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Getting Asian Americans INFORMED to Facilitate COVID-19 Testing and Vaccination

Study Protocol

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Objective

The INFORMED study aimed to support Chinese, Vietnamese, and Hmong Americans with up-to-date information in multiple languages related to COVID-19 testing.

The acronym INFORMED stands for "Individual and Family Oriented Responsive Messaging Education." The study aimed to deliver updated information that keeps pace with the rapidly changing landscape of COVID-19. Additionally, the messages were adapted accordingly to the feedback received from community members to ensure its relevance and understandability. The ultimate objective was to empower these communities to make informed decisions regarding safety practices and testing for COVID-19.

Study Design

The INFORMED study was conducted as a randomized controlled trial (RCT) involving 247 RCT participants with assessments at baseline, weeks 4, 8, 12 and 16. All participants received intervention via SMS text messaging. Participants who were randomly assigned to the intervention group received educational outreach from lay health workers (LHW) through Zoom or other mutually agreed online video conferencing platforms or in-person adhering to the local COVID-19 social gathering safety practice, as well as by telephone or instant messaging.

Methods

Academic and Community Partnership

The INFORMED study team consisted of researchers from the University of California and three community-based organizations: the Chinese Community Health Resource Center (CCHRC), The Fresno Center (TFC), and the Immigrant Resettlement and Cultural Center (IRCC). Each community partnering agency has a long history of serving their respective targeted communities: Chinese (CCHRC), Hmong (TFC), and Vietnamese (IRCC). In addition, a Community Advisory Board (CAB) included 7 members with expertise in health education, medicine, public health, media communications, social services, and immigrant health. CAB members provided valuable insights into the evolving community needs and ensured the cultural relevance and appropriateness of the study materials, facilitating effective information delivery and outreach to Chinese, Hmong, and Vietnamese American community members.

Participants Eligibility

The inclusion criteria for participants in the randomized controlled trial (RCT) were: i) age 18 and older; ii) self-identified as Chinese, Hmong, or Vietnamese; iii) ability to read and/or speak English, Chinese (Cantonese/Mandarin), Hmong, or Vietnamese; iv) access to a mobile phone to receive SMS text messages (participants received reimbursement if their mobile phone had limited SMS services); v) access to a telephone to be contacted by research staff (to obtain informed consent) and/or by Lay Health Workers (LHWs) for educational sessions when video conferencing on mobile or computer devices was not available.

Participants Recruitment and Payment Incentives

Recruitment utilized multi-pronged strategies proven effective in previous trials involving LHW outreach in various Asian communities. Trained LHWs initially reached out to their social networks. Partnering agencies conducted recruitment through their client population via social media announcements or various events. The program was described as the “Healthy Family Project,” focusing on staying healthy by getting informed about COVID-19 testing updates. Each participant received up to $70 for completing all the surveys online: $20 for the baseline survey (15-20 minutes long), $10 for each brief survey at weeks 4, 8, and 12 (5-10 minutes), and $20 for the final survey at week 16 (15-20 minutes) for outcome evaluation.

Procedures

All study procedures and contacts were conducted in the participants’ preferred language: English, Chinese (Cantonese or Mandarin), Hmong, or Vietnamese. The procedures were reviewed and approved by the Institutional Review Board (IRB) at the University of California, San Francisco.

Enrollment & Informed Consent

Interested participants were provided a URL to complete an eligibility survey. Once eligibility was confirmed, participants were provided an informed consent form describing the study, which they signed online to indicate their willingness to participate. Those who had questions about the informed consent form and/or their participation in the study could contact the research staff, who provided the needed information in the language they preferred. Once informed consent was obtained, participants completed a baseline survey where they indicated whether they would be participating individually or with a partner (friend or family member) together in the study.

Randomization

Randomization took place at the individual level. A randomization unit consisted of either an individual participating alone or with a partner to form a dyad and was stratified by partnering agency/Asian ethnicity. Prior to randomization, participants chose their mode of participation (individually or with a partner as a dyad). Randomization occurred after the completion of the baseline assessment. Participants were assigned to either the INFORMED intervention group, which received both LHW educational outreach and a 12-week automated SMS text messaging intervention, or the control group, which received only the SMS text messaging program without LHW support.

Intervention Group Activities

Participants assigned to the intervention group received the INFORMED intervention (described below). They were assessed via online follow-up surveys with links and reminders delivered by SMS at weeks 4, 8, 12, and 16. Each participant will receive up to $70 for completing all the surveys as described earlier (Participant recruitment and payment incentives).

