, Yes) compared across trial arms using chi-squared tests.

- *COVID-19 vaccine intent (initial series)*. For participants who are unvaccinated, we will assess their intentions of getting a COVID-19 vaccine, this will be evaluated using the Net Promoter Score approach, where the three responses – Yes, Not Sure, No – will be evaluated as analogous to promoter, neutral, and detractor, respectively. The question will be evaluated using the NPS analysis, described above.

- *COVID-19 vaccine intent (booster)*. For participants who have completed an initial vaccine series, this will be evaluated using the Net Promoter Score approach, where the three responses – Yes, Not Sure, No – will be evaluated as analogous to promoter, neutral, and detractor, respectively. The question will be evaluated using the NPS analysis, described above.

- *COVID-19 vaccine intent (future vaccine recommendations).* Participants' intent to get COVID-19 vaccines regularly in the future if they are recommended will be evaluated using the Net Promoter Score approach, where the three responses – Yes, Not Sure, No – will be evaluated as analogous to promoter, neutral, and detractor, respectively. The question will be evaluated using the NPS analysis, described above.

- *Feeling informed about the COVID-19 vaccines.* The degree to which participants' feel informed about the COVID-19 vaccines (have enough information and understand that information) will be evaluated using a continuous variable, calculated as the mean scale

score across two items ((1) having enough information, (2) understanding the information) for each participant. The mean of all mean scores will be compared across trial arms with two-sample unpaired t-tests.

- *Identification of COVID-19 vaccine information and misinformation.* Subjects' identification of COVID-19 vaccine information and misinformation will be scored on a scale of zero to four and treated as a continuous linear variable. Results will be compared across trial arms with two sample unpaired t-tests.

- *Trust in COVID-19 information from different sources.* Subjects' trust in COVID-19 information from different sources will be evaluated using a continuous variable, calculated as the mean scale score across three items for each participant. The mean of all mean scores will be compared across trial arms with two-sample unpaired t-tests.

- *Change from baseline in secondary outcomes.* Change from baseline will be scored as a binary variable with an increased value scored as one and a no change or decreased value scored as zero. For each evaluation after baseline, each arm will be compared using two-proportion z-tests. For vaccine and booster intent questions, where the intent question is not repeated if the participant indicates an increase in vaccination status, intent will be imputed from uptake. To be clear, an individual who is unvaccinated at T0, then returns at T1 and indicates that he or she is now vaccinated, will be presented with the vaccine intent question at T0 but not at T1. Because the individual is now vaccinated, asking about vaccine intent at T1 would be confusing. For analyzing change in vaccine intent, the individual whose vaccine status increases would be considered to have positive intent at T1. A similar approach will be used for booster intent.

- *As treated analysis of primary and secondary outcomes.* Primary and secondary outcome analyses will be repeated, limited to the as treated samples.

Aim 2

To determine if LTCWs' characteristics and other factors mediate and moderate the interventions' impact on vaccine confidence and other secondary outcomes.

We hypothesize that increased perceptions of feeling informed about the vaccines, identification of vaccine information and misinformation, and trust in vaccine information provided by different sources will explain (mediate) the relationship between the interventions and vaccine confidence, as well as other secondary outcomes (*Hypothesis 2.1)*.

We will also conduct exploratory heterogeneity of treatment effects (HTE) analyses to identify whether certain participant characteristics and beliefs moderate the relationships among each of the interventions and vaccine confidence, as well as other secondary outcomes. Variables to be explored will include, but are not limited to, baseline vaccination status, religious beliefs, perceived influence of others, age, race, ethnicity and personal experiences with COVID-19.

Corresponding analyses

Mediation analysis
We hypothesize that the relationship between participants' assigned trial arm and primary and secondary outcomes will be mediated by the effects of feeling informed, trust in vaccine information, and beliefs about vaccines (measured through questions to determine each participant's ability to correctly classify vaccine information and misinformation). Responses for these three variables will be evaluated at each time point versus outcomes by randomization arm to identify differences by arm using the Kruskal-Wallis test. Significant relationships will be explored for mediation effects in the primary and secondary outcome analyses using the method of Barron and Kenny [2]. If this results in a significant improvement in model prediction, hypothesis 2.1 will be supported.

Heterogeneity of treatment effects/Moderation analysis
To understand how the relationship between study interventions and outcomes are moderated by participant characteristics including age, gender, location (level of regional analysis selected for appropriate granularity), educational attainment, race and ethnicity, health insurance status, health literacy, religiosity, LTCW role, duration of experience in long-term care, extent influenced by others regarding COVID-19 vaccination, personal experiences with COVID-19 and the vaccines, and baseline vaccination status, we will evaluate the primary and secondary outcomes using linear and logistic regression in a mixed-effects model.

Exploratory analyses
Change from baseline in COVID-19 Vaccine Confidence. Looking deeper at the change in vaccine confidence, analyses will consider (a) the proportion of positive (agree and strongly agree) responses in the VCI, (b) positive responses in each of the three VCI questions. Significant correlates with demographic, contextual, and study variables will be evaluated.

External contextual factors. Outside of the study surveys and throughout the trial, we will monitor external factors that may impact participants' views and actions towards the COVID-19 vaccines. This may include monitoring policy and mandate changes for LTCWs and changes in the nature of the pandemic, among other things.

Additional analyses. Any unvalidated thresholds utilized in the primary or secondary analyses will be evaluated for sensitivity to the choice of threshold in ROC analyses. Nonlinear higher-dimensional effects and interactions among variables will be identified by identifying positive or negative outcomes grouped around specific baseline characteristics that are highly unlikely to result from random chance.

Duplicate and missing data
Participants must complete a baseline (T0) survey to be considered enrolled in the study. In the event of duplicate complete T0 submissions, the first complete survey will be used. For participants who complete duplicate follow-up surveys (T1, T2 or T3), the first complete survey

will also be used. In order to be included in primary and secondary outcome analyses, participants must have valid primary outcome data at both T0 and T1.

The study team will endeavor to minimize missing data; however, it is possible that efforts to ensure complete data collection within the response windows will be unsuccessful or because participants may choose not to respond to one or more questions. Should any primary and/or secondary outcome variables have >5% missing data, the reasons for any missing data will be considered through an analysis for common baseline characteristics of individuals with specific responses missing, those who were lost to follow-up, and those who did not respond to one or more evaluations but were not lost to follow-up. Specific questions with significantly higher rates of missing data will be reviewed for wording bias or missing response options. Based on these considerations, a stochastic outcome set model will be created using multiple imputation and Bayesian methods, as appropriate, to provide a high confidence range for imputed values. Using this approach, an expected result and confidence intervals will be produced for the missing data and the resulting analysis of the full data set, taking into account the statistical uncertainty attributed to the missing data. If available, data from both baseline and subsequent follow-up evaluations will be used in imputing missing results (e.g., responses from T0 and T2 evaluations could be used to impute T1 responses) through multiple imputation regression modeling [3].

Response rates and the frequency of missing data in the ITT and as-treated populations will be reported with the results.

Fraudulent enrollment

Identity verification of some participants will occur after they have completed their journey in the study (using TransUnion's TLOxp verification service). We will also conduct a rigorous review of survey metadata (e.g., IP addresses) and other responses to identify duplicate survey completions or other suspicious survey activity [4,5]. Upon discovery of compelling evidence of fraudulent or illegitimate enrollment, such subjects will be excluded from the study prior to any outcome analyses.

Methods to minimize bias

A naïve analysis will be conducted at the end of the study based only on the unmodified data reflecting ITT assignments of eligible subjects to establish an initial estimator. All primary and secondary analyses will be conducted based on the statistical analysis plan. The statistician member of the DSMB will also independently replicate primary study analyses to confirm their validity.

Multiple testing

The primary outcome involves three separate tests, one a two-tailed equivalence test and two one-tailed superiority tests. In order to achieve a family-wise error rate less than 0.050, the Bonferroni method was employed to set a p-value threshold at 0.016 for each of the three primary outcome analyses. For each comparison, mean-value separation will be considered significant based on a 98.4% confidence interval, which translates to +/- 2.45 times the standard

error for the sample mean for the equivalence test and greater than 2.15 times the standard error for the superiority analyses.

Based on the high number of secondary outcome analyses (cross-sectional T1; change from baseline; ITT; as-treated), results data for these outcomes will be viewed in more aggregate form as trending in one direction or not, rather than adopting a specific Bonferroni-corrected p-value threshold.

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