The INFORMED intervention consisted of two components:

1. Lay Health Worker (LHW) outreach/support providing responsive education and support, and
2. a 12-week automated SMS text messaging program.

Intervention Component #1:

The LHW educational outreach component included 2 small group educational sessions and 2 individual follow-up calls. The small group sessions were delivered via video calls using Zoom or other mutually agreed platforms. Each LHW outreach session, lasting under 1 hour, involved 2 to 6 participants. The sessions included presentations on COVID-19 testing and related information (including vaccination and safe practices) aimed at enhancing participants' understanding of updated COVID-19 testing information, informing them about free testing availability, and motivating them to get tested. Sessions were spaced approximately 1 month apart, with follow-up calls conducted within 2 weeks after each session. Thus, the 4 LHW outreach contacts (group sessions and follow-up calls) were completed within 6 to 8 weeks. Participants who chose to participate as a dyad attended the sessions together. The educational sessions utilized culturally

appropriate PowerPoint presentations with simple texts and images to present current information on:

- COVID-19 testing,
- reasons for getting tested,
- current testing guidelines/who should be tested,
- types of tests available (e.g., antigens and antibodies tests using nose swabs and saliva tests),
- understanding test results (positive versus negative) and the limitations of tests (false negatives),
- the importance of repeated testing, and addressing barriers to testing.

LHW sessions provided a socially and culturally acceptable platform for participants to share personal stories, ask questions, and address concerns. At the end of each session, participants were encouraged to choose an "action item" from their 'Healthy Action Plan' to enhance their knowledge and/or make informed decisions about testing, and if appropriate, take steps toward getting tested (such as identifying test sites). LHW outreach education is responsive to both culture and the rapid changing landscape of the pandemic situation as our intervention contents will be updated accordingly.

Intervention Component #2:

The 12-week automated SMS text messaging component sent weekly messages covering topics taught in the LHW educational outreach sessions. Designed as non-intensive, weekly contact updates, participants received approximately 2 messages on the 6 topics described in the LHW education curriculum. Each message included a link to the full information on the study website "INFORMED."

Messages were responsive to the rapidly evolving developments and changes related to COVID-19 testing guidelines. Participants were notified by text when free testing resources became available in their county. Thus, there were at least 12 pre-programmed messages, along with additional messages responsive to updates in testing resources and related advancements.

All intervention group participants

Control Group Activities:

The control group participated in a 12-week SMS text messaging program only, without LHW educational outreach (as described in Intervention Component #2). The SMS text messaging intervention was identical to that received by the INFORMED participants. All control participants were assessed on the same schedule: baseline, weeks 4, 8, 12, and 16. They received the same amount of incentives ($70 for completing all assessments).

Statistics Analysis Plan

We conducted our primary outcome using multilevel mixed effects models, controlling for baseline values and incorporating relevant covariates. Additional details of the statistical methods, covariates, and model specifications are provided below. All analyses were conducted using SAS.

Primary Outcome Analysis

1) **Primary Outcome**

   Decisional Conflict for Getting Tested for COVID-19 measured by "SURE" score

2) **Model Construction**
   a) **Multilevel Mixed Effects Model**: Using GLIMMIX procedure of SAS, we constructed the final multilevel mixed effects model to analyze the primary outcome at week 16 by treatment group (LHW + text message or text message alone). These models were adjusted for the baseline value of the outcome variable and include a random effect to account for participant clustering.
   b) **Model Specification**:
      i) Fixed Effects: Treatment group, baseline outcome value, covariates at individual, interpersonal and community levels.
      ii) Random Effects: Participant cluster (random intercepts for participation mode: individual vs dyad)

3) **Covariates**
   a) **Individual-Level Covariates**: Asian cultural groups, age, sex at birth, current employment status, education, health insurance, self-rated health, preferred language (English vs non-English)
   b) **Interpersonal-Level Covariates**: marital status, household type (family with kids, multigenerational, and no kids/others)
   c) **Community-Level Covariates**: COVID cases per 100,000 populations (matched participants' county and month of survey date), California Healthy Place Index

   The following covariates were considered but were not included in the final model due to multicollinearity with other covariates: English proficiency and nativity (highly correlated with preferred language), and income (correlated with current employment status)

Secondary Outcome Analysis

Additional models were constructed to analyze secondary outcomes at week 16: COVID-19 testing receipt (proportion of participants received COVID-19 testing during the past 30 days); intention for getting COVID-19 testing as much as needed; and "SURE" score for getting COVID-19 vaccination. These models will follow the same structure as the primary outcome model, controlling for baseline values and including relevant covariates